CUMULATIVE
SUPPLEMENT 2
FEBRUARY 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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

24th EDITION

Cumulative Supplement 2

February 2004

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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
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

24th EDITION

CUMULATIVE SUPPLEMENT2
February 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

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	JUN 2004	SEP 2004	DEC 2004
DRUG PRODUCTS LISTED	10665			
SINGLE SOURCE	2423 (22.7%)			
MULTISOURCE	8134 (76.3%)			
THERAPEUTICALLY EQUIVALENT	7856 (73.7%)			
NOT THERAPEUTICALLY EQUIVALENT	278 (2.6%)			
EXCEPTIONS[1]	108 (1.0%)			
NEW MOLECULAR ENTITIES APPROVED	6			
NUMBER OF APPLICANTS	601			

[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.

ACETYLCYSTEINE
INJECTABLE; INTRAVENOUS
ACETADOTE
\+ CUMBERLAND PHARMS 6GM/30ML(200MG/ML) N21539 001 JAN 23, 2004 JAN NEWA

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
>A> 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

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;0.14M G/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIA L;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; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K
INJECTABLE; IV (INFUSION)
M.V.I. ADULT
\+ 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/V IAL;1MG/VIAL;10MG/VIAL;0.15MG/VIAL N21625 001 JAN 30, 2004 JAN NEWA
>A> M.V.I. ADULT (PHARMACY BULK PACKAGE)
>A> \+ AAIPHARMA LLC 200MG/5ML;0.06MG/5ML;0.005MG/5ML;15

			MG/5ML;0.005MG/5ML;0.6MG/5ML;40MG/5 ML;6MG/5ML;3.6MG/5ML;6MG/5ML;1MG/5M L;10MG/5ML;0.15MG/5ML	N21643	001	FEB 18, 2004	FEB	NEWA
	BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE							
	OINTMENT; OPHTHALMIC							
	NEOMYCIN AND POLYMYXIN B SULFATE AND BACITRACIN ZINC							
>A>	AT	AKORN	400 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N65088	001	FEB 06, 2004	FEB	NEWA
	BENAZEPRIL HYDROCHLORIDE							
	TABLET; ORAL							
>A>		BENAZEPRIL HCL						
>A>	AB	ANDRX PHARMS	5MG	N76267	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76267	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76267	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76267	004	FEB 11, 2004	FEB	NEWA
>A>	AB	EON	5MG	N76402	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76402	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76402	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76402	004	FEB 11, 2004	FEB	NEWA
>A>	AB	GENPHARM	5MG	N76476	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76476	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76476	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76476	004	FEB 11, 2004	FEB	NEWA
>A>	AB	IVAX PHARMS	5MG	N76333	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76333	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76333	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76333	004	FEB 11, 2004	FEB	NEWA
>A>	AB	KV PHARM	5MG	N76118	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76118	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76118	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76118	004	FEB 11, 2004	FEB	NEWA
>A>	AB	MYLAN	5MG	N76430	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76430	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76430	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76430	004	FEB 11, 2004	FEB	NEWA
>A>	AB	RANBAXY	5MG	N76344	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76344	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76344	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76344	004	FEB 11, 2004	FEB	NEWA
>A>	AB	TEVA	5MG	N76211	001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG	N76211	002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG	N76211	003	FEB 11, 2004	FEB	NEWA
>A>	AB		40MG	N76211	004	FEB 11, 2004	FEB	NEWA
		LOTENSIN						
>D>		NOVARTIS	5MG	N19851	001	JUN 25, 1991	FEB	CFTG
>A>	AB		5MG	N19851	001	JUN 25, 1991	FEB	CFTG
>D>			10MG	N19851	002	JUN 25, 1991	FEB	CFTG
>A>	AB		10MG	N19851	002	JUN 25, 1991	FEB	CFTG
>D>			20MG	N19851	003	JUN 25, 1991	FEB	CFTG
>A>	AB		20MG	N19851	003	JUN 25, 1991	FEB	CFTG
>D>	+		40MG	N19851	004	JUN 25, 1991	FEB	CFTG
>A>	AB +		40MG	N19851	004	JUN 25, 1991	FEB	CFTG

BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

BENAZEPRIL HCL AND HYDROCHLOROTHIAZIDE

>A>	AB	ANDRX PHARMS	5MG;6.25MG	N76342 001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG;12.5MG	N76342 002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;12.5MG	N76342 003	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;25MG	N76342 004	FEB 11, 2004	FEB	NEWA
>A>	AB	EON	5MG;6.25MG	N76631 001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG;12.5MG	N76631 002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;12.5MG	N76631 003	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;25MG	N76631 004	FEB 11, 2004	FEB	NEWA
>A>	AB	GENPHARM	5MG;6.25MG	N76612 001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG;12.5MG	N76612 002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;12.5MG	N76612 003	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;25MG	N76612 004	FEB 11, 2004	FEB	NEWA
>A>	AB	IVAX PHARMS	5MG;6.25MG	N76348 001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG;12.5MG	N76348 002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;12.5MG	N76348 003	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;25MG	N76348 004	FEB 11, 2004	FEB	NEWA
>A>	AB	MYLAN	5MG;6.25MG	N76688 001	FEB 11, 2004	FEB	NEWA
>A>	AB		10MG;12.5MG	N76688 002	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;12.5MG	N76688 003	FEB 11, 2004	FEB	NEWA
>A>	AB		20MG;25MG	N76688 004	FEB 11, 2004	FEB	NEWA

LOTENSIN HCT

>D>		NOVARTIS	5MG;6.25MG	N20033 001	MAY 19, 1992	FEB	CFTG
>A>	AB		5MG;6.25MG	N20033 001	MAY 19, 1992	FEB	CFTG
>D>			10MG;12.5MG	N20033 002	MAY 19, 1992	FEB	CFTG
>A>	AB		10MG;12.5MG	N20033 002	MAY 19, 1992	FEB	CFTG
>D>	+		20MG;25MG	N20033 003	MAY 19, 1992	FEB	CFTG
>D>			20MG;12.5MG	N20033 004	MAY 19, 1992	FEB	CFTG
>A>	AB +		20MG;25MG	N20033 003	MAY 19, 1992	FEB	CFTG
>A>	AB		20MG;12.5MG	N20033 004	MAY 19, 1992	FEB	CFTG

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL

BETAMETHASONE DIPROPIONATE

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

>D> BETAMETHASONE SODIUM PHOSPHATE

>D> INJECTABLE; INJECTION

>D> BETAMETHASONE SODIUM PHOSPHATE

>D>	AP	STERIS	EQ 3MG BASE/ML	N85738 001		FEB	DISC
>A>		@	EQ 3MG BASE/ML	N85738 001		FEB	DISC

>D> CELESTONE

>D>	AP +	SCHERING	EQ 3MG BASE/ML	N17561 001		FEB	DISC
>A>		@	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

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

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

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

CEFUROXIME SODIUM
INJECTABLE; IM-IV
CEFUROXIME

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

INJECTABLE; INJECTION

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

CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE
TABLET, EXTENDED RELEASE; ORAL
CIPRO XR

+	BAYER PHARMS	425.2MG;EQ 574.9MG BASE	N21473 002	AUG 28, 2003	FEB	CDFR

TABLET; ORAL
CIPRO XR

+	BAYER PHARMS	425.2MG;EQ 574.9MG BASE	N21473 002	AUG 28, 2003	FEB	CDFR

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

CROMOLYN SODIUM
AEROSOL, METERED; INHALATION
INTAL

	+	KING PHARMS	0.8MG/INH	N18887	001	DEC 05, 1985	JAN	CAHN

SOLUTION; INHALATION

AN	+	KING PHARMS	10MG/ML	N18596	001	MAY 28, 1982	JAN	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

DESOGESTREL; ETHINYL ESTRADIOL
TABLET; ORAL-28
CYCLESSA

>D>	+	ORGANON USA INC	0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG	N21090	001	DEC 20, 2000	FEB	CFTG
>A>	AB +		0.1MG,0.125MG,0.15MG;0.025MG,0.025MG,0.025MG	N21090	001	DEC 20, 2000	FEB	CFTG

>A> VELIVET

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

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

>D>	+	IMCOR	0.92MG/VIAL;0.092MG/VIAL	N21191	001	MAY 31, 2002	FEB	CAHN
>A>	+	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

	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	
	ESTRADIOL						
>A>	GEL; TOPICAL						
>A>	ESTROGEL						
>A>	SOLVAY	0.06%	N21166 001	FEB 09, 2004	FEB	NEWA	
>A>	GEL, METERED; TOPICAL						
>A>	SOLVAY	0.06%	N21166 002	FEB 09, 2004	FEB	NEWA	
	ESTROGENS, CONJUGATED SYNTHETIC A						
	TABLET; ORAL						
	CENESTIN						
>A>	DURAMED	0.45MG	N20992 005	FEB 05, 2004	FEB	NEWA	
	ETHAMBUTOL HYDROCHLORIDE						
	TABLET; ORAL						
	MYAMBUTOL						
>A>	@ ELAN PHARMS	100MG	N16320 001		FEB	CAHN	
>A>	@	200MG	N16320 002		FEB	CAHN	
>A>	@	400MG	N16320 003		FEB	CAHN	
>A>	@	500MG	N16320 004		FEB	CAHN	
>D>	@ LEDERLE	100MG	N16320 001		FEB	CAHN	
>D>	@	200MG	N16320 002		FEB	CAHN	
>D>	@	400MG	N16320 003		FEB	CAHN	
>D>	@	500MG	N16320 004		FEB	CAHN	
	ETHINYL ESTRADIOL; LEVONORGESTREL						
	TABLET; ORAL						
	PREVEN EMERGENCY CONTRACEPTIVE KIT						
>A>	+ DURAMED	0.05MG;0.25MG	N20946 001	SEP 01, 1998	FEB	CAHN	
>D>	+ GYNETICS	0.05MG;0.25MG	N20946 001	SEP 01, 1998	FEB	CAHN	
	ETHINYL ESTRADIOL; NORGESTIMATE						
	TABLET; ORAL-28						
	PREVIFEM						
AB	ANDRX PHARMS	0.035MG;0.25MG	N76334 001	JAN 09, 2004	JAN	NEWA	

FENTANYL CITRATE
TROCHE/LOZENGE; ORAL
ACTIQ

>D>		ANESTA	EQ 0.2MG BASE	N20747	001	NOV 04, 1998	FEB	CAHN
>D>			EQ 0.4MG BASE	N20747	002	NOV 04, 1998	FEB	CAHN
>D>			EQ 0.6MG BASE	N20747	003	NOV 04, 1998	FEB	CAHN
>D>			EQ 0.8MG BASE	N20747	004	NOV 04, 1998	FEB	CAHN
>D>			EQ 1.2MG BASE	N20747	005	NOV 04, 1998	FEB	CAHN
>D>	+		EQ 1.6MG BASE	N20747	006	NOV 04, 1998	FEB	CAHN
>A>		CEPHALON	EQ 0.2MG BASE	N20747	001	NOV 04, 1998	FEB	CAHN
>A>			EQ 0.4MG BASE	N20747	002	NOV 04, 1998	FEB	CAHN
>A>			EQ 0.6MG BASE	N20747	003	NOV 04, 1998	FEB	CAHN
>A>			EQ 0.8MG BASE	N20747	004	NOV 04, 1998	FEB	CAHN
>A>			EQ 1.2MG BASE	N20747	005	NOV 04, 1998	FEB	CAHN
>A>	+		EQ 1.6MG BASE	N20747	006	NOV 04, 1998	FEB	CAHN

FOMIVIRSEN SODIUM
INJECTABLE; INJECTION
VITRAVENE PRESERVATIVE FREE

	+	NOVARTIS	6.6MG/ML	N20961	001	AUG 26, 1998	JAN	CAHN

GENTAMICIN SULFATE
SOLUTION/DROPS; OPHTHALMIC
GARAMYCIN

AT	+	SCHERING	EQ 0.3% BASE	N50039	002		JAN	CDFR

GENTAMICIN SULFATE

AT		ALTANA	EQ 0.3% BASE	N65121	001	JAN 30, 2004	JAN	NEWA

GLYBURIDE; METFORMIN HYDROCHLORIDE
TABLET; ORAL
GLUCOVANCE

>D>		BRISTOL MYERS SQUIBB	1.25MG;250MG	N21178	001	JUL 31, 2000	FEB	CFTG
>A>	AB		1.25MG;250MG	N21178	001	JUL 31, 2000	FEB	CFTG
>D>			2.5MG;500MG	N21178	002	JUL 31, 2000	FEB	CFTG
>A>	AB		2.5MG;500MG	N21178	002	JUL 31, 2000	FEB	CFTG
>D>	+		5MG;500MG	N21178	003	JUL 31, 2000	FEB	CFTG
>A>	AB +		5MG;500MG	N21178	003	JUL 31, 2000	FEB	CFTG

GLYBURIDE AND METFORMIN HCL

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

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

>D>	AP		GENSIA SICOR PHARMS	5MG/VIAL	N65037 003	MAY 01, 2002	FEB	CTEC
>A>		+		5MG/VIAL	N65037 003	MAY 01, 2002	FEB	CTEC

ISONIAZID
INJECTABLE; INJECTION
NYDRAZID

>D>		+	APOTHECON	100MG/ML	N08662 001		FEB	CAHN
>A>		+	SANDOZ	100MG/ML	N08662 001		FEB	CAHN

KETOCONAZOLE
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

>D>		+	NOVARTIS	EQ 0.025% BASE	N21066 001	JUL 02, 1999	FEB	CAHN
>A>		+		EQ 0.025% BASE	N21066 001	JUL 02, 1999	FEB	CAHN

LEVOCABASTINE HYDROCHLORIDE
SUSPENSION/DROPS; OPHTHALMIC
LIVOSTIN

>D>		+	NOVARTIS	EQ 0.05% BASE	N20219 001	NOV 10, 1993	FEB	CAHN
>A>		+		EQ 0.05% BASE	N20219 001	NOV 10, 1993	FEB	CAHN

LEVONORGESTREL
TABLET; ORAL
PLAN B

>A>		+	DURAMED	0.75MG	N21045 001	JUL 28, 1999	FEB	CAHN
>D>		+	WOMENS CAPITAL	0.75MG	N21045 001	JUL 28, 1999	FEB	CAHN

LIDOCAINE HYDROCHLORIDE; OXYTETRACYCLINE
INJECTABLE; INJECTION
TERRAMYCIN

>D>			PFIZER	2%;50MG/ML	N60567 001		FEB	CRLD
>D>				2%;125MG/ML	N60567 002		FEB	CRLD
>A>		+		2%;50MG/ML	N60567 001		FEB	CRLD

>A>		+	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						
>D>		KOS	20MG;500MG	N21249 001	DEC 17, 2001		FEB	CRLD
>D>			20MG;750MG	N21249 002	DEC 17, 2001		FEB	CRLD
>A>		+	20MG;500MG	N21249 001	DEC 17, 2001		FEB	CRLD
>A>		+	20MG;750MG	N21249 002	DEC 17, 2001		FEB	CRLD
		MERCAPTOPURINE						
		TABLET; ORAL						
>A>		MERCAPTOPURINE						
>A>	AB	PROMETHEUS LABS	50MG	N40461 001	FEB 11, 2004		FEB	NEWA
>A>	AB	ROXANE	50MG	N40528 001	FEB 13, 2004		FEB	NEWA
		PURINETHOL						
>D>		+ TEVA	50MG	N09053 002			FEB	CFTG
>A>	AB	+	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						
		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
		METHAMPHETAMINE HYDROCHLORIDE						
		TABLET; ORAL						
		DESOXYN						
>D>		+ OVATION PHARMS	5MG	N05378 002			FEB	CFTG
>A>	AB	+	5MG	N05378 002			FEB	CFTG
>A>		METHAMPHETAMINE HCL						
>A>	AB	ABLE	5MG	N40529 001	FEB 25, 2004		FEB	NEWA
		METOLAZONE						
		TABLET; ORAL						
		METOLAZONE						
	AB	TEVA	2.5MG	N76600 001	JAN 06, 2004		JAN	NEWA
		MYKROX						
		@ CELLTECH PHARMS	0.5MG	N19532 001	OCT 30, 1987		JAN	DISC

METOPROLOL TARTRATE
TABLET; ORAL
METOPROLOL TARTRATE

		CARACO	25MG	N76670 001	JAN 15, 2004	JAN	NEWA
	+	MYLAN	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

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

MYCOPHENOLIC ACID
TABLET, EXTENDED RELEASE; ORAL
MYFORTIC

>A>		NOVARTIS	180MG	N50791 001	FEB 27, 2004	FEB	NEWA
>A>	+		360MG	N50791 002	FEB 27, 2004	FEB	NEWA

NABILONE
CAPSULE; ORAL
CESAMET

		@ VALEANT	1MG	N18677 001	DEC 26, 1985	JAN	CAHN

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

>D>	AA	MK LABS	500MG	N83525 001		FEB	DISC
>A>		@	500MG	N83525 001		FEB	DISC
>D>	AA	TABLICAPS	500MG	N84237 001		FEB	DISC

>A>		@	500MG	N84237 001			FEB	DISC
		NIACOR						
>D>	AA	UPSHER SMITH	500MG	N40378 001	MAY 03, 2000		FEB	CRLD
>A>	AA +		500MG	N40378 001	MAY 03, 2000		FEB	CRLD
	OXYCODONE HYDROCHLORIDE							
	TABLET; ORAL							
>A>		OXYCODONE HCL						
>A>	AB	AMIDE PHARM	15MG	N76636 001	FEB 06, 2004		FEB	NEWA
>A>	AB		30MG	N76636 002	FEB 06, 2004		FEB	NEWA
		ROXICODONE						
>D>	+	AAIPHARMA	15MG	N21011 001	AUG 31, 2000		FEB	CFTG
>A>	AB +		15MG	N21011 001	AUG 31, 2000		FEB	CFTG
>D>			30MG	N21011 002	AUG 31, 2000		FEB	CFTG
>A>	AB		30MG	N21011 002	AUG 31, 2000		FEB	CFTG
>A>	PEMETREXED DISODIUM							
>A>	INJECTABLE; IV (INFUSION)							
>A>		ALIMTA						
>A>	+	LILLY	EQ 500MG BASE/VIAL	N21462 001	FEB 04, 2004		FEB	NEWA
	POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE							
	FOR SOLUTION; ORAL							
		NULYTELY						
>D>	+	BRAINTREE	420GM/BOT;1.48GM/BOT;5.72GM/BOT;11.2GM/BOT	N19797 001	APR 22, 1991		FEB	CFTG
>A>	AA +		420GM/BOT;1.48GM/BOT;5.72GM/BOT;11.2GM/BOT	N19797 001	APR 22, 1991		FEB	CFTG
		NULYTELY-FLAVORED						
>D>	+	BRAINTREE	420GM/BOT;1.48GM/BOT;5.72GM/BOT;11.2GM/BOT	N19797 002	NOV 18, 1994		FEB	CFTG
>A>	AA +		420GM/BOT;1.48GM/BOT;5.72GM/BOT;11.2GM/BOT	N19797 002	NOV 18, 1994		FEB	CFTG
>A>		TRILYTE						
>A>	AA	SCHWARZ PHARMA	420GM/BOT;1.48GM/BOT;5.72GM/BOT;11.2GM/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							
	SYRUP; ORAL							
>D>		PROMETH PLAIN						
>D>	AA +	ALPHARMA	6.25MG/5ML	N85953 001			FEB	DISC
>A>		@	6.25MG/5ML	N85953 001			FEB	DISC
		PROMETHAZINE HCL						
>D>	AA	HI TECH PHARMA	6.25MG	N40026 001	SEP 25, 1998		FEB	CRLD
>A>	AA +		6.25MG/5ML	N40026 001	SEP 25, 1998		FEB	CRLD

PROPRANOLOL HYDROCHLORIDE
INJECTABLE; INJECTION
PROPRANOLOL

	AP		AM PHARM PARTNERS	1MG/ML	N75826 001	AUG 31, 2001	JAN	NEWA

SIROLIMUS
TABLET; ORAL
RAPAMUNE

>D>		+	WYETH PHARMS INC	2MG	N21110 002	AUG 22, 2002	FEB	CRLD
>A>				2MG	N21110 002	AUG 22, 2002	FEB	CRLD
>A>		+		5MG	N21110 003	FEB 23, 2004	FEB	NEWA

SODIUM FERRIC GLUCONATE COMPLEX
INJECTABLE; INJECTION
FERRLECIT

>D>		+	R AND D LABS	62.5MG/5ML	N20955 001	FEB 18, 1999	FEB	CAHN
>A>		+	WATSON PHARMS	62.5MG/5ML	N20955 001	FEB 18, 1999	FEB	CAHN

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

SUCRALFATE
TABLET; ORAL
CARAFATE

>A>	AB	+	AXCAN SCANDIPHARM	1GM	N18333 001		FEB	CAHN
>D>	AB	+	BLUE RIDGE	1GM	N18333 001		FEB	CAHN

TERBINAFINE
GEL; TOPICAL
LAMISIL

			NOVARTIS	1%	N20846 001	APR 29, 1998	JAN	CMFD

TIOTROPIUM BROMIDE MONOHYDRATE
CAPSULE; INHALATION
SPIRIVA

		+	BOEHRINGER INGELHEIM	EQ 0.018MG BASE	N21395 001	JAN 30, 2004	JAN	NEWA

TIZANIDINE HYDROCHLORIDE
TABLET; ORAL
TIZANIDINE HCL

	AB		TORPHARM	EQ 2MG BASE	N76533 001	JAN 16, 2004	JAN	NEWA
	AB			EQ 4MG BASE	N76533 002	JAN 16, 2004	JAN	NEWA

VALACYCLOVIR HYDROCHLORIDE
TABLET; ORAL
VALTREX

>D>			GLAXOSMITHKLINE	EQ 1GM BASE	N20487 002	JUN 23, 1995	FEB	CRLD
>A>		+		EQ 1GM BASE	N20487 002	JUN 23, 1995	FEB	CRLD

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC
VASOCON-A

>D>	+ NOVARTIS	0.5%;0.05%	N18746 002	JUL 11, 1994	FEB	CAHN
>A>	+	0.5%;0.05%	N18746 002	JUL 11, 1994	FEB	CAHN

CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

>A>	SUSPENSION; ORAL					
>A>	CHLIDREN'S ADVIL ALLERGY SINUS					
>A>	+ WYETH CONS	1MG/5ML;100MG/5ML;15MG/5ML	N21587 001	FEB 24, 2004	FEB	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

LORATADINE; PSEUDOEPHEDRINE SULFATE
TABLET, EXTENDED RELEASE; ORAL
LORATADINE AND PSEUDOEPHEDRINE SULFATE

ANDRX PHARMS	5MG;120MG	N76208 001	JAN 28, 2004	JAN	NEWA

TERBINAFINE HYDROCHLORIDE
SPRAY; TOPICAL
LAMISIL AT

>A>	+ 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 2 FEBRUARY 2004

NO FEBRUARY 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
February 2004

Generic Name/ Trade Name (if present):	Date Designated = DD Date Approved= MA	Indication Designated:	Sponsor and Address
Corporation *Rituxan*	DD: 1/29/2004 MA:	Treatment of chronic lymphocytic leukemia	IDEC Pharmaceuticals 3030 Callan Road San Diego CA 92121
(1S)-1-(9-deazahypoxanthin-9-yl)-1, Pharmaceuticals, Inc. **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 Drive Birmingham AL 35244
3-4'aminoisoindoline-1'-one)-1-pipe ridine-2,6-dione (CC-5013) *REVIMID*	DD: 1/29/2004 MA:	Treatment of myelodysplastic syndromes	Celgene Corporation 7 Powder Horn Drive Warren NJ 07059
90Y-hPAMA4 *PAN-Cide*	DD: 1/29/2004 MA:	Treatment of pancreatic cancer	Immunomedics, Inc. 300 American Road Morris Plains NJ 07950
antivenin crotaline (pit-viper) Therapeutics, Inc. **equine immune F(ab)2** *Antivipmyn*	DD: 1/29/2004 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
Miltefosine solution Corporation *Miltex solution*	DD: 1/29/2004 MA:	For use as a topical pallative treatment for cutaneous metastases of breast cancer	Baxter Healthcare One Baxter Parkway One Baxter Parkway Deerfield IL 60015
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
Staphylococcus aureus Immune Globulin (Human) *Altastaph*	DD: 1/29/2004 MA:	Prophylaxis against Staphylococcus aureus infections in low birth weight neonates	Nabi Biopharmaceuticals 12276 Wilkins Avenue Rockville MD 20852
tetrahydrobiopterin Inc.	DD: 1/29/2004 MA:	For treatment of hyperphenylalaninemia	Biomarin Pharmaceutical 371 Bel Marin Blvd. Novato CA 94949

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

NO FEBRUARY 2004 ADDITIONS

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
	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		
>ADD>	020949 001	ALBUTEROL SULFATE;ACCUNEB	6702997	DEC 28, 2021	U558		
>ADD>	020949 002	ALBUTEROL SULFATE;ACCUNEB	6702997	DEC 28, 2021	U558		
>ADD>	021540 001	AMLODIPINE BESYLATE;CADUET	5273995	DEC 28, 2010	DS DP U162	NC	JAN 30, 2007
>ADD>			5273995*PED	JUN 28, 2011			
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>ADD>			5969156	JUL 08, 2016	DS		
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>ADD>			6126971	JAN 19, 2013	DP		
>ADD>			6126971*PED	JUL 19, 2013			
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>ADD>			4879303*PED	SEP 25, 2007			
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>ADD>			5273995	DEC 28, 2010	DS DP U162		
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>ADD>			6455574	AUG 11, 2018	U552		
>ADD>			5969156	JUL 08, 2016	DS		
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>ADD>			6126971	JAN 19, 2013	DP		
>ADD>			6126971*PED	JUL 19, 2013			
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>ADD>			4879303*PED	SEP 25, 2007			
>ADD>			4572909	JUL 31, 2006	DS DP U3		
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>ADD>			5273995	DEC 28, 2010	DS DP U162		
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>ADD>	021540 004	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
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>ADD>			4572909	JUL 31, 2006	DS DP U3		
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>ADD>			5273995	DEC 28, 2010	DS DP U162		
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>ADD>			5969156	JUL 08, 2016	DS		
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>ADD>			5686104	NOV 11, 2014	DP U213		
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>ADD>	021540 005	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
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>ADD>			4879303*PED	SEP 25, 2007			
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>ADD>			5273995*PED	JUN 28, 2011			
>ADD>			6455574	AUG 11, 2018	U552		
>ADD>			5969156	JUL 08, 2016	DS		
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>ADD>			5686104	NOV 11, 2014	DP U213		
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>ADD>			6126971*PED	JUL 19, 2013			
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>ADD>			4879303*PED	SEP 25, 2007			
>ADD>			4572909	JUL 31, 2006	DS DP U3		
>ADD>			4572909*PED	JAN 31, 2007			
>ADD>			5273995	DEC 28, 2010	DS DP U162		
>ADD>			5273995*PED	JUN 28, 2011			
>ADD>			6455574	AUG 11, 2018	U552		
>ADD>			5969156	JUL 08, 2016	DS		
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>ADD>			4572909	JUL 31, 2006	DS DP U3		
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>ADD>			5273995	DEC 28, 2010	DS DP U162		
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>ADD>			6455574	AUG 11, 2018	U552		
>ADD>			5969156	JUL 08, 2016	DS		
>ADD>			5969156*PED	JAN 08, 2017			

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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
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>ADD>			4572909*PED	JAN 31, 2007			
>ADD>			5273995	DEC 28, 2010	DS DP U162		
>ADD>			5273995*PED	JUN 28, 2011			
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>ADD>			5969156	JUL 08, 2016	DS		
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>ADD>			6126971	JAN 19, 2013	DP		
>ADD>			6126971*PED	JUL 19, 2013			
	020114 001	AZELASTINE HYDROCHLORIDE;ASTELIN	5164194	NOV 01, 2010	U207		
			5164194*PED	MAY 01, 2011			
>ADD>	019851 001	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
>ADD>						PED	SEP 02, 2007
>ADD>	019851 002	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
>ADD>						PED	SEP 02, 2007
>ADD>	019851 003	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
>ADD>						PED	SEP 02, 2007
>ADD>	019851 004	BENAZEPRIL HYDROCHLORIDE;LOTENSIN				M-30	MAR 02, 2007
>ADD>						PED	SEP 02, 2007
>ADD>	020746 001	BUDESONIDE;RHINOCORT	6686346	APR 29, 2017	DP U557		
>ADD>	020746 002	BUDESONIDE;RHINOCORT	6686346	APR 29, 2017	DP U557		
	020452 001	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
	020452 002	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
	020452 003	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	DP U175		
>ADD>	021587 001	CHLORPHENIRAMINE MALEATE;CHLIDREN'S ADVIL ALL				NP	FEB 24, 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			
>ADD>	021473 002	CIPROFLOXACIN;CIPRO XR	4670444	DEC 09, 2003	DS DP U555		
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	021644 001	CLOBETASOL PROPIONATE;CLOBEX				NDF	FEB 05, 2007
>ADD>	021371 001	ESTRADIOL HEMIHYDRATE;ESTRASORB				NDF	OCT 09, 2006
	021166 001	ESTRADIOL;ESTROGEL				NDF	FEB 09, 2007
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>ADD>	020992 003	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
>ADD>	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

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
	021490 001	ETHINYL ESTRADIOL;OVCON-35	6667050	JUN 12, 2021	DP U1		
	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>	021604 001	IBUPROFEN;CHILDREN'S ELIXSURE				NP	JAN 07, 2007
>ADD>	020723 001	IMIQUIMOD;ALDARA				I-420	MAR 02, 2007
>ADD>	020685 001	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
>ADD>	020685 003	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
>ADD>	020685 005	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
>ADD>	020685 006	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
>ADD>	020571 001	IRINOTECAN HYDROCHLORIDE;CAMPTOSAR	4604463	AUG 20, 2007			
>ADD>			6403569	APR 28, 2020	U449		
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>ADD>	021571 001	LEVOFLOXACIN;LEVOFLOXACIN				NP	MAR 01, 2007
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>ADD>	075505 001	LORATADINE;LORATADINE				PC	AUG 20, 2004
	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		
	013217 001	METAXALONE;SKELAXIN	6683102	DEC 03, 2021	U189		
	013217 002	METAXALONE;SKELAXIN	6683102	DEC 03, 2021	U189		
	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
	021598 001	MOXIFLOXACIN HYDROCHLORIDE;VIGAMOX				NCE	DEC 10, 2004
						PED	JUN 10, 2005
	020381 002	NIACIN;NIASPAN	6676967	SEP 20, 2013	U548		
	020381 003	NIACIN;NIASPAN	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
	020381 004	NIACIN;NIASPAN	6676967	SEP 20, 2013	U548		
	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>	021462 001	PEMETREXED DISODIUM;ALIMTA	5217974	MAR 29, 2011	U551	NCE	FEB 04, 2009
>ADD>			5344932	SEP 06, 2011	DS DP		
	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		
	021042 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	OCT 11, 2005
			5691374*PED	NOV 18, 2015		PED	FEB 06, 2007
			6063811*PED	NOV 06, 2017			
			6239173*PED	DEC 24, 2013			
	021042 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	OCT 11, 2005
			5691374*PED	NOV 18, 2015		PED	FEB 06, 2007
			6063811*PED	NOV 06, 2017			
			6239173*PED	DEC 24, 2013			
	021042 003	ROFECOXIB;VIOXX	6239173	JUN 24, 2013		NCE	MAY 20, 2004
			5474995	JUN 24, 2013	U266	I-353	APR 11, 2005
			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
			6063811*PED	NOV 06, 2017			
			6239173*PED	DEC 24, 2013			

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
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			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			
>ADD>	020926 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 11, 2013			
>ADD>	021179 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 11, 2013			
>ADD>	021110 003	SIROLIMUS;RAPAMUNE				NCE	SEP 15, 2004
>ADD>						I-386	APR 11, 2006
	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			
			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			

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
	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			
>ADD>	021368 001	TADALAFIL;CIALIS	5859006	JAN 12, 2016	DS DP		
>ADD>			6140329	JUL 11, 2016	DP U155		
>ADD>	021368 002	TADALAFIL;CIALIS	5859006	JAN 12, 2016	DS DP		
>ADD>			6140329	JUL 11, 2016	DP U155		
>ADD>	021368 003	TADALAFIL;CIALIS	5859006	JAN 12, 2016	DS DP		
>ADD>			6140329	JUL 11, 2016	DP U155		
>ADD>	021388 001	TALC;TALC				ODE	DEC 24, 2004
>ADD>	020846 001	TERBINAFINE;LAMISIL	5681849	OCT 28, 2014	DP		
>ADD>			6121314	MAY 18, 2012	DP U504		
			6121314	MAY 18, 2012	DP U540		
			6121314	MAY 18, 2012	DP U502		
>ADD>	020898 001	THYROTROPIN ALFA;THYROGEN	6365127	NOV 24, 2015	DP U556		
	021395 001	TIOTROPIUM BROMIDE MONOHYDRATE;SPIRIVA				NCE	JAN 30, 2009
	020771 002	TOLTERODINE TARTRATE;DETROL	5559269	NOV 05, 2013	U318		
			5559269*PED	MAY 05, 2014			
	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		

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

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.

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

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

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)

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