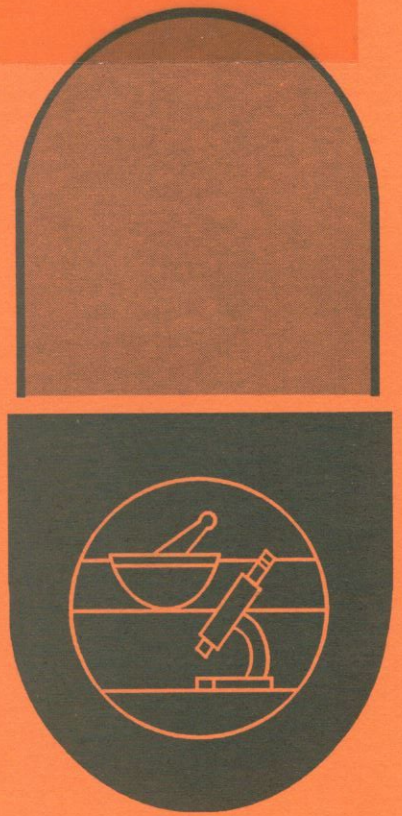
CUMULATIVE SUPPLEMENT 1
JAN'97



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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New 17th Edition

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION
1997

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

Cumulative Supplement 1

JANUARY 1997

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

CUMULATIVE SUPPLEMENT 1
JANUARY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)

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

> ADD >	AA		EON	500MG;5MG	N40149 001
> ADD >					JAN 27, 1997
> ADD >	AA			750MG;7.5MG	N40149 002
> ADD >					JAN 27, 1997

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM

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

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN SULFATE

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

AMOXICILLIN

CAPSULE; ORAL
AMOXIL

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

POWDER FOR RECONSTITUTION; ORAL
AMOXIL

> DLT >	AB	+	SMITHKLINE BEECHAM	125MG/5ML	N50460 001
> DLT >	AB			125MG/5ML	N62226 001

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL
AMOXIL

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

LAROTID

> DLT >	AB		SMITHKLINE BEECHAM	50MG/ML	N50460 006
> ADD >		@		50MG/ML	N50460 006

AMPHOTERICIN B

OINTMENT; TOPICAL
FUNGIZONE

> DLT >		+	APOTHECON	3%	N50313 001
> ADD >		@		3%	N50313 001

ATRACURIUM BESYLATE

INJECTABLE; INJECTION
ATRACURIUM BESYLATE

> DLT >	AP		ABBOTT	10MG/ML	N74633 001
> DLT >					DEC 23, 1996
> ADD >	AP		OHMEDA	10MG/ML	N74753 001
> ADD >					JAN 23, 1997

ATRACURIUM BESYLATE PRESERVATIVE FREE

> ADD >	AP		ABBOTT	10MG/ML	N74633 001
> ADD >					DEC 23, 1996
> ADD >	AP		OHMEDA	10MG/ML	N74768 001
> ADD >					JAN 23, 1997

TRACRIUM

> DLT >	AP	+	GLAXO WELLCOME	10MG/ML	N18831 001
> DLT >					NOV 23, 1983
> ADD >	AP	+		10MG/ML	N18831 002
> ADD >					JUN 20, 1985

TRACRIUM PRESERVATIVE FREE

> ADD >	AP	+	GLAXO WELLCOME	10MG/ML	N18831 001
> ADD >					NOV 23, 1983

AZITHROMYCIN DIHYDRATE

INJECTABLE; INJECTION
ZITHROMAX
+ PFIZER — EQ 500MG BASE/VIAL — N50733 001 — JAN 30, 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	

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

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

CHLORTHALIDONE

TABLET; ORAL
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

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
CIMETIDINE HCL

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

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
	@ 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	

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

> ADD >		**AKPENTOLATE**			
> ADD >	**AT**	AKORN	**1%**	**N40164 001**	
> ADD				JAN 13, 1997	
> ADD >	**AT**		**2%**	**N40165 001**	
> ADD >				JAN 13, 1997	
		CYCLOGYL			
> ADD >	**AT**	+ ALCON	**2%**	**N84108 001**	

DEXTROTHYROXINE SODIUM

TABLET; ORAL

	CHOLOXIN			
> DLT >		KNOLL PHARM	1MG	N12302 005
> ADD >		@	1MG	N12302 005

DIMENHYDRINATE

INJECTABLE; INJECTION

	DIMENHYDRINATE			
> DLT >	**AP**	ELKINS SINN	**50MG/ML**	**N84767 001**
> ADD >		@	50MG/ML	N84767 001

ECONAZOLE NITRATE

CREAM; TOPICAL

	SPECTAZOLE		
> ADD >	+ J AND J	1%	N18751 001
> ADD >			DEC 23, 1982
> DLT >	+ JOHNSON RW	1%	N18751 001
> DLT >			DEC 23, 1982

FLUCONAZOLE

INJECTABLE; INJECTION

> DLT >		DIFLUCAN		
> DLT >		+ PFIZER	200MG/100ML	N19950 001
> DLT >				JAN 29, 1990
> ADD >		DIFLUCAN IN DEXTROSE 5% IN PLASTIC CONTAINER		
> ADD >		+ PFIZER	200MG/100ML	N19950 003
> ADD >				SEP 29, 1992
> ADD >		@	2MG/ML	N19950 005
> ADD >				JUL 08, 1994

FLUCONAZOLE

INJECTABLE; INJECTION

> ADD >		DIFLUCAN IN SODIUM CHLORIDE 0.9%		
> ADD >		+ PFIZER	200MG/100ML	N19950 001
> ADD >				JAN 29, 1990
> ADD >		DIFLUCAN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER		
> ADD >		+ PFIZER	200MG/100ML	N19950 002
> ADD >				JAN 29, 1990
> ADD >		@	2MG/ML	N19950 004
> ADD >				JUL 08, 1994

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

		GUANFACINE HCL		
> ADD >	**AB**	MYLAN	**EQ 1MG BASE**	**N74796 001**
> ADD >				JAN 27, 1997
> ADD >	**AB**		**EQ 2MG BASE**	**N74796 002**
> ADD >				JAN 27, 1997

HEPARIN SODIUM

INJECTABLE; INJECTION

		HEPARIN SODIUM		
> DLT >	**AP**	STERIS	**1,000 UNITS/ML**	**N17064 002**
> ADD >		@	1,000 UNITS/ML	N17064 002

HYDROXYZINE PAMOATE

CAPSULE; ORAL

> DLT >		**HY-PAM**		
> DLT >	**AB**	EON	**EQ 25MG HCL**	**N87479 001**
		HYDROXYZINE PAMOATE		
> ADD >	**AB**	EON	**EQ 25MG HCL**	**N87479 001**

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

		ATROVENT		
> ADD >	**AN**	+ BOEHRINGER INGELHEIM	**0.02%**	**N20228 001**
> ADD >				SEP 29, 1993
> ADD >		**IPRATROPIUM BROMIDE**		
> ADD >	**AN**	DEY	**0.02%**	**N74755 001**
> ADD >				JAN 10, 1997

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HCL

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

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
HUMEGON

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

REPRONAL

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

METHACHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; INHALATION
PROVOCHOLINE

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

METHOTREXATE SODIUM

INJECTABLE; INJECTION
MEXATE-AQ PRESERVED

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

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

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

METOLAZONE

TABLET; ORAL
MYKROX

> DLT >		MEDEVA	0.5MG	N19532 001	
> DLT >				OCT 30, 1987	
> ADD >		+	0.5MG	N19532 001	
> ADD >				OCT 30, 1987	

METRONIDAZOLE

GEL; VAGINAL
METROGEL-VAGINAL

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

MICONAZOLE NITRATE

LOTION; TOPICAL
MONISTAT-DERM

> ADD >		@ J AND J	2%	N17739 001	
> DLT >		@ JOHNSON RW	2%	N17739 001	

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE AND NALOXONE HYDROCHLORIDES

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

TALWIN NX

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

NEDOCROMIL SODIUM

AEROSOL, METERED; INHALATION
TILADE

>DLT<		+ FISONS	1.75MG/INH	N19660 001	
>DLT<				DEC 30, 1992	
>ADD<		+ RHONE POULENC RORER	1.75MG/INH	N19660 001	
>ADD<				DEC 30, 1992	

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING
NEO-RX

>ADD<	AA	PHARMA TEK	100%	N61579 001
>DLT<			100%	N61579 001
>ADD<		NEOMYCIN SULFATE		
>ADD<	AA	PADDOCK	100%	N62385 001
>ADD<				JUN 01, 1982

ONDANSETRON HYDROCHLORIDE

SOLUTION; ORAL
ZOFRAN

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

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
OXYCONTIN

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

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL
PEDIAPRED

>DLT<		+ FISONS	EQ 5MG BASE/5ML	N19157 001
>DLT<				MAY 28, 1986
>ADD<		+ MEDEVA	EQ 5MG BASE/5ML	N19157 001
>ADD<				MAY 28, 1986

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

>DLT<	AB	ROXANE	40MG	N70518 001
>DLT<				JUL 07, 1986
>ADD<		@	40MG	N70518 001
>ADD<				JUL 07, 1986

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL
ELDEPRYL

>DLT<	AB	+ SOMERSET	5MG	N20647 001
>DLT<				MAY 15, 1996
>ADD<		+	5MG	N20647 001
>ADD<				MAY 15, 1996

TABLET; ORAL
SELEGILINE HCL

>ADD<	AB	LEMMON	5MG	N74744 001
>ADD<				JAN 27, 1997

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS

>DLT<	AP	ABBOTT	50MG/VIAL	N71555 001
>DLT<				NOV 16, 1987
>ADD<		@	50MG/VIAL	N71555 001
>ADD<				NOV 16, 1987

TERFENADINE

TABLET; ORAL

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

TOPIRAMATE

TABLET; ORAL

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

TRETINOIN

CREAM; TOPICAL

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

> ADD > TROGLITAZONE

TABLET; ORAL

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

VINCRISTINE SULFATE

INJECTABLE; INJECTION

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

> ADD > ZINC ACETATE

CAPSULE; ORAL

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

> ADD > CROMOLYN SODIUM

> ADD > SPRAY, METERED; NASAL
> ADD > NASALCROM
> ADD > + MCNEIL 5.2MG/SPRAY N20463 001
> ADD > JAN 03, 1997

IBUPROFEN

TABLET; ORAL
JUNIOR STRENGTH MOTRIN
> DLT > MCNEIL 100MG N20602 001
> DLT > JUN 10, 1996
> ADD > + 100MG N20602 001
> ADD > JUN 10, 1996

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE
> ADD > TARO 2% N74444 001
> ADD > JAN 13, 1997

NAPROXEN SODIUM

TABLET; ORAL
> ADD > NAPROXEN SODIUM
> ADD > INVAMED EQ 200MG BASE N74646 001
> ADD > JAN 13, 1997
> ADD > NOVOPHARM EQ 200MG BASE N74635 001
> ADD > JAN 13, 1997
> ADD > PERRIGO EQ 200MG BASE N74661 001
> ADD > JAN 13, 1997

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 1/ JAN '97

NO JANUARY 1997 APPROVALS

List of Orphan Product Designations and Approvals

January, 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= / /
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= / /
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 JANUARY 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

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

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
>ADD>	20291 001	ALBUTEROL SULFATE; COMBIVENT	5603918	JUN 09, 2015		NC	OCT 24, 1999
>ADD>	20503 001	ALBUTEROL SULFATE; PROVENTIL-HFA	5225183	JUL 06, 2010		NP	AUG 15, 1999
>ADD>	20702 001	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
>ADD>			5273995	DEC 28, 2010	U-162		
>ADD>			4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
>ADD>	20702 002	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
>ADD>			5273995	DEC 28, 2010	U-162		
>ADD>			4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
>ADD>	20702 003	ATORVASTATIN CALCIUM; LIPITOR	5385929	MAY 04, 2014	U-59		
>ADD>			5273995	DEC 28, 2010	U-162		
>ADD>			4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
>ADD>	20486 001	BECLOMETHASONE DIPROPIONATE; VANCERIL DOUBLE STRENGTH				NP	DEC 24, 1999
>ADD>	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
>ADD>	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
>ADD>	20664 001	CABERGOLINE; DOSTINEX	4526892	JUL 02, 2002		NCE	DEC 23, 2001
>ADD>	20554 001	CALCIPOTRIENE; DOVONEX				NCE	DEC 29, 1998
>ADD>	19847 001	CIPROFLOXACIN; CIPRO	4705789	NOV 10, 2004		I-179	OCT 21, 1999
>ADD>	19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4808583	FEB 28, 2006		I-179	OCT 21, 1999
>ADD>	19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4705789	NOV 10, 2004		I-179	OCT 21, 1999
>ADD>	20463 001	CROMOLYN SODIUM; NASALCROM				NP	JAN 03, 2000
>ADD>	18723 001	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
>ADD>	18723 002	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
>ADD>	18723 003	DIVALPROEX SODIUM; DEPAKOTE				I-181	JUN 20, 1999
>ADD>	19680 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008		I-181	JUN 20, 1999
>ADD>	20417 001	ESTRADIOL; FEMPATCH	5006342	APR 09, 2008			
>ADD>			4906463	MAR 06, 2007		NP	DEC 03, 1999
>ADD>	19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
>ADD>	19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
>ADD>	18922 005	ETODOLAC; LODINE				I-24	JUN 28, 1999
>ADD>	20410 001	FERUMOXSIL; GASTROMARK	5219554	JUN 15, 2010			
>ADD>			5069216	MAY 09, 2006	U-171	NCE	DEC 06, 2001
>ADD>			5055288	OCT 08, 2008			
>ADD>			4951675	SEP 13, 2005	U-169		
>ADD>			4827945	MAY 09, 2006	U-170		
>ADD>			4770183	SEP 13, 2005	U-169		
>ADD>			4695393	SEP 22, 2004			
>ADD>			4695392	SEP 22, 2004			
>ADD>	20622 001	GLATIRAMER ACETATE; COPAXONE				ODE	DEC 20, 2003
>ADD>	20329 001	GLIPIZIDE; GLUCOTROL XL	5591454	JAN 07, 2014	U-150		

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
>ADD>	20329 002	GLIPIZIDE; GLUCOTROL XL	5591454	JAN 07, 2014	U-150		
>ADD>	20267 002	IBUPROFEN; JUNIOR STRENGTH ADVIL				NP	JUN 16, 1998
>ADD>	20083 001	ITRACONAZOLE; SPORANOX				I-178	DEC 06, 1999
>ADD>	20641 001	LORATADINE; CLARITIN	4659716	APR 21, 2004	U-142		
>ADD>	20704 001	LORATADINE; CLARITIN REDITABS	4659716	APR 21, 2004	U-142		
>ADD>			4282233	JUN 19, 2002	U-77	NCE	APR 12, 1998
>ADD>	20636 001	NEVIRAPINE; VIRAMUNE	5366972	NOV 22, 2011	U-167	NCE	JUN 21, 2001
>ADD>	19810 001	OMEPRAZOLE; PRILOSEC	5599794	FEB 04, 2014	U-166		
>ADD>			5093342	FEB 02, 2010	U-166		
>ADD>			4636499	MAY 30, 2005			
>ADD>	19810 003	OMEPRAZOLE; PRILOSEC	5599794	FEB 04, 2014	U-166		
>ADD>			5093342	FEB 02, 2010	U-166		
>ADD>			4636499	MAY 30, 2005			
>ADD>	20605 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	5578628	JUN 24, 2006	U-44		
>ADD>	20031 001	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
>ADD>	20031 002	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
>ADD>	20031 003	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
>ADD>	20031 004	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
>ADD>	20031 005	PAROXETINE HYDROCHLORIDE; PAXIL				I-150	MAY 07, 1999
>ADD>	19627 002	PROPOFOL; DIPRIVAN				NP	JUN 11, 1999
>ADD>	20168 001	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				ODE	DEC 30, 2003
>ADD>	20168 002	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				ODE	DEC 30, 2003
>ADD>	19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
~~>DLT>~~	~~19057 001~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~5504207~~	~~APR 29, 2013~~	~~U-3~~		
>ADD>			5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
~~>DLT>~~	~~19057 002~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~5504207~~	~~APR 29, 2013~~	~~U-3~~		
>ADD>			5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
~~>DLT>~~	~~19057 003~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~5504207~~	~~APR 29, 2013~~	~~U-3~~		
>ADD>			5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207	APR 29, 2013			
~~>DLT>~~	~~19057 004~~	~~TERAZOSIN HYDROCHLORIDE; HYTRIN~~	~~5504207~~	~~APR 29, 2013~~	~~U-3~~		
>ADD>			5294615	APR 29, 2013	U-165		
>ADD>			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
>ADD>	20347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	20347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	20347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	20347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
>ADD>			5294615	APR 29, 2013	U-3		
>ADD>	20192 001	TERBINAFINE HYDROCHLORIDE; LAMISIL				I-180	JAN 21, 2000
>ADD>	20719 001	TROGLITAZONE; PRELAY	5478852	SEP 15, 2013	U-163		
>ADD>			5457109	SEP 15, 2013	U-164		
>ADD>			4572912	AUG 28, 2004		NCE	JAN 29, 2002
>ADD>			5104888	AUG 28, 2004			
>ADD>	20719 002	TROGLITAZONE; PRELAY	5478852	SEP 15, 2013	U-163		
>ADD>			5457109	SEP 15, 2013	U-164		
>ADD>			4572912	AUG 28, 2004		NCE	JAN 29, 2002
>ADD>			5104888	AUG 28, 2004			
>ADD>	20720 001	TROGLITAZONE; REZULIN	5478852	SEP 15, 2013	U-163		
>ADD>			5457109	SEP 15, 2013	U-164		
>ADD>			4572912	AUG 28, 2004		NCE	JAN 29, 2002
>ADD>			5104888	AUG 28, 2004			
>ADD>	20720 002	TROGLITAZONE; REZULIN	5478852	SEP 15, 2013	U-163		
>ADD>			5457109	SEP 15, 2013	U-164		
>ADD>			4572912	AUG 28, 2004		NCE	JAN 29, 2002
>ADD>			5104888	AUG 28, 2004			
>ADD>	20471 001	ZILEUTON; ZYFLO	4873259	FEB 10, 2007	U-168		
>ADD>	20471 003	ZILEUTON; ZYFLO	4873259	FEB 10, 2007	U-168		
>ADD>	20458 001	ZINC ACETATE; GALZIN				NP	JAN 28, 2000
>ADD>	20458 002	ZINC ACETATE; GALZIN				NP	JAN 28, 2000

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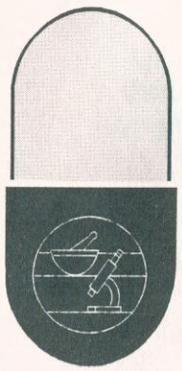

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