CUMULATIVE
SUPPLEMENT 5
MAY'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

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CONTENTS

		PAGE
1.0	INTRODUCTION	iii
1.1	How to Use the Cumulative Supplement	iii
1.2	Applicant Name Changes	iv
1.3	Diclofenac Sodium Ophthalmic Solution	v
1.4	Availability of the Edition	vi
1.5	Report of Counts for the Prescription Drug Product List	vii
2.0	DRUG PRODUCT LISTS	
2.1	Prescription Drug Product List	1
2.2	OTC Drug Product List	26
2.3	Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List	28
2.4	Orphan Product Designations and Approvals List	29
2.5	Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution	37
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM		
A.	Patent and Exclusivity Terms	38
B.	Patent and Exclusivity Lists	33

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CUMULATIVE SUPPLEMENT 5
MAY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 – MAY 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

TABLET; ORAL
ACETAMINOPHEN, CAFFEINE, AND DIHYDROCODONE BITARTRATE

+	MIKART	712.8MG;60MG;32MG	N40316 001	APR 28, 1999

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
ALLAY

AA	NORTON HN	500MG;5MG	N89907 001	JAN 13, 1989
AA	ZENITH GOLDLINE	500MG;5MG	N89907 001	JAN 13, 1989

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

AB	CARLSBAD	400MG	N75382 001	APR 30, 1999
AB		800MG	N75382 002	APR 30, 1999

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

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

AMCINONIDE

CREAM; TOPICAL
CYCLOCORT
@ FUJISAWA HLTHCARE — 0.025% — N18116 001
+ — 0.1% — N18116 002
LEDERLE — 0.025% — N18116 001
+ — 0.1% — N18116 002

AMCINONIDE

LOTION; TOPICAL
CYCLOCORT
+ FUJISAWA HLTHCARE — 0.1% — N19729 001 JUN 13, 1988
+ LEDERLE — 0.1% — N19729 001 JUN 13, 1988

OINTMENT; TOPICAL
CYCLOCORT
+ FUJISAWA HLTHCARE — 0.1% — N18498 001
+ WYETH AYERST — 0.1% — N18498 001

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL
AB ALPHAPHARM — 200MG — N75188 001 FEB 24, 1999
AB NOVOPHARM — 200MG — N74895 001 APR 16, 1999

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
ENDEP
AB ROCHE — 10MG — N83639 001
AB — 25MG — N83639 002
AB — 50MG — N83639 003
AB — 75MG — N83639 004
AB — 100MG — N83639 005
@ — 10MG — N83639 001
@ — 25MG — N83639 002
@ — 50MG — N83639 003
@ — 75MG — N83639 004
@ — 100MG — N83639 005

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN
AB RANBAXY — 250MG — N65016 001 APR 08, 1999
AB — 500MG — N65016 002 APR 08, 1999

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL				
AMOXIL				
	SMITHKLINE BEECHAM	200MG/5ML	N50760 001	APR 15, 1999
+		400MG/5ML	N50760 002	APR 15, 1999
TABLET, CHEWABLE; ORAL				
AMOXIL				
	SMITHKLINE BEECHAM	200MG	N50761 001	APR 15, 1999
+		400MG	N50761 002	APR 15, 1999

AMPRENAVIR

CAPSULE; ORAL				
AGENERASE				
	GLAXO WELLCOME	50MG	N21007 001	APR 15, 1999
+		150MG	N21007 002	APR 15, 1999
SOLUTION; ORAL				
AGENERASE				
+	GLAXO WELLCOME	15MG/ML	N21039 001	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				
AB	STEVENS J	**385MG;30MG;25MG**	**N74988 001**	APR 30, 1999
AB		**770MG;60MG;50MG**	**N74988 002**	APR 30, 1999

ATENOLOL

TABLET; ORAL				
ATENOLOL				
AB	APOTHECON	**50MG**	**N73317 001**	**MAR 20, 1992**
AB		**100MG**	**N73318 001**	**MAR 20, 1992**
@		50MG	N73317 001	MAR 20, 1992
@		100MG	N73318 001	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

BUTOCONAZOLE NITRATE

CREAM; VAGINAL

>_DLT_>	FEMSTAT			
>_DLT_>	+ SYNTEX	2%	N19215 001	NOV 25, 1985
>_DLT_>				
>_ADD_>	@	2%	N19215 001	NOV 25, 1985
>_ADD_>				

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

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

SOLUTION; IRRIGATION

	ENDOSOL EXTRA			
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	
@		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			
AB	BAKER NORTON	**12.5MG**	**N74590 004**	AUG 30, 1996
AB		**25MG**	**N74590 002**	AUG 30, 1996

CAPTOPRIL

TABLET; ORAL
CAPTOPRIL

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

>_DLT_> CARBENICILLIN DISODIUM

>_DLT_> INJECTABLE; INJECTION
>_DLT_> GEOPEN

>_DLT_>	+ ROERIG	EQ 1GM BASE/VIAL	N50306 001	>_DLT_>
>_DLT_>	+	EQ 2GM BASE/VIAL	N50306 004	
>_DLT_>	+	EQ 5GM BASE/VIAL	N50306 002	
>_DLT_>	+	EQ 10GM BASE/VIAL	N50306 006	
>_DLT_>	+	EQ 30GM BASE/VIAL	N50306 007	
>_ADD_>	@	EQ 1GM BASE/VIAL	N50306 001	
>_ADD_>	@	EQ 2GM BASE/VIAL	N50306 004	
>_ADD_>	@	EQ 5GM BASE/VIAL	N50306 002	
>_ADD_>	@	EQ 10GM BASE/VIAL	N50306 006	
>_ADD_>	@	EQ 30GM BASE/VIAL	N50306 007	>_ADD_>

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OCUPRESS

+	CIBA	1%	N19972 001	MAY 23, 1990
+	OTSUKA	1%	N19972 001	MAY 23, 1990

CEFADROXIL/CEFADROXIL HEMIHYDRATE

TABLET; ORAL
CEFADROXIL

AB	RANBAXY	EQ 1GM BASE	N65018 001	APR 23, 1999

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION
CEPTAZ

AP	+ GLAXO WELLCOME	1GM/VIAL	N50646 002	SEP 27, 1990
AP	+	2GM/VIAL	N50646 003	SEP 27, 1990
AP	+	10GM/VIAL	N50646 004	SEP 27, 1990
	+	1GM/VIAL	N50646 002	SEP 27, 1990
	+	2GM/VIAL	N50646 003	SEP 27, 1990
	+	10GM/VIAL	N50646 004	SEP 27, 1990

PENTACEF

AP	SMITHKLINE BEECHAM	1GM/VIAL	N63322 001	NOV 07, 1995
AP		1GM/VIAL	N64006 001	MAR 31, 1992
AP		2GM/VIAL	N63322 002	NOV 07, 1995
AP		2GM/VIAL	N64006 002	MAR 31, 1992
AP		10GM/VIAL	N64008 002	MAR 31, 1992
		6GM/VIAL	N64008 001	MAR 31, 1992
	@	1GM/VIAL	N63322 001	NOV 07, 1995
	@	1GM/VIAL	N64006 001	MAR 31, 1992
	@	2GM/VIAL	N63322 002	NOV 07, 1995
	@	2GM/VIAL	N64006 002	MAR 31, 1992
	@	6GM/VIAL	N64008 001	MAR 31, 1992
	@	10GM/VIAL	N64008 002	MAR 31, 1992

CERIVASTATIN SODIUM

TABLET; ORAL
BAYCOL

>_DLT_> +	BAYER	0.3MG	N20740 004	JUN 26, 1997 >_DLT_>

CERIVASTATIN SODIUM

TABLET; ORAL
BAYCOL

>ADD<	BAYER	0.3MG	N20740 004	
>ADD<			JUN 26, 1997	
>ADD<	+	0.4MG	N20740 005	
>ADD<			MAY 24, 1999	

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
CHLORPROMAZINE HCL

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

CHOLESTYRAMINE

POWDER; ORAL
CHOLESTYRAMINE

AB	BAKER NORTON	**EQ 4GM RESIN/PACKET**	**N74771 001**
			JUL 09, 1997
AB		**EQ 4GM RESIN/SCOOPFUL**	**N74771 002**
			JUL 09, 1997
AB	ZENITH GOLDLINE	**EQ 4GM RESIN/PACKET**	**N74771 001**
			JUL 09, 1997
AB		**EQ 4GM RESIN/SCOOPFUL**	**N74771 002**
			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

CREAM; TOPICAL
CLOBETASOL PROPIONATE (EMOLLIENT)

>ADD<			
>ADD< **AB2**	ALTANA	**0.05%**	**N75430 001**
>ADD<			MAY 26, 1999

GEL; TOPICAL
CLOBETASOL PROPIONATE

>ADD< **AB**	TARO	**0.05%**	**N75279 001**
>ADD<			MAY 28, 1999

SOLUTION; TOPICAL
CLOBETASOL PROPIONATE

AT	ALTANA	**0.05%**	**N75391 001**
			FEB 08, 1999

CLOXACILLIN SODIUM

CAPSULE; ORAL
CLOXAPEN

AB	SMITHKLINE BEECHAM	**EQ 250MG BASE**	**N62233 001**
AB		**EQ 500MG BASE**	**N62233 002**
	@	EQ 250MG BASE	N62233 001
	@	EQ 500MG BASE	N62233 002

POWDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM

>DLT< **AA**	TEVA	**EQ 125MG BASE/5ML**	**N62268 001**
>ADD<	+	EQ 125MG BASE/5ML	N62268 001
>DLT<	**TEGOPEN**		
>DLT< **AA**	+ APOTHECON	**EQ 125MG BASE/5ML**	**N61453 001**
>ADD<	@	EQ 125MG BASE/5ML	N61453 001

CLOZAPINE

TABLET; ORAL
CLOZAPINE

>DLT< **AB**	CREIGHTON	**25MG**	**N74546 001**
>DLT<			AUG 30, 1996
>DLT< **AB**		**100MG**	**N74546 002**
>DLT<			AUG 30, 1996
>ADD< **AB**	GENEVA PHARMS	**25MG**	**N74546 001**
>ADD<			AUG 30, 1996
>ADD< **AB**		**100MG**	**N74546 002**
>ADD<			AUG 30, 1996

CLOZAPINE

TABLET; ORAL

		CLOZAPINE				
> ADD >	AB	MYLAN	25MG	N75417 001	> DLT >	
> ADD				MAY 27, 1999	> DLT >	
> ADD >	AB		100MG	N75417 002	> ADD >	
> ADD >				MAY 27, 1999	> ADD >	
					> ADD >	

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

CAPSULE; ORAL

		GASTROCROM				
	+	MEDEVA	100MG	N19188 001		
				DEC 22, 1989		
	@		100MG	N19188 001		
				DEC 22, 1989		

SOLUTION/DROPS; OPHTHALMIC

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

CYTARABINE

INJECTABLE, LIPOSOMAL; INJECTION

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

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

		CERUBIDINE				
> ADD >	AP +	BEDFORD	EQ 20MG BASE/VIAL	N64103 001		
> ADD >				FEB 03, 1995		

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

		CERUBIDINE				
> DLT >	+	BEDFORD	EQ 20MG BASE/VIAL	N64103 001		
> DLT >				FEB 03, 1995		
> ADD >		DAUNORUBICIN HCL				
> ADD >	AP	BIGMAR	EQ 20MG BASE/VIAL	N65000 001		
> ADD >				MAY 25, 1999		

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		

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

		DEXTROAMPHETAMINE SULFATE			> ADD >	
	AA	ENDO PHARMS	5MG	N40299 001	> ADD >	
				MAY 13, 1999	> ADD >	

DIAZEPAM

GEL; RECTAL

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

CREAM; TOPICAL

DIFLORASONE DIACETATE					
AB TARO	0.05%	N75331 001	> ADD >		
		MAY 14, 1999	> ADD >		

OINTMENT; TOPICAL

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

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD					
AB3 + CARDERM	120MG	N20062 001	> ADD >		
		AUG 10, 1992	> ADD >		
AB3 +	180MG	N20062 002	> ADD >		
		DEC 27, 1991	> ADD >		
AB3 +	240MG	N20062 003	> ADD >		
		DEC 27, 1991	> ADD >		
	300MG	N20062 004	> ADD >		
		DEC 27, 1991	> DLT >		
BC +	120MG	N20062 001	> DLT >		
		AUG 10, 1992	> DLT >		
BC +	180MG	N20062 002	> DLT >		
		DEC 27, 1991	> DLT >		
BC +	240MG	N20062 003	> DLT >		
		DEC 27, 1991	> DLT >		
BC +	300MG	N20062 004	> DLT >		
		DEC 27, 1991			
CARTIA XT					
> ADD > AB3 ANDRX PHARMS	120MG	N74752 002			
> ADD >		JUL 09, 1998			

† SEE SECTION 1.3 OF INTRODUCTION

† SEE SECTION 1.3 OF INTRODUCTION

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARTIA XT

> ADD >	**AB3**	ANDRX PHARMS	**180MG**	**N74752 001** JUL 09, 1998
> ADD				**N74752 003** JUL 09, 1998
> ADD >	**AB3**		**240MG**	**N74752 004** JUL 09, 1998
> ADD >	**AB3**		**300MG**	N74752 002 JUL 09, 1998
> ADD >				N74752 001 JUL 09, 1998
> DLT >		@	120MG	N74752 003 JUL 09, 1998
> DLT >		@	180MG	N74752 004 JUL 09, 1998
> DLT >		@	240MG	
> DLT >		@	300MG	

INJECTABLE; INJECTION

DILTIAZEM HCL

AP	MERIDIAN MEDCL TECHN	**5MG/ML**	**N75106 001** 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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION

DOXIL

+	ALZA	2MG/ML	N50718 001 NOV 17, 1995
+	SEQUUS	2MG/ML	N50718 001 NOV 17, 1995

EPINEPHRINE

INJECTABLE; INJECTION

SUS-PHRINE

+	FOREST LABS	5MG/ML	N07942 001

SUS-PHRINE SULFITE-FREE

	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 MAR 05, 1999

ESTRADIOL

> DLT >	**AB**	MENOREST	**0.0375MG/24HR**	**N20538 001** JUL 31, 1996
> DLT >				
> DLT >	**AB**		**0.05MG/24HR**	**N20538 003** JUL 31, 1996
> DLT >				
> DLT >	**AB**		**0.075MG/24HR**	**N20538 002** JUL 31, 1996
> DLT >				
> DLT >	**AB**		**0.1MG/24HR**	**N20538 004** JUL 31, 1996
> DLT >				

VIVELLE-DOT

> ADD >	**AB**	NOVARTIS	**0.0375MG/24HR**	**N20538 001** JUL 31, 1996
> ADD >				

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

VIVELLE-DOT

> ADD >	AB	NOVARTIS	0.05MG/24HR	N20538 003 JUL 31, 1996
> ADD >	AB		0.075MG/24HR	N20538 002 JUL 31, 1996
> ADD >	AB		0.1MG/24HR	N20538 004 JUL 31, 1996

TABLET; ORAL

ESTRADIOL

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

TABLET; VAGINAL

VAGIFEM

+	NOVO NORDISK	25 UGM	N20908 001 MAR 26, 1999

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTIN

	DURAMED	0.9MG	N20992 003 MAR 24, 1999
		0.625MG	N20992 002 MAR 24, 1999
+		0.9MG	N20992 003 MAR 24, 1999

ESTROPIPATE

CREAM; VAGINAL

OGEN

+	ABBOTT	1.5MG/GM	N84710 001
+	PHARMACIA AND UPJOHN	1.5MG/GM	N84710 001

TABLET; ORAL

OGEN .625

AB	ABBOTT	0.75MG	N83220 001
AB	PHARMACIA AND UPJOHN	0.75MG	N83220 001

ESTROPIPATE

TABLET; ORAL

OGEN 1.25

AB	ABBOTT	1.5MG	N83220 002
AB	PHARMACIA AND UPJOHN	1.5MG	N83220 002

OGEN 2.5

AB	+ ABBOTT	3MG	N83220 003
AB	+ PHARMACIA AND UPJOHN	3MG	N83220 003

OGEN 5

AB	ABBOTT	6MG	N83220 004
AB	PHARMACIA AND UPJOHN	6MG	N83220 004

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
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

AB	NOVOPHARM	400MG	N74847 001 APR 23, 1999

ETODOLAC

TABLET; ORAL
ETODOLAC

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

ETOPOSIDE

INJECTABLE; INJECTION
VEPESID

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

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	> DLT > > DLT >
	*	EQ 20MG BASE	N20974 002 MAR 09, 1999	> DLT > > DLT >
	+	EQ 10MG BASE	N20974 001 MAR 09, 1999	> ADD > > ADD >
	@	EQ 20MG BASE	N20974 002 MAR 09, 1999	> ADD > > ADD >

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

AP	ABBOTT	10MG/ML	N75241 001 MAY 28, 1999

GALLAMINE TRIETHIODIDE

INJECTABLE; INJECTION
FLAXEDIL

*	DAVIS AND GECK	20MG/ML	N07842 001
*		100MG/ML	N07842 002
@		20MG/ML	N07842 001
@		100MG/ML	N07842 002

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)

AB	MOVA	4.5MG	N74591 003 DEC 22, 1997
		4.5MG	N74591 003 DEC 22, 1997
AB	NOVOPHARM	1.5MG	N74686 001 APR 20, 1999
AB		3MG	N74686 002 APR 20, 1999
AB		4.5MG	N74686 003 APR 20, 1999
AB		6MG	N74686 004 APR 20, 1999

GLYCOPYRROLATE

TABLET; ORAL
ROBINUL

+	HORIZON PHARM	1MG	N12827 001

GLYCOPYRROLATE

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

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE
> ADD > **AO** GENSIA SICOR PHARMS **EQ 50MG BASE/ML** **N75393 001** MAY 11, 1999
> ADD >
> ADD > **AO** **EQ 100MG BASE/ML** **N75393 002** MAY 11, 1999
> ADD >

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

HYDROCORTISONE

ENEMA; RECTAL
CORTENEMA
> ADD > **AB** + SOLVAY **100MG/60ML** **N16199 001**
> DLT > **BR** + **100MG/60ML** **N16199 001**
HYDROCORTISONE
> ADD > **AB** COPLEY PHARM **100MG/60ML** **N74171 001** MAY 27, 1994
> ADD >
> DLT > **BR** **100MG/60ML** **N74171 001** MAY 27, 1994
> DLT >

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREDRINE
> ADD > + AKORN 1% N00004 004
> DLT > + PHARMICS 1% N00004 004

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
AB NORTON HN **400MG** **N71145 001** SEP 23, 1986
AB **600MG** **N71146 001** SEP 23, 1986
AB **800MG** **N71769 001** MAY 08, 1987
AB ZENITH GOLDLINE **400MG** **N71145 001** SEP 23, 1986
AB **600MG** **N71146 001** SEP 23, 1986
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**

IBUPROFEN

TABLET; ORAL
MOTRIN

AB	MCNEIL CONS	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

AB	EON	75MG	N74464 001
			MAY 28, 1998

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

AB	EON	75MG	N74464 001
			MAY 28, 1998

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
IPRATROPIUM BROMIDE

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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

AN	+	INTL MEDICATION	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

ISOFLURANE

LIQUID; INHALATION
FORANE

> ADD >	AN	+ BAXTER PHARM PROD	99.9%	N17624 001
> DLT >	AN	+ OHMEDA	99.9%	N17624 001

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 >ADD<
MAR 30, 1999 >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

INJECTABLE; INJECTION
LABETALOL HCL
AP BEDFORD 5MG/ML N75303 001
MAY 28, 1999

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
LEUCOVORIN CALCIUM
AP + ABBOTT EQ 10MG BASE/ML N40147 001
JUN 25, 1997

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

AP	+	ABBOTT	EQ 10MG BASE/ML	N40147 001 JUN 25, 1997

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM

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

TABLET; ORAL
LEUCOVORIN CALCIUM

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

WELLCOVORIN

> DLT > AB		GLAXO WELLCOME	EQ 5MG BASE	N18342 001 JUL 08, 1983
> DLT > AB	+		EQ 25MG BASE	N18342 002 JUL 08, 1983
> ADD >	@		EQ 5MG BASE	N18342 001 JUL 08, 1983
> ADD >	@		EQ 25MG BASE	N18342 002 JUL 08, 1983

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

AB	+	JANSSEN	2MG	N17694 001
	@		2MG	N17690 001
AB	+	MCNEIL CONS	2MG	N17694 001
	@		2MG	N17690 001

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

VERMOX

AB	+	JANSSEN	100MG		N17481 001
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
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

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL

DEMEROL

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

MEPERIDINE HCL

AA		AMIDE PHARM	50MG	> ADD >	N40331 001
				> ADD >	MAY 28, 1999
AA			100MG	> ADD >	N40331 002
				> ADD >	MAY 28, 1999

METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLUCOPHAGE

	+	BRISTOL MYERS SQUIBB	500MG	> DLT >	N20357 001
				> DLT >	MAR 03, 1995
			625MG	> DLT >	N20357 003
				> DLT >	NOV 05, 1998
			750MG	> DLT >	N20357 004
				> DLT >	NOV 05, 1998
			500MG	> ADD >	N20357 001
				> ADD >	MAR 03, 1995
	@		625MG	> ADD >	N20357 003
				> ADD >	NOV 05, 1998
	@		750MG	> ADD >	N20357 004
				> ADD >	NOV 05, 1998

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
AP			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	>ADD> >ADD>

MICONAZOLE NITRATE

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE

AB	ALPHARMA US PHARM	200MG	N73508 001 NOV 19, 1993	>ADD>
AB	NMC	200MG	N73508 001 NOV 19, 1993	>ADD> >ADD> >ADD>

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

NADOLOL

TABLET; ORAL
CORGARD

AB	BRISTOL MYERS SQUIBB	80MG	N18063 002
AB		120MG	N18063 003
AB +		160MG	N18063 004

NALTREXONE HYDROCHLORIDE

TABLET; ORAL
NALTREXONE HCL

AB	AMIDE PHARM	50MG	N75274 001 MAY 26, 1999	>ADD> >ADD>

NAPROXEN

TABLET, DELAYED RELEASE; ORAL
NAPROXEN

AB	SIDMAK LABS CA	375MG	N75337 001 MAY 26, 1999	>ADD> >ADD>
AB		500MG	N75337 002 MAY 26, 1999	>ADD> >ADD>

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

ORLISTAT

	CAPSULE; ORAL			> DLT >	
	XENICAL			> DLT >	
	+ ROCHE	120MG	N20766 001 APR 23, 1999	> ADD >	

ORPHENADRINE CITRATE

	TABLET, EXTENDED RELEASE; ORAL			> DLT >	
	ORPHENADRINE CITRATE			> DLT >	
AB	KIEL	**100MG**	**N40249 001 JAN 29, 1999**	> ADD >	

OXYBUTYNIN CHLORIDE

	SYRUP; ORAL				
	OXYBUTYNIN CHLORIDE				
AA	MIKART	**5MG/5ML**	**N75039 001 JAN 29, 1999**		

> DLT >	OXYTETRACYCLINE CALCIUM				
> DLT >	SYRUP; ORAL				
> DLT >	TERRAMYCIN				
> DLT >	+ PFIZER	EQ 125MG BASE/5ML	N60595 001		
> ADD >	@	EQ 125MG BASE/5ML	N60595 001		

OXYTETRACYCLINE HYDROCHLORIDE

> DLT >	INJECTABLE; INJECTION				
> DLT >	TERRAMYCIN				
> DLT >	+ PFIZER	EQ 250MG BASE/VIAL	N60586 001		
> DLT >	+	EQ 500MG BASE/VIAL	N60586 002		
> ADD >	@	EQ 250MG BASE/VIAL	N60586 001		

OXYTETRACYCLINE HYDROCHLORIDE

> ADD >	INJECTABLE; INJECTION				
> ADD >	TERRAMYCIN				
> ADD >	@ PFIZER	EQ 500MG BASE/VIAL	N60586 002		

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE

> DLT >	OINTMENT; OTIC				
> DLT >	TERRAMYCIN W/ POLYMYXIN				
> DLT >	+ PFIZER	EQ 5MG BASE/GM; 10,000 UNITS/GM	N61841 001		
> ADD >	@	EQ 5MG BASE/GM; 10,000 UNITS/GM	N61841 001		
> DLT >	TABLET; VAGINAL				
> DLT >	TERRAMYCIN-POLYMYXIN				
> DLT >	+ PFIZER	EQ 100MG BASE; 100,000 UNITS	N61009 001		
> ADD >	@	EQ 100MG BASE; 100,000 UNITS	N61009 001		

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

		PENTOXIFYLLINE			
> ADD >	**AB**	SIDMAK LABS NJ	**400MG**		**N74874 001**
> ADD >					MAY 25, 1999
		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**

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

		MICRO-K			
	AB	ROBINS AH	**8MEQ**		**N18238 001**
		MICRO-K 10			
	AB	+ KV PHARM	**10MEQ**		**N18238 002**
					MAY 14, 1984
	AB	+ ROBINS AH	**10MEQ**		**N18238 002**
					MAY 14, 1984

GRANULE, FOR RECONSTITUTION ER; ORAL

		MICRO-K LS			
		@ KV PHARM	20MEQ/PACKET		N19561 003
					AUG 26, 1988
		@ ROBINS AH	20MEQ/PACKET		N19561 003
					AUG 26, 1988

POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE

INJECTABLE; INJECTION

		THAM-E			
		+ ABBOTT	370MG/VIAL;1.75GM/VIAL; 36GM/VIAL		N13025 001
		@	370MG/VIAL;1.75GM/VIAL; 36GM/VIAL		N13025 001

POTASSIUM CITRATE

POWDER FOR RECONSTITUTION; ORAL

		POTASSIUM CITRATE			
		@ MISSION PHARMA	10MEQ/PACKET		N19647 002
					OCT 13, 1988
		@	20MEQ/PACKET		N19647 001
					OCT 13, 1988
		@ UNIV TX	10MEQ/PACKET		N19647 002
					OCT 13, 1988
		@	20MEQ/PACKET		N19647 001
					OCT 13, 1988

PREDNISOLONE

SYRUP; ORAL

		PREDNISOLONE			
> ADD >	**AA**	HALSEY	**15MG/5ML**		**N40287 001**
> ADD >					MAY 28, 1999

PREDNISOLONE

SYRUP; ORAL
PREDNISOLONE
> ADD > AA UDL 15MG/5ML N40323 001
> ADD MAY 13, 1999

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
> DLT > AB GRANUTEC PHARMS EQ 150MG BASE N74488 001
> DLT > JUL 31, 1997
> DLT > AB EQ 300MG BASE N74488 002
> DLT > JUL 31, 1997
> ADD > AB NOVOPHARM NC EQ 150MG BASE N74488 001
> ADD > JUL 31, 1997
> ADD > AB EQ 300MG BASE N74488 002
> ADD > JUL 31, 1997
AB PAR PHARM EQ 150MG BASE N75180 001
JAN 28, 1999
AB EQ 300MG BASE N75180 002
JAN 28, 1999

RISPERIDONE

TABLET; ORAL
RISPERDAL
> ADD > JANSSEN 0.25MG N20272 008
> ADD > MAY 10, 1999
\+ 0.5MG N20272 007
JAN 27, 1999

RITONAVIR

SOLUTION; ORAL
NORVIR
> DLT > ABBOTT 80MG/ML N20659 001
> DLT > MAR 01, 1996
> ADD > + 80MG/ML N20659 001
> ADD > MAR 01, 1996

> ADD > ROFECOXIB

> ADD > SUSPENSION; ORAL
> ADD > VIOXX
> ADD > MERCK 12.5MG/5ML N21052 001
> ADD > MAY 20, 1999
> ADD > + 25MG/5ML N21052 002
> ADD > MAY 20, 1999

> ADD > TABLET; ORAL
> ADD > VIOXX
> ADD > MERCK 12.5MG N21042 001
> ADD > MAY 20, 1999

> ADD > ROFECOXIB

> ADD > TABLET; ORAL
> ADD > VIOXX
> ADD > + MERCK 25MG N21042 002
> ADD > MAY 20, 1999

> ADD > ROSIGLITAZONE MALEATE

> ADD > TABLET; ORAL
> ADD > AVANDIA
> ADD > SMITHKLINE BEECHAM EQ 2MG BASE N21071 002
> ADD > MAY 25, 1999
> ADD > EQ 4MG BASE N21071 003
> ADD > MAY 25, 1999
> ADD > + EQ 8MG BASE N21071 004
> ADD > MAY 25, 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

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
> DLT > **SODIUM SULFACETAMIDE**
> DLT > **AT AKORN 10% N83021 001**
> DLT > **AT 15% N83021 002**
> DLT > **AT 30% N83021 003**
> ADD > @ 10% N83021 001

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
> ADD > **SODIUM SULFACETAMIDE**
> ADD > @ AKORN 15% N83021 002
> ADD > @ 30% N83021 003
> ADD > **SULFACETAMIDE SODIUM**
> ADD > **AT** AKORN **10%** **N40215 001**
> ADD > MAY 25, 1999
> ADD > **AT** **30%** **N40216 001**
> ADD > MAY 25, 1999

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
DUPONT PHARMS N/A N18263 001
MAR 25, 1983

TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION

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

TERBUTALINE SULFATE

INJECTABLE; INJECTION

	BRETHINE				
> DLT >	AP + NOVARTIS	1MG/ML	N18571 001		
> ADD >	+	1MG/ML	N18571 001		
> DLT >	BRICANYL				
> DLT >	AP + HOECHST MARION RSSL	1MG/ML	N17466 001		
> ADD >	@	1MG/ML	N17466 001		

TERIPARATIDE ACETATE

INJECTABLE; INJECTION

> DLT >	PARATHAR			
> DLT >	+ RHONE POULENC RORER	200 UNITS/VIAL	N19498 001	
> DLT >			DEC 23, 1987	
> ADD >	@	200 UNITS/VIAL	N19498 001	
> ADD >			DEC 23, 1987	

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

	TETRACYCLINE HCL			
> DLT > AB	PUREPAC PHARM	250MG	N60290 001	
> DLT > AB		500MG	N60290 002	
> ADD >	@	250MG	N60290 001	
> ADD >	@	500MG	N60290 002	
> DLT >	TETRACYN			
> DLT > AB	PFIPHARMECS	250MG	N60082 003	
> DLT > AB		500MG	N60082 004	
> ADD >	@	250MG	N60082 003	
> ADD >	@	500MG	N60082 004	

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

TABLET, EXTENDED RELEASE; ORAL

> DLT >	SUSTAIRE			
> DLT > BC	ROERIG	100MG	N85665 001	
> DLT > BC		300MG	N85665 002	
> ADD >	@	100MG	N85665 001	
> ADD >	@	300MG	N85665 002	

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

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

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOTHIXENE HCL

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

TIAGABINE HYDROCHLORIDE

TABLET; ORAL
GABITRIL

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

SOLUTION/DROPS; OPHTHALMIC
TIMOLOL MALEATE

AT	ADV REMEDIES	EQ 0.5% BASE	N74466 001 MAR 25, 1997	> ADD >
AT	AKORN	EQ 0.5% BASE	N74466 001 MAR 25, 1997	> ADD >
AT	ALCON	EQ 0.25% BASE	N74261 001 APR 28, 1995	> DLT >
AT		EQ 0.5% BASE	N74262 001 APR 28, 1995	> DLT >
	@ FALCON PHARMS	EQ 0.25% BASE	N74261 001 APR 28, 1995	> DLT >
	@	EQ 0.5% BASE	N74262 001 APR 28, 1995	> DLT >

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
TOBREX

AT	+ ALCON	0.3%	N50541 001	> ADD >
				> DLT >

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
TOBREX

AT	+ FALCON PHARMS	0.3%	N50541 001

TRETINOIN

SOLUTION; TOPICAL
TRETINOIN

AT	MORTON GROVE	0.05%	N75260 001 JAN 25, 1999

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
ARISTOCORT

AT	FUJISAWA HLTHCARE	0.025%	N83017 003	> ADD >
AT		0.1%	N83016 004	> ADD >
AT		0.5%	N83015 002	> ADD >
AT	LEDERLE	0.025%	N83017 003	> DLT >
AT		0.1%	N83016 004	> DLT >
AT		0.5%	N83015 002	> DLT >

ARISTOCORT A

AT	FUJISAWA HLTHCARE	0.025%	N83017 004	> ADD >
AT		0.025%	N88818 001 OCT 16, 1984	> ADD >
AT		0.1%	N83016 005	> ADD >
AT		0.1%	N88819 001 OCT 16, 1984	> ADD >
AT		0.5%	N83015 003	> ADD >
AT		0.5%	N88820 001 OCT 16, 1984	> ADD >
AT	LEDERLE	0.025%	N83017 004	> DLT >
AT		0.025%	N88818 001 OCT 16, 1984	> DLT >
AT		0.1%	N83016 005	> DLT >
AT		0.1%	N88819 001 OCT 16, 1984	> DLT >
AT		0.5%	N83015 003	> DLT >
AT		0.5%	N88820 001 OCT 16, 1984	> DLT >

GEL; TOPICAL
ARISTOGEL

@	FUJISAWA HLTHCARE	0.1%	N83380 001
@	LEDERLE	0.1%	N83380 001

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

		ARISTOCORT				
>ADD>	AT	FUJISAWA HLTHCARE	0.1%		N80750 004	
>ADD>	AT		0.5%		N80745 002	
>DLT>	AT	LEDERLE	0.1%		N80750 004	
>DLT>	AT		0.5%		N80745 002	
		ARISTOCORT A				
>ADD>	AT	FUJISAWA HLTHCARE	0.1%		N80750 003	
>ADD>	AT	+	0.5%		N80745 003	
>ADD>		@	0.5%		N88781 001	
>ADD>					OCT 05, 1984	
>DLT>	AT	LEDERLE	0.1%		N80750 003	
>DLT>	AT	+	0.5%		N80745 003	
>DLT>		@	0.5%		N88781 001	
>DLT>					OCT 05, 1984	

TRIAMCINOLONE DIACETATE

SYRUP; ORAL

>ADD>	ARISTOCORT				
>ADD>	FUJISAWA HLTHCARE	2MG/5ML		N11960 004	
>ADD>	LEDERLE	2MG/5ML		N11960 004	
>DLT>					

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

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

TABLET, EXTENDED RELEASE; ORAL

		VERAPAMIL HCL			
>ADD>	AB	DURAMED	**120MG**	**N75072 001**	
>ADD>					MAY 25, 1999
>ADD>	AB		**240MG**	**N75072 003**	
>ADD>					MAY 25, 1999

WARFARIN SODIUM

TABLET; ORAL

	COUMADIN			
>DLT>	AB	+ DUPONT MERCK	**2MG**	**N09218 013**

WARFARIN SODIUM

TABLET; ORAL

COUMADIN

> ADD >	**AB**		DUPONT MERCK	2MG	N09218 013
> DLT >	**AB**			2.5MG	N09218 018
> ADD >	**AB**	+		2.5MG	N09218 018
> DLT >	**AB**			5MG	N09218 007
> ADD >	**AB**	+		5MG	N09218 007

ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACETAMINOPHEN			
ASCENT PEDS	120MG	N18337 003	SEP 12, 1983
	325MG	N18337 002	
	650MG	N18337 001	
UPSHER SMITH	120MG	N18337 003	SEP 12, 1983
	325MG	N18337 002	
	650MG	N18337 001	

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	CONTAC			
>_DLT_>	+ SMITHKLINE	8MG;75MG	N18099 001	
>_DLT_>	@	8MG;75MG	N18099 001	
>_ADD_>	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE			
>_DLT_>	CENT PHARMS	8MG;75MG	N18809 001	MAY 07, 1984
>_DLT_>				
>_ADD_>	+	8MG;75MG	N18809 001	MAY 07, 1984
>_ADD_>				

TABLET, EXTENDED RELEASE; ORAL

>_DLT_>	TRIAMINIC-12			
>_DLT_>	+ NOVARTIS	12MG;75MG	N18115 001	
>_ADD_>	@	12MG;75MG	N18115 001	

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

EPINEPHRINE BITARTRATE

AEROSOL, METERED; INHALATION

MEDIHALER-EPI			
+ 3M	0.3MG/INH	N10374 003	
@	0.3MG/INH	N10374 003	

IBUPROFEN

SUSPENSION; ORAL

IBUPROFEN			
ALPHARMA	100MG/5ML	N74916 001	APR 30, 1999

TABLET; ORAL

IBUPROFEN			
LNK	200MG	N75010 001	MAR 01, 1999
	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			
>_DLT_>	+ NOVARTIS	200MG	N20402 001	
>_DLT_>				APR 20, 1995
>_ADD_>	+ WHITEHALL ROBINS	200MG	N20402 001	
>_ADD_>				APR 20, 1995

MICONAZOLE NITRATE

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

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

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

NMC 100MG N73507 001 NOV 19, 1993 > ADD >

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICOTINE POLACRILEX
CIRCA EQ 2MG BASE N74507 001 MAR 15, 1999 > ADD >

EQ 4MG BASE N74707 001 MAR 19, 1999 > ADD >

NONOXYNOL-9

SPONGE; VAGINAL
TODAY
@ ALLENDALE PHARMS 1GM N18683 001 APR 01, 1983 > ADD >

@ WHITEHALL ROBINS 1GM N18683 001 APR 01, 1983 > ADD >

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL
PERRIGO 120MG N75153 001 FEB 26, 1999 > ADD >

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HCL
RANBAXY EQ 75MG BASE N75132 001 > ADD >

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

+ WARNER LAMBERT EQ 75MG BASE N20520 001 DEC 19, 1995 > ADD >

TERBINAFINE HYDROCHLORIDE

CREAM; TOPICAL
LAMISIL
+ NOVARTIS 1% N20980 001 MAR 09, 1999 > ADD >

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST

CUMULATIVE SUPPLEMENT NUMBER 5 MAY '99

NO MAY 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
May 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-Strase 76 35041 Marburg Germany, DD=10/16/1992 MA=04/01/1999

Orphan Product Designations and Approvals List
May 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

Orphan Product Designations and Approvals List
May 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
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
Decitabine TN=	Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999

Orphan Product Designations and Approvals List
May 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
Etanercept TN= Enbrel	Treatment of Wegener's granulomatosis.	Stone, MD, MPH, John H. 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

Orphan Product Designations and Approvals List
May 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
Japanese encephalitis vaccine (live, attenuated) TN=	Prevention of Japanese encephalitis.	Boran Pharmaceuticals 3F, Koryo Academytel, 437-3 Ahyun-Dong, Mapo-Gu, Seoul 121-010 South Korea, DD=05/19/1999
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
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
Lisofylline TN=	Treatment of patients undergoing induction therapy for acute myeloid leukemia.	Cell Therapeutics, Inc. 201 Elliot Ave. W., Suite 400 Seattle, WA 98119 DD=06/03/1999

Orphan Product Designations and Approvals List
May 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Marijuana TN=	Treatment of HIV-associated wasting syndrome.	Multidisciplinary Association for Psychedelic Studies, Inc. 3 Francis St. Belmont, MA 02478 DD=05/25/1999
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, UK 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
Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine TN= MEDI-491	Prevention of transient aplastic crisis in patients with sickle cell anemia.	MedImmune, Inc. 35 West Watkins Mill Rd. Gaithersburg, MD 20878 DD=05/07/1999
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
May 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
May 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 DD=04/06/1999
Transgenic human alpha 1 antitrypsin TN=	Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland U.K. DD=05/19/1999

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

NO MAY 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.

ABBREVIATIONS

NP* NEW PRODUCT (MINT FLAVORED)

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
I-262	TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE AND FOR THE PREVENTION OF EXERCISE INDUCED BRONCHOSPASM IN CHILDREN AGES 4-12
I-263	TREATMENT OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION FOR THE PREVENTION OF ISCHEMIC COMPLICATIONS IN PATIENTS ON CONCURRENT ASPIRIN THERAPY

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

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

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.
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
U-267	METHOD FOR PREVENTING HEARTBURN

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
>ADD>	020503	001	ALBUTEROL SULFATE;PROVENTIL-HFA				I-262	JUN 02, 2002
	020886	001	ALITRETINOIN;PANRETIN				ODE	FEB 02, 2006
	021007	001	AMPRENAVIR;AGENERASE				NCE	FEB 02, 2004
	021007	002	AMPRENAVIR;AGENERASE				NCE	APR 15, 2004
	021039	001	AMPRENAVIR;AGENERASE				NCE	APR 15, 2004
	020500	001	ATOVAQUONE;MEPRON	5585397	DEC 17, 2013		NCE	APR 15, 2004
							ODE	JAN 05, 2006
	020711	002	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013		I-255	JAN 05, 2002
	020711	003	BUPROPION HYDROCHLORIDE;ZYBAN	5763493	AUG 12, 2013			
	020954	001	BUSULFAN;BUSULFEX	5430057	SEP 30, 2013	U-263	ODE	FEB 04, 2006
				5559148	MAY 24, 2015	U-264	NDF	FEB 04, 2002
>ADD>	020313	002	CALCITONIN, SALMON;MIACALCIN	5759565	JUN 02, 2015			
	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			
>ADD>	020740	005	CERIVASTATIN SODIUM;BAYCOL	5006530	JAN 17, 2009		NS	MAY 24, 2002
>ADD>				5177080	NOV 26, 2011			
	020638	001	CIDOFOVIR;VISTIDE	5142051	JUN 26, 2010			
	020863	001	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
	020863	002	CILOSTAZOL;PLETAL				NCE	JAN 15, 2004
	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-263	MAY 25, 2002
							I-259	MAR 30, 2002
>ADD>	020287	003	DALTEPARIN SODIUM;FRAGMIN				I-263	MAY 25, 2002
							I-259	MAR 30, 2002
>ADD>	020287	004	DALTEPARIN SODIUM;FRAGMIN				I-263	MAY 25, 2002
							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		

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
	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 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			
	020363	001	FAMCICLOVIR;FAMVIR	5246937	SEP 21, 2010	U-96		
	020363	003	FAMCICLOVIR;FAMVIR	5246937	SEP 21, 2010	U-96		
>ADD>	020325	001	FAMOTIDINE;PEPCID AC	5854267	DEC 29, 2015	U-267		
	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
	020955	001	FERRIC SODIUM GLUCONATE;FERRLECIT				NCE	FEB 18, 2004
>ADD>	020625	001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5855912	FEB 28, 2015			
>ADD>				5738872	FEB 28, 2015			
	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			
	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		
	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			
>ADD>	020564	001	LAMIVUDINE;EPIVIR	5905082	MAY 18, 2016			
>ADD>	020564	002	LAMIVUDINE;EPIVIR-HBV	5905082	MAY 18, 2016		I-257	DEC 08, 2001
				5047407	FEB 08, 2009			
				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

PRESCRIPTION AND OTC DRUG PRODUCT
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	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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		
	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
	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
	020385	001	NICOTINE;NICOTROL	5656255	AUG 12, 2014			
>ADD>	021008	001	OCTREOTIDE ACETATE;SANDOSTATIN LAR	5688530	NOV 18, 2014	U-268	ODE	NOV 25, 2005
>ADD>				4395403	NOV 21, 2002	U-269		
>ADD>				5538739	JUL 23, 2013			
>ADD>				5639480	JUN 17, 2014			
>ADD>	021008	002	OCTREOTIDE ACETATE;SANDOSTATIN LAR	5688530	NOV 18, 2014	U-268	ODE	NOV 25, 2005
>ADD>				4395403	NOV 21, 2002	U-269		
>ADD>				5538739	JUL 23, 2013			
>ADD>				5639480	JUN 17, 2014			
>ADD>	021008	003	OCTREOTIDE ACETATE;SANDOSTATIN LAR	5688530	NOV 18, 2014	U-268	ODE	NOV 25, 2005
>ADD>				4395403	NOV 21, 2002	U-269		
>ADD>				5538739	JUL 23, 2013			
>ADD>				5639480	JUN 17, 2014			
	020766	001	ORLISTAT;XENICAL				NCE	APR 23, 2004
>ADD>	020897	001	OXYBUTYNIN CHLORIDE;DITROPAN XL	4783337	SEP 16, 2003		NP	DEC 16, 2001
>ADD>				5674895	MAY 22, 2015			
>ADD>				5082668	SEP 16, 2003			
>ADD>				5840754	MAY 22, 2015			
>ADD>				4612008	SEP 16, 2007			
>ADD>				4519801	MAY 28, 2002			
>ADD>	020897	002	OXYBUTYNIN CHLORIDE;DITROPAN XL	5840754	MAY 22, 2015		NP	DEC 16, 2001
>ADD>				5674895	MAY 22, 2015			
>ADD>				5082668	SEP 16, 2003			
>ADD>				4783337	SEP 16, 2003			
>ADD>				4612008	SEP 16, 2007			
>ADD>				4519801	MAY 28, 2002			

PRESCRIPTION AND OTC DRUG PRODUCT
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	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			
	020031	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015		I-261	MAY 17, 2002
				5900423	MAY 19, 2015			
	020031	002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015		I-261	MAY 17, 2002
				5900423	MAY 19, 2015			
	020031	003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015		I-261	MAY 17, 2002
				5900423	MAY 19, 2015			
	020031	004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015		I-261	MAY 17, 2002
				5900423	MAY 19, 2015			
	020031	005	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015		I-261	MAY 17, 2002
				5900423	MAY 19, 2015			
	020710	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
				5900423	MAY 19, 2015			
	020885	001	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
				5900423	MAY 19, 2015			
	020885	002	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
				5900423	MAY 19, 2015			
	020885	003	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
				5900423	MAY 19, 2015			
	020885	004	PAROXETINE HYDROCHLORIDE;PAXIL	5872132	MAY 19, 2015			
				5900423	MAY 19, 2015			
	020936	001	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132	MAY 19, 2015		NDF	FEB 16, 2002
				4839177	JUN 13, 2006			
				5422123	JUN 06, 2012			
				4721723	DEC 29, 2006			
				5900423	MAY 19, 2015			
	020936	002	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132	MAY 19, 2015		NDF	FEB 16, 2002
				4839177	JUN 13, 2006			
				5422123	JUN 06, 2012			
				4721723	DEC 29, 2006			
				5900423	MAY 19, 2015			
	020698	001	POLYETHYLENE GLYCOL 3350;MIRALAX	5710183	JUL 14, 2015	U-265	NP	FEB 18, 2002
	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>	020272	008	RISPERIDONE;RISPERDAL	4804663	DEC 29, 2007	U-90	D-37	OCT 17, 2000
>ADD>				5158952	DEC 29, 2007	U-90		
	021042	001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
				5691374	NOV 25, 2017			
	021042	002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
				5691374	NOV 25, 2017			

PRESCRIPTION AND OTC DRUG PRODUCT
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	APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	021052	001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
				5691374	NOV 25, 2017			
	021052	002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U-266	NCE	MAY 20, 2004
				5691374	NOV 25, 2017			
>ADD>	021071	002	ROSIGLITAZONE MALEATE;AVANDIA				NCE	MAY 25, 2004
>ADD>	021071	003	ROSIGLITAZONE MALEATE;AVANDIA				NCE	MAY 25, 2004
>ADD>	021071	004	ROSIGLITAZONE MALEATE;AVANDIA				NCE	MAY 25, 2004
>ADD>	020980	001	TERBINAFINE HYDROCHLORIDE;LAMISIL	4680291	JUL 14, 2004	U-73		
>ADD>				4755534	DEC 30, 2006	U-73		
	020646	005	TIAGABINE HYDROCHLORIDE;GABITRIL	5010090	OCT 07, 2008		NCE	SEP 30, 2002
				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			

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