CUMULATIVE
SUPPLEMENT 1
JANUARY 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 1

January 2003

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

23rd EDITION

CUMULATIVE SUPPLEMENT 1
January 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)

No applicant name changes for January 2003.

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[1]	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.
CMS2	Change. Miscellaneous deletion
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						
>A>		SOLUTION; ORAL						
>A>		ACETAMINOPHEN AND BUTALBITAL AND CAFFEINE						
>A>	+	MIKART	325MG/15ML;50MG/15ML;40MG/15ML	N40387	001	JAN 31, 2003	JAN	NEWA
		ACETAMINOPHEN; CODEINE PHOSPHATE						
		TABLET; ORAL						
		ACETAMINOPHEN AND CODEINE PHOSPAHTE						
>A>	AA	ANDRX PHARMS	300MG;15MG	N40443	001	JAN 22, 2003	JAN	NEWA
>A>	AA		300MG;30MG	N40443	002	JAN 22, 2003	JAN	NEWA
>A>	AA		300MG;60MG	N40443	003	JAN 22, 2003	JAN	NEWA
		ACETAMINOPHEN AND CODEINE PHOSPHATE						
>D>	AA	IVAX PHARMS	300MG;60MG	N87083	001		JAN	CAHN
>A>	AA	RANBAXY	300MG;60MG	N87083	001		JAN	CAHN
		ACETAMINOPHEN W/ CODEINE PHOSPHATE #3						
>D>	AA	IVAX PHARMS	300MG;30MG	N85868	001		JAN	CAHN
>A>	AA	RANBAXY	300MG;30MG	N85868	001		JAN	CAHN
		ACETAMINOPHEN; HYDROCODONE BITARTRATE						
		TABLET; ORAL						
		ACETAMINOPHEN AND HYDROCODONE BITARTRATE						
>A>	AA	ABLE	650MG;7.5MG	N40474	001	JAN 02, 2003	JAN	NEWA
		HYDROCODONE BITARTRATE AND ACETAMINOPHEN						
>A>	AA	MIKART	325MG;7.5MG	N40432	001	JAN 22, 2003	JAN	NEWA
		ALPRAZOLAM						
>A>		TABLET, EXTENDED RELEASE; ORAL						
>A>		XANAX XR						
>A>		PHARMACIA AND UPJOHN	0.5MG	N21434	001	JAN 17, 2003	JAN	NEWA
>A>			1MG	N21434	002	JAN 17, 2003	JAN	NEWA
>A>			2MG	N21434	003	JAN 17, 2003	JAN	NEWA
>A>	+		3MG	N21434	004	JAN 17, 2003	JAN	NEWA
		AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE						
		CAPSULE, EXTENDED RELEASE; ORAL						
		ADDERALL XR 10						
>A>		SHIRE LABS	2.5MG;2.5MG;2.5MG;2.5MG	N21303	001	OCT 11, 2001	JAN	CAHN
>D>		SHIRE PHARM	2.5MG;2.5MG;2.5MG;2.5MG	N21303	001	OCT 11, 2001	JAN	CAHN
		ADDERALL XR 15						
>A>		SHIRE LABS	3.75MG;3.75MG;3.75MG;3.75MG	N21303	006	MAY 22, 2002	JAN	CAHN
>D>		SHIRE PHARM	3.75MG;3.75MG;3.75MG;3.75MG	N21303	006	MAY 22, 2002	JAN	CAHN
		ADDERALL XR 20						
>A>		SHIRE LABS	5MG;5MG;5MG;5MG	N21303	002	OCT 11, 2001	JAN	CAHN
>D>		SHIRE PHARM	5MG;5MG;5MG;5MG	N21303	002	OCT 11, 2001	JAN	CAHN
		ADDERALL XR 25						
>A>		SHIRE LABS	6.25MG;6.25MG;6.25MG;6.25MG	N21303	004	MAY 22, 2002	JAN	CAHN
>D>		SHIRE PHARM	6.25MG;6.25MG;6.25MG;6.25MG	N21303	004	MAY 22, 2002	JAN	CAHN
		ADDERALL XR 30						
>A>	+	SHIRE LABS	7.5MG;7.5MG;7.5MG;7.5MG	N21303	003	OCT 11, 2001	JAN	CAHN
>D>	+	SHIRE PHARM	7.5MG;7.5MG;7.5MG;7.5MG	N21303	003	OCT 11, 2001	JAN	CAHN

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

ADDERALL XR 5

>A>			SHIRE LABS	1.25MG;1.25MG;1.25MG;1.25MG	N21303	005	MAY 22, 2002	JAN	CAHN
>D>			SHIRE PHARM	1.25MG;1.25MG;1.25MG;1.25MG	N21303	005	MAY 22, 2002	JAN	CAHN

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPIRONE HCL

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

DIGOXIN

TABLET; ORAL

DIGOXIN

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

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOPRAM

>A>	AP	+	BAXTER HLTHCARE CORP	20MG/ML	N14879	001		JAN	CAHN
>D>	AP	+	ROBINS AH	20MG/ML	N14879	001		JAN	CAHN

DOXAPRAM HCL

>A>	AP		BEDFORD	20MG/ML	N76266	001	JAN 10, 2003	JAN	NEWA

ENOXAPARIN SODIUM

INJECTABLE; SUBCUTANEOUS

LOVENOX

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

ESTROGENS, ESTERIFIED

TABLET; ORAL

MENEST

>D>		+	MONARCH PHARMS	0.3MG	N84951	001		JAN	CRLD
>A>				0.3MG	N84951	001		JAN	CRLD

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

OVCON-35

>D>			WARNER CHILCOTT	0.035MG;0.4MG	N17716	001		JAN	CRLD
>A>		+		0.035MG;0.4MG	N17716	001		JAN	CRLD

OVCON-50

>D>			WARNER CHILCOTT	0.05MG;1MG	N17576	001		JAN	CRLD
>A>		+		0.05MG;1MG	N17576	001		JAN	CRLD

TRI-NORINYL 28-DAY

>D>			WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977	002	APR 13, 1984	JAN	CRLD
>A>		+		0.035MG,0.035MG;0.5MG,1MG	N18977	002	APR 13, 1984	JAN	CRLD

ETIDRONATE DISODIUM
TABLET; ORAL
ETIDRONATE DISODIUM

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

FLECAINIDE ACETATE
TABLET; ORAL
FLECAINIDE ACETATE

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

FLUDROCORTISONE ACETATE
TABLET; ORAL
FLUDROCORTISONE ACETATE

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

FLUORESCEIN SODIUM
INJECTABLE; INJECTION
FUNDUSCEIN-25

>D>	+	NOVARTIS	25%	N17869	001		JAN	DISC
>A>	@		25%	N17869	001		JAN	DISC

GLIMEPIRIDE
TABLET; ORAL
AMARYL

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

METHOCARBAMOL
TABLET; ORAL
>A> METHOCARBAMOL

>A>	AA	VINTAGE PHARMS	500MG	N40489	001	JAN 29, 2003	JAN	NEWA
>A>	AA		750MG	N40489	002	JAN 29, 2003	JAN	NEWA

MIRTAZAPINE
TABLET; ORAL
>A> MIRTAZAPINE

>A>	AB	TEVA	15MG	N76119	001	JAN 24, 2003	JAN	NEWA
>A>	AB		30MG	N76119	002	JAN 24, 2003	JAN	NEWA
		REMERON						
>D>	+	ORGANON	15MG	N20415	001	JUN 14, 1996	JAN	CFTG
>A>	AB +		15MG	N20415	001	JUN 14, 1996	JAN	CFTG
>D>			30MG	N20415	002	JUN 14, 1996	JAN	CFTG
>A>	AB		30MG	N20415	002	JUN 14, 1996	JAN	CFTG

MUPIROCIN
OINTMENT; TOPICAL
MUPIROCIN

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

NABUMETONE
TABLET; ORAL
NABUMETONE

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

NIZATIDINE
CAPSULE; ORAL
NIZATIDINE

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

OMEPRAZOLE
CAPSULE, DELAYED REL PELLETS; ORAL
OMEPRAZOLE

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

PHENTERMINE HYDROCHLORIDE
CAPSULE; ORAL
PHENTERMINE HCL

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

RILUZOLE
TABLET; ORAL
RILUTEK

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

>A> RILUZOLE

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

RIMANTADINE HYDROCHLORIDE
TABLET; ORAL
RIMANTADINE HCL

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

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

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

SOLUTION; ORAL

>A>		+ DRAXIMAGE	1,000mCi/ML	N21305 001	JAN 24, 2003	JAN	NEWA

STRONTIUM CHLORIDE, SR-89

INJECTABLE; INJECTION

METASTRON

>D>		+	AMERSHAM HLTH	1mCi/ML	N20134 001	JUN 18, 1993	JAN	CFTG
>A>	AP	+		1mCi/ML	N20134 001	JUN 18, 1993	JAN	CFTG
>A>			STRONTIUM CHLORIDE SR-89					
>A>	AP		BIO NUCLEONICS	1mCi/ML	N75941 001	JAN 06, 2003	JAN	NEWA

THALIDOMIDE

CAPSULE; ORAL

THALOMID

>A>			CELGENE	100MG	N20785 002	JAN 17, 2003	JAN	NEWA
>A>		+		200MG	N20785 003	JAN 17, 2003	JAN	NEWA

GUAIFENESIN
TABLET, EXTENDED RELEASE; ORAL
MUCINEX

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

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE
TABLET; ORAL
IMODIUM ADVANCED

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

LORATADINE
TABLET; ORAL
LORATADINE

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

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

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

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY '03

NO JANUARY 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
January 2003

2',3',5'-tri-o-acetyluridine	DD: 1/13/2003 MA:	Treatment of mitochondrial disease	Repligen Corporation 41 Seyon Street Building 1, Suite 100 Waltham MA 02453
a-(3-aminophthalimido) *Actimid*	DD: 1/15/2003 MA:	Treatment of multiple myeloma	Celgene Corporation 7 Powder Horn Drive Warren NJ 07059
a-Galactosidase A *Plant-Produced Human a-Glactosidase*	DD: 1/21/2003 MA:	Treatment of Fabry's disease	Large Scale Biology Corporation 3333 Vacaville Parkway Suite 1000 Vacaville CA 95688
alteplase *Activase*	DD: 1/27/2003 MA:	Treatment of intraventricular hemmorage associated with intracerebral hemmorrhage	Daniel F. Hanley, MD Johns Hopkins University Johns Hopkins University 600 N. Wolfe St., Jefferson 1-109 Baltimore MD 21287
bifidobacterium longum infantis 35624	DD: 1/16/2003 MA:	Treatment of pediatric Crohn's disease	Alimentary Health Limited Guardwell, Kinsale County Cork, Ireland
bortezomib *VELCADE*	DD: 1/15/2003 MA:	To treat multiple myeloma	Millennium Pharmaceuticals, Inc. 75 Sidney Street Cambridge MA 02139
civamide *Zucapsaicin*	DD: 12/9/2002 MA:	Treatment of postherpetic neuralgia of the trigeminal nerve	Winston Laboratories, Inc. 100 Fairway Drive, Suite 134 100 Fairway Drive, Suite 134 Vernon Hills IL 60061
Human Anti-tumor Necrosis factor alpha monoclonal antibody	DD: 1/16/2003 MA:	Treatment of uveitis of the posterior segment of non-infectious etiology and refractory to conventional therapy	Centocor, Inc. 200 Great Valley Parkway Malvern PA 19355-1307
INGN 201 *ADVEXIN*	DD: 1/27/2003 MA:	Treatment of head and neck cancer	Introgen Therapeutics, Inc. 2250 Holcombe Blvd Houston TX 77030

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 EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021434 001	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
>ADD>	021434 002	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
>ADD>	021434 003	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
>ADD>	021434 004	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
>ADD>	020221 002	AMIFOSTINE;ETHYOL	5424471	JUL 31, 2012			
>ADD>	020965 001	AMINOLEVULINIC ACID HYDROCHLORIDE;LEVULAN	5954703	OCT 31, 2017	U-289		
>ADD>	021436 001	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
>ADD>			5006528	OCT 20, 2009			
>ADD>	021436 002	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
>ADD>			5006528	OCT 20, 2009			
>ADD>	021436 003	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
>ADD>			5006528	OCT 20, 2009			
>ADD>	021436 004	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
>ADD>			5006528	OCT 20, 2009			
>ADD>	021436 005	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
>ADD>			5006528	OCT 20, 2009			
>ADD>	021436 006	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
>ADD>			5006528	OCT 20, 2009			
>ADD>	021411 001	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494		
>ADD>	021411 002	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494		
>ADD>	021411 003	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494		
>ADD>	021411 004	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494		
>ADD>	021411 005	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494		
>ADD>	021411 006	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494		
>ADD>	020637 001	CARMUSTINE;GLIADEL	4789724	AUG 01, 2006		I-382	FEB 25, 2006
>ADD>			4757128	AUG 01, 2006			
>ADD>	021473 001	CIPROFLOXACIN;CIPRO XR				NDF	DEC 13, 2005
>ADD>	020839 001	CLOPIDOGREL BISULFATE;PLAVIX	6504030	JUN 10, 2019			
>ADD>	019758 001	CLOZAPINE;CLOZARIL				I-380	DEC 18, 2005
>ADD>	019758 002	CLOZAPINE;CLOZARIL				I-380	DEC 18, 2005
>ADD>	021165 001	DESLORATADINE;CLARINEX	4659716	APR 21, 2004	U-427	NCE	DEC 21, 2006
>ADD>			4863931	SEP 15, 2008		PED	JUN 21, 2007
>ADD>			4804666	FEB 14, 2006	U-428		
>ADD>			5595997	DEC 30, 2014	U-429		
>ADD>			6100274	JUL 07, 2019			
>ADD>			4659716*PED	OCT 21, 2004	U-427		
>ADD>			4804666*PED	AUG 14, 2006	U-428		
>ADD>			4863931*PED	MAR 15, 2009			
>ADD>			5595997*PED	JUN 30, 2015	U-429		
>ADD>			6100274*PED	JAN 07, 2020			
>ADD>	021312 001	DESLORATADINE;CLARINEX				NCE	DEC 21, 2006
>ADD>						PED	JUN 21, 2007
>ADD>	020401 006	DILTIAZEM HYDROCHLORIDE;TIAZAC	5529791	JUN 25, 2013			
>ADD>	021360 001	EFAVIRENZ;SUSTIVA	5663169	SEP 02, 2014			

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
>ADD>	019813 001	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
>ADD>			4588580*PED	JAN 23, 2005	U-43		
>ADD>	019813 002	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
>ADD>			4588580*PED	JAN 23, 2005	U-43		
>ADD>	019813 003	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
>ADD>			4588580*PED	JAN 23, 2005	U-43		
>ADD>	019813 004	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
>ADD>			4588580*PED	JAN 23, 2005	U-43		
>ADD>	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-192		
>ADD>			5855912	FEB 28, 2015			
>ADD>			5738872	FEB 28, 2015			
>ADD>			5932247	FEB 28, 2015			
>ADD>			6037353	MAR 14, 2017	U-138		
>ADD>			6113942	FEB 28, 2015			
>ADD>			6187791	MAY 11, 2012	U-138		
>ADD>			6399632	MAY 11, 2012	U-468		
>ADD>			5578610*PED	MAY 26, 2014	U-192		
>ADD>			5738872*PED	AUG 28, 2015			
>ADD>			5855912*PED	AUG 28, 2015			
>ADD>			5932247*PED	AUG 28, 2015			
>ADD>			6037353*PED	SEP 14, 2017	U-138		
>ADD>			6113942*PED	AUG 28, 2015			
>ADD>			6187791*PED	NOV 11, 2012	U-138		
>ADD>			6399632*PED	NOV 11, 2012	U-468		
>ADD>	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
>ADD>			5932247	FEB 28, 2015		PED	AUG 25, 2003
>ADD>			5855912	FEB 28, 2015			
>ADD>			6037353	MAR 14, 2017	U-138		
>ADD>			6113942	FEB 28, 2015			
>ADD>			6187791	MAY 11, 2012	U-138		
>ADD>			6399632	MAY 11, 2012	U-468		
>ADD>			5578610*PED	MAY 26, 2014	U-139		
>ADD>			5855912*PED	AUG 28, 2015			
>ADD>			5932247*PED	AUG 28, 2015			
>ADD>			6037353*PED	SEP 14, 2017	U-138		
>ADD>			6113942*PED	AUG 28, 2015			
>ADD>			6187791*PED	NOV 11, 2012	U-138		
>ADD>			6399632*PED	NOV 11, 2012	U-468		
>ADD>	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
>ADD>			5932247	FEB 28, 2015		PED	AUG 25, 2003
>ADD>			5855912	FEB 28, 2015			
>ADD>			6037353	MAR 14, 2017	U-138		
>ADD>			6113942	FEB 28, 2015			
>ADD>			6187791	MAY 11, 2012	U-138		
>ADD>			6399632	MAY 11, 2012	U-468		
>ADD>			5578610*PED	MAY 26, 2014	U-139		
>ADD>			5855912*PED	AUG 28, 2015			
>ADD>			5932247*PED	AUG 28, 2015			
>ADD>			6037353*PED	SEP 14, 2017	U-138		
>ADD>			6113942*PED	AUG 28, 2015			
>ADD>			6187791*PED	NOV 11, 2012	U-138		
>ADD>			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
>ADD>	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
>ADD>			5932247	FEB 28, 2015		PED	AUG 25, 2003
>ADD>			5855912	FEB 28, 2015			
>ADD>			6037353	MAR 14, 2017	U-138		
>ADD>			6113942	FEB 28, 2015			
>ADD>			6187791	MAY 11, 2012	U-138		
>ADD>			6399632	MAY 11, 2012	U-468		
>ADD>			5578610*PED	MAY 26, 2014	U-139		
>ADD>			5855912*PED	AUG 28, 2015			
>ADD>			5932247*PED	AUG 28, 2015			
>ADD>			6037353*PED	SEP 14, 2017	U-138		
>ADD>			6113942*PED	AUG 28, 2015			
>ADD>			6187791*PED	NOV 11, 2012	U-138		
>ADD>			6399632*PED	NOV 11, 2012	U-468		
>ADD>	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	5578610	NOV 26, 2013			
>ADD>			5855912	FEB 28, 2015			
>ADD>			6037353	MAR 14, 2017	U-138		
>ADD>			6039974	JUL 31, 2018			
>ADD>			6113942	FEB 28, 2015			
>ADD>			6187791	MAY 11, 2012	U-138		
>ADD>			6399632	MAY 11, 2012	U-468		
>ADD>			5578610*PED	MAY 26, 2014			
>ADD>			5855912*PED	AUG 28, 2015			
>ADD>			6037353*PED	SEP 14, 2017	U-138		
>ADD>			6039974*PED	JAN 31, 2019			
>ADD>			6113942*PED	AUG 28, 2015			
>ADD>			6187791*PED	NOV 11, 2012	U-138		
>ADD>			6399632*PED	NOV 11, 2012	U-468		
>ADD>	020101 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
>ADD>						PED	JUL 03, 2006
>ADD>	020974 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
>ADD>						PED	JUL 03, 2006
>ADD>	020974 002	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
>ADD>						PED	JUL 03, 2006
>ADD>	021077 001	FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
>ADD>			5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
>ADD>			4992474	FEB 12, 2008	U-211		
>ADD>			5225445	FEB 12, 2008	U-211		
>ADD>			5126375	FEB 12, 2008			
>ADD>			5290815	MAR 01, 2011	U-386		
>ADD>			4355121*PED	MAY 14, 2004			
>ADD>			4992474*PED	AUG 12, 2008	U-211		
>ADD>			5126375*PED	AUG 12, 2008			
>ADD>			5225445*PED	AUG 12, 2008	U-211		
>ADD>			5270305*PED	MAR 07, 2011	U-387		
>ADD>			5290815*PED	SEP 01, 2011	U-396		

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
>ADD>	021077 002	FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
>ADD>			5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
>ADD>			4992474	FEB 12, 2008	U-211		
>ADD>			5225445	FEB 12, 2008	U-211		
>ADD>			5126375	FEB 12, 2008			
>ADD>			5290815	MAR 01, 2011	U-386		
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>			4992474*PED	AUG 12, 2008	U-211		
>ADD>			5126375*PED	AUG 12, 2008			
>ADD>			5225445*PED	AUG 12, 2008	U-211		
>ADD>			5270305*PED	MAR 07, 2011	U-387		
>ADD>			5290815*PED	SEP 01, 2011	U-386		
>ADD>	021077 003	FLUTICASONE PROPIONATE;ADVAIR DISKUS 500/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
>ADD>			5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
>ADD>			4992474	FEB 12, 2008	U-211		
>ADD>			5225445	FEB 12, 2008	U-211		
>ADD>			5126375	FEB 12, 2008			
>ADD>			5290815	MAR 01, 2011	U-386		
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>			4992474*PED	AUG 12, 2008	U-211		
>ADD>			5126375*PED	AUG 12, 2008			
>ADD>			5225445*PED	AUG 12, 2008	U-211		
>ADD>			5270305*PED	MAR 07, 2011	U-387		
>ADD>			5290815*PED	SEP 01, 2011	U-386		
>ADD>	019957 001	FLUTICASONE PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>	019958 001	FLUTICASONE PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>	020121 001	FLUTICASONE PROPIONATE;FLONASE	4335121	NOV 14, 2003		D-76	MAY 23, 2005
>ADD>			4335121*PED	MAY 14, 2004		PED	NOV 23, 2005
>ADD>	020548 001	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>	020548 002	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>	020548 003	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
>ADD>			4335121*PED	MAY 14, 2004			
>ADD>	020549 001	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
>ADD>			4335121*PED	MAY 14, 2004	U-409		
>ADD>	020549 002	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
>ADD>			4335121*PED	MAY 14, 2004	U-409		
>ADD>	020549 003	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
>ADD>			4335121*PED	MAY 14, 2004	U-409		
>ADD>	020833 001	FLUTICASONE PROPIONATE;FLOVENT DISKUS 50	4335121	NOV 14, 2003	U-409		
>ADD>			4335121*PED	MAY 14, 2004	U-409		

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
>ADD>	020833 002	FLUTICASONE PROPIONATE;FLOVENT DISKUS 100	4335121	NOV 14, 2003	U-409		
>ADD>			4335121*PED	MAY 14, 2004	U-409		
>ADD>	020833 003	FLUTICASONE PROPIONATE;FLOVENT DISKUS 250	4335121	NOV 14, 2003	U-409		
>ADD>			4335121*PED	MAY 14, 2004	U-409		
>ADD>	020261 001	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011	U-109		
>ADD>			5354772	OCT 11, 2011	U-413		
>ADD>	020261 002	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011	U-109		
>ADD>			5354772	OCT 11, 2011	U-413		
>ADD>	021192 001	FLUVASTATIN SODIUM;LESCOL XL	5354772	OCT 11, 2011	U-413		
>ADD>			5354772	OCT 11, 2011	U-109		
>ADD>	020831 001	FORMOTEROL FUMARATE;FORADIL	6488027	MAR 08, 2019			
>ADD>	019915 002	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
>ADD>			5006344	JUL 10, 2009			
>ADD>			5006344*PED	JAN 10, 2010			
>ADD>			4337201*PED	JUN 04, 2003			
>ADD>	019915 003	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
>ADD>			5006344	JUL 10, 2009			
>ADD>			5006344*PED	JAN 10, 2010			
>ADD>			4337201*PED	JUN 04, 2003			
>ADD>	019915 004	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
>ADD>			5006344	JUL 10, 2009			
>ADD>			5006344*PED	JAN 10, 2010			
>ADD>			4337201*PED	JUN 04, 2003			
>ADD>	020286 001	FOSINOPRIL SODIUM;MONOPRIL-HCT	4337201	DEC 04, 2002			
>ADD>			5006344	JUL 10, 2009			
>ADD>			5006344*PED	JAN 10, 2010			
>ADD>			4337201*PED	JUN 04, 2003			
>ADD>	020286 002	FOSINOPRIL SODIUM;MONOPRIL-HCT	4337201	DEC 04, 2002			
>ADD>			5006344	JUL 10, 2009			
>ADD>			5006344*PED	JAN 10, 2010			
>ADD>			4337201*PED	JUN 04, 2003			
>ADD>	021321 001	ICODEXTRIN;EXTRANEAL	6248726	JUN 19, 2018	U-495		
>ADD>			4761237	AUG 02, 2005	U-495		
>ADD>			4886789	DEC 12, 2006	U-495		
>ADD>			6077836	JUN 20, 2017	U-495		
>ADD>	021130 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
>ADD>	021130 002	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
>ADD>	021131 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
>ADD>	021132 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
>ADD>	020386 001	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	020386 002	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	020386 003	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
>ADD>	021410 001	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
>ADD>	021410 002	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004

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
>ADD>	021410 003	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
>ADD>	076119 001	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 16, 2003
>ADD>	076119 002	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 16, 2003
>ADD>	020926 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
>ADD>	021179 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
>ADD>	021179 002	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
>ADD>	020280 007	SOMATROPIN RECOMBINANT;GENOTROPIN				ODE	OCT 31, 2004
>ADD>	020280 001	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 002	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 003	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 005	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 008	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 009	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 010	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 011	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 012	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020280 013	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	021454 001	TESTOSTERONE;TESTIM				NP	OCT 31, 2005
>ADD>	020550 001	VALACYCLOVIR HYDROCHLORIDE;VALTREX				I-381	SEP 09, 2005
>ADD>	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

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☐☐☐☐ (expiration date)

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