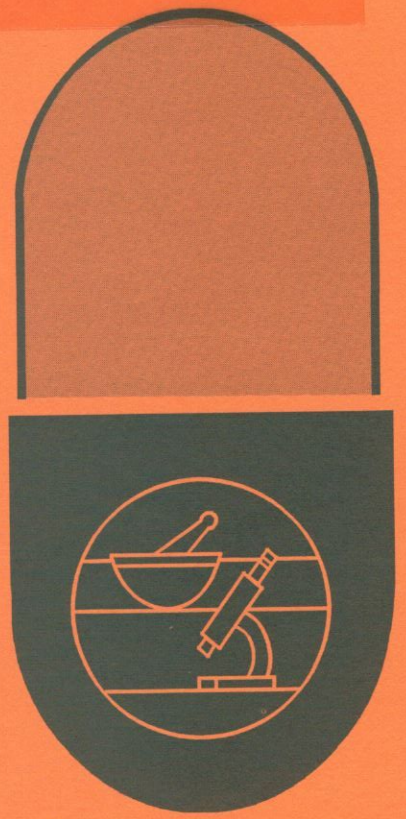
CUMULATIVE SUPPLEMENT 3
JAN'97-MAR'97



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

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

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

Cumulative Supplement 3

MARCH 1997

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

CUMULATIVE SUPPLEMENT 3
MARCH 1997

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

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	9493		
SINGLE SOURCE	2383 (25.4%)	2387 (25.1%)		
MULTISOURCE	6905 (73.5%)	6991 (73.7%)		
THERAPEUTICALLY EQUIVALENT	6463 (68.8%)	6549 (69.0%)		
NOT THERAPEUTICALLY EQUIVALENT	442 (4.7%)	442 (4.7%)		
EXCEPTIONS[1]	104 (1.1%)	115 (1.2%)		
NEW MOLECULAR ENTITIES APPROVED	--	6		
NUMBER OF APPLICANTS	650	662		

[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
AA	WATSON LABS	500MG;10MG	N40148 002	FEB 14, 1997
	LORTAB			
AA	+ GRAHAM DM	500MG;10MG	N40100 001	JAN 26, 1996
	NORCO			
	+ WATSON LABS	325MG;10MG	N40148 001	FEB 14, 1997

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

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

ACETIC ACID, GLACIAL; DESONIDE

SOLUTION/DROPS; OTIC
TRIDESILON

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

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

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

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

INJECTABLE; INJECTION
CLINIMIX E 2.75/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER

+	BAXTER HLTHCARE	2.75%;33MG/100ML;10GM/100ML; 51MG/100ML;261MG/100ML;217MG/100ML; 112MG/100ML	N20678 002 MAR 26, 1997

CLINIMIX E 2.75/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER

+	BAXTER HLTHCARE	2.75%;33MG/100ML;25GM/100ML; 51MG/100ML;261MG/100ML;217MG/100ML; 112MG/100ML	N20678 005 MAR 26, 1997

CLINIMIX E 2.75/5 SULFITE-FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER

+	BAXTER HLTHCARE	2.75%;33MG/100ML;5GM/100ML; 51MG/100ML;261MG/100ML;217MG/100ML; 112MG/100ML	N20678 001 MAR 26, 1997

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

>ADD> INJECTABLE; INJECTION
>ADD> CLINIMIX E 4.25/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 4.25%;33MG/100ML;10GM/100ML;
>ADD> 51MG/100ML;261MG/100ML;297MG/100ML;
>ADD> 77MG/100ML N20678 009
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 4.25/20 SULFITE-FREE W/ ELECT IN DEXTROSE 20% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 4.25%;33MG/100ML;20GM/100ML;
>ADD> 51MG/100ML;261MG/100ML;297MG/100ML;
>ADD> 77MG/100ML N20678 011
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 4.25/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 4.25%;33MG/100ML;25GM/100ML;
>ADD> 51MG/100ML;261MG/100ML;297MG/100ML;
>ADD> 77MG/100ML N20678 012
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 4.25/5 SULFITE-FREE W/ ELECT IN DEXTROSE 5% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 4.25%;33MG/100ML;5GM/100ML;
>ADD> 51MG/100ML;261MG/100ML;297MG/100ML;
>ADD> 77MG/100ML N20678 008
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 5/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 5%;33MG/100ML;10GM/100ML;51MG/100ML;
>ADD> 261MG/100ML;340MG/100ML;
>ADD> 59MG/100ML N20678 016
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 5/15 SULFITE-FREE W/ ELECT IN DEXTROSE 15% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 5%;33MG/100ML;15GM/100ML;51MG/100ML;
>ADD> 261MG/100ML;340MG/100ML;
>ADD> 59MG/100ML N20678 017
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 5/20 SULFITE-FREE W/ ELECT IN 20% DEXTROSE W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 5%;33MG/100ML;20GM/100ML;51MG/100ML;
>ADD> 261MG/100ML;340MG/100ML;
>ADD> 59MG/100ML N20678 018
>ADD> MAR 26, 1997

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

>ADD> INJECTABLE; INJECTION
>ADD> CLINIMIX E 5/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 5%;33MG/100ML;25GM/100ML;51MG/100ML;
>ADD> 261MG/100ML;340MG/100ML;
>ADD> 59MG/100ML N20678 019
>ADD> MAR 26, 1997
>ADD> CLINIMIX E 5/35 SULFITE FREE W/ ELECT IN DEXTROSE 35% W/
>ADD> CALCIUM IN PLASTIC CONTAINER
>ADD> + BAXTER HLTHCARE 5%;33MG/100ML;35GM/100ML;51MG/100ML;
>ADD> 261MG/100ML;340MG/100ML;
>ADD> 59MG/100ML N20678 021
>ADD> MAR 26, 1997

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

		LIMBITROL		
AB	+	ROCHE	**EQ 25MG BASE;10MG**	**N16949 002**
		LIMBITROL DS		
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

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**

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

	AMOXIL			
AB	SMITHKLINE BEECHAM	50MG/ML	N62226 005	
AB	+	50MG/ML	N62226 005	
	@	125MG/5ML	N50460 001	
	@	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

> ADD > ANAGRELIDE HYDROCHLORIDE

> ADD > CAPSULE; ORAL

> ADD > AGRYLIN

> ADD >	ROBERTS LABS	EQ 0.5MG BASE	N20333 001 MAR 14, 1997
> ADD >	+	EQ 1MG BASE	N20333 002 MAR 14, 1997

ATRACURIUM BESYLATE

INJECTABLE; INJECTION

	ATRACURIUM BESYLATE		
AP	ABBOTT	10MG/ML	N74633 001 DEC 23, 1996
> ADD > AP	FAULDING	10MG/ML	N74740 001 MAR 28, 1997
AP	OHMEDA	10MG/ML	N74753 001 JAN 23, 1997
	ATRACURIUM BESYLATE PRESERVATIVE FREE		
AP	ABBOTT	10MG/ML	N74633 001 DEC 23, 1996
> ADD > AP		10MG/ML	N74639 001 MAR 25, 1997
> ADD > AP	FAULDING	10MG/ML	N74741 001 MAR 28, 1997

ATRACURIUM BESYLATE

INJECTABLE; INJECTION

	ATRACURIUM BESYLATE PRESERVATIVE FREE		
AP	OHMEDA	10MG/ML	N74768 001 JAN 23, 1997
	TRACRIUM		
AP	+ GLAXO WELLCOME	10MG/ML	N18831 001 NOV 23, 1983
AP	+	10MG/ML	N18831 002 JUN 20, 1985
	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

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC

	ALPHAGAN		
> ADD >	+ ALLERGAN	0.5%	N20490 001 MAR 13, 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

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

BUTORPHANOL TARTRATE PRESERVATIVE FREE

AP		ABBOTT	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

CALCIPOTRIENE

SOLUTION; TOPICAL

DOVONEX

> ADD >		+ BRISTOL MYERS SQUIBB	0.005%	N20611 001 MAR 03, 1997

CAPTOPRIL

TABLET; ORAL

CAPOTEN

> DLT >	AB	+	BRISTOL MYERS SQUIBB	25MG	N18343 002
> ADD >	AB			25MG	N18343 002

CAPTOPRIL

> ADD >	AB		PUREPAC PHARM	12.5MG	N74640 001 MAR 31, 1997
> ADD >	AB			25MG	N74640 002 MAR 31, 1997
> ADD >	AB			50MG	N74640 003 MAR 31, 1997
> ADD >	AB			100MG	N74640 004 MAR 31, 1997
> ADD >	AB		WOCKHARDT	12.5MG	N74532 001 MAR 28, 1997
> ADD >	AB			25MG	N74532 002 MAR 28, 1997
> ADD >	AB			50MG	N74532 003 MAR 28, 1997
> ADD >	AB			100MG	N74532 004 MAR 28, 1997

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
AB	TEVA	100MG	N73524 001 JUL 29, 1992

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

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

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

> ADD >	AA	AMIDE PHARM	350MG	N40188 001 MAR 07, 1997

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP	LEMMON	EQ 250MG BASE/VIAL	N63016 001 MAR 14, 1989

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

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

CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
OPHTHOCORT

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

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
CHLORHEXIDINE GLUCONATE

AT	LEMMON	0.12%	N74522 001 DEC 15, 1995
AT	TEVA	0.12%	N74522 001 DEC 15, 1995

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

AA	KV PHARM	4MG	N87164 001

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

@	KV PHARM	4MG	N87164 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

@	LEMMON	50MG	N88651 001 MAY 30, 1985
@	TEVA	50MG	N88651 001 MAY 30, 1985

THALITONE

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

AA	LEMMON	500MG	N89859 001 MAY 04, 1988
AA	TEVA	500MG	N89859 001 MAY 04, 1988

CIMETIDINE

TABLET; ORAL
CIMETIDINE

AB	LEMMON	200MG	N74365 001 FEB 28, 1995
AB		300MG	N74365 002 FEB 28, 1995
AB		400MG	N74365 003 FEB 28, 1995

CIMETIDINE

TABLET; ORAL
CIMETIDINE

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

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

> ADD >	**AP**	SANOFI	**EQ 300MG BASE/2ML**	**N74296 001**	MAR 28, 1997
> ADD >	**AP**		**EQ 300MG BASE/2ML**	**N74412 001**	MAR 28, 1997

SOLUTION; ORAL
CIMETIDINE HCL

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

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE

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

CLEMASTINE FUMARATE

TABLET; ORAL
CLEMASTINE FUMARATE

AB	LEMMON	**2.68MG**	**N73283 001**	**JAN 31, 1992**
	@	1.34MG	**N73282 001**	**JAN 31, 1992**
AB	TEVA	**2.68MG**	**N73283 001**	JAN 31, 1992
	@	1.34MG	N73282 001	JAN 31, 1992

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

AT	LEMMON	**EQ 1% BASE**	**N62930 001**	**JUN 28, 1989**
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	

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**

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
OPTICROM
@ 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**
@ 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**

DEXAMETHASONE SODIUM PHOSPHATE

> DLT > > DLT > > DLT > > ADD >
CREAM; TOPICAL
DECADRON
+ MERCK SHARP DOHME EQ 0.1% PHOSPHATE N11983 002
@ EQ 0.1% PHOSPHATE N11983 002

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

DIMENHYDRINATE

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

DOXAZOSIN MESYLATE

TABLET; ORAL
CARDURA
> DLT > > DLT > > DLT > > DLT > > ADD > > ADD > > ADD > > ADD >
PFIZER EQ 1MG BASE N19668 001 NOV 02, 1990
+ EQ 8MG BASE N19668 004 NOV 02, 1990
+ EQ 1MG BASE N19668 001 NOV 02, 1990
EQ 8MG BASE N19668 004 NOV 02, 1990

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

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
> ADD > > ADD > > ADD >
ALESSE
+ WYETH AYERST 0.02MG;0.1MG N20683 001 MAR 27, 1997

TABLET; ORAL-28
> ADD > > ADD > > ADD >
ALESSE
WYETH AYERST 0.02MG;0.1MG N20683 002 MAR 27, 1997

ETODOLAC

TABLET; ORAL

	ETODOLAC		
AB	INVAMED	400MG	N74846 001 FEB 28, 1997
AB	PUREPAC PHARM	400MG	N74819 001 FEB 28, 1997
AB	ZENITH GOLDLINE	400MG	N74883 001 FEB 28, 1997
	LODINE		
AB	WYETH AYERST	400MG	N18922 004 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		
AB	AMIDE PHARM	EQ 1MG BASE	N74673 001 FEB 28, 1997
AB		EQ 2MG BASE	N74673 002 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

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

HYDROCORTISONE BUTEPRATE

CREAM; TOPICAL

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

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

	HYDROCORTISONE SODIUM SUCCINATE		
AP	ELKINS SINN	EQ 1GM BASE/VIAL	N87569 001
@		EQ 1GM BASE/VIAL	N87569 001

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

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

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

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

INDAPAMIDE

TABLET; ORAL

	INDAPAMIDE			
> ADD > **AB**	MYLAN	**1.25MG**	**N74461 002**	> DLT >
> ADD >			MAR 26, 1997	> ADD >

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

LEUCOVORIN CALCIUM

TABLET; ORAL

	LEUCOVORIN CALCIUM			
AB	PHARMACHEMIE	**EQ 5MG BASE**	**N73099 001**	
			MAR 28, 1997	
AB		**EQ 25MG BASE**	**N73101 001**	
			MAR 28, 1997	

LEUPROLIDE ACETATE

INJECTABLE; INJECTION

	LUPRON DEPOT-3			
+	TAP HOLDINGS	11.25MG/VIAL	N20708 001	
			MAR 07, 1997	

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL

	LITHOBID			
	SOLVAY	300MG	N18027 001	
+		300MG	N18027 001	

LORAZEPAM

SOLUTION; ORAL
LORAZEPAM
+ ROXANE — 0.5MG/5ML — N74648 001 MAR 18, 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

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL
AA ROXANE — 50MG — N40110 001 MAR 12, 1997
AA — 100MG — N40110 002 MAR 12, 1997

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE
AA JVL — 10MG/5ML — N74702 001 MAR 24, 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
AP FAULDING — EQ 5MG BASE/ML — N71990 001 JAN 18, 1989
@ — EQ 5MG BASE/ML — N71990 001 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

METOLAZONE

TABLET; ORAL
MYKROX
+ MEDEVA 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
AB WATSON LABS **150MG** **N74711 001** FEB 26, 1997 >ADD>
AB **200MG** **N74711 002** FEB 26, 1997 >ADD>
AB **250MG** **N74711 003** FEB 26, 1997 >ADD>
>ADD>
>ADD>
>ADD>
>ADD>

MICONAZOLE NITRATE

LOTION; TOPICAL
MONISTAT-DERM
@ J AND J 2% N17739 001
@ JOHNSON RW 2% N17739 001

MIRTAZAPINE

TABLET; ORAL
REMERON
>DLT> + ORGANON 30MG N20415 002 JUN 14, 1996
>DLT>
>ADD> 30MG N20415 002 JUN 14, 1996
>ADD>
>ADD> + 45MG N20415 003 MAR 17, 1997
>ADD>

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

NELFINAVIR MESYLATE

POWDER FOR RECONSTITUTION; ORAL
VIRACEPT
+ AGOURON EQ 50MG BASE/SCOOPFUL N20778 001 MAR 14, 1997

TABLET; ORAL
VIRACEPT
+ AGOURON EQ 250MG BASE N20779 001 MAR 14, 1997

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING
NEO-RX
AA PHARMA TEK **100%** **N61579 001**
100% N61579 001

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
AA MORTON GROVE — **5MG/5ML** — **N74868 001** 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

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL
> ADD > **AA** KING PHARMS — **30MG** — **N40083 001** MAR 07, 1997

PODOFILOX

> ADD > GEL; TOPICAL
> ADD > CONDYLOX
> ADD > + OCLASSEN — 0.5% — N20529 001 MAR 13, 1997

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC
POLYTRIM
AT + ALLERGAN — **10,000 UNITS/ML; EQ 1MG BASE/ML** — **N50567 001** OCT 20, 1988

TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE
AT BAUSCH AND LOMB — **10,000 UNITS/ML; EQ 1MG BASE/ML** — **N64120 001** 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

> ADD > SAMARIUM SM 153 LEXIDRONAM PENTASODIUM

> ADD > INJECTABLE; INJECTION
> ADD > QUADRAMET
> ADD > CYTOGEN — 50mCi/ML — N20570 001 MAR 28, 1997

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL
ELDEPRYL
AB + SOMERSET — **5MG** — **N20647 001** MAY 15, 1996
+ — 5MG — N20647 001 MAY 15, 1996

SELEGILINE HYDROCHLORIDE

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
GANTANOL

+	ROCHE	500MG/5ML	N13664 002	
@		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

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION
THALLOUS CHLORIDE TL 201

> DLT >	AP	DUPONT	1mCi/ML	N17806 001	
> ADD >	AP	+	1mCi/ML	N17806 001	
> DLT >	AP	MALLINCKRODT	1mCi/ML	N18150 001	
> ADD >	AP	+	1mCi/ML	N18150 001	
> ADD >	AP	+ MEDI PHYSICS	1mCi/ML	N18110 002	FEB 27, 1996
> ADD >					
> DLT >			1mCi/ML	N18110 002	FEB 27, 1996
> DLT >					

> ADD > TILUDRONATE DISODIUM

TABLET; ORAL
SKELID

> ADD >	+ SANOFI	EQ 200MG BASE	N20707 001	MAR 07, 1997

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

> ADD >	AT	ADV REMEDIES	EQ 0.25% BASE	N74465 001	MAR 25, 1997
> ADD >	AT		EQ 0.5% BASE	N74466 001	MAR 25, 1997
> ADD >	AT	AKORN	EQ 0.25% BASE	N74515 001	MAR 25, 1997
> ADD >	AT		EQ 0.5% BASE	N74516 001	MAR 25, 1997
> ADD >	AT	BAUSCH AND LOMB	EQ 0.25% BASE	N74778 001	MAR 25, 1997
> ADD >	AT		EQ 0.5% BASE	N74776 001	MAR 25, 1997
> ADD >	AT	FOUGERA	EQ 0.25% BASE	N74667 001	MAR 25, 1997
> ADD >	AT		EQ 0.5% BASE	N74668 001	MAR 25, 1997
> ADD >	AT	PACIFIC PHARMA	EQ 0.25% BASE	N74746 001	MAR 25, 1997
> ADD >	AT		EQ 0.5% BASE	N74747 001	MAR 25, 1997

TIOCONAZOLE

OINTMENT; VAGINAL
VAGISTAT-1

+	BRISTOL MYERS	6.5%	N19355 001	DEC 30, 1986

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM

AB	LEMMON	EQ 600MG BASE	N74729 001	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

	RETIN-A MICRO			
	+ ADV POLYMER	0.1%	N20475 001	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

WARFARIN SODIUM

TABLET; ORAL

	COUMADIN				
> ADD >	AB DUPONT MERCK	1MG	**N09218 022**	MAR 01, 1990	
> ADD >	AB +	2MG	**N09218 013**		
> ADD >	AB	2.5MG	**N09218 018**		
> ADD >	AB	4MG	**N09218 023**	AUG 24, 1993	
> ADD >	AB	5MG	**N09218 007**		
> ADD >	AB	7.5MG	**N09218 016**		
> ADD >	AB +	10MG	**N09218 005**		
	WARFARIN SODIUM				
> ADD >	AB BARR	1MG	**N40145 001**	MAR 26, 1997	
> ADD >	AB	2MG	**N40145 002**	MAR 26, 1997	
> ADD >	AB	2.5MG	**N40145 003**	MAR 26, 1997	
> ADD >	AB	4MG	**N40145 004**	MAR 26, 1997	
> ADD >	AB	5MG	**N40145 005**	MAR 26, 1997	
> ADD >	AB	7.5MG	**N40145 006**	MAR 26, 1997	
> ADD >	AB	10MG	**N40145 007**	MAR 26, 1997	

ZINC ACETATE

CAPSULE; ORAL

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

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

>_DLT_>	COLD CAPSULE IV				
>_DLT_>	+ GRAHAM DM	12MG;75MG	N18793 001 APR 25, 1985	>_ADD_>	
>_DLT_>				>_ADD_>	
>_ADD_>	@	12MG;75MG	N18793 001 APR 25, 1985		
>_ADD_>					
>_DLT_>	COLD CAPSULE V				
>_DLT_>	GRAHAM DM	8MG;75MG	N18794 001 APR 23, 1985		
>_DLT_>					
>_ADD_>	@	8MG;75MG	N18794 001 APR 23, 1985		
>_ADD_>					

CLEMASTINE FUMARATE

TABLET; ORAL

CLEMASTINE FUMARATE			
LEMMON	1.34MG	N73282 002 DEC 03, 1992	
TEVA	1.34MG	N73282 002 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	

MICONAZOLE NITRATE

SUPPOSITORY; VAGINAL

MICONAZOLE NITRATE			
+ PERRIGO	100MG	N74395 001 MAR 20, 1997	

MINOXIDIL

SOLUTION; TOPICAL

MINOXIDIL (FOR MEN)			
MORTON GROVE	2%	N74767 001 FEB 28, 1997	

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM			
INVAMED	EQ 200MG BASE	N74646 001 JAN 13, 1997	
NOVOPHARM	EQ 200MG BASE	N74635 001 JAN 13, 1997	
PERRIGO	EQ 200MG BASE	N74661 001 JAN 13, 1997	
PVT FORM	EQ 200MG BASE	N74789 001 FEB 27, 1997	

TIOCONAZOLE

OINTMENT; VAGINAL

VAGISTAT-1			
+ BRISTOL MYERS SQUIBB	6.5%	N20676 001 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 3/ MAR '97

NO MARCH APPROVALS

Orphan Product Designations and Approvals List
January 1997 through March 1997

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
8 Cyclopentyl 1,3-dipropylxanthine TN=	Treatment of cystic fibrosis.	SciClone Pharmaceuticals, Inc. 901 Mariner's Island Boulevard Suite 315 San Mateo, CA 94404 DD=03/24/97 MA= / /
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= / /
Anagrelide TN= Agrylin	Treatment of essential thrombocythemia.	Roberts Pharmaceutical Corp. Meridian Center III 6 Industrial Way West Eatontown, NJ 07724 DD=01/27/88 MA=03/14/97
Beta alethine TN= Betathine	Treatment of multiple myeloma.	Dovetail Technologies, Inc. 10615 Mantz Road Silver Spring, MD 20903 DD=03/24/97 MA= / /
Beta alethine TN= Betathine	Treatment of metastatic melanoma.	Dovetail Technologies, Inc. 10615 Mantz Road Silver Spring, MD 20903 DD=03/24/97 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

Orphan Product Designations and Approvals List
January 1997 through March 1997

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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= / /
MART-1 adenoviral gene therapy for malignant melanoma TN=	Treatment of metastatic melanoma.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=03/28/97 MA= / /
Paclitaxel TN= Taxol	Treatment of AIDS-related Kaposi's sarcoma.	Bristol-Myers Squibb Pharmaceutical Research Institute 5 Research Parkway P.O. Box 5100 Wallingford, CT 06492 DD=03/25/97 MA= / /

Orphan Product Designations and Approvals List
January 1997 through March 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= / /
Poly-ICLC TN=	Treatment of primary brain tumors.	Salazar, Andres M. M.D. and Levy, Hilton B. Ph.D. 3202 Cleveland Avenue N.W. Washington, DC 20008 DD=03/17/97 MA= / /
Porfiromycin TN= Promycin	Treatment of cervical cancer.	Vion Pharmaceuticals, Inc. Four Science Park New Haven, CT 06511 DD=03/13/97 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
gp100 adenoviral gene therapy TN=	Treatment of metastatic melanoma.	Genzyme P.O. Box 9322 One Mountain Road Framingham, MA 01701 DD=03/25/97 MA= / /

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

NO MARCH 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 DOSING SCHEDULE

D-33 ONCE DAILY DOSING FOR PLAQUE PSORIASIS

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

I-183 MAINTENANCE THERAPY IN THE MANAGEMENT OF MILD TO MODERATE ASTHMA IN PEDIATRIC PATIENTS AGES 6-11

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	5605674	FEB 25, 2014			
			5439670	JUL 06, 2010			
			5225183	JUL 06, 2010		NP	AUG 15, 1999
>ADD>	20333 001	ANAGRELIDE HYDROCHLORIDE; AGRYLIN				ODE	MAR 14, 2004
>ADD>						NCE	MAR 14, 2002
>ADD>	20333 002	ANAGRELIDE HYDROCHLORIDE; AGRYLIN				ODE	MAR 14, 2004
>ADD>						NCE	MAR 14, 2002
	20702 001	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
			5273995	DEC 28, 2010	U-162		
			4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
	20702 002	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
			5273995	DEC 28, 2010	U-162		
			4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
	20702 003	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
			5273995	DEC 28, 2010	U-162		
			4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
	20486 001	BECLOMETHASONE DIPROPIONATE; VANCERIL DOUBLE STRENGTH				NP	DEC 24, 1999
>ADD>	20490 001	BRIMONIDINE TARTRATE; ALPHAGAN				NP	MAR 13, 2000
>ADD>						NCE	SEP 06, 2001
	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
	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
>ADD>	20273 001	CALCIPOTRIENE; DOVONEX	4866048	SEP 12, 2006	U-88		
~~>DLT>~~			~~4866048~~	~~DEC 29, 2007~~	~~U-88~~		
>ADD>						D-33	MAR 20, 2000
	20554 001	CALCIPOTRIENE; DOVONEX				NCE	DEC 29, 1998
>ADD>	20611 001	CALCIPOTRIENE; DOVONEX	4866048	SEP 12, 2006		NCE	DEC 29, 1998
>ADD>						NDF	MAR 03, 2000
	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
	20430 001	DANAPAROID SODIUM; ORGARAN	5164377	OCT 03, 2010		NCE	DEC 24, 2001
	20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 03, 2007		I-163	JUL 23, 1999
			4829088	APR 14, 2007			
	18723 001	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
	18723 002	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 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
	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			
						NP	DEC 30, 1999
	19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4906463	MAR 06, 2007		NP	DEC 03, 1999
	19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
	18922 005	ETODOLAC; LODINE	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
	20410 001	FERUMOXSIL; GASTROMARK				I-24	JUN 28, 1999
			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			
	20235 001	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000	U-86	NCE	DEC 30, 1998
	20235 002	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000	U-86	NCE	DEC 30, 1998
	20235 003	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000	U-86	NCE	DEC 30, 1998
	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
	20723 001	IMIQUIMOD; ALDARA	5238944	AUG 24, 2010			
			4689338	AUG 25, 2004	U-172	NCE	FEB 27, 2002
	20083 001	ITRACONAZOLE; SPORANOX				I-178	DEC 06, 1999
	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
>ADD>	19660 001	NEDOCROMIL SODIUM; TILADE				I-183	MAR 06, 2000
>ADD>	20778 001	NELFINAVIR MESYLATE; VIRACEPT				NCE	MAR 14, 2002
>ADD>	20779 001	NELFINAVIR MESYLATE; VIRACEPT				NCE	MAR 14, 2002
	20636 001	NEVIRAPINE; VIRAMUNE	5366972	NOV 22, 2011	U-167	NCE	JUN 21, 2001
	20688 001	OLOPATADINE HYDROCHLORIDE; PATANOL	5116863	MAY 26, 2009			
			4923892	MAY 08, 2007	U-174		
			4871865	OCT 03, 2006		NCE	DEC 18, 2001

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
	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
>ADD>	20529 001	PODOFILOX; CONDYLOX				NDF	MAR 13, 2000
	19627 002	PROPOFOL; DIPRIVAN				NP	JUN 11, 1999
>ADD>	20570 001	SAMARIUM SM 153 LEXIDRONAM; QUADRAMET				NCE	MAR 28, 2002
>ADD>	20570 002	SAMARIUM SM 153 LEXIDRONAM; QUADRAMET				NCE	MAR 28, 2002
>ADD>	19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				ODE	DEC 30, 2003
>ADD>	19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				ODE	DEC 30, 2003
	20168 001	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				ODE	DEC 30, 2003
						I-182	DEC 30, 1999
	20168 002	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				ODE	DEC 30, 2003
						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		

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
	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>	20707 001	TILUDRONATE DISODIUM; SKELID	4980171	APR 06, 2009			
>ADD>			4876248	OCT 24, 2006		NCE	MAR 07, 2002
	20676 001	TIOCONAZOLE; VAGISTAT-1				NP	FEB 11, 2000
	20475 001	TRETINOIN; RETIN-A MICRO				NP	FEB 07, 2000
	20719 001	TROGLITAZONE; PRELAY	5602133	SEP 15, 2013	U-173		
			5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			5104888	AUG 28, 2004			
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
	20719 002	TROGLITAZONE; PRELAY	5602133	SEP 15, 2013	U-173		
			5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			5104888	AUG 28, 2004			
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
	20720 001	TROGLITAZONE; REZULIN	5602133	SEP 15, 2013	U-173		
			5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			5104888	AUG 28, 2004			
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
	20720 002	TROGLITAZONE; REZULIN	5602133	SEP 15, 2013	U-173		
			5478852	SEP 15, 2013	U-163		
			5457109	SEP 15, 2013	U-164		
			5104888	AUG 28, 2004			
			4572912	AUG 28, 2004		NCE	JAN 29, 2002
	20665 001	VALSARTAN; DIOVAN	5399578	MAR 21, 2012	U-3	NCE	DEC 23, 2001
	20665 002	VALSARTAN; DIOVAN	5399578	MAR 21, 2012	U-3	NCE	DEC 23, 2001
	20471 001	ZILEUTON; ZYFLO	4873259	FEB 10, 2007	U-168		
	20471 003	ZILEUTON; ZYFLO	4873259	FEB 10, 2007	U-168		

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
20458 001	ZINC ACETATE; GALZIN				NP	JAN 28, 2000
					ODE	JAN 28, 2004
20458 002	ZINC ACETATE; GALZIN				NP	JAN 28, 2000
					ODE	JAN 28, 2004

*U.S. Government Printing Office: 1997 — 417-599/40010

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