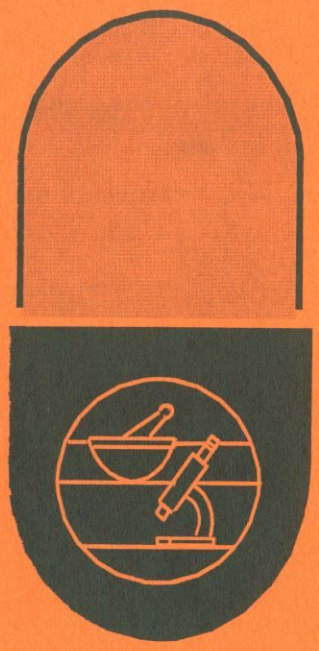
CUMULATIVE
SUPPLEMENT 3
MARCH 2001



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

21ST EDITION

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

2001

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 3

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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, 21st 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 21st Edition List will then be added to the "Discontinued Drug Product List" appearing in the 22nd 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)
CAMALL CO INC (CAMALL)	ABC HOLDING CORPORATION (ABC HOLDING)
MEDEVA AMERICAS INC (MEDEVA)	CELLTECH PHARMACEUTICALS INC (CELLTECH PHARM)
MEDEVA PHARMACEUTICALS INC (MEDEVA)	CELLTECH PHARMACEUTICALS INC (CELLTECH PHARM)
MEDEVA INC (MEDEVA)	CELLTECH PHARMACEUTICALS INC (CELLTECH PHARM)
MEDEVA PHARMACEUTICALS CA INC (MEDEVA PHARMS CA)	CELLTECH MANUFACTURING CA INC (CELLTECH MFG CA INC)
MEDEVA PHARMACEUTICALS MA INC (MEDEVA PHARMS MA)	CELLTECH MANUFACTURING INC (CELLTECH MFG INC)
NOVOPHARM LTD (NOVOPHARM)	TEVA PHARMACEUTICALS USA (TEVA)
NOVOPHARM PHARMACEUTICAL CO (NOVOPHARM PHARM)	TEVA PHARMACEUTICALS USA (TEVA)
NOVOPHARM NC INC (NOVOPHARM NC)	TEVA PHARMACEUTICALS USA (TEVA)

1.3 AVAILABILITY OF THE EDITION

The 21st 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 $101.00 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 21st annual edition of the 2000 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/21bookpub.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 2000) 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 2000	MAR 2001	JUN 2001	SEP 2001
	10360	10372		
DRUG PRODUCTS LISTED	2682 (25.9%)	2696 (26.0%)		
SINGLE SOURCE	7568 (73.1%)	7566 (72.9%)		
MULTISOURCE	7257 (70.0%)	7263 (70.0%)		
THERAPEUTICALLY EQUIVALENT				
NOT THERAPEUTICALLY EQUIVALENT	311 (3.0%)	303 (2.9%)		
EXCEPTIONS[1]	110 (1.1%)	110 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	2	6		
NUMBER OF APPLICANTS	594	582		

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

Please Note

1.5 CUMULATIVE SUPPLEMENT LEGEND

The 21st Edition Orange book (OB) Cumulative Supplement (CS) layout has changed. The new format follows the Annual Edition and previous CS format. The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form;Route and then by trade name. The manner of displaying the individual product information has changed.

The individual product record follows the previous format layout for Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. Two new columns have been added to provide more information. 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 throuth 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.
CFTG	Change. A first time generic for the innovator product. A TE Code is added.
DISC	Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition.
CTNA	Change. Trade Name.
CRLD	Change. Reference Listed Drug.
CTEC	Change. Therapeutic Equivalence Code.
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
CAPSULE; ORAL
TRIAPRIN
@ DUNHALL — 325MG;50MG — N89268 001 JUL 02, 1987 FEB WDRP

ACETAMINOPHEN; BUTALBITAL; CAFFEINE
CAPSULE; ORAL
ANOQUAN
@ ROBERTS AND HAUCK — 325MG;50MG;40MG — N87628 001 OCT 01, 1986 FEB WDRP

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE
CAPSULE; ORAL
>A> BUTALBITAL; ACETAMINOPHEN; AND CAFFEINE WITH CODEINE PHOSPHATE
>A> AB WEST WARD — 325MG;50MG;40MG;30MG — N75618 001 MAR 23, 2001 MAR NEWA
>A> FIORICET W/ CODEINE
>A> AB + NOVARTIS — 325MG;50MG;40MG;30MG — N20232 001 JUL 30, 1992 MAR CFTG
>D> + — 325MG;50MG;40MG;30MG — N20232 001 JUL 30, 1992 MAR CFTG

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE
TABLET; ORAL
ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE
+ MIKART — 712.8MG;60MG;32MG — N40316 001 APR 28, 1999 JAN CTNA

ACETAMINOPHEN; CODEINE PHOSPHATE
TABLET; ORAL
CAPITAL WITH CODEINE
@ CARNRICK — 325MG;30MG — N83643 001 MAY 31, 1974 FEB WDRP

ACETAMINOPHEN; HYDROCODONE BITARTRATE
TABLET; ORAL
LORTAB
AA + WATSON LABS — 325MG;5MG — N40099 001 JUN 25, 1997 JAN CAHN

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE
TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN
AB MALLINCKRODT — 650MG;100MG — N75738 001 FEB 02, 2001 FEB NEWA
AB VINTAGE PHARMS — 325MG;50MG — N74843 002 FEB 15, 2001 FEB NEWA

ACYCLOVIR SODIUM
INJECTABLE; INJECTION
>A> ACYCLOVIR
>A> AP GENSIA SICOR PHARMS — EQ 50MG BASE/ML — N75627 001 MAR 28, 2001 MAR NEWA

ALBUTEROL SULFATE
SOLUTION; INHALATION
ALBUTEROL SULFATE
AN ROXANE — EQ 0.083% BASE — N75129 001 FEB 13, 2001 FEB NEWA

		ALBUTEROL SULFATE; IPRATROPIUM BROMIDE					
		SOLUTION; INHALATION					
>A>		DUONEB					
>A>	+	DEY	EQ 0.083% BASE;0.017% BASE	N20950 001	MAR 21, 2001	MAR	NEWA
		AMIODARONE HYDROCHLORIDE					
		TABLET; ORAL					
		AMIODARONE HCL					
	AB	BARR	200MG	N75389 001	JAN 25, 2001	JAN	NEWA
>A>	AB	TARO	200MG	N75424 001	MAR 30, 2001	MAR	NEWA
		AMOXICILLIN					
		CAPSULE; ORAL					
		AMOXICILLIN					
		@ LABS ATRAL	250MG	N62528 001	AUG 07, 1985	FEB	WDRP
		@	500MG	N62528 002	AUG 07, 1985	FEB	WDRP
		AMPHOTERICIN B					
		INJECTABLE, LIPID COMPLEX; INJECTION					
		AMPHOTEC					
	+	INTERMUNE PHARMS	50MG/VIAL	N50729 001	NOV 22, 1996	FEB	CAHN
	+		100MG/VIAL	N50729 002	NOV 22, 1996	FEB	CAHN
		AMPICILLIN/AMPICILLIN TRIHYDRATE					
		FOR SUSPENSION; ORAL					
		TOTACILLIN					
		@ SMITHKLINE BEECHAM	EQ 125MG BASE/5ML	N60666 001	MAY 07, 1970	FEB	WDRP
		@	EQ 250MG BASE/5ML	N60666 002	MAY 07, 1970	FEB	WDRP
		ARBUTAMINE HYDROCHLORIDE					
>D>		INJECTABLE; INJECTION					
>D>		GENESA					
>D>	+	GENSIA AUTOMEDICS	0.05MG/ML	N20420 001	SEP 12, 1997	MAR	DISC
>A>		@	0.05MG/ML	N20420 001	SEP 12, 1997	MAR	DISC
		ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K					
		INJECTABLE; IV (INFUSION)					
		INFUVITE PEDIATRIC					
	+	SABEX	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL	N21265 001	FEB 21, 2001	FEB	NEWA
		ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E					
		FOR SOLUTION; IV (INFUSION)					
		M.V.I. PEDIATRIC					
	+	ASTRAZENECA	80MG/VIAL;0.02MG/VIAL;0.00				

			1MG/VIAL;5MG/VIAL;0.01MG/V IAL;0.14MG/VIAL;17MG/VIAL; 0.2MG/VIAL;1MG/VIAL;1.4MG/ VIAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/V IAL	N18920 001	SEP 21, 2000	FEB	NEWA
	ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE						
	TABLET; ORAL						
	INVAGESIC						
AB	GENEVA PHARMS TECH		385MG;30MG;25MG	N74817 001	NOV 27, 1996	JAN	CAHN
	INVAGESIC FORTE						
AB	GENEVA PHARMS TECH		770MG;60MG;50MG	N74817 002	NOV 27, 1996	JAN	CAHN
	ATORVASTATIN CALCIUM						
	TABLET; ORAL						
	LIPITOR						
>A>	PFIZER		EQ 10MG BASE	N20702 001	DEC 17, 1996	MAR	CAHN
>A>			EQ 20MG BASE	N20702 002	DEC 17, 1996	MAR	CAHN
>A>			EQ 40MG BASE	N20702 003	DEC 17, 1996	MAR	CAHN
>A>	+		EQ 80MG BASE	N20702 004	APR 07, 2000	MAR	CAHN
>D>	PFIZER IRELAND PHARM		EQ 10MG BASE	N20702 001	DEC 17, 1996	MAR	CAHN
>D>			EQ 20MG BASE	N20702 002	DEC 17, 1996	MAR	CAHN
>D>			EQ 40MG BASE	N20702 003	DEC 17, 1996	MAR	CAHN
>D>	+		EQ 80MG BASE	N20702 004	APR 07, 2000	MAR	CAHN
	ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE						
	TABLET; ORAL						
	DIPHENOXYLATE HCL AND ATROPINE SULFATE						
	@ INWOOD LABS		0.025MG;2.5MG	N85509 001	MAR 09, 1978	FEB	WDRP
	BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE						
	OINTMENT; OPHTHALMIC						
	NEO-POLYCIN						
	@ DOW PHARM		500 UNITS/GM;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N60647 001	APR 19, 1954	FEB	WDRP
>A>	BIMATOPROST						
>A>	SOLUTION/DROPS; OPHTHALMIC						
>A>	LUMIGAN						
>A>	+ ALLERGAN		0.03%	N21275 001	MAR 16, 2001	MAR	NEWA
	BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE						
	TABLET; ORAL						
	BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE						
AB	TEVA		2.5MG;6.25MG	N75686 001	JAN 19, 2001	JAN	NEWA
AB			5MG;6.25MG	N75686 002	JAN 19, 2001	JAN	NEWA
AB			10MG;6.25MG	N75686 003	JAN 19, 2001	JAN	NEWA
	BRIMONIDINE TARTRATE						
	SOLUTION/DROPS; OPHTHALMIC						
>A>	ALPHAGAN P						
>A>	+ ALLERGAN		0.15%	N21262 001	MAR 16, 2001	MAR	NEWA

		BUSPIRONE HYDROCHLORIDE					
		TABLET; ORAL					
>A>		BUSPAR					
>A>	AB	BRISTOL MYERS SQUIBB	5MG	N18731 001	SEP 29, 1986	MAR	CFTG
>A>	AB		10MG	N18731 002	SEP 29, 1986	MAR	CFTG
>A>	AB		15MG	N18731 003	APR 22, 1996	MAR	NEWA
>D>			5MG	N18731 001	SEP 29, 1986	MAR	CFTG
>D>			10MG	N18731 002	SEP 29, 1986	MAR	CFTG
>A>		BUSPIRONE HCL					
>A>	AB	DANBURY PHARMA	5MG	N74253 001	MAR 28, 2001	MAR	NEWA
>A>	AB		10MG	N74253 002	MAR 28, 2001	MAR	NEWA
>A>	AB	MYLAN	15MG	N75272 003	MAR 28, 2001	MAR	NEWA
>A>	AB	PAR PHARM	7.5MG	N75467 002	MAR 28, 2001	MAR	NEWA
		CAPTOPRIL					
		TABLET; ORAL					
		CAPTOPRIL					
	AB	GENEVA PHARMS TECH	12.5MG	N74481 001	FEB 13, 1996	JAN	CAHN
	AB		25MG	N74481 002	FEB 13, 1996	JAN	CAHN
	AB		50MG	N74481 003	FEB 13, 1996	JAN	CAHN
	AB		100MG	N74481 004	FEB 13, 1996	JAN	CAHN
		CARBACHOL					
		SOLUTION; INTRAOCULAR					
		CARBASTAT					
	AT	NOVARTIS	0.01%	N73677 001	APR 28, 1995	FEB	CAHN
		CARBIDOPA; LEVODOPA					
		TABLET; ORAL					
		CARBIDOPA AND LEVODOPA					
		@ SCS	10MG;100MG	N74080 001	MAR 25, 1994	FEB	WDRP
		@	25MG;100MG	N74080 002	MAR 25, 1994	FEB	WDRP
		@	25MG;250MG	N74080 003	MAR 25, 1994	FEB	WDRP
		CASPOFUNGIN ACETATE					
		INJECTABLE; IV (INFUSION)					
		CANCIDAS					
	+	MERCK RES	50MG/VIAL	N21227 001	JAN 26, 2001	JAN	NEWA
	+		70MG/VIAL	N21227 002	JAN 26, 2001	JAN	NEWA
		CEFACLOR					
		TABLET, EXTENDED RELEASE; ORAL					
		CECLOR CD					
AB	+	LILLY	EQ 500MG BASE	N50673 002	JUN 28, 1996	JAN	CFTG
		CEFACLOR					
AB		ZENITH GOLDLINE	EQ 500MG BASE	N65057 001	JAN 05, 2001	JAN	NEWA
		CEFTAZIDIME					
		INJECTABLE; INJECTION					
		TAZICEF					
AP		ABBOTT	500MG/VIAL	N62662 001	MAR 06, 1986	JAN	CAHN
AP			1GM/VIAL	N62662 002	MAR 06, 1986	JAN	CAHN

AP		1GM/VIAL	N64032 001	OCT 31, 1993	JAN	CAHN
AP		2GM/VIAL	N62662 003	MAR 06, 1986	JAN	CAHN
AP		2GM/VIAL	N64032 002	OCT 31, 1993	JAN	CAHN
AP		6GM/VIAL	N62662 004	MAR 06, 1986	JAN	CAHN

CEFUROXIME SODIUM
INJECTABLE; INJECTION
CEFUROXIME AND DEXTROSE IN DUPLEX CONTAINER

+	B BRAUN	EQ 15MG BASE/ML	N50780 001	FEB 21, 2001	FEB	NEWA
+		EQ 30MG BASE/ML	N50780 002	FEB 21, 2001	FEB	NEWA

CHLORAMPHENICOL
SOLUTION/DROPS; OPHTHALMIC
CHLORAMPHENICOL

@	AKORN	0.5%	N62042 001	AUG 31, 1981	FEB	WDRP

CHLORDIAZEPOXIDE HYDROCHLORIDE
CAPSULE; ORAL
CHLORDIAZACHEL

@	RACHELLE	5MG	N85086 001	MAY 11, 1976	FEB	WDRP
@		10MG	N84639 001	MAY 11, 1976	FEB	WDRP
@		25MG	N85087 001	MAY 11, 1976	FEB	WDRP

CHLORDIAZEPOXIDE HCL

@	FERRANTE	5MG	N85118 001	SEP 02, 1981	FEB	WDRP
@		10MG	N85119 001	SEP 02, 1976	FEB	WDRP
@		25MG	N85120 001	SEP 02, 1976	FEB	WDRP

CHLORPHENIRAMINE MALEATE
TABLET; ORAL
CHLORPHENIRAMINE MALEATE

@	PHARMAVITE	4MG	N85104 001	FEB 11, 1977	FEB	WDRP
@	WEST WARD	4MG	N83787 001	OCT 18, 1973	FEB	WDRP

CIMETIDINE
TABLET; ORAL
CIMETIDINE

AB	GENEVA PHARMS TECH	200MG	N74506 001	JAN 24, 1996	JAN	CAHN
AB		300MG	N74506 002	JAN 24, 1996	JAN	CAHN
AB		400MG	N74506 003	JAN 24, 1996	JAN	CAHN
AB		800MG	N74506 004	JAN 24, 1996	JAN	CAHN

CLINDAMYCIN HYDROCHLORIDE
CAPSULE; ORAL
CLEOCIN HCL

AB	+ PHARMACIA AND UPJOHN	EQ 300MG BASE	N50162 003	APR 14, 1988	FEB	CFTG

CLINDAMYCIN HCL

AB	RANBAXY	EQ 150MG BASE	N65061 001	FEB 02, 2001	FEB	NEWA
AB		EQ 300MG BASE	N65061 002	FEB 02, 2001	FEB	NEWA

CLOBETASOL PROPIONATE
CREAM; TOPICAL
CLOBETASOL PROPIONATE

AB1	STIEFEL	0.05%	N75338 001	FEB 09, 2001	FEB	NEWA

CLORAZEPATE DIPOTASSIUM
CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

	@ ABLE	3.75MG	N71777 001	JUL 14, 1987	JAN	DISC
	@	7.5MG	N71778 001	JUL 14, 1987	JAN	DISC
	@	15MG	N71779 001	JUL 14, 1987	JAN	DISC

CROMOLYN SODIUM
SOLUTION/DROPS; OPHTHALMIC
CROMOLYN SODIUM

AT	NOVEX	4%	N75615 001	JAN 26, 2001	JAN	NEWA

DESERPIDINE; HYDROCHLOROTHIAZIDE
TABLET; ORAL
ORETICYL 25

>D>	ABBOTT	0.125MG;25MG	N12148 001	DEC 14, 1959	MAR	DISC
>A>	@	0.125MG;25MG	N12148 001	DEC 14, 1959	MAR	DISC

ORETICYL 50

>D>	+ ABBOTT	0.125MG;50MG	N12148 003	DEC 14, 1959	MAR	DISC
>A>	@	0.125MG;50MG	N12148 003	DEC 14, 1959	MAR	DISC

ORETICYL FORTE

>D>	ABBOTT	0.25MG;25MG	N12148 002	DEC 14, 1959	MAR	DISC
>A>	@	0.25MG;25MG	N12148 002	DEC 14, 1959	MAR	DISC

DESONIDE
OINTMENT; TOPICAL
DESONIDE

>A> AB	ALTANA	0.05%	N75751 001	MAR 12, 2001	MAR	NEWA

DEXAMETHASONE SODIUM PHOSPHATE
INJECTABLE; INJECTION
DEXAMETHASONE SODIUM PHOSPHATE

@ DELL LABS	EQ 4MG PHOSPHATE/ML	N83161 001	JUN 06, 1978	FEB	WDRP

SOLUTION/DROPS; OTIC

@ AKORN	EQ 0.1% PHOSPHATE	N84855 001	JUN 29, 1976	FEB	WDRP

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
OINTMENT; OPHTHALMIC
DEXACIDIN

AT	NOVARTIS	0.1%;EQ 3.5MG BASE/GM;10,000 UNITS/GM	N62566 001	FEB 22, 1985	FEB	CAHN

SUSPENSION/DROPS; OPHTHALMIC

AT	NOVARTIS	0.1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62544 001	OCT 29, 1984	FEB	CAHN

DEXTROAMPHETAMINE SULFATE
TABLET; ORAL
DEXTROAMPHETAMINE SULFATE

AA	BARR	5MG	N40361 001	JAN 31, 2001	JAN	NEWA
AA		10MG	N40361 002	JAN 31, 2001	JAN	NEWA

DEXTROSTAT

AA +	SHIRE RICHWOOD	10MG	N84051 002	MAY 29, 1975	JAN	CFTG

DICLOFENAC POTASSIUM
TABLET; ORAL
DICLOFENAC POTASSIUM

	AB	EON	50MG	N75582 001	FEB 23, 2001	FEB	NEWA

DICLOFENAC SODIUM
GEL; TOPICAL
SOLARAZE

>A>		+ BIOGLAN PHARMA PLC	3%	N21005 001	OCT 16, 2000	MAR	CAHN
>D>		+ SKYEPHARMA	3%	N21005 001	OCT 16, 2000	MAR	CAHN

DILTIAZEM HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HCL

>D>	AB1	MYLAN	120MG	N75124 002	MAR 18, 2098	MAR	CTEC
>A>	AB2		120MG	N75124 002	MAR 18, 2098	MAR	CTEC

DIPHENHYDRAMINE HYDROCHLORIDE
CAPSULE; ORAL
DIPHENHYDRAMINE HCL

		@ NEWTRON PHARMS	25MG	N86543 001	FEB 08, 1979	FEB	WDRP
		@	50MG	N86544 001	FEB 08, 1979	FEB	WDRP

DISULFIRAM
TABLET; ORAL
ANTABUSE

		ODYSSEY PHARMS	250MG	N88482 001	DEC 08, 1983	JAN	CAHN
		+	500MG	N88483 001	DEC 08, 1983	JAN	CAHN
>A>		@ SIDMAK LABS	250MG	N07883 003	NOV 03, 1970	MAR	CAHN
>A>		@	500MG	N07883 002	JUN 01, 1953	MAR	CAHN
>D>		@ WYETH AYERST	250MG	N07883 003	NOV 03, 1970	MAR	CAHN
>D>		@	500MG	N07883 002	JUN 01, 1953	MAR	CAHN

DOXAZOSIN MESYLATE
TABLET; ORAL
DOXAZOSIN MESYLATE

	AB	TEVA	EQ 1MG BASE	N75353 001	JAN 12, 2001	JAN	NEWA
	AB		EQ 2MG BASE	N75353 002	JAN 12, 2001	JAN	NEWA
	AB		EQ 4MG BASE	N75353 003	JAN 12, 2001	JAN	NEWA
	AB		EQ 8MG BASE	N75353 004	JAN 12, 2001	JAN	NEWA

DOXYCYCLINE
FOR SUSPENSION; ORAL
DOXYCHEL

		@ RACHELLE	EQ 25MG BASE/5ML	N61720 001	JUN 18, 1973	FEB	WDRP

VIBRAMYCIN

		+ PFIZER	EQ 25MG BASE/5ML	N50006 001	DEC 06, 1967	FEB	CTEC

DOXYCYCLINE HYCLATE
INJECTABLE; INJECTION
DOXYCHEL HYCLATE

		@ RACHELLE	EQ 100MG BASE/VIAL	N61953 001	SEP 10, 1980	FEB	WDRP

DOXYCYCLINE HYCLATE
TABLET; ORAL
DOXYCHEL HYCLATE
TABLET; ORAL
PERIOSTAT

	+	COLLAGENEX PHARMS	20MG	N50783 001	FEB 02, 2001	FEB	NEWA

ENALAPRIL MALEATE
TABLET; ORAL
ENALAPRIL MALEATE

	AB	TARO	2.5MG	N75657 001	JAN 23, 2001	JAN	NEWA
	AB		5MG	N75657 002	JAN 23, 2001	JAN	NEWA
	AB		10MG	N75657 003	JAN 23, 2001	JAN	NEWA
	AB		20MG	N75657 004	JAN 23, 2001	JAN	NEWA
>A>	AB	TORPHARM	2.5MG	N75178 002	MAR 23, 2001	MAR	NEWA
>A>	AB		5MG	N75178 001	MAR 23, 2001	MAR	NEWA
>A>	AB		10MG	N75178 003	MAR 23, 2001	MAR	NEWA
>A>	AB		20MG	N75178 004	MAR 23, 2001	MAR	NEWA

ENFLURANE
LIQUID; INHALATION
ENFLURANE

	AN	MINRAD	99.9%	N74396 001	JUL 29, 1994	FEB	CAHN

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE
INJECTABLE; INJECTION
LIDOCATON

	@	PHARMATON	0.02MG/ML;2%	N84728 001	AUG 17, 1983	FEB	WDRP

ERGOCALCIFEROL
CAPSULE; ORAL
VITAMIN D

	@	IMPAX LABS	50,000 IU	N80951 001	JUL 13, 1973	FEB	DISC

ESOMEPRAZOLE MAGNESIUM
CAPSULE, DELAYED REL PELLETS; ORAL
NEXIUM

	+	ASTRAZENECA	EQ 20MG BASE	N21153 001	FEB 20, 2001	FEB	NEWA
	+		EQ 40MG BASE	N21153 002	FEB 20, 2001	FEB	NEWA

ESTRADIOL; NORETHINDRONE ACETATE
FILM, EXTENDED RELEASE; TRANSDERMAL
COMBIPATCH

>D>		AVENTIS	0.05MG/24HR;0.14MG/24HR	N20870 001	AUG 07, 1998	MAR	CAHN
>D>	+		0.05MG/24HR;0.25MG/24HR	N20870 002	AUG 07, 1998	MAR	CAHN
>A>		NOVARTIS	0.05MG/24HR;0.14MG/24HR	N20870 001	AUG 07, 1998	MAR	CAHN
>A>	+		0.05MG/24HR;0.25MG/24HR	N20870 002	AUG 07, 1998	MAR	CAHN

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE
TABLET; ORAL-28
PREMPRO

	+	WYETH AYERST	0.625MG;0.625MG;2.5MG;2.5MG	N20527 001	NOV 17, 1995	JAN	CTNA

	+		0.625MG;0.625MG;5MG;5MG	N20527 003	JAN 09, 1998	JAN	CTNA
		PREMPRO (PREMARIN;CYCRIN)					
	+	WYETH AYERST	0.625MG;0.625MG;2.5MG;2.5M G	N20303 001	DEC 30, 1994	JAN	CTNA
		ESTROPIPATE					
		TABLET; ORAL					
		ORTHO-EST					
AB		WOMEN FIRST HLTHCARE	0.75MG	N89567 001	FEB 27, 1991	JAN	CAHN
AB			1.5MG	N89582 001	JUL 17, 1991	JAN	CAHN
		ETHINYL ESTRADIOL; NORETHINDRONE ACETATE					
		TABLET; ORAL-28					
		LOESTRIN FE 1.5/30					
AB	+	PARKE DAVIS	0.03MG;1.5MG	N17355 001	APR 30, 1973	FEB	CFTG
		LOESTRIN FE 1/20					
AB	+	PARKE DAVIS	0.02MG;1MG	N17354 001	APR 30, 1973	FEB	CFTG
		MICROGESTIN FE 1.5/30					
AB		WATSON LABS	0.03MG;1.5MG	N75548 001	FEB 05, 2001	FEB	NEWA
		MICROGESTIN FE 1/20					
AB		WATSON LABS	0.02MG;1MG	N75647 001	FEB 05, 2001	FEB	NEWA
		ETHOSUXIMIDE					
		SYRUP; ORAL					
		ZARONTIN					
AA	+	PARKE DAVIS	250MG/5ML	N80258 001	FEB 13, 1974	JAN	CRLD
		ETODOLAC					
		TABLET, EXTENDED RELEASE; ORAL					
		ETODOLAC					
AB		TEVA	400MG	N75665 003	FEB 05, 2001	FEB	NEWA
		FAMCICLOVIR					
		TABLET; ORAL					
		FAMVIR					
		NOVARTIS	125MG	N20363 003	DEC 11, 1995	JAN	CAHN
			250MG	N20363 001	APR 26, 1996	JAN	CAHN
	+		500MG	N20363 002	JUN 29, 1994	JAN	CAHN
		FENTANYL CITRATE					
		INJECTABLE; INJECTION					
		FENTANYL CITRATE PRESERVATIVE FREE					
		@ MARSAM	EQ 0.05MG BASE/ML	N74917 001	FEB 03, 1998	JAN	DISC
		FLOXURIDINE					
		INJECTABLE; INJECTION					
		FLOXURIDINE					
AP		AM PHARM PARTNERS	500MG/VIAL	N75837 001	FEB 22, 2001	FEB	NEWA
		FLUOROMETHOLONE					
		SUSPENSION; OPHTHALMIC					
		FLUOR-OP					
AB		NOVARTIS	0.1%	N70185 001	FEB 27, 1986	FEB	CAHN

FLUOXETINE HYDROCHLORIDE
CAPSULE, DELAYED REL PELLETS; ORAL
PROZAC WEEKLY

	+	LILLY	EQ 90MG BASE	N21235 001	FEB 26, 2001	FEB NEWA

FLUVOXAMINE MALEATE
TABLET; ORAL
FLUVOXAMINE MALEATE

	AB	BARR	25MG	N75897 001	JAN 25, 2001	JAN NEWA
	AB		50MG	N75897 002	JAN 25, 2001	JAN NEWA
	AB		100MG	N75897 003	JAN 25, 2001	JAN NEWA
	AB	INVAMED	25MG	N75887 001	JAN 05, 2001	JAN NEWA
	AB		50MG	N75887 002	JAN 05, 2001	JAN NEWA
	AB		100MG	N75887 003	JAN 05, 2001	JAN NEWA
	AB	SYNTHON PHARMS	25MG	N75899 001	JAN 17, 2001	JAN NEWA
	AB		50MG	N75899 002	JAN 17, 2001	JAN NEWA
	AB		100MG	N75899 003	JAN 17, 2001	JAN NEWA
>A>	AB	ZENITH GOLDLINE	25MG	N75898 001	MAR 12, 2001	MAR NEWA
>A>	AB		50MG	N75898 002	MAR 12, 2001	MAR NEWA
>A>	AB		100MG	N75898 003	MAR 12, 2001	MAR NEWA

FORMOTEROL FUMARATE
CAPSULE; INHALATION
FORADIL

	+	NOVARTIS	0.012MG/INH	N20831 001	FEB 16, 2001	FEB NEWA

GABAPENTIN
CAPSULE; ORAL
NEURONTIN

>D>		PARKE DAVIS PHARMS	100MG	N20235 001	DEC 30, 1993	MAR	CAHN
>D>			300MG	N20235 002	DEC 30, 1993	MAR	CAHN
>D>	+		400MG	N20235 003	DEC 30, 1993	MAR	CAHN
>A>		PFIZER	100MG	N20235 001	DEC 30, 1993	MAR	CAHN
>A>			300MG	N20235 002	DEC 30, 1993	MAR	CAHN
>A>	+		400MG	N20235 003	DEC 30, 1993	MAR	CAHN

GALANTAMINE HYDROBROMIDE
TABLET; ORAL
REMINYL

		JANSSEN RES FDN	EQ 4MG BASE	N21169 001	FEB 28, 2001	FEB NEWA
			EQ 8MG BASE	N21169 002	FEB 28, 2001	FEB NEWA
	+		EQ 12MG BASE	N21169 003	FEB 28, 2001	FEB NEWA

GEMFIBROZIL
TABLET; ORAL
GEMFIBROZIL

	AB	GENEVA PHARMS TECH	600MG	N74615 001	SEP 29, 1995	JAN	CAHN

GENTAMICIN SULFATE
INJECTABLE; INJECTION
U-GENCIN

		@ PHARMACIA AND UPJOHN	EQ 10MG BASE/ML	N62248 001	MAY 02, 1980	FEB	WDRP

		@	EQ 40MG BASE/ML	N62248	002	MAY 02, 1980	FEB	WDRP
		OINTMENT; OPHTHALMIC						
		GENTACIDIN						
	AT	NOVARTIS	EQ 0.3% BASE	N62501	001	JUL 26, 1984	FEB	CAHN
		SOLUTION/DROPS; OPHTHALMIC						
	AT	NOVARTIS	EQ 0.3% BASE	N62480	001	MAR 30, 1984	FEB	CAHN
		GLIPIZIDE						
		TABLET; ORAL						
		GLIPIZIDE						
	AB	GENEVA PHARMS TECH	5MG	N74542	001	JUN 20, 1995	JAN	CAHN
	AB		10MG	N74542	002	JUN 20, 1995	JAN	CAHN
		GRISEOFULVIN, MICROCRYSTALLINE						
		SUSPENSION; ORAL						
		GRIFULVIN V						
>D>		J AND J	125MG/5ML	N62483	001	JAN 26, 1984	MAR	CRLD
>A>		+	125MG/5ML	N62483	001	JAN 26, 1984	MAR	CRLD
>D>		+ JOHNSON AND JOHNSON	125MG/5ML	N50448	001	MAY 19, 1972	MAR	DISC
>A>		@	125MG/5ML	N50448	001	MAY 19, 1972	MAR	DISC
		HALOPERIDOL LACTATE						
		INJECTABLE; INJECTION						
		HALOPERIDOL LACTATE						
>A>	AP	AM PHARM PARTNERS	EQ 5MG BASE/ML	N75689	001	MAR 09, 2001	MAR	NEWA
		HALOTHANE						
		LIQUID; INHALATION						
		HALOTHANE						
		@ BH	99.99%	N84977	001	JUL 14, 1976	JAN	DISC
		HEPARIN SODIUM						
		INJECTABLE; INJECTION						
		HEPARIN SODIUM PRESERVATIVE FREE						
		@ PHARMA SERVE NY	1,000 UNITS/ML	N86129	001	FEB 22, 1980	FEB	WDRP
		HYDRALAZINE HYDROCHLORIDE						
		INJECTABLE; INJECTION						
		HYDRALAZINE HCL						
>A>	AP	AM PHARM PARTNERS	20MG/ML	N40388	001	MAR 13, 2001	MAR	NEWA
		HYDROCHLOROTHIAZIDE; RESERPINE						
		TABLET; ORAL						
		RESERPINE AND HYDROCHLOROTHIAZIDE-50						
		@ WEST WARD	50MG;0.125MG	N88189	001	MAY 10, 1984	FEB	WDRP
		HYDROCORTISONE						
		CREAM; TOPICAL						
		HC (HYDROCORTISONE)						
		@ C AND M PHARMA	0.5%	N80482	003	MAR 20, 1973	FEB	WDRP
		@	1%	N80482	004	MAR 20, 1973	FEB	WDRP
		HYDROCORTISONE						
		@ TOPIDERM	1%	N89273	001	FEB 17, 1989	FEB	WDRP

HYDROCORTISONE
CREAM; TOPICAL
PROCTOCORT
@ MONARCH PHARMS 1% N83011 001 APR 26, 1973 FEB DISC
LOTION; TOPICAL
BETA-HC
@ BETA DERMAC 1% N89495 001 JAN 25, 1988 FEB WDRP
GLYCORT
@ HERAN 1% N87489 001 OCT 03, 1983 FEB WDRP
OINTMENT; TOPICAL
HC (HYDROCORTISONE)
@ C AND M PHARMA 1% N80481 002 MAR 20, 1973 FEB WDRP
POWDER; FOR RX COMPOUNDING
H-CORT
@ TORCH 100% N87834 001 MAR 29, 1982 FEB WDRP

HYDROCORTISONE ACETATE
CREAM; TOPICAL
MICORT-HC
FERNDALE LABS 2.5% N40396 001 FEB 27, 2001 FEB NEWA

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE
SUSPENSION/DROPS; OPHTHALMIC
COR-OTICIN
@ AKORN 1.5%;EQ 3.5MG BASE/ML N60188 001 OCT 26, 1968 FEB WDRP

HYDROXYZINE PAMOATE
CAPSULE; ORAL
HYDROXYZINE PAMOATE
@ VANGARD EQ 50MG HCL N88393 001 SEP 19, 1983 FEB WDRP

INDAPAMIDE
TABLET; ORAL
INDAPAMIDE
AB GENEVA PHARMS TECH 1.25MG N74594 001 MAY 23, 1996 JAN CAHN
AB 2.5MG N74594 002 MAY 23, 1996 JAN CAHN

IPRATROPIUM BROMIDE
SOLUTION; INHALATION
IPRATROPIUM BROMIDE
AN ASLUNG PHARM 0.02% N75693 001 JAN 26, 2001 JAN NEWA
>A> AN NOVEX 0.02% N75441 001 MAR 28, 2001 MAR NEWA
AN WARRICK PHARMS 0.02% N75507 001 JAN 19, 2001 JAN NEWA

ISOFLURANE
LIQUID; INHALATION
ISOFLURANE
AN MINRAD 99.9% N74416 001 SEP 30, 1994 FEB CAHN

LAMOTRIGINE
TABLET, CHEWABLE; ORAL
LAMICTAL CD
>A> GLAXO WELLCOME 2MG N20764 004 SEP 08, 2000 MAR NEWA

		LEUCOVORIN CALCIUM				
		INJECTABLE; INJECTION				
		LEUCOVORIN CALCIUM PRESERVATIVE FREE				
	AP	LUITPOLD	EQ 50MG BASE/VIAL	N40338 001	JAN 31, 2001	JAN NEWA
		LEVOCARNITINE				
		INJECTABLE; INJECTION				
>A>		CARNITOR				
>A>	AP +	SIGMA TAU	200MG/ML	N20182 001	DEC 16, 1992	MAR CFTG
>D>	+		200MG/ML	N20182 001	DEC 16, 1992	MAR CFTG
>A>		LEVOCARNITINE				
>A>	AP	BEDFORD	200MG/ML	N75567 001	MAR 29, 2001	MAR NEWA
>A>	AP	GENSIA SICOR PHARMS	200MG/ML	N75881 001	MAR 29, 2001	MAR NEWA
		LIDOCAINE HYDROCHLORIDE				
		INJECTABLE; INJECTION				
		LIDOCATON				
		@ PHARMATON	2%	N84727 001	AUG 17, 1983	FEB WDRP
		MEPROBAMATE				
		TABLET; ORAL				
		AMOSENE				
		FERNDALE LABS	400MG	N84030 001	MAY 10, 1974	FEB WDRP
		MESALAMINE				
		SUPPOSITORY; RECTAL				
		CANASA				
	+	AXCAN SCANDIPHARM	500MG	N21252 001	JAN 05, 2001	JAN NEWA
		METAPROTERENOL SULFATE				
		SOLUTION; INHALATION				
		METAPROTERENOL SULFATE				
	AN	NOVEX	0.4%	N75402 001	FEB 28, 2001	FEB NEWA
	AN		0.6%	N75403 001	FEB 28, 2001	FEB NEWA
		METHIMAZOLE				
		TABLET; ORAL				
		METHIMAZOLE				
>A>	AB	EON	5MG	N40411 001	MAR 27, 2001	MAR NEWA
>A>	AB		10MG	N40411 002	MAR 27, 2001	MAR NEWA
		METHOTREXATE SODIUM				
		TABLET; ORAL				
>A>		TREXALL				
>A>		BARR	EQ 5MG BASE	N40385 001	MAR 21, 2001	MAR NEWA
>A>			EQ 7.5MG BASE	N40385 002	MAR 21, 2001	MAR NEWA
>A>			EQ 10MG BASE	N40385 003	MAR 21, 2001	MAR NEWA
>A>	+		EQ 15MG BASE	N40385 004	MAR 21, 2001	MAR NEWA

METHYLPHENIDATE HYDROCHLORIDE
TABLET; ORAL
METHYLPHENIDATE HCL

>A>	AB	ABLE	5MG	N40404 001	MAR 29, 2001	MAR	NEWA
>A>	AB		10MG	N40404 002	MAR 29, 2001	MAR	NEWA
>A>	AB		20MG	N40404 003	MAR 29, 2001	MAR	NEWA

TABLET, EXTENDED RELEASE; ORAL

	AB	DANBURY PHARMA	20MG	N40410 001	FEB 09, 2001	FEB	NEWA

METHYLTESTOSTERONE
TABLET; BUCCAL
ORETON

		@ SCHERING	10MG	N80281 001	AUG 03, 1979	FEB	DISC

METOCLOPRAMIDE HYDROCHLORIDE
SOLUTION; INJECTION
METOCLOPRAMIDE

	AA	UDL	EQ 5MG BASE/5ML	N75051 001	JAN 26, 2001	JAN	NEWA

TABLET; ORAL
METOCLOPRAMIDE HCL

	AB	GENEVA PHARMS TECH	EQ 5MG BASE	N74478 001	OCT 05, 1995	JAN	CAHN
	AB		EQ 10MG BASE	N74478 002	OCT 05, 1995	JAN	CAHN

METOPROLOL SUCCINATE
TABLET, EXTENDED RELEASE; ORAL
TOPROL-XL

	+	ASTRAZENECA	EQ 25MG TARTRATE	N19962 004	FEB 05, 2001	FEB	NEWA

METRONIDAZOLE
TABLET; ORAL
PROTOSTAT

>D>	AB	JOHNSON RW	250MG	N18871 001	MAR 02, 1983	MAR	DISC
>D>	AB		500MG	N18871 002	MAR 02, 1983	MAR	DISC
>A>		@	250MG	N18871 001	MAR 02, 1983	MAR	DISC
>A>		@	500MG	N18871 002	MAR 02, 1983	MAR	DISC

MINOCYCLINE HYDROCHLORIDE
CAPSULE; ORAL
MINOCIN

>A>	AB	LEDERLE	EQ 75MG BASE	N50649 003	FEB 12, 2001	MAR	NEWA
>D>	AB		EQ 100MG BASE	N50649 002	MAY 31, 1990	MAR	CRLD
>A>	AB +		EQ 100MG BASE	N50649 002	MAY 31, 1990	MAR	CRLD

MINOCYCLINE HCL

>D>	AB +	DANBURY PHARMA	EQ 100MG BASE	N63065 001	DEC 30, 1991	MAR	CRLD
>A>	AB		EQ 100MG BASE	N63065 001	DEC 30, 1991	MAR	CRLD

POWDER, EXTENDED RELEASE; DENTAL
ARESTIN

	+	ORAPHARMA	EQ 1MG BASE	N50781 001	FEB 16, 2001	FEB	NEWA

MIRTAZAPINE
TABLET, ORALLY DISINTEGRATING; ORAL
REMERON SOLTAB

+	ORGANON INC	15MG	N21208	001	JAN 12, 2001	JAN NEWA
		30MG	N21208	002	JAN 12, 2001	JAN NEWA
		45MG	N21208	003	JAN 12, 2001	JAN NEWA

MORPHINE SULFATE
TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

AB	WATSON LABS	100MG	N75656	001	JAN 30, 2001	JAN NEWA

NADOLOL
TABLET; ORAL
NADOLOL

AB	GENEVA PHARMS TECH	20MG	N74501	001	NOV 09, 1995	JAN	CAHN
AB		40MG	N74501	002	NOV 09, 1995	JAN	CAHN
AB		80MG	N74501	003	NOV 09, 1995	JAN	CAHN

NALOXONE HYDROCHLORIDE
INJECTABLE; INJECTION
NALOXONE

@	WYETH AYERST	0.02MG/ML	N70188	001	SEP 24, 1986	JAN	DISC
@		0.02MG/ML	N70189	001	SEP 24, 1986	JAN	DISC
@		0.4MG/ML	N70190	001	SEP 24, 1986	JAN	DISC
@		0.4MG/ML	N70191	001	SEP 24, 1986	JAN	DISC

NAPHAZOLINE HYDROCHLORIDE
SOLUTION/DROPS; OPHTHALMIC
VASOCON

AT	NOVARTIS	0.1%	N80235	002	MAR 24, 1983	FEB	CAHN

NAPROXEN SODIUM
TABLET; ORAL
NAPROXEN SODIUM

AB	GENEVA PHARMS TECH	EQ 250MG BASE	N74495	001	DEC 05, 1994	JAN	CAHN
AB		EQ 500MG BASE	N74495	002	DEC 05, 1994	JAN	CAHN

NIFEDIPINE
CAPSULE; ORAL
NIFEDIPINE

@	CHASE LABS NJ	10MG	N72409	001	JUL 04, 1990	FEB	WDRP
@		20MG	N73421	001	JUN 19, 1991	FEB	WDRP

TABLET, EXTENDED RELEASE; ORAL

AB2	BIOVAIL	30MG	N75289	002	FEB 06, 2001	FEB	NEWA

PROCARDIA XL

AB2	+ PFIZER	30MG	N19684	001	SEP 06, 1989	FEB	CTEC

NITROFURAZONE
POWDER; TOPICAL
FURACIN

@	ROBERTS LABS	0.2%	N83791	001	OCT 17, 1975	FEB	WDRP

NYSTATIN
TABLET; VAGINAL
KOROSTATIN
@ HOLLAND RANTOS — 100,000 UNITS — N61718 001 SEP 30, 1974 FEB WDRP

OXACILLIN SODIUM
INJECTABLE; INJECTION
BACTOCILL
@ SMITHKLINE BEECHAM — EQ 1GM BASE/VIAL — N62736 001 DEC 19, 1986 FEB DISC
@ — EQ 2GM BASE/VIAL — N62736 002 DEC 19, 1986 FEB DISC
OXACILLIN SODIUM
AP + APOTHECON — EQ 1GM BASE/VIAL — N61490 003 APR 08, 1971 FEB CRLD
AP + — EQ 2GM BASE/VIAL — N62737 002 DEC 23, 1986 FEB CRLD

OXAPROZIN
TABLET; ORAL
DAYPRO
AB + SEARLE — 600MG — N18841 004 OCT 29, 1992 JAN CFTG
OXAPROZIN
AB DR REDDYS LABS LTD — 600MG — N75855 001 JAN 31, 2001 JAN NEWA
AB EON — 600MG — N75845 001 JAN 31, 2001 JAN NEWA
AB GENPHARM — 600MG — N75847 001 FEB 28, 2001 FEB NEWA
AB WATSON LABS — 600MG — N75848 001 FEB 09, 2001 FEB NEWA

OXYTETRACYCLINE HYDROCHLORIDE
CAPSULE; ORAL
OXYTETRACYCLINE HCL
@ IMPAX LABS — EQ 250MG BASE — N60760 001 AUG 09, 1967 FEB DISC
@ PROTER — EQ 250MG BASE — N60869 001 JAN 29, 1964 FEB WDRP

PACLITAXEL
INJECTABLE; INJECTION
PACLITAXEL
>A> AP ZENITH GOLDLINE — 6MG/ML — N75297 001 MAR 27, 2001 MAR NEWA

PANTOPRAZOLE SODIUM
>A> INJECTABLE; IV (INFUSION)
>A> PROTONIX IV
>A> + WYETH AYERST — EQ 40MG BASE/VIAL — N20988 001 MAR 22, 2001 MAR NEWA

PEMOLINE
TABLET; ORAL
PEMOLINE
>A> AB MALLINCKRODT — 18.75MG — N75726 003 MAR 30, 2001 MAR NEWA
>A> AB — 37.5MG — N75726 002 MAR 30, 2001 MAR NEWA
>A> AB — 75MG — N75726 001 MAR 30, 2001 MAR NEWA

PENICILLIN G SODIUM
INJECTABLE; IM-IV
PENICILLIN G SODIUM
+ BIOCHEMIE — 5,000,000 UNITS/VIAL — N65068 001 FEB 26, 2001 FEB NEWA
@ MARSAM — 5,000,000 UNITS/VIAL — N63014 001 SEP 13, 1988 FEB DISC

	PERPHENAZINE							
>D>	CONCENTRATE; ORAL							
>D>	TRILAFON							
>D>	+ SCHERING	16MG/5ML	N11557	001	DEC 12, 1958	MAR	DISC	
>A>	@	16MG/5ML	N11557	001	DEC 12, 1958	MAR	DISC	
	PHENYTOIN							
	SUSPENSION; ORAL							
	PHENYTOIN							
AB	UDL	125MG/5ML	N40342	001	JAN 31, 2001	JAN	NEWA	
	PREDNICARBATE							
	OINTMENT; TOPICAL							
	DERMATOP							
>D>	@ AVENTIS PHARMS	0.1%	N19568	001	SEP 23, 1991	MAR	CMFD	
>A>	+	0.1%	N19568	001	SEP 23, 1991	MAR	CMFD	
	PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM							
	OINTMENT; OPHTHALMIC							
	VASOCIDIN							
AT	NOVARTIS	0.5%;10%	N88791	001	OCT 05, 1984	FEB	CAHN	
	SUSPENSION/DROPS; OPHTHALMIC							
	METIMYD							
	+ SCHERING	0.5%;10%	N10210	001	FEB 24, 1956	FEB	CTEC	
	PREDAMIDE							
	@ AKORN	0.5%;10%	N88059	001	JUL 29, 1983	FEB	WDRP	
	SULPHRIN							
	@ BAUSCH AND LOMB	0.5%;10%	N88089	001	DEC 28, 1982	FEB	WDRP	
	PREDNISOLONE SODIUM PHOSPHATE							
	SOLUTION/DROPS; OPHTHALMIC							
	INFLAMASE FORTE							
AT	+ NOVARTIS	EQ 0.9% PHOSPHATE	N80751	002	DEC 19, 1973	FEB	CAHN	
	INFLAMASE MILD							
AT	+ NOVARTIS	EQ 0.11% PHOSPHATE	N80751	001	DEC 19, 1973	FEB	CAHN	
	PREDNISOLONE SODIUM PHOSPHATE							
	@ AKORN	EQ 0.11% PHOSPHATE	N83358	001	AUG 21, 1974	FEB	WDRP	
	@	EQ 0.9% PHOSPHATE	N83358	002	AUG 21, 1974	FEB	WDRP	
	PROCHLORPERAZINE MALEATE							
	TABLET; ORAL							
	PROCHLORPERAZINE MALEATE							
AB	GENEVA PHARMS TECH	EQ 5MG BASE	N40101	001	JUL 19, 1996	JAN	CAHN	
AB		EQ 10MG BASE	N40101	002	JUL 19, 1996	JAN	CAHN	
AB		EQ 25MG BASE	N40101	003	JUL 19, 1996	JAN	CAHN	
	PROTRIPTYLINE HYDROCHLORIDE							
	TABLET; ORAL							
>D>	PROTRIPTYLINE HCL							
AB	ODYSSEY PHARMS	5MG	N73644	001	AUG 24, 1995	JAN	CAHN	
AB		10MG	N73645	001	AUG 24, 1995	JAN	CAHN	
>A>	VIVACTIL							

PROTRIPTYLINE HYDROCHLORIDE
TABLET; ORAL
VIVACTIL

>D>	AB		ODYSSEY PHARMS	5MG	N73644 001	AUG 24, 1995	MAR	CTNA
>A>	AB			5MG	N73644 001	AUG 24, 1995	MAR	CTNA
>D>	AB			10MG	N73645 001	AUG 24, 1995	MAR	CTNA
>A>	AB	+		10MG	N73645 001	AUG 24, 1995	MAR	CTNA
>D>	AB		SIDMAK LABS	5MG	N16012 001	SEP 27, 1967	MAR	DISC
>D>	AB	+		10MG	N16012 002	SEP 27, 1967	MAR	DISC
>A>		@		5MG	N16012 001	SEP 27, 1967	MAR	DISC
>A>		@		10MG	N16012 002	SEP 27, 1967	MAR	DISC

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE
SYRUP; ORAL
TRILITRON

		@	NEWTRON PHARMS	30MG/5ML;1.25MG/5ML	N88474 001	FEB 12, 1985	FEB	WDRP

QUINIDINE GLUCONATE
TABLET, EXTENDED RELEASE; ORAL
QUINAGLUTE

>D>	AB	+	BERLEX LABS	324MG	N16647 001	DEC 08, 1969	MAR	CTEC
>A>	BX	+		324MG	N16647 001	DEC 08, 1969	MAR	CTEC

QUINIDINE GLUCONATE

>D>	AB		DANBURY PHARMA	324MG	N87810 001	SEP 29, 1982	MAR	CTEC
>A>	BX			324MG	N87810 001	SEP 29, 1982	MAR	CTEC
>D>	AB		GENEVA PHARMS	324MG	N89894 001	DEC 15, 1988	MAR	DISC
>A>		@		324MG	N89894 001	DEC 15, 1988	MAR	DISC
>D>	AB		MUTUAL PHARM	324MG	N89338 001	FEB 11, 1987	MAR	CTEC
>A>	BX			324MG	N89338 001	FEB 11, 1987	MAR	CTEC

QUINIDINE SULFATE
TABLET; ORAL
QUINIDINE SULFATE

		@	IMPAX LABS	200MG	N83347 001	DEC 08, 1976	FEB	DISC

RIFAMPIN
CAPSULE; ORAL
RIFAMPIN

>A>	AB		VERSAPHARM	150MG	N65028 001	MAR 14, 2001	MAR	NEWA
>A>	AB			300MG	N65028 002	MAR 14, 2001	MAR	NEWA

SECOBARBITAL SODIUM
CAPSULE; ORAL
SECOBARBITAL SODIUM

		@	ICN	100MG	N85477 001	DEC 10, 1981	FEB	WDRP

SULFACETAMIDE SODIUM
SOLUTION/DROPS; OPHTHALMIC
SULF-10

		@	NOVARTIS	10%	N80025 001	JUN 03, 1971	FEB	CAHN

SULF-15

	AT		NOVARTIS	15%	N89047 001	OCT 31, 1995	FEB	CAHN

SULTEN-10

	SULFACETAMIDE SODIUM						
	SOLUTION/DROPS; OPHTHALMIC						
	SULTEN-10						
	@ BAUSCH AND LOMB	10%	N87818 001	FEB 03, 1983	FEB	WDRP	
	SULFAMETHOXAZOLE; TRIMETHOPRIM						
	SUSPENSION; ORAL						
	TRIMETH/SULFA						
	@ NASKA	200MG/5ML;40MG/5ML	N72399 001	MAY 23, 1988	FEB	WDRP	
	SULFANILAMIDE						
	CREAM; VAGINAL						
	AVC						
AT	+ NOVAVAX	15%	N06530 003	JAN 27, 1987	JAN	CAHN	
	SUPPOSITORY; VAGINAL						
	+ NOVAVAX	1.05GM	N06530 004	JAN 27, 1987	JAN	CAHN	
	TERAZOSIN HYDROCHLORIDE						
	CAPSULE; ORAL						
	TERAZOSIN HCL						
AB	ZENITH GOLDLINE	EQ 1MG BASE	N75614 002	JAN 30, 2001	JAN	NEWA	
AB		EQ 2MG BASE	N75614 001	JAN 30, 2001	JAN	NEWA	
AB		EQ 5MG BASE	N75614 003	JAN 30, 2001	JAN	NEWA	
AB		EQ 10MG BASE	N75614 004	JAN 30, 2001	JAN	NEWA	
	THYROGLOBULIN						
	TABLET; ORAL						
	THYROGLOBULIN						
	@ IMPAX LABS	64.8MG	N80151 001	AUG 07, 1973	FEB	DISC	
	TOPIRAMATE						
	TABLET; ORAL						
	TOPAMAX						
>D>	JOHNSON RW	25MG	N20505 004	DEC 24, 1996	MAR	CRLD	
>A>	+	25MG	N20505 004	DEC 24, 1996	MAR	CRLD	
>D>	+	200MG	N20505 002	DEC 24, 1996	MAR	CRLD	
>A>		200MG	N20505 002	DEC 24, 1996	MAR	CRLD	
>A>	TRAVOPROST						
>A>	SOLUTION/DROPS; OPHTHALMIC						
>A>	TRAVATAN						
>A>	+ ALCON UNIVERSAL	0.004%	N21257 001	MAR 16, 2001	MAR	NEWA	
	TRIAMCINOLONE						
	TABLET; ORAL						
	TRIAMCINOLONE						
	@ IMPAX LABS	4MG	N84340 001	APR 22, 1975	FEB	DISC	
	TRIAMCINOLONE ACETONIDE						
	CREAM; TOPICAL						
	TRIAMCINOLONE ACETONIDE						
	@ TOPIDERM	0.025%	N89274 001	FEB 21, 1989	FEB	WDRP	
	@	0.1%	N89275 001	FEB 21, 1989	FEB	WDRP	

	@	0.5%	N89276 001	FEB 21, 1989	FEB	WDRP
	TRICHLORMETHIAZIDE					
	TABLET; ORAL					
	TRICHLOREX					
	@ LANNETT	4MG	N85630 001	MAY 16, 1977	FEB	WDRP
	TRIFLUOPERAZINE HYDROCHLORIDE					
	TABLET; ORAL					
	TRIFLUOPERAZINE HCL					
AB	GENEVA PHARMS TECH	EQ 1MG BASE	N40153 001	OCT 25, 1996	JAN	CAHN
AB		EQ 2MG BASE	N40153 002	OCT 25, 1996	JAN	CAHN
AB		EQ 5MG BASE	N40153 003	OCT 25, 1996	JAN	CAHN
AB		EQ 10MG BASE	N40153 004	OCT 25, 1996	JAN	CAHN
>A>	VALGANCICLOVIR HYDROCHLORIDE					
>A>	TABLET; ORAL					
>A>	VALCYTE					
>A>	+ SYNTEX (USA) INC LLC	EQ 450MG BASE	N21304 001	MAR 29, 2001	MAR	NEWA
	VITAMIN A PALMITATE					
	CAPSULE; ORAL					
	VITAMIN A					
	@ WEST WARD	EQ 50,000 UNITS BASE	N80967 001	MAY 04, 1973	FEB	WDRP
	ZIPRASIDONE HYDROCHLORIDE					
	CAPSULE; ORAL					
	GEODON					
	PFIZER	20MG	N20825 001	FEB 05, 2001	FEB	NEWA
		40MG	N20825 002	FEB 05, 2001	FEB	NEWA
		60MG	N20825 003	FEB 05, 2001	FEB	NEWA
	+	80MG	N20825 004	FEB 05, 2001	FEB	NEWA
	ZOLMITRIPTAN					
	TABLET, ORALLY DISINTEGRATING; ORAL					
	ZOMIG-ZMT					
	ASTRAZENECA	2.5MG	N21231 001	FEB 13, 2001	FEB	NEWA

	ACETAMINOPHEN						
	SUPPOSITORY; RECTAL						
	ACETAMINOPHEN						
>A>	ALPHARMA US PHARM	120MG	N18337 003	SEP 12, 1983	MAR	CAHN
>A>		325MG	N18337 002	AUG 21, 1981	MAR	CAHN
>A>	+	650MG	N18337 001	APR 22, 1980	MAR	CAHN
>D>	ASCENT PEDS	120MG	N18337 003	SEP 12, 1983	MAR	CAHN
>D>		325MG	N18337 002	AUG 21, 1981	MAR	CAHN
>D>	+	650MG	N18337 001	APR 22, 1980	MAR	CAHN
	INFANTS' FEVERALL					
>A>	ALPHARMA US PHARM	80MG	N18337 004	AUG 26, 1992	MAR	CAHN
>D>	ASCENT PEDS	80MG	N18337 004	AUG 26, 1992	MAR	CAHN
	ACETAMINOPHEN; CLEMASTINE FUMARATE; PSEUDOEPHEDRINE HYDROCHLORIDE					
	TABLET; ORAL					
>A>	TAVIST ALLERGY/SINUS/HEADACHE					
>A>	+ NOVARTIS	500MG;EQ 0.25MG BASE;30MG	N21082 001	MAR 01, 2001	MAR	NEWA
	CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE					
	TABLET, EXTENDED RELEASE; ORAL					
	TAVIST-D					
	@ NOVARTIS	1.34MG;75MG	N18298 002	AUG 21, 1992	JAN	DISC
	@	1.34MG;75MG	N20640 001	AUG 09, 1996	JAN	DISC
	MICONAZOLE NITRATE					
	CREAM; TOPICAL					
	MONISTAT 3 COMBINATION PACK					
	+ PERSONAL PRODS	2%;4%	N21261 001	FEB 02, 2001	FEB	NEWA
	CREAM; VAGINAL					

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 '01

NO MARCH 2001 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
February 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Alendronate disodium TN=Fosamax	Treatment of the bone manifestations of Gaucher disease	Richard J. Wenstrup, M.D. Division of Human Genetics Children's Hospital Research Cincinnati OH 45229-3039 DD= 2/13/01 MA=
B Lymphocyte Stimulator TN=BLyS	Treatment of common variable immunodeficiency (CVID)	Human Genome Sciences, Inc. 9410 Key West Avenue Rockville MD 20850 DD= 2/21/01 MA=
Busulfan TN=Spartajet-Busulfan	Intrathecal therapy for neoplastic meningitis	The Brain Tumor Center at Duke Duke University Medical Center Room 047, Baker House, South Durham NC 27710 DD= 3/5/01 MA=
Coenzyme Q10 TN=	For the treatrment of Huntington's disease	Vitaline Corporation 385 Williamson Way Ashland OR 97520 DD= 3/5/01 MA=
docosahexanoic acid-paclitaxel TN=Taxoprexin	Treatment of hormone-refractory prostate cancer.	Protarga, Inc. 1100 East Hector Street Suite 450 Conshohocken PA 19428-2377 DD= 3/5/01 MA=
h5G1.1mAb TN=	Idiopathic membranous glomerular nephropathy	Alexion Pharmaceuticals, Inc. 352 Knotter Drive Cheshire CT 06410 DD= 3/5/01 MA=

Orphan Products Designations and Approvals List
Febuary 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Hsp E7 TN=	Treatment of recurrent respiratory papillomatosis (RRP)	StressGen Biotechnologies, Inc. 409 2nd Avenue Suite 201 Collegeville PA 19426-2655 DD= 3/19/01 MA=
Imatinib TN=Glivec	Treatment of chronic myelogenous leukemia	Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936-1080 DD= 1/31/01 MA=
Medroxyprogesterone acetate TN=Hematrol	Treatment of immune thrombocytopenic purpura.	InKine Pharmaceutical Company, 1787 Sentry Parkway West Building 18, Suite 440 Blue Bell PA 19422 DD= 2/22/01 MA=
MTC-DOX for Injection TN=	Treatment of hepatocellular carcinoma	FeRx Incorporated 4330 La Jolla Village Drive Suite #250 San Diego CA 92122 DD= 1/3/01 MA=
Nitroprusside TN=	Treatment and prevention of cerebral vasospasm following subarachnoid hemorrhage.	Thomas, MD, Jeffrey Evan Thomas Jefferson University and 834 Walnut Street, Suite 650 Philadelphia PA 19107-5102 DD= 2/21/01 MA=
Novel Acting Thrombolytic (NAT) TN=	Treatment of peripheral arterial occlusion (PAO)	Amgen, Inc. One Amgen Center Drive Thousand Oaks CA 91320-1799 DD= 1/26/01 MA=

Orphan Products Designations and Approvals List
Febuary 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
p1-(uridine 5'-)-p4-(2'-deoxycytidine 5'-) tetraphosphate, tetrasodium salt TN=	For the treatment of cystic fibrosis	Inspire Pharmaceuticals, Inc. 4222 Emperor Blvd. Suite 470 Durham NC 27703 DD= 3/7/01 MA=
Polyethylene glycol (PEG)-uricase TN=	To control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective.	Bio-Technology General Corporation 70 Wood Avenue South Iselin NJ 08830 DD= 2/21/01 MA=
Pyruvate TN=	Treatment of interstitial lung disease.	Cellular Sciences, Inc 84 park Avenue P.O. Box 968 Flemington NJ 08822 DD= 2/21/01 MA=
Recombinant Human Alpha-Fetoprotein TN=	Treatment of myasthenia gravis	Atlantic Biopharmaceuticals, Inc. 50 Church Street 5th floor Cambridge MA 02138 DD= 2/22/01 MA=
Synthetic Human Parathyroid Hormone 1-34 TN=	Treatment of hypoparathyroidism	Orphan Pharmaceuticals, U.S., Inc. 1101 Kermit Drive, Suite 608 Nashville TN 37217 DD= 1/26/01 MA=
Unconjugated Chimeric (human-murine) G250 IgG monoclonal antibody TN=	Treatment of renal cell carcinoma.	Wilex Biotechnology GmbH Grillparzerstrasse 10B 81675 Munich Germany DE DD= 3/22/01 MA=

Orphan Products Designations and Approvals List
Febuary 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Vasoactive intestinal peptide TN=	Treatment of Acute Respiratory Distress Syndrome.	Sami I. Said, M.D. State University of New York at Health Sciences Center T17, 040 Stony Brook NY 11794-8172 DD= 3/9/01 MA=
Virulizin TN= Virulizin	Treatment of pancreatic cancer.	Lorus Therapeutics Inc. 7100 Woodbine Avenue, Suite 215 Markham, ON L3R 5J2 Canada DD= 2/1/01 MA=

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

NO MARCH 2001 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
	021205 001	ABACAVIR SULFATE;TRIZIVIR	6180639	JAN 30, 2018	U-248		
	021082 001	ACETAMINOPHEN;TAVIST ALLERGY/SINUS				NC	MAR 01, 2004
	020760 001	ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE	6194429	JUL 23, 2018			
	020760 002	ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE	6194429	JUL 23, 2018		NCE	DEC 18, 2002
	020950 001	ALBUTEROL SULFATE;DUONEB				NP	MAR 21, 2004
	020983 001	ALBUTEROL SULFATE;VENTOLIN HFA				I-235	SEP 23, 2001
						I-262	JUN 02, 2002
	020560 001	ALENDRONATE SODIUM;FOSAMAX	6194004	DEC 02, 2012			
>ADD>	020560 004	ALENDRONATE SODIUM;FOSAMAX	6225294	JUL 17, 2018			
>ADD>	020560 005	ALENDRONATE SODIUM;FOSAMAX	6225294	JUL 17, 2018			
>ADD>	021001 001	ALMOTRIPTAN MALATE;ALMOTRIPTAN				NCE	MAY 07, 2006
>ADD>	021001 002	ALMOTRIPTAN MALATE;ALMOTRIPTAN				NCE	MAY 07, 2006
	021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX	5360800	FEB 02, 2010			
	021078 001	ATOVAQUONE;MALARONE	6166046	NOV 25, 2013		NC	JUL 14, 2003
			5053432	OCT 01, 2008			
	021078 002	ATOVAQUONE;MALARONE PEDIATRIC	5053432	OCT 01, 2008		NC	JUL 14, 2003
>ADD>	019408 002	BETAMETHASONE DIPROPIONATE;DIPROLENE	4489070	MAY 13, 2003			
	021275 001	BIMATOPROST;LUMIGAN	5688819	SEP 21, 2012		NCE	MAR 16, 2006
	021262 001	BRIMONIDINE TARTRATE;ALPHAGAN P				NP	MAY 16, 2004
	074253 001	BUSPIRONE HYDROCHLORIDE;BUSPIRONE HCL				PC	SEP 26, 2001
	074253 002	BUSPIRONE HYDROCHLORIDE;BUSPIRONE HCL				PC	SEP 26, 2001
	075272 003	BUSPIRONE HYDROCHLORIDE;BUSPIRONE HCL				PC	SEP 24, 2001
	075467 002	BUSPIRONE HYDROCHLORIDE;BUSPIRONE HCL				PC	SEP 26, 2001
	018874 001	CALCITRIOL;CALCIJEX	4308264	JAN 28, 2001			
			6051567	AUG 02, 2019			
			4308264*PED	JUL 28, 2001			
			6051567*PED	FEB 02, 2020			
	018874 002	CALCITRIOL;CALCIJEX	4308264	JAN 28, 2001			
			6051567	AUG 02, 2019			
			4308264*PED	JUL 28, 2001			
			6051567*PED	FEB 02, 2020			
	019976 001	CALCIUM ACETATE;PHOSLO	4870105	APR 07, 2007	U-381		
	021160 001	CALCIUM ACETATE;PHOSLO	4870105	APR 07, 2007	U-381		
	021160 002	CALCIUM ACETATE;PHOSLO	4870105	APR 07, 2007	U-381		
	021160 003	CALCIUM ACETATE;PHOSLO	4870105	APR 07, 2007	U-381		
	020896 001	CAPECITABINE;XELODA				I-323	APR 30, 2004
	020896 002	CAPECITABINE;XELODA				I-323	APR 30, 2004
	021227 001	CASPOFUNGIN ACETATE;CANCIDAS	5952300	MAR 28, 2017		NCE	JAN 26, 2006
			5378804	MAR 16, 2013			
			5514650	MAR 16, 2013			
			5792746	MAR 16, 2013			
			6136783	MAR 28, 2017			
	021227 002	CASPOFUNGIN ACETATE;CANCIDAS	5952300	MAR 28, 2017		NCE	JAN 26, 2006
			5378804	MAR 16, 2013			
			5514650	MAR 16, 2013			
			5792746	MAR 16, 2013			
			6136783	MAR 28, 2017			

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
	019111 001	CHLORPHENIRAMINE POLISTIREX;TUSSIONEX	4762709	AUG 09, 2005			
	021022 001	CICLOPIROX;PENLAC	4957730	SEP 18, 2007	U-379		
	020705 001	DELAVIRDINE MESYLATE;RESCRIPTOR	6177101	JUN 11, 2018			
	021005 001	DICLOFENAC SODIUM;SOLARAZE				NP	OCT 16, 2003
	020154 002	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
			5880106	JUL 22, 2011			
	020154 003	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
			5880106	JUL 22, 2011			
	020154 004	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
			5880106	JUL 22, 2011			
	020154 005	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
			5880106	JUL 22, 2011			
	020154 006	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
			5880106	JUL 22, 2011			
	020155 003	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	020155 004	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	020155 005	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	020156 001	DIDANOSINE;VIDEX	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	021183 001	DIDANOSINE;VIDEX EC	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	021183 002	DIDANOSINE;VIDEX EC	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	021183 003	DIDANOSINE;VIDEX EC	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	021183 004	DIDANOSINE;VIDEX EC	4861759	AUG 29, 2006	U-248		
			5254539	AUG 29, 2006	U-248		
	020623 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011			
	020623 002	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011			
	020624 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906755	JUL 02, 2011			
>ADD>	021098 001	DROSPIRENONE;YASMIN				NC	MAY 11, 2004
	018998 001	ENALAPRIL MALEATE;VASOTEC				M-7	DEC 13, 2004
	018998 002	ENALAPRIL MALEATE;VASOTEC				M-7	DEC 13, 2004
	018998 003	ENALAPRIL MALEATE;VASOTEC				M-7	DEC 13, 2004
	018998 005	ENALAPRIL MALEATE;VASOTEC				M-7	DEC 13, 2004
	020164 002	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
			4692435	DEC 24, 2004	U-123		
			5389618	FEB 14, 2012			

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020164 003	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
		4692435	DEC 24, 2004	U-123		
		5389618	FEB 14, 2012			
020164 004	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
		4692435	DEC 24, 2004	U-123		
		5389618	FEB 14, 2012			
020164 005	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
		4692435	DEC 24, 2004	U-123		
		5389618	FEB 14, 2012			
020164 006	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001			
		4692435	DEC 24, 2004	U-123		
		5389618	FEB 14, 2012			
020164 007	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
		4692435	DEC 24, 2004	U-123		
		5389618	FEB 14, 2012			
020164 008	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
		4692435	DEC 24, 2004	U-123		
		5389618	FEB 14, 2012			
021153 001	ESOMEPRAZOLE MAGNESIUM;NEXIUM	4255431	APR 05, 2001	U-373	NP	FEB 20, 2004
		4738974	APR 19, 2005	U-373		
		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
		6147103	OCT 09, 2018			
		6166213	OCT 09, 2018			
		6191148	OCT 09, 2018			
021153 002	ESOMEPRAZOLE MAGNESIUM;NEXIUM	4255431	APR 05, 2001	U-373	NP	FEB 20, 2004
		4738974	APR 19, 2005	U-373		
		4636499	MAY 30, 2005	U-373		
		5900424	MAY 04, 2016	U-373		
		4786505	APR 20, 2007	U-373		
		4853230	APR 20, 2007	U-373		
		5714504	FEB 03, 2015	U-373		
		5877192	MAY 27, 2014	U-373		
		5093342	FEB 02, 2010	U-373		
		5599794	FEB 04, 2014	U-373		
		5629305	FEB 04, 2014	U-373		
		5690960	NOV 25, 2014	U-373		
		6147103	OCT 09, 2018			
		6166213	OCT 09, 2018			
		6191148	OCT 09, 2018			

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020538 005	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
			5474783	DEC 12, 2012			
			5656286	AUG 12, 2014			
			5958446	DEC 12, 2012			
	020538 006	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
			5474783	DEC 12, 2012			
			5656286	AUG 12, 2014			
			5958446	DEC 12, 2012			
	020538 007	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
			5474783	DEC 12, 2012			
			5656286	AUG 12, 2014			
			5958446	DEC 12, 2012			
	020538 008	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
			5474783	DEC 12, 2012			
			5656286	AUG 12, 2014			
			5958446	DEC 12, 2012			
	020946 001	ETHINYL ESTRADIOL;PREVEN EMERGENCY CON	6156742	DEC 05, 2020	U-374		
	020584 001	ETODOLAC;LODINE XL				I-321	AUG 11, 2003
	020584 002	ETODOLAC;LODINE XL				I-321	AUG 11, 2003
	020584 003	ETODOLAC;LODINE XL				I-321	AUG 11, 2003
>ADD>	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6187791	MAY 11, 2012	U-138		
>ADD>	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6187791	MAY 11, 2012	U-138		
>ADD>	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6187791	MAY 11, 2012	U-138		
>ADD>	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6187791	MAY 11, 2012	U-138		
>ADD>	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	6187791	MAY 11, 2012	U-138		
	021235 001	FLUOXETINE HYDROCHLORIDE;PROZAC WEEKLY				NDF	FEB 26, 2004
	018936 007	FLUOXETINE HYDROCHLORIDE;SARAFEM				PED	JAN 06, 2004
	020831 001	FORMOTEROL FUMARATE;FORADIL				NCE	FEB 16, 2006
	021169 001	GALANTAMINE HYDROBROMIDE;REMINYL	4663318	JAN 15, 2006		NCE	FEB 28, 2006
	021169 002	GALANTAMINE HYDROBROMIDE;REMINYL	4663318	JAN 15, 2006		NCE	FEB 28, 2006
	021169 003	GALANTAMINE HYDROBROMIDE;REMINYL	4663318	JAN 15, 2006		NCE	FEB 28, 2006
	020387 001	HYDROCHLOROTHIAZIDE;HYZAAR	5608075	MAR 04, 2014			
	020387 002	HYDROCHLOROTHIAZIDE;HYZAAR	5608075	MAR 04, 2014			
	020402 002	IBUPROFEN POTASSIUM;ADVIL MIGRAINE LIQUI				NP	MAR 16, 2003
	021128 001	IBUPROFEN;CHILDREN'S MOTRIN CO	6211246	JUN 10, 2019			
>ADD>	021335 002	IMATINIB MESYLATE;GLEEVEC				NCE	MAY 10, 2006
>ADD>						ODE	MAY 10, 2008
	021081 001	INSULIN GLARGINE;LANTUS	5656722	SEP 12, 2014			
>ADD>	020394 001	IPRATROPIUM BROMIDE;ATROVENT				I-327	OCT 27, 2003
	020857 001	LAMIVUDINE;COMBIVIR	6180639	JAN 30, 2018	U-248		
	020564 001	LAMIVUDINE;EPIVIR	6180639	JAN 30, 2018	U-248		
	020596 001	LAMIVUDINE;EPIVIR	6180639	JAN 30, 2018	U-248		
>ADD>	021281 001	LANSOPRAZOLE;PREVACID				I-316	NOV 30, 2003
>ADD>						M-1	JUL 06, 2002
>ADD>						D-42	JUL 20, 2001

PRESCRIPTION AND OTC DRUG PRODUCT
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021281 002	LANSOPRAZOLE;PREVACID				I-316	NOV 30, 2003
>ADD>						M-1	JUL 06, 2002
>ADD>						D-42	JUL 20, 2001
	020905 001	LEFLUNOMIDE;ARAVA	4284786	DEC 13, 2001			
	020905 002	LEFLUNOMIDE;ARAVA	4284786	DEC 13, 2001			
	020905 003	LEFLUNOMIDE;ARAVA	4284786	DEC 13, 2001			
	020386 001	LOSARTAN POTASSIUM;COZAAR	5608075	MAR 04, 2014			
	020386 002	LOSARTAN POTASSIUM;COZAAR	5608075	MAR 04, 2014			
	020357 001	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				M-6	APR 19, 2004
	020357 002	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				M-6	APR 19, 2004
	020357 003	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				M-6	APR 19, 2004
	020357 004	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				M-6	APR 19, 2004
	020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				M-6	APR 19, 2004
	021121 001	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4783337	SEP 16, 2003	U-372		
	021121 002	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4783337	SEP 16, 2003	U-372		
	021121 003	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4783337	SEP 16, 2003	U-372	NP	AUG 01, 2003
	019962 001	METOPROLOL SUCCINATE;TOPROL-XL	4927640	MAY 22, 2007		I-194	FEB 05, 2004
			5246714	SEP 21, 2010			
	019962 002	METOPROLOL SUCCINATE;TOPROL-XL	4927640	MAY 22, 2007		I-194	FEB 05, 2004
			5246714	SEP 21, 2010			
	019962 003	METOPROLOL SUCCINATE;TOPROL-XL	4927640	MAY 27, 2007		I-194	FEB 05, 2004
			5246714	SEP 21, 2010			
	019962 004	METOPROLOL SUCCINATE;TOPROL-XL	4957745	SEP 18, 2007	U-107	NS	FEB 05, 2004
			5001161	MAR 19, 2008	U-107	I-194	FEB 05, 2004
			5081154	JAN 14, 2009	U-107		
			4927640	MAY 22, 2007			
			5246714	SEP 21, 2010			
	021208 001	MIRTAZAPINE;REMERON SOLTAB	5178878	JAN 12, 2010		NCE	JUN 14, 2001
	021208 002	MIRTAZAPINE;REMERON SOLTAB	5178878	JAN 12, 2010		NCE	JUN 14, 2001
	021208 003	MIRTAZAPINE;REMERON SOLTAB	5178878	JAN 12, 2010		NCE	JUN 14, 2001
	019297 001	MITOXANTRONE HYDROCHLORIDE;NOVANTRONE				I-324	OCT 13, 2003
	020829 002	MONTELUKAST SODIUM;SINGULAIR	5565473	FEB 03, 2012	U-228		
	020830 001	MONTELUKAST SODIUM;SINGULAIR	5565473	FEB 03, 2012	U-228		
	020830 002	MONTELUKAST SODIUM;SINGULAIR	5565473	FEB 03, 2012	U-228		
	021204 001	NATEGLINIDE;STARLIX	RE34878	MAR 28, 2006			
			5463116	OCT 21, 2012			
			5488150	JAN 30, 2013			
	021204 002	NATEGLINIDE;STARLIX	RE34878	MAR 28, 2006			
			5463116	OCT 21, 2012			
			5488150	JAN 30, 2013			
	075269 001	NIFEDIPINE;NIFEDIPINE				PC	JUN 05, 2001
	075269 002	NIFEDIPINE;NIFEDIPINE				PC	JUN 05, 2001
	021008 001	OCTREOTIDE ACETATE;SANDOSTATIN LAR	5753618	JUL 08, 2008			
	021008 002	OCTREOTIDE ACETATE;SANDOSTATIN LAR	5753618	JUL 08, 2008			

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021008 003	OCTREOTIDE ACETATE;SANDOSTATIN LAR	5753618	JUL 08, 2008			
020592 005	OLANZAPINE;ZYPREXA	5229382	APR 23, 2011	U-149	NCE	SEP 30, 2001
		5605897	FEB 25, 2014	U-176		
021086 001	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
021086 002	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
021086 003	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
021086 004	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
019810 001	OMEPRAZOLE;PRILOSEC	6150380	NOV 10, 2018		PED	DEC 29, 2001
		6147103	OCT 09, 2018			
		6166213	OCT 09, 2018			
		6191148	OCT 09, 2018			
		4255431*PED	OCT 05, 2001	U-108		
		4636499*PED	JAN 30, 2006			
		4786505*PED	OCT 20, 2007	U-108		
		4853230*PED	OCT 20, 2007	U-108		
		5093342*PED	AUG 02, 2010	U-166		
		5599794*PED	AUG 04, 2014	U-166		
		5629305*PED	AUG 04, 2014	U-188		
		6147103*PED	APR 09, 2019			
		6150380*PED	MAY 10, 2019			
		6166213*PED	APR 09, 2018			
		6191148*PED	APR 09, 2019			
		4508905	APR 02, 2002			
019810 002	OMEPRAZOLE;PRILOSEC	6150380	NOV 10, 2018		PED	DEC 29, 2001
		6147103	OCT 09, 2018			
		6166213	OCT 09, 2018			
		6191148	OCT 09, 2018			
		4255431*PED	OCT 05, 2001	U-108		
		4636499*PED	JAN 30, 2006			
		4786505*PED	OCT 20, 2007	U-108		
		4853230*PED	OCT 20, 2007	U-108		
		5093342*PED	AUG 02, 2010	U-166		
		5599794*PED	AUG 04, 2014			
		5629305*PED	AUG 04, 2014	U-166		
		6147103*PED	APR 09, 2019	U-188		
		6150380*PED	MAY 10, 2019			
		6166213*PED	APR 09, 2018			
		6191148*PED	APR 09, 2019			
		4508905	APR 02, 2002			
019810 003	OMEPRAZOLE;PRILOSEC	6150380	NOV 10, 2018		I-229	JUN 29, 2001
		6147103	OCT 09, 2018		PED	DEC 29, 2001
		6166213	NOV 10, 2018			
		6191148	OCT 09, 2018			
		4255431*PED	OCT 05, 2001	U-108		
		4636499*PED	JAN 30, 2006			
		4786505*PED	OCT 20, 2007	U-108		
		4853230*PED	OCT 20, 2007	U-108		
		5093342*PED	AUG 02, 2010	U-166		
		5599794*PED	AUG 04, 2014	U-166		
		5629305*PED	AUG 04, 2014	U-188		
		6147103*PED	APR 09, 2019			
		6150380*PED	MAY 10, 2019			
		6166213*PED	APR 09, 2018			

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
			6191148*PED	APR 09, 2019			
			4508905	APR 02, 2002			
	021246 001	OSELTAMIVIR PHOSPHATE;TAMIFLU	5763483	DEC 27, 2016	U-376	I-317	NOV 17, 2003
			5866601	FEB 02, 2016		NDF	DEC 14, 2003
			5952375	FEB 02, 2016		NCE	OCT 27, 2004
	020897 001	OXYBUTYNIN CHLORIDE;DITROPAN XL	6124355	MAY 22, 2015	U-378		
	020897 002	OXYBUTYNIN CHLORIDE;DITROPAN XL	6124355	MAY 22, 2015	U-378		
	020897 003	OXYBUTYNIN CHLORIDE;DITROPAN XL	6124355	MAY 22, 2015	U-378		
	020262 001	PACLITAXEL;TAXOL	6150398	MAY 08, 2011	U-380		
	020988 001	PANTOPRAZOLE SODIUM;PROTONIX IV	4758579	JUL 19, 2005		NDF	MAR 22, 2004
						NCE	FEB 02, 2005
>ADD>	020031 001	PAROXETINE HYDROCHLORIDE;PAXIL				I-326	APR 13, 2004
>ADD>	020031 002	PAROXETINE HYDROCHLORIDE;PAXIL				I-326	APR 13, 2004
>ADD>	020031 003	PAROXETINE HYDROCHLORIDE;PAXIL				I-326	APR 13, 2004
>ADD>	020031 004	PAROXETINE HYDROCHLORIDE;PAXIL				I-326	APR 13, 2004
>ADD>	020031 005	PAROXETINE HYDROCHLORIDE;PAXIL				I-326	APR 13, 2004
	020936 003	PAROXETINE HYDROCHLORIDE;PAXIL CR	4721723	DEC 29, 2006			
			4839177	JUN 13, 2006			
			5422123	JUN 06, 2012			
			5789449	JAN 06, 2009	U-286		
			5872132	MAY 19, 2015			
			5900423	MAY 19, 2015			
			6063927	APR 23, 2019			
			6080759	MAY 19, 2015			
			6121291	MAR 17, 2017	U-286		
			6133289	MAY 19, 2015	U-286		
			6172233	JAN 15, 2018			
>ADD>	020667 005	PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	MAR 25, 2011			
	019627 002	PROPOFOL;DIPRIVAN				I-322	FEB 20, 2004
>ADD>	020973 002	RABEPRAZOLE SODIUM;ACIPHEX	5045552	SEP 03, 2008	U-385		
>ADD>			5035899	APR 04, 2009	U-385		
	020815 001	RALOXIFENE HYDROCHLORIDE;EVISTA	4418068	APR 03, 2002			
>ADD>	020903 001	RIBAVIRIN;REBETOL	5767097*PED	JUL 23, 2016	U-235	PED	JUN 09, 2002
>ADD>			5914128*PED	JUN 22, 2018		PED	DEC 03, 2001
>ADD>			6051252*PED	JUN 22, 2018			
>ADD>			6172046*PED	MAR 21, 2018	U-377		
>ADD>			6063772*PED	JUL 23, 2017	U-375		
			6172046	SEP 21, 2017	U-377		
	020632 001	SIBUTRAMINE HYDROCHLORIDE;MERIDIA				D-65	FEB 16, 2004
	020632 002	SIBUTRAMINE HYDROCHLORIDE;MERIDIA				D-65	FEB 16, 2004
	020632 003	SIBUTRAMINE HYDROCHLORIDE;MERIDIA				D-65	FEB 16, 2004
	020280 001	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT	6152897	JUN 11, 2018			
	020280 002	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT	6152897	JUN 11, 2018			
	020280 003	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT	6152897	JUN 11, 2018			

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020280 005	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT	6152897	JUN 11, 2018			
	020280 008	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT	6152897	JUN 11, 2018			
	020280 009	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT	6152897	JUN 11, 2018			
>ADD>	021151 001	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
>ADD>						PED	AUG 22, 2003
>ADD>	021151 002	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
>ADD>						PED	AUG 22, 2003
>ADD>	021151 003	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
>ADD>						PED	AUG 22, 2003
>ADD>	021257 001	TRAVOPROST;TRAVATAN	6235781	JUN 15, 2019	U-382	NCE	MAR 16, 2006
			6011062	DEC 22, 2014			
			5631287	DEC 22, 2014	U-382		
			5849792	DEC 22, 2014	U-382		
			5889052	AUG 03, 2013	U-383		
					U-383		
	020468 001	TRIAMCINOLONE ACETONIDE;NASACORT AQ	6143329	JUL 03, 2016			
	020759 001	TROVAFLOXACIN MESYLATE;TROVAN	6187341	JAN 20, 2019			
	020759 002	TROVAFLOXACIN MESYLATE;TROVAN	6187341	JAN 20, 2019			
>ADD>	021304 001	VALGANCICLOVIR HYDROCHLORIDE;VALCYTE	6083953	JUL 28, 2014	U-384	NE	MAR 29, 2004
>ADD>	020151 001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR				I-325	MAY 02, 2004
>ADD>	020151 002	VENLAFAXINE HYDROCHLORIDE;EFFEXOR				I-325	MAY 02, 2004
>ADD>	020151 003	VENLAFAXINE HYDROCHLORIDE;EFFEXOR				I-325	MAY 02, 2004
>ADD>	020151 004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR				I-325	MAY 02, 2004
>ADD>	020151 005	VENLAFAXINE HYDROCHLORIDE;EFFEXOR				I-325	MAY 02, 2004
>ADD>	020151 006	VENLAFAXINE HYDROCHLORIDE;EFFEXOR				I-325	MAY 02, 2004
>ADD>	020699 001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-325	MAY 02, 2004
>ADD>	020699 002	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-325	MAY 02, 2004
>ADD>	020699 004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-325	MAY 02, 2004
>ADD>	020547 001	ZAFIRLUKAST;ACCOLATE				I-328	SEP 17, 2002
>ADD>	020547 003	ZAFIRLUKAST;ACCOLATE				I-328	SEP 17, 2002
>ADD>	020859 001	ZALEPLON;SONATA				M-8	FEB 22, 2004
>ADD>	020859 002	ZALEPLON;SONATA				M-8	FEB 22, 2004
	020825 001	ZIPRASIDONE HYDROCHLORIDE;GEODON	4831031	MAR 02, 2007		NCE	FEB 05, 2006
			5312925	SEP 01, 2012			
	020825 002	ZIPRASIDONE HYDROCHLORIDE;GEODON	4831031	MAR 02, 2007		NCE	FEB 05, 2006
			5312925	SEP 01, 2012			
	020825 003	ZIPRASIDONE HYDROCHLORIDE;GEODON	4831031	MAR 02, 2007		NCE	FEB 05, 2006
			5312925	SEP 01, 2012			
	020825 004	ZIPRASIDONE HYDROCHLORIDE;GEODON	4831031	MAR 02, 2007		NCE	FEB 05, 2006
			5312925	SEP 01, 2012			
>ADD>	021231 001	ZOLMITRIPTAN;ZOMIG-ZMT				NDF	FEB 13, 2004

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, 21ST 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

REFERENCES

NEW DOSING SCHEDULE

D-65 CHANGE DOSING AND ADMINISTRATION TO INDICATE MAINTENANCE OF WEIGHT LOSS OVER AN 18 MONTH PERIOD THUS EXTENDING THE USE OF THIS DRUG FROM ONE TO TWO YEARS

NEW INDICATION

I-321 JUVENILE RHEUMATOID ARTHRITIS
I-322 USE OF DIPRIVAN IN PATIENTS 3 MONTHS TO 16 YEARS
I-323 COLORECTAL CANCER
I-324 REDUCING NEUROLOGIC DISABILITY AND/OR FREQUENCY OF CLINICAL RELAPSES IN PATIENTS WITH SECONDARY (CHRONIC) PROGRESSIVE, PROGRESSIVE RELAPSING, OR WORSENING RELAPSING-REMITTING MULTIPLE SCLEROSIS
I-325 PREVENTION OF RELAPSE AND RECURRENCE OF DEPRESSION
I-326 GENERALIZED ANXIETY DISORDER
I-327 SYMPTOMATIC RELIEF OF RHINOORRHEA ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS IN PATIENTS 5 YEARS AND OLDER
I-328 PROPHYLAXIS AND CHRONIC TREATMENT OF ASTHMA IN PATIENTS 5-6 YEARS OF AGE

MISCELLANEOUS EXCLUSIVITY CODES

M-6 ADDITIONAL INFORMATION REGARDING CLINICAL STUDIES DONE WITH GLUOPHAGE/GLYBURIDE COMBINATION ADDED TO CLIN PHARM AND DOSING AND ADMIN
M-7 CLINICAL PHARMACOLOGY IN PEDIATRIC PATIENTS; DOSAGE AND ADMINISTRATION INFORMATION
M-8 ADDITIONAL INFORMATION FOR THE USE OF SONATA CAPSULES FOR UP TO 5 WEEKS (35 NIGHTS) OF TREATMENT IN A CONTROLLED TRIAL SETTING

PATENT USE CODE

U-372 METHOD FOR ADMINISTERING A BENEFICIAL DRUG TO THE GI TRACT OF AN ANIMAL, WHICH METHOD COMPRISES ADMITTING AN OSMOTIC DEVICE ORALLY INTO THE ANIMAL...

U-373 GENERAL USE CLAIM SUBMITTED FOR 12 NEXIUM PATIENTS STATING "PERTINENT TO THE CAPSULE FORMULATION FOR NEXIUM AND ITS INDICATIONS FOR THE TREATMENT OFGERD AND ERADICATION OF H.PYLORI TO REDUCE THE RISK OF DUODENAL ULCER RECURRENCE

U-374 KIT ADAPTED AND DESIGNED TO PROVIDE BOTH DATA ON THE CURRENT REPRODUCTIVE STATUS OF A PATIENT AND CONTRACEPTION FOR THOSE WHO ARE NOT PREGNANT, BUT RECENTLY ENGAGED IN UNPROTECTED SEX

U-375 METHOD OF USING RIBAVIRIN FOR TREATING A DISEASE RESPONSIVE TO RIBAVIRIN, E.G. HEPATITIS C

U-376 TREATMENT OF INFLUENZA

PATENT AND EXCLUSIVITY TERMS

REFERENCES
PATENT USE CODE

U-377	METHOD OF TREATING PT WITH CHRONIC HEPATITIS C HAVING HCV GENOTYPE 1 AND VIRAL LOAD GREATER THAN 2 MILLION COPIES/ML TO ERADICATE DETECTABLE HCV-RNA BY ADMIN COMBINATION OF RIBAVIRIN AND INTERFERON ALFA-2B FOR A LEAST 24 WEEKS
U-378	METHOD FOR TREATING INCONTINENCE
U-379	METHOD OF TREATING ONYCHROMYCOSIS
U-380	COMBINATIONS OF TAXOL (PACLITAXEL) AND CISPLATIN WHICH ARE SUITABLE FOR THE TREATMENT OF OVARIAN AND NON-SMALL CELL LUNG CARCINOMAS
U-381	TREATMENT OF HYPERPHOSPHATEMIA
U-382	METHOD OF STABLIZING PROSTAGLANDIN
U-383	METHOD FOR TREATING GLAUCOMA AND OCULAR HYPERTENSION
U-384	TREATMENT OF CMV RETINITIS
U-385	TREATMENT OF PEPTIC ULCERS

*U.S. Government Printing Office: 2001— 472-432/21010