CUMULATIVE
SUPPLEMENT 4
APRIL 2004

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

24th EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

2004

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

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Please Note:

The 24th Edition of the Orange Book will be the last paper version. All the components of the paper Orange Book are and have been available on the Internet since 1997. Refer to the Introduction 1.3, Availability of the Edition, for specific locations. Additional details will be made available in future Cumulative Supplement publications.

APPROVED DRUG PRODUCTS
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24th EDITION

CUMULATIVE SUPPLEMENT 4
April 2004

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, 24th 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 23rd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 24th Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. 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 A, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>A>**. The Patent and Exclusivity Data are indicated by the symbol **>ADD>** to the left of the line on which new information exists. The **>ADD>** symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol **>D>** (DELETE) to the left of the line. The information line with the **>D>** symbol is dropped in subsequent Cumulative Supplements for that item.

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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
BERLEX (BERLEX)	BERLEX INC (BERLEX INC)
BERLEX LABORATORIES INC (BERLEX LABS)	BERLEX INC (BERLEX INC)
BERLEX LABORATORIES INC SUB SCHERING AG (BERLEX)	BERLEX INC (BERLEX INC)

1.3 RIBAVIRIN 200MG ORAL CAPSULE

The footnote for Ribabvirin 200MG capsule product 001 was inadvertently omitted from the 24th Edition. The footnote: Indicated for use and comarketed with interferon alfa-2b, recombinant (Intron A), as Rebetron Combination Therapy.

1.4 AVAILABILITY OF THE EDITION

The 24th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800 or toll free 866-512-1800. The cost is $110.00 annually. A GPO Orange Book Subscription form is provided at the end of each cumulative supplement.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

The Electronic Orange Book Query (EOB) is at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant 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. The data is updated concurrently with the publication of the monthly cumulative supplements.

The Internet version of the Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.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 zipobtxt.exe. The files are updated concurrently with the publication of the monthly cumulative supplements. Appendix A and Appendix B text files of the paper annual Orange Book are updated quarterly.

The 24th annual edition of the 2003 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/24bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at http://www.fda.gov/cder/orange/supplement/patents.pdf.

The Patent Term Extension and new Patents, Docket Number *95S-0117, is at
http://www.fda.gov/cder/orange/docket.pdf. It is updated approximately weekly.

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 Program Support Center Forms Download Website,
http://forms/psc.gov/forms/FDA/fda.html

The current listing of the Orphan Product Designations and Approvals is available at http://www.fda.gov/orphan/designat/list.htm.

1.5 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 2003) 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	DEC 2003	MAR 2004	JUN 2004	SEP 2004
DRUG PRODUCTS LISTED	10665	10668		
SINGLE SOURCE	2423 (22.7%)	2404 (22.5%)		
MULTISOURCE	8134 (76.3%)	8156 (76.5%)		
THERAPEUTICALLY EQUIVALENT	7856 (73.7%)	7885 (73.9%)		
NOT THERAPEUTICALLY EQUIVALENT	278 (2.6%)	271 (2.5%)		
EXCEPTIONS[1]	108 (1.0%)	108 (1.0%)		
NEW MOLECULAR ENTITIES APPROVED	6	3		
NUMBER OF APPLICANTS	601	586		

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

1.6 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 Approval 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.
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; CODEINE PHOSPHATE

SUSPENSION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

>D>	AA		AMARIN PHARMS	120MG/5ML;12MG/5ML	N86024	001		Apr CRLD
>A>	AA	+		120MG/5ML;12MG/5ML	N86024	001		Apr CRLD

ACETYLCYSTEINE

INJECTABLE; INTRAVENOUS

ACETADOTE

		+	CUMBERLAND PHARMS	6GM /30ML(200MG/ML)	N21539	001	Jan 23, 2004	Jan NEWA

ACITRETIN

CAPSULE; ORAL

SORIATANE

			CONNETICS	10MG	N19821	001	Oct 28, 1996	Mar CAHN
		+		25MG	N19821	002	Oct 28, 1996	Mar CAHN

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR SODIUM

>A>	AP		MAYNE PHARMA USA	EQ 50MG BASE/ML	N75065	001	Feb 25, 1999	Apr CAHN
>D>	AP		MERIDIAN MEDCL TECHN	EQ 50MG BASE/ML	N75065	001	Feb 25, 1999	Apr CAHN

ALBUTEROL SULFATE

TABLET, EXTENDED RELEASE; ORAL

ALBUTEROL SULFATE

		+	PLIVA	EQ 4MG BASE	N76130	002	Sep 26, 2002	Jan CRLD
		+		EQ 8MG BASE	N76130	003	Sep 26, 2002	Jan CRLD

VOLMAX

		@	MURO	EQ 4MG BASE	N19604	002	Dec 23, 1992	Jan DISC
		@		EQ 8MG BASE	N19604	001	Dec 23, 1992	Jan DISC

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HYDROCHLORIDE

	AP		INTL MEDICATION SYS	50MG/ML	N21594	001	Feb 04, 2004	Feb NEWA

AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM

TABLET; ORAL

CADUET

			PFIZER	EQ 5MG BASE;EQ 10MG BASE	N21540	001	Jan 30, 2004	Jan NEWA
				EQ 5MG BASE;EQ 20MG BASE	N21540	002	Jan 30, 2004	Jan NEWA
				EQ 5MG BASE;EQ 40MG BASE	N21540	003	Jan 30, 2004	Jan NEWA
				EQ 5MG BASE;EQ 80MG BASE	N21540	004	Jan 30, 2004	Jan NEWA
				EQ 10MG BASE;EQ 10MG BASE	N21540	005	Jan 30, 2004	Jan NEWA
				EQ 10MG BASE;EQ 20MG BASE	N21540	006	Jan 30, 2004	Jan NEWA
				EQ 10MG BASE;EQ 40MG BASE	N21540	007	Jan 30, 2004	Jan NEWA
		+		EQ 10MG BASE;EQ 80MG BASE	N21540	008	Jan 30, 2004	Jan NEWA

AMLODIPINE MALEATE

TABLET; ORAL

AMVAZ

		@	DR REDDYS LABS INC	2.5MG	N21435	001	Oct 31, 2003	Mar DISC

TABLET; ORAL

AMVAZ

@	DR REDDYS LABS INC	5MG	N21435	002	Oct 31, 2003	Mar	DISC
@		10MG	N21435	003	Oct 31, 2003	Mar	DISC

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB	TEVA	600MG/5ML;EQ 42.9MG BASE/5ML	N65162	001	Mar 12, 2004	Mar	NEWA

AUGMENTIN ES-600

AB	+ GLAXOSMITHKLINE	600MG/5ML;EQ 42.9MG BASE/5ML	N50755	001	Jun 22, 2001	Mar	CFTG

APOMORPHINE HYDROCHLORIDE

INJECTABLE; SUBCUTANEOUS

APOKYN

>A>	BERTEK	20MG/2ML (10MG/ML)	N21264	001	Apr 20, 2004	Apr	NEWA
>A>	+	30MG/3ML (10MG/ML)	N21264	002	Apr 20, 2004	Apr	NEWA

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

INJECTABLE; IV (INFUSION)

INFUVITE PEDIATRIC (PHARMACY BULK PACKAGE)

+	SABEX 2002	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21646	001	Jan 29, 2004	Jan	NEWA

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

FOR SOLUTION; IV (INFUSION)

M.V.I. PEDIATRIC

>D>	+ AAIPHARMA LLC	80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL;5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;17MG/VIAL;0.2MG/VIAL;1MG/VIAL;1.4MG/VIAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/VIAL	N18920	001	Sep 21, 2000	Apr	CAHN
>A>	+ MAYNE PHARMA USA	80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL;5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;17MG/VIAL;0.2MG/VIAL;1MG/VIAL;1.4MG/VIAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/VIAL	N18920	001	Sep 21, 2000	Apr	CAHN

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

M.V.I.-12

>D>	+ AAIPHARMA LLC	10MG/ML;0.006MG/ML;0.5UGM/ML;1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;0.4MG/ML;0.36MG/ML;0.3MG/ML;330 UNITS/ML;1 IU/ML	N08809	004	Aug 08, 1985	Apr	CAHN
>A>	+ MAYNE PHARMA USA	10MG/ML;0.006MG/ML;0.5UGM/ML;1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;0.4MG/ML;0.36MG/ML;0.3MG/ML;330 UNITS/ML;1 IU/ML	N08809	004	Aug 08, 1985	Apr	CAHN

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K

INJECTABLE; IV (INFUSION)

M.V.I. ADULT

>D>	+	AAIPHARMA LLC	200MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;0.005MG/VIAL;0.6MG/VIAL;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6MG/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL	N21625	001	Jan 30, 2004	Apr	CAHN
	+		200MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;0.005MG/VIAL;0.6MG/VIAL;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6MG/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL	N21625	001	Jan 30, 2004	Jan	NEWA
>A>	+	MAYNE PHARMA USA	200MG/VIAL;0.06MG/VIAL;0.005MG/VIAL;15MG/VIAL;0.005MG/VIAL;0.6MG/VIAL;40MG/VIAL;6MG/VIAL;3.6MG/VIAL;6MG/VIAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL	N21625	001	Jan 30, 2004	Apr	CAHN

M.V.I. ADULT (PHARMACY BULK PACKAGE)

>D>	+	AAIPHARMA LLC	200MG/5ML;0.06MG/5ML;0.005MG/5ML;15MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5ML;10MG/5ML;0.15MG/5ML	N21643	001	Feb 18, 2004	Apr	CAHN
	+		200MG/5ML;0.06MG/5ML;0.005MG/5ML;15MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5ML;10MG/5ML;0.15MG/5ML	N21643	001	Feb 18, 2004	Feb	NEWA
>A>	+	MAYNE PHARMA USA	200MG/5ML;0.06MG/5ML;0.005MG/5ML;15MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5ML;10MG/5ML;0.15MG/5ML	N21643	001	Feb 18, 2004	Apr	CAHN

AZITHROMYCIN

CAPSULE; ORAL

ZITHROMAX

@		PFIZER	EQ 250MG BASE	N50670	001	Nov 01, 1991	Mar	DISC

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

CORTISPORIN

AT		MONARCH PHARMS	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50416	002		Mar	CRLD

NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE

AT	+	BAUSCH AND LOMB	400 UNITS/GM;1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N64068	001	Oct 30, 1995	Mar	CRLD

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATE AND BACITRACIN ZINC

AT		AKORN	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N65088	001	Feb 06, 2004	Feb	NEWA

NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC

AT	+	BAUSCH AND LOMB	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N64064	001	Oct 30, 1995	Mar	CRLD

NEOSPORIN

AT		MONARCH PHARMS	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N50417	001		Mar	CRLD

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN ZINC AND POLYMYXIN B SULFATE

AT	+	BAUSCH AND LOMB	500 UNITS/GM;10,000 UNITS/GM	N64046	001	Jan 26, 1995	Mar	CRLD

OINTMENT; OPHTHALMIC

POLYSPORIN

AT	MONARCH PHARMS	500 UNITS/GM;10,000 UNITS/GM	N61229	001		Mar	CRLD

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL

BENAZEPRIL HCL

AB	ANDRX PHARMS	5MG	N76267	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76267	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76267	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76267	004	Feb 11, 2004	Feb	NEWA
AB	EON	5MG	N76402	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76402	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76402	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76402	004	Feb 11, 2004	Feb	NEWA
AB	GENPHARM	5MG	N76476	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76476	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76476	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76476	004	Feb 11, 2004	Feb	NEWA
AB	IVAX PHARMS	5MG	N76333	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76333	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76333	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76333	004	Feb 11, 2004	Feb	NEWA
AB	KV PHARM	5MG	N76118	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76118	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76118	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76118	004	Feb 11, 2004	Feb	NEWA
AB	MYLAN	5MG	N76430	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76430	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76430	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76430	004	Feb 11, 2004	Feb	NEWA
AB	RANBAXY	5MG	N76344	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76344	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76344	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76344	004	Feb 11, 2004	Feb	NEWA
AB	TEVA	5MG	N76211	001	Feb 11, 2004	Feb	NEWA
AB		10MG	N76211	002	Feb 11, 2004	Feb	NEWA
AB		20MG	N76211	003	Feb 11, 2004	Feb	NEWA
AB		40MG	N76211	004	Feb 11, 2004	Feb	NEWA

LOTENSIN

AB	NOVARTIS	5MG	N19851	001	Jun 25, 1991	Feb	CFTG
AB		10MG	N19851	002	Jun 25, 1991	Feb	CFTG
AB		20MG	N19851	003	Jun 25, 1991	Feb	CFTG
AB +		40MG	N19851	004	Jun 25, 1991	Feb	CFTG

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

BENAZEPRIL HCL AND HYDROCHLOROTHIAZIDE

AB	ANDRX PHARMS	5MG;6.25MG	N76342	001	Feb 11, 2004	Feb	NEWA
AB		10MG;12.5MG	N76342	002	Feb 11, 2004	Feb	NEWA
AB		20MG;12.5MG	N76342	003	Feb 11, 2004	Feb	NEWA
AB		20MG;25MG	N76342	004	Feb 11, 2004	Feb	NEWA
AB	EON	5MG;6.25MG	N76631	001	Feb 11, 2004	Feb	NEWA
AB		10MG;12.5MG	N76631	002	Feb 11, 2004	Feb	NEWA
AB		20MG;12.5MG	N76631	003	Feb 11, 2004	Feb	NEWA
AB		20MG;25MG	N76631	004	Feb 11, 2004	Feb	NEWA

TABLET; ORAL

BENAZEPRIL HCL AND HYDROCHLOROTHIAZIDE

AB		GENPHARM	5MG;6.25MG	N76612	001	Feb 11, 2004	Feb	NEWA
AB			10MG;12.5MG	N76612	002	Feb 11, 2004	Feb	NEWA
AB			20MG;12.5MG	N76612	003	Feb 11, 2004	Feb	NEWA
AB			20MG;25MG	N76612	004	Feb 11, 2004	Feb	NEWA
AB		IVAX PHARMS	5MG;6.25MG	N76348	001	Feb 11, 2004	Feb	NEWA
AB			10MG;12.5MG	N76348	002	Feb 11, 2004	Feb	NEWA
AB			20MG;12.5MG	N76348	003	Feb 11, 2004	Feb	NEWA
AB			20MG;25MG	N76348	004	Feb 11, 2004	Feb	NEWA
AB		MYLAN	5MG;6.25MG	N76688	001	Feb 11, 2004	Feb	NEWA
AB			10MG;12.5MG	N76688	002	Feb 11, 2004	Feb	NEWA
AB			20MG;12.5MG	N76688	003	Feb 11, 2004	Feb	NEWA
AB			20MG;25MG	N76688	004	Feb 11, 2004	Feb	NEWA

LOTENSIN HCT

AB		NOVARTIS	5MG;6.25MG	N20033	001	May 19, 1992	Feb	CFTG
AB			10MG;12.5MG	N20033	002	May 19, 1992	Feb	CFTG
AB			20MG;12.5MG	N20033	004	May 19, 1992	Feb	CFTG
AB	+		20MG;25MG	N20033	003	May 19, 1992	Feb	CFTG

BENZOYL PEROXIDE; ERYTHROMYCIN

GEL; TOPICAL

BENZAMYCIN

AB	+	DERMIK LABS	5%;3%	N50557	001	Oct 26, 1984	Mar	CFTG

ERYTHROMYCIN AND BENZOYL PEROXIDE

AB		ATRIX	5%;3%	N65112	001	Mar 29, 2004	Mar	NEWA

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

AB		ATRIX	EQ 0.05% BASE	N76603	001	Jan 23, 2004	Jan	NEWA

BETAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

BETAMETHASONE SODIUM PHOSPHATE

		@ STERIS	EQ 3MG BASE/ML	N85738	001		Feb	DISC

CELESTONE

		@ SCHERING	EQ 3MG BASE/ML	N17561	001		Feb	DISC

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HCL

AB		IMPAX LABS	100MG	N75913	001	Jan 28, 2004	Jan	NEWA
AB			150MG	N75913	002	Mar 22, 2004	Mar	NEWA

BUPROPRION HCL

AB		EON	150MG	N75932	002	Mar 22, 2004	Mar	NEWA

WELLBUTRIN SR

AB	+	GLAXOSMITHKLINE	150MG	N20358	003	Oct 04, 1996	Mar	CFTG

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPIRONE HCL

AB		TEVA	30MG	N75022	004	Mar 25, 2004	Mar	NEWA

CALCITRIOL

INJECTABLE; INJECTION

CALCITRIOL

AP	MAYNE PHARMA USA	0.001MG/ML	N75816	001	Jan 16, 2004	Jan	NEWA
AP		0.002MG/ML	N75816	002	Jan 16, 2004	Jan	NEWA

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL

CARBATROL

	SHIRE PHARM	100MG	N20712	003	Sep 30, 1997	Mar	CRLD
		200MG	N20712	001	Sep 30, 1997	Mar	CRLD

CARBOPLATIN

INJECTABLE; IV (INFUSION)

PARAPLATIN

+	BRISTOL MYERS SQUIBB	EQ 600MG /60ML(10MG/ML)	N20452	004	Jan 15, 2004	Jan	NEWA

CEFACLOR

CAPSULE; ORAL

CEFACLOR

AB	CARLSBAD	EQ 250MG BASE	N65146	001	Jan 22, 2004	Jan	NEWA
AB		EQ 500MG BASE	N65146	002	Jan 22, 2004	Jan	NEWA

CEFIXIME

SUSPENSION; ORAL

SUPRAX

+	LUPIN	100MG/5ML	N65129	001	Feb 23, 2004	Feb	NEWA

TABLET; ORAL

SUPRAX

+	LUPIN	400MG	N65130	001	Feb 12, 2004	Feb	NEWA

CEFTAZIDIME

INJECTABLE; INJECTION

>A>	CEFTAZIDIME						
>A> AP	ACS DOBFAR	500MG/VIAL	N62640	001	Nov 20, 1985	Apr	CTNA
>A> AP		1GM/VIAL	N62640	002	Nov 20, 1985	Apr	CTNA
>A> AP		2GM/VIAL	N62640	003	Nov 20, 1985	Apr	CTNA
>D>	TAZIDIME						
>D> AP	LILLY	500MG/VIAL	N62640	001	Nov 20, 1985	Apr	CTNA
>D> AP		1GM/VIAL	N62640	002	Nov 20, 1985	Apr	CTNA
>D> AP		1GM/VIAL	N62655	001	Nov 20, 1985	Apr	DISC
>A>	@	1GM/VIAL	N62655	001	Nov 20, 1985	Apr	DISC
>D> AP		2GM/VIAL	N62640	003	Nov 20, 1985	Apr	CTNA
>D> AP		2GM/VIAL	N62655	002	Nov 20, 1985	Apr	DISC
>A>	@	2GM/VIAL	N62655	002	Nov 20, 1985	Apr	DISC

CEFUROXIME SODIUM

INJECTABLE; IM-IV

CEFUROXIME

AB	HIKMA FARMACEUTICA	EQ 750MG BASE/VIAL	N65048	001	Jan 09, 2004	Jan	NEWA

INJECTABLE; INJECTION

CEFUROXIME

AP	HIKMA FARMACEUTICA	EQ 1.5GM BASE/VIAL	N65048	002	Jan 09, 2004	Jan	NEWA
AP		EQ 7.5GM BASE/VIAL	N65046	001	Jan 09, 2004	Jan	NEWA

CETIRIZINE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL

		ZYRTEC						
		PFIZER	5MG	N21621	001	Mar 16, 2004	Mar	NEWA
	+		10MG	N21621	002	Mar 16, 2004	Mar	NEWA

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

		CHLORHEXIDINE GLUCONATE						
	AT	MORTON GROVE	0.12%	N75006	001	Mar 03, 2004	Mar	NEWA

CHORIOGONADOTROPIN ALFA

INJECTABLE; SUBCUTANEOUS

		OVIDREL						
>D>	+	SERONO INC	EQ 0.25MG /0.5ML0.5MG/ML	N21149	002	Oct 06, 2003	Apr	CPOT
>A>	+		EQ 0.25MG /0.5ML	N21149	002	Oct 06, 2003	Apr	CPOT

CINACALCET HYDROCHLORIDE

TABLET; ORAL

		SENSIPAR						
		AMGEN	EQ 30MG BASE	N21688	001	Mar 08, 2004	Mar	NEWA
			EQ 60MG BASE	N21688	002	Mar 08, 2004	Mar	NEWA
	+		EQ 90MG BASE	N21688	003	Mar 08, 2004	Mar	NEWA

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

		CIPRO XR						
	+	BAYER PHARMS	425.2MG;EQ 574.9MG BASE	N21473	002	Aug 28, 2003	Feb	CDFR

CLADRIBINE

INJECTABLE; INJECTION

		CLADRIBINE						
>A>	AP	AM PHARM	1MG/ML	N76571	001	Apr 22, 2004	Apr	NEWA

CLEMASTINE FUMARATE

TABLET; ORAL

		CLEMASTINE FUMARATE						
	AB +	TEVA	2.68MG	N73283	001	Jan 31, 1992	Mar	CRLD
		TAVIST						
		@ NOVARTIS	2.68MG	N17661	001		Mar	DISC

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

		CLINDAMYCIN HCL						
	AB	COREPHARMA	EQ 150MG BASE	N65194	001	Mar 22, 2004	Mar	NEWA
	AB		EQ 300MG BASE	N65194	002	Mar 22, 2004	Mar	NEWA

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL

		CLINDAMYCIN PHOSPHATE						
	AT	TARO PHARM INDS	EQ 1% BASE	N65184	001	Mar 31, 2004	Mar	NEWA

CLOBETASOL PROPIONATE

SHAMPOO; TOPICAL

CLOBEX

	+	GALDERMA LABS	0.05%	N21644	001	Feb 05, 2004	Feb	NEWA

CLOZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

FAZACLO

		ALAMO PHARMS	25MG	N21590	001	Feb 10, 2004	Feb	NEWA
	+		100MG	N21590	002	Feb 10, 2004	Feb	NEWA

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION

COLISTIMETHATE

AP		PADDOCK	EQ 150MG BASE/VIAL	N65177	001	Mar 19, 2004	Mar	NEWA

CROMOLYN SODIUM

AEROSOL, METERED; INHALATION

INTAL

	+	KING PHARMS	0.8MG/INH	N18887	001	Dec 05, 1985	Jan	CAHN

SOLUTION; INHALATION

INTAL

AN	+	KING PHARMS	10MG/ML	N18596	001	May 28, 1982	Jan	CAHN

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN

>A>	AP	BIONICHE ANIM HLTH	1MG/ML	N40451	001	Sep 23, 2003	Apr	CAHN
>D>	AP	PHARMAFORCE	1MG/ML	N40451	001	Sep 23, 2003	Apr	CAHN

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

	AP	AM PHARM	100MG/ML	N76512	001	Jan 15, 2004	Jan	NEWA
	AP +	MAYNE PHARMA USA	100MG/ML	N75383	001	Nov 22, 1999	Jan	CFTG

DEFEROXAMINE MESYLATE

INJECTABLE; INJECTION

DEFEROXAMINE MESYLATE

	AP	ABBOTT	500MG/VIAL	N76019	001	Mar 17, 2004	Mar	NEWA
	AP		2GM/VIAL	N76019	002	Mar 17, 2004	Mar	NEWA

DESFERAL

	AP +	NOVARTIS	500MG/VIAL	N16267	001		Mar	CFTG
	AP +		2GM/VIAL	N16267	002	May 25, 2000	Mar	CFTG

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DECLOMYCIN

	AB	ESP PHARMA	150MG	N50261	002		Mar	CFTG
	AB +		300MG	N50261	003		Mar	CFTG

DEMECLOCYCLINE HCL

	AB	IMPAX LABS	150MG	N65094	001	Mar 22, 2004	Mar	NEWA
	AB		300MG	N65094	002	Mar 22, 2004	Mar	NEWA

DESIRUDIN

INJECTABLE; SUBCUTANEOUS

IPRIVASK

>D>		+	AVENTIS PHARMS	15MG/VIAL	N21271	001	Apr 04, 2003	Apr	CAHN
>A>		+	CANYON	15MG/VIAL	N21271	001	Apr 04, 2003	Apr	CAHN

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

CYCLESSA

	AB	+	ORGANON USA INC	0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG	N21090	001	Dec 20, 2000	Feb	CFTG

VELIVET

	AB		DURAMED PHARMS BARR	0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG	N76455	001	Feb 24, 2004	Feb	NEWA

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

DEXACIDIN

>D>									
>D>	AT		NOVARTIS	0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62544	001	Oct 29, 1984	Apr	DISC
>A>			@	0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62544	001	Oct 29, 1984	Apr	DISC

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

>A>	AP		PARENTA PHARMS	5MG/ML	N76815	001	Apr 15, 2004	Apr	NEWA

DICLOFENAC POTASSIUM

TABLET; ORAL

DICLOFENAC POTASSIUM

	AB		TORPHARM	50MG	N76561	001	Mar 18, 2004	Mar	NEWA

DICLOXACILLIN SODIUM

CAPSULE; ORAL

DICLOXACILLIN SODIUM

SANDOZ

				EQ 125MG BASE	N61454	002		Mar	CAHN
	AB			EQ 250MG BASE	N61454	001		Mar	CAHN
	AB	+		EQ 500MG BASE	N61454	003		Mar	CAHN

DILTIAZEM HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

BIOVAIL

				120MG	N21392	001	Feb 06, 2003	Jan	CRLD
				180MG	N21392	002	Feb 06, 2003	Jan	CRLD
				240MG	N21392	003	Feb 06, 2003	Jan	CRLD
				300MG	N21392	004	Feb 06, 2003	Jan	CRLD
				360MG	N21392	005	Feb 06, 2003	Jan	CRLD

DIMYRISTOYL LECITHIN; PERFLEXANE

INJECTABLE; INTRAVENOUS

IMAGENT

		+	IMCOR PH	0.92MG/VIAL;0.092MG/VIAL	N21191	001	May 31, 2002	Feb	CAHN

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL

DEPAKOTE

		ABBOTT	EQ 125MG VALPROIC ACID	N18723	003	Oct 26, 1984	Jan	CRLD
			EQ 250MG VALPROIC ACID	N18723	001	Mar 10, 1983	Jan	CRLD

DOXEPIN HYDROCHLORIDE

CONCENTRATE; ORAL

DOXEPIN HCL

	AA	PHARM ASSOC	EQ 10MG BASE/ML	N75924	001	Jan 15, 2004	Jan	NEWA

DOXERCALCIFEROL

CAPSULE; ORAL

HECTOROL

>A>		BONE CARE	0.5UGM	N20862	002	Apr 23, 2004	Apr	NEWA

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

>D>	AB	AXIOM PHARM	EQ 50MG BASE	N65041	001	Apr 28, 2000	Apr	CAHN
>D>	AB		EQ 100MG BASE	N65041	002	Apr 28, 2000	Apr	CAHN
>A>	AB	WATSON LABS	EQ 50MG BASE	N65041	001	Apr 28, 2000	Apr	CAHN
>A>	AB		EQ 100MG BASE	N65041	002	Apr 28, 2000	Apr	CAHN

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

>D>	AB	AXIOM PHARM	EQ 50MG BASE	N61717	001		Apr	CAHN
>D>	AB		EQ 100MG BASE	N61717	002		Apr	CAHN
>A>	AB	WATSON LABS	EQ 50MG BASE	N61717	001		Apr	CAHN
>A>	AB		EQ 100MG BASE	N61717	002		Apr	CAHN

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYC

	AB	WARNER CHILCOTT	250MG	N62338	001		Jan	CMFD

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL

ERYTHROMYCIN ESTOLATE

		ALPHARMA	EQ 125MG BASE/5ML	N62353	001	Nov 18, 1982	Jan	CTEC
	+		EQ 250MG BASE/5ML	N62409	001	Dec 16, 1982	Jan	CRLD

ILOSONE

		@ LILLY	EQ 125MG BASE/5ML	N50010	001		Jan	DISC
		@	EQ 250MG BASE/5ML	N50010	002		Jan	DISC

ESCITALOPRAM OXALATE

TABLET; ORAL

LEXAPRO

>D>		@ FOREST LABS	5MG	N21323	001	Aug 14, 2002	Apr	CMFD
>A>			5MG	N21323	001	Aug 14, 2002	Apr	CMFD

ESTRADIOL

GEL, METERED; TOPICAL

	ESTROGEL						
	SOLVAY	0.06%	N21166	002	Feb 09, 2004	Feb	NEWA

GEL; TOPICAL

	ESTROGEL						
	SOLVAY	0.06%	N21166	001	Feb 09, 2004	Feb	NEWA
+		0.06%	N21166	001	Feb 09, 2004	Mar	CRLD

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

	CENESTIN						
	DURAMED	0.45MG	N20992	005	Feb 05, 2004	Feb	NEWA

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

	MYAMBUTOL						
	@ ELAN PHARMS	100MG	N16320	001		Feb	CAHN
	@	200MG	N16320	002		Feb	CAHN
	@	400MG	N16320	003		Feb	CAHN
	@	500MG	N16320	004		Feb	CAHN

>D> ETHINYL ESTRADIOL

TABLET; ORAL

>D>	ESTINYL						
>D>	SCHERING	0.02MG	N05292	001		Apr	DISC
>A>	@	0.02MG	N05292	001		Apr	DISC
>D>		0.05MG	N05292	002		Apr	DISC
>A>	@	0.05MG	N05292	002		Apr	DISC
>D>	+	0.5MG	N05292	003		Apr	DISC
>A>	@	0.5MG	N05292	003		Apr	DISC

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL

	PREVEN EMERGENCY CONTRACEPTIVE KIT						
+	DURAMED	0.05MG;0.25MG	N20946	001	Sep 01, 1998	Feb	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

>A>		BALZIVA-21						
>A>	AB	BARR	0.035MG;0.4MG	N76198	001	Apr 22, 2004	Apr	NEWA
		OVCON-35						
>D>		+ WARNER CHILCOTT	0.035MG;0.4MG	N18127	001		Apr	CFTG
>A>	AB	+	0.035MG;0.4MG	N18127	001		Apr	CFTG

TABLET; ORAL-28

>A>		BALZIVA-28						
>A>	AB	BARR	0.035MG;0.4MG	N76238	001	Apr 22, 2004	Apr	NEWA
		ORTHO-NOVUM 1/35-28						
	AB	+ ORTHO MCNEIL PHARM	0.035MG;1MG	N17919	002		Mar	CRLD
		OVCON-35						
>D>		+ WARNER CHILCOTT	0.035MG;0.4MG	N17716	001		Apr	CFTG
>A>	AB	+	0.035MG;0.4MG	N17716	001		Apr	CFTG

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

PREVIFEM

AB	ANDRX PHARMS	0.035MG;0.25MG	N76334	001	Jan 09, 2004	Jan	NEWA

TRI-PREVIFEM

AB	ANDRX PHARMS	0.035MG,0.035MG,0.035MG;0.18MG,0.215MG,0.025MG	N76335	001	Mar 26, 2004	Mar	NEWA

FENTANYL CITRATE

TROCHE/LOZENGE; ORAL

ACTIQ

	CEPHALON	EQ 0.2MG BASE	N20747	001	Nov 04, 1998	Feb	CAHN
		EQ 0.4MG BASE	N20747	002	Nov 04, 1998	Feb	CAHN
		EQ 0.6MG BASE	N20747	003	Nov 04, 1998	Feb	CAHN
		EQ 0.8MG BASE	N20747	004	Nov 04, 1998	Feb	CAHN
		EQ 1.2MG BASE	N20747	005	Nov 04, 1998	Feb	CAHN
+		EQ 1.6MG BASE	N20747	006	Nov 04, 1998	Feb	CAHN

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

FLUDARABINE PHOSPHATE

>A>	+ GENSIA SICOR PHARMS	50MG/2ML (25MG/ML)	N76661	001	Apr 28, 2004	Apr	NEWA

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

>D>	@ KING PHARMS	25MG/ML	N74966	001	Apr 16, 1998	Apr	CAHN
>A>	@ MAYNE PHARMA USA	25MG/ML	N74966	001	Apr 16, 1998	Apr	CAHN

FOLLITROPIN ALFA/BETA

INJECTABLE; IM-SC

FOLLISTIM

BX	ORGANON USA INC	75 IU/VIAL	N20582	001	Sep 29, 1997	Mar	CDFR
BX		150 IU/VIAL	N20582	002	Sep 29, 1997	Mar	CDFR

INJECTABLE; SUBCUTANEOUS

FOLLISTIM AQ

	ORGANON USA INC	300 IU/0.525ML	N21211	001	Mar 23, 2004	Mar	NEWA
+		600 IU/0.885ML	N21211	002	Mar 23, 2004	Mar	NEWA

GONAL-F

	SERONO INC	37.5 IU/VIAL	N21765	001	Mar 25, 2004	Mar	NEWA
BX		75 IU/VIAL	N20378	001	Sep 29, 1997	Mar	CDFR
		75 IU/VIAL	N21765	002	Mar 25, 2004	Mar	NEWA
BX		150 IU/VIAL	N20378	002	Sep 29, 1997	Mar	CDFR
+		150 IU/VIAL	N21765	003	Mar 25, 2004	Mar	NEWA
		450 IU/VIAL	N20378	005	Mar 26, 2004	Mar	NEWA
>D>	+	1,200 IU/VIAL	N20378	004	Feb 28, 2001	Apr	CPOT
>A>	+	1,050 IU/VIAL	N20378	004	Feb 28, 2001	Apr	CPOT
	+	1,200 IU/VIAL	N20378	004	Feb 28, 2001	Mar	CAIN

FOMIVIRSEN SODIUM

INJECTABLE; INJECTION

VITRAVENE PRESERVATIVE FREE

+	NOVARTIS	6.6MG/ML	N20961	001	Aug 26, 1998	Jan	CAHN

FOSINOPRIL SODIUM

TABLET; ORAL

FOSINOPRIL SODIUM

>A>	AB		EON	10MG	N76483	001	Apr 23, 2004	Apr	NEWA
>A>	AB			20MG	N76483	002	Apr 23, 2004	Apr	NEWA
>A>	AB			40MG	N76483	003	Apr 23, 2004	Apr	NEWA
>A>	AB		RANBAXY	10MG	N76580	001	Apr 23, 2004	Apr	NEWA
>A>	AB			20MG	N76580	002	Apr 23, 2004	Apr	NEWA
>A>	AB			40MG	N76580	003	Apr 23, 2004	Apr	NEWA

FUROSEMIDE

TABLET; ORAL

FUROSEMIDE

	AB		VINTAGE PHARMS	20MG	N76796	001	Mar 26, 2004	Mar	NEWA
	AB			40MG	N76796	002	Mar 26, 2004	Mar	NEWA
	AB			80MG	N76796	003	Mar 26, 2004	Mar	NEWA

GABAPENTIN

TABLET; ORAL

GABAPENTIN

>A>			IVAX PHARMS	100MG	N76017	001	Apr 28, 2004	Apr	NEWA
>A>				300MG	N76017	002	Apr 28, 2004	Apr	NEWA
>A>				400MG	N76017	003	Apr 28, 2004	Apr	NEWA

GEMIFLOXACIN MESYLATE

TABLET; ORAL

FACTIVE

>D>		+	GENESOFT PHARMS	EQ 320MG BASE	N21158	001	Apr 04, 2003	Apr	CAHN
>A>		+	OSCIENT	EQ 320MG BASE	N21158	001	Apr 04, 2003	Apr	CAHN

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

GARAMYCIN

	AT	+	SCHERING	EQ 0.3% BASE	N50039	002		Jan	CDFR

GENTAMICIN SULFATE

	AT		ALTANA	EQ 3% BASE	N65121	001	Jan 30, 2004	Jan	NEWA

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLUCOVANCE

	AB		BRISTOL MYERS SQUIBB	1.25MG;250MG	N21178	001	Jul 31, 2000	Feb	CFTG
	AB			2.5MG;500MG	N21178	002	Jul 31, 2000	Feb	CFTG
	AB	+		5MG;500MG	N21178	003	Jul 31, 2000	Feb	CFTG

GLYBURIDE AND METFORMIN HCL

	AB		IVAX PHARMS	1.25MG;250MG	N76345	001	Feb 18, 2004	Feb	NEWA
	AB			2.5MG;500MG	N76345	002	Feb 18, 2004	Feb	NEWA
	AB			5MG;500MG	N76345	003	Feb 18, 2004	Feb	NEWA

>D> HALAZEPAM

>D> TABLET; ORAL

>D> PAXIPAM

>D>			SCHERING	20MG	N17736	003		Apr	DISC
>A>			@	20MG	N17736	003		Apr	DISC
>D>		+		40MG	N17736	004		Apr	DISC
>A>			@	40MG	N17736	004		Apr	DISC

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

		HALOPERIDOL DECANOATE						
>D>		@ KING PHARMS	EQ 50MG BASE/ML	N75176	001	Feb 09, 2000	Apr	CAHN
>D>		@	EQ 100MG BASE/ML	N75176	002	Feb 09, 2000	Apr	CAHN
>A>		@ MAYNE PHARMA USA	EQ 50MG BASE/ML	N75176	001	Feb 09, 2000	Apr	CAHN
>A>		@	EQ 100MG BASE/ML	N75176	002	Feb 09, 2000	Apr	CAHN

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

		ACCURETIC						
AB		PFIZER PHARMS	12.5MG;EQ 10MG BASE	N20125	001	Dec 28, 1999	Mar	CFTG
AB			12.5MG;EQ 20MG BASE	N20125	002	Dec 28, 1999	Mar	CFTG
AB	+		25MG;EQ 20MG BASE	N20125	003	Dec 28, 1999	Mar	CFTG
		QUINARETIC						
AB		AMIDE PHARM	12.5MG;EQ 10MG BASE	N76374	001	Mar 31, 2004	Mar	NEWA
AB			12.5MG;EQ 20MG BASE	N76374	002	Mar 31, 2004	Mar	NEWA
AB			25MG;EQ 20MG BASE	N76374	003	Mar 31, 2004	Mar	NEWA

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL

		HYDROCODONE BITARTRATE AND IBUPROFEN						
	+	INTERPHARM	5MG;200MG	N76642	002	Mar 18, 2004	Mar	NEWA

HYDROCORTISONE

CREAM; TOPICAL

		HYDROCORTISONE						
AT		VINTAGE PHARMS	2.5%	N40503	001	Mar 12, 2004	Mar	NEWA

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

		HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%						
>A>	BX	BOCA PHARMA	1%;1%	N89440	001	May 17, 1988	Apr	CAHN
>D>	BX	COPLEY PHARM	1%;1%	N89440	001	May 17, 1988	Apr	CAHN

HYDROCORTISONE BUTYRATE

SOLUTION; TOPICAL

		HYDROCORTISONE BUTYRATE						
AT		TARO PHARM INDS	0.1%	N76364	001	Jan 14, 2004	Jan	NEWA
		LOCOID						
AT	+	FERNDALE LABS	0.1%	N19116	001	Feb 25, 1987	Jan	CFTG

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

		IDARUBICIN HCL						
	+	GENSIA SICOR PHARMS	5MG/VIAL	N65037	003	May 01, 2002	Feb	CTEC

>A> INSULIN GLULISINE RECOMBINANT

>A> INJECTABLE; SUBCUTANEOUS

>A> APIDRA

>A>	+	AVENTIS PHARMS	100 UNITS/ML	N21629	001	Apr 16, 2004	Apr	NEWA

IOPROMIDE

INJECTABLE; INJECTION

ULTRAVIST (PHARMACY BULK)

		+	BERLEX	49.9%	N21425	003	Mar 12, 2004	Mar	NEWA
		+		62.3%	N21425	001	Sep 20, 2002	Mar	CPOT
		+		76.9%	N21425	002	Sep 20, 2002	Mar	CPOT

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

>D>	AN		ASLUNG PHARM	0.02%	N75693	001	Jan 26, 2001	Apr	CAHN
>A>	AN		HOLOPACK INTL	0.02%	N75693	001	Jan 26, 2001	Apr	CAHN

ISONIAZID

INJECTABLE; INJECTION

NYDRAZID

		+	SANDOZ	100MG/ML	N08662	001		Feb	CAHN

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

IMDUR

>D>	AB	+	SCHERING PLOUGH	30MG	N20225	001	Aug 12, 1993	Apr	CRLD
>A>	AB			30MG	N20225	001	Aug 12, 1993	Apr	CRLD
>D>	AB	+		60MG	N20225	002	Aug 12, 1993	Apr	CRLD
>A>	AB			60MG	N20225	002	Aug 12, 1993	Apr	CRLD

KETOCONAZOLE

CREAM; TOPICAL

KETOCONAZOLE

>A>	AB		ALTANA	2%	N76294	001	Apr 28; 2004	Apr	NEWA
>D>	AB		TEVA	2%	N75581	001	Apr 25, 2000	Apr	CRLD
>A>	AB	+		2%	N75581	001	Apr 25, 2000	Apr	CRLD

>D>

NIZORAL

>D>	AB	+	JANSSEN PHARMA	2%	N19084	001	Dec 31, 1985	Apr	DISC
>A>			@	2%	N19084	001	Dec 31, 1985	Apr	DISC

SHAMPOO; TOPICAL

KETOCONAZOLE

	AB		CLAY PARK	2%	N76419	001	Jan 07, 2004	Jan	NEWA

NIZORAL

	AB	+	MCNEIL CONS SPECLT	2%	N19927	001	Aug 31, 1990	Jan	CFTG

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE

	AP	+	BEDFORD	15MG/ML	N75222	001	Apr 26, 1999	Jan	CRLD
	AP	+		30MG/ML	N75222	002	Apr 26, 1999	Jan	CRLD

TORADOL

			@ ROCHE PALO	15MG/ML	N19698	001	Nov 30, 1989	Jan	DISC
			@	30MG/ML	N19698	002	Nov 30, 1989	Jan	DISC

KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC

ZADITOR

		+	NOVARTIS	EQ 0.025% BASE	N21066	001	Jul 02, 1999	Feb	CAHN

LAMOTRIGINE

TABLET; ORAL

LAMICTAL

>D>		GLAXOSMITHKLINE	25MG	N20241	005	Dec 27, 1994	Apr	CRLD
>A>	+		25MG	N20241	005	Dec 27, 1994	Apr	CRLD
>D>	+		200MG	N20241	003	Dec 27, 1994	Apr	CRLD
>A>			200MG	N20241	003	Dec 27, 1994	Apr	CRLD

LEVOCABASTINE HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

LIVOSTIN

	+	NOVARTIS	EQ 0.05% BASE	N20219	001	Nov 10, 1993	Feb	CAHN

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

IQUIX

	+	SANTEN	1.5%	N21571	001	Mar 01, 2004	Mar	NEWA

LEVONORGESTREL

TABLET; ORAL

PLAN B

	+	DURAMED	0.75MG	N21045	001	Jul 28, 1999	Feb	CAHN

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	B BRAUN	200MG/100ML	N18967	001	Mar 30, 1984	Apr	DISC
>A>		@	200MG/100ML	N18967	001	Mar 30, 1984	Apr	DISC

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	B BRAUN	400MG/100ML	N18967	002	Mar 30, 1984	Apr	DISC
>A>		@	400MG/100ML	N18967	002	Mar 30, 1984	Apr	DISC

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER

>D>	AP	B BRAUN	800MG/100ML	N18967	003	Mar 30, 1984	Apr	DISC
>A>		@	800MG/100ML	N18967	003	Mar 30, 1984	Apr	DISC

LIDOCAINE HYDROCHLORIDE; OXYTETRACYCLINE

INJECTABLE; INJECTION

TERRAMYCIN

	+	PFIZER	2%;50MG/ML	N60567	001		Feb	CRLD
	+		2%;125MG/ML	N60567	002		Feb	CRLD

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL

LITHIUM CARBONATE

	AB	ROXANE	450MG	N76691	001	Jan 05, 2004	Jan	NEWA

LOVASTATIN; NIACIN

TABLET, EXTENDED RELEASE; ORAL

ADVICOR

	+	KOS	20MG;500MG	N21249	001	Dec 17, 2001	Feb	CRLD
	+		20MG;750MG	N21249	002	Dec 17, 2001	Feb	CRLD

MERCAPTOPURINE

TABLET; ORAL

MERCAPTOPURINE

AB		PROMETHEUS LABS	50MG	N40461	001	Feb 11, 2004	Feb	NEWA
AB		ROXANE	50MG	N40528	001	Feb 13, 2004	Feb	NEWA

PURINETHOL

AB	+	TEVA	50MG	N09053	002		Feb	CFTG

MESNA

INJECTABLE; INTRAVENOUS

MESNA

AP		BEDFORD	100MG/ML	N75739	001	Jan 09, 2004	Jan	NEWA

METFORMIN HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

FORTAMET

>A>	BX	ANDRX	500MG	N21574	001	Apr 27, 2004	Apr	NEWA
>A>	+		1GM	N21574	002	Apr 27, 2004	Apr	NEWA

GLUCOPHAGE XR

AB		BRISTOL MYERS SQUIBB	500MG	N21202	001	Oct 13, 2000	Jan	CFTG

METFORMIN HCL

AB		IVAX PHARMS	500MG	N76545	001	Dec 01, 2003	Jan	NEWA

METHADONE HYDROCHLORIDE

TABLET; ORAL

METHADONE HCL

>A>	AA	MALLINCKRODT	5MG	N40517	001	Apr 27, 2004	Apr	NEWA
>A>	AA		10MG	N40517	002	Apr 27, 2004	Apr	NEWA

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

AB	+	OVATION PHARMS	5MG	N05378	002		Feb	CFTG

METHAMPHETAMINE HCL

AB		ABLE	5MG	N40529	001	Feb 25, 2004	Feb	NEWA

METHIMAZOLE

TABLET; ORAL

TAPAZOLE

AB		KING PHARMS	5MG	N07517	002		Mar	CAHN
AB			10MG	N07517	004		Mar	CAHN

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

RITALIN LA

>A>		NOVARTIS	10MG	N21284	004	Apr 10, 2004	Apr	NEWA

METOLAZONE

TABLET; ORAL

METOLAZONE

>A>	AB	ROXANE	10MG	N76482	002	Apr 29, 2004	Apr	NEWA
	AB	TEVA	2.5MG	N76600	001	Jan 06, 2004	Jan	NEWA
	AB		5MG	N76833	001	Mar 01, 2004	Mar	NEWA

MYKROX

		@ CELLTECH PHARMS	0.5MG	N19532	001	Oct 30, 1987	Jan	DISC

METOPROLOL TARTRATE

TABLET; ORAL

LOPRESSOR

AB		NOVARTIS	100MG	N17963	002		Mar	CRLD

METOPROLOL TARTRATE

		CARACO	25MG	N76670	001	Jan 15, 2004	Jan	NEWA
AB			25MG	N76670	001	Jan 15, 2004	Mar	CTEC
AB		MYLAN	25MG	N76704	001	Jan 16, 2004	Mar	CTEC
	+		25MG	N76704	001	Jan 16, 2004	Jan	NEWA
AB			50MG	N76704	002	Jan 16, 2004	Jan	NEWA
AB			100MG	N76704	003	Jan 16, 2004	Jan	NEWA
AB	+		100MG	N76704	003	Jan 16, 2004	Mar	CRLD

METRONIDAZOLE

CAPSULE; ORAL

METRONIDAZOLE

AB		KALI LABS	375MG	N76522	001	Jan 29, 2004	Jan	NEWA

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL

MINOCYCLINE HCL

AB		MEDICIS	EQ 50MG BASE	N65131	001	Apr 16, 2003	Jan	CFTG
AB			EQ 75MG BASE	N65131	002	Apr 16, 2003	Jan	CFTG
AB	+		EQ 100MG BASE	N65131	003	Apr 16, 2003	Jan	CFTG
AB		RANBAXY	EQ 50MG BASE	N65156	001	Jan 06, 2004	Jan	NEWA
AB			EQ 75MG BASE	N65156	002	Jan 06, 2004	Jan	NEWA
AB			EQ 100MG BASE	N65156	003	Jan 06, 2004	Jan	NEWA

MIRTAZAPINE

TABLET; ORAL

MIRTAZAPINE

>A>		CARACO	7.5MG	N76541	004	Apr 22, 2004	Apr	NEWA
>A>	AB		15MG	N76541	001	Apr 22, 2004	Apr	NEWA
>A>	AB		30MG	N76541	002	Apr 22, 2004	Apr	NEWA
>A>	AB		45MG	N76541	003	Apr 22, 2004	Apr	NEWA

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

ORAMORPH SR

BC	+	AAIPHARMA	60MG	N19977	002	Aug 15, 1991	Mar	CRLD

MYCOPHENOLIC ACID

TABLET, EXTENDED RELEASE; ORAL

MYFORTIC

		NOVARTIS	180MG	N50791	001	Feb 27, 2004	Feb	NEWA
	+		360MG	N50791	002	Feb 27, 2004	Feb	NEWA

NABILONE

CAPSULE; ORAL

CESAMET

		@ VALEANT	1MG	N18677	001	Dec 26, 1985	Jan	CAHN

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

		@ KING PHARMS	10MG/ML	N74471	001	Mar 19, 1998	Mar	DISC

NAPROXEN

TABLET; ORAL

NAPROXEN

AB		WESTWARD	250MG	N76494	001	Jan 14, 2004	Jan	NEWA
AB			375MG	N76494	002	Jan 14, 2004	Jan	NEWA
AB			500MG	N76494	003	Jan 14, 2004	Jan	NEWA

NEDOCROMIL SODIUM

AEROSOL, METERED; INHALATION

TILADE

	+	KING PHARMS	1.75MG/INH	N19660	001	Dec 30, 1992	Jan	CAHN

NIACIN

TABLET; ORAL

NIACIN

		@ MK LABS	500MG	N83525	001		Feb	DISC
		@ TABLICAPS	500MG	N84237	001		Feb	DISC

NIACOR

AA	+	UPSHER SMITH	500MG	N40378	001	May 03, 2000	Feb	CRLD

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

NIFEDIPINE

AB2		MARTEC	90MG	N75414	003	Mar 23, 2004	Mar	NEWA

PROCARDIA XL

AB2	+	PFIZER	90MG	N19684	003	Sep 06, 1989	Mar	CFTG

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

MACROBID

AB	+	PROCTER AND GAMBLE	75MG;25MG	N20064	001	Dec 24, 1991	Mar	CFTG

NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)

>D>	AB	MYLAN	EQ 75MG BASE;25MG	N76648	001	Mar 22, 2004	Apr	CPOT
>A>	AB		75MG;25MG	N76648	001	Mar 22, 2004	Apr	CPOT
	AB		EQ 75MG BASE;25MG	N76648	001	Mar 22, 2004	Mar	NEWA

OLANZAPINE

INJECTABLE; INTRAMUSCULAR

ZYPREXA

	+	LILLY	10MG/VIAL	N21253	001	Mar 29, 2004	Mar	NEWA

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

AP	+	APOTHECON	EQ 250MG BASE/VIAL	N61490	001		Mar	CRLD
AP	+		EQ 2GM BASE/VIAL	N61490	004		Mar	NEWA
AP			EQ 2GM BASE/VIAL	N62737	002	Dec 23, 1986	Mar	CRLD

OXAMNIQUINE

CAPSULE; ORAL

VANSIL

	@ PFIZER	250MG	N18069	001		Mar	DISC

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OXYCODONE HCL

AB	ENDO PHARMS	10MG	N75923	001	Mar 23, 2004	Mar	NEWA
AB		20MG	N75923	002	Mar 23, 2004	Mar	NEWA
AB		40MG	N75923	003	Mar 23, 2004	Mar	NEWA
AB	TEVA	80MG	N76168	001	Mar 23, 2004	Mar	NEWA

OXYCONTIN

AB	PURDUE PHARMA LP	10MG	N20553	001	Dec 12, 1995	Mar	CFTG
AB		20MG	N20553	002	Dec 12, 1995	Mar	CFTG
AB +		40MG	N20553	003	Dec 12, 1995	Mar	CFTG
AB +		80MG	N20553	004	Jan 06, 1997	Mar	CFTG

TABLET; ORAL

OXYCODONE HCL

AB	AMIDE PHARM	15MG	N76636	001	Feb 06, 2004	Feb	NEWA
AB		30MG	N76636	002	Feb 06, 2004	Feb	NEWA

ROXICODONE

AB +	AAIPHARMA	15MG	N21011	001	Aug 31, 2000	Feb	CFTG
AB		30MG	N21011	002	Aug 31, 2000	Feb	CFTG

PARICALCITOL

INJECTABLE; INJECTION

ZEMPLAR

	ABBOTT	0.002MG/ML	N20819	002	Feb 01, 2000	Mar	NEWA

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAROXETINE HCL

AB	ALPHAPHARM	EQ 10MG BASE	N75716	001	Mar 08, 2004	Mar	NEWA
AB		EQ 20MG BASE	N75716	002	Mar 08, 2004	Mar	NEWA
AB		EQ 30MG BASE	N75716	003	Mar 08, 2004	Mar	NEWA
AB		EQ 40MG BASE	N75716	004	Mar 08, 2004	Mar	NEWA
AB	SANDOZ	EQ 10MG BASE	N75566	001	Mar 08, 2004	Mar	NEWA
AB		EQ 20MG BASE	N75566	002	Mar 08, 2004	Mar	NEWA
AB		EQ 30MG BASE	N75566	003	Mar 08, 2004	Mar	NEWA
AB		EQ 40MG BASE	N75566	004	Mar 08, 2004	Mar	NEWA

PEMETREXED DISODIUM

INJECTABLE; IV (INFUSION)

ALIMTA

+	LILLY	EQ 500MG BASE/VIAL	N21462	001	Feb 04, 2004	Feb	NEWA

PHENYTOIN

SUSPENSION; ORAL

PHENYTOIN

AB	TARO	125MG/5ML	N40521	001	Mar 08, 2004	Mar	NEWA

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL

NULYTELY

AA	+	BRAINTREE	420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT	N19797	001	Apr 22, 1991	Feb	CFTG

NULYTELY-FLAVORED

AA	+	BRAINTREE	420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT	N19797	002	Nov 18, 1994	Feb	CFTG

TRILYTE

AA		SCHWARZ PHARMA	420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT	N76491	001	Feb 05, 2004	Feb	NEWA

PREDNISONE

TABLET; ORAL

PREDNISONE

AB		WEST WARD	2.5MG	N40538	001	Jan 08, 2004	Jan	NEWA

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HCL

AP		BEDFORD LABS	25MG/ML	N40524	001	Mar 17, 2004	Mar	NEWA
AP			50MG/ML	N40524	002	Mar 17, 2004	Mar	NEWA

SYRUP; ORAL

PROMETH PLAIN

	@	ALPHARMA	6.25MG/5ML	N85953	001		Feb	DISC

PROMETHAZINE HCL

AA	+	HI TECH PHARMA	6.25MG/5ML	N40026	001	Sep 25, 1998	Feb	CRLD

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL

PROPAFENONE HCL

>A>	AB		PLIVA	150MG	N76550	001	Apr 23, 2004	Apr	NEWA
>A>	AB			225MG	N76550	002	Apr 23, 2004	Apr	NEWA
>A>	AB			300MG	N76550	003	Apr 23, 2004	Apr	NEWA

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL

AP		AM PHARM PARTNERS	1MG/ML	N75826	001	Aug 31, 2001	Jan	NEWA

PROTAMINE SULFATE

INJECTABLE; INJECTION

PROTAMINE SULFATE

	+	AM PHARM PARTNERS	10MG/ML	N89454	001	Apr 07, 1987	Mar	CRLD
	@	LILLY	10MG/ML	N06460	002		Mar	DISC

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT; ORAL

ZANTAC 25

>A>		GLAXOSMITHKLINE	EQ 25MG BASE	N20251	003	Apr 01, 2004	Apr	NEWA

RIBAVIRIN

CAPSULE; ORAL

REBETOL

>D>		+	SCHERING PLOUGH RES	200MG	N20903	002	Jul 25, 2001	Apr	CFTG
>A>	AB	+		200MG	N20903	002	Jul 25, 2001	Apr	CFTG

		CAPSULE; ORAL							
>A>		RIBASPHERE							
>A>	AB	THREE RIVERS PHARMS	200MG	N76203	001	Apr 06, 2004	Apr	NEWA	
>A>		RIBAVIRIN							
>A>	AB	SANDOZ	200MG	N76192	001	Apr 06, 2004	Apr	NEWA	
		SECRETIN SYNTHETIC HUMAN							
		FOR SOLUTION; INTRAVENOUS							
>A>		HUMAN SECRETIN							
>A>	+	CHIRHOCLIN	16UGM/VIAL	N21256	001	Apr 09, 2004	Apr	NEWA	
		SIROLIMUS							
		TABLET; ORAL							
		RAPAMUNE							
		WYETH PHARMS INC	2MG	N21110	002	Aug 22, 2002	Feb	CRLD	
	+		5MG	N21110	003	Feb 23, 2004	Feb	NEWA	
		SODIUM FERRIC GLUCONATE COMPLEX							
		INJECTABLE; INJECTION							
		FERRLECIT							
	+	WATSON PHARMS	62.5MG/5ML	N20955	001	Feb 18, 1999	Feb	CAHN	
		SODIUM IODIDE, I-131							
>D>		SOLUTION; ORAL							
>D>		SODIUM IODIDE I 131							
>D>	+	CIS	50mCi/ML	N17315	001		Apr	DISC	
>A>		@	50mCi/ML	N17315	001		Apr	DISC	
		SOMATROPIN RECOMBINANT							
		INJECTABLE; INJECTION							
		SEROSTIM							
	BX	SERONO	4MG/VIAL	N20604	003	Jul 25, 1997	Jan	CTEC	
		@	8.8MG/VIAL	N20604	004	Sep 06, 2001	Jan	DISC	
		SOTALOL HYDROCHLORIDE							
		TABLET; ORAL							
		SOTALOL HCL							
>A>	AB2	MUTUAL PHARM	80MG	N76576	001	Apr 08, 2004	Apr	NEWA	
>A>	AB2		120MG	N76576	002	Apr 08, 2004	Apr	NEWA	
>A>	AB2		160MG	N76576	003	Apr 08, 2004	Apr	NEWA	
		SPARFLOXACIN							
		TABLET; ORAL							
		ZAGAM							
		@ MYLAN	200MG	N20677	001	Dec 19, 1996	Mar	DISC	
		SUCRALFATE							
		TABLET; ORAL							
		CARAFATE							
	AB +	AXCAN SCANDIPHARM	1GM	N18333	001		Feb	CAHN	
		SULFACETAMIDE SODIUM							
		SOLUTION/DROPS; OPHTHALMIC							
		SULF-10							
	AT	NOVARTIS	10%	N80025	001		Mar	CMFD	

	>A>		TELITHROMYCIN							
NEWA	>A>		TABLET; ORAL							
	>A>		KETEK							
NEWA	>A>	+	AVENTIS PHARMS	400MG	N21144	001	Apr 01, 2004	Apr	NEWA	
			TERBINAFINE							
			GEL; TOPICAL							
			LAMISIL							
NEWA			NOVARTIS	1%	N20846	001	Apr 29, 1998	Jan	CMFD	
			TERBUTALINE SULFATE							
			INJECTABLE; INJECTION							
			BRETHINE							
CRLD	>D>	+	AAIPHARMA LLC	1MG/ML	N18571	001		Apr	CFTG	
NEWA	>A>	AP +		1MG/ML	N18571	001		Apr	CFTG	
	>A>		TERBUTALINE SULFATE							
	>A>	AP	BEDFORD	1MG/ML	N76770	001	Apr 23, 2004	Apr	NEWA	
			TERCONAZOLE							
CAHN			CREAM; VAGINAL							
			TERAZOL 3							
	>D>	+	ORTHO MCNEIL PHARM	0.8%	N19964	001	Feb 21, 1991	Apr	CFTG	
	>A>	AB +		0.8%	N19964	001	Feb 21, 1991	Apr	CFTG	
	>A>		TERCONAZOLE							
DISC	>A>	AB	TARO	0.8%	N75953	001	Apr 06, 2004	Apr	NEWA	
DISC										
			THEOPHYLLINE							
			TABLET, EXTENDED RELEASE; ORAL							
			THEOPHYLLINE							
	>A>	AB	ABLE	300MG	N40548	001	Apr 30, 2004	Apr	NEWA	
CTEC	>A>	AB		400MG	N40543	001	Apr 27, 2004	Apr	NEWA	
DISC	>A>	AB		450MG	N40546	001	Apr 30, 2004	Apr	NEWA	
	>A>	AB		600MG	N40539	001	Apr 27, 2004	Apr	NEWA	
			UNIPHYL							
	>D>	+	PURDUE FREDERICK	400MG	N87571	001	Sep 01, 1982	Apr	CFTG	
	>A>	AB +		400MG	N87571	001	Sep 01, 1982	Apr	CFTG	
NEWA	>D>	+		600MG	N40086	001	Apr 15, 1996	Apr	CFTG	
NEWA	>A>	AB +		600MG	N40086	001	Apr 15, 1996	Apr	CFTG	
NEWA										
			TIOTROPIUM BROMIDE MONOHYDRATE							
			CAPSULE; INHALATION							
			SPIRIVA							
		+	BOEHRINGER INGELHEIM	EQ 0.018MG BASE	N21395	001	Jan 30, 2004	Jan	NEWA	
DISC										
			TIZANIDINE HYDROCHLORIDE							
			TABLET; ORAL							
			TIZANIDINE HCL							
		AB	TORPHARM	EQ 2MG BASE	N76533	001	Jan 16, 2004	Jan	NEWA	
CAHN		AB		EQ 4MG BASE	N76533	002	Jan 16, 2004	Jan	NEWA	
			TRIAMCINOLONE ACETONIDE							
			AEROSOL, METERED; INHALATION							
			AZMACORT							
CMFD	>D>	+	AVENTIS	0.1MG/INH	N18117	001	Apr 23, 1982	Apr	CAHN	
	>A>	+	KOS	0.1MG/INH	N18117	001	Apr 23, 1982	Apr	CAHN	

SPRAY, METERED; NASAL

>A>		NASACORT HFA						
>A>	+	AVENTIS PHARMS	0.055MG/SPRAY	N20784	001	Apr 07, 2004	Apr	NEWA

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

		VALTREX						
	+	GLAXOSMITHKLINE	EQ 1GM BASE	N20487	002	Jun 23, 1995	Feb	CRLD

VINCRISTINE SULFATE

INJECTABLE; INJECTION

		ONCOVIN						
		@ LILLY	1MG/ML	N14103	003	Mar 07, 1984	Mar	DISC

VITAMIN A PALMITATE

INJECTABLE; INJECTION

		AQUASOL A						
>D>	+	AAIPHARMA LLC	EQ 50,000 UNITS BASE/ML	N06823	001		Apr	CAHN
>A>	+	MAYNE PHARMA USA	EQ 50,000 UNITS BASE/ML	N06823	001		Apr	CAHN

ZOLPIDEM TARTRATE

TABLET; ORAL

		AMBIEN						
>D>		LOREX	5MG	N19908	001	Dec 16, 1992	Apr	CAHN
>D>	+		10MG	N19908	002	Dec 16, 1992	Apr	CAHN
>A>		SANOFI SYNTHELABO	5MG	N19908	001	Dec 16, 1992	Apr	CAHN
>A>	+		10MG	N19908	002	Dec 16, 1992	Apr	CAHN

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VASOCON-A

+	NOVARTIS	0.5%;0.05%	N18746	002	Jul 11, 1994	Feb	CAHN

CHLORPHENIRAMINE MALEATE

CAPSULE, EXTENDED RELEASE; ORAL
CHLORPHENIRAMINE MALEATE

>D>	+	SANDOZ	12MG	N70797	001	Aug 12, 1988	Apr	DISC
>A>		@	12MG	N70797	001	Aug 12, 1988	Apr	DISC

TABLET, EXTENDED RELEASE; ORAL
EFIDAC 24 CHLORPHENIRAMINE MALEATE

+	ALZA	16MG	N19746	002	Nov 18, 1994	Mar	CRLD

CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

SUSPENSION; ORAL
CHILDREN'S ADVIL ALLERGY SINUS

+	WYETH CONS	1MG/5ML;100MG/5ML;15MG/5ML	N21587	001	Feb 24, 2004	Feb	NEWA

DEXTROMETHORPHAN HYDROBROMIDE; GUAIFENESIN

TABLET, EXTENDED RELEASE; ORAL
MUCINEX DM

>A>		ADAMS LABS	30MG;600MG	N21620	002	Apr 29, 2004	Apr	NEWA
>A>	+		60MG;1.2GM	N21620	001	Apr 29, 2004	Apr	NEWA

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S ELIXSURE

		TARO	100MG/5ML	N21604	001	Jan 07, 2004	Jan	NEWA

TABLET, CHEWABLE; ORAL
IBUPROFEN

		PERRIGO	50MG	N76359	001	Jan 16, 2004	Jan	NEWA
			100MG	N76359	002	Jan 16, 2004	Jan	NEWA

IBUPROFEN POTASSIUM; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL
ADVIL COLD AND SINUS

+	WYETH CONS	200MG;30MG	N21374	001	May 30, 2002	Mar	CAIN

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
LORATADINE AND PSEUDOEPHEDRINE SULFATE

		ANDRX PHARMS	5MG;120MG	N76208	001	Jan 28, 2004	Jan	NEWA
		IMPAX LABS	10MG;240MG	N75989	001	Mar 04, 2004	Mar	NEWA

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MICONAZOLE 7 COMBINATION PACK

		G AND W LABS	2%,100MG	N76585	001	Mar 26, 2004	Mar	NEWA

CREAM; TOPICAL, VAGINAL
MICONAZOLE 3 COMBINATION PACK

		PERRIGO	2%,4%	N76357	001	Mar 30, 2004	Mar	NEWA

NAPROXEN SODIUM; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

NAPROXEN SODIUM AND PSEUDOEPHEDRINE HCL

PERRIGO	EQ 200MG BASE;120MG	N76518	001	Mar 17, 2004	Mar	NEWA

TERBINAFINE HYDROCHLORIDE

SPRAY; TOPICAL

LAMISIL AT

+	NOVARTIS	1%	N21124	002	Mar 17, 2000	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 4 APRIL 2004

NO APRIL 2004 APPROVALS

This data is provided to the Office of Generic Drugs from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Products Designations and Approvals List
April 2004

Generic Name/ Trade Name (if present):	Date Designated = DD Date Approved= MA	Indication Designated:	Sponsor and Address
Rituxan	DD: 1/29/2004 MA:	Treatment of chronic lymphocytic leukemia	Biogen IDEC, Inc. 3030 Callan Road San Diego CA 92121
Biopharmaceuticals, Ltd.	DD: 3/17/2004	Treatment of the West Nile virus infection	q OMRIX
Institute	MA:		Plasma Fractionation Sheba Hospital Ramat Gan 52621
(1S)-1-(9-deazahypoxanthin-9-yl)-1, 4-dideoxy-1,4-imino-D-ribitol-hydr ochloride	DD: 1/29/2004 MA:	Treatment of T-cell non-Hodgkin's lymphoma	BioCryst 2190 Parkway Lake Birmingham AL 35244
1-Deoxygalactonojirimycin	DD: 2/25/2004	Treatment of Fabry Disease	Amicus Therapeutics,
08902	MA:		675 US Route 1 North Brunswick NJ
3-4'aminoisoindoline-1'-one)-1-pipe ridine-2,6-dione (CC-5013) REVIMID	DD: 1/29/2004 MA: MA:	Treatment of myelodysplastic syndromes	Celgene Corporation 7 Powder Horn Drive Warren NJ 07059
5-methyl-1-phenyl-2-(1H)-pyridone(CAS 53179-13-8) Pirfenidone	DD: 3/5/2004 MA: MA:	Treatment of idiopathic pulmonary fibrosis	InterMune, Inc. 3280 Bayshore Blvd Brisbane CA 94005
90Y-hPAMA4 PAN-Cide	DD: 1/29/2004 MA:	Treatment of pancreatic cancer	Immunomedics, Inc. 300 American Road Morris Plains NJ 07950
Alpha-1-acid glycoprotein	DD: 3/17/2004 MA:	Treatment of tricyclic antidepressant poisoning	Bio Products Laboratory Dagger Lane Elstree, Hertfordshire

Orphan Products Designations and Approvals List

April 2004

alpha-1-acid glycoprotein	DD: 3/5/2004 MA:	Treatment of cocaine overdose	Bio Products Laboratory Dagger Lane, Elstree Hertfordshire
antivenin crotaline (pit-viper) Therapeutics, Inc. equine immune F(ab)2 Antivipmyn	DD: 1/29/2004 MA: MA:	Treatment of envenomation by Crotaline snakes	Rare Disease 1101 Kermit Drive, Suite 608 Nashville TN 37217
chenodeoxycholic acid Chenofalk	DD: 1/29/2004 MA:	Treatment of cerebrotendinous xanthomatosis	Dr. Falk Pharma GmbH Leinenweberstrasse 5 Leinenweberstrasse 5 Postfach 6529
DEAE-rebeccamycin 94083-0511	DD: 3/1/2004 MA:	Treatment of bile duct tumors	Exelixis, Inc. 170 Harbor Way South San Francisco CA
Dexrazoxane Copenhagen	DD: 3/25/2004 MA:	Treatment of anthracycline extravasation during chemotherapy	Topo Target A/S Fruebjergvej 3, 2100
Idebenone (INN)	DD: 3/25/2004 MA:	Treatment of cardiomyopathy associated with Friedreich's ataxia	MyoContract Ltd. Hammerstrasse 25 CH-4410 Liestal
multi-vitiam infusion without vitamin K ParkDrive M.V.I.-12	DD: 3/8/2004 MA:	Prevention of vitamin deficiency and thromboembolic complications in people receiving home parenteral nutrition and warfarin-type anticoagulant therapy	aaiPharma, Inc. 2320 Scientific Wilmington NC 28405
oral unfractionated heparin 94019	DD: 1/29/2004 MA:	Treatment of sickle cell disease	TRF Technologies, Inc. 108 Eagle Trace Drive Half Moon Bay CA
Recombinant Porcine Factor VIII, B-domain Deleted	DD: 3/16/2004 MA:	Treatment and prevention of episodic bleeding in patients with inhibitor antibodies to human coagulation factor VIII	Ipsen Limited 190 Bath Road Berkshire S11 3XE

Orphan Products Designations and Approvals List

April 2004

rh-microplasmin Office Park	DD: 3/16/2004 MA:	Adjunct to surgery in cases of pediatric vitrectomy	ThromboGenics Ltd Unit 14, Bridgecourt Dublin 12
rofecoxib VIOXX	DD: 3/16/2004 MA:	Treatment of juvenile rheumatoid arthritis	MERCK & Co., Inc. 126 East Lincoln Ave. Rahway NJ 07065
SGN-30 (anti-CD30 antibody) Southeast	DD: 2/18/2004 MA:	For the treatment of CD30 positive T-cell lymphomas	Seattle Genetics, Inc. 21823 30th Drive Bothell WA 98021
sodium thiosulfate Inc. Crescent	DD: 3/17/2004 MA:	Prevention of platinum-induced ototoxicity in pediatric patients	Adherex Technologies, 600 Peter Morand Ottawa, Ontario
somatropin Serostim	DD: 3/16/2004 MA:	Treatment of patients with HIV-associated adipose redistribution syndrome	Serono, Inc. One Technology Place One Technology Place Rockland MA 02370
Staphylococcus aureus Immune Globulin (Human) Altastaph	DD: 1/29/2004 MA: MA:	Prophylaxis against Staphylococcus aureus infections in low birth weight neonates	Nabi Biopharmaceuticals 12276 Wilkins Avenue Rockville MD 20852
Suberoylanilide Hydroxamic Acid Road 6717	DD: 3/17/2004 MA:	Treatment of mesothelioma	Aton Pharma, Inc. 777 Old Saw Mill River Tarrytown NY 10591-
Suberoylanilide Hydroxamic Acid (SAHA) Road 6717	DD: 3/16/2004 MA:	Treatment of T-cell non-Hodgkin's lymphoma	Aton Pharma, Inc. 777 Old Saw Mill River Tarrytown NY 10591-
tetrahydrobiopterin Pharmaceutical Inc.	DD: 1/29/2004 MA:	For treatment of hyperphenylalaninemia	Biomarin 371 Bel Marin Blvd. Novato CA 94949

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

NO APRIL 2004 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes for information regarding report content

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
021320 001	ABARELIX;PLENAXIS	5968895	DEC 11, 2016	DP		
		6180608	DEC 11, 2016	DP U549		
		6423686	JUN 07, 2015	DS		
		6455499	JUN 07, 2015	U549		
		5843901	DEC 01, 2015	DS DP		
		6699833	DEC 11, 2016	DP		
021539 001	ACETYLCYSTEINE;ACETADOTE				ODE	JAN 23, 2011
020949 001	ALBUTEROL SULFATE;ACCUNEB	6702997	DEC 28, 2021	U558		
020949 002	ALBUTEROL SULFATE;ACCUNEB	6702997	DEC 28, 2021	U558		
020886 001	ALITRETINOIN;PANRETIN	5932622	AUG 03, 2016	U562		
021540 001	AMLODIPINE BESYLATE;CADUET	5273995	DEC 28, 2010	DS DP U162	NC	JAN 30, 2007
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
		4681893	SEP 24, 2009	DS DP U161		
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
021540 002	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 003	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
021540 004	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 005	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 006	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 007	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
			5686104	NOV 11, 2014	DP U213		
			5686104*PED	MAY 11, 2015			
			6126971	JAN 19, 2013	DP		
			6126971*PED	JUL 19, 2013			
	021540 008	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
			4681893*PED	MAR 24, 2010			
			4879303	MAR 25, 2007	DS DP		
			4879303*PED	SEP 25, 2007			
			4572909	JUL 31, 2006	DS DP U3		
			4572909*PED	JAN 31, 2007			
			5273995	DEC 28, 2010	DS DP U162		
			5273995*PED	JUN 28, 2011			
			6455574	AUG 11, 2018	U552		
			5969156	JUL 08, 2016	DS		
			5969156*PED	JAN 08, 2017			
			5686104	NOV 11, 2014	DP U213		
			5686104*PED	MAY 11, 2015			
			6126971	JAN 19, 2013	DP		
			6126971*PED	JUL 19, 2013			
>ADD>	021264 001	APOMORPHINE HYDROCHLORIDE;APOKYN				NCE	APR 20, 2009
>ADD>	021264 002	APOMORPHINE HYDROCHLORIDE;APOKYN				NCE	APR 20, 2009
>ADD>	021248 001	ARSENIC TRIOXIDE;TRISENOX	6723351	NOV 10, 2018	U573		
	020114 001	AZELASTINE HYDROCHLORIDE;ASTELIN	5164194	NOV 01, 2010	U207		
			5164194*PED	MAY 01, 2011			
	019851 001	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
						PED	SEP 02, 2007
	019851 002	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
						PED	SEP 02, 2007
	019851 003	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
						PED	SEP 02, 2007
	019851 004	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
						PED	SEP 02, 2007
	021602 001	BORTEZOMIB;VELCADE	6713446	JAN 25, 2022	DP		
	020746 001	BUDESONIDE;RHINOCORT	6686346	APR 29, 2017	DP U557		
	020746 002	BUDESONIDE;RHINOCORT	6686346	APR 29, 2017	DP U557		
>ADD>	019880 001	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	U175		
>ADD>			4657927*PED	OCT 14, 2004			
>ADD>	019880 002	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	U175		
>ADD>			4657927*PED	OCT 14, 2004			
>ADD>	019880 003	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	U175		
>ADD>			4657927*PED	OCT 14, 2004			
>ADD>	020452 001	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
>ADD>			4657927*PED	OCT 14, 2004			
>ADD>	020452 002	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
>ADD>			4657927*PED	OCT 14, 2004			
>ADD>	020452 003	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
>ADD>			4657927*PED	OCT 14, 2004			
>ADD>	020452 004	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
>ADD>			4657927*PED	OCT 14, 2004			
	021621 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007	DS DP U565		
			4525358*PED	DEC 25, 2007			
			6455533	JUL 02, 2018	DP		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
	021621 002	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007	DS DP U565		
			4525358*PED	DEC 25, 2007			
			6455533	JUL 02, 2018	DP		
	021587 001	CHLORPHENIRAMINE MALEATE;CHILDREN'S ADVIL ALL				NP	FEB 24, 2007
>ADD>	021149 002	CHORIOGONADOTROPIN ALFA;OVIDREL	6706681	MAR 16, 2021	DP		
	021688 001	CINACALCET HYDROCHLORIDE;SENSIPAR	6031003	DEC 14, 2016	U559	ODE	MAR 08, 2011
			6211244	OCT 23, 2015	DS DP U560	NCE	MAR 08, 2009
			6313146	DEC 14, 2016	DS DP		
			6011068	DEC 14, 2016	DS DP		
	021688 002	CINACALCET HYDROCHLORIDE;SENSIPAR	6031003	DEC 14, 2016		ODE	MAR 08, 2011
			6211244	OCT 23, 2015	DS DP U560	NCE	MAR 08, 2009
			6313146	DEC 14, 2016	DS DP		
			6011068	DEC 14, 2016	DS DP		
	021688 003	CINACALCET HYDROCHLORIDE;SENSIPAR	6031003	DEC 14, 2016	U559	ODE	MAR 08, 2011
			6211244	OCT 23, 2015	DS DP U560	NCE	MAR 08, 2009
			6313146	DEC 14, 2016	DS DP		
			6011068	DEC 14, 2016	DS DP		
	019537 001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	019537 002	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	019537 003	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	019537 004	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	019847 001	CIPROFLOXACIN;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	020780 001	CIPROFLOXACIN;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	020780 002	CIPROFLOXACIN;CIPRO				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	019857 001	CIPROFLOXACIN;CIPRO IN DEXTROSE 5%				I-421	MAR 25, 2007
						PED	SEP 25, 2007
	019858 001	CIPROFLOXACIN;CIPRO IN SODIUM CHLO	4670444	DEC 09, 2003			
			4705789	NOV 10, 2004			
			4957922	SEP 18, 2007			
			4808583	FEB 28, 2006			
			4670444*PED	JUN 09, 2004			
			4705789*PED	MAY 10, 2005			
			4808583*PED	AUG 28, 2006			
			4957922*PED	MAR 18, 2008			
	021473 002	CIPROFLOXACIN;CIPRO XR	4670444	DEC 09, 2003	DS DP U555		
			4670444*PED	JUN 09, 2004			
	021644 001	CLOBETASOL PROPIONATE;CLOBEX				NDF	FEB 05, 2007
>ADD>	021038 001	DEXMEDETOMIDINE;PRECEDEX	6716867	MAR 31, 2019	U572		
	021392 001	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
	021392 002	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
	021392 003	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
	021392 004	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
	021392 005	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
	021392 006	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
	021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6528090	DEC 18, 2018	DP		

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
	021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6528090	DEC 18, 2018	DP		
			6528091	DEC 18, 2018			
	020931 001	DOFETILIDE;TIKOSYN	4959366	SEP 25, 2007			
	020931 002	DOFETILIDE;TIKOSYN	4959366	SEP 25, 2007			
	020931 003	DOFETILIDE;TIKOSYN	4959366	SEP 25, 2007			
	020869 001	DORZOLAMIDE HYDROCHLORIDE;COSOPT	6316443	APR 17, 2011	DP U561		
>ADD>	020408 001	DORZOLAMIDE HYDROCHLORIDE;TRUSOPT	4797413	APR 28, 2008	DS DP U103		
>ADD>			4619939	OCT 28, 2003	DP U104		
>ADD>	020862 001	DOXERCALCIFEROL;HECTOROL				I-424	APR 23, 2007
>ADD>	020862 002	DOXERCALCIFEROL;HECTOROL				I-424	APR 23, 2007
	018651 001	DRONABINOL;MARINOL	6703418	FEB 26, 2011	U563		
	018651 002	DRONABINOL;MARINOL	6703418	FEB 26, 2011	U563		
	018651 003	DRONABINOL;MARINOL	6703418	FEB 26, 2011	U563		
	021500 001	EMTRICITABINE;EMTRIVA	6703396	MAR 09, 2021	DS DP		
	021371 001	ESTRADIOL HEMIHYDRATE;ESTRASORB				NDF	OCT 09, 2006
	021166 001	ESTRADIOL;ESTROGEL				NDF	FEB 09, 2007
	020992 002	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
	020992 003	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
	020992 004	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
	020992 006	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				NS	FEB 05, 2007
						D-85	FEB 05, 2007
	021490 001	ETHINYL ESTRADIOL;OVCON-35	6667050	JUN 12, 2021	DP U1		
	019922 001	FENOLDOPAM MESYLATE;CORLOPAM				I-422	APR 01, 2007
>ADD>	020180 001	FINASTERIDE;PROSCAR	4760071	JUN 19, 2006	DS DP U262		
>ADD>			5886184	NOV 19, 2012	DS		
>ADD>			6046183	MAR 20, 2011	DP U577		
	019949 001	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019949 002	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019949 003	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019949 004	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	020090 001	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	020090 002	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019950 003	FLUCONAZOLE;DIFLUCAN IN DEXTROSE	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019950 005	FLUCONAZOLE;DIFLUCAN IN DEXTROSE	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019950 001	FLUCONAZOLE;DIFLUCAN IN SODIUM C	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019950 002	FLUCONAZOLE;DIFLUCAN IN SODIUM C	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	019950 004	FLUCONAZOLE;DIFLUCAN IN SODIUM C	4404216	JAN 29, 2004			
			4404216*PED	JUL 29, 2004			
	020985 001	FLUOROURACIL;CARAC	6670335	JUN 02, 2021	DP U68		
	021235 001	FLUOXETINE HYDROCHLORIDE;PROZAC WEEKLY	5910319	MAY 29, 2017	U396		
			5985322	MAY 29, 2017	U397		
>ADD>	021077 001	FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50				M-33	APR 21, 2007

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021211 001	FOLLITROPIN ALFA/BETA;FOLLISTIM AQ	5929028	JAN 14, 2018	DP U567		
>ADD>			5767251	JUN 16, 2015	DS		
>ADD>			4589402	JUL 26, 2004	U568		
>ADD>			4589402	JUL 26, 2004	U569		
>ADD>			4589402	JUL 26, 2004	U570		
>ADD>	021211 002	FOLLITROPIN ALFA/BETA;FOLLISTIM AQ	5929028	JAN 14, 2018	DP U567		
>ADD>			4589402	JUL 26, 2004	U568		
>ADD>			5767251	JUN 16, 2015	DS		
>ADD>			4589402	JUL 26, 2004	U569		
>ADD>			4589402	JUL 26, 2004	U570		
>ADD>	021765 001	FOLLITROPIN ALFA/BETA;GONAL-F				NP	MAR 25, 2007
>ADD>	021765 002	FOLLITROPIN ALFA/BETA;GONAL-F				NP	MAR 25, 2007
>ADD>	021765 003	FOLLITROPIN ALFA/BETA;GONAL-F				NP	MAR 25, 2007
	021493 001	GATIFLOXACIN;ZYMAR	6333045	AUG 20, 2019	DP		
>ADD>	076345 001	GLYBURIDE;GLYBURIDE AND METFOR				PC	OCT 31, 2004
>ADD>	076345 002	GLYBURIDE;GLYBURIDE AND METFOR				PC	OCT 31, 2004
>ADD>	076345 003	GLYBURIDE;GLYBURIDE AND METFOR				PC	OCT 31, 2004
	021604 001	IBUPROFEN;CHILDREN'S ELIXSURE				NP	JAN 07, 2007
	076478 001	IBUPROFEN;IBUPROFEN AND PSEUDO				PC	JUL 29, 2004
	020723 001	IMIQUIMOD;ALDARA				I-420	MAR 02, 2007
	020685 001	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
	020685 003	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
	020685 005	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
	020685 006	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
>ADD>	021629 001	INSULIN GLULISINE;APIDRA				NCE	APR 16, 2009
	020571 001	IRINOTECAN HYDROCHLORIDE;CAMPTOSAR	4604463	AUG 20, 2007			
			6403569	APR 28, 2020	U449		
			4604463*PED	FEB 20, 2008			
			6403569*PED	OCT 28, 2020			
>ADD>	020905 001	LEFLUNOMIDE;ARAVA				M-32	MAR 05, 2007
>ADD>						PED	SEP 05, 2007
>ADD>	020905 002	LEFLUNOMIDE;ARAVA				M-32	MAR 05, 2007
>ADD>						PED	SEP 05, 2007
>ADD>	020905 003	LEFLUNOMIDE;ARAVA				M-32	MAR 05, 2007
>ADD>						PED	SEP 05, 2007
	020182 001	LEVOCARNITINE;CARNITOR	6696493	JAN 18, 2021	U433		
	021571 001	LEVOFLOXACIN;IQUIX				NP	MAR 01, 2007
	021451 001	LIDOCAINE;ORAQIX	6031007	APR 01, 2017	DP U553		
	021226 001	LOPINAVIR;KALETRA	6703403	JUN 26, 2016	U257		
	021251 001	LOPINAVIR;KALETRA	6703403	JUN 26, 2016	U257		
	075505 001	LORATADINE;LORATADINE				PC	AUG 20, 2004
>ADD>	020386 001	LOSARTAN POTASSIUM;COZAAR				NPP	MAR 11, 2007
>ADD>						PED	SEP 11, 2007
>ADD>	020386 002	LOSARTAN POTASSIUM;COZAAR				NPP	MAR 11, 2007
>ADD>						PED	SEP 11, 2007
>ADD>	020386 003	LOSARTAN POTASSIUM;COZAAR				NPP	MAR 11, 2007
>ADD>						PED	SEP 11, 2007
>ADD>	020803 001	LOTEPREDNOL ETABONATE;ALREX	5747061	OCT 25, 2013	DP U576		
>ADD>	020583 001	LOTEPREDNOL ETABONATE;LOTEMAX	5747061	OCT 25, 2013	DP U575		
	021249 001	LOVASTATIN;ADVICOR	6676967	SEP 20, 2013	U548		
	021249 002	LOVASTATIN;ADVICOR	6676967	SEP 20, 2013	U548		
	021249 003	LOVASTATIN;ADVICOR	6676967	SEP 20, 2013	U548		

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
	013217 001	METAXALONE;SKELAXIN	6683102	DEC 03, 2021	U189		
	013217 002	METAXALONE;SKELAXIN	6683102	DEC 03, 2021	U189		
>ADD>	021574 001	METFORMIN HYDROCHLORIDE;FORTAMET				NP	APR 27, 2007
>ADD>	021574 002	METFORMIN HYDROCHLORIDE;FORTAMET				NP	APR 27, 2007
	076545 001	METFORMIN HYDROCHLORIDE;METFORMIN HCL				PC	MAY 29, 2004
	021308 001	MICONAZOLE NITRATE;MONISTAT 1 COMBINATI				RTO	JUN 29, 2004
	076307 001	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 14, 2004
	076307 002	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 14, 2004
>ADD>	020762 001	MOMETASONE FUROATE MONOHYDRATE;NASONEX	6723713	JAN 27, 2014	U574		
>ADD>			6723713*PED	JUL 27, 2014			
>ADD>	021598 001	MOXIFLOXACIN HYDROCHLORIDE;VIGAMOX	6716830	SEP 20, 2019	DP	NCE	DEC 10, 2004
>ADD>			6716830*PED	MAR 29, 2020		PED	JUN 10, 2005
	020381 002	NIACIN;NIASPAN	6676967	SEP 20, 2013	U548		
	020381 003	NIACIN;NIASPAN	6676967	SEP 20, 2013	U548		
	020381 004	NIACIN;NIASPAN	6676967	SEP 20, 2013	U548		
>ADD>	076648 001	NITROFURANTOIN;NITROFURANTOIN (MONO				PC	SEP 19, 2004
	020592 001	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007
			5229382	APR 23, 2001	U547		
	020592 002	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007
			5229382	APR 23, 2011	U547		
	020592 003	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007
			5229382	APR 23, 2011	U547		
	020592 004	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007
			5229382	APR 23, 2011	U547		
	020592 005	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007
			5229382	APR 23, 2011	U547		
	020592 006	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007
			5229382	APR 23, 2011	DS DP U547		
>ADD>	021253 001	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	DS DP U571	NDF	MAR 29, 2007
						NP	MAR 29, 2007
	021086 001	OLANZAPINE;ZYPREXA ZYDIS				I-417	JAN 14, 2007
						I-400	JUL 10, 2006
	021086 002	OLANZAPINE;ZYPREXA ZYDIS				I-417	JAN 14, 2007
						I-400	JUL 10, 2006
	021086 003	OLANZAPINE;ZYPREXA ZYDIS				I-417	JAN 14, 2007
						I-400	JUL 10, 2006
	021086 004	OLANZAPINE;ZYPREXA ZYDIS				I-417	JAN 14, 2007
						I-400	JUL 10, 2006
>ADD>	021087 001	OSELTAMIVIR PHOSPHATE;TAMIFLU	5866601*PED	AUG 02, 2016		NCE	OCT 27, 2004
			5763483	DEC 27, 2016		PED	APR 27, 2005
			5866601	FEB 02, 2016			
			5952375*PED	AUG 02, 2016			
			5952375	FEB 02, 2016			
			5763483*PED	JUN 27, 2017			
	021246 001	OSELTAMIVIR PHOSPHATE;TAMIFLU	5866601	FEB 02, 2016		NCE	OCT 27, 2004
			5952375	FEB 02, 2016		PED	APR 27, 2005
			5763483	DEC 27, 2016	U376		
			5763483*PED	JUN 27, 2017			
			5866601*PED	AUG 02, 2016			
			5952375*PED	AUG 02, 2016			
>ADD>	021492 001	OXALIPLATIN;ELOXATIN				I-425	JAN 09, 2007
>ADD>	021492 002	OXALIPLATIN;ELOXATIN				I-425	JAN 09, 2007

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>ADD>	076168 001	OXYCODONE HYDROCHLORIDE;OXYCODONE HCL				PC	SEP 26, 2004
	020819 001	PARICALCITOL;ZEMPLAR				M-31	MAR 31, 2007
						PED	OCT 01, 2007
	020819 002	PARICALCITOL;ZEMPLAR	5246925	APR 17, 2012	U314	M-31	MAR 31, 2007
			5246925*PED	OCT 17, 2012		PED	OCT 01, 2007
			5587497	DEC 24, 2013			
			5587497*PED	JUN 24, 2014			
			6136799	APR 08, 2018			
			6136799*PED	OCT 08, 2019			
			6361758	APR 08, 2018	DP		
			6361758*PED	OCT 08, 2018			
	021462 001	PEMETREXED DISODIUM;ALIMTA	5217974	MAR 29, 2011	U551	NCE	FEB 04, 2009
			5344932	SEP 06, 2011	DS DP	ODE	FEB 04, 2011
	020639 001	QUETIAPINE FUMARATE;SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419	JAN 12, 2007
						I-418	JAN 12, 2007
	020639 002	QUETIAPINE FUMARATE;SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419	JAN 12, 2007
						I-418	JAN 12, 2007
	020639 003	QUETIAPINE FUMARATE;SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419	JAN 12, 2007
						I-418	JAN 12, 2007
	020639 004	QUETIAPINE FUMARATE;SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419	JAN 12, 2007
						I-418	JAN 12, 2007
	020639 005	QUETIAPINE FUMARATE;SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419	JAN 12, 2007
						I-418	JAN 12, 2007
	020741 001	REPAGLINIDE;PRANDIN	6677358	JUN 12, 2018	DS DP U546		
	020741 002	REPAGLINIDE;PRANDIN	6677358	JUN 12, 2018	DS DP U546		
	020741 003	REPAGLINIDE;PRANDIN	6677358	JUN 12, 2018	DS DP U546		
	020903 002	RIBAVIRIN;REBETOL	6177074	NOV 01, 2016	U454		
			6177074*PED	MAY 01, 2017	U454		
			6461605	NOV 01, 2016	U478		
			6461605*PED	MAY 01, 2017	U478		
			6472373	SEP 21, 2017	U479		
			6472373*PED	MAR 21, 2018	U479		
			6524570	NOV 01, 2016	U499		
			6524570*PED	MAY 01, 2017	U499		
	076203 001	RIBAVIRIN;RIBASPHERE				PC	OCT 03, 2004
	076192 001	RIBAVIRIN;RIBAVIRIN				PC	OCT 03, 2004
	020659 001	RITONAVIR;NORVIR	6703403	JUN 26, 2016	U564		
	020945 001	RITONAVIR;NORVIR	6703403	JUN 26, 2016	U564		
>ADD>	021042 001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	DS DP U266	NCE	MAY 20, 2004
>ADD>			6239173	JUN 24, 2013	DS DP U266	I-353	APR 11, 2005
			5691374	MAY 18, 2015		M-27	AUG 06, 2006
			5691374*PED	NOV 18, 2015		PED	NOV 20, 2004
			6239173*PED	DEC 24, 2013		PED	OCT 11, 2005
			6063811*PED	NOV 06, 2017		PED	FEB 06, 2007
>ADD>			5474995*PED	DEC 24, 2013		I-423	MAR 26, 2007
			6063811	MAY 06, 2017	U266		
>ADD>	021042 002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	DS DP U266	NCE	MAY 20, 2004
>ADD>			6239173	JUN 24, 2013	DS DP U266	I-353	APR 11, 2005
			5691374	MAY 18, 2015		M-27	AUG 06, 2006
			5691374*PED	NOV 18, 2015		PED	NOV 20, 2004
			6239173*PED	DEC 24, 2013		PED	OCT 11, 2005
			6063811*PED	NOV 06, 2017		PED	FEB 06, 2007
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			6063811	MAY 06, 2017	U266		

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>ADD>	021042 003	ROFECOXIB;VIOXX	6239173	JUN 24, 2013	DS DP U266	NCE	MAY 20, 2004
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			5691374	MAY 18, 2015		M-27	AUG 06, 2006
			6063811	MAY 06, 2017		PED	NOV 20, 2004
			5474995*PED	DEC 24, 2013		PED	OCT 11, 2005
			5691374*PED	NOV 18, 2015		PED	FEB 06, 2007
>ADD>			6063811*PED	NOV 06, 2017		I-423	MAR 26, 2007
			6239173*PED	DEC 24, 2013			
	021052 001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U266	NCE	MAY 20, 2004
			5691374	MAY 18, 2015		I-353	APR 11, 2005
			6063811	MAY 06, 2017	U266	M-27	AUG 06, 2006
			6239173	JUN 24, 2013		PED	NOV 20, 2004
			5474995*PED	DEC 24, 2013		PED	FEB 06, 2007
			5691374*PED	NOV 18, 2015		PED	OCT 11, 2005
			6063811*PED	NOV 06, 2017			
			6239173*PED	DEC 24, 2013			
	021052 002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U266	NCE	MAY 20, 2004
			5691374	MAY 18, 2015		I-353	APR 11, 2005
			6063811	MAY 06, 2017	U266	M-27	AUG 06, 2006
			6239173	JUN 24, 2013		PED	NOV 20, 2004
			5474995*PED	DEC 24, 2013		PED	FEB 06, 2007
			5691374*PED	NOV 18, 2015		PED	OCT 11, 2005
			6063811*PED	NOV 06, 2017			
			6239173*PED	DEC 24, 2013			
	021256 001	SECRETIN SYNTHETIC HUMAN;HUMAN SECRETIN				ODE	APR 04, 2009
						NCE	APR 09, 2009
	020926 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 11, 2013			
	021179 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 11, 2013			
	021110 003	SIROLIMUS;RAPAMUNE				NCE	SEP 15, 2004
						I-386	APR 11, 2006
>ADD>	020168 001	SOMATROPIN RECOMBINANT;NUTROPIN	5096885	MAR 17, 2009	DP		
>ADD>	020168 002	SOMATROPIN RECOMBINANT;NUTROPIN	5096885	MAR 17, 2009	DP		
>ADD>	020522 001	SOMATROPIN RECOMBINANT;NUTROPIN AQ	5763394	JUN 09, 2015	DP		
>ADD>	020522 002	SOMATROPIN RECOMBINANT;NUTROPIN AQ PEN	5763394	JUN 09, 2015	DP		
	020080 001	SUMATRIPTAN SUCCINATE;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008	U72		
			4816470*PED	JUN 28, 2007			
			5037845*PED	FEB 06, 2009			
	020132 001	SUMATRIPTAN SUCCINATE;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008	U72		
			6368627	MAR 02, 2012	U444		
			5863559	JAN 26, 2016	U72		
			6020001	MAR 02, 2012	U444		
			6020001*PED	SEP 02, 2012			
			6368627*PED	SEP 02, 2012			
			4816470*PED	JUN 28, 2007			
			5037845*PED	FEB 06, 2009			
			5863559*PED	JUL 26, 2016			
	020132 002	SUMATRIPTAN SUCCINATE;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008	U72		
			6368627	MAR 02, 2012	U444		
			5863559	JAN 26, 2016	U72		
			6020001	MAR 02, 2012	U444		
			6020001*PED	SEP 02, 2012			
			6368627*PED	SEP 02, 2012			
			4816470*PED	JUN 28, 2007			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes for information regarding report content

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
			5037845*PED	FEB 06, 2009			
			5863559*PED	JUL 26, 2016			
	020132 003	SUMATRIPTAN SUCCINATE;IMITREX	5037845	AUG 06, 2008	U72		
			4816470	DEC 28, 2006	U72		
			6368627	MAR 02, 2012	U444		
			5863559	JAN 26, 2016	U72		
			6020001	MAR 02, 2012	U444		
			6020001*PED	SEP 02, 2012			
			6368627*PED	SEP 02, 2012			
			4816470*PED	JUN 28, 2007			
			5037845*PED	FEB 06, 2009			
			5863559*PED	JUL 26, 2016			
	020626 001	SUMATRIPTAN;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008			
			5307953	DEC 02, 2012			
			5554639	SEP 10, 2013	U232		
			5705520	DEC 10, 2011	U232		
			5554639*PED	MAR 10, 2014			
			5705520*PED	JUN 10, 2012			
			4816470*PED	JUN 28, 2007			
			5037845*PED	FEB 06, 2009			
			5307953*PED	JUN 02, 2013			
	020626 002	SUMATRIPTAN;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008			
			5307953	DEC 02, 2012			
			5554639	SEP 10, 2013	U232		
			5705520	DEC 10, 2011	U232		
			5554639*PED	MAR 10, 2014			
			5705520*PED	JUN 10, 2012			
			4816470*PED	JUN 28, 2007			
			5037845*PED	FEB 06, 2009			
			5307953*PED	JUN 02, 2013			
	020626 003	SUMATRIPTAN;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008			
			5307953	DEC 02, 2012			
			5554639	SEP 10, 2013	U232		
			5705520	DEC 10, 2011	U232		
			5554639*PED	MAR 10, 2014			
			5705520*PED	JUN 10, 2012			
			4816470*PED	JUN 28, 2007			
			5037845*PED	FEB 06, 2009			
			5307953*PED	JUN 02, 2013			
	021368 001	TADALAFIL;CIALIS	5859006	JAN 12, 2016	DS DP		
			6140329	JUL 11, 2016	DP U155		
	021368 002	TADALAFIL;CIALIS	5859006	JAN 12, 2016	DS DP		
			6140329	JUL 11, 2016	DP U155		
	021368 003	TADALAFIL;CIALIS	5859006	JAN 12, 2016	DS DP		
			6140329	JUL 11, 2016	DP U155		
	021388 001	TALC;TALC				ODE	DEC 24, 2004
>ADD>	021144 001	TELITHROMYCIN;KETEK	D459798	SEP 24, 2015	DP	NCE	APR 01, 2009
>ADD>			5635485	APR 21, 2015	DS DP U578		
	021124 002	TERBINAFINE HYDROCHLORIDE;LAMISIL AT	5681849	OCT 28, 2014			
			4755534	DEC 30, 2006	U73		
			4680291	JUL 14, 2004	U73		
			6121314	MAY 18, 2012	U504		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
See report footnotes for information regarding report content

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
020846 001	TERBINAFINE;LAMISIL	5681849	OCT 28, 2014	DP		
		6121314	MAY 18, 2012	DP U504		
		6121314	MAY 18, 2012	DP U540		
		6121314	MAY 18, 2012	DP U502		
020898 001	THYROTROPIN ALFA;THYROGEN	6365127	NOV 24, 2015	DS DP U556		
021395 001	TIOTROPIUM BROMIDE MONOHYDRATE;SPIRIVA	5610163	MAR 11, 2014	DS DP U566	NCE	JAN 30, 2009
020771 002	TOLTERODINE TARTRATE;DETROL	5559269	NOV 05, 2013	U318		
		5559269*PED	MAY 05, 2014			
021257 001	TRAVOPROST;TRAVATAN	6011062	DEC 22, 2014	DP		
		5849792	DEC 22, 2014	DP U383		
		5889052	DEC 02, 2014	DP U383		
		5510383	AUG 03, 2013	DP U383		
021630 001	VORICONAZOLE;VFEND	5116844	AUG 11, 2009	DP U540	NCE	MAY 24, 2007
		5364938	NOV 15, 2011	DS	I-409	NOV 14, 2006
		5567817	OCT 22, 2013	DS DP U540		
		5773443	JAN 25, 2011	DS DP U540		

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(c)(3)(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. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 24TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION. THE MOST CURRENT COMPLETE LIST OF ALL PATENT AND EXCLUSIVITY TERMS IS AVAILABLE AT HTTP://WWW.FDA.GOV/CDER/ORANGE/PATEX.HTM.

PATENT & EXCLUSIVITY ABBREVIATIONS

W	EXCLUSIVITY ON THIS APPLICATION EXPIRING ON THIS DATE HAS BEEN WAIVED BY SPONSOR - SEE SECTION 1.8 OF ORANGE BOOK PREFACE WAIVED EXCLUSIVITY

EXCLUSIVITY DOSING SCHEDULE

D-85	LOWER RECOMMENDED STARTING DOSE GUIDELINES FOR TREATMENT OF MODERATE TO SEVERE VASOMOTOR SYMPTOMS ASSOCIATED WITH THE MENOPAUSE

EXCLUSIVITY INDICATION

I-417	USE IN THE LONG TERM TREATMENT OF BIPOLAR I DISORDER
I-418	ADJUNCTIVE THERAPY W/ MOOD STABILIZERS (LITHIUM OR DIVALPROEX) IN THE TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDERS
I-419	MONOTHERAPY IN THE TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
I-420	TOPICAL TREATMENT OF CLINICALLY TYPICAL, NONHYPERKERATOTIC, NONHYPERTROPHIC ACTINIC KERATOSES ON THE FACE OR SCALP IN IMMUNOCOMPETENT ADULTS
I-421	TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS AND PYELONEPHRITIS DUE TO E.COLI FOR PED PATIENTS (1-17) NOT AS FIRST CHOICE
I-422	INDICATED FOR THE IN-HOSPITAL SHORT-TERM (UP TO 4 HOURS) REDUCTION IN BLOOD PRESSURE IN PEDIATRIC PATIENTS
I-423	ACUTE TREATMENT OF MIGRAINE ATTACKS WITH OR WITHOUT AURA IN ADULTS
I-424	MANAGEMENT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS WITH MODERATE TO SEVERE CHRONIC RENAL INSUFFICIENCY NOT YET ON DIALYSIS
I-425	FLOXATIN IN COMBINATION WITH INFUSIONAL 5-FLUOROURACIL (5-FU) AND LEUCOVORIN (LV) FOR THE TREATMENT OF PATIENTS PREVIOUSLY UNTREATED FOR ADVANCED COLORECTAL CANCER

EXCLUSIVITY MISCELLANEOUS

M-30	CHANGES TO CLINICAL PHARMACOLOGY, PRECAUTIONS, AND DOSAGE AND ADMINISTRATION SECTIONS OF LABELING CONCERNING USE OF LOTENSIN IN PEDIATRIC PATIENTS WITH HYPERTENSION
M-31	INFORMATION FOR USE IN PEDIATRIC PATIENTS WITH CHRONIC KIDNEY DISEASE STAGE 5 (END-STAGE RENAL DISEASE)
M-32	ADDITIONAL LANGUAGE TO CLINICAL PHARMACOLOGY AND CLINICAL STUDIES
M-33	INFORMATION FOR USE OF ADVAIR DISKUS 100/50 IN CHILDREN 4 TO 11 YEARS OF AGE WITH ASTHMA

PATENT USE

U-546 USE OF REPAGLINIDE IN COMBINATION WITH METFORMIN TO LOWER BLOOD GLUCOSE
U-547 MAINTENANCE MONOTHERAPY FOR BIPOLAR DISORDER
U-548 A METHOD OF REDUCING FLUSH IN AN INDIVIDUAL BEING TREATED FOR A LIPIDEMIC DISORDER AND EFFECTIVELY TREATING THE LIPIDEMIC DISORDER
U-549 USE IN THE TREATMENT OF MEN WITH ADVANCED SYMPTOMATIC PROSTATE CANCER
U-550 TREATMENT OF BIPOLAR MANIA AND SCHIZOPHRENIA
U-551 METHOD FOR REDUCING TOXICITY OF ALIMTA TREATED PATIENTS BY ADMINISTERING FOLIC ACID
U-552 TREATMENT OF HYPERTENSION AND HYPERLIPIDEMIA WITH A SINGLE COMPOSITION
U-553 MANAGEMENT OF PAIN AND DISCOMFORT ASSOCIATED WITH PERIDONTAL SCALING AND ROOT PLANNING PROCEDURES BY APPLICATION OF AN EUTECTIC MIXTURE OF LOCAL ANESTHETICS TO PERIDONTAL POCKETS
U-554 TREATING HIV INFECTION WITH INDINAVIR SULFATE IN COMBINATION WITH ANTIRETROVIRAL AGENTS
U-555 TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS AND ACUTE UNCOMPLICATED PYELONEPHRITIS
U-556 USE AS ADJUNCT DIAGNOSTIC FOR SERUM THYROGLOBULIN (TG) TESTING
U-557 NASAL TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS
U-558 INDICATED FOR THE RELIEF OF BRONCHOSPASM IN PATIENTS 2-12 YEARS OF AGE WITH ASTHMA REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE)
U-559 METHOD OF DECREASING OR REDUCING PARATHYROID HORMONE LEVEL; METHOD OF MODULATING PARATHYROID HORMONE SECRETION; METHOD OF TREATING HYPERPARATHYROIDISM; METHOD OF REDUCING SERUM IONIZED CALCIUM LEVEL
U-560 METHOD OF DECREASING PARATHYROID HORMONE LEVEL; METHOD OF TREATING HYPERPARATHYROIDISM
U-561 COSOPT IS INDICATED FOR THE REDUCTION OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION WHO ARE INSUFFICIENTLY RESPONSIVE TO BETA BLOCKERS
U-562 TOPICAL TREATMENT OF CUTANEOUS LESIONS IN PATIENTS WITH AIDS-RELATED KAPOSI'S SARCOMA
U-563 MARINOL IS INDICATED FOR, INTER ALIA, ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS
U-564 TREATMENT OF HIV IN CONCOMITANT THERAPY
U-565 TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS, AND CHRONIC URTICARIA
U-566 FOR THE LONG-TERM, ONCE-DAILY, MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA
U-567 METHOD OF TREATING INFERTILITY
U-568 METHOD OF USING FSH ALONE (WITHOUT EXOGENOUS LH) IN IN VITRO FERTILIZATION
U-569 METHOD OF USING FSH ALONE (WITHOUT EXOGENOUS LH) IN IN VITRO FERTILIZATION AND WHEREIN THEREAFTER AN OVULATORY INDUCING AMOUNT OF HCG IS ADMINISTERED
U-570 METHOD OF USING FSH ALONE (WITHOUT EXOGENOUS LH) IN IN VITRO FERTILIZATION AND WHEREIN THE DAILY AMOUNT OF FSH IS ABOUT 5-10 IU/KG
U-571 TREATMENT OF AGITATION ASSOCIATED WITH SCHIZOPHRENIA AND BIPOLAR I MANIA
U-572 INTENSIVE CARE UNIT SEDATION
U-573 TREATMENT OF ACUTE PROMYELOGENOUS LEUKEMIA (APL)
U-574 PROPHYLAXIS AND TREATMENT OF THE NASAL SYMPTOMS OF SEASONAL ALLERGIC RHINITIS AND TREATMENT OF THE NASAL SYMPTOMS OF PERENNIAL ALLERGIC RHINITIS IN ADULTS AND PEDIATRIC PATIENTS 12 YEARS OF AGE AND OLDER
U-575 LOTEMAX IS INDICATED FOR STEROID-RESPONSIVE INFLAMMATORY OCULAR CONDITIONS FOR WHICH A CORTICOSTEROID IS INDICATED AND WHERE SUPERFICIAL BACTERIAL OCULAR INFECTION OR A RISK OF BACTERIAL OCULAR INFECTION EXISTS
U-576 ALREX IS INDICATED FOR STEROID-RESPONSIVE INFLAMMATORY OCULAR CONDITIONS FOR WHICH A CORTICOSTEROID IS INDICATED AND WHERE SUPERFICIAL BACTERIAL OCULAR INFECTION OR A RISK OF BACTERIAL OCULAR INFECTION EXISTS.
U-577 TREATMENT OF BENIGN PROSTATIC HYPERPLASIA WITH FINASTERIDE IN COMBINATION WITH DOXAZOSIN
U-578 TREATMENT OF COMMUNITY ACQUIRED PNEUMONIA, ACUTE EXACERBATION OF CHRONIC BRONCHITIS, AND ACUTE BACTERIAL SINUSITIS CAUSED BY SUSCEPTIBLE STRAINS OF DESIGNATED MICROORGANISMS IN PATIENTS 18 YEARS AND OLDER.

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