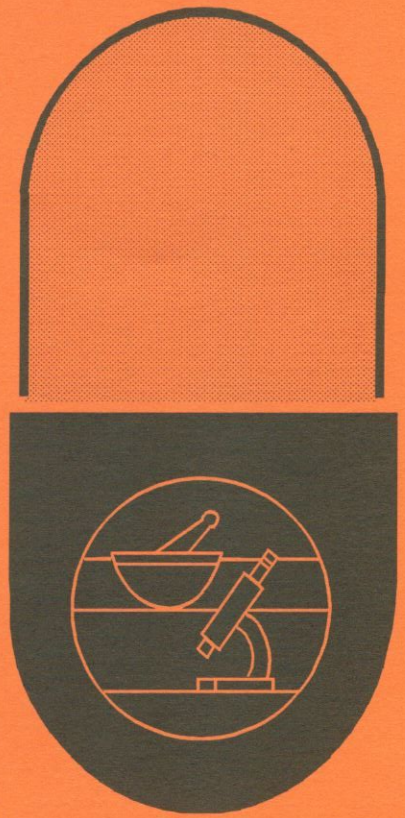
CUMULATIVE SUPPLEMENT 2 FEB'99



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 2

FEBRUARY 1999

CONTENTS

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

CUMULATIVE SUPPLEMENT 2
FEBRUARY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 – FEBRUARY1999

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.

The 19th annual edition of the 1998 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/19bookpub.pdf.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at
http://www.fda.gov/cder/orange/supplement/patents.pdf.

The current listing of the Orphan Product Designations and Approvals is available at
http://www.fda.gov/orphan/designat/list.htm.

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

AA	MALLINCKRODT	500MG;5MG	N88956 001	
			JUL 19, 1985	

ZYDONE

AA	MALLINCKRODT	500MG;5MG	N88956 001	
			JUL 19, 1985	

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100

AB	TEVA	650MG;100MG	N70107 001	
			JUN 12, 1985	
	@	650MG;100MG	N70107 001	
			JUN 12, 1985	

ACYCLOVIR

CAPSULE; ORAL
ACYCLOVIR

AB	STASON	200MG	N75090 001	
			JAN 26, 1999	

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR SODIUM

> ADD >	AP	+	AM PHARM PARTNERS	EQ 50MG BASE/ML	N74930 001
> ADD >					MAY 13, 1998
> DLT >		*		EQ 50MG BASE/ML	N74930 001
> DLT >					MAY 13, 1998
> ADD >	AP		MERIDIAN MEDCL TECHN	EQ 50MG BASE/ML	N75065 001
> ADD >					FEB 25, 1999

ALBUTEROL

AEROSOL, METERED; INHALATION
ALBUTEROL

AB	MEDEVA	0.09MG/INH	N72273 001	
			AUG 14, 1996	
AB	MEDEVA PHARMS MA	0.09MG/INH	N72273 001	
			AUG 14, 1996	

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

> ADD >	AN		HI TECH PHARMA	EQ 0.083% BASE	N75063 001
> ADD >					FEB 09, 1999

ALITRETINOIN

GEL; TOPICAL
PANRETIN

> ADD >		+	LIGAND	EQ 0.1% BASE	N20886 001
> ADD >					FEB 02, 1999

ALLOPURINOL

TABLET; ORAL
ZYLOPRIM

AB			FARO PHARMS	100MG	N16084 001
AB		+		300MG	N16084 002
AB			GLAXO WELLCOME	100MG	N16084 001
AB		*		300MG	N16084 002

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL

> ADD >	AB	ALPHAPHARM	200MG	N75188 001
> ADD >				FEB 24, 1999

BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL
CORZIDE

		APOTHECON	5MG;40MG	N18647 001
				MAY 25, 1983
	+		5MG;80MG	N18647 002
				MAY 25, 1983
		BRISTOL MYERS SQUIBB	5MG;40MG	N18647 001
				MAY 25, 1983
	*		5MG;80MG	N18647 002
				MAY 25, 1983

BETAMETHASONE VALERATE

> ADD > AEROSOL; TOPICAL
> ADD > LUXIQ
> ADD > + CONNETICS EQ 0.12% BASE N20934 001
> ADD > FEB 28, 1999

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
WELLBUTRIN
> DLT > + GLAXO WELLCOME 50MG N20358 001
> DLT > OCT 04, 1996
> DLT > + 100MG N20358 002
> DLT > OCT 04, 1996
> DLT > + 150MG N20358 003
> DLT > OCT 04, 1996

WELLBUTRIN SR
> ADD > + GLAXO WELLCOME 50MG N20358 001
> ADD > OCT 04, 1996
> ADD > + 100MG N20358 002
> ADD > OCT 04, 1996
> ADD > + 150MG N20358 003
> ADD > OCT 04, 1996

BUSULFAN

> ADD > INJECTABLE; INJECTION
> ADD > BUSULFEX
> ADD > + ORPHAN MEDCL 6MG/ML N20954 001
> ADD > FEB 04, 1999

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

INJECTABLE; INJECTION
ISOLYTE R W/ DEXTROSE 5% IN PLASTIC CONTAINER
B BRAUN 37MG/100ML;5GM/100ML;31MG/100ML; 120MG/100ML;330MG/100ML; 88MG/100ML N18271 001

@ 37MG/100ML;5GM/100ML;31MG/100ML; 120MG/100ML;330MG/100ML; 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
B BRAUN 35MG/100ML;5GM/100ML;30MG/100ML; 74MG/100ML;640MG/100ML;500MG/100ML; 74MG/100ML N18269 002
JAN 17, 1983

@ 35MG/100ML;5GM/100ML;30MG/100ML; 74MG/100ML;640MG/100ML;500MG/100ML; 74MG/100ML N18269 002
JAN 17, 1983

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
CHLORPROMAZINE HCL
AA PHARM ASSOC 100MG/ML **N40224 001**
JAN 26, 1999

CILOSTAZOL

TABLET; ORAL
PLETAL
OTSUKA 50MG N20863 001
JAN 15, 1999
+ 100MG N20863 002
JAN 15, 1999

CLOBETASOL PROPIONATE

SOLUTION; TOPICAL
CLOBETASOL PROPIONATE
> ADD > **AT** ALTANA 0.05% **N75391 001**
> ADD > FEB 08, 1999

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION
> ADD > COLISTIMETHATE
> ADD > **AP** PHARMA TEK EQ 150MG BASE/VIAL **N64216 001**
> ADD > FEB 26, 1999

COLY-MYCIN M
> ADD > **AP** + PARKEDALE EQ 150MG BASE/VIAL **N50108 002**

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION
COLY-MYCIN M

> DLT >	*	PARKEDALE	EQ 150MG BASE/VIAL	N50108 002

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DDAVP

AB	+	RHONE POULENC RORER	0.01MG/SPRAY	N17922 003 AUG 07, 1996
	*		0.01MG/SPRAY	N17922 003 AUG 07, 1996

DESMOPRESSIN ACETATE

AB		BAUSCH AND LOMB	0.01MG/SPRAY	N74830 001 JAN 25, 1999

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
MAXITROL

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

SUSPENSION/DROPS; OPHTHALMIC
MAXITROL

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

DIAZEPAM

GEL; RECTAL
DIASTAT

	*	ATHENA	2.5MG/0.5ML	N20648 001 JUL 29, 1997
			5MG/ML	N20648 002 JUL 29, 1997
			10MG/2ML	N20648 003 JUL 29, 1997
			15MG/3ML	N20648 004 JUL 29, 1997

DIAZEPAM

GEL; RECTAL
DIASTAT

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

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM

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

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM

> ADD >	AB	MARTEC	50MG	N74986 001 FEB 26, 1999
> ADD >	AB		75MG	N74986 002 FEB 26, 1999

DICYCLOMINE HYDROCHLORIDE

TABLET; ORAL
DICYCLOMINE HCL

> ADD >	AB	LANNETT	20MG	N40230 001 FEB 26, 1999

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL
DYNABAC

	*	LILLY	250MG	N50678 001 JUN 19, 1995

† SEE SECTION 1.3 OF INTRODUCTION

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL

		DYNABAC			
	+	SANOFI	250MG	N50678 001	
				JUN 19, 1995	

EPINEPHRINE

INJECTABLE; INJECTION

> DLT >		SUS-PHRINE			
> DLT >	+	FOREST LABS	5MG/ML	N07942 001	
> ADD >		SUS-PHRINE SULFITE-FREE			
> ADD >		FOREST LABS	1.5MG/AMP	N07942 003	
> ADD >				FEB 05, 1999	
> ADD >	+		5MG/ML	N07942 001	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

		BREVICON 21-DAY			
> DLT >	AB	SEARLE	0.035MG;0.5MG	N17566 001	
> ADD >	AB	WATSON LABS	0.035MG;0.5MG	N17566 001	
		NORINYL 1+35 21-DAY			
	AB	SEARLE	0.035MG;1MG	N17565 001	
	AB	WATSON LABS	0.035MG;1MG	N17565 001	
		TRI-NORINYL 21-DAY			
> DLT >	+	SEARLE	0.035MG,0.035MG;0.5MG,1MG	N18977 001	
> DLT >				APR 13, 1984	
> ADD >	+	WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977 001	
> ADD >				APR 13, 1984	

TABLET; ORAL-28

		BREVICON 28-DAY			
> DLT >	AB	SEARLE	0.035MG;0.5MG	N17743 001	
> ADD >	AB	WATSON LABS	0.035MG;0.5MG	N17743 001	
		NORINYL 1+35 28-DAY			
	AB	SEARLE	0.035MG;1MG	N17565 002	
	AB	WATSON LABS	0.035MG;1MG	N17565 002	
		TRI-NORINYL 28-DAY			
> DLT >		SEARLE	0.035MG,0.035MG;0.5MG,1MG	N18977 002	
> DLT >				APR 13, 1984	
> ADD >		WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977 002	
> ADD >				APR 13, 1984	

ETOPOSIDE

INJECTABLE; INJECTION

		VEPESID			
AP	+	BRISTOL	20MG/ML	N18768 001	
				NOV 10, 1983	
AP	+	BRISTOL MYERS SQUIBB	20MG/ML	N18768 001	
				NOV 10, 1983	

> ADD > FERRIC SODIUM GLUCONATE

> ADD > INJECTABLE; INJECTION

> ADD >		FERRLECIT			
> ADD >	+	R AND D LABS	62.5MG/5ML	N20955 001	
> ADD >				FEB 18, 1999	

HYDROXYUREA

CAPSULE; ORAL

		HYDROXYUREA			
> ADD >	AB	PAR PHARM	500MG	N75340 001	
> ADD >				FEB 24, 1999	

IBUPROFEN

SUSPENSION; ORAL

		MOTRIN			
AB	+	MCNEIL	100MG/5ML	N19842 001	
				SEP 19, 1989	
AB	+	MCNEIL CONS	100MG/5ML	N19842 001	
				SEP 19, 1989	

TABLET; ORAL

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

IBUPROFEN

TABLET; ORAL

MOTRIN					
MCNEIL CONS	100MG	N20418 001			
		NOV 16, 1994			

TABLET, CHEWABLE; ORAL

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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL					
AN INTL MEDICATION	**0.08%**	**N86651 002**			
AN	**0.1%**	**N86651 003**			
AN +	0.1%	N86651 003			
AN	**0.167%**	**N86651 005**			
AN +	0.167%	N86651 005			
AN	**0.25%**	**N86651 007**			
AN +	**0.25%**	**N86651 007**			
+	0.08%	N86651 002			
ISOETHARINE HCL S/F					
AN + DEY	**0.08%**	**N89817 001**			
		NOV 22, 1988			
AN +	**0.1%**	**N89818 001**			
		NOV 22, 1988			
AN +	**0.17%**	**N89819 001**	> DLT >		
		NOV 22, 1988	> DLT >		
AN +	**0.25%**	**N89820 001**	> ADD >		
		NOV 22, 1988	> ADD >		
@	0.08%	N89817 001			
		NOV 22, 1988			
@	0.1%	N89818 001			
		NOV 22, 1988	> DLT >		
@	0.17%	N89819 001	> DLT >		
		NOV 22, 1988	> ADD >		
@	0.25%	N89820 001	> ADD >		
		NOV 22, 1988			

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE					
AP ABBOTT	**15MG/ML**	**N74993 001**			
		JAN 27, 1999			
AP	**30MG/ML**	**N74993 002**			
		JAN 27, 1999			

LABETALOL HYDROCHLORIDE

TABLET; ORAL

TRANDATE					
AB FARO PHARMS	**100MG**	**N18716 001**			
		MAY 24, 1985			
AB	**200MG**	**N18716 002**			
		AUG 01, 1984			
AB	**300MG**	**N18716 003**			
		AUG 01, 1984			
@	400MG	N18716 004			
		AUG 01, 1984			
AB GLAXO WELLCOME	**100MG**	**N18716 001**			
		MAY 24, 1985			
AB	**200MG**	**N18716 002**			
		AUG 01, 1984			
AB	**300MG**	**N18716 003**			
		AUG 01, 1984			
@	400MG	N18716 004			
		AUG 01, 1984			

LAMIVUDINE

SOLUTION; ORAL

EPIVIR-HBV					
+ GLAXO WELLCOME	5MG/ML	N21004 001			
		DEC 08, 1998			
+	5MG/ML	N20596 002			
		DEC 08, 1998			

TABLET; ORAL

EPIVIR-HBV					
+ GLAXO WELLCOME	100MG	N21003 001			
		DEC 08, 1998			
+	100MG	N20564 002			
		DEC 08, 1998			

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

> DLT >		LEUCOVORIN CALCIUM			
> DLT >	AP	+ ABBOTT	EQ 10MG BASE/ML	N40147 001	JUN 25, 1997
> DLT >					
> DLT >	AP	+ BEDFORD	EQ 200MG BASE/VIAL	N40056 001	MAY 23, 1995
> DLT >					
> ADD >		LEUCOVORIN CALCIUM PRESERVATIVE FREE			
> ADD >	AP	+ ABBOTT	EQ 10MG BASE/ML	N40147 001	JUN 25, 1997
> ADD >					
> ADD >	AP	+ BEDFORD	EQ 200MG BASE/VIAL	N40056 001	MAY 23, 1995
> ADD >					
> ADD >	AP	BIGMAR	EQ 10MG BASE/ML	N40286 001	FEB 26, 1999
> ADD >					
> ADD >	AP		EQ 200MG BASE/VIAL	N40258 001	FEB 26, 1999
> ADD >					

LIDOCAINE; PRILOCAINE

AEROSOL; TOPICAL

> DLT >		EMLA			
> DLT >		+ ASTRA PHARMS	2.5%;2.5%	N20962 001	FEB 04, 1998
> DLT >					

DISC; TOPICAL

> ADD >		EMLA			
> ADD >		+ ASTRA PHARMS	2.5%;2.5%	N20962 001	FEB 04, 1998
> ADD >					

LISINOPRIL

TABLET; ORAL

		ZESTRIL			
		ZENECA	30MG	N19777 006	JAN 20, 1999

LITHIUM CARBONATE

CAPSULE; ORAL

> DLT >		LITHONATE			
> DLT >	AB	SOLVAY	300MG	N16782 001	
> ADD >		@	300MG	N16782 001	

TABLET; ORAL

		LITHIUM CARBONATE			
> DLT >	AB	PFIZER	300MG	N16834 001	

LITHIUM CARBONATE

TABLET; ORAL

> ADD >		LITHIUM CARBONATE			
> ADD >	AB	+ PFIZER	300MG	N16834 001	
> DLT >					
> DLT >		LITHOTABS			
> ADD >	AB	+ SOLVAY	300MG	N16980 001	
		@	300MG	N16980 001	

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

SYRUP; ORAL

	DEMEROL			
AA	+ ABBOTT	50MG/5ML		N05010 005
AA	+ SANOFI	50MG/5ML		N05010 005

TABLET; ORAL

	DEMEROL			
AA	+ ABBOTT	50MG		N05010 001
AA	+	100MG		N05010 004
AA	+ SANOFI	50MG		N05010 001
AA	+	100MG		N05010 004

METHOTREXATE SODIUM

INJECTABLE; INJECTION

> ADD >		METHOTREXATE		
> ADD >	AP	BIGMAR	EQ 25MG BASE/ML	N40263 001 FEB 26, 1999
> ADD >				
> ADD >		METHOTREXATE PRESERVATIVE FREE		
> ADD >	AP	BIGMAR	EQ 25MG BASE/ML	N40265 001 FEB 26, 1999
> ADD >				
> ADD >	AP		EQ 1GM BASE/VIAL	N40266 001 FEB 26, 1999
> ADD >				
> DLT >		METHOTREXATE SODIUM		
> DLT >		+ LEDERLE	EQ 1GM BASE/VIAL	N11719 009 APR 07, 1988
> DLT >				

METHOTREXATE SODIUM

INJECTABLE; INJECTION

> ADD > **METHOTREXATE SODIUM PRESERVATIVE FREE**

> ADD > **AP** + LEDERLE **EQ 1GM BASE/VIAL** **N11719 009**

> ADD > APR 07, 1988

METHOTRIMEPRAZINE

> DLT > INJECTABLE; INJECTION

> DLT > LEVOPROME

> DLT > + IMMUNEX 20MG/ML N15865 001

> ADD > @ 20MG/ML N15865 001

METHOXSALEN

> ADD > INJECTABLE; INJECTION

> ADD > UVADEX

> ADD > + THERAKOS 0.02MG/ML N20969 001

> ADD > FEB 25, 1999

NADOLOL

TABLET; ORAL

CORGARD

AB APOTHECON **20MG** **N18063 005**

OCT 28, 1986

AB **40MG** **N18063 001**

AB **80MG** **N18063 002**

AB **120MG** **N18063 003**

AB + **160MG** **N18063 004**

AB BRISTOL MYERS SQUIBB **20MG** **N18063 005**

OCT 28, 1986

AB **40MG** **N18063 001**

AB **80MG** **N18063 002**

AB **120MG** **N18063 003**

AB * **160MG** **N18063 004**

NITROGLYCERIN

OINTMENT; TRANSDERMAL

NITROGLYCERIN

> DLT > ALTANA 2% N87355 001

> DLT > JUL 08, 1988

NITROGLYCERIN

OINTMENT; TRANSDERMAL

NITROGLYCERIN

> ADD > + ALTANA 2% N87355 001

> ADD > JUL 08, 1988

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL

ZOFRAN ODT

GLAXO WELLCOME EQ 4MG BASE N20781 001

JAN 27, 1999

+ EQ 8MG BASE N20781 002

JAN 27, 1999

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL

ORPHENADRINE CITRATE

AB KIEL **100MG** **N40249 001**

JAN 29, 1999

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

OXYBUTYNIN CHLORIDE

AA MIKART **5MG/5ML** **N75039 001**

JAN 29, 1999

PAROXETINE HYDROCHLORIDE

> ADD > TABLET, EXTENDED RELEASE; ORAL

> ADD > PAXIL CR

> ADD > + SMITHKLINE BEECHAM EQ 12.5MG BASE N20936 001

> ADD > FEB 16, 1999

> ADD > + EQ 25MG BASE N20936 002

> ADD > FEB 16, 1999

PEMOLINE

TABLET; ORAL

CYLERT

AB ABBOTT **37.5MG** **N16832 002**

PEMOLINE

TABLET; ORAL

		CYLERT		
AB	+	ABBOTT	75MG	N16832 003
			37.5MG	N16832 002
	*		75MG	N16832 003
		PEMOLINE		
AB		COPLEY PHARM	37.5MG	N75030 001 JAN 29, 1999
AB			75MG	N75030 002 JAN 29, 1999

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

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

> ADD > POLYETHYLENE GLYCOL 3350

> ADD > POWDER FOR RECONSTITUTION; ORAL

> ADD >		MIRALAX		
> ADD >	+	BRAINTREE	17GM/SCOOPFUL	N20698 001 FEB 18, 1999

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

		ECONOPRED PLUS		
AB		ALCON	1%	N17469 001
AB		FALCON PHARMS	1%	N17469 001

PREDNISOLONE SODIUM PHOSPHATE

> DLT >		INJECTABLE; INJECTION		
> DLT >		HYDELTRASOL		
> DLT >	*	MERCK	EQ 20MG PHOSPHATE/ML	N11583 002
> ADD >	@		EQ 20MG PHOSPHATE/ML	N11583 002

PROPOFOL

INJECTABLE; INJECTION

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

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

		RANITIDINE HCL		
AB		PAR PHARM	EQ 150MG BASE	N75180 001 JAN 28, 1999
AB			EQ 300MG BASE	N75180 002 JAN 28, 1999

RISPERIDONE

TABLET; ORAL

		RISPERDAL		
	+	JANSSEN	0.05MG	N20272 007 JAN 27, 1999

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

		ELDEPRYL		
	@	SOMERSET	5MG	N19334 001 JUN 05, 1989
		SELEGILINE HCL		
AB	+	SOMERSET	5MG	N19334 001 JUN 05, 1989

SPIRONOLACTONE

TABLET; ORAL

		SPIRONOLACTONE		
AB		PUREPAC PHARM	25MG	N87998 001 OCT 14, 1983

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

@	PUREPAC PHARM	25MG	N87998 001	OCT 14, 1983

THEOPHYLLINE

INJECTABLE; INJECTION
THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER

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

THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER

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

THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER

@	B BRAUN	160MG/100ML	N19083 003	NOV 07, 1984
@	MCGAW	160MG/100ML	N19083 003	NOV 07, 1984

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOTHIXENE HCL

AA	ALPHARMA	EQ 5MG BASE/ML	N70969 001	OCT 16, 1987
@		EQ 5MG BASE/ML	N70969 001	OCT 16, 1987

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC
TIMOLOL MALEATE

AB	ALCON	EQ 0.25% BASE	N20963 001	OCT 21, 1998
AB	FALCON PHARMS	EQ 0.25% BASE	N20963 001	OCT 21, 1998

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

AT	ADV REMEDIES	EQ 0.5% BASE	N74466 001	MAR 25, 1997

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

AT	AKORN	EQ 0.5% BASE	N74466 001	MAR 25, 1997

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
TOBREX

AT	+ ALCON	0.3%	N50541 001	
AT	+ FALCON PHARMS	0.3%	N50541 001	

TRETINOIN

SOLUTION; TOPICAL
TRETINOIN

AT	MORTON GROVE	0.05%	N75260 001	JAN 25, 1999

UREA, C-13

>ADD> POWDER FOR RECONSTITUTION; ORAL
>ADD> PYLORI-CHEK BREATH TEST
>ADD>

+	ALIMENTERICS	100MG/VIAL	N20900 001	FEB 04, 1999

CLOTRIMAZOLE

CREAM; TOPICAL
LOTRIMIN AF

>_DLT_>		SCHERING PLOUGH	1%	N17619 002
>_DLT_>				OCT 27, 1989

LOTION; TOPICAL
LOTRIMIN AF

>_DLT_>		SCHERING	1%	N18813 002
>_DLT_>				OCT 27, 1989

SOLUTION; TOPICAL
LOTRIMIN AF

>_DLT_>		SCHERING PLOUGH	1%	N17613 002
>_DLT_>				OCT 27, 1989

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL

>_ADD_>				
>_ADD_>		PERRIGO	120MG	N75153 001
>_ADD_>				FEB 26, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
ZANTAC 75

	*	GLAXO WELLCOME	EQ 75MG BASE	N20520 001
				DEC 19, 1995
	+	WARNER LAMBERT	EQ 75MG BASE	N20520 001
				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 2 FEB '99

NO FEBRUARY 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
February 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
166Ho-DOTMP TN=	Treatment of multiple myeloma.	NeoRx Corporation 410 W. Harrison Seattle, WA 98119 DD=02/10/1999
Alitretinoin TN= Panretin	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998 MA=02/02/1999
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
Autologous DNP-conjugated tumor vaccine TN= M-Vax	For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).	Avax Technologies, Inc. 4520 Main St. Suite 930 Kansas City, MO 64111 DD=02/23/1999
Bleomycin TN= Blenoxane	Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999

Orphan Product Designations and Approvals List
February 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Busulfan TN= Busulfex	As preparative therapy in the treatment of malignancies with bone marrow transplantation.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=07/28/1994 MA=02/04/1999
Decitabine TN=	Treatment of myelodysplastic syndromes.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands DD=03/08/1999
Decitabine TN=	Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem The Netherlands DD=03/08/1999
Denileukin diftitox TN= Ontak	Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/1996 MA=02/05/1999
Humanized MAb (IDEC-131) to CD40L TN=	Treatment of systemic lupus erythematosus.	Idec Pharmaceuticals Corporation 3030 Callan Rd. San Diego, CA 92121 DD=02/09/1999
Interferon beta-1a (recombinant human) TN= Avonex	Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999

Orphan Product Designations and Approvals List
February 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) TN= 131IchTNT-1	Treatment of glioblastoma multiforme and anaplastic astrocytoma.	Techniclone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999
L-5-hydroxytryptophan TN=	Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA 91718 DD=01/20/1999
N-acetylgalactosamine-4-sulfatase, recombinant human TN=	Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=02/17/1999
Recombinant human C1-esterase inhibitor TN=	Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel Belgium, DD=02/23/1999
Recombinant human C1-esterase inhibitor TN=	Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel Belgium, DD=02/23/1999

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

NO FEBRUARY 1999 ADDITIONS

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER 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). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

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)**
I-255	**PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP)**
I-256	**USE IN TREATMENT OF SMALL CELL LUNG CANCER SENSITIVE DISEASE AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY**
I-257	**TREATMENT OF CHRONIC HEPATITIS B ASSOCIATED WITH EVIDENCE OF HEPATITIS B VIRAL REPLICATION AND ACTIVE LIVER INFLAMMATION**

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**
U-258	**TREATMENT OF NEURODEGENERATIVE DISEASES**

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
	020482	004	ACARBOSE;PRECOSE				I-252	SEP 29, 2001
							I-253	SEP 29, 2001
	020886	001	ALITRETINOIN;PANRETIN				ODE	FEB 02, 2006
>ADD>							NCE	FEB 02, 2004
	020500	001	ATOVAQUONE;MEPRON				ODE	JAN 05, 2006
>ADD>							I-255	JAN 05, 2002
	020711	002	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
	020711	003	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
	020954	001	BUSULFAN;BUSULFEX				ODE	FEB 04, 2006
>ADD>							NDF	FEB 04, 2002
>ADD>	020638	001	CIDOFOVIR;VISTIDE	5142051	JUN 26, 2010			
>ADD>	020863	001	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
>ADD>	020863	002	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
>ADD>	021041	001	CYTARABINE;DEPOCYT				NP	APR 01, 2002
>ADD>	017922	001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
>ADD>	017922	002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
>ADD>	017922	003	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
>ADD>	018938	001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
>ADD>	018938	002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
>ADD>	019955	001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
>ADD>	019955	002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	020972	001	EFAVIRENZ;SUSTIVA	5811423	AUG 07, 2012	U-256		
				5519021	MAY 21, 2013			
				5663169	SEP 02, 2014	U-257		
	020972	002	EFAVIRENZ;SUSTIVA	5811423	AUG 07, 2012	U-256		
				5519021	MAY 21, 2013			
				5663169	SEP 02, 2014	U-257		
	020972	003	EFAVIRENZ;SUSTIVA	5519021	MAY 21, 2013			
				5663169	SEP 02, 2014	U-257		
				5811423	AUG 07, 2012	U-256		
	020375	001	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
	020375	002	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
	020375	003	ESTRADIOL;CLIMARA				I-254	MAR 05, 2002
	020375	004	ESTRADIOL;CLIMARA	5223261	JUN 29, 2010		I-254	MAR 05, 2002
	020908	001	ESTRADIOL;VAGIFEM				NP	MAR 26, 2002
	020992	002	ESTROGENS, CONJUGATED;CENESTIN				NP	MAR 24, 2002
	020992	003	ESTROGENS, CONJUGATED;CENESTIN				NP	MAR 24, 2002
	020527	003	ESTROGENS, CONJUGATED;PREMPRO 14/14	4826831	MAY 02, 2006			
				5547948	JAN 17, 2015			
	019304	002	FENOFIBRATE;TRICOR (MICRONIZED)	4895726	JAN 19, 2009			
	020747	001	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747	002	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747	003	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747	004	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747	005	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
	020747	006	FENTANYL CITRATE;ACTIQ				NP	NOV 04, 2001
>ADD>	020882	001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
>ADD>				5084479	JAN 02, 2010	U-258		
>ADD>	020882	002	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
>ADD>				5084479	JAN 02, 2010	U-258		

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
	020083	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
	020657	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
	020966	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
>ADD>	020564	002	LAMIVUDINE;EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
>ADD>				5532246	JUL 02, 2013	U-250		
>ADD>	020596	002	LAMIVUDINE;EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
>ADD>				5532246	JUL 02, 2013	U-250		
	020764	001	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
	020764	002	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
	020764	003	LAMOTRIGINE;LAMICTAL CD				I-247	DEC 14, 2001
	020612	001	LIDOCAINE;LIDODERM				ODE	MAR 19, 2006
	019777	006	LISINOPRIL;ZESTRIL	4374829	DEC 30, 2001			
	019643	002	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
	019643	003	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
	019643	004	LOVASTATIN;MEVACOR				I-250	MAR 11, 2002
	020969	001	METHOXSALEN;UVADEX				NP	FEB 25, 2002
	020717	001	MODAFINIL;PROVIGIL	4177290	MAR 09, 1999			
				5618845	OCT 06, 2014	U-255		
				4927855	MAY 22, 2007	U-255		
	020717	002	MODAFINIL;PROVIGIL	4177290	MAR 09, 1999			
				5618845	OCT 06, 2014	U-255		
				4927855	MAY 22, 2007	U-255		
>ADD>	018612	003	NICOTINE POLACRILEX;NICORETTE (MINT)				NP	DEC 23, 2001
>ADD>	020066	003	NICOTINE POLACRILEX;NICORETTE (MINT)				NP	DEC 23, 2001
	020897	001	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
	020897	002	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
	020031	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031	002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031	003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031	004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020031	005	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020710	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885	002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885	003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
	020885	004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
>ADD>	020936	001	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132	MAY 19, 2015		NDF	FEB 16, 2002
>ADD>	020936	002	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132	MAY 19, 2015		NDF	FEB 16, 2002
>ADD>	020698	001	POLYETHYLENE GLYCOL 3350;MIRALAX				NP	FEB 18, 2002
	020639	004	QUETIAPINE FUMARATE;SEROQUEL	4879288	MAR 20, 2007		NCE	SEP 26, 2002
	020272	007	RISPERIDONE;RISPERDAL	5158952	DEC 29, 2007	U-90	D-37	OCT 17, 2000
				4804663	DEC 29, 2007	U-90		
	020912	001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAY 14, 2012	U-230		
				5880136	SEP 27, 2010	U-254		
	020913	001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAY 14, 2012	U-230		
				5880136	SEP 27, 2010	U-254		
>ADD>	020671	001	TOPOTECAN HYDROCHLORIDE;HYCAMTIN				I-256	NOV 30, 2001
	020699	001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
	020699	002	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002

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
020699	003	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
020699	004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-251	MAR 11, 2002
019614	004	VERAPAMIL HYDROCHLORIDE;VERELAN	4863742	JUN 19, 2007			

*U.S. Government Printing Office: 1999 — 454-723/00009