

ST. LOUIS COLLEGE OF PHARMACY LIBRARY

FEB 23 1994

300
1993
RM
301.45
.A66
1993
Nov
Suppl

**CUMULATIVE
SUPPLEMENT 11**

JAN'93-NOV'93

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION



RM301.45 .A66 1993 Nov Suppl

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

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

SUBSCRIBE NOW!

Available in March 1994

New 14th Edition

Library Use Only



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**14TH EDITION
1994**

CONTENTS

- Prescription Drug Product List
- OTC Drug Product List
- Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products List
- Discontinued Drug Product List
- USP Monograph Title Additions or Changes
- Orphan Drug Product Designations
- Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution
- Biopharmaceutic Guidance Availability
- ANDA Suitability Petitions
- Patent and Exclusivity Information

See Subscription Form Inside Back Cover

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

Cumulative Supplement 11

NOVEMBER 1993

CONTENTS

	PAGE
1.0 INTRODUCTION	iii
1.1 How to Use the Cumulative Supplement	iii
1.2 Products Requiring Revised Labeling for Full Approval	v
1.3 Applicant Name Changes	vi
1.4 USP Monograph Title Additions or Changes	viii
1.5 Report of Counts for the Prescription Drug Product List	ix
2.0 DRUG PRODUCT LISTS	
2.1 Prescription Drug Product List	1
2.2 OTC Drug Product List	80
2.3 Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List	84
2.4 Orphan Drug Product Designations	85
2.5 Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution	91
2.6 Biopharmaceutic Guidance Availability	92
2.7 ANDA Suitability Petitions	93
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Exclusivity Terms	96
B. Patent and Exclusivity Lists	97

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

CUMULATIVE SUPPLEMENT 11

NOVEMBER 1993

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, 13th 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, OTC Drug Product List, and 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 overstruck 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 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th 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.

Products

Federal Register Reference

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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

AH ROBINS CO
(ROBINS)

AH ROBINS CO
(ROBINS AH)

ALLERGAN HERBERT SKIN CARE
DIV ALLERGAN INC
(ALLERGAN HERBERT)

ALLERGAN HERBERT
DIV ALLERGAN INC
(ALLERGAN INC)

ASTRA PHARMACEUTICAL PRODUCTS INC
(ASTRA)

ASTRA USA INC
(ASTRA)

BAKER CUMMINS PHARMACEUTICALS INC
(BAKER CUMMINS)

BAKER NORTON PHARMACEUTICALS INC
(BAKER NORTON)

BENEDICT NUCLEAR PHARMACEUTICALS INC
(BENEDICT)

NORTH AMERICAN CHEMICAL CORPORATION
(NORTH AM CHEM)

BOLAR PHARMACEUTICAL CO INC
(BOLAR)

CIRCA PHARMACEUTICALS INC
(CIRCA)

CIS US INC
(CIS)

CIS US INC
(CIS)
formerly
(CIS US)

CUTTER BIOLOGICAL DIV
MILES LABORATORIES INC
(CUTTER)

MILES LABORATORIES INC
(MILES LABS)

DANBURY PHARMACAL INC
(DANBURY)

DANBURY PHARMACAL INC
(DANBURY PHARMA)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

FUJISAWA PHARMACEUTICAL CO
(FUJISAWA)

FUJISAWA USA INC
(FUJISAWA)

GENSIA PHARMACEUTICAL INC
(GENSIA)

GENSIA INC
(GENSIA)

HERBERT LABORATORIES DIV
SMITH KLINE AND FRENCH CO
(HERBERT)

ALLERGAN HERBERT
DIV ALLERGAN INC
(ALLERGAN HERBERT)

ICI PHARMACEUTICALS GROUP
DIV ICI AMERICAS
(ICI)

ZENECA PHARMACEUTICALS GROUP
DIV ZENECA INC
(ZENECA)
formerly
ZENECA PHARMACEUTICALS GROUP

LEMMON CO
(LEMMON)

LEMMON CO SUB TEVA PHARMACEUTICALS
(LEMMON)

LYPHOMED DIV FUJISAWA USA INC
(LYPHOMED)

FUJISAWA USA INC
(FUJISAWA)

OWEN GALDERMA LABORATORIES INC
(OWEN GALDERMA)

GALDERMA LABORATORIES INC
(GALDERMA)

PIONEER PHARMACEUTICALS INC
(PIONEER PHARMS)

PIONEER PHARMACEUTICALS CO INC
(PIONEER PHARMS)

ROXANE LABORATORIES INC
(ROXANE)

ROXANE LABORATORIES INC
(ROXANE)
formerly
(ROXANE LABS)

RW JOHNSON PHARMACEUTICAL RESEARCH
INSTITUTE DIV MCNEILAB
(JOHNSON RW)

RW JOHNSON PHARMACEUTICAL RESEARCH
INSTITUTE DIV ORTHO PHARMACEUTICAL
CORP
(JOHNSON RW)

SCHIAPPARELLI SEARLE
(SCHIAPPARELLI SEARLE)

SCS PHARMACEUTICALS
(SCS PHARMS)

SCHWARZ PHARMA KERMERS URBAN
(SCHWARZ PHARMA)

SCHWARZ PHARMA DIV KREMERS URBAN CO
(SCHWARZ PHARMA)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

SOMERSET PHARMACEUTICALS INC
(SOMERSET)

SOMERSET PHARMACEUTICALS INC
(SOMERSET PHARMS)

STERLING DRUG INC
(STERLING)

STERLING WINTHROP INC
(STERLING WINTHROP)

1.4 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 NOVEMBER 1993.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under 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 1992) 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 1992</u>	<u>MAR 1993</u>	<u>JUN 1993</u>	<u>SEP 1993</u>
DRUG PRODUCTS LISTED	9488	9392	9194	9142
SINGLE SOURCE	2245 (23.7%)	2243 (23.9%)	2119 (23.0%)	2151 (23.5%)
MULTISOURCE	7243 (76.3%)	7149 (76.1%)	7075 (77.0%)	6991 (76.5%)
THERAPEUTICALLY EQUIVALENT	6516 (68.6%)	6432 (68.5%)	6357 (69.1%)	6276 (68.7%)
NOT THERAPEUTICALLY EQUIVALENT	577 (6.1%)	562 (5.9%)	555 (6.1%)	532 (5.8%)
EXCEPTIONS ¹	150 (1.6%)	155 (1.7%)	163 (1.8%)	183 (2.0%)
NEW MOLECULAR ENTITIES APPROVED	--	3	2	9
NUMBER OF APPLICANTS	477	484	508	515

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

ALCOJAN

/MALLARD/

/325MG; 50MG; 40MG/

/N87628/001/

/DEC/23, 1988/

OCT 01, 1986

AB ROBERTS HAUCK

325MG; 50MG; 40MG

TABLET; ORAL

/FEST/

/FOREST/PHARMS/

/325MG; 50MG; 40MG/

/N89660/001/

/DEC/23, 1988/

DEC 23, 1988

3 FOREST PHARMS

325MG; 50MG; 40MG

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

COMPAL

PURDUE FREDERICK

356.4MG; 30MG; 16MG

N88584 001

MAR 04, 1986

/N88584/001/

/MAR/04, 1986/

/SOLVAY/

/356.4MG; 30MG; 16MG/

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

300MG; 30MG

300MG; 30MG

N88324 001

DEC 29, 1983

/N88324/001/

/DEC/29, 1983/

/ACETAMINOPHEN/M/ /CODEINE/03/

/LEMON/

SOLUTION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

PENNEX PHARMS

/PHARM/BASIS/

120MG/5ML; 12MG/5ML

/120MG/5ML; 12MG/5ML/

N87006 001

/N87006/001/

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

/PHARM/ALP/

/300MG; 30MG/

/N87762/001/

/DEC/10, 1982/

N87762 001

DEC 10, 1982

> DLT > /AA/

> DLT > /AA/

> ADD > AA

> ADD >

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

/LUCHEM/

/500MG; 5MG/

/N89907/001/

/JAN/13, 1989/

JAN 13, 1989

AA NORTON HN

500MG; 5MG

/BANGAP/HC/

/FOREST/PHARMS/

/500MG; 5MG/

/N87961/001/

/MAR/17, 1983/

MAR 17, 1983

3 FOREST PHARMS

500MG; 5MG

TABLET; ORAL

ANEXSIA

BOEHRINGER MANNHEIM

500MG; 5MG

N89160 001

APR 23, 1987

/N89160/001/

/APR/23, 1987/

/AA/

/SKCP/

/500MG; 5MG/

ANEXSIA 7.5/650

650MG; 7.5MG

N89725 001

SEP 30, 1987

/N89725/001/

/SEP/30, 1987/

AA BOEHRINGER MANNHEIM

650MG; 7.5MG

/SKCP/

/650MG; 7.5MG/

/AA/

/DURADINE/HC/

/500MG; 5MG/

/MAR/17, 1983/

MAR 17, 1983

3 FOREST PHARMS

500MG; 5MG

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

/LUCHEM/

/500MG; 5MG/

/N89696/001/

/APR/21, 1988/

APR 21, 1988

AA NORTON HN

500MG; 5MG

/NORDET/

/ABANA/

/500MG; 5MG/

/N88871/001/

/MAY/15, 1986/

MAY 15, 1986

3 ABANA

500MG; 5MG

/FIDUCET/

/JOHNSON/PH/

/500MG; 5MG/

/N89385/001/

/AUG/27, 1986/

AUG 27, 1986

3 JOHNSON RW

500MG; 5MG

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

/AB/ /HALSEY/ /325MG;50MG/

/AS/ /HALSEY/ /50MG;100MG/

3 HALSEY

325MG;50MG

3

650MG;100MG

/N72105/001/

/MAY/13,1988/

/N72106/001/

/MAY/13,1988/

N72105 001

MAY 13, 1988

N72106 001

MAY 13, 1988

EQ 0.083% BASE

N73495 001

MAY 28, 1993

EQ 2MG BASE/5ML

N73165 001

APR 29, 1993

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

/AP/ /QUAD/ /ACETAZOLAMIDE SODIUM/

/EQ 500MG/VIAL/

3 QUAD

EQ 500MG/VIAL

/N89619/001/

/JAN/13,1988/

N89619 001

JAN 13, 1988

EQ 2MG BASE

N72779 001

JUN 25, 1993

EQ 4MG BASE

N72780 001

JUN 25, 1993

DIAZOL

/AP/ /LEDERLE/

/EQ 500MG/VIAL/

LEDERLE

EQ 500MG/VIAL

/N09388/001/

/DEC/05,1990/

N09388 001

DEC 05, 1990

/EQ 4MG BASE/

/N19383/001/

/JUL/13,1987/

N19383 001

JUL 13, 1987

ACETYLCHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; OPHTHALMIC

MIOCHOL-E

+ IOLAB

20MG/VIAL

N20213 001

SEP 22, 1993

/BC/ /SCHERING/

/EQ 4MG BASE/

/N19604/002/

/DEC/23,1992/

N19604 002

DEC 23, 1992

BC + MURO

EQ 4MG BASE

+

EQ 8MG BASE

N19604 001

DEC 23, 1992

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ZOVIRAX

+ BURROUGHS WELLCOME

EQ 1GM BASE/VIAL

3

EQ 250MG BASE/VIAL

N18603 002

JUN 29, 1989

N18603 003

AUG 30, 1983

ALPRAZOLAM

CONCENTRATE; ORAL

ALPRAZOLAM

ROXANE

1MG/ML

N74312 001

OCT 31, 1993

SOLUTION; ORAL

ALPRAZOLAM

ROXANE

0.5MG/5ML

N74314 001

OCT 31, 1993

AMPICILLIN/AMPCILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

PRENCEPEN

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

AB /
AB /
AB /

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

AMPCILLIN/AMPCILLIN TRIHYDRATE; PROBENECID

CAPSULE; ORAL

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

POWDER FOR RECONSTITUTION; ORAL

POLYCYCLIN-PRD

APOTHECON

EQ 3.5GM BASE/BOI;
EQ 3.5GM BASE/BOI;
EQ 3.5GM BASE/BOI;

N61898 001
N61898 002
N61898 003

APOTHECON

EQ 3.5GM BASE/BOI;
EQ 3.5GM BASE/BOI;
EQ 3.5GM BASE/BOI;

N61898 001
N61898 002
N61898 003

ANISOTROPINE METHYLBROMIDE

CAPSULE; ORAL

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 100MG BASE/ML

N61394 002
N61394 003
N61394 001

APRACLOINIDINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

IOPTIDINE

ALCON

EQ 0.5% BASE

N20258 001
JUL 30, 1993

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;
RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E

INJECTION

ASTRA

100MG/VIAL; 0.06MG/VIAL; 0.005MG/VIAL;
15MG/VIAL; 5UG/VIAL; 0.4MG/VIAL;
40MG/VIAL; 4MG/VIAL; 3.6MG/VIAL;
3MG/VIAL; 1MG/VIAL;
10MG/VIAL

ASTRA

100MG/VIAL; 0.06MG/VIAL; 0.005MG/VIAL;
15MG/VIAL; 5UG/VIAL; 0.4MG/VIAL;
40MG/VIAL; 4MG/VIAL; 3.6MG/VIAL;
3MG/VIAL; 1MG/VIAL;
10MG/VIAL

N18933 002
AUG 08, 1985

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE
HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE
HYDROCHLORIDE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

FUJISAWA

10MG/ML; 0.006MG/ML; 0.5UG/ML;
1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML;
0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
330 UNITS/ML; 1 IU/ML
10MG/ML; 0.006MG/ML; 0.5UG/ML;
1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML;
0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
330 UNITS/ML; 1 IU/ML

10MG/ML; 0.006MG/ML; 0.5UG/ML;
1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML;
0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
330 UNITS/ML; 1 IU/ML
10MG/ML; 0.006MG/ML; 0.5UG/ML;
1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML;
0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
330 UNITS/ML; 1 IU/ML

N18440 002
AUG 08, 1985

ASPIRIN; BUTALBITAL

AXOTAL

ADRIA

650MG; 50MG

N88305 001
OCT 13, 1983

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

> DLT > /AB/ BUTALBITAL W/ ASPIRIN & CAFFEINE
> DLT > /PHARMALAIR/ /32.5MG; 50MG; 40MG/
> ADD > AB PHARMERAL 32.5MG; 50MG; 40MG
> ADD >

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

/AB/ /QUAD/ /ED 100MG BASE/VIAL/
EQ 100MG BASE/VIAL
N71056 001
JUN 08, 1988
/N71056/001/
/JUN/08/1988/

ASPIRIN; PROPOXYPHENE NAPSYLATE

/TABLET; ORAL/
/PROXYPH-N/W/ASA/
@ LILLY

/32.5MG; 100MG/
32.5MG; 100MG
N16863 001
/N16863/001/

ATENOLOL

TABLET; ORAL
ATENOLOL

AB MUTUAL PHARM 50MG
AB 100MG
AB NOVOPHARM 50MG
AB 100MG
N73475 001
MAR 30, 1993
N73476 001
MAR 30, 1993
N73315 001
MAY 28, 1993
N73316 001
MAY 28, 1993

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

AB ATENOLOL AND CHLORTHALIDONE 50MG; 25MG
AB 100MG; 25MG
AB MYLAN 50MG; 25MG
AB 100MG; 25MG
N73581 001
APR 29, 1993
N73582 001
APR 29, 1993
N74203 001
OCT 31, 1993
N74203 002
OCT 31, 1993

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

> DLT > /AB/ DIPHENOXYLATE HCL AND ATROPINE SULFATE
> ADD > AB /PHARMALAIR/ /0.025MG; 2.5MG/
PHARMERAL 0.025MG; 2.5MG

IVURAN

/AB/ /BURROUGHS WELLCOME/ /ED 100MG BASE/VIAL/
EQ 100MG BASE/VIAL
N17391 001
/N17391/001/

AZLOCELLIN SODIUM

INJECTABLE; INJECTION

AZLIN /MILES/
EQ 2GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 4GM BASE/VIAL
EQ 4GM BASE/VIAL
EQ 4GM BASE/VIAL
N62388 001
SEP 08, 1982
N62417 001
OCT 12, 1982
N62388 003
SEP 08, 1982
N62417 003
OCT 12, 1982
/N62388/001/
/SEP/08/1982/
/N62417/001/
/OCT/12/1982/
/N62388/003/
/SEP/08/1982/
/N62417/003/
/OCT/12/1982/
/N62388/003/
/SEP/08/1982/
/N62417/003/
/OCT/12/1982/

AZTREONAM

INJECTABLE; INJECTION

AZACTAM IN PLASTIC CONTAINER
/SQUIBB/
EQ 10MG/ML
N50632 003
MAY 24, 1989

/N50632/003/
/MAY/24/1989/
N50632 003
MAY 24, 1989

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

ointment; OPHTHALMIC

CORTISPORIN

/AT/ /BURROUGHS/NEOMYCIN/ /400 UNITS/GM; 12:EQ 3.5MG BASE/GM; /
/10,000 UNITS/GM; /N50167/001/
+ BURROUGHS WELLCOME 400 UNITS/GM; 12:EQ 3.5MG BASE/GM;
10,000 UNITS/GM N50416 002
/ZINC; BACITRACIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE G/
/HYDROCORTISONE/
/AT/ /PHARMAFAIR/ /400 UNITS/GM; 12:EQ 3.5MG BASE/GM; /
/10,000 UNITS/GM; /N62381/001/
3 PHARMAFAIR 400 UNITS/GM; 12:EQ 3.5MG BASE/GM;
10,000 UNITS/GM N62389 001
JUL 02, 1982

ointment; TOPICAL

CORTISPORIN

/AT/ /BURROUGHS/NEOMYCIN/ /400 UNITS/GM; 12:EQ 3.5MG BASE/GM; /
/5,000 UNITS/GM; /N50168/002/
+ BURROUGHS WELLCOME 400 UNITS/GM; 12:EQ 3.5MG BASE/GM;
5,000 UNITS/GM N50168 002
MAY 04, 1984
/NEOMYCIN; POLYMYXIN B SULFATES G BACITRACIN ZINC G/
/HYDROCORTISONE/
/AT/ /PHARMAFAIR/ /400 UNITS/GM; 12:EQ 3.5MG BASE/GM; /
/5,000 UNITS/GM; /N62381/001/
3 PHARMAFAIR 400 UNITS/GM; 12:EQ 3.5MG BASE/GM;
5,000 UNITS/GM N62381 001
SEP 06, 1985

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

ointment; OPHTHALMIC

BACITRACIN ZINC-NEOMYCIN SULFATE-POLYMYXIN B SULFATE

/AT/ /PHARMAFAIR/ /400 UNITS/GM; 12:EQ 3.5MG BASE/GM; /
/10,000 UNITS/GM; /N62386/001/
3 PHARMAFAIR 400 UNITS/GM; 12:EQ 3.5MG BASE/GM;
10,000 UNITS/GM N62386 001
SEP 09, 1982

BACITRACIN-NEOMYCIN-POLYMYXIN

/PHARMADERM/

3 PHARMADERM /400 UNITS/GM; 12:EQ 3.5MG BASE/GM; /
/5,000 UNITS/GM; /N62167/001/
5,000 UNITS/GM; 12:EQ 3.5MG BASE/GM;
N62167 001

BENTONITE

SOLUTION; ORAL

CHYNEX

/ADRIA/ /500MG/7.5ML/
500MG/7.5ML
DEC 29, 1983

BENTONITE; SULFUR

/POYTHRESS/ /TOPICAL/
/BENSULFID/ /
/POYTHRESS/ /
3 POYTHRESS /66.64%; 33.34%/
66.64%; 33.32% /N02918 001

BENZONATE

CAPSULE; ORAL

BENZONATE

AA PHARMACAPS 100MG
N81297 001
JAN 29, 1993

TESSALON

AA FOREST LABS 100MG
N11210 001

BENZPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DIDREX

/UPJOHN/ /25MG/
3 UPJOHN 25MG
/N12427/003/
N12427 003

BENZTHIAZIDE

TABLET; ORAL

/ADJATAS/

/BP/ /SOLVAY/ /50MG/
3 SOLVAY 50MG
/N16001/002/
N16001 002

EXNA

/BP/ /ROBINS/ /AH/ /50MG/
+ ROBINS AH 50MG
/N12489/001/
N12489 001

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL

/AB/ /BEPIDIL/

/200MG/

/N19136/001/

/AB/ /WALLACE/

/300MG/

/DEC/28,1990/

/AB/ /WALLACE/

/400MG/

/DEC/28,1990/

3 WALLACE

200MG

/DEC/28,1990/

3

300MG

/DEC/28,1990/

3

400MG

/DEC/28,1990/

VASCO

/AB/ /JOHNSON/RW/

/200MG/

/N19136/001/

/AB/

/300MG/

/DEC/28,1990/

/AB/ /+

/400MG/

/DEC/28,1990/

+ JOHNSON RW

400MG

/DEC/28,1990/

200MG

/DEC/28,1990/

300MG

/DEC/28,1990/

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

/AB/ /PHARMADERM/ /EQ 0.05% BASE/

EQ 0.05% BASE

/N19136/001/

/JUN/26,1984/

/N19136 001

JUN 26, 1984

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

/AB/ /PHARMADERM/ /EQ 0.05% BASE/

EQ 0.05% BASE

/N19136/001/

/JUN/26,1984/

/N19136 001

JUN 26, 1984

BETAMETHASONE DIPROPIONATE

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

/AB/ /PHARMADERM/ /EQ 0.05% BASE/

EQ 0.05% BASE

/N19140/001/

/SEP/04,1984/

N19140 001

SEP 04, 1984

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE

/AB/ /PHARMADERM/ /EQ 0.1% BASE/

EQ 0.1% BASE

/N18860/002/

/AUG/31,1983/

N18860 002

AUG 31, 1983

LOTION; TOPICAL

BETAMETHASONE VALERATE

/AB/ /PHARMADERM/ /EQ 0.1% BASE/

EQ 0.1% BASE

/N18870/001/

/AUG/31,1983/

N18870 001

AUG 31, 1983

OINTMENT; TOPICAL

BETAMETHASONE VALERATE

AB NMC /EQ 0.1% BASE/

EQ 0.1% BASE

/N70051 001

OCT 10, 1984

BETAMETHASONE VALERATE

/AB/ /PHARMADERM/ /EQ 0.1% BASE/

EQ 0.1% BASE

/N18864/001/

/AUG/31,1983/

N18864 001

AUG 31, 1983

/AB/ /NMC/ /EQ 0.1% BASE/

EQ 0.1% BASE

/N70051/001/

/OCT/10,1984/

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ZIAC

+ LEDERLE

10MG;6.25MG

N20186 002

MAR 26, 1993

2.5MG;6.25MG

N20186 003

MAR 26, 1993

5MG;6.25MG

N20186 001

MAR 26, 1993

CALCITONIN, SALMON

INJECTABLE; INJECTION

CALCTHAR
/AP/ /RHONE/POULENC/RORER/200 IU/ML/
AP + RHONE POULENC RORER 200 IU/ML
/54002/
/100/10/ML/
100 IU/ML
@ SANDOZ

/N17769/001/
N17769 001
/N17808/001/
N17808 001
JUL 03, 1986

/AP/ /PHARMAFAIR/
0.01%
@ PHARMAFAIR
/AP/ /ALCON/
+ ALCON
0.01%
/N16968/001/
N16968 001
MAY 21, 1986

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

SOLUTION; IRRIGATION

ENDOSOL EXTRA

AT ALLERGAN

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;
0.2MG/ML; 0.32MG/ML; 2.1MG/ML;
7.14MG/ML; 0.42MG/ML
N20079 001
NOV 27, 1991

ENDOSOL PLUS

/AT/ /ALLERGAN/

/0.154MG/ML; 0.94MG/ML; 0.184MG/ML;
/0.2MG/ML; 0.32MG/ML; 2.1MG/ML;
/7.14MG/ML; 0.42MG/ML/
/N20079/001/
/NOV 27, 1991/

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

INJECTABLE; INJECTION

ISOLYTE R IN DEXTROSE 5%
MCGAN
37MG/100ML; 5GM/100ML; 31MG/100ML;
120MG/100ML; 330MG/100ML;
88MG/100ML
N19864 001
JUN 10, 1993

CALCIUM GLUCEPATE

INJECTABLE; INJECTION

CALCIUM GLUCEPTATE

/AP/ /ABBOTT/
+ ABBOTT
/AP/ /LILLY/
@ LILLY
/AP/ /LYPHOMED/
@ LYPHOMED
EQ 90MG CALCIUM/5ML

/N80001/001/
N80001 001
/N06470/001/
N06470 001
/N89373/001/
/APR 30, 1987/
N89373 001
APR 30, 1987

CARBACHOL

INJECTABLE; INJECTION

/AP/ /CARBACHOL/
/PHARMAFAIR/
0.01%
@ PHARMAFAIR
/AP/ /ALCON/
+ ALCON
0.01%
/N16968/001/
N16968 001
MAY 21, 1986

CARBENICILLIN DISODIUM

INJECTABLE; INJECTION

GEOPEN

/AP/ /ROERIG/
/AP/ /ROERIG/
/AP/ /ROERIG/
/AP/ /ROERIG/

/EQ 1GM BASE/VIAL/
/EQ 2GM BASE/VIAL/
/EQ 5GM BASE/VIAL/
/EQ 10GM BASE/VIAL/
EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 5GM BASE/VIAL
EQ 10GM BASE/VIAL
N50306 001
N50306 004
N50306 002
N50306 006

ROERIG

PTOPEN

/AP/ /SMITHKLINE/BEECHAM/
/AP/ /SMITHKLINE/BEECHAM/
/AP/ /SMITHKLINE/BEECHAM/
/AP/ /SMITHKLINE/BEECHAM/

/EQ 1GM BASE/VIAL/
/EQ 2GM BASE/VIAL/
/EQ 5GM BASE/VIAL/
/EQ 10GM BASE/VIAL/
EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 5GM BASE/VIAL
EQ 10GM BASE/VIAL
EQ 20GM BASE/VIAL
N50298 001
N50298 002
N50298 003
N50298 006
N50298 007

@ SMITHKLINE BEECHAM

@ SMITHKLINE BEECHAM

@ SMITHKLINE BEECHAM

@ SMITHKLINE BEECHAM

@ SMITHKLINE BEECHAM

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

AB PUREPAC

10MG;100MG

N74260 001
SEP 03, 1993

AB

25MG;100MG

N74260 002
SEP 03, 1993

AB

25MG;250MG

N74260 003
SEP 03, 1993

CARBIDOPA LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

WATSON LABS

10MG; 100MG

N73381 001

SEP 28, 1993

25MG; 100MG

N73382 001

SEP 28, 1993

25MG; 250MG

N73383 001

SEP 28, 1993

CARBINOXAMINE MALEATE

TABLET; ORAL
CLISTIN
 JOHNSON RW
 JOHNSON RW

4MG
4MG

N08915/001
N08915 001

CARTISOPRODOL

CAPSULE; ORAL
SCIN
 WALLACE
 WALLACE

250MG
250MG

N11792/003
N11792 003

TABLET; ORAL

CARTISOPRODOL

AB / PIONEER PHARMS

350MG

N09390/001
N09390 001

3 PIONEER PHARMS

350MG

N12155/001
N12155 001

AB / SCHERING
 3 SCHERING

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIPRESS

EUROPHARM/NEILSON / 1%

OTSUKA

1%

N19972/001
N19972 001
 MAY 23, 1990

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

DURICEF

AB + BRISTOL MYERS SQUIBB EQ 500MG BASE
AB / HEAD/JOHNSON / EQ 500MG BASE

N50512 001
N50512/001

POWDER FOR RECONSTITUTION; ORAL

DURICEF

AB + BRISTOL MYERS SQUIBB EQ 125MG BASE/5ML
AB + BRISTOL MYERS SQUIBB EQ 250MG BASE/5ML
AB + BRISTOL MYERS SQUIBB EQ 500MG BASE/5ML
AB / HEAD/JOHNSON / EQ 125MG BASE/5ML
AB / HEAD/JOHNSON / EQ 250MG BASE/5ML
AB / HEAD/JOHNSON / EQ 500MG BASE/5ML

N50527 002
N50527 003
N50527 001
N50527/002
N50527/003
N50527/001

TABLET; ORAL

DURICEF

AB + BRISTOL MYERS SQUIBB EQ 1GM BASE
AB / HEAD/JOHNSON / EQ 1GM BASE

N50528 001
N50528/001

CEFAMANDOLE NAFATE

INJECTABLE; INJECTION

MANDOL

+ LILLY

EQ 10GM BASE/VIAL

N50504 004

CEFTIOXIME SODIUM

INJECTABLE; INJECTION
/CEFTIOXIME SODIUM/
3 TAKEDA

EQ 1GM BASE/VIAL

N50601 001
DEC 30, 1988

CEFOXITIN SODIUM

INJECTABLE; INJECTION
MEFOXIN IN PLASTIC CONTAINER
MERCK

EQ 20MG BASE/ML

EQ 40MG BASE/ML

N63182 001
JAN 25, 1993
N63182 002
JAN 25, 1993

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
/CEFTIZOXIME SODIUM/
/WYETH/AYERST/

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 10GM BASE/VIAL

3 WYETH AYERST

3

3

N50633 002
JAN 31, 1989
N50633 003
JAN 31, 1989
N50633 005
JAN 31, 1989

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFIZOX
FUJISAWA

EQ 500MG BASE/VIAL

EQ 10GM BASE/VIAL

N50560 001
SEP 15, 1983
N50560 005
MAR 19, 1993

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN
ROCHE

EQ 250MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

N63239 001
AUG 13, 1993
N63239 002
AUG 13, 1993
N63239 003
AUG 13, 1993

CEFTAZIDIME

INJECTABLE; INJECTION
TATICEF

AP SMITHKLINE BEECHAM

1GM/VIAL

2GM/VIAL

N64032 001
OCT 31, 1993
N64032 002
OCT 31, 1993

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER
/ROCHE/
3 ROCHE

EQ 10MG BASE/ML

N50624 001
FEB 11, 1987

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
CEFTAZIDIME SODIUM IN PLASTIC CONTAINER

EQ 10MG BASE/ML

EQ 20MG BASE/ML

EQ 40MG BASE/ML

N63221 001
APR 29, 1993
N63221 002
APR 29, 1993
N63221 003
APR 29, 1993

FORIAZ IN PLASTIC CONTAINER

EQ 10MG BASE/ML

EQ 20MG BASE/ML

EQ 40MG BASE/ML

N50634 001
APR 28, 1989
N50634 002
APR 28, 1989
N50634 003
APR 28, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION

CEFURXIME

AP MARSAM

EQ 750MG BASE/VIAL

N64035 001
FEB 26, 1993

EQ 1.5GM BASE/VIAL

N64035 002
FEB 26, 1993

EQ 7.5GM BASE/VIAL

N64036 001
FEB 26, 1993

AP KEFUROX

EQ 7.5GM BASE/VIAL

N62591 003
DEC 17, 1987

AP LILLY

EQ 7.5GM BASE/VIAL

N50558 004
OCT 23, 1986

AP ZITHACEF

EQ 7.5GM BASE/VIAL

CELLULOSE SODIUM PHOSPHATE

POWDER; ORAL
CALCIBIND

/+/MISSEDION/PHARMIA/

/P.5GM/PACKET/

2.5GM/PACKET

N18757 002
DEC 28, 1982

CEPHALEXIN

CAPSULE; ORAL

CEFALEX

AB APOTHECON

EQ 250MG BASE

EQ 500MG BASE

/EQ.250MG. BASE/

/EQ.500MG. BASE/

/AB/ /PARISOTOL/NIERS/

/AB/ /PARISOTOL/NIERS/

EQ 250MG BASE

EQ 500MG BASE

/EQ.250MG. BASE/

/EQ.500MG. BASE/

AB CEFALOTIN

AB APOTHECON

AB

/AB/ /SCOTT'S MARK/

/AB/ /SCOTT'S MARK/

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

CEPHALOTHIN SODIUM

/AP/

/EQ.1GM. BASE/VIAL/

/N62548/001/

/AP/

/EQ.2GM. BASE/VIAL/

/N62548/002/

3 ABBOTT

EQ 1GM BASE/VIAL

SEP 11, 1985

3

EQ 2GM BASE/VIAL

SEP 11, 1985

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION

CEFADYL

3 APOTHECON

EQ 500MG BASE/VIAL

EQ 500MG BASE/VIAL

SEP 20, 1988

3

EQ 1GM BASE/VIAL

SEP 20, 1988

3

EQ 2GM BASE/VIAL

SEP 20, 1988

EQ 2GM BASE/VIAL

SEP 20, 1988

EQ 2GM BASE/VIAL

SEP 20, 1988

EQ 4GM BASE/VIAL

SEP 20, 1988

EQ 4GM BASE/VIAL

SEP 20, 1988

EQ 4GM BASE/VIAL

SEP 20, 1988

EQ 20GM BASE/VIAL

SEP 20, 1988

/EQ.500MG. BASE/VIAL/

/N50446/005

/EQ.1GM. BASE/VIAL/

/N50446/001

/EQ.1GM. BASE/VIAL/

/N50446/001

/EQ.1GM. BASE/VIAL/

/N50446/001

/EQ.1GM. BASE/VIAL/

/N50446/001

/EQ.1GM. BASE/VIAL/

/N50446/001

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION

CHLORFENIRAMINE MALEATE

/AD/ /STERIS/ /100MG/ML/ /100MG/ML/

STERIS

/BELL/MAR/

3 BEL MAR

/AD/ /BELL/MAR/ /100MG/ML/ /100MG/ML/

100MG/ML

/N866495/001/

N86095 001

/N83733/001/

N83733 001

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/NEWTRON/ /4MG/

3 NEWTRON

/3/ PHARMALFAIR/

3 PHARMAL

4MG

4MG

4MG

/N86519/001/

N86519 001

/N83753/001/

N83753 001

CHLORPROMAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

CHLORFENMAZINE HCL

3 PENNEX PHARMS

30MG/ML

100MG/ML

/30MG/ML/

/100MG/ML/

/100MG/ML/

N87032 001

JUL 08, 1982

N87053 001

/N87053/001/

/JUL/08/1982/

/N87053/001/

INJECTABLE; INJECTION

CHLORFENMAZINE HCL

3 LYPHONED

/25MG/ML/

25MG/ML

/N84911/001/

N84911 001

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

3 ABBOTT

/PHARM/BASICS/

3 PHARM BASICS

/50MG/

50MG

/50MG/

/50MG/

50MG

/N87384/001/

N87384 001

/N89052/001/

/JUN/01/1987/

N89052 001

JUN 01, 1987

CHLORTHALIDONE; METOPROLOL TARTRATE

/CAPSULE; ORAL/

/LOPRESSIDONE/

/3/ CIBA

/25MG; 100MG/

/25MG; 100MG/

25MG; 100MG

25MG; 200MG

3

/N14451/001/

/DEC/31/1987/

/N14451/001/

/DEC/31/1987/

N14451 001

DEC 31, 1987

N14451 002

DEC 31, 1987

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

/ADA/ /PIONEER/PHARMS/

/ADA/

/250MG/

/500MG/

250MG

500MG

/N86592/001/

/JAN/06/1989/

/N89948/001/

/JAN/06/1989/

N89592 001

JAN 06, 1989

N89948 001

JAN 06, 1989

CHYMOPAPAIN

INJECTABLE; INJECTION

CHYMODIACIN

/BOOTS/

/10,000 UNITS/VIAL/

10,000 UNITS/VIAL

3 BOOTS

/N18663/001/

/NOV/10/1982/

N18663 001

NOV 10, 1982

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC

CATARASE

+ IOLAB

3

/300 UNITS/VIAL/

/150 UNITS/VIAL/

/150 UNITS/VIAL/

/300 UNITS/VIAL/

N16938 001

/N16121/001/

N18121 001

/N16938/001/

CISAPRIDE MONOHYDRATE

TABLET; ORAL
PROPULSID
/+/JANSSEN/

JANSSEN

3

/EQ 10MG BASE/

EQ 10MG BASE

EQ 20MG BASE

/N50162/001/
/JUL/29/1993/

N20210 001

JUL 29, 1993

N20210 002

JUL 29, 1993

> ADD >
> ADD >

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER

+ UPJOHN

N50639 003

APR 10, 1991

CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%
/EQ 12MG BASE/ML/

3 LYPHOMED

EQ 12MG BASE/ML

/N50636/001/
/DEC/22/1989/

N50636 001

DEC 22, 1989

CLADIRIBINE

INJECTABLE; INJECTION
LEUSTATIN
+ JOHNSON RW

1MG/ML

N20229 001

FEB 26, 1993

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONOTINE HCL

/AB/ /BIOCRAT/

/0.1MG/

/0.2MG/

/0.3MG/

3 BIOCRAT

3

3

0.1MG

0.2MG

0.3MG

JUL 08, 1986

N70702 001

JUL 08, 1986

N70659 001

JUL 08, 1986

N70461 001

JUL 08, 1986

N70460 001

JUL 08, 1986

N70459 001

JUL 08, 1986

/AB/ /PAR/

/AB/

/AB/

/0.1MG/

/0.2MG/

/0.3MG/

3 PAR

3

3

0.1MG

0.2MG

0.3MG

JUL 08, 1986

N70461 001

JUL 08, 1986

N70460 001

JUL 08, 1986

N70459 001

JUL 08, 1986

TABLET; ORAL

CLEMASTINE FUMARATE

GENEVA

2.68MG

N73459 001

OCT 31, 1993

EQ 0.5MG BASE/5ML

AA

CLEMASTINE FUMARATE

SYRUP; ORAL

CLEMASTINE FUMARATE

BARRE

N74075 001

OCT 31, 1993

TABLET; ORAL

CLEMASTINE FUMARATE

GENEVA

2.68MG

N73459 001

OCT 31, 1993

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLECEIN

+ UPJOHN

EQ 75MG BASE

/EQ 75MG BASE/

EQ 150MG BASE

/EQ 150MG BASE/

EQ 75MG BASE

EQ 150MG BASE

N50162 001

/N50162/001/

N50162 002

/N50162/002/

N51809 001

N61809 002

3 PAR

3

3

0.1MG

0.2MG

0.3MG

JUL 08, 1986

N70461 001

JUL 08, 1986

N70460 001

JUL 08, 1986

N70459 001

JUL 08, 1986

CLOTIRIMAZOLE

CREAM; TOPICAL

CLOTIRIMAZOLE

TARO

1 1/2

N72640 001

AUG 31, 1993

LOTIRIMIN

/BT/+SCHERING/

AB + SCHERING PLOUGH

1 1/2

/N17619/001/

N17619 001

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLECEIN PHOSPHATE

+ UPJOHN

EQ 150MG BASE/ML

N50441 001

0.1%; EQ 3.5MG BASE/GM;
10.000 UNITS/GM

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL IN DEXTROSE 5%

AP + ABBOTT EQ 50MG BASE/100ML

N20269 001

AP + EQ 100MG BASE/100ML

OCT 19, 1993

AP + EQ 200MG BASE/100ML

OCT 19, 1993

DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT EQ 50MG BASE/100ML

OCT 19, 1993

AP EQ 100MG BASE/100ML

OCT 19, 1993

AP EQ 200MG BASE/100ML

OCT 19, 1993

AP + BAXTER EQ 50MG BASE/100ML

OCT 19, 1993

AP + EQ 100MG BASE/100ML

OCT 19, 1993

AP + EQ 200MG BASE/100ML

OCT 19, 1993

AP + EQ 400MG BASE/100ML

OCT 19, 1993

DOBUTREX

AP + LILLY

EQ 12.5MG BASE/ML

N17820 002

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL

AP + ASTRA

AP + EQ 40MG/ML

N176647 001

AP + EQ 80MG/ML

OCT 23, 1985

AP + EQ 160MG/ML

OCT 23, 1985

AP + EQ 160MG/ML

OCT 23, 1985

AP + EQ 160MG/ML

OCT 23, 1985

AP + ASTRA

EQ 40MG/ML

N70087 001

AP + EQ 80MG/ML

OCT 23, 1985

AP + EQ 160MG/ML

OCT 23, 1985

AP + EQ 160MG/ML

OCT 23, 1985

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL

AP + FUJISAMA

EQ 40MG/ML

N18549 001

AP + LYPHOMED

EQ 40MG/ML

N70012 001

AP + PENNEX PHARMS

EQ 10MG BASE/ML

N71918 001

DOXEPIN HYDROCHLORIDE

CONCENTRATE; ORAL

AA DOXEPIN HCL

EQ 10MG BASE/ML

JUL 20, 1988

AA DOXEPIN HCL

EQ 10MG BASE/ML

JUL 20, 1988

AA DOXEPIN HCL

EQ 10MG BASE/ML

JUL 20, 1988

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE MONOHYDRATE

AP + VINTAGE

EQ 100MG BASE

DEC 29, 1989

AP + VINTAGE

EQ 100MG BASE

DEC 29, 1989

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

AP + PAR

EQ 50MG BASE

DEC 22, 1983

AP + PAR

EQ 100MG BASE

DEC 22, 1983

AP + PAR

EQ 50MG BASE

DEC 22, 1983

TABLET; ORAL

DOXY-TABS

EQ 50MG BASE

N62269 003

DOXY-TABS

EQ 50MG BASE

N62269 003

DOXYCYCLINE HYCLATE

TABLET; ORAL
DOXYCYCLINE HYCLATE

/AP/ /HEATHER/
3 HEATHER
EQ 100MG BASE

/N62462/001/
/MAY/11, 1983/
MAY 11, 1983

/N62462/001/
/MAY/11, 1983/
MAY 11, 1983

EFLORNITHINE HYDROCHLORIDE

/INJECTABLE; INJECTION/
EFLORNITHINE HYDROCHLORIDE

/AP/ /MERRELL DOM/
3 MERRELL DOM
200MG/ML

/N19879/002/
/NOV/28, 1991/
NOV 28, 1991

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL

/AP/ /QUAD/
3 QUAD
2.5MG/ML

/N71941/001/
/AUG/17, 1983/
AUG 17, 1983

/N71941/001/
/AUG/17, 1983/
AUG 17, 1983

/AP/ /SHITH/NEPHEN/SOLOPAK/
3 SHITH/NEPHEN/SOLOPAK
2.5MG/ML

/N71754/001/
/SEP/06, 1988/
SEP 06, 1988

/N71754/001/
/SEP/06, 1988/
SEP 06, 1988

AP SOLOPAK

2.5MG/ML

N71754 001

3 BRISTOL

25MG

AP

2.5MG/ML

N71755 001

3

50MG

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE AND DROPERIDOL

/AP/ /ASTRA/
3 ASTRA
EQ 0.05MG BASE/ML

/N72028/001/
/APR/13, 1989/
APR 13, 1989

/N72028/001/
/APR/13, 1989/
APR 13, 1989

3 ASTRA

2.5MG/ML;
EQ 0.05MG BASE/ML

N72028 001

3

400MG

EDETATE DISODIUM

INJECTABLE; INJECTION
EDETATE DISODIUM

/AP/ /STERIS/
3 STERIS
150MG/ML

/N84356/001/
/MAY/11, 1983/
MAY 11, 1983

/N84356/001/
/MAY/11, 1983/
MAY 11, 1983

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
ENOXAPARIN SODIUM

/AP/ /LOVENOX/
3 LOVENOX
30MG/0.3ML

/N20164/001/
/MAR/29, 1993/
MAR 29, 1993

ENOXACIN

TABLET; ORAL
ENOXACIN

/AP/ /PARKE/DAVIS/
3 PARKE/DAVIS
400MG

/N19616/005/
/DEC/31, 1991/
DEC 31, 1991

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

3

200MG

N19616 005

3

200MG

N19616 004

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

STERLING WINTHROP 0.01MG/ML; 2% 2%

AP 0.02MG/ML; 2% 2%

LIDOCAINE HCL W/ EPINEPHRINE

/A6/ /BEL/MAR/ 0.01MG/ML; 1% 1%

/A6/ /BEL/MAR/ 0.01MG/ML; 1% 1%

3 BEL MAR 0.01MG/ML; 1% 1%

3 0.01MG/ML; 2% 2%

EPINEPHRINE; PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROCAINE HCL W/ EPINEPHRINE

/A6/ /BEL/MAR/ 0.02MG/ML; 1% 1%

/A6/ /BEL/MAR/ 0.02MG/ML; 1% 1%

3 BEL MAR 0.02MG/ML; 1% 1%

3 0.02MG/ML; 2% 2%

ERGOLOID MESYLATES

TABLET; ORAL

HYDERGINE

/SANDOZ/

3 SANDOZ

TABLET; SUBLINGUAL

HYDROSOLVATED ERGOT ALKALOIDS

/A6/ /ZENITH/ 0.5MG/

3 ZENITH 0.5MG

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

ERCOMAT

/A6/ /FISONS/

AA LOTUS

2MG

CAPSULE, DELAYED REL PELLETS; ORAL

/ERYC/SPIRINKLES/

/A6/ /FAULDING/ 125MG

3 FAULDING

GEL; TOPICAL

ERYGEL

/A6/ /HERBERT/

AT + HERBERT

AT STIEFEL

ERYTHROMYCIN

AT STIEFEL

OINTMENT; OPHTHALMIC

ERYTHROMYCIN

/A6/ /PHARMADERM/

3 PHARMADERM

/A6/ /PHARMAFAIR/

3 PHARMAFAIR

/A6/ /PHARMADERM/

3 PHARMADERM

/A6/ /PHARMAFAIR/

3 PHARMAFAIR

/PADOCK/ FOR RX COMPOUNDING

/ERYTHROMYCIN/

/A6/ /PADOCK/

3 PADOCK

SOLUTION; TOPICAL

ERYTHRA-DEEM

AT PADOCK

/A6/ /PADOCK/

3 PADOCK

ERYTHROMYCIN

AT BARRE

/A6/ /NASKA/

AT PENNEX PHARMS

/A6/ /NASKA/

3 PENNEX PHARMS

/N50593/001/
/JUL/22/1985/
N50593 001
JUL 22, 1985/N50617/001/
/OCT/21/1987/
N50617 001
OCT 21, 1987N63211 001
JAN 29, 1993/N62446/001/
/SEP/26/1983/
N62446 001
SEP 26, 1983
/N62481/001/
/APR/05/1984/
N62481 001
APR 05, 1984/N50610/001/
/NOV/07/1986/
N50610 001
NOV 07, 1986N62687 001
FEB 05, 1988N62957 001
JUL 21, 1988
/N62957/001/
/JUL/21/1988/
N62957 001
OCT 23, 1987

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

/AT/ /PHACOL/EST/CS/

/42/

/AT/ /PHACOL/FAIR/

/42/

3 PHARMAFAIR

1.5%

/AT/ /PADOCK/

/42/

SWAB; TOPICAL

C-SOLVE-2

SYOSSET

2%

AT

TABLET, COATED PARTICLES; ORAL

PCE

/+/ /PADOCK/

/333H6/

+ ABBOTT

500MG

333MG

/333H6/

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL

ERYTHROMYCIN ESTOLATE

3 LIFE LABS

EQ 250MG BASE/5ML

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

/KV/

/EQ 250MG BASE/5ML/

3 KV

/EQ 250MG BASE/5ML/

3

EQ 200MG BASE/5ML

EQ 400MG BASE/5ML

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROMYCIN LACTOBIONATE

GENSIA

AP

EQ 500MG BASE/VIAL

AP

EQ 1GM BASE/VIAL

/AP/ /LYPHOMED/

/EQ 500MG BASE/VIAL/

/AP/

/EQ 1GM BASE/VIAL/

3 LYPHOMED

EQ 500MG BASE/VIAL

3

EQ 1GM BASE/VIAL

N62751 001

JUL 30, 1993

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC

+ ANAQUEST

10MG/ML

+

250MG/ML

/PUPPOT/

/10MG/ML/

/250MG/ML/

N50611 002

AUG 22, 1990

SEP 09, 1986

/N50611/002/

/AUG/22/1990/

N19386 001

AUG 15, 1988

N19386 002

DEC 31, 1986

/N19386/001/

/AUG/15/1988/

/N19386/002/

/DEC/31/1986/

ESTRADIOL

TABLET; ORAL

ESTRACE

BRISTOL MYERS SQUIBB 0.5MG

N62362 001

DEC 17, 1982

ESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL

PREMARIN

+ AVERST

/+/ /WYETH/AYERST/

0.625MG/GM

/0.625MG/GM/

N62047 001

DEC 17, 1982

/N62047/001/

/N62047/002/

N62047 001

EQ 200MG BASE/5ML

N20216 001

/N62047/001/

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

/S/ ZENITH/
/S/ 3MG/
/S/ 0.625MG/
/S/ 1.25MG/
/S/ 2.5MG/
/S/ 5MG/
PREMARIN
+ MYETH AYERST
/S/ 1.25MG
/S/ 2.5MG
/S/ 5MG
/S/ 10MG
/S/ 2.5MG

ESTROPIPAATE

TABLET; ORAL
ESTROPIPAATE
WATSON LABS

AB N81213 001
SEP 23, 1993
0.75MG
AB N81214 001
SEP 23, 1993
1.5MG
AB N81215 001
SEP 23, 1993
3MG
AB N81216 001
SEP 23, 1993
6MG
OGEN 1.25
/S/ ABBOTT/
/S/ 1.25MG
OGEN 2.5
/S/ ABBOTT/
/S/ 2.5MG
OGEN 5
/S/ ABBOTT/
/S/ 5MG

ETHINYL ESTRADIOL; FERROUS FUMARATE; NORETHINDRONE ACETATE

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

/TABLET; ORAL-28/
/NORLESTIN/FE/1/56/
/S/ PARKE/DAVIS/
@ PARKE DAVIS
/NORLESTIN/FE/1/56/
/S/ PARKE/DAVIS/
@ PARKE DAVIS

/S/ 0.05MG; 75MG; 1MG
/S/ 0.05MG; 75MG; 1MG
/S/ 0.05MG; 75MG; 1MG
/S/ 0.05MG; 75MG; 1MG

ETHINYL ESTRADIOL; FLUOXIMESTERONE

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

/TABLET; ORAL/
/HALOGEN/
/S/ UPJOHN/
@ UPJOHN

/S/ 0.02MG; 1MG
/S/ 0.02MG; 1MG

/N11267/001/
N11267 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/35E-21
ROBERTS

AB N71480 001
APR 12, 1988
/S/ 0.035MG; 1MG
/S/ 0.035MG; 1MG
/S/ 0.035MG; 1MG
/S/ 0.035MG; 1MG

N71480 001
APR 12, 1988
/N71480/001/
/N71480/001/
/N71480/001/

TABLET; ORAL-28
NORETHIN 1/35E-28
ROBERTS

AB N71481 001
APR 12, 1988
/S/ 0.035MG; 1MG
/S/ 0.035MG; 1MG
/S/ 0.035MG; 1MG
/S/ 0.035MG; 1MG

N71481 001
APR 12, 1988
/N71481/001/
/N71481/001/
/N71481/001/

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

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

/TABLET; ORAL-21/
/NORLESTIN/21/1/56/
/S/ PARKE/DAVIS/
@ PARKE DAVIS

/S/ 0.05MG; 1MG
/S/ 0.05MG; 1MG

/N16749/001/
N16749 001

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

/NORLESTIN/21/1/56/
/S/ PARKE/DAVIS/
@ PARKE DAVIS

/S/ 0.05MG; 2.5MG
/S/ 0.05MG; 2.5MG

/N16852/001/
N16852 001

ETHOSUXIMIDE

SYRUP; ORAL
ETHOSUXIMIDE
AA COPLEY

250MG/5ML

N81306 001
JUL 30, 1993

AA ZARONTIN
PARKE DAVIS

250MG/5ML

N80258 001

ETHYNODIOL DIACETATE; MESTRANOL

/TABLET; ORAL-21/
/OVULEN-21/
/S/ SEARLE/

/S/ 0.1MG; 0.1MG

/N16854/001/
N16854 001

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
PROZAC
LILLY

EQ 10MG BASE

N18936 006
DEC 23, 1992

ELIXIR; ORAL

PROLIXIN
AA APOTHECON
/500166/

2.5MG/5ML
/2.516/5ML/

N12145 003
/N12145/003/

FLUOXYMESTERONE

TABLET; ORAL
/ANDRODIP-1/
/BP/ /ICN/
@ ICN

10MG
/10MG/

/N87196/001/
N87196 001

INJECTABLE; INJECTION

PROLIXIN
AP + APOTHECON
/AP/ /500166/

2.5MG/ML
/2.516/ML/

N11751 005
/N11751/005/

FLUOXYMESTERONE

/BP/ /ICN/
@ ICN

10MG
/10MG/

/N88221/001/
N88221 001
MAY 05, 1983

TABLET; ORAL
PROLIXIN
APOTHECON

1MG
2.5MG
5MG
10MG
1MG
2.5MG
5MG
10MG
/N11751/004/
/N11751/001/
/N11751/003/
/N11751/002/
/N11751/004/
/N11751/001/
/N11751/003/
/N11751/002/

N11751 004
N11751 001
N11751 003
N11751 002
N11751 004
N11751 001
N11751 003
N11751 002
N11751 004
N11751 001
N11751 003
N11751 002

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION
PROLIXIN DECANOATE
AO + APOTHECON
/AO/ /500166/

25MG/ML
/2516/ML/

N16727 001
/N16727/001/

TABLET; EXTENDED/RELEASE; ORAL/
/PERMITIL/
/4/ /SCHERING/
@ SCHERING

/N12419/004/
N12419 004

FLUPHENAZINE ENANTHATE

INJECTABLE; INJECTION
PROLIXIN ENANTHATE
+ APOTHECON
/500166/

25MG/ML
/2516/ML/

N16110 001
/N16110/001/

FOLIC ACID

TABLET; ORAL
FOLIC ACID

> DLT >
> ADD >

/BP/ /500166/ /1MG/
/BP/ /PIONEER/PHARMS/
@ PIONEER PHARMS

1MG
1MG
1MG

/N84158/001/
N84158 001
/N84158/001/
/SEP/13/1985/
N88949 001
SEP 13, 1985

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
PROLIXIN
AA APOTHECON

5MG/ML
/5MG/ML/

N70533 001
NOV 07, 1985
/N70533/001/
/NOV/07/1985/

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE
/BP/ /ASTRA/

10MG/ML
10MG/ML

/N70014/001/
N70014 001
SEP 09, 1985

ELIXIR; ORAL
FLUPHENAZINE HCL
AA COPLEY

2.5MG/5ML

N81310 001
APR 29, 1993

FUROSEMIDE

SOLUTION; ORAL
FUROSEMIDE

AA PENNEX PHARMS

10MG/ML

/10MG/ML/

N70655 001
OCT 02, 1987
/N70655/001/
/OCT/02/1987/

600MG

N18422 003
NOV 20, 1986

TABLET; ORAL

LOPID

AB + PARKE DAVIS

GEMFIBROZIL

TABLET; ORAL

FUROSEMIDE

/AB/ /PARKE DAVIS/

/20MG/

/N18419/001/
/JAN/31/1983/
/N18419/002/
/JAN/31/1983/
/N18419/003/
/NOV/13/1984/
N18419 001
JAN 31, 1983
N18419 002
JAN 31, 1983
N18419 003
NOV 13, 1984

/EQ 1MG BASE/GM/

/N62530/001/
/JUL/05/1984/
N62530 001
JUL 05, 1984

EQ 1MG BASE/GM

3 WARNER CHILCOTT

INJECTABLE; INJECTION

GENTAMICIN SULFATE

/AB/

/MYETH AYERST/

/EQ 10MG BASE/ML/

/N62264/001/
/N62264/002/
N62264 001
N62264 002

3 MYETH AYERST

EQ 10MG BASE/ML

N62264 001
N62264 002

GADODIAMIDE

INJECTABLE; INJECTION

OMNISCAN

STERLING WINTHROP

287MG/ML

N20123 001
JAN 08, 1993

GEMFIBROZIL

CAPSULE; ORAL

GEMFIBROZIL

AB NYLAN

300MG

N73466 001
JAN 25, 1993
N72929 001
JAN 29, 1993

AB PUREPAC

300MG

LOPID

AB + PARKE DAVIS

300MG

N18422 002

TABLET; ORAL

GEMFIBROZIL

AB LEDERLE

600MG

N74270 001
SEP 27, 1993
N74256 001
OCT 31, 1993

AB LEMMON

600MG

GLYBURIDE

TABLET; ORAL

GLYNASE

/BX/ /UPJOHN/

/+/

/1.5MG/

/3MG/

UPJOHN

3MG

+

6MG

1.5MG

4.5MG

/N20051/002/

/MAR/04, 1992/

/N20051/001/

/MAR/04, 1992/

/N20051/002/

MAR 04, 1992

N20051 004

SEP 24, 1993

N20051 001

MAR 04, 1992

N20051 003

SEP 24, 1993

GONADORELIN ACETATE

INJECTABLE; INJECTION

LUTREPULSE KIT

+ FERRING

0.8MG/VIAL

+

3.2MG/VIAL

/LUTREPULSE/PLUP/KIT/

/FERRING/

/0.8MG/VIAL/

/3.2MG/VIAL/

N19687 001

OCT 10, 1989

N19687 002

OCT 10, 1989

/N19687/001/

/OCT/10, 1989/

/N19687/002/

/OCT/10, 1989/

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

/AP/

AP

/AP/

AP

/5,000 UNITS/VIAL/

/5,000 UNITS/VIAL/

/10,000 UNITS/VIAL/

/10,000 UNITS/VIAL/

/N17054/001/

N17054 001

/N17054/002/

N17054 002

GOSERELIN ACETATE

IMPLANT; IMPLANTATION

ZOLADEX

/+/ /HUPERAL/CHEN/

/EQ/3.6MG/BASE/

+ ZENECA

EQ 3.6MG BASE

/N19726/001/

/DEC/29, 1989/

N19726 001

DEC 29, 1989

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

/N60427/001/

/AT/ /DOM/

@ DOM

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

/10,000 UNITS/ML/

/N60427/001/

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

10,000 UNITS/ML

N60427 001

GRISEOFULVIN, MICROCRYSTALLINE

CAPSULE; ORAL

GRISACTIN

/MYETH/AYERST/

@ MYETH AYERST

/125MG/

125MG

/N50051/002/

N50051 002

HALOFANTRINE HYDROCHLORIDE

/TABLET; ORAL/

/HALFAN/

/+/ /SMITHKLINE/BEECHAM/ /250MG/

@ SMITHKLINE BEECHAM

250MG

/N20250/001/

/JUL/24, 1992/

N20250 001

JUL 24, 1992

HALOPERIDOLTABLET; ORALHALOPERIDOL/AD/ /LEPERIE//0.5MG//N72727/001//AD//1MG//N72728/001//AD//2MG//N72729/001//AD//5MG//N72730/001//AD//10MG//N72731/001//AD//20MG//N72732/001/3 LEDERLE0.5MGN72727 00131MGN72728 00132MGN72729 00135MGN72730 001310MGN72731 001320MGN72732 001SEP 19, 1989HALOPERIDOL LACTATECONCENTRATE; ORALHALOPERIDOL3 PENNEX PHARMSAAPHARM ASSOCEQ 2MG BASE/MLN70710 001EQ 2MG BASE/MLN73037 001/EQ 2MG BASE/ML//N70710/001//MAR/07/1986/AASILARXEQ 2MG BASE/MLN73364 001SEP 28, 1993INJECTABLE; INJECTIONHALOPERIDOLAP MARSAMEQ 5MG BASE/MLN72516 001APEQ 5MG BASE/MLN72517 001FEB 25, 1993HALOPERIDOL LACTATEINJECTABLE; INJECTIONHALOPERIDOL/AP//SHITH/NEPHEN/SOLOPAK/ED 5MG BASE/ML//N70801/001//AP//ED 5MG BASE/ML//N70801/001/APSOLOPAKEQ 5MG BASE/MLDEC 14, 1987APEQ 5MG BASE/MLDEC 14, 1987HEPARIN SODIUMINJECTABLE; INJECTIONLYCAEMIN SODIUM/AP//ORGANON//N00552/001//AP/3 ORGANON/N00552/001/340,000 UNITS/MLN00552 002HEXACHLOROPHENEAEROSOL; TOPICAL/PUREX//XITRIUM//N18375/001/3 XITRIUMN18375 001EMULSION; TOPICAL/HEXA-CERN//HUNTINGTON//N17411/001//AT/ 3 HUNTINGTONN17411 001PHISOX/STERLING//N08402/001/3 STERLINGN08402 001/PUREX//N19055/001//AT/ 3 XITRIUMN19055 0013NOV 30, 1984SOLUTIONS; TOPICAL/DIAL//ARMOUR/DIAL//N17421/002//AT/ 3 DIALN17421 002/BETHA-MEDICA//HUNTINGTON//N17412/001/3 HUNTINGTONN17412 001

HEXACHLOROPHENE

/ SOLUTION / NOCTICAL /
/ GEMMA-DEBACH / NG /
/ HUNTINGTON /
/ HUNTINGTON

/ 0.25% /
/ 0.25% /

/ N17412 / 002 /
/ N17412 / 002 /

/ N08303 / 003 /
/ N08303 / 003 /

/ SPONGE, TOPICAL /
/ HUNTINGTON /

/ HUNTINGTON /

/ PROF / DSPLS /

/ PROF DSPLS /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

/ STERLING /

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
APRESOLINE

AP + CIBA

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

HYDROCHLOROTHIAZIDE

SOLUTION; ORAL

HYDROCHLOROTHIAZIDE

3 PENNEX PHARMS

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

50MG/5ML

HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE

3 PENNEX PHARMS

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

IBUPROFEN

TABLET; ORAL

/AP/ /EFN/

/AD/ /LUCHEM/

/AD/ /LUCHEM/

/AD/ /LUCHEM/

/400MG/

/600MG/

/800MG/

/N17145/001/

/SEP/23/1986/

/N17146/001/

/SEP/23/1986/

/N17169/001/

/MAR/08/1987/

/N18956/001/

/DEC/26/1985/

IOHEXOL

/SOLUTION; INJECTION; ORAL/

/OMNIPAGUE/300/

/STERILIS/

/64.7% /

SOLUTION; INJECTION, ORAL, RECTAL
OMNIPAGUE 180

+ STERLING

38.8%

N18956 001
DEC 26, 1985

OMNIPAGUE 240

+ STERLING

51.8%

N18956 002
DEC 26, 1985

OMNIPAGUE 300

+ STERLING

64.7%

N18956 003
DEC 26, 1985IDOXURIDINE

/OINTMENT; OPHTHALMIC/

/STOXIL/

/+/SMITHKLINE/BEECHAM/ 0.5% /

a SMITHKLINE BEECHAM 0.5%

/N15868/001/

N15868 001

SOLUTION/DROPS; OPHTHALMIC

/STOXIL/

/AT/ /SMITHKLINE/BEECHAM/ 0.1% /

a SMITHKLINE BEECHAM 0.1%

/N13934/001/

N13934 001

INDAPAMIDE

TABLET; ORAL

LOZOL

RHONE POULENC RORER 1.25MG

N18538 002

APR 29, 1993

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION

/ODOCHIPPURATE SODIUM I 131/

/CIS/

/0.2MG/ML/

0.2MCI/ML

/N17313/001/

N17313 001

/AP/ /CIS/

/AP/ /SORIN/

IOHEXOL

/INJECTABLE; INJECTION/

/OMNIPAGUE/300/

/STERILIS/

/38.8% /

/N18956/001/

/DEC/26/1985/

/SOLUTION; INJECTION; ORAL/

/OMNIPAGUE/240/

/STERILIS/

/51.8% /

/N18956/001/

/DEC/26/1985/

EQ 50MG IRON/ML

N17441 001

/EQ/50MG/IRON/ML/

/N17441/001/

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ATROVENT

+ BOEHRINGER INGELHEIM 0.02%

N20228 001
SEP 29, 1993IRON DEXTRAN

INJECTABLE; INJECTION

INFE

BP + SCHEIN PHARM

/IRON/DEXTRAN/

/BP/ /STERIS/

/N19580/001/

/DEC/07/1989/

/N19580/002/

/DEC/07/1989/

N19580 001

DEC 07, 1989

N19580 002

DEC 07, 1989

/EQ/190MG/IODINE/ML/

/EQ/240MG/IODINE/ML/

EQ 190MG IODINE/ML

EQ 240MG IODINE/ML

a BERLEX

a

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

/AN/ /ASTRA/ /0.145%/
/0.08%/
0.062%
0.125%
/AN/ /PARKE/DAVIS/ /1%/
/0.5%/
0.5%
1%

/N07938/001/
/NOV/15/1982/
/N07937/001/
/NOV/15/1982/
N87937 001
NOV 15, 1982
N87938 001
NOV 15, 1982
/N05889/001/
/N05997/001/
N85997 001
N85889 001

ISOFLURANE

LIQUID; INHALATION

FORANE

AN + ANAQUEST

ISOFLURANE

AN ABBOTT

99.9%
99.9%

ISONIAZID

INJECTABLE; INJECTION

NYDRAZID

+ APOTHECON

/SQUIBB/

100MG/ML
/100MG/ML/

TABLET; ORAL

ISONIAZID

/AA/ /EON/LABS/

AA + EON LABS

/AA/

AA +

/STANDARD/

/EVERYLIFE/

0 EVERYLIFE

/100MG/
100MG
/100MG/
300MG
/100MG/
300MG

ISOPROPAMIDE IODIDE

TABLET; ORAL

PARBID

/SMITHKLINE/BEECHAM/

0 SMITHKLINE BEECHAM

/ED/5MG/BASE/
EQ 5MG BASE

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION

AEROLONE

/AN/

+ LILLY

/ISOPROTERENOL HCL/

/PARKE/DAVIS/

0 PARKE DAVIS

0

/0.25%/
0.25%
/0.25%/
0.25%
0.5%
0.5%

/N07245/001/
N07245 001
/N05994/001/
/N05994/001/
N85994 001
N85540 001

ISUPREL

/AN/

+ STERLING

/STERLING/

0 STERLING WINTHROP

/WAGG/

/FISONS/

0 FISONS

/0.5%/
0.5%
/0.5%/
0.5%
0.5%
0.5%

/N06327/002/
N06327 002
/N16813/001/
N16813 001

TABLET; RECTAL, SUBLINGUAL

ISUPREL

/STERLING/

0 STERLING

/N06328/002/
N06328 002

ISOSORBIDE DINITRATE

TABLET; ORAL

ISORBITRATE

/AB/

/JCI/

/20MG/
/30MG/
/40MG/
20MG
30MG
40MG

/N06645/002/
/AUG/21/1990/
/N08124/001/
/AUG/21/1990/
/N08125/001/
/AUG/21/1990/
N86405 002
AUG 21, 1990
N88124 001
AUG 21, 1990
N88125 001
AUG 21, 1990

ISOSORBIDE MONONITRATE

TABLET; ORAL

ISMO

/AB/

/MYETH/

BX + MYETH

/20MG/
20MG

/N19091/001/
/DEC/30/1991/
N19091 001
DEC 30, 1991

ISOSORBIDE MONONITRATE

TABLET; ORAL

MONOKET

BX SCHWARZ PHARMA

20MG

N20215 001

AB

CAPSULE; ORAL

KETOPROFEN

LEDERLE

25MG

N74014 001

JAN 29, 1993

10MG

N20215 002

AB

LEDERLE

50MG

N74014 002

JAN 29, 1993

TABLET, EXTENDED RELEASE; ORAL

INDUR

3 SCHERING PLOUGH

30MG

N20225 001

AB

LEDERLE

75MG

N74014 003

JAN 29, 1993

TABLET, EXTENDED RELEASE; ORAL

ORUVAIL

+ MYETH AVERST

200MG

N20225 002

AB

LEDERLE

200MG

N19816 001

SEP 24, 1993

KANAMYCIN SULFATE

CAPSULE; ORAL

KANTREX

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

APOTHECON

EQ 500MG BASE

N62726 001

AB

LEDERLE

10GM/15ML

N17657/001

LIDOCAINE

/SUPPOSITORIES/RECTAL/
/XYLOCAINE/
/ASTRA/
@ ASTRA

/100MG/
100MG

/N19477/001/
N13077 001

N88190 001
AUG 16, 1984
/N19477/001/
/AUG/16./1984/

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

/AB/ /ABOTT/

/100/

/N87980/001/
/FEB/02./1983/

N88191 001
SEP 18, 1984
/N19477/001/
/SEP/18./1984/

/AB/ /BEL/NAAR/

100/

N80760 001

/AB/ /BEL MAR

100/

N80710 001

/AB/ /FARIS/

100/

N80760 001

/AB/ /FUJISAWA

100/

N80404 002

/AB/ /LYPHOMED/

100/

N80390 001

/AB/ /LYPHOMED/

100/

N80390 002

/AB/ /LYPHOMED

100/

N86761 001

/AB/ /LYPHOMED

100/

N86761 002

JELLY; TOPICAL
LIDOCAINE HCL
COPLY

200/

N81318 001
APR 29, 1993

SOLUTION; ORAL
XYLOCAINE

/AT/ PENNEX PHARMS

200/

N87872 001

/AT/ /PHARM/PHARM/

100/

N87881 001

SOLUTION; TOPICAL
XYLOCAINE

/AT/ /PHARM/PHARM/

100/

N87881 001

@ PENNEX PHARMS

400/

N87881 001

LINDANE

LOTION; TOPICAL

LINDANE

/AT/ PENNEX PHARMS

100/

N88190 001

/AT/ /PHARM/PHARM/

100/

N88190 001

SHAMPOO; TOPICAL

LINDANE

/AT/ PENNEX PHARMS

100/

N88191 001

/AT/ /PHARM/PHARM/

100/

N88191 001

LIOTRIX (T4;T3)

TABLET; ORAL

THYROLAR-0.25

/RHONE/POULENC/RODER//0.0125MG;0.0031MG/
THYROLAR-0.5

N16807 001
/N16807/001/

FOREST LABS

/RHONE/POULENC/RODER//0.025MG;0.00625MG/
THYROLAR-1

N16807 005
/N16807/005/

FOREST LABS

/RHONE/POULENC/RODER//0.05MG;0.0125MG/
THYROLAR-2

N16807 004
/N16807/004/

FOREST LABS

/RHONE/POULENC/RODER//0.1MG;0.025MG/
THYROLAR-3

N16807 002
/N16807/002/

* FOREST LABS

/+ /RHONE/POULENC/RODER//0.15MG;0.0375MG/
THYROLAR-5

N16807 003
/N16807/003/

LISINOPRIL

TABLET; ORAL

ZESTRIL

/AB/ /IMPERIAL/CHEM/

100/

N19477/001/

/AB/ /IMPERIAL/CHEM/

100/

N19477/001/

/AB/ /IMPERIAL/CHEM/

100/

N19477/001/

/AB/ /IMPERIAL/CHEM/

100/

N19477/001/

LISINAPRIL

TABLET; ORAL

ZESTRIL

AB ZENECA

5MG

N19777 001

AB

10MG

MAY 19, 1988

AB

20MG

MAY 19, 1988

AB

40MG

MAY 19, 1988

AB +

2.5MG

MAY 19, 1988

AB

2.5MG

APR 29, 1993

LITHIUM CARBONATE

TABLET; ORAL

ESCALITH

AB / + / SMITHKLINE BEECHAM / 300MG

300MG

N17971 001

AB

300MG

JUL 18, 1985

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

AB

300MG

MAY 19, 1988

LORATADINE

TABLET; ORAL

CLARITIN

+ SCHERING

10MG

N19658 001

APR 12, 1993

LORAZEPAM

TABLET; ORAL

LORAZEPAM

/PAR/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

/0.5MG/

/N176675/001/

/AB/

/1MG/

/N176676/001/

/AB/

/2MG/

/N176677/001/

/AB/

MANNITOL

INJECTABLE; INJECTION

AP MANNITOL 20% IN PLASTIC CONTAINER
MCGAW 20GM/100ML

AP MANNITOL 5% IN PLASTIC CONTAINER
MCGAW 5GM/100ML

MASOPROCOL

CREAM; TOPICAL
ACTINEX
+ BLOCK DRUG

10%
/S/CHENE/

MEGESTROL ACETATE

SUSPENSION; ORAL

MEGACE
+ BRISTOL MYERS SQUIBB 40MG/ML

MENADIOL SODIUM DIPHOSPHATE

INJECTABLE; INJECTION

/S/NAVITE/
/ROCHE/
3 ROCHE
3
3
5MG/ML
10MG/ML
37.5MG/ML

/TABLET; ORAL/
/S/NAVITE/
/ROCHE/
3 ROCHE

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

AP MEPERIDINE HCL
ASTRA

10MG/ML

/45/45/ML/

/50/45/ML/

/50/45/ML/

/50/45/ML/

/75/45/ML/

/100/45/ML/

/100/45/ML/

3

25MG/ML

50MG/ML

50MG/ML

75MG/ML

100MG/ML

100MG/ML

10MG/ML

INTL MEDICATION

AP

TABLET; ORAL
MEPERIDINE HCL

AA HALSEY

AA

/45/45/ML/

/AA/ HALSEY/

/AA/

/N03718/004/
/N03718/006/
/N03718/008/
N03718 004
N03718 006
N03718 008

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/AA/ /LEE/LABS/

3 LEE LABS

/S/PHARMAFAIR/
3 PHARMERAL

/400MG/

400MG

/400MG/

400MG

N81002 001
JUL 30, 1993

/N89781/001/

/MAR/31/1989/

/N89782/001/

/MAR/31/1989/

/N89783/001/

/MAR/31/1989/

/N89785/001/

/MAR/31/1989/

/N89785/001/

/MAR/31/1989/

/N89787/001/

/MAR/31/1989/

N89781 001

MAR 31, 1989

N89782 001

MAR 31, 1989

N89783 001

MAR 31, 1989

N89785 001

MAR 31, 1989

N89786 001

MAR 31, 1989

N89787 001

MAR 31, 1989

N81309 001

AUG 30, 1993

N80448 001

N80448 002

/N80448/001/

/N80448/002/

/N89781/001/

/NOV/25/1987/

N89538 001

NOV 25, 1987

/N89781/001/

N89153 001

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL
PENTASA
+ MARION MERRELL DOW 250MG

MESTRANOL; NORETHINDRONE

/TABLET; ORAL-28/
NORETHINOL
/SYNTEX/
@ SYNTEX

/0.1MG; 0.05MG/
0.1MG; 2MG

TABLET; ORAL-21
NORETHINOL 1/50M-21
ROBERTS

0.05MG; 1MG

/66/ /SCHLAPPARELLI/SEARLE/0.05MG; 1MG/
/66/

TABLET; ORAL-28
NORETHINOL 1/50M-28
ROBERTS

0.05MG; 1MG

/66/ /SCHLAPPARELLI/SEARLE/0.05MG; 1MG/
/66/

MESTRANOL; NORETHYNODREL

/TABLET; ORAL/
NORETHYNOL
/SEARLE/
@ SEARLE
@

/0.15MG; 0.05MG/
/0.075MG; 0.05MG/
0.075MG; 5MG
0.15MG; 9.85MG

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE
@ PENNEX PHARMS 5%

/66/ /PHARM/BASICS/
/66/

N72190 001
JUN 07, 1988
/N72190/001/
/JUN/07/1988/

METAPROTERENOL SULFATE

SYRUP; ORAL

METAPROTERENOL SULFATE

AA PENNEX PHARMS 10MG/5ML
/66/ /PHARM/BASICS/
/66/

N71656 001
OCT 13, 1987
/N71656/001/
/OCT/13/1987/

METARAMINOL BITARTRATE

INJECTABLE; INJECTION

METARAMINOL BITARTRATE

AP FUJISANA EQ 10MG BASE/ML
AP EQ 10MG BASE/ML
/66/ /CIPHARM/ EQ 10MG BASE/ML
/66/ /EQ 10MG BASE/ML/

N80431 001
N80722 001
/N80431/001/
/N80722/001/

METHADONE HYDROCHLORIDE

TABLET; ORAL

AA METHADONE 5MG
MALLINCKRODT

N40050 001
APR 15, 1993
N40050 002
APR 15, 1993

TABLET, DISPERSIBLE; ORAL

METHADONE HCL

AA LILLY 40MG
AA METHADONE 40MG
MALLINCKRODT

N17058 001
N74184 001
APR 29, 1993

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

/66/ /METHAMPHETAMINE/
/66/ @ LEMMON
@ LEMMON

/N83889/001/
N83889 001

METHAMPHETAMINE HCL

/66/ /METHAMPHETAMINE/
/66/ @ LEMMON
/66/ /REXAR/
REXAR

/N86359/001/
N86359 001
/N84931/002/
N84931 002

METHANTHELINE BROMIDE

TABLET; ORAL

BANTHINE
ROBERTS
/SCHTAPPARELLI/SEARLE/50MG/
50MG

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

AB COWLEY 25MG

AB 50MG

AB 25MG

AB 50MG

NEPTAZANE

AB LEDERLE 25MG

AB + 50MG

METHICILLIN SODIUM

INJECTABLE; INJECTION

STAPHICILLIN

+ APOTHECON

+

/PARASITOL/

EQ 900MG BASE/VIAL

EQ 3.6GM BASE/VIAL

EQ 5.4GM BASE/VIAL

/EQ/900MG BASE/VIAL/

/EQ/3.6GM BASE/VIAL/

/EQ/5.4GM BASE/VIAL/

N61449 001

N61449 002

N61449 003

/N61449/001/

/N61449/002/

/N61449/003/

METHOCARBAMOL

TABLET; ORAL

/DELANTIN/

/FERNDALE/

3 FERNDALE

/500MG/

500MG

METHOCARBAMOL

NYLOS TRADING

/3/PHARMERAL/

/3/

3 PHARMERAL

3

750MG

/500MG/

/750MG/

500MG

750MG

> DLT >

> DLT >

> ADD >

> ADD >

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

/AA/ /PIONEER/PHARMS/

/AA/

N07390 001

/N07390/001/

/500MG/

/750MG/

3 PIONEER PHARMS

3

500MG

750MG

/AA/ /TABLICAPS/

/AA/ /UPSHER/SMITH/

/AA/

N40001 001

JUN 30, 1993

N40001 002

JUN 30, 1993

N40036 001

JUN 30, 1993

N40036 002

JUN 30, 1993

/750MG/

/500MG/

/750MG/

500MG

750MG

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM

/AP/ /AKORN/

/AP/ /LYPHOMED/

3 LYPHOMED

3

3 LYPHOMED

3

3 LYPHOMED

3

/EQ 25MG BASE/ML/

/EQ 25MG BASE/ML/

EQ 25MG BASE/ML

EQ 25MG BASE/ML

EQ 25MG BASE/ML

EQ 25MG BASE/ML

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N88648/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/50MG/ML/

/50MG/ML/

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

/N76652/001/

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

/AB/ /CHELSEA/ /4MG/

B* CHELSEA

/N85161/001/
/FEB/08/1982/
N86161 001
FEB 09, 1982

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

/M-PREDOL/

/BP/ /BEL/ /40MG/ML/
/BP/ /BEL/ /80MG/ML/

3 BEL MAR

3

/N86666/001/
/N87135/001/
N86666 001
N87135 001

ointment; TOPICAL
MEDROL ACETATE

/UPJOHN/

3 UPJOHN

/12/
12

> DLT >
> ADD >

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

/AB/ /ABBOTT/

3 ABBOTT

/EQ 1GM BASE/VIAL/

EQ 1GM BASE/VIAL

METHYLPREDNISOLONE SODIUM SUCCINATE

/LYPHOMED/

/AB/ /EQ 40MG BASE/VIAL/

/AB/ /EQ 125MG BASE/VIAL/

/AB/ /EQ 500MG BASE/VIAL/

/AB/ /EQ 1GM BASE/VIAL/

3 LYPHOMED

3

3

3

3

EQ 40MG BASE/VIAL

EQ 125MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

METHYLTESTOSTERONE

CAPSULE; ORAL

METHYLTESTOSTERONE

/BP/ /HEATHER/ /10MG/
3 HEATHER

/N84467/001/
N84467 001

TESTED

/BP/ /ICN/

BP + ICN

/N83976/001/
N83976 001

TABLET; BUCCAL

/ANDROID/

/ICN/

3 ICN

/N87222/001/
N87222 001

TABLET; ORAL

METHYLTESTOSTERONE

/BP/ /INWOOD/

3 INWOOD

3

/N80839/001/
N80839 001
N80973 001

METHYPRYLON

/CAPSULE; /ORAL/

/NOUDAR/

/ROCHE/

3 ROCHE

/N09660/008/
N09660 008

/TABLET; /ORAL/

/NOUDAR/

/ROCHE/

3 ROCHE

/N09660/004/
N09660 004

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

/AP/ /AKORN/

/AP/ /FUJISAWA/

3 FUJISAWA

3 NORBROOK

/EQ 10MG BASE/2ML/

/EQ 10MG BASE/2ML/

EQ 10MG BASE/2ML

EQ 10MG BASE/2ML

/N70293/001/
JAN 24, 1986
N70892 001
AUG 26, 1988

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; ORAL
METOCLOPRAMIDE HCL

AA LENTION
AA LIQUIPHARM
AA PENNEX PHARMS
/AD/ /PHARM/BASICS/
EQ 5MG BASE/5ML
EQ 5MG BASE/5ML
EQ 5MG BASE/5ML
/EQ 5MG BASE/5ML/

N71315 001
JUN 30, 1993
N71402 001
JUN 25, 1993
N70949 001
MAR 06, 1987
/N70949/001/
/MAR/06, 1987/

/EQ 1GM BASE/VIAL/
EQ 1GM BASE/VIAL
EQ 1GM BASE/VIAL
/EQ 2GM BASE/VIAL/
EQ 2GM BASE/VIAL
/EQ 3GM BASE/VIAL/
EQ 3GM BASE/VIAL
/EQ 4GM BASE/VIAL/
EQ 4GM BASE/VIAL

/N62333/001/
N62333 001
N62372 005
JAN 13, 1983
/N62333/002/
N62333 002
/N62333/003/
N62333 003
/N62333/004/
N62333 004

TABLET; ORAL
METOCLOPRAMIDE HCL

AB BIOCRRAFT
AB MUTUAL PHARM
/AD/ /PAR/
EQ 10MG BASE
EQ 10MG BASE

N72801 001
JUN 15, 1993
N71536 001
APR 28, 1993
/N70342/001/
/MAR/28, 1986/
N70342 001
MAR 25, 1986

MICONAZOLE NITRATE
/CREAM; VAGINAL/
/MONISTAT-7/
/JOHNSON/RW/

/2%/
/N17450/001/

METRONIDAZOLE

GEL; TOPICAL
METROGEL
/+/CURATEK/
+ GALDERMA

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

/0.75%/
0.75%

/N19737/001/
/NOV/22, 1988/
N19737 001
NOV 22, 1988

/2%/
2%

/N17739/001/
N17739 001

TABLET; ORAL
/SANTO/
/SANTO/
/AD/ /SANTO/
/AD/

3 SAVAGE

250MG

N70029 001
MAR 19, 1985
N70731 001
JUN 08, 1987

200MG

N73508 001
NOV 19, 1993

200MG

N18888 001
AUG 15, 1984

/100MG/

/N18520/001/
/MAR/15, 1982/

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION

MEZLIN

/MILES/
3 MILES

/EQ 1GM BASE/VIAL/
EQ 1GM BASE/VIAL
EQ 1GM BASE/VIAL
/EQ 2GM BASE/VIAL/
EQ 2GM BASE/VIAL
/EQ 3GM BASE/VIAL/
EQ 3GM BASE/VIAL
/EQ 4GM BASE/VIAL/
EQ 4GM BASE/VIAL

/N62333/001/
N62333 001
N62372 005
JAN 13, 1983
/N62333/002/
N62333 002
/N62333/003/
N62333 003
/N62333/004/
N62333 004

CREAM, SUPPOSITORY; TOPICAL, VAGINAL

MONISTAT DUAL-PAK

+ JOHNSON RW

2%:200MG

N18888 002
OCT 17, 1988

SUPPOSITORY; VAGINAL

MICONAZOLE NITRATE

ABLE

200MG

N73508 001
NOV 19, 1993

MONISTAT 3

+ JOHNSON RW

200MG

N18888 001
AUG 15, 1984

/MONISTAT-7/
/JOHNSON/RW/

/100MG/

/N18520/001/
/MAR/15, 1982/

MILTRINONE LACTATE

INJECTABLE; INJECTION

MILTRINONE LACTATE

+ STERLING

/3/

EQ 1MG BASE/ML

/EQ/1MG/BASE/ML/

N19436 001

DEC 31, 1987

/N19436/661/

/DEC/31,1987/

1MG

N18677 001
DEC 26, 1985

/CAPSULE; ORAL/

/CESAME/

3 LILLY

MITOXANTHONE HYDROCHLORIDE

INJECTABLE; INJECTION

NOVANTRONE

+ IMPUNEX

/LEDERLE/

EQ 2MG BASE/ML

/EQ/2MG/BASE/ML/

N19297 001

DEC 23, 1987

/N19297/661/

/DEC/23,1987/

20MG

N18063 005
OCT 28, 1986

N18063 001

N18064 001

N18063 002

N18064 002

MORICIZINE HYDROCHLORIDE

TABLET; ORAL

ETHIOZINE

/PUPPOT/

/260MG/

/250MG/

/360MG/

/N19753/661/

/JUN/19,1990/

/N19753/661/

/JUN/19,1990/

/N19753/661/

/JUN/19,1990/

ROBERTS

200MG

250MG

300MG

N19753 001

JUN 19, 1990

N19753 002

JUN 19, 1990

N19753 003

JUN 19, 1990

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NAFCIL

APOTHECON

AP

AP

AP

AP

AP

AP

AP

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 10GM BASE/VIAL

N62527 001
AUG 02, 1984

N62527 002

AUG 02, 1984

N62732 001

DEC 23, 1986

N62527 003

AUG 02, 1984

N62732 002

DEC 23, 1986

N62527 004

AUG 02, 1984

> ADD >
> ADD >

NABILONE

/CAPSULE; ORAL/

/CESAME/

/3 LILLY

/1MG/

/N18677/661/

/DEC/26,1985/

NAFACILLIN SODIUM

INJECTABLE; INJECTION

NAFACIL

/AP/ /ERISTOL/ /EQ 500MG BASE/VIAL/ /N62527/001/ /APR/11/1989/

/AS/ /ERISTOL/ /EQ 1GM BASE/VIAL/ /N62527/001/ /APR/11/1989/

/AP/ /ERISTOL/ /EQ 1GM BASE/VIAL/ /N62527/001/ /APR/11/1989/

/AP/ /ERISTOL/ /EQ 2GM BASE/VIAL/ /N62527/001/ /APR/11/1989/

/AP/ /ERISTOL/ /EQ 2GM BASE/VIAL/ /N62527/001/ /APR/11/1989/

/AP/ /ERISTOL/ /EQ 1GM BASE/VIAL/ /N62527/001/ /APR/11/1989/

POWDER FOR RECONSTITUTION; ORAL

UNIPEN

3 NYETH AYERST

/EQ 250MG BASE/5ML/ /N50199/001/

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

HALBUPHINE HCL

/AP/ /ASTRA/ /10MG/ML/ /N72071/001/

/AP/ /ASTRA/ /10MG/ML/ /N72072/001/

/AP/ /ASTRA/ /20MG/ML/ /N72074/001/

/AP/ /ASTRA/ /20MG/ML/ /N72075/001/

/AP/ /ASTRA/ /10MG/ML/ /N72071/001/

/AP/ /ASTRA/ /10MG/ML/ /N72072/001/

/AP/ /ASTRA/ /20MG/ML/ /N72074/001/

/AP/ /ASTRA/ /20MG/ML/ /N72075/001/

NALBUPHINE HYDROCHLORIDE

ABBOTT

/1.5MG/ML/ /N20200/001/

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

HALOXONE HCL

/AP/ /ASTRA/ /0.02MG/ML/ /N72082/001/

/AP/ /ASTRA/ /0.02MG/ML/ /N72083/001/

/AP/ /ASTRA/ /0.02MG/ML/ /N72084/001/

/AP/ /ASTRA/ /0.02MG/ML/ /N72085/001/

/AP/ /ASTRA/ /0.4MG/ML/ /N72087/001/

/AP/ /ASTRA/ /0.4MG/ML/ /N72088/001/

/AP/ /ASTRA/ /0.4MG/ML/ /N72089/001/

/AP/ /ASTRA/ /0.4MG/ML/ /N72090/001/

/AP/ /ASTRA/ /1MG/ML/ /N72092/001/

/AP/ /ASTRA/ /1MG/ML/ /N72093/001/

/AP/ /ASTRA/ /0.02MG/ML/ /N72096/001/

3 ASTRA

3

3

3

3

3

3

3

3

3

3

3

3

3

3

3

3

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALCAN

/AB/ /PUPONT/

/0.4MG/ML/

/N71083/001/

/AB/

/1MG/ML/

/N71084/001/

/AB/

/1MG/ML/

/N71311/001/

3 DUPONT

0.4MG/ML

JUL 28, 1988

3

1MG/ML

JUL 28, 1988

3

1MG/ML

JUL 28, 1988

NANDROLONE DECANOATE

INJECTABLE; INJECTION

NANDROLONE DECANOATE

/AB/ /LPHOMED/

/100MG/ML/

/N88290/001/

/AB/

/200MG/ML/

/N88317/001/

3 LYPHOMED

100MG/ML

OCT 03, 1983

3

200MG/ML

OCT 14, 1983

NAPROXEN SODIUM

TABLET; ORAL

ANAFROX

AB SYNTEX

275MG

N18164 001

AB ANAFROX DS

550MG

N18164 003

AB + SYNTEX

SEP 30, 1987

NAFROXEN SODIUM

HAMILTON

275MG

N74106 001

AB

550MG

AUG 31, 1993

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

/AB/ /EON LABS/

/EQ 350MG BASE/

/N61586/001/

3 EON LABS

EQ 350MG BASE

N61586 001

NIACIN

CAPSULE; ORAL

WALLACE AP

3 WALLACE

/500MG/

/N11073/003/

500MG

N11073 003

TABLET; ORAL

NIACIN

ZENITH

3 ZENITH

/500MG/

/N83180/001/

500MG

N83180 001

NIFEDIPINE

CAPSULE; ORAL

FLEMINGTON

AB

10MG

N72781 001

JUL 30, 1993

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC

BC MILES

30MG

N20198 001

60MG

APR 21, 1993

90MG

APR 21, 1993

30MG

SEP 06, 1989

60MG

SEP 06, 1989

90MG

SEP 06, 1989

30MG

SEP 06, 1989

60MG

SEP 06, 1989

90MG

SEP 06, 1989

30MG

SEP 06, 1989

60MG

SEP 06, 1989

90MG

SEP 06, 1989

30MG

SEP 06, 1989

60MG

SEP 06, 1989

90MG

SEP 06, 1989

30MG

SEP 06, 1989

60MG

SEP 06, 1989

90MG

SEP 06, 1989

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

ZENITH

3 ZENITH

/50MG/

/N80078/002/

50MG

N80078 002

100MG

N80078 001

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
MACROBID
+ P AND G

75MG;25MG

N20064 001
DEC 24, 1991

/CAPSULE; EXTENDED RELEASE; ORAL/
/MACROBID/
/333P AND G/
/75MG;25MG/
/N20064/001/
/DEC/24/1991/

CREAM; TOPICAL

NYSTATIN

AT

BARRE

100,000 UNITS/GM

N62949 001
JUN 13, 1988
/N62949/001/
/JUN/13/1988/
N64022 001
JAN 29, 1993

/100,000 UNITS/GM/
/AT/ /NASKA/

100,000 UNITS/GM

AT TARO

ointment; TOPICAL

NYSTATIN

AT

BARRE

100,000 UNITS/GM

N62840 001
NOV 13, 1987
/N62840/001/
/NOV/13/1987/

/100,000 UNITS/GM/
/AT/ /NASKA/

PONDER; ORAL

BARSATIN

/AA/

BARLAN

/100%/
100%

/N62449/001/
/APR/27/1988/
N62489 001
APR 27, 1988

NITROGLYCERIN

INJECTABLE; INJECTION

NITRO-BID

/MARION MERRELL/DOW/ 10MG/ML/

EQ 10MG/ML

SUSPENSION; ORAL

MYCOSTATIN

AA

APOTHECON

100,000 UNITS/ML

N61533 001

/100,000 UNITS/ML/
/AA/ /BIDISTOL/HIERS/SQUIBB/

100,000 UNITS/ML

AA BARRE

100,000 UNITS/ML

N62571 001
OCT 29, 1985

/100,000 UNITS/ML/
/AA/ /NASKA/

100,000 UNITS/ML

AA PENNEX PHARMS

100,000 UNITS/ML

N62512 001
OCT 29, 1984

100,000 UNITS/ML

EQ

100,000 UNITS/ML

N62835 001
NOV 19, 1987

/100,000 UNITS/ML/
/AA/ /PHARM/BASICS/

100,000 UNITS/ML

/AA/

100,000 UNITS/ML

/N62512/001/
/OCT/29/1984/

/100,000 UNITS/ML/
/AA/

100,000 UNITS/ML

/AA/ /PHARM/BASICS/

100,000 UNITS/ML

/N62835/001/
/NOV/19/1987/

/100,000 UNITS/ML/
/AA/

100,000 UNITS/ML

/AA/ /PHARM/BASICS/

100,000 UNITS/ML

/N62518/001/
/JUL/06/1984/

100,000 UNITS/ML

EQ PHARMADERM

100,000 UNITS/ML

N62518 001
JUL 06, 1984

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

NORTRIPTYLINE HCL

NYLAN

EQ 10MG BASE

N74234 001

JUL 26, 1993

EQ 25MG BASE

N74234 002

JUL 26, 1993

EQ 50MG BASE

N74234 003

JUL 26, 1993

EQ 75MG BASE

N74234 004

JUL 26, 1993

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT BARRE 100.000 UNITS/GM; 0.1%

N63010 001

DEC 20, 1988

/AT/

/N63010/

/100.000 UNITS/GM; 0.1%
 /DEC/20/1988/

NYSTATIN-TRIAMCINOLONE ACETONIDE

/AT/

/PHARMADERM/

/N62596/001

OCT 08, 1985

3 PHARMADERM

/100.000 UNITS/GM; 0.1%
 /OCT/08/1985/

ONTMENT; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AT TARO 100.000 UNITS/GM; 0.1%

N63305 001

MAR 29, 1993

OCREOTIDE ACETATE

INJECTABLE; INJECTION

SANDOSTATIN

/SANDOSTATIN/

/EQ/0.05MG BASE/ML

/N19667/001

OCT 21, 1988

SANDOZ

/EQ/0.1MG BASE/ML

/N19667/002

OCT 21, 1988

/EQ/0.2MG BASE/ML

/N19667/003

JUN 12, 1991

/EQ/0.5MG BASE/ML

/N19667/004

OCT 21, 1988

/EQ/1MG BASE/ML

/N19667/005

JUN 12, 1991

OFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

OCUFLOX

+ ALLERGAN

0.3%

N19921 001

JUL 30, 1993

OXACILLIN SODIUM

CAPSULE; ORAL

PROSTAPHILIN

AB APOTHECON

EQ 250MG BASE

N61450 002

/EQ/250MG BASE/

/N61450/001

/AB/

/PROSTAPHILIN/

/EQ/250MG BASE/

/N61450/001

/AB/

/PROSTAPHILIN/

/EQ/250MG BASE/

/N61450/001

POWDER FOR RECONSTITUTION; ORAL

PROSTAPHILIN

AA APOTHECON

EQ 250MG BASE/5ML

N61457 001

/EQ/250MG BASE/5ML/

/N61457/001

OPRENOLOL HYDROCHLORIDE

CAPSULE; ORAL

TRANSICOR

/160MG/

/N18166/004

/160MG/

/N18166/001

/160MG/

/N18166/002

/160MG/

/N18166/003

/160MG/

/N18166/004

/160MG/

/N18166/005

/160MG/

/N18166/006

/160MG/

/N18166/007

/160MG/

/N18166/008

/160MG/

/N18166/009

/160MG/

/N18166/010

/160MG/

/N18166/011

/160MG/

/N18166/012

/160MG/

/N18166/013

/160MG/

/N18166/014

/160MG/

/N18166/015

/160MG/

/N18166/016

/160MG/

/N18166/017

/160MG/

/N18166/018

/160MG/

/N18166/019

/160MG/

/N18166/020

/160MG/

/N18166/021

/160MG/

/N18166/022

/160MG/

/N18166/023

/160MG/

/N18166/024

/160MG/

/N18166/025

/160MG/

/N18166/026

/160MG/

/N18166/027

/160MG/

/N18166/028

/160MG/

/N18166/029

/160MG/

/N18166/030

/160MG/

/N18166/031

/160MG/

/N18166/032

/160MG/

/N18166/033

/160MG/

/N18166/034

/160MG/

/N18166/035

/160MG/

/N18166/036

/160MG/

/N18166/037

/160MG/

/N18166/038

/160MG/

/N18166/039

/160MG/

/N18166/040

/160MG/

/N18166/041

/160MG/

/N18166/042

/160MG/

/N18166/043

/160MG/

/N18166/044

OXTRIPHYLLINE

SYRUP; ORAL

C-TOLEDYL

/AA/ /PARKER/DAVIS/ /50MG/5ML/ /N09268 011/

/AA/ /OXTRIPHYLLINE, PENTATHIN/ /50MG/5ML/ /N09268 011/

3 PENNEX PHARMS

50MG/5ML

DEC 05, 1983

OXYPHENBUTAZONE

TABLET; ORAL

TANDEARIL

3 GEIGY

100MG

/3/RHONE-POULENC/ROPER//100MG/

N12542 004
SEP 03, 1982
/N12542/004/
/SEP/03//1982/

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

AREDIA

+ CIBA GEIGY

60MG/VIAL

90MG/VIAL

N20036 003
MAY 06, 1993
N20036 004
MAY 06, 1993

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

/AB/ /ASTRA/

/2MG/ML/

3 ASTRA

2MG/ML

/N12772/005/
/MAR/31//1986/
N72212 001
MAR 31, 1983

PARAMETHASONE ACETATE

TABLET; ORAL

HALDRONE

/3//LILLY/

/2MG/

/1MG/

3 LILLY

3

2MG

/N12772/005/
/N12772/005/
N12772 005
N12772 006

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAXIL

/3//SMITHKLINE/BEECHAM/ /EQ/10MG/BASE/

/3// /EQ/50MG/BASE/

3 SMITHKLINE BEECHAM

EQ 10MG BASE

/EQ/40MG/BASE/

EQ 40MG BASE

EQ 50MG BASE

/N00031/001/
/DEC/29//1992/
/N00031/001/
/DEC/29//1992/
/N00031 001
DEC 29, 1992
/N00031/005/
/DEC/29//1992/
/N00031 005
DEC 29, 1992
/N00031 004
DEC 29, 1992

PENICILLIN G BENZATHINE

INJECTABLE; INJECTION

BICILLIN L-A

/3//MYETH/AYERST/

+ MYETH AYERST

3

/300,000 UNITS/ML/
300,000 UNITS/ML
300,000 UNITS/ML
/300,000 UNITS/ML/

/N50141/003/
N50141 003
N50131 001
/N50141/003/

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN

/AA/ /BIOCRRAFT/

BIOCRRAFT

/PENTIDS/4000/

3 APOTHECON

/PENTIDS/4000/

3 APOTHECON

/400,000 UNITS/5ML/
200,000 UNITS/5ML
/400,000 UNITS/5ML/
200,000 UNITS/5ML
/400,000 UNITS/5ML/
400,000 UNITS/5ML

/N60307 002/
N60307 002
/N62149 001/
N62149 001
/N62149/002/
N62149 002

PENICILLIN G POTASSIUM

TABLET; ORAL

3 APOTHECON

/500MG/

250,000 UNITS

/250,000 UNITS/

N60392 003
/N60392/003/

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL

/AA/ /55MG/ 35MG
/ZENITH/
a LEIMON

TABLET; ORAL

/AA/ /55MG/ 35MG
/FERNDALE/
a FERNDALE
/AA/ /55MG/ 35MG
/SOLVAY/
a SOLVAY
/AA/ /55MG/ 35MG
/FOREST PHARMS/
a FOREST PHARMS

PHENDIMETRAZINE TARTRATE

/AA/ /55MG/ 35MG

/ANABOLIC/
a ANABOLIC

/AA/ /55MG/ 35MG

/FERNDALE/
a FERNDALE

/AA/ /55MG/ 35MG

/GENEVA/
a SOLVAY

PHENDIMETRAZINE HYDROCHLORIDE

> DLT >
> DLT >
> DLT >
> ADD >
/AA/ /55MG/ 35MG
/ZENITH/
a LEIMON
/AA/ /55MG/ 35MG
/FOREST PHARMS/
a FOREST PHARMS
/AA/ /55MG/ 35MG
/SOLVAY/
a SOLVAY
/AA/ /55MG/ 35MG
/FOREST PHARMS/
a FOREST PHARMS

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

/AA/ /55MG/ 35MG
/ZENITH/
a LEIMON
/AA/ /55MG/ 35MG
/FERNDALE/
a FERNDALE

PHENTERMINE HCL

/AA/ /55MG/ 35MG
/LEIMON/
a LEIMON
/AA/ /55MG/ 35MG
/PHARM BASICS/
a PHARM BASICS

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

/AA/ /55MG/ 35MG
/ZENITH/
a ZENITH

TABLET; ORAL

/AA/ /55MG/ 35MG
/SOLVAY/
a SOLVAY

PHENYL BUTAZONE

CAPSULE; ORAL

/AA/ /55MG/ 35MG
/ZENITH/
a ZENITH

PHENYL BUTAZONE

/AA/ /55MG/ 35MG

/BARR/
a BARR

/AA/ /55MG/ 35MG

/CHELSEA/
a CHELSEA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/AA/ /55MG/ 35MG

/GENEVA/
a GENEVA

/N86329/001/
N86329 001

/N86035/001/
N86035 001

/N86319/001/
N86319 001

/N86044/001/
DEC 04, 1985
/DEC/04, 1985/
N86994 001

/N86774/001/
DEC 17, 1982
/DEC/17, 1982/
N87774 001

/N86774/001/
JUN 16, 1982
/JUN/16, 1982/
N87774 001

/N86319/001/
N86319 008

/N86035/001/
DEC 04, 1985
/DEC/04, 1985/
N86151 001

/N86774/001/
APR 21, 1982
/APR/21, 1982/
N87674 001

/N86319/001/
N86319 008

/N86035/001/
DEC 04, 1985
/DEC/04, 1985/
N86151 001

/N86774/001/
APR 21, 1982
/APR/21, 1982/
N87674 001

/N86319/001/
N86319 008

/N86035/001/
DEC 04, 1985
/DEC/04, 1985/
N86151 001

/N86774/001/
APR 21, 1982
/APR/21, 1982/
N87674 001

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE VC PLAIN
@ PENNEX PHARMS

5MG/5ML; 6.25MG/5ML

/AA/ PHARMA/PAKISTAN/

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

N88897 001
JAN 04, 1985
/N88897/001/
/JAN/04, 1985/

INJECTABLE; INJECTION
ZOSYN

+ LEDERLE

EQ 2GM BASE/VIAL;
EQ 250MG BASE/VIAL

N50684 001
OCT 22, 1993

+

EQ 3GM BASE/VIAL;
EQ 375MG BASE/VIAL

N50684 002
OCT 22, 1993

+

EQ 4GM BASE/VIAL;
EQ 500MG BASE/VIAL

N50684 003
OCT 22, 1993

+

EQ 36GM BASE/VIAL;
EQ 4.5GM BASE/VIAL

N50684 004
OCT 22, 1993

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

PHENYTOIN SODIUM
/S/PHARM/PAKISTAN/
@ PHARMERAL

/100MG/
100MG

/N85435/001/
N85435 001

PHYTONADIONE

INJECTABLE; INJECTION

AQUAPHYTON

/BP/ MSD

/10MG/ML/
10MG/ML

/N1223 001/
N1223 001

KONAKION

/BP/ ROCHE/
BP ROCHE

/10MG/ML/
10MG/ML

/N11745/003/
N11745 003

PINDOLOL

TABLET; ORAL

PINDOLOL
GENEVA

5MG

N73608 001
MAR 29, 1993

10MG

N73609 001
MAR 29, 1993

AB NOVOPHARM

5MG

N73661 001
OCT 31, 1993

10MG

N73661 002
OCT 31, 1993

AB PUREPAC

5MG

N74125 001
APR 28, 1993

10MG

N74125 002
APR 28, 1993

AB ZENITH

5MG

N73687 001
FEB 26, 1993

10MG

N73687 002
FEB 26, 1993

PIROXICAM

CAPSULE; ORAL

PIROXICAM

AB MEPHA AG

10MG

N74116 001
JUN 15, 1993

AB

AB

20MG

N74118 001
JUN 15, 1993

AB

MUTUAL PHARM

10MG

N73535 001
MAR 12, 1993

AB

AB

20MG

N73536 001
MAR 12, 1993

AB

ROXANE

10MG

N73651 001
FEB 26, 1993

AB

20MG

N73651 002
FEB 26, 1993

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM

BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

PEG-LYTE

AA INVAMED

236GM/BOI; 2.97GM/BOI; 6.74GM/BOI;
5.86GM/BOI; 22.74GM/BOI

N73098 001
AUG 31, 1993

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE
/AD/ /ADRI/ /8MEQ/
/AD/ /ADRI/ /10 MEQ/
AB SAVAGE 8MEQ
AB 10 MEQ

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

FUJISAWA 2MEQ/ML
AP 2MEQ/ML
AP 2MEQ/ML
/AD/ /LUTIPOL/ 2MEQ/ML
/AD/ /LUTIPOL/ 2MEQ/ML
a LUTIPOLD 2MEQ/ML
a 2MEQ/ML
/AD/ /LUTIPOL/ 2MEQ/ML
/AD/ /LUTIPOL/ 2MEQ/ML

TABLET, EXTENDED RELEASE; ORAL

K-9
AB ALRA 8MEQ
KAON CL
/ADRI/ /6.7MEQ/
SAVAGE 6.7MEQ
KAON CL-10
/BC/ /ADRI/ /10MEQ/
BC SAVAGE 10MEQ

POTASSIUM CITRATE

POTASSIUM CITRATE
/ADRI/ /ADRI/ /20MEQ/PACKET/
/ADRI/ /ADRI/ /10MEQ/PACKET/
/ADRI/ /ADRI/ /10MEQ/PACKET/
a UNIV TX 10MEQ/PACKET
a 20MEQ/PACKET

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL
POTASSIUM CITRATE
/ADRI/ /ADRI/ /5MEQ/
+ UNIV TX 10MEQ
5MEQ

PRAVASTATIN SODIUM

TABLET; ORAL
PRIVACHOL

/ADRI/ /ADRI/ /5MEQ/
+ BRISTOL MYERS SQUIBB 40MG
20MG

PRAZEPAM

TABLET; ORAL/
CENTRA
/ADRI/ /ADRI/ /10MG/
a PARKE DAVIS 10MG

PREDNICARBATE

CREAM; TOPICAL
DERMATOP
HOECHST ROUSSEL 0.1%

OINTMENT; TOPICAL

/ADRI/ /ADRI/ /5MEQ/
a HOECHST ROUSSEL 0.1%

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE
/ADRI/ /ADRI/ /5MG/
a PRIVATE FORM 5MG

/ADRI/ /ADRI/ /5MEQ/
/ADRI/ /ADRI/ /10MEQ/
/ADRI/ /ADRI/ /5MEQ/
AUG 31, 1992
N19071 001
AUG 30, 1985

/ADRI/ /ADRI/ /5MEQ/
/ADRI/ /ADRI/ /10MEQ/
/ADRI/ /ADRI/ /5MEQ/
AUG 31, 1992
N19071 001
AUG 30, 1985

/ADRI/ /ADRI/ /5MEQ/
/ADRI/ /ADRI/ /10MEQ/
/ADRI/ /ADRI/ /5MEQ/
AUG 31, 1992
N19071 001
AUG 30, 1985

/ADRI/ /ADRI/ /5MEQ/
/ADRI/ /ADRI/ /10MEQ/
/ADRI/ /ADRI/ /5MEQ/
AUG 31, 1992
N19071 001
AUG 30, 1985

/ADRI/ /ADRI/ /5MEQ/
/ADRI/ /ADRI/ /10MEQ/
/ADRI/ /ADRI/ /5MEQ/
AUG 31, 1992
N19071 001
AUG 30, 1985

/ADRI/ /ADRI/ /5MEQ/
/ADRI/ /ADRI/ /10MEQ/
/ADRI/ /ADRI/ /5MEQ/
AUG 31, 1992
N19071 001
AUG 30, 1985

PROPOFOL

INJECTABLE; INJECTION

DIPRIVAN
/ICN/
+ ZENECA
/10MG/ML/
10MG/ML
/N19627/001/
/OCT/02, 1989/
N19627 001
OCT 02, 1989

PROPRANOLOL HYDROCHLORIDE

SOLUTION; ORAL

PROPRANOLOL HCL
@ PENNEX PHARMS

@
/3/PHARM/BASIS/
/3/
/20MG/5ML/
40MG/5ML
/10MG/5ML/
/40MG/5ML/
/N71984/001/
MAR 03, 1989
N71985 001
MAR 03, 1989
/N71984/001/
/MAR/03, 1989/
/N71985/001/
/MAR/03, 1989/

/SUSPENSION; ORAL/
/THERAL/
/WYETH/AYERST/

@ WYETH AYERST

/10MG/ML/
10MG/ML
/N19536/001/
/DEC/12, 1986/
N19536 001
DEC 12, 1986

TABLET; ORAL

PROPRANOLOL HCL

/AB/
/MYLAN/
/60MG/
60MG
@ MYLAN
/N72275/001/
/JUN/09, 1989/
N72275 001
JUN 09, 1989

PROPYLIDONE

/SUSPENSION; INTRATRACHEAL/
/DIONOSIL/OLLY/
/GLAXO/
@ GLAXO

/60%/
60%
/N09309/002/
N09309 002

PROTAMINE SULFATE

INJECTABLE; INJECTION

PROTAMINE SULFATE

/AB/
/QUAD/
@ QUAD
10MG/ML
/10MG/ML/
/N09306/001/
/MAR/30, 1986/
N09306 001
MAY 30, 1986

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

/HISTAFED/
/AB/
/LIFE/LABZ/
@ CENCI

/30MG/5ML; 1.25MG/5ML/
30MG/5ML; 1.25MG/5ML
/N08283/001/
/APR/20, 1984/
N08283 001
APR 20, 1984

PYRANTEL PAMOATE

/SUSPENSION; ORAL/
/ANTHIMIN/
/+/ROBERTS/
/EQ/250MG/BASE/5ML/
/N16883/001/
/N16883/001/

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

/AB/
/AP/
/ICN/
ROCHE

/5MG/ML/
5MG/ML
/N09830/001/
N09830 001

SYRUP; ORAL

MESTINON

/ICN/
ROCHE

/60MG/5ML/
60MG/5ML
/N15193/001/
N15193 001

TABLET; ORAL

MESTINON

/+/ICN/
+ ROCHE

/60MG/
60MG
/N09829/002/
N09829 002

TABLET; EXTENDED RELEASE; ORAL

MESTINON

/+/ICN/
+ ROCHE

/180MG/
180MG
/N11665/001/
N11665 001

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL

/AP/ /QUAD/ /10MG/ML/

@ QUAD

10MG/ML

/N19443/001/
/JUN/03, 1986/
/N19443/002/
/JUN/03, 1986/
/N19443/001/
/JUN/03, 1986/
/N19443/002/
/JUN/03, 1986/

/INJECTABLE; INJECTION/
/SODIUM BICARBONATE/IN/PLASTIC/CONTAINER/
@ ABBOTT

1MEQ/ML

/N19443/001/
/JUN/03, 1986/
/N19443/002/
/JUN/03, 1986/

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

SELENIUM SULFIDE

@ PENNEX PHARMS

/AP/ /PHARM/BASIC/ /2.5%/

/N83228/001/
/SEP/01, 1983/
/N83228/001/
/SEP/01, 1983/

SERACTIDE ACETATE

/INJECTABLE; INJECTION/
/ACTHAP/SEL-SYNTHETIC/
/ARMOUR/

@ ARMOUR

80 UNITS/ML

/N17861/001/
/N17861/002/
/N17861/001/
/N17861/002/

SILVER SULFADIAZINE

/WHESSING/TOPICAL/

@ BIOPLASTY

1%

/SILVIMAC/

/FENGUAY/

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

SODIUM BICARBONATE

/INJECTABLE; INJECTION/
/SODIUM BICARBONATE/IN/PLASTIC/CONTAINER/
/ABBOTT/

/0.9MEQ/ML/

1MEQ/ML

/N17315/001/
/JUN/03, 1986/
/N17315/002/
/JUN/03, 1986/

/50MCI/ML/
50MCI/ML

SOLUTION; ORAL
SODIUM IODIDE I 131
/CIS/
CIS

/N17315/001/
/N17315/002/

SODIUM BICARBONATE

/INJECTABLE; INJECTION/
/SODIUM BICARBONATE/IN/PLASTIC/CONTAINER/
@ ABBOTT

1MEQ/ML

/N19443/001/
/JUN/03, 1986/
/N19443/002/
/JUN/03, 1986/

SODIUM CHLORIDE

INJECTABLE; INJECTION

BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP FUJISAWA

/AP/ /LPHOMED/ /234MG/ML/

/N88911/001/
/FEB/07, 1985/
/N88911/001/
/FEB/07, 1985/

SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER

@ FUJISAWA

234MG/ML

/N19329/001/
/APR/22, 1987/
/N19329/001/
/APR/22, 1987/

/AP/ /LPHOMED/ /234MG/ML/

SODIUM CHROMATE, CR-51

INJECTABLE; INJECTION

CHROMITOPES SODIUM

@ SQUIBB

/2MCI/VIAL/
2MCI/VIAL

/N13993/002/
/N13993/002/

SODIUM IODIDE, I-131

CAPSULE; ORAL

SODIUM IODIDE I 131

@ CIS

/50UCI/
50 UCI

/N17316/001/
/N17316/002/

/100UCI/
100 UCI

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
@ PENNEX PHARMS 453.6GM/BOT
/AA/ /PHARM/BASIC/ /453.6GM/BOT/

SIRONITIUM CHLORIDE, SR-89

INJECTABLE; INJECTION
METASTRON
MEDI PHYSICS
1MCI/ML

N20134 001
JUN 18, 1993

SULFACETAMIDE SODIUM

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
@ PENNEX PHARMS 15GM/60ML
/AA/ /PHARM/BASIC/ /15GM/60ML/

SOINTMENT; OPHTHALMIC

/AA/ /SULFACETAMIDE/ /100/

/N888888/001/
/DEC/22/1982/
N88000 001
DEC 22, 1982

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
HUMATROPE
BX + LILLY 5MG/VIAL
NUTROPIN 5MG/VIAL
GENENTECH 10MG/VIAL
+

SULFADIAZINE

TABLET; ORAL
SULFADIAZINE
/ABBOTT/ @ ABBOTT
/300MG/ 300MG

/N04125/005/
N04125 005

SULFAMETHIZOLE

TABLET; ORAL
THIOSULFIL
/MYETH/AYERST/
@ MYETH AYERST
/250MG/ 250MG

/N08565/001/
N08565 001

SOYBEAN OIL

INJECTABLE; INJECTION
NUTRILIPID 10%
AP MCGAW 10%
NUTRILIPID 20%
AP MCGAW 20%

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AA/ /CHELSEA/
B* CHELSEA
/UPSHER/SMITH/
@ UPSHER SMITH

/N87078/001/
N87078 001
/N87554/001/
N87554 001

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
TRIMETH/SULFA
AB BARRE
200MG/5ML; 40MG/5ML
200MG/5ML; 40MG/5ML

N72289 001
MAY 23, 1988
N72398 001
MAY 23, 1988

TABLET; ORAL
/SANTALIN-03/
/ROCHE/
@ ROCHE
/1GM/ 1GM

/N12715/003/
N12715 003

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

TRIMETH/SULFA

/AB/

/N/A/N/A/

/AB/

/200MG/5ML; 400MG/5ML/

/200MG/5ML; 400MG/5ML/

/N72289/001/

/MAY/23./1988/

/N72308/001/

/MAY/23./1988/

N73038 001

JUN 22, 1993

N73039 001

JUN 22, 1993

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

/INTERPHARM/

> DLT > /P*/

> DLT > /P*/

> DLT > /P*/

> DLT > /P*/

> ADD >

> ADD >

> ADD >

/400MG; 80MG/

/400MG; 80MG/

/400MG; 80MG/

/400MG; 80MG/

/800MG; 160MG/

/N71309/001/

/OCT/27./1987/

/N71309/001/

/OCT/27./1987/

/N71299 001

OCT 27, 1987

/N71300 001

OCT 27, 1987

N20070 004

SEP 09, 1993

N20070 001

SEP 09, 1993

N20070 002

SEP 09, 1993

N20070 003

SEP 09, 1993

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/HEATHER/

/HEATHER/

/PHARMERAL/

/PHARMERAL/

/AB/

> DLT >

> ADD >

/500MG/

/500MG/

/500MG/

/500MG/

/N80189/001/

/N80189 001

/N84385/001/

/N84385 001

/EQ/10MG/BASE/

/EQ 10MG BASE

/N17970/001/

N17970 001

SULFISOXAZOLE ACETYL

/EMULSION; ORAL/

/LIPID/SANTRISIN/

/ROCHE/

/ROCHE/

/EQ/1GM/BASE/5ML/

/EQ 1GM BASE/5ML

/N89182/009/

/N89182 009

/A-N-STANNOUS/AGGREGATED/ALBUMIN/

/N/A/

/N/A/

/N17916/001/

N17916 001

SULFISOXAZOLE DIOLAMINE

/OINTMENT; OPHTHALMIC/

/SANTRISIN/

/ROCHE/

/ROCHE/

BS

AN-MAA

SORIN

N/A

N/A

N/A

N/A

N/A

N17792 001

/N17792/001/

N17792 001

/N17792/001/

/EQ/4% BASE/

/EQ 4% BASE

/N88414/002/

/N88414 002

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

/AMERICAN MDP KIT/

/AMERICAN/

N/A

N/A

N/A

N18335/001/

/AUG/05./1982/

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
/AMERSHAM NPP KIT/
@ AMERSHAM

N/A

N18335 001
AUG 05, 1982

/4MG/

EQ 2MG BASE

EQ 2MG/BASE

/4MG/

EQ 1MG BASE

EQ 1MG BASE

/4MG/

TECHNETIUM TC-99M SODIUM Pertechnetate GENERATOR

SOLUTION; INJECTION, ORAL

/Minitec/
/SQUIBB/
@ SQUIBB

/0.22-2.22Ci/GENERATOR/
0.22-2.22Ci/GENERATOR N17339 001

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM
DANBURY PHARMA

15MG

N71446 001
MAY 21, 1993

/5MG/

EQ 5MG BASE

EQ 5MG BASE

/5MG/

EQ 10MG BASE

EQ 10MG BASE

/5MG/

30MG

N71447 001
MAY 21, 1993

/10MG/

EQ 10MG BASE

EQ 10MG BASE

/10MG/

EQ 10MG BASE

EQ 10MG BASE

/10MG/

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL

TESTODERM

+ ALZA

4MG/24HR

N19762 001

6MG/24HR

OCT 12, 1993

6MG/24HR

N19762 002

6MG/24HR

OCT 12, 1993

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION

TESTOSTERONE PROPIONATE

/BEL/MAR/

25MG/ML

N80741 001

50MG/ML

N80741 001

100MG/ML

N80743 001

25MG/ML

N80741 001

50MG/ML

N80742 001

100MG/ML

N80743 001

TICARCILLIN DISODIUM

INJECTABLE; INJECTION
TICAR
+ SMITHKLINE BEECHAM
+

EQ 20GM BASE/VIAL
EQ 30GM BASE/VIAL

N50497 004
N50497 005
APR 04, 1984

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

TABLET; ORAL
TOLAZAMIDE

/B4/ /INTERPHARM/

/250MG/

/N71271/001/
/SEP 23, 1986/
/N71271/001/
/SEP 23, 1986/
N71270 001
SEP 23, 1986
N71271 001
SEP 23, 1986

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLID
+ SYNTEX
@

250MG

125MG

/250MG/

N19979 002
OCT 31, 1991
N19979 001
MAR 24, 1993
/N19979/002/
/05-7/31, 1993/

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

AB MYLAN

EQ 400MG BASE

N73393 001
MAY 27, 1993

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
TIMOPTIC-XE
+ MERCK

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

EQ 0.25% BASE

EQ 0.5% BASE

N20330 001
NOV 04, 1993
N20330 002
NOV 04, 1993

TABLET; ORAL
TOLMETIN SODIUM

AB GENEVA

EQ 600MG BASE

N74002 001
SEP 27, 1993

TORSEMIDE

INJECTABLE; INJECTION

DENADEX

+ BOEHRINGER MANNHEIM

10MG/ML

N20137 002
AUG 23, 1993

TABLET; ORAL

TIMOLOL MALEATE

AB NOVOPHARM

5MG

10MG

20MG

N72648 001
JUN 16, 1993
N72649 001
JUN 16, 1993
N72650 001
JUN 16, 1993

TABLET; ORAL

DENADEX

+ BOEHRINGER MANNHEIM

100MG

N20136 004
AUG 23, 1993
N20136 001
AUG 23, 1993
N20136 002
AUG 23, 1993
N20136 003
AUG 23, 1993

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC
TOBRAMYCIN

> ADD >
> ADD >
> ADD >

0.3%

BAUSCH AND LOMB

N64052 001
NOV 29, 1993

TOBREX

+ ALCON

0.3%

0.3%

N50541 001
N62535 001
DEC 13, 1984

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE
@ PENNEX PHARMS

0 e

/3/ PHARM/BASICS/

/d/

0 e

2 PHARMAFAIR

LOTION; TOPICAL
TRIAMCINOLONE ACETONIDE
PENNEX PHARMS

AT	PENNEX PHARMS
AT	
/AT/	/PHARM/BASICS/
/AT/	

VITAMIN A PALMITATE

CAPSULE; ORAL

AFAXIN
3 STERLING

VITAMIN A

3 WHARTON

3 WHARTON

3 ZENITH

3 ZENITH

3

EQ 50,000 UNITS BASE

N83187 001

EQ 50,000 UNITS BASE

N83665 001

EQ 50,000 UNITS BASE

N83665 001

EQ 50,000 UNITS BASE

N83665 001

EQ 50,000 UNITS BASE

N83035 001

EQ 50,000 UNITS BASE

N83190 001

EQ 50,000 UNITS BASE

N83190 001

INJECTABLE; INJECTION

AQUASOL A

ASTRA

ASTRA

VITAMIN A PALMITATE

BELMAR

3 BEL MAR

EQ 50,000 UNITS BASE/ML

N06823 001

EQ 50,000 UNITS BASE/ML

N06823 001

EQ 50,000 UNITS BASE/ML

N06819 001

EQ 50,000 UNITS BASE/ML

N06819 001

EQ 50,000 UNITS BASE/ML

N06819 001

WARFARIN SODIUM

TABLET; ORAL

COUNADIN

DUPONT

DUPONT

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

+

GAS; INHALATION

XENON XE 133

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

DUPONT

N17884/004/

N17884/005/

N17884/006/

N17884/007/

N17884/008/

N17884/009/

N17884/010/

N17884/011/

N17884/012/

N17884/013/

N17884/014/

N17884/015/

N17884/016/

N17884/017/

N17884/018/

N17884/019/

N17884/020/

N17884/021/

N17884/022/

N17884/023/

N17884/024/

N17884/025/

N17884/026/

N17884/027/

N17884/028/

N17884/029/

N17884/030/

N17884/031/

N17884/032/

N17884/033/

N17884/034/

N17884/035/

N17884/036/

N17884/037/

N17884/038/

N17884/039/

N17884/040/

N17884/041/

N17884/042/

N17884/043/

N17884/044/

N17884/045/

N17884/046/

N17884/047/

N17884/048/

N17884/049/

N17884/050/

N17884/051/

N17884/052/

N17884/053/

N17884/054/

N17884/055/

N17884/056/

N17884/057/

N17884/058/

N17884/059/

N17884/060/

N17884/061/

N17884/062/

N17884/063/

N17884/064/

N17884/065/

ACETAMINOPHEN

SUPPOSITORY; RECTAL
NEOPAP
/ALCOA/
POLYMEDICA

/120MG/
120MG
/N16461/001/
N16401 001

CHLORPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
CHLOR-TRIMETON
/SCHERING/

/8MG/
12MG
8MG
/N07638/001/
N07638 002

ACETAMINOPHEN; DEBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE
SULFATE

TABLET, EXTENDED RELEASE; ORAL
DRIXORAL PLUS
/SCHERING/

/500MG;3MG;60MG/
500MG;3MG;60MG
/N19453/001/
/MAR/22/1987/
N19453 001
MAY 22, 1987

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
DEMIZIN
/SCHERING/

/4MG;25MG/
4MG;25MG
/N18556/001/
/MAR/14/1984/
N18556 001
MAY 14, 1984

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
/ALUMINUM/HYDROXIDE/AND/MAGNESIUM/TRISILICATE/
/PENNEX/

80MG;20MG
/N89449/001/
/NOV/27/1987/
N89449 001
NOV 27, 1987

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
/TSOLVOR/
/CIBA/

/8MG;120MG/
8MG;120MG
/N18747/001/
/MAR/06/1986/
N18747 001
MAR 06, 1986

BACITRACIN; POLYMYXIN B SULFATE

/AFROSOL:/TOPICAL/
/LANCETOTIC/
/CIBA/

/500 UNITS/GM;
5,000 UNITS/GM
500 UNITS/GM;
5,000 UNITS/GM
/N50598/001/
/SEP/22/1986/
N50598 001
SEP 22, 1986

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
CHLOR-TRIMETON
/SCHERING/
+ SCHERING PLOUGH

/8MG;120MG/
8MG;120MG
/N18397/001/
N18397 001

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
HIBISTAT
/STUART/
+ ZENECA

/0.5%/
0.5%
/N18300/001/
N18300 001

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

/SUSPENSION;/EXTENDED RELEASE;/ORAL/
/PENITUS/
/FISONS/

/EQ;4MG/MALEATE/5ML;
/EQ;10MG/BASE/5ML/
EQ 4MG MALEATE/5ML;
EQ 10MG BASE/5ML
/N18928/001/
/AUG/14/1985/
N18928 001
AUG 14, 1985

TINCTURE; TOPICAL
HIBITANE
/STUART/
+ ZENECA

/0.5%/
0.5%
/N18049/001/
N18049 001

TINCTURE; TOPICAL

HIBITANE
/S/STUARY/
3 ZENEC

/S.5%/
0.5%
N18049 001

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

/SUSPENSION; EXTENDED RELEASE; ORAL/

/COPOLYMER/
/ISONS/
/EQ/4MG MALEATE/5ML;
/EQ/37.5MG HCL/5ML/
/JAN/04; 1984/

EQ 4MG MALEATE/5ML;
EQ 37.5MG HCL/5ML

N18050 001
JAN 04, 1984

LOTION; TOPICAL
LOTIMIN AF
+ SCHERING

N18813 002
OCT 27, 1989
/N18813/002/
/OCT/27; 1989/
/OCT/27; 1989/

CLEMASTINE FUMARATE

TABLET; ORAL
CLEMASTINE FUMARATE
GENEVA

1.34MG

N73458 001
OCT 31, 1993

SOLUTION; TOPICAL
LOTIMIN AF
/SCHERING/
+ SCHERING PLOUGH

/N17613/002/
/OCT/27; 1989/
N17613 002
OCT 27, 1989

CLOTRIMAZOLE

CREAM; TOPICAL
CLOTRIMAZOLE
TARO

1%

N72640 002
AUG 31, 1993

LOTIMIN AF
/SCHERING/
+ SCHERING PLOUGH

1%

/N17613/002/
/OCT/27; 1989/
N17619 002
OCT 27, 1989

TABLET, EXTENDED RELEASE; ORAL
DISOPHROL
/SCHERING/
SCHERING PLOUGH

/N13483/004/
/SEP/13; 1982/
N13483 004
SEP 13, 1982

CREAM; VAGINAL
CLOTRIMAZOLE
NMC

1%

N74165 001
JUL 16, 1993

GYNE-LOTIMIN
/SCHERING/
+ SCHERING PLOUGH

1%

/N18052/002/
/NOV/30; 1990/
N18052 002
NOV 30, 1990

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

DIPHEN
PENNEX PHARMS

12.5MG/5ML

/PHARM/PASTIC/
DIPHENHYDRAMINE HCL
BARRE

12.5MG/5ML

N70118 001
OCT 01, 1985
/N70118/001/
/OCT/01; 1985/

/N70497/001/
APR 25, 1989
/N70497/001/
/APR/25; 1989/

12.5MG/5ML

N70497 001
APR 25, 1989
/N70497/001/
/APR/25; 1989/

IBUPROFEN

TABLET; ORAL
IBUPROFEN
/LILLY/

/200MG/

/N72901/001/
/DEC/19/1991/
/N72903/001/
/DEC/19/1991/

> ADD >
> ADD >

2MG

N73528 001
NOV 30, 1993
N73254 001
JUL 30, 1993

IBUPROFEN
NORTON HN

200MG

N71144 001

JAN 20, 1987

N72901 001

DEC 19, 1991

N72903 001

DEC 19, 1991

/IBUPROFEN/
/OHM/

/200MG/

/N71154/001/
/DEC/27/1987/

> ADD >
> ADD >
> ADD >

100MG

N73507 001
NOV 19, 1993

IBUPROFEN
ZENITH

200MG

N71154 001

OCT 27, 1987

IBUPROFEN
OHM

200MG

N71214 001

DEC 01, 1986

/NEUWIL/
/LILLY/

/200MG/

/N71144/001/
/JAN/20/1987/

> ADD >
> ADD >
> ADD >

0.025%

N18471/001/
/MAY/30/1986/
N18471 001
MAY 30, 1986

INSULIN SUSP PROTAMINE ZINC BEEF/PORK

/INJECTABLE; INJECTION/
/PROTAMINE; ZINC/ILETTIN/1 (BEEF-PORK)/
/LILLY/

/100 UNITS/ML/
/100 UNITS/ML/
/100 UNITS/ML/
/100 UNITS/ML/

3 LILLY
3

N17932 001
N17932 002

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
WATSON LABS

1MG/5ML

N73062 001
MAY 28, 1993

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL
LOPERAMIDE HCL
ABLE

2MG

NOVOPHARM

2MG

N73528 001
NOV 30, 1993
N73254 001
JUL 30, 1993

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MONISTAT 7 COMBINATION PACK
+ ADVANCED CARE
2%;100MG

N20288 002
APR 26, 1993

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE
ABLE

100MG

N73507 001
NOV 19, 1993

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OCUCLEAR
/SCHERING/

0.025%

N18471/001/
/MAY/30/1986/
N18471 001
MAY 30, 1986

SCHERING PLOUGH

0.025%

PSEUDOEPHEDRINE HYDROCHLORIDE

/CAPSULE; EXTENDED RELEASE; ORAL/
/SUDAFED/12 HOUR/
/BURROUGHS WELLCOME/ 120MG
3 BURROUGHS WELLCOME 120MG

N17941/001/
N17941 002

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

/CAPSULE; ORAL/
/ACTIFED/
/BURROUGHS WELLCOME/ 60MG; 2.5MG/

N19268/001/
/JAN/15/1985/

CAPSULE; EXTENDED RELEASE; ORAL
/ACTIFED/
/BURROUGHS WELLCOME/ 120MG; 5MG/

N18996/001/
/JUN/17/1985/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

/ACTIFED/

a BURROUGHS WELLCOME 120MG/5MG

N18996 001

JUN 17, 1985

/SYRUP; ORAL/

/ACTIFED/

/BURROUGHS WELLCOME/ 30MG/5ML; 1.25MG/5ML/

/N11935/003/

/NOV/26, 1982/

/TABLET/

/BARE/

/30MG/5ML; 1.25MG/5ML/

/N188115/001/

/MAR/04, 1983/

/TRIPROSED/

/HAL-SEY/

/30MG/5ML; 1.25MG/5ML/

/N188213/002/

/MAR/30, 1984/

/TABLET; ORAL/

/ACTIFED/

/BURROUGHS WELLCOME/ 60MG; 2.5MG/

/N11936/003/

/NOV/26, 1982/

/TABLET; ORAL/

/ACTIFED/

/BURROUGHS WELLCOME/ 60MG; 2.5MG/

/N185024/003/

/JAN/10, 1984/

/TRIPROSED/

/HAL-SEY/

/60MG; 2.5MG/

/N188112/001/

/JAN/20, 1983/

/TRIPROSED/

/HAL-SEY/

/60MG; 2.5MG/

/N188114/002/

/JAN/26, 1984/

/TRIPROLIDINE/HCL/ AND PSEUDOEPHEDRINE/HCL/

/CHELSEA/

/60MG; 2.5MG/

PSEUDOEPHEDRINE POLISTIREX

/SUSPENSION; EXTENDED RELEASE; ORAL/

/PSEUDO-12/

/FISONS/

/EQ/ 60MG HCL/5ML/

/N119401/001/

/JUN/19, 1987/

N19401 001

JUN 19, 1987

a FISONS

EQ 60MG HCL/5ML

PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

AFRINOL

/SCHERING/

/N18191/001/

PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

AFRINOL

+ SCHERING PLOUGH 120MG

N18191 001

TRIPROLIDINE HYDROCHLORIDE

/SYRUP; ORAL/

/ACTIFED/

/BURROUGHS WELLCOME/ 1.25MG/5ML/

/N11496/002/

/JUL/01, 1983/

N11496 002

JUL 01, 1983

a BURROUGHS WELLCOME 1.25MG/5ML

/TABLET; ORAL/

/ACTIFED/

/BURROUGHS WELLCOME/ 2.5MG/

/N11110/002/

/JUL/01, 1983/

N11110 002

JUL 01, 1983

a BURROUGHS WELLCOME 2.5MG

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 11 / NOV '93INDIUM¹¹¹ CHLORIDE

SOLUTION; INJECTION

INDICLOR

AMERSHAM

N/A

N19862
DEC 29, 1992

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January thru November 1993]

Chemical
Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD = Date Designated

MA = Marketing Approval

ESULFATED HEPARIN EROPIN	TREATMENT OF CYSTIC FIBROSIS.	KENNEDY & HOIDAL, MDs. 7702 PARHAM ROAD RICHMOND VA 23294 DD 09/17/93 MA / /
NOXSALEN INDEX	FOR USE IN CONJUNCTION WITH THE UVAR PHOTOPHERESIS TO TREAT DIFFUSE SYSTEMIC SCLEROSIS.	THERAKOS, INCORPORATED 201 BRANDYWINE PARKWAY WEST CHESTER PA 19380 DD 06/22/93 MA / /
PYRIDYLMETHYL]-9- GUANINE	TREATMENT OF CUTANEOUS T-CELL LYMPHOMA.	BIOCRYST PHARMACEUTICALS, INCORPORATED 2190 PARKWAY LAKE DRIVE BIRMINGHAM AL 35244 DD 10/05/93 MA / /
SALICYLATE SODIUM	TREATMENT OF CROHN'S DISEASE.	SYNCOM PHARMACEUTICALS, INC. 155 PASSAIC AVENUE FAIRFIELD NJ 07004 DD 04/06/93 MA / /
IDINE BBROMICINA	TREATMENT OF TUBERCULOSIS.	KANYOK, THOMAS P. PHARM.D. UNIVERSITY OF RHODE ISLAND PROVIDENCE RI 02908-4735 DD 05/14/93 MA / /
IDINE BBROMICINA	TREATMENT OF MYCOBACTERIUM AVIUM COMPLEX.	KANYOK, THOMAS P. PHARM.D. UNIVERSITY OF RHODE ISLAND PROVIDENCE RI 02908-4735 DD 11/15/93 MA / /
PRONE DIO-AQUEOUS	TREATMENT OF INCESSANT VENTRICULAR TACHYCARDIA.	ACADEMIC PHARMACEUTICALS, INC. 25720 SAUNDERS ROAD NORTH LAKE FOREST IL 60045 DD 08/17/93 MA / /
THYMOCYTE SERUM SHVILLE RABBIT THYMOCYTE SERUM	TREATMENT OF ALLOGRAFT REJECTION, INCLUDING SOLID ORGAN (KIDNEY, LIVER, HEART, LUNG, AND PANCREAS) AND BONE MARROW TRANSPLANTATION.	APPLIED MEDICAL RESEARCH 1600 HAYES STREET NASHVILLE TN 37203 DD 06/02/93 MA / /
PHINE HCL INJECTION	TREATMENT OF THE ON-OFF FLUCTUATIONS ASSOCIATED WITH LATE-STAGE PARKINSON'S DISEASE.	BRITANNIA PHARMACEUTICALS LTD FORUM HOUSE, BRIGHTON ROAD REDHILL, SURREY UK DD 04/22/93 MA / /
MIN ASYLOL	FOR PROPHYLACTIC USE TO REDUCE PERIOPERATIVE BLOOD LOSS AND THE HOMOLOGOUS BLOOD TRANSFUSION REQUIREMENT IN PATIENTS UNDERGOING REPEAT CARDIOPULMONARY BYPASS SURGERY IN THE COURSE OF REPEAT CORONARY ARTERY BYPASS GRAFT SURGERY, AND IN SELECTED CASES OF PRIMARY CORONARY ARTERY BYPASS GRAFT SURGERY WHERE THE RISK OF BLEEDING IS ESPECIALLY HIGH OR WHERE TRANSFUSION IS UNAVAILABLE OR UNACCEPTABLE.	MILES, INC. 400 MORGAN LANE WEST HAVEN CT 06516 DD 11/17/93 MA / /
DUONE ERON	TREATMENT AND SUPPRESSION OF TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
DUONE ERON	PRIMARY PROPHYLAXIS OF HIV-INFECTED PERSONS AT HIGH RISK FOR DEVELOPING TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
SIFIC ANTIBODY 520C9x22	IN VIVO SEROTHERAPY OF PATIENTS WITH OVARIAN CANCER.	MEDAREX 12 COMMERCE AVENUE WEST LEBANON NH 03784 DD 10/05/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD= Date Designated
MA= Marketing Approval

BLEOMYCIN SULFATE
TN= BLENOXANE

TREATMENT OF MALIGNANT PLEURAL EFFUSION.

BRISTOL-MYERS SQUIBB
PO BOX 4000
PRINCETON NJ 08543-4000
DD 09/17/93 MA / /

BOVINE WHEY PROTEIN CONCENTRATE
TN= IMMUNO-C

TREATMENT OF CRYPTOSPORIDIOSIS CAUSED BY THE PRESENCE
OF CRYPTOSPORIDIUM PARVUM IN THE GASTROINTESTINAL TRACT
OF PATIENTS WHO ARE IMMUNODEFICIENT/IMMUNOCOMPROMISED
OR IMMUNOCOMPETENT.

BIOMUNE SYSTEMS, INCORPORATED
40 EAST SOUTH TEMPLE SUITE 310
SALT LAKE CITY UT 84111
DD 09/30/93 MA / /

CLADRIBINE
TN= LEUSTATIN INJECTION

TREATMENT OF NON-HODGKIN'S LYMPHOMA.

R.W. JOHNSON RESEARCH INSTITUTE
ROUTE 202 SOUTH, P.O. BOX 300
RARITAN NJ 08869-0602
DD 04/19/93 MA / /

COLFOSCERIL PALMITATE, CETYL
ALCOHOL, TYLOXAPOL
TN= EXOSURF

TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.

BURROUGHS WELLCOME COMPANY
3030 CORNWALLIS ROAD
RESEARCH TRIANGLE PK NC 27709
DD 01/11/93 MA / /

CYSTIC FIBROSIS TRANSMEMBRANE
CONDUCTANCE REGULATOR GENE
TN=

TREATMENT OF CYSTIC FIBROSIS.

GENETIC THERAPY, INC.
19 FIRSTFIELD ROAD
GAITHERSBURG MD 20878
DD 01/08/93 MA / /

DEPOFOAM ENCAPSULATED CYTARABINE
TN=

TREATMENT OF NEOPLASTIC MENINGITIS.

DEPOTEC CORPORATION
11025 NORTH TORREY PINES ROAD
SUITE 100
LA JOLLA CA 92037
DD 06/02/93 MA / /

DISODIUM CLODRONATE
TN=

TREATMENT OF HYPERCALCEMIA OF MALIGNANCY.

DISCOVERY EXPERIMENTAL &
DEVELOPMENT, INC
29949 S.R. 54 WEST
WESLEY CHAPEL FL 33543
DD 06/16/93 MA / /

FACTOR XIII, RECOMBINANT
TN=

TREATMENT OF CONGENITAL FACTOR XIII DEFICIENCY.

ZYMOGENETICS, INC.
4225 ROOSEVELT WAY
SEATTLE WA 98105
DD 04/22/93 MA / /

HUMANIZED ANTI-TAC
TN=

PREVENTION OF ACUTE RENAL ALLOGRAFT REJECTION.

HOFFMANN-LA ROCHE, INC.
340 KINGSLAND STREET
NUTLEY NJ 07110
DD 03/05/93 MA / /

HUMANIZED ANTI-TAC
TN=

PREVENTION OF ACUTE GRAFT-VS-HOST DISEASE FOLLOWING
BONE MARROW TRANSPLANTATION.

HOFFMANN-LA ROCHE, INC.
340 KINGSLAND STREET
NUTLEY NJ 07110
DD 03/05/93 MA / /

IMMUNE GLOBULIN INTRAVENOUS
(HUMAN)
TN= GAMIMUNE N

INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS AFFECTED
WITH THE HUMAN IMMUNODEFICIENCY VIRUS.

MILES, INC.
4TH & PARKER STREETS
BERKELEY CA 94710
DD 02/18/93 MA / /

IMMUNE GLOBULIN INTRAVENOUS
(HUMAN)
TN= IMMUNE GLOBULIN INTRAVENOUS
(HUMAN) IMMUNO, IVEEGAM

TREATMENT OF PATIENTS WITH ACUTE MYOCARDITIS.

IMMUNO CLINICAL RESEARCH
CORPORATION
750 LEXINGTON AVENUE
NEW YORK NY 10022
DD 11/22/93 MA / /

INTERFERON BETA (RECOMBINANT
HUMAN)
TN=

TREATMENT OF PRIMARY BRAIN TUMORS.

BIODIN, INC.
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02142
DD 01/13/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated

MA=Marketing Approval

Chemical
Trade NameLEUKIN-3, HUMAN,
PREPARATION

FOR SEQUENTIAL ADMINISTRATION WITH SARGRAMOSTIM TO ACCELERATE NEUTROPHIL AND PLATELET RECOVERY IN PATIENTS UNDERGOING AUTOLOGOUS BONE MARROW TRANSPLANTATION FOR THE TREATMENT OF HODGKIN'S DISEASE OR NON-HODGKIN'S LYMPHOMA.

SANDOZ PHARMACEUTICALS CORP.
59 ROUTE 10
EAST HANOVER NJ 07936-1080
DD 09/30/93 MA / /

ARNITINE
ARNITOR

TREATMENT OF PEDIATRIC CARDIOMYOPATHY.

SIGMA-TAU PHARMACEUTICALS, INC.
200 ORCHARD RIDGE DRIVE, SUITE 300
GAITHERSBURG MD 20878
DD 11/22/93 MA / /

DAL DAUNORUBICIN
DAUNOXOME

TREATMENT OF PATIENTS WITH ADVANCED HIV-ASSOCIATED KAPOSI'S SARCOMA.

VESTAR, INC.
650 CLIFFSIDE DRIVE
SAN DIMAS CA 91773
DD 05/14/93 MA / /

MIN

TREATMENT OF CIRCADIAN RHYTHM SLEEP DISORDERS IN BLIND PEOPLE WITH NO LIGHT PERCEPTION.

SACK, ROBERT, M.D.
3181 S.W. SAM JACKSON PARK ROAD
PORTLAND OR 97201-3098
DD 11/15/93 MA / /

REXATE
RHEUMATREX

TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.

LEDERLE LABORATORIES
401 N. MIDDLETOWN ROAD
PEARL RIVER NY 10965-1299
DD 08/23/93 MA / /

NIL

TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.

CEPHALON, INC.
145 BRANDYWINE PARKWAY
WEST CHESTER PA 19380-4245
DD 03/15/93 MA / /

ONAL ANTIBODY FOR
TATION AGAINST LUPUS
ITIS

TREATMENT OF LUPUS NEPHRITIS.

MEDCLONE, INC.
2435 MILITARY AVENUE
LOS ANGELES CA 90064
DD 01/07/93 MA / /

URIN
LORIN

TREATMENT OF CONGENITAL PRIMARY ICHTHYOSIS.

CELLEGY PHARMACEUTICALS, INC.
371 BEL MARIN KEYS, SUITE 210
NOVATO CA 94949
DD 04/29/93 MA / /

CIN-C

TREATMENT OF REFRACTORY GLAUCOMA AS AN ADJUNCT TO AB EXTERNO GLAUCOMA SURGERY.

IOP INCORPORATED
3100 AIRWAY AVENUE
COSTA MESA CA 92626
DD 08/20/93 MA / /

OXIDE

TREATMENT OF PERSISTENT PULMONARY HYPERTENSION IN THE NEWBORN.

ANAQUEST, INCORPORATED
110 ALLEN ROAD
LIBERTY CORNER NJ 07938
DD 06/22/93 MA / /

GUINE PHOSPHATE

FOR USE IN COMBINATION WITH CLINDAMYCIN HYDROCHLORIDE IN THE TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA ASSOCIATED WITH ACQUIRED IMMUNODEFICIENCY SYNDROME.

STERLING WINTHROP INC.
90 PARK AVENUE
NEW YORK NY 10016
DD 07/23/93 MA / /

GLANDIN E1
CYCLODEXTRIN
SOPROST

TREATMENT OF SEVERE PERIPHERAL ARTERIAL OCCLUSIVE DISEASE (CRITICAL LIMB ISCHEMIA) IN PATIENTS WHERE OTHER PROCEDURES, GRAFTS OR ANGIOPLASTY, ARE NOT INDICATED.

SCHWARZ PHARMA
5600 WEST COUNTY LINE ROAD
MEQUON WI 53092
DD 10/20/93 MA / /

N C CONCENTRATE
PROTEIN C CONCENTRATE
VAPOR HEATED, IMMUNO

FOR USE IN THE PREVENTION AND TREATMENT OF PURPURA FULMINANS IN MENINGOCOCCEMIA.

IMMUNO CLINICAL RESEARCH CORP.
750 LEXINGTON AVENUE, 19TH FLOOR
NEW YORK NY 10022
DD 04/22/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical

TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated

MA=Marketing Approval

PROTIRELIN
TN=

PREVENTION OF INFANT RESPIRATORY DISTRESS SYNDROME
ASSOCIATED WITH PREMATURITY.

UCB PHARMACEUTICALS, INC.
5505-A ROBIN HOOD ROAD
NORFOLK VA 23513
DD 08/24/93 MA / /

PULMONARY SURFACTANT REPLACEMENT,
PORCINE
TN= CUROSURF

FOR THE TREATMENT AND PREVENTION OF RESPIRATORY
DISTRESS SYNDROME IN PREMATURE INFANTS.

CHIESI PHARMACEUTICALS, INC.
150 DANBURY ROAD
RIDGEFIELD CT 06877
DD 08/02/93 MA / /

RECOMBINANT RETROVIRAL VECTOR -
GLUCOCEREBROSIDASE
TN=

FOR USE AS ENZYME REPLACEMENT THERAPY FOR PATIENTS WITH
TYPES I, II, OR III GAUCHER DISEASE.

GENETIC THERAPY, INC.
19 FIRSTFIELD ROAD
GAITHERSBURG MD 20878
DD 11/15/93 MA / /

RHO(D) IMMUNE GLOBULIN (HUMAN)
TN= WINRHO SD

TREATMENT OF IMMUNE THROMBOCYTOPENIC PURPURA.

RH PHARMACEUTICALS, INC.
104 CHANCELLOR MATHESON ROAD
WINNIPEG, MANITOBA
DD 11/09/93 MA / /

RII RETINAMIDE
TN=

TREATMENT OF MYELODYSPLASTIC SYNDROMES.

SPARTA PHARMACEUTICALS,
INCORPORATED
PO BOX 13288
RESEARCH TRIANGLE PK NC 27709
DD 05/06/93 MA / /

RILUZOLE
TN=

TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.

RHONE-POULENC RORER PHARM.
500 ARCOLA ROAD, PO BOX 1200
COLLEGEVILLE PA 19426-0107
DD 03/16/93 MA / /

ROQUINIMEX
TN= LINOMIDE

TO PROLONG TIME TO RELAPSE IN LEUKEMIA PATIENTS WHO
HAVE UNDERGONE AUTOLOGOUS BONE MARROW TRANSPLANTATION.

KABI PHARMACIA, INC.
800 CENTENNIAL AVENUE
PISCATAWAY NJ 08855-1327
DD 07/01/93 MA / /

SECALCIFEROL
TN= OSTEO-D

TREATMENT OF FAMILIAL HYPOPHOSPHATEMIC RICKETS.

LEMMON COMPANY
650 CATHILL ROAD
SELLERSVILLE PA 18960
DD 07/26/93 MA / /

SODIUM BENZOATE/SODIUM
PHENYLACETATE
TN=

TREATMENT OF UREA CYCLE DISORDERS: CARBAMYLPHOSPHATE
SYNTHETASE DEFICIENCY, ORNITHINE TRANSCARBAMYLASE
DEFICIENCY, AND ARGININOSUCCINIC ACID SYNTHETASE
DEFICIENCY.

BRUSILOW, SAUL W. M.D.
JOHNS HOPKINS MEDICAL
INSTITUTIONS
BALTIMORE MD 21205
DD 11/22/93 MA / /

SODIUM PHENYLBUTYRATE
TN=

TREATMENT OF UREA CYCLE DISORDERS: CARBAMYLPHOSPHATE
SYNTHETASE DEFICIENCY, ORNITHINE TRANSCARBAMYLASE
DEFICIENCY, AND ARGININOSUCCINIC ACID SYNTHETASE
DEFICIENCY.

BRUSILOW, SAUL W. M.D.
JOHNS HOPKINS MEDICAL
INSTITUTIONS
BALTIMORE MD 21205
DD 11/22/93 MA / /

SOMATROPIN
TN= BIOTROPIN

TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS.

BIO-TECHNOLOGY GENERAL
CORPORATION
1250 BROADWAY, 20th FLOOR
NEW YORK NY 10001
DD 02/12/93 MA / /

SUCRALFATE
TN=

TREATMENT OF ORAL MUCOSITIS AND STOMATITIS FOLLOWING
RADIATION THERAPY FOR HEAD AND NECK CANCER.

FUISZ TECHNOLOGIES, LTD.
3810 CONCORDE PARKWAY, SUITE
CHANTILLY VA 22021
DD 07/15/93 MA / /

THALIDOMIDE
TN=

TREATMENT OF THE CLINICAL MANIFESTATIONS OF
MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM
TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA.

CELGENE CORPORATION
7 POWDER HORN DRIVE
WARREN NJ 07059
DD 01/12/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD - Date Designated

MA - Marketing Approval

Chemical
Trade NameMIFENE
ESTRINEX

TREATMENT OF DESMOID TUMORS.

ADRIA LABORATORIES
P.O. BOX 16529
COLUMBUS OH 43216-6529
DD 08/17/93 MA / /RETINOIN
RETINOIN LF, IV

TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.

ARGUS PHARMACEUTICALS, INC.
3400 RESEARCH FOREST DRIVE
THE WOODLANDS TX 77381
DD 01/14/93 MA / /NECROSIS FACTOR-BINDING
EIN 1TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED
IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH
CD4 COUNTS LESS THAN 200 CELLS PER MM3.SERONO LABORATORIES, INC.
100 LONGWATER CIRCLE
NORWELL MA 02061
DD 01/06/93 MA / /NECROSIS FACTOR-BINDING
EIN IITREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED
IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH
CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM3.SERONO LABORATORIES, INC.
100 LONGWATER CIRCLE
NORWELL MA 02061
DD 01/06/93 MA / /CTIVE INTESTINAL
EPTIDE

TREATMENT OF ACUTE ESOPHAGEAL FOOD IMPACTION.

RESEARCH TRIANGLE
PHARMACEUTICALS
200 WESTPARK CORPORATE CENTER
DURHAM NC 27713
DD 06/23/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical

TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD= Date Designated

MA= Marketing Approval

NOVEMBER 1993 ADDI

Orphan Drug Approvals

ANTIHEMOPHILIC FACTOR (RECOMBINANT) TN= KOGENATE	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94701 DD 09/25/89 MA 02/25/93
CLADRIBINE TN= LEUSTATIN INJECTION	TREATMENT OF HAIRY CELL LEUKEMIA.	R.W. JOHNSON RESEARCH INSTITUTE ROUTE 202, PO BOX 300 RARITAN NJ 08869-0602 DD 11/15/90 MA 02/26/93
FELBAMATE TN= FELBATOL	TREATMENT OF LENNOX-GASTAUT SYNDROME.	WALLACE LABORATORIES 301B COLLEGE ROAD EAST PRINCETON NJ 08540 DD 01/24/89 MA 07/29/93
INTERFERON BETA, RECOMBINANT HUMAN TN=BETASERON	TREATMENT OF MULTIPLE SCLEROSIS.	CHIRON CORPORATION 4560 HORTON STREET EMERYVILLE CA 94608 DD 11/17/88 MA 07/23/93
LEUPROLIDE ACETATE TN= LUPRON INJECTION	TREATMENT OF CENTRAL PRECOCIOUS PUBERTY.	TAP PHARMACEUTICALS, INC. 2355 WAUKEGAN ROAD DEERFIELD IL 60015 DD 07/25/88 MA 04/16/93
LEVOMETHADYL ACETATE HYDROCHLORIDE TN=ORLAAM	TREATMENT OF HEROIN ADDICTS SUITABLE FOR MAINTENANCE ON OPIATE AGONISTS.	BIODEVELOPMENT CORPORATION 1300 NORTH 17TH STREET, SUITE 300 ARLINGTON VA 22209-2306 DD 01/24/84 MA 07/09/93
LODOXAMIDE TROMETHAMINE TN= ALOMIDE OPHTHALMIC SOLUTION	TREATMENT OF VERNAL KERATOCONJUNCTIVITIS.	ALCON LABORATORIES, INC. 6201 SOUTH FREEWAY FORT WORTH TX 76134 DD 10/16/91 MA 09/23/93
MEGESTROL ACETATE TN= MEGACE	TREATMENT OF PATIENTS WITH ANOREXIA, CACHEXIA, OR SIGNIFICANT WEIGHT LOSS ($\geq$ 10% OF BASELINE BODY WEIGHT) AND CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BRISTOL-MYERS SQUIBB 2400 WEST LLOYD EXPRESSWAY EVANSVILLE IN 47721-0001 DD 04/13/88 MA 09/10/93

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

NOVEMBER 1993 ADDITIONS

TUTE

ITE

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISION
-------------------------	------	----------

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTS. 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, 13TH EDITION FOR A FULL LIST OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

BUMETANIDE (TABLET)	APR 23, 1993
BUSIPRONE HYDROCHLORIDE (TABLET)	AUG 13, 1993
CEFACLOR (CAPSULE AND SUSPENSION)	APR 23, 1993
CAPTOPRIL (TABLET)	MAY 13, 1993
CHOLESTYRYRAMINE (POWDER)	JUL 15, 1993
GLIPIZIDE (TABLET)	APR 23, 1993
GLYBURIDE (TABLET)	APR 23, 1993
GUANABENZ ACETATE (TABLET)	APR 23, 1993
INDAPAMIDE (TABLET)	APR 23, 1993
KETOPROFEN (CAPSULE)	APR 23, 1993
ORAL EXTENDED (CONTROLLED RELEASE)	SEP 09, 1993
PINDOLOL (TABLET)	APR 23, 1993
RANITIDINE HYDROCHLORIDE (TABLET)	APR 23, 1993
TRIAZOLAM (TABLET)	DEC 24, 1992

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

REVISED DATE	DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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, 4-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857. FOR 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.						
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 2.5MG	92 P-0282/ CP3	MIKART	NEW COMBINATION	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 5MG	92 P-0282/ CP1	MIKART	NEW COMBINATION	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 7.5MG	92 P-0282/ CP2	MIKART	NEW COMBINATION NEW STRENGTH	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 10MG	92 P-0282/ CP4	MIKART	NEW COMBINATION	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 2.5MG	92 P-0282/ CP3	MIKART	NEW COMBINATION NEW DOSAGE FORM	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 5MG	92 P-0282/ CP1	MIKART	NEW COMBINATION NEW DOSAGE FORM	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 7.5MG	92 P-0282/ CP2	MIKART	NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH	APPROVED NOV 10, 1993
	ETAMINOPHEN; IRIN; DOCODONE BITARTRATE SULE; ORAL	150MG 180MG 10MG	92 P-0282/ CP4	MIKART	NEW COMBINATION NEW DOSAGE FORM	APPROVED NOV 10, 1993
	ETAMINOPHEN; EINE PHOSPHATE SULE; ORAL	500MG 45MG	93 P-0314/ CP1	MIKART	NEW DOSAGE FORM NEW STRENGTH	APPROVED NOV 10, 1993
	ETAMINOPHEN; EINE PHOSPHATE SULE; ORAL	500MG 45MG	93 P-0314/ CP1	MIKART	NEW STRENGTH	APPROVED NOV 10, 1993
	ECLOVIR SODIUM ECTABLE; INJECTION	EQ 50MG BASE/ML (10ML/VIAL) (20ML/VIAL)	92 P-0468/ CP1	BULL	NEW DOSAGE FORM	APPROVED SEP 01, 1993

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
AMINOSALICYLIC ACID GRANULES, ENTERIC-COATED; ORAL	4GM/PACKET	92 P-0356/ CP1	JACOBUS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 03, 1993
CARBOPLATIN INJECTABLE; INJECTION	10MG/ML (5ML/VIAL) (15ML/VIAL) (45ML/VIAL)	92 P-0467/ CP1	BULL	NEW DOSAGE FORM	APPROVED MAY 20, 1993
CHLORPROMAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0284/ CP1	UDL	NEW STRENGTH	APPROVED JAN 07, 1993
DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION	EQ 12.5MG BASE/ML (40ML/VIAL)	92 P-0365/ CP1	LYPHOMED	NEW STRENGTH	APPROVED FEB 11, 1993
CISPLATIN INJECTABLE; INJECTION	1MG/ML (200ML/VIAL)	93 P-0084/ CP1	FUJISAWA	NEW STRENGTH	APPROVED NOV 10, 1993
DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION	EQ 12.5MG BASE/ML (100ML/CONTAINER)	92 P-0045/ CP1	MARSAM	NEW STRENGTH	APPROVED SEP 01, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (12.5MG/VIAL)	92 P-0355/ CP1	LEDERLE	NEW STRENGTH	APPROVED JAN 07, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/CONTAINER)	91 P-0460/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 11, 1993
LACTULOSE CRYSTAL; ORAL	10GM/PACKET	92 P-0370/ CP1	BENNETT AND COMPANY	NEW DOSAGE FORM	APPROVED JAN 07, 1993
METHYLPHENIDATE HYDROCHLORIDE; TABLET, EXTENDED RELEASE; ORAL	10MG	92 P-0400/ CP1	MD PHARM	NEW STRENGTH	APPROVED MAR 22, 1993
PREDNISOLONE SYRUP; ORAL	10MG/5ML	92 P-0439/ CP1	WE PHARMS	NEW STRENGTH	APPROVED MAY 20, 1993
PREDNISONE TABLET, CHEWABLE; ORAL	5MG 10MG	92 P-0336/ CP1	WE PHARMS	NEW DOSAGE FORM	APPROVED NOV 10, 1993
PROPRANOLOL HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	10MG 20MG 60MG 80MG 90MG	93 P-0049/ CP1	FLEMINGTON PHARM	NEW DOSAGE FORM NEW STRENGTH	APPROVED SEP 01, 1993
TRIMETHOPRIM SOLUTION; ORAL	25MG/5ML	92 P-0500/ CP1	ASCENT PHARMS	NEW DOSAGE FORM	APPROVED MAY 20, 1993

NAME
DOSAGE FORM; ROUTE

AMITON
TOPICAL

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

STATUS	NAME SE FORM: ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
APPROVED MAR 03, 1993	AMITON TOPICAL	10%	92 P-0249/ CP1	HAMER	NEW DOSAGE FORM	DENIED NOV 10, 1993
APPROVED MAY 20, 1993						
APPROVED JAN 07, 1993						
APPROVED FEB 11, 1993						
APPROVED NOV 10, 1993						
APPROVED SEP 01, 1993						
APPROVED JAN 07, 1993						
APPROVED FEB 11, 1993						
APPROVED JAN 07, 1993						
APPROVED MAR 22, 1993						
APPROVED MAY 20, 1993						
APPROVED NOV 10, 1993						
APPROVED SEP 01, 1993						
APPROVED MAY 20, 1993						

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER TO APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH 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 SUPPLEMENT.

REFERENCES

NEW DOSING SCHEDULE

D-20 SINGLE 32MG DOSE

REFERENCES

NEW INDICATION

I-87 RENAL IMAGING AGENT FOR USE IN CHILDREN
I-88 MANAGEMENT OF ENDOMETRIOSIS
I-89 EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE
I-90 INTENSIVE CARE UNIT SEDATION
I-91 MONOTHERAPY USE FOR HYPERTENSION
I-92 ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE
I-93 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS
I-94 USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITATE VISUALIZATION OF LESIONS IN THE BODY
THE HEART]
I-95 TREATMENT OF LEFT VENTRICULAR DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION
I-96 TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA
I-97 ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINATION OF THE GASTROINTESTINAL TRACT
I-98 TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE ASSOCIATED WITH CHRONIC RENAL INSUFFICIENCY

REFERENCES

PATENT USE CODE

U-74 METHOD OF PROVIDING HYPNOTIC EFFECT
U-75 RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
U-76 USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM
U-77 TREATMENT OF SYMPTOMS OF SEASONAL ALLERGIC RHINITIS
U-78 ULCERATIVE COLITIS
U-79 SYMPTOMATIC TREATMENT OF PATIENTS WITH NOCTURNAL HEARTBURN DUE TO GERD
U-80 METHOD OF TREATING OCULAR BACTERIAL INFECTIONS
U-81 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS
U-82 TREATMENT FOR DEMENTIA IN PATIENTS WITH ALZHEIMER'S DISEASE
U-83 TREATMENT OF SEIZURES
U-84 A METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS

EXCLUS
 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
18473 001	ALBUTEROL; VENTOLIN	4851229	JUN 14, 2005		1-93	JUL 20, 1996
19489 001	ALBUTEROL SULFATE; VENTOLIN ROTACAPS	4777049	OCT 11, 2005		1-93	JUL 20, 1996
19604 001	ALBUTEROL SULFATE; VOLMAX	4751071	JUN 14, 2005			
19604 002	ALBUTEROL SULFATE; VOLMAX	4851229	JUN 14, 2005			
		4777049	OCT 11, 2005			
		4751071	JUN 14, 2005		NS	DEC 23, 1995
18276 004	ALPRAZOLAM; XANAX	5061494	OCT 29, 2008			
20258 001	APRACLOININE HYDROCHLORIDE; IOPIDINE	4517199	MAY 14, 2002	U-15	NS	JUL 30, 1996
19402 001	ASTEMIZOLE; HISMANAL	4219559	AUG 26, 1999		NCE	DEC 29, 1993
20045 001	AVOBENZONE; SHADE UVAGUARD	4522807	JUN 11, 2002		NC	DEC 07, 1995
		4387089	JUN 07, 2002			
19807 001	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
19807 002	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
20186 001	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
20186 002	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NC	FEB 26, 1996
20186 003	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
		4258062	MAR 24, 1998	U-63	NC	FEB 26, 1996
18343 001	CAPTAPRIL; CAPOTEN	4105776	AUG 08, 1995		1-95	SEP 23, 1996
18343 002	CAPTAPRIL; CAPOTEN	4105776	AUG 08, 1995		1-95	SEP 23, 1996
18343 003	CAPTAPRIL; CAPOTEN	4105776	AUG 08, 1995		1-95	SEP 23, 1996
18343 005	CAPTAPRIL; CAPOTEN	4105776	AUG 08, 1995		1-95	SEP 23, 1996
20210 001	CISAPRIDE MONOHYDRATE; PROPULSID	4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998
20210 002	CISAPRIDE MONOHYDRATE; PROPULSID	4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998
20229 001	CLADRIIBINE; LEUSTATIN				NCE	FEB 26, 1998
19287 001	DIAZEPAM; DIAZAC	RE32393	SEP 18, 1996		ODE	FEB 26, 2000
18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008		NDF	JUN 18, 1996
18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
19680 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	5212326	JAN 29, 2008			
19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	5212326	JAN 29, 2008			

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
18651 001	DRONABINOL; MARINOL				CODE	DEC 22, 1999
18651 002	DRONABINOL; MARINOL				CODE	DEC 22, 1999
18651 003	DRONABINOL; MARINOL				CODE	DEC 22, 1999
19879 002	EFLORNITHINE HYDROCHLORIDE; ORNIDYL	4399151	AUG 16, 2000		NCE	NOV 28, 1995
19616 004	ENOXACIN; PENETREX	4359578	NOV 16, 2001		NCE	DEC 31, 1996
19616 005	ENOXACIN; PENETREX	4359578	NOV 16, 2001		NCE	DEC 31, 1996
20164 001	ENOXAPARIN SODIUM; LOVENOX				NCE	MAR 29, 1998
20189 001	FELBAMATE; FELBATOL	5082861	JAN 21, 2009	U-83	CODE	JUL 29, 2000
		4978680	DEC 18, 2007	U-83	NCE	JUL 29, 1998
20189 002	FELBAMATE; FELBATOL	5082861	JAN 21, 2009	U-83	CODE	JUL 29, 2000
20189 003	FELBAMATE; FELBATOL	4978680	DEC 18, 2007	U-83	NCE	JUL 29, 1998
		5082861	JAN 21, 2009	U-83	CODE	JUL 29, 2000
		4978680	DEC 18, 2007	U-83	NCE	JUL 29, 1998
20073 001	FLUMAZENIL; MAZICON	4316839	MAR 03, 2003		NCE	DEC 20, 1996
>ADD>	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003	U-84		
>ADD>	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003	U-84		
		4314081	FEB 02, 2001			
		4194009	APR 19, 1994			
		4018895	APR 19, 1994	U-12		
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003	U-84		
20068 001	FOSCARNET SODIUM; FOSCAVIR	4215113	JUN 06, 2000	U-64	NCE	SEP 27, 1996
20123 001	GADODIAMIDE; OMNISCAN	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
19596 001	GADOPENTETATE DIMETHYLAMINE; MAGNEVIST	4957939	MAR 03, 2004		1-94	AUG 17, 1996
17783 003	GLIPIZIDE; GLUCOTROL				NCE	MAY 08, 1994
20051 003	GLYBURIDE; GLYNASE	4916163	APR 10, 2007		NP	MAR 04, 1995
		4735805	APR 05, 2005		NCE	MAR 01, 1994
20051 004	GLYBURIDE; GLYNASE	4916163	APR 10, 2007		NP	MAR 04, 1995
		4735805	APR 05, 2005		NCE	MAR 01, 1994
19726 001	GOSERELIN ACETATE; ZOLADEX	4735805	APR 10, 2007		NCE	MAY 01, 1994
19032 001	GUANFACINE HYDROCHLORIDE; TENEX				1-88	FEB 02, 1996
19032 002	GUANFACINE HYDROCHLORIDE; TENEX				1-91	MAY 11, 1996
19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5				1-91	MAY 11, 1996
19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NS	NOV 18, 1996
					NCE	JAN 11, 1994
19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NDF	DEC 07, 1995
					NCE	JAN 11, 1994
					NDF	DEC 07, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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
18538 002	INDAPAMIDE; LOZOL				NS	APR 29, 1996
18956 001	IOHEXOL; OMNIPAQUE 180	4250113	DEC 26, 1999		NCE	JUL 06, 1993
19710 005	IOVERSOL; OPTIRAY 350	4021481	MAY 03, 1994		I-97	JUL 13, 1996
20228 001	IPRATROPIUM BROMIDE; ATROVENT				NR	JUL 13, 1996
20215 001	ISOSORBIDE MONONITRATE; MONOKET				I-48	JUL 27, 1996
20215 002	ISOSORBIDE MONONITRATE; MONOKET				NDF	SEP 29, 1996
20225 001	ISOSORBIDE MONONITRATE; IMDUR				NCE	DEC 30, 1996
20225 002	ISOSORBIDE MONONITRATE; IMDUR				NCE	DEC 30, 1996
19084 001	KETOCOMAZOLE; NIZORAL				NS	JUN 30, 1996
19700 001	KETOROLAC TROMETHAMINE; ACULAR				NCE	DEC 30, 1996
20263 001	LEUPROLIDE ACETATE; LUPRON	4355125	JUN 15, 1999		NCE	DEC 30, 1996
		5110493	MAY 05, 2009	U-75	NDF	AUG 12, 1996
		4454151	JUN 12, 2001	U-75	NDF	AUG 12, 1996
		4089969	MAY 16, 1997	U-75	NDF	AUG 12, 1996
		4917893	MAR 24, 2004		I-30	JAN 27, 1996
		4849228	JUL 18, 2006		NCE	NOV 30, 1994
		4728721	MAR 01, 2005		NDF	NOV 09, 1995
		4677191	JUN 30, 2004		NP	APR 16, 1996
		4652441	MAR 24, 2004			
		4005063	JAN 25, 1996		ODE	APR 16, 2000
		4917893	MAR 24, 2004		NP	APR 16, 1996
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
20263 002	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4005063	JAN 25, 1996		ODE	APR 16, 2000

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
20263 003	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893 4849228 4728721 4677191 4652441 4005063	MAR 24, 2004 JUL 18, 2006 MAR 01, 2005 JUN 30, 2004 MAR 24, 2004 JAN 25, 1996		NP	APR 16, 1996
20263 004	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893 4849228 4728721 4677191 4652441 4005063	MAR 24, 2004 JUL 18, 2006 MAR 01, 2005 JUN 30, 2004 MAR 24, 2004 JAN 25, 1996		ODE NP	APR 16, 2000 APR 16, 1996
18948 001	LEVOCARNITINE; CARNITOR				ODE I-86 ODE I-86	APR 16, 2000 DEC 16, 1995 DEC 16, 1999 DEC 16, 1995
18948 002	LEVOCARNITINE; CARNITOR				ODE NCE	DEC 16, 1999 JUL 09, 1998
20315 001	LEVOMETHADYL ACETATE HYDROCHLORIDE; ORLAAM				ODE I-92 I-92 I-92 I-92 I-92 I-92 I-92 I-92 NCE ODE	JUL 09, 2000 JUN 09, 1996 JUN 09, 1996 JUN 09, 1996 JUN 09, 1996 JUN 09, 1996 JUN 09, 1996 JUN 09, 1996 JUN 09, 1996 JUL 09, 1998 JUL 09, 2000
19558 001	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19558 002	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19558 003	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19558 004	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19777 001	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19777 002	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19777 003	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19777 004	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
19777 005	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		I-92	JUN 09, 1996
20191 001	LODOXAMIDE TROMETHAMINE; ALOMIDE	4374829	DEC 30, 2001		NCE ODE	SEP 23, 1998 SEP 23, 2000
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	MAY 05, 2005	U-36	NCE	SEP 23, 2000
19558 001	LORATADINE; CLARITIN	4282233	AUG 04, 1998	U-77	NCE	FEB 21, 1997
20264 001	MEGESTROL ACETATE; MEGACE				NCE	APR 12, 1998
20049 001	MESALAMINE; PENTASA	4980173	DEC 25, 2007	U-78	ODE	SEP 10, 2000
20098 001	MIVACURIUM CHLORIDE; MIVACRON	4496553	JAN 29, 2002	U-78	NP	MAY 10, 1996
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418 4761418	JAN 22, 2006 JAN 22, 2006		NCE NCE	JAN 22, 1997 JAN 22, 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
1583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2002		NCE	DEC 24, 1996
1583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2002		NCE	DEC 24, 1996
20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
19356 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
20150 001	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
20150 002	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
20150 003	NICOTINE; NICOTROL	4915950	APR 10, 2007		NP	APR 22, 1995
20666 001	NICOTINE POLACRILEX; NICORETTE DS	4892741	JAN 09, 2007		NCE	JAN 13, 1994
20198 001	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
20198 002	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
20198 003	NIFEDIPINE; ADALAT CC	4551456	NOV 05, 2002			
19921 001	OFLOXACIN; OCUFLOX	4382892	MAY 10, 2000	U-80	NDF	JUL 30, 1996
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 03, 2005			
20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 03, 2005			
20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	JAN 03, 2005			
20036 001	PAMIDRONATE DISODIUM; AREDIA	3962432	JUL 16, 1996	U-53		
20036 003	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			
20036 004	PAMIDRONATE DISODIUM; AREDIA	3962432	JUL 16, 1996	U-53	NCE	OCT 31, 1996
20091 001	PERFLUBRON; IMAGENT	4711880	DEC 08, 2004			
20014 001	PIRBUTEROL ACETATE; MAXAIR	3962432	JUL 16, 1996	U-53	NCE	OCT 31, 1996
19795 001	PODOFLOX; CONDYLOX	4664107	MAY 12, 2004		NCE	AUG 13, 1998
19898 004	PRAVASTATIN SODIUM; PRAVACHOL				NCE	DEC 13, 1995
19568 001	PREDNICARBATE; DERMATOP	4346227	AUG 24, 1999		NCE	OCT 31, 1996
20279 001	PREDNICARBATE; DERMATOP	4242334	DEC 30, 1999	U-50	NE	SEP 23, 1994
19627 001	PROPOFOL; DIPRIVAN	4242334	DEC 30, 1999	U-50	NE	SEP 23, 1994
19664 001	PSEUDOEPHEDRINE HYDROCHLORIDE; SELDANE-D	4996061	FEB 26, 2008		I-90	MAR 08, 1996
		4929605	MAY 29, 2007	U-81		
		4254129	MAR 03, 1998	U-81		
19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005		I-92	OCT 29, 1996
19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005		I-92	OCT 29, 1996
19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005		I-92	OCT 29, 1996
19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005		I-92	OCT 29, 1996
50689 001	RIFABUTIN; MYCOBUTIN	4743450	MAY 10, 2005		ODE	DEC 23, 1999

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
19649 001	RIMANTADINE HYDROCHLORIDE; FLUMADINE				NCE	SEP 17, 1998
19650 001	RIMANTADINE HYDROCHLORIDE; FLUMADINE				NCE	SEP 17, 1998
19839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
19839 002	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
19839 003	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
19839 004	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005		NCE	DEC 30, 1996
19766 001	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
20168 001	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				I-98	NOV 17, 1996
20168 002	SOMATROPIN, BIOSYNTHETIC; NUTROPIN				I-98	NOV 17, 1996
20134 001	STRONTIUM CHLORIDE, SR-89; METASTRON				NCE	JUN 18, 1998
19050 001	SUFENTANIL CITRATE; SUFENTA				NR	MAR 19, 1996
					I-89	MAR 19, 1996
20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4816470	MAR 28, 2006	U-72		
20070 001	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
20070 002	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
20070 003	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
20070 004	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3				I-87	NOV 27, 1995
20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
18163 003	TEMAZEPAM; RESTORIL	5211954	MAY 18, 2010			
19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5030632	JUL 09, 2008	U-70	NS	OCT 25, 1994
>ADD>						
19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-3	I-96	SEP 29, 1996
>ADD>						
19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-3	I-96	SEP 29, 1996
>ADD>						
19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-3	I-96	SEP 29, 1996
>ADD>						
20223 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-3	I-96	SEP 29, 1996
		4112097	SEP 05, 1995			
		4026894	MAY 31, 1994			
20223 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000		I-96	SEP 29, 1996
		4112097	SEP 05, 1995			
		4026894	MAY 31, 1994			

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
20223 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000			
		4112097	SEP 05, 1995			
		4026894	MAY 31, 1994		1-96	SEP 29, 1996
20223 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000			
		4112097	SEP 05, 1995			
		4026894	MAY 31, 1994		1-96	SEP 29, 1996
		4254129	MAR 03, 1998	U-81		
18949 001	TERFENADINE; SELDANE					
19762 001	TESTOSTERONE; TESTODERM	4591592	NOV 01, 2005		NDF	OCT 12, 1996
19762 002	TESTOSTERONE; TESTODERM	4051141	SEP 27, 1996		NDF	OCT 12, 1996
19979 001	TICLOPIDINE HYDROCHLORIDE; TICLID	4591592	NOV 01, 2005		NCE	OCT 31, 1996
19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4051141	SEP 27, 1996		NCE	OCT 31, 1996
		4051141	SEP 27, 1996		NP	NOV 04, 1996
					NP	NOV 04, 1996
20330 001	TIMOLOL MALEATE; TIMOPTIC-XE	4822807	APR 18, 2006		NCE	AUG 23, 1998
20330 002	TIMOLOL MALEATE; TIMOPTIC-XE	4018929	APR 19, 1994			
20136 001	TORSEMIDE; DEMADEX	RE30633	APR 19, 1994			
20136 002	TORSEMIDE; DEMADEX	4822807	APR 18, 2006		NCE	AUG 23, 1998
20136 003	TORSEMIDE; DEMADEX	4018929	APR 19, 1994			
20136 004	TORSEMIDE; DEMADEX	RE30633	APR 19, 1994			
20137 002	TORSEMIDE; DEMADEX	4822807	APR 18, 2006		NCE	AUG 23, 1998
18207 004	TRAZODONE HYDROCHLORIDE; DESYREL	4018929	APR 19, 1994			
18776 003	VECURONIUM BROMIDE; NORCURON	RE30633	APR 19, 1994			
19908 001	ZOLPIDEM TARTRATE; AMBIEN	4258027	MAR 24, 1998		NCE	APR 30, 1994
19908 002	ZOLPIDEM TARTRATE; AMBIEN	4215104	JUL 29, 1997		NCE	DEC 16, 1997
		4297351	OCT 27, 1998		NCE	DEC 16, 1997
		4237126	DEC 02, 1997		NCE	DEC 16, 1997
		4382938	MAY 10, 2000	U-74		
		4382938	MAY 10, 2000	U-74		

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION**Order Processing Code**

* 7229

**Charge your order.
It's easy!**



— subscriptions of **APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, ADP**, and the monthly Cumulative Supplements, for \$55.00 per year.

The total cost of my order is \$_____. Prices include regular domestic postage and handling and are subject to change. International customers please add 25%.

For privacy protection, check the box below:

☐ Do not make my name available to other mailers.

Please choose method of payment:

☐ Check payable to Superintendent of Documents☐ GPO Deposit Account

--	--	--	--	--	--	--	--

 -

--

☐ VISA or MasterCard

Thank you for your order!

(Credit card expiration date)

(Authorizing Signature)

(04/93)

(Company or personal name)

(Additional address/attention line)

(Street address)

(City, State, ZIP Code)

()
(Daytime phone including area code)

(Purchase Order No.)

Mail To: Superintendent of Documents, Government Printing Office, P.O. Box 371954 Pittsburgh, PA 15250-7954
To FAX your charge order, call (202) 512-2233.
To charge your subscription call (202) 783-3238.

Library Use Only

ST. LOUIS COLLEGE OF PHARMACY



3 2201 90036 5103

RM301.45 .A66 1993 Nov Suppl

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

Library Use Only