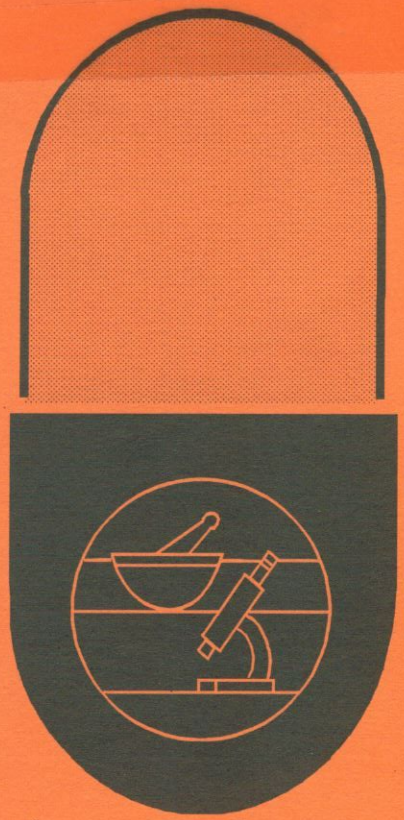
CUMULATIVE
SUPPLEMENT 1
JAN'99



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGMENT AND SERVICES

1999

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

Cumulative Supplement 1

JANUARY 1999

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Library Use Only

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19TH EDITION

CUMULATIVE SUPPLEMENT 1
JANUARY 1999

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, 19th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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 19th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 20th Edition.

1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)

NO APPLICANT NAME CHANGES – JANUARY 1999

1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Falcon Pharms' (Alcon) NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

1.4 AVAILABILITY OF THE EDITION

The 19th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is $78.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at http://www.fda.gov/cder/ob. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the hard copy monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.htm. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product prescription, OTC and discontinued data at http://www.fda.gov/cder/orange/obreadme.htm. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements.
Appendix A and Appendix B are updated quarterly.

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 section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1997) 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 1998	MAR 1999	JUN 1999	SEP 1999
DRUG PRODUCTS LISTED	9923			
SINGLE SOURCE	2504 (25.2%)			
MULTISOURCE	7308 (73.6%)			
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)			
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)			
EXCEPTIONS[1]	111 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	10			
NUMBER OF APPLICANTS	563			

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

>ADD<	AA	MALLINCKRODT	500MG;5MG	N88956 001	
>ADD<				JUL 19, 1985	
		ZYDONE			
>DLT<	AA	MALLINCKRODT	500MG;5MG	N88956 001	
>DLT<				JUL 19, 1985	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPACET 100

>DLT<					
>DLT<	AB	TEVA	650MG;100MG	N70107 001	
>DLT<				JUN 12, 1985	
>ADD<		@	650MG;100MG	N70107 001	
>ADD<				JUN 12, 1985	

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

>ADD<	AB	STASON	200MG	N75090 001	
>ADD<				JAN 26, 1999	

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL

>DLT<	AB	MEDEVA	0.09MG/INH	N72273 001	
>DLT<				AUG 14, 1996	
>ADD<	AB	MEDEVA PHARMS MA	0.09MG/INH	N72273 001	
>ADD<				AUG 14, 1996	

ALLOPURINOL

TABLET; ORAL

ZYLOPRIM

>ADD<	AB	FARO PHARMS	100MG	N16084 001	
>ADD<	AB	+	300MG	N16084 002	
>DLT<	AB	GLAXO WELLCOME	100MG	N16084 001	
>DLT<	AB	+	300MG	N16084 002	

BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL

CORZIDE

>ADD<		APOTHECON	5MG;40MG	N18647 001	
>ADD<				MAY 25, 1983	
>ADD<		+	5MG;80MG	N18647 002	
>ADD<				MAY 25, 1983	
>DLT<		BRISTOL MYERS SQUIBB	5MG;40MG	N18647 001	
>DLT<				MAY 25, 1983	
>DLT<		+	5MG;80MG	N18647 002	
>DLT<				MAY 25, 1983	

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

ISOLYTE R W/ DEXTROSE 5% IN PLASTIC CONTAINER

>DLT<		B BRAUN	37MG/100ML;5GM/100ML;31MG/100ML;		
>DLT<			120MG/100ML;330MG/100ML;		
>DLT<			88MG/100ML	N18271 001	
>ADD<		@	37MG/100ML;5GM/100ML;31MG/100ML;		
>ADD<			120MG/100ML;330MG/100ML;		
>ADD<			88MG/100ML	N18271 001	

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION

ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER

>DLT<		B BRAUN	35MG/100ML;5GM/100ML;30MG/100ML;		
>DLT<			74MG/100ML;640MG/100ML;500MG/100ML;		
>DLT<			74MG/100ML	N18269 002	
>DLT<				JAN 17, 1983	
>ADD<		@	35MG/100ML;5GM/100ML;30MG/100ML;		
>ADD<			74MG/100ML;640MG/100ML;500MG/100ML;		
>ADD<			74MG/100ML	N18269 002	
>ADD<				JAN 17, 1983	

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

CHLORPROMAZINE HCL

>ADD<	AA	PHARM ASSOC	100MG/ML	N40224 001	
>ADD<				JAN 26, 1999	

> ADD > CILOSTAZOL

> ADD > TABLET; ORAL
> ADD > PLETAL

> ADD >		OTSUKA	50MG	N20863 001	
> ADD >				JAN 15, 1999	
> ADD >	+		100MG	N20863 002	
> ADD >				JAN 15, 1999	

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DDAVP

> ADD >	AB	+ RHONE POULENC RORER	0.01MG/SPRAY	N17922 003	
> ADD >				AUG 07, 1996	
> DLT >		*	0.01MG/SPRAY	N17922 003	
> DLT >				AUG 07, 1996	
> ADD >		DESMOPRESSIN ACETATE			
> ADD >	AB	BAUSCH AND LOMB	0.01MG/SPRAY	N74830 001	
> ADD >				JAN 25, 1999	

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
MAXITROL

> DLT >	AT	* ALCON	0.1%;EQ 3.5MG BASE/GM;		
> DLT >			10,000 UNITS/GM	N50065 002	
> ADD >	AT	+ FALCON PHARMS	0.1%;EQ 3.5MG BASE/GM;		
> ADD >			10,000 UNITS/GM	N50065 002	

SUSPENSION/DROPS; OPHTHALMIC
MAXITROL

> DLT >	AT	* ALCON	0.1%;EQ 3.5MG BASE/ML;		
> DLT >			10,000 UNITS/ML	N50023 002	
> ADD >	AT	+ FALCON PHARMS	0.1%;EQ 3.5MG BASE/ML;		
> ADD >			10,000 UNITS/ML	N50023 002	

DIAZEPAM

GEL; RECTAL
DIASTAT

> DLT >		* ATHENA	2.5MG/0.5ML	N20648 001	
> DLT >				JUL 29, 1997	
> DLT >			5MG/ML	N20648 002	
> DLT >				JUL 29, 1997	

DIAZEPAM

GEL; RECTAL
DIASTAT

> DLT >		ATHENA	10MG/2ML	N20648 003	
> DLT >				JUL 29, 1997	
> DLT >			15MG/3ML	N20648 004	
> DLT >				JUL 29, 1997	
> DLT >		*	20MG/4ML	N20648 005	
> DLT >				JUL 29, 1997	
> ADD >		+ ELAN PHARMS	2.5MG/0.5ML	N20648 001	
> ADD >				JUL 29, 1997	
> ADD >			5MG/ML	N20648 002	
> ADD >				JUL 29, 1997	
> ADD >			10MG/2ML	N20648 003	
> ADD >				JUL 29, 1997	
> ADD >			15MG/3ML	N20648 004	
> ADD >				JUL 29, 1997	
> ADD >		+	20MG/4ML	N20648 005	
> ADD >				JUL 29, 1997	

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM

> DLT >	AB	ALCON	0.1%	N20809 001	
> DLT >				MAY 04, 1998	
> ADD >	AB	FALCON PHARMS	0.1% †	N20809 001	
> ADD >				MAY 04, 1998	

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL
DYNABAC

> DLT >		* LILLY	250MG	N50678 001	
> DLT >				JUN 19, 1995	
> ADD >		+ SANOFI	250MG	N50678 001	
> ADD >				JUN 19, 1995	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORINYL 1+35 21-DAY

> DLT >	AB	SEARLE	0.035MG;1MG	N17565 001	
> ADD >	AB	WATSON LABS	0.035MG;1MG	N17565 001	

† SEE SECTION 1.3 OF INTRODUCTION

† SEE SECTION 1.3 OF INTRODUCTION

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28
NORINYL 1+35 28-DAY

> DLT >	AB		SEARLE	0.035MG;1MG	N17565 002	
> ADD >	AB		WATSON LABS	0.035MG;1MG	N17565 002	

ETOPOSIDE

INJECTABLE; INJECTION
VEPESID

> DLT >	AP	*	BRISTOL	20MG/ML	N18768 001	
> DLT >					NOV 10, 1983	
> ADD >	AP	+	BRISTOL MYERS SQUIBB	20MG/ML	N18768 001	
> ADD >					NOV 10, 1983	

IBUPROFEN

SUSPENSION; ORAL
MOTRIN

> DLT >	AB	*	MCNEIL	100MG/5ML	N19842 001	
> DLT >					SEP 19, 1989	
> ADD >	AB	+	MCNEIL CONS	100MG/5ML	N19842 001	
> ADD >					SEP 19, 1989	

TABLET; ORAL
MOTRIN

> DLT >	AB		MCNEIL	300MG	N17463 003	
> DLT >	AB			400MG	N17463 002	
> DLT >	AB			600MG	N17463 004	
> DLT >	AB	*		800MG	N17463 005	
> DLT >					MAY 22, 1985	
> DLT >				100MG	N20418 001	
> DLT >					NOV 16, 1994	
> ADD >	AB		MCNEIL CONS	300MG	N17463 003	
> ADD >	AB			400MG	N17463 002	
> ADD >	AB			600MG	N17463 004	
> ADD >	AB	+		800MG	N17463 005	
> ADD >					MAY 22, 1985	
> ADD >				100MG	N20418 001	
> ADD >					NOV 16, 1994	

TABLET, CHEWABLE; ORAL
MOTRIN

> DLT >			MCNEIL	50MG	N20135 001	
> DLT >					NOV 16, 1994	

IBUPROFEN

TABLET, CHEWABLE; ORAL
MOTRIN

> DLT >		*	MCNEIL	100MG	N20135 002	
> DLT >					NOV 16, 1994	
> ADD >			MCNEIL CONS	50MG	N20135 001	
> ADD >					NOV 16, 1994	
> ADD >		+		100MG	N20135 002	
> ADD >					NOV 16, 1994	

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

> DLT >	AN		INTL MEDICATION	0.08%	N86651 002	
> DLT >	AN			0.1%	N86651 003	
> ADD >	AN	+		0.1%	N86651 003	
> DLT >	AN			0.167%	N86651 005	
> ADD >	AN	+		0.167%	N86651 005	
> DLT >	AN			0.25%	N86651 007	
> ADD >	AN	+		0.25%	N86651 007	
> ADD >		+		0.08%	N86651 002	

ISOETHARINE HCL S/F

> DLT >	AN	*	DEY	0.08%	N89817 001	
> DLT >					NOV 22, 1988	
> DLT >	AN	+		0.1%	N89818 001	
> DLT >					NOV 22, 1988	
> DLT >	AN	+		0.17%	N89819 001	
> DLT >					NOV 22, 1988	
> DLT >	AN	+		0.25%	N89820 001	
> DLT >					NOV 22, 1988	
> ADD >		@		0.08%	N89817 001	
> ADD >					NOV 22, 1988	
> ADD >		@		0.1%	N89818 001	
> ADD >					NOV 22, 1988	
> ADD >		@		0.17%	N89819 001	
> ADD >					NOV 22, 1988	
> ADD >		@		0.25%	N89820 001	
> ADD >					NOV 22, 1988	

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

> ADD >	AP		ABBOTT	15MG/ML	N74993 001	
> ADD >					JAN 27, 1999	

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

> ADD >	AP	ABBOTT	30MG/ML	N74993 002	
> ADD				JAN 27, 1999	

LISINOPRIL

TABLET; ORAL
ZESTRIL

> ADD >		ZENECA	30MG	N19777 006	
> ADD >				JAN 20, 1999	

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
DEMEROL

> ADD >	AP	+ ABBOTT	25MG/ML	N05010 007	
> ADD >	AP	+	50MG/ML	N05010 002	
> ADD >	AP	+	75MG/ML	N05010 009	
> ADD >	AP	+	100MG/ML	N05010 003	
> DLT >	AP	+ SANOFI	25MG/ML	N05010 007	
> DLT >	AP	+	50MG/ML	N05010 002	
> DLT >	AP	+	75MG/ML	N05010 009	
> DLT >	AP	+	100MG/ML	N05010 003	

SYRUP; ORAL
DEMEROL

> ADD >	AA	+ ABBOTT	50MG/5ML	N05010 005	
> DLT >	AA	+ SANOFI	50MG/5ML	N05010 005	

TABLET; ORAL
DEMEROL

> ADD >	AA	+ ABBOTT	50MG	N05010 001	
> ADD >	AA	+	100MG	N05010 004	
> DLT >	AA	+ SANOFI	50MG	N05010 001	
> DLT >	AA	+	100MG	N05010 004	

NADOLOL

TABLET; ORAL
CORGARD

> ADD >	AB	APOTHECON	20MG	N18063 005	
> ADD >				OCT 28, 1986	
> ADD >	AB		40MG	N18063 001	

NADOLOL

TABLET; ORAL
CORGARD

> ADD >	AB	APOTHECON	80MG	N18063 002	
> ADD >	AB		120MG	N18063 003	
> ADD >	AB	+	160MG	N18063 004	
> DLT >	AB	BRISTOL MYERS SQUIBB	20MG	N18063 005	
> DLT >				OCT 28, 1986	
> DLT >	AB		40MG	N18063 001	
> DLT >	AB		80MG	N18063 002	
> DLT >	AB		120MG	N18063 003	
> DLT >	AB	+	160MG	N18063 004	

> ADD > ONDANSETRON

> ADD > TABLET, ORALLY DISINTEGRATING; ORAL
> ADD > ZOFRAN ODT

> ADD >		GLAXO WELLCOME	EQ 4MG BASE	N20781 001	
> ADD >				JAN 27, 1999	
> ADD >		+	EQ 8MG BASE	N20781 002	
> ADD >				JAN 27, 1999	

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

> ADD >	AB	KIEL	100MG	N40249 001	
> ADD >				JAN 29, 1999	

OXYBUTYNIN CHLORIDE

SYRUP; ORAL
OXYBUTYNIN CHLORIDE

> ADD >	AA	MIKART	5MG/5ML	N75039 001	
> ADD >				JAN 29, 1999	

PEMOLINE

TABLET; ORAL
CYLERT

> ADD >	AB	ABBOTT	37.5MG	N16832 002	
> ADD >	AB	+	75MG	N16832 003	
> DLT >			37.5MG	N16832 002	
> DLT >		+	75MG	N16832 003	

PEMOLINE

TABLET; ORAL

>ADD>		**PEMOLINE**			
>ADD>	**AB**	COPLEY PHARM	**37.5MG**	**N75030 001**	
>ADD>				JAN 29, 1999	
>ADD>	**AB**		**75MG**	**N75030 002**	
>ADD>				JAN 29, 1999	

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

>DLT>		**FASTIN**			
>DLT>	**AA**	+ SMITHKLINE BEECHAM	**30MG**	**N17352 001**	
>ADD>		@	30MG	N17352 001	
		PHENTERMINE HCL			
>DLT>	**AA**	EON	**30MG**	**N86945 001**	
>DLT>				JUL 20, 1983	
>ADD>	**AA**	+	**30MG**	**N86945 001**	
>ADD>				JUL 20, 1983	

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

		ECONOPRED PLUS			
>DLT>	**AB**	ALCON	**1%**	**N17469 001**	
>ADD>	**AB**	FALCON PHARMS	**1%**	**N17469 001**	

PROPOFOL

INJECTABLE; INJECTION

		DIPRIVAN			
>ADD>	**AB**	+ ZENECA	**10MG/ML**	**N19627 002**	
>ADD>				JUN 11, 1996	
>DLT>		+	10MG/ML	N19627 002	
>DLT>				JUN 11, 1996	
>ADD>		**PROPOFOL**			
>ADD>	**AB**	GENSIA SICOR PHARMS	**10MG/ML**	**N75102 001**	
>ADD>				JAN 04, 1999	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

		RANITIDINE HCL			
>ADD>	**AB**	PAR PHARM	**EQ 150MG BASE**	**N75180 001**	
>ADD>				JAN 28, 1999	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

		RANITIDINE HCL			
>ADD>	**AB**	PAR PHARM	**EQ 300MG BASE**	**N75180 002**	
>ADD>				JAN 28, 1999	

RISPERIDONE

TABLET; ORAL

		RISPERDAL			
>ADD>		+ JANSSEN	0.05MG	N20272 007	
>ADD>				JAN 27, 1999	

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

>DLT>		ELDEPRYL			
>DLT>		@ SOMERSET	5MG	N19334 001	
>DLT>				JUN 05, 1989	
>ADD>		**SELEGILINE HCL**			
>ADD>	**AB**	+ SOMERSET	**5MG**	**N19334 001**	
>ADD>				JUN 05, 1989	

SPIRONOLACTONE

TABLET; ORAL

		SPIRONOLACTONE			
>DLT>	**AB**	PUREPAC PHARM	**25MG**	**N87998 001**	
>DLT>				OCT 14, 1983	
>ADD>		@	25MG	N87998 001	
>ADD>				OCT 14, 1983	

THEOPHYLLINE

INJECTABLE; INJECTION

THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	@ B BRAUN	40MG/100ML	N19083 001
>ADD>			NOV 07, 1984
>DLT>	@ MCGAW	40MG/100ML	N19083 001
>DLT>			NOV 07, 1984

THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER

>ADD>	@ B BRAUN	80MG/100ML	N19083 002
>ADD>			NOV 07, 1984

THEOPHYLLINE

INJECTABLE; INJECTION

THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER

>DLT>		@ MCGAW	80MG/100ML	N19083 002	
>DLT>				NOV 07, 1984	
		THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER			
>ADD>		@ B BRAUN	160MG/100ML	N19083 003	
>ADD>				NOV 07, 1984	
>DLT>		@ MCGAW	160MG/100ML	N19083 003	
>DLT>				NOV 07, 1984	

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL

>DLT>	**AA**	ALPHARMA	**EQ 5MG BASE/ML**	**N70969 001**
>DLT>				OCT 16, 1987
>ADD>		@	EQ 5MG BASE/ML	N70969 001
>ADD>				OCT 16, 1987

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC

TIMOLOL MALEATE

>DLT>	**AB**	ALCON	**EQ 0.25% BASE**	**N20963 001**
>DLT>				OCT 21, 1998
>ADD>	**AB**	FALCON PHARMS	**EQ 0.25% BASE**	**N20963 001**
>ADD>				OCT 21, 1998

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

>DLT>	**AT**	ADV REMEDIES	**EQ 0.5% BASE**	**N74466 001**
>DLT>				MAR 25, 1997
>ADD>	**AT**	AKORN	**EQ 0.5% BASE**	**N74466 001**
>ADD>				MAR 25, 1997

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBREX

>DLT>	**AT**	+	ALCON	0.3%	**N50541 001**
>ADD>	**AT**	+	FALCON PHARMS	0.3%	**N50541 001**

TRETINOIN

SOLUTION; TOPICAL

TRETINOIN

>ADD>	**AT**	MORTON GROVE	0.05%		**N75260 001**
>ADD>					JAN 25, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

	ZANTAC 75			
> DLT >	+ GLAXO WELLCOME	EQ 75MG BASE	N20520 001	
> DLT >			DEC 19, 1995	
> ADD >	+ WARNER LAMBERT	EQ 75MG BASE	N20520 001	
> ADD >			DEC 19, 1995	

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 '99

NO JANUARY 1999 APPROVALS

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Product Designations and Approvals List
January 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Atovaquone TN= Mepron	Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3.	Glaxo Wellcome Research and Development 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=08/14/1991 MA=01/05/1999
Interferon beta-1a (recombinant human) TN= Avonex	Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999
L-5-hydroxytryptophan TN=	Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA DD=01/20/1999

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

NO JANUARY 1999 ADDITIONS

PATENT AND EXCLUSIVITY TERMS PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 18TH EDITION FOR A FULL LISTING OF PATENT AND 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-250	**PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C**
I-251	**TREATMENT OF GENERALIZED ANXIETY DISORDER**
I-252	**NEW COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS METFORMIN**
I-253	**COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS INSULIN**
I-254	**PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS (LOSS OF BONE MASS)**

PATENT USE CODE

U-254	**USE OF AGGRASTAT IN COMBINATION WITH HEPARIN**
U-255	**IMPROVED WAKEFULNESS IN PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY**
U-256	**TREATMENT OF HIV INFECITON IN COMBINATION WITH ONE OR MORE ADDITIONAL HIV ANTIVIRAL AGENTS**
U-257	**TREATMENT OF HIV INFECTION**

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020482	004	ACARBOSE;PRECOSE				I-252	SEP 29, 2001
>ADD>							I-253	SEP 29, 2001
>ADD>	020886	001	ALITRETINOIN;PANRETIN				ODE	FEB 02, 2006
>ADD>	020500	001	ATOVAQUONE;MEPRON				ODE	JAN 05, 2006
>ADD>	020711	002	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
>ADD>	020711	003	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
>ADD>	020954	001	BUSULFAN;BUSULFEX				ODE	FEB 04, 2006
>ADD>	020972	001	EFAVIRENZ;SUSTIVA	5811423	AUG 07, 2012	U-256		
>ADD>				5519021	MAY 21, 2013			
>ADD>				5663169	SEP 02, 2014	U-257		
>ADD>	020972	002	EFAVIRENZ;SUSTIVA	5811423	AUG 07, 2012	U-256		
>ADD>				5519021	MAY 21, 2013			
>ADD>				5663169	SEP 02, 2014	U-257		
>ADD>	020972	003	EFAVIRENZ;SUSTIVA	5519021	MAY 21, 2013			
>ADD>				5663169	SEP 02, 2014	U-257		
>ADD>				5811423	AUG 07, 2012	U-256		
>ADD>	020375	001	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
>ADD>	020375	002	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
>ADD>	020375	003	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
>ADD>	020375	004	ESTRADIOL;CLIMARA	5223261	JUN 29, 2010		I-254	MAR 05, 2002
>ADD>	020908	001	ESTRADIOL;VAGIFEM				NP	MAR 26, 2002
>ADD>	020992	002	ESTROGENS, CONJUGATED;CENESTIN				NP	MAR 24, 2002
>ADD>	020992	003	ESTROGENS, CONJUGATED;CENESTIN				NP	MAR 24, 2002
>ADD>	020527	003	ESTROGENS, CONJUGATED;PREMPRO 14/14	4826831	MAY 02, 2006			
>ADD>				5547948	JAN 17, 2015			
>ADD>	019304	002	FENOFIBRATE;TRICOR (MICRONIZED)	4895726	JAN 19, 2009			
>ADD>	020747	001	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020747	002	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020747	003	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020747	004	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020747	005	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020747	006	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020083	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
>ADD>	020657	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
>ADD>	020966	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
>ADD>	021003	001	LAMIVUDINE;EPIVIR-HBV				NP	DEC 08, 2001
>ADD>	021004	001	LAMIVUDINE;EPIVIR-HBV				NP	DEC 08, 2001
>ADD>	020764	001	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
>ADD>	020764	002	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
>ADD>	020764	003	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
>ADD>	020612	001	LIDOCAINE;LIDODERM				ODE	MAR 19, 2006
>ADD>	019777	006	LISINOPRIL;ZESTRIL	4374829	DEC 30, 2001			
>ADD>	019643	002	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
>ADD>	019643	003	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
>ADD>	019643	004	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
>ADD>	020969	001	METHOXSALEN;UVADEX				NP	FEB 25, 2002
>ADD>	020717	001	MODAFINIL;PROVIGIL	4177290	MAR 09, 1999			
>ADD>				5618845	OCT 06, 2014	U-255		
>ADD>				4927855	MAY 22, 2007	U-255		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
*PED and PED represent Pediatric Exclusivity

	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020717	002	MODAFINIL;PROVIGIL	4177290	MAR 09, 1999			
>ADD>				5618845	OCT 06, 2014	U-255		
>ADD>				4927855	MAY 22, 2007	U-255		
>ADD>	020897	001	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
>ADD>	020897	002	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
>ADD>	020031	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020031	002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020031	003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020031	004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020031	005	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020710	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020885	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020885	002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020885	003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020885	004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020936	001	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132	MAY 19, 2015			
>ADD>	020936	002	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132	MAY 19, 2015			
>ADD>	020639	004	QUETIAPINE FUMARATE;SEROQUEL	4879288	MAR 20, 2007		NCE	SEP 26, 2002
>ADD>	020272	007	RISPERIDONE;RISPERDAL	5158952	DEC 29, 2007	U-90	D-37	OCT 17, 2000
>ADD>				4804663	DEC 29, 2007	U-90		
>ADD>	020912	001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAY 14, 2012	U-230		
>ADD>				5880136	SEP 27, 2010	U-254		
>ADD>	020913	001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAY 14, 2012	U-230		
>ADD>				5880136	SEP 27, 2010	U-254		
>ADD>	020699	001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
>ADD>	020699	002	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
>ADD>	020699	003	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
>ADD>	020699	004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
>ADD>	019614	004	VERAPAMIL HYDROCHLORIDE;VERELAN	4863742	JUN 19, 2007			

*U.S. Government Printing Office: 1999 — 454-723/00008