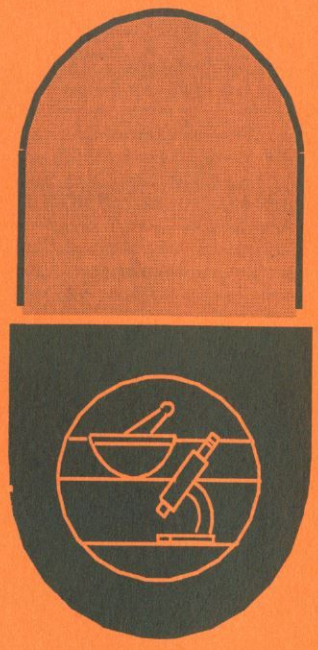
CUMULATIVE
SUPPLEMENT 1
JANUARY 2001



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 1

January 2001

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CUMULATIVE SUPPLEMENT 1
JANUARY 2001

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.)

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 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at http://www.fda.gov/cder/orange/20bookpub.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 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 1999) 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
DRUG PRODUCTS LISTED	10360			
SINGLE SOURCE	2682 (25.9%)			
MULTISOURCE	7568 (73.1%)			
THERAPEUTICALLY EQUIVALENT	7257 (70.0%)			
NOT THERAPEUTICALLY EQUIVALENT	311 (3.0%)			
EXCEPTIONS[1]	110 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	2			
NUMBER OF APPLICANTS	594			

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

SEP 2001

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.

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE
TABLET; ORAL

>A>			ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODEINE BITARTRATE					
>A>		+	MIKART	712.8MG;60MG;32MG	N40316 001	APR 28, 1999	JAN	CTNA
>D>			ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODONE BITARTRATE					
>D>		+		712.8MG;60MG;32MG	N40316 001	APR 28, 1999	JAN	CTNA

ACETAMINOPHEN; HYDROCODONE BITARTRATE
TABLET; ORAL
LORTAB

>D>	AA	+	UCB PHARMA	325MG;5MG	N40099 001	JUN 25, 1997	JAN	CAHN
>A>	AA	+	WATSON LABS	325MG;5MG	N40099 001	JUN 25, 1997	JAN	CAHN

AMIODARONE HYDROCHLORIDE
TABLET; ORAL
AMIODARONE HCL

>A>	AB		BARR	200MG	N75389 001	JAN 25, 2001	JAN	NEWA

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE
TABLET; ORAL
INVAGESIC

>A>	AB		GENEVA PHARMS TECH	385MG;30MG;25MG	N74817 001	NOV 27, 1996	JAN	CAHN
>D>	AB		INVAMED	385MG;30MG;25MG	N74817 001	NOV 27, 1996	JAN	CAHN

INVAGESIC FORTE

>A>	AB		GENEVA PHARMS TECH	770MG;60MG;50MG	N74817 002	NOV 27, 1996	JAN	CAHN
>D>	AB		INVAMED	770MG;60MG;50MG	N74817 002	NOV 27, 1996	JAN	CAHN

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE
TABLET; ORAL
BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

>A>	AB		TEVA	2.5MG;6.25MG	N75686 001	JAN 19, 2001	JAN	NEWA
>A>	AB			5MG;6.25MG	N75686 002	JAN 19, 2001	JAN	NEWA
>A>	AB			10MG;6.25MG	N75686 003	JAN 19, 2001	JAN	NEWA

CAPTOPRIL
TABLET; ORAL
CAPTOPRIL

>A>	AB		GENEVA PHARMS TECH	12.5MG	N74481 001	FEB 13, 1996	JAN	CAHN
>A>	AB			25MG	N74481 002	FEB 13, 1996	JAN	CAHN
>A>	AB			50MG	N74481 003	FEB 13, 1996	JAN	CAHN
>A>	AB			100MG	N74481 004	FEB 13, 1996	JAN	CAHN
>D>	AB		INVAMED	12.5MG	N74481 001	FEB 13, 1996	JAN	CAHN
>D>	AB			25MG	N74481 002	FEB 13, 1996	JAN	CAHN
>D>	AB			50MG	N74481 003	FEB 13, 1996	JAN	CAHN
>D>	AB			100MG	N74481 004	FEB 13, 1996	JAN	CAHN

>A> CASPOFUNGIN ACETATE
>A> INJECTABLE; IV (INFUSION)
>A> CANCIDAS

>A>		+	MERCK RES	50MG/VIAL	N21227 001	JAN 26, 2001	JAN	NEWA
>A>		+		70MG/VIAL	N21227 002	JAN 26, 2001	JAN	NEWA

CEFACLOR
TABLET, EXTENDED RELEASE; ORAL
CECLOR CD

>A>	AB	+	LILLY	EQ 500MG BASE	N50673 002	JUN 28, 1996	JAN	CFTG
>D>		+		EQ 500MG BASE	N50673 002	JUN 28, 1996	JAN	CFTG

CEFACLOR

>A>	AB		ZENITH GOLDLINE	EQ 500MG BASE	N65057 001	JAN 05, 2001	JAN	NEWA

CEFTAZIDIME
INJECTABLE; INJECTION
TAZICEF

>A>	AP		ABBOTT	500MG/VIAL	N62662 001	MAR 06, 1986	JAN	CAHN
>A>	AP			1GM/VIAL	N62662 002	MAR 06, 1986	JAN	CAHN
>A>	AP			1GM/VIAL	N64032 001	OCT 31, 1993	JAN	CAHN
>A>	AP			2GM/VIAL	N62662 003	MAR 06, 1986	JAN	CAHN
>A>	AP			2GM/VIAL	N64032 002	OCT 31, 1993	JAN	CAHN
>A>	AP			6GM/VIAL	N62662 004	MAR 06, 1986	JAN	CAHN
>D>	AP		SMITHKLINE BEECHAM	500MG/VIAL	N62662 001	MAR 06, 1986	JAN	CAHN
>D>	AP			1GM/VIAL	N62662 002	MAR 06, 1986	JAN	CAHN
>D>	AP			1GM/VIAL	N64032 001	OCT 31, 1993	JAN	CAHN
>D>	AP			2GM/VIAL	N62662 003	MAR 06, 1986	JAN	CAHN
>D>	AP			2GM/VIAL	N64032 002	OCT 31, 1993	JAN	CAHN
>D>	AP			6GM/VIAL	N62662 004	MAR 06, 1986	JAN	CAHN

CIMETIDINE
TABLET; ORAL
CIMETIDINE

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

CLORAZEPATE DIPOTASSIUM
CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

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

CROMOLYN SODIUM
SOLUTION/DROPS; OPHTHALMIC
CROMOLYN SODIUM

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

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

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

DEXTROSTAT

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

DISULFIRAM

TABLET; ORAL

ANTABUSE

>A>			ODYSSEY PHARMS	250MG	N88482 001	DEC 08, 1983	JAN	CAHN
>A>		+		500MG	N88483 001	DEC 08, 1983	JAN	CAHN
>D>	BX		SIDMAK LABS NJ	250MG	N88482 001	DEC 08, 1983	JAN	CAHN
>D>	BX			500MG	N88483 001	DEC 08, 1983	JAN	CAHN

DOXAZOSIN MESYLATE

TABLET; ORAL

DOXAZOSIN MESYLATE

>A>	AB		TEVA	EQ 1MG BASE	N75353 001	JAN 12, 2001	JAN	NEWA
>A>	AB			EQ 2MG BASE	N75353 002	JAN 12, 2001	JAN	NEWA
>A>	AB			EQ 3MG BASE	N75353 003	JAN 12, 2001	JAN	NEWA
>A>	AB			EQ 4MG BASE	N75353 004	JAN 12, 2001	JAN	NEWA

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

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

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

PREMPRO

>A>								
>A>		+	WYETH AYERST	0.625MG;2.5MG	N20527 001	NOV 17, 1995	JAN	CTNA
>A>		+		0.625MG;5MG	N20527 003	JAN 09, 1998	JAN	CTNA

PREMPRO (PREMARIN;CYCRIN 14/14)

>D>								
>D>		+	WYETH AYERST	0.625MG;5MG	N20303 001	JAN 09, 1998	JAN	CTNA

PREMPRO (PREMARIN;CYCRIN)

>A>								
>A>		+	WYETH AYERST	0.625MG;2.5MG	N20303 001	DEC 30, 1994	JAN	CTNA

PREMPRO 14/14

>D>								
>D>		+	WYETH AYERST	0.625MG;2.5MG	N20527 001	DEC 30, 1994	JAN	CTNA
>D>		+		0.625MG;2.5MG	N20527 003	NOV 17, 1995	JAN	CTNA

ESTROPIPATE

TABLET; ORAL

ORTHO-EST

>D>	AB		JOHNSON RW	0.75MG	N89567 001	FEB 27, 1991	JAN	CAHN
>D>	AB			1.5MG	N89582 001	JUL 17, 1991	JAN	CAHN
>A>	AB		WOMEN FIRST HLTHCARE	0.75MG	N89567 001	FEB 27, 1991	JAN	CAHN
>A>	AB			1.5MG	N89582 001	JUL 17, 1991	JAN	CAHN

ETHOSUXIMIDE
SYRUP; ORAL
ZARONTIN

>A>	AA	+	PARKE DAVIS	250MG/5ML	N80258 001	FEB 13, 1974	JAN	CRLD
>D>	AA			250MG/5ML	N80258 001	FEB 13, 1974	JAN	CRLD

FAMCICLOVIR
TABLET; ORAL
FAMVIR

>A>			NOVARTIS	125MG	N20363 003	DEC 11, 1995	JAN	CAHN
>A>				250MG	N20363 001	APR 26, 1996	JAN	CAHN
>A>		+		500MG	N20363 002	JUN 29, 1994	JAN	CAHN
>D>			SMITHKLINE BEECHAM	125MG	N20363 003	DEC 11, 1995	JAN	CAHN
>D>				250MG	N20363 001	APR 26, 1996	JAN	CAHN
>D>		+		500MG	N20363 002	JUN 29, 1994	JAN	CAHN

FENTANYL CITRATE
INJECTABLE; INJECTION
FENTANYL CITRATE PRESERVATIVE FREE

>D>	AP		MARSAM	0.05MG	N74917 001	FEB 03, 1998	JAN	DISC
>A>			@	0.05MG	N74917 001	FEB 03, 1998	JAN	DISC

FLUVOXAMINE MALEATE
TABLET; ORAL
FLUVOXAMINE MALEATE

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

GEMFIBROZIL
TABLET; ORAL
GEMFIBROZIL

>A>	AB		GENEVA PHARMS TECH	600MG	N74615 001	SEP 29, 1995	JAN	CAHN
>D>	AB		INVAMED	600MG	N74615 001	SEP 29, 1995	JAN	CAHN

GLIPIZIDE
TABLET; ORAL
GLIPIZIDE

>A>	AB		GENEVA PHARMS TECH	5MG	N74542 001	JUN 20, 1995	JAN	CAHN
>A>	AB			10MG	N74542 002	JUN 20, 1995	JAN	CAHN
>D>	AB		INVAMED	5MG	N74542 001	JUN 20, 1995	JAN	CAHN
>D>	AB			10MG	N74542 002	JUN 20, 1995	JAN	CAHN

HALOTHANE
LIQUID; INHALATION
HALOTHANE

>D>	AN	BH CHEMS	99.99%	N84977 001	JUL 14, 1976	JAN	DISC
>A>		@	99.99%	N84977 001	JUL 14, 1976	JAN	DISC

INDAPAMIDE
TABLET; ORAL
INDAPAMIDE

>A>	AB	GENEVA PHARMS TECH	1.25MG	N74594 001	MAY 23, 1996	JAN	CAHN
>A>	AB		2.5MG	N74594 002	MAY 23, 1996	JAN	CAHN
>D>	AB	INVAMED	1.25MG	N74594 001	MAY 23, 1996	JAN	CAHN
>D>	AB		2.5MG	N74594 002	MAY 23, 1996	JAN	CAHN

IPRATROPIUM BROMIDE
SOLUTION; INHALATION
IPRATROPIUM BROMIDE

>A>	AN	ASLUNG PHARM	0.02%	N75693 001	JAN 26, 2001	JAN	NEWA
>A>	AN	WARRICK PHARMS	0.02%	N75507 001	JAN 19, 2001	JAN	NEWA

LEUCOVORIN CALCIUM
INJECTABLE; INJECTION
LEUCOVORIN CALCIUM PRESERVATIVE FREE

>A>	AP	LUITPOLD	EQ 50MG BASE/VIAL	N40338 001	JAN 31, 2001	JAN	NEWA

MESALAMINE
>A> SUPPOSITORY; RECTAL
>A> CANASA

>A>	+	AXCAN SCANDIPHARM	500MG	N21252 001	JAN 05, 2001	JAN	NEWA

METOCLOPRAMIDE HYDROCHLORIDE
SOLUTION; INJECTION
METOCLOPRAMIDE

>A>	AA	UDL	5MG	N75051 001	JAN 26, 2001	JAN	NEWA

TABLET; ORAL
METOCLOPRAMIDE HCL

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

>A> MIRTAZAPINE
>A> TABLET, ORALLY DISINTEGRATING; ORAL
>A> REMERON SOLTAB

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

MORPHINE SULFATE
TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

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

NADOLOL
TABLET; ORAL
NADOLOL

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

NALOXONE HYDROCHLORIDE
INJECTABLE; INJECTION
NALOXONE

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

NAPROXEN SODIUM
TABLET; ORAL
NAPROXEN SODIUM

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

OXAPROZIN
TABLET; ORAL
DAYPRO

>A>	AB	+ SEARLE	600MG	N18841 004	OCT 29, 1992	JAN	CFTG
>D>		+	600MG	N18841 004	OCT 29, 1992	JAN	CFTG
>A>		OXAPROZIN					
>A>	AB	DR REDDYS LABS LTD	600MG	N75855 001	JAN 31, 2001	JAN	NEWA
>A>	AB	EON	600MG	N75845 001	JAN 31, 2001	JAN	NEWA

PHENYTOIN
SUSPENSION; ORAL
PHENYTOIN

>A>	AB	UDL	125MG	N40342 001	JAN 31, 2001	JAN	NEWA

PROCHLORPERAZINE MALEATE
TABLET; ORAL
PROCHLORPERAZINE MALEATE

>A>	AB	GENEVA PHARMS TECH	EQ 5MG BASE	N40101 001	JUL 19, 1996	JAN	CAHN
>A>	AB		EQ 10MG BASE	N40101 002	JUL 19, 1996	JAN	CAHN
>A>	AB		EQ 25MG BASE	N40101 003	JUL 19, 1996	JAN	CAHN
>D>	AB	INVAMED	EQ 5MG BASE	N40101 001	JUL 19, 1996	JAN	CAHN
>D>	AB		EQ 10MG BASE	N40101 002	JUL 19, 1996	JAN	CAHN
>D>	AB		EQ 25MG BASE	N40101 003	JUL 19, 1996	JAN	CAHN

PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

PROTRIPTYLINE HCL

>A>	AB		ODYSSEY PHARMS	5MG	N73644 001	AUG 24, 1995	JAN	CAHN
>A>	AB			10MG	N73645 001	AUG 24, 1995	JAN	CAHN
>D>	AB		SIDMAK LABS NJ	5MG	N73644 001	AUG 24, 1995	JAN	CAHN
>D>	AB			10MG	N73645 001	AUG 24, 1995	JAN	CAHN

SULFANILAMIDE

CREAM; VAGINAL

AVC

>D>	AT	+	KING PHARMS	15%	N06530 003	JAN 27, 1987	JAN	CAHN
>A>	AT	+	NOVAVAX	15%	N06530 003	JAN 27, 1987	JAN	CAHN

SUPPOSITORY; VAGINAL

>D>		+	KING PHARMS	1.05GM	N06530 004	JAN 27, 1987	JAN	CAHN
>A>		+	NOVAVAX	1.05GM	N06530 004	JAN 27, 1987	JAN	CAHN

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HCL

>A>	AB		ZENITH GOLDLINE	EQ 1MG BASE	N75614 002	JAN 30, 2001	JAN	NEWA
>A>	AB			EQ 2MG BASE	N75614 001	JAN 30, 2001	JAN	NEWA
>A>	AB			EQ 5MG BASE	N75614 003	JAN 30, 2001	JAN	NEWA
>A>	AB			EQ 10MG BASE	N75614 004	JAN 30, 2001	JAN	NEWA

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

>A>	AB		GENEVA PHARMS TECH	EQ 1MB BASE	N40153 001	OCT 25, 1996	JAN	CAHN
>A>	AB			EQ 2MG BASE	N40153 002	OCT 25, 1996	JAN	CAHN
>A>	AB			EQ 5MG BASE	N40153 003	OCT 25, 1996	JAN	CAHN
>A>	AB			EQ 10MG BASE	N40153 004	OCT 25, 1996	JAN	CAHN
>D>	AB		INVAMED	EQ 1MG BASE	N40153 001	OCT 25, 1996	JAN	CAHN
>D>	AB			EQ 2MG BASE	N40153 002	OCT 25, 1996	JAN	CAHN
>D>	AB			EQ 5MG BASE	N40153 003	OCT 25, 1996	JAN	CAHN
>D>	AB			EQ 10MG BASE	N40153 004	OCT 25, 1996	JAN	CAHN

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST-D

>A>	@ NOVARTIS	1.34MG;75MG	N18298	002	AUG 21, 1992	JAN	DISC
>D>	+	1.34MG;75MG	N18298	002	AUG 21, 1992	JAN	DISC
>A>	@	1.34MG;75MG	N20640	001	AUG 09, 1996	JAN	DISC
>D>		1.34MG;75MG	N20640	001	AUG 09, 1996	JAN	DISC

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

CUMULATIVE SUPPLEMENT NUMBER 1 JANUARY '01

NO JANUARY 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
January 2001

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Imatinib TN=Glivec	Treatment of chronic myelogenous leukemia	Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936-1080 DD= 1/31/01 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=
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=
Synthetic Human Parathyroid Hormone 1-34 TN=	Treatment of hypoparathyroidism	Orphan Pharmaceuticals, U.S., 1101 Kermit Drive, Suite 608 Nashville TN 37217 DD= 1/26/01 MA=

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

NO JANUARY 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
>ADD>	021205 001	ABACAVIR SULFATE;TRIZIVIR	6180639	JAN 30, 2018	U-248		
>ADD>	021082 001	ACETAMINOPHEN;TAVIST ALLERGY/SINUS				NC	MAR 01, 2004
>ADD>	020760 001	ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE	6194429	JUL 23, 2018			
>ADD>	020760 002	ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE	6194429	JUL 23, 2018		NCE	DEC 18, 2002
>ADD>	020560 001	ALENDRONATE SODIUM;FOSAMAX	6194004	DEC 02, 2012			
>ADD>	021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX	5360800	FEB 02, 2010			
>ADD>	021078 001	ATOVAQUONE;MALARONE	6166046	NOV 25, 2013		NC	JUL 14, 2003
>ADD>			5053432	OCT 01, 2008			
>ADD>	021078 002	ATOVAQUONE;MALARONE PEDIATRIC	5053432	OCT 01, 2008		NC	JUL 14, 2003
>ADD>	018874 001	CALCITRIOL;CALCIJEX	4308264	JAN 28, 2001			
>ADD>			6051567	AUG 02, 2019			
>ADD>			4308264*PED	JUL 28, 2001			
>ADD>			6051567*PED	FEB 02, 2020			
>ADD>	018874 002	CALCITRIOL;CALCIJEX	4308264	JAN 28, 2001			
>ADD>			6051567	AUG 02, 2019			
>ADD>			4308264*PED	JUL 28, 2001			
>ADD>			6051567*PED	FEB 02, 2020			
>ADD>	021005 001	DICLOFENAC SODIUM;SOLARAZE				NP	OCT 16, 2003
>ADD>	020164 002	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	020164 003	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	020164 004	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	020164 005	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	020164 006	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001			
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	020164 007	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	020164 008	ENOXAPARIN SODIUM;LOVENOX	4486420	DEC 04, 2001	U-122		
>ADD>			4692435	DEC 24, 2004	U-123		
>ADD>			5389618	FEB 14, 2012			
>ADD>	021153 001	ESOMEPRAZOLE MAGNESIUM;NEXIUM	4255431	APR 05, 2001	U-373	NP	FEB 20, 2004
>ADD>			4738974	APR 19, 2005	U-373		
>ADD>			4636499	MAY 30, 2005	U-373		
>ADD>			5900424	MAY 04, 2016	U-373		
>ADD>			4786505	APR 20, 2007	U-373		
>ADD>			4853230	APR 20, 2007	U-373		
>ADD>			5714504	FEB 03, 2015	U-373		
>ADD>			5877192	MAY 27, 2014	U-373		
>ADD>			5093342	FEB 02, 2010	U-373		
>ADD>			5599794	FEB 04, 2014	U-373		
>ADD>			5629305	FEB 04, 2014	U-373		
>ADD>			5690960	NOV 25, 2014	U-373		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021153 002	ESOMEPRAZOLE MAGNESIUM;NEXIUM	4255431	APR 05, 2001	U-373	NP	FEB 20, 2004
>ADD>			4738974	APR 19, 2005	U-373		
>ADD>			4636499	MAY 30, 2005	U-373		
>ADD>			5900424	MAY 04, 2016	U-373		
>ADD>			4786505	APR 20, 2007	U-373		
>ADD>			4853230	APR 20, 2007	U-373		
>ADD>			5714504	FEB 03, 2015	U-373		
>ADD>			5877192	MAY 27, 2014	U-373		
>ADD>			5093342	FEB 02, 2010	U-373		
>ADD>			5599794	FEB 04, 2014	U-373		
>ADD>			5629305	FEB 04, 2014	U-373		
>ADD>			5690960	NOV 25, 2014	U-373		
>ADD>	020538 005	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
>ADD>			5474783	DEC 12, 2012			
>ADD>			5656286	AUG 12, 2014			
>ADD>			5958446	DEC 12, 2012			
>ADD>	020538 006	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
>ADD>			5474783	DEC 12, 2012			
>ADD>			5656286	AUG 12, 2014			
>ADD>			5958446	DEC 12, 2012			
>ADD>	020538 007	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
>ADD>			5474783	DEC 12, 2012			
>ADD>			5656286	AUG 12, 2014			
>ADD>			5958446	DEC 12, 2012			
>ADD>	020538 008	ESTRADIOL;VIVELLE-DOT	6024976	JAN 07, 2014			
>ADD>			5474783	DEC 12, 2012			
>ADD>			5656286	AUG 12, 2014			
>ADD>			5958446	DEC 12, 2012			
>ADD>	020946 001	ETHINYL ESTRADIOL;PREVEN EMERGENCY CON	6156742	DEC 05, 2020	U-374		
>ADD>	020584 001	ETODOLAC;LODINE XL				I-321	AUG 11, 2003
>ADD>	020584 002	ETODOLAC;LODINE XL				I-321	AUG 11, 2003
>ADD>	020584 003	ETODOLAC;LODINE XL				I-321	AUG 11, 2003
>ADD>	021235 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NDF	FEB 26, 2004
>ADD>	020831 001	FORMOTEROL FUMARATE;FORADIL				NCE	FEB 16, 2006
>ADD>	021169 001	GALANTAMINE HYDROBROMIDE;REMINYL	4663318	JAN 15, 2006		NCE	FEB 28, 2006
>ADD>	021169 002	GALANTAMINE HYDROBROMIDE;REMINYL	4663318	JAN 15, 2006		NCE	FEB 28, 2006
>ADD>	021169 003	GALANTAMINE HYDROBROMIDE;REMINYL	4663318	JAN 15, 2006		NCE	FEB 28, 2006
>ADD>	020857 001	LAMIVUDINE;COMBIVIR	6180639	JAN 30, 2018	U-248		
>ADD>	020564 001	LAMIVUDINE;EPIVIR	6180639	JAN 30, 2018	U-248		
>ADD>	020596 001	LAMIVUDINE;EPIVIR	6180639	JAN 30, 2018	U-248		
>ADD>	021121 001	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4783337	SEP 16, 2003	U-372		
>ADD>	021121 002	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4783337	SEP 16, 2003	U-372		
>ADD>	021121 003	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA	4783337	SEP 16, 2003	U-372	NP	AUG 01, 2003
>ADD>	019962 001	METOPROLOL SUCCINATE;TOPROL-XL	4927640	MAY 22, 2007		I-194	FEB 05, 2004
>ADD>			5246714	SEP 21, 2010			

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>	019962 002	METOPROLOL SUCCINATE;TOPROL-XL	4927640	MAY 22, 2007		I-194	FEB 05, 2004
>ADD>			5246714	SEP 21, 2010			
>ADD>	019962 003	METOPROLOL SUCCINATE;TOPROL-XL	4927640	MAY 27, 2007		I-194	FEB 05, 2004
>ADD>			5246714	SEP 21, 2010			
>ADD>	019962 004	METOPROLOL SUCCINATE;TOPROL-XL	4957745	SEP 18, 2007	U-107	NS	FEB 05, 2004
>ADD>			5001161	MAR 19, 2008	U-107	I-194	FEB 05, 2004
>ADD>			5081154	JAN 14, 2009	U-107		
>ADD>			4927640	MAY 22, 2007			
>ADD>			5246714	SEP 21, 2010			
>ADD>	021208 001	MIRTAZAPINE;REMERON	5178878	JAN 12, 2010		NCE	JUN 14, 2001
>ADD>	021208 002	MIRTAZAPINE;REMERON	5178878	JAN 12, 2010		NCE	JUN 14, 2001
>ADD>	021208 003	MIRTAZAPINE;REMERON	5178878	JAN 12, 2010		NCE	JUN 14, 2001
>ADD>	020829 002	MONTELUKAST SODIUM;SINGULAIR	5565473	FEB 03, 2012	U-228		
>ADD>	020830 001	MONTELUKAST SODIUM;SINGULAIR	5565473	FEB 03, 2012	U-228		
>ADD>	020830 002	MONTELUKAST SODIUM;SINGULAIR	5565473	FEB 03, 2012	U-228		
>ADD>	075269 001	NIFEDIPINE;NIFEDIPINE				PC	JUN 05, 2001
>ADD>	075269 002	NIFEDIPINE;NIFEDIPINE				PC	JUN 05, 2001
>ADD>	021086 001	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
>ADD>	021086 002	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
>ADD>	021086 003	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
>ADD>	021086 004	OLANZAPINE;ZYPREXA ZYDIS	6020487	SEP 23, 2017			
>ADD>	019810 001	OMEPRAZOLE;PRILOSEC	6150380	NOV 10, 2018			
>ADD>			6147103	OCT 09, 2018			
>ADD>			6166213	OCT 09, 2018			
>ADD>			6191148	OCT 09, 2018			
>ADD>	019810 002	OMEPRAZOLE;PRILOSEC	6150380	NOV 10, 2018			
>ADD>			6147103	OCT 09, 2018			
>ADD>			6166213	OCT 09, 2018			
>ADD>			6191148	OCT 09, 2018			
>ADD>	019810 003	OMEPRAZOLE;PRILOSEC	6150380	NOV 10, 2018			
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>ADD>			6166213	NOV 10, 2018			
>ADD>			6191148	OCT 09, 2018			
>ADD>	021246 001	OSELTAMIVIR PHOSPHATE;TAMIFLU	5763483	DEC 27, 2016	U-376	I-317	NOV 17, 2003
>ADD>			5866601	FEB 02, 2016		NDF	DEC 14, 2003
>ADD>			5952375	FEB 02, 2016		NCE	OCT 27, 2004
>ADD>	020815 001	RALOXIFENE HYDROCHLORIDE;EVISTA	4418068	APR 03, 2002			
>ADD>	020903 001	RIBAVIRIN;REBETOL	6063772	JAN 23, 2016	U-375		
>ADD>			6172046	SEP 21, 2017	U-377		
>ADD>	020632 001	SIBUTRAMINE HYDROCHLORIDE;MERIDIA				D-65	FEB 16, 2004
>ADD>	020632 002	SIBUTRAMINE HYDROCHLORIDE;MERIDIA				D-65	FEB 16, 2004
>ADD>	020632 003	SIBUTRAMINE HYDROCHLORIDE;MERIDIA				D-65	FEB 16, 2004
>ADD>	020468 001	TRIAMCINOLONE ACETONIDE;NASACORT AQ	6143329	JUL 03, 2016			
>ADD>	020759 001	TROVAFLOXACIN MESYLATE;TROVAN	6187341	JAN 20, 2019			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020759 002	TROVAFLOXACIN MESYLATE;TROVAN	6187341	JAN 20, 2019			
>ADD>	020825 001	ZIPRASIDONE HYDROCHLORIDE;ZELDOX	4831031	MAR 02, 2007		NCE	FEB 05, 2006
>ADD>			5312925	SEP 01, 2012			
>ADD>	020825 002	ZIPRASIDONE HYDROCHLORIDE;ZELDOX	4831031	MAR 02, 2007		NCE	FEB 05, 2006
>ADD>			5312925	SEP 01, 2012			
>ADD>	020825 003	ZIPRASIDONE HYDROCHLORIDE;ZELDOX	4831031	MAR 02, 2007		NCE	FEB 05, 2006
>ADD>			5312925	SEP 01, 2012			
>ADD>	020825 004	ZIPRASIDONE HYDROCHLORIDE;ZELDOX	4831031	MAR 02, 2007		NCE	FEB 05, 2006
>ADD>			5312925	SEP 01, 2012			

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

MISCELLANEOUS EXCLUSIVITY CODES

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

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.S. Government Printing Office: 2001— 472-432/21008

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