

**CUMULATIVE
SUPPLEMENT 9**

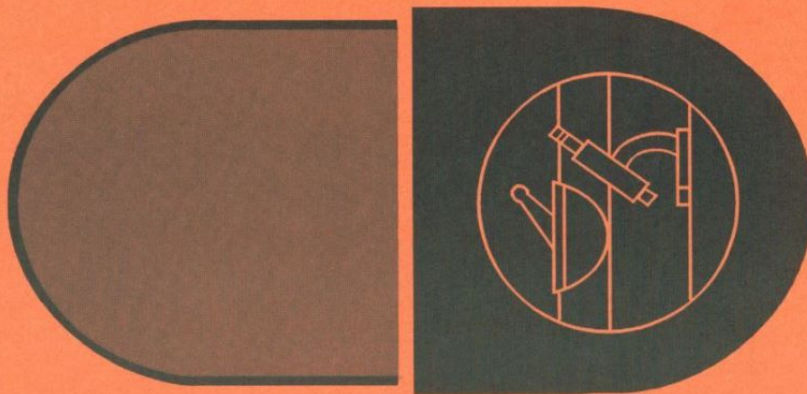
JAN'94-SEP'94

APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DRUG INFORMATION RESOURCES**



RM
301.45
.A66
1994
Sep
Suppl

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

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Available in March 1995

New 15th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**15TH EDITION
1995**

Library Use Only

CONTENTS

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See Subscription Form Inside Back Cover

RM301.45 .A66 1994 Sep Suppl

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

Cumulative Supplement 9

SEPTEMBER 1994

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

CUMULATIVE SUPPLEMENT 9

SEPTEMBER 1994

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, 14th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

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.)

Additions new 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.

Deletions new to the Prescription Drug Product List and the OTC Drug Product List are indicated by the symbol >DLT> (DELETE) to the left of the line containing shaded print. Deletions new to the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. 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 for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

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 14th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 15th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

<u>Products</u>	<u>Federal Register Reference</u>
Nitroglycerin (capsule, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (film, extended release; transdermal*)	JUL 15, 1993 (58 FR 38129)
Nitroglycerin (tablet, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 05, 1985 (50 FR 27688)

*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

1.3 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 automatically 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

<u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u>
ADRIA LABORATORIES DIV ERBAMONT INC (ADRIA)	PHARMACIA INC (PHARMACIA)
BANNER GELATIN PRODUCTS CORP (BANNER GELATIN)	BANNER PHARMACAPS INC (BANNER PHARMACAPS)
CLONMEL CHEMICALS CO LTD (CLONMEL)	CLONMEL HEALTHCARE LIMITED (CLONMEL)
DUPONT PHARMACEUTICALS (DUPONT)	DUPONT MERCK PHARMACEUTICALS CO (DUPONT MERCK)
GYNEX INC (GYNEX)	BTG PHARMACEUTICALS CORP SUB BIOTECHNOLOGY GENERAL CORP (BTG PHARMS)
KABI PHARMACIA INC (KABI)	PHARMACIA INC (PHARMACIA)
MALLINCKRODT SPECIALTY CHEMICALS CO (MALLINCKRODT)	MALLINCKRODT CHEMICAL INC (MALLINCKRODT)
NORTH AMERICAN CHEMICAL CORP (NORTH AM CHEM)	GOLDEN PHARMACEUTICALS INC (GOLDEN PHARM)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

PHARMACEUTICAL BASICS INC
(PHARM BASICS)

ROSEMONT PHARMACEUTICAL CORPORATION
(ROSEMONT PHARM)

RICHLYN LABORATORIES INC
(RICHLYN)

GLOBAL PHARMACEUTICAL CORPORATION
(GLOBAL PHARM)

SQUIBB DIAGNOSTICS
(SQUIBB)

BRACCO DIAGNOSTICS INC
(BRACCO)

1.4 NEW INDICATIONS FOR PREVIOUSLY APPROVED DRUG PRODUCTS

When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by the same firm, the application is either submitted as a supplement to the original NDA (if the clinical expertise for the review of the new indication resides in the same division that reviewed the original NDA), or as a "Type 6 NDA" and assigned a new NDA number (if the clinical expertise for the review of the new indication resides in another review division). When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by a different firm, the application is classified as "Type 6" and assigned a new NDA number. For administrative purposes, FDA has been listing all "Type 6 NDA's" in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, (ADP), even when the application was submitted by the original NDA holder. However, FDA has determined that the practice of listing a separate "Type 6 NDA" number in the ADP when the applicant is the original NDA holder may cause confusion to the ADP reader.

Accordingly, to prevent confusion and to eliminate duplicity of data, the approval of an application for a new indication for a previously approved drug product submitted by the original NDA holder will no longer be listed in the ADP. Any exclusivity awarded for that approval will be shown in the Patent and Exclusivity Information Addendum under the original NDA number. However, approval of an application for a new indication submitted by an applicant other than the original NDA holder will be shown in the appropriate drug product list of the ADP. Any exclusivity awarded will be shown under the NDA number of the new applicant.

All approvals of "Type 6" applications submitted by the original NDA holder currently in the ADP are listed in the table below. For reference purposes, the original NDA number is listed next to the corresponding "Type 6 NDA Number". This data ("Type 6 NDA Number") will continue to be listed in the remaining Cumulative Supplements to the 14th Edition of the ADP; but it will not appear in the 15th Edition of the ADP.

<u>TYPE 6 NDA NUMBER</u>	<u>ORIGINAL NDA NUMBER</u>	<u>ACTIVE INGREDIENT (TRADE NAME)</u>	<u>DOSAGE FORM (ROUTE)</u>
17-117	16-020	AMANTADINE HCL (SYMMETREL)	CAPSULE (ORAL)
17-118	16-023	AMANTADINE HCL (SYMMETREL)	SYRUP (ORAL)
50-697	50-662	CLARITHROMYCIN (BIAxin)	TABLET (ORAL)
19-576	19-084	KETOCONAZOLE (NIZORAL)	CREAM (TOPICAL)
19-648	19-084	KETOCONAZOLE (NIZORAL)	CREAM (TOPICAL)
18-064	18-063	NADOLOL (CORGARD)	TABLET (ORAL)
20-109	19-886	NAFARELIN ACETATE (SYNAREL)	SPRAY, METERED (NASAL)
20-223	19-057	TERAZOSIN HCL (HYTRIN)	TABLET (ORAL)

1.5 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE
(FORMER ADP DOSAGE FORM; ROUTE)

NEW USP MONOGRAPH TITLE
(NEW ADP DOSAGE FORM; ROUTE)

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF
SEPTEMBER 1994.

1.6 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 sections 505 and 507 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 1993) 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

<u>CATEGORIES COUNTED</u>	<u>DEC 1993</u>	<u>MAR 1994</u>	<u>JUN 1994</u>	<u>SEP 1994</u>
DRUG PRODUCTS LISTED	9140	9153	9079	
SINGLE SOURCE	2144 (23.5%)	2151 (23.5%)	2150 (23.7%)	
MULTISOURCE	6996 (76.5%)	7002 (76.5%)	6929 (76.3%)	
THERAPEUTICALLY EQUIVALENT	6292 (68.8%)	6306 (68.9%)	6290 (69.3%)	
NOT THERAPEUTICALLY EQUIVALENT	527 (5.8%)	513 (5.6%)	458 (5.0%)	
EXCEPTIONS ¹	177 (1.9%)	183 (2.0%)	181 (2.0%)	
NEW MOLECULAR ENTITIES APPROVED	--	6	5	
NUMBER OF APPLICANTS	526	528	490	

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

PRESCRIPTION DRUG PRODUCT LIST
14TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'94 - SEP'94

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

AA CO-CECIC US CHEM 325MG; 50MG; 40MG N89115 001
 CAPSULE; ORAL
 MEDIGESIC PLUS
 JAN 14, 1986
 N89115 001
 JAN 14, 1986
 325MG; 50MG; 40MG

N19806 001
 MAR 25, 1994
 8MG; 60MG
 SEMPRES-D
 + BURROUGHS WELLCOME

ACETAMINOPHEN; HYDROCODONE BITARTRATE

> DLT >
 > DLT >
 > DLT >
 > ADD >
 > ADD >

AA CO-CECIC CENT PHARMS 500MG; 5MG N89360 001
 CAPSULE; ORAL
 MAR 02, 1988
 N89360 001
 MAR 02, 1988
 500MG; 5MG

EQ 2MG BASE/5ML
 ALBUTEROL SULFATE

SYRUP; ORAL
 ALBUTEROL SULFATE
 MOVA

> ADD >
 > ADD >

N74302 001
 SEP 30, 1994

ACETIC ACID, GLACIAL; ALUMINUM ACETATE

SOLUTION/DROPS; OTIC
 ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE
 AT BAUSCH AND LOMB 2%; 0.79%

N40063 001
 FEB 25, 1994

AT BOOPAIR PHARMAFAIR 2%; 0.79% N88606 001
 CAPSULE; ORAL
 AUG 21, 1985
 N88606 001
 AUG 21, 1985
 2%; 0.79%

ALPRAZOLAM

TABLET; ORAL
 ALPRAZOLAM
 MYLAN

0.25MG

N74215 001
 JAN 27, 1994

0.5MG

N74215 002
 JAN 27, 1994

1MG

N74215 003
 JAN 27, 1994

2MG

N74215 004
 JAN 27, 1994

0.25MG

N74085 001
 FEB 16, 1994

0.5MG

N74085 002
 FEB 16, 1994

1MG

N74085 003
 FEB 16, 1994

0.25MG

N74294 001
 JUL 29, 1994

0.5MG

N74294 002
 JUL 29, 1994

ACETYLCHOLINE

SOLUTION; INHALATION, ORAL
 ACETYLCHOLINE
 AN ABBOTT 10%

10%

N73664 001
 AUG 30, 1994

20%

N74037 001
 AUG 30, 1994

ZENITH LABS

N74085 003
 FEB 16, 1994

N74294 002
 JUL 29, 1994

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM
ZENITH LABS

AB 1MG
AB 2MG

N74294 003
JUL 29, 1994
N74294 004
JUL 29, 1994

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKACIN
BEDFORD

AP EQ 50MG BASE/ML
AP EQ 250MG BASE/ML
AP EQ 50MG BASE/ML
AP EQ 50MG BASE/ML
AP + EQ 50MG BASE/ML
AP EQ 250MG BASE/ML
AP + EQ 250MG BASE/ML

N63313 001
APR 11, 1994
N63315 001
APR 11, 1994
N63274 001
MAY 18, 1992
N63274 001
MAY 18, 1992
N63275 001
MAY 18, 1992
N63275 001
MAY 18, 1992

AMIKIN
@ APOTHECON

AP *
AP *
AP *

EQ 50MG BASE/ML
EQ 250MG BASE/ML
EQ 50MG BASE/ML
EQ 50MG BASE/ML
EQ 250MG BASE/ML
EQ 250MG BASE/ML
EQ 50MG BASE/ML
EQ 250MG BASE/ML
SEP 20, 1984
N50495 002
N62562 002
SEP 20, 1984
N62562 001
SEP 20, 1984
N62562 002
SEP 20, 1984

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER
ABBOTT

@
N19565 001
DEC 17, 1986
N19565 001
DEC 17, 1986
5%; 25GM/100ML
5%; 25GM/100ML

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE
FUJISAWA

AP 25MG/ML
@ 25MG/ML

N87886 001
AUG 30, 1983
N87886 001
AUG 30, 1983
N86606 001
N86606 001

AP KING PHARMS
AP SMITHKLINE BEECHAM

25MG/ML
25MG/ML

TABLET; ORAL

AMINOPHYLLINE
GLOBAL PHARMS

AB 100MG
AB 200MG
BD 100MG
BD 200MG
@ 100MG
@ 200MG
BD 100MG
BD 200MG
BD 100MG
BD 200MG

N84574 001
N84576 001
N84588 001
N84588 002
N84588 001
N84588 002
N84574 001
N84576 001

AMINOSALICYLIC ACID

GRANULE, DELAYED RELEASE; ORAL

PASER
+ JACOBUS

N74346 001
JUN 30, 1994

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL
LEMMON

AB 10MG
AB 25MG
AB 50MG
AB 75MG
AB 100MG
AB 150MG
@ 10MG
@ 25MG
@ 50MG
@ 75MG
@ 100MG
@ 150MG

N86610 001
N86859 001
N86857 001
N86860 001
N86854 001
N86853 001
N86610 001
N86859 001
N86857 001
N86860 001
N86854 001
N86853 001

ATENOLOL

TABLET; ORAL
ATENOLOL
INVADED

100MG

N74265 001
FEB 28, 1994

BENZYL BENZOATE

EMULSION; TOPICAL
BENZYL BENZOATE
* LANNETT
@

50%
50%

N84535 001
N84535 001

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

LOFENE
LANNETT
@

0.025MG; 2.5MG
0.025MG; 2.5MG

N85372 001
N85372 001

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL

DIPROLENE
* SCHERING

EQ 0.05% BASE

N19408 001
JAN 31, 1986
N19408 001
JAN 31, 1986

@

EQ 0.05% BASE

AZITHROMYCIN DIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
ZITHROMAX
+ PFIZER

N50693 001
SEP 28, 1994

GEL; TOPICAL
DIPROLENE
+ SCHERING

N19408 002
NOV 22, 1991

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE
TARO PHARMS

EQ 0.05% BASE

N74272 001
SEP 30, 1994

ointment; OPHTHALMIC

BACITRACIN

@ PHARMADERM

@ PHARMAFAIR

500 UNITS/GM
500 UNITS/GM
500 UNITS/GM
500 UNITS/GM

N62158 001
N62158 001
N62453 001
MAR 28, 1984
N62453 001
MAR 28, 1984

ointment; TOPICAL
BETAMETHASONE DIPROPIONATE
TARO PHARMS

EQ 0.05% BASE

N74271 001
SEP 15, 1994

BACLOFEN

TABLET; ORAL

BACLOFEN

ROYCE LABS

10MG

N73092 001
JAN 28, 1994

20MG

N73093 001
JAN 28, 1994

ointment; TOPICAL

BETAMETHASONE VALERATE

CLAY PARK

EQ 0.1% BASE

N71478 001
DEC 23, 1987

@

EQ 0.1% BASE

N71478 001
DEC 23, 1987

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

LANNETT

5MG
10MG

N84702 001
N84712 001

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE
LANNETT

AA 25MG
5MG
10MG
25MG

N84074 001
N84702 001
N84712 001
N84074 001

BR SUPPOSITORY; RECTAL
MIGERGOT
G AND W LABS 100MG; 2MG
N86557 001
OCT 04, 1983
BR MIGRAINE
ORGANON 100MG; 2MG
N86557 001
OCT 04, 1983

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE;
PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL
DIMETANE-DX
ROBINS AH

AA 2MG/5ML; 10MG/5ML; 30MG/5ML N11694 007
MAR 25, 1984

CAPSULE; ORAL
CALDEROL
ORGANON 0.02MG
+ 0.05MG
N18312 001
N18312 002

BUDESONIDE

AEROSOL, METERED; NASAL
RHINOCORT
+ ASTRA

0.05MG/INH
N20233 001
FEB 14, 1994

CALCIFEDIOL, ANHYDROUS

CAPSULE, ORAL
CALDEROL
ORGANON

0.02MG
0.05MG
N18312 001
N18312 002

BUTABARBITAL SODIUM

ELIXIR; ORAL
BUTALAN
LANNETT

33.3MG/5ML
33.3MG/5ML

N85880 001
N85880 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE;
SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELFLX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN
PLASTIC CONTAINER

AT FRESNIUS

18.4MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N20171 001
AUG 19, 1992

DELFLX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN
PLASTIC CONTAINER

AT FRESNIUS

18.4MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N20171 002
AUG 19, 1992

DELFLX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN
PLASTIC CONTAINER

AT FRESNIUS

18.4MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N20171 003
AUG 19, 1992

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE;
SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
BAXTER
18.3MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20183 001
DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
BAXTER
18.3MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20183 002
DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
BAXTER
18.3MG/100ML; 3.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20183 003
DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
BAXTER
18.3MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20183 004
DEC 04, 1992

DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
BAXTER
18.3MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N17512 004
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
ABBOTT
18.4MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20374 001
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
ABBOTT
18.3MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20374 002
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
ABBOTT
18.3MG/100ML; 3.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20374 003
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
ABBOTT
18.4MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML N20374 004
JUN 13, 1994

CARBACHOL

INJECTABLE; INJECTION

CARBACHOL
@ PHARMAFAIR 0.01% N70292 001
MAY 21, 1986
MIOSTAT
* ALCON 0.01% N16368 001

SOLUTION; INTRAOCULAR

CARBACHOL
@ PHARMAFAIR 0.01% N70292 001
MAY 21, 1986
MIOSTAT
+ ALCON 0.01% N16368 001

CARBAMAZEPINE

SUSPENSION; ORAL
TEGRETOL
+ BASEL PHARMS 100MG/5ML N18927 001
DEC 18, 1987
* GEIGY 100MG/5ML N18927 001
DEC 18, 1987

TABLET; ORAL

TEGRETOL
AB + BASEL PHARMS 200MG N16608 001
AB * GEIGY 200MG N16608 001

TABLET; CHEWABLE; ORAL

TEGRETOL
AB + BASEL PHARMS 100MG N18281 001
AB * GEIGY 100MG N18281 001

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA
SCS 10MG; 100MG N74080 001
MAR 25, 1994
25MG; 100MG N74080 002
MAR 25, 1994
25MG; 250MG N74080 003
MAR 25, 1994

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
SINEMET CR
MERCK SHARP DOHME 25MG;100MG

N19856 002
DEC 24, 1992

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
CEFADROXIL
APOTHECON
ZENITH LABS

AB EQ 500MG BASE
AB EQ 500MG BASE
AB EQ 500MG BASE

N62291 001
N62766 001
MAR 03, 1987
N62766 001
MAR 03, 1987

AB ULTRACEF
BRISTOL

EQ 500MG BASE

N62291 001

POWDER FOR RECONSTITUTION; ORAL

CEFADROXIL
APOTHECON

AB EQ 125MG BASE/5ML
AB EQ 250MG BASE/5ML
AB EQ 500MG BASE/5ML
AB EQ 125MG BASE/5ML
AB EQ 250MG BASE/5ML
AB EQ 500MG BASE/5ML

N62334 001
N62334 002
N62334 003
N62334 001
N62334 002
N62334 003

TABLET; ORAL
CEFADROXIL
ZENITH LABS

AB EQ 1GM BASE
EQ 1GM BASE

N62774 001
APR 08, 1987
N62774 001
APR 08, 1987

AB ULTRACEF
APOTHECON
BRISTOL

AB EQ 1GM BASE
EQ 1GM BASE

N62390 001
JUN 10, 1982
N62390 001
JUN 10, 1982

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM
FUJISAWA

EQ 500MG BASE/VIAL

N62688 002
NOV 17, 1986

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM
FUJISAWA

EQ 1GM BASE/VIAL

N62688 003
NOV 17, 1986

EQ 10GM BASE/VIAL

N62688 004
NOV 17, 1986

EQ 20GM BASE/VIAL

N62688 005
AUG 03, 1987

EQ 500MG BASE/VIAL

N62688 002
NOV 17, 1986

EQ 1GM BASE/VIAL

N62688 003
NOV 17, 1986

EQ 10GM BASE/VIAL

N62688 004
NOV 17, 1986

EQ 20GM BASE/VIAL

N62688 005
AUG 03, 1987

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFTIZOX
FUJISAWA

EQ 1GM BASE/VIAL

N63294 002
MAR 31, 1994

EQ 2GM BASE/VIAL

N63294 003
MAR 31, 1994

CEFUROXIME AXETIL

POWDER FOR RECONSTITUTION; ORAL
CEFTIN
+ GLAXO

EQ 125MG BASE/5ML

N50672 001
JUN 30, 1994

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
SEFFIN
GLAXO

EQ 1GM BASE/VIAL

N62435 001
NOV 15, 1983

EQ 2GM BASE/VIAL

N62435 002
NOV 15, 1983

EQ 10GM BASE/VIAL

N62435 003
NOV 15, 1983

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

SEFFIN

@ GLAXO

@

EQ 1GM BASE/VIAL

N62435 001

NOV 15, 1983

EQ 2GM BASE/VIAL

N62435 002

NOV 15, 1983

EQ 10GM BASE/VIAL

N62435 003

NOV 15, 1983

CHLORAMPHENICOL

OINTMENT; OPHTHALMIC

CHLOROPAIR

@ PHARMACAIR

1%

@

1%

N62439 001

APR 21, 1983

N62439 001

APR 21, 1983

SOLUTION/DROPS; OPHTHALMIC

CHLOROPAIR

@ PHARMACAIR

0.5%

@

0.5%

N62437 001

APR 14, 1983

N62437 001

APR 14, 1983

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

PERIDEXAT + PROCTER AND GAMBLE

0.12%

PERIOGARDAT COLGATE PALMOLIVE

0.12%

CHLORMERODRIN, HG-197

INJECTABLE; INJECTION

CHLORMERODRIN HG 197

@ BRACCO DXS

@ SQUIBB

0.6-1.4mCi/ML

0.6-1.4mCi/ML

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATEAA

@ ZENITH

@ ZENITH LABS

4MG

4MG

N80779 001

N80779 001

CHLORTHALIDONE

TABLET; ORAL

THALITONE

HORUS THERAP

15MG

15MG

N19574 001

DEC 20, 1988

N19574 001

DEC 20, 1988

CHOLESTYRAMINE

TABLET; ORAL

QUESTRAN

+ BRISTOL MYERS SQUIBB EQ 1GM RESIN

N73403 001

APR 28, 1994

CIMETIDINE

TABLET; ORAL

CIMETIDINE

ENDO LABS

200MG

N74281 001

MAY 17, 1994

300MG

N74281 002

MAY 17, 1994

400MG

N74281 003

MAY 17, 1994

800MG

N74329 001

MAY 17, 1994

200MG

N74246 001

MAY 17, 1994

300MG

N74246 002

MAY 17, 1994

400MG

N74246 003

MAY 17, 1994

800MG

N74246 004

MAY 17, 1994

200MG

N74151 001

MAY 17, 1994

CIMETIDINE

TABLET; ORAL
CIMETIDINE
NOVOPHARM

AB	300MG	N74151 002	
		MAY 17, 1994	
AB	400MG	N74151 003	
		MAY 17, 1994	
AB	800MG	N74463 001	
		MAY 17, 1994	
AB	200MG	N17920 002	
		MAY 17, 1994	
AB	300MG	N17920 003	
		MAY 17, 1994	
AB	400MG	N17920 004	
		DEC 14, 1983	
AB	800MG	N17920 005	
		APR 30, 1986	

TAGAMET
SMITHKLINE BEECHAM

AB	200MG	N17920 002	
		MAY 17, 1994	
AB	300MG	N17920 003	
		MAY 17, 1994	
AB	400MG	N17920 004	
		DEC 14, 1983	
AB	800MG	N17920 005	
		APR 30, 1986	

AB +

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

AP	EQ 300MG BASE/2ML	N74005 001	
		AUG 31, 1994	

AP

TAGAMET
SMITHKLINE BEECHAM

AP	EQ 300MG BASE/2ML	N17939 002	
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SOLUTION; ORAL

CIMETIDINE HCL

AA	EQ 300MG BASE/5ML	N74176 001	
		JUN 01, 1994	

AA

TAGAMET
SMITHKLINE BEECHAM

AA	EQ 300MG BASE/5ML	N17924 001	
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CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE
LEMMON

AA	EQ 0.5MG BASE/5ML	N73399 001	
		JUN 30, 1994	

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	EQ 150MG BASE/ML	N63163 001	
		JUN 30, 1994	

AP

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	EQ 150MG BASE/ML	N62908 001	
		FEB 01, 1989	
AP	EQ 150MG BASE/ML	N62908 001	
		FEB 01, 1989	
AP	EQ 150MG BASE/ML	N62747 001	
		JUN 03, 1988	
AP	EQ 150MG BASE/ML	N62747 001	
		JUN 03, 1988	

SOLUTION; TOPICAL

CLEOCIN

UPJOHN

EQ 1% BASE

N50537 002

FEB 22, 1994

CLOBETASOL PROPIONATE

CREAM; TOPICAL

CLOBETASOL PROPIONATE
COPLEY PHARM

AB	0.05%	N74087 001	
		FEB 16, 1994	
AB	0.05%	N74139 001	
		AUG 03, 1994	

AB

TEMOVATE

+ GLAXO

AB	0.05%	N19322 001	
		DEC 27, 1985	
AB	0.05%	N20340 001	
		JUN 17, 1994	

AB

GEL; TOPICAL

TEMOVATE

+ GLAXO

N20337 001

APR 29, 1994

ointment; TOPICAL

CLOBETASOL PROPIONATE
COPLEY PHARM

AB	0.05%	N74089 001	
		FEB 16, 1994	
AB	0.05%	N74128 001	
		AUG 03, 1994	

AB

TEMOVATE

+ GLAXO

N19323 001

DEC 27, 1985

CLOMIPRAMINE HYDROCHLORIDE

capsule; oral
ANAFRANIL
BASEL PHARMS

25MG

N19906 001
DEC 29, 1989

50MG

N19906 002
DEC 29, 1989

75MG

N19906 003
DEC 29, 1989

25MG

N19906 001
DEC 29, 1989

50MG

N19906 002
DEC 29, 1989

75MG

N19906 003
DEC 29, 1989

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE VC W/ CODEINE

10MG/5ML; 5MG/5ML;
6.25MG/5ML

PENNEX

N88896 001
JAN 04, 1985

@ PENNEX PHARMS

10MG/5ML; 5MG/5ML;
6.25MG/5ML

N88896 001
JAN 04, 1985

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE W/ CODEINE

10MG/5ML; 6.25MG/5ML

PENNEX

10MG/5ML; 6.25MG/5ML

N88875 001
DEC 17, 1984

N88875 001
DEC 17, 1984

COLESTIPOL HYDROCHLORIDE

TABLET; ORAL

COLESTID

UPJOHN

1GM

N20222 001
JUL 19, 1994

CORTISONE ACETATE

INJECTABLE; INJECTION

CORTISONE ACETATE

STERIS

25MG/ML

25MG/ML

50MG/ML

50MG/ML

25MG/ML

25MG/ML

50MG/ML

50MG/ML

25MG/ML

25MG/ML

25MG/ML

25MG/ML

25MG/ML

25MG/ML

TABLET; ORAL

CORTISONE ACETATE

INWOOD

@ INWOOD LABS

25MG

25MG

CROMOLYN SODIUM

SOLUTION; INHALATION

CROMOLYN SODIUM

AN DEY

AN INTAL

AN + Fisons

AN INTAL

AN + Fisons

CYANOCOBALAMIN, CO-57

CYANOCOBALAMIN, CO-57

CAPSULE; ORAL

RUBRATOPE-57

BRACCO DXS

SQUIBB

0.5-1 uCi

0.5-1 uCi

CYANOCOBALAMIN, CO-60

CYANOCOBALAMIN, CO-60

CAPSULE; ORAL

RUBRATOPE-60

@ BRACCO DXS

0.5-1 uCi

N83147 003

N85677 001

N83147 004

N85677 002

N83147 003

N85677 001

N83147 004

N85677 002

N88126 002

N08126 002

N07110 002

N07110 003

N07110 002

N07110 003

N80731 001

N80731 001

N74209 001
APR 26, 1994

N18596 001
MAY 28, 1982

N16089 002

N16089 002

N16090 002

CYANOCOBALAMIN, CO-60

CAPSULE; ORAL
RUBRATOPE-60
@ SQUIBB

0.5-1 uci

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOGYL

AT * ALCON 0.5%
+ 0.5%

PENTOLAIR

AT BAUSCH AND LOMB 1%

AT PHARMAFAIR 0.5%

AT 1%

@ 0.5%

@ 1%

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

AA CHELSEA 4MG
@ CHELSEA LABS 4MG

CYSTEAMINE BITARTRATE

CAPSULE; ORAL
CYSTRAGON
MYLAN

EQ 50MG BASE

EQ 150MG BASE

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

+ BULL D 20MG/ML

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

AP CETUS BEN VENUE 1GM/VIAL

AP 2GM/VIAL

CYTOSAR-U

AP + UPJOHN 1GM/VIAL

AP + 2GM/VIAL

DACTINOMYCIN

INJECTABLE; INJECTION

COSMEGEN

+ MERCK SHARP DOHME

* MSD

0.5MG/VIAL

0.5MG/VIAL

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

DESMOPRESSIN ACETATE

+ RHONE POULENC RORER 0.15MG/INH

DESONIDE

OINTMENT; TOPICAL

DESONIDE

TARO

AB 0.05%

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

DEXASPORIN

AT BAUSCH AND LOMB

0.1%; EQ 3.5MG BASE/GM;

10,000 UNITS/GM

N16090 002

N84109 001
N84109 001

N40075 001

APR 29, 1994

N88643 001

FEB 09, 1987

N88150 001

FEB 25, 1983

N88643 001

FEB 09, 1987

N88150 001

FEB 25, 1983

N86165 001

N86165 001

N20392 001

AUG 15, 1994

N20392 002

AUG 15, 1994

N72945 001

FEB 28, 1994

N74245 001
AUG 31, 1994

N74245 002
AUG 31, 1994

N16793 003
DEC 21, 1987

N16793 004
DEC 21, 1987

N50682 001
N60467 001

N20355 001
MAR 07, 1994

N74254 001
AUG 03, 1994

N64063 001
JUL 25, 1994

DEXAMETHASONE SODIUM PHOSPHATE

AEROSOL; NASAL

DECADRON

* MSD

DEXACORT

+ MEDEVA

EQ 0.1MG PHOSPHATE/INH

N14242 001

EQ 0.1MG PHOSPHATE/INH

N14242 001

AEROSOL, METERED; INHALATION

DECADRON

* MSD

DEXACORT

+ MEDEVA

EQ 0.1MG PHOSPHATE/INH

N13413 001

EQ 0.1MG PHOSPHATE/INH

N13413 001

SOLUTION/DROPS; OPHTHALMIC

DEXAIR

PHARMAFAIR

@

EQ 0.1% PHOSPHATE

N88433 001

EQ 0.1% PHOSPHATE

DEC 15, 1983

DEXTROAMPHETAMINE SULFATE

ELIXIR; ORAL

DEADDRINE

* SMITHKLINE BEECHAM

@

5MG/5ML

N83902 001

5MG/5ML

N83902 001

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

LANNETT

@

5MG

N83903 001

10MG

15MG

5MG

10MG

15MG

N83903 001

N83903 003

N85652 001

N83903 001

N83903 003

N85652 001

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE W/ DEXTROMETHORPHAN

PENNEX

@

15MG/5ML; 6.25MG/5ML

N88864 001

15MG/5ML; 6.25MG/5ML

JAN 04, 1985

N88864 001

JAN 04, 1985

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

AP

MCRAW

50MG/ML

N16730 002

DEXTROTHYROXINE SODIUM

TABLET; ORAL

CHOLIXIN

BOOTS

*

+

@

4MG

8MG

4MG

6MG

N12302 004

N12302 006

N12302 004

N12302 006

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

CARDIOGRAFIN

@ BRACCO DXS

@ SQUIBB

85%

N11620 002

N11620 002

DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINE

SOLUTION; INTRAUTERINE

SINOGRAFIN

BRACCO DXS

SQUIBB

52.7%; 26.8%

N11324 002

N11324 002

DICLOXACILLIN SODIUM

CAPSULE; ORAL

DYNAPEN

APOTHECON

EQ 500MG BASE

N61454 003

DICUMAROL

TABLET; ORAL

DICUMAROL

ABBOTT

+

25MG

N05545 003

N05545 003

DIENESTROL

CREAM; VAGINAL

ESTRAGUARD

SOLVAX

0.01%
0.01%

N84436 001
N84436 001

N74084 001
FEB 25, 1994
N74084 002
FEB 25, 1994

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

TEPANIL

3M

25MG
25MG

N11673 001
N11673 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

LANNETT

25MG
50MG
25MG
50MG
50MG
50MG

N80868 001
N80868 002
N80868 001
N80868 002
N80635 001
N80635 001

DIETHYLSTILBESTROL

TABLET; ORAL

DIETHYLSTILBESTROL

LILLY

1MG
5MG
1MG
5MG

N04041 004
N04041 005
N04041 004
N04041 005

+ STILBESTROL

TABLICAPS

1MG
5MG
1MG
5MG

N83002 001
N83006 001
N83002 001
N83006 001

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

DIPIVEFRIN HCL

ALCON

0.1%

N73636 001
JUN 30, 1994

AT

PROPINE

AT + ALLERGAN

0.1%

N18239 001

TABLET, DELAYED RELEASE; ORAL

STILBESTROL

TABLICAPS

0.5MG
1MG
5MG
0.5MG
1MG
5MG

N83003 001
N83005 001
N83007 001
N83003 001
N83005 001
N83007 001

DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT

EQ 400MG BASE/100ML

AP

AP + BAXTER

N20201 006
JUL 07, 1994
N20255 005
OCT 19, 1993

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

+ GENDERM

5%

N20126 001
APR 01, 1994

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

ORTHO-NOVUM 7/14-21

© JOHNSON RW

0.035MG, 0.035MG; 0.5MG, 1MG N19004 001
APR 04, 1984

TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

WATSON

0.035MG, 0.035MG; 0.5MG, 1MG N1042 001
SEP 24, 1991

AB WATSON LABS

0.035MG, 0.035MG; 0.5MG, 1MG N71042 001
SEP 24, 1991

AB ORTHO-NOVUM 7/14-28

© JOHNSON RW

0.035MG, 0.035MG; 0.5MG, 1MG N19004 002
APR 04, 19840.035MG, 0.035MG; 0.5MG, 1MG N19004 002
APR 04, 1984ETODOLAC

TABLET; ORAL

LODINE

+ WYETH AVERST

400MG

N18922 004
JUL 29, 1993ETOPOSIDE

INJECTABLE; INJECTION

ETOPOSIDE

AP GENSLA

20MG/ML

N74284 001
FEB 10, 1994

AP VEPESID

+ BRISTOL

20MG/ML

N18768 001
NOV 10, 1983FAMCICLOVIR

TABLET; ORAL

FAMVIR

+ SMITHKLINE BEECHAM

500MG

N20363 002
JUN 29, 1994FAMOTIDINE

INJECTABLE; INJECTION

PEPCID IN PLASTIC CONTAINER

+ MERCK

0.4MG/ML

N20249 001
FEB 18, 1994FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

PLENDIL

+ ASTRA MERCK

2.5MG

N19834 004
SEP 22, 1994

N19834 001

JUL 25, 1991

N19834 002

JUL 25, 1991

N19834 001

JUL 25, 1991

N19834 002

JUL 25, 1991

N19834 002

JUL 25, 1991

FLUCONAZOLE

TABLET; ORAL

DIFLUCAN

* PFIZER

50MG

N19949 001

JAN 29, 1990

N19949 002

JAN 29, 1990

N19949 001

JAN 29, 1990

N19949 002

JAN 29, 1990

N20322 001

JUN 30, 1994

FLUDEOXYGLUCOSE, F-18

INJECTABLE; INJECTION

FLUDEOXYGLUCOSE F 18

+ DOWNSTATE CLINCL

6.8-35.7mCi/ML

N20306 001
AUG 19, 1994

FLURBIPROFEN

TABLET; ORAL

FLURBIPROFENAB

MYLAN

100MGN74358 002
JUN 20, 1994AT
AT

+ SCHERING

EQ 0.1% BASE
EQ 1MG BASE/GMN60462 001
N60462 001FOLIC ACID

TABLET; ORAL

FOLIC ACIDAA

LANBETT

1MG

N80816 001

AT

CLAY PARK

EQ 0.1% BASE
EQ 1MG BASE/GMN62307 001
N62307 001AA

PUREPAC

1MG

N80784 001

AT

GENTAMICIN SULFATE

EQ 0.1% BASE
EQ 1MG BASE/GMN62458 001
N62458 001AA

PUREPAC PHARM

1MG

N80784 001

AT

BAUSCH AND LOMB

EQ 0.1% BASE
EQ 1MG BASE/GMN64056 001
APR 29, 1994FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDEAP

MARSAM

10MG/MLN74017 001
JUN 30, 1994AT

NMC

EQ 0.1% BASE
EQ 1MG BASE/GMN62471 001
SEP 27, 1983AP

ORGANON

10MG/MLN70017 001
DEC 15, 1986AT

THAMES

EQ 0.1% BASE
EQ 1MG BASE/GMN62427 001
MAY 26, 1983AA

WARNER CHILCOTT

10MG/MLN18420 001
FEB 26, 1982AT

THAMES

EQ 0.1% BASE
EQ 1MG BASE/GMN62427 001
MAY 26, 1983AA

WARNER CHILCOTT

10MG/MLN18420 001
FEB 26, 1982AT

INJECTABLE; INJECTION

EQ 0.1% BASE
EQ 1MG BASE/GMN62427 001
MAY 26, 1983GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

GALLIUM CITRATE GA 67BS

DUPONT

2mCi/ML

N17478 001

AT

+ SCHERING

EQ 2MG BASE/ML

N50505 001

BS

DUPONT MERCK

2mCi/ML

N17478 001

AT

+ SCHERING

EQ 2MG BASE/ML

N50505 001

GEMFIBROZIL

TABLET; ORAL

GEMFIBROZILAB

PUREPAC PHARM

600MGN74360 001
AUG 31, 1994AT

+ SCHERING

EQ 0.3% BASE
EQ 3MG BASE/GMN50425 001
N50425 001AT

IOLAB

EQ 0.3% BASEN62501 001
JUL 26, 1984AT

+ SCHERING

EQ 0.3% BASE
EQ 3MG BASE/GMN62501 001
JUL 26, 1984

GENTAMICIN SULFATE

OINTMENT; OPHTHALMIC

GENTACIDIN
IOLAB

EQ 3MG BASE/GM

N62501 001
 JUL 26, 1984

EQ 3MG BASE/ML

N62452 001
 OCT 10, 1984

OINTMENT; TOPICAL

GARAMYCIN
 + SCHERING

EQ 0.1% BASE
EQ 1MG BASE/GM

N60463 001
 N60463 001

EQ 0.3% BASE

N62480 001
 MAR 30, 1984

GENTAFAIR
PHARMAFAIR

EQ 0.1% BASE
EQ 0.1% BASE

N62444 001
 MAY 26, 1983
 N62444 001
 MAY 26, 1983

EQ 0.3% BASE

N62440 001
 MAY 03, 1983

@

GENTAMICIN
CLAY PARK

EQ 0.1% BASE
EQ 1MG BASE/GM

N62351 001
 FEB 18, 1982
 N62351 001
 FEB 18, 1982

EQ 0.3% BASE

N62635 001
 JAN 08, 1987

GENTAMICIN SULFATE

BAUSCH AND LOMB

EQ 0.1% BASE
EQ 0.1% BASE

N64054 001
 APR 29, 1994
 N62533 001
 OCT 05, 1984

EQ 3MG BASE/ML

N62635 001
 JAN 08, 1987

FOUGERA

EQ 1MG BASE/GM

N62533 001
 OCT 05, 1984

EQ 0.3% BASE

N64048 001
 MAY 11, 1994

NMC

EQ 0.1% BASE

N62496 001

EQ 0.3% BASE

N62523 001
 NOV 25, 1985

AT

EQ 1MG BASE/GM

MAR 14, 1984

EQ 3MG BASE/ML

N62523 001
 NOV 25, 1985

PHARMADERM

EQ 0.1% BASE

N62534 001

5MG

N74226 001
 MAY 10, 1994

AT

EQ 1MG BASE/GM

OCT 10, 1984

10MG

N74226 002
 MAY 10, 1994

AT

EQ 0.1% BASE

DEC 23, 1983

GLUCOTROL
PFIZER

5MG

N17783 001
 MAY 08, 1984

AT

EQ 1MG BASE/GM

DEC 23, 1983

10MG

N17783 002
 MAY 08, 1984

SOLUTION/DROPS; OPHTHALMIC

GARAMYCIN
 + SCHERING

EQ 0.3% BASE
EQ 3MG BASE/ML

N50039 002
 N50039 002

TABLET, EXTENDED RELEASE; ORAL
 GLUCOTROL XL

5MG

N20329 001
 APR 26, 1994

GENOPTIC
ALLERGAN

EQ 0.3% BASE

N62452 001
 OCT 10, 1984

10MG

N20329 002
 APR 26, 1994

GLUTETHIMIDETABLET; ORALGLUTETHIMIDEAAHALISEY250MG

N89458 001

OCT 10, 1986

250MG

N89458 001

AALANNETT250MG

N83475 001

OCT 10, 1986

500MG

N85571 001

N83475 001

N85571 001

@

@

GLYCOPYRROLATEINJECTABLE; INJECTIONGLYCOPYRROLATEAPFUJISAWA0.2MG/ML

N88475 001

JUN 12, 1984

0.2MG/ML

N88475 001

JUN 12, 1984

@

GONADOTROPIN, CHORIONICINJECTABLE; INJECTIONA.P.L.* WYETH AYERSTAP

> DLT >

> ADD >

+

CHORIONIC GONADOTROPINAPFUJISAWA5,000 UNITS/VIAL

N17055 003

20,000 UNITS/VIAL

N17055 003

5,000 UNITS/VIAL

N17067 001

20,000 UNITS/VIAL

N17067 003

20,000 UNITS/VIAL

N17067 003

20,000 UNITS/VIAL

N17016 004

15,000 UNITS/VIAL

N17016 010

15,000 UNITS/VIAL

FEB 15, 1985

15,000 UNITS/VIAL

N17016 010

20,000 UNITS/VIAL

FEB 15, 1985

20,000 UNITS/VIAL

N17016 004

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATESOLUTION/DROPS; OPHTHALMICNEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDINATPHARMAFAIR0.025MG/ML; EQ 1.75MG BASE/ML;

N62383 001

AUG 31, 1982

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATESOLUTION/DROPS; OPHTHALMICNEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN

@ PHARMAFAIR

0.025MG/ML; EQ 1.75MG BASE/ML;

N62383 001

AUG 31, 1982

GRANISETRON HYDROCHLORIDEINJECTABLE; INJECTION

KYTRIL

* SMITHKLINE BEECHAM

EQ 3MG BASE/ML

N20239 001

DEC 29, 1993

+

EQ 1MG BASE/ML

N20239 002

MAR 11, 1994

@

EQ 3MG BASE/ML

N20239 001

DEC 29, 1993

GUANABENZ ACETATETABLET; ORALGUANABENZ ACETATE

COPLEY PHARM

ABEQ 4MG BASE

N74267 001

JUN 01, 1994

ABEQ 8MG BASE

N74267 002

JUN 01, 1994

ABEQ 4MG BASE

N74025 001

FEB 28, 1994

ABEQ 8MG BASE

N74025 002

FEB 28, 1994

WYTENSIN

WYETH AYERST

ABEQ 4MG BASE

N18587 001

SEP 07, 1982

ABEQ 8MG BASE

N18587 002

SEP 07, 1982

HEPARIN CALCIUMINJECTABLE; INJECTION

CALCIPARINE

+ CHOAY

* DUPONT

25,000 UNITS/ML

25,000 UNITS/ML

N18237 001

N18237 001

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL
ANIDE PHARM

> DLT >
> DLT >
> DLT >
> DLT >
> ADD >
> ADD >
> ADD >
> ADD >

N88560 001
OCT 04, 1984
N88649 001
OCT 18, 1984
N88560 001
OCT 04, 1984
N88649 001
OCT 18, 1984

25MG
50MG
25MG
50MG

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

RESERPINE, HYDRALAZINE
DANBURY PHARMA

BP
N87556 001
N87556 001

25MG
25MG;15MG;0.1MG
25MG;15MG;0.1MG

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE
WEST WARD

> DLT >
> ADD >
> DLT >
> ADD >

N84899 001
N84899 001
N84858 001
N84658 001

25MG
25MG
50MG
50MG

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL
NORMOZIDE
SCHERING

*
@
@
@

25MG;100MG
25MG;200MG
25MG;300MG
25MG;100MG
25MG;200MG
25MG;300MG

N19046 001
APR 06, 1987
N19046 002
APR 06, 1987
N19046 003
APR 06, 1987
N19046 001
APR 06, 1987
N19046 002
APR 06, 1987
N19046 003
APR 06, 1987

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDROCHLOROTHIAZIDE W/ RESERPINE
ROXANE

BP
N84603 001
N84603 001

50MG;0.125MG
50MG;0.125MG

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

DIAZIDE
* SMITHKLINE BEECHAM

N16042 002
N16042 003
MAR 03, 1994
N16042 002

25MG;50MG
25MG;37.5MG

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

GENEVA PHARMS

AB
N73191 001
JUL 31, 1991
N73191 001
JUL 31, 1991

25MG;50MG
25MG;50MG

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
LEMON

AT
N85191 001
N85191 001
N87838 001
JUL 28, 1982
N87838 001
JUL 28, 1982

1%
1%
1%
1%

ENEMA; RECTAL
CORTENEMA
+ SOLVAY

AT
N16199 001
N74171 001
MAY 27, 1994

100MG/60ML
100MG/60ML

GEL; TOPICAL
NUTRACORT
* GALDERMA

AT
N84698 001
N84698 001
N8215 001
JUN 06, 1984

1%
1%
1%

AT
PENECORT
ALLERGAN HERBERT

HYDROCORTISONEGEL; TOPICAL
PENECORT
+ ALLERGAN HERBERT

1%

N88215 001
JUN 06, 1984

LOTION; TOPICAL

HYDROCORTISONE
CLAY PARK

1%

N85663 001
N85663 001

OINTMENT; TOPICAL

HYDROCORTISONE
CLAY PARK

1%

N85028 001
N85028 001

TABLET; ORAL

HYDROCORTISONE
DANEURY PHARMA

20MG

N80355 001

20MG

N80355 001

20MG

N80732 001

20MG

N80732 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE
PHARMAFAIR1%;EQ 3.5MG BASE/ML;
10,000 UNITS/MLN62394 001
SEP 29, 19821%;EQ 3.5MG BASE/ML;
10,000 UNITS/MLN62394 001
SEP 29, 1982

SUSPENSION; OTIC

OTICAIR
PHARMAFAIR1%;EQ 3.5MG BASE/ML;
10,000 UNITS/MLN62399 001
NOV 18, 19821%;EQ 3.5MG BASE/ML;
10,000 UNITS/MLN62399 001
NOV 18, 1982HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE
PARK DAVIS

1%

N89914 001
JAN 03, 1989
N89914 001
JAN 03, 1989

INJECTABLE; INJECTION

HYDROCORTISONE ACETATE
STERIS50MG/ML
50MG/MLN85214 001
N85214 001HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

LOCOID

* BROCADES PHARMA

0.1%

N18514 001

+ YAMANOUCHI

0.1%

N18514 001
MAR 31, 1982

OINTMENT; TOPICAL

LOCOID

* BROCADES PHARMA

0.1%

N18652 001

+ YAMANOUCHI

0.1%

N18652 001
OCT 29, 1982

SOLUTION; TOPICAL

LOCOID

* BROCADES PHARMA

0.1%

N19116 001

+ YAMANOUCHI

0.1%

N19116 001
FEB 25, 1987HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-HYDROCORT
ABBOTT

EQ 250MG BASE/VIAL

N89578 001

EQ 500MG BASE/VIAL

N89579 001

EQ 1GM BASE/VIAL

N89580 001

INDOMETHACIN

CAPSULE; ORAL

AB INDOMETHACIN

CHELSEA

50MGN18690 002
JUL 31, 1984

@ CHELSEA LABS

25MG

N18690 001

50MG

JUL 31, 1984

@

N18690 002
JUL 31, 1984INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION

HUMULIN R

+ LILLY

500 UNITS/ML

N18780 004
MAR 31, 1994INVERT SUGAR

INJECTABLE; INJECTION

TFAVERT 10% IN PLASTIC CONTAINER

10GM/100ML
10GM/100ML

BAYER

@

N16717 001
N16717 001IOBENGUANE SULFATE I 131

INJECTABLE; INJECTION

IOBENGUANE SULFATE I 131

CIS

2.3mCi/ML

N20084 001
MAR 25, 1994IODAMIDE MEGLUMINE

INJECTABLE; INJECTION

RENOVUE-65

+ BRACCO DXS

* SQUIBB

65%

65%

IODIPAMIDE MEGLUMINE

INJECTABLE; INJECTION

CHOLOGRAFIN MEGLUMINE

+ BRACCO DXS

10.3%

N09321 007

IODIPAMIDE MEGLUMINE

INJECTABLE; INJECTION

CHOLOGRAFIN MEGLUMINE

+ BRACCO DXS

* SQUIBB

52%

10.3%

52%

N09321 003
N09321 007
N09321 003IODIPAMIDE SODIUM

INJECTABLE; INJECTION

CHOLOGRAFIN SODIUM

@ BRACCO DXS

@ SQUIBB

20%

20%

N09321 001
N09321 001IODOHIPPURATE SODIUM, I-123

INJECTABLE; INJECTION

NEPHROFLOW

MEDI PHYSICS

1mCi/ML

N18389 001
DEC 28, 1984
N18289 001
DEC 28, 1984

@

1mCi/ML

IODOXAMATE MEGLUMINE

INJECTABLE; INJECTION

CHOLOVUE

@ BRACCO DXS

@ SQUIBB

9.9%

40.3%

9.9%

40.3%

N18077 001
N18076 001
N18077 001
N18076 001IOHEXOL

SOLUTION; URETHRAL

OMNIPAQUE 70

+ STERLING WINTHROP

15.1%

N17902 001

N17902 001

N18956 007
JUN 01, 1994IPODATE CALCIUM

GRANULE; ORAL

ORAGRAFIN CALCIUM

BRACCO DXS

3GM/PACKET

N12968 001

IPODATE CALCIUM

GRANULE; ORAL
ORAGRAFIN CALCIUM
SQUIBB

3GM/PACKET

N12968 001

IPODATE SODIUM

CAPSULE; ORAL

ORAGRAFIN SODIUM

AA BRACCO DXS
AA SQUIBB

500MG
500MG

N12967 001
N12967 001

ISOFLURANE

LIQUID; INHALATION
ISOFLURANE
INHALON

99.9%

N74416 001
SEP 30, 1994

ISONIAZID; PYRAZINAMIDE; RIFAMPIN

TABLET; ORAL

RIFATER

+ MARION MERRELL DOW 50MG; 300MG; 120MG

N50705 001
MAY 31, 1994

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION
ISUPREL

* STERLING WINTHROP 0.113MG/INH
+ 0.131MG/INH

N11178 001
N11178 001

ISOSORBIDE MONONITRATE

TABLET; ORAL

ISMO

AB + WYETH

20MG

N19091 001
DEC 30, 1991

BX *

20MG

N19091 001
DEC 30, 1991

MONOKET

SCHWARZ PHARMA

20MG

N20215 001
JUN 30, 1993

ISOSORBIDE MONONITRATE

TABLET; ORAL

MONOKET

BX SCHWARZ PHARMA

20MG

N20215 001
JUN 30, 1993

ISRADIPINE

CAPSULE; ORAL

DYNACIRC

SANDOZ

5MG

N19546 002
DEC 20, 1990

+

5MG

N19546 002
DEC 20, 1990

TABLET, EXTENDED RELEASE; ORAL

DYNACIRC CR

+ SANDOZ

5MG

N20336 001
JUN 01, 1994

+

10MG

N20336 002
JUN 01, 1994

KANAMYCIN SULFATE

CAPSULE; ORAL

KANTREX

* APOTHECON

EQ 500MG BASE
EQ 500MG BASE

N61911 001
MAR 06, 1987

@

@

+

EQ 500MG BASE
EQ 500MG BASE
EQ 500MG BASE

N60516 001
N61911 001
N62726 001

AB * BRISTOL

EQ 500MG BASE

MAR 06, 1987
N60516 001

INJECTABLE; INJECTION

KANTREX

* APOTHECON

EQ 75MG BASE/2ML
EQ 75MG BASE/2ML
EQ 75MG BASE/2ML
EQ 500MG BASE/2ML
EQ 500MG BASE/2ML
EQ 500MG BASE/2ML
EQ 1GM BASE/3ML
EQ 1GM BASE/3ML
EQ 1GM BASE/3ML

N61855 003
N61901 003
N61901 003
N61855 001
N61901 001
N61901 001
N61855 002
N61901 002
N61901 002

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANTREX

@ APOTHECON

EQ 75MG BASE/2ML

EQ 75MG BASE/2ML

EQ 500MG BASE/2ML

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

EQ 1GM BASE/3ML

BRISTOL

EQ 75MG BASE/2ML

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

APAPAPKLEBCIL

@ KING PHARMS

EQ 75MG BASE/2ML

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

EQ 75MG BASE/2ML

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

@ SMITHKLINE BEECHAM

@

@

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

@ ELKINS SINN

EQ 100MG BASE/VIAL

EQ 3MG BASE/ML

EQ 3MG BASE/ML

AP

* IMMUNEX

@

LEVONORDEFRIN

SOLUTION/DROPS; OPHTHALMIC

BETAGAN

AT + ALLERGAN

0.25%

AT +

0.5%

LEVONORDEFRIN HCL

BAUSCH AND LOMB

0.25%

ATLEVONORDEFRIN

SOLUTION/DROPS; OPHTHALMIC

LEVONORDEFRIN HCL

BAUSCH AND LOMB

0.5%

N61655 003

N62564 001

SEP 21, 1984

N61655 001

N62564 002

SEP 21, 1984

N61655 002

N62564 003

SEP 21, 1984

N62564 001

SEP 21, 1984

N62564 002

SEP 21, 1984

N62564 003

SEP 21, 1984

N62170 001

N62170 002

N62170 003

N62170 001

N62170 002

N62170 003

N74326 001
MAR 04, 1994N85010 001
N85010 001N87881 001
NOV 18, 1982
N87881 001
NOV 18, 1982N88572 001
JUL 31, 1984
N88572 001
JUL 31, 1984N16680 001
N16680 001N16680 002
N16680 002N16680 003
N16680 003N16680 004
N16680 004LIOTRIX (T4.T3)

TABLET; ORAL

EUTHROID-0.5

PARKE DAVIS

@

EUTHROID-1

PARKE DAVIS

@

EUTHROID-2

PARKE DAVIS

@

EUTHROID-3

PARKE DAVIS

* @

0.03MG; 0.0075MG
0.03MG; 0.0075MG0.06MG; 0.015MG
0.06MG; 0.015MG0.12MG; 0.03MG
0.12MG; 0.03MG0.18MG; 0.045MG
0.18MG; 0.045MG

LISINAPRIL

TABLET; ORAL
AB PRINIVIL
 MERCK

2.5MG

N19558 006
 JAN 28, 1994

AB ZESTRIL
 ZENECA

2.5MG

N19777 005
 APR 29, 1993

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL
 LITHOBID
 + CIBA

300MG
300MG

N18027 001
 N18027 001

LORAZEPAM

INJECTABLE; INJECTION

AP ATIVAN
AP + WYETH AYERST
AP + LORAZEPAM
 ABBOTT

2MG/ML

4MG/ML

2MG/ML

2MG/ML

4MG/ML

4MG/ML

2MG/ML

4MG/ML

2MG/ML

2MG/ML

4MG/ML

MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION
 DEPO-PROVERA
 UPJOHN

150MG/ML

150MG/ML

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
 HUMEGON
 ORGANON

75 IU/VIAL;75 IU/VIAL

150 IU/VIAL;150 IU/VIAL

75 IU/AMP;75 IU/AMP

150 IU/AMP;150 IU/AMP

TABLET; ORAL
AB LORAZEPAM
 WARNER CHILCOTT

1MG

N71038 001
 JAN 12, 1988

LORAZEPAM

TABLET; ORAL

AB LORAZEPAM
 WARNER CHILCOTT

2MG

@

1MG

@

2MG

N71039 001
 JAN 12, 1988
 N71038 001
 JAN 12, 1988
 N71039 001
 JAN 12, 1988

MAGNESIUM SULFATE

INJECTABLE; INJECTION
 MAGNESIUM SULFATE IN PLASTIC CONTAINER
 ABBOTT

4GM/100ML

80MG/ML

N20309 001
 JUN 24, 1994
 N20309 002
 JUN 24, 1994

N20246 001
 OCT 29, 1992
 N20246 001
 OCT 29, 1992

N20328 001
 SEP 01, 1994
 N20328 002
 SEP 01, 1994

N17646 001
 N17646 002
 MAY 20, 1985

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

@ ABBOTT

EQ 500MG BASE/VIAL

N89575 001
FEB 22, 1991

METHYLPREDNISOLONE

ORGANON

EQ 500MG BASE/VIAL

N87535 001
JUN 25, 1982

EQ 1GM BASE/VIAL

N87535 002
JUN 25, 1982

EQ 500MG BASE/VIAL

N87535 001
JUN 25, 1982

EQ 1GM BASE/VIAL

N87535 002
JUN 25, 1982

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

METHYLTESTOSTERONE

PRIVATE FORM

@ PVT FORM

TABLICAPS

@

5MG

5MG

10MG

10MG

TABLET; ORAL

METHYLTESTOSTERONE

DANBURY PHARM

@

PUREPAC

@

PUREPAC PHARM

@

TABLICAPS

@

WEST WARD

@

WEST WARD PHARM

@

10MG

25MG

10MG

25MG

10MG

25MG

10MG

25MG

10MG

25MG

10MG

25MG

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

MAXOLON

AB KING PHARMS

EQ 10MG BASE

N70106 001
MAR 04, 1986

AB SMITHKLINE BEECHAM

EQ 10MG BASE

N70106 001
MAR 04, 1986

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

AB APOTHECON

50MG

N74258 001
JAN 27, 1994

100MG

N74258 002
JAN 27, 1994

50MG

N74333 001
JAN 27, 1994

100MG

N74333 002
JAN 27, 1994

50MG

N73288 001
MAR 25, 1994

100MG

N73289 001
MAR 25, 1994

50MG

N74143 001
SEP 30, 1994

100MG

N74143 002
SEP 30, 1994

50MG

N74380 001
JUL 29, 1994

100MG

N74380 002
JUL 29, 1994

50MG

N74217 001
MAY 27, 1994

100MG

N74217 002
MAY 27, 1994

MILRINONE LACTATE

INJECTABLE; INJECTION

MILRINONE LACTATE

* STERLING WINTHROP

EQ 1MG BASE/ML

N19436 001
DEC 31, 1987

PRIMACOR

+ STERLING WINTHROP

EQ 1MG BASE/ML

N19436 001
DEC 31, 1987

MILRINONE LACTATE

INJECTABLE; INJECTION
PRINACOR IN DEXTROSE 5% IN PLASTIC CONTAINER
@ STERLING WINTHROP
EQ 10MG BASE/100ML
@
EQ 15MG BASE/100ML
+
EQ 20MG BASE/100ML
N20343 001
AUG 09, 1994
N20343 002
AUG 09, 1994
N20343 003
AUG 09, 1994

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL

MINOCIN
@ LEDERLE

EQ 50MG BASE
EQ 100MG BASE

N50451 003
AUG 10, 1982
N50451 002
AUG 10, 1982

MINOCYCLINE HCL
LEDERLE

EQ 50MG BASE
EQ 100MG BASE

N50451 003
AUG 10, 1982
N50451 002
AUG 10, 1982

NADOLOL

TABLET; ORAL

CORGARD
SQUIBB

AB 120MG
AB 120MG
AB 160MG
AB 160MG

N18063 003
N18064 003
N18063 004
N18064 004

AB NADOLOL
AB COPLEY PHARM

N74368 001
AUG 31, 1994

AB 120MG

N74368 002
AUG 31, 1994

AB 160MG

N74368 003
AUG 31, 1994

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NAFCIL
APOTHECON

EQ 500MG BASE/VIAL

N61984 001

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NAFCIL
APOTHECON

AP EQ 1GM BASE/VIAL N61984 002
AP EQ 2GM BASE/VIAL N61984 003
AP EQ 4GM BASE/VIAL N61984 005
AP EQ 500MG BASE/VIAL N61984 001
AP EQ 1GM BASE/VIAL N61984 002
AP EQ 2GM BASE/VIAL N61984 003
AP EQ 4GM BASE/VIAL N61984 005

UNIPEN
WYETH AYERST

AP EQ 10GM BASE/VIAL N50320 005
@ EQ 20GM BASE/VIAL N50320 006

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

AT NAFAZALIN

BAUSCH AND LOMB 0.1%

AT PHARMAFAIR 0.1%

@ 0.1%

N40073 001
MAY 25, 1994
N88101 001
APR 15, 1983
N88101 001
APR 15, 1983

NAPROXEN

SUSPENSION; ORAL

AB NAPROSYN
+ SYNTEX

25MG/ML

N18965 001
MAR 23, 1987

AB NAPROXEN
ROXANE

25MG/ML

N74190 001
MAR 30, 1994

TABLET; ORAL

AB NAPROSYN
SYNTEX

500MG

N17581 004
APR 15, 1982
N17581 004
APR 15, 1982

AB +

500MG

AB NAPROXEN
ROXANE

250MG

N74211 001
FEB 28, 1994

375MG

N74211 002
FEB 28, 1994

NAPROXEN

TABLET; ORAL
NAPROXEN
ROXANE

500MG N74211 003
FEB 28, 1994

AB	FORNERS	50MG
AB	LANNETT	100MG
AB		50MG
		100MG

N80017 001
N80017 002
N80017 001
N80017 002

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM
COPLEY PHARM

<u>AB</u>	<u>COPILEY PHARM</u>	<u>EQ 250MG BASE</u>	N74289 001	JAN 27, 1994
<u>AB</u>		<u>EQ 500MG BASE</u>	N74289 002	JAN 27, 1994
<u>AB</u>	MYLAN	<u>EQ 250MG BASE</u>	N74367 001	AUG 31, 1994
<u>AB</u>		<u>EQ 500MG BASE</u>	N74367 002	AUG 31, 1994

AT
OINTMENT; TOPICAL
NITROFURAZONE
LANNETT
(2)

N84393 001
N84393 001

NEOMYCIN SULFATE

TABLET; ORAL
NEOMYCIN SULFATE
LANEET
©

EQ 350MG BASE

N60607 001
N60607 001

N70026 001
SEP 10, 1985

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

HABITROL
BASEL PHARMCS
7MG/24HR

N20076 001
NOV 27 1991

7MG/24HR + 3C

N20076 001
NOV 27, 1991

14MG/24HR

NOV 27, 1991
N20076 002
NOV 27 1991

14MG/24HR
+ ac +

NOV 27 1991
N20076 002
NOV 27 1991

21 MG/24 HR

NOV 27, 1991
N20076 003
NOV 27 1991

21MG/24HR +

NOV 27 1991
N20076 003
NOV 27 1991

AP	ATACORD	5MG/NL
PARKE DAVIS		10MG/NL

N70863 001
JAN 08, 1987
N70871 001

LONGER CUT

JAN 08, 1987
N70872 C01
JAN 08, 1987

© EMC / MT

JAN 08, 1987
N70863 001

10 MC / MT

JAN 08, 1987
N70871 001

(c) LFC / CMC

JAN 08, 1987
N70872 001

NORETHINDRONE

TABLET; ORAL

NORLUTIN

* PARKE DAVIS

Ⓐ

5MG
5MGNYSTATIN

SUSPENSION; ORAL

NYSTATIN

BAUSCH AND LOMB

100,000 UNITS/ML

N64042 001

FEB 28, 1994

AA PHARMAFAIR

100,000 UNITS/ML

N62541 001

JAN 16, 1985

Ⓐ

100,000 UNITS/ML

N62541 001

JAN 16, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYCOLOG-II

AT + APOTHECON

100,000 UNITS/GM;0.1%

N60576 002

MAY 01, 1985

100,000 UNITS/GM;0.1%

N62606 001

MAY 15, 1985

100,000 UNITS/GM;0.1%

N60576 002

MAY 01, 1985

100,000 UNITS/GM;0.1%

N62606 001

MAY 15, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

FAIRLE

100,000 UNITS/GM;0.1%

N63010 001

DEC 20, 1988

100,000 UNITS/GM;0.1%

N63010 001

DEC 20, 1988

100,000 UNITS/GM;0.1%

N62186 002

JUN 06, 1985

100,000 UNITS/GM;0.1%

N62186 002

JUN 06, 1985

100,000 UNITS/GM;0.1%

N62857 001

JUL 30, 1986

100,000 UNITS/GM;0.1%

N62657 001

JUL 30, 1986

OINTMENT; TOPICAL

NYSTATIN-TRIAMCINOLONE ACETONIDE

PHARMADERM

100,000 UNITS/GM;0.1%

N62603 001

OCT 09, 1985

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

NYSTATIN-TRIAMCINOLONE ACETONIDE

Ⓐ PHARMADERM

100,000 UNITS/GM;0.1%

N62603 001

OCT 09, 1985

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRIOSEC

+ ASTRA MERCK

20MG

N19810 001

SEP 14, 1989

* MERCK

20MG

N19810 001

SEP 14, 1989

ORPHENADRINE HYDROCHLORIDE

TABLET; ORAL

DISIPAL

3M

Ⓐ

50MG

N10653 001

N10653 001

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAXIL

SMITHKLINE BEECHAM

EQ 30MG BASE

N20031 003

DEC 29, 1992

N20031 003

DEC 29, 1992

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

Ⓐ APOTHECON

1,000,000 UNITS/VIAL

N60362 001

5,000,000 UNITS/VIAL

N60362 003

10,000,000 UNITS/VIAL

N60362 004

20,000,000 UNITS/VIAL

N60362 002

1,000,000 UNITS/VIAL

N60362 001

5,000,000 UNITS/VIAL

N60362 003

10,000,000 UNITS/VIAL

N60362 004

20,000,000 UNITS/VIAL

N60362 002

AP

AP

AP

AP

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

BETAPEN-VK
@ APOTHECONEQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5MLN61149 001
N61149 002
N61149 001
N61149 002

AA BRISTOL

AA VEETIDS

AA APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5MLN61410 001
N61410 002

TABLET; ORAL

UTICILLIN VK

@ UPJOHN

EQ 500MG BASE
EQ 500MG BASEN61651 002
N61651 002

AB

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTACARINAT

RHONE POULENC RORER

300MG/VIAL

N73447 001
APR 28, 1994

AP

PENTOBARBITAL SODIUM

CAPSULE; ORAL

PENTOBARBITAL SODIUM

LANNETT

50MG
100MG
50MG
100MGN85937 001
N85915 001
N85937 001
N85915 001

AA

AA

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

@ ZENITH

35MG

N85611 001

N85611 001

AA

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

LANNETT

30MG

N87022 001
FEB 03, 1983

AA

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

@ LANNETT

30MG

N87022 001
FEB 03, 1983PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE VC PLAIN

PENNEX

5MG/5ML; 5.25MG/5ML

N88897 001

@ PENNEX PHARMS

5MG/5ML; 6.25MG/5ML

JAN 04, 1985
N88897 001
JAN 04, 1985

AA

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

DIPHENYLAN SODIUM

LANNETT

100MG
30MG
30MG
100MGN80857 002
N80857 001
N80857 001
N80857 002

BX

@

@

PHYTONADIONE

INJECTABLE; INJECTION

PHYTONADIONE

SMITHKLINE BEECHAM

1MG/0.5ML
10MG/ML
1MG/0.5ML
10MG/MLN84060 001
N84060 002
N84060 001
N84060 002

EP

BP

@

@

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL

SALAGEN

+ MGI

5MG

N20237 001
MAR 22, 1994

PINDOLOL

TABLET; ORAL

AB PINDOLOL
MUTUAL PHARM

5MG

AB 10MG

N74063 001
JAN 27, 1994
N74063 002
JAN 27, 1994

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE
@ FUJISAWA

2MEQ/ML

N87885 001
FEB 03, 1983

PIPERAZINE CITRATE

SYRUP; ORAL

AA VERMIDOL
SOLVAY

EQ 500MG BASE/5ML
EQ 500MG BASE/5ML

N80992 001
N80992 001

PIROXICAM

CAPSULE; ORAL

AB PIROXICAM
NOVOPHARM

10MG

AB 20MG

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

N73637 001
JAN 28, 1994
N73638 001
JAN 28, 1994

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

EX BUNNY

5MG

EX ICN

5MG

EX INWOOD

5MG

EX INWOOD LABS

5MG

EX TABICAPS

5MG

5MG

N83675 001
N83675 001
N80236 001
N80236 001
N80236 001
N80748 001
N80748 001
N85170 001
N85170 001
N85170 001

POLYMYXIN B SULFATE

INJECTABLE; INJECTION

AP AEROSPORIN
* BURROUGHS WELLCOME

EQ 500,000 UNITS/VIAL
EQ 500,000 U BASE/VIAL

N62036 001
N62036 001

AP POLYMYXIN B SULFATE
PFIZER

EQ 500,000 UNITS/VIAL
EQ 500,000 U BASE/VIAL

N60716 001
N60716 001

AP POLYMYXIN B SULFATE
PHARMA TEK

EQ 500,000 U BASE/VIAL

N63000 001
SEP 30, 1994

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

AT PREDAIR FORTE
PHARMAPAIR

EQ 0.9% PHOSPHATE

N88165 001
MAR 28, 1983
N88165 001
MAR 28, 1983

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

AP FUJISAWA

N87885 001
FEB 03, 1983

PREDNISOLONE SODIUM PHOSPHATE

BAUSCH AND LOMB

EQ 0.11% PHOSPHATE

N40065 001
JUL 29, 1994
N40070 001
JUL 29, 1994

AT EQ 0.9% PHOSPHATE

PREDNISONE

TABLET; ORAL
PREDNISONE

BX @ 1ST TX 5MG
BX @ BRANDY 5MG
BX @ DANBURY PHARMA 5MG
BX @ FERRANTE 5MG
BX @ FIRST TX 5MG
BX @ ICN 5MG
BX @ INWOOD 1MG
BX @ INWOOD LABS 2.5MG
BX @ NK 2.5MG
BX @ NYLOS 5MG
BX @ RECALL 5MG
BX @ SPERTI 1MG
BX @ 2.5MG
BX @ 5MG
BX @ 1MG
BX @ 2.5MG
BX @ 5MG
BX @ 20MG
BX @ 20MG
BX @ WHITE TOWNE PAULSEN
BX @ WHITEWORTH TOWNE 20MG

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE PLAIN

AA PENNEX 6.25MG/5ML
@ PENNEX PHARMS 6.25MG/5ML

TABLET; ORAL

PROMETHAZINE HCL
TABLICAPS

BP 12.5MG
BP 25MG
@ 12.5MG
@ 25MG

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

BP REMSED 25MG
@ DUPONT 25MG
@ DUPONT MERCK

PROPANTHELINE BROMIDE

TABLET; ORAL

AA PRO-BANTHINE 7.5MG
AA ROBERTS LABS 15MG
AA SCS PHARMS 7.5MG
AA 15MG

PROPACARCAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

AT KAINALK 0.5%
@ PHARMAPAIR 0.5%
@ JUN 07, 1983
@ JUN 07, 1983
@ JUN 07, 1983

PROPYLTHIOURACIL

TABLET; ORAL

BD PROPYLTHIOURACIL 50MG
@ DANBURY PHARMA 50MG
@ LANNETT 50MG
@ TABLICAPS 50MG
@ 50MG

PROTIRELIN

INJECTABLE; INJECTION

AP RELEFACT TRH 0.5MG/ML
@ FERRING LABS
AP THYREL TRH 0.5MG/ML
@ FERRING LABS

N80371 001
N83676 001
N83676 001
N86867 001
N86867 001
N80563 001
N80563 002
N80371 001
N80237 001
N80237 001
N80328 001
N80306 001
N80328 001
N80306 001
N80563 001
N80563 002
N85115 001
N85115 001
N80232 001
N80232 001
N80359 001
N80359 002
N80359 003
N80359 003
N80359 001
N80359 002
N80359 003
N84913 002
N84913 002

N87953 001
NOV 15, 1982
N87953 001
NOV 15, 1982

N84080 001
N84027 001
N84080 001
N84027 001

N83176 002
N83176 002

N08732 003
N08732 002
N08732 003
N08732 002

N88087 001
JUN 07, 1983
N88087 001
JUN 07, 1983

N80932 001
N80932 001
N80916 001
N80016 001
N80840 001
N80840 001

N18087 001
N18087 001

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

AA ALLERFED
PRIVATE FORM60MG; 2.5MGN88860 001

JAN 31, 1985

60MG; 2.5MG

N88860 001

JAN 31, 1985

@ PVT FORM

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL

PYRIDOSTIGMINE BROMIDE
KALI DUPHAR30MGN89572 001

NOV 27, 1990

30MG

N89572 001

NOV 27, 1990

@ SOLVAY

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDEXAB + ROBINS AH300MGN12796 002QUINIDINE SULFATE300MGN40045 001

JUN 30, 1994

@ COFLEY PHARMRANITIDINE HYDROCHLORIDE

CAPSULE; ORAL

ZANTAC 150GLAXO

EQ 150MG BASE

N20095 001

MAR 08, 1994

ZANTAC 300+ GLAXO

EQ 300MG BASE

N20095 002

MAR 08, 1994

GRANULE, EFFERVESCENT; ORAL

ZANTAC 150+ GLAXO

EQ 150MG BASE/PACKET

N20251 002

MAR 31, 1994

TABLET, EFFERVESCENT; ORAL

ZANTAC 150+ GLAXO

EQ 150MG BASE

N20251 001

MAR 31, 1994

ROCURONIUM BROMIDE

INJECTABLE; INJECTION

ZEMURON+ ORGANON

10MG/ML

N20214 002

MAR 17, 1994

ZEMURON (P/F)+ ORGANON

10MG/ML

N20214 001

MAR 17, 1994

ROSE BENGAL SODIUM, I-131

INJECTABLE; INJECTION

ROBENGATOPE@ BRACCO DXS

0.5mCi/VIAL

1mCi/VIAL

2mCi/VIAL

0.5mCi/VIAL

1mCi/VIAL

2mCi/VIAL

N16224 001N16224 002N16224 003N16224 001N16224 002N16224 003SALMETEROL XINAFOATE

AEROSOL, METERED; INHALATION

SEREVENT+ GLAXO

EQ 0.021MG BASE/INH

N20236 001

FEB 04, 1994

SECOBARBITAL SODIUM

CAPSULE; ORAL

SECOBARBITAL SODIUMLANNETT50MG100MG

50MG

100MG

100MG

N85909 001N85903 001N85909 001N85903 001N85903 001SECONAL SODIUMKILBY50MG

50MG

N86101 001

OCT 03, 1983

N86101 001

OCT 03, 1983

SELENOMETHIONINE, SE-75

INJECTABLE; INJECTION
SETHOTOPE
@ BRACCO DXS
@ SQUIBB

85-550 uCi/ML
85-550 uCi/ML

N17047 001
N17047 001

N18450 001

SILVER SULFADIAZINE

DRESSING; TOPICAL
SILDIMAC
@ BIOPLASTY
@ ENQUAY

1%
1%

N19608 001
NOV 30, 1989
N19608 001
NOV 30, 1989

N10927 001
N10927 001

SODIUM CHROMATE, CR-51

INJECTABLE; INJECTION
CHROMITOPE SODIUM
BRACCO DXS

250 uCi/VIAL
1mCi/VIAL
2mCi/VIAL
250 uCi/VIAL
1mCi/VIAL
2mCi/VIAL

N13993 001
N13993 003
N13993 002
N13993 001
N13993 003
N13993 002

N19865 005
APR 20, 1994

SODIUM IODIDE, I-131

CAPSULE; ORAL
IODOTOPE
BRACCO DXS
@ SQUIBB

8-100 uCi
1-50mCi
8-100 uCi
1-50mCi

N10929 001
N10929 003
N10929 001
N10929 003

N20412 001
JUN 24, 1994
N20412 002
JUN 24, 1994
N20412 003
JUN 24, 1994
N20412 004
JUN 24, 1994
N20412 005
JUN 24, 1994

SOLUTION; ORAL
IODOTOPE
BRACCO DXS
@ SQUIBB

7-106mCi/BOT
7-106mCi/BOT

N10929 002
N10929 002

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS
@ ABBOTT

50MG/VIAL

N18450 001

N60111 001
N60111 001

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS
@ ABBOTT

50MG/VIAL

N18450 001

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL
PHOSPHOTOPE
@ BRACCO DXS
@ SQUIBB

1-8mCi/VIAL
1-8mCi/VIAL

N10927 001
N10927 001

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
BERLEX

120MG

N19865 005
APR 20, 1994

STAVUDINE

CAPSULE; ORAL
ZERIT
@ BRISTOL MYERS SQUIBB

5MG

15MG

20MG

30MG

40MG

+

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION
STREPTOMYCIN SULFATE
@ PFIZER

EQ 1GM BASE/2ML
EQ 1GM BASE/2.5ML

N60111 001
N60111 001

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

AT SULFAIR FORTE 30%
PHARMFAIR

@
 30%

AT SULFAIR-15 15%
PHARMFAIR

@
 15%

N88385 001
OCT 13, 1983

N88385 001
OCT 13, 1983

N88186 001
MAY 25, 1983

N88186 001
MAY 25, 1983

SULFADIAZINE

TABLET; ORAL

AB + SULFADIAZINE 500MG
EON LABS

AB EON MANUFACTURE LABS 500MG

AB * LILLY 500MG
 @ 500MG

N40091 001
JUL 29, 1994

N40091 001
JUL 29, 1994

N04122 002
N04122 002

N04122 002
N04122 002

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

AP SULFAMETHOXAZOLE AND TRIMETHOPRIM 80MG/ML; 16MG/ML
FUJISAWA

@
 80MG/ML; 16MG/ML

N70223 001
DEC 29, 1987

N70223 001
DEC 29, 1987

SUSPENSION; ORAL

AB * BACTRIM 200MG/5ML; 40MG/5ML
 @ 200MG/5ML; 40MG/5ML

AB * ROCHE 200MG/5ML; 40MG/5ML
 @ 200MG/5ML; 40MG/5ML

AB BACTRIM PEDIATRIC 200MG/5ML; 40MG/5ML
 @ 200MG/5ML; 40MG/5ML

AB * ROCHE 200MG/5ML; 40MG/5ML
 @ 200MG/5ML; 40MG/5ML

AB TRIMETH/SULFA 200MG/5ML; 40MG/5ML
 @ 200MG/5ML; 40MG/5ML

AB BARRE 200MG/5ML; 40MG/5ML
 @ 200MG/5ML; 40MG/5ML

N72398 001
MAY 23, 1988

N72398 001
MAY 23, 1988

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

AB SULFAMETHOXAZOLE AND TRIMETHOPRIM 400MG; 80MG
EON LABS

@
 400MG; 80MG

AB UROPLUS DS 800MG; 160MG
SHIONOGI

@
 800MG; 160MG

AB UROPLUS SS 400MG; 80MG
SHIONOGI

@
 400MG; 80MG

N18598 003
MAY 19, 1982

N18598 003
MAY 19, 1982

N71816 001
SEP 28, 1987

N71816 001
SEP 28, 1987

N71815 001
SEP 28, 1987

N71815 001
SEP 28, 1987

SULFASALAZINE

SUSPENSION; ORAL

AB AZULFIDINE 250MG/5ML
KABI

@ 250MG/5ML
 + 250MG/5ML

N18605 001
N18605 001

N18605 001
N18605 001

N86983 001
N86983 001

SULFISOXAZOLE

TABLET; ORAL

AB SULFISOXAZOLE 500MG
KARNETT

@
 500MG

N80085 001
N80085 001

TACROLIMUS

CAPSULE; ORAL

AB PROGRAF EQ 1MG BASE
 + FUJISAWA

@
 EQ 5MG BASE

N50708 001
APR 08, 1994

N50708 002
APR 08, 1994

INJECTABLE; INJECTION

AB PROGRAF EQ 5MG BASE/ML
 + FUJISAWA

N50709 001
APR 08, 1994

TAMOXIFEN CITRATE

TABLET; ORAL
NOLVADEX
+ ZENECA

EQ 20MG BASE

N17970 002
MAR 21, 1994

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL

TESULOID
SQUIBB

N/A

N16923 001

SOLUTION; INTRAVENOUS, ORAL

TESULOID
BRACCO DXS

N/A

N16923 001

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

MACROTEC

BRACCO DXS

N/A

SQUIBB

N/A

N17833 001
N17833 001

TECHNETIUM TC-99M PERPENTETATE KIT

INJECTABLE; INJECTION

RENOTEC

@ BRACCO DXS

N/A

SQUIBB

N/A

N17045 001
N17045 001

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

MDP-SQUIBB

BRACCO DXS

N/A

SQUIBB

N/A

N18107 001
N18107 001

TECHNETIUM TC-99M OXIDRONATE KIT

INJECTABLE; INJECTION

OSTEOSCAN HDP

MALLINCKRODT

N/A

TECHNISCAN HDP

MALLINCKRODT

N/A

N18321 001

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION

CARDIOLITE

DUPONT

N/A

DUPONT MERCK

N/A

N19785 001

DEC 21, 1990

N19785 001

DEC 21, 1990

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

@

500MG

500MG

N60471 002

N60471 002

FIBER, EXTENDED RELEASE; PERIODONTAL
ACTISITE

+ ON SITE

12.7MG/FIBER

N50653 001

MAR 25, 1994

SYRUP; ORAL

ACHROMYCIN V

+ LEDERLE

SUMYCIN

SQUIBB

TETRACYCLINE HCL

BARRE

MK LABS

12.5MG/5ML

12.5MG/5ML

12.5MG/5ML

12.5MG/5ML

12.5MG/5ML

12.5MG/5ML

N50263 002

N60400 001

N60400 001

N60633 001

N60174 001

TETRACYCLINE HYDROCHLORIDE

SYRUP; ORAL

TETRACYCLINE HCL
PUREPAC PHARM

AB 125MG/5ML N60291 001

AB TETRACYN

AB PFIPHARMECS 125MG/5ML N60095 001

AB TETRAMED

AB ZENITH LABS 125MG/5ML N61468 001

TABLET; ORAL

PAMMYCIN

AB 500MG N61705 002

@ UPJOHN

AB 250MG N61705 001

@ SUMYCIN

AB 500MG N61147 004

AB * APOTHECON

AB 500MG N61147 004

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SLO-BID

AB RHONE POULENC RORER 100MG N87892 001

AB 125MG N89540 001

AB 200MG N87893 001

AB 300MG N87894 001

AB INWOOD LABS 100MG N40052 001

AB 125MG N40052 002

AB 200MG N40052 003

AB 300MG N40052 004

AB ELIXIR; ORAL

LANOPHYLLIN

AB 80MG/15ML N84578 001

AB 80MG/15ML N84578 001

AB 80MG/15ML N89223 001

AB THEOPHYLLINE

AB BARRE

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

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AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

AB 80MG/15ML N89223 001

THEOPHYLLINE

ELIXIR; ORAL

THEOPHYLLINE

@ BARRE 80MG/15ML N89223 001

@ CENCI 80MG/15ML N87679 001

AA LIFE LABS 80MG/15ML N87679 001

AA 80MG/15ML N87679 001

AA 80MG/15ML N87679 001

AA 80MG/15ML N87679 001

AA 80MG/15ML N87679 001

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AA 80MG/15ML N87679 001

AA 80MG/15ML N87679 001

THYROGLOBULIN

TABLET; ORAL
THYROGLOBULIN
BP RICHLYN

64.8MG

N60151 001

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN
STERIS

0.3%

N63176 001
MAY 25, 1994

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP APOTHECON

EQ 10MG BASE/ML

N64021 001
MAY 31, 1994

AP APOTHECON

EQ 40MG BASE/ML

N64021 002
MAY 31, 1994

AP APOTHECON

EQ 40MG BASE/ML

N64026 001
MAY 31, 1994

TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC
CONTAINER
+ ABBOTT

N63081 006
JUN 02, 1993

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM
MYLAN

EQ 600MG BASE

N74473 001
AUG 30, 1994

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE
BP NYLAN

2MG
2MG

N84406 001
N84406 001

TRIAMCINOLONE ACETONIDE

AEROSOL; TOPICAL
KENALOG

0.147MG/GM
0.147MG/GM

N12104 001
N12104 001

CREAM; TOPICAL
KENALOG

AT + APOTHECON 0.025%
AT + 0.1%
AT + 0.5%
AT + WESTWOOD SQUIBB 0.025%
AT + 0.1%
AT + 0.5%

N11601 003
N11601 006
N83943 001
N11601 003
N11601 006
N11601 003
N83943 001

OINTMENT; TOPICAL
KENALOG

AT + APOTHECON 0.025%
AT + 0.1%
AT + 0.5%
AT + WESTWOOD SQUIBB 0.025%
AT + 0.1%
AT + 0.5%

N11600 003
N11600 001
N83944 001
N11600 003
N11600 001
N83944 001

TRIAMCINOLONE ACETONIDE

TARO PHARMS

0.025%

N40040 001

SEP 30, 1994
N40037 001
SEP 30, 1994

TABLET; ORAL

HALCION
UPJOHN

0.125MG

N17892 003
APR 26, 1985
N17892 001
NOV 15, 1982

0.25MG

N74031 001
MAR 25, 1994
N74031 002
MAR 25, 1994
N74224 001
JUN 01, 1994
N74224 002
JUN 01, 1994

TRIAZOLAM
ALPHAPHARM

0.125MG

N74031 001

0.25MG

N74031 002

0.125MG

N74224 001

0.25MG

N74224 002

TRIHENXYPHENIDYL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

* LEBERK5MG
5MG
5MG
5MGN06773 010
N12947 001
N06773 010
N12947 001VINBLASTINE SULFATE

INJECTABLE; INJECTION

VINBLASTINE SULFATEAP BULL 10MG/VIALN89565 001
AUG 18, 1987
N89565 001
AUG 18, 1987AP FAULDING 10MG/VIALTRISULFAPYRIMIDINES (SULFADIAZINE; SULFAMERAZINE; SULFAMETHAZINE)

SUSPENSION; ORAL

LANTRISUL
LANNETT167MG/5ML; 167MG/5ML;
167MG/5ML
167MG/5ML; 167MG/5ML;
167MG/5MLN80123 002
N80123 002AP FUJISAWA 1MG/MLN70411 001
SEP 10, 1986
N70411 001
SEP 10, 1986

1MG/ML

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

HYDRALFAIR
PHARMOPAIR

0.5%

N88274 001
SEP 16, 1983
N88230 001
SEP 16, 1983

0.5%

N88274 001
SEP 16, 1983
N88230 001
SEP 16, 1983TROPICAMIDE

BAUSCH AND LOMB

0.5%

N40067 001
JUL 27, 1994
N40064 001
JUL 27, 1994

1%

N40067 001
JUL 27, 1994
N40064 001
JUL 27, 1994VERAPAMIL HYDROCHLORIDETABLET, EXTENDED RELEASE; ORAL
ISOPTIN SRAB + KNOLL PHARM

180MG

N19152 002
DEC 15, 1989VERAPAMIL HCL
BAKER NORTON

180MG

N74330 001
JAN 31, 1994

ACETAMINOPHEN

SUPPOSITORY; RECTAL
INFANTS' FEVERALL
UPSHER SMITH

80MG

N18337 004
AUG 26, 1992

TABLET, EXTENDED RELEASE; ORAL
TYLENOL
+ MCNEIL

650MG

N19872 001
JUN 08, 1994

BACITRACIN

ointment; TOPICAL
BACITRACIN
COMBE

500 UNITS/GM

N62799 001
MAY 14, 1987
N62799 001
MAY 14, 1987

500 UNITS/GM

@

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MYCELEX-7 COMBINATION PACK
MILES

1%, 100MG

N20389 002
JUN 23, 1994

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
BARRE

12.5MG/5ML

N70497 001
APR 25, 1989
N70497 001
APR 25, 1989

12.5MG/5ML

@

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MCNEIL
PVT FORM

200MG

N73019 001
MAR 30, 1994
N73691 001
FEB 25, 1994

200MG

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION

HUMULIN BR
* Lilly

100 UNITS/ML

N19529 001
APR 28, 1986
N19529 001
APR 28, 1986

@

100 UNITS/ML

INSULIN SUSP ISOPHANE BEEF

INJECTABLE; INJECTION

NPH INSULIN
* NOVO NORBISK

40 UNITS/ML

N17929 001
N17929 001

@

40 UNITS/ML

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

NAPHCON-A

+ ALCON

0.025%; 0.3%

N20226 001
JUN 08, 1994

OPCON-A

+ BAUSCH AND LOMB

0.027%; 0.315%

N20065 001
JUN 08, 1994

NAPROXEN SODIUM

TABLET; ORAL

ALEVE

HAMILTON PHARMS

EQ 200MG BASE

N20204 002
JAN 11, 1994

PERMETHRIN

LOTION; TOPICAL

NIX

* BURROUGHS WELLCOME

1%

N19918 001
MAY 02, 1990

+ WARNER WELLCOME

1%

N19918 001
MAY 02, 1990

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC/24

+ CIBA CONS 240MG

PSEUDOEPHEDRINE HCL
ALZA

240MG

SUDAFED 12 HOUR

* BURROUGHS WELLCOME

120MG

+ WARNER WELLCOME

120MG

N20021 002
DEC 15, 1992

N20021 002
DEC 15, 1992

N73585 001
OCT 31, 1991
N73585 001
OCT 31, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 9 / SEPTEMBER '94

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP

INJECTABLE; INJECTION	
BLOOD PACK UNIT CPDA-1 IN PLASTIC CONTAINER	N940404
BAXTER HLTHCARE	JUL 28, 1994

INDIUM IN¹¹¹ CHLORIDE STERILE SOLUTION

INJECTABLE; INJECTION	
NONE	N19841
MALLINCKRODT	SEP 27, 1994
N/A	

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January-September, 1994]

NAME <i>Generic/Chemical</i> <i>TN= Trade Name</i>	INDICATION DESIGNATED	SPONSOR & ADDRESS <i>DD=Date Designated</i> <i>MA=Marketing Approval</i>
8-METHOXSALEN TN= UVADEX	FOR THE PREVENTION OF ACUTE REJECTION OF CARDIAC ALLOGRAFTS.	THERAKOS, INCORPORATED 201 BRANDYWINE PARKWAY WEST CHESTER PA 19380 DD 05/12/94 MA / /
AMINOSALICYLIC ACID TN= PASER GRANULES	TREATMENT OF TUBERCULOSIS INFECTIONS.	JACOBUS PHARMACEUTICAL COMPANY 37 CLEVELAND LANE PRINCETON NJ 08540 DD 02/19/92 MA 06/30/94
AMINOSIDINE TN= PAROMOMYCIN	TREATMENT OF VISCERAL LEISHMANIASIS (KALA-AZAR).	KANYOK, THOMAS P. PHARM.D. UNIV. OF ILLINOIS AT CHICAGO CHICAGO IL 60612 DD 09/09/94 MA / /
AMIODARONE HCL TN= CORDARONE	FOR THE ACUTE TREATMENT AND PROPHYLAXIS OF LIFE-THREATENING VENTRICULAR TACHYCARDIA OR VENTRICULAR FIBRILLATION.	WYETH-AYERST LABORATORIES P.O. BOX 8299 PHILADELPHIA PA 19101-1245 DD 03/16/94 MA / /
AMMONIUM TETRATHIOMOLYBDATE TN=	TREATMENT OF WILSON'S DISEASE.	BREWER, GEORGE J. M.D. UNIVERSITY OF MICHIGAN MEDICAL SCHOOL ANN ARBOR MI 48109-0618 DD 01/31/94 MA / /
ANTIVENIN, POLYVALENT CROTALID (OVINE) FAB TN= CROTAB	TREATMENT OF ENVENOMATIONS INFLICTED BY NORTH AMERICAN CROTALID SNAKES.	THERAPEUTIC ANTIBODIES INC. 1500 21ST AVENUE SOUTH, SUITE 310 NASHVILLE TN 37212 DD 01/12/94 MA / /
ARGININE BUTYRATE TN=	TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA.	VERTEX PHARMACEUTICALS INC. 40 ALLSTON STREET CAMBRIDGE MA 02139-4211 DD 05/25/94 MA / /
AUTOLYMPHOCYTE THERAPY TN=	TREATMENT OF RENAL CELL CARCINOMA.	CELLCOR INCORPORATED 200 WELLS AVENUE NEWTON MA 02159 DD 07/12/94 MA / /
BACLOFEN TN= LIORESAL INTRATHECAL	TREATMENT OF SPASTICITY ASSOCIATED WITH CEREBRAL PALSY.	MEDTRONIC, INCORPORATED 800 53RD AVENUE N.E. MINNEAPOLIS MN 55432 DD 09/26/94 MA / /
BETAINE TN=	TREATMENT OF HOMOCYSTEINURIA.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 05/16/94 MA / /
BOVINE IMMUNOGLOBULIN CONCENTRATE, CRYPTOSPORIDIUM PARVUM TN= SPORIDIN-G	TREATMENT AND SYMPTOMATIC RELIEF OF CRYPTOSPORIDIUM PARVUM INFECTION OF THE GASTROINTESTINAL TRACT IN IMMUNOCOMPROMISED PATIENTS.	GALAGEN, INCORPORATED 4001 LEXINGTON AVENUE NORTH ARDEN HILLS MN 55126-2998 DD 03/01/94 MA / /
BUPRENORPHINE HYDROCHLORIDE TN=	TREATMENT OF OPIATE ADDICTION IN OPIATE USERS.	RECKITT & COLMAN PHARMACEUTICALS, INC. 1901 HUGUENOT ROAD RICHMOND VA 23235 DD 06/15/94 MA / /
BUSULFAN TN=	FOR USE AS PREPARATIVE THERAPY FOR MALIGNANCIES TREATED WITH BONE MARROW TRANSPLANTATION.	SPARTA PHARMACEUTICALS, INC. P.O. BOX 13288 RESEARCH TRIANGLE PK NC 27709 DD 04/21/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
BUSULFAN TN=	AS PREPARATIVE THERAPY IN THE TREATMENT OF MALIGNANCIES WITH BONE MARROW TRANSPLANTATION.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 07/28/94 MA / /
CCD 1042 TN=	TREATMENT OF INFANTILE SPASMS.	COCENSYS, INC. 213 TECHNOLOGY DRIVE IRVINE CA 92718 DD 05/25/94 MA / /
CHIMERIC (MURINE VARIABLE, HUMAN CONSTANT) MAB TO CD20 TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	IDEC PHARMACEUTICALS CORPORATION 11011 TORREYANA ROAD SAN DIEGO CA 92121 DD 06/13/94 MA / /
CHOLINE CHLORIDE TN=	TREATMENT OF CHOLINE DEFICIENCY, SPECIFICALLY THE CHOLINE DEFICIENCY, HEPATIC STEATOSIS, AND CHOLESTASIS, ASSOCIATED WITH LONG-TERM PARENTERAL NUTRITION.	BUCHMAN, ALAN M.D. 6550 FANNIN, SUITE 1122 HOUSTON TX 77030 DD 02/10/94 MA / /
CLADRIBINE TN= LEUSTATIN	TREATMENT OF THE CHRONIC PROGRESSIVE FORM OF MULTIPLE SCLEROSIS.	R.W. JOHNSON RESEARCH INSTITUTE 700 ROUTE 200 SOLUTH, P.O. BOX 670 RARITAN NJ 08869-0670 DD 04/19/94 MA / /
CLONAZEPAM TN= KLOPIN	TREATMENT OF HYPEREKPLEXIA (STARTLE DISEASE).	HOFFMAN-LA ROCHE, INCORPORATED 340 KINGSLAND STREET NUTLEY NJ 07110-1199 DD 08/04/94 MA / /
CY-1899 TN=	TREATMENT OF CHRONIC ACTIVE HEPATITIS B INFECTION IN HLA-A2 POSITIVE PATIENTS.	CYTEL CORPORATION 3525 JOHN HOPKINS COURT SAN DIEGO CA 92121 DD 03/16/94 MA / /
CYSTEAMINE TN= CYSTAGON	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	MYLAN LABORATORIES, INC 781 CHESTNUT RIDGE ROAD, PO BOX 4310 MORGANTOWN WV 26504-4310 DD 01/25/91 MA 08/15/94
DEHYDROEPIANDROSTERONE TN=	TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND THE REDUCTION IN THE USE OF STEROIDS IN STEROID-DEPENDENT SLE PATIENTS.	GENELABS TECHNOLOGIES, INC. 505 PENOBSCOT DRIVE REDWOOD CITY CA 94063 DD 07/13/94 MA / /
DESMOPRESSIN ACETATE TN=	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD COLLEGEVILLE PA 19426 DD 01/22/91 MA 03/07/94
ELLIOTT'S B SOLUTION TN=	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIAS AND ACUTE LYMPHOBLASTIC LYMPHOMAS.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 08/24/94 MA / /
FGN-1 TN=	FOR THE SUPPRESSION AND CONTROL OF COLONIC ADENOMATOUS POLYPS IN THE INHERITED DISEASE ADENOMATOUS POLYPOSIS COLI.	CELL PATHWAYS, INC. 1700 BROADWAY, SUITE 2000 DENVER CO 80290 DD 02/14/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
GAMMALINOLENIC ACID TN=	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	ZURIER, ROBERT B. M.D. 55 LAKE AVE. UNIV. OF MASS. MED. CTR. WORCESTER MA 01655 DD 07/27/94 MA / /
HEME ARGINATE TN= NORMOSANG	TREATMENT OF MYELODYSPLASTIC SYNDROMES.	LEIRAS, INCORPORATED 1850 CENTENNIAL PARK DRIVE, SUITE 450 RESTON VA 22091 DD 03/01/94 MA / /
I-131 RADIOLABELED B1 MONOCLONAL ANTIBODY TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	COULTER CORPORATION 11800 S.W. 147 AVENUE, P.O. BOX 169015 MIAMI FL 33116-9015 DD 05/16/94 MA / /
IMIGLUCERASE TN= CEREZYME	FOR REPLACEMENT THERAPY IN PATIENTS WITH TYPES I, II, AND III GAUCHER'S DISEASE.	GENZYME CORPORATION ONE KENDALL SQUARE CAMBRIDGE MA 02139 DD 11/05/91 MA 05/23/94
IN-111 MURINE MAB(2B8-MX-DTPA) & Y-90 MURINE MAB(2B8-MXDTPA) TN=	TREATMENT OF B-CELL NON-HODGKIN'S LYMPHOMA.	IDEC PHARMACEUTICALS CORPORATION 11011 TORREYANA ROAD SAN DIEGO CA 92121 DD 09/06/94 MA / /
ISOBUTYRAMIDE TN=	TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA.	VERTEX PHARMACEUTICALS INC. 40 ALLSTON STREET CAMBRIDGE MA 02139-4211 DD 05/25/94 MA / /
L-2-OXOTHIAZOLIDINE-4-CARBOXYLIC ACID TN= PROCYSTEINE	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	FREE RADICAL SCIENCES, INC. 245 FIRST STREET CAMBRIDGE MA 02142 DD 06/14/94 MA / /
L-CYSTEINE TN=	FOR THE PREVENTION AND LESSENING OF PHOTOSENSITIVITY IN ERYTHROPOIETIC PROTOPORPHYRIA.	TYSON AND ASSOCIATES 12832 SOUTH CHADRON AVENUE HAWTHORNE CA 90250 DD 05/16/94 MA / /
LIPOSOME ENCAPSULATED RECOMBINANT INTERLEUKIN-2 TN=	TREATMENT OF CANCERS OF THE KIDNEY AND RENAL PELVIS.	ONCOTHERAPEUTICS, INC. 1002 EASTPARK BOULEVARD CRANBURY NJ 08512 DD 06/20/94 MA / /
MITOGUAZONE TN=	TREATMENT OF DIFFUSE NON-HODGKIN'S LYMPHOMA, INCLUDING AIDS-RELATED DIFFUSE NON-HODGKIN'S LYMPHOMA.	CTRC RESEARCH FOUNDATION 11812 BECKET STREET POTOMAC MD 20854 DD 03/18/94 MA / /
MONOCLONAL AB(MURINE) ANTI-IDIOTYPE MELANOMA ASS'ED ANTIGEN TN= MELIMMUNE	TREATMENT OF INVASIVE CUTANEOUS MELANOMA.	IDEC PHARMACEUTICALS CORPORATION 11011 TORREYANA ROAD SAN DIEGO CA 92121 DD 09/19/94 MA / /
N-TRIFLUOROACETYLADRIAMYCIN-14-V ALERATE TN=	TREATMENT OF CARCINOMA IN SITU OF THE URINARY BLADDER.	ANTHRA PHARMACEUTICALS, INC. 19 CARSON ROAD PRINCETON NJ 08540 DD 05/23/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
NEUROTROPHIN-1 TN=	TREATMENT OF MOTOR NEURON DISEASE/AMYOTROPHIC LATERAL SCLEROSIS.	ERICSSON, ARTHUR DALE, M.D. 6560 FANNIN, SCURLOCK TOWER, SUITE 720 HOUSTON TX 77303 DD 09/13/94 MA / /
OXANDROLONE TN= HEPANDRIN	TREATMENT OF MODERATE/SEVERE ACUTE ALCOHOLIC HEPATITIS IN THE PRESENCE OF MODERATE PROTEIN CALORIE MALNUTRITION.	BIO-TECHNOLOGY GENERAL CORP. 70 WOOD AVENUE SOUTH ISELIN NJ 08830 DD 03/18/94 MA / /
PEGASPARGASE TN= ONCASPAR	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL).	ENZON, INC. 40 KINGSBRIDGE ROAD PISCATAWAY NJ 08854-3998 DD 10/20/89 MA 02/01/94
PILOCARPINE TN= SALAGEN	TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER.	MGI PHARMA, INC. SUITE 300 E, 9900 BREN ROAD EAST MINNEAPOLIS MN 55343-9667 DD 09/24/90 MA 03/22/94
RECOMBINANT HUMAN GELSOLIN TN=	TREATMENT OF THE RESPIRATORY SYMPTOMS OF CYSTIC FIBROSIS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02124 DD 01/12/94 MA / /
RECOMBINANT VACCINIA (HUMAN PAPILLOMAVIRUS) TN= TA-HPV	TREATMENT OF CERVICAL CANCER.	CANTAB PHARMACEUTICALS RESEARCH, LTD. 184 CAMBRIDGE SCIENCE PARK CAMBRIDGE CB4 4GN UK DD 08/24/94 MA / /
REDUCED L-GLUTATHIONE TN= CACHEXON	TREATMENT OF AIDS-ASSOCIATED CACHEXIA.	TELLURIDE PHARMACEUTICAL CORPORATION 146 FLANDERS DRIVE HILLSBOROUGH NJ 08876-4656 DD 02/14/94 MA / /
RICIN (BLOCKED) CONJUGATED MURINE MOAB (CD6) TN=	TREATMENT OF CUTANEOUS T-CELL LYMPHOMAS, ACUTE T-CELL LEUKEMIA-LYMPHOMA, AND RELATED MATURE T-CELL MALIGNANCIES.	IMMUNOGEN, INC. 148 SIDNEY STREET CAMBRIDGE MA 02139-4239 DD 09/06/94 MA / /
RIFAMPIN, ISONIAZID, PYRAZINAMIDE TN= RIFATER	SHORT-COURSE TREATMENT OF TUBERCULOSIS.	MARION MERRELL DOW, INC. P.O. BOX 9627 KANSAS CITY MO 64134-0627 DD 09/12/85 MA 05/31/94
SOMATROPIN TN= GENOTROPIN/GENOTONORM	TREATMENT OF ADULTS WITH GROWTH HORMONE DEFICIENCY.	PHARMACIA, INC. P.O. BOX 16529 COLUMBUS OH 43216-6529 DD 09/06/94 MA / /
SOMATROPIN TN= NUTROPIN (EXCLUSIVITY NOT APPLICABLE)	FOR USE IN THE LONG-TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	GENENTECH, INC. 460 POINT SAN BRUNO BOULEVARD SOUTH SAN FRANCISCO CA 94080 DD 03/06/87 MA 03/09/94
SULFADIAZINE TN=	FOR USE IN COMBINATION WITH PYRIMETHAMINE FOR THE TREATMENT OF TOXOPLASMA GONDII ENCEPHALITIS IN PATIENTS WITH AND WITHOUT ACQUIRED IMMUNODEFICIENCY SYNDROME.	EON LABS MANUFACTURING, INC. 227-15 NORTH CONDUIT AVENUE LAURELTON NY 11413 DD 03/14/94 MA 07/29/94

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical

TN- Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD- Date Designated

MA- Marketing Approval

TIZANIDINE HCL
TN= ZANAFLEXTREATMENT OF SPASTICITY ASSOCIATED WITH MULTIPLE
SCLEROSIS AND SPINAL CORD INJURY.ATHENA NEUROSCIENCES, INC.
800F GATEWAY BOULEVARD
SOUTH SAN FRANCISCO CA 94080
DD 01/31/94 MA / /TREOSULFAN
TN= OVASTAT

TREATMENT OF OVARIAN CANCER.

MEDAC GmbH c/o PRINCETON REG.
ASSOC.
65 SOUTH MAIN STREET
PENNINGTON NJ 08534
DD 05/16/94 MA / /

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

NO SEPTMBER 1994 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)DATEREVISED DATE

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 14TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ALBUTEROL (METERED DOSE INHALER - *IN VIVO*)
FLURBIPROFEN (TABLET)
PHENYTOIN (SUSPENSION AND CHEWABLE TABLET)
PHENYTOIN SODIUM (CAPSULE, EXTENDED AND PROMPT)

JAN 27, 1994
DEC 24, 1992
MAR 04, 1994
MAR 04, 1994

FEB 04, 1994

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ACYCLOVIR TABLET; ORAL	200MG	93 P-0339/ CP1	NOVOPHARM	NEW DOSAGE FORM	APPROVED FEB 08, 1994
ACYCLOVIR SODIUM INJECTABLE; INJECTION	25MG/ML (20ML/VIAL) (40ML/VIAL)	93 P-0469/ CP1	FAULDING	NEW DOSAGE FORM	APPROVED JUN 09, 1994
ESTRADIOL TABLET; ORAL	1.5MG	93 P-0344/ CP1	BRISTOL MYERS SQUIBB	NEW STRENGTH	APPROVED JUN 08, 1994
LOPERAMIDE HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	1MG	93 P-0332/ CP1	ELLIS PHARM CONSULTING	NEW DOSAGE FORM	APPROVED FEB 08, 1994
METHYLTESTOSTERONE CAPSULE; ORAL	25MG	93 P-0459/ CP1	ICN	NEW DOSAGE FORM	APPROVED JUN 08, 1994
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	15MG 60MG 100MG	93 P-0446/ CP1	PHARMA CONSULT	NEW DOSAGE FORM	APPROVED JUN 08, 1994
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	90MG	93 P-0446/ CP1	PHARMA CONSULT	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUN 08, 1994
PREDNISONE TABLET, CHEWABLE; ORAL	1MG 2.5MG 20MG 50MG	93 P-0333/ CP1	DURA	NEW DOSAGE FORM	APPROVED JUN 08, 1994
PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE CAPSULE, EXTENDED RELEASE; ORAL	120MG 60MG	93 P-0367/ CP1	EURAND AMERICA	NEW DOSAGE FORM	APPROVED FEB 08, 1994

ERRATA

CIMETIDINE TABLET, EFFERVESCENT; ORAL	200MG 300MG 400MG 800MG	93 P-0048/ CP1*	FLEMINGTON PHARM	NEW DOSAGE FORM	APPROVED SEP 18, 1993
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*Not previously published

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 14TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW DOSING SCHEDULE

D-21	ALTERNATIVE DOSAGE OF 300MG ONCE DAILY AFTER THE EVENING MEAL
D-22	REDUCTION IN INFUSION TIME FROM 24 TO 4 HOURS FOR THE 60MG DOSE
D-23	INCREASE MAXIMUM DOSE AND VARIATIONS IN THE DOSING REGIMEN
D-24	FOR OVARIAN CANCER THE RECOMMENDED REGIMEN IS 135MG/M ² OR 175MG/M ² INTRAVENOUSLY OVER THREE HOURS EVERY THREE WEEKS

REFERENCES

NEW INDICATION

I-99	PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER
I-100	TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY
I-101	TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY
I-102	TREATMENT OF OBSESSIVE-COMPULSIVE DISORDER
I-103	PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOCOMPROMISED AND CONSIDERED TO BE AT RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA
I-104	TREATMENT OF PULMONARY AND EXTRAPULMONARY ASPERGILLOSIS IN PATIENTS WHO ARE INTOLERANT OF OR WHO ARE REFRACTORY TO AMPHOTERICIN B THERAPY
I-105	TREATMENT OF METASTATIC CARCINOMA OF THE BREAST AFTER FAILURE OF FIRST-LINE OR SUBSEQUENT CHEMOTHERAPY
I-106	TREATMENT OF ACROMEGALY
I-107	VAGINAL CANDIDIASIS
I-108	EXPANDED USE-FOR ICU PATIENTS UNDERGOING LONG-TERM INFUSION DURING MECHANICAL VENTILATION
I-109	TYPHOID FEVER
I-110	PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH RADIOTHERAPY
I-111	TREATMENT OF PAGET'S DISEASE OF BONE
I-112	MANAGEMENT OF MODERATE TO SEVERE PAIN

REFERENCES

PATENT USE CODE

U-91	ALTERNATIVE THERAPY TO TRIMETHOPRIM-SULFAMETHOXAZOLE FOR TREATMENT OF MODERATE-TO-SEVERE PNEUMOCYSTIS CARINII PNEUMONIA IN IMMUNOCOMPROMISED AND AIDS PATIENTS
U-92	TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN DEPENDENT DIABETES MELLITUS AND RETINOPATHY
U-93	USE AS AN ANTIHISTAMINE/DECONGESTANT
U-94	TREATMENT OF ADULTS WITH ADVANCED HIV INFECTION WHO ARE INTOLERANT OF APPROVED THERAPIES WITH PROVEN CLINICAL BENEFIT OR WHO HAVE EXPERIENCED SIGNIFICANT CLINICAL OR IMMUNOLOGIC DETERIORATION WHILE RECEIVING THESE THERAPIES OR FOR WHOM SUCH THERAPIES ARE CONTRAINDICATED
U-95	SHORT TERM MANAGEMENT OF MODERATE PRURITIS IN ADULTS WITH ATOPIC DERMATITIS AND LICHEN SIMPLEX CHRONICUS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19872 001	ACETAMINOPHEN; TYLENOL	4650807	MAR 17, 2004	U-93	NDF	JUN 08, 1997
19806 001	ACRIVASTINE; SEMPRES-D	4501893	FEB 26, 2002		NC	MAR 25, 1997
74346 001	AMINOSALICYLIC ACID; PASER				ODE	JUN 30, 2001
18700 001	AMINONE LACTATE; INOCOR	4072746	JUL 31, 1998	U-7	NCE	JUL 31, 1994
20304 001	APROTININ BOVINE; TRASYLOL				ODE	DEC 29, 2000
18831 001	ATRACURIUM BESYLATE; TRACRIUM	4179507	DEC 18, 1996		I-108	JUN 06, 1997
20233 001	BUDESONIDE; RHINOCORT				NCE	FEB 14, 1999
18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
18343 001	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 002	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 003	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 005	CAPTOPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 006	CAPTOPRIL; CAPOTEN	4105776	AUG 08, 1995		I-101	JAN 28, 1997
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	I-95	SEP 23, 1996
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	I-66	JUL 21, 1997
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	I-109	JUL 21, 1997
20392 001	CYSTEAMINE BITARTRATE; CYSTAGON				I-66	JUL 21, 1997
20392 002	CYSTEAMINE BITARTRATE; CYSTAGON				I-109	JUL 21, 1997
20355 001	DESMOPRESSIN ACETATE; DESMOPRESSIN ACETATE				I-66	JUL 21, 1997
20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		I-109	JUL 21, 1997
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		NCE	AUG 15, 1999
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		ODE	AUG 15, 2001
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		NCE	AUG 15, 1999
20126 001	DOXEPIN HYDROCHLORIDE; ZONALON	4395420	JUL 26, 2000	U-95	ODE	AUG 15, 2001
81295 001	ESTRADIOL; ESTRACE				NP	MAR 07, 1997
18922 004	ETODOLAC; LODINE	4076831	FEB 28, 1997	U-45	ODE	MAR 07, 2001
20363 002	FAMCICLOVIR; FAMVIR	4283408	AUG 11, 2000			
20249 001	FAMOTIDINE; PEPICID					
					NDF	APR 01, 1997
					I-76	SEP 08, 1995
					NCE	JAN 31, 1996
					NCE	JUN 29, 1999
					I-69	DEC 10, 1994

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	18934 004 FELODIPINE; PLENOIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
	19304 001 FENOFIBRATE; LIPIDIL	4058552	NOV 15, 1994		NCE	DEC 31, 1998
>ADD>	19960 001 FLOSEQUINAN; MANOPLAX	4552884	DEC 31, 2006	U-71		
>DLT>	19960-001 FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
>ADD>	19960 002 FLOSEQUINAN; MANOPLAX	4552884	DEC 31, 2006	U-71		
>DLT>	19960-002 FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
>ADD>	19960 003 FLOSEQUINAN; MANOPLAX	4552884	DEC 31, 2006	U-71		
>DLT>	19960-003 FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
>ADD>	19960 004 FLOSEQUINAN; MANOPLAX	4552884	DEC 31, 2006	U-71		
>DLT>	19960-004 FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
	19949 001 FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	19949 002 FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	19949 003 FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	19950 001 FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
	20322 001 FLUCONAZOLE; DIFLUCAN	4552884	NOV 12, 2002		I-100	DEC 30, 1996
		4302460	NOV 24, 1998		NCE	JAN 29, 1995
					NS	JUN 30, 1997
					I-107	JUN 30, 1997
18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4018895	APR 19, 1994	U-12	I-102	FEB 28, 1997
18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997
20235 001	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 002	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 003	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20123 001	GADODIAMIDE; OMNISCAN	4687659	JAN 08, 2007	U-76	NCE	JAN 08, 1998
>ADD>	20123-001 GADODIAMIDE; OMNISCAN	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
>DLT>	20329 001 GLIPIZIDE; GLUCOTROL XL				NDF	APR 26, 1997
20329 002	GLIPIZIDE; GLUCOTROL XL				NDF	APR 26, 1997
19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5					
		4472380	SEP 18, 2001			
19888 001	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5	4374829	DEC 30, 2001	U-3	NS	NOV 18, 1996
		4472380	SEP 18, 2001			
19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25	4374829	DEC 30, 2001	U-3		
19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5	4374829	DEC 30, 2001	U-3		
		4472380	SEP 18, 2001		NS	NOV 18, 1996
>ADD>	19771 001 IBUPROFEN; ADVIL COLD AND SINUS	4374829	DEC 30, 2001	U-3		
		4552899	NOV 12, 2002			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20367 001	IMIGLUCERASE; CEREZYME				NCE	MAY 23, 1999
20314 001	INDIUM IN-111 PENTETREOTIDE KIT; OCTREOSCAN				ODE	MAY 23, 2001
20084 001	IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131	4584187	APR 22, 2003		NCE	JUN 02, 1999
50705 001	ISONIAZID; RIFATER				NCE	MAR 25, 1999
20336 001	ISRADIPINE; DYNACIRC CR	5030456	JUL 09, 2008		ODE	MAY 31, 2001
		4950486	AUG 21, 2007		NDF	JUN 01, 1997
		4946687	AUG 07, 2007		NCE	DEC 20, 1995
		4816263	MAR 28, 2006	U-3		
		4783337	SEP 16, 2003	U-3		
		4466972	AUG 21, 2003	U-3		
20336 002	ISRADIPINE; DYNACIRC CR	5030456	JUL 09, 2008		NDF	JUN 01, 1997
		4950486	AUG 21, 2007		NCE	DEC 20, 1995
		4946687	AUG 07, 2007			
		4816263	MAR 28, 2006	U-3		
		4783337	SEP 16, 2003	U-3		
		4466972	AUG 21, 2003	U-3		
20083 001	ITRACONAZOLE; SPORANOX				I-104	MAR 29, 1997
18754 001	KETOPROFEN; ORUDIS				I-112	JAN 06, 1997
18754 002	KETOPROFEN; ORUDIS				I-112	JAN 06, 1997
18754 003	KETOPROFEN; ORUDIS				I-112	JAN 06, 1997
19816 001	KETOPROFEN; ORUVAIL				NDF	SEP 24, 1996
20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4369184	JAN 18, 2000		NCE	NOV 10, 1998
19558 006	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19658 001	LORATADINE; CLARITIN	4282233	AUG 04, 2000	U-77	NCE	APR 12, 1998
19658 001	LORATADINE; CLARITIN	4282233	AUG 04, 1998	U-77	NCE	APR 12, 1998
20264 001	MEGESTROL ACETATE; MEGACE				NDF	SEP 10, 1997
20343 001	MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5%	4313951	FEB 02, 2001			
20343 002	MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5%	4313951	FEB 02, 2001		NC	JUN 08, 1997
20343 003	MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5%	4313951	FEB 02, 2001		NC	JUN 08, 1997
20065 001	NAPHAZOLINE HYDROCHLORIDE; OPCON-A				NS	JAN 11, 1997
20226 001	NAPHAZOLINE HYDROCHLORIDE; NAPHCON-A				NCE	DEC 30, 1997
20204 002	NAPROXEN SODIUM; ALEVE				NCE	DEC 30, 1997
19660 001	NEDOCROMIL SODIUM; TILADE	4474787	OCT 02, 2006			
19660 001	NEDOCROMIL SODIUM; TILADE	4474787	OCT 02, 2001		NCE	DEC 30, 1997

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	20165 001 NICOTINE; NICODERM	5344656	APR 02, 2008			
>ADD>	20165 002 NICOTINE; NICODERM	5344656	APR 02, 2008			
>ADD>	20165 003 NICOTINE; NICODERM	5344656	APR 02, 2008			
	19667 001 OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002			I-106 MAY 03, 1997
	19667 002 OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002			I-106 MAY 03, 1997
	19667 003 OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002			I-106 MAY 03, 1997
	19667 004 OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002			I-106 MAY 03, 1997
	19667 005 OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002			I-106 MAY 03, 1997
>ADD>	20103 001 ONDANSETRON HYDROCHLORIDE; ZOFAN					I-110 SEP 26, 1997
>ADD>	20103 002 ONDANSETRON HYDROCHLORIDE; ZOFAN					I-110 SEP 26, 1997
	20262 001 PACLITAXEL; TAXOL					I-105 APR 13, 1997
	20036 001 PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			D-24 JUN 22, 1997
>ADD>	20036 003 PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			D-22 APR 15, 1997
>ADD>	20036 004 PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			I-111 SEP 21, 1997
	20031 001 PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12		D-22 APR 15, 1997
>ADD>	20031 002 PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12		I-111 SEP 21, 1997
>ADD>	20031 003 PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12		NCE DEC 29, 1997
>ADD>	20031 004 PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12		NCE DEC 29, 1997
>ADD>	20031 005 PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12		NCE DEC 29, 1997
	20184 001 PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002			NCE DEC 30, 1998
	20184 002 PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002			NCE DEC 30, 1998
	20184 003 PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002			NCE DEC 30, 1998
	20237 001 PILOCARPINE HYDROCHLORIDE; SALAGEN					ODE MAR 22, 2001
>ADD>	19898 002 PRAVASTATIN SODIUM; PRAVACHOL	4346227	JAN 09, 2004			NDF MAR 22, 1997
>DLT>	19898 002 PRAVASTATIN SODIUM; PRAVACHOL	4346227	AUG 24, 1999			NCE OCT 31, 1996
>ADD>	19898 003 PRAVASTATIN SODIUM; PRAVACHOL	4346227	JAN 09, 2004			NCE OCT 31, 1996
>DLT>	19898 003 PRAVASTATIN SODIUM; PRAVACHOL	4346227	AUG 24, 1999			NCE OCT 31, 1996
>ADD>	19898 004 PRAVASTATIN SODIUM; PRAVACHOL	4346227	JAN 09, 2004			NCE OCT 31, 1996
>DLT>	19898 004 PRAVASTATIN SODIUM; PRAVACHOL	4346227	AUG 24, 1999			NCE OCT 31, 1996
	20279 001 PREDNICARBATE; DERMATOP					NDF OCT 29, 1996
	19627 001 PROPOFOL; DIPRIVAN					I-99 OCT 26, 1996

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20021 002	PSEUDOEPHEDRINE HYDROCHLORIDE; EFIDAC/24	4801461	MAY 05, 2004			
		4576604	MAR 18, 2003			
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995		D-21	FEB 28, 1997
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	4128658	DEC 05, 1995		D-21	FEB 28, 1997
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4521431	JUN 04, 2002		D-21	FEB 28, 1997
20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5028432	JUL 02, 2008			
		4521431	JUN 04, 2002		I-75	MAY 19, 1995
		4128658	DEC 05, 1995		D-21	FEB 28, 1997
20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008			
		4521431	JUN 04, 2002		I-75	MAY 19, 1995
		4128658	DEC 05, 1995		D-21	FEB 28, 1997
20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009			
		4521431	JUN 04, 2002		I-75	MAY 19, 1995
		4128658	DEC 05, 1995		D-21	FEB 28, 1997
20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	5102665	APR 07, 2009			
		4521431	JUN 04, 2002		I-75	MAY 19, 1995
		4128658	DEC 05, 1995		D-21	FEB 28, 1997
20214 001	ROCURONIUM BROMIDE; ZEMURON (P/F)	4894369	JAN 16, 2007		NCE	MAR 17, 1999
20214 002	ROCURONIUM BROMIDE; ZEMURON	4894369	JAN 16, 2007		NCE	MAR 17, 1999
20236 001	SALMETEROL XINAFOATE; SEREVENT	4992474	FEB 12, 2008		NCE	FEB 04, 1999
19766 001	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
19766 002	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
19766 003	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
19766 004	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				D-23	APR 15, 1997
19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				D-23	APR 15, 1997
19865 005	SOTALOL HYDROCHLORIDE; BETAPACE				NCE	OCT 30, 1997
					ODE	OCT 30, 1999
20412 001	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 002	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 003	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 004	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
20412 005	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999
40091 001	SULFADIAZINE; SULFADIAZINE				ODE	JUL 29, 2001
17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-103	JAN 07, 1997
17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-103	JAN 07, 1997

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
17377 001	SULFAMETHOXAZOLE; BACTRIM	4816470	DEC 29, 2006	U-72		I-103 JAN 07, 1997
17377 002	SULFAMETHOXAZOLE; BACTRIM DS	4816470	MAR 28, 2006	U-72		I-103 JAN 07, 1997
17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC	4536516	AUG 20, 2002			I-103 JAN 07, 1997
17598 001	SULFAMETHOXAZOLE; SEPTRA	4867982	FEB 16, 2005			I-103 JAN 07, 1997
17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE	4725439	FEB 16, 2005			I-103 JAN 07, 1997
20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4704282	NOV 03, 2004			I-103 JAN 07, 1997
20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4867982	FEB 16, 2005			
17970 002	TAMOXIFEN CITRATE; NOLVADEX	4725439	FEB 16, 2005			
19762 001	TESTOSTERONE; TESTODERM	4704282	NOV 03, 2004		NDF	OCT 12, 1996
19762 002	TESTOSTERONE; TESTODERM	4867982	FEB 16, 2005			
		4725439	FEB 16, 2005			
		4704282	NOV 03, 2004		NDF	OCT 12, 1996
20330 001	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
20330 002	TIMOLOL MALEATE; TIMOPTIC-XE	4195085	MAR 25, 1997		NP	NOV 04, 1996
		4861760	AUG 29, 2006			
20326 001	TRIMETREXATE GLUCURONATE; NEUTREXIN	4195085	MAR 25, 1997		NP	NOV 04, 1996
19908 001	ZOLPIDEM TARTRATE; AMBIEN	4694007	SEP 15, 2004	U-91	ODE	DEC 17, 2000
19908 001	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2005	U-74	NCE	DEC 16, 1997
19908 002	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 05, 2000	U-74	NCE	DEC 16, 1997
19908 002	ZOLPIDEM TARTRATE; AMBIEN	4382938	MAY 10, 2005	U-74	NCE	DEC 16, 1997
		4382938	MAY 05, 2000	U-74	NCE	DEC 16, 1997

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