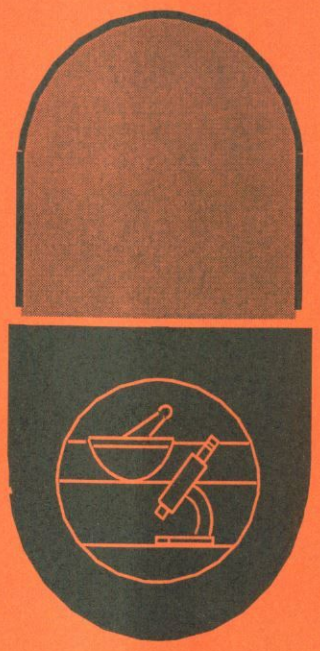
CUMULATIVE
SUPPLEMENT 2
FEBRUARY 2003



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

23rd EDITION

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

2003

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

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

23RD EDITION

Cumulative Supplement 2

February 2003

CONTENTS

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

23rd EDITION

CUMULATIVE SUPPLEMENT 2
February 2003

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, 23rd 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, 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)
SYNTEX (USA) INC LLC (SYNTEX USA INC)	ROCHE PALO ALTO LLC (ROCHE PALO)

1.3 AVAILABILITY OF THE EDITION

The 22nd 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 $108.00 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.

There is an Electronic Orange Book Query (EOB) 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 hard copy Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the hard copy monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.htm.

There are ASCII text files of the Orange Book drug product 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 are updated quarterly.

The 23rd annual edition of the 2002 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/23bookpub.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 monthly as soon as available and as otherwise needed.
The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:
http://www.fda.gov/cder/orange/patdecl.pdf

http://www.fda.gov/cder/orange/patdecl.html

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

1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2002) 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 2002	JUN 2003	SEP 2003	DEC 2003
DRUG PRODUCTS LISTED	10465			
SINGLE SOURCE	2420 (23.1%)			
MULTISOURCE	7939 (75.9%)			
THERAPEUTICALLY EQUIVALENT	7659 (73.2%)			
NOT THERAPEUTICALLY EQUIVALENT	280 (2.7%)			
EXCEPTIONS	106 (1.0%)			
NEW MOLECULAR ENTITIES APPROVED	6			
NUMBER OF APPLICANTS	598			

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

1.5 CUMULATIVE SUPPLEMENT LEGEND

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

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug 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; BUTALBITAL; CAFFEINE

SOLUTION; ORAL

ACETAMINOPHEN AND BUTALBITAL AND CAFFEINE

+	MIKART	325MG/15ML;50MG/15ML;40MG/15ML	N40387 001	JAN 31, 2003	JAN	NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPAHTE

AA	ANDRX PHARMS	300MG;15MG	N40443 001	JAN 22, 2003	JAN	NEWA
AA		300MG;30MG	N40443 002	JAN 22, 2003	JAN	NEWA
AA		300MG;60MG	N40443 003	JAN 22, 2003	JAN	NEWA

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	RANBAXY	300MG;60MG	N87083 001		JAN	CAHN

ACETAMINOPHEN W/ CODEINE PHOSPHATE #3

AA	RANBAXY	300MG;30MG	N85868 001		JAN	CAHN

CODRIX

>A>	+ ANDRX PHARMS	500MG;15MG	N40447 001	FEB 26, 2003	FEB	NEWA

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA	ABLE	650MG;7.5MG	N40474 001	JAN 02, 2003	JAN	NEWA

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	MIKART	325MG;7.5MG	N40432 001	JAN 22, 2003	JAN	NEWA

ALPRAZOLAM

TABLET, EXTENDED RELEASE; ORAL

XANAX XR

	PHARMACIA AND UPJOHN	0.5MG	N21434 001	JAN 17, 2003	JAN	NEWA
		1MG	N21434 002	JAN 17, 2003	JAN	NEWA
		2MG	N21434 003	JAN 17, 2003	JAN	NEWA
+		3MG	N21434 004	JAN 17, 2003	JAN	NEWA

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

ADDERALL XR 10

	SHIRE LABS	2.5MG;2.5MG;2.5MG;2.5MG	N21303 001	OCT 11, 2001	JAN	CAHN

ADDERALL XR 15

	SHIRE LABS	3.75MG;3.75MG;3.75MG;3.75MG	N21303 006	MAY 22, 2002	JAN	CAHN

ADDERALL XR 20

	SHIRE LABS	5MG;5MG;5MG;5MG	N21303 002	OCT 11, 2001	JAN	CAHN

ADDERALL XR 25

	SHIRE LABS	6.25MG;6.25MG;6.25MG;6.25MG	N21303 004	MAY 22, 2002	JAN	CAHN

ADDERALL XR 30

+	SHIRE LABS	7.5MG;7.5MG;7.5MG;7.5MG	N21303 003	OCT 11, 2001	JAN	CAHN

ADDERALL XR 5

	SHIRE LABS	1.25MG;1.25MG;1.25MG;1.25MG	N21303 005	MAY 22, 2002	JAN	CAHN

AZATHIOPRINE
TABLET; ORAL
AZASAN

>A>		AAIPHARMA LLC	25MG	N75252 002	FEB 03, 2003	FEB	NEWA
>A>	AB		50MG	N75252 001	JUN 07, 1999	FEB	NEWA
>A>			75MG	N75252 003	FEB 03, 2003	FEB	NEWA
>A>			100MG	N75252 004	FEB 03, 2003	FEB	NEWA

BUSPIRONE HYDROCHLORIDE
TABLET; ORAL
BUSPIRONE HCL

	AB	EGIS	15MG	N75119 003	JAN 23, 2003	JAN	NEWA

CALCITRIOL
INJECTABLE; INJECTION
CALCITRIOL

>A>	AP	AAIPHARMA	0.001MG/ML	N75766 001	FEB 20, 2003	FEB	NEWA
>A>	AP		0.002MG/ML	N75766 002	FEB 20, 2003	FEB	NEWA

CICLOPIROX
SHAMPOO; TOPICAL
LOPROX

>A>		+ MEDICIS	1%	N21159 001	FEB 28, 2003	FEB	NEWA

CYCLOSPORINE
CAPSULE; ORAL
GENGRAF

>D>	AB1	ABBOTT	25MG	N65003 001	MAY 12, 2000	FEB	CTNA
>A>	AB1		25MG	N65003 001	MAY 12, 2000	FEB	CTNA
>D>	BX		50MG	N65003 002	MAY 12, 2000	FEB	CTNA
>A>	BX		50MG	N65003 002	MAY 12, 2000	FEB	CTNA
>D>	AB1		100MG	N65003 003	MAY 12, 2000	FEB	CTNA
>A>	AB1		100MG	N65003 003	MAY 12, 2000	FEB	CTNA

DALFOPRISTIN; QUINUPRISTIN
INJECTABLE; IV (INFUSION)
SYNERCID

>D>		+ AVENTIS	350MG/VIAL;150MG/VIAL	N50748 001	SEP 21, 1999	FEB	CAHN
>D>		@	420MG/VIAL;180MG/VIAL	N50748 002	AUG 24, 2000	FEB	CAHN
>A>		+ KING PHARMS	350MG/VIAL;150MG/VIAL	N50748 001	SEP 21, 1999	FEB	CAHN
>A>		@	420MG/VIAL;180MG/VIAL	N50748 002	AUG 24, 2000	FEB	CAHN

DIGOXIN
TABLET; ORAL
DIGOXIN

	AB	CARACO	0.125MG	N76363 001	JAN 31, 2003	JAN	NEWA
	AB		0.25MG	N76363 002	JAN 31, 2003	JAN	NEWA

DILTIAZEM HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

>A>		CARDIZEM LA						
>A>	+	BIOVAIL	120MG	N21392	001	FEB 06, 2003	FEB	NEWA
>A>	+		180MG	N21392	002	FEB 06, 2003	FEB	NEWA
>A>	+		240MG	N21392	003	FEB 06, 2003	FEB	NEWA
>A>	+		300MG	N21392	004	FEB 06, 2003	FEB	NEWA
>A>	+		360MG	N21392	005	FEB 06, 2003	FEB	NEWA
>A>	+		420MG	N21392	006	FEB 06, 2003	FEB	NEWA

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

		DOPRAM						
AP	+	BAXTER HLTHCARE CORP	20MG/ML	N14879	001		JAN	CAHN
		DOXAPRAM HCL						
AP		BEDFORD	20MG/ML	N76266	001	JAN 10, 2003	JAN	NEWA

DOXYCYCLINE HYCLATE

CAPSULE, COATED PELLETS; ORAL

		DORYX						
>A>		FAULDING	EQ 75MG BASE	N50582	002	AUG 13, 2001	FEB	NEWA

ENOXAPARIN SODIUM

INJECTABLE; SUBCUTANEOUS

		LOVENOX						
	+	AVENTIS	300MG/3ML	N20164	009	JAN 23, 2003	JAN	NEWA

ESTROGENS, ESTERIFIED

TABLET; ORAL

		MENEST						
		MONARCH PHARMS	0.3MG	N84951	001		JAN	CRLD

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

>D>		TRI-NORINYL 21-DAY						
>D>	+	WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977	001	APR 13, 1984	FEB	DISC
>A>		@	0.035MG,0.035MG;0.5MG,1MG	N18977	001	APR 13, 1984	FEB	DISC

TABLET; ORAL-28

		ORTHO-NOVUM 7/7/7-28						
>D>	AB	ORTHO MCNEIL PHARM	0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .75MG	N18985	002	APR 04, 1984	FEB	CRLD
>A>	AB +		0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .75MG	N18985	002	APR 04, 1984	FEB	CRLD
		OVCON-35						
	+	WARNER CHILCOTT	0.035MG;0.4MG	N17716	001		JAN	CRLD
		OVCON-50						
	+	WARNER CHILCOTT	0.05MG;1MG	N17576	001		JAN	CRLD
		TRI-NORINYL 28-DAY						
	+	WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977	002	APR 13, 1984	JAN	CRLD

ETHINYL ESTRADIOL; NORGESTREL

TABLET; ORAL-21

OGESTREL 0.5/50-21

>D>	AB	SCS	0.05MG;0.5MG	N75406 001	DEC 15, 1999	FEB	CAHN
>A>	AB	WATSON LABS	0.05MG;0.5MG	N75406 001	DEC 15, 1999	FEB	CAHN

TABLET; ORAL-28

OGESTREL 0.5/50-28

>D>	AB	SCS	0.05MG;0.5MG	N75406 002	DEC 15, 1999	FEB	CAHN
>A>	AB	WATSON LABS	0.05MG;0.5MG	N75406 002	DEC 15, 1999	FEB	CAHN

ETIDRONATE DISODIUM

TABLET; ORAL

ETIDRONATE DISODIUM

AB	GENPHARM	200MG	N75800 001	JAN 24, 2003	JAN	NEWA
AB		400MG	N75800 002	JAN 24, 2003	JAN	NEWA

FLECAINIDE ACETATE

TABLET; ORAL

FLECAINIDE ACETATE

AB	ROXANE	50MG	N76278 001	JAN 14, 2003	JAN	NEWA
AB		100MG	N76278 002	JAN 14, 2003	JAN	NEWA
AB		150MG	N76278 003	JAN 14, 2003	JAN	NEWA

FLUDROCORTISONE ACETATE

TABLET; ORAL

FLUDROCORTISONE ACETATE

AB	BARR	0.1MG	N40425 001	JAN 21, 2003	JAN	NEWA

FLUORESCEIN SODIUM

INJECTABLE; INJECTION

FUNDUSCEIN-25

	@ NOVARTIS	25%	N17869 001		JAN	DISC

GENTAMICIN SULFATE

CREAM; TOPICAL

GARAMYCIN

>D>								
>D>	AT +	SCHERING	EQ 0.1% BASE	N60462 001		FEB	DISC
>A>		@	EQ 0.1% BASE	N60462 001		FEB	DISC

GENTAMICIN SULFATE

>D>	AT	FOUGERA	EQ 0.1% BASE	N62531 001	JUL 05, 1984	FEB	CRLD
>A>	AT +		EQ 0.1% BASE	N62531 001	JUL 05, 1984	FEB	CRLD

GLIMEPIRIDE

TABLET; ORAL

AMARYL

	+ AVENTIS PHARMS	1MG	N20496 001	NOV 30, 1995	JAN	CRLD
		4MG	N20496 003	NOV 30, 1995	JAN	CRLD

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

>D>	@ ALCON	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62423 001	AUG 25, 1983	FEB	CMFD

>A>	AT		1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62423 001	AUG 25, 1983	FEB	CMFD
		SUSPENSION/DROPS; OPHTHALMIC					
>D>		@ ALCON UNIVERSAL	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62874 001	MAY 11, 1988	FEB	CMFD
>A>	AT		1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62874 001	MAY 11, 1988	FEB	CMFD
		SUSPENSION/DROPS; OTIC					
>D>		@ ALCON UNIVERSAL	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62488 001	NOV 06, 1985	FEB	CMFD
>A>	AT		1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62488 001	NOV 06, 1985	FEB	CMFD
		HYDROXYZINE HYDROCHLORIDE					
		TABLET; ORAL					
>D>		ATARAX					
>A>		@ PFIZER	10MG	N10392 001		FEB	DISC
>A>		@	25MG	N10392 004		FEB	DISC
>A>		@	50MG	N10392 006		FEB	DISC
>A>		@	100MG	N10392 005		FEB	DISC
>D>	AB +	ROERIG	10MG	N10392 001		FEB	DISC
>D>	AB +		25MG	N10392 004		FEB	DISC
>D>	AB +		50MG	N10392 006		FEB	DISC
>D>	AB +		100MG	N10392 005		FEB	DISC
		HYDROXYZINE HCL					
>D>	AB	SIDMAK LABS NJ	10MG	N88617 001	JAN 10, 1986	FEB	CRLD
>A>	AB +		10MG	N88617 001	JAN 10, 1986	FEB	CRLD
>D>	AB		25MG	N88618 001	JAN 10, 1986	FEB	CRLD
>A>	AB +		25MG	N88618 001	JAN 10, 1986	FEB	CRLD
>D>	AB		50MG	N88619 001	JAN 10, 1986	FEB	CRLD
>A>	AB +		50MG	N88619 001	JAN 10, 1986	FEB	CRLD
>D>	AB		100MG	N81054 001	SEP 25, 1995	FEB	DISC
>A>		@	100MG	N81054 001	SEP 25, 1995	FEB	DISC
		LEUPROLIDE ACETATE					
		INJECTABLE; SUBCUTANEOUS					
>A>		ELIGARD					
>A>	+	ATRIX	30MG/VIAL	N21488 001	FEB 13, 2003	FEB	NEWA
		LEVORPHANOL TARTRATE					
		TABLET; ORAL					
>D>		LEVO-DROMORAN					
>D>	AB +	ICN	2MG	N08720 001	DEC 19, 1991	FEB	DISC
>A>		@	2MG	N08720 001	DEC 19, 1991	FEB	DISC
		LEVORPHANOL TARTRATE					
>D>	AB	ROXANE	2MG	N74278 001	MAR 31, 2000	FEB	CRLD
>A>	+		2MG	N74278 001	MAR 31, 2000	FEB	CRLD
		LIDOCAINE HYDROCHLORIDE					
		JELLY; TOPICAL					
		LIDOCAINE HCL					
>A>	AT	AKORN	2%	N40433 001	FEB 12, 2003	FEB	NEWA
		LISINOPRIL					
		TABLET; ORAL					
		LISINOPRIL					
>A>	AB	RANBAXY	30MG	N75944 006	FEB 11, 2003	FEB	NEWA

		LITHIUM CARBONATE						
		CAPSULE; ORAL						
		LITHIUM CARBONATE						
>D>		ROXANE	150MG	N17812 002	JAN 28, 1987	FEB	CTEC
>A>	AB		150MG	N17812 002	JAN 28, 1987	FEB	CTEC
>A>	AB	WEST WARD	150MG	N76243 002	FEB 24, 2003	FEB	NEWA
		LORAZEPAM						
		INJECTABLE; INJECTION						
		ATIVAN						
>A>	AP +	BAXTER HLTHCARE CORP	2MG/ML	N18140 001		FEB	CAHN
>A>	AP +		4MG/ML	N18140 002		FEB	CAHN
>D>	AP +	WYETH AYERST	2MG/ML	N18140 001		FEB	CAHN
>D>	AP +		4MG/ML	N18140 002		FEB	CAHN
		MEPHENTERMINE SULFATE						
		INJECTABLE; INJECTION						
		WYAMINE SULFATE						
>A>		@ BAXTER HLTHCARE CORP	EQ 15MG BASE/ML	N08248 002		FEB	CAHN
>A>		@	EQ 30MG BASE/ML	N08248 001		FEB	CAHN
>D>		@ WYETH AYERST	EQ 15MG BASE/ML	N08248 002		FEB	CAHN
>D>		@	EQ 30MG BASE/ML	N08248 001		FEB	CAHN
		METFORMIN HYDROCHLORIDE						
		TABLET; ORAL						
		METFORMIN HCL						
>D>	AB	PUREPAC PHARM	1GM	N76033 003	JAN 24, 2001	FEB	CMS1
>A>	AB		1GM	N76033 003	JAN 24, 2002	FEB	CMS1
		METHADONE HYDROCHLORIDE						
		INJECTABLE; INJECTION						
		DOLOPHINE HCL						
>D>		+ ROXANE	10MG/ML	N06134 006		FEB	DISC
>A>		@	10MG/ML	N06134 006		FEB	DISC
>A>		+	10MG/ML	N21624 001		FEB	CMS1
>D>			10MG/ML	N21624 001		FEB	CMS1
		METHOCARBAMOL						
		TABLET; ORAL						
		METHOCARBAMOL						
	AA	VINTAGE PHARMS	500MG	N40489 001	JAN 29, 2003	JAN	NEWA
	AA		750MG	N40489 002	JAN 29, 2003	JAN	NEWA
		MIRTAZAPINE						
		TABLET; ORAL						
		MIRTAZAPINE						
	AB	TEVA	15MG	N76119 001	JAN 24, 2003	JAN	NEWA
	AB		30MG	N76119 002	JAN 24, 2003	JAN	NEWA
		REMERON						
	AB +	ORGANON	15MG	N20415 001	JUN 14, 1996	JAN	CFTG
	AB		30MG	N20415 002	JUN 14, 1996	JAN	CFTG

MUPIROCIN
OINTMENT; TOPICAL
MUPIROCIN

	BX	CLAY PARK LABS	2%	N50788	001	DEC 04, 2002	JAN	CRLD

MYCOPHENOLATE MOFETIL
CAPSULE; ORAL
CELLCEPT

>D>		+ ROCHE GLOBAL DEV	250MG	N50722	001	MAY 03, 1995	FEB	CAHN
>A>		+ ROCHE PALO	250MG	N50722	001	MAY 03, 1995	FEB	CAHN

SUSPENSION; ORAL

>D>		+ ROCHE GLOBAL DEV	200MG/ML	N50759	001	OCT 01, 1998	FEB	CAHN
>A>		+ ROCHE PALO	200MG/ML	N50759	001	OCT 01, 1998	FEB	CAHN

TABLET; ORAL

>D>		+ ROCHE GLOBAL DEV	500MG	N50723	001	JUN 19, 1997	FEB	CAHN
>A>		+ ROCHE PALO	500MG	N50723	001	JUN 19, 1997	FEB	CAHN

MYCOPHENOLATE MOFETIL HYDROCHLORIDE
INJECTABLE; INJECTION

>D>		+ ROCHE GLOBAL DEV	500MG/VIAL	N50758	001	AUG 12, 1998	FEB	CAHN
>A>		+ ROCHE PALO	500MG/VIAL	N50758	001	AUG 12, 1998	FEB	CAHN

NABUMETONE
TABLET; ORAL
NABUMETONE

	AB	IVAX PHARMS	500MG	N76009	001	JAN 24, 2003	JAN	NEWA
	AB		750MG	N76009	002	JAN 24, 2003	JAN	NEWA

NIZATIDINE
CAPSULE; ORAL
NIZATIDINE

	AB	TORPHARM	150MG	N76383	001	JAN 23, 2003	JAN	NEWA
	AB		300MG	N76383	002	JAN 23, 2003	JAN	NEWA

OMEPRAZOLE
CAPSULE, DELAYED REL PELLETS; ORAL
OMEPRAZOLE

	AB	LEK SVCS	10MG	N75757	001	JAN 28, 2003	JAN	NEWA
	AB		20MG	N75757	002	JAN 28, 2003	JAN	NEWA

>A> OXYBUTYNIN
>A> FILM, EXTENDED RELEASE; TRANSDERMAL
>A> OXYTROL

>A>		+ WATSON LABS (UTAH)	3.9MG/24HR	N21351	002	FEB 26, 2003	FEB	NEWA

PERPHENAZINE
TABLET; ORAL
PERPHENAZINE

>D>	AB	IVAX PHARMS	16MG	N89457	001	SEP 10, 1987	FEB	CRLD
>A>	AB +		16MG	N89457	001	SEP 10, 1987	FEB	CRLD
>D>		TRILAFON						
>D>	AB	SCHERING	2MG	N10775	001		FEB	DISC

>A>		@	2MG	N10775 001		FEB	DISC
>D>	AB		4MG	N10775 002		FEB	DISC
>A>		@	4MG	N10775 002		FEB	DISC
>D>	AB		8MG	N10775 003		FEB	DISC
>A>		@	8MG	N10775 003		FEB	DISC
>D>	AB +		16MG	N10775 004		FEB	DISC
>A>		@	16MG	N10775 004		FEB	DISC

PHENTERMINE HYDROCHLORIDE
CAPSULE; ORAL
PHENTERMINE HCL

	AA	AMIDE PHARM	15MG	N40460 001	JAN 14, 2003	JAN	NEWA
	AA		30MG	N40448 001	JAN 22, 2003	JAN	NEWA

PHENYTOIN SODIUM, EXTENDED
CAPSULE; ORAL
DILANTIN

>D>		+ PARKE DAVIS	30MG	N84349 001		FEB	CRLD
>A>			30MG	N84349 001		FEB	CRLD

PREDNISOLONE
SYRUP; ORAL
PREDNISOLONE

>A>	AA	HI TECH PHARMA	15MG/5ML	N40401 001	FEB 27, 2003	FEB	NEWA

PREDNISONE
TABLET; ORAL
PREDNISONE

>A>	AB	VINTAGE PHARMS	20MG	N40392 001	FEB 12, 2003	FEB	NEWA

PROMETHAZINE HYDROCHLORIDE
SUPPOSITORY; RECTAL
PHENERGAN

>D>	BR +	WYETH AYERST	50MG	N11689 001		FEB	CTEC
>A>	AB +		50MG	N11689 001		FEB	CTEC
		PROMETHAZINE HCL					
>A>	AB	ABLE	50MG	N40449 001	FEB 27, 2003	FEB	NEWA

PROPRANOLOL HYDROCHLORIDE
INJECTABLE; INJECTION
PROPRANOLOL HCL

>A>	AP	SABEX 2002	1MG/ML	N76400 001	FEB 26, 2003	FEB	NEWA

PYRIDOSTIGMINE BROMIDE
TABLET; ORAL

>D>		PYRIDOSTIGMINE BROMIDE					
>A>		@ US ARMY	30MG	N20414 001	FEB 05, 2003	FEB	DISC
>D>			30MG	N20414 001	FEB 05, 2003	FEB	DISC

RILUZOLE
TABLET; ORAL
RILUTEK

	AB +	AVENTIS	50MG	N20599 001	DEC 12, 1995	JAN	CFTG

RILUZOLE
TABLET; ORAL
RILUZOLE

AB	IMPAX LABS	50MG	N76173 001	JAN 29, 2003	JAN	NEWA

RIMANTADINE HYDROCHLORIDE
TABLET; ORAL
RIMANTADINE HCL

AB	AMIDE PHARM	100MG	N76375 001	JAN 14, 2003	JAN	NEWA

SODIUM IODIDE, I-131
CAPSULE; ORAL
SODIUM IODIDE I 131

+	DRAXIMAGE	1-250mCi	N21305 002	JAN 24, 2003	JAN	NEWA
+		1-500mCi	N21305 003	JAN 24, 2003	JAN	NEWA

SOLUTION; ORAL
SODIUM IODIDE I 131, KIT

>D>	+	DRAXIMAGE	1-250mCi	N21305 002	JAN 24, 2003	FEB	CDFR
>D>	+		1-500mCi	N21305 003	JAN 24, 2003	FEB	CDFR
>A>	+		1-250mCi/0.25ML	N21305 002	JAN 24, 2003	FEB	CDFR
>A>	+		1-500mCi/0.5ML	N21305 003	JAN 24, 2003	FEB	CDFR

SOMATROPIN RECOMBINANT
INJECTABLE; INJECTION
TEV-TROVIN

>D>	BX	+	BIO TECH GEN	5MG/ML	N19774 002	JAN 04, 2002	FEB	CTNA

TEV-TROPIN

>A>	BX	+	BIO TECH GEN	5MG/ML	N19774 002	JAN 04, 2002	FEB	CTNA

STRONTIUM CHLORIDE, SR-89
INJECTABLE; INJECTION
METASTRON

AP	+	AMERSHAM HLTH	1mCi/ML	N20134 001	JUN 18, 1993	JAN	CFTG

STRONTIUM CHLORIDE SR-89

AP	BIO NUCLEONICS	1mCi/ML	N75941 001	JAN 06, 2003	JAN	NEWA

TAMOXIFEN CITRATE
TABLET; ORAL
NOLVADEX

>D>		ASTRAZENECA	EQ 10MG BASE	N17970 001		FEB	CTEC
>A>	AB		EQ 10MG BASE	N17970 001		FEB	CTEC
>D>	+		EQ 20MG BASE	N17970 002	MAR 21, 1994	FEB	CTEC
>A>	AB	+	EQ 20MG BASE	N17970 002	MAR 21, 1994	FEB	CTEC

TAMOXIFEN CITRATE

>A>	AB	ANDRX PHARMS	EQ 10MG BASE	N76179 001	FEB 20, 2003	FEB	NEWA
>A>	AB		EQ 20MG BASE	N76179 002	FEB 20, 2003	FEB	NEWA
>A>	AB	BARR	EQ 10MG BASE	N70929 001	FEB 20, 2003	FEB	NEWA
>A>	AB		EQ 20MG BASE	N70929 002	FEB 20, 2003	FEB	NEWA
>A>	AB	IVAX PHARMS	EQ 10MG BASE	N75740 001	FEB 20, 2003	FEB	NEWA
>A>	AB		EQ 20MG BASE	N75740 002	FEB 20, 2003	FEB	NEWA
>A>	AB	MYLAN	EQ 10MG BASE	N74732 002	FEB 20, 2003	FEB	NEWA
>A>	AB		EQ 20MG BASE	N74732 001	FEB 20, 2003	FEB	NEWA

>A>	AB		PHARMACHEMIE	EQ 20MG BASE	N74858 001	FEB 20, 2003	FEB	NEWA
>A>	AB		ROXANE	EQ 10MG BASE	N76027 001	FEB 20, 2003	FEB	NEWA
>A>	AB			EQ 20MG BASE	N76027 002	FEB 20, 2003	FEB	NEWA
>A>	AB		TEVA	EQ 10MG BASE	N75797 001	FEB 20, 2003	FEB	NEWA
		THALIDOMIDE						
		CAPSULE; ORAL						
		THALOMID						
			CELGENE	100MG	N20785 002	JAN 17, 2003	JAN	NEWA
		+		200MG	N20785 003	JAN 17, 2003	JAN	NEWA
		THIOTHIXENE						
		CAPSULE; ORAL						
		NAVANE						
>A>	AB		PFIZER	1MG	N16584 001		FEB	CAHN
>A>	AB			2MG	N16584 002		FEB	CAHN
>A>	AB	+		5MG	N16584 003		FEB	CAHN
>A>	AB			10MG	N16584 004		FEB	CAHN
>A>				20MG	N16584 005		FEB	CAHN
>D>	AB		ROERIG	1MG	N16584 001		FEB	CAHN
>D>	AB			2MG	N16584 002		FEB	CAHN
>D>	AB	+		5MG	N16584 003		FEB	CAHN
>D>	AB			10MG	N16584 004		FEB	CAHN
>D>				20MG	N16584 005		FEB	CAHN
		THIOTHIXENE HYDROCHLORIDE						
		CONCENTRATE; ORAL						
>A>	AA	+	PFIZER	EQ 5MG BASE/ML	N16758 001		FEB	CAHN
>D>	AA	+	ROERIG	EQ 5MG BASE/ML	N16758 001		FEB	CAHN
		INJECTABLE; INJECTION						
>A>			@ PFIZER	EQ 2MG BASE/ML	N16904 001		FEB	CAHN
>A>		+		EQ 10MG BASE/VIAL	N16904 002		FEB	CAHN
>D>			@ ROERIG	EQ 2MG BASE/ML	N16904 001		FEB	CAHN
>D>		+		EQ 10MG BASE/VIAL	N16904 002		FEB	CAHN
		VINORELBINE TARTRATE						
		INJECTABLE; INJECTION						
		NAVELBINE						
>D>		+	GLAXOSMITHKLINE	EQ 10MG BASE/ML	N20388 001	DEC 23, 1994	FEB	CFTG
>A>	AP	+		EQ 10MG BASE/ML	N20388 001	DEC 23, 1994	FEB	CFTG
>A>			VINORELBINE TARTRATE					
>A>	AP		GENSIA SICOR PHARMS	EQ 10MG BASE/ML	N76028 001	FEB 03, 2003	FEB	NEWA

GUAIFENESIN
TABLET, EXTENDED RELEASE; ORAL
MUCINEX

	ADAMS LABS	600MG	N21282	001	JUL 12, 2002	JAN	CRLD
+		1.2GM	N21282	002	DEC 18, 2002	JAN	NEWA

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE
TABLET; ORAL
IMODIUM ADVANCED

+	MCNEIL CONS SPECLT	2MG;125MG	N21140	001	NOV 30, 2000	JAN	CRLD

LORATADINE
TABLET; ORAL
LORATADINE

	GENEVA PHARMS	10MG	N75209	001	JAN 21, 2003	JAN	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL

>A>	WYETH CONS	10MG	N75822	001	FEB 10, 2003	FEB	NEWA

LORATADINE; PSEUDOEPHEDRINE SULFATE
>A> TABLET, EXTENDED RELEASE; ORAL
>A> LORATADINE AND PSEUDOEPHEDRINE HCL

>A> +	ANDRX PHARMS	10MG;240MG	N75706	001	FEB 21, 2003	FEB	NEWA

LORATADINE AND PSEUDOEPHEDRINE SULFATE

	IMPAX LABS	5MG;120MG	N76050	001	JAN 30, 2003	JAN	NEWA

MINOXIDIL
SOLUTION; TOPICAL
MINOXIDIL EXTRA STRENGTH (FOR MEN)

>A>	MORTON GROVE	5%	N75438	001	FEB 27, 2003	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 '03

NO FEBRUARY 2003 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 2003

anti-CD23 IgG1, kappa monoclonal antibody	DD: 2/12/2003 MA:	Treatment of chronic lymphocytic leukemia	IDEC Pharmaceuticals, Inc. 3030 Callan Road San Diego CA 92121
recombinant inhibitor of human plasma kallikrein	DD: 2/4/2003 MA:	Treatment of angioedema	Dyax Corp 300 Technology Square Cambridge MA 02139

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

NO FEBRUARY 2003 ADDITIONS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	021434 001	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	021434 002	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	021434 003	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	021434 004	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	020221 002	AMIFOSTINE;ETHYOL	5424471	JUL 31, 2012			
	020965 001	AMINOLEVULINIC ACID HYDROCHLORIDE;LEVULAN	5954703	OCT 31, 2017	U-289		
>ADD>	021303 001	AMPHETAMINE ASPARTATE;ADDERALL XR 10	6322819	OCT 21, 2018			
>ADD>	021303 006	AMPHETAMINE ASPARTATE;ADDERALL XR 15	6322819	OCT 21, 2018			
>ADD>	021303 002	AMPHETAMINE ASPARTATE;ADDERALL XR 20	6322819	OCT 21, 2018			
>ADD>	021303 004	AMPHETAMINE ASPARTATE;ADDERALL XR 25	6322819	OCT 21, 2018			
>ADD>	021303 003	AMPHETAMINE ASPARTATE;ADDERALL XR 30	6322819	OCT 21, 2018			
>ADD>	021303 005	AMPHETAMINE ASPARTATE;ADDERALL XR 5	6322819	OCT 21, 2018			
	021436 001	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 002	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 003	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 004	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 005	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 006	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
>ADD>	021411 001	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590*PED	JUL 11, 2015	U-494	NCE	NOV 26, 2007
>ADD>			5658590	JAN 11, 2015	U-494	PED	MAY 26, 2008
>ADD>	021411 002	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590*PED	JUL 11, 2015	U-494	NCE	NOV 26, 2007
>ADD>			5658590	JAN 11, 2015	U-494	PED	MAY 26, 2008
>ADD>	021411 003	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590*PED	JUL 11, 2015	U-494	NCE	NOV 26, 2007
>ADD>			5658590	JAN 11, 2015	U-494	PED	MAY 26, 2008
>ADD>	021411 004	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590*PED	JUL 11, 2015	U-494	NCE	NOV 26, 2007
>ADD>			5658590	JAN 11, 2015	U-494	PED	MAY 26, 2008
>ADD>	021411 005	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590*PED	JUL 11, 2015	U-494	NCE	NOV 26, 2007
>ADD>			5658590	JAN 11, 2015	U-494	PED	MAY 26, 2008
>ADD>	021411 006	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590*PED	JUL 11, 2015	U-494	NCE	NOV 26, 2007
>ADD>			5658590	JAN 11, 2015	U-494	PED	MAY 26, 2008
	020637 001	CARMUSTINE;GLIADEL	4789724	AUG 01, 2006		I-382	FEB 25, 2006
			4757128	AUG 01, 2006			
>ADD>	021150 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC-D 12 HOUR	4525358	JUN 25, 2007	U-295		
>ADD>			4525358*PED	DEC 25, 2007	U-295		
>ADD>			6469009	JUL 13, 2019	U-295		
>ADD>			6469009*PED	JAN 13, 2020	U-295		
>ADD>			6489329	APR 08, 2016			
>ADD>			6489329*PED	OCT 08, 2016			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	021473 001	CIPROFLOXACIN;CIPRO XR				NDF	DEC 13, 2005
	020839 001	CLOPIDOGREL BISULFATE;PLAVIX	6504030	JUN 10, 2019			
	019758 001	CLOZAPINE;CLOZARIL				I-380	DEC 18, 2005
	019758 002	CLOZAPINE;CLOZARIL				I-380	DEC 18, 2005
	021165 001	DESLORATADINE;CLARINEX	4659716	APR 21, 2004	U-427	NCE	DEC 21, 2006
			4863931	SEP 15, 2008		PED	JUN 21, 2007
			4804666	FEB 14, 2006	U-428		
			5595997	DEC 30, 2014	U-429		
			6100274	JUL 07, 2019			
			4659716*PED	OCT 21, 2004	U-427		
			4804666*PED	AUG 14, 2006	U-428		
			4863931*PED	MAR 15, 2009			
			5595997*PED	JUN 30, 2015	U-429		
			6100274*PED	JAN 07, 2020			
	021312 001	DESLORATADINE;CLARINEX				NCE	DEC 21, 2006
						PED	JUN 21, 2007
	020401 006	DILTIAZEM HYDROCHLORIDE;TIAZAC	5529791	JUN 25, 2013			
>ADD>	021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6511678	DEC 18, 2018			
>ADD>	021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6511678	DEC 18, 2018			
	021360 001	EFAVIRENZ;SUSTIVA	5663169	SEP 02, 2014			
	019813 001	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	019813 002	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	019813 003	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	019813 004	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-192		
			5855912	FEB 28, 2015			
			5738872	FEB 28, 2015			
			5932247	FEB 28, 2015			
			6037353	MAR 14, 2017	U-138		
			6113942	FEB 28, 2015			
			6187791	MAY 11, 2012	U-138		
			6399632	MAY 11, 2012	U-468		
			5578610*PED	MAY 26, 2014	U-192		
			5738872*PED	AUG 28, 2015			
			5855912*PED	AUG 28, 2015			
			5932247*PED	AUG 28, 2015			
			6037353*PED	SEP 14, 2017	U-138		
			6113942*PED	AUG 28, 2015			
			6187791*PED	NOV 11, 2012	U-138		
			6399632*PED	NOV 11, 2012	U-468		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015		PED	AUG 25, 2003
		5855912	FEB 28, 2015			
		6037353	MAR 14, 2017	U-138		
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012	U-138		
		6399632	MAY 11, 2012	U-468		
		5578610*PED	MAY 26, 2014	U-139		
		5855912*PED	AUG 28, 2015			
		5932247*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017	U-138		
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012	U-138		
		6399632*PED	NOV 11, 2012	U-468		
020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015		PED	AUG 25, 2003
		5855912	FEB 28, 2015			
		6037353	MAR 14, 2017	U-138		
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012	U-138		
		6399632	MAY 11, 2012	U-468		
		5578610*PED	MAY 26, 2014	U-139		
		5855912*PED	AUG 28, 2015			
		5932247*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017	U-138		
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012	U-138		
		6399632*PED	NOV 11, 2012	U-468		
020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015		PED	AUG 25, 2003
		5855912	FEB 28, 2015			
		6037353	MAR 14, 2017	U-138		
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012	U-138		
		6399632	MAY 11, 2012	U-468		
		5578610*PED	MAY 26, 2014	U-139		
		5855912*PED	AUG 28, 2015			
		5932247*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017	U-138		
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012	U-138		
		6399632*PED	NOV 11, 2012	U-468		
020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	5578610	NOV 26, 2013			
		5855912	FEB 28, 2015			
		6037353	MAR 14, 2017	U-138		
		6039974	JUL 31, 2018			
		6113942	FEB 28, 2015			
		6187791	MAY 11, 2012	U-138		
		6399632	MAY 11, 2012	U-468		
		5578610*PED	MAY 26, 2014			
		5855912*PED	AUG 28, 2015			
		6037353*PED	SEP 14, 2017	U-138		
		6039974*PED	JAN 31, 2019			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
		6113942*PED	AUG 28, 2015			
		6187791*PED	NOV 11, 2012	U-138		
		6399632*PED	NOV 11, 2012	U-468		
020101 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
					PED	JUL 03, 2006
020974 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
					PED	JUL 03, 2006
020974 002	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
					PED	JUL 03, 2006
021077 001	FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
		5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
		4992474	FEB 12, 2008	U-211		
		5225445	FEB 12, 2008	U-211		
		5126375	FEB 12, 2008			
		5290815	MAR 01, 2011	U-386		
		4355121*PED	MAY 14, 2004			
		4992474*PED	AUG 12, 2008	U-211		
		5126375*PED	AUG 12, 2008			
		5225445*PED	AUG 12, 2008	U-211		
		5270305*PED	MAR 07, 2011	U-387		
		5290815*PED	SEP 01, 2011	U-396		
021077 002	FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
		5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
		4992474	FEB 12, 2008	U-211		
		5225445	FEB 12, 2008	U-211		
		5126375	FEB 12, 2008			
		5290815	MAR 01, 2011	U-386		
		4335121*PED	MAY 14, 2004			
		4992474*PED	AUG 12, 2008	U-211		
		5126375*PED	AUG 12, 2008			
		5225445*PED	AUG 12, 2008	U-211		
		5270305*PED	MAR 07, 2011	U-387		
		5290815*PED	SEP 01, 2011	U-386		
021077 003	FLUTICASONE PROPIONATE;ADVAIR DISKUS 500/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
		5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
		4992474	FEB 12, 2008	U-211		
		5225445	FEB 12, 2008	U-211		
		5126375	FEB 12, 2008			
		5290815	MAR 01, 2011	U-386		
		4335121*PED	MAY 14, 2004			
		4992474*PED	AUG 12, 2008	U-211		
		5126375*PED	AUG 12, 2008			
		5225445*PED	AUG 12, 2008	U-211		
		5270305*PED	MAR 07, 2011	U-387		
		5290815*PED	SEP 01, 2011	U-386		

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	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
019957 001	FLUTICASONE PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
019958 001	FLUTICASONE PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020121 001	FLUTICASONE PROPIONATE;FLONASE	4335121	NOV 14, 2003		D-76	MAY 23, 2005
		4335121*PED	MAY 14, 2004		PED	NOV 23, 2005
020548 001	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020548 002	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020548 003	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
		4335121*PED	MAY 14, 2004			
020549 001	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
		4335121*PED	MAY 14, 2004	U-409		
020549 002	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
		4335121*PED	MAY 14, 2004	U-409		
020549 003	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
		4335121*PED	MAY 14, 2004	U-409		
020833 001	FLUTICASONE PROPIONATE;FLOVENT DISKUS 50	4335121	NOV 14, 2003	U-409		
		4335121*PED	MAY 14, 2004	U-409		
020833 002	FLUTICASONE PROPIONATE;FLOVENT DISKUS 100	4335121	NOV 14, 2003	U-409		
		4335121*PED	MAY 14, 2004	U-409		
020833 003	FLUTICASONE PROPIONATE;FLOVENT DISKUS 250	4335121	NOV 14, 2003	U-409		
		4335121*PED	MAY 14, 2004	U-409		
020261 001	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011	U-109		
		5354772	OCT 11, 2011	U-413		
020261 002	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011	U-109		
		5354772	OCT 11, 2011	U-413		
021192 001	FLUVASTATIN SODIUM;LESCOL XL	5354772	OCT 11, 2011	U-413		
		5354772	OCT 11, 2011	U-109		
020831 001	FORMOTEROL FUMARATE;FORADIL	6488027	MAR 08, 2019			
019915 002	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
		5006344	JUL 10, 2009			
		5006344*PED	JAN 10, 2010			
		4337201*PED	JUN 04, 2003			
019915 003	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
		5006344	JUL 10, 2009			
		5006344*PED	JAN 10, 2010			
		4337201*PED	JUN 04, 2003			
019915 004	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
		5006344	JUL 10, 2009			
		5006344*PED	JAN 10, 2010			
		4337201*PED	JUN 04, 2003			
020286 001	FOSINOPRIL SODIUM;MONOPRIL-HCT	4337201	DEC 04, 2002			
		5006344	JUL 10, 2009			
		5006344*PED	JAN 10, 2010			
		4337201*PED	JUN 04, 2003			

PRESCRIPTION AND OTC DRUG PRODUCT
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020286 002	FOSINOPRIL SODIUM;MONOPRIL-HCT	4337201	DEC 04, 2002			
			5006344	JUL 10, 2009			
			5006344*PED	JAN 10, 2010			
			4337201*PED	JUN 04, 2003			
	021321 001	ICODEXTRIN;EXTRANEAL	6248726	JUN 19, 2018	U-495		
			4761237	AUG 02, 2005	U-495		
			4886789	DEC 12, 2006	U-495		
			6077836	JUN 20, 2017	U-495		
>ADD>	021425 001	IOPROMIDE;ULTRAVIST (PHARMACY	4364921	MAR 06, 2005	U-498		
>ADD>	021425 002	IOPROMIDE;ULTRAVIST (PHARMACY	4364921	MAR 06, 2005	U-498		
>ADD>	020857 001	LAMIVUDINE;COMBIVIR	5047407*PED	MAY 17, 2010			
>ADD>			5047407	NOV 17, 2009			
>ADD>	021003 001	LAMIVUDINE;EPIVIR-HBV	5047407	NOV 17, 2009			
>ADD>			5047407*PED	MAY 17, 2010			
>ADD>	021004 001	LAMIVUDINE;EPIVIR-HBV	5047407	NOV 17, 2009			
>ADD>			5047407*PED	MAY 17, 2010			
	021130 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021130 002	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021131 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021132 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
>ADD>	021226 001	LOPINAVIR;KALETRA	6521651	NOV 01, 2017			
	020386 001	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
	020386 002	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
	020386 003	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
	021410 001	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
	021410 002	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
	021410 003	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
	076119 001	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 16, 2003
	076119 002	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 16, 2003
>ADD>	019921 001	OFLOXACIN;OCUFLOX	4382892	SEP 02, 2003		ODE	MAY 22, 2003
>ADD>			4551456	NOV 14, 2003	U-80	PED	NOV 22, 2003
>ADD>			4382892*PED	MAR 02, 2004			
>ADD>			4551456*PED	MAY 14, 2004	U-80		
>ADD>	020776 001	OXAPROZIN POTASSIUM;DAYPRO ALTA	6030643	MAY 16, 2017	U-497		
	020926 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
	021179 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
	021179 002	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
	020280 007	SOMATROPIN RECOMBINANT;GENOTROPIN				ODE	OCT 31, 2004
	020280 001	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 002	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 003	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 005	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 008	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 009	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004

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020280 010	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
020280 011	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
020280 012	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
020280 013	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
021454 001	TESTOSTERONE;TESTIM				NP	OCT 31, 2005
020550 001	VALACYCLOVIR HYDROCHLORIDE;VALTREX				I-381	SEP 09, 2005
020550 002	VALACYCLOVIR HYDROCHLORIDE;VALTREX				I-381	SEP 09, 2005

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, 23RD 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 INDICATION

I-380	TO TREAT PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER AT RISK FOR EMERGENT SUICIDAL BEHAVIOR
I-381	TREATMENT OF COLD SORES (HERPES LABIALIS) IN ADULT AND ADOLESCENT PATIENTS 12 YEARS OF AGE AND OLDER
I-382	FOR NEWLY-DIAGNOSED HIGH GRADE MALIGNANT GLIOMA PATIENTS AS AN ADJUNCT TO SURGERY AND RADIATION
I-383	TREATMENT OF TYPE 2 DIABETIC NEPHROPATHY

PATENT USE

U-494	TREATMENT OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER
U-495	PERITONEAL DIALYSIS SOLUTION
U-496	METHOD FOR TREATING CHRONIC RENAL FAILURE
U-497	RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS
U-498	INTRA-ARTERIAL AND INTRAVENOUS USES OF ULTRAVIST

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