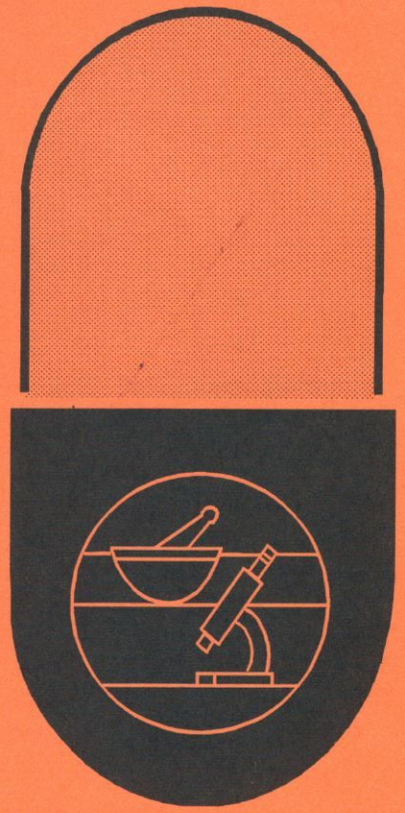
CUMULATIVE
SUPPLEMENT 5
MAY 2000



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH 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 MANAGEMENT AND SERVICES

2000

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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, 20th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 and OTC Drug Product List 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.

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 20h Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st 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)
GALDERMA LABS INC (GALDERMA)	GALDERMA LABORATORIES LP (GALDERMA LABS LP)
GLOBAL PHARMACEUTICAL CORP (GLOBAL PHARM)	IMPAX LABORATORIES INC (IMPAX LABS)
HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL)	AVENTIS PHARMACEUTICALS INC (AVENTIS PHARMS)
RHONE POULENC RORER PHARMACEUTICALS INC (RHONE POULENCE RORER)	AVENTIS PHARMACEUTICALS PRODUCTS INC (AVENTIS PHARM PROD)
TAP HOLDINGS INC (TAP HOLDINGS)	TAP PHARMACEUTICAL PRODUCTS INC (TAP PHARM)
ZENECA INC (ZENECA)	ASTRAZENECA PHARMACEUTICALS LP (ASTRAZENECA PHARMS)
ZENECA LTD (ZENECA)	ASTRAZENECA UK LTD (ASTRAZENECA UK)
ZENECA PHARMACEUTICALS DIV ZENECA INC (ZENECA)	ASTRAZENECA PHARMACEUTICALS LP (ASTRAZENECA PHARMS)

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 20th 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 $90.00 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 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/20bookpub.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 Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:
http://www.fda.gov/cder/orange/patdecl.pdf
http://www.fda.gov/cder/orange/patdecl.html

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 1999) 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 1999	MAR 2000	JUN 2000	SEP 2000
DRUG PRODUCTS LISTED	10045	10082		
SINGLE SOURCE	2599 (25.9%)	2596 (25.7%)		
MULTISOURCE	7335 (73.0%)	7375 (73.2%)		
THERAPEUTICALLY EQUIVALENT	6986 (69.5%)	7040 (69.8%)		
NOT THERAPEUTICALLY EQUIVALENT	349 (3.5%)	335 (3.3%)		
EXCEPTIONS[1]	111 (1.1%)	111 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	0	6		
NUMBER OF APPLICANTS	576	575		

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

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL

PHRENILIN FORTE

AB	+	AMARIN PHARMS	650MG;50MG	N88831 001 JUN 19, 1985
AB	+	CARNRICK	650MG;50MG	N88831 001 JUN 19, 1985

TABLET; ORAL

PHRENILIN

AB	+	AMARIN PHARMS	325MG;50MG	N87811 001 JUN 19, 1985
AB	+	CARNRICK	325MG;50MG	N87811 001 JUN 19, 1985

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA		AMARIN PHARMS	120MG/5ML;12MG/5ML	N86024 001
AA		CARNRICK	120MG/5ML;12MG/5ML	N86024 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

	AA	UCB	325MG;10MG	N40248 002 APR 28, 2000
		+	325MG;7.5MG	N40248 001 APR 28, 2000
> ADD >	AA	VINTAGE PHARMS	325MG;10MG	N40355 001 MAY 31, 2000
> ADD >	AA		500MG;10MG	N40356 001 MAY 31, 2000
> ADD >	AA		660MG;10MG	N40358 001 MAY 31, 2000

LORTAB

		UCB	325MG;5MG	N40099 001 JUN 25, 1997
		@	325MG;5MG	N40099 001 JUN 25, 1997

NORCO

AA	+	WATSON LABS	325MG;10MG	N40148 001 FEB 14, 1997
	+		325MG;10MG	N40148 001 FEB 14, 1997

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE HCL AND ACETAMINOPHEN

AB		WATSON LABS	650MG;EQ 25MG BASE	N74699 001 MAR 24, 2000

TALACEN

AB	+	SANOFI SYNTHELABO	650MG;EQ 25MG BASE	N18458 001 SEP 23, 1982
	+		650MG;EQ 25MG BASE	N18458 001 SEP 23, 1982

ACETOHEXAMIDE

TABLET; ORAL

DYMELOR

> DLT >				
> DLT >	AB	LILLY	250MG	N13378 002
> DLT >	AB	+	500MG	N13378 001
> ADD >		@	250MG	N13378 002
> ADD >		@	500MG	N13378 001

ADAPALENE

CREAM; TOPICAL

DIFFERIN

> ADD >				
> ADD >				
> ADD >		+ GALDERMA LABS LP	0.1%	N20748 001 MAY 26, 2000
> ADD >				

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL

> DLT >	AB	MEDISOL	0.09MG/INH	N74072 001 AUG 01, 1996
> DLT >				
> ADD >	AB	SIDMAK LABS CA	0.09MG/INH	N74072 001 AUG 01, 1996
> ADD >				

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN		BAUSCH AND LOMB	EQ 0.083% BASE	N75358 001 MAR 29, 2000

ALOSETRON HYDROCHLORIDE

TABLET; ORAL
LOTRONEX
+ GLAXO WELLCOME — EQ 1MG BASE — N21107 001 — FEB 09, 2000

> ADD > ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN;
> ADD > CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID;
> ADD > NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE
> ADD > SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE

> ADD > INJECTABLE; INJECTION
> ADD > MULTI-12
> ADD > + SABEX — 2 IU/ML;20MG/ML;12 UGM/ML;40 IU/ML; 1 UGM/ML;3MG/ML;80 UGM/ML;8MG/ML; 0.8MG/ML;0.72MG/ML;0.6MG/ML; 600 IU/ML — N21163 001 — MAY 18, 2000

ALTRETAMINE

CAPSULE; ORAL
HEXALEN
+ MEDIMMUNE ONCOLOGY — 50MG — N19926 001 — DEC 26, 1990
+ US BIOSCIENCE — 50MG — N19926 001 — DEC 26, 1990

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL
AB GENEVA PHARMS TECH — **100MG** — **N71293 001** — FEB 18, 1987
AB INVAMED — **100MG** — **N71293 001** — FEB 18, 1987

AMIFOSTINE

INJECTABLE; INJECTION
ETHYOL
+ MEDIMMUNE ONCOLOGY — 500MG/VIAL — N20221 001 — DEC 08, 1995

> DLT > AMIFOSTINE
> DLT >
> ADD >
> ADD >

INJECTABLE; INJECTION
ETHYOL
+ US BIOSCIENCE — 500MG/VIAL — N20221 001 — DEC 08, 1995

AMINO ACIDS

INJECTABLE; INJECTION
TROPHAMINE
B BRAUN — 6% — N19018 001 — JUL 20, 1984
+ — 6% — N19018 001 — JUL 20, 1984

TROPHAMINE 10%
B BRAUN — 10% — N19018 003 — SEP 07, 1988
+ — 10% — N19018 003 — SEP 07, 1988

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
AB GLOBAL PHARM — **100MG** — **N84574 001**
AB — **200MG** — **N84576 001**
@ IMPAX LABS — 100MG — N84574 001
@ — 200MG — N84576 001

AMRINONE LACTATE

INJECTABLE; INJECTION
AMRINONE
AP BEDFORD — **EQ 5MG BASE/ML** — **N75513 001** — MAY 09, 2000

AMRINONE LACTATE
AP BAXTER PHARM PROD — **EQ 5MG BASE/ML** — **N75542 001** — MAY 10, 2000

ARDEPARIN SODIUM

INJECTABLE; INJECTION
NORMIFLO
+ PHARMACIA AND UPJOHN — 5,000 UNITS/0.5ML — N20227 002 — MAY 23, 1997

ARDEPARIN SODIUM

INJECTABLE; INJECTION
NORMIFLO
+ PHARMACIA AND UPJOHN 10,000 UNITS/0.5ML N20227 001 MAY 23, 1997
+ WYETH AYERST 5,000 UNITS/0.5ML N20227 002 MAY 23, 1997
+ 10,000 UNITS/0.5ML N20227 001 MAY 23, 1997

ARTICAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION
SEPTOCAINE
+ DEPROCO 4%;EQ 0.01MG BASE/ML N20971 001 APR 03, 2000

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E

> ADD >
INJECTABLE; INJECTION
KABIVITE PED F + W KIT
+ FRESENIUS KABI N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A, 0.001MG/VIAL;400 IU/10ML,N/A;N/A, 0.14MG/VIAL;N/A,17MG/VIAL;N/A, 5MG/VIAL;0.2MG/10ML,N/A;N/A, 1MG/VIAL;N/A,1.4MG/VIAL;N/A, 1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML, N/A;7 IU/10ML,N/A N20176 001 DEC 29, 1993

VITAPED
@ FRESENIUS KABI N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A, 0.001MG/VIAL;400 IU/10ML,N/A;N/A, 0.14MG/VIAL;N/A,17MG/VIAL;N/A, 5MG/VIAL;0.2MG/10ML,N/A;N/A, 1MG/VIAL;N/A,1.4MG/VIAL;N/A, 1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML, N/A;7 IU/10ML,N/A N20176 001 DEC 29, 1993

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
> ADD > AA PAR PHARM 0.025MG;2.5MG N40357 001 MAY 02, 2000

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
ENLON-PLUS
+ BAXTER PHARM PROD 0.14MG/ML;10MG/ML N19677 001 NOV 06, 1991
+ 0.14MG/ML;10MG/ML N19678 001 NOV 06, 1991
+ OHMEDA 0.14MG/ML;10MG/ML N19677 001 NOV 06, 1991
+ 0.14MG/ML;10MG/ML N19678 001 NOV 06, 1991

AZELASTINE HYDROCHLORIDE

> ADD >
SOLUTION/DROPS; OPHTHALMIC
OPTIVAR
+ ASTA 0.05% N21127 001 MAY 22, 2000

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE
AA GENEVA PHARMS TECH 0.5MG N72264 001 FEB 27, 1989
AA 1MG N72265 001 FEB 27, 1989
AA 2MG N72266 001 FEB 27, 1989
AA INVAMED 0.5MG N72264 001 FEB 27, 1989
AA 1MG N72265 001 FEB 27, 1989
AA 2MG N72266 001 FEB 27, 1989

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION
URECHOLINE
+ MERCK 5MG/ML N06536 001
@ 5MG/ML N06536 001

TABLET; ORAL
BETHANECHOL CHLORIDE
> DLT > AA DANBURY PHARMA 10MG N84408 001
> DLT > AA 25MG N84441 001
> DLT > AA 50MG N87444 001
> ADD > @ 10MG N84408 001
> ADD > @ 25MG N84441 001
> ADD > @ 50MG N87444 001
> DLT > DUVOID
> DLT > AA ROBERTS LABS 10MG N86262 001
> DLT > AA 25MG N86263 001
> DLT > AA 50MG N85882 003
> ADD > @ 10MG N86262 001
> ADD > @ 25MG N86263 001
> ADD > @ 50MG N85882 003
> DLT > MYOTONACHOL
> DLT > AA GLENWOOD 5MG N84188 001
> DLT > AA 10MG N84188 003
> DLT > AA 25MG N84188 004
> ADD > @ 5MG N84188 001
> ADD > @ 10MG N84188 003
> ADD > @ 25MG N84188 004
URECHOLINE
AA + MERCK 5MG N06536 003
AA + 10MG N06536 002
AA + 25MG N06536 004
AA + 50MG N06536 005
@ 5MG N06536 003
@ 10MG N06536 002
@ 25MG N06536 004
@ 50MG N06536 005
> ADD > + ODYSSEY PHARMS 5MG N89095 001
> ADD > DEC 19, 1985
> ADD > + 10MG N88440 001
> ADD > MAY 29, 1984
> ADD > + 25MG N88441 001
> ADD > MAY 29, 1984
> ADD > + 50MG N89096 001
> ADD > DEC 19, 1985
> DLT > AA + SIDMAK LABS NJ 5MG N89095 001
> DLT > DEC 19, 1985

BETHANECHOL CHLORIDE

TABLET; ORAL
URECHOLINE
> DLT > AA + SIDMAK LABS NJ 10MG N88440 001
> DLT > MAY 29, 1984
> DLT > AA + 25MG N88441 001
> DLT > MAY 29, 1984
> DLT > AA + 50MG N89096 001
> DLT > DEC 19, 1985

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLEOMYCIN
AP FAULDING EQ 15 UNITS BASE/VIAL N65031 001
MAR 10, 2000
AP EQ 30 UNITS BASE/VIAL N65031 002
MAR 10, 2000

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
AP ASTRAZENECA 50MG/ML N71151 001
AUG 10, 1987
@ 50MG/ML N71151 001
AUG 10, 1987

BUPROPION HYDROCHLORIDE

TABLET; ORAL
BUPROPION HCL
AB INVAMED 75MG N75584 001
FEB 07, 2000
AB 100MG N75584 002
FEB 07, 2000
AB MYLAN 75MG N75491 001
APR 17, 2000
AB 100MG N75491 002
APR 17, 2000

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION
BUTORPHANOL TARTRATE

AP	ABBOTT	1MG/ML	N75559 001	MAR 20, 2000
AP		2MG/ML	N75559 002	MAR 20, 2000

CALCIUM CHLORIDE

INJECTABLE; INJECTION
CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER

+	ABBOTT	100MG/ML	N21117 001	JAN 28, 2000

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC
CARDIOPLEGIC IN PLASTIC CONTAINER

AT	BAXTER HLTHCARE	17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML	N75323 001	APR 21, 2000

PLEGISOL IN PLASTIC CONTAINER

AT +	ABBOTT	17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML	N18608 001	FEB 26, 1982
+		17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML	N18608 001	FEB 26, 1982

CANDICIDIN

OINTMENT; VAGINAL
VANOBID

@	AVENTIS PHARMS	0.6MG/GM	N61596 001	
+	HOECHST MARION RSSL	0.6MG/GM	N61596 001	

TABLET; VAGINAL
VANOBID

@	AVENTIS PHARMS	3MG	N61613 001	
+	HOECHST MARION RSSL	3MG	N61613 001	

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
CARBIDOPA AND LEVODOPA

AB	MYLAN	25MG;100MG	N75091 002	APR 21, 2000

SINEMET CR

AB	DUPONT PHARMS	25MG;100MG	N19856 002	DEC 24, 1992
		25MG;100MG	N19856 002	DEC 24, 1992

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CARTEOLOL HCL

AT	ALCON	1%	N75476 001	JAN 03, 2000
AT	BAUSCH AND LOMB	1%	N75546 001	JAN 20, 2000

OCUPRESS

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

CEFDINIR

CAPSULE; ORAL
OMNICEF

+	ABBOTT	300MG	N50739 001	DEC 04, 1997
+	PARKE DAVIS	300MG	N50739 001	DEC 04, 1997

POWDER FOR RECONSTITUTION; ORAL
OMNICEF

+	ABBOTT	125MG/5ML	N50749 001	DEC 04, 1997
+	PARKE DAVIS	125MG/5ML	N50749 001	DEC 04, 1997

CEFOTAXIME SODIUM

INJECTABLE; INJECTION
CEFOTAXIME

AP		AM PHARM PARTNERS	EQ 500MG BASE/VIAL	N64200 001 MAR 24, 2000
AP			EQ 1GM BASE/VIAL	N64200 002 MAR 24, 2000
AP			EQ 2GM BASE/VIAL	N64200 003 MAR 24, 2000
AP			EQ 10GM BASE/VIAL	N64201 001 MAR 24, 2000
	+		EQ 20GM BASE/VIAL	N64201 002 MAR 24, 2000

CLAFORAN

AP	+	AVENTIS PHARMS	EQ 500MG BASE/VIAL	N50547 001
AP	+		EQ 1GM BASE/VIAL	N50547 002
AP	+		EQ 2GM BASE/VIAL	N50547 003
AP	+		EQ 10GM BASE/VIAL	N50547 004 DEC 29, 1983
	+	HOECHST MARION RSSL	EQ 500MG BASE/VIAL	N50547 001
	+		EQ 1GM BASE/VIAL	N50547 002
	+		EQ 2GM BASE/VIAL	N50547 003
	+		EQ 10GM BASE/VIAL	N50547 004 DEC 29, 1983

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL
CEDAX

+	DJ PHARMA	EQ 400MG BASE	N50685 002 DEC 20, 1995
+	SCHERING PLOUGH	EQ 400MG BASE	N50685 002 DEC 20, 1995

POWDER FOR RECONSTITUTION; ORAL
CEDAX

	DJ PHARMA	EQ 90MG BASE/5ML	N50686 001 DEC 20, 1995
+		EQ 180MG BASE/5ML	N50686 002 DEC 20, 1995
+	SCHERING PLOUGH	EQ 90MG BASE/5ML	N50686 001 DEC 20, 1995
+		EQ 180MG BASE/5ML	N50686 002 DEC 20, 1995

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN

+	HLR	EQ 250MG BASE/VIAL	N50585 001 DEC 21, 1984
+		EQ 500MG BASE/VIAL	N50585 002 DEC 21, 1984
+		EQ 1GM BASE/VIAL	N50585 003 DEC 21, 1984
+		EQ 2GM BASE/VIAL	N50585 004 DEC 21, 1984
+		EQ 10GM BASE/VIAL	N50585 005 DEC 21, 1984
+	ROCHE	EQ 250MG BASE/VIAL	N50585 001 DEC 21, 1984
+		EQ 500MG BASE/VIAL	N50585 002 DEC 21, 1984
+		EQ 1GM BASE/VIAL	N50585 003 DEC 21, 1984
+		EQ 2GM BASE/VIAL	N50585 004 DEC 21, 1984
+		EQ 10GM BASE/VIAL	N50585 005 DEC 21, 1984

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

@	HLR	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987
+		EQ 20MG BASE/ML	N50624 002 FEB 11, 1987
+		EQ 40MG BASE/ML	N50624 003 FEB 11, 1987
@	ROCHE	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987
+		EQ 20MG BASE/ML	N50624 002 FEB 11, 1987
+		EQ 40MG BASE/ML	N50624 003 FEB 11, 1987

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION
ROCEPHIN KIT

+	HLR	EQ 1GM BASE/VIAL,N/A;N/A, 1%	N50585 006 MAY 08, 1996
+		EQ 500MG BASE/VIAL,N/A;N/A, 1%	N50585 007 MAY 08, 1996

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION
ROCEPHIN KIT

	+	ROCHE	EQ 1GM BASE/VIAL,N/A;N/A, 1%	N50585 006 MAY 08, 1996	
	+		EQ 500MG BASE/VIAL,N/A;N/A, 1%	N50585 007 MAY 08, 1996	

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL
KEFLEX

AB	+	LILLY	EQ 125MG BASE/5ML	N50406 001	
AB	+		EQ 250MG BASE/5ML	N50406 002	
AB			EQ 250MG BASE/5ML	N62117 003	
AB	+		EQ 250MG BASE/5ML	N62117 003	
	@		EQ 125MG BASE/5ML	N50406 001	
	@		EQ 250MG BASE/5ML	N50406 002	

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC

	+	SNOWBRAND	EQ 30MG BASE	N20989 002 JAN 11, 2000	

CHENODIOL

TABLET; ORAL
CHENIX

	@	AXCAN	250MG	N18513 002 JUL 28, 1983	
	@	AXCAN SCANDIPHARM	250MG	N18513 002 JUL 28, 1983	> ADD > > ADD > > ADD > > ADD >

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

AA		GLOBAL PHARM	4MG	N80809 001
	@	IMPAX LABS	4MG	N80809 001

CICLOPIROX

CREAM; TOPICAL
LOPROX

	+	AVENTIS PHARMS	0.77%	N18748 001 DEC 30, 1982

LOTION; TOPICAL
LOPROX

	+	AVENTIS PHARMS	0.77%	N19824 001 DEC 30, 1988

CICLOPIROX OLAMINE

CREAM; TOPICAL
LOPROX

	+	HOECHST MARION RSSL	1%	N18748 001 DEC 30, 1982

LOTION; TOPICAL
LOPROX

	+	HOECHST MARION RSSL	1%	N19824 001 DEC 30, 1988

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
CIMETIDINE HCL

AA	NOVEX	EQ 300MG BASE/5ML	N75560 001 MAR 15, 2000

CISPLATIN

INJECTABLE; INJECTION
CISPLATIN

AP		GENSIA SICOR PHARMS	1MG/ML	N74814 001 MAY 16, 2000
AP		PHARMACHEMIE	1MG/ML	N74656 001 MAY 16, 2000

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CELEXA

	FOREST LABS	EQ 40MG BASE	N20822 003 JUL 17, 1998

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CELEXA
+ FOREST LABS — EQ 60MG BASE — N20822 004 JUL 17, 1998
+ — EQ 40MG BASE — N20822 003 JUL 17, 1998
@ — EQ 60MG BASE — N20822 004 JUL 17, 1998

CLADRIBINE

INJECTABLE; INJECTION
CLADRIBINE
AP BEDFORD — 1MG/ML — N75405 001 FEB 28, 2000

CLARITHROMYCIN

TABLET; ORAL
BIAXIN
ABBOTT — 250MG — N50662 001 OCT 31, 1991
+ — 250MG — N50662 001 OCT 31, 1991

TABLET, EXTENDED RELEASE; ORAL
BIAXIN XL
+ ABBOTT — 500MG — N50775 001 MAR 03, 2000

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
CLEOCIN T
AB + PHARMACIA AND UPJOHN — EQ 1% BASE — N50615 001 JAN 07, 1987
+ — EQ 1% BASE — N50615 001 JAN 07, 1987

CLINDAMYCIN PHOSPHATE
AB ALTANA — EQ 1% BASE — N64160 001 JAN 28, 2000

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE
> ADD > AT CLAY PARK — EQ 1% BASE — N65049 001 MAY 25, 2000 > ADD >

CLOBETASOL PROPIONATE

> ADD > AEROSOL; TOPICAL
> ADD > OLUX FOAM
> ADD > + CONNETICS — 0.05% — N21142 001 MAY 26, 2000
> ADD >

CREAM; TOPICAL
CLOBETASOL PROPIONATE
> ADD > AB2 TARO — 0.05% — N75633 001 MAY 17, 2000 > ADD >

GEL; TOPICAL
CLOBETASOL PROPIONATE
AB ALTANA — 0.05% — N75368 001 FEB 15, 2000

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM
AB TARO — 3.75MG — N75731 003 APR 27, 2000
AB — 7.5MG — N75731 002 APR 27, 2000
AB — 15MG — N75731 001 APR 27, 2000

> ADD > COLESEVELAM HYDROCHLORIDE

> ADD > CAPSULE; ORAL
> ADD > WELCHOL
> ADD > + GELTEX — 375MG — N21141 001 MAY 26, 2000
> ADD >

> ADD > TABLET; ORAL
> ADD > WELCHOL
> ADD > + GELTEX — 625MG — N21176 001 MAY 26, 2000
> ADD >

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE
BP GLOBAL PHARM — 25MG — N09458 001
@ IMPAX LABS — 25MG — N09458 001

CROMOLYN SODIUM

CONCENTRATE; ORAL
GASTROCROM
+ MEDEVA 100MG/5ML N20479 001 FEB 29, 1996

SOLUTION; INHALATION
CROMOLYN SODIUM
AN STERIPAK 10MG/ML N75271 001 JAN 18, 2000
AN WARRICK PHARMS 10MG/ML N75437 001 APR 21, 2000

SOLUTION, CONCENTRATE; ORAL
GASTROCROM
+ MEDEVA 100MG/5ML N20479 001 FEB 29, 1996

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN
@ AVENTIS PHARMS 1MG/ML N80564 001
AP HOECHST MARION RSSL 1MG/ML N80564 001

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL
AT ALCON UNIVERSAL 1% N89162 001 JAN 24, 1991
AT STERIS 1% N89162 001 JAN 24, 1991

CYCLOSPORINE

CAPSULE; ORAL
CYCLOSPORINE
> ADD > AB ABBOTT 25MG N65003 001 MAY 12, 2000
> ADD > AB 50MG N65003 002 MAY 12, 2000
> ADD > AB 100MG N65003 003 MAY 12, 2000

CYCLOSPORINE

CAPSULE; ORAL
CYCLOSPORINE
AB EON 25MG N65017 002 JAN 13, 2000
AB 100MG N65017 001 JAN 13, 2000

NEORAL
AB NOVARTIS 25MG N50715 001 JUL 14, 1995
AB 50MG N50715 003 JUL 14, 1995
AB + 100MG N50715 002 JUL 14, 1995
BX 25MG N50715 001 JUL 14, 1995
BX 50MG N50715 003 JUL 14, 1995
BX + 100MG N50715 002 JUL 14, 1995

SOLUTION; ORAL
CYCLOSPORINE
AB ABBOTT 100MG/ML N65025 001 MAR 03, 2000

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL
AP + BEDFORD EQ 5MG BASE/ML N50731 001 JAN 30, 1998
AP + EQ 5MG BASE/ML N50731 001 JAN 30, 1998
AP GENSIA SICOR PHARMS EQ 5MG BASE/ML N65035 001 JAN 24, 2000
+ EQ 50MG BASE/VIAL N64212 002 MAY 03, 1999

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
DECLOMYCIN
+ LEDERLE 150MG N50262 001
@ 150MG N50262 001

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DESMOPRESSIN ACETATE

AP	BEDFORD	0.004MG/ML	N74575 001	FEB 18, 2000

DESMOPRESSIN ACETATE PRESERVATIVE FREE

AP	BEDFORD	0.004MG/ML	N74574 001	FEB 18, 2000

SPRAY, METERED; NASAL
STIMATE

	+ AVENTIS BEHRING	0.15MG/SPRAY	N20355 001	MAR 07, 1994
	+ CENTEON	0.15MG/SPRAY	N20355 001	MAR 07, 1994

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

AT	ALCON UNIVERSAL	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62721 001	NOV 17, 1986
AT	STERIS	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62721 001	NOV 17, 1986

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.1% PHOSPHATE	N88771 001	JAN 16, 1985

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT	STERIS	EQ 0.1% PHOSPHATE	N88771 001	JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML	N62714 001	JUL 21, 1986

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT	STERIS	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML	N62714 001	JUL 21, 1986

DICLOFENAC POTASSIUM

TABLET; ORAL
DICLOFENAC POTASSIUM

AB	GENEVA PHARMS TECH	50MG	N75229 001	NOV 20, 1998
AB	INVAMED	50MG	N75229 001	NOV 20, 1998

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM

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

VOLTAREN

AB	+ CIBA	0.1%	N20037 001	MAR 28, 1991
	+	0.1%	N20037 001	MAR 28, 1991

TABLET, EXTENDED RELEASE; ORAL
DICLOFENAC SODIUM

AB	BIOVAIL	100MG	N75492 001	FEB 11, 2000

VOLTAREN-XR

AB	+ NOVARTIS	100MG	N20254 001	MAR 08, 1996
	+	100MG	N20254 001	MAR 08, 1996

DIENESTROL

SUPPOSITORY; VAGINAL
DV

	@ AVENTIS PHARMS	0.7MG	N83517 001

† SEE SECTION 1.3 OF INTRODUCTION

DIENESTROL

SUPPOSITORY; VAGINAL
DV

+	HOECHST MARION RSSL	0.7MG	N83517 001

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE DIACETATE

AB	TARO	**0.05%**	**N75508 001** APR 24, 2000

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HCL

AB3	BIOVAIL	**120MG**	**N20939 001** JAN 28, 2000
AB3		**180MG**	**N20939 002** JAN 28, 2000
AB3		**240MG**	**N20939 003** JAN 28, 2000
AB3		**300MG**	**N20939 004** JAN 28, 2000

INJECTABLE; INJECTION
DILTIAZEM HCL

AP	ABBOTT	**5MG/ML**	**N75004 001** FEB 16, 2000

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
TIAMATE

+	HOECHST MARION RSSL	EQ 120MG HCL	N20506 001 OCT 04, 1996
+		EQ 180MG HCL	N20506 002 OCT 04, 1996
+		EQ 240MG HCL	N20506 003 OCT 04, 1996
+	MERCK	EQ 120MG HCL	N20506 001 OCT 04, 1996
+		EQ 180MG HCL	N20506 002 OCT 04, 1996

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
TIAMATE

+	MERCK	EQ 240MG HCL	N20506 003 OCT 04, 1996

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

AA	GLOBAL PHARM	**25MG**	**N80807 001**
AA		**50MG**	**N80807 002**
	IMPAX LABS	25MG	N80807 001
@		50MG	N80807 002

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL
ZONALON

+	BIOGLAN PHAR	5%	N20126 001 APR 01, 1994
+	MEDICIS	5%	N20126 001 APR 01, 1994

DOXERCALCIFEROL

INJECTABLE; INJECTION
HECTOROL

+	BONE CARE	2 UGM/ML	N21027 001 APR 06, 2000

DOXYCYCLINE

CAPSULE; ORAL
DOXYCYCLINE

AB	HALSEY	**EQ 50MG BASE**	**N65041 001** APR 28, 2000
AB		**EQ 100MG BASE**	**N65041 002** APR 28, 2000

MONODOX

AB	OCLASSEN	**EQ 50MG BASE**	**N50641 002** FEB 10, 1992
AB +		**EQ 100MG BASE**	**N50641 001** DEC 29, 1989

DOXYCYCLINE

CAPSULE; ORAL

		MONODOX			
		OCLASSEN	EQ 50MG BASE		N50641 002 FEB 10, 1992
	+		EQ 100MG BASE		N50641 001 DEC 29, 1989

ENFLURANE

LIQUID; INHALATION

		ETHRANE			
AN	+	BAXTER PHARM PROD	99.9%		N17087 001
AN	+	OHMEDA	99.9%		N17087 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

> DLT >		ERGOMAR			
> DLT >	AA	LOTUS BIOCHEM	2MG		N87693 001 FEB 24, 1983
> ADD >	+		2MG		N87693 001 FEB 24, 1983
> DLT >		ERGOSTAT			
> DLT >	AA	PARKE DAVIS	2MG		N88337 001 JUN 08, 1984
> ADD >	@		2MG		N88337 001 JUN 08, 1984
> DLT >		WIGRETTES			
> DLT >	AA +	ORGANON	2MG		N86750 001 JUL 29, 1982
> ADD >	@		2MG		N86750 001 JUL 29, 1982

ERYTHROMYCIN

SOLUTION; TOPICAL

		SANSAC			
> DLT >	AT	GALDERMA LABS	2%		N62522 001 JAN 24, 1985
> ADD >	AT	HEALTHPOINT	2%		N62522 001 JAN 24, 1985

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

		PEDIAMYCIN			
AB		ROSS LABS	EQ 200MG BASE/5ML		N62305 001
	@		EQ 200MG BASE/5ML		N62305 001

SUSPENSION/DROPS; ORAL

		PEDIAMYCIN			
	+	ROSS LABS	EQ 100MG BASE/2.5ML		N62305 002
	@		EQ 100MG BASE/2.5ML		N62305 002

TABLET, CHEWABLE; ORAL

		PEDIAMYCIN			
AB		ROSS LABS	EQ 200MG BASE		N62306 001
	@		EQ 200MG BASE		N62306 001

ESTRADIOL

CREAM; VAGINAL

		ESTRACE			
	+	BRISTOL MYERS SQUIBB	0.01%		N86069 001 JAN 31, 1984
	+	WARNER CHILCOTT	0.01%		N86069 001 JAN 31, 1984

FILM, EXTENDED RELEASE; TRANSDERMAL

		CLIMARA			
AB	+	BERLEX LABS	0.05MG/24HR		N20375 001 DEC 22, 1994
AB	+		0.1MG/24HR		N20375 002 DEC 22, 1994
BX	+		0.05MG/24HR		N20375 001 DEC 22, 1994
BX	+		0.1MG/24HR		N20375 002 DEC 22, 1994
		ESTRADIOL			
BX		CYGNUS CA	0.05MG/24HR		N21048 001 SEP 20, 1999
BX			0.075MG/24HR		N21048 002 SEP 20, 1999
BX			0.1MG/24HR		N21048 003 SEP 20, 1999
	@	JOHNSON RW	0.05MG/24HR		N21048 001 SEP 20, 1999
	@		0.075MG/24HR		N21048 002 SEP 20, 1999

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

	ESTRADIOL		
	@ JOHNSON RW	0.1MG/24HR	N21048 003 SEP 20, 1999
AB	MYLAN TECHNOLOGIES	0.05MG/24HR	N75233 001 FEB 24, 2000
AB		0.1MG/24HR	N75182 001 FEB 24, 2000

TABLET; ORAL

	ESTRADIOL		
AB	APPLIED ANAL	0.5MG	N40138 001 JAN 30, 1998
AB		1MG	N40138 002 JAN 30, 1998
AB		2MG	N40138 003 JAN 30, 1998
AB	ENDEAVOR	0.5MG	N40138 001 JAN 30, 1998
AB		1MG	N40138 002 JAN 30, 1998
AB		2MG	N40138 003 JAN 30, 1998

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

	ETHAMOLIN		
+	CYPROS	50MG/ML	N19357 001 DEC 22, 1988
+	QUESTCOR PHARM	50MG/ML	N19357 001 DEC 22, 1988

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

	TRIVORA-21		
AB	SEARLE	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 001 DEC 18, 1997
AB	WATSON LABS	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 001 DEC 18, 1997

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28

	TRIVORA-28		
AB	SEARLE	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 002 DEC 18, 1997
AB	WATSON LABS	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 002 DEC 18, 1997

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

	OVCON-35		
+	BRISTOL MYERS SQUIBB	0.035MG;0.4MG	N18127 001
+	WARNER CHILCOTT	0.035MG;0.4MG	N18127 001
	OVCON-50		
@	BRISTOL MYERS SQUIBB	0.05MG;1MG	N18128 001
@	WARNER CHILCOTT	0.05MG;1MG	N18128 001

TABLET; ORAL-28

	OVCON-35		
	BRISTOL MYERS SQUIBB	0.035MG;0.4MG	N17716 001
	WARNER CHILCOTT	0.035MG;0.4MG	N17716 001
	OVCON-50		
	BRISTOL MYERS SQUIBB	0.05MG;1MG	N17576 001
	WARNER CHILCOTT	0.05MG;1MG	N17576 001

ETODOLAC

TABLET; ORAL

	ETODOLAC		
AB	TARO PHARM INDS	500MG	N75074 002 APR 25, 2000

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

	CORLOPAM		
+	ABBOTT	EQ 10MG BASE/ML	N19922 001 SEP 23, 1997
+	ELAN PHARMA	EQ 10MG BASE/ML	N19922 001 SEP 23, 1997

FENTANYL CITRATE

INJECTABLE; INJECTION
SUBLIMAZE PRESERVATIVE FREE

AP	+ AKORN MFG	**EQ 0.05MG BASE/ML**	**N16619 001**	
AP	+ JANSSEN	**EQ 0.05MG BASE/ML**	**N16619 001**	

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL
ALLEGRA

AVENTIS PHARMS	30MG	N20872 001	FEB 25, 2000
	60MG	N20872 002	FEB 25, 2000
+	180MG	N20872 004	FEB 25, 2000

FLOXURIDINE

INJECTABLE; INJECTION
FLOXURIDINE

AP	BEDFORD	**500MG/VIAL**	**N75387 001**	APR 16, 2000

FUDR

AP	+ ROCHE	**500MG/VIAL**	**N16929 001**	
	+	500MG/VIAL	N16929 001	

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN

PFIZER	150MG	N20322 001	JUN 30, 1994
	150MG	N19949 004	JUN 30, 1994

> ADD >

FLUMAZENIL

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

INJECTABLE; INJECTION
ROMAZICON

+ HLR	0.1MG/ML	N20073 001	DEC 20, 1991
+ ROCHE	0.1MG/ML	N20073 001	DEC 20, 1991

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

AP	GENSIA SICOR PHARMS	**50MG/ML**	**N40333 001**	JAN 27, 2000
AP		**50MG/ML**	**N40334 001**	FEB 25, 2000

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE

+ ROBERTS LABS	50MG/15ML	N11323 002	
+ SHIRE LABS	50MG/15ML	N11323 002	

TABLET; ORAL
FUROXONE

+ ROBERTS LABS	100MG	N11270 002	
+ SHIRE LABS	100MG	N11270 002	

GABAPENTIN

SOLUTION; ORAL
NEURONTIN

+ PARKE DAVIS	250MG/5ML	N21129 001	MAR 02, 2000

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST

+ BERLEX LABS	469.01MG/ML	N21037 001	MAR 10, 2000

GEMTUZUMAB OZOGAMICIN

INJECTABLE; INJECTION
MYLOTARG

+ WYETH AYERST	5MG/VIAL	N21174 001	MAY 17, 2000

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

AT	ALCON UNIVERSAL	EQ 0.3% BASE	N62523 001 NOV 25, 1985
AT	STERIS	EQ 0.3% BASE	N62523 001 NOV 25, 1985

GLYBURIDE

TABLET; ORAL
GLYBURIDE (MICRONIZED)

AB	AVENTIS PHARMS	6MG	N20055 003 MAR 08, 2000

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN

AT	IPHARM	0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML	N62818 001 OCT 11, 1988
	@	0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML	N62818 001 OCT 11, 1988

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL
GRIS-PEG

AB	ALLERGAN HERBERT	125MG	N50475 001
AB		250MG	N50475 002
AB	PEDINOL	125MG	N50475 001
AB		250MG	N50475 002

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

AO	APOTEX	EQ 50MG BASE/ML	N75440 001 FEB 28, 2000
AO		EQ 100MG BASE/ML	N75440 002 FEB 28, 2000

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

AO	KING PHARMS	EQ 50MG BASE/ML	N75176 001 FEB 09, 2000
AO		EQ 100MG BASE/ML	N75176 002 FEB 09, 2000

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

	@ STERIS	100 UNITS/ML	N17064 001
	@	100 UNITS/ML	N17064 001

HEPARIN SODIUM

AP	STERIS	5,000 UNITS/ML	N17064 003
AP		10,000 UNITS/ML	N17064 004
AP		20,000 UNITS/ML	N17064 005
AP		40,000 UNITS/ML	N17064 006
	@	5,000 UNITS/ML	N17064 003
	@	10,000 UNITS/ML	N17064 004
	@	20,000 UNITS/ML	N17064 005
	@	40,000 UNITS/ML	N17064 006

HISTRELIN ACETATE

INJECTABLE; INJECTION
SUPPRELIN

	+ ROBERTS LABS	EQ 0.2MG BASE/ML	N19836 001 DEC 24, 1991
	+	EQ 0.5MG BASE/ML	N19836 002 DEC 24, 1991
	+	EQ 1MG BASE/ML	N19836 003 DEC 24, 1991
	+ SHIRE LABS	EQ 0.2MG BASE/ML	N19836 001 DEC 24, 1991
	+	EQ 0.5MG BASE/ML	N19836 002 DEC 24, 1991
	+	EQ 1MG BASE/ML	N19836 003 DEC 24, 1991

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

AP		GENSIA SICOR PHARMS	20MG/ML	N40373 001 FEB 23, 2000	
AP	+	LUITPOLD	20MG/ML	N40136 001 JUN 30, 1997	
	+		20MG/ML	N40136 001 JUN 30, 1997	

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

AB		MYLAN	12.5MG	N75640 001 JAN 28, 2000

MICROZIDE

AB	+	WATSON LABS	12.5MG	N20504 001 DEC 27, 1996
	+		12.5MG	N20504 001 DEC 27, 1996

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB		GLOBAL PHARM	100MG	N85098 001
	@	IMPAX LABS	100MG	N85098 001

HYDROCORTISONE

CREAM; TOPICAL

NUTRACORT

> DLT >	AT		GALDERMA LABS	0.5%	N80442 002
> DLT >	AT			1%	N80442 003
> ADD >	AT		HEALTHPOINT	1%	N80442 003
> ADD >		@		0.5%	N80442 002

GEL; TOPICAL

NUTRACORT

> DLT >		@	GALDERMA LABS	1%	N84698 001
> ADD >		@	HEALTHPOINT	1%	N84698 001

LOTION; TOPICAL

NUTRACORT

> DLT >	AT		GALDERMA LABS	0.5%	N80443 002
> DLT >	AT			1%	N80443 003

HYDROCORTISONE

LOTION; TOPICAL

NUTRACORT

> DLT >	AT		GALDERMA LABS	2.5%	N87644 001 AUG 24, 1982
> DLT					
> ADD >	AT		HEALTHPOINT	1%	N80443 003
> ADD >	AT			2.5%	N87644 001 AUG 24, 1982
> ADD >		@		0.5%	N80443 002

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT		ALCON UNIVERSAL	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62874 001 MAY 11, 1988
AT		STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62874 001 MAY 11, 1988

SUSPENSION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT		ALCON UNIVERSAL	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62488 001 NOV 06, 1985
AT		STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62488 001 NOV 06, 1985

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

EPIFOAM

BX	SCHWARZ PHARMA	1%;1%	N86457 001

PROCTOFOAM HC

BX	SCHWARZ PHARMA	1%;1%	N86195 001

DISC; TOPICAL

EPIFOAM

BX	SCHWARZ PHARMA	1%;1%	N86457 001

PROCTOFOAM HC

BX	SCHWARZ PHARMA	1%;1%	N86195 001

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL
LOCOID
> DLT > @ GALDERMA LABS 0.1% N18795 001 JAN 07, 1983
> DLT >
> ADD > @ YAMANOUCHI 0.1% N18795 001 JAN 07, 1983
> ADD >

OINTMENT; TOPICAL
LOCOID
> DLT > @ GALDERMA LABS 0.1% N19106 001 JUL 03, 1984
> DLT >
> ADD > @ YAMANOUCHI 0.1% N19106 001 JUL 03, 1984
> ADD >

SOLUTION; TOPICAL
LOCOID
> DLT > @ GALDERMA LABS 0.1% N19819 001 SEP 15, 1988
> DLT >
> ADD > @ YAMANOUCHI 0.1% N19819 001 SEP 15, 1988
> ADD >

HYDROCORTISONE VALERATE

CREAM; TOPICAL
HYDROCORTISONE VALERATE
> ADD > **AB** CLAY PARK **0.2%** **N75666 001** MAY 24, 2000
> ADD >

INSULIN GLARGINE

INJECTABLE; INJECTION
LANTUS
+ AVENTIS PHARMS 100 UNITS/ML N21081 001 APR 20, 2000

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50
+ LILLY 50 UNITS/ML;50 UNITS/ML N21018 001 DEC 22, 1999

HUMALOG MIX 75/25
+ LILLY 25 UNITS/ML;75 UNITS/ML N21017 001 DEC 22, 1999

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50
+ LILLY 100 UNITS/ML N21018 001 DEC 22, 1999

HUMALOG MIX 75/25
+ LILLY 100 UNITS/ML N21017 001 DEC 22, 1999

INULIN

INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE
+ CYPROS 100MG/ML N02282 001
+ QUESTCOR PHARM 100MG/ML N02282 001

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
GLOFIL-125
CYPROS 250-300 uCi/ML N17279 001
QUESTCOR PHARM 250-300 uCi/ML N17279 001

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
IPRATROPIUM BROMIDE
AN STERIPAK **0.02%** **N75313 001** FEB 07, 2000

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION
ISUPREL
+ SANOFI SYNTHELABO 0.103MG/INH N11178 001
@ 0.103MG/INH N11178 001

SOLUTION; INHALATION
ISUPREL
+ SANOFI SYNTHELABO 0.5% N06327 002
+ 1% N06327 003
@ 0.5% N06327 002
@ 1% N06327 003

ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL

> DLT >		ISORDIL			
> DLT >	AB	+ WYETH AYERST	40MG	N12882 001	
> DLT >				JUL 29, 1988	
> ADD >		@	40MG	N12882 001	
> ADD >				JUL 29, 1988	
		ISOSORBIDE DINITRATE			
> DLT >	AB	INWOOD LABS	40MG	N40009 001	
> DLT >				DEC 30, 1998	
> ADD >		+	40MG	N40009 001	
> ADD >				DEC 30, 1998	

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

	IMDUR			
AB	+ SCHERING	120MG	N20225 003	
			MAR 30, 1995	
	+	120MG	N20225 003	
			MAR 30, 1995	
	ISOSORBIDE MONONITRATE			
AB	DEXCEL LTD	60MG	N75522 001	
			APR 17, 2000	
AB	KREMERS URBAN	30MG	N75155 002	
			JAN 13, 2000	
AB	KV PHARM	30MG	N75395 001	
			MAR 16, 2000	
AB		60MG	N75395 002	
			MAR 16, 2000	
AB		120MG	N75395 003	
			MAR 16, 2000	

KETOCONAZOLE

CREAM; TOPICAL

	KETOCONAZOLE			
AB	TEVA	2%	N75581 001	
			APR 25, 2000	
	NIZORAL			
AB	+ MCNEIL CONS	2%	N19084 001	
			DEC 31, 1985	
	+	2%	N19084 001	
			DEC 31, 1985	

KETOCONAZOLE

SHAMPOO; TOPICAL

NIZORAL			
+ JANSSEN	2%	N19927 001	
		AUG 31, 1990	
+ MCNEIL CONS	2%	N19927 001	
		AUG 31, 1990	

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

	LEUCOVORIN CALCIUM PRESERVATIVE FREE			
AP	+ ABBOTT	EQ 10MG BASE/ML	N40147 001	
			JUN 25, 1997	
	+	EQ 10MG BASE/ML	N40147 001	
			JUN 25, 1997	
AP	BEDFORD	EQ 10MG BASE/ML	N40347 001	
			APR 25, 2000	
AP		EQ 350MG BASE/VIAL	N40335 001	
			APR 20, 2000	

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION

VIADUR			
+ ALZA	EQ 65MG BASE	N21088 001	
		MAR 03, 2000	

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

BETAXON			
+ ALCON	EQ 0.5% BASE	N21114 001	
		FEB 23, 2000	

LEVOBUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHIROCAINE			
> ADD > DARWIN DISCOVERY	EQ 2.5MG BASE/ML	N20997 001	
> ADD >		AUG 05, 1999	
> ADD >	EQ 5MG BASE/ML	N20997 002	
> ADD >		AUG 05, 1999	

LEVOBUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHIROCAINE

> ADD >	+	DARWIN DISCOVERY	EQ 7.5MG BASE/ML	N20997 003 AUG 05, 1999
> ADD >		PURDUE PHARMA	EQ 2.5MG BASE/ML	N20997 001 AUG 05, 1999
> DLT >			EQ 5MG BASE/ML	N20997 002 AUG 05, 1999
> DLT >	+		EQ 7.5MG BASE/ML	N20997 003 AUG 05, 1999

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN

AB	+	ICN	**2MG**	**N08720 001** DEC 19, 1991
	+		2MG	N08720 001 DEC 19, 1991

LEVORPHANOL TARTRATE

AB		ROXANE	**2MG**	**N74278 001** MAR 31, 2000

LINEZOLID

GRANULE, FOR RECONSTITUTION; ORAL
ZYVOX

	+	PHARMACIA AND UPJOHN	100MG/5ML	N21132 001 APR 18, 2000

INJECTABLE; INJECTION
ZYVOX

	+	PHARMACIA AND UPJOHN	200MG/100ML	N21131 001 APR 18, 2000

TABLET; ORAL
ZYVOX

		PHARMACIA AND UPJOHN	400MG	N21130 001 APR 18, 2000
	+		600MG	N21130 002 APR 18, 2000

LORAZEPAM

INJECTABLE; INJECTION
LORAZEPAM

AP		MOVA	**2MG/ML**	**N74793 001** MAR 16, 2000
AP			**4MG/ML**	**N74793 002** MAR 16, 2000

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE

AP		ABBOTT	**500MG/ML**	**N75151 001** APR 25, 2000
AP	+	AM PHARM PARTNERS	**500MG/ML**	**N19316 001** SEP 08, 1986
	+		500MG/ML	N19316 001 SEP 08, 1986

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
AMEN

BP	AMARIN PHARMS	10MG	N83242 001
BP	CARNRICK	10MG	N83242 001

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

AB	PHARMACHEMIE	**40MG**	**N74745 001** FEB 27, 1998
AB	TEVA	**40MG**	**N74745 001** FEB 27, 1998

MELOXICAM

TABLET; ORAL
MOBIC

	+	BOEHRINGER INGELHEIM	7.5MG	N20938 001 APR 13, 2000

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
MENOTROPINS

	@ FERRING	75 IU/VIAL;75 IU/VIAL	N73598 001	JAN 30, 1997
	@	150 IU/VIAL;150 IU/VIAL	N73599 001	JAN 30, 1997
	REPRONEX			
AB	FERRING	75 IU/VIAL;75 IU/VIAL	N73598 001	JAN 30, 1997
AB		150 IU/VIAL;150 IU/VIAL	N73599 001	JAN 30, 1997

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION
WYAMINE SULFATE

+	WYETH AYERST	EQ 10MG BASE/ML	N08248 001
@		EQ 30MG BASE/ML	N08248 001

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
NORINYL

@	SEARLE	0.1MG;2MG	N13625 004
@	WATSON LABS	0.1MG;2MG	N13625 004

TABLET; ORAL-21
NORINYL 1+50 21-DAY

AB	SEARLE	0.05MG;1MG	N13625 002
AB	WATSON LABS	0.05MG;1MG	N13625 002

METAPROTERENOL SULFATE

SOLUTION; INHALATION
ALUPENT

> DLT >	AN +	BOEHRINGER INGELHEIM	5%	N17659 001
> ADD >	+		5%	N17659 001
> DLT >	**PROMETA**			
> DLT >	AN	MURO	5%	N73340 001 MAR 30, 1992
> DLT >				
> ADD >	@		5%	N73340 001 MAR 30, 1992
> ADD >				

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE

AA	NOVEX	10MG/5ML	N75235 001 JAN 27, 2000

METHIMAZOLE

TABLET; ORAL
METHIMAZOLE

AB	APPLIED ANAL	5MG	N40320 001 MAR 31, 2000
AB		10MG	N40320 002 MAR 31, 2000
AB	GENPHARM	5MG	N40350 001 MAR 29, 2000
AB		10MG	N40350 002 MAR 29, 2000
	TAPAZOLE		
AB	LILLY	5MG	N07517 002
AB +		10MG	N07517 004
		5MG	N07517 002
+		10MG	N07517 004

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
METADATE ER

> ADD >	BX +	MEDEVA	10MG	N40306 001 OCT 20, 1999
> ADD >				
> DLT >	+		10MG	N40306 001 OCT 20, 1999
> DLT >				
> ADD >	**METHYLIN ER**			
> ADD >	AB	MALLINCKRODT	20MG	N75629 002 MAY 09, 2000
> ADD >				
> ADD >	BX		10MG	N75629 001 MAY 09, 2000
> ADD >				

METHYLTESTOSTERONE

TABLET; ORAL
ORETON METHYL

> DLT >				
> DLT >	BP	SCHERING	10MG	N03158 001
> DLT >	BP		25MG	N03158 002
> ADD >	@		10MG	N03158 001

METHYLTESTOSTERONE

TABLET; ORAL

> ADD >		ORETON METHYL		
> ADD >		@ SCHERING	25MG	N03158 002

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

		MINOCYCLINE HCL		
AB	+	DANBURY PHARMA	**EQ 75MG BASE**	**N63065 002**
				JUN 10, 1999
> DLT >				
> DLT >				
> DLT >	+		EQ 75MG BASE	N63065 002
> ADD >				JUN 10, 1999

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL

		SINGULAIR		
		MERCK	EQ 4MG BASE	N20830 002
				MAR 03, 2000

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

		MORPHINE SULFATE		
AB		ESI LEDERLE	**15MG**	**N75407 001**
				JAN 28, 2000

NABUMETONE

TABLET; ORAL

> ADD >		**NABUMETONE**		
> ADD >	AB	TEVA	**500MG**	**N75189 001**
> ADD >				MAY 26, 2000
		RELAFEN		
> ADD >	AB	SMITHKLINE BEECHAM	**500MG**	**N19583 001**
> ADD >				DEC 24, 1991
> DLT >			500MG	N19583 001
> DLT >				DEC 24, 1991

NADOLOL

TABLET; ORAL

		CORGARD		
AB		APOTHECON	**40MG**	**N18063 001**
AB	+		**40MG**	**N18063 001**

NAFCILLIN SODIUM

TABLET, ORAL

> DLT >		**UNIPEN**		
> DLT >	+	WYETH AYERST	EQ 500MG BASE	N50462 001
> ADD >	@		EQ 500MG BASE	N50462 001

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION

		REVEX		
	+	BAXTER PHARM PROD	EQ 0.1MG BASE/ML	N20459 001
				APR 17, 1995
	+		EQ 1MG BASE/ML	N20459 002
				APR 17, 1995
	+	OHMEDA	EQ 0.1MG BASE/ML	N20459 001
				APR 17, 1995
	+		EQ 1MG BASE/ML	N20459 002
				APR 17, 1995

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

	PENTAZOCINE AND NALOXONE HYDROCHLORIDES		
AB	RANBAXY	**EQ 0.5MG BASE; EQ 50MG BASE**	**N75523 001**
			MAR 17, 2000

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

	NALTREXONE HCL		
AB	EON	**50MG**	**N75434 001**
			MAR 08, 2000

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

		NAPROXEN			
AB		GENEVA PHARMS TECH	**375MG**	**N75061 001**	
				FEB 18, 1998	
AB			**500MG**	**N75061 002**	
				FEB 18, 1998	
AB		INVAMED	**375MG**	**N75061 001**	
				FEB 18, 1998	
AB			**500MG**	**N75061 002**	
				FEB 18, 1998	

NIACIN

TABLET; ORAL

		NIACIN			
AA		GLOBAL PHARM	**500MG**	**N83115 001**	
		@ IMPAX LABS	500MG	N83115 001	
> ADD >		**NIACOR**			
> ADD > **AA**		UPSHER SMITH	**500MG**	**N40378 001**	
> ADD >				MAY 03, 2000	

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

		ADALAT CC			
AB	+	BAYER	**30MG**	**N20198 001**	
				APR 21, 1993	
BC	+		30MG	N20198 001	
				APR 21, 1993	
		NIFEDIPINE			
AB		ELAN PHARM	**30MG**	**N75128 001**	
				MAR 10, 2000	

NITROFURAZONE

CREAM; TOPICAL

		FURACIN			
> DLT >	+	ROBERTS LABS	0.2%	N83789 001	
> ADD >	+	SHIRE LABS	0.2%	N83789 001	

OINTMENT; TOPICAL

		FURACIN			
AT	+	ROBERTS LABS	**0.2%**	**N05795 001**	
AT	+	SHIRE LABS	**0.2%**	**N05795 001**	

NITROGLYCERIN

TABLET; SUBLINGUAL

		NITROSTAT			
		PARKE DAVIS	0.3MG	N21134 001	
				MAY 01, 2000	
			0.4MG	N21134 002	
				MAY 01, 2000	
	+		0.6MG	N21134 003	
				MAY 01, 2000	

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

		NORTRIPTYLINE HCL			
AB		TARO	**EQ 10MG BASE**	**N75520 004**	
				MAY 08, 2000	
AB			**EQ 25MG BASE**	**N75520 003**	
				MAY 08, 2000	
AB			**EQ 50MG BASE**	**N75520 001**	
				MAY 08, 2000	
AB			**EQ 75MG BASE**	**N75520 002**	
				MAY 08, 2000	

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

		SANDOSTATIN			
		NOVARTIS	**EQ 0.2MG BASE/ML**	**N19667 004**	
				JUN 12, 1991	
			EQ 1MG BASE/ML	**N19667 005**	
				JUN 12, 1991	
	+		EQ 0.2MG BASE/ML	N19667 004	
				JUN 12, 1991	
	+		EQ 1MG BASE/ML	N19667 005	
				JUN 12, 1991	
		SANDOSTATIN LAR			
		NOVARTIS	**EQ 10MG BASE/VIAL**	**N21008 001**	
				NOV 25, 1998	
			EQ 20MG BASE/VIAL	**N21008 002**	
				NOV 25, 1998	
	+		EQ 10MG BASE/VIAL	N21008 001	
				NOV 25, 1998	
	+		EQ 20MG BASE/VIAL	N21008 002	
				NOV 25, 1998	

OLANZAPINE

TABLET; ORAL
ZYPREXA

	LILLY	2.5MG	N20592 001 SEP 30, 1996
+		10MG	N20592 004 SEP 30, 1996
@		15MG	N20592 005 SEP 09, 1997
+		2.5MG	N20592 001 SEP 30, 1996
		10MG	N20592 004 SEP 30, 1996
+		15MG	N20592 005 SEP 09, 1997

TABLET, ORALLY DISINTEGRATING; ORAL
ZYPREXA ZYDIS

	LILLY	5MG	N21086 001 APR 06, 2000
		10MG	N21086 002 APR 06, 2000
		15MG	N21086 003 APR 06, 2000
+		20MG	N21086 004 APR 06, 2000

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

AB	EON	100MG	N40327 001 FEB 15, 2000
AB	GENEVA PHARMS TECH	100MG	N40284 001 JUN 19, 1998
AB	INVAMED	100MG	N40284 001 JUN 19, 1998

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL

	NOVARTIS	150MG	N21014 001 JAN 14, 2000
		300MG	N21014 002 JAN 14, 2000

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL

+	NOVARTIS	600MG	N21014 003 JAN 14, 2000

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
OXYCONTIN

BX	+	PURDUE PHARMA	10MG	N20553 001 DEC 12, 1995
	+		10MG	N20553 001 DEC 12, 1995

ROXICODONE

BX		ROXANE	10MG	N20932 001 OCT 26, 1998
	+		30MG	N20932 002 OCT 26, 1998
	@		10MG	N20932 001 OCT 26, 1998
	@		30MG	N20932 002 OCT 26, 1998

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
PROTONIX

	+	WYETH AYERST	EQ 40MG BASE	N20987 001 FEB 02, 2000

PEMOLINE

TABLET; ORAL
PEMOLINE

AB	AMIDE PHARM	18.75MG	N75595 001 FEB 28, 2000
AB		37.5MG	N75595 002 FEB 28, 2000
AB		75MG	N75595 003 FEB 28, 2000
AB	COPLEY PHARM	18.75MG	N75030 003 FEB 22, 2000
AB	GENEVA PHARMS TECH	18.75MG	N75286 001 DEC 27, 1999

PEMOLINE

TABLET; ORAL

	PEMOLINE			
AB	GENEVA PHARMS TECH	**37.5MG**	**N75286 002**	JUN 30, 1999
AB		**75MG**	**N75286 003**	JUN 30, 1999
AB	INVAMED	**18.75MG**	**N75286 001**	DEC 27, 1999
AB		**37.5MG**	**N75286 002**	JUN 30, 1999
AB		**75MG**	**N75286 003**	JUN 30, 1999
AB	VINTAGE PHARMS	**18.75MG**	**N75328 001**	APR 19, 2000
AB		**37.5MG**	**N75328 002**	APR 19, 2000
AB		**75MG**	**N75328 003**	APR 19, 2000

TABLET, CHEWABLE; ORAL

	CYLERT			
AB	+ ABBOTT	**37.5MG**	**N17703 001**	
	+	37.5MG	N17703 001	
	PEMOLINE			
AB	COPLEY PHARM	**37.5MG**	**N75555 001**	FEB 18, 2000

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

> DLT >		**PENTACARINAT**		
> DLT >	**AP**	ARMOUR PHARM	**300MG/VIAL**	**N73447 001**
> DLT >				APR 28, 1994
> ADD >		@	300MG/VIAL	N73447 001
> ADD >				APR 28, 1994

PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL

SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS

+	US ARMY	50%;50%	N21084 001 FEB 17, 2000

PERINDOPRIL ERBUMINE

TABLET; ORAL

	ACEON			
	@ SOLVAY	2MG	**N20184 001**	DEC 30, 1993
	@	4MG	**N20184 002**	DEC 30, 1993
	@	8MG	**N20184 003**	DEC 30, 1993
	SOLVAY PHARMA	2MG	N20184 001	DEC 30, 1993
		4MG	N20184 002	DEC 30, 1993
+		8MG	N20184 003	DEC 30, 1993

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

	BONTRIL PDM		
AA	AMARIN PHARMS	**35MG**	**N85272 001**
AA	CARNRICK	**35MG**	**N85272 001**

PREDNISOLONE

SYRUP; ORAL

	PREDNISOLONE			
AA	COPLEY PHARM	**15MG/5ML**	**N40322 001**	JAN 19, 2000

TABLET; ORAL

	PREDNISOLONE			
BX	GLOBAL PHARM	5MG	N80780 001	
	@ IMPAX LABS	5MG	N80780 001	
BX	PHOENIX LABS NY	5MG	N80322 001	
	@	5MG	N80322 001	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

	PREDNISOLONE SODIUM PHOSPHATE			
AT	ALCON UNIVERSAL	**EQ 0.11% PHOSPHATE**	**N81043 001**	OCT 24, 1991
AT		**EQ 0.9% PHOSPHATE**	**N81044 001**	OCT 24, 1991

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE

AT	STERIS	EQ 0.11% PHOSPHATE	N81043 001	OCT 24, 1991
AT		EQ 0.9% PHOSPHATE	N81044 001	OCT 24, 1991

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.23% PHOSPHATE;10%	N73630 001	MAY 27, 1993
AT	STERIS	EQ 0.23% PHOSPHATE;10%	N73630 001	MAY 27, 1993

PREDNISONE

SYRUP; ORAL
LIQUID PRED

> DLT >	+ MURO	5MG/5ML	N87611 002	SEP 07, 1982
> ADD >	@	5MG/5ML	N87611 002	SEP 07, 1982

TABLET; ORAL
PREDNICEN-M

> DLT > AB	CENT PHARMS	5MG	N84655 001	
> ADD >	@ SCHWARZ PHARMA	5MG	N84655 001	

PREDNISONE

BX	PHOENIX LABS NY	5MG	N80321 001	
BX		20MG	N83807 001	
	@	5MG	N80321 001	
	@	20MG	N83807 001	

PROGESTERONE

CAPSULE; ORAL
PROMETRIUM

SCHERING PLOUGH	100MG	N19781 001	MAY 14, 1998
	200MG	N19781 002	OCT 15, 1999

PROGESTERONE

CAPSULE; ORAL
PROMETRIUM

+ SCHERING PLOUGH	300MG	N19781 003	OCT 15, 1999
UNIMED PHARMS	100MG	N19781 001	MAY 14, 1998
+	200MG	N19781 002	OCT 15, 1999
@	300MG	N19781 003	OCT 15, 1999

PROPARACAINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC
PROPARACAINE HCL

AT	TAYLOR PHARMA	0.5%	N40277 001	MAR 16, 2000

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL
VENTAIRE

@ AVENTIS PHARMS	2MG	N83459 001	
+ HOECHST MARION RSSL	2MG	N83459 001	

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

AB	PHARMAVITE	200MG	N84627 001	
	@	200MG	N84627 001	

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE

AB	RANBAXY	EQ 150MG BASE	N75439 001	APR 19, 2000
AB		EQ 300MG BASE	N75439 002	APR 19, 2000

RESERPINE

TABLET; ORAL
RESERPINE

BP	GLOBAL PHARM	0.1MG	N09627 001	> DLT >	
BP		0.25MG	N09627 002	> DLT >	
	@ IMPAX LABS	0.1MG	N09627 001	> DLT >	
	@	0.25MG	N09627 002	> DLT >	

RIVASTIGMINE TARTRATE

CAPSULE; ORAL
EXELON

	NOVARTIS	EQ 1.5MG BASE	N20823 003 APR 21, 2000	> DLT >	
		EQ 3MG BASE	N20823 004 APR 21, 2000	> DLT >	
		EQ 4.5MG BASE	N20823 005 APR 21, 2000	> DLT >	
	+	EQ 6MG BASE	N20823 006 APR 21, 2000	> ADD >	

SOLUTION; ORAL
EXELON

	+ NOVARTIS	EQ 2MG BASE/ML	N21025 001 APR 21, 2000	> ADD >	

SODIUM FLUORIDE, F-18

INJECTABLE; INTRAVENOUS
FLUORINE F-18

	@ NYCOMED AMERSHAM	2mCi/ML	N17042 001	> ADD >	

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE

> ADD >	**AB**	BERLEX LABS	**80MG**	**N19865 001** OCT 30, 1992	> ADD >
> ADD >	**AB**		**120MG**	**N19865 005** APR 20, 1994	> ADD >
> ADD >	**AB**	+	**160MG**	**N19865 002** OCT 30, 1992	> ADD >
> ADD >	**AB**		**240MG**	**N19865 003** OCT 30, 1992	> ADD >

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE

	BERLEX LABS	80MG	N19865 001 OCT 30, 1992	> DLT >	
		120MG	N19865 005 APR 20, 1994	> DLT >	
	+	160MG	N19865 002 OCT 30, 1992	> DLT >	
		240MG	N19865 003 OCT 30, 1992	> DLT >	

BETAPACE AF

	BERLEX LABS	80MG	N21151 001 FEB 22, 2000		
		120MG	N21151 002 FEB 22, 2000		
	+	160MG	N21151 003 FEB 22, 2000		

SOTALOL HCL

	EON	**80MG**	**N75366 001** MAY 01, 2000	> ADD >	
		120MG	**N75366 002** MAY 01, 2000	> ADD >	**AB**
		160MG	**N75366 003** MAY 01, 2000	> ADD >	**AB**
		240MG	**N75366 004** MAY 01, 2000	> ADD >	**AB**
	GENPHARM	**80MG**	**N75237 001** MAY 01, 2000	> ADD >	**AB**
		120MG	**N75237 002** MAY 01, 2000	> ADD >	**AB**
		160MG	**N75237 003** MAY 01, 2000	> ADD >	**AB**
		240MG	**N75237 004** MAY 01, 2000	> ADD >	**AB**
	TEVA	**80MG**	**N75429 001** MAY 01, 2000	> ADD >	**AB**
		120MG	**N75429 002** MAY 01, 2000	> ADD >	**AB**
		160MG	**N75429 003** MAY 01, 2000	> ADD >	**AB**
		240MG	**N75429 004** MAY 01, 2000	> ADD >	**AB**

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM

AT	ALCON UNIVERSAL	10%	N89560 001	
			OCT 18, 1988	
AT	STERIS	10%	N89560 001	
			OCT 18, 1988	

TAMOXIFEN CITRATE

TABLET; ORAL
TAMOXIFEN CITRATE

> ADD >	@ PHARMACHEMIE	EQ 10MG BASE	N74539 001	
> ADD >			MAY 31, 2000	
> ADD >				

TELMISARTAN

TABLET; ORAL
MICARDIS

+	BOEHRINGER INGELHEIM	20MG	N20850 003	
			APR 04, 2000	

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
TERAZOSIN HCL

AB	MYLAN	EQ 1MG BASE	N75140 002	
			FEB 11, 2000	
AB		EQ 2MG BASE	N75140 003	
			FEB 11, 2000	
AB		EQ 5MG BASE	N75140 001	
			FEB 11, 2000	
AB		EQ 10MG BASE	N75140 004	
			FEB 11, 2000	

TABLET; ORAL
TERAZOSIN HCL

AB	INVAMED	EQ 1MG BASE	N74657 001	
			APR 28, 2000	
AB		EQ 2MG BASE	N74657 002	
			APR 28, 2000	
AB		EQ 5MG BASE	N74657 003	
			APR 28, 2000	
AB		EQ 10MG BASE	N74657 004	
			APR 28, 2000	

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL
TERAZOSIN HCL

> ADD >	AB	NOVOPHARM	EQ 1MG BASE	N74446 001
> ADD >				MAY 18, 2000
> ADD >	AB		EQ 2MG BASE	N74446 002
> ADD >				MAY 18, 2000
> ADD >	AB		EQ 5MG BASE	N74446 003
> ADD >				MAY 18, 2000
> ADD >	AB		EQ 10MG BASE	N74446 004
> ADD >				MAY 18, 2000
	AB	ZENITH GOLDLINE	EQ 1MG BASE	N74530 001
				APR 21, 2000
	AB		EQ 2MG BASE	N74530 002
				APR 21, 2000
	AB		EQ 5MG BASE	N74530 003
				APR 21, 2000
	AB		EQ 10MG BASE	N74530 004
				APR 21, 2000

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM

BX	+	THERATECH	5MG/24HR	N20489 002
				MAY 02, 1997
	+		2.5MG/24HR	N20489 001
				SEP 29, 1995
BX	+	WATSON LABS	5MG/24HR	N20489 002
				MAY 02, 1997
	+		2.5MG/24HR	N20489 001
				SEP 29, 1995

GEL; TOPICAL
ANDROGEL

+	UNIMED PHARMS	1%	N21015 001	
			FEB 28, 2000	

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-PHYLLIN

@	AVENTIS PHARM PROD	60MG	N85206 001
			MAY 24, 1982
@		125MG	N85203 001
			MAY 24, 1982

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

		SLO-PHYLLIN			
		@ AVENTIS PHARM PROD	250MG		N85205 001 MAY 24, 1982
	BC	RHONE POULENC RORER	125MG		N85203 001 MAY 24, 1982
	BC		250MG		N85205 001 MAY 24, 1982
			60MG		N85206 001 MAY 24, 1982

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

		BETALIN S			
> DLT <	**AP**	**+ LILLY**	**100MG/ML**		**N80853 001**
> ADD <		@	100MG/ML		N80853 001
		THIAMINE HCL			
> DLT <	**AP**	**AM PHARM PARTNERS**	**100MG/ML**		**N80556 001**
> ADD <	**AP**	**+**	**100MG/ML**		**N80556 001**

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

		TICLOPIDINE HCL			
AB		**DANBURY PHARMA**	**250MG**		**N75309 001** APR 26, 2000

TOLBUTAMIDE

TABLET; ORAL

		TOLBUTAMIDE			
AB		**CHELSEA LABS**	**500MG**		**N86109 001**
AB	**+**		**500MG**		**N86109 001**
AB	**+**	**EON**	**500MG**		**N12678 001**
		@	500MG		N12678 001

TRETINOIN

GEL; TOPICAL

		RETIN-A			
AB	**+**	JOHNSON AND JOHNSON	**0.025%**		**N17579 002**
BT	**+**		0.025%		N17579 002

TRETINOIN

GEL; TOPICAL

		TRETINOIN			
AB		**SPEAR PHARMS**	**0.025%**		**N75529 001** FEB 22, 2000

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

		ARISTOCORT A			
AT	**+**	**FUJISAWA HLTHCARE**	**0.5%**		**N80745 003**
AT			**0.5%**		**N80745 003**
		FLUTEX			
AT		**ZENITH GOLDLINE**	**0.025%**		**N87375 001** NOV 01, 1988
AT	**+**		**0.025%**		**N87375 001** NOV 01, 1988
AT			**0.1%**		**N87377 001** NOV 01, 1988
AT	**+**		**0.1%**		**N87377 001** NOV 01, 1988
AT			**0.5%**		**N87376 001** NOV 01, 1988
AT	**+**		**0.5%**		**N87376 001** NOV 01, 1988
		KENALOG			
AT	**+**	**APOTHECON**	**0.025%**		**N11600 003**
AT			**0.025%**		**N11600 003**
AT	**+**		**0.1%**		**N11600 001**
AT			**0.1%**		**N11600 001**

SPRAY, METERED; NASAL

		TRI-NASAL			
	+	MURO	0.05MG/SPRAY		N20120 001 FEB 04, 2000

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

		TRIHEXYPHENIDYL HCL			
AA		**WEST WARD**	**2MG**		**N40337 002** FEB 16, 2000
AA			**5MG**		**N40337 001** FEB 16, 2000

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL
ASCENT PEDS — EQ 25MG BASE/5ML — N74374 001 JUN 23, 1995
\+ — EQ 25MG BASE/5ML — N74374 001 JUN 23, 1995
\+ — EQ 50MG BASE/5ML — N74973 001 JAN 24, 2000

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
NEUTREXIN
\+ MEDIMMUNE ONCOLOGY — EQ 25MG BASE/VIAL — N20326 001 DEC 17, 1993
\+ US BIOSCIENCE — EQ 25MG BASE/VIAL — N20326 001 DEC 17, 1993

TROGLITAZONE

TABLET; ORAL
PRELAY

AB	SANKYO	200MG	N20719 001 JAN 29, 1997	
AB		300MG	N20719 003 AUG 04, 1997	> ADD >
AB		400MG	N20719 002 JAN 29, 1997	> ADD >
	@	200MG	N20719 001 JAN 29, 1997	
	@	300MG	N20719 003 AUG 04, 1997	
	@	400MG	N20719 002 JAN 29, 1997	

REZULIN

AB	PARKE DAVIS PHARMS	200MG	N20720 001 JAN 29, 1997
AB		300MG	N20720 003 AUG 04, 1997
AB		400MG	N20720 002 JAN 29, 1997
	@	200MG	N20720 001 JAN 29, 1997
	@	300MG	N20720 003 AUG 04, 1997

TROGLITAZONE

TABLET; ORAL
REZULIN
@ PARKE DAVIS PHARMS 400MG — N20720 002 JAN 29, 1997

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

AT	ALCON UNIVERSAL	1%	N89172 001 DEC 28, 1990
AT	STERIS	1%	N89172 001 DEC 28, 1990

URSODIOL

CAPSULE; ORAL
ACTIGALL

AB	\+ NOVARTIS	300MG	N19594 002 DEC 31, 1987
	\+	300MG	N19594 002 DEC 31, 1987

URSODIOL

AB	AMIDE PHARM	300MG	N75517 001 MAR 14, 2000	
AB	COPLEY PHARM	300MG	N75592 001 MAY 25, 2000	

TABLET; ORAL
URSO

	\+ AXCAN	250MG	N20675 001 DEC 10, 1997
	\+ AXCAN SCANDIPHARM	250MG	N20675 001 DEC 10, 1997

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
COVERA-HS

BC	SEARLE	180MG	N20552 001 FEB 26, 1996
BC	\+	180MG	N20552 001 FEB 26, 1996

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

	COVERA-HS			
BC	SEARLE	240MG	N20552 002	
			FEB 26, 1996	
BC	+	240MG	N20552 002	
			FEB 26, 1996	

VERTEPORFIN

INJECTABLE; INJECTION

	VISUDYNE		
	+ QLT	15MG/VIAL	N21119 001
			APR 12, 2000

VITAMIN A

CAPSULE; ORAL

	VITAMIN A		
AA	GLOBAL PHARM	50,000 USP UNITS	N80952 001
	@ IMPAX LABS	50,000 USP UNITS	N80952 001

VITAMIN A PALMITATE

CAPSULE; ORAL

	VITAMIN A		
AA	GLOBAL PHARM	EQ 50,000 UNITS BASE	N80953 001
AA		EQ 50,000 UNITS BASE	N80955 001
	@ IMPAX LABS	EQ 50,000 UNITS BASE	N80953 001
	@	EQ 50,000 UNITS BASE	N80955 001

ZOLMITRIPTAN

TABLET; ORAL

	ZOMIG		
	IPR	2.5MG	N20768 001
			NOV 25, 1997
	+	5MG	N20768 002
			NOV 25, 1997
	ZENECA	2.5MG	N20768 001
			NOV 25, 1997
	+	5MG	N20768 002
			NOV 25, 1997

ZONISAMIDE

CAPSULE; ORAL

	ZONEGRAN		
	+ DAINIPPON	100MG	N20789 001
			MAR 27, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN'2000 - MAY'2000

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL

ACETAMINOPHEN		
PERRIGO	650MG	N75077 001 FEB 25, 2000

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL

8-HOUR BAYER		
+ BAYER	650MG	N16030 001
@	650MG	N16030 001
MEASURIN		
+ BAYER	650MG	N16030 002
@	650MG	N16030 002

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL

E-Z SCRUB		
BECTON DICKINSON	4%	N73416 001 MAR 14, 2000

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CONTAC		
@ SMITHKLINE	8MG;75MG	N18099 001
+	8MG;75MG	N18099 001

CIMETIDINE

TABLET; ORAL

CIMETIDINE		
LEINER	200MG	N74961 001 JUN 19, 1998
NOVOPHARM	200MG	N74961 001 JUN 19, 1998

CLOTRIMAZOLE

CREAM; VAGINAL

TRIVAGIZOLE 3		
+ TARO	2%	N21143 001 APR 12, 2000

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN		
PHARM FORM	200MG	N74782 001 JUL 06, 1998
+	200MG	N74782 001 JUL 06, 1998

TABLET; ORAL

IBUPROFEN		
LEINER	200MG	N74931 001 JUL 20, 1998
NOVOPHARM	200MG	N74931 001 JUL 20, 1998

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL

LOPERAMIDE HCL		
LEINER	2MG	N73254 001 JUL 30, 1993
NOVOPHARM NC	2MG	N73254 001 JUL 30, 1993
PERRIGO	2MG	N75232 001 JAN 06, 2000

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM		
LEINER	EQ 200MG BASE	N74635 001 JAN 13, 1997
NOVOPHARM NC	EQ 200MG BASE	N74635 001 JAN 13, 1997

PERMETHRIN

LOTION; TOPICAL
PERMETHRIN
ALPHARMA 1% N75014 001
MAR 28, 2000

PIPERONYL BUTOXIDE; PYRETHRINS

AEROSOL; TOPICAL
RID MOUSSE
+ PFIZER 4%;EQ 0.33% BASE N21043 001
MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE
CHELSEA LABS EQ 75MG BASE N75212 001
JAN 14, 2000
CHEMINOR DRUGS EQ 75MG BASE N75294 001
MAR 28, 2000
GENPHARM EQ 75MG BASE N75497 001
JAN 14, 2000
LEINER EQ 75MG BASE N75094 001
JUN 21, 1999
RANBAXY EQ 75MG BASE N75132 001
JAN 14, 2000
EQ 75MG BASE N75254 001
JAN 14, 2000
> ADD > TORPHARM EQ 75MG BASE N75167 001
> ADD > MAY 04, 2000
ZENITH GOLDLINE EQ 75MG BASE N75296 001
JAN 14, 2000

RANITIDINE HCL
NOVOPHARM EQ 75MG BASE N75094 001
JUN 21, 1999

TABLET, EFFERVESCENT; ORAL
ZANTAC 75
+ GLAXO WELLCOME EQ 75MG BASE N20745 001
FEB 26, 1998
@ WARNER LAMBERT EQ 75MG BASE N20745 001
FEB 26, 1998

TERBINAFINE HYDROCHLORIDE

SOLUTION; TOPICAL
LAMISIL AT
+ NOVARTIS 1% N21124 001
MAR 17, 2000

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 '00

NO MAY 2000 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 Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate TN=	Treatment of hormone refractory prostate carcinoma.	Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 DD= 1/18/00 MA=
3-(3,5-Dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one TN=	Treatment of von Hippel-Lindau disease.	Sugen, Inc. 230 East Grand Ave. South San Francisco CA 94080 DD= 3/23/00 MA=
Angiotensin 1-7 TN=	Treatment of neutropenia associated with autologous bone marrow transplantation.	Maret Pharmaceuticals 4041 MacArthur Blvd. Suite 375 Newport Beach CA 92660 DD= 2/16/00 MA=
Arsenic trioxide TN=Atrivex	Treatment of multiple myeloma.	Cell Therapeutics, Inc. 201 Elliott Ave. West, Suite Seattle WA 98119 DD= 4/28/00 MA=
Bis(4-fluorophenyl)phenylacetamide TN=	Treatment of sickle cell disease.	ICAgen Inc. Ion Channel Advances PO Box 14487 Durham NC 27709 DD= 3/2/00 MA=

Orphan Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Brimonidine TN=Alphagan	Treatment of anterior ischemic optic neuropathy.	Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine CA 92623-9534 DD= 2/7/00 MA=
Cisplatin/epinephrine TN=IntraDose	Treatment of squamous cell carcinoma of the head and neck.	Matrix Pharmaceutical, Inc. 34700 Campus Drive Fremont CA 94555-3612 DD= 4/3/00 MA=
DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2 TN=Leuvectin	Treatment of renal cell carcinoma.	Vical Incorporated 9373 Towne Center Dr. Suite 100 San Diego CA 92121-3088 DD= 4/28/00 MA=
Ethyl eicosapentaenoate TN=	Treatment of Huntington's disease.	Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA=
Halofuginone TN=Stenorol	Treatment of systemic sclerosis.	Collgard Biopharmaceuticals Textile House, 2 Koifman St. Tel-Aviv 68012 Israel IL DD= 2/7/00 MA=

Orphan Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Histamine TN=Maxamine	For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.	Maxim Pharmaceuticals, Inc. 8899 University Center Lane Suite 400 San Diego CA 92122 DD= 2/1/00 MA=
Hypericin TN=	Treatment of cutaneous T-cell lymphoma.	Nexell Therapeutics, Inc. 2751 Centerville Rd., Suite Wilmington DE 19808 DD= 2/7/00 MA=
IL-4 Pseudomonas Toxin Fusion Protein (IL-4(38-37)-PE38KDEL) TN=	Treatment of astrocytic glioma.	Neurocrine Biosciences, Inc. 10555 Science Center Dr. San Diego CA 92121 DD= 4/6/00 MA=
Iodine I 131 bis(indium-diethylenetriaminepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')2 bispecific monoclonal antibody TN= Pentacea	Treatment of small-cell lung cancer.	IBC Pharmaceuticals, L.L.C. 300 American Rd. Morris Plains NJ 07950 DD= 2/22/00 MA=
Levodopa and carbidopa TN= Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215 DD= 1/18/00 MA=

Orphan Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Meropenem TN=Merrem IV	Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms.	Zeneca Pharmaceuticals 1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437 DD= 4/27/00 MA=
Natural human lymphoblastoid interferon-alpha TN=	Treatment of Behcet's disease.	Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo TX 79101-3206 DD= 1/18/00 MA=
Omega-3 (n-3) polyunsaturated fatty acids TN=Omacor	Treatment of IgA nephropathy.	Pronova Biocare, AS PO Box 420 1327 Lysaker Norway DD= 5/4/00 MA=
Phenylbutyrate TN=	Treatment of acute promyelocytic leukemia.	Elan Corporation 1300 Gould Dr. Gainesville GA 30504 DD= 1/19/00 MA=
Recombinant human antithrombin III TN=	Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.	AT III LLC c/o Genzyme Corporation 15 Pleasant St. Connector, Framingham MA 01701 DD= 4/6/00 MA=

Orphan Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Recombinant human insulin-like growth factor-I TN= PV802	Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines.	GroPep Pty Ltd. Gate 11, Victoria Dr. Adelaide SA 5000 Australia AU DD= 2/16/00 MA=
Remacemide TN= Ecovia	Treatment of Huntington's disease.	AstraZeneca LP 725 Chesterbrook Blvd. Wayne PA 19087-5677 DD= 3/6/00 MA=
rSP-C lung surfactant TN= Venticute	Treatment of adult respiratory distress syndrome.	Byk Gulden Pharmaceuticals Byk-Gulden StraBe 2 78467 Konstanz Germany DE DD= 4/3/00 MA=
Soluble complement receptor type 1 TN=	Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.	Avant Immunotherapeutics, 119 Fourth Ave. Needham MA 02494-2725 DD= 3/6/00 MA=
Synthetic human secretin TN=	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4176 DD= 3/7/00 MA=

Orphan Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Synthetic porcine secretin	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4176
TN=		DD= 3/7/00 MA=
Technetium Tc 99m pterotetramide	For the identification of ovarian carcinomas.	Endocyte, Inc. 1205 Kent Ave. Lafayette IN 47906
TN=		DD= 2/16/00 MA=
Tetraiodothyroacetic acid	Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland.	Danforth, Jr., MD, Elliot University of Vermont 84 Beartown Rd. Underhill VT 05489
TN=		DD= 5/1/00 MA=
Thymalfasin	Treatment of hepatocellular carcinoma.	SciClone Pharmaceuticals, 901 Mariner's Blvd., Suite San Mateo CA 94404
TN= Zadaxin		DD= 3/6/00 MA=
Vapreotide	Treatment of gastrointestinal and pancreatic fistulas.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH
TN= Octastatin		DD= 1/10/00 MA=

Orphan Products Designations and Approvals List
January through May, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Vapreotide TN=Octastatin	Prevention of early postoperative complications following pancreatic resection.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 3/6/00 MA=
Vapreotide TN=Octastatin	Treatment of esophageal variceal hemorrhage patients with portal hypertension.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 1/10/00 MA=

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

NO MAY 2000 ADDITIONS

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	075077 001	ACETAMINOPHEN;ACETAMINOPHEN				PC	NOV 12, 2000
	020560 001	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303	M-3	NOV 24, 2002
	020560 002	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303	M-3	NOV 24, 2002
	020560 003	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303	M-3	NOV 24, 2002
	021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX				NCE	FEB 09, 2005
	020221 001	AMIFOSTINE;ETHYOL				I-283	JUN 24, 2002
	020221 002	AMIFOSTINE;ETHYOL				I-283	JUN 24, 2002
	021007 001	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2013	U-257		
			5646180	JUL 08, 2014	U-257		
			5585397	DEC 17, 2013			
	021007 002	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2015	U-257		
			5646180	JUL 08, 2014	U-257		
			5585397	DEC 17, 2013			
	021039 001	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2015	U-257		
			5646180	JUL 08, 2014	U-257		
>ADD>	020541 001	ANASTROZOLE;ARIMIDEX	RE36617	DEC 27, 2009			
	020971 001	ARTICAINE HYDROCHLORIDE;SEPTOCAINE				NC	APR 03, 2003
	021127 001	AZELASTINE HYDROCHLORIDE;OPTIVAR				NCE	NOV 01, 2001
						NDF	MAY 22, 2003
	021055 001	BEXAROTENE;TARGRETIN				ODE	DEC 29, 2006
	019982 001	BISOPROLOL FUMARATE;ZEBETA	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	019982 002	BISOPROLOL FUMARATE;ZEBETA	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	020186 001	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	020186 002	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	020186 003	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
			4358062*PED	SEP 24, 2000	U-63		
>ADD>	050443 002	BLEOMYCIN SULFATE;BLENOXANE				ODE	FEB 20, 2003
	020711 002	BUPROPION HYDROCHLORIDE;ZYBAN				D-54	SEP 10, 2002
	020711 003	BUPROPION HYDROCHLORIDE;ZYBAN				D-54	SEP 10, 2002
	018731 001	BUSPIRONE HYDROCHLORIDE;BUSPAR	4182763	MAY 22, 2000	U-13		
			5015646	MAY 14, 2008			
			4182763*PED	NOV 22, 2000	U-13		
			5015646*PED	NOV 14, 2008			
	018731 002	BUSPIRONE HYDROCHLORIDE;BUSPAR	4182763	MAY 22, 2000	U-13		
			5015646	MAY 14, 2008			
			4182763*PED	NOV 22, 2000	U-13		
			5015646*PED	NOV 14, 2008			
	018731 003	BUSPIRONE HYDROCHLORIDE;BUSPAR	5015646	MAY 14, 2008			
			4182763	MAY 22, 2000	U-13		
			4182763*PED	NOV 22, 2000	U-13		
			5015646*PED	NOV 14, 2008			

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
018731 004	BUSPIRONE HYDROCHLORIDE;BUSPAR	4182763	MAY 22, 2000	U-13		
		5015646	MAY 14, 2008			
		4182763*PED	NOV 22, 2000			
		5015646*PED	NOV 14, 2008	U-13		
020793 001	CAFFEINE CITRATE;CAFCIT				ODE	SEP 21, 2006
018874 001	CALCITRIOL;CALCIJEX	6051567	AUG 02, 2019			
018874 002	CALCITRIOL;CALCIJEX	6051567	AUG 02, 2019			
020297 001	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
020297 002	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
020297 003	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
020297 004	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
020989 002	CEVIMELINE HYDROCHLORIDE;EVOXAC	4855290	AUG 08, 2006		NCE	JAN 11, 2005
		5340821	AUG 23, 2011	U-309		
		5580880	JUN 06, 2015	U-310		
021143 001	CLOTRIMAZOLE;TRIVAGIZOLE 3				NP	NOV 24, 2001
021141 001	COLESEVELAM HYDROCHLORIDE;WELCHOL	5624963	APR 29, 2014	U-323	NCE	MAY 26, 2005
		5679717	APR 29, 2014	U-323		
		5693675	DEC 02, 2014			
		5607669	JUN 10, 2014	U-323		
		5917007	APR 29, 2014	U-323		
		5919832	JUN 10, 2014			
021176 001	COLESEVELAM HYDROCHLORIDE;WELCHOL	5919832	JUN 10, 2014		NCE	MAY 26, 2005
		5917007	APR 29, 2014	U-323		
		5607669	JUN 10, 2014	U-323		
		5693675	DEC 02, 2014			
		5679717	APR 29, 2014	U-323		
		5624963	APR 29, 2014	U-323		
020154 004	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
021027 001	DOXERCALCIFEROL;HECTOROL	5602116	APR 03, 2115	U-321	NDF	APR 06, 2003
		5707980	FEB 11, 2117	U-321	NCE	JUN 09, 2004
019221 001	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
		4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
		4472380*PED	MAR 18, 2002			
019221 003	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
		4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
		4472380*PED	MAR 18, 2002			
018998 001	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
018998 002	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
018998 003	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			

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
018998 005	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
019309 001	ENALAPRILAT;VASOTEC	4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
020444 001	EPOPROSTENOL SODIUM;FLOLAN				ODE	APR 14, 2007
					I-296	APR 14, 2003
020444 002	EPOPROSTENOL SODIUM;FLOLAN				ODE	APR 14, 2007
					I-296	APR 14, 2003
020907 001	ESTRADIOL;ACTIVELLE				I-295	APR 11, 2003
021040 001	ESTRADIOL;ORTHO-PREFEST	5108995	APR 28, 2009	U-311		
		5382573	JAN 17, 2012			
020584 001	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
		4966768	OCT 30, 2007			
020584 002	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
		4966768	OCT 30, 2007			
020584 003	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
		4966768	OCT 30, 2007			
019304 002	FENOFIBRATE;TRICOR (MICRONIZED)				I-298	APR 24, 2003
019304 003	FENOFIBRATE;TRICOR (MICRONIZED)				I-298	APR 24, 2003
019304 004	FENOFIBRATE;TRICOR (MICRONIZED)				I-298	APR 24, 2003
020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017	U-138		
020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015			
		5855912	FEB 28, 2015			
		4254129	FEB 17, 2001	U-139		
		6037353	MAR 14, 2017	U-138		
020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015			
		5855912	FEB 28, 2015			
		4254129	FEB 17, 2001	U-139		
		6037353	MAR 14, 2017	U-138		
020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
		5932247	FEB 28, 2015			
		5855912	FEB 28, 2015			
		4254129	FEB 17, 2001	U-139		
		6037353	MAR 14, 2017	U-138		
020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	6037353	MAR 14, 2017	U-138		
		6039974	JUL 31, 2018			
019949 004	FLUCONAZOLE;DIFLUCAN	4416682	JUN 02, 2001			
		4404216	JAN 29, 2004			
020235 001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
		5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
		4894476*PED	NOV 02, 2008			
		4087544*PED	JUL 16, 2000	U-86		
		5084479*PED	JUL 02, 2010	U-125		
		4894476	MAY 02, 2008			
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			

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
020235 002	GABAPENTIN;NEURONTIN	4894476	MAY 02, 2008		PED	MAR 29, 2002
		5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
		4087544	JAN 16, 2000	U-86		
		5084479*PED	JUL 02, 2010	U-125		
		4894476*PED	NOV 02, 2008			
		4087544*PED	JUL 16, 2000	U-86		
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			
020235 003	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
		5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
		4894476	MAY 02, 2008			
		4087544*PED	JUL 16, 2000	U-86		
		5084479*PED	JUL 02, 2010			
		4894476*PED	NOV 02, 2008			
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			
020882 001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
		4894476	MAY 02, 2008			
		5084479	JAN 02, 2010	U-258		
		5084479*PED	JUL 02, 2010	U-258		
		4087544*PED	JUL 16, 2000	U-106		
		4894476*PED	NOV 02, 2008			
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			
020882 002	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-106		
		4894476	MAY 02, 2008			
		5084479	JAN 02, 2010	U-258		
		4087544*PED	JUL 16, 2000	U-106		
		4894476*PED	NOV 02, 2008			
		5084479*PED	JUL 02, 2010	U-258		
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			
021037 001	GADOPENTETATE DIMEGLUMINE;MAGNEVIST	5362475	NOV 08, 2011			
		5560903	OCT 01, 2013			
		4647447	MAR 03, 2004			
		4957939	MAR 03, 2004			
		4963344	MAR 03, 2004			
020460 002	GANCICLOVIR;CYTOVENE	4507305	MAY 21, 2001	U-64		
		4423050	MAY 21, 2001	U-64		
		4355032	JUN 23, 2003	U-64		
		4642346	JUN 24, 2005			
021174 001	GEMTUZUMAB OZOGAMICIN;MYLOTARG	5606040	FEB 25, 2014		ODE	MAY 17, 2007
		5693762	DEC 02, 2014		NCE	MAY 17, 2005
		5739116	APR 14, 2015			
		5767285	JUN 16, 2015			
		5773001	JUN 30, 2015	U-320		
		4970198	NOV 30, 2007			
		5079233	JAN 07, 2009			
		5585089	DEC 17, 2013			

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
	020622 001	GLATIRAMER ACETATE;COPAXONE	5981589	MAY 24, 2014			
			6054430	MAY 24, 2014			
	020125 001	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
	020125 002	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
	020125 003	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
	019778 001	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001			
	019778 002	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001			
	019778 003	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001	U-3		
>ADD>	020986 001	INSULIN ASPART;NOVOLOG				NCE	JUN 07, 2005
	021081 001	INSULIN GLARGINE;LANTUS				PED	OCT 20, 2005
						NCE	APR 20, 2005
	020563 001	INSULIN LISPRO;HUMALOG				D-56	APR 04, 2003
	021018 001	INSULIN LISPRO;HUMALOG MIX 50/50				NC	DEC 22, 2002
	020563 002	INSULIN LISPRO;HUMALOG PEN	5474978	JUN 16, 2014		D-56	APR 04, 2003
			5514646	MAY 07, 2013	U-111	NCE	JUN 14, 2001
	020571 001	IRINOTECAN HYDROCHLORIDE;CAMPTOSAR				I-299	APR 20, 2003
	019084 001	KETOCONAZOLE;NIZORAL	4942162	FEB 11, 2003			
	020857 001	LAMIVUDINE;COMBIVIR	5905082	MAY 18, 2016	U-248		
	020564 001	LAMIVUDINE;EPIVIR	5047407	NOV 17, 2009			
	020596 001	LAMIVUDINE;EPIVIR	5047407	NOV 17, 2009			
	021088 001	LEUPROLIDE ACETATE;VIADUR	5728396	JAN 30, 2017	U-316	NP	MAR 03, 2003
			5932547	JUN 13, 2017			
			5985305	JAN 30, 2017			
	021114 001	LEVOBETAXOLOL HYDROCHLORIDE;BETAXON				NP	FEB 23, 2003
	020612 001	LIDOCAINE;LIDODERM				NP	MAR 19, 2002
	021130 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	021130 002	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	021131 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	021132 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	019558 001	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 002	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 003	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 004	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 006	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019777 001	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 002	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 003	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 004	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 005	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 006	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	020938 001	MELOXICAM;MOBIC				NCE	APR 13, 2005
	020049 001	MESALAMINE;PENTASA	4980173	JAN 29, 2002	U-78		
	020357 001	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000

PRESCRIPTION AND OTC DRUG PRODUCT
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	020357 002	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000
	020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000
	019815 001	MIDODRINE HYDROCHLORIDE;PROAMATINE				ODE	SEP 06, 2003
	019815 002	MIDODRINE HYDROCHLORIDE;PROAMATINE				ODE	SEP 06, 2003
	020830 002	MONTELUKAST SODIUM;SINGULAIR	5565473	NOV 30, 2010	U-228	I-300	MAR 03, 2003
						NS	MAR 03, 2003
						NCE	FEB 20, 2003
	020152 001	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 002	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 003	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 004	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 005	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 006	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	021134 001	NITROGLYCERIN;NITROSTAT				NDF	MAY 01, 2003
	021134 002	NITROGLYCERIN;NITROSTAT				NDF	MAY 01, 2003
	021134 003	NITROGLYCERIN;NITROSTAT				NDF	MAY 01, 2003
>ADD>	019921 001	OFLOXACIN;OCUFLOX	4382892	SEP 02, 2003			
			4551456	NOV 14, 2003	U-80		
>ADD>						I-297	MAR 17, 2003
	020592 001	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
	020592 002	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
	020592 003	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
	020592 004	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
	020592 005	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
	020592 006	OLANZAPINE;ZYPREXA				NCE	SEP 30, 2001
	021086 001	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013			
			5229382	APR 23, 2011	U-324		
			5605897	FEB 25, 2014	U-325		
			5627178	APR 23, 2011	U-326		
			5736541	MAR 24, 2015	U-328		
			5817655	APR 23, 2011	U-327		
			5817656	APR 23, 2011	U-326		
	021086 002	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
			5229382	APR 23, 2011	U-324		
			5605897	FEB 25, 2014	U-325		
			5627178	APR 23, 2011	U-326		
			5736541	MAR 24, 2015	U-328		
			5817655	APR 23, 2011	U-327		
			5817656	APR 23, 2011	U-326		
	021086 003	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
			5736541	MAR 24, 2015	U-328		
			5817655	APR 23, 2011	U-327		
			5817656	APR 23, 2011	U-326		
			5229382	APR 23, 2011	U-324		
			5605897	FEB 25, 2014	U-325		
			5627178	APR 23, 2011	U-326		

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
	021086 004	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
			5229382	APR 23, 2011	U-324		
			5605897	FEB 25, 2014	U-325		
			5627178	APR 23, 2011	U-326		
			5736541	MAR 24, 2015	U-328		
			5817655	APR 23, 2011	U-327		
			5817656	APR 23, 2011	U-326		
>ADD>	020688 001	OLOPATADINE HYDROCHLORIDE;PATANOL				I-301	MAR 20, 2003
	019715 001	OLSALAZINE SODIUM;DIPENTUM	4559330	JUL 31, 2004	U-58		
>ADD>	020781 001	ONDANSETRON;ZOFRAN ODT	6063802	NOV 14, 2015			
>ADD>			5578628	JUN 24, 2006	U-330		
>ADD>			4695578	JUN 25, 2005	U-330		
>ADD>			4753789	JUN 24, 2006	U-329		
			5955488	NOV 14, 2015			
>ADD>	020781 002	ONDANSETRON;ZOFRAN ODT	6063802	NOV 14, 2015			
>ADD>			5578628	JUN 24, 2006	U-330		
>ADD>			4695578	JUN 25, 2005	U-330		
>ADD>			4753789	JUN 24, 2006	U-330		
			5955488	NOV 14, 2015			
	020766 001	ORLISTAT;XENICAL	6004996	JAN 06, 2018			
	021014 001	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
	021014 002	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
	021014 003	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>	020262 001	PACLITAXEL;TAXOL				D-57	JUN 20, 2003
	020987 001	PANTOPRAZOLE SODIUM;PROTONIX	4758579	JUL 19, 2005		NCE	FEB 02, 2005
	020819 001	PARICALCITOL;ZEMPLAR	5246925	SEP 21, 2010	U-314		
			5587497	DEC 24, 2013			
>ADD>	020031 001	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020031 002	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020031 003	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020031 004	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020031 005	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020710 001	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020885 001	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020885 002	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020885 003	PAROXETINE HYDROCHLORIDE;PAXIL	6063927	APR 23, 2019			
>ADD>	020885 004	PAROXETINE HYDROCHLORIDE;PAXIL	6062927	APR 23, 2019			
>ADD>	020936 001	PAROXETINE HYDROCHLORIDE;PAXIL CR	6063927	APR 23, 2019			
>ADD>	020936 002	PAROXETINE HYDROCHLORIDE;PAXIL CR	6063927	APR 23, 2019			
	021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER;SKIN EXPOSURE REDUCT	5607979	MAY 30, 2015		NCE	FEB 17, 2005
>ADD>	019898 002	PRAVASTATIN SODIUM;PRAVACHOL				I-281	JUN 09, 2003
						I-287	FEB 10, 2003
						I-286	JAN 18, 2003
						D-51	JAN 18, 2003

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	019898 003	PRAVASTATIN SODIUM;PRAVACHOL				I-281	JUN 09, 2003
						I-287	FEB 10, 2003
						I-286	JAN 18, 2003
						D-51	JAN 18, 2003
>ADD>	019898 004	PRAVASTATIN SODIUM;PRAVACHOL				I-281	JUN 09, 2003
						I-287	FEB 10, 2003
						I-286	JAN 18, 2003
						D-51	JAN 18, 2003
	019157 001	PREDNISOLONE SODIUM PHOSPHATE;PEDIAPRED	4448774	DEC 22, 2002			
	020630 001	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583*PED	AUG 15, 2009		NPP	OCT 15, 2002
			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
			5019583	FEB 15, 2009		PED	JAN 12, 2002
			5466700*PED	MAR 01, 2014	U-156	NCE	JUL 12, 2001
	020630 002	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
			5019583*PED	AUG 15, 2009		PED	JAN 12, 2002
			5466700*PED	MAR 01, 2014		NCE	JUL 12, 2001
	020630 003	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
			5019583*PED	AUG 15, 2009		PED	JAN 12, 2002
			5466700*PED	MAR 01, 2014	U-156	NCE	JUL 12, 2001
	020903 001	RIBAVIRIN;REBETOL	6051252	DEC 22, 2017			
	020835 001	RISEDRONATE SODIUM;ACTONEL				I-292	APR 14, 2003
						I-291	APR 14, 2003
						I-290	APR 14, 2003
						I-293	APR 14, 2003
	020588 001	RISPERIDONE;RISPERDAL	5453425	JUL 11, 2014			
			5616587	JUL 11, 2014			
	020659 001	RITONAVIR;NORVIR	6037157	JUN 26, 2016			
			5674882	OCT 07, 2014			
			5886036	DEC 29, 2012			
	020823 003	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
			5602176	FEB 11, 2014	U-322		
	020823 004	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
			5602176	FEB 11, 2014	U-322		
	020823 005	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
			5602176	FEB 11, 2014	U-322		
	020823 006	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
			5602176	FEB 11, 2014	U-322		
	021025 001	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
			5602176	FEB 11, 2014	U-322		
	020864 001	RIZATRIPTAN BENZOATE;MAXALT	5602162	FEB 11, 2014			
			5602162	FEB 11, 2014			
	020864 002	RIZATRIPTAN BENZOATE;MAXALT	5602162	FEB 11, 2014			
			5602162	FEB 11, 2014			

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021042 001	ROFECOXIB;VIOXX	6063811	MAY 16, 2017	U-266		
>ADD>	021042 002	ROFECOXIB;VIOXX	6063811	MAY 16, 2017	U-266		
>ADD>	021052 001	ROFECOXIB;VIOXX	6063811	MAY 16, 2017	U-266		
>ADD>	021052 002	ROFECOXIB;VIOXX	6063811	MAY 16, 2017	U-266		
>ADD>	021071 002	ROSIGLITAZONE MALEATE;AVANDIA	5002953	AUG 30, 2008	U-329	I-289	APR 03, 2003
>ADD>			5741803	APR 21, 2015	U-329		
>ADD>	021071 003	ROSIGLITAZONE MALEATE;AVANDIA	5002953	AUG 30, 2008	U-329	I-289	APR 03, 2003
>ADD>			5741803	APR 21, 2015	U-329		
>ADD>	021071 004	ROSIGLITAZONE MALEATE;AVANDIA	5002953	AUG 30, 2008	U-329	I-289	APR 03, 2003
>ADD>			5741803	APR 21, 2015	U-329		
	020990 001	SERTRALINE HYDROCHLORIDE;ZOLOFT	4536518	DEC 30, 2005	U-286		
			4940731	AUG 30, 2009	U-312		
>ADD>	020478 001	SEVOFLURANE;ULTANE	6074668	JAN 09, 2018			
>ADD>	020280 006	SOMATROPIN RECOMBINANT;GENOTROPIN				I-302	JUN 20, 2003
>ADD>	020280 007	SOMATROPIN RECOMBINANT;GENOTROPIN				I-302	JUN 20, 2003
>ADD>	020280 001	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 002	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 003	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 004	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 005	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2000
>ADD>	020280 008	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 009	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 010	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 011	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 012	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
>ADD>	020280 013	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				I-302	JUN 20, 2003
	019721 001	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019721 002	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019676 001	SOMATROPIN RECOMBINANT;NUTROPIN				D-55	APR 13, 2003
						M-2	DEC 01, 2002
	019676 002	SOMATROPIN RECOMBINANT;NUTROPIN				D-55	APR 13, 2003
						M-2	DEC 01, 2002
	020522 001	SOMATROPIN RECOMBINANT;NUTROPIN AQ				D-55	APR 13, 2003
						M-2	DEC 01, 2002
	021151 001	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
	021151 002	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
	021151 003	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
	021124 001	TERBINAFINE HYDROCHLORIDE;LAMISIL AT	4680291	JUL 14, 2004	U-73		
			4755534	DEC 30, 2006	U-73		
			5681849	OCT 28, 2014			
	021015 001	TESTOSTERONE;ANDROGEL				NDF	FEB 28, 2003
	020771 001	TOLTERODINE TARTRATE;DETROL	5559269	MAY 05, 2015	U-318		
	020771 002	TOLTERODINE TARTRATE;DETROL	5559269	MAY 05, 2015	U-318		
	020281 001	TRAMADOL HYDROCHLORIDE;ULTRAM				PED	SEP 03, 2000
						PED	FEB 21, 2002
						NCE	MAR 03, 2000
						D-44	AUG 21, 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
	020281 002	TRAMADOL HYDROCHLORIDE;ULTRAM				PED	FEB 21, 2002
						PED	SEP 03, 2000
						NCE	MAR 03, 2000
						D-44	AUG 21, 2001
>ADD>	074973 001	TRIMETHOPRIM HYDROCHLORIDE;PRIMSOL	5763449	AUG 07, 2016			
>ADD>			5962461	AUG 07, 2016			
	020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
	020326 002	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
>ADD>	020715 001	TRIPTORELIN PAMOATE;TRELSTAR DEPOT				NCE	JUN 15, 2005
	020719 001	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
	020719 002	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
	020719 003	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
	020720 001	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
	020720 002	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
	020720 003	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
	020552 001	VERAPAMIL HYDROCHLORIDE;COVERA-HS	5232705	AUG 31, 2010			
			5200196	JAN 22, 2008			
			5141752	JUN 27, 2006			
			5082668	JAN 21, 2009			
			5030456	NOV 07, 2008			
			4946687	OCT 02, 2007			
			5785994	OCT 22, 2009	U-315		
	020552 002	VERAPAMIL HYDROCHLORIDE;COVERA-HS	5232705	AUG 31, 2010			
			5200196	JAN 22, 2008			
			5141752	JUN 27, 2006			
			5082668	JAN 21, 2009			
			5030456	NOV 07, 2008			
			4946687	OCT 02, 2007			
			5785994	OCT 22, 2009	U-315		
	021119 001	VERTEPORFIN;VISUDYNE				NCE	APR 12, 2005
	021036 001	ZANAMIVIR;RELENZA				I-294	APR 26, 2003
	020789 001	ZONISAMIDE;ZONEGRAN				NCE	MAR 27, 2005

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, 20TH 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

NPP	NEW PATIENT POPULATION

REFERENCES

NEW DOSING SCHEDULE

D-51	OPTIONAL STARTING DOSE OF 40MG/DAY
D-52	ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY
D-53	USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE
D-54	USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS
D-55	ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)
D-56	ADDITION OF POSTPRANDIAL DOSING
D-57	3-HOUR INFUSION OF TAXOL GIVEN EVERY THREE WEEKS AT A DOSE OF 175MG/M2 FOLLOWED BY CISPLATIN AT A DOSE OF 75MG/M2 FOR THE FIRST-LINE TREATMENT OF ADVANCED OVARIAN CANCER

NEW INDICATION

I-283	TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS
I-286	TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III
I-287	USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH
I-288	CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINOPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE
I-289	USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL
I-290	TREATMENT OF CORTICOSTEOID-INDUCED OSTEOPOROSIS
I-291	PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
I-292	TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
I-293	TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS
I-294	TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS
I-295	PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

I-296	LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY
I-297	SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
I-298	TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA
I-299	USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM
I-300	PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE
I-301	TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS
I-302	TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME

MISCELLANEOUS EXCLUSIVITY CODES

M-2	APPROVAL FOR ADDTION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE
M-3	ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN

PATENT USE CODE

U-266	RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS; MANAGEMENT OF ACUTE PAIN IN ADULTS; TREATMENT OF PRIMARY DYSMENORRHEA
U-309	TREATING SJOEGREN SYNDROME
U-310	TREATMENT OF XEROSTOMIA
U-311	HORMONE REPLACEMENT
U-312	PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER
U-313	TREATMENT OF CONGESTIVE HEART FAILURE
U-314	METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY
U-315	METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT
U-316	METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER
U-317	METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE
U-318	TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE
U-319	TREATMENT OF MICROBIAL INFECTIONS
U-320	INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA
U-321	REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS
U-322	TREATMENT OF ALZHEIMER'S DEMENTIA
U-323	USE AS A BILE ACID SEQUESTRANT
U-324	METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE
U-325	METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE
U-326	METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER
U-327	METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE
U-328	METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

U-329	**USE OF AVANDIA AS MONOTHERAPY, IN COMBINATION WITH METFORMIN, AND IN COMBINATION WITH SULFONYLUREAS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS**
U-330	**TREATMENT OF NAUSEA AND VOMITING**