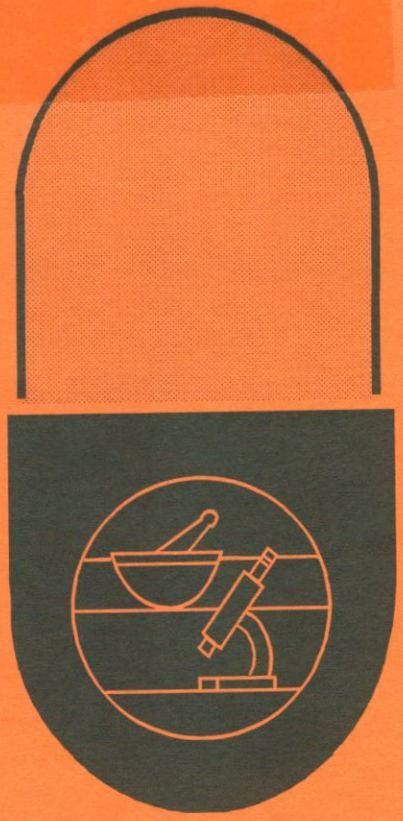
CUMULATIVE
SUPPLEMENT 4
APR'99



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 4

APRIL 1999

CONTENTS

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THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

CUMULATIVE SUPPLEMENT 4
APRIL 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 – APRIL 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 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 1998) 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	9975		
SINGLE SOURCE	2504 (25.2%)	2520 (25.3%)		
MULTISOURCE	7308 (73.6%)	7344 (73.6%)		
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)	6969 (69.9%)		
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)	375 (3.8%)		
EXCEPTIONS[1]	111 (1.1%)	111 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	10	3		
NUMBER OF APPLICANTS	563	570		

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

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

> ADD > TABLET; ORAL
> ADD > ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODONE BITARTRATE
> ADD > + MIKART 712.8MG;60MG;32MG N40316 001 APR 28, 1999
> ADD >

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
ALLAY
> DLT > AA NORTON HN 500MG;5MG N89907 001 JAN 13, 1989
> DLT >
> ADD > AA ZENITH GOLDLINE 500MG;5MG N89907 001 JAN 13, 1989
> ADD >

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA MALLINCKRODT 500MG;5MG N88956 001 JUL 19, 1985

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN
AA DURAMED 500MG;5MG N40289 001 MAR 16, 1999

TABLET; ORAL
OXYCODONE AND ACETAMINOPHEN
AA AMIDE PHARM 325MG;5MG N40203 001 MAR 15, 1999

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

TABLET; ORAL
ACYCLOVIR
> ADD > AB CARLSBAD 400MG N75382 001 APR 30, 1999
> ADD >
> ADD > AB 800MG N75382 002 APR 30, 1999
> ADD >

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR SODIUM
AP + AM PHARM PARTNERS EQ 50MG BASE/ML N74930 001 MAY 13, 1998
+ EQ 50MG BASE/ML N74930 001 MAY 13, 1998
AP MERIDIAN MEDCL TECHN EQ 50MG BASE/ML N75065 001 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
AN HI TECH PHARMA EQ 0.083% BASE N75063 001 FEB 09, 1999

SYRUP; ORAL
ALBUTEROL SULFATE
AA UDL EQ 2MG BASE/5ML N75262 001 MAR 30, 1999

ALITRETINOIN

GEL; TOPICAL
PANRETIN
+ LIGAND — EQ 0.1% BASE — N20886 001 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

> ADD > ALPHA-TOCOPHEROL; ASCORBIC ACID; BIOTIN, D-; CHOLECALCIFEROL; CYANOCOBALAMIN; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A

INJECTABLE; INJECTION
CERNEVIT-12
+ BAXTER HLTHCARE — 11.2 IU/VIAL;125MG/VIAL;60 UGM/VIAL; 200 IU/VIAL;5.5MG/VIAL;414 UGM/VIAL; 46MG/VIAL;17.25MG/VIAL;4.53MG/VIAL; 4.14MG/VIAL;3.51MG/VIAL; 3,500 IU/VIAL — N20924 001 APR 06, 1999

ALPROSTADIL

INJECTABLE; INJECTION
ALPROSTADIL

> ADD > AP		GENSIA SICOR PHARMS	0.5MG/ML	N75196 001 APR 30, 1999

AMCINONIDE

CREAM; TOPICAL
CYCLOCORT

> ADD >		@ FUJISAWA HLTHCARE	0.025%	N18116 001
> ADD >	+		0.1%	N18116 002
> DLT >		LEDERLE	0.025%	N18116 001
> DLT >	*		0.1%	N18116 002

AMCINONIDE

LOTION; TOPICAL
CYCLOCORT

> ADD >	+	FUJISAWA HLTHCARE	0.1%	N19729 001 JUN 13, 1988
> ADD > > DLT > > DLT >	*	LEDERLE	0.1%	N19729 001 JUN 13, 1988

OINTMENT; TOPICAL
CYCLOCORT

> ADD >	+	FUJISAWA HLTHCARE	0.1%	N18498 001
> DLT >	*	NYETH AYERST	0.1%	N18498 001

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL

AB	ALPHAPHARM	200MG	N75188 001 FEB 24, 1999
> ADD > > ADD > AB	NOVOPHARM	200MG	N74895 001 APR 16, 1999

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
ENDEP

> DLT > AB	ROCHE	10MG	N83639 001
> DLT > AB		25MG	N83639 002
> DLT > AB		50MG	N83639 003
> DLT > AB		75MG	N83639 004
> DLT > AB		100MG	N83639 005
> ADD >	@	10MG	N83639 001
> ADD >	@	25MG	N83639 002
> ADD >	@	50MG	N83639 003
> ADD >	@	75MG	N83639 004
> ADD >	@	100MG	N83639 005

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

> ADD > AB	RANBAXY	250MG	N65016 001 APR 08, 1999
> ADD > > ADD > AB		500MG	N65016 002 APR 08, 1999

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL
AMOXIL

> ADD >	SMITHKLINE BEECHAM	200MG/5ML	N50760 001	
> ADD >			APR 15, 1999	
> ADD >	+	400MG/5ML	N50760 002	
> ADD >			APR 15, 1999	

TABLET, CHEWABLE; ORAL
AMOXIL

> ADD >	SMITHKLINE BEECHAM	200MG	N50761 001	
> ADD >			APR 15, 1999	
> ADD >	+	400MG	N50761 002	
> ADD >			APR 15, 1999	

AMPRENAVIR

CAPSULE; ORAL
AGENERASE

> ADD >	GLAXO WELLCOME	50MG	N21007 001	
> ADD >			APR 15, 1999	
> ADD >	+	150MG	N21007 002	
> ADD >			APR 15, 1999	

SOLUTION; ORAL
AGENERASE

> ADD >	+ GLAXO WELLCOME	15MG/ML	N21039 001	
> ADD >			APR 15, 1999	

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL
BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE

AB	ENDO PHARMS	325MG;50MG;40MG;30MG	N75351 001	
			MAR 05, 1999	

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENADRINE CITRATE, ASPIRIN, AND CAFFEINE

> ADD > AB	STEVENS J	385MG;30MG;25MG	N74988 001	
> ADD >			APR 30, 1999	
> ADD > AB		770MG;60MG;50MG	N74988 002	
> ADD >			APR 30, 1999	

ATENOLOL

TABLET; ORAL
ATENOLOL

> DLT > AB	APOTHECON	50MG	N73317 001	
> DLT >			MAR 20, 1992	
> DLT > AB		100MG	N73318 001	
> DLT >			MAR 20, 1992	
> ADD >	@	50MG	N73317 001	
> ADD >			MAR 20, 1992	
> ADD >	@	100MG	N73318 001	
> ADD >			MAR 20, 1992	

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL W/ ATROPINE SULFATE

AA	ZENITH GOLDLINE	0.025MG;2.5MG	N86727 001	
	@	0.025MG;2.5MG	N86727 001	

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

AEROSOL; TOPICAL
LUXIQ

	+ CONNETICS	EQ 0.12% BASE	N20934 001	
			FEB 28, 1999	

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
WELLBUTRIN

	+ GLAXO WELLCOME	50MG	N20358 001	
			OCT 04, 1996	

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

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

BUSULFAN

INJECTABLE; INJECTION

	BUSULFEX			
+	ORPHAN MEDCL	6MG/ML	N20954 001	FEB 04, 1999

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

	ENDOSOL EXTRA			
AT	AKORN	0.154MG/ML;0.92MG/ML;0.184MG/ML; 0.2MG/ML;0.38MG/ML;2.1MG/ML; 7.14MG/ML;0.42MG/ML	N20079 001	NOV 27, 1991
AT	ALLERGAN	0.154MG/ML;0.92MG/ML;0.184MG/ML; 0.2MG/ML;0.38MG/ML;2.1MG/ML; 7.14MG/ML;0.42MG/ML	N20079 001	NOV 27, 1991

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	
	@ B BRAUN	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

CAPTOPRIL

TABLET; ORAL

		CAPTOPRIL				
> DLT >	AB	BAKER NORTON	12.5MG	N74590 004	AUG 30, 1996	
> DLT >	AB		25MG	N74590 002	AUG 30, 1996	
> DLT >	AB		50MG	N74590 001	AUG 30, 1996	
> DLT >	AB		100MG	N74590 003	AUG 30, 1996	
> ADD >	AB	ZENITH GOLDLINE	12.5MG	N74590 004	AUG 30, 1996	
> ADD >	AB		25MG	N74590 002	AUG 30, 1996	
> ADD >	AB		50MG	N74590 001	AUG 30, 1996	
> ADD >	AB		100MG	N74590 003	AUG 30, 1996	

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

		OCUPRESS			
>ADD<	+	CIBA	1%	N19972 001	
>ADD<				MAY 23, 1990	
>DLT<	+	OTSUKA	1%	N19972 001	
>DLT<				MAY 23, 1990	

CEFADROXIL/CEFADROXIL HEMIHYDRATE

TABLET; ORAL

		CEFADROXIL			
>ADD<	AB	RANBAXY	EQ 1GM BASE	N65018 001	
>ADD<				APR 23, 1999	

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION

		CEPTAZ			
>DLT<	AP	+ GLAXO WELLCOME	1GM/VIAL	N50646 002	
>DLT<				SEP 27, 1990	
>DLT<	AP	+	2GM/VIAL	N50646 003	
>DLT<				SEP 27, 1990	
>DLT<	AP	+	10GM/VIAL	N50646 004	
>DLT<				SEP 27, 1990	
>ADD<		+	1GM/VIAL	N50646 002	
>ADD<				SEP 27, 1990	
>ADD<		+	2GM/VIAL	N50646 003	
>ADD<				SEP 27, 1990	
>ADD<		+	10GM/VIAL	N50646 004	
>ADD<				SEP 27, 1990	
>DLT<		PENTACEF			
>DLT<	AP	SMITHKLINE BEECHAM	1GM/VIAL	N63322 001	
>DLT<				NOV 07, 1995	
>DLT<	AP		1GM/VIAL	N64006 001	
>DLT<				MAR 31, 1992	
>DLT<	AP		2GM/VIAL	N64006 002	
>DLT<				MAR 31, 1992	
>DLT<	AP		10GM/VIAL	N64008 002	
>DLT<				MAR 31, 1992	
>DLT<			6GM/VIAL	N64008 001	
>DLT<				MAR 31, 1992	
>ADD<		@	1GM/VIAL	N63322 001	
>ADD<				NOV 07, 1995	
>ADD<		@	1GM/VIAL	N64006 001	
>ADD<				MAR 31, 1992	

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION

		PENTACEF			
>ADD<		@ SMITHKLINE BEECHAM	2GM/VIAL	N64006 002	
>ADD<				MAR 31, 1992	
>ADD<		@	6GM/VIAL	N64008 001	
>ADD<				MAR 31, 1992	
>ADD<		@	10GM/VIAL	N64008 002	
>ADD<				MAR 31, 1992	

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

		CHLORPROMAZINE HCL			
AA		PHARM ASSOC	100MG/ML	N40224 001	
				JAN 26, 1999	

CHOLESTYRAMINE

POWDER; ORAL

		CHOLESTYRAMINE			
>DLT<	AB	BAKER NORTON	EQ 4GM RESIN/PACKET	N74771 001	
>DLT<				JUL 09, 1997	
>DLT<	AB		EQ 4GM RESIN/SCOOPFUL	N74771 002	
>DLT<				JUL 09, 1997	
>ADD<	AB	ZENITH GOLDLINE	EQ 4GM RESIN/PACKET	N74771 001	
>ADD<				JUL 09, 1997	
>ADD<	AB		EQ 4GM RESIN/SCOOPFUL	N74771 002	
>ADD<				JUL 09, 1997	
		CHOLESTYRAMINE LIGHT			
AB		COPLEY PHARM	EQ 4GM RESIN/SCOOPFUL	N74555 002	
				SEP 30, 1998	

CILOSTAZOL

TABLET; ORAL

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

CLOBETASOL PROPIONATE

SOLUTION; TOPICAL

		CLOBETASOL PROPIONATE		
AT		ALTANA	0.05%	N75391 001 FEB 08, 1999

CLOXACILLIN SODIUM

CAPSULE; ORAL

		CLOXAPEN		
> DLT >	AB	SMITHKLINE BEECHAM	EQ 250MG BASE	N62233 001
> DLT >	AB		EQ 500MG BASE	N62233 002
> ADD >		@	EQ 250MG BASE	N62233 001
> ADD >		@	EQ 500MG BASE	N62233 002

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION

		COLISTIMETHATE		
AP		PHARMA TEK	EQ 150MG BASE/VIAL	N64216 001 FEB 26, 1999
		COLY-MYCIN M		
AP	+	PARKEDALE	EQ 150MG BASE/VIAL	N50108 002
	#		EQ 150MG BASE/VIAL	N50108 002

CROMOLYN SODIUM

> DLT >		CAPSULE; ORAL		
> DLT >		GASTROCROM		
> DLT >	+	MEDEVA	100MG	N19188 001
> DLT >				DEC 22, 1989
> ADD >		@	100MG	N19188 001
> ADD >				DEC 22, 1989

SOLUTION/DROPS; OPHTHALMIC

> ADD >		CROMOPTIC		
> ADD >	AT	KING PHARMS	4%	N75088 001 APR 27, 1999
> ADD >				

CYTARABINE

INJECTABLE, LIPOSOMAL; INJECTION

> ADD >		DEPOCYT		
> ADD >	+	DEPOTECH	10MG/ML	N21041 001 APR 01, 1999
> ADD >				

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
	#		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

DIAZEPAM

GEL; RECTAL
DIASTAT

	ELAN PHARMS	10MG/2ML	N20648 003	> DLT >	
			JUL 29, 1997	> DLT >	
		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

AB	MARTEC	50MG	N74986 001		
			FEB 26, 1999		
AB		75MG	N74986 002		
			FEB 26, 1999		
AB	NOVOPHARM	50MG	N74723 001		
			MAR 30, 1999		

DICYCLOMINE HYDROCHLORIDE

TABLET; ORAL
DICYCLOMINE HCL

AB	LANNETT	20MG	N40230 001		
			FEB 26, 1999		

DIFLORASONE DIACETATE

OINTMENT; TOPICAL
DIFLORASONE DIACETATE

> ADD >					
> ADD >	AB	ALTANA	0.05%	N75374 001	
> ADD >				APR 27, 1999	
		PSORCON			
> ADD >	AB	+ PHARMACIA AND UPJOHN	0.05%	N19260 001	
> ADD >				AUG 28, 1985	

DIFLORASONE DIACETATE

OINTMENT; TOPICAL
PSORCON

	+ PHARMACIA AND UPJOHN	0.05%	N19260 001	> DLT >	
			AUG 28, 1985	> DLT >	

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION
DILTIAZEM HCL

				> ADD >	
AP	MERIDIAN MEDCL TECHN	5MG/ML	N75106 001	> ADD >	
			APR 29, 1999		

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
DIPIVEFRIN HCL

AT	ALCON	0.1%	N73636 001
			JUN 30, 1994
AT	FALCON PHARMS	0.1%	N73636 001
			JUN 30, 1994

DIPYRIDAMOLE

TABLET; ORAL
DIPYRIDAMOLE

AB	PUREPAC PHARM	25MG	N89425 001
			JUL 12, 1990
	#	25MG	N89425 001
			JUL 12, 1990

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL
DYNABAC

	# LILLY	250MG	N50678 001
			JUN 19, 1995
	+ SANOFI	250MG	N50678 001
			JUN 19, 1995

† SEE SECTION 1.3 OF INTRODUCTION

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION

		DOXIL			
> ADD >	+	ALZA	2MG/ML	N50718 001	
> ADD >				NOV 17, 1995	
> DLT >	+	SEQUUS	2MG/ML	N50718 001	> ADD >
> DLT >				NOV 17, 1995	> ADD >

EPINEPHRINE

INJECTABLE; INJECTION

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

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

		CLIMARA			
BX	+	BERLEX LABS	0.025MG/24HR	N20375 004	> DLT >
				MAR 05, 1999	> ADD >

TABLET; ORAL

		ESTRADIOL			
> ADD >	AB	MYLAN	0.5MG	N40326 001	
> ADD >				APR 21, 1999	
> ADD >	AB		1MG	N40326 002	
> ADD >				APR 21, 1999	
> ADD >	AB		2MG	N40326 003	
> ADD >				APR 21, 1999	

TABLET; VAGINAL

		VAGIFEM			
	+	NOVO NORDISK	25 UGM	N20908 001	
				MAR 26, 1999	

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

		CENESTIN			
> DLT >		DURAMED	0.9MG	N20992 003	
> DLT >				MAR 24, 1999	

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

		CENESTIN			
> ADD >		DURAMED	0.625MG	N20992 002	
> ADD >				MAR 24, 1999	
> DLT >	+		0.9MG	N20992 003	> ADD >
> DLT >				MAR 24, 1999	> ADD >

ESTROPIPATE

CREAM; VAGINAL

		OGEN			
	+	ABBOTT	1.5MG/GM	N84710 001	> DLT >
	+	PHARMACIA AND UPJOHN	1.5MG/GM	N84710 001	> ADD >

TABLET; ORAL

		OGEN .625			
AB		ABBOTT	0.75MG	N83220 001	> DLT >
AB		PHARMACIA AND UPJOHN	0.75MG	N83220 001	> ADD >
		OGEN 1.25			
AB		ABBOTT	1.5MG	N83220 002	> DLT >
AB		PHARMACIA AND UPJOHN	1.5MG	N83220 002	> ADD >
		OGEN 2.5			
AB	+	ABBOTT	3MG	N83220 003	> DLT >
AB	+	PHARMACIA AND UPJOHN	3MG	N83220 003	> ADD >
		OGEN 5			
AB		ABBOTT	6MG	N83220 004	> DLT >
AB		PHARMACIA AND UPJOHN	6MG	N83220 004	> ADD >

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

	BREVICON 21-DAY			
AB	SEARLE	0.035MG;0.5MG	N17566 001	
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			
	+ SEARLE	0.035MG,0.035MG;0.5MG,1MG	N18977 001	
			APR 13, 1984	
	+ WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977 001	
			APR 13, 1984	

TABLET; ORAL-28

	BREVICON 28-DAY			
AB	SEARLE	0.035MG;0.5MG	N17743 001	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28

	BREVICON 28-DAY			
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			
	SEARLE	0.035MG,0.035MG;0.5MG,1MG	N18977 002 APR 13, 1984	
	WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977 002 APR 13, 1984	

ETODOLAC

TABLET; ORAL

	ETODOLAC			
>ADD> AB	NOVOPHARM	400MG	N74847 001 APR 23, 1999	
>ADD> AB		500MG	N74847 002 APR 23, 1999	

ETOPOSIDE

INJECTABLE; INJECTION

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

FERRIC SODIUM GLUCONATE

INJECTABLE; INJECTION

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

FLUOROURACIL

INJECTABLE; INJECTION

	FLUOROURACIL			
AP	BIGMAR	50MG/ML	N40291 001 MAR 24, 1999	

FLUOXETINE HYDROCHLORIDE

TABLET; ORAL

	PROZAC			
	LILLY	EQ 10MG BASE	N20974 001 MAR 09, 1999	
+		EQ 20MG BASE	N20974 002 MAR 09, 1999	

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

	GENTAMICIN SULFATE			
AT	ALCON	EQ 0.3% BASE	N62196 001	
AT	FALCON PHARMS	EQ 0.3% BASE	N62196 001	

GLYBURIDE

TABLET; ORAL

	GLYBURIDE (MICRONIZED)			
>ADD> AB	MOVA	4.5MG	N74591 003 DEC 22, 1997	
>DLT>		4.5MG	N74591 003 DEC 22, 1997	
>ADD> AB	NOVOPHARM	1.5MG	N74686 001 APR 20, 1999	
>ADD> AB		3MG	N74686 002 APR 20, 1999	
>ADD> AB		4.5MG	N74686 003 APR 20, 1999	
>ADD> AB		6MG	N74686 004 APR 20, 1999	

GLYCOPYRROLATE

TABLET; ORAL

	ROBINUL		
+	HORIZON PHARM	1MG	N12827 001
+	ROBINS AH	1MG	N12827 001
	ROBINUL FORTE		
+	HORIZON PHARM	2MG	N12827 002
+	ROBINS AH	2MG	N12827 002

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

	AVALIDE			
	@ SANOFI	12.5MG;75MG	N20758 001	SEP 30, 1997
		12.5MG;150MG	N20758 002	SEP 30, 1997
	+	12.5MG;300MG	N20758 003	AUG 31, 1998
	AVAPRO HCT			
	@ SANOFI	12.5MG;75MG	N20758 001	SEP 30, 1997
	+	12.5MG;150MG	N20758 002	SEP 30, 1997

HYDROXYUREA

CAPSULE; ORAL

	HYDROXYUREA			
AB	PAR PHARM	500MG	N75340 001	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

		IBUPROFEN			
>DLT>	AB	NORTON HN	400MG	N71145 001	SEP 23, 1986
>DLT>	AB		600MG	N71146 001	SEP 23, 1986
>DLT>	AB		800MG	N71769 001	MAY 08, 1987
>ADD>	AB	ZENITH GOLDLINE	400MG	N71145 001	SEP 23, 1986
>ADD>	AB		600MG	N71146 001	SEP 23, 1986
>ADD>	AB		800MG	N71769 001	MAY 08, 1987
		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
			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
	+	100MG	N20135 002	NOV 16, 1994

INDOMETHACIN

CAPSULE; ORAL

		INDOMETHACIN			
>DLT>	AB	EON	75MG	N74464 001	MAY 28, 1998

CAPSULE, EXTENDED RELEASE; ORAL

		INDOMETHACIN			
>ADD>	AB	EON	75MG	N74464 001	MAY 28, 1998

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

		IPRATROPIUM BROMIDE			
>ADD>	AN	ALPHARMA	0.02%	N75111 001	APR 22, 1999

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 NOV 22, 1988	
AN	+	0.25%	N89820 001 NOV 22, 1988	
	@	0.08%	N89817 001 NOV 22, 1988	
	@	0.1%	N89818 001 NOV 22, 1988	
	@	0.17%	N89819 001 NOV 22, 1988	
	@	0.25%	N89820 001 NOV 22, 1988	

ISOSORBIDE DINITRATE

TABLET; ORAL

	SORBITRATE		
AB	ZENECA	30MG	N88124 001 AUG 21, 1990
	@	30MG	N88124 001 AUG 21, 1990

ITRACONAZOLE

INJECTABLE; INJECTION

	SPORANOX		
	+ JANSSEN	10MG/ML	N20966 001 MAR 30, 1999

> ADD >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

	KETOPROFEN		
AB	ANDRX PHARMS	100MG	N75270 002 MAR 24, 1999
AB		150MG	N75270 003 MAR 24, 1999
AB		200MG	N75270 001 MAR 24, 1999
	ORUVAIL		
AB	WYETH AYERST	100MG	N19816 003 FEB 08, 1995
AB		150MG	N19816 002 FEB 08, 1995
		100MG	N19816 003 FEB 08, 1995
		150MG	N19816 002 FEB 08, 1995

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

	KETOROLAC TROMETHAMINE		
AP	ABBOTT	15MG/ML	N74993 001 JAN 27, 1999
AP		30MG/ML	N74993 002 JAN 27, 1999
AP	BEDFORD	15MG/ML	N75222 001 APR 26, 1999
AP		30MG/ML	N75222 002 APR 26, 1999
AP		30MG/ML	N75228 001 APR 26, 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

LABETALOL HYDROCHLORIDE

TABLET; ORAL

	TRANDATE			
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

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

LEUCOVORIN CALCIUM

TABLET; ORAL

	LEUCOVORIN CALCIUM			
AB	INVAMED	EQ 15MG BASE	N75327 001	MAR 24, 1999

LEVALBUTEROL HYDROCHLORIDE

SOLUTION; INHALATION

	XOPENEX			
+	SEPRACOR	EQ 0.021% BASE	N20837 001	MAR 25, 1999
+		EQ 0.042% BASE	N20837 002	MAR 25, 1999

LIDOCAINE

FILM, EXTENDED RELEASE; TRANSDERMAL

	LIDODERM			
+	HIND HLTHCARE	700MG/12HR	N20612 001	MAR 19, 1999

LIDOCAINE; PRILOCAINE

AEROSOL; TOPICAL

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

DISC; TOPICAL

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

LISINOPRIL

TABLET; ORAL

	ZESTRIL			
	ZENECA	30MG	N19777 006	JAN 20, 1999

LITHIUM CARBONATE

CAPSULE; ORAL

		LITHONATE		
AB		SOLVAY	300MG	N16782 001
		@	300MG	N16782 001

TABLET; ORAL

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

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

			IMODIUM		
> DLT >	AB	+	JANSSEN	2MG	N17694 001
			@	2MG	N17690 001
> DLT >					N17694 001
> ADD >	AB	+	MCNEIL CONS	2MG	N17690 001
			@	2MG	
> ADD >					

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

			VERMOX		
> DLT >	AB	+	JANSSEN	100MG	N17481 001
> ADD >	AB	+	MCNEIL CONS	100MG	N17481 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
			MEPERIDINE HCL		
AP	+		ABBOTT	10MG/ML	N88432 001 AUG 16, 1984

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

		MEPERIDINE HCL		
AP		ASTRA PHARMS	10MG/ML	N81002 001 JUL 30, 1993
AP		INTL MEDICATION	10MG/ML	N81309 001 AUG 30, 1993
AP		MALLINCKRODT	10MG/ML	N40163 001 MAY 12, 1997
AP		STERIS	10MG/ML	N73443 001 MAR 17, 1992
		MEPERIDINE HCL PRESERVATIVE FREE		
AP	+	ABBOTT	10MG/ML	N88432 001 AUG 16, 1984
AP		ASTRA PHARMS	10MG/ML	N81002 001 JUL 30, 1993
AP		FAULDING	10MG/ML	N40305 001 MAR 10, 1999
AP		INTL MEDICATION	10MG/ML	N81309 001 AUG 30, 1993
AP		MALLINCKRODT	10MG/ML	N40163 001 MAY 12, 1997
AP		STERIS	10MG/ML	N73443 001 MAR 17, 1992

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

	METHOTREXATE		
AP	BIGMAR	EQ 25MG BASE/ML	N40263 001 FEB 26, 1999
	METHOTREXATE PRESERVATIVE FREE		
AP	BIGMAR	EQ 25MG BASE/ML	N40265 001 FEB 26, 1999

METHOTREXATE SODIUM

INJECTABLE; INJECTION

		METHOTREXATE PRESERVATIVE FREE		
AP		BIGMAR	**EQ 1GM BASE/VIAL**	**N40266 001**
				FEB 26, 1999
		METHOTREXATE SODIUM		
	+	LEDERLE	EQ 1GM BASE/VIAL	N11719 009
				APR 07, 1988
		METHOTREXATE SODIUM PRESERVATIVE FREE		
AP	+	LEDERLE	**EQ 1GM BASE/VIAL**	**N11719 009**
				APR 07, 1988

METHOTRIMEPRAZINE

INJECTABLE; INJECTION

		LEVOPROME		
	+	IMMUNEX	20MG/ML	N15865 001
	@		20MG/ML	N15865 001

METHOXSALEN

INJECTABLE; INJECTION

		UVADEX		
	+	THERAKOS	0.02MG/ML	N20969 001
				FEB 25, 1999

MICONAZOLE NITRATE

SUPPOSITORY; VAGINAL

> ADD >		**MICONAZOLE NITRATE**		
> ADD >	**AB**	ALPHARMA US PHARM	**200MG**	**N73508 001**
> ADD >				NOV 19, 1993
> DLT >	**AB**	NMC	**200MG**	N73508 001
> DLT >				NOV 19, 1993

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

		MINOCYCLINE HCL		
AB		GLOBAL PHARM	**EQ 50MG BASE**	**N65005 001**
				MAR 23, 1999
AB			**EQ 100MG BASE**	**N65005 002**
				MAR 23, 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		
		ALTANA	2%	N87355 001
				JUL 08, 1988
	+		2%	N87355 001
				JUL 08, 1988

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

		PRILOSEC		
	*	ASTRA PHARMS	10MG	N19810 003
				OCT 05, 1995
			10MG	N19810 003
				OCT 05, 1995

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

> ADD > ORLISTAT

> ADD >	CAPSULE; ORAL			
> ADD >	XENICAL			
> ADD >	+ ROCHE	120MG	N20766 001	
> ADD >			APR 23, 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

	TABLET, EXTENDED RELEASE; ORAL			
	PAXIL CR			
	+ SMITHKLINE BEECHAM	EQ 12.5MG BASE	N20936 001	
			FEB 16, 1999	
	+	EQ 25MG BASE	N20936 002	
			FEB 16, 1999	

PEMOLINE

	TABLET; ORAL			
	CYLERT			
AB	ABBOTT	37.5MG	N16832 002	
AB	+	75MG	N16832 003	
		18.75MG	N16832 001	
		37.5MG	N16832 002	
	*	75MG	N16832 003	
	+	18.75MG	N16832 001	
	PEMOLINE			
AB	COPLEY PHARM	37.5MG	N75030 001	
			JAN 29, 1999	
AB		75MG	N75030 002	
			JAN 29, 1999	

PENTOXIFYLLINE

	TABLET, EXTENDED RELEASE; ORAL			
	PENTOXIL			
AB	UPSHER SMITH	400MG	N74962 001	
			MAR 31, 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	

POLYETHYLENE GLYCOL 3350

	POWDER FOR RECONSTITUTION; ORAL			
	MIRALAX			
	+ BRAINTREE	17GM/SCOOPFUL	N20698 001	
			FEB 18, 1999	

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

	SOLUTION/DROPS; OPHTHALMIC			
	TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE			
AT	ALCON	10,000 UNITS/ML; EQ 1MG BASE/ML	N64211 001	
			APR 13, 1998	
AT	FALCON PHARMS	10,000 UNITS/ML; EQ 1MG BASE/ML	N64211 001	
			APR 13, 1998	

POTASSIUM CHLORIDE

	CAPSULE, EXTENDED RELEASE; ORAL			
	MICRO-K			
AB	KV PHARM	8MEQ	N18238 001	
> ADD > > DLT > AB	ROBINS AH	8MEQ	N18238 001	
	MICRO-K 10			
> ADD > AB	+ KV PHARM	10MEQ	N18238 002	
> ADD >			MAY 14, 1984	

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
MICRO-K 10

> DLT >	AB	+	ROBINS AH	10MEQ	N18238 002
> DLT					MAY 14, 1984

GRANULE, FOR RECONSTITUTION ER; ORAL
MICRO-K LS

> ADD >			@ KV PHARM	20MEQ/PACKET	N19561 003
> ADD >					AUG 26, 1988
> DLT >			@ ROBINS AH	20MEQ/PACKET	N19561 003
> DLT >					AUG 26, 1988

POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE

> DLT >			INJECTABLE; INJECTION		
> DLT >			THAM-E		
> DLT >			+ ABBOTT	370MG/VIAL;1.75GM/VIAL;	
> DLT >				36GM/VIAL	N13025 001
> ADD >			@	370MG/VIAL;1.75GM/VIAL;	
> ADD >				36GM/VIAL	N13025 001

POTASSIUM CITRATE

POWDER FOR RECONSTITUTION; ORAL
POTASSIUM CITRATE

> ADD >			@ MISSION PHARMA	10MEQ/PACKET	N19647 002
> ADD >					OCT 13, 1988
> ADD >			@	20MEQ/PACKET	N19647 001
> ADD >					OCT 13, 1988
> DLT >			@ UNIV TX	10MEQ/PACKET	N19647 002
> DLT >					OCT 13, 1988
> DLT >			@	20MEQ/PACKET	N19647 001
> DLT >					OCT 13, 1988

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC
ECONOPRED PLUS

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

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
HYDELTRASOL

	+	MERCK	EQ 20MG PHOSPHATE/ML	N11583 002
	@		EQ 20MG PHOSPHATE/ML	N11583 002

PROBENECID

TABLET; ORAL
BENEMID

AB	+	MERCK	500MG	N07898 004
	@		500MG	N07898 004

PROBENECID

AB		MYLAN	500MG	N84211 002
AB	+		500MG	N84211 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**
	@	25MG		N87998 001 OCT 14, 1983

TACROLIMUS

CAPSULE; ORAL

	PROGRAF			
	+ FUJISAWA HLTHCARE	EQ 1MG BASE		N50708 001 APR 08, 1994
		EQ 0.5MG BASE		N50708 003 AUG 24, 1998
		EQ 1MG BASE		N50708 001 APR 08, 1994

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

	A-N STANNOUS AGGREGATED ALBUMIN			
	@ NORTH AM CHEMS	N/A		N17916 001
	@ SYNCOR PHARMS	N/A		N17916 001
	PULMOLITE			
BS	CIS	N/A		N17776 001
BS	DUPONT PHARMS	N/A		N17776 001

TECHNETIUM TC-99M ALBUMIN COLLOID KIT

INJECTABLE; INJECTION

	MICROLITE			
	CIS	N/A		N18263 001 MAR 25, 1983

TECHNETIUM TC-99M ALBUMIN COLLOID KIT

INJECTABLE; INJECTION

	MICROLITE			
	DUPONT PHARMS	N/A		N18263 001 MAR 25, 1983

TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION

	HEPATOLITE			
	CIS	N/A		N18467 001 MAR 16, 1982
	DUPONT PHARMS	N/A		N18467 001 MAR 16, 1982

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

	OSTEOLITE			
AP	CIS	**N/A**		**N17972 001**
AP	DUPONT PHARMS	**N/A**		**N17972 001**

TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

INJECTABLE; INJECTION

	PYROLITE			
	CIS	N/A		N17684 001
	DUPONT PHARMS	N/A		N17684 001

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

THEOPHYLLINE

INJECTABLE; INJECTION
THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER

	@ 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

TIAGABINE HYDROCHLORIDE

TABLET; ORAL
GABITRIL

>ADD< >ADD<	+ ABBOTT	2MG		N20646 005 APR 16, 1999

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC
TIMOLOL MALEATE

AB	ALCON	EQ 0.25% BASE		N20963 001 OCT 21, 1998
>DLT< >DLT< AB		EQ 0.5% BASE		N20963 002 OCT 21, 1998
AB	FALCON PHARMS	EQ 0.25% BASE		N20963 001 OCT 21, 1998
>ADD< >ADD< AB		EQ 0.5% BASE		N20963 002 OCT 21, 1998

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

AT	ADV REMEDIES	EQ 0.5% BASE		N74466 001 MAR 25, 1997
AT	AKORN	EQ 0.5% BASE		N74466 001 MAR 25, 1997
AT	ALCON	EQ 0.25% BASE		N74261 001 APR 28, 1995
AT		EQ 0.5% BASE		N74262 001 APR 28, 1995

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

	@ FALCON PHARMS	EQ 0.25% BASE		N74261 001 APR 28, 1995
	@	EQ 0.5% BASE		N74262 001 APR 28, 1995

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

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

TABLET; ORAL
SULFA-TRIPLE #2

AB	+ GLOBAL PHARM	167MG;167MG;167MG		N80079 001
	@	167MG;167MG;167MG		N80079 001
	TRIPLE SULFOID			
AB	PAL PAK	167MG;167MG;167MG		N80094 001
	+	167MG;167MG;167MG		N80094 001

UREA, C-13

POWDER FOR RECONSTITUTION; ORAL
PYLORI-CHEK BREATH TEST

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

VALRUBICIN

SOLUTION;
VALSTAR PRESERVATIVE FREE

+	ANTHRA	40MG/ML	N20892 001	SEP 25, 1998

SOLUTION; INTRAVESICAL
VALSTAR PRESERVATIVE FREE

+	ANTHRA	40MG/ML	N20892 001	SEP 25, 1998

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

> ADD >			VERAPAMIL HCL		
> ADD >	AB		MYLAN	120MG	N75138 001
> ADD >					APR 20, 1999
> ADD >	AB			180MG	N75138 002
> ADD >					APR 20, 1999
> ADD >	AB			240MG	N75138 003
> ADD >					APR 20, 1999
			VERELAN		
> ADD >	AB	+	ELAN	120MG	N19614 001
> ADD >					MAY 29, 1990
> ADD >	AB	+		180MG	N19614 003
> ADD >					JAN 09, 1992
> ADD >	AB	+		240MG	N19614 002
> ADD >					MAY 29, 1990
> DLT >		+		120MG	N19614 001
> DLT >					MAY 29, 1990
> DLT >		+		180MG	N19614 003
> DLT >					JAN 09, 1992
> DLT >		+		240MG	N19614 002
> DLT >					MAY 29, 1990

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN
ASCENT PEDS 120MG N18337 003 SEP 12, 1983 >_DLT_<
325MG N18337 002 >_DLT_<
650MG N18337 001 >_DLT_<
UPSHER SMITH 120MG N18337 003 SEP 12, 1983 >_DLT_<
325MG N18337 002 >_DLT_<
650MG N18337 001 >_DLT_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<

CLOTRIMAZOLE

CREAM; TOPICAL
LOTRIMIN AF
SCHERING PLOUGH 1% N17619 002 OCT 27, 1989

LOTION; TOPICAL
LOTRIMIN AF
SCHERING 1% N18813 002 OCT 27, 1989

SOLUTION; TOPICAL
LOTRIMIN AF
SCHERING PLOUGH 1% N17613 002 OCT 27, 1989 >_DLT_<
>_DLT_<
>_ADD_<
>_ADD_<

EPINEPHRINE BITARTRATE

>_DLT_<
>_DLT_<
>_DLT_<
>_ADD_<
AEROSOL, METERED, INHALATION
MEDIHALER-EPI
* 3M 0.3MG/INH N10374 003 >_ADD_<
@ 0.3MG/INH N10374 003 >_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<
>_ADD_<

IBUPROFEN

>_ADD_<
>_ADD_<
>_ADD_<
SUSPENSION; ORAL
IBUPROFEN
ALPHARMA 100MG/5ML N74916 001 APR 30, 1999 >_ADD_<
>_ADD_<

TABLET; ORAL
IBUPROFEN
LNK 200MG N75010 001 MAR 01, 1999 >_DLT_<
>_DLT_<

IBUPROFEN

TABLET; ORAL
IBUPROFEN
LNK 200MG N75139 001 MAR 01, 1999
NORTON HN 200MG N71144 001 JAN 20, 1987
200MG N72901 001 DEC 19, 1991
200MG N72903 001 DEC 19, 1991
ZENITH GOLDLINE 200MG N71144 001 JAN 20, 1987
200MG N72901 001 DEC 19, 1991
200MG N72903 001 DEC 19, 1991

JUNIOR STRENGTH IBUPROFEN
PERRIGO 100MG N75367 001 APR 22, 1999

IBUPROFEN POTASSIUM

CAPSULE; ORAL
PROVEL
@ NOVARTIS 200MG N20402 001 APR 20, 1995
\+ 200MG N20402 001 APR 20, 1995

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
M-ZOLE 3 COMBINATION PACK
ALPHARMA US PHARM 2%,200MG N74926 001 APR 16, 1999

MICONAZOLE NITRATE COMBINATION PACK
PERRIGO 2%,200MG N75329 001 APR 20, 1999

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE
ALPHARMA US PHARM 100MG N73507 001 NOV 19, 1993
NMC 100MG N73507 001 NOV 19, 1993

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICOTINE POLACRILEX

CIRCA	EQ 2MG BASE	N74507 001 MAR 15, 1999
	EQ 4MG BASE	N74707 001 MAR 19, 1999

NONOXYNOL-9

SPONGE; VAGINAL
TODAY

@ ALLENDALE PHARMS	1GM	N18683 001 APR 01, 1983
@ WHITEHALL ROBINS	1GM	N18683 001 APR 01, 1983

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL

PERRIGO	120MG	N75153 001 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 4 APR '99

NO APRIL 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
April 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
6-hydroxymethylacylfulvene TN=	Treatment of histologically confirmed advanced or metastatic pancreatic cancer.	MGI Pharma, Inc. Suite 300E, Opus Center 9900 Bren Road East Minnetonka, MN 55343 DD=04/06/1999
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
Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized TN= Humate-P	Treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric patients.	Centeon Pharma GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany, DD=10/16/1992 MA=04/01/1999

Orphan Product Designations and Approvals List
April 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
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
Beraprost TN=	Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).	United Therapeutics Corporation 68 T.W. Alexander Drive, PO Box 14186 Research Triangle Park, NC 27709 DD=04/29/1999
Bleomycin TN= Blenoxane	Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999
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
CT-2584 mesylate TN=	Treatment of adult soft tissue sarcoma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Suite 400 Seattle, WA 98119 DD=04/16/1999

Orphan Product Designations and Approvals List
April 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
CT-2584 mesylate TN=	Treatment of malignant mesothelioma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Seattle, WA 98119 DD=04/16/1999
Coagulation factor VIIa (recombinant) TN= NovoSeven	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.	Novo Nordisk Pharmaceuticals, Inc. 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=06/06/1988 MA=03/25/1999
Cytarabine liposomal TN= DepoCyt	Treatment of neoplastic meningitis.	DepoTech Corporation 10450 Science Center Drive San Diego, CA 92121 DD=06/02/1993 MA=04/01/1999
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
Epoprostenol TN= Flolan	Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.	Glaxo Wellcome Inc. Five Moore Dr. PO Box 13398 Research Triangle Park, NC 27709 DD=03/22/1999

Orphan Product Designations and Approvals List
April 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Etanercept TN= Enbrel	Treatment of Wegener's granulomatosis.	Stone, John H., MD, MPH Johns Hopkins Vasculitis Center, Division of Rheumatology 1830 East Monument St., Suite 7500 Baltimore, MD 21205 DD=04/06/1999
Fluoxetine TN= Prozac	Treatment of autism.	Hollander, MD, Eric Mt. Sinai School of Medicine, Dept. of Psychiatry Box 1230, One Gustave L. Levy Place New York, NY 10029 DD=04/30/1999
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
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

Orphan Product Designations and Approvals List
April 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
Lidocaine patch 5% TN= Lidoderm Patch	For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.	Hind Health Care, Inc. 3707 Williams Rd., Suite 101 San Jose, CA 95117 DD=10/24/1995 MA=03/19/1999
Murine MAb to polymorphic epithelial mucin, human milk fat globule 1 TN= Theragyn	Adjuvant treatment of ovarian cancer.	Antisoma West Africa House, Hanger Lane London W5 3QR United Kingdom DD=03/22/1999
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
Pegylated arginine deiminase TN= Hepacid	Treatment of hepatocellular carcinoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=03/26/1999
Pegylated arginine deiminase TN= Melanocid	Treatment of invasive malignant melanoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=04/12/1999

Orphan Product Designations and Approvals List
April 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
Recombinant human nerve growth factor TN=	Treatment of HIV-associated sensory neuropathy.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=04/16/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of solid organ transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of pancreatic islet cell transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Rifalazil TN=	Treatment of pulmonary tuberculosis.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=04/13/1999
SCH 58500 TN=	Treatment of primary ovarian cancer.	Schering Corporation 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=04/12/1999

Orphan Product Designations and Approvals List
April 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Sodium 1,3-propanedisulfonate TN=	Treatment of secondary amyloidosis.	Neurochem, Inc. 7220 Frederick Banting, Suite 100 Saint-Laurent, Quebec Canada H4S 2A1 DD=04/06/1999
Thalidomide TN= Thalomid	Treatment of Crohn's disease.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059

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

NO APRIL 1999 ADDITIONS

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, 19TH 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
I-258	FOR PERENNIAL NONALLERGIC RHINITIS FOR AGES FOUR AND ABOVE
I-259	PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT), WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY
I-260	EXPANDED PEDIATRIC USE IN CHILDREN YOUNGER THAN ONE MONTH OF AGE TO BIRTH (WITH A GESTATIONAL AGE OF 37 WEEKS OR GREATER)
I-261	TREATMENT OF SOCIAL ANXIETY DISORDER

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
U-259	TREATMENT OF ANDROGENIC ALOPECIA BY ORAL ADMINISTRATION OF DRUG SUBSTANCE
U-260	REDUCTION OF INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION WHO ARE INTOLERANT OF OTHER IOP LOWERING MEDICATIONS OR INSUFFICIENTLY RESPONSIVE TO ANOTHER IOP LOWERING MEDICATION
U-261	TREATING BENIGN PROSTATIC HYPERPLASIA WITH A GENUS OF COMPOUNDS, INCLUDING FINASTERIDE
U-262	TREATING BENIGN PROSTATIC HYPERTROPHY WITH FINASTERIDE
U-263	METHOD OF TREATING A MALIGNANT CONDITION THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING LEUKEMIA OR LYMPHOMA IN A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVENOUS ADMINISTRATION OF BUSULFAN.

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

U-264	METHOD OF TREATING A MALIGNANT DISEASE THROUGH PARENTERAL ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN.
U-265	USE AS A LAXATIVE
U-266	OSTEOARTHRITIS

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
							NCE	FEB 02, 2004
>ADD>	021007	001	AMPRENAVIR;AGENERASE				NCE	APR 15, 2004
>ADD>	021007	002	AMPRENAVIR;AGENERASE				NCE	APR 15, 2004
>ADD>	021039	001	AMPRENAVIR;AGENERASE	5585397	DEC 17, 2013		NCE	APR 15, 2004
	020500	001	ATOVAQUONE;MEPRON				ODE	JAN 05, 2006
							I-255	JAN 05, 2002
	020711	002	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
	020711	003	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
>ADD>	020954	001	BUSULFAN;BUSULFEX	5430057	SEP 30, 2013	U-263	ODE	FEB 04, 2006
>ADD>				5559148	MAY 24, 2015	U-264	NDF	FEB 04, 2002
	020998	001	CELECOXIB;CELEBREX	5760068	JUN 02, 2015	U-19		
				5466823	NOV 30, 2013			
				5563165	NOV 30, 2013			
	020998	002	CELECOXIB;CELEBREX	5760068	JUN 02, 2015	U-19		
				5466823	NOV 30, 2013			
				5563165	NOV 30, 2013			
	020638	001	CIDOFOVIR;VISTIDE	5142051	JUN 26, 2010			
	020863	001	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
	020863	002	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
>ADD>	020767	001	CISAPRIDE MONOHYDRATE;PROPULSID QUICKSOLV	5648093	JUL 15, 2014			
	021041	001	CYTARABINE;DEPOCYT				ODE	APR 01, 2006
							NP	APR 01, 2002
>ADD>	020287	001	DALTEPARIN SODIUM;FRAGMIN				I-259	MAR 30, 2002
>ADD>	020287	003	DALTEPARIN SODIUM;FRAGMIN				I-259	MAR 30, 2002
>ADD>	020287	004	DALTEPARIN SODIUM;FRAGMIN				I-259	MAR 30, 2002
	017922	001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	017922	002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	017922	003	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	018938	001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	018938	002	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	019955	001	DESMOPRESSIN ACETATE;DDAVP	5763407	JUN 29, 2013			
	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

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020992	002	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				NP	MAR 24, 2002
	020992	003	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				NP	MAR 24, 2002
	020527	003	ESTROGENS, CONJUGATED;PREMPRO 14/14	4826831	MAY 02, 2006			
				5547948	JAN 17, 2015			
>ADD>	020363	001	FAMCICLOVIR;FAMVIR	5246937	SEP 21, 2010	U-96		
>ADD>	020363	003	FAMCICLOVIR;FAMVIR	5246937	SEP 21, 2010	U-96		
	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>	020955	001	FERRIC SODIUM GLUCONATE;FERRLECIT				NCE	FEB 18, 2004
	020788	001	FINASTERIDE;PROPECIA	5571817	NOV 05, 2013	U-259		
				5886184	NOV 19, 2012			
	020180	001	FINASTERIDE;PROSCAR	4760071	JUN 19, 2006	U-262		
				5886184	NOV 19, 2012			
				4377584	MAR 22, 2000	U-261		
	020974	001	FLUOXETINE HYDROCHLORIDE;PROZAC	4314081	FEB 02, 2001			
				4626549	DEC 02, 2003			
	020974	002	FLUOXETINE HYDROCHLORIDE;PROZAC	4314081	FEB 02, 2001			
				4626549	DEC 02, 2003			
>ADD>	020121	001	FLUTICASONE PROPIONATE;FLONASE				I-258	DEC 11, 2001
	020882	001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
				5084479	JAN 02, 2010	U-258		
	020882	002	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
				5084479	JAN 02, 2010	U-258		
>ADD>	020758	003	HYDROCHLOROTHIAZIDE;AVALIDE	5270317	MAR 20, 2011		NCE	SEP 30, 2002
	020083	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
	020657	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
	020966	001	ITRACONAZOLE;SPORANOX	4791111	DEC 23, 2005			
				4267179	JUN 23, 2000			
	020564	002	LAMIVUDINE;EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
				5532246	JUL 02, 2013	U-250		
	020596	002	LAMIVUDINE;EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
				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
	020597	001	LATANOPROST;XALATAN	5296504	MAR 22, 2011	U-260		
				5422368	MAR 22, 2011	U-260		
				4599353	JUL 28, 2006	U-260		
>ADD>	019941	001	LIDOCAINE;EMLA				I-260	MAR 11, 2002
	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

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020969	001	METHOXSALEN;UVADEX	4845075	APR 11, 2009		NP	FEB 25, 2002
				5036102	APR 11, 2009			
	020682	001	MIGLITOL;GLYSET	4639436	JAN 27, 2009	U-111		
	020682	002	MIGLITOL;GLYSET	4639436	JAN 27, 2009	U-111		
	020682	003	MIGLITOL;GLYSET	4639436	JAN 27, 2009	U-111		
	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		
	018612	003	NICOTINE POLACRILEX;NICORETTE (MINT)				NP	DEC 23, 2001
	020066	003	NICOTINE POLACRILEX;NICORETTE (MINT)				NP	DEC 23, 2001
>ADD>	020385	001	NICOTINE;NICOTROL	5656255	AUG 12, 2014			
>ADD>	020766	001	ORLISTAT;XENICAL				NCE	APR 23, 2004
	020897	001	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
	020897	002	OXYBUTYNIN CHLORIDE;DITROPAN XL				NP	DEC 16, 2001
	020553	001	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
				5656295	FEB 05, 2008			
	020553	002	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
				5656295	FEB 05, 2008			
	020553	003	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
				5656295	FEB 05, 2008			
	020553	004	OXYCODONE HYDROCHLORIDE;OXYCONTIN	5508042	APR 16, 2013			
				5656295	FEB 05, 2008			
>ADD>	020031	001	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015		I-261	MAY 17, 2002
				5872132	MAY 19, 2015			
>ADD>	020031	002	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015		I-261	MAY 17, 2002
				5872132	MAY 19, 2015			
>ADD>	020031	003	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015		I-261	MAY 17, 2002
				5872132	MAY 19, 2015			
>ADD>	020031	004	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015		I-261	MAY 17, 2002
				5872132	MAY 19, 2015			
>ADD>	020031	005	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015		I-261	MAY 17, 2002
				5872132	MAY 19, 2015			
>ADD>	020710	001	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015			
				5872132	MAY 19, 2015			
>ADD>	020885	001	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015			
				5872132	MAY 19, 2015			
>ADD>	020885	002	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015			
				5872132	MAY 19, 2015			
>ADD>	020885	003	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015			
				5872132	MAY 19, 2015			
>ADD>	020885	004	PAROXETINE HYDROCHLORIDE;PAXIL	5900423	MAY 19, 2015			
				5872132	MAY 19, 2015			
>ADD>	020936	001	PAROXETINE HYDROCHLORIDE;PAXIL CR	5900423	MAY 19, 2015		NDF	FEB 16, 2002
				5872132	MAY 19, 2015			
				4839177	JUN 13, 2006			
				5422123	JUN 06, 2012			
				4721723	DEC 29, 2006			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020936	002	PAROXETINE HYDROCHLORIDE;PAXIL CR	5900423	MAY 19, 2015		NDF	FEB 16, 2002
				5872132	MAY 19, 2015			
				4839177	JUN 13, 2006			
				5422123	JUN 06, 2012			
				4721723	DEC 29, 2006			
>ADD>	020698	001	POLYETHYLENE GLYCOL 3350;MIRALAX	5710183	JUL 14, 2015	U-265	NP	FEB 18, 2002
>ADD>	075102	001	PROPOFOL;PROPOFOL				PC	OCT 16, 1999
	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		
>ADD>	021042	001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
>ADD>				5691374	NOV 25, 2017			
>ADD>	021042	002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
>ADD>				5691374	NOV 25, 2017			
>ADD>	021052	001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
>ADD>				5691374	NOV 25, 2017			
>ADD>	021052	002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
>ADD>				5691374	NOV 25, 2017			
>ADD>	020192	002	TERBINAFINE HYDROCHLORIDE;LAMISIL	4680291	JUL 14, 2004	U-73		
>ADD>				4755534	DEC 30, 2006	U-73		
>ADD>	020646	005	TIAGABINE HYDROCHLORIDE;GABITRIL	5010090	OCT 07, 2008		NCE	SEP 30, 2002
>ADD>				5354760	MAR 24, 2012			
	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		
	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
	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			
	020943	001	VERAPAMIL HYDROCHLORIDE;VERELAN PM	4863742	JUN 19, 2007			
	020943	002	VERAPAMIL HYDROCHLORIDE;VERELAN PM	4863742	JUN 19, 2007			
	020943	003	VERAPAMIL HYDROCHLORIDE;VERELAN PM	4863742	JUN 19, 2007			

*U.S. Government Printing Office: 1999 — 454-723/00011