CUMULATIVE
SUPPLEMENT 3
MARCH 2002

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

22nd EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Information Technology
Division of Data Management and Services

2002

Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
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CONTENTS

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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, 22nd 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 place an asterisk (*) 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. [Strength(s) which already exist in the List will not be repeated for context.]

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, 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 22nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 23rd 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 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)
DANBURY PHARMACEUTICALS INC (DANBURY PHARMA)	WATSON LABORATORIES INC (WATSON LABS)
DURAMED PHARMACEUTICALS INC (DURAMED)	DURAMED PHARMACEUTICALS INC SUB OF BARR LABORATORIES INC (DURAMED PHARM BARR)
DERMIK LABORATORIES INC (DERMIK LABS)	DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS)
DERMIK LABORATORIES INC SUB RORER (DERMIK LABS)	DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS)
McNEIL CONSUMER HEALTHCARE DIVISION (McNEIL CONS)	McNEIL CONSUMER AND SPECIALTY PHARMACEUTICALS DIVISION McNEIL PPC (McNEIL CONS SPECLT)

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. The cost is $105.00 annually.

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 annual edition or 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. Changes to the annual edition are listed separately by month.

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 annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 22nd annual edition of the 2001 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/22bookpub.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 2001) 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 2001	MAR 2002	JUN 2002	SEP 2002
DRUG PRODUCTS LISTED	10166	10357		
SINGLE SOURCE	2665 26.2%)	2645 (25.5%)		
MULTISOURCE	7391 72.7%)	7602 (73.4%)		
THERAPEUTICALLY EQUIVALENT	7105 69.9%)	7309 (70.6%)		
NOT THERAPEUTICALLY EQUIVALENT	286 (2.8%)	293 (2.8%)		
EXCEPTIONS[1]	110 (1.1%)	110 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	10	1		
NUMBER OF APPLICANTS	574	574		

[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>. >D> >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. >D> >A>

The change code and description:

NEWA	New drug product approval usually in the supplement month. >A>
CAHN	Applicant holder firm name has changed. >A>
CDFR	Change. Dosage Form; Route of Administration. >A>
CFTG	Change. A first time generic for the innovator product. A TE Code is added. >D>
CMFD	Change. The product is moved from the Discontinued Section due to a change in marketing status. >A>
CPOT	Change. Potency amount/unit. >D>
CRLD	Change. Reference Listed Drug. >A>
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; HYDROCODONE BITARTRATE
SOLUTION; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA		KV PHARM	500MG/15ML;7.5MG/15ML	N40366 001	JAN 23, 2002	JAN	NEWA

ALBUTEROL SULFATE
AEROSOL, METERED; INHALATION
PROVENTIL-HFA

>D>		+	3M	EQ 0.09MG BASE/INH	N20503 001	AUG 15, 1996	MAR	CTEC
>A>	BX	+		EQ 0.09MG BASE/INH	N20503 001	AUG 15, 1996	MAR	CTEC

VENTOLIN HFA

>D>		+	GLAXOSMITHKLINE	EQ 0.09MG BASE/INH	N20983 001	APR 19, 2001	MAR	CTEC
>A>	BX	+		EQ 0.09MG BASE/INH	N20983 001	APR 19, 2001	MAR	CTEC

AMOXICILLIN; CLAVULANATE POTASSIUM
FOR SUSPENSION; ORAL
AUGMENTIN '400'

			GLAXOSMITHKLINE	400MG/5ML;EQ 57MG BASE/5ML	N50725 002	MAY 31, 1996	FEB	CRLD

TABLET; ORAL

>A>			AMOXICILLIN AND CLAVULANATE POTASSIUM					
>A>	AB		GENEVA PHARMS	500MG;EQ 125MG BASE	N65064 001	MAR 15, 2002	MAR	NEWA
>A>	AB			875MG;EQ 125MG BASE	N65063 001	MAR 14, 2002	MAR	NEWA

AUGMENTIN '500'

>D>			GLAXOSMITHKLINE	500MG;EQ 125MG BASE	N50564 002	AUG 06, 1984	MAR	CFTG
>A>	AB			500MG;EQ 125MG BASE	N50564 002	AUG 06, 1984	MAR	CFTG

AUGMENTIN '875'

>D>		+	GLAXOSMITHKLINE	875MG;EQ 125MG BASE	N50720 001	FEB 13, 1996	MAR	CFTG
>A>	AB	+		875MG;EQ 125MG BASE	N50720 001	FEB 13, 1996	MAR	CFTG

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE
TABLET; ORAL
ADDERALL 10

AB			SHIRE LABS	2.5MG;2.5MG;2.5MG;2.5MG	N11522 007	FEB 13, 1996	FEB	CFTG

ADDERALL 20

AB			SHIRE LABS	5MG;5MG;5MG;5MG	N11522 008	FEB 13, 1996	FEB	CTFG

ADDERALL 30

AB		+	SHIRE LABS	7.5MG;7.5MG;7.5MG;7.5MG	N11522 010	MAY 12, 1997	FEB	CFTG

ADDERALL 5

AB			SHIRE LABS	1.25MG;1.25MG;1.25MG;1.25MG	N11522 009	MAY 12, 1997	FEB	CFTG

DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE

AB			BARR	1.25MG;1.25MG;1.25MG;1.25MG	N40422 001	FEB 11, 2002	FEB	NEWA
AB				2.5MG;2.5MG;2.5MG;2.5MG	N40422 002	FEB 11, 2002	FEB	NEWA
AB				5MG;5MG;5MG;5MG	N40422 003	FEB 11, 2002	FEB	NEWA
AB				7.5MG;7.5MG;7.5MG;7.5MG	N40422 004	FEB 11, 2002	FEB	NEWA

AMPHOTERICIN B
INJECTABLE, LIPID COMPLEX; INJECTION
ABELCET

		+	ELAN PHARMS	5MG/ML	N50724 001	NOV 20, 1995	JAN	CAHN

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

>A>			AMPICILLIN AND SULBACTAM					
>A>	AP		ESI LEDERLE	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	N65074 001	MAR 19, 2002	MAR	NEWA
>A>	AP			EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	N65074 002	MAR 19, 2002	MAR	NEWA
>A>	AP			EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	N65076 001	MAR 19, 2002	MAR	NEWA
			UNASYN					
>D>		+	PFIZER	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	N50608 002	DEC 31, 1986	MAR	CFTG
>A>	AP	+		EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	N50608 002	DEC 31, 1986	MAR	CFTG
>D>		+		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	N50608 001	DEC 31, 1986	MAR	CFTG
>A>	AP	+		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	N50608 001	DEC 31, 1986	MAR	CFTG
>D>		+		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	N50608 005	DEC 10, 1993	MAR	CFTG
>A>	AP	+		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	N50608 005	DEC 10, 1993	MAR	CFTG

ATROPINE; PRALIDOXIME CHLORIDE

INJECTABLE; INTRAMUSCULAR

			ATNAA					
		+	@ US ARMY	2.1MG/0.7ML;600MG/2ML	N21175 001	JAN 17, 2002	JAN	NEWA
			@	2.1MG/0.7ML;600MG/2ML	N21175 001	JAN 17, 2002	FEB	NEWA

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

			BACITRACIN ZINC AND POLYMYXIN B SULFATE					
	AT		ALTANA	500 UNITS/GM;10,000 UNITS/GM	N65022 001	FEB 27, 2002	FEB	NEWA

BENZONATATE

CAPSULE; ORAL

			TESSALON					
>A>		+	FOREST LABS	200MG	N11210 003	JUN 25, 1999	MAR	NEWA

BROMOCRIPTINE MESYLATE

TABLET; ORAL

			BROMOCRIPTINE MESYLATE					
	AB		LEK SVCS	EQ 2.5MG BASE	N74631 001	JAN 13, 1998	JAN	CMFD
			PARLODEL					
	AB	+	NOVARTIS	EQ 2.5MG BASE	N17962 001	JUN 28, 1978	JAN	CFTG

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

			BUPIVACINE HCL PRESERVATIVE FREE					
	AP		INTL MEDICATED	0.25%	N76012 001	JAN 09, 2002	JAN	NEWA
	AP			0.5%	N76012 002	JAN 09, 2002	JAN	NEWA
	AP			0.75%	N76012 003	JAN 09, 2002	JAN	NEWA

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

			BUSPIRONE HCL					
>A>	AB		EGIS	5MG	N75119 001	MAR 14, 2002	MAR	NEWA
>A>	AB			10MG	N75119 002	MAR 14, 2002	MAR	NEWA
>A>	AB		GENEVA PHARMS	5MG	N75413 001	MAR 19, 2002	MAR	NEWA
>A>	AB			10MG	N75413 002	MAR 19, 2002	MAR	NEWA
>A>	AB			15MG	N75413 003	MAR 19, 2002	MAR	NEWA

	AB	KV PHARM	5MG	N75572 001	FEB 27, 2002	FEB	NEWA
	AB		10MG	N75572 002	FEB 27, 2002	FEB	NEWA
	AB		15MG	N75572 003	FEB 27, 2002	FEB	NEWA
>A>	AB	MYLAN	5MG	N75272 001	MAR 01, 2002	MAR	NEWA
>A>	AB		10MG	N75272 002	MAR 01, 2002	MAR	NEWA
	AB	PAR PHARM	5MG	N75467 001	FEB 28, 2002	FEB	NEWA
	AB		10MG	N75467 003	FEB 28, 2002	FEB	NEWA
	AB		15MG	N75467 004	FEB 28, 2002	FEB	NEWA
	AB	TEVA	5MG	N75022 001	FEB 28, 2002	FEB	NEWA
	AB		10MG	N75022 002	FEB 28, 2002	FEB	NEWA
	AB		15MG	N75022 003	FEB 28, 2002	FEB	NEWA
>A>	AB	ZENITH GOLDLINE	5MG	N75385 001	MAR 01, 2002	MAR	NEWA
>A>	AB		10MG	N75385 002	MAR 01, 2002	MAR	NEWA
>A>	AB		15MG	N75385 003	MAR 01, 2002	MAR	NEWA

BUTORPHANOL TARTRATE
SPRAY, METERED; NASAL
BUTORPHANOL TARTRATE

>A>	AB	ROXANE	1MG/SPRAY	N75824 001	MAR 12, 2002	MAR	NEWA

CALCIPOTRIENE
OINTMENT; TOPICAL
DOVONEX

	+	BRISTOL MYERS SQUIBB	0.005%	N20273 001	DEC 29, 1993	FEB	CAHN

SOLUTION; TOPICAL

	+	BRISTOL MYERS SQUIBB	0.005%	N20611 001	MAR 03, 1997	FEB	CAHN

CARBAMAZEPINE
TABLET; ORAL
CARBAMAZEPINE

AB		APOTEX	200MG	N75948 001	FEB 27, 2002	FEB	NEWA

CARTEOLOL HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC
CARTEOLOL HCL

AT		NOVEX	1%	N76097 001	FEB 06, 2002	FEB	NEWA

CEFUROXIME AXETIL
TABLET; ORAL
CEFTIN

AB		GLAXOSMITHKLINE	EQ 125MG BASE	N50605 001	DEC 28, 1987	FEB	CFTG
AB			EQ 250MG BASE	N50605 002	DEC 28, 1987	FEB	CFTG
AB	+		EQ 500MG BASE	N50605 003	DEC 28, 1987	FEB	CFTG

CEFUROXIME AXETIL

AB		RANBAXY	EQ 125MG BASE	N65043 003	FEB 15, 2002	FEB	NEWA
AB			EQ 250MG BASE	N65043 002	FEB 15, 2002	FEB	NEWA
AB			EQ 500MG BASE	N65043 001	FEB 15, 2002	FEB	NEWA

CERIVASTATIN SODIUM
TABLET; ORAL
BAYCOL

	@	BAYER	0.2MG	N20740 003	JUN 26, 1997	JAN	DISC
	@		0.3MG	N20740 004	JUN 26, 1997	JAN	DISC

	@	0.4MG	N20740 005	MAY 24, 1999	JAN	DISC
	@	0.8MG	N20740 006	JUL 24, 2000	JAN	DISC
	CHLOROTRIANISENE					
>D>	CAPSULE; ORAL					
>D>	TACE					
>D>	+ AVENTIS PHARMS	12MG	N08102 004	AUG 31, 1951	MAR	WDAG
>A>	@	12MG	N08102 004	AUG 31, 1951	MAR	WDAG
	CHORIOGONADOTROPIN ALFA					
	INJECTABLE; INJECTION					
	OVIDREL					
	+ SERONO INC	0.25MG/VIAL	N21149 001	SEP 20, 2000	FEB	CAHN
	CIMETIDINE					
	TABLET; ORAL					
	CIMETIDINE					
AB	LEK LJUBLJANA	300MG	N74250 002	JUN 29, 1995	FEB	CMFD
AB		400MG	N74250 003	JUN 29, 1995	FEB	CMFD
AB		800MG	N74250 004	JUN 29, 1995	FEB	CMFD
	CLADRIBINE					
	INJECTABLE; INJECTION					
	LEUSTATIN					
>D>	+ JOHNSON RW	1MG/ML	N20229 001	FEB 26, 1993	MAR	CAHN
>A>	+ ORTHO BIOTECH	1MG/ML	N20229 001	FEB 26, 1993	MAR	CAHN
	CLINDAMYCIN PHOSPHATE					
	LOTION; TOPICAL					
	CLEOCIN T					
AB	+ PHARMACIA AND UPJOHN	EQ 1% BASE	N50600 001	MAY 31, 1989	JAN	CFTG
	CLINDAMYCIN PHOSPHATE					
AB	ALTANA	EQ 1% BASE	N65067 001	JAN 31, 2002	JAN	NEWA
	SWAB; TOPICAL					
AT	CLAY PARK	EQ 1% BASE	N65049 001	MAY 25, 2000	FEB	CDFR
	CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58					
	N/A; N/A					
	DICOPAC KIT					
	@ AMERSHAM HLTH	N/A;N/A;N/A	N17406 001	JUN 10, 1974	FEB	DISC
	CYCLOSPORINE					
	SOLUTION; ORAL					
	CYCLOSPORINE					
AB	ABBOTT	100MG/ML	N65025 001	MAR 03, 2000	JAN	CMFD
	DEFEROXAMINE MESYLATE					
	INJECTABLE; INJECTION					
	DESFERAL					
	+ NOVARTIS	2GM/VIAL	N16267 002	MAY 25, 2000	FEB	CPOT

DESONIDE
LOTION; TOPICAL
DESONIDE

>A>	AB		ALTANA	0.05%	N75860 001	MAR 19, 2002	MAR	NEWA
			DESOWEN					
>D>		+	GALDERMA LABS LP	0.05%	N72354 001	JAN 24, 1992	MAR	CFTG
>A>	AB	+		0.05%	N72354 001	JAN 24, 1992	MAR	CFTG

DEXTROAMPHETAMINE SULFATE
CAPSULE, EXTENDED RELEASE; ORAL
DEXEDRINE

AB		+	GLAXOSMITHKLINE	5MG	N17078 001	AUG 02, 1976	JAN	CFTG
AB		+		10MG	N17078 002	AUG 02, 1976	JAN	CFTG
AB		+		15MG	N17078 003	AUG 02, 1976	JAN	CFTG
			DEXTROAMPHETAMINE SULFATE					
AB			BARR	5MG	N76137 001	JAN 18, 2002	JAN	NEWA
AB				10MG	N76137 002	JAN 18, 2002	JAN	NEWA
AB				15MG	N76137 003	JAN 18, 2002	JAN	NEWA
			TABLET; ORAL					
AA			MALLINCKRODT	5MG	N40436 001	JAN 29, 2002	JAN	NEWA
AA				10MG	N40436 002	JAN 29, 2002	JAN	NEWA

DICLOFENAC POTASSIUM
TABLET; ORAL
DICLOFENAC POTASSIUM

AB			MUTUAL PHARM	50MG	N75470 001	FEB 21, 2002	FEB	NEWA

DICLOFENAC SODIUM
TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM

AB			ALPHAPHARM	50MG	N75281 002	FEB 12, 2002	FEB	NEWA
AB				75MG	N75281 003	FEB 12, 2002	FEB	NEWA
			TABLET, EXTENDED RELEASE; ORAL					
AB			PUREPAC PHARM	100MG	N75910 001	JAN 07, 2002	JAN	NEWA

EFAVIRENZ
TABLET; ORAL
SUSTIVA

			BRISTOL MYERS SQUIBB	300MG	N21360 001	FEB 01, 2002	FEB	NEWA
		+		600MG	N21360 002	FEB 01, 2002	FEB	NEWA

EPTIFIBATIDE
INJECTABLE; INJECTION
INTEGRILIN

		+	MILLENNIUM PHARMS	2MG/ML	N20718 001	MAY 18, 1998	FEB	CAHN
		+		75MG/100ML	N20718 002	MAY 18, 1998	FEB	CAHN

ERYTHROMYCIN
GEL; TOPICAL

>A>			E-GLADES					
>A>	AT		GLADES PHARMS	2%	N65009 001	MAR 18, 2002	MAR	NEWA

ETHINYL ESTRADIOL; LEVONORGESTREL
TABLET; ORAL-21
ALESSE

>D>	AB	+	WYETH AYERST	0.02MG;0.1MG	N20683	001	MAR 27, 1997	MAR	CTEC
>A>	AB1	+		0.02MG;0.1MG	N20683	001	MAR 27, 1997	MAR	CTEC

AVIANE-21

>D>	AB		DURAMED PHARM BARR	0.02MG;0.1MG	N75796	002	APR 30, 2001	MAR	CTEC
>A>	AB1			0.02MG;0.1MG	N75796	002	APR 30, 2001	MAR	CTEC

LESSINA-21

>A>	AB2		BARR	0.02MG;0.1MG	N75803	001	MAR 20, 2002	MAR	NEWA

LEVLITE

>D>	BX	+	BERLEX LABS	0.02MG;0.1MG	N20860	001	JUL 13, 1998	MAR	CTEC
>A>	AB2	+		0.02MG;0.1MG	N20860	001	JUL 13, 1998	MAR	CTEC

TABLET; ORAL-28
ALESSE

>D>	AB		WYETH AYERST	0.02MG;0.1MG	N20683	002	MAR 27, 1997	MAR	CTEC
>A>	AB1			0.02MG;0.1MG	N20683	002	MAR 27, 1997	MAR	CTEC

AVIANE-28

>D>	AB		DURAMED PHARM BARR	0.02MG;0.1MG	N75796	001	APR 30, 2001	MAR	CTEC
>A>	AB1			0.02MG;0.1MG	N75796	001	APR 30, 2001	MAR	CTEC

LESSINA-28

>A>	AB		BARR	0.02MG;0.1MG	N75803	002	MAR 20, 2002	MAR	NEWA

LEVLITE

>D>	BX		BERLEX LABS	0.02MG;0.1MG	N20860	002	JUL 13, 1998	MAR	CTEC
>A>	AB2			0.02MG;0.1MG	N20860	002	JUL 13, 1998	MAR	CTEC

FLUDROCORTISONE ACETATE
TABLET; ORAL
FLORINEF

>D>		+	KING PHARMS	0.1MG	N10060	001	AUG 18, 1955	MAR	CFTG
>A>	AB	+		0.1MG	N10060	001	AUG 18, 1955	MAR	CFTG

>A> FLUDROCORTISONE ACETATE

>A>	AB		IMPAX LABS	0.1MG	N40431	001	MAR 18, 2002	MAR	NEWA

FLUNISOLIDE
SPRAY, METERED; NASAL
FLUNISOLIDE

	AB		BAUSCH AND LOMB	0.025MG/SPRAY	N74805	001	FEB 20, 2002	FEB	NEWA

NASALIDE

	AB	+	IVAX RES	0.025MG/SPRAY	N18148	001	SEP 24, 1981	FEB	CTEC

FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN
CREAM; TOPICAL
TRI-LUMA

		+	HILL DERMAC	0.01%;4%;0.05%	N21112	001	JAN 18, 2002	JAN	NEWA

FLUOXETINE HYDROCHLORIDE
CAPSULE; ORAL
FLUOXETINE

	AB		ALPHAPHARM	EQ 10MG BASE	N75577	001	JAN 29, 2002	JAN	NEWA
	AB			EQ 20MG BASE	N75577	002	JAN 29, 2002	JAN	NEWA
	AB		BARR	EQ 10MG BASE	N74803	002	JAN 30, 2002	JAN	NEWA

AB	CARLSBAD	EQ 10MG BASE	N76022 001	JAN 30, 2002	JAN	NEWA
AB		EQ 20MG BASE	N76022 002	JAN 30, 2002	JAN	NEWA
AB	DR REDDYS LABS INC	EQ 10MG BASE	N75465 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75465 002	JAN 29, 2002	JAN	NEWA
AB	EON	EQ 10MG BASE	N75807 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75807 002	JAN 29, 2002	JAN	NEWA
AB	IVAX PHARMS	EQ 10MG BASE	N75245 002	JAN 31, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75245 001	JAN 31, 2002	JAN	NEWA
AB	MALLINCKRODT	EQ 10MG BASE	N75658 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75658 002	JAN 29, 2002	JAN	NEWA
AB	MUTUAL PHARMA	EQ 10MG BASE	N75787 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75787 002	JAN 29, 2002	JAN	NEWA
AB	MYLAN	EQ 10MG BASE	N75207 001	JAN 30, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75207 002	JAN 30, 2002	JAN	NEWA
AB	RANBAXY	EQ 10MG BASE	N76165 001	FEB 01, 2002	FEB	NEWA
AB		EQ 20MG BASE	N76165 002	FEB 01, 2002	FEB	NEWA
AB	SIDMAK LABS	EQ 10MG BASE	N76001 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N76001 002	JAN 29, 2002	JAN	NEWA
AB	SIEGFRIED	EQ 10MG BASE	N75464 001	JAN 30, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75464 002	JAN 30, 2002	JAN	NEWA
AB	TEVA	EQ 10MG BASE	N75452 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75452 002	JAN 29, 2002	JAN	NEWA
AB		EQ 40MG BASE	N75452 003	JAN 29, 2002	JAN	NEWA
AB	WATSON LABS	EQ 10MG BASE	N75662 001	JAN 29, 2002	JAN	NEWA
AB		EQ 20MG BASE	N75662 002	JAN 29, 2002	JAN	NEWA
	FLUOXETINE HCL					
AB	GENEVA PHARMS	EQ 20MG BASE	N75049 002	JAN 29, 2002	JAN	NEWA
AB		EQ 40MG BASE	N75049 003	JAN 29, 2002	JAN	NEWA
	SOLUTION; ORAL					
	FLUOXETINE					
AA	ALPHARMA	EQ 20MG BASE/5ML	N75690 001	JAN 31, 2002	JAN	NEWA
AA	MALLINCKRODT	EQ 20MG BASE/5ML	N75920 001	JAN 29, 2002	JAN	NEWA
AA	NOVEX	EQ 20MG BASE/5ML	N75292 001	FEB 07, 2002	FEB	NEWA
AA	PHARM ASSOC	EQ 20MG BASE/5ML	N76015 001	JAN 30, 2002	JAN	NEWA
	TABLET; ORAL					
	FLUOXETINE HCL					
AB	BARR	EQ 10MG BASE	N75810 001	FEB 01, 2002	FEB	NEWA
AB	DR REDDYS LABS INC	EQ 10MG BASE	N76006 001	JAN 30, 2002	JAN	NEWA
AB	EON	EQ 10MG BASE	N76024 001	JAN 29, 2002	JAN	NEWA
AB	TEVA	EQ 10MG BASE	N75872 001	JAN 29, 2002	JAN	NEWA
AB	ZENITH GOLDLINE	EQ 10MG BASE	N75865 001	FEB 28, 2002	FEB	NEWA
	FOLIC ACID					
	TABLET; ORAL					
	FOLIC ACID					
AA +	WATSON LABS	1MG	N80680 001	DEC 23, 1971	FEB	CAHN
	GLIPIZIDE					
	TABLET, EXTENDED RELEASE; ORAL					
	GLUCOTROL XL					
	PFIZER	2.5MG	N20329 003	AUG 10, 1999	FEB	CRLD
		5MG	N20329 001	APR 26, 1994	FEB	CRLD

HYDROCHLOROTHIAZIDE
TABLET; ORAL
ESIDRIX

>D>	AB	NOVARTIS	100MG	N11793 009	AUG 31, 1976	MAR	CRLD
>A>	AB +		100MG	N11793 009	AUG 31, 1976	MAR	CRLD

HYDROCHLOROTHIAZIDE

>A>	AB	VINTAGE PHARMS	25MG	N40412 001	MAR 29, 2002	MAR	NEWA
>A>	AB		50MG	N40412 002	MAR 29, 2002	MAR	NEWA

>D> HYDRODIURIL

>D>	AB	MERCK	25MG	N11835 003	AUG 22, 1963	MAR	DISC
>A>		@	25MG	N11835 003	AUG 22, 1963	MAR	DISC
>D>	AB +		50MG	N11835 006	AUG 22, 1963	MAR	DISC
>A>		@	50MG	N11835 006	AUG 22, 1963	MAR	DISC
>D>	AB		100MG	N11835 007	JAN 01, 1975	MAR	DISC
>A>		@	100MG	N11835 007	JAN 01, 1975	MAR	DISC

HYDROCORTISONE ACETATE
CREAM; TOPICAL
MICORT-HC

>A>		+ FERNDALE LABS	2%	N40398 001	MAR 29, 2002	MAR	NEWA

HYDROCORTISONE BUTYRATE
CREAM; TOPICAL
LOCOID

>A>		+ FERNDALE LABS	0.1%	N18514 001	MAR 31, 1982	MAR	CAHN
>D>		+ YAMANOUCHI	0.1%	N18514 001	MAR 31, 1982	MAR	CAHN

LOCOID LIPOCREAM

>A>		+ FERNDALE LABS	0.1%	N20769 001	SEP 08, 1997	MAR	CAHN
>D>		+ YAMANOUCHI	0.1%	N20769 001	SEP 08, 1997	MAR	CAHN

OINTMENT; TOPICAL
LOCOID

>A>		+ FERNDALE LABS	0.1%	N18652 001	OCT 29, 1982	MAR	CAHN
>D>		+ YAMANOUCHI	0.1%	N18652 001	OCT 29, 1982	MAR	CAHN

IFOSFAMIDE; MESNA
INJECTABLE; INTRAVENOUS
IFOSFAMIDE/MESNA KIT

		+ GENSIA SICOR PHARMS	1GM /20ML(50MG/ML);1GM /10ML(100MG/ML)	N75874 001	FEB 26, 2002	FEB	NEWA
		+	3GM /60ML(50MG/ML);1GM /10ML(100MG/ML)	N75874 002	FEB 26, 2002	FEB	NEWA

INDOMETHACIN
CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

	AB	ABLE	75MG	N76114 001	FEB 06, 2002	FEB	NEWA

KETOCONAZOLE
TABLET; ORAL
KETOCONAZOLE

	AB	TORPHARM	200MG	N75912 001	JAN 10, 2002	JAN	NEWA

			KETOPROFEN					
			CAPSULE, EXTENDED RELEASE; ORAL					
			KETOPROFEN					
CRLD		AB	MYLAN	100MG	N75679 003	FEB 20, 2002	FEB	NEWA
CRLD		AB		150MG	N75679 002	FEB 20, 2002	FEB	NEWA
		AB		200MG	N75679 001	FEB 20, 2002	FEB	NEWA
NEWA								
NEWA			KETOROLAC TROMETHAMINE					
			INJECTABLE; INJECTION					
DISC			KETOROLAC TROMETHAMINE					
DISC		AP	AM PHARM PARTNERS	15MG/ML	N75784 001	JAN 11, 2002	JAN	NEWA
DISC		AP		30MG/ML	N75784 002	JAN 11, 2002	JAN	NEWA
DISC								
DISC			LACTULOSE					
DISC			SOLUTION; ORAL					
			LACTULOSE					
		AA	NOVEX	10GM/15ML	N75911 001	FEB 21, 2002	FEB	NEWA
			LAMOTRIGINE					
NEWA			TABLET, CHEWABLE; ORAL					
			LAMICTAL CD					
	>D>		GLAXOSMITHKLINE	25MG	N20764 002	AUG 24, 1998	MAR	CRLD
	>A>	+		25MG	N20764 002	AUG 24, 1998	MAR	CRLD
	>D>	+		100MG	N20764 003	AUG 24, 1998	MAR	DISC
CAHN	>A>	@		100MG	N20764 003	AUG 24, 1998	MAR	DISC
CAHN								
			LEUPROLIDE ACETATE					
CAHN			INJECTABLE; SUBCUTANEOUS					
CAHN			ELIGARD					
		+	ATRIX	7.5MG/VIAL	N21343 001	JAN 23, 2002	JAN	NEWA
CAHN			LEVOTHYROXINE SODIUM					
CAHN			TABLET; ORAL					
	>A>		LEVO-T					
	>A>	BX	MOVA	0.025MG	N21342 001	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.05MG	N21342 002	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.075MG	N21342 003	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.088MG	N21342 004	MAR 01, 2002	MAR	NEWA
NEWA	>A>	BX		0.1MG	N21342 005	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.112MG	N21342 006	MAR 01, 2002	MAR	NEWA
NEWA	>A>	BX		0.125MG	N21342 007	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.15MG	N21342 008	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.175MG	N21342 009	MAR 01, 2002	MAR	NEWA
	>A>	BX		0.2MG	N21342 010	MAR 01, 2002	MAR	NEWA
	>A>	BX +		0.3MG	N21342 011	MAR 01, 2002	MAR	NEWA
NEWA								
			MEFLOQUINE HYDROCHLORIDE					
			TABLET; ORAL					
			LARIAM					
		AB +	ROCHE	250MG	N19591 001	MAY 02, 1989	FEB	CFTG
NEWA			MEFLOQUINE HCL					
		AB	GENEVA PHARMS TECH	250MG	N76175 001	FEB 20, 2002	FEB	NEWA

MEGESTROL ACETATE
SUSPENSION; ORAL
MEGESTROL ACETATE

	AB		ROXANE	40MG/ML	N75997 001	FEB 15, 2002	FEB	NEWA

MESNA
INJECTABLE; INTRAVENOUS
MESNEX

>D>	AP	+	ASTA	100MG/ML	N19884 001	DEC 30, 1988	MAR	CAHN
>A>	AP	+	BAXTER HLTHCARE	100MG/ML	N19884 001	DEC 30, 1988	MAR	CAHN

>A> TABLET; ORAL

>A>		+	BRISTOL MYERS SQUIBB	400MG	N20855 001	MAR 21, 2002	MAR	NEWA

MESTRANOL; NORETHINDRONE
TABLET; ORAL-28
NORINYL 1+50 28-DAY

	AB		WATSON LABS	0.05MG;1MG	N16659 001	NOV 17, 1967	JAN	CAHN

METFORMIN HYDROCHLORIDE
TABLET; ORAL
GLUCOPHAGE

	AB		BRISTOL MYERS SQUIBB	500MG	N20357 001	MAR 03, 1995	JAN	CFTG
	AB			850MG	N20357 002	MAR 03, 1995	JAN	CFTG
	AB	+		1GM	N20357 005	NOV 05, 1998	JAN	CFTG

METFORMIN HCL

	AB		ALPHAPHARM	500MG	N75969 001	JAN 29, 2002	JAN	NEWA
	AB			850MG	N75969 002	JAN 29, 2002	JAN	NEWA
	AB			1GM	N75969 003	JAN 29, 2002	JAN	NEWA
	AB		ANDRX PHARMS	500MG	N75961 001	JAN 25, 2002	JAN	NEWA
	AB			850MG	N75961 002	JAN 25, 2002	JAN	NEWA
	AB			1GM	N75961 003	JAN 25, 2002	JAN	NEWA
	AB		BARR	500MG	N75971 001	JAN 25, 2002	JAN	NEWA
	AB			850MG	N75971 002	JAN 25, 2002	JAN	NEWA
	AB			1GM	N75971 003	JAN 25, 2002	JAN	NEWA
	AB		CARACO	500MG	N75967 001	JAN 29, 2002	JAN	NEWA
	AB			850MG	N75967 002	JAN 29, 2002	JAN	NEWA
	AB			1GM	N75967 003	JAN 29, 2002	JAN	NEWA
	AB		EON	500MG	N75965 001	JAN 25, 2002	JAN	NEWA
	AB			850MG	N75965 002	JAN 25, 2002	JAN	NEWA
	AB			1GM	N75965 003	JAN 25, 2002	JAN	NEWA
	AB		GENEVA PHARMS TECH	500MG	N75985 001	JAN 25, 2002	JAN	NEWA
	AB			850MG	N75985 002	JAN 25, 2002	JAN	NEWA
	AB			1GM	N75985 003	JAN 25, 2002	JAN	NEWA
	AB		GENPHARM	500MG	N75973 001	JAN 25, 2002	JAN	NEWA
	AB			850MG	N75973 002	JAN 25, 2002	JAN	NEWA
	AB			1GM	N75973 003	JAN 25, 2002	JAN	NEWA
	AB		GOLDLINE	500MG	N75972 001	JAN 24, 2002	JAN	NEWA
	AB			625MG	N75972 005	JAN 24, 2002	JAN	NEWA
	AB			750MG	N75972 004	JAN 24, 2002	JAN	NEWA
	AB			850MG	N75972 002	JAN 24, 2002	JAN	NEWA
	AB			1GM	N75972 003	JAN 24, 2002	JAN	NEWA
	AB		MUTUAL PHARMA	500MG	N76038 001	FEB 21, 2002	FEB	NEWA

AB		850MG	N76038 002	FEB 21, 2002	FEB	NEWA
AB		1GM	N76038 003	FEB 21, 2002	FEB	NEWA
AB	MYLAN	500MG	N75976 001	JAN 24, 2002	JAN	NEWA
AB		850MG	N75976 002	JAN 24, 2002	JAN	NEWA
AB		1GM	N75976 003	JAN 24, 2002	JAN	NEWA
AB	PUREPAC PHARM	500MG	N76033 001	JAN 24, 2002	JAN	NEWA
AB		850MG	N76033 002	JAN 24, 2002	JAN	NEWA
AB		1GM	N76033 003	JAN 24, 2001	JAN	NEWA
AB	TEVA	500MG	N75978 001	JAN 25, 2002	JAN	NEWA
AB		850MG	N75978 002	JAN 25, 2002	JAN	NEWA
AB	WATSON LABS	500MG	N75979 001	JAN 24, 2002	JAN	NEWA
AB		850MG	N75979 002	JAN 24, 2002	JAN	NEWA
AB		1GM	N75979 003	JAN 24, 2002	JAN	NEWA
AB	ZENITH GOLDLINE	500MG	N75975 001	JAN 24, 2002	JAN	NEWA
AB		625MG	N75975 004	JAN 24, 2002	JAN	NEWA
AB		750MG	N75975 005	JAN 24, 2002	JAN	NEWA
AB		850MG	N75975 002	JAN 24, 2002	JAN	NEWA
AB		1GM	N75975 003	JAN 24, 2002	JAN	NEWA

METHOHEXITAL SODIUM
INJECTABLE; INJECTION
BREVITAL SODIUM

+	KING PHARMS	500MG/VIAL	N11559 001	JUN 27, 1960	FEB	CAHN
+		2.5GM/VIAL	N11559 002	JUN 27, 1960	FEB	CAHN
+		5GM/VIAL	N11559 003	MAY 08, 1961	FEB	CAHN

METHYLPHENIDATE HYDROCHLORIDE
TABLET; ORAL
METHYLPHENIDATE HCL

AB	PUREPAC PHARM	5MG	N40321 001	FEB 05, 2002	FEB	NEWA
AB		10MG	N40321 002	FEB 05, 2002	FEB	NEWA
AB		20MG	N40321 003	FEB 05, 2002	FEB	NEWA

MIDAZOLAM HYDROCHLORIDE
SYRUP; ORAL

>A>		MIDAZOLAM HCL					
>A>	AA	RANBAXY	EQ 2MG BASE/ML	N76058 001	MAR 15, 2002	MAR	NEWA
		VERSED					
>D>	+	ROCHE	EQ 2MG BASE/ML	N20942 001	OCT 15, 1998	MAR	CFTG
>A>	AA +		EQ 2MG BASE/ML	N20942 001	OCT 15, 1998	MAR	CFTG

MOMETASONE FUROATE
OINTMENT; TOPICAL
ELOCON

>D>	+	SCHERING	0.1%	N19543 001	APR 30, 1987	MAR	CFTG
>A>	AB +		0.1%	N19543 001	APR 30, 1987	MAR	CFTG
		MOMETASONE FUROATE					
>A>	AB	CLAY PARK	0.1%	N76067 001	MAR 18, 2002	MAR	NEWA

MORPHINE SULFATE
CAPSULE, EXTENDED RELEASE; ORAL

>A>		AVINZA					
>A>		ELAN PHARM	30MG	N21260 001	MAR 20, 2002	MAR	NEWA

>A>			60MG	N21260 002	MAR 20, 2002	MAR	NEWA
>A>			90MG	N21260 003	MAR 20, 2002	MAR	NEWA
>A>	+		120MG	N21260 004	MAR 20, 2002	MAR	NEWA

NABUMETONE
TABLET; ORAL
NABUMETONE

AB		EON	500MG	N75280 001	FEB 25, 2002	FEB	NEWA
AB			750MG	N75280 002	FEB 25, 2002	FEB	NEWA
AB		INVAMED	500MG	N75590 001	FEB 25, 2002	FEB	NEWA
AB			750MG	N75590 002	FEB 25, 2002	FEB	NEWA

NALTREXONE HYDROCHLORIDE
TABLET; ORAL
NALTREXONE HCL

>A>		MALLINCKRODT	25MG	N76264 001	MAR 22, 2002	MAR	NEWA
>A>	AB		50MG	N76264 002	MAR 22, 2002	MAR	NEWA
>A>	+		100MG	N76264 003	MAR 22, 2002	MAR	NEWA

NISOLDIPINE
TABLET, EXTENDED RELEASE; ORAL
SULAR

>A>	+	FIRST HORIZON	10MG	N20356 001	FEB 02, 1995	MAR	CAHN
>A>	+		20MG	N20356 002	FEB 02, 1995	MAR	CAHN
>A>	+		30MG	N20356 003	FEB 02, 1995	MAR	CAHN
>A>	+		40MG	N20356 004	FEB 02, 1995	MAR	CAHN
>D>	+	WHITEHALL ROBINS	10MG	N20356 001	FEB 02, 1995	MAR	CAHN
	+		10MG	N20356 001	FEB 02, 1995	FEB	CAHN
			20MG	N20356 002	FEB 02, 1995	FEB	CAHN
>D>	+		30MG	N20356 003	FEB 02, 1995	MAR	CAHN
>D>	+		40MG	N20356 004	FEB 02, 1995	MAR	CAHN
	+		40MG	N20356 004	FEB 02, 1995	FEB	CAHN

NITISINONE
CAPSULE; ORAL
ORFADIN

		R R REGISTRATIONS	2MG	N21232 001	JAN 18, 2002	JAN	NEWA
			5MG	N21232 002	JAN 18, 2002	JAN	NEWA
	+		10MG	N21232 003	JAN 18, 2002	JAN	NEWA

NITROFURANTOIN
SUSPENSION; ORAL
FURADANTIN

	+	FIRST HORIZON	25MG/5ML	N09175 001	DEC 23, 1953	JAN	CAHN

OFLOXACIN
INJECTABLE; INJECTION
FLOXIN

AP	+	JOHNSON RW	40MG/ML	N20087 003	MAR 31, 1992	JAN	CFTG

OFLOXACIN

AP		BEDFORD	40MG/ML	N75762 001	JAN 16, 2002	JAN	NEWA

		OXAPROZIN						
		TABLET; ORAL						
		OXAPROZIN						
	AB	CARACO	600MG	N75844	001	JAN 03, 2002	JAN	NEWA
		PAMIDRONATE DISODIUM						
>A>		INJECTABLE; IV (INFUSION)						
>A>		PAMIDRONATE DISODIUM						
>A>	AP	BEDFORD	30MG /10ML(3MG/ML)	N21113	001	MAR 04, 2002	MAR	NEWA
>A>	AP +		90MG /10ML(9MG/ML)	N21113	002	MAR 04, 2002	MAR	NEWA
>A>	AP	GENSIA SICOR PHARMS	30MG /10ML(3MG/ML)	N76153	001	MAR 27, 2002	MAR	NEWA
>A>	AP		90MG /10ML(9MG/ML)	N76153	002	MAR 27, 2002	MAR	NEWA
		PHENDIMETRAZINE TARTRATE						
		TABLET; ORAL						
		PHENDIMETRAZINE TARTRATE						
>D>		@ MIKART	35MG	N89452	001	OCT 30, 1991	MAR	CMFD
>A>	AA		35MG	N89452	001	OCT 30, 1991	MAR	CMFD
		PHENTERMINE HYDROCHLORIDE						
		CAPSULE; ORAL						
		PHENTERMINE HCL						
	AA	VINTAGE PHARMS	37.5MG	N40377	001	JAN 04, 2002	JAN	NEWA
		PODOFILOX						
		SOLUTION; TOPICAL						
		CONDYLOX						
	AT +	PADDOCK	0.5%	N19795	001	DEC 13, 1990	JAN	CFTG
		PODOFILOX						
	AT	PADDOCK	0.5%	N75600	001	JAN 29, 2002	JAN	NEWA
		PRAVASTATIN SODIUM						
		TABLET; INJECTION						
		PRAVACHOL						
>A>		+ BRISTOL MYERS SQUIBB	80MG	N19898	008	DEC 18, 2001	MAR	NEWA
		TABLET; ORAL						
>D>		+ BRISTOL MYERS SQUIBB	40MG	N19898	004	MAR 22, 1993	MAR	CRLD
>A>			40MG	N19898	004	MAR 22, 1993	MAR	CRLD
		PROMETHAZINE HYDROCHLORIDE						
		SUPPOSITORY; RECTAL						
		PHENERGAN						
	AB +	WYETH AYERST	25MG	N10926	001	MAY 05, 1958	FEB	CTEC
		PROMETHAZINE HCL						
	AB	G AND W LABS	25MG	N40428	001	FEB 05, 2002	FEB	NEWA
		PROPAFENONE HYDROCHLORIDE						
		TABLET; ORAL						
		PROPAFENONE HCL						
	AB	KV PHARM	150MG	N76193	001	FEB 07, 2002	FEB	NEWA
	AB		225MG	N76193	002	FEB 07, 2002	FEB	NEWA
	AB		300MG	N76193	003	FEB 07, 2002	FEB	NEWA

PROPRANOLOL HYDROCHLORIDE
TABLET; ORAL
PROPRANOLOL HCL

	@ LEDERLE	60MG	N71495 001	DEC 31, 1987	FEB	DISC
	@	90MG	N71496 001	DEC 31, 1987	FEB	DISC

SULFASALAZINE
TABLET; ORAL
SULFASALAZINE

AB	VINTAGE PHARMS	500MG	N40349 001	JAN 11, 2002	JAN	NEWA

TABLET, DELAYED RELEASE; ORAL
AZULFIDINE EN-TABS

AB	+ PHARMACIA AND UPJOHN	500MG	N07073 002	APR 06, 1983	JAN	CFTG

SULFASALAZINE

AB	VINTAGE PHARMS	500MG	N75339 001	JAN 11, 2002	JAN	NEWA

TERBUTALINE SULFATE
INJECTABLE; INJECTION
BRETHINE

	+ NEOSAN PHARMS	1MG/ML	N18571 001	NOV 30, 1981	FEB	CAHN

TABLET; ORAL

AB	NEOSAN PHARMS	2.5MG	N17849 001	MAY 17, 1976	FEB	CAHN
AB	+	5MG	N17849 002	MAY 17, 1976	FEB	CAHN

TESTOSTERONE
FILM, EXTENDED RELEASE; TRANSDERMAL
TESTODERM TTS

BX	+ ALZA	5MG/24HR	N20791 001	DEC 18, 1997	JAN	CTNA

TETRACYCLINE HYDROCHLORIDE
FIBER, EXTENDED RELEASE; PERIODONTAL
ACTISITE

	+ ALZA	12.7MG/FIBER	N50653 001	MAR 25, 1994	FEB	CAHN

THIOTEPA
INJECTABLE; INJECTION
THIOTEPA

AP	AM PHARM PARTNERS	15MG/VIAL	N75698 001	SEP 20, 2001	FEB	CAHN

THIOTHIXENE HYDROCHLORIDE
CONCENTRATE; ORAL
THIOTHIXENE HCL INTENSOL

	@ ROXANE	EQ 5MG BASE/ML	N73494 001	JUN 30, 1992	JAN	DISC

TOBRAMYCIN
SOLUTION/DROPS; OPHTHALMIC
TOBRAMYCIN

AT	NOVEX	0.3%	N65087 001	FEB 25, 2002	FEB	NEWA

TOBRAMYCIN SULFATE
INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

	@ ASTRAZENECA	EQ 40MG BASE/ML	N63120	001	OCT 31, 1994	FEB	DISC
	@	EQ 40MG BASE/ML	N63122	001	OCT 31, 1994	JAN	DISC

TOPIRAMATE
TABLET; ORAL
TOPAMAX

+	JOHNSON AND JOHNSON	25MG	N20505	004	DEC 24, 1996	JAN	CAHN
	@	50MG	N20505	005	DEC 24, 1996	JAN	CAHN
		100MG	N20505	001	DEC 24, 1996	JAN	CAHN
		200MG	N20505	002	DEC 24, 1996	JAN	CAHN
	@	300MG	N20505	003	DEC 24, 1996	JAN	CAHN
	@	400MG	N20505	006	DEC 24, 1996	JAN	CAHN

TRAMADOL HYDROCHLORIDE
TABLET; ORAL
ULTRAM

+	JOHNSON AND JOHNSON	50MG	N20281	002	MAR 03, 1995	FEB	CAHN
	@	100MG	N20281	001	MAR 03, 1995	FEB	CAHN

TRIMETHOBENZAMIDE HYDROCHLORIDE
CAPSULE; ORAL
TIGAN

+	KING PHARMS	300MG	N17531	006	DEC 13, 2001	JAN	NEWA

INJECTABLE; INJECTION
TRIMETHOBENZAMIDE HCL

	@ STERIS	100MG/ML	N87939	001	DEC 28, 1982	FEB	DISC

URSODIOL
CAPSULE; ORAL
ACTIGALL

	@ WATSON PHARMS	150MG	N19594	001	DEC 31, 1987	FEB	CAHN
AB +		300MG	N19594	002	DEC 31, 1987	FEB	CAHN

VALACYCLOVIR HYDROCHLORIDE
TABLET; ORAL
VALTREX

>D>	+ GLAXOSMITHKLINE	EQ 500MG BASE	N20487	001	JUN 23, 1995	MAR	DISC
>A>	@	EQ 500MG BASE	N20487	001	JUN 23, 1995	MAR	DISC
>D>	@	EQ 1GM BASE	N20487	002	JUN 23, 1995	MAR	DISC
>A>	@	EQ 1GM BASE	N20487	002	JUN 23, 1995	MAR	DISC

ACETAMINOPHEN
TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN

>A>	COREPHARMA	650MG	N76200	001	MAR 19, 2022	MAR	NEWA

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
CONTAC 12 HOUR

	@ GLAXOSMITHKLINE	8MG;75MG	N18099	001	FEB 04, 1980	JAN	DISC

PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE

	@ CENT PHARMS	8MG;75MG	N18809	001	MAY 07, 1984	FEB	DISC

FAMOTIDINE
TABLET; ORAL
FAMOTIDINE

>A>	TORPHARM	10MG	N75610	001	MAR 12, 2002	MAR	NEWA

IBUPROFEN
TABLET; ORAL
IBUPROFEN

>A>	PERRIGO	200MG	N75995	001	MAR 14, 2002	MAR	NEWA

INSULIN PURIFIED PORK
INJECTABLE; INJECTION
REGULAR PURIFIED PORK INSULIN

	@ NOVO NORDISK	100 UNITS/ML	N18381	001	MAR 17, 1980	FEB	DISC

INSULIN SUSP ISOPHANE PURIFIED PORK
INJECTABLE; INJECTION
NPH PURIFIED PORK ISOPHANE INSULIN

	@ NOVO NORDISK	100 UNITS/ML	N18623	001	JUL 30, 1981	FEB	DISC

INSULIN ZINC SUSP PURIFIED PORK
INJECTABLE; INJECTION
LENTE

	@ NOVO NORDISK	100 UNITS/ML	N18383	001	MAR 17, 1980	FEB	DISC

KETOPROFEN
TABLET; ORAL
KETOPROFEN

	PERRIGO	12.5MG	N75364	001	FEB 07, 2002	FEB	NEWA

MINOXIDIL
SOLUTION; TOPICAL
MINOXIDIL EXTRA STRENGTH (FOR MEN)

>A>	CLAY PARK	5%	N75737	001	MAR 15, 2002	MAR	NEWA

>D>	MINOXIDIL EXTRA STRENGTH FOR MEN						
>D>	NOVEX	5%	N75839	001	OCT 01, 2001	MAR	CTNA
>A>	MINOXIDIL EXTRA STRENTH (FOR MEN)						
>A>	NOVEX	5%	N75839	001	OCT 01, 2001	MAR	CTNA

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

CUMULATIVE SUPPLEMENT NUMBER 3 MARCH '02

NEWA

NO MARCH 2002 APPROVALS

DISC

DISC

NEWA

NEWA

DISC

DISC

DISC

NEWA

NEWA

CTNA

CTNA

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Products Designations and Approvals List
March 2002

Generic Name: **albuterol**
Trade Name: NONE ASSIGNED

Designated Indication: *Prevention of paralysis due to spinal cord injury*

Sponsor: MotoGen, Inc.
Address: 3 Pine View Road
Mount Kisco NY 10549

Date Designated: 3/12/2002
Market Approval Date: Not currently Approved

Generic Name: **aztreonam**
Trade Name: NONE ASSIGNED

Designated Indication: *Inhalation therapy for control of gram-negative bacteria in the respiratory tract of patients with cystic fibrosis*

Sponsor: Corus Pharma
Address: 2025 First Ave., Suite 800
Seattle WA 98121

Date Designated: 3/12/2002
Market Approval Date: Not currently Approved

Generic Name: **Bioartificial liver system utilizing xenogenic hepatocytes in a hollow fiber bioreactor cartridge (BAL)**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of patients with acute liver failure presenting with encephalopathy deteriorating beyond Parson's grade 2*

Sponsor: Excorp Medical, Inc.
Address: Suite 235
7200 Hudson Blvd.
Oakdale MN 55128

Date Designated: 2/11/2002
Market Approval Date: Not currently Approved

Generic Name: **carbamic acid, [[4-[[3-[[4-[1-(4-hydroxyphenyl)-1-methyl-ethyl]phenoxy]methyl]phenyl]methoxy]-phenyl]iminomethyl]-,ethyl ester**
Trade Name: NONE ASSIGNED

Designated Indication: *Management of cystic fibrosis*

Sponsor: Boehringer Ingelheim Pharmaceuticals, Inc
Address: 900 Ridgebury Road
P.O. Box 368
Ridgefield CT 06877

Date Designated: 1/15/2002
Market Approval Date: Not currently Approved

Orphan Products Designations and Approvals List
March 2002

Generic Name: **clofarabine**
Trade Name: Clofarex

Designated Indication: *Treatment of acute myelogenous leukemia*

Sponsor: Ilex Products, Inc.
Address: 4545 Horizon Hill Blvd.
San Antonio TX 78229-2263

Date Designated: 3/14/2002
Market Approval Date: Not currently Approved

Generic Name: **clofarabine**
Trade Name: Clofarex

Designated Indication: *Treatment of acute lymphoblastic leukemia*

Sponsor: Ilex Products, Inc.
Address: 4545 Horizon Hill Blvd.
San Antonio TX 78229-2263

Date Designated: 2/7/2002
Market Approval Date: Not currently Approved

Generic Name: **creatine**
Trade Name: Creapure

Designated Indication: *Treatment of amyotrophic lateral sclerosis*

Sponsor: Avicena Group, Inc.
Address: 580 California St.
Suite 1600
San Francisco CA 94104

Date Designated: 2/12/2002
Market Approval Date: Not currently Approved

Generic Name: **homoharringtonine**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment for chronic myelogenous leukemia*

Sponsor: American BioScience, Inc.
Address: 2730 Wilshire Blvd. #110
Santa Monica CA 90403

Date Designated: 2/8/2002
Market Approval Date: Not currently Approved

Generic Name: **human anti-transforming growth factor beta 1 monoclonal antibody**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of systemic sclerosis*

Sponsor: Genzyme Corporation
Address: One Kendall Square
Cambridge MA 02139

Date Designated: 1/11/2002
Market Approval Date: Not currently Approved

Orphan Products Designations and Approvals List
March 2002

Generic Name: **hyaluronic acid**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of emphysema in patients due to alpha-1 antitrypsin deficiency*

Sponsor: Exhale Therapeutics, Inc.
Address: 1301 Shoreway Road
Suite 320
Belmont CA 94002

Date Designated: 3/19/2002
Market Approval Date: Not currently Approved

Generic Name: **I(131)-TM-601 (chlorotoxin)**
Trade Name: NONE ASSIGNED

Designated Indication: *treatment of malignant glioma*

Sponsor: TransMolecular, Inc.
Address: 3800 Colonnade Parkway
Suite 240
Birmingham AL 35243

Date Designated: 2/14/2002
Market Approval Date: Not currently Approved

Generic Name: **lactic acid bacteria (Lactobacilli, Bifidobacteria, and Steptococci)**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of active chronic pouchitis*

Sponsor: VSL Pharmaceuticals, Inc.
Address: 800 S. Frederick Avenue
Gaithersburg MD 20877

Date Designated: 1/15/2002
Market Approval Date: Not currently Approved

Generic Name: **lactic acid bacteria (Lactobacilli, Bifidobacteria, and Streptococcus species)**
Trade Name: NONE ASSIGNED

Designated Indication: *Prevention of disease relapse in patients with chronic pouchitis*

Sponsor: VSL Pharmaceuticals, Inc.
Address: 800 S. Frederick Ave.
Gaithersburg MD 20877

Date Designated: 1/15/2002
Market Approval Date: Not currently Approved

Generic Name: **lipase, amylase, and protease**
Trade Name: TheraCLEC-Total

Designated Indication: *Treatment of pancreatic insufficiency*

Sponsor: Altus Biologics Inc.
Address: 625 Putnam Avenue
Cambridge MA 02139

Date Designated: 1/23/2002
Market Approval Date: Not currently Approved

Orphan Products Designations and Approvals List
March 2002

Generic Name: **nitazoxanide** Trade Name: Cryptaz

Designated Indication: *Treatment of intestinal giardiasis*

Sponsor: Romark Laboratories, L.C.
Address: 6200 Courtney Campbell Causeway
Suite 880
Tampa FL 33607

Date Designated: 2/14/2002
Market Approval Date: Not currently Approved

Generic Name: **phenylephrine** Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of ileal pouch anal anastomosis related fecal incontinence*

Sponsor: S.L.A. Pharma
Address: Unit 3, Hill Farm Industrial Estate
Leavesden, Watford
United Kingdom WD25 7SA

Date Designated: 2/14/2002
Market Approval Date: Not currently Approved

Generic Name: **recombinant human endostatin protein** Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of metastatic melanoma*

Sponsor: EntreMed, Inc.
Address: 9640 Medical Center Drive
Rockville MD 20850

Date Designated: 2/21/2002
Market Approval Date: Not currently Approved

Generic Name: **rituximab** Trade Name: Rituxan

Designated Indication: *Treatment of immune thrombocytopenic purpura*

Sponsor: Genentech, Inc.
Address: 1 DNA Way
South San Francisco CA 94080-4990

Date Designated: 3/12/2002
Market Approval Date: Not currently Approved

Generic Name **S(-)-3-[3-amino-phthalimido]-glutaramide** Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of multiple myeloma*

Sponsor: EntreMed Incorporated
Address: 9640 Medical Center Dr.
Rockville MD 20850

Date Designated: 3/14/2002
Market Approval Date: Not currently Approved

Orphan Products Designations and Approvals List
March 2002

Generic Name: **SS1(dsFv)-PE38**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of epithelial ovarian cancer*

Sponsor: NeoPharm, Inc.
Address: 150 Field Drive
Suite 195
Lake Forest IL 60045

Date Designated: 2/11/2002
Market Approval Date: Not currently Approved

Generic Name: **SS1(dsFv)-PE38**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of malignant mesothelioma*

Sponsor: NeoPharm Incorporated
Address: 150 Field Drive
Suite 195
Lake Forest IL 60045

Date Designated: 2/11/2002
Market Approval Date: Not currently Approved

Generic Name: **toralizumab**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of immune thrombocytopenic purpura*

Sponsor: IDEC Pharmaceuticals Corporation
Address: 3030 Callan Road
San Diego CA 92121

Date Designated: 3/14/2002
Market Approval Date: Not currently Approved

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

NO MARCH 2002 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
	020503 001	ALBUTEROL SULFATE;PROVENTIL-HFA	6352684	NOV 28, 2009			
	021303 001	AMPHETAMINE ASPARTATE;ADDERALL XR 10	6322819	NOV 27, 2018			
	021303 002	AMPHETAMINE ASPARTATE;ADDERALL XR 20	6322819	NOV 27, 2018			
	021303 003	AMPHETAMINE ASPARTATE;ADDERALL XR 30	6322819	NOV 27, 2018			
	020883 001	ARGATROBAN;ARGATROBAN				I-352	APR 03, 2005
	020911 002	BECLOMETHASONE DIPROPIONATE;QVAR 40	6352684	NOV 28, 2009			
	020911 001	BECLOMETHASONE DIPROPIONATE;QVAR 80	6352684	NOV 28, 2009			
	018731 001	BUSPIRONE HYDROCHLORIDE;BUSPAR				M-12	JUL 19, 2004
						PED	JAN 19, 2005
						W	JUL 19, 2004
						W	JAN 19, 2005
	018731 002	BUSPIRONE HYDROCHLORIDE;BUSPAR				M-12	JUL 19, 2004
						PED	JAN 19, 2005
						W	JUL 19, 2004
						W	JAN 19, 2005
	018731 003	BUSPIRONE HYDROCHLORIDE;BUSPAR				M-12	JUL 19, 2004
						PED	JAN 19, 2005
						W	JUL 19, 2004
						W	JAN 19, 2005
	018731 004	BUSPIRONE HYDROCHLORIDE;BUSPAR				M-12	JUL 19, 2004
						PED	JAN 19, 2005
						W	JUL 19, 2004
						W	JAN 19, 2005
	020954 001	BUSULFAN;BUSULFEX	5430057	SEP 30, 2013	U-263	ODE	FEB 04, 2006
			5559148	MAY 24, 2015	U-264	NDF	FEB 04, 2002
			5430057*PED	MAR 30, 2014	U-263	PED	AUG 04, 2002
			5559148*PED	NOV 24, 2015	U-264	PED	AUG 04, 2006
	019835 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007			
			4525358*PED	DEC 25, 2007			
	019835 002	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007			
			4525358*PED	DEC 25, 2007			
	020346 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007			
			4525358*PED	DEC 25, 2007			
>ADD>	020369 001	CIPROFLOXACIN HYDROCHLORIDE;CILOXAN	4670444	DEC 09, 2003	U-223		
	020839 001	CLOPIDOGREL BISULFATE;PLAVIX				I-349	FEB 27, 2005
	021165 001	DESLORATADINE;CLARINEX	6100274	JUL 07, 2019			
	075863 001	DESOGESTREL;DESOGESTREL AND ETHI				PC	JUN 04, 2002
>ADD>	020690 001	DONEPEZIL HYDROCHLORIDE;ARICEPT	6372760	MAR 31, 2019			
>ADD>	020690 002	DONEPEZIL HYDROCHLORIDE;ARICEPT	6372760	MAR 31, 2019			
>ADD>	021153 001	ESOMEPRAZOLE MAGNESIUM;NEXIUM	6369085	MAY 25, 2018			
>ADD>	021153 002	ESOMEPRAZOLE MAGNESIUM;NEXIUM	6369085	MAY 25, 2018			
	020655 001	ESTRADIOL;ALORA				I-351	APR 05, 2005
	020655 002	ESTRADIOL;ALORA				I-351	APR 05, 2005
	020655 003	ESTRADIOL;ALORA				I-351	APR 05, 2005

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
	020655 004	ESTRADIOL;ALORA	5122383	MAY 17, 2011		I-351	APR 05, 2005
			5227169	MAY 17, 2011			
			5212199	MAY 17, 2011			
			5164190	DEC 11, 2010			
	075753 002	FENOFIBRATE;FENOFIBRATE				PC	SEP 15, 2002
	075753 003	FENOFIBRATE;FENOFIBRATE				PC	SEP 15, 2002
>ADD>	075442 001	FLECAINIDE ACETATE;FLECAINIDE ACETATE				PC	OCT 28, 2002
>ADD>	075442 002	FLECAINIDE ACETATE;FLECAINIDE ACETATE				PC	OCT 28, 2002
>ADD>	075442 003	FLECAINIDE ACETATE;FLECAINIDE ACETATE				PC	OCT 28, 2002
	021345 001	FONDAPARINUX SODIUM;ARIXTRA	4818816	AUG 19, 2003			
	020235 001	GABAPENTIN;NEURONTIN	5084479	JAN 02, 2010	U-258		
			5084479*PED	JUL 02, 2010	U-258		
	020235 002	GABAPENTIN;NEURONTIN	5084479	JAN 02, 2010	U-258		
			5084479*PED	JUL 02, 2010	U-258		
	020235 003	GABAPENTIN;NEURONTIN	5084479	JAN 02, 2010	U-258		
			5084479*PED	JUL 02, 2010	U-258		
>ADD>	020622 001	GLATIRAMER ACETATE;COPAXONE	6362161	MAY 24, 2014	U-441		
			6342476	MAY 24, 2014	U-441		
	020387 001	HYDROCHLOROTHIAZIDE;HYZAAR	5153197	OCT 06, 2009	U-3		
			5138069	AUG 11, 2009			
			5608075	MAR 04, 2014			
			5138069*PED	FEB 11, 2010			
			5153197*PED	APR 06, 2010	U-3		
			5608075*PED	SEP 04, 2014			
	020387 002	HYDROCHLOROTHIAZIDE;HYZAAR	5138069	AUG 11, 2009			
			5153197	OCT 06, 2009	U-3		
			5608075	MAR 04, 2014			
			5138069*PED	FEB 11, 2010			
			5153197*PED	APR 06, 2010	U-3		
			5608075*PED	SEP 04, 2014			
	020716 001	HYDROCODONE BITARTRATE;VICOPROFEN	6348216	JUN 10, 2017			
	021373 001	IBUPROFEN;CHILDREN'S ADVIL COL				NP	AUG 01, 2003
						PED	FEB 01, 2004
	019700 001	KETOROLAC TROMETHAMINE;ACULAR				M-16	FEB 08, 2005
	020811 001	KETOROLAC TROMETHAMINE;ACULAR PRESERVATIVE				M-16	FEB 08, 2005
	021343 001	LEUPROLIDE ACETATE;ELIGARD	5599552	FEB 04, 2014			
			5733950	OCT 03, 2008			
			5739176	OCT 03, 2008			
			4938763	OCT 03, 2008			
			5278201	JAN 11, 2011			
			5324519	OCT 20, 2011			
	020634 003	LEVOFLOXACIN;LEVAQUIN				I-305	FEB 02, 2003
	020386 001	LOSARTAN POTASSIUM;COZAAR	5138069	AUG 11, 2009			
			5153197	OCT 06, 2009	U-3		
			5608075	MAR 04, 2014			
			5138069*PED	FEB 11, 2010			
			5153197*PED	APR 06, 2010	U-3		
			5608075*PED	SEP 04, 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
	020386 002	LOSARTAN POTASSIUM;COZAAR	5153197	OCT 06, 2009	U-3		
			5138069	AUG 11, 2009			
			5608075	MAR 04, 2014			
			5138069*PED	FEB 11, 2010			
			5153197*PED	APR 06, 2010	U-3		
			5608075*PED	SEP 04, 2014			
	020386 003	LOSARTAN POTASSIUM;COZAAR	5138069	AUG 11, 2009			
			5153197	OCT 06, 2009	U-3		
			5608075	MAR 04, 2014			
			5138069*PED	FEB 11, 2010			
			5153197*PED	APR 06, 2010	U-3		
			5608075*PED	SEP 04, 2014			
	019643 002	LOVASTATIN;MEVACOR				PED	AUG 14, 2005
						I-350	FEB 14, 2005
	019643 003	LOVASTATIN;MEVACOR				PED	AUG 14, 2005
						I-350	FEB 14, 2005
	019643 004	LOVASTATIN;MEVACOR				PED	AUG 14, 2005
						I-350	FEB 14, 2005
>ADD>	076175 001	MEFLOQUINE HYDROCHLORIDE;MEFLOQUINE HCL				PC	NOV 03, 2002
	020922 001	MEQUINOL;SOLAGE	6353029	AUG 24, 2020			
	020357 001	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	JUN 15, 2004
						I-320	DEC 15, 2003
						W	DEC 15, 2003
						W	JUN 15, 2004
	020357 002	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	JUN 15, 2004
						I-320	DEC 15, 2003
						W	DEC 15, 2003
						W	JUN 15, 2004
	020357 003	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	JUN 15, 2004
						I-320	DEC 15, 2003
						W	DEC 15, 2003
						W	JUN 15, 2004
	020357 004	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	JUN 15, 2004
						I-320	DEC 15, 2003
						W	DEC 15, 2003
						W	JUN 15, 2004
	020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	JUN 15, 2004
						I-320	DEC 15, 2003
						W	DEC 15, 2003
						W	JUN 15, 2004
	021121 004	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4519801	JUL 12, 2002		NP	AUG 01, 2003
			4612008	SEP 16, 2003			
			4783337	SEP 16, 2003	U-372		
			5082668	SEP 16, 2003			

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
	020415 001	MIRTAZAPINE;REMERON				M-18	APR 09, 2005
	020415 002	MIRTAZAPINE;REMERON				M-18	APR 09, 2005
	020415 003	MIRTAZAPINE;REMERON				M-18	APR 09, 2005
	019297 001	MITOXANTRONE HYDROCHLORIDE;NOVANTRONE				ODE	OCT 13, 2007
	021260 001	MORPHINE SULFATE;AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005
	021260 002	MORPHINE SULFATE;AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005
	021260 003	MORPHINE SULFATE;AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005
	021260 004	MORPHINE SULFATE;AVINZA	6066339	NOV 25, 2017		NP	MAR 20, 2005
	020076 004	NICOTINE;HABITROL				D-71	NOV 12, 2002
	020076 005	NICOTINE;HABITROL				D-71	NOV 12, 2002
	020076 006	NICOTINE;HABITROL				D-71	NOV 12, 2002
>ADD>	020555 001	NIZATIDINE;AXID AR	4375547	APR 12, 2002			
	019810 001	OMEPRAZOLE;PRILOSEC	4636499*PED	NOV 30, 2005			
			6166213*PED	APR 19, 2019			
	019810 002	OMEPRAZOLE;PRILOSEC	4636499*PED	NOV 30, 2005			
			6166213*PED	APR 19, 2019			
	019810 003	OMEPRAZOLE;PRILOSEC	4636499*PED	NOV 30, 2005			
			6166213*PED	APR 19, 2019			
	020766 001	ORLISTAT;XENICAL	4598089	JUN 18, 2009			
	021285 001	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
	020553 001	OXYCODONE HYDROCHLORIDE;OXYCONTIN	4970075	AUG 29, 2006			
			5266331	OCT 26, 2007			
			5549912	OCT 26, 2007			
			5508042	APR 16, 2013	U-443		
			5656295	OCT 26, 2007	U-443		
	020553 002	OXYCODONE HYDROCHLORIDE;OXYCONTIN	4970075	AUG 29, 2006			
			5266331	OCT 26, 2007			
			5549912	OCT 26, 2007			
			5508042	APR 16, 2013	U-443		
			5656295	OCT 26, 2007	U-443		
	020553 003	OXYCODONE HYDROCHLORIDE;OXYCONTIN	4970075	AUG 29, 2006			
			5266331	OCT 26, 2007			
			5549912	OCT 26, 2007			
			5508042	APR 16, 2013	U-443		
			5656295	OCT 26, 2007	U-443		
	020553 004	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013	U-443		
			5656295	OCT 26, 2007	U-443		
			4970075	AUG 29, 2006			
			5266331	OCT 26, 2007			
			5549912	OCT 26, 2007			
	020553 005	OXYCODONE HYDROCHLORIDE;OXYCONTIN	4970075	AUG 29, 2006			
			5266331	OCT 26, 2007			
			5549912	OCT 26, 2007			
			5508042	APR 16, 2013	U-443		
			5656295	OCT 26, 2007	U-443		

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
	020629 001	PENCICLOVIR SODIUM;DENAVIR	5075445	SEP 24, 2010			
	021302 001	PIMECROLIMUS;ELIDEL	6352998	OCT 26, 2015			
			6352998*PED	APR 26, 2016			
	021073 001	PIOGLITAZONE HYDROCHLORIDE;ACTOS	6303640	AUG 09, 2016	U-425		
	021073 002	PIOGLITAZONE HYDROCHLORIDE;ACTOS	6303640	AUG 09, 2016	U-425		
	021073 003	PIOGLITAZONE HYDROCHLORIDE;ACTOS	6303640	AUG 09, 2016	U-425		
>ADD>	019898 008	PRAVASTATIN SODIUM;PRAVACHOL	4346227	OCT 20, 2005			
>ADD>			5030447	JUL 09, 2008			
>ADD>			5180589	JUL 09, 2008			
>ADD>			5622985	APR 22, 2014	U-335		
	020815 001	RALOXIFENE HYDROCHLORIDE;EVISTA	4418068	APR 03, 2003			
	020272 001	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020272 002	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020272 003	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020272 004	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020272 005	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020272 007	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020272 008	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
	020588 001	RISPERIDONE;RISPERDAL				M-15	MAR 03, 2005
>ADD>	020864 001	RIZATRIPTAN BENZOATE;MAXALT	5298520	JUN 29, 2012	U-240		
>ADD>	020864 002	RIZATRIPTAN BENZOATE;MAXALT	5298520	JUN 29, 2012	U-240		
>ADD>	020865 001	RIZATRIPTAN BENZOATE;MAXALT-MLT	5298520	JUN 29, 2012	U-240		
>ADD>	020865 002	RIZATRIPTAN BENZOATE;MAXALT-MLT	5298520	JUN 29, 2012	U-240		
>ADD>	021042 001	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
>ADD>			6063811	MAY 06, 2017	U-266		
>ADD>	021042 002	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
>ADD>			6063811	MAY 06, 2017	U-266		
>ADD>	021042 003	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
>ADD>			6063811	MAY 06, 2017			
>ADD>	021052 001	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
>ADD>			6063811	MAY 06, 2017	U-266		
>ADD>	021052 002	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
>ADD>			6063811	MAY 06, 2017	U-266		
	020658 001	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020658 002	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020658 003	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020658 004	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020658 005	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020658 006	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020658 007	ROPINIROLE HYDROCHLORIDE;REQUIP	4452808	DEC 07, 2007			
	020692 001	SALMETEROL XINAFOATE;SEREVENT				I-348	MAR 22, 2005
	020828 001	SAQUINAVIR;FORTOVASE	6352717	NOV 16, 2019			
			6008228	JUN 06, 2015			
	021209 001	SECRETIN PORCINE SYNTHETIC;TRADE NAME NOT GIVEN				NP	APR 04, 2005
						ODE	APR 04, 2009

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
	019839 001	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
	019839 002	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
	019839 003	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
	019839 004	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
	019839 005	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12		
	020478 001	SEVOFLURANE;ULTANE				M-17	MAR 30, 2004
	020632 001	SIBUTRAMINE HYDROCHLORIDE;MERIDIA	4746680	JUN 11, 2007			
			5436272	JUL 25, 2012	U-439		
	020632 002	SIBUTRAMINE HYDROCHLORIDE;MERIDIA	4746680	JUN 11, 2007			
			5436272	JUL 25, 2012	U-439		
	020632 003	SIBUTRAMINE HYDROCHLORIDE;MERIDIA	4746680	JUN 11, 2007			
			5436272	JUL 25, 2012	U-439		
	020677 001	SPARFLOXACIN;ZAGAM	4795751	FEB 04, 2010	U-160		
>ADD>	020132 001	SUMATRIPTAN SUCCINATE;IMITREX	6368627	MAR 02, 2012	U-444		
>ADD>	020132 002	SUMATRIPTAN SUCCINATE;IMITREX	6368627	MAR 02, 2012	U-444		
>ADD>	020132 003	SUMATRIPTAN SUCCINATE;IMITREX	6368627	MAR 02, 2012	U-444		
	019785 001	TECHNETIUM TC-99M SESTAMIBI KIT;CARDIOLITE	4452774	DEC 21, 2004			
	019785 003	TECHNETIUM TC-99M SESTAMIBI KIT;MIRALUMA	4452774	DEC 21, 2004			
	020791 001	TESTOSTERONE;TESTODERM TTS	6348210	NOV 10, 2019	U-440		
	020785 001	THALIDOMIDE;THALOMID	6315720	OCT 23, 2020	U-442		
>ADD>	020697 001	TOLCAPONE;TASMAR	5236952	JAN 29, 2012			
>ADD>	020697 002	TOLCAPONE;TASMAR	5236952	JAN 29, 2012			
	021228 001	TOLTERODINE TARTRATE;DETROL LA	5559269	NOV 05, 2013	U-318		
	021228 002	TOLTERODINE TARTRATE;DETROL LA	5559269	NOV 05, 2013	U-318		
	020550 001	VALACYCLOVIR HYDROCHLORIDE;VALTREX	4957924	JUN 23, 2009			
			5879706	JAN 19, 2016			
			6107302	JAN 19, 2016			
	020550 002	VALACYCLOVIR HYDROCHLORIDE;VALTREX	4957924	JUN 23, 2009			
			5879706	JAN 19, 2016			
			6107302	JAN 19, 2016			
	020593 001	VALPROATE SODIUM;DEPACON				D-72	JAN 24, 2005
	021036 001	ZANAMIVIR;RELENZA	6294572	DEC 15, 2014			
	020789 001	ZONISAMIDE;ZONEGRAN	6342515	DEC 21, 2018	U-438		

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, 22ND 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.

ABBREVIATIONS

W	EXCLUSIVITY ON THIS APPLICATION EXPIRING ON THIS DATE HAS BEEN WAIVED BY SPONSOR

REFERENCES

NEW DOSING SCHEDULE

D-71	EIGHT WEEK DOSING REGIMEN
D-72	INFORMATION REGARDING INCREASED RATE OF INFUSION FOR DEPACON

NEW INDICATION

I-348	LONG-TERM, TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD (INCLUDING EMPHYSEMA AND CHRONIC BRONCHITIS)
I-349	ACUTE CORONARY SYNDROME
I-350	TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA IN ADOLESCENT BOYS AND GIRLS AT LEAST ONE YEAR POSTMENARCHAL, AGES 10 TO 17 YEARS, WITH A RECOMMENDED DOSING RANGE OF 10 TO 40MG ONCE DAILY
I-351	PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR ALL STRENGTHS
I-352	ANTICOAGULANT IN PATIENTS WITH OR AT RISK FOR HEPARIN-INDUCED THROMBOCYTOPENIA UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS (PCI)
I-353	TREATMENT OF SIGNS AND SYMPTOMS OF RHEUMATOID ARTHRITIS

MISCELLANEOUS EXCLUSIVITY CODES

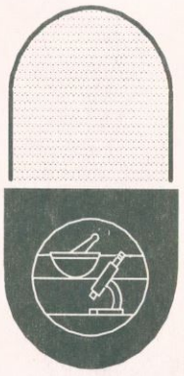
M-15	LONGER TERM EFFICACY INFORMATION FOR RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA
M-16	CHANGE IN WORDING OF THE PEDIATRIC SECTION OF THE PACKAGE INSERT
M-17	INFORMATION REGARDING USE OF ULTANE IN PEDIATRIC PATIENTS WITH CONGENITAL HEART DISEASE
M-18	INFORMATION DENOTING THE EFFICACY OF REMERON IN MAINTAINING A RESPONSE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)

PATENT USE CODES

U-438 TREATMENT/PREVENTION OF NEURODEGENERATIVE DISEASE
U-439 TREATMENT OF OBESITY
U-440 METHOD FOR TRANSDERMAL ADMINISTRATION OF A DRUG THROUGH NON-SCROTAL SKIN USING A TRANSDERMAL DRUG DELIVERY DEVICE CONTAINING THE DRUG AND HAVING AN ADHESIVE SURFACE
U-441 METHOD OF TREATING MS BY ADMINISTERING COPAXONE
U-442 METHOD FOR DELIVERING A DRUG TO A PATIENT IN NEED OF THE DRUG, WHILE AVOIDING THE OCCURENCE OF AN ADVERSE SIDE EFFECT KNOWN OR SUSPECTED OF BEING CAUSED BY SAID DRUG
U-443 MANAGEMENT OF MODERATE TO SEVERE PAIN WHEN A CONTINUOUS, AROUND-THE-CLOCK ANALGESIC IS NEEDED FOR AN EXTENDED PERIOD OF TIME
U-444 METHOD OF TREATING

*U.S. Government Printing Office: 2002— 491-214/40011

New 22nd Edition



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