CUMULATIVE
SUPPLEMENT 2
JAN'97-FEB'97

APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DATABASE MANAGEMENT

Approved drug products with therapeutic equivalence

Prepared By
Division of Database Management
Office of Management
Center for Drug Evaluation and Research, FDA

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THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

Cumulative Supplement 2

FEBRUARY 1997

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CUMULATIVE SUPPLEMENT 2
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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, 17th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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.

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.)

New additions to the Prescription Drug Product List, OTC Drug Product List, and 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, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**DLT**> (DELETE) to the left of the line. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition. However, the overstruck data in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements (hard copy).

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 16th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 17th Edition.

1.2 COURT ORDER AFFECTING URUGUAY ROUND AGREEMENTS ACT-EXTENDED PATENTS

As a result of the April 4, 1996, decision of the United States Court of Appeals for the Federal Circuit in Merck, et al. v. Kessler, patent expiration dates for certain patents subject to patent term extensions under the Uruguay Round Agreements Act and to the patent term extension provisions at 35 U.S.C. § 156 may be changed. FDA has published a notice in the March 14, 1997, *Federal Register* advising NDA and NADA

applicants that patent expiration dates changed by the Merck decision must be submitted within 60 days. Because there may be changes in listed patents as a result of the Merck decision, users of this publication should consult the most recent supplement, and are encouraged to confirm that patent information upon which they intend to rely is current. (See the *Patent and Exclusivity Addendum* to the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 16th Edition that explains the background information on this court decision).

1.3 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 automatically 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. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
CIBA GEIGY CORP (CIBA GEIGY)	NOVARTIS PHARMACEUTICAL CORP (NOVARTIS)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
CIBA GEIGY CORP PHARMACEUTICALS DIV (CIBA GEIGY)	NOVARTIS PHARMACEUTICAL CORP (NOVARTIS)
CIBA PHARMACEUTICAL CO DIV CIBA GEIGY CORP (CIBA)	NOVARTIS PHARMACEUTICAL CORP (NOVARTIS)
CIBA SELF MEDICATION INC DIV CIBA GEIGY CORP (CIBA)	NOVARTIS CONSUMER HEALTH INC (NOVARTIS)
CIBA VISION CORP (CIBA)	CIBA VISION CORPORATION A NOVARTIS COMPANY (CIBA)
CIBA VISION OPHTHALMICS DIV CIBA VISION CORP (CIBA)	CIBA VISION CORPORATION A NOVARTIS COMPANY (CIBA)
FERRING LABORATORIES INC (FERRING)	FERRING PHARMACEUTICALS INC (FERRING)
GEIGY PHARMACEUTICALS DIV CIBA GEIGY CORP (GEIGY)	NOVARTIS PHARMACEUTICAL CORP (NOVARTIS)
SANDOZ CONSUMER HEALTH CARE GROUP DIV SANDOZ PHARMACEUTICALS (SANDOZ)	NOVARTIS CONSUMER HEALTH INC (NOVARTIS)
SANDOZ PHARMACEUTICALS CORP DIV SANDOZ INC (SANDOZ)	NOVARTIS PHARMACEUTICAL CORP (NOVARTIS)
SANDOZ RESEARCH INSTITUTE INC (SANDOZ)	NOVARTIS PHARMACEUTCAL CORP (NOVARTIS)

1.4 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The *Approved Drug Products with Therapeutic Equivalence Evaluations* (Prescription Drug Products, OTC Drug Products and the Discontinued Drug Product Lists) is available on diskette, on a quarterly basis, from the National Technical Information Service. The telephone number for the Subscription Department is (703) 487-6430. Written inquiries regarding this subscription may be forwarded to 5285 Port Royal Road Springfield, VA 22161.

The following *Approved Drug Products with Therapeutic Equivalence Evaluations* files are now available on Internet and are updated each October and April: Prescription Drug Product List; OTC Drug Products; Discontinued Drug Products; and Appendices. The update in October will include drug products that have been approved through August and the update in April will include drug products that have been approved through December.

These files may be accessed on the Internet's World Wide Web. FDA's Internet site replaced the Agency's electronic bulletin board. To access the CDER Home Page, use this Uniform Resource Locator (URL): http://www.fda.gov/cder. You do not need an Internet connection to reach the FDA Home Page; you can use the free dial-up connection (800) 222-0185 for text based, non-graphical use only. For further assistance, please call (301) 443-4908.

The Prescription Drug Products and OTC Drug Product files will be available on a monthly basis in the near future.

1.5 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 sections 505 and 507 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 1996) 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 1996*	MAR 1997	JUN 1997	SEP 1997
DRUG PRODUCTS LISTED	9392			
SINGLE SOURCE	2383 (25.4%)			
MULTISOURCE	6905 (73.5%)			
THERAPEUTICALLY EQUIVALENT	6463 (68.8%)			
NOT THERAPEUTICALLY EQUIVALENT	442 (4.7%)			
EXCEPTIONS[1]	104 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	--			
NUMBER OF APPLICANTS	650			

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

*Exceptions were originally included in the total count of the Multisource Drug Products. Beginning with December 1996, exceptions will no longer be included in the Multisource Drug Products total count, but will be included in the total count of the Drug Products Listed.

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	EON	500MG;5MG	N40149 001	JAN 27, 1997
AA		750MG;7.5MG	N40149 002	JAN 27, 1997
>ADD> AA	WATSON LABS	500MG;10MG	N40148 002	FEB 14, 1997

LORTAB

>ADD> AA +	GRAHAM DM	500MG;10MG	N40100 001	JAN 26, 1996

NORCO

>ADD> +	WATSON LABS	325MG;10MG	N40148 001	FEB 14, 1997

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

>ADD> AB	VINTAGE PHARMS	650MG;100MG	N74843 001	FEB 12, 1997

ACETIC ACID, GLACIAL; DESONIDE

SOLUTION/DROPS; OTIC
TRIDESILON

>DLT>	BAYER	2%;0.05%	N17914 001	
>ADD> @		2%;0.05%	N17914 001	

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

AB	ROYCE LABS	0.25MG	N74479 001	JAN 21, 1997
AB		0.5MG	N74479 002	JAN 21, 1997
AB		1MG	N74479 003	JAN 21, 1997

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN SULFATE

AP	ELKINS SINN	EQ 50MG BASE/ML	N63274 001	MAY 18, 1992
@		EQ 50MG BASE/ML	N63274 001	MAY 18, 1992

AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE

INJECTABLE; INJECTION
AMINOSYN II 5% W/ ELECTROLYTES IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER

>DLT>	ABBOTT	5%;36.8MG/100ML;25GM/100ML; 51MG/100ML;22.4MG/100ML;261MG/100ML; 205MG/100ML	N19683 004	NOV 07, 1988
>ADD> @		5%;36.8MG/100ML;25GM/100ML; 51MG/100ML;22.4MG/100ML;261MG/100ML; 205MG/100ML	N19683 004	NOV 07, 1988

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL
LIMBITROL

>DLT> AB +	ROCHE	EQ 25MG BASE;10MG	N16949 002	

LIMBITROL DS

>ADD> AB +	ROCHE	EQ 25MG BASE;10MG	N16949 002	

AMOXICILLIN

CAPSULE; ORAL
AMOXIL

AB +	SMITHKLINE BEECHAM	250MG	N50459 001	
AB		250MG	N62216 001	
AB +		250MG	N62216 001	
AB +		500MG	N50459 002	
AB		500MG	N62216 004	
AB +		500MG	N62216 004	
@		250MG	N50459 001	
@		500MG	N50459 002	

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

		AMOXIL				
AB	+	SMITHKLINE BEECHAM	125MG/5ML	N50460 001		
AB			125MG/5ML	N62226 001		
AB	+		125MG/5ML	N62226 001		
AB	+		250MG/5ML	N50460 002		
AB	+		50MG/ML	N50460 005		
AB			250MG/5ML	N62226 002		
AB	+		250MG/5ML	N62226 002		
AB			50MG/ML	N62226 005	> ADD >	
AB	+		50MG/ML	N62226 005	> ADD >	
	@		125MG/5ML	N50460 001	> ADD >	
	@		250MG/5ML	N50460 002		
	@		50MG/ML	N50460 005		
		LAROTID				
AB		SMITHKLINE BEECHAM	50MG/ML	N50460 006		
	@		50MG/ML	N50460 006		

AMPHOTERICIN B

OINTMENT; TOPICAL

		FUNGIZONE				
	+	APOTHECON	3%	N50313 001		
	@		3%	N50313 001		

ATRACURIUM BESYLATE

INJECTABLE; INJECTION

		ATRACURIUM BESYLATE				
AP		ABBOTT	10MG/ML	N74633 001 DEC 23, 1996		
AP		OHMEDA	10MG/ML	N74753 001 JAN 23, 1997		
		ATRACURIUM BESYLATE PRESERVATIVE FREE				
AP		ABBOTT	10MG/ML	N74633 001 DEC 23, 1996	> DLT >	
AP		OHMEDA	10MG/ML	N74768 001 JAN 23, 1997	> DLT > > ADD > > ADD >	
		TRACRIUM				
AP	+	GLAXO WELLCOME	10MG/ML	N18831 001 NOV 23, 1983		
AP	+		10MG/ML	N18831 002 JUN 20, 1985	> DLT > > DLT >	
		TRACRIUM PRESERVATIVE FREE				
AP	+	GLAXO WELLCOME	10MG/ML	N18831 001 NOV 23, 1983		

AZITHROMYCIN DIHYDRATE

INJECTABLE; INJECTION

		ZITHROMAX				
	+	PFIZER	EQ 500MG BASE/VIAL	N50733 001 JAN 30, 1997		

BUTOCONAZOLE NITRATE

CREAM; VAGINAL

		FEMSTAT ONE				
	+	SYNTEX	2%	N19881 001 FEB 07, 1997		

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

		BUTORPHANOL TARTRATE PRESERVATIVE FREE				
AP		ABBOTT	1MG/ML	N74620 001 JAN 22, 1997		
AP			1MG/ML	N74626 001 JAN 23, 1997		
AP			2MG/ML	N74620 002 JAN 22, 1997		
AP			2MG/ML	N74626 002 JAN 23, 1997		
		STADOL				
AP	+	APOTHECON	2MG/ML	N17857 004		
		STADOL PRESERVATIVE FREE				
AP	+	APOTHECON	1MG/ML	N17857 001		
AP	+		2MG/ML	N17857 002		

CARBAMAZEPINE

TABLET; ORAL

		EPITOL				
AB		LEMMON	200MG	N70541 001 SEP 17, 1986		
AB		TEVA	200MG	N70541 001 SEP 17, 1986		

TABLET, CHEWABLE; ORAL

		EPITOL				
AB		LEMMON	100MG	N73524 001 JUL 29, 1992		

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL
EPITOL

> ADD >	**AB**	TEVA	**100MG**	**N73524 001**	
> ADD				JUL 29, 1992	

CARBIDOPA; LEVODOPA

TABLET; ORAL
CARBIDOPA AND LEVODOPA

> DLT >	**AB**	LEMMON	**10MG;100MG**	**N73618 001**	
> DLT >				AUG 28, 1992	
> DLT >	**AB**		**25MG;100MG**	**N73589 001**	
> DLT >				AUG 28, 1992	
> DLT >	**AB**		**25MG;250MG**	**N73607 001**	
> DLT >				AUG 28, 1992	
> ADD >	**AB**	TEVA	**10MG;100MG**	**N73618 001**	
> ADD >				AUG 28, 1992	
> ADD >	**AB**		**25MG;100MG**	**N73589 001**	
> ADD >				AUG 28, 1992	
> ADD >	**AB**		**25MG;250MG**	**N73607 001**	
> ADD >				AUG 28, 1992	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

> DLT >	**AP**	LEMMON	**EQ 250MG BASE/VIAL**	**N63016 001**	
> DLT >				MAR 14, 1989	
> DLT >	**AP**		**EQ 500MG BASE/VIAL**	**N63016 002**	
> DLT >				MAR 14, 1989	
> DLT >	**AP**		**EQ 1GM BASE/VIAL**	**N63016 003**	
> DLT >				MAR 14, 1989	
> DLT >	**AP**		**EQ 5GM BASE/VIAL**	**N63018 001**	
> DLT >				MAR 05, 1990	
> DLT >	**AP**		**EQ 10GM BASE/VIAL**	**N63018 002**	
> DLT >				MAR 05, 1990	
> ADD >	**AP**	TEVA	**EQ 250MG BASE/VIAL**	**N63016 001**	
> ADD >				MAR 14, 1989	
> ADD >	**AP**		**EQ 500MG BASE/VIAL**	**N63016 002**	
> ADD >				MAR 14, 1989	
> ADD >	**AP**		**EQ 1GM BASE/VIAL**	**N63016 003**	
> ADD >				MAR 14, 1989	
> ADD >	**AP**		**EQ 5GM BASE/VIAL**	**N63018 001**	
> ADD >				MAR 05, 1990	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

> ADD >	**AP**	TEVA	**EQ 10GM BASE/VIAL**	**N63018 002**	
> ADD				MAR 05, 1990	

CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
OPHTHOCORT

> DLT >		+ PARKE DAVIS	10MG/GM;5MG/GM;		
> DLT >			10,000 UNITS/GM		N50201 002
> ADD >		@	10MG/GM;5MG/GM;		
> ADD >			10,000 UNITS/GM		N50201 002

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
CHLORHEXIDINE GLUCONATE

> DLT >	**AT**	LEMMON	**0.12%**	**N74522 001**	
> DLT >				DEC 15, 1995	
> ADD >	**AT**	TEVA	**0.12%**	**N74522 001**	
> ADD >				DEC 15, 1995	

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

AA		KV PHARM	**4MG**	**N87164 001**	
		@	4MG		N87164 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

> DLT >		@ LEMMON	50MG	N88651 001	
> DLT >				MAY 30, 1985	
> ADD >		@ TEVA	50MG	N88651 001	
> ADD >				MAY 30, 1985	

THALITONE

BX		HORUS THERAP	**25MG**	**N88051 001**	
				NOV 12, 1982	
		+	15MG	N19574 001	
				DEC 20, 1988	

CHLORTHALIDONE

TABLET; ORAL
THALITONE

BX	MONARCH PHARMS	25MG	N19574 002		
			FEB 12, 1992		
+		15MG	N19574 001		
			DEC 20, 1988		
@		25MG	N88051 001		
			NOV 12, 1982		

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

> DLT >	AA	LEMMON	500MG	N89859 001	
				MAY 04, 1988	
> ADD >	AA	TEVA	500MG	N89859 001	
				MAY 04, 1988	

CIMETIDINE

TABLET; ORAL
CIMETIDINE

> DLT >	AB	LEMMON	200MG	N74365 001	
				FEB 28, 1995	
> DLT >	AB		300MG	N74365 002	
				FEB 28, 1995	
> DLT >	AB		400MG	N74365 003	
				FEB 28, 1995	
> DLT >	AB		800MG	N74365 004	
				FEB 28, 1995	
> ADD >	AB	SIDMAK LABS NJ	200MG	N74568 001	
				FEB 27, 1997	
> ADD >	AB		300MG	N74568 002	
				FEB 27, 1997	
> ADD >	AB		400MG	N74568 003	
				FEB 27, 1997	
> ADD >	AB		800MG	N74566 001	
				FEB 27, 1997	
> ADD >	AB	TEVA	200MG	N74365 001	
				FEB 28, 1995	
> ADD >	AB		300MG	N74365 002	
				FEB 28, 1995	
> ADD >	AB		400MG	N74365 003	
				FEB 28, 1995	

CIMETIDINE

TABLET; ORAL
CIMETIDINE

> ADD >	AB	TEVA	800MG	N74365 004	
				FEB 28, 1995	

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
CIMETIDINE HCL

AA	PHARM ASSOC	EQ 300MG BASE/5ML	N74553 001		
			JAN 27, 1997		

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE

> DLT >	AA	LEMMON	EQ 0.5MG BASE/5ML	N73399 001	
				JUN 30, 1994	
> ADD >	AA	TEVA	EQ 0.5MG BASE/5ML	N73399 001	
				JUN 30, 1994	

TABLET; ORAL
CLEMASTINE FUMARATE

> DLT >	AB	LEMMON	2.68MG	N73283 001	
				JAN 31, 1992	
> DLT >	@		1.34MG	N73282 001	
				JAN 31, 1992	
> ADD >	AB	TEVA	2.68MG	N73283 001	
				JAN 31, 1992	
> ADD >	@		1.34MG	N73282 001	
				JAN 31, 1992	

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

> DLT >	AT	LEMMON	EQ 1% BASE	N62930 001	
				JUN 28, 1989	
> ADD >	AT	TEVA	EQ 1% BASE	N62930 001	
				JUN 28, 1989	

CROMOLYN SODIUM

AEROSOL, METERED; INHALATION
INTAL
+ FISONS 0.8MG/INH N18887 001 DEC 05, 1985
+ RHONE POULENC RORER 0.8MG/INH N18887 001 DEC 05, 1985

CAPSULE; INHALATION
INTAL
+ FISONS 20MG N16990 001
+ RHONE POULENC RORER 20MG N16990 001 > ADD > > ADD >

SOLUTION; INHALATION
INTAL
AN + FISONS 10MG/ML N18596 001 MAY 28, 1982
AN + RHONE POULENC RORER 10MG/ML N18596 001 MAY 28, 1982

SOLUTION/DROPS; OPHTHALMIC
OPTICROM
@ FISONS 4% N18155 001 OCT 03, 1984
@ RHONE POULENC RORER 4% N18155 001 OCT 03, 1984

SPRAY, METERED; NASAL
NASALCROM
+ FISONS 5.2MG/SPRAY N18306 001 MAR 18, 1983

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
AK-PENTOLATE
AT AKORN 1% N85555 001 > ADD > > ADD >
@ 1% N85555 001
AKPENTOLATE
AT AKORN 1% N40164 001 JAN 13, 1997
AT 2% N40165 001 JAN 13, 1997
CYCLOGYL
AT + ALCON 2% N84108 001 > ADD > > ADD > > ADD >

DEXTROTHYROXINE SODIUM

TABLET; ORAL
CHOLOXIN
KNOLL PHARM 1MG N12302 005
@ 1MG N12302 005

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL
AB WEST WARD 10MG N40204 001 FEB 28, 1997 > ADD > > ADD >

DIMENHYDRINATE

INJECTABLE; INJECTION
DIMENHYDRINATE
AP ELKINS SINN 50MG/ML N84767 001
@ 50MG/ML N84767 001

ECONAZOLE NITRATE

CREAM; TOPICAL
SPECTAZOLE
+ J AND J 1% N18751 001 DEC 23, 1982
+ JOHNSON RW 1% N18751 001 DEC 23, 1982

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN
AT STIEFEL 2% N64127 001 FEB 14, 1997 > ADD > > ADD >

ETODOLAC

TABLET; ORAL
ETODOLAC
AB INVAMED 400MG N74846 001 FEB 28, 1997 > ADD > > ADD > > ADD >

ETODOLAC

TABLET; ORAL

>ADD>		**ETODOLAC**			
>ADD>	**AB**	PUREPAC PHARM	**400MG**	**N74819 001**	
>ADD>				FEB 28, 1997	
>ADD>	**AB**	ZENITH GOLDLINE	**400MG**	**N74883 001**	
>ADD>				FEB 28, 1997	
		LODINE			
>ADD>	**AB**	WYETH AYERST	**400MG**	**N18922 004**	
>ADD>				JUL 29, 1993	

FLUCONAZOLE

INJECTABLE; INJECTION

	DIFLUCAN			
	+ PFIZER	200MG/100ML	N19950 001	
			JAN 29, 1990	
	DIFLUCAN IN DEXTROSE 5% IN PLASTIC CONTAINER			
	+ PFIZER	200MG/100ML	N19950 003	
			SEP 29, 1992	
	@	2MG/ML	N19950 005	
			JUL 08, 1994	
	DIFLUCAN IN SODIUM CHLORIDE 0.9%			
	+ PFIZER	200MG/100ML	N19950 001	
			JAN 29, 1990	
	DIFLUCAN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
	+ PFIZER	200MG/100ML	N19950 002	
			JAN 29, 1990	
	@	2MG/ML	N19950 004	
			JUL 08, 1994	

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

		GUANFACINE HCL			
>ADD>	**AB**	AMIDE PHARM	**EQ 1MG BASE**	**N74673 001**	
>ADD>				FEB 28, 1997	
>ADD>	**AB**		**EQ 2MG BASE**	**N74673 002**	
>ADD>				FEB 28, 1997	
	AB	MYLAN	**EQ 1MG BASE**	**N74796 001**	
				JAN 27, 1997	
	AB		**EQ 2MG BASE**	**N74796 002**	
				JAN 27, 1997	

HEPARIN SODIUM

INJECTABLE; INJECTION

>DLT>		**HEP FLUSH KIT IN PLASTIC CONTAINER**		
>DLT>	**AP**	FUJISAWA	**10 UNITS/ML**	**N17029 017**
>DLT>				DEC 05, 1985
>DLT>	**AP**		**100 UNITS/ML**	**N17029 018**
>DLT>				DEC 05, 1985
>ADD>		@	10 UNITS/ML	N17029 017
>ADD>				DEC 05, 1985
>ADD>		@	100 UNITS/ML	N17029 018
>ADD>				DEC 05, 1985
		HEPARIN SODIUM		
>ADD>	**AP**	FUJISAWA	**20,000 UNITS/ML**	**N17029 004**
	AP	STERIS	**1,000 UNITS/ML**	**N17064 002**
		@	1,000 UNITS/ML	N17064 002

>ADD> HYDROCORTISONE BUTEPRATE

CREAM; TOPICAL

>ADD>	PANDEL		
>ADD>	+ SAVAGE LABS	0.1%	N20453 001
>ADD>			FEB 28, 1997

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

		HYDROCORTISONE SODIUM SUCCINATE		
>DLT>	**AP**	ELKINS SINN	**EQ 1GM BASE/VIAL**	**N87569 001**
>ADD>		@	EQ 1GM BASE/VIAL	N87569 001

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

		HYDROXYZINE HCL			
>DLT>	**AB**	KV PHARM	**10MG**	**N87819 001**	
>DLT>				JUN 23, 1982	
>DLT>	**AB**		**25MG**	**N87820 001**	
>DLT>				JUN 23, 1982	
>DLT>	**AB**		**50MG**	**N87821 001**	
>DLT>				JUN 23, 1982	
>DLT>	**AB**		**100MG**	**N87822 001**	
>DLT>				JUN 23, 1982	
>ADD>		@	10MG	N87819 001	
>ADD>				JUN 23, 1982	

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL

> ADD >	@ KV PHARM	25MG	N87820 001	
> ADD >			JUN 23, 1982	
> ADD >	@	50MG	N87821 001	
> ADD >			JUN 23, 1982	
> ADD >	@	100MG	N87822 001	
> ADD >			JUN 23, 1982	

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HY-PAM

AB	EON	**EQ 25MG HCL**	**N87479 001**

HYDROXYZINE PAMOATE

AB	EON	**EQ 25MG HCL**	**N87479 001**

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

IDAMYCIN PFS

> ADD >	+	PHARMACIA AND UPJOHN	1MG/ML	N50734 001
> ADD >				FEB 17, 1997

> ADD > IMIQUIMOD

CREAM; TOPICAL

ALDARA

> ADD >	+	3M	5%	N20723 001
> ADD >				FEB 27, 1997

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ATROVENT

AN	+	BOEHRINGER INGELHEIM	**0.02%**	**N20228 001**
				SEP 29, 1993

IPRATROPIUM BROMIDE

AN		DEY	**0.02%**	**N74755 001**
				JAN 10, 1997

ITRACONAZOLE

SOLUTION; ORAL

SPORANOX

> ADD >	+	JANSSEN	10MG/ML	N20657 001
> ADD >				FEB 21, 1997

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

AA	VINTAGE PHARMS	**12.5MG**	**N40179 001**
			JAN 30, 1997
AA		**25MG**	**N40179 002**
			JAN 30, 1997

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION

HUMEGON

AB	+	ORGANON	**75 IU/VIAL;75 IU/VIAL**	**N20328 001**
				SEP 01, 1994
AB			**75 IU/VIAL;75 IU/VIAL**	**N20328 001**
				SEP 01, 1994
AB	+		**150 IU/VIAL;150 IU/VIAL**	**N20328 002**
				SEP 01, 1994
AB			**150 IU/VIAL;150 IU/VIAL**	**N20328 002**
				SEP 01, 1994

REPRONAL

AB		FERRING	**75 IU/VIAL;75 IU/VIAL**	**N73598 001**
				JAN 30, 1997
AB			**150 IU/VIAL;150 IU/VIAL**	**N73599 001**
				JAN 30, 1997

METHACHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; INHALATION

PROVOCHOLINE

	METHAPHARM	100MG/VIAL	N19193 001
			OCT 31, 1986
	ROCHE	100MG/VIAL	N19193 001
			OCT 31, 1986

METHOTREXATE SODIUM

INJECTABLE; INJECTION
MEXATE-AQ PRESERVED

AP	BRISTOL MYERS	**EQ 25MG BASE/ML**	**N89887 001**	
			APR 14, 1989	
	@ BRISTOL MYERS SQUIBB	EQ 25MG BASE/ML	N89887 001	
			APR 14, 1989	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

> DLT >	**AP**	FAULDING	**EQ 5MG BASE/ML**	**N71990 001**	
> DLT >				JAN 18, 1989	
> ADD >		@	EQ 5MG BASE/ML	N71990 001	
> ADD >				JAN 18, 1989	

TABLET; ORAL
METOCLOPRAMIDE HCL

AB	MUTUAL PHARM	**EQ 5MG BASE**	**N71536 002**	
			JAN 16, 1997	

METOLAZONE

TABLET; ORAL
MYKROX

	MEDEVA	0.5MG	N19532 001	
			OCT 30, 1987	
	+	0.5MG	N19532 001	
			OCT 30, 1987	

METRONIDAZOLE

GEL; VAGINAL
METROGEL-VAGINAL

	+ 3M	0.75%	N20208 001	
			AUG 17, 1992	
	+ CURATEK	0.75%	N20208 001	
			AUG 17, 1992	

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL
MEXILETINE HCL

> ADD >	**AB**	WATSON LABS	**150MG**	**N74711 001**	
> ADD >				FEB 26, 1997	
> ADD >	**AB**		**200MG**	**N74711 002**	
> ADD >				FEB 26, 1997	
> ADD >	**AB**		**250MG**	**N74711 003**	
> ADD >				FEB 26, 1997	

MICONAZOLE NITRATE

LOTION; TOPICAL
MONISTAT-DERM

	@ J AND J	2%	N17739 001
	@ JOHNSON RW	2%	N17739 001

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE AND NALOXONE HYDROCHLORIDES

AB	ROYCE LABS	**EQ 0.5MG BASE;**		
		EQ 50MG BASE	**N74736 001**	
			JAN 21, 1997	

TALWIN NX

AB	+ SANOFI WINTHROP	**EQ 0.5MG BASE;**		
		EQ 50MG BASE	**N18733 001**	
			DEC 16, 1982	

NEDOCROMIL SODIUM

AEROSOL, METERED; INHALATION
TILADE

+	FISONS	1.75MG/INH	N19660 001
			DEC 30, 1992
+	RHONE POULENC RORER	1.75MG/INH	N19660 001
			DEC 30, 1992

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING
NEO-RX

AA	PHARMA TEK	**100%**	**N61579 001**	
		100%	N61579 001	

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING
NEOMYCIN SULFATE

AA	PADDOCK	**100%**	**N62385 001**	
			JUN 01, 1982	

ONDANSETRON HYDROCHLORIDE

SOLUTION; ORAL
ZOFRAN

	+ GLAXO WELLCOME	EQ 4MG BASE/5ML	N20605 001	
			JAN 24, 1997	

OXYBUTYNIN CHLORIDE

SYRUP; ORAL
OXYBUTYNIN CHLORIDE

> ADD >	**AA** MORTON GROVE	**5MG/5ML**	**N74868 001**	
> ADD >			FEB 12, 1997	

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
OXYCONTIN

	+ PURDUE FREDERICK	10MG	N20553 001	
			DEC 12, 1995	
	+	20MG	N20553 002	
			DEC 12, 1995	
	+	40MG	N20553 003	
			DEC 12, 1995	
	+ PURDUE PHARMA	10MG	N20553 001	
			DEC 12, 1995	
	+	20MG	N20553 002	
			DEC 12, 1995	
	+	40MG	N20553 003	
			DEC 12, 1995	
	+	80MG	N20553 004	
			JAN 06, 1997	

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC
POLYTRIM

> ADD >	**AT** + ALLERGAN	**10,000 UNITS/ML;**		
> ADD >		**EQ 1MG BASE/ML**	**N50567 001**	
> ADD >			OCT 20, 1988	

TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE

> ADD >	**AT** BAUSCH AND LOMB	**10,000 UNITS/ML;**		
> ADD >		**EQ 1MG BASE/ML**	**N64120 001**	
> ADD >			FEB 14, 1997	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL
PEDIAPRED

	+ FISONS	EQ 5MG BASE/5ML	N19157 001	
			MAY 28, 1986	
	+ MEDEVA	EQ 5MG BASE/5ML	N19157 001	
			MAY 28, 1986	

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

AB	ROXANE	**40MG**	**N70518 001**	
			JUL 07, 1986	
	@	40MG	N70518 001	
			JUL 07, 1986	

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL
ELDEPRYL

AB	+ SOMERSET	**5MG**	**N20647 001**	
			MAY 15, 1996	
	+	5MG	N20647 001	
			MAY 15, 1996	

TABLET; ORAL
SELEGILINE HCL

AB	LEMMON	**5MG**	**N74744 001**	
			JAN 27, 1997	

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION

	NITROPRESS			
AP	ABBOTT	**50MG/VIAL**	**N71555 001**	
			NOV 16, 1987	
	@	50MG/VIAL	N71555 001	
			NOV 16, 1987	

SULFAMETHOXAZOLE

SUSPENSION; ORAL

>DLT>	GANTANOL			
>DLT>	+ ROCHE	500MG/5ML	N13664 002	
>ADD>	@	500MG/5ML	N13664 002	

TERFENADINE

TABLET; ORAL

	SELDANE			
AB	+ HOECHST MARION RSSL	**60MG**	**N18949 001**	
			MAY 08, 1985	
	TERFENADINE			
AB	BAKER NORTON	**60MG**	**N74475 001**	
			JAN 03, 1997	

TIOCONAZOLE

OINTMENT; VAGINAL

>DLT>	VAGISTAT-1			
>DLT>	+ BRISTOL MYERS	6.5%	N19355 001	
>DLT>			DEC 30, 1986	

TOLMETIN SODIUM

TABLET; ORAL

	TOLMETIN SODIUM			
>ADD> **AB**	LEMMON	**EQ 600MG BASE**	**N74729 001**	
>ADD>			FEB 27, 1997	

TOPIRAMATE

TABLET; ORAL

	TOPAMAX			
	@ JOHNSON RW	400MG	N20505 006	
			DEC 24, 1996	

TRETINOIN

CREAM; TOPICAL

	AVITA			
AB	PENEDERM	**0.025%**	**N20404 003**	
			JAN 14, 1997	
	RETIN-A			
AB	+ J AND J	**0.025%**	**N19049 001**	
			SEP 16, 1988	

GEL; TOPICAL

>ADD>	RETIN-A MICRO			
>ADD>	+ ADV POLYMER	0.1%	N20475 001	
>ADD>			FEB 07, 1997	

TROGLITAZONE

TABLET; ORAL

	PRELAY			
AB	SANKYO	**200MG**	**N20719 001**	
			JAN 29, 1997	
AB		**400MG**	**N20719 002**	
			JAN 29, 1997	
	REZULIN			
AB	PARKE DAVIS	**200MG**	**N20720 001**	
			JAN 29, 1997	
AB		**400MG**	**N20720 002**	
			JAN 29, 1997	

VINCRISTINE SULFATE

INJECTABLE; INJECTION

	VINCREX			
AP	+ BRISTOL MYERS	**5MG/VIAL**	**N70867 001**	
			JUL 12, 1988	
	@ BRISTOL MYERS SQUIBB	5MG/VIAL	N70867 001	
			JUL 12, 1988	
	VINCRISTINE SULFATE			
AP	FAULDING	**5MG/VIAL**	**N71561 001**	
			APR 11, 1988	

VINCRISTINE SULFATE

INJECTABLE; INJECTION			
VINCRISTINE SULFATE			
+ FAULDING	5MG/VIAL	N71561 001	
		APR 11, 1988	

ZINC ACETATE

CAPSULE; ORAL			
GALZIN			
LEMMON	EQ 25MG ZINC	N20458 001	
		JAN 28, 1997	
+	EQ 50MG ZINC	N20458 002	
		JAN 28, 1997	

CLEMASTINE FUMARATE

TABLET; ORAL
CLEMASTINE FUMARATE

>DLT<	LEMMON	1.34MG	N73282 002	
>DLT<			DEC 03, 1992	
>ADD<	TEVA	1.34MG	N73282 002	
>ADD<			DEC 03, 1992	

CROMOLYN SODIUM

SPRAY, METERED; NASAL
NASALCROM

+	MCNEIL	5.2MG/SPRAY	N20463 001	
			JAN 03, 1997	

IBUPROFEN

TABLET; ORAL
JUNIOR STRENGTH MOTRIN

	MCNEIL	100MG	N20602 001
			JUN 10, 1996
+		100MG	N20602 001
			JUN 10, 1996

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE

	TARO	2%	N74444 001
			JAN 13, 1997

MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)

>ADD<	MORTON GROVE	2%	N74767 001
>ADD<			FEB 28, 1997

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

	INVAMED	EQ 200MG BASE	N74646 001
			JAN 13, 1997

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM

	NOVOPHARM	EQ 200MG BASE	N74635 001
			JAN 13, 1997
	PERRIGO	EQ 200MG BASE	N74661 001
			JAN 13, 1997
>ADD<	PVT FORM	EQ 200MG BASE	N74789 001
>ADD<			FEB 27, 1997

>ADD< TIOCONAZOLE

>ADD< OINTMENT; VAGINAL
>ADD< VAGISTAT-1

>ADD<	+ BRISTOL MYERS SQUIBB	6.5%	N20676 001
>ADD<			FEB 11, 1997

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 2/ FEB '97

NO FEBRUARY 1997 APPROVALS

Orphan Product Designations and Approvals List
January 1, 1997 thru February, 1997

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
9-cis-retinoic acid TN=	Prevention of retinal detachment due to proliferative vitreoretinopathy.	Allergan 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92623 DD=01/02/97 MA= / /
Coagulation Factor IX (recombinant) TN= BeneFix	Treatment of hemophilia B.	Genetics Institute, Inc. 87 Cambridge Park Drive Cambridge, MA 02140 DD=10/03/94 MA=02/11/97
Dehydroepiandrosterone sulfate sodium TN=	To accelerate the re-epithelialization of donor sites in those hospitalized burn patients who must undergo autologous skin grafting.	Pharmadigm, Inc. 2401 Foothill Drive Salt Lake City, UT 84109 DD=01/28/97 MA= / /
Dehydroepiandrosterone sulfate sodium TN=	Treatment of serious burns requiring hospitalization.	Pharmadigm, Inc. 2401 Foothill Drive Salt Lake City, UT 84109 DD=01/29/97 MA= / /
Enadoline hydrochloride TN=	Treatment of severe head injury.	Warner-Lambert Company Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor, MI 48105 DD=01/28/97 MA= / /
Lepirudin TN= Refludan	Treatment of heparin-associated thrombocytopenia Type II.	Behringwerke AG P.O. Box 1140 D-35001 Marburg Germany, DD=02/13/97 MA= / /

Orphan Product Designations and Approvals List
January 1, 1997 thru February, 1997

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Patul-end TN=	Treatment of patulous eustachian tube.	The Ear Foundation 24209 Castillo Street, Suite. 100 Santa Barbara, CA 93105 DD=02/18/97 MA= / /
Zinc acetate TN= Galzin	Treatment of Wilson's disease.	Lemmon Company 1510 Delp Drive Kulpsville, PA 19443 DD=11/06/85 MA=01/28/97

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

NO FEBRUARY 1997 ADDITIONS

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 17TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW INDICATION

I-177	TREATMENT OF MODERATE ACNE VULGARIS IN FEMALES, GREATER OR EQUAL TO 15 YEARS OF AGE, WHO HAVE NO KNOWN CONTRAINDICATIONS TO ORAL CONTRACEPTIVE THERAPY, DESIRE CONTRACEPTION, HAVE ACHIEVED MENARCHE AND ARE UNRESPONSIVE TO TOPICAL ANTI-ACNE MEDICATIONS
I-178	TREATMENT OF ONCHOMYCOSIS OF THTE FINGERNAIL WITHOUT CONCOMITANT ONCHOMYCOSIS OF THE TOENAIL WITH A PULSE DOSING REGIMEN
I-179	NOSOCOMIAL PNEUMONIA-MILD TO MODERATE AND SEVERE CAUSED BY HAEMOPHILUS INFLUENZAE OR KLEBSIELLA PNEUMONIAE
I-180	TREATMENT OF PLANTAR TINEA PEDIS (MOCCASIN TYPE)
I-181	TREATMENT OF PATIENTS WITH COMPLEX PARTIAL SEIZURES WITH AND WITHOUT SECONDARY GENERALIZATION
I-182	TREATMENT OF GROWTH FAILURE ASSOCIATED WITH TURNER SYNDROME

PATENT USE CODE

U-161	METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS IN A PATIENT
U-162	METHOD OF USE TO INHIBIT CHOLESTEROL SYNTHESIS IN A HUMAN SUFFERING FROM HYPERCHOLESTEROLEMIA
U-163	METHOD OF USING TROGLITAZONE TO TREAT IMPAIRED GLUCOSE TOLERANCE TO PREVENT OR DELAY THE ONSET OF NONINSULIN-DEPENDENT DIABETES MELLITUS
U-164	METHOD OF USING TROGLITAZONE TO PREVENT OR DELAY THE ONSET OF NONINSULIN-DEPENDENT DIABETES MELLITUS IN A DEFINED POPULATION OF PATIENTS
U-165	TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA
U-166	TREATMENT OF H. PYLORI ASSOCIATED DUODENAL ULCER
U-167	METHOD FOR TREATING HIV-1 INFECTION
U-168	METHOD OF INHIBITING LIPOXYGENASE ACTIVITY IN A MAMMAL WHICH IS THE MODE OF ACTION IN THE TREATMENT OF ASTHMA
U-169	METHODS OF USING THE COMPOUND/DRUG PRODUCT AS A CONTRAST AGENT IN MAGNETIC RESONANCE IMAGING
U-170	METHOD OF OBTAINING AN MR IMAGE USING THE COMPOSITION/DRUG PRODUCT AS A CONTRAST AGENT
U-171	METHODS OF USING THE COMPOUND/DRUG PRODUCT AS AN ORAL CONTRAST AGENT IN MAGNETIC RESONANCE IMAGING OF THE GASTROINTESTINAL TRACT
U-172	TREATMENT OF GENITAL WARTS
U-173	ADMINISTRATION TO A HOST SUFFERING FROM GESTATIONAL DIABETES
U-174	USE AS AN ANTIHISTAMINE AGENT

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20291 001	ALBUTEROL SULFATE; COMBIVENT	5603918	JUN 09, 2015		NC	OCT 24, 1999
	20503 001	ALBUTEROL SULFATE; PROVENTIL-HFA	5225183	JUL 06, 2010		NP	AUG 15, 1999
>ADD>			5439670	JUL 06, 2010			
>ADD>			5605674	FEB 25, 2014			
	20702 001	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
			5273995	DEC 28, 2010	U-162		
	20702 002	ATORVASTATIN CALCIUM; LIPITOR	4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
			5385929	MAY 04, 2014	U-59		
			5273995	DEC 28, 2010	U-162		
	20702 003	ATORVASTATIN CALCIUM; LIPITOR	4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
			5385929	MAY 04, 2014	U-59		
			5273995	DEC 28, 2010	U-162		
	20486 001	BECLOMETHASONE DIPROPIONATE; VANCERIL DOUBLE STRENGTH	4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
						NP	DEC 24, 1999
	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
>ADD>	19881 001	BUTOCONAZOLE NITRATE; FEMSTAT ONE	4078071	MAR 07, 1997		NP	FEB 07, 2000
	20664 001	CABERGOLINE; DOSTINEX	4526892	JUL 02, 2002		NCE	DEC 23, 2001
	20554 001	CALCIPOTRIENE; DOVONEX				NCE	DEC 29, 1998
	19847 001	CIPROFLOXACIN; CIPRO	4705789	NOV 10, 2004		I-179	OCT 21, 1999
	19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4808583	FEB 28, 2006		I-179	OCT 21, 1999
	19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4705789	NOV 10, 2004		I-179	OCT 21, 1999
	20463 001	CROMOLYN SODIUM; NASALCROM				NP	JAN 03, 2000
>ADD>	20430 001	DANAPAROID SODIUM; ORGARAN	5164377	OCT 03, 2010			
>ADD>	20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 03, 2007			
>ADD>			4829088	APR 14, 2007			
	18723 001	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
	18723 002	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
	18723 003	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
	19680 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008		I-181	JUN 20, 1999
	20417 001	ESTRADIOL; FEMPATCH	5006342	APR 09, 2008			
			4906463	MAR 06, 2007		NP	DEC 03, 1999
	19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
	19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
	18922 005	ETODOLAC; LODINE				I-24	JUN 28, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20410 001	FERUMOXSIL; GASTROMARK	5219554	JUN 15, 2010			
			5069216	MAY 09, 2006	U-171	NCE	DEC 06, 2001
			5055288	OCT 08, 2008			
			4951675	SEP 13, 2005	U-169		
			4827945	MAY 09, 2006	U-170		
			4770183	SEP 13, 2005	U-169		
			4695393	SEP 22, 2004			
			4695392	SEP 22, 2004			
>ADD>	20235 001	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000			
>ADD>	20235 002	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000			
>ADD>	20235 003	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000			
	20622 001	GLATIRAMER ACETATE; COPAXONE				ODE	DEC 20, 2003
	20329 001	GLIPIZIDE; GLUCOTROL XL	5591454	JAN 07, 2014	U-150		
	20329 002	GLIPIZIDE; GLUCOTROL XL	5591454	JAN 07, 2014	U-150		
	20267 002	IBUPROFEN; JUNIOR STRENGTH ADVIL				NP	JUN 16, 1998
>ADD>	20723 001	IMIQUIMOD; ALDARA	4689338	AUG 25, 2004	U-172	NCE	FEB 27, 2002
>ADD>			5238944	AUG 24, 2010			
	20083 001	ITRACONAZOLE; SPORANOX				I-178	DEC 06, 1999
>ADD>	20657 001	ITRACONAZOLE; SPORANOX				NDF	FEB 21, 2000
	20641 001	LORATADINE; CLARITIN	4659716	APR 21, 2004	U-142		
	20704 001	LORATADINE; CLARITIN REDITABS	4659716	APR 21, 2004	U-142		
			4282233	JUN 19, 2002	U-77	NCE	APR 12, 1998
	20636 001	NEVIRAPINE; VIRAMUNE	5366972	NOV 22, 2011	U-167	NCE	JUN 21, 2001
>ADD>	20688 001	OLOPATADINE HYDROCHLORIDE; PATANOL	4871865	OCT 03, 2006			
>ADD>			4923892	MAY 08, 2007	U-174		
>ADD>			5116863	MAY 26, 2009			
	19810 001	OMEPRAZOLE; PRILOSEC	5599794	FEB 04, 2014	U-166		
			5093342	FEB 02, 2010	U-166		
			4636499	MAY 30, 2005			
	19810 003	OMEPRAZOLE; PRILOSEC	5599794	FEB 04, 2014	U-166		
			5093342	FEB 02, 2010	U-166		
			4636499	MAY 30, 2005			
	20605 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	5578628	JUN 24, 2006	U-44		
	20031 001	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
	20031 002	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
	20031 003	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
	20031 004	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
	20031 005	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
	19627 002	PROPOFOL; DIPRIVAN				NP	JUN 11, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20168 001	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				ODE	DEC 30, 2003
>ADD>						I-182	DEC 30, 1999
	20168 002	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				ODE	DEC 30, 2003
>ADD>						I-182	DEC 30, 1999
	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
			5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
			5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
			5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
			5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
			5294615	APR 29, 2013	U-3		
	20192 001	TERBINAFINE HYDROCHLORIDE; LAMISIL				I-180	JAN 21, 2000
>ADD>	20676 001	TIOCONAZOLE; VAGISTAT-1				NP	FEB 11, 2000
>ADD>	20475 001	TRETINOIN; RETIN-A MICRO				NP	FEB 07, 2000
	20719 001	TROGLITAZONE; PRELAY	5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
			5104888	AUG 28, 2004			
>ADD>			5602133	SEP 15, 2013	U-173		
	20719 002	TROGLITAZONE; PRELAY	5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
			5104888	AUG 28, 2004			
>ADD>			5602133	SEP 15, 2013	U-173		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	20720 001	TROGLITAZONE; REZULIN	5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
			5104888	AUG 28, 2004			
>ADD>			5602133	SEP 15, 2013	U-173		
	20720 002	TROGLITAZONE; REZULIN	5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
			5104888	AUG 28, 2004			
>ADD>			5602133	SEP 15, 2013	U-173		
>ADD>	20665 001	VALSARTAN; DIOVAN	5399578	MAR 21, 2012	U-3		
>ADD>	20665 002	VALSARTAN; DIOVAN	5399578	MAR 21, 2012	U-3		
	20471 001	ZILEUTON; ZYFLO	4873259	FEB 10, 2007	U-168		
	20471 003	ZILEUTON; ZYFLO	4873259	FEB 10, 2007	U-168		
	20458 001	ZINC ACETATE; GALZIN				NP	JAN 28, 2000
>ADD>						ODE	JAN 28, 2004
	20458 002	ZINC ACETATE; GALZIN				NP	JAN 28, 2000
>ADD>						ODE	JAN 28, 2004

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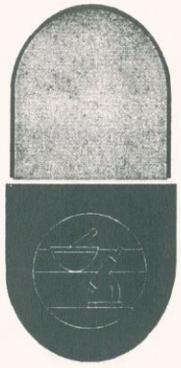

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