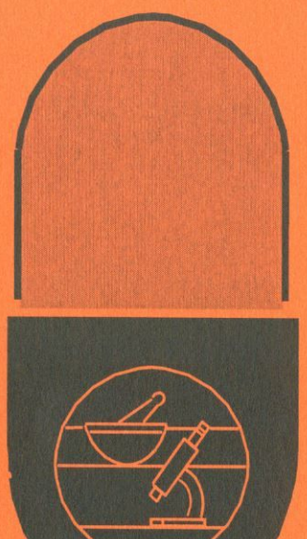
CUMULATIVE
SUPPLEMENT 4
APRIL 2002



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
Food and Drug Administration

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CUMULATIVE SUPPLEMENT 4
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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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)
WHITEHALL LABORATORIES INC DIV AMERICAN HOME PRODUCTS CORP (WHITEHALL LABS)	WYETH CONSUMER HEALTHCARE (WYETH CONS)
WHITEHALL ROBINS HEALTHCARE (WHITEHALL ROBINS)	WYETH CONSUMER HEALTHCARE (WYETH CONS)
WHITEHALL ROBINS HEALTHCARE DIV AMERICAN HOME PRODUCTS CORP (WHITEHALL LABS)	WYETH CONSUMER HEALTHCARE (WYETH CONS)

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>.

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.
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; CODEINE PHOSPHATE
CAPSULE; ORAL
ACETAMINOPHEN, BUTALBITAL, CAFFEINE, AND CODEINE PHOSPHATE

>A>	AB		VINTAGE PHARMS	325MG;50MG;40MG;30MG	N75929 001	APR 22, 2002	APR	NEWA

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

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

VENTOLIN HFA

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

ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE
INJECTABLE; INJECTION
MULTI-12

>D>		+	SABEX	2 IU/ML;20MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;80UGM/ML;8MG/ML;0.8MG/ML;0.72MG/ML;0.6MG/ML;600 IU/ML	N21163 001	MAY 18, 2000	APR	CAHN
>A>		+	SABEX 2002	2 IU/ML;20MG/ML;12UGM/ML;40 IU/ML;1UGM/ML;3MG/ML;80UGM/ML;8MG/ML;0.8MG/ML;0.72MG/ML;0.6MG/ML;600 IU/ML	N21163 001	MAY 18, 2000	APR	CAHN

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

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

TABLET; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

	AB		GENEVA PHARMS	500MG;EQ 125MG BASE	N65064 001	MAR 15, 2002	MAR	NEWA
	AB			875MG;EQ 125MG BASE	N65063 001	MAR 14, 2002	MAR	NEWA

AUGMENTIN '500'

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

AUGMENTIN '875'

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

TABLET, CHEWABLE; ORAL
AMOXICILLIN AND CLAVULANATE POTASSIUM

>A>								
	AB		GENEVA PHARMS	200MG;EQ 28.5MG BASE	N65065 001	APR 18, 2002	APR	NEWA
	AB			400MG;EQ 57MG BASE	N65065 002	APR 18, 2002	APR	NEWA

>A> AUGMENTIN '200'

>D>			GLAXOSMITHKLINE	200MG;EQ 28.5MG BASE	N50726 001	MAY 31, 1996	APR	CFTG
>A>	AB			200MG;EQ 28.5MG BASE	N50726 001	MAY 31, 1996	APR	CFTG

AUGMENTIN '400'

>D>		+	GLAXOSMITHKLINE	400MG;EQ 57MG BASE	N50726 002	MAY 31, 1996	APR	CFTG

>A>	AB	+		400MG;EQ 57MG BASE	N50726 002	MAY 31, 1996	APR	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	CFTG

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

AMPICILLIN AND SULBACTAM

AP		ESI LEDERLE	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	N65074 001	MAR 19, 2002	MAR	NEWA
AP			EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	N65074 002	MAR 19, 2002	MAR	NEWA
AP			EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	N65076 001	MAR 19, 2002	MAR	NEWA

UNASYN

AP	+	PFIZER	EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL	N50608 002	DEC 31, 1986	MAR	CFTG
AP	+		EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL	N50608 001	DEC 31, 1986	MAR	CFTG
AP	+		EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL	N50608 005	DEC 10, 1993	MAR	CFTG

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

INJECTABLE; IV (INFUSION)

INFUVITE PEDIATRIC

>D>	+	SABEX	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14M G/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIA L;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21265 001	FEB 21, 2001	APR	CAHN
>A>	+	SABEX 2002	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14M G/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIA L;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21265 001	FEB 21, 2001	APR	CAHN

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						
+	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		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						
AB	EGIS	5MG	N75119 001	MAR 14, 2002	MAR	NEWA
AB		10MG	N75119 002	MAR 14, 2002	MAR	NEWA
AB	GENEVA PHARMS	5MG	N75413 001	MAR 19, 2002	MAR	NEWA
AB		10MG	N75413 002	MAR 19, 2002	MAR	NEWA
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
AB	MYLAN	5MG	N75272 001	MAR 01, 2002	MAR	NEWA
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	TORPHARM	5MG	N75521 001	APR 05, 2002	APR	NEWA
>A> AB		10MG	N75521 002	APR 05, 2002	APR	NEWA
>A> AB		15MG	N75521 003	APR 05, 2002	APR	NEWA

AB	ZENITH GOLDLINE	5MG	N75385 001	MAR 01, 2002	MAR	NEWA
AB		10MG	N75385 002	MAR 01, 2002	MAR	NEWA
AB		15MG	N75385 003	MAR 01, 2002	MAR	NEWA

BUTORPHANOL TARTRATE
SPRAY, METERED; NASAL
BUTORPHANOL TARTRATE

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

CEPHALEXIN
FOR SUSPENSION; ORAL
CEPHALEXIN

>D>	AB	TEVA	EQ 125MG BASE/5ML	N62873 001	MAY 23, 1988	APR	DISC
>A>		@	EQ 125MG BASE/5ML	N62873 001	MAY 23, 1988	APR	DISC
>D>	AB		EQ 250MG BASE/5ML	N62867 001	APR 15, 1988	APR	DISC
>A>		@	EQ 250MG BASE/5ML	N62867 001	APR 15, 1988	APR	DISC

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

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
\+ 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

CLOBETASOL PROPIONATE
GEL; TOPICAL
EMBELINE
>A> AB HEALTHPOINT 0.05% N76141 001 APR 12, 2002 APR NEWA

CROMOLYN SODIUM
CAPSULE; ORAL
GASTROCROM
@ CELLTECH PHARMS 100MG N19188 001 DEC 22, 1989 MAR MAGC
SOLUTION; INHALATION
CROMOLYN SODIUM
>A> AN NOVEX 10MG/ML N75333 001 APR 30, 2002 APR NEWA

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58
N/A; N/A
DICOPAC KIT
@ AMERSHAM HLTH N/A;N/A;N/A N17406 001 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
		DESOGESTREL; ETHINYL ESTRADIOL						
		TABLET; ORAL-28						
>A>		KARIVA						
>A>	AB	BARR	0.15MG,0.02MG;N/A,N/A;N/A,0.01MG	N75863	001	APR 05, 2002	APR	NEWA
>A>		MIRCETTE						
>D>		+ ORGANON	0.15MG;0.02MG,0.01MG	N20713	001	APR 22, 1998	APR	CFTG
>A>	AB	+	0.15MG,0.02MG;N/A,N/A;N/A,0.01MG	N20713	001	APR 22, 1998	APR	CFTG
		DESONIDE						
		LOTION; TOPICAL						
		DESONIDE						
	AB	ALTANA	0.05%	N75860	001	MAR 19, 2002	MAR	NEWA
		DESOWEN						
	AB	+ GALDERMA LABS LP	0.05%	N72354	001	JAN 24, 1992	MAR	CFTG
		DEXAMETHASONE ACETATE						
		INJECTABLE; INJECTION						
>D>		DECADRON-LA						
>D>	BP	+ MERCK	EQ 8MG BASE/ML	N16675	001		APR	DISC
>A>		@	EQ 8MG BASE/ML	N16675	001		APR	DISC
		DEXAMETHASONE ACETATE						
>D>	BP	STERIS	EQ 8MG BASE/ML	N84315	001		APR	DISC
>A>		@	EQ 8MG BASE/ML	N84315	001		APR	DISC
>D>		+	EQ 16MG BASE/ML	N87711	001	MAY 24, 1982	APR	DISC
>A>		@	EQ 16MG BASE/ML	N87711	001	MAY 24, 1982	APR	DISC
		DEXTROAMPHETAMINE SULFATE						
		CAPSULE, EXTENDED RELEASE; ORAL						
		DEXEDRINE						
	AB	+ GLAXOSMITHKLINE	5MG	N17078	001		JAN	CFTG
	AB	+	10MG	N17078	002		JAN	CFTG
	AB	+	15MG	N17078	003		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

FEB CPOT		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

DILTIAZEM HYDROCHLORIDE
INJECTABLE; INJECTION
DILTIAZEM HCL

APR NEWA									
APR CFTG									
APR CFTG	>A>		+	GENSIA SICOR PHARMS	10MG/ML	N74894 002	APR 19, 2002	APR	NEWA

EFAVIRENZ
TABLET; ORAL
SUSTIVA

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

EPTIFIBATIDE
INJECTABLE; INJECTION
INTEGRILIN

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

ERYTHROMYCIN
GEL; TOPICAL
E-GLADES

APR DISC									
APR DISC									
APR DISC		AT		GLADES PHARMS	2%	N65009 001	MAR 18, 2002	MAR	NEWA
APR DISC									

ESTRADIOL
FILM, EXTENDED RELEASE; TRANSDERMAL
ALORA

	>A>	BX		WATSON LABS	0.025MG/24HR	N20655 004	APR 16, 2002	APR	NEWA

TABLET; ORAL
ESTRADIOL

JAN CFTG									
JAN CFTG									
JAN CFTG	>A>	AB		USL PHARMA	0.5MG	N40297 001	APR 17, 2002	APR	NEWA
	>A>	AB			1MG	N40297 002	APR 17, 2002	APR	NEWA
JAN NEWA	>A>	AB			2MG	N40297 003	APR 17, 2002	APR	NEWA
JAN NEWA									
JAN NEWA									

ETHINYL ESTRADIOL; LEVONORGESTREL
TABLET; ORAL-21
ALESSE

JAN NEWA									
JAN NEWA		AB	+	WYETH AYERST	0.02MG;0.1MG	N20683 001	MAR 27, 1997	MAR	CTEC

AVIANE-21

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

LESSINA-21

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

LEVLITE

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

TABLET; ORAL-28
ALESSE

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28

		ALESSE						
	AB1	WYETH AYERST	0.02MG;0.1MG	N20683	002	MAR 27, 1997	MAR	CTEC
		AVIANE-28						
	AB1	DURAMED PHARM BARR	0.02MG;0.1MG	N75796	001	APR 30, 2001	MAR	CTEC
		LESSINA-28						
	AB	BARR	0.02MG;0.1MG	N75803	002	MAR 20, 2002	MAR	NEWA
		LEVLITE						
	AB	BERLEX LABS	0.02MG;0.1MG	N20860	002	JUL 13, 1998	MAR	CTEC

FAMOTIDINE

INJECTABLE; INJECTION

		FAMOTIDINE						
		@ APOTHECON	10MG/ML	N75707	001	APR 16, 2001	MAR	MAGC
>A>	AP	BAXTER HLTHCARE	10MG/ML	N75799	001	APR 30, 2002	APR	NEWA
		FAMOTIDINE PRESERVATIVE FREE						
		@ APOTHECON	10MG/ML	N75708	001	APR 16, 2001	MAR	WDAG
>A>	AP	BAXTER HLTHCARE	10MG/ML	N75789	001	APR 30, 2002	APR	NEWA

FENOFIBRATE

CAPSULE; ORAL

>A>		FENOFIBRATE (MICRONIZED)						
>A>	AB	TEVA	134MG	N75753	002	APR 09, 2002	APR	NEWA
>A>	AB		200MG	N75753	003	APR 09, 2002	APR	NEWA
		TRICOR (MICRONIZED)						
>D>		ABBOTT	134MG	N19304	003	JUN 30, 1999	APR	CFTG
>A>	AB		134MG	N19304	003	JUN 30, 1999	APR	CFTG
>D>	+		200MG	N19304	004	JUN 30, 1999	APR	CFTG
>A>	AB +		200MG	N19304	004	JUN 30, 1999	APR	CFTG

FLOXURIDINE

INJECTABLE; INJECTION

		FUDR						
>A>	AP +	FAULDING	500MG/VIAL	N16929	001		APR	CAHN
>D>	AP +	ROCHE	500MG/VIAL	N16929	001		APR	CAHN

FLUDROCORTISONE ACETATE

TABLET; ORAL

		FLORINEF						
	AB +	KING PHARMS	0.1MG	N10060	001		MAR	CFTG
		FLUDROCORTISONE ACETATE						
	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		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

		FLUVOXAMINE MALEATE						
		TABLET; ORAL						
		FLUVOXAMINE MALEATE						
>A>	AB	MUTUAL PHARM	25MG	N76125 001	APR 29, 2002	APR	NEWA	
>A>	AB		50MG	N76125 002	APR 29, 2002	APR	NEWA	
>A>	AB		100MG	N76125 003	APR 29, 2002	APR	NEWA	
		FOLIC ACID						
		TABLET; ORAL						
		FOLIC ACID						
	AA +	WATSON LABS	1MG	N80680 001		FEB	CAHN	
>A>		FULVESTRANT						
>A>		INJECTABLE; INTRAMUSCULAR						
>A>		FASLODEX						
>A>		+ ASTRAZENECA	50MG/ML	N21344 001	APR 25, 2002	APR	NEWA	
		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	
		GUANFACINE HYDROCHLORIDE						
		TABLET; ORAL						
		TENEX						
>A>	AB	ESP PHARMA	EQ 1MG BASE	N19032 001	OCT 27, 1986	APR	CAHN	
>A>	AB +		EQ 2MG BASE	N19032 002	NOV 07, 1988	APR	CAHN	
>A>	@		EQ 3MG BASE	N19032 003	NOV 07, 1988	APR	CAHN	
>D>	AB	WYETH AYERST	EQ 1MG BASE	N19032 001	OCT 27, 1986	APR	CAHN	
>D>	AB +		EQ 2MG BASE	N19032 002	NOV 07, 1988	APR	CAHN	
>D>	@		EQ 3MG BASE	N19032 003	NOV 07, 1988	APR	CAHN	
		HALOTHANE						
		LIQUID; INHALATION						
>D>		FLUOTHANE						
>D>	AN +	WYETH AYERST	99.99%	N11338 001		APR	DISC	
>A>	@		99.99%	N11338 001		APR	DISC	
		HALOTHANE						
>D>	AN	ABBOTT	99.99%	N83254 001		APR	CTEC	
>A>	AN +		99.99%	N83254 001		APR	CTEC	
		HYDROCHLOROTHIAZIDE						
		TABLET; ORAL						
		ESIDRIX						
	AB +	NOVARTIS	100MG	N11793 009		MAR	CRLD	
		HYDROCHLOROTHIAZIDE						
	AB	VINTAGE PHARMS	25MG	N40412 001	MAR 29, 2002	MAR	NEWA	
	AB		50MG	N40412 002	MAR 29, 2002	MAR	NEWA	
		HYDRODIURIL						
		@ MERCK	25MG	N11835 003		MAR	DISC	
		@	50MG	N11835 006		MAR	DISC	

	@	100MG	N11835 007			MAR	DISC
	HYDROCORTISONE ACETATE						
	CREAM; TOPICAL						
	MICORT-HC						
	+ FERNDALE LABS	2%	N40398 001	MAR 29, 2002		MAR	NEWA
	HYDROCORTISONE BUTYRATE						
	CREAM; TOPICAL						
	LOCOID						
	+ FERNDALE LABS	0.1%	N18514 001	MAR 31, 1982		MAR	CAHN
	LOCOID LIPOCREAM						
	+ FERNDALE LABS	0.1%	N20769 001	SEP 08, 1997		MAR	CAHN
	OINTMENT; TOPICAL						
	LOCOID						
	+ FERNDALE LABS	0.1%	N18652 001	OCT 29, 1982		MAR	CAHN
	HYDROXYZINE HYDROCHLORIDE						
	SYRUP; ORAL						
	HYDROXYZINE HCL						
>A> AA	VINTAGE PHARMS	10MG/5ML	N40391 001	APR 10, 2002		APR	NEWA
	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						
AB	MYLAN	100MG	N75679 003	FEB 20, 2002		FEB	NEWA
AB		150MG	N75679 002	FEB 20, 2002		FEB	NEWA
AB		200MG	N75679 001	FEB 20, 2002		FEB	NEWA
	KETOROLAC TROMETHAMINE						
	INJECTABLE; INJECTION						
	KETOROLAC TROMETHAMINE						
AP	AM PHARM PARTNERS	15MG/ML	N75784 001	JAN 11, 2002		JAN	NEWA
AP		30MG/ML	N75784 002	JAN 11, 2002		JAN	NEWA
	@ APOTHECON	15MG/ML	N75348 001	NOV 28, 2000		MAR	MAGC

		@	30MG/ML	N75348 002	NOV 28, 2000	MAR	MAGC
		LACTULOSE						
		SOLUTION; ORAL						
		LACTULOSE						
	AA	NOVEX	10GM/15ML	N75911 001	FEB 21, 2002	FEB	NEWA
		LAMOTRIGINE						
		TABLET, CHEWABLE; ORAL						
		LAMICTAL CD						
		+ GLAXOSMITHKLINE	25MG	N20764 002	AUG 24, 1998	MAR	CRLD
		@	100MG	N20764 003	AUG 24, 1998	MAR	DISC
		LEUPROLIDE ACETATE						
		INJECTABLE; SUBCUTANEOUS						
		ELIGARD						
		+ ATRIX	7.5MG/VIAL	N21343 001	JAN 23, 2002	JAN	NEWA
		LEVOTHYROXINE SODIUM						
		TABLET; ORAL						
		LEVO-T						
	BX	MOVA	0.025MG	N21342 001	MAR 01, 2002	MAR	NEWA
	BX		0.05MG	N21342 002	MAR 01, 2002	MAR	NEWA
	BX		0.075MG	N21342 003	MAR 01, 2002	MAR	NEWA
	BX		0.088MG	N21342 004	MAR 01, 2002	MAR	NEWA
	BX		0.1MG	N21342 005	MAR 01, 2002	MAR	NEWA
	BX		0.112MG	N21342 006	MAR 01, 2002	MAR	NEWA
	BX		0.125MG	N21342 007	MAR 01, 2002	MAR	NEWA
	BX		0.15MG	N21342 008	MAR 01, 2002	MAR	NEWA
	BX		0.175MG	N21342 009	MAR 01, 2002	MAR	NEWA
	BX		0.2MG	N21342 010	MAR 01, 2002	MAR	NEWA
	BX +		0.3MG	N21342 011	MAR 01, 2002	MAR	NEWA
		MAZINDOL						
		TABLET; ORAL						
>D>		MAZANOR						
>D>	BP	WYETH AYERST	1MG	N17980 002		APR	DISC
>A>		@	1MG	N17980 002		APR	DISC
		SANOREX						
>D>	BP	NOVARTIS	1MG	N17247 001		APR	CTEC
>A>			1MG	N17247 001		APR	CTEC
		MEFLOQUINE HYDROCHLORIDE						
		TABLET; ORAL						
		LARIAM						
	AB	+ ROCHE	250MG	N19591 001	MAY 02, 1989	FEB	CFTG
		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

MEQUINOL; TRETINOIN
SOLUTION; TOPICAL
SOLAGE

>A>	+	GALDERMA LABS	2%;0.01%	N20922 001	DEC 10, 1999	APR	CAHN
>D>	+	WESTWOOD SQUIBB	2%;0.01%	N20922 001	DEC 10, 1999	APR	CAHN

MESNA
INJECTABLE; INTRAVENOUS
MESNEX

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

TABLET; ORAL

	+	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		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
>A>	AB		TORPHARM	500MG	N75984 001	APR 23, 2002	APR	NEWA
>A>	AB			850MG	N75984 002	APR 23, 2002	APR	NEWA
>A>	AB			1GM	N75984 003	APR 23, 2002	APR	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		FEB	CAHN
		+		2.5GM/VIAL	N11559 002		FEB	CAHN
		+		5GM/VIAL	N11559 003		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						
		INJECTABLE; INJECTION						
		MIDAZOLAM HCL						
		@	APOTHECON	EQ 1MG BASE/ML	N75620 001	NOV 01, 2000	MAR	MAGC
		@		EQ 5MG BASE/ML	N75620 002	NOV 01, 2000	MAR	MAGC
		@		EQ 5MG BASE/ML	N75641 001	OCT 19, 2000	MAR	MAGC
		@	ASTRAZENECA	EQ 5MG BASE/ML	N75263 001	JUN 26, 2000	MAR	MAGC
		SYRUP; ORAL						
	AA		RANBAXY	EQ 2MG BASE/ML	N76058 001	MAR 15, 2002	MAR	NEWA
>A>	AA		ROXANE	EQ 2MG BASE/ML	N75873 001	APR 30, 2002	APR	NEWA
		VERSED						
	AA	+	ROCHE	EQ 2MG BASE/ML	N20942 001	OCT 15, 1998	MAR	CFTG
		MOMETASONE FUROATE						
		OINTMENT; TOPICAL						
		ELOCON						
	AB	+	SCHERING	0.1%	N19543 001	APR 30, 1987	MAR	CFTG

MOMETASONE FUROATE
OINTMENT; TOPICAL
MOMETASONE FUROATE

AB	CLAY PARK	0.1%	N76067 001	MAR 18, 2002	MAR	NEWA

MORPHINE SULFATE
CAPSULE, EXTENDED RELEASE; ORAL
AVINZA

	ELAN PHARM	30MG	N21260 001	MAR 20, 2002	MAR	NEWA
		60MG	N21260 002	MAR 20, 2002	MAR	NEWA
		90MG	N21260 003	MAR 20, 2002	MAR	NEWA
+		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

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

NISOLDIPINE
TABLET, EXTENDED RELEASE; ORAL
SULAR

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

		NITROGLYCERIN						
		AEROSOL; SUBLINGUAL						
		NITROLINGUAL						
>A>		@ FIRST HORIZON	0.4MG/SPRAY	N18705 001	OCT 31, 1985	APR	CAHN
>D>		@ POHL BOSKAMP	0.4MG/SPRAY	N18705 001	OCT 31, 1985	APR	CAHN
		SPRAY, METERED; SUBLINGUAL						
		NITROLINGUAL PUMPSPRAY						
>A>	+	FIRST HORIZON	0.4MG/SPRAY	N18705 002	JAN 10, 1997	APR	CAHN
>D>	+	POHL BOSKAMP	0.4MG/SPRAY	N18705 002	JAN 10, 1997	APR	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
>A>		OLMESARTAN MEDOXOMIL						
>A>		TABLET; ORAL						
>A>		BENICAR						
>A>		SANKYO	5MG	N21286 001	APR 25, 2002	APR	NEWA
>A>			20MG	N21286 003	APR 25, 2002	APR	NEWA
>A>	+		40MG	N21286 004	APR 25, 2002	APR	NEWA
		OXAPROZIN						
		TABLET; ORAL						
		OXAPROZIN						
AB		CARACO	600MG	N75844 001	JAN 03, 2002	JAN	NEWA
		PAMIDRONATE DISODIUM						
		INJECTABLE; IV (INFUSION)						
		PAMIDRONATE DISODIUM						
AP		BEDFORD	EQ 30MG /10ML(3MG/ML)	N21113 001	MAR 04, 2002	MAR	NEWA
AP	+		EQ 90MG /10ML(9MG/ML)	N21113 002	MAR 04, 2002	MAR	NEWA
AP		GENSIA SICOR PHARMS	EQ 30MG /10ML(3MG/ML)	N76153 001	MAR 27, 2002	MAR	NEWA
AP			EQ 90MG /10ML(9MG/ML)	N76153 002	MAR 27, 2002	MAR	NEWA
		PENTAGASTRIN						
>D>		INJECTABLE; INJECTION						
>D>		PEPTAVLON						
>D>	+	WYETH AYERST	0.25MG/ML	N17048 001		APR	DISC
>A>		@	0.25MG/ML	N17048 001		APR	DISC
		PHENDIMETRAZINE TARTRATE						
		TABLET; ORAL						
		PHENDIMETRAZINE TARTRATE						
AA		MIKART	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

PHENYTOIN
SUSPENSION; ORAL
PHENTYTOIN

>A>	AB		MORTON GROVE	125MG/5ML	N40420 001	APR 19, 2002	APR	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

POTASSIUM CHLORIDE
TABLET, EXTENDED RELEASE; ORAL
POTASSIUM CHLORIDE

>A>	AB		ANDRX PHARMS	10MEQ	N75604 001	APR 10, 2002	APR	NEWA
>A>	AB			20MEQ	N75604 002	APR 10, 2002	APR	NEWA
>A>	AB		KV PHARM	20MEQ	N76044 001	APR 05, 2002	APR	NEWA

PRAVASTATIN SODIUM

>D>			TABLET; INJECTION					
			PRAVACHOL					
		+	BRISTOL MYERS SQUIBB	80MG	N19898 008	DEC 18, 2001	MAR	NEWA
>A>			TABLET; ORAL					
			BRISTOL MYERS SQUIBB	40MG	N19898 004	MAR 22, 1993	MAR	CRLD
>D>		+		80MG	N19898 008	DEC 18, 2001	APR	CDFR
>A>		+		80MG	N19898 008	DEC 18, 2001	APR	CDFR

PREDNISOLONE
SYRUP; ORAL
PREDNISOLONE

>A>	AA		KV PHARM	15MG/5ML	N40364 001	APR 10, 2002	APR	NEWA

PROMETHAZINE HYDROCHLORIDE
SUPPOSITORY; RECTAL
PHENERGAN

	AB	+	WYETH AYERST	25MG	N10926 001		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

QUINETHAZONE

>D>		TABLET; ORAL					
>D>		HYDROMOX					
>D>	+	LEDERLE	50MG	N13264 001		APR	DISC
>A>		@	50MG	N13264 001		APR	DISC

SECRETIN

>A>		FOR SOLUTION; INTRAVENOUS					
>A>		SECREFLO					
>A>	+	CHIRHOCLIN	16UGM/VIAL	N21209 001	APR 04, 2002	APR	NEWA

SELEGILINE HYDROCHLORIDE

		TABLET; ORAL					
		SELEGILINE HCL					
>A>	AB	CLONMEL HLTHCARE	5MG	N74641 001	AUG 02, 1996	APR	CAHN
>D>	AB	ESI LEDERLE	5MG	N74641 001	AUG 02, 1996	APR	CAHN

SULFAMETHOXAZOLE; TRIMETHOPRIM

		SUSPENSION; ORAL					
>D>		BACTRIM PEDIATRIC					
>D>	AB +	WOMEN FIRST HLTHCARE	200MG/5ML;40MG/5ML	N17560 002		APR	DISN
>A>		@	200MG/5ML;40MG/5ML	N17560 002		APR	DISN
		SEPTRA					
>D>	AB	MONARCH PHARMS	200MG/5ML;40MG/5ML	N17598 001		APR	CRLD
>A>	AB +		200MG/5ML;40MG/5ML	N17598 001		APR	CRLD

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		FEB	CAHN
		TABLET; ORAL					
	AB	NEOSAN PHARMS	2.5MG	N17849 001		FEB	CAHN
	AB +		5MG	N17849 002		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

SUSPENSION; ORAL

ACHROMYCIN V

>D>	AB	+	LEDERLE	125MG/5ML	N50263 002		APR	DISC
>A>			@	125MG/5ML	N50263 002		APR	DISC

SUMYCIN

>D>	AB		APOTHECON	125MG/5ML	N60400 001		APR	CTEC
>A>		+		125MG/5ML	N60400 001		APR	CTEC

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

TINZAPARIN SODIUM

INJECTABLE; INJECTION

INNOHEP

>D>		+	BRISTOL MYERS SQUIBB	20,000 IU/ML	N20484 001	JUL 14, 2000	APR	CAHN
>A>		+	LEO PHARM	20,000 IU/ML	N20484 001	JUL 14, 2000	APR	CAHN

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

VERAPAMIL HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
VERELAN
>A> AB + ELAN DRUG 120MG N19614 001 MAY 29, 1990 APR CAHN
>A> AB + 180MG N19614 003 JAN 09, 1992 APR CAHN
>A> AB + 240MG N19614 002 MAY 29, 1990 APR CAHN
>A> + 360MG N19614 004 MAY 10, 1996 APR CAHN
>D> AB + ELAN PHARM 120MG N19614 001 MAY 29, 1990 APR CAHN
>D> AB + 180MG N19614 003 JAN 09, 1992 APR CAHN
>D> AB + 240MG N19614 002 MAY 29, 1990 APR CAHN
>D> + 360MG N19614 004 MAY 10, 1996 APR CAHN

	ACETAMINOPHEN						
	TABLET, EXTENDED RELEASE; ORAL						
	ACETAMINOPHEN						
	COREPHARMA	650MG	N76200 001	MAR 19, 2002	MAR	NEWA
	CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE						
	CAPSULE, EXTENDED RELEASE; ORAL						
	CONTAC 12 HOUR						
	@ GLAXOSMITHKLINE	8MG;75MG	N18099 001		JAN	DISC
	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE						
	@ CENT PHARMS	8MG;75MG	N18809 001	MAY 07, 1984	FEB	DISC
	FAMOTIDINE						
	TABLET; ORAL						
	FAMOTIDINE						
	TORPHARM	10MG	N75610 001	MAR 12, 2002	MAR	NEWA
	IBUPROFEN						
	TABLET; ORAL						
	IBUPROFEN						
	PERRIGO	200MG	N75995 001	MAR 14, 2002	MAR	NEWA
	IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE						
	SUSPENSION; ORAL						
>A>	CHILDREN'S ADVIL COLD						
>A>	WYETH CONS	100MG/5ML;15MG/5ML	N21373 001	APR 18, 2002	APR	NEWA
	TABLET; ORAL						
>A>	IBUPROFEN AND PSEUDOEPHEDRINE HCL						
>A>	PHARM FORM	200MG;30MG	N75588 001	APR 08, 2002	APR	NEWA
	INSULIN PURIFIED PORK						
	INJECTABLE; INJECTION						
	REGULAR PURIFIED PORK INSULIN						
	@ NOVO NORDISK	100 UNITS/ML	N18381 001		FEB	DISC
	INSULIN SUSP ISOPHANE PURIFIED PORK						
	INJECTABLE; INJECTION						
	NPH PURIFIED PORK ISOPHANE INSULIN						
	@ NOVO NORDISK	100 UNITS/ML	N18623 001		FEB	DISC
	INSULIN ZINC SUSP PURIFIED PORK						
	INJECTABLE; INJECTION						
	LENTE						
	@ NOVO NORDISK	100 UNITS/ML	N18383 001		FEB	DISC
	KETOPROFEN						
	TABLET; ORAL						
	KETOPROFEN						
	PERRIGO	12.5MG	N75364 001	FEB 07, 2002	FEB	NEWA

MINOXIDIL

SOLUTION; TOPICAL

MINOXIDIL EXTRA STRENGTH (FOR MEN)

CLAY PARK	5%	N75737 001	MAR 15, 2002	MAR	NEWA
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 4 APRIL '02

NO APRIL 2002 APPROVALS

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
April 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: **autologous antigen presenting cells pulsed with autologous tumor Ig idiotype**
Trade Name: Mylovenge

Designated Indication: *Treatment of multiple myeloma*

Sponsor: Dendreon Corporation
Address: 3005 First Avenue
Seattle WA 98121

Date Designated: 4/18/2002
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
April 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: **genetically engineered herpes simplex virus (G207)** | Trade Name: NONE ASSIGNED

Designated Indication: *Tretament of malignant glioma*

Sponsor: MediGene, Inc.
Address: 9880 Campus Point Drive, Suite A
San Diego CA 92121

Date Designated: 4/29/2002
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
April 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
April 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: **retroviral gamma-c cDNA containing vector** Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of X linked severe combined immune deficiency disease*

Sponsor: AVAX technologies, Inc.
Address: 9200 Indian Creek Parkway
Building 9, Suite 200
Overland Park KS 66210

Date Designated: 4/29/2002
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

Orphan Products Designations and Approvals List
April 2002

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

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: **tinidazole**
Trade Name: NONE ASSIGNED

Designated Indication: *Treatment of giardiasis*

Sponsor: Presutti Laboratories, Inc.
Address: 1607 N. Douglas Ave.
Arlington Heights IL 60004

Date Designated: 4/18/2002
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 APRIL 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
>ADD>	020911 002	BECLOMETHASONE DIPROPIONATE;QVAR 40	6352684	NOV 28, 2009		NP	SEP 15, 2003
>ADD>						NPP	MAY 10, 2005
>ADD>	020911 001	BECLOMETHASONE DIPROPIONATE;QVAR 80	6352684	NOV 28, 2009		NP	SEP 15, 2003
>ADD>						NPP	MAY 10, 2005
>ADD>	020490 001	BRIMONIDINE TARTRATE;ALPHAGAN				NPP	DEC 20, 2004
>ADD>						PED	JUN 20, 2005
>ADD>	020613 001	BRIMONIDINE TARTRATE;ALPHAGAN				NPP	DEC 20, 2004
>ADD>						PED	JUN 20, 2005
>ADD>	021262 001	BRIMONIDINE TARTRATE;ALPHAGAN P				NPP	DEC 20, 2004
>ADD>						PED	JUN 20, 2005
	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			
	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			

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
	075863 001	DESOGESTREL;KARIVA				PC	JUN 04, 2002
>ADD>	021278 001	DEXMETHYLPHENIDATE HYDROCHLORIDE;FOCALIN	6355656	DEC 04, 2015			
>ADD>	021278 002	DEXMETHYLPHENIDATE HYDROCHLORIDE;FOCALIN	6355656	DEC 04, 2015			
>ADD>	021278 003	DEXMETHYLPHENIDATE HYDROCHLORIDE;FOCALIN	6355656	DEC 04, 2015			
	020690 001	DONEPEZIL HYDROCHLORIDE;ARICEPT	6372760	MAR 31, 2019			
	020690 002	DONEPEZIL HYDROCHLORIDE;ARICEPT	6372760	MAR 31, 2019			
	021153 001	ESOMEPRAZOLE MAGNESIUM;NEXIUM	6369085	MAY 25, 2018			
	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
	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			
>ADD>	020538 005	ESTRADIOL;VIVELLE-DOT				I-254	AUG 16, 2003
>ADD>	020538 006	ESTRADIOL;VIVELLE-DOT				I-254	AUG 16, 2003
>ADD>	020538 007	ESTRADIOL;VIVELLE-DOT				I-254	AUG 16, 2003
>ADD>	020538 008	ESTRADIOL;VIVELLE-DOT				I-254	AUG 16, 2003
	075753 002	FENOFIBRATE;FENOFIBRATE (MICRONI				PC	SEP 15, 2002
	075753 003	FENOFIBRATE;FENOFIBRATE (MICRONI				PC	SEP 15, 2002
	075442 001	FLECAINIDE ACETATE;FLECAINIDE ACETATE				PC	OCT 28, 2002
	075442 002	FLECAINIDE ACETATE;FLECAINIDE ACETATE				PC	OCT 28, 2002
	075442 003	FLECAINIDE ACETATE;FLECAINIDE ACETATE				PC	OCT 28, 2002
	021345 001	FONDAPARINUX SODIUM;ARIXTRA	4818816	AUG 19, 2003			
>ADD>	021344 001	FULVESTRANT;FASLODEX				NCE	APR 25, 2007
>ADD>	020235 001	GABAPENTIN;NEURONTIN	5084479	JAN 02, 2010	U-258	I-354	MAY 24, 2005
			5084479*PED	JUL 02, 2010	U-258		
>ADD>	020235 002	GABAPENTIN;NEURONTIN	5084479	JAN 02, 2010	U-258	I-354	MAY 24, 2005
			5084479*PED	JUL 02, 2010	U-258		
>ADD>	020235 003	GABAPENTIN;NEURONTIN	5084479	JAN 02, 2010	U-258	I-354	MAY 24, 2005
			5084479*PED	JUL 02, 2010	U-258		
>ADD>	020882 001	GABAPENTIN;NEURONTIN				I-354	MAY 24, 2005
>ADD>	020882 002	GABAPENTIN;NEURONTIN				I-354	MAY 24, 2005
>ADD>	021129 001	GABAPENTIN;NEURONTIN				I-354	MAY 24, 2005
	020622 001	GLATIRAMER ACETATE;COPAXONE	6342476	MAY 24, 2014	U-441		
			6362161	MAY 24, 2014	U-441		
>ADD>	020818 001	HYDROCHLOROTHIAZIDE;DIOVAN HCT	6294197	JUN 18, 2017	U-3		
>ADD>	020818 002	HYDROCHLOROTHIAZIDE;DIOVAN HCT	6294197	JUN 18, 2017	U-3		
	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			

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
	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
>ADD>	075874 001	IFOSFAMIDE;IFOSFAMIDE/MESNA KIT				PC	OCT 05, 2002
>ADD>	075874 002	IFOSFAMIDE;IFOSFAMIDE/MESNA KIT				PC	OCT 05, 2002
	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			
>ADD>	021088 001	LEUPROLIDE ACETATE;VIADUR	6375978	DEC 17, 2018			
>ADD>	020634 001	LEVOFLOXACIN;LEVAQUIN				I-357	APR 08, 2003
>ADD>	020634 002	LEVOFLOXACIN;LEVAQUIN				I-357	APR 08, 2003
	020634 003	LEVOFLOXACIN;LEVAQUIN				I-305	FEB 02, 2003
>ADD>						I-357	APR 08, 2003
>ADD>	020635 001	LEVOFLOXACIN;LEVAQUIN				I-357	APR 08, 2003
>ADD>	020635 002	LEVOFLOXACIN;LEVAQUIN IN DEXTROSE				I-357	APR 08, 2003
>ADD>	020635 003	LEVOFLOXACIN;LEVAQUIN IN DEXTROSE				I-357	APR 08, 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			
	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			

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
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
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			
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
020555 001	NIZATIDINE;AXID AR	4375547	APR 12, 2002			

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>	021286 001	OLMESARTAN MEDOXOMIL;BENICAR				NCE	APR 25, 2007
>ADD>	021286 003	OLMESARTAN MEDOXOMIL;BENICAR				NCE	APR 25, 2007
>ADD>	021286 004	OLMESARTAN MEDOXOMIL;BENICAR				NCE	APR 25, 2007
	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		
>ADD>	020987 001	PANTOPRAZOLE SODIUM;PROTONIX				I-356	APR 19, 2005
>ADD>	020987 002	PANTOPRAZOLE SODIUM;PROTONIX	4758579	JUL 19, 2005		I-356	APR 19, 2005
>ADD>	020936 001	PAROXETINE HYDROCHLORIDE;PAXIL CR				I-358	FEB 12, 2005
>ADD>	020936 002	PAROXETINE HYDROCHLORIDE;PAXIL CR				I-358	FEB 12, 2005
>ADD>	020936 003	PAROXETINE HYDROCHLORIDE;PAXIL CR				I-358	FEB 12, 2005
	020629 001	PENCICLOVIR SODIUM;DENAVIR	5075445	SEP 24, 2010			
	021302 001	PIMECROLIMUS;ELIDEL	6352998	OCT 26, 2015			
			6352998*PED	APR 26, 2016			

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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		
	019898 008	PRAVASTATIN SODIUM;PRAVACHOL	4346227	OCT 20, 2005			
			5030447	JUL 09, 2008			
			5180589	JUL 09, 2008			
			5622985	APR 22, 2014	U-335		
	020815 001	RALOXIFENE HYDROCHLORIDE;EVISTA	4418068	APR 03, 2003			
>ADD>	020835 001	RISEDRONATE SODIUM;ACTONEL				D-73	MAY 17, 2005
>ADD>						D-74	MAY 17, 2005
>ADD>	020835 002	RISEDRONATE SODIUM;ACTONEL				D-73	MAY 17, 2005
>ADD>						D-74	MAY 17, 2005
	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
	020864 001	RIZATRIPTAN BENZOATE;MAXALT	5298520	JUN 29, 2012	U-240		
	020864 002	RIZATRIPTAN BENZOATE;MAXALT	5298520	JUN 29, 2012	U-240		
	020865 001	RIZATRIPTAN BENZOATE;MAXALT-MLT	5298520	JUN 29, 2012	U-240		
	020865 002	RIZATRIPTAN BENZOATE;MAXALT-MLT	5298520	JUN 29, 2012	U-240		
	021042 001	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
			6063811	MAY 06, 2017	U-266		
	021042 002	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
			6063811	MAY 06, 2017	U-266		
	021042 003	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
			6063811	MAY 06, 2017			
	021052 001	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
			6063811	MAY 06, 2017	U-266		
	021052 002	ROFECOXIB;VIOXX	5691374	MAY 18, 2015		I-353	APR 11, 2005
			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			

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
	021209 001	SECRETIN;SECREFLO				NP	APR 04, 2005
						ODE	APR 04, 2009
>ADD>	019839 001	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12	I-355	MAY 16, 2005
>ADD>	019839 002	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12	I-355	MAY 16, 2005
>ADD>	019839 003	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12	I-355	MAY 16, 2005
>ADD>	019839 004	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12	I-355	MAY 16, 2005
>ADD>	019839 005	SERTRALINE HYDROCHLORIDE;ZOLOFT	5248699*PED	FEB 13, 2013	U-12	I-355	MAY 16, 2005
>ADD>	020990 001	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-355	MAY 16, 2005
	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		
>ADD>	020572 001	SODIUM PHENYLBUTYRATE;BUPHENYL	4457942	AUG 20, 2004	U-136		
>ADD>	020573 001	SODIUM PHENYLBUTYRATE;BUPHENYL	4457942	AUG 20, 2004	U-136		
>ADD>	021075 001	SOMATROPIN RECOMBINANT;NUTROPIN DEPOT	5912015	MAR 12, 2012			
>ADD>	021075 002	SOMATROPIN RECOMBINANT;NUTROPIN DEPOT	5912015	MAR 12, 2012			
>ADD>	021075 003	SOMATROPIN RECOMBINANT;NUTROPIN DEPOT	5912015	MAR 12, 2012			
	020677 001	SPARFLOXACIN;ZAGAM	4795751	FEB 04, 2010	U-160		
	020132 001	SUMATRIPTAN SUCCINATE;IMITREX	6368627	MAR 02, 2012	U-444		
	020132 002	SUMATRIPTAN SUCCINATE;IMITREX	6368627	MAR 02, 2012	U-444		
	020132 003	SUMATRIPTAN SUCCINATE;IMITREX	6368627	MAR 02, 2012	U-444		
>ADD>	017970 001	TAMOXIFEN CITRATE;NOLVADEX	4536516	AUG 20, 2002			
>ADD>			4536516*PED	FEB 20, 2003			
>ADD>	017970 002	TAMOXIFEN CITRATE;NOLVADEX	4536516	AUG 20, 2002			
>ADD>			4536516*PED	FEB 20, 2003			
	019785 001	TECHNETIUM TC-99M SESTAMIBI KIT;CARDIOLITE	4452774	DEC 21, 2004			
	019785 003	TECHNETIUM TC-99M SESTAMIBI KIT;MIRALUMA	4452774	DEC 21, 2004			
>ADD>	020846 001	TERBINAFINE;LAMISIL	4755534	DEC 30, 2008	U-445		
>ADD>			4680291	JUL 14, 2004	U-445		
	020791 001	TESTOSTERONE;TESTODERM TTS	6348210	NOV 10, 2019	U-440		
	020785 001	THALIDOMIDE;THALOMID	6315720	OCT 23, 2020	U-442		
	020697 001	TOLCAPONE;TASMAR	5236952	JAN 29, 2012			
	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		
>ADD>	021272 001	TREPROSTINIL SODIUM;REMODULIN				NCE	MAY 21, 2007
>ADD>	021272 002	TREPROSTINIL SODIUM;REMODULIN				NCE	MAY 21, 2007
>ADD>	021272 003	TREPROSTINIL SODIUM;REMODULIN				NCE	MAY 21, 2007
>ADD>	021272 004	TREPROSTINIL SODIUM;REMODULIN				NCE	MAY 21, 2007
>ADD>	021289 001	UROFOLLITROPIN;BRAVELLE				NP	MAY 06, 2005
	020550 001	VALACYCLOVIR HYDROCHLORIDE;VALTREX	4957924	JUN 23, 2009			
			5879706	JAN 19, 2016			
			6107302	JAN 19, 2016			

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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
>ADD>	021283 001	VALSARTAN;DIOVAN	6294197	JUN 18, 2017	U-3		
>ADD>	021283 002	VALSARTAN;DIOVAN	6294197	JUN 18, 2017	U-3		
>ADD>	021283 003	VALSARTAN;DIOVAN	6294197	JUN 18, 2017	U-3		
>ADD>	021266 001	VORICONAZOLE;VFEND				NCE	MAY 24, 2007
>ADD>	021266 002	VORICONAZOLE;VFEND				NCE	MAY 24, 2007
>ADD>	021267 001	VORICONAZOLE;VFEND				NCE	MAY 24, 2007
	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
D-73	ONCE A WEEK DOSING FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
D-74	ONCE A WEEK DOSING FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

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
I-354	MANAGEMENT OF POST HERPETIC NEURALGIA
I-355	PREMENSTRUAL DYSPHORIC DISORDER
I-356	TREATMENT OF PATHOLOGICAL HYPERSECRETORY CONDITIONS, INCLUDING ZOLLINGER-ELLISON SYNDROME
I-357	TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS
I-358	TREATMENT OF PANIC DISORDER

MISCELLANEOUS EXCLUSIVITY CODES

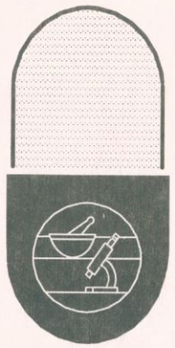
M-15	LONGER TERM EFFICACY INFORMATION FOR RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA
M-16	CHANGE IN WORDING OF THE PEDIATRIC SECTION OF THE PACKAGE INSERT
M-17	INFORMATION REGARDING USE OF ULTANE IN PEDIATRIC PATIENTS WITH CONGENITAL HEART DISEASE
M-18	INFORMATION DENOTING THE EFFICACY OF REMERON 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-445 USE AS AN ANTIMYCOTIC AGENT

*U.S. Government Printing Office: 2002 — 491-214/40012

New 22nd Edition



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