

DEC 08 1993

CUMULATIVE
SUPPLEMENT 9

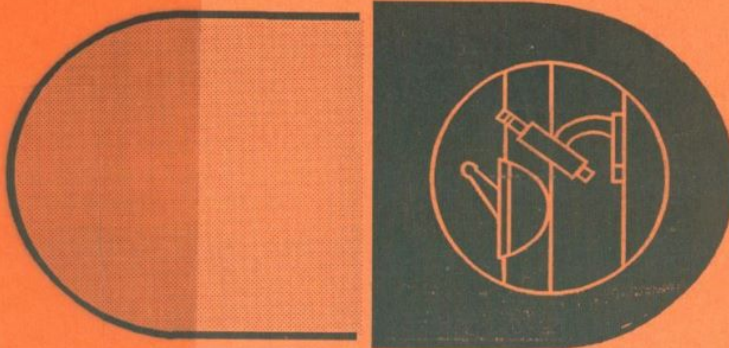
JAN'93-SEP'93

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

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



RM
301.45
.A66
1993
Sep
Suppl

RM301.45 .A66 1993 Sep 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

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**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 9

SEPTEMBER 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	70
2.3 Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List	72
2.4 Orphan Drug Product Designations	73
2.5 Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution	78
2.6 Biopharmaceutic Guidance Availability	79
2.7 ANDA Suitability Petitions	80
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Exclusivity Terms	81
B. Patent and Exclusivity Lists	82

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

CUMULATIVE SUPPLEMENT 9

SEPTEMBER 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)

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)

FUJISAWA PHARMACEUTICAL CO
(FUJISAWA)

FUJISAWA USA INC
(FUJISAWA)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

HERBERT LABORATORIES DIV
SMITH KLINE AND FRENCH CO
(HERBERT)

ALLERGAN HERBERT SKIN CARE
DIV ALLERGAN INC
(ALLERGAN HERBERT)
formerly
ALLERGAN HERBERT DIV ALLERGAN INC

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)

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 SEPTEMBER 1993.

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.

DEFINITIONSDrug 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	
SINGLE SOURCE	2245 (23.7%)	2243 (23.9%)	2119 (23.0%)	
MULTISOURCE	7243 (76.3%)	7149 (76.1%)	7075 (77.0%)	
THERAPEUTICALLY EQUIVALENT	6516 (68.6%)	6432 (68.5%)	6357 (69.1%)	
NOT THERAPEUTICALLY EQUIVALENT	577 (6.1%)	562 (5.9%)	555 (6.1%)	
EXCEPTIONS ¹	150 (1.6%)	155 (1.7%)	163 (1.8%)	
NEW MOLECULAR ENTITIES APPROVED	--	3	2	
NUMBER OF APPLICANTS	477	484	508	

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

ANACIAN

/AA/ /MALIAR/

/325MG; 50MG; 40MG/

AB

ROBERTS HAUCK

325MG; 50MG; 40MG

/N87628/001/
/DEC/23/1986/

N87628 001
OCT 01, 1986

TABLET; ORAL

/ESGIC/

/AA/ /FOREST/PHARMS/

/325MG; 50MG; 40MG/

325MG; 50MG; 40MG

/N89660/001/
/DEC/23/1988/

N89660 001
DEC 23, 1988

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

COMPAL

/AA/ /PURDUE FREDERICK

356.4MG; 30MG; 16MG

/AA/ /SOLVAY/

/356.4MG; 30MG; 16MG/

/N88584/001/
/MAR/04/1986/

N88584 001
MAR 04, 1986

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

3 LEMTON

300MG; 30MG

/ACETAMINOPHEN/M/ /CODEINE/H/ /300MG; 30MG/

/N88324/001/
/DEC/29/1983/

N88324 001
DEC 29, 1983

SOLUTION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

PENNEX PHARMS

/AA/ /PHARM/PAKIST/

120MG/5ML; 12MG/5ML

/N87006/001/
/N87666/001/

N87006 001
N87666 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

/AA/ /LUCHEM/

/500MG; 5MG/

500MG; 5MG

/N89907/001/
/JAN/13/1989/

N89907 001
JAN 13, 1989

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ANEXIA

/AA/ /FOREST/PHARMS/

/500MG; 5MG/

3 FOREST PHARMS

500MG; 5MG

/N87961/001/
/MAR/17/1983/

N87961 001
MAR 17, 1983

TABLET; ORAL

ANEXIA

/AA/ /BOEHRINGER MANNHEIM

500MG; 5MG

/AA/ /SKCP/

/500MG; 5MG/

/N89160/001/
/APR/23/1987/

N89160 001
APR 23, 1987

ANEXIA 7.5/650

/AA/ /BOEHRINGER MANNHEIM

650MG; 7.5MG

/AA/ /SKCP/

/650MG; 7.5MG/

/N89725/001/
/SEP/30/1987/

N89725 001
SEP 30, 1987

/AA/ /PURADINE INC/

/500MG; 5MG/

/AA/ /FOREST/PHARMS/

/500MG; 5MG/

/N87809/001/
/MAR/17/1983/

N87809 001
MAR 17, 1983

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

/AA/ /LUCHEM/

/500MG; 5MG/

AA NORTON HN

500MG; 5MG

/N89696/001/
/APR/21/1988/

N89696 001
APR 21, 1988

/AA/ /HARVEY/

/500MG; 5MG/

3 ABANA

500MG; 5MG

/N88871/001/
/MAY/15/1986/

N88871 001
MAY 15, 1986

/AA/ /TYGOLIT/

/AA/ /JOHNSON/PH/

/500MG; 5MG/

3 JOHNSON PH

500MG; 5MG

/N89385/001/
/AUG/27/1986/

N89385 001
AUG 27, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

/AD/ /HALSEY/ /N172105/001/

/AD/ /HALSEY/ /N172106/001/

/AD/ /HALSEY/ /N172105/001/

> ADD > 325MG; 50MG

> ADD > 650MG; 100MG

/N172105/001/

/MAY 13, 1988/

/N172106/001/

/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

ACETAZOLAMIDE SODIUM

/AP/ /QUAD/ /EQ 500MG/VIAL/

/AP/ /QUAD/ /EQ 500MG/VIAL/

> ADD > 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

DIAMOX

LEDERLE

/AP/ /LEDERLE/ /EQ 500MG/VIAL/

/AP/ /LEDERLE/ /EQ 500MG/VIAL/

> ADD > 500MG/VIAL

/N89388/001/

/DEC 05, 1990/

N89388 001

DEC 05, 1990

EQ 4MG BASE

N19283 001

JUL 13, 1987

ACETYLCHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; OPHTHALMIC

MIOCHOL-E

+ IOLAB

> ADD > 20MG/VIAL

> ADD > 20MG/VIAL

N20213 001

SEP 22, 1993

EQ 4MG BASE

N19604 002

DEC 23, 1992

EQ 8MG BASE

N19604 001

DEC 23, 1992

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ZOVIRAX

+ BURROUGHS WELLCOME

> ADD > 1GM BASE/VIAL

> ADD > 250MG BASE/VIAL

N18603 002

JUN 29, 1989

N18603 003

AUG 30, 1983

EQ 100MG

N71382 001

JAN 21, 1987

SYRUP; ORAL

AMANTADINE HCL

MIKART

50MG/5ML

N74028 001

JUN 28, 1993

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HCL

CIPICA

EQ 100MG

N71382 001

JAN 21, 1987

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC

INJECTABLE; INJECTION
/N14054N/11/3.5%N/
/ABBOTT/

3 ABBOTT

/3.5%;30MG/100ML;97MG/100ML/ N19437/007
/12.0MG/100ML;49MG/100ML/ N19437/007
/APR/05,1986/
3.5%;30MG/100ML;97MG/100ML; N19437 007
120MG/100ML;49MG/100ML APR 03, 1986

AMINOCAPROIC ACID

INJECTABLE; INJECTION
AMINOCAPROIC ACID
/LYPHOMED/

3 LYPHOMED

/250MG/5ML/
250MG/ML

/N70522/001/
/JUN/17,1986/
N70522 001
JUN 17, 1986

AMINOPHYLLINE

/ENEMA; RECTAL/
/SCHOTT/

3 FISOXS

/300MG/5ML/
300MG/5ML

/N18232/001/
/APR/02,1982/
N18232 001
APR 02, 1982

INJECTABLE; INJECTION
AMINOPHYLLINE

/AB/ /BRISTOL/
AP FUJISANA

3 /LYPHOMED/

/25MG/ML/
25MG/ML
/25MG/ML/
25MG/ML

/N87431/001/
N87431 001
JAN 25, 1984
/N87431/001
/JAN/25,1984/

SOLUTION; ORAL
AMINOPHYLLINE
3 PENNEX PHARMS

/AB/ /PHARM/BASIC/

105MG/5ML
/105MG/5ML/

N88156 001
DEC 05, 1983
/N88156/001/
/DEC/05,1983/

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
/AB/ /SEARLE/

3 SEARLE

/100MG/
100MG
200MG

/N02386/002/
N02386 002
N02386 003

AMINOPHYLLINE
/AB/ /ROXANE/

AB + ROXANE

/100MG/
100MG
200MG

/N87501/001/
/FEB/09,1982/
N87501 001
FEB 09, 1982
/N87501/001/
/FEB/09,1982/
N87501 001
FEB 09, 1982

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

ELAVIL
/AB/ /HSD/
AP ZENECA

/10MG/ML/
10MG/ML

/N12704/001/
N12704 001

TABLET; ORAL

ELAVIL
/AB/ /HSD/
AP ZENECA

/10MG/
10MG
25MG
25MG
50MG
50MG
75MG
75MG
100MG
100MG
150MG
150MG
10MG
25MG
50MG
75MG
100MG
150MG

/N12703/001/
N12703 001
N12703 003
N12703 004
N12703 005
N12703 006
N12703 007

AMOXICILLIN

CAPSULE; ORAL
/EDLYN/

/450MG/
450MG

/N61885/001/
N61885 001

AMPHOTERICIN B

ointment; topical

fungizone

+ apothecan

/301166/

3%
/3%/
/301166/

N50313 001
/N50313/001/

AMPICILLIN SODIUM

injectable; injection

ampicillin sodium

hanford

EQ 125MG BASE/VIAL

N63143 001

AP

INJECTABLE; INJECTION

EQ 125MG BASE/VIAL

/N61395/001/

EQ 250MG BASE/VIAL

N63145 001

AP

INJECTABLE; INJECTION

EQ 250MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

N63146 001

AP

INJECTABLE; INJECTION

EQ 500MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

N63147 001

AP

INJECTABLE; INJECTION

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

N62772 001

AP

INJECTABLE; INJECTION

EQ 1GM BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

N63139 001

AP

INJECTABLE; INJECTION

EQ 1GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

N63140 001

AP

INJECTABLE; INJECTION

EQ 2GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

N63141 001

AP

INJECTABLE; INJECTION

EQ 2GM BASE/VIAL

/N61395/001/

EQ 10GM BASE/VIAL

N63142 001

AP

INJECTABLE; INJECTION

EQ 10GM BASE/VIAL

/N61395/001/

EQ 125MG BASE/VIAL

N62797 001

AP

INJECTABLE; INJECTION

EQ 125MG BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

N62797 002

AP

INJECTABLE; INJECTION

EQ 2GM BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N62565/001/

AP

INJECTABLE; INJECTION

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N62565/001/

AP

INJECTABLE; INJECTION

EQ 1GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N62565/001/

AP

INJECTABLE; INJECTION

EQ 2GM BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

N62565 001

AP

INJECTABLE; INJECTION

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

N62565 002

AP

INJECTABLE; INJECTION

EQ 1GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

N62565 003

AP

INJECTABLE; INJECTION

EQ 2GM BASE/VIAL

/N61395/001/

EQ 4GM BASE/VIAL

/N50072/006/

AP

INJECTABLE; INJECTION

EQ 4GM BASE/VIAL

/N61395/006/

penbritin-s

/N50072/006/

EQ 4GM BASE/VIAL

/N50072/006/

AP

INJECTABLE; INJECTION

EQ 4GM BASE/VIAL

/N61395/006/

AMPICILLIN SODIUM

INJECTABLE; INJECTION

/POLYCELLIN-N/

/BRISOL/

EQ 125MG BASE/VIAL

/N61395/001/

EQ 125MG BASE/VIAL

/N61395/001/

EQ 250MG BASE/VIAL

/N61395/001/

EQ 250MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N61395/001/

EQ 2GM BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

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EQ 1GM BASE/VIAL

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EQ 2GM BASE/VIAL

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EQ 2GM BASE/VIAL

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EQ 500MG BASE/VIAL

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EQ 500MG BASE/VIAL

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EQ 1GM BASE/VIAL

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EQ 1GM BASE/VIAL

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EQ 500MG BASE/VIAL

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EQ 2GM BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 500MG BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

EQ 1GM BASE/VIAL

/N61395/001/

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

/INJECTABLE; INJECTION/
/H.V.I.-12 LOPHILATED/
/ASTRA/
100MG/VIAL; 0.06MG/VIAL; 0.005MG/VIAL;
15MG/VIAL; 500IU/VIAL; 0.4MG/VIAL;
40MG/VIAL; 4MG/VIAL; 3.6MG/VIAL;
3MG/VIAL; 1MG/VIAL;
10MG/VIAL
N18933 002
AUG 08, 1985

3 ASTRA

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

INJECTABLE; INJECTION

H.V.G. 983

AP FUJISANA

10MG/ML; 0.006MG/ML; 0.50MG/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
10MG/ML; 0.006MG/ML; 0.50MG/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

/AP/ /LYPHILATED/

ASPIRIN; BUTALBITAL

TABLET; ORAL

AXOTAL

/+//ADRIA/

+ SAVAGE

650MG; 50MG
N8305 001
OCT 13, 1983

ATENOLOL

TABLET; ORAL

ATENOLOL

AB MUTUAL PHARM

50MG

N73475 001
MAR 30, 1993
N73476 001
MAR 30, 1993
N73315 001
MAY 28, 1993
N73316 001
MAY 28, 1993

100MG/VIAL; 0.06MG/VIAL; 0.005MG/VIAL;
15MG/VIAL; 500IU/VIAL; 0.4MG/VIAL;
40MG/VIAL; 4MG/VIAL; 3.6MG/VIAL;
3MG/VIAL; 1MG/VIAL;
10MG/VIAL
N18933 002
AUG 08, 1985

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

50MG; 25MG

AB MUTUAL PHARM

N73581 001
APR 29, 1993
N73582 001
APR 29, 1993

100MG; 25MG

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

/AZATHIOPRINE/

/AP/ /QUAD/

/EQ 100MG BASE/VIAL/

3 QUAD

EQ 100MG BASE/VIAL

/N11056 001/
/JUN 08, 1988/
N71056 001
JUN 08, 1988

IMURAN

/BURROUGHS WELLCOME/

/EQ 100MG BASE/VIAL/

EQ 100MG BASE/VIAL

/N11391 001/
N11391 001

BENZTHIAZIDE

TABLET; ORAL

EXNA

/B/P/+//ROBINSON/AH/
+ ROBINS AH

/50MG/
50MG

/N12489/001/
N12489 001

/AB/
/PHARMADERM/

/EQ 0.05% BASE/
EQ 0.05% BASE

/N706274/001/
/AUG/31,1983/
N70274 001
AUG 12, 1985

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL

/WALLACE/

/400MG/
400MG

/N19001/001/
/DEC/28,1990/
N19001 002

/300MG/
300MG

/N19001/002/
/DEC/28,1990/
N19001 003

/200MG/
200MG

/N19001/003/
/DEC/28,1990/
N19001 001

+ WALLACE

+ 300MG

+ 400MG

VASCO

/JOHNSON/RH/

/400MG/
400MG

/N19002/001/
/DEC/28,1990/
N19002 001

/300MG/
300MG

/N19002/002/
/DEC/28,1990/
N19002 002

/200MG/
200MG

/N19002/003/
/DEC/28,1990/
N19002 003

+ JOHNSON RH

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

/EQ 0.05% BASE/
EQ 0.05% BASE

/N19136/001/
/JUN/26,1984/
N19136 001
JUN 26, 1984

+ PHARMADERM

/EQ 0.1% BASE/
EQ 0.1% BASE

/N19136/001/
/JUN/26,1984/
N19136 001
JUN 26, 1984

/AB/
/PHARMADERM/

/EQ 0.1% BASE/
EQ 0.1% BASE

/AB/
/PHARMADERM/

/EQ 0.1% BASE/
EQ 0.1% BASE

/N18864/001/
/AUG/31,1983/
N18864 001
AUG 31, 1983

/AB/
/PHARMADERM/

/N18864/001/
/AUG/31,1983/
N18864 001
AUG 31, 1983

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

/EQ 0.05% BASE/
EQ 0.05% BASE

/N706274/001/
/AUG/31,1983/
N70274 001
AUG 12, 1985

+ PHARMADERM

/EQ 0.05% BASE/
EQ 0.05% BASE

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

/EQ 0.05% BASE/
EQ 0.05% BASE

/N19140/001/
/SEP/04,1984/
N19140 001
SEP 04, 1984

+ PHARMADERM

/EQ 0.05% BASE/
EQ 0.05% BASE

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE

/EQ 0.1% BASE/
EQ 0.1% BASE

/N18860/002/
/AUG/31,1983/
N18860 002
AUG 31, 1983

+ PHARMADERM

/EQ 0.1% BASE/
EQ 0.1% BASE

LOTION; TOPICAL

BETAMETHASONE VALERATE

/EQ 0.1% BASE/
EQ 0.1% BASE

/N18870/001/
/AUG/31,1983/
N18870 001
AUG 31, 1983

+ PHARMADERM

/EQ 0.1% BASE/
EQ 0.1% BASE

OINTMENT; TOPICAL

BETAMETHASONE VALERATE

/EQ 0.1% BASE/
EQ 0.1% BASE

/N70051/001/
/OCT/10,1984/
N70051 001
OCT 10, 1984

/AB/
/PHARMADERM/

/EQ 0.1% BASE/
EQ 0.1% BASE

/AB/
/PHARMADERM/

/EQ 0.1% BASE/
EQ 0.1% BASE

/N18864/001/
/AUG/31,1983/
N18864 001
AUG 31, 1983

/AB/
/PHARMADERM/

/N18864/001/
/AUG/31,1983/
N18864 001
AUG 31, 1983

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
ZIAC
+ LEDERLE

10MG; 6.25MG
2.5MG; 6.25MG
5MG; 6.25MG

N20186 002
MAR 26, 1993
N20186 003
MAR 26, 1993
N20186 001
MAR 26, 1993

BRETYLIUM IOSYLATE

INJECTABLE; INJECTION

BRETYLIUM IOSYLATE

/ASITH/
50MG/ML

/N71152/001/
/AUG/10/1987/
N71152 001
AUG 10, 1987

> DLT > /AD/
> DLT >
> ADD >
> ADD >

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE

SYRUP; ORAL

MYDARIL

AA PENNEX PHARMS

12.5MG/5ML; 10MG/5ML
/12.5MG/5ML; 10MG/5ML/

N88626 001
OCT 12, 1984
/N88626/001/
/OCT/12/1984/

/AA/ /PHARM/PAASICS/

BROMPHENTRAMINE MALEATE

TABLET; ORAL

BROMPHENTRAMINE MALEATE

/AA/ /ANABOLIC/ 4MG/
/AA/ /ANABOLIC/ 4MG/
/AA/ /NEUTRON/ 4MG/
/AA/ /NEUTRON/ 4MG/
/AA/ /NYLOS TRADING/ 4MG/
/AA/ /TABLITAP/ 4MG/
/AA/ /ZENITH/ 4MG/
/AA/ /ZENITH/ 4MG/

/N86187/001/
N86187 001
/N86187/001/
N86187 001
/N86187/001/
N86187 001
/N86187/001/
N86187 001

BROMPHENTRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

MYPHETANE DC

AA PENNEX PHARMS

2MG/5ML; 10MG/5ML;
12.5MG/5ML

N88904 001
FEB 21, 1985
/N88904/001/
/FEB/21/1985/

/AA/ /PHARM/PAASICS/
/2MG/5ML; 10MG/5ML;
12.5MG/5ML/

BROMPHENTRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE;

PSEUDOPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

MYPHETANE DC

AA PENNEX PHARMS

2MG/5ML; 10MG/5ML;
30MG/5ML

N88911 001
JUN 07, 1985
/N88911/001/
/JUN/07/1985/

/AA/ /PHARM/PAASICS/
/2MG/5ML; 10MG/5ML;
30MG/5ML/

BROMPHENTRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

BIPHETAP

AA PENNEX PHARMS

4MG/5ML; 25MG/5ML

N88687 001
SEP 26, 1984
/N88687/001/
/SEP/26/1984/

/AA/ /PHARM/PAASICS/
/4MG/5ML; 25MG/5ML/

BUTABARBITAL SODIUM

ELIXIR; ORAL

BUTABARBITAL SODIUM

AA PENNEX PHARMS

30MG/5ML

N85383 001

/AA/ /PHARM/PAASICS/
/30MG/5ML/

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

STADOL

+ APOTHECON

+ /PDS/001/

1MG/ML
2MG/ML
/1MG/ML/
/2MG/ML/

N17857 001
N17857 002
/N17857/001/
/N17857/002/

CALCIFEDIOL, ANHYDROUS

CAPSULE; ORAL

CALDEROL

+ ORGANON

/ / 100 IU/ML

0.05MG

0.02MG

0.01MG

0.005MG

N18312 002

N18312 001

N18312/002

N18312/001

CALCITONIN, SALMON

INJECTABLE; INJECTION

CALCIBAR

/ / 100 IU/ML

AP + RHONE POULENC RORER 200 IU/ML

MIACALCIN

/ / 100 IU/ML

100 IU/ML

3 SANDOZ

N17763/001

N17763 001

N17763/001

JUL/03/1986

JUL 03, 1986

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

SOLUTION; IRRIGATION

ENDOSOL EXTRA

ALLERGAN

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;

0.2MG/ML; 0.38MG/ML; 2.1MG/ML;

7.14MG/ML; 0.42MG/ML

N20079 001

NOV 27, 1991

ENDOSOL PLUS

ALLERGAN

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;

0.2MG/ML; 0.38MG/ML; 2.1MG/ML;

7.14MG/ML; 0.42MG/ML

N18664/001

NOV/27/1991

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

INJECTABLE; INJECTION

ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER

MEGAN

37MG/100ML; 5GM/100ML; 31MG/100ML;

120MG/100ML; 330MG/100ML;

88MG/100ML

N19864 001

JUN 10, 1993

CALCIUM GLUCEPATE

INJECTABLE; INJECTION

CALCIUM GLUCEPATE

/ / 90MG

AP + ABBOTT

/ / 90MG

AP + LILLY

/ / 90MG

AP + LYPHOMED

/ / 90MG

3 LYPHOMED

/ / 90MG

EQ 90MG CALCIUM/5ML

/ / 90MG

EQ 90MG CALCIUM/5ML

/ / 90MG

EQ 90MG CALCIUM/5ML

/ / 90MG

EQ 90MG CALCIUM/5ML

APR 30, 1987

CARBENICILLIN DISODIUM

INJECTABLE; INJECTION

GEOPEN

/ / 1GM

AP + ROERIG

/ / 1GM

AP + ROERIG

/ / 1GM

EQ 1GM BASE/VIAL

/ / 1GM

EQ 2GM BASE/VIAL

/ / 1GM

EQ 5GM BASE/VIAL

/ / 1GM

EQ 10GM BASE/VIAL

/ / 1GM

EQ 1GM BASE/VIAL

/ / 1GM

EQ 2GM BASE/VIAL

/ / 1GM

EQ 5GM BASE/VIAL

/ / 1GM

EQ 10GM BASE/VIAL

PTOPEN

/ / 1GM

AP + SMITHKLINE BEECHAM

/ / 1GM

AP + SMITHKLINE BEECHAM

/ / 1GM

EQ 1GM BASE/VIAL

/ / 1GM

EQ 2GM BASE/VIAL

/ / 1GM

EQ 5GM BASE/VIAL

/ / 1GM

EQ 10GM BASE/VIAL

/ / 1GM

EQ 20GM BASE/VIAL

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

PUREPAC

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

10MG; 100MG

25MG; 100MG

25MG; 250MG

N74260 001

SEP 03, 1993

N74260 002

SEP 03, 1993

N74260 003

SEP 03, 1993

TABLET; ORAL

CARBIDOL AND LEVODOPA

WATSON LABS

10MG; 100MG

N73381 001

SEP 28, 1993

N73382 001

SEP 28, 1993

N73383 001

SEP 28, 1993

25MG; 100MG

25MG; 250MG

25MG; 250MG

25MG; 250MG

25MG; 250MG

25MG; 250MG

CARBINOXAMINE MALEATE

TABLET; ORAL

/CLISTIN/

/JOHNSON/RW/

a JOHNSON RW

/4MG/

4MG

CARISOPRODOL

CAPSULE; ORAL

/SCIN/

/WALLACE/

a WALLACE

/250MG/

250MG

TABLET; ORAL

CARISOPRODOL

/PIONEER/PHARMS/

/PIONEER/PHARMS/

a PIONEER PHARMS

/350MG/

350MG

/SCHERING/

/SCHERING/

a SCHERING

/350MG/

350MG

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIPRESS

/BURROUGHS/

/BURROUGHS/

1%.

OTSUKA

MAY 23, 1990

CAPSULE; ORAL

DURICEF

AB + BRISTOL MYERS SQUIBB

/AB//+/HEAD/JOHNSON/

/EQ 500MG BASE/

/EQ 500MG BASE/

/EQ 500MG BASE/

/EQ 500MG BASE/

/EQ 500MG BASE/

/EQ 500MG BASE/

/EQ 500MG BASE/

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/EQ 500MG BASE/

/EQ 500MG BASE/

/EQ 500MG BASE/

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

/AP/ /BEN/VIAL/

/AP/

/AP/

/AP/

/AP/

/EQ 250MG BASE/VIAL/

/EQ 500MG BASE/VIAL/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/EQ 5GM BASE/VIAL/

/N62894/001/

/N62894/002/

/N62894/003/

/N62894/004/

/N62894/005/

3 BEN VENUE

3

3

3

3

JUL 21, 1988

JUL 21, 1988

JUL 21, 1988

JUL 21, 1988

JUL 21, 1988

/EQ 250MG BASE/VIAL/

/EQ 500MG BASE/VIAL/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/N50571/001/

/N50571/002/

/N50571/003/

/EQ 500MG BASE/VIAL/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/DEC 30, 1987

/DEC 30, 1987

/DEC 30, 1987

/EQ 500MG BASE/VIAL/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/DEC 30, 1987

/DEC 30, 1987

/DEC 30, 1987

CEFONICID SODIUM

INJECTABLE; INJECTION

MONOCID

SMITHKLINE BEECHAM

3

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/EQ 4GM BASE/VIAL/

/N63295/001/

/N63295/002/

/N63295/003/

/N63295/004/

/N63295/005/

/JUL 26, 1993

/JUL 26, 1993

/JUL 26, 1993

/JUL 26, 1993

/JUL 26, 1993

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CLAFORAN

HOECHST ROUSSEL

/EQ 500MG BASE/VIAL/

/N50547/001/

CEFOTETAN DISODIUM

INJECTABLE; INJECTION

CEFOTAN

/AP/ /SIN/

/AP/

/AP/

/AP/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/EQ 4GM BASE/VIAL/

/EQ 8GM BASE/VIAL/

/N50548/001/

/N50548/002/

/N50548/003/

/N50548/004/

/N50548/005/

/DEC 27, 1985

/DEC 27, 1985

/DEC 27, 1985

/DEC 27, 1985

/DEC 27, 1985

/N50588/001/

/N50588/002/

/N50588/003/

/N50588/004/

/N50588/005/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/EQ 4GM BASE/VIAL/

/EQ 8GM BASE/VIAL/

/DEC 27, 1985

/DEC 27, 1985

/DEC 27, 1985

/DEC 27, 1985

/DEC 27, 1985

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/EQ 4GM BASE/VIAL/

/EQ 8GM BASE/VIAL/

/N50694/001/

/N50694/002/

/N50694/003/

/N50694/004/

/N50694/005/

/JUL 30, 1993

/JUL 30, 1993

/JUL 30, 1993

/JUL 30, 1993

/JUL 30, 1993

CEFOTAN IN PLASTIC CONTAINER

+ ZENCA

+ ZENCA

/EQ 20MG BASE/ML/

/EQ 40MG BASE/ML/

/N50694/001/

/N50694/002/

/N50694/003/

CEFOTIAM HYDROCHLORIDE

INJECTABLE; INJECTION

CEFAMIN

/AP/

/EQ 1GM BASE/VIAL/

/EQ 2GM BASE/VIAL/

/N50661/001/

/N50661/002/

/N50661/003/

CEFOTIAM HYDROCHLORIDE

/INJECTABLE; INJECTION/
/CERADON/
/TAKEDA/

/EQ/1GM/BASE/VIAL/

/N50601/001/
/DEC/30/1988/

CEFOXITIN SODIUM

/INJECTABLE; INJECTION/
/CERADON/
@ 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

CEFTIRAMIDE SODIUM

/INJECTABLE; INJECTION/
/CEFTIRAMIDE/SODIUM/
/WYETH/AYERST/

/EQ/1GM/BASE/VIAL/

/EQ/2GM/BASE/VIAL/

/EQ/10GM/BASE/VIAL/

@ WYETH AYERST

@

@

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 10GM BASE/VIAL

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

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
CEFTAZIDIME SODIUM IN PLASTIC CONTAINER

AP BAXTER

AP

AP

AP

EQ 10MG BASE/ML

EQ 20MG BASE/ML

EQ 40MG BASE/ML

EQ 10MG BASE/ML

EQ 20MG BASE/ML

EQ 40MG BASE/ML

FORTAZ IN PLASTIC CONTAINER

AP GLAXO

AP

AP

AP

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

CEFTIRAXONE 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

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER
/ROCHE/

EQ 10MG BASE/ML

/N50624/001/
/FEB/11/1987/
N50624 001
FEB 11, 1987

CEFUROXIME SODIUM

INJECTABLE; INJECTION
CEFUROXIME
HARSAN

AP

AP

AP

EQ 750MG BASE/VIAL

EQ 1.5GM BASE/VIAL

EQ 7.5GM BASE/VIAL

N64035 001
FEB 26, 1993
N64035 002
FEB 26, 1993
N64036 001
FEB 26, 1993

KEFUROX

LILLY

ZITHACEF

GLAXO

EQ 7.5GM BASE/VIAL

EQ 7.5GM BASE/VIAL

N62591 003
DEC 17, 1987
N50558 004
OCT 23, 1986

CELLULOSE SODIUM PHOSPHATE

POWDER; ORAL

CALCIBIND

/:/INJECTION/PHARMA/

@ MISSION PHARMA

/E.5GM/PACKET/

2.5GM/PACKET

/N18757/002/
/DEC/28/1982/
N18757 002
DEC 28, 1982

CEPHALEXIN

CAPSULE; ORAL

CEFALEX

AB APOTHECON

EQ 250MG BASE

N63063 001

SEP 29, 1989

EQ 500MG BASE

N63063 002

SEP 29, 1989

/EQ 250MG BASE/

/N63063/001/

/EQ 500MG BASE/

/SEP 29, 1989/

/EQ 250MG BASE/

/SEP 29, 1989/

CEPHALEXIN

AB APOTHECON

EQ 250MG BASE

N62973 001

NOV 08, 1988

EQ 500MG BASE

N62974 001

NOV 23, 1988

/EQ 250MG BASE/

/N62973/001/

/EQ 500MG BASE/

/NOV 23, 1988/

/EQ 250MG BASE/

/NOV 23, 1988/

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION

CEFAOYL

3 APOTHECON

EQ 500MG BASE/VIAL

N50446 005

SEP 20, 1988

EQ 500MG BASE/VIAL

N62961 001

SEP 20, 1988

EQ 1GM BASE/VIAL

N50446 001

SEP 20, 1988

EQ 1GM BASE/VIAL

N61769 001

SEP 20, 1988

EQ 1GM BASE/VIAL

N62724 001

DEC 23, 1986

EQ 1GM BASE/VIAL

N62961 002

SEP 20, 1988

EQ 2GM BASE/VIAL

N50446 002

SEP 20, 1988

EQ 2GM BASE/VIAL

N61769 002

SEP 20, 1988

EQ 2GM BASE/VIAL

N62724 002

DEC 23, 1986

EQ 2GM BASE/VIAL

N62961 003

SEP 20, 1988

EQ 4GM BASE/VIAL

N50446 003

SEP 20, 1988

EQ 4GM BASE/VIAL

N61769 003

SEP 20, 1988

EQ 4GM BASE/VIAL

N62961 004

SEP 20, 1988

EQ 20GM BASE/VIAL

N50446 004

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION

CEFAOYL

3 APOTHECON

EQ 500MG BASE/VIAL

N50446/005/

EQ 1GM BASE/VIAL

N50446/001/

EQ 2GM BASE/VIAL

N61769/001/

EQ 1GM BASE/VIAL

N62724/001/

EQ 1GM BASE/VIAL

DEC 23, 1986/

EQ 2GM BASE/VIAL

N50446/002/

EQ 2GM BASE/VIAL

N61769/002/

EQ 2GM BASE/VIAL

N62724/002/

EQ 2GM BASE/VIAL

DEC 23, 1986/

EQ 4GM BASE/VIAL

N50446/003/

EQ 4GM BASE/VIAL

N61769/003/

EQ 4GM BASE/VIAL

N50446/004/

EQ 500MG BASE/VIAL

SEP 20, 1988/

EQ 1GM BASE/VIAL

SEP 20, 1988/

EQ 1GM 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/

CEPHAPIRIN SODIUM
LYPHOMED

3

EQ 500MG BASE/VIAL

N62723/001/

3

EQ 1GM BASE/VIAL

N62723/002/

3

EQ 2GM BASE/VIAL

N62723/003/

3

EQ 4GM BASE/VIAL

N62723/004/

3

EQ 500MG BASE/VIAL

N62723 001

3

EQ 1GM BASE/VIAL

N62723 002

3

EQ 2GM BASE/VIAL

N62723 003

3

EQ 4GM BASE/VIAL

N62723 004

3

EQ 500MG BASE/VIAL

N62723 001

3

EQ 1GM BASE/VIAL

N62723 002

3

EQ 2GM BASE/VIAL

N62723 003

3

EQ 4GM BASE/VIAL

N62723 004

3

EQ 500MG BASE/VIAL

N62723 001

3

EQ 1GM BASE/VIAL

N62723 002

3

EQ 2GM BASE/VIAL

N62723 003

3

EQ 4GM BASE/VIAL

N62723 004

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

NYCHEL-S

3 RACHELLE

EQ 1GM BASE/VIAL

N60132/001/

EQ 1GM BASE/VIAL

N60132 001

CHLORTHALIDONE; METOPROLOL TARTRATE

/CAPSULE; ORAL/
/LOPRESSIDONE/
/CIBA/

/25MG; 200MG/

/25MG; 100MG/

3 CIBA

25MG; 100MG

3

25MG; 200MG

/N19451/001/
/DEC/31/1987/
/N19451/001/
/DEC/31/1987/
/N19451/001/
/DEC/31/1987/

DEC 31, 1987

DEC 31, 1987

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

/PIONEER PHARMS/

/250MG/

/N89592/001/
/JAN/06/1989/

/500MG/

/N89592/001/
/JAN/06/1989/

/500MG/

/N89592/001/
/JAN/06/1989/

3 PIONEER PHARMS

250MG

3

500MG

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC

CATARASE

+ IOLAB

300 UNITS/VIAL

/150/UNITS/VIAL/

150 UNITS/VIAL

/300/UNITS/VIAL/

N16938 001

/N16938/001/

N18121 001

/N18121/001/

CISAPRIDE MONOHYDRATE

TABLET; ORAL

PROPULSID

+ JANSSEN

EQ 20MG BASE

EQ 10MG BASE

N20210 002

JUL 29, 1993

N20210 001

JUL 29, 1993

CLADRIKINE

INJECTABLE; INJECTION

LEUSTATIN

+ JOHNSON RW

1MG/ML

N20229 001
FEB 26, 1993

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLEOCIN

AB + UPJOHN

/AB/1/1/

AB +

/AB/1/1/

3

3

EQ 75MG BASE

/EQ 75MG BASE/

EQ 150MG BASE

/EQ 150MG BASE/

EQ 75MG BASE

/EQ 75MG BASE/

N50162 001

/N50162/001/

N50162 002

/N50162/002/

N61809 001

/N61809/001/

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLEOCIN PHOSPHATE

AP + UPJOHN

/AP/1/1/

CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%

/EQ 12MG BASE/ML/

EQ 150MG BASE/ML

/EQ 150MG BASE/ML/

N50441 001

/N50441/001/

N50636 001

/N50636/001/

DEC 22, 1989

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

/AB/1/1/

/AB/1/1/

/AB/1/1/

/0.1MG/

/0.2MG/

/0.3MG/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

/N18121/001/

CORTICOTROPIN

INJECTABLE; INJECTION

H.P. ACTHAR GEL

/BC/ /ACTHAR/

/BC/ /ACTHAR/

BC RHONE POULENC RORER

BC +

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

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CYANOCOBALAMIN

INJECTABLE; INJECTION

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

/BC/ /ACTHAR/

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3 ORGANON

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/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

CORTICOTROPIN-ZINC HYDROXIDE

INJECTABLE; INJECTION

H.P. ACTHAR GEL

/BC/ /ACTHAR/

/BC/ /ACTHAR/

BC RHONE POULENC RORER

BC +

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

/BC/ /ACTHAR/

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3 ORGANON

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/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

CORTICOTROPIN-ZINC HYDROXIDE

INJECTABLE; INJECTION

H.P. ACTHAR GEL

/BC/ /ACTHAR/

/BC/ /ACTHAR/

BC RHONE POULENC RORER

BC +

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

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/BC/ /ACTHAR/

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3 ORGANON

3

/BC/ /ACTHAR/

/BC/ /ACTHAR/

3 ORGANON

3

INJECTABLE; INJECTION

AP
NEOEAR
ADRIA

100MG/VIAL
200MG/VIAL
500MG/VIAL
1GH/VIAL
2GH/VIAL

N40015 001
APR 29, 1993
N40015 002
APR 29, 1993
N40015 003
APR 29, 1993
N40015 004
APR 29, 1993
N40015 005
APR 29, 1993

CYPROHEPTADINE HYDROCHLORIDE

SYRUP; ORAL

CYPROHEPTADINE HCL
@ PENNEX PHARMS

2MG/5ML

/AA/ /PHARM/PLASTICS/
/2MG/5ML/

N87001 001
NOV 04, 1982
/N87001/001/
/NOV/04/1982/

TABLET; ORAL

CYPROHEPTADINE HCL
/MYLAN/
@ MYLAN

/4MG/
4MG

DESIPRAMINE HYDROCHLORIDE

/CAPSULE; ORAL/
/PERTOPHANE/
/+/RHONE/POULENC/RORER/

/50MG/
/25MG/
/50MG/

@ RHONE POULENC RORER
@

DESLANOSIDE

/INJECTABLE; INJECTION/
/SANDOZ/
@ SANDOZ

/0.2MG/ML/
0.2MG/ML

DEXAMETHASONE ACETATE

SPRAY, METERED; NASAL
DDVP

RHONE POULENC RORER 0.01MG/INH

N17922 002
FEB 06, 1989

DESOXYCORTICOSTERONE PIVALATE

/INJECTABLE; INJECTION/
/PERCORTEN/
/CIBA/
@ CIBA

/25MG/ML/
25MG/ML

/N88822/001/
N08822 001

DEXAMETHASONE

ELIXIR; ORAL

DEXAMETHASONE

AA

BARRE

0.5MG/5ML

/AA/ /NASKA/
/0.5MG/5ML/

N88997 001
OCT 10, 1986
/N88997/001/
/OCT/10/1986/

MYMETHASONE

PENNEX PHARMS

AA

PHARM/PLASTICS/

0.5MG/5ML

/AA/ /PHARM/PLASTICS/
/0.5MG/5ML/

N88254 001
JUL 27, 1983
/N88254/001/
/JUL/27/1983/

SOLUTION; ORAL

DEXAMETHASONE

/3/ROXANE/

/0.5MG/5ML/

ROXANE

0.5MG/5ML

/N88248/001/
/SEP/01/1983/
N88248 001
SEP 01, 1983

TABLET; ORAL

DEXADRON

MSD

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

0.5MG

0.75MG

1.5MG

4MG

/0.5MG/

/0.75MG/

/1.5MG/

/4MG/

N11664 001
N11664 002
N11664 003
N11664 005
/N11664/001/
/N11664/002/
/N11664/003/
/N11664/005/

CONSTITUTIONAL COURT OF THE UNITED STATES
WASHINGTON, D.C.

INJECTABLE; INJECTION

POLYTE H IN DEXTROSE 5% IN PLASTIC CONTAINER
 5GM/100ML; 30MG/100ML; 97MG/100ML;
 220MG/100ML; 140MG/100ML N19844 001
 JUN 10, 1993

N72370 001
JAN 29, 1993
N72371 001
JAN 29, 1993
N72397 001
JAN 29, 1993

5MG/ML

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION

AP
ISOLYTE 5 IN DEXTROSE 5% IN PLASTIC CONTAINER
MCGAW
5GM/100ML; 30MG/100ML; 37MG/100ML;
370MG/100ML; 530MG/100ML;
500MG/100ML
N19843 001
AUG 09, 1993

NI9287 001
JUN 18, 1993

5MG/ML

DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC;
SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

OLYTE M IN DEXTROSE 5% IN PLASTIC CONTAINER
5GM/100ML; 150MG/100ML; 130MG/100ML;
280MG/100ML; 91MG/100ML N19870 001
MCGAW JUN 10, 1993

JUN 10, 1993

DIATRIZOATE MEGGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/H/PAQUE-H.75%/ /STERLING/ @ STERLING	/56%:55%/ 50%:25%	/N10220/003/ N10220 003
/H/PAQUE-H.90%/ /STERLING/ @ STERLING	/60%:56%/ 60%:30%	/N10220/002/ N10220 002

156%; 25%
50%; 25%

60%; 30%
/60%; 30%/
/NY0420/002/
NY0220 002

200 0220TN
/499/9229TN

156%; 25%
50%; 25%

DIATRIZOATE SODIUM

Lactarius stipitatus: 100%

EDITION; OVERFALL	/20% /	N09561/002
WPAQUE; SQUIN; 20% /	/20% /	N09561/002
STERLING	20% /	N09561/002
STERLING	20% /	N09561/002

CAPSULE; ORAL
PROGLYCEN
+ BAKER NORTON
//MEDCL/NKTC/

50MG
/50MG/

NI7425 001
/NI7425/66Y/

+ BAKER NORTON
//HÉDCL/HKTS/50MG
/50MG/

NI7425 001
/NI7425/66Y/

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLONINE HCL
/PIONEER/PHARMS/
/AB/

/N71968/661/
 /JAN/26./1968/
 N71908 001
 JAN 26. 1988

JAN/26, 1988
N71908 001
JAN 26, 1988

TABLET: ORAL

NI6996 001
/NI6996/001/

TABLET: ORAL

166/
DICYCLOTHINE HCL
/PIONEER/PHARMS/

/N26637/661/
 MAR/28, 1991
 N20037 001
 MAR 28, 1991

/INJECTABLE://INJECTION/
/STILBESTROL/
/SQUIBB/

DIETHYLSTILBESTROL

EQ 250MG BASE
EQ 500MG BASE

160254/002
160254/003

/suppository; /vaxinal/

EQ 125NG BASE
EQ 250NG BASE
EQ 125NG BASE
EQ 250NG BASE

N61454 002
N61454 001
/N61454/002/
/N61454/001/

TARIET. DELAYED RELEASE; ORAL

~~EQ 62.5MG BASE/5ML~~

N61455 001
/N61455/001/

TARIET. DELAYED RELEASE; ORAL

STILBETIN
/SQUIBB/
SQUIBB

N61455 001
/N61455/001/

400 N05545 /599/54559N

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

BC + CARDERM 180MG
BC + 240MG
+ 120MG
+ 300MG
/BC/+ /MARION/MERRELL/DOW/ 180MG/
/BC/+ / 240MG/
/+ / 120MG/
/+ / 300MG/

TABLET; ORAL
DILTIAZEM HCL
APOTHECON

AB 30MG
AB 60MG
AB 90MG
AB 120MG

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/AA/ 25MG/
/AB/ 50MG/
3 LEMON 25MG
3 50MG

INJECTABLE; INJECTION

DIPHENHYDRAMINE HCL

/AP/ 10MG/ML/
3 BEL MAR 10MG/ML
/AP/ 10MG/ML/
3 FUJISAWA 10MG/ML

N20062 002
DEC 27, 1991
N20062 003
DEC 27, 1991
N20062 001
AUG 10, 1992
N20062 004
DEC 27, 1991
/N20062/002/
/DEC/27/1991/
/N20062/003/
/DEC/27/1991/
/N20062/001/
/AUG/10/1992/
/N20062/004/
/DEC/27/1991/

N74051 001
MAR 31, 1993
N74051 002
MAR 31, 1993
N74051 003
MAR 31, 1993
N74051 004
MAR 31, 1993

/N05874/001/
/N05874/002/
N05874 001
N05874 002

/N00666/001/
/N00666/002/
N00666 001
N00666 002

CAPSULE; EXTENDED RELEASE; ORAL

SMITHKLINE BEECHAM

/+ /SMITHKLINE/BEECHAM/ 5MG/
3 SMITHKLINE BEECHAM 5MG
/N11945/001/
N11945 001

DISOPYRAMIDE PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

DISOPYRAMIDE PHOSPHATE

/AB/ /KV/ /EQ/100MG BASE/

B* KV EQ 100MG BASE

DIVALPROEX SODIUM

TABLET; DELAYED RELEASE; ORAL

DEPARKOTEC

/AB/ /KV/ /EQ/250MG BASE/

B* KV EQ 250MG BASE

B* KV EQ 500MG BASE

/N19794/001/
/JUL/11/1990/
/N19794/002/
/JUL/11/1990/
N19794 001
JUL 11, 1990
N19794 002
JUL 11, 1990

/N11945/001/
/AUG/19/1988/
N11945 001
AUG 19, 1988

ERLATE DISODIUM

INJECTABLE; INJECTION
/DIETHYLAMINE ACETATE/
/AP/ STERIS/
3 STERIS

/150MG/ML/
150MG/ML

/N84356/001/
N84356 001

N20164 001
MAR 29, 1993

EFLORNIHINE HYDROCHLORIDE

/INJECTABLE; INJECTION/
/MERRELL/POW/
3 MERRELL DOW

/200MG/ML/
200MG/ML

/N19879/002/
N19879 002
NOV 28, 1990

ENCAINIDE HYDROCHLORIDE

/CAPSULE; POAL/
/ENKAID/
/3/ PARISTOL/

/50MG/
/25MG/
/30MG/
25MG
35MG
50MG

/N18981/002/
DEC 24, 1986
N18981 003
DEC 24, 1986
N18981 004
DEC 24, 1986

ENOXACIN

TABLET; ORAL
PENETREX
/3/ PARISTOL/POW/

/400MG/
/200MG/
400MG
200MG

+ RHONE POULENC RORER

/N19616/005/
DEC 31, 1991
N19616 004
DEC 31, 1991

ENDOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX
RHONE POULENC RORER

30MG/0.3ML

N20164 001
MAR 29, 1993

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCATHE HCL AND EPINEPHRINE
STERLING WINTHROP

0.01MG/ML; 2%
0.02MG/ML; 2%

N40057 002
FEB 26, 1993
N40057 001
FEB 26, 1993

LIDOCAINE HCL W/ EPINEPHRINE
/BEL/NAR/
/AP/ 3 BEL MAR
3

/N80757/001/
N80757 001
N80757 001
FEB 26, 1993

EPINEPHRINE; PROCAINE HYDROCHLORIDE

/INJECTABLE; INJECTION/
/PROCAINE/HCL/W/ EPINEPHRINE/
/BEL/NAR/
3 BEL MAR
3

/N80758/001/
N80758 001
N80758 001
FEB 26, 1993

ERGOLOID MESYLATES

TABLET; ORAL
HYDERGINE
/SANDUZ/
3 SANDUZ

/0.5MG/
0.5MG

/N17993/003/
N17993 003

TABLET; SUBLINGUAL

HYDROGENATED ERGOT ALKALOIDS
/ZENITH/
3 ZENITH

/0.5MG/
0.5MG

/N87186/001/
N87186 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
ERGOMAR
/FISOLIS/
/AP/ 2MG/
2MG

/N87643/001/
FEB 24, 1993

ERYTHROMYCIN

SOLUTION; TOPICAL

N87693 001
FEB 24, 1983

MYTHROMYCIN
CAPSULE, DELAYED REL PELLETS; ORAL

CAPSULE, DELAYED REL PELLETS; ORAL
/EPYC/SPTINKLES/
/+/FAULDING/ 125mg/

125MG

SWAB; TOPICAL

AT SYOSSET
G-SOLVET

/N50617/001/
 /001/21/1937/
 N50617 001
 OCT 21, 1937

TABLET, COATED PARTICLES; ORAL
PCE

N63211 001
JAN 29, 1993

N63211 001
JAN 29, 1993

16+ / ERYTHROMYCIN / OINTMENT; OPHTHALMIC / 4MG/GM /

ERYTHROMYCIN	5MG/GM
/AT/	5MG/GM
/PHARMACEDON	5MG/GM

3 PHARMADERM	5MG/GM
1441 / 0440N/4444 /	/ 5MG/GM/

AT/	PHARM/FAIR/	ENG/GM/
3	PHARMAFAIR	ENG/GM

3 PHARMAFATR 5MG/GM

POUNDER: /FOR/RS/COMPOUNDS/
/ERYTHROLYCAN/
/PÁDÚCK/ /166

100%

SOLUTION; TOPICAL
ERYTHRA-DERM
AT PADDOCK 2%

PADDOCK 2%

N62957 001
 JUL 21, 1988
 /N62957/001/
 /JUL 21, 1988/
 N62825 001
 OCT 23, 1987
 /N62825/001/
 /OCT 23, 1987/
 N62667 001
 FEB 05, 1988
 /N62667/001/
 /FEB 05, 1988/

N62751 001
JUL 30, 1993

/N50611/001/
 /SEP/09, /1986/
 N50611 002
 AUG 22, 1990
 N50611 001
 SEP 09, 1986
 /N50611/002/
 /AUG/22, /1990/

N62362 001
DEC 17, 1982

N63253 001
JUL 30, 1993
N63253 002
JUL 30, 1993

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROMYCIN LACTOBIONATE

/AB/ /LACTHIO/ /EQ 500MG BASE/VIAL/

/AB/ /LACTHIO/ /EQ 1GM BASE/VIAL/

Q LYPHOMED EQ 500MG BASE/VIAL

Q EQ 1GM BASE/VIAL

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC

+ ANAQUEST

+ /PUPHIT/

10MG/ML

250MG/ML

/LACTHIO/

/LACTHIO/

ESTRADIOL

TABLET; ORAL

ESTRACE

BRISTOL MYERS SQUIBB 0.5MG

ESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL

PREMARIN

+ AYERST

/LACTHIO/

0.625MG/GM

/LACTHIO/

TABLET; ORAL

PREMARIN

+ NYETH AYERST

/LACTHIO/

1.25MG

/LACTHIO/

/LACTHIO/

2.5MG

ESTROPIRATE

TABLET; ORAL

ESTROPIRATE

NATSON LABS

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

0.75MG

1.5MG

3MG

6MG

/LACTHIO/

OGEN 1.25

/AB/ /LACTHIO/

OGEN 2.5

+ ABBOTT

/LACTHIO/

OGEN 5

ABBOTT

> ADD > AB

> ADD > AB

> ADD > AB

> ADD > AB

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHIN 1/35E-21

ROBERTS

/LACTHIO/

/LACTHIO/

0.035MG; 1MG

/LACTHIO/

/LACTHIO/

N71480 001

APR 12, 1988

/LACTHIO/

/LACTHIO/

TABLET; ORAL-28

NORETHIN 1/35E-28

ROBERTS

/LACTHIO/

/LACTHIO/

0.035MG; 1MG

/LACTHIO/

/LACTHIO/

N71481 001

APR 12, 1988

/LACTHIO/

/LACTHIO/

ETHOSUXIMIDE

SYRUP; ORAL

ETHOSUXIMIDE

COPLY

AA

AA

ZARONTIN

PARKE DAVIS

250MG/5ML

250MG/5ML

N20216 001

JUN 30, 1993

N04782 001

JUN 30, 1993

/LACTHIO/

/LACTHIO/

/LACTHIO/

N04782 002

N81213 001

SEP 23, 1993

/LACTHIO/

/LACTHIO/

N81214 001

SEP 23, 1993

/LACTHIO/

/LACTHIO/

N81215 001

SEP 23, 1993

/LACTHIO/

/LACTHIO/

N81216 001

SEP 23, 1993

/LACTHIO/

/LACTHIO/

N83220 003

/LACTHIO/

/LACTHIO/

N83220 004

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL		FLUOCINOLONE ACETONIDE	
/PHARMAFAIR/		/0.01%/	
> DLT >	> /AT/	> DLT >	> /0.01%/
> DLT >	>	> DLT >	>
> DLT >	> /AT/	> DLT >	> /0.025%/
> DLT >	>	> DLT >	>
> ADD >	>	> ADD >	0.01%
> ADD >	>	> ADD >	>
> ADD >	>	> ADD >	0.025%
> ADD >	>	> ADD >	>

/N88499 001
 /AUG 02, 1984
 /N88506 001
 /AUG 02, 1984
 N88499 001
 AUG 02, 1984
 N88506 001
 AUG 02, 1984

ointment; topical

50MG/ML
/50MG/ML/[illegible]

/N88046/001
 /DEC 16, 1982
 N88046 001
 /N88047/001
 /FEB 27, 1984
 N88047 001
 /N88048/001
 /FEB 27, 1984
 N88048 001

SUSPENSION; ORAL

600MG/5ML

SOLUTION; TOPICAL
FLUOROTHOLONE ACETONIDE
a PENNEX PHARMS 0.01%
/AT/ /PHARM/BASICS/ /0.01%/

N88312 001
JAN 27, 1984
/N88312/001/
/JAN/27/1984/

CREAM: TOPICAL

FLUORALPHACETONIDE	
/Δt/	/PHARMACUM/
/Δt/	/0.01%
/Δt/	/0.025%
a PHARMACUM	0.01%
a	0.025%

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
PROZAC
LILLY

REQ 10MG BASE

NI8936 006
DEC 23, 1992

/N87791/001
 /JAN/18, 1983
 N87791 001
 JAN 18, 1983

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION
PROLOXIN DECANOATE
AA + APOTHECON
/AA/ /5001PB/

25MG/ML
/2501PB/

N16727 001
/N16727/001/

/TABLET; EXTENDED/RELEASE; ORAL/
/PERMITT/
/SCHERING/
@ SCHERING

/N12419/004/
N12419 004

FLUPHENAZINE ENANTHATE

INJECTABLE; INJECTION
PROLOXIN ENANTHATE
+ APOTHECON
/5001PB/

25MG/ML
/2501PB/

N16110 001
/N16110/001/

/N16849/001/
/SEP/13/1985/
N16849 001
SEP 13, 1985

TABLET; ORAL
FOLIC ACID
/AA/ /PIONEER/PHARMS/
@ PIONEER PHARMS

/1MG/
1MG

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

PROLOXIN
AA APOTHECON

5MG/ML

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

INJECTABLE; INJECTION
FUROSEMIDE
/ASTRA/

/10MG/ML/
10MG/ML

> DLT > /AP/
> DLT >
> ADD >
> ADD >

/N70014/001/
/SEP/09/1985/
N70014 001
SEP 09, 1985

ELIXIR; ORAL

FLUPHENAZINE HCL
COPELY

2.5MG/5ML

N81310 001
APR 29, 1993

SOLUTION; ORAL
FUROSEMIDE
AA PENNEX PHARMS

10MG/ML

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

2.5MG/5ML
/2.51PB/5ML/

/AA/ /PHARM/BASICS/
/10MG/ML/

INJECTABLE; INJECTION

PROLOXIN
AP + APOTHECON
/AP/ /5001PB/

2.5MG/ML
/2.51PB/ML/

N11751 005
/N11751/005/

TABLET; ORAL
FUROSEMIDE
/AB/ /PARKE/DAVIS/
/AB/ /40MG/
/AB/ /40MG/
/AB/ /40MG/

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

/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

TABLET; ORAL
PROLOXIN
APOTHECON

1MG
2.5MG
5MG
10MG
15MG
20MG
25MG
30MG
40MG
50MG

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

@ WARNER CHILCOTT

20MG

@

40MG

@

80MG

GADODIAMIDE

INJECTABLE; INJECTION
O'BUSCAN
STERLING WINTHROP

287MG/ML

N20123 001
JAN 08, 1993

TABLET; ORAL
GLUCOTROL
+ PFIZER

10MG
2.5MG
5MG

N17783 002
MAY 08, 1984
N17783 003
MAY 11, 1993
N17783 001
MAY 08, 1984
/N17783/002/
/N17783/003/
/N17783/001/
/MAY/08,1984/
/MAY/08,1984/

GENFIBROZIL

CAPSULE; ORAL
GENFIBROZIL
MYLAN

300MG

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

/+/ROPERID/

/1.0MG/
/5MG/

PUREPAC

300MG

LOPID
+ PARKE DAVIS

300MG

N18422 002

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION

GLUCAGON

TABLET; ORAL
GENFIBROZIL
LEDERLE

600MG

N74270 001
SEP 27, 1993

/ED 1MG BASE/VIAL/
EQ 1MG BASE/VIAL/
/ED 1MG BASE/VIAL/
/ED 1MG BASE/VIAL/
EQ 1MG BASE/VIAL

/N12122/001/
N12122 001
/N12122/001/
/MAR/06,1987/
N71022 001
MAR 04, 1987

LOPID
+ PARKE DAVIS

600MG

N18422 003
NOV 20, 1986

GENTAMICIN SULFATE

CREAM; TOPICAL
GENTAMICIN SULFATE
/FARNAM/

/ED 1MG BASE/GM/
EQ 1MG BASE/GM

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

CAPSULE; ORAL
DORTIDEN

/DORTIDEN/POULENC/ROPERID/500MG/

/N60519/001/

INJECTABLE; INJECTION
GENTAMICIN SULFATE
/WYETH/AYERST/

/ED 10MG BASE/ML/
EQ 10MG BASE/ML
EQ 40MG BASE/ML

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

TABLET; ORAL

/GLUCOTROL/
/POX/ /HOECHST/ROUSSEL/

/1.5MG/
/5MG/

/N20055/001/
/APR/17,1992/
/N20055/002/
/APR/17,1992/
N20055 001
APR 17, 1992
N20055 002
APR 17, 1992

OPHTHALMIC

/GENFIBROZIL/
/FARNAM/FAIR/

/ED 3MG BASE/GM/
EQ 3MG BASE/GM

/N62443/001/
/MAY/06,1983/
N62443 001
MAY 26, 1983

+ PHARMACIA

TABLET; ORAL

GLYNASE

/BX/ /LUPJCHN/

/:/

UP-JOHN

+

> ADD >
> ADD >

> ADD >
> ADD >

/X.5MG/
/3MG/
3MG
6MG
1.5MG
4.5MG
MAR 04, 1992
SEP 24, 1993
N20051 001
MAR 04, 1992
SEP 24, 1993
N20051 003

SOLUTION/DROPS; OPHTHALMIC
/HED-POLYCHN/
/AT/ /DOM/
@ DOM
10,000 UNITS/ML
N60427 001

GRISOEFLUVIN, MICROCRYSTALLINE

CAPSULE; ORAL

GRISACTIN
/MYETH/AYERST/
@ MYETH AYERST

/150051/001/
N50051 002

GONADORELIN ACETATE

INJECTABLE; INJECTION

LUTREPULSE KIT

+ FERRING

+

/LUPJCHN/

0.8MG/VIAL
3.2MG/VIAL
MAR 04, 1992
SEP 24, 1993
N20051 001
MAR 04, 1992
SEP 24, 1993
N20051 003

HALOFANTRINE HYDROCHLORIDE

TABLET; ORAL

HALOFANTRINE
/+/SHITKLINE/BEECHAM/

@ SMITHKLINE BEECHAM 250MG

/N20250 001/
JUL 24, 1992

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL
@ PENNEX PHARMS

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

@ BEL MAR

@

5,000 UNITS/VIAL
10,000 UNITS/VIAL
MAR 04, 1992
SEP 24, 1993
N20051 001
MAR 04, 1992
SEP 24, 1993
N20051 003

EQ 2MG BASE/ML

EQ 2MG BASE/ML

EQ 2MG BASE/ML

EQ 2MG BASE/ML

N70710 001
MAR 07, 1986
N73037 001
FEB 26, 1993
/N73037 001/
/MAR/07/1986/
N73364 001
SEP 28, 1993

GOSERELIN ACETATE

IMPLANT; IMPLANTATION

ZOLADEX

/+/SHITKLINE/BEECHAM/

+ ZENECA

EQ 3.6MG BASE

DEC 29, 1989
N17054 002

INJECTABLE; INJECTION

HALOPERIDOL

MARSAM

AP

AP

AP

AP

N72516 001
FEB 25, 1993
N72517 001
FEB 25, 1993
/N72517 001/
/DEC/14/1987/
/N72517 001/
/DEC/14/1987/

HALOPERIDOL LACTATEINJECTABLE; INJECTIONHALOPERIDOL

AP SOLOPAK

AP

EQ 5MG BASE/ML

N70801 001

DEC 14, 1987

EQ 5MG BASE/ML

N70864 001

DEC 14, 1987

HEPARIN SODIUMINJECTABLE; INJECTIONLINJAETIN SODIUM

AP

AP

/40,000 UNITS/ML/

/40,000 UNITS/ML/

20,000 UNITS/ML

40,000 UNITS/ML

/N00552/001/

/N00552/002/

N00552 001

N00552 002

HEXACHLOROPHENEAEROSOL; TOPICAL

/N00734/

/XITRIUM/

a XITRIUM

EMULSION; TOPICAL

/N00734/

/HUNTINGTON/

a HUNTINGTON

/32/

32

/32/

32

/32/

32

/32/

32

32

0.25%

/12/

12

/0.25%/

0.25%

/12/

12

/0.25%/

0.25%

HEXACHLOROPHENESPONGE; TOPICAL

/N00734/

/PROF/USPLS/

a PROF DSPLS

/N00734/

/STERLING/

a STERLING

/N00734/

/330MG/

a 3M

/32/

32

/32/

32

/32/

32

/32/

32

HEXAFLUORENIUM BROMIDE

/N00734/

/WALLACE/

a WALLACE

/N00734/

/20MG/ML/

20MG/ML

HISTAMINE PHOSPHATEINJECTABLE; INJECTION

/N00734/

/LILLY/

a LILLY

/N00734/

/EQ 0.1MG BASE/ML/

EQ 0.1MG BASE/ML

/N00734/

/EQ 0.2MG BASE/ML/

EQ 0.2MG BASE/ML

/N00734/

/EQ 1MG BASE/ML/

EQ 1MG BASE/ML

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATESYRUP; ORAL

/N00734/

/PENIEX PHARMS

a PENIEX PHARMS

/N00734/

/1.5MG/5ML; 5MG/5ML/

1.5MG/5ML; 5MG/5ML

N00734 001

MAR 03, 1983

/N00734/001/

/N00734/001/

/N00734/001/

/N00734/001/

HYDRALAZINE HYDROCHLORIDE; RESERPINE

/N00734/

/SERPINE/

a SERPINE

/N00734/

/50MG; 0.1MG/

50MG; 0.1MG

/N00734/

/50MG; 0.2MG/

50MG; 0.2MG

/N00734/001/

/N00734/001/

/N00734/001/

/N00734/001/

/N00734/001/

/N00734/001/

/N00734/001/

/N00734/001/

HYDROXOCOBALAMININJECTABLE; INJECTION

HYDROXYCOTIN
/AP/ /BEL/HAR/
3 BEL HAR

/1MG/ML/
1MG/ML

/N84629/001/
N84629 001

TABLET; ORAL

IBUPROFEN
NORTON HN

400MG

N71145 001
SEP 23, 1986

500MG

N71146 001
SEP 23, 1986

800MG

N71769 001
MAY 08, 1987

HYDROXYZINE HYDROCHLORIDEINJECTABLE; INJECTION

HYDROXYZINE HCL
FUJISANA

25MG/ML

N88184 001
MAR 31, 1983

50MG/ML

N88185 001
MAR 31, 1983

/10MG/ML/
10MG/ML

/N88186/001/
N88186 001

/10MG/ML/
10MG/ML

/N88187/001/
N88187 001

/10MG/ML/
10MG/ML

/N86258/001/
N86258 001

50MG/ML

N86258 002

SYRUP; ORAL

HYDROXYZINE HCL
BARRE

10MG/5ML

N88785 001
FEB 03, 1988

/10MG/5ML/
10MG/5ML

/N88786/001/
N88786 001

10MG/5ML

N87294 001
APR 12, 1982

/10MG/5ML/
10MG/5ML

/N87295/001/
N87295 001

IDOXURIDINE

/OPHTHALMIC;
/STOIC/
3 SMITHKLINE BEECHAM

/0.5%/
0.5%

/N15868/001/
N15868 001

SOLUTION/DROPS; OPHTHALMIC

/STOIC/
3 SMITHKLINE BEECHAM

/0.1%/
0.1%

/N13934/001/
N13934 001

INDAPAMIDETABLET; ORAL

LOZOL

RHONE POULENC RORER

1.25MG

N18538 002
APR 29, 1993

/N86827/001/
N86827 001

/N86828/001/
N86828 001

/N86829/001/
N86829 001

/N86830/001/
N86830 001

TABLET; ORAL

HYDROXYZINE HCL
CHELSEA

10MG

25MG

50MG

/N86831/001/
N86831 001

/N86832/001/
N86832 001

/N86833/001/
N86833 001

INJECTABLE; INJECTION

IODOHIPPURATE SODIUM I 131

/AP/ /CIS/
AP SORIN

/0.2MCI/ML/
0.2MCI/ML

/N17313/001/
N17313 001

IOHEXOL

/INJECTABLE; INJECTION/
/CHINPAQUE 180/
/STERLING/
/38.8%/
/N18956/001/
/DEC/26, 1985/

/SOLUTION; INJECTION; ORAL/
/CHINPAQUE 240/
/STERLING/
/51.8%/
/N18956/002/
/DEC/26, 1985/

/CHINPAQUE 300/
/STERLING/
/64.7%/
/N18956/003/
/DEC/26, 1985/

SOLUTION; INJECTION, ORAL, RECTAL
CHINPAQUE 180
+ STERLING
38.8%
N18956 001
DEC 26, 1985

CHINPAQUE 240
+ STERLING
51.8%
N18956 002
DEC 26, 1985

CHINPAQUE 300
+ STERLING
64.7%
N18956 003
DEC 26, 1985

IOTROLAN

/INJECTABLE; INTRATHORACIC/
/CHINPAQUE 180/
/STERLING/
/EQ 190MG IODINE/ML/
/DEC/07, 1989/
/N19580/002/
/DEC/07, 1989/

3 DERLEX

3

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
ATROVENT
+ BOEHRINGER INGELHEIM 0.02%
N20228 001
SEP 29, 1993

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

IRON DEXTRAN

INJECTABLE; INJECTION
INFED
BP + SCHEIN PHARM
/IRON/DEXTRAN/
/BP/ /STERIS/
EQ 50MG IRON/ML
/EQ/50MG/IRON/ML/
N17441 001
/N17441/001/

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL
/AN/ /ASTRA/
/0.125%/
/0.062%/
0.062%
0.125%
3 ASTRA
3
/AN/ /PARKE/DAVIS/
/0.5%/
0.5%
1%
3 PARKE DAVIS
3

/N87937/001/
/NOV/15, 1982/
/N87937/001/
/NOV/15, 1982/
/N87937 001/
NOV 15, 1982
N87938 001
NOV 15, 1982
/N85997/001/
/N85997 001/
N85889 001

/N87938/001/
/NOV/15, 1982/
/N87937/001/
/NOV/15, 1982/
/N87937 001/
NOV 15, 1982
N87938 001
NOV 15, 1982
/N85997/001/
/N85997 001/
N85889 001

ISOFLURANE

LIQUID; INHALATION

FORANE

AN + ANAQUEST

AN ISOFLURANE

AN ABBOTT

N17624 001

N74097 001

JAN 25, 1993

ISONIAZID

INJECTABLE; INJECTION

MYDRAZID

+ APOTHECON

/300MG/

100MG/ML
/100MG/ML/

N08662 001
/N08662/001/

TABLET; ORAL

ISONIAZID

/AA/ /EON/LABS/

AA + EON LABS

/AA/ /AA/

AA +

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

/N08678/002/
N08678 002
/N08678/003/
N08678 003

LEUCOVORIN CALCIUM

TABLET; ORAL
LEUCOVORIN CALCIUM
ROXANE

AB
EQ 5MG BASE
AB
EQ 10MG BASE
AB
EQ 15MG BASE
AB
EQ 25MG BASE

N72733 001
FEB 22, 1993
N72734 001
FEB 22, 1993
N72735 001
FEB 22, 1993
N72736 001
FEB 22, 1993

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON
/3//33/

+ TAP
5MG/ML
5MG/ML

LUPRON DEPOT
+ TAP
3.75MG/VIAL
7.5MG/VIAL

+
3.75MG/VIAL
7.5MG/VIAL

LUPRON DEPOT-PED
+ TAP
3.75MG/VIAL & 7.5MG/VIAL
7.5MG/VIAL & 7.5MG/VIAL
7.5MG/VIAL

N20011 001
OCT 22, 1990
N19732 001
JAN 26, 1989
N120011/001/
/OCT/22/1990/
/N19732/001/
/JAN/26/1989/
N20263 003
APR 16, 1993
N20263 004
APR 16, 1993
N20263 002
APR 16, 1993

LEVONETHADYL ACETATE HYDROCHLORIDE

CONCENTRATE; ORAL
ORLAAM
BIODEVELOPMENT

10MG/ML
/BIONE/PE/5/

N20315 001
JUL 09, 1993
/N20315/001/
/JUL/09/1993/

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

LEVONORDEFIN; PROCAINE HYDROCHLORIDE; PROPOXYCAINE
HYDROCHLORIDE

/INJECTABLE; INJECTION/
/PROCAINE AND NOVOCAIN/ /NEO-CODEF/ /
/CODE/ /
STERLING WINTHROP
0.05MG/ML; 2%; 0.4%

/N08592/001/
N08592 007

LIDOCAINE

/SOLUTION; INJECTION/
/LIDOCAINE/
/ASTRA/
ASTRA

/N13077/001/
N13077 001

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
/BEL/ /HAR/

/AP/ /
/AP/ /
BEL MAR
ASTRA

/N08076/001/
/N08076/001/
N80760 001
N80710 001

/AP/ /
/AP/ /
FUJISAWA

/N08039/001/
/N08039/001/
N80404 002
N80404 003

/AP/ /
/AP/ /
LYPHOMED
LYPHOMED

/N08039/001/
/N08039/001/
N80404 002
N80404 003

/AP/ /
/AP/ /
LYPHOMED
LYPHOMED

/N08039/001/
/N08039/001/
N80404 002
N80404 003

JELLY; TOPICAL
LIDOCAINE HCL
AT
COPLY

N81318 001
APR 29, 1993

SOLUTION; ORAL
MYLOCAINE
PENNEX PHARMS

AT
/AT/ /
/AT/ /

N87872 001
NOV 18, 1982
/N87872/001/
/NOV/18/1982/

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL

/blydcaine/

/AT/ /PHARM/BASICS/

/42/

/N87881/001/

/AD/

/ZESTRIL/

/5MG/

/MAY 19, 1988/

@ PENNEX PHARMS

42

N87881 001

/AD/

/ZESTRIL/

/10MG/

/MAY 19, 1988/

LINDANE

42

N88190 001

/AD/

/ZESTRIL/

/5MG/

MAY 19, 1988

LOTION; TOPICAL

LINDANE

AT PENNEX PHARMS

42

AUG 16, 1984

/AD/

/ZESTRIL/

/10MG/

MAY 19, 1988

/AT/ /PHARM/BASICS/

/42/

/N88190/001/

/AD/

/ZESTRIL/

/20MG/

MAY 19, 1988

SHAMPOO; TOPICAL

42

N88191 001

/AD/

/ZESTRIL/

/2.5MG/

APR 29, 1993

LINDANE

42

N88191 001

/AD/

/ZESTRIL/

/40MG/

MAY 19, 1988

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LIOTRIX (T4;T3)

42

N88191 001

/AD/

/ZESTRIL/

/300MG/

SEP 23, 1993

LISINOPRIL

TABLET; ORAL

ZESTRIL

/AD/ /SMITHKLINE/BEECHAM/

/5MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/10MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/20MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/40MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/50MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/100MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/200MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/400MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/800MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/1600MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/3200MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/6400MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/12800MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/25600MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/51200MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/102400MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/204800MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/409600MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/819200MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/1638400MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/3276800MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/6553600MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/13107200MG/

/MAY 19, 1988/

/AD/ /SMITHKLINE/BEECHAM/

/26214400MG/

/MAY 19, 1988/

$$\begin{array}{r} > \text{ADD} > \\ > \text{ADD} > \\ > \text{ADD} > \\ > \text{ADD} > \end{array}$$

N19658 001
 APR 12, 1993

SUSPENSION; ORAL
MEGACE
+ BRISTOL MYERS

N20264 001
SEP 10, 1993

2-METHYLMENADIOL SODIUM DIPHOSPHATE

/INJECTABLE:/INJECTION/
/SÝNKÁVITĚ/EQ 85MG BASE/GM
/EQ/85MG/BASE/GM/

NI6763 001
/NI6763/001/

/N03718/004/
 /N03718/005/
 /N03718/006/
 N03718 004
 N03718 006
 N03718 008

5MG/ML
10MG/ML
37.5MG/ML
5MG/ML
10MG/ML
37.5MG/ML

MANGANESE SULFATE

ROCHE

INJECTABLE; INJECTION
MANGANESE SULFATE

EQ 0.1MG MANGANESE/ML

N19228 001
MAY 05, 1987
/N19228/001/
MAY/05, 1987/

TABLET; /ORAL/
/SÝNKA VÝTĚ/
/RÓCHÉ/
a ROCHE

/L'YRHDMEB/

010 8120N
/010/010/010/

MANNITOL

INJECTABLE; INJECTION

AP	MCGAW	10GM/100ML
<u>MAINTAIN 10% IN PLASTIC CONTAINER</u>		

N20006 002
JUL 26, 1993

AP	MCGAN	15GM/100ML	<u>MANITOL 15% IN PLASTIC CONTAINER</u>
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N20006 003
JUL 26, 1993

AP	MCGAW	20CM/100ML	<u>MAINTAIN 20% IN PLASTIC CONTAINER</u>
----	-------	------------	--

N20006 004
JUL 26, 1993

AP	MCGAW	5GM/100ML
<u>MAINTAIN 5% IN PLASTIC CONTAINER</u>		

N20006 001
JUL 26, 1993

MASOPROCOL

CREAM; TOPICAL
ACTINEX
+ BLOCK DRUG

10%

N19940 001
 SEP 04, 1992
 /N19940/661/
 /SEP/64/1992/

15091

SEP 04, 1992
/N19946/661/
/SEP/64/1992/

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL
ASTRA

AP	10MG/ML	N81002 001 JUL 30, 1993
> DLT > /AP/	/45MG/ML/	/N89781/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/	/50MG/ML/	/N89782/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/	/50MG/ML/	/N89783/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/	/45MG/ML/	/N89784/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/	/40MG/ML/	/N89785/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/		/N89786/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/		/N89787/001/
> DLT >		/MAR/31/1989/
> DLT > /AP/		/N81309 001/
> DLT >		AUG 30, 1993
> ADD >	25MG/ML	N89781 001
> ADD >		MAR 31, 1989
> ADD >	50MG/ML	N89782 001
> ADD >		MAR 31, 1989
> ADD >	50MG/ML	N89783 001
> ADD >		MAR 31, 1989
> ADD >	75MG/ML	N89785 001
> ADD >		MAR 31, 1989
> ADD >	100MG/ML	N89786 001
> ADD >		MAR 31, 1989
> ADD >	100MG/ML	N89787 001
> ADD >		MAR 31, 1989
> ADD >	10MG/ML	N81309 001
> ADD >		AUG 30, 1993

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE
LEE LABS

AA/	400MG/	/N89538/001/
		/NOV/25/1989/
	400MG	N89538 001
		NOV 25, 1989

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL
PENTASA
+ MARION MERRELL DOW

	250MG	N20049 001
		MAY 10, 1993

MESTRANOL; NORETHINDRONE

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

	/0.1MG;2MG/	/N13625/004/
		N13625 004

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

AB	0.05MG;1MG	N71539 001
		APR 12, 1988
		/N1553/001/
		/APR/12/1988/

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

AB	0.05MG;1MG	N71540 001
		APR 12, 1988
		/N1554/001/
		/APR/12/1988/

MESTRANOL; NORETHYNODREL

/TABLET; ORAL-/
/SYNTEX/
/SYNTEX/
@ SEARLE

	/0.15MG;0.85MG/	/N10976/008/
		N10976 008
		0.075MG;5MG
		0.15MG;9.85MG
		N10976 005

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE
@ PENNEX PHARMS

AA/	5%	N72190 001
		JUN 07, 1988
		/N172190/001/
		/JUN/07/1988/

SYRUP; ORAL

METAPROTERENOL SULFATE

AA	10MG/5ML	N71656 001
		OCT 13, 1987
		/N71656/001/
		/OCT/13/1987/

INJECTABLE; INJECTION

METARACINOL BITARTRATE

AP FUJISAWA
AP
/AP/ /Lypionef/
/AP/ EQ 10MG BASE/ML
/AP/ EQ 10MG BASE/ML
/AP/ EQ 10MG BASE/ML

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

EQ 10MG BASE/ML

N40001 001
JUN 30, 1993
N40001 002
JUN 30, 1993
N40036 001
JUN 30, 1993
N40036 002
JUN 30, 1993

METHADONE HYDROCHLORIDE

TABLET; ORAL

METHADONE

AA MALLINCKRODT

5MG

N40050 001

N11721 002

AA

10MG

APR 15, 1993

NOV 25, 1991

TABLET, DISPERSIBLE; ORAL

METHADONE HCL

AA LILLY

40MG

N17058 001

N61449 001

AA

METHADONE

40MG

N74184 001

N61449 002

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

METHAMPHETAMINE HCL

AA LEMMON

10MG

/N83889/001/

N85454 001

AA

METHAMPHETAMINE HCL

5MG

/N86359/001/

N85033 001

AA

METHAMPHETAMINE HCL

10MG

/N86359/001/

N85033 001

AA

METHAMPHETAMINE HCL

10MG

/N86359/001/

N85033 001

METHANTHELINE BROMIDE

TABLET; ORAL

BANTHINE

AA

50MG

N07390 001

N87453 001

AA

METHANTHELINE BROMIDE

50MG

/N07390/001/

N87454 001

TABLET; ORAL

METHANTHELINE BROMIDE

AB

25MG

N40001 001

AB

50MG

N40001 002

AB

25MG

N40036 001

AB

50MG

N40036 002

NEPTAZANE

AB

25MG

N11721 002

AB

50MG

N11721 001

METHICILLIN SODIUM

INJECTABLE; INJECTION

STAPHICILLIN

+

APOTHECON

EQ 900MG BASE/VIAL

N61449 001

+

APOTHECON

EQ 3.6GM BASE/VIAL

N61449 002

+

APOTHECON

EQ 5.4GM BASE/VIAL

N61449 003

+

APOTHECON

EQ 9.0GM BASE/VIAL

N61449 004

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

AA

500MG

N85454 001

AA

METHOCARBAMOL

750MG

N85033 001

AA

METHOCARBAMOL

750MG

N85033 001

AA

METHOCARBAMOL

750MG

N85033 001

AA

METHOCARBAMOL

750MG

N85033 001

3

PIONEER PHARMS

500MG

N88731 001

3

PIONEER PHARMS

750MG

N89082 001

3

PIONEER PHARMS

750MG

N89082 001

3

PIONEER PHARMS

750MG

N89082 001

3

PIONEER PHARMS

750MG

N89082 001

METHOTREXATE, SODIUM

INJECTABLE; INJECTION
METHOTREXATE SODIUM

/AB/ /AKQIN/ /EQ 25MG BASE/ML/ /N86648 /001/
/AB/ /LYPHOMED/ /EQ 25MG BASE/ML/ /N89143 /001/
EQ 25MG BASE/ML /N89144 /001/
EQ 25MG BASE/ML /N89145 /001/
AP NORBROOK JUN 13, 1986
EQ 25MG BASE/ML /N89146 /001/
MAY 09, 1986

METHOXYFLURANE

/SOLUTIONS /ANALATION/
/PENTHRANE/
/ABEOTT/

/99.9%/
/N13056 /003/

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION
METHYLDOPATE HCL

/AB/ /LYPHOMED/ /50MG/ML/ /N70652 /001/
EQ 50MG/ML /N70652 /001/
JUN 03, 1986

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

/AB/ /CHELSEA/ /4MG/ /N86161 /001/
B* CHELSEA 4MG /N86161 /001/
FEB 09, 1982

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

/M-PREDROL/ /40MG/ML/ /N86666 /001/
/BEL/MAR/ /40MG/ML/ /N86666 /001/
EQ BEL MAR 80MG/ML /N87135 /001/
EQ 80MG/ML /N87135 /001/

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

/AB/ /LYPHOMED/ /EQ 40MG BASE/VIAL/ /N89143 /001/
/AB/ /EQ 125MG BASE/VIAL/ /N89144 /001/
/AB/ /EQ 500MG BASE/VIAL/ /N89145 /001/
/AB/ /EQ 1GM BASE/VIAL/ /N89146 /001/
EQ 40MG BASE/VIAL /N89143 /001/
EQ 125MG BASE/VIAL /N89144 /001/
EQ 500MG BASE/VIAL /N89145 /001/
EQ 1GM BASE/VIAL /N89146 /001/
MAR 28, 1986
MAR 28, 1986
MAR 28, 1986
MAR 28, 1986

METHYLTESTOSTERONE

CAPSULE; ORAL
METHYLTESTOSTERONE

/BP/ /HEATHER/ /10MG/ /N84967 /001/
EQ 10MG /N84967 /001/

TESTED
/BP/ /ICN/ /10MG/ /N83976 /001/
BP + ICN 10MG /N83976 /001/

METHYPRYLON

/CAPSULE /ORAL/
/ROCHE/ /300MG/ /N86660 /000/
EQ ROCHE 300MG /N86660 /000/

/TABLET /ORAL/
/ROCHE/ /200MG/ /N89660 /004/
EQ ROCHE 200MG /N89660 /004/

NIACIN

CAPSULE; ORAL
/NALLACE/
a NALLACE

/500MG/
500MG

/N11073/001/
N11073 003

CAPSULE; ORAL
NITROFURANTOIN
ZENITH

50MG

N73671 001
JAN 28, 1993
N73652 001
JAN 28, 1993

TABLET; ORAL

NIACIN
/ZENITH/
a ZENITH

/500MG/
500MG

/N83180/001/
N83180 001

NITROGLYCERIN

INJECTABLE; INJECTION
NITRO-BID
/MARION/MERRELL/DOW/ /10MG/ML/

CAPSULE; ORAL
NIFEDIPINE
FLEMINGTON

10MG

N72781 001
JUL 30, 1993

/N71159/001/
/FEB/28/1993/
N71159 001
FEB 28, 1990

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC
HILES

30MG

N20198 001
APR 21, 1993

60MG

N20198 002
APR 21, 1993

90MG

N20198 003
APR 21, 1993

PROCARDIA XL
BC + PFIZER

30MG

N19684 001
SEP 06, 1989

60MG

N19684 002
SEP 06, 1989

90MG

N19684 003
SEP 06, 1989

/30MG/

/N19684/001/
/SEP/06/1989/

/60MG/

/N19684/002/
/SEP/06/1989/

/90MG/

/N19684/003/
/SEP/06/1989/

CAPSULE; ORAL

NORTRIPTYLINE HCL
MYLAN

AB

EQ 10MG BASE

N74234 001
JUL 26, 1993

AB

EQ 25MG BASE

N74234 002
JUL 26, 1993

AB

EQ 50MG BASE

N74234 003
JUL 26, 1993

AB

EQ 75MG BASE

N74234 004
JUL 26, 1993

NORTRIPTYLINE HYDROCHLORIDE

NIACIN

CREAM; TOPICAL

MYSTATIN
BARRE

AT

100,000 UNITS/GM

N62949 001
JUN 13, 1988

/AT/

/100,000 UNITS/GM/

/N62949/001/
/JUN/13/1988/

AT

100,000 UNITS/GM

N64022 001
JAN 29, 1993

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN
ZENITH

/500MG/

/N80078/002/
N80078 002

/100MG/

/N80078 001/
N80078 001

ointment; TOPICAL

MYSTATIN
BARRE

AT

100,000 UNITS/GM

N62840 001
NOV 13, 1987

/AT/

/100,000 UNITS/GM/

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

OXPRENOLOL HYDROCHLORIDE

/CAPSULE; ORAL/
/PARKE/DAVIS/
/CIBA/

/150MG/

/150MG/

/150MG/

/150MG/

3 CIBA

3

3

3

3

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

/N18166/001/
/DEC/28, 1983/

OXTRIPHYLLINE

SOLUTION; ORAL

CHOLEBYL

/AA/ /PARKE/DAVIS/

PARKE DAVIS

/AA/ /PARKE/DAVIS/

/PARKE/DAVIS/

3 PENNEX PHARMS

/100MG/5ML/

100MG/5ML

/100MG/5ML/

100MG/5ML

SYRUP; ORAL

CHOLEBYL

/AA/ /PARKE/DAVIS/

PARKE DAVIS

/AA/ /PARKE/DAVIS/

/PARKE/DAVIS/

3 PENNEX PHARMS

/50MG/5ML/

50MG/5ML

/50MG/5ML/

50MG/5ML

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

AREIDIA

+ CIBA GEIGY

+

60MG/VIAL

90MG/VIAL

N20036 003

MAY 06, 1993

N20036 004

MAY 06, 1993

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

/ASTRA/

& ASTRA

& ADD >

> ADD >

/2MG/ML/

2MG/ML

/N17212/001/

/MAR/31, 1988/

N72212 001

MAR 31, 1988

PARAMETHASONE ACETATE

TABLET; ORAL

HALDRONE

/LILLY/

& LILLY

&

/1MG/

1MG

2MG

/N12772/005/

/N12772/005/

N12772 005

N12772 006

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAXIL

/SANTALINI/

/SANTALINI/

/SANTALINI/

/SANTALINI/

/SANTALINI/

/SANTALINI/

/SANTALINI/

/SANTALINI/

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/SANTALINI/

/SANTALINI/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

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/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/EQ/10MG/PAKSE/

/N20031 001

DEC 29, 1992

/N20031 005

DEC 29, 1992

/N20031 005

DEC 29, 1992

/N20031 004

DEC 29, 1992

/N20031 004

DEC 29, 1992

/N20031 004

DEC 29, 1992

/N20031 004

DEC 29, 1992

/N20031 004

DEC 29, 1992

/N20031 004

DEC 29, 1992

/N20031 004

DEC 29, 1992

PENTOBARBITAL SODIUM

INJECTABLE; INJECTION
/PENTOBARBITAL SODIUM/
/ELKINS-SINN/
@ ELKINS SINN

/50MG/ML/
50MG/ML

/N83270/001/
N83270 001

/AA/ /FERNDALE/
/35MG/

/N86834/001/
/SEP/15/1983/
N86834 001
SEP 15, 1983

PERFLUBRON

LIQUID; ORAL
IMAGENT
+ ALLIANCE PHARM

100%

N20091 001
AUG 13, 1993

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
ADTEK-P
/LEMON/
/ORANGE/
/FERNDALE/
@ FERNDALE

/AA/ /30MG/
/AA/ /30MG/
@ FERNDALE
30MG

/N86911/001/
/N86329/001/
N87144 001

PERMETHRIN

/LOTION; TOPICAL/
/NIN/
/AT/ /BURROUGHS WELLCOME/ /1%/
@ BURROUGHS WELLCOME

1%

/N19435/001/
/MAR/31/1986/
N19435 001
MAR 31, 1986

PHENTERMINE HCL

@ LEMON
/ZENITH/
@ ZENITH

/AA/ /30MG/
/AA/ /30MG/
@ ZENITH
30MG

N86911 001
/N86329/001/
N86329 001

PERPHENAZINE

/TABLET; EXTENDED RELEASE; ORAL/
/TRIAXON/
/SCHERING/
@ SCHERING

/8MG/
8MG

/N11361/002/
N11361 002

> ADD > AB
> ADD >
> DLT > /B#/
> DLT >

/100MG/
/100MG/
/100MG/

N87756 001
DEC 17, 1982
/N87756/001/
/DEC/17/1982/

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL
/STANTON/
/LEMON/
@ LEMON

/35MG/
35MG

/N85507/001/
N85507 001

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE VC PLATH
@ PENNEX PHARMS

/AA/ /PHARM/BASIC/
/5MG/5ML; 6.25MG/5ML/
5MG/5ML; 6.25MG/5ML

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

PHYTONADIONE

INJECTABLE; INJECTION
AQUAPHYTON
/BP/ /MSD/
BP + MSD

/10MG/ML/
10MG/ML

/N12223/001/
N12223 001

PHENDIMETRAZINE TARTRATE

/ANABOLIC/
@ ANABOLIC

/35MG/
35MG

/N86020/001/
N86020 001

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

NY 1745/003

/N73398/001
 JAN 28, 1992
 /N72427/001
 MAR 28, 1990

SAVAGE

N73608 001

INJECTABLE; I

FUJISAWA
AP —
ZMEQ/HL
ZMEQ/HL

1818 1819

AP/	2 MEG/M	2 MEG/M
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9
10	10	10
11	11	11
12	12	12
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94	94	94
95	95	95
96	96	96
97	97	97
98	98	98
99	99	99
100	100	100

1971 1972

TABLET, EXTENDED RELEASE; ORAL

AB ALRA

KAON CL

SAVAGE

/BC/ /ADRIA/

POTASSIUM CITRATE

/+/UNIV/IX/

[illegible]

e VINU XL TX

20MEQ/PACKET

OCT 13, 1988
N19647 001
OCT 13, 1988

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL
POTASSIUM CITRATE

/SHEA/
UNIV TX

10MEQ

5MEQ

/N19071/002/
AUG 31, 1992

/N19071/001/
AUG 30, 1985

0.25%; 10%

OINTMENT; OPHTHALMIC

CETAPRED

ALCON

N87771 001

AUG 06, 1993

SUSPENSION/DROPS; OPHTHALMIC

/PREDNISOLONE/

/PHARMACIA/

3 PHARMAFAIR

0.5%; 10%

0.5%; 10%

N88007 001

APR 19, 1983

PRAVASTATIN SODIUM

TABLET; ORAL

PRIVACHOL

/SHEA/
BRISTOL MYERS SQUIBB

40MG

20MG

/N19898/004/
MAR 22, 1993

/N19898/003/
OCT 31, 1991

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

EQ 0.23% PHOSPHATE; 10%

STERIS

EQ 0.23% PHOSPHATE; 10%

EQ 0.23% PHOSPHATE; 10%

EQ 0.23% PHOSPHATE; 10%

N18988 001

AUG 26, 1988

PRAZEPAM

TABLET; ORAL

CENTRAX

/SHEA/
PARKE DAVIS

10MG

/N17415/001/
SEP 23, 1991

/N17415/001/
SEP 23, 1991

PREDNISONE

SOLUTION; ORAL

PREDNISONE

3 PENNEX PHARMS

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

5MG/5ML

PREDNICARBATE

OINTMENT; TOPICAL

PREDNICARBATE

HOECHST ROUSSEL

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

0.1%

PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

WEST WARD

5MG

5MG

5MG

5MG

5MG

5MG

5MG

5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

2.5MG

N09986 005

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

/N09986/005/
AUG 02, 1988

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

/BP/ /CIRCA/

@ CIRCA

/BP/ /ZENITH/

@ ZENITH

/25MG/

25MG

/50MG/

50MG

/N83204/001

N83204 001

/N83613/001

N83613 001

/SUSPENSION; INTRATRACHEAL/

/VIOGOSIL/001/

@ GLAXO

/60% /

/N83609/002

N83609 002

PROPOFOL

INJECTABLE; INJECTION

DIPRIVAN

/ICX/

+ ZENECA

/10MG/ML/

10MG/ML

/N19627/001

N19627 001

OCT 02, 1989

INJECTABLE; INJECTION

PROTAMINE SULFATE

/AP/ /QUAD/

@ QUAD

/10MG/ML/

10MG/ML

/N83306/001

N83306 001

MAY 30, 1986

PROPRANLOL HYDROCHLORIDE

SOLUTION; ORAL

PROPRANLOL HCL

@ PENNEX PHARMS

@

/S/ PHARM/BASICS/

/S/

20MG/5ML

40MG/5ML

/20MG/5ML/

/40MG/5ML/

N71984 001

MAR 03, 1989

N71985 001

MAR 03, 1989

/N71984/001

/N71985/001

/N71985/001

/MAR/03/1989

SYRUP; ORAL

/HISTAFED/

/LIFE/LABS/

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

30MG/5ML; 1.25MG/5ML

/N88283/001

N88283 001

APR 20, 1984

PYRANTEL PAMOATE

/SUSPENSION; ORAL/

/ANTHIN/

/S/ROEHS/

/60/250MG/PASTE/5ML/

/N16883/001

/SUSPENSION; ORAL/

/ANTHIN/

/ANTHIN/AYERST/

@ WYETH AYERST

/10MG/ML/

10MG/ML

/N19536/001

/DEC/12/1986

N19536 001

DEC 12, 1986

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

/AP/ /ROCHE

/5MG/ML/

/N09830/001

N09830 001

TABLET; ORAL

PROPRANLOL HCL

/AP/ /MYLAN/

@ MYLAN

/60MG/

60MG

/N72275/001

JUN/09/1989

N72275 001

JUN 09, 1989

SYRUP; ORAL

MESTINON

/JCN/

ROCHE

/60MG/5ML/

60MG/5ML

/N15193/001

N15193 001

TABLET; ORAL

MESTINON

/S/ /JCN/

+ ROCHE

/60MG/

60MG

/N09829/002

N09829 002

TABLET, EXTENDED RELEASE; ORAL

MESTINON
/+/ICN/
+ ROCHE

/N11665/001/
N11665 001

BP +
/BP/ /SQUIBB/
/BP/ /

50MG
100MG
/50MG/
/100MG/

N08842 001
N08842 002
/N08842/001/
/N08842/002/

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

/BP/ /LILLY/
+ LILLY

/100MG/ML/
100MG/ML

/N80854/001/
N80854 001

BP +
/BP/ /LILLY/
/BP/ /

/N80854/001/
/N80854/002/
/N80854/003/
/N80854/004/

PYRIDOXINE HCL

/BP/ /DEL/MAR/
+ DEL MAR
AP FUJISAWA
/BP/ /FUJISAWA/

/100MG/ML/
100MG/ML
100MG/ML
/100MG/ML/

/N80761/001/
N80761 001
N80618 001
/N80618/001/

BP +
/BP/ /LEMON/
+ LEMON
+ 0.25MG

/N80618/001/
/N80618/002/
/N80618/003/
/N80618/004/

QUAZEPAM

TABLET; ORAL

DORAL
/+/WAKER/NORICH/

/15MG/
/15MG/

+ WALLACE

15MG
7.5MG

/N18708/001/
DEC 27, 1985
N18708 003
FEB 26, 1987

BP +
/BP/ /SCHERING/
+ SCHERING

/N12265/001/
N12265 003

RESERPINE; TRICHLORMETHIAZIDE

TABLET; ORAL

/BP/ /SCHERING/
+ SCHERING

/0.1MG; 4MG/
0.1MG; 4MG

RIMANTADINE HYDROCHLORIDE

SYRUP; ORAL

FLUMADINE
+ FOREST LABS

50MG/5ML

N19650 001
SEP 17, 1993

TABLET, EXTENDED RELEASE; ORAL

/BP/ /WARNER CHILCOTT/
+ WARNER CHILCOTT

/330MG/
330MG

/N17917/001/
N17917 001

BP +
/BP/ /FOREST LABS/
+ FOREST LABS

100MG

N19649 001
SEP 17, 1993

QUINIDINE SULFATE

TABLET; ORAL

/BP/ /WARNER CHILCOTT/
+ WARNER CHILCOTT

/200MG/
200MG

/N83879/001/
N83879 001

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL

/AP/ /QUAD/

3 QUAD

/10MG/ML/

10MG/ML

/N70700/001/
/DEC/86./1986/

N70700 001
OCT 06, 1986

SODIUM BICARBONATE

/ANJECTABLE; INJECTION/

/SODIUM/BICARBONATE/IN/PLASTIC/CONTAINER/

3 ABBOTT

3

0.9MEQ/ML
1MEQ/ML

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

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

SELENIUM SULFIDE

3 PENNEX PHARMS

2.5%

/AT/ /HARP/PLASTIC/

/4.52/

N88228 001
SEP 01, 1983
/N88228/001/
/SEP/83./1983/

SERACITIDE ACETATE

/INJECTABLE; INJECTION/
/ACETATE/SEL-SYNTHETIC/

/AP/

3 ARMOUR

3

/40/UNITS/ML/
/40/UNITS/ML/
40 UNITS/ML
80 UNITS/ML

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

SILVER SULFADIAZINE

/DRESSINGS/ TOPICAL/

/SILVADIAZ/

3 BIOPLASTY

1%

N19608 001
NOV 30, 1989

/SILVADIAZ/
/ENQUAY/

1%

/N19608/001/
/NOV/89./1989/

SODIUM BICARBONATE

/INJECTABLE; INJECTION/

/SODIUM/BICARBONATE/IN/PLASTIC/CONTAINER/

/ABBOTT/

/1MEQ/ML/

/50MCI/ML/
50MCI/ML

SOLUTION; ORAL

SODIUM IODIDE I 131

/CIS/
CIS

/N19443/001/
/JUN/83./1986/
/N19443/002/
/JUN/83./1986/

INJECTABLE; INJECTION

BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP FUJISAWA

2MG/ML

/AP/ /1.5PH/0H/EP/

/2MG/ML/

N88911 001
FEB 07, 1985
/N88911/001/
/FEB/85./1985/

SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER

3 FUJISAWA

234MG/ML

/3/ /1.5PH/0H/EP/

/23.4MG/ML/

N19329 001
APR 22, 1987
/N19329/001/
/APR/87./1987/

SODIUM CHROMATE, CR-51

INJECTABLE; INJECTION

CHROMITOPES SODIUM

/SQUID/

3 SQUIDB

/2MCI/VIAL/
2MCI/VIAL

/N13993/002/
N13993 002

SODIUM IODIDE, I-131

CAPSULE; ORAL

SODIUM IODIDE I 131

/3/CIS/
3 CIS

/50/UCI/
50 UCI
/100/UCI/
100 UCI

/N17316/001/
N17316 001
/N17316/002/
N17316 002

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
a PENNEX PHARMS 453.6GM/BOT
/AA/ /PHARM/PA/S/CS/ /453.6GM/BOT/

SUSPENSION; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
a PENNEX PHARMS 15GM/60ML
/AA/ /PHARM/PA/S/CS/ /15GM/60ML/

SOYBEAN OIL

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

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AB/ /CHELSEA/ 25MG
B* CHELSEA
/AB/ /UPSHER/SMITH/ 25MG
a UPSHER SMITH

STRONTIUM CHLORIDE, SR-89

INJECTABLE; INJECTION
METASTRON
MEDI PHYSICS IMCI/ML

SULFACETAMIDE SODIUM

ointment; OPHTHALMIC
/SULFACET/10/
a PHARMAFAIR/ /10%/
> DLT >
> DLT >
> DLT >

SULFACETAMIDE SODIUM

ointment; OPHTHALMIC
/SULFACET/10/
a PHARMAFAIR 10%
> DLT >
> ADD >
> ADD >

SULFADIAZINE

TABLET; ORAL
SULFADIAZINE
/ABBOTT/ 300MG
a ABBOTT

SULFAMETHIZOLE

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

SULFAMETHOXAZOLE

TABLET; ORAL
/SANTALINOL-D/S/ 1GM
/ROCHE/ 1GM
a ROCHE

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
TRIMETH/SULFA
AB BARRE 200MG/5ML; 40MG/5ML
AB 200MG/5ML; 40MG/5ML
/AB/ /NAXA/ 200MG/5ML; 40MG/5ML
/AB/ 200MG/5ML; 40MG/5ML
N72289 001
MAY 23, 1988
N72398 001
MAY 23, 1988
/N72289/001/
/NAX/23/1988/
/N72398/001/
/NAX/23/1988/

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE
/AB/ /HEATHER/ 500MG
a HEATHER

N88000 001
DEC 22, 1982

/N06125/005/
N04125 005

/N06565/001/
N08565 001

/N12715/003/
N12715 003

N72289 001
MAY 23, 1988
N72398 001
MAY 23, 1988
/N72289/001/
/NAX/23/1988/
/N72398/001/
/NAX/23/1988/

/N06125/001/
N80189 001

N20134 001
JUN 18, 1993

/N06000/001/
DEC/22/1982/

SULFISOXAZOLE ACETYL

/EMULSION; ORAL/
/LIPID/EMULSION/
/ROCHE/
@ ROCHE

/ED/10MG/BASE/PHL/
EQ 1GM BASE/5ML

/N09182/009/
N09182 009

N17916 001

SULFISOXAZOLE DIOLAMINE

/DIAMINATE; ORAL/
/LIPID/EMULSION/
/ROCHE/
@ ROCHE

/ED/40MG/BASE/
EQ 4% BASE

/N08414/002/
N08414 002

N17792 001
/N17792/001/
/N17773/001/
N17773 001

SULINDAC

TABLET; ORAL

SULINDAC
MYLAN

AB

AB

150MG

200MG

N73038 001
JUN 22, 1993
N73039 001
JUN 22, 1993

/N18335/001/
/AUS/05/1982/
N18335 001
AUG 05, 1982

TACRINE HYDROCHLORIDE

CAPSULE; ORAL
COGNEX

+ PARKE DAVIS

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

EQ 40MG BASE
EQ 10MG BASE
EQ 20MG BASE
EQ 30MG BASE

N20070 004
SEP 09, 1993
N20070 001
SEP 09, 1993
N20070 002
SEP 09, 1993
N20070 003
SEP 09, 1993

/N17339/001/
0.22-2.22CI/GENERATOR
N17339 001

TAMOXIFEN CITRATE

TABLET; ORAL

NOLVADEX

/Z/STUARD/
+ ZENECA

/ED/10MG/BASE/
EQ 10MG BASE

/N17970/001/
N17970 001

N71446 001
MAY 21, 1993
N71447 001
MAY 21, 1993

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

/A-N/STAINBOS/AGGREGATED/ALBUMIN/
@ NORTH AM CHEM

N/A

BS

AN-MAA

SORIN

N/A

/N/A/
/N/A/
/N/A/
N/A

/TECHNETIUM/TC/99M/MAA/
/BS/ /MEDI/PHYSICS/
@ MEDI PHYSICS

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

/AMERSHAM/MDP KIT/
/BS/ /AMERSHAM/
/N/A/
N/A

N/A

@ AMERSHAM

TECHNETIUM TC-99M SODIUM Pertechnetate GENERATOR

SOLUTION; INJECTION, ORAL

/MAYNITIC/
/SQUIBB/
@ SQUIBB

/0.22-2.22CI/GENERATOR/
0.22-2.22CI/GENERATOR

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

AB DANBURY PHARMA

AB

15MG
30MG

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

/A-N/STAINBOS/AGGREGATED/ALBUMIN/
/BS/ /NORTH AM CHEM/
/N/A/
/N17916/001/
/N17916/001/

TICARCILLIN DISODIUM

INJECTABLE; INJECTION
TICAR
+ SMITHKLINE BEECHAM
+

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

N50497 004
N50497 005
APR 04, 1984

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLID
+ SYNTAX

250MG

N19979 002
OCT 31, 1991
N19979 001

MAR 24, 1993
/N19979/001/
/001/31,1991/

125MG
/250mg/

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE
NOVOPHARM

AB

5MG

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

AB

10MG

AB

20MG

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM
MYLAN

AB

EQ 400MG BASE

N73393 001
MAY 27, 1993

TABLET; ORAL
TOLMETIN SODIUM
GENEVA

>_ADD_>
>_ADD_>

EQ 600MG BASE

N74002 001
SEP 27, 1993

TORSEMIDE

INJECTABLE; INJECTION
DEMADEX
+ BOEHRINGER MANNHEIM

10MG/ML

N20137 002
AUG 23, 1993

TORSEMIDE

TABLET; ORAL
DEMADEX
+ BOEHRINGER MANNHEIM

100MG

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

5MG

10MG

20MG

TRANLYCYPROMINE SULFATE

TABLET; ORAL
PARNATE
+ SKF

EQ 10MG BASE

N12342 003
AUG 16, 1985

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
DESTREL
+ APOTHECON

AB

50MG

N18207 001

AB

100MG

N18207 002

AB

150MG

N18207 003

AB

300MG

N18207 004

AB

150MG

N18207 005

AB

150MG

N18207 006

AB

150MG

N18207 007

AB

150MG

N18207 008

AB

150MG

N18207 009

AB

150MG

N18207 010

AB

150MG

N18207 011

AB

150MG

N18207 012

AB

150MG

N18207 013

AB

150MG

N18207 014

AB

150MG

N18207 015

AB

150MG

N18207 016

AB

150MG

N18207 017

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150MG

N18207 018

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150MG

N18207 019

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150MG

N18207 020

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150MG

N18207 021

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N18207 032

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N18207 033

AB

150MG

N18207 034

AB

150MG

N18207 035

AB

150MG

N18207 036

AB

150MG

N18207 037

AB

150MG

N18207 038

TRIAMCINOLONE ACETONIDE

ointment; topical

N89913 001
DEC 23, 1988
/N89913/001/
/DEC/23/1988/
N88090 001

0.1%	0.1%
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SEP 01, 1983
N88092 001
SEP 01, 1983
/N88666/001/
/SEP/01./1983/
/N88666/144/

13/	16.53/
14/	16.0252/

PHARMADERM 0.025%
0.1%

TRIFLUOPERAZINE HYDROCHLORIDE

1985787/661/
APR/15, 1982/

AA	GENEVA	EQ 10MG BASE/ML	TOTAL INHIBITORY UNITS
1	1	1	1
2	2	2	2
3	3	3	3
4	4	4	4
5	5	5	5
6	6	6	6
7	7	7	7
8	8	8	8
9	9	9	9
10	10	10	10
11	11	11	11
12	12	12	12
13	13	13	13
14	14	14	14
15	15	15	15
16	16	16	16
17	17	17	17
18	18	18	18
19	19	19	19
20	20	20	20
21	21	21	21
22	22	22	22
23	23	23	23
24	24	24	24
25	25	25	25
26	26	26	26
27	27	27	27
28	28	28	28
29	29	29	29
30	30	30	30
31	31	31	31
32	32	32	32
33	33	33	33
34	34	34	34
35	35	35	35
36	36	36	36
37	37	37	37
38	38	38	38
39	39	39	39
40	40	40	40
41	41	41	41
42	42	42	42
43	43	43	43
44	44	44	44
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46	46	46	46
47	47	47	47
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49	49	49	49
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89	89	89	89
90	90	90	90
91	91	91	91
92	92	92	92
93	93	93	93
94	94	94	94
95	95	95	95
96	96	96	96
97	97	97	97
98	98	98	98
99	99	99	99
100	100	100	100

TRIFLUOPRAZINE HCL
a PENNEX PHARMS
EQ 10MG BASE/ML

AA/ /PHARM/BASICS/ /EQ LONG BASE/PIL/

185785/881/
185786/881/
185789/881/
185788/881/

/N65785/66Y/
 /N65786/66Y/
 /N65789/66Y/
 /N65788/66Y/

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

GENEVA

EQ 1MG BASE
EQ 2MG BASE
EQ 5MG BASE
EQ 10MG BASE

N85785 001
N85786 001
N85789 001
N85788 001

/EQ/2.5MG/BASE/5ML/

SYRUP; ORAL

TRIMEPAZINE TARTRATE

/3/PHARM/PAKISTAN/

/N85445/001/
/APR/12/1985/

TRIFLUPROMAZINE

/SUSPENSION; ORAL/

VESEPIN/

/SQUIBB/

3 APOTHECON

/EQ/50MG/HCL/5ML/
EQ 50MG HCL/5ML

/N12697/001/
N12697 001

/5MG/
5MG

TRIFLUPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

VESEPIN

AP + APOTHECON

AP + /SQUIBB/

/EQ/

10MG/ML
20MG/ML
/EQ/10MG/ML/
/EQ/20MG/ML/

N11325 004
N11325 001
/N11345/004/
/N11345/001/

TABLET; ORAL

TRIPLENNAMINE HCL

/AA/

/HEATHER/

3 HEATHER

AA NYLOS TRADING

/AA/ /TAB/ICAPS/

/50MG/
50MG
50MG
/50MG/

/N85484/001/
N83989 001
N85412 001
/N85412/001/

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION

TUBOCURARINE CHLORIDE

/AB/

/SQUIBB/

3 QUAD

3MG/ML

/3MG/ML/
3MG/ML

/N85443/001/
/AUS/12/1988/
N89442 001
AUG 12, 1988

VALPROIC ACID

TRIHENXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHENXYPHENIDYL HCL

AA NYLOS TRADING

/AA/ /TAB/ICAPS/

5MG
/EQ/

N85622 001
/N85622/001/

CAPSULE; ORAL

VALPROIC ACID

AB PHARMACAPS

250MG

N73484 001
JUN 29, 1993

TRIMEPAZINE TARTRATE

SYRUP; ORAL

TRIMEPAZINE TARTRATE

3 PENNEX PHARMS

EQ 2.5MG BASE/5ML

SYRUP; ORAL

MYPROIC ACID

AA PENNEX PHARMS

/AA/ /PHARM/PAKISTAN/

250MG/5ML
/250MG/5ML/

N70868 001
JUL 01, 1986
/N70868/001/
/JUL/01/1986/

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION
VANCOCIN HCL IN PLASTIC CONTAINER
+ LILLY

EQ 500MG BASE/100ML

N50671 001
APR 29, 1993

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

ISOPTIN
/KNOX/
+ KNOX

VERAPAMIL HCL

MARSH

2.5MG/ML
2.5MG/ML

N18485 001
N18485 001

N72233 001
FEB 26, 1993
N73485 001
SEP 27, 1993

MARFARIN SODIUM

TABLET; ORAL

COUMADIN

/BX/ /BX/ /BX/

/BX/ /BX/ /BX/

/BX/ /BX/ /BX/

/BX/ /BX/ /BX/

/BX/ /BX/ /BX/

/BX/ /BX/ /BX/

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/BX/ /BX/ /BX/

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE
FUJISAWA

/X/ /X/ /X/

/X/ /X/ /X/

/X/ /X/ /X/

/X/ /X/ /X/

/X/ /X/ /X/

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/X/ /X/ /X/

/X/ /X/ /X/

VITAMIN A PALMITATE

CAPSULE; ORAL

AFAXIN

@ STERLING

VITAMIN A

@ WHARTON

/ZENITH/

@ ZENITH

@

@

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XENON, XE-133

GAS; INHALATION

XENON XE 133

/DUPONT/

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EQ 50,000 UNITS BASE

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N83187 001

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N17284 004/
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XYLOSE

POWDER; ORAL

XYLO-PFAN

/AA/

AA

/AA/

SAVAGE

/256N/001/
256N/001

/N17605/001/
N17605 001

ZINC SULFATE

/INJECTION/

/ZINC/SULFATE/

/LPHOMED/

a LPHOMED

/EQ/IMG/ZINC/ML/

EQ IMG ZINC/ML

/N19229/002/
/MAY/05/1987/

N19229 002
MAY 05, 1987

ACETAMINOPHEN

SUPPOSITORY; RECTAL
NEOPAP
/KICOM/
POLYMEDICA

12.6mg/
120MG

NY6401 001
/YpP/YpP/6dy/

N72640 002
AUG 31, 1993

CLOTRIMAZOLE

CREAM; TOPICAL
CLOTRIMAZOLE
TARO

1%

TABLET, CHEWABLE; ORAL

ALUMINUM/HYDROXIDE/AND/MAGNESIUM/TRISILICATE/
/PENNEX/
/60mg; 20mg/

a PENNEX

N89449 001
NOV 27, 1987

N74165 001
JUL 16, 1993

ALUMINIUM HYDROXIDE; MAGNESIUM TRISILICATE

CREAM; VAGINAL
CLOTRIMAZOLE
NMC

7%

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
GYNE-LOTRIMIN COMBINATION PACK
+ SCHERING PLOUGH 1%; 100MG

N20289 002
APR 26, 1993

BACITRACIN; POLYMYXIN B SULFATE

ΚΕΡΕΣΟΙ: /ΤΟΡΥΣΑΙ/
/ΛΙΑΒΕΙΩΤΙΣ/
/ΣΟΜΕ/

a COMB.

N50598 001
SEP 22, 1986

PENNEX PHARMS 12.5MG/5ML
/PHARM/BASICS/ 12.5MG/5ML/

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

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
HIBISTAT
/sɪˈstæt/
+ ZENECA

0.5%
16.5%

N18300 001
/Y99/9938YN/

BARRE	12.5MG/5ML
/NASKA/	/12.5MG/5ML/

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

TINCTURE; TOPICAL
 HIBITANE
 /S/S/STUART/
 @ ZENECA

0.5%
1.5-5.1

NY8649 001
/Y86/6498YN/

$\text{LUCHEH} /$

/N72961/661/
 /DEC/19/1991/
 /N72963/661/
 /DEC/19/1991/

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

ISOCLOL
CIBA

8MG; 120MG

N18747 001
MAR 06, 1986

12. 12. 1996

/tʉpʁɔfɛn/
/dɪn/

1986/10/23
DEC/81/1006/1
1986/10/23
1986/10/23

IBUPROFEN

TABLET; ORAL
IBUPROFEN
/ZENITH/

/400MG/

3 ZENITH

200MG

/N71154/001/
OCT 27, 1987

IBUPROHIM
OHM

200MG

/N71214 001
DEC 01, 1986

/NEUVIL/
/LUNETH/

/400MG/

/N71144/001/
JAN/26, 1987

INSULIN SUSP PROTAMINE ZINC BEEF/PORK

/INJECTABLES/INJECTION/
/PROTAMINE/ZINC/ALLETIAN/1/(BEEF-PORKS)/
/LILLY/

/40 UNITS/ML/
/100 UNITS/ML/
40 UNITS/ML
100 UNITS/ML

/N17932/001/
N17932 001
N17932 002

3 LILLY
3

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
WATSON LABS

1MG/5ML

N73062 001
MAY 28, 1993

TABLET; ORAL
LOPERAMIDE HCL
NOVOPHARM

2MG

N73254 001
JUL 30, 1993

MICONAZOLE NITRATE

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

N20288 002
APR 26, 1993

PSEUDOEPHEDRINE HYDROCHLORIDE, TRIPROLIDINE HYDROCHLORIDE

/CAPSULES/ORAL/
/ACTIFED/
/BURROUGHS/MELLICOME/ /60MG;2;.5MG/

/N19368/001/
JAN/15, 1985

/SYRUP; ORAL/
/ACTIFED/
/BURROUGHS/MELLICOME/ /30MG;5ML;2;.25MG;5ML/

/N11935/003/
NOV/26, 1982

/TRIOFED/
/BARRE/

/30MG;5ML;2;.25MG;5ML/

/N88115/001/
MAR/04, 1983

/TRIOFED/
/HALSEY/

/30MG;5ML;2;.25MG;5ML/

/N88233/002/
MAR/30, 1984

/TABLETS/ORAL/
/ACTIFED/
/BURROUGHS/MELLICOME/ /60MG;2;.5MG/

/N11936/002/
NOV/26, 1982

/TRIOFED/
/HALSEY/

/60MG;2;.5MG/

/N88234/002/
JAN/10, 1984

/TRIPROPRINE/
/PANEURX/PHARM/

/60MG;2;.5MG/

/N88112/001/
JAN/26, 1983

/TRIOFED/
/HALSEY/

/60MG;2;.5MG/

/N88193/002/
MAR/01, 1984

/TRIPROLIDINE/HCL/AND/PSUEDOEPHEDRINE/HCL/
/CHELSEA/

/N88118/002/
JAN/26, 1984

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 9 / SEP '93

INDIUM¹¹¹ CHLORIDE

SOLUTION; INJECTION
INDICLOR
AMERSHAM

N/A

N19862
DEC 29, 1992

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

Chemical
Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated

MA=Marketing Approval

RESULFATED HEPARIN HEROPIN	TREATMENT OF CYSTIC FIBROSIS.	KENNEDY & HOIDAL, MDs. 7702 PARHAM ROAD RICHMOND VA 23294 DD 09/17/93 MA / /
THIOXSALEN MADEX	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 / /
ASALICYLATE SODIUM	TREATMENT OF CROHN'S DISEASE.	SYNCOM PHARMACEUTICALS, INC. 155 PASSAIC AVENUE FAIRFIELD NJ 07004 DD 04/06/93 MA / /
OSIDINE CABBROMICTNA	TREATMENT OF TUBERCULOSIS.	KANYOK, THOMAS P. PHARM.D. UNIVERSITY OF RHODE ISLAND PROVIDENCE RI 02908-4735 DD 05/14/93 MA / /
BARONE AMIO-AQUEOUS	TREATMENT OF INCESSANT VENTRICULAR TACHYCARDIA.	ACADEMIC PHARMACEUTICALS, INC. 25720 SAUNDERS ROAD NORTH LAKE FOREST IL 60045 DD 08/17/93 MA / /
THYMOCYTE SERUM NASHVILLE 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 / /
MORPHINE 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 / /
IAQUONE MEPRON	TREATMENT AND SUPPRESSION OF TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
IAQUONE MEPRON	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 / /
MYCIN SULFATE BLENOXANE	TREATMENT OF MALIGNANT PLEURAL EFFUSION.	BRISTOL-MYERS SQUIBB PO BOX 4000 PRINCETON NJ 08543-4000 DD 09/17/93 MA / /
INE WHEY PROTEIN CONCENTRATE 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 / /
ORIBINE 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 / /
FOSCERIL PALMITATE, CETYL HOL, TYLOXAPOL EXOSURF	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 01/11/93 MA / /
IC FIBROSIS TRANSMEMBRANE UCTANCE REGULATOR GENE	TREATMENT OF CYSTIC FIBROSIS.	GENETIC THERAPY, INC. 19 FIRSTFIELD ROAD GAITHERSBURG MD 20878 DD 01/08/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
DEPOFOAM ENCAPSULATED CYTARABINE TN=	TREATMENT OF NEOPLASTIC MENINGITIS.	KIM, SINIL M.D. UCSD CANCER CENTER/0812 SAN DIEGO CA 92103 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 / /
INTERFERON BETA (RECOMBINANT HUMAN) TN=	TREATMENT OF PRIMARY BRAIN TUMORS.	BIOMEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 01/13/93 MA / /
INTERLEUKIN-3, HUMAN, RECOMBINANT TN=	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 / /
LIPOSOMAL DAUNORUBICIN TN= 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 / /
METHOTREXATE TN= RHEUMATREX	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	LEDERLE LABORATORIES 401 N. MIDDLETOWN ROAD PEARL RIVER NY 10965-1299 DD 08/23/93 MA / /
MODAFINIL TN=	TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.	CEPHALON, INC. 145 BRANDYWINE PARKWAY WEST CHESTER PA 19380-4245 DD 03/15/93 MA / /
MONOCLONAL ANTIBODY FOR IMMUNIZATION AGAINST LUPUS NEPHRITIS TN=	TREATMENT OF LUPUS NEPHRITIS.	MEDCLONE, INC. 2435 MILITARY AVENUE LOS ANGELES CA 90064 DD 01/07/93 MA / /
MONOLAURIN TN= GLYLORIN	TREATMENT OF CONGENITAL PRIMARY ICHTHYOSIS.	CELLEGY PHARMACEUTICALS, INC 371 BEL MARIN KEYS, SUITE 210 NOVATO CA 94949 DD 04/29/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

Chemical
Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD-Date Designated

MA-Marketing Approval

WEIN-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 / /
C OXIDE	TREATMENT OF PERSISTENT PULMONARY HYPERTENSION IN THE NEWBORN.	ANAQUEST, INCORPORATED 110 ALLEN ROAD LIBERTY CORNER NJ 07938 DD 06/22/93 MA / /
QUINE 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 / /
WEIN C CONCENTRATE PROTEIN C CONCENTRATE (N) 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 / /
RELIN	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 / /
DIARY SURFACTANT REPLACEMENT, NE DIOSURF	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 / /
RETINAMIDE	TREATMENT OF MYELODYSPLASTIC SYNDROMES.	SPARTA PHARMACEUTICALS, INCORPORATED PO BOX 13288 RESEARCH TRIANGLE PK NC 27709 DD 05/06/93 MA / /
TOLE	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD, PO BOX 1200 COLLEGEVILLE PA 19426-0107 DD 03/16/93 MA / /
INIMEX INOMIDE	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 / /
ACIFEROL OSTEO-D	TREATMENT OF FAMILIAL HYPOPHOSPHATEMIC RICKETS.	LEMMON COMPANY 650 CATHILL ROAD SELLERSVILLE PA 18960 DD 07/26/93 MA / /
TROPIN BIOTROPIN	TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS.	BIO-TECHNOLOGY GENERAL CORPORATION 1250 BROADWAY, 20th FLOOR NEW YORK NY 10001 DD 02/12/93 MA / /
ALFATE	TREATMENT OF ORAL MUCOSITIS AND STOMATITIS FOLLOWING RADIATION THERAPY FOR HEAD AND NECK CANCER.	FUISZ TECHNOLOGIES, LTD. 3810 CONCORDE PARKWAY, SUITE 100 CHANTILLY VA 22021 DD 07/15/93 MA / /
NC- 210 IDOMIDE	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

NAME

Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated
MA=Marketing Approval

TOREMIFENE
TN= ESTRINEX

TREATMENT OF DESMOID TUMORS.

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

TRETINOIN
TN= TRETINOIN LF, IV

TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.

ARGUS PHARMACEUTICALS, INC.
3400 RESEARCH FOREST DRIVE
THE WOODLANDS TX 77381
DD 01/14/93 MA / /

TUMOR NECROSIS FACTOR-BINDING
PROTEIN 1
TN=

TREATMENT 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 / /

TUMOR NECROSIS FACTOR-BINDING
PROTEIN II
TN=

TREATMENT 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 / /

VASOACTIVE INTESTINAL
POLYPEPTIDE
TN=

TREATMENT OF ACUTE ESOPHAGEAL FOOD IMPACTION.

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

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

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

Chemical
Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD = Date Designated

MA = Marketing Approval

Orphan Drug Approvals

OL ACETATE
ACE

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

NO SEPTEMBER 1993 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING 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
CEFACLOX (CAPSULE AND SUSPENSION)	APR 23, 1993
CAPTAPRIL (TABLET)	MAY 13, 1993
CHOLESTYRAMINE (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

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, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.					
REFER BACK TO THE <u>APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS</u> , 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.					
AMINOSALICYLIC ACID GRANULES, ENTERIC-COATED; ORAL	4GM/PACKET	92 P-0356/ CP1	JACOBUS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 03, 1993
ACYCLOVIR SODIUM INJECTABLE; INJECTION	EQ 50MG BASE/ML (10ML/VIAL) (20ML/VIAL)	92 P-0468/ CP1	BULL	NEW DOSAGE FORM	APPROVED SEP 01, 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
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
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

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EXCLUSIVITY TERMS

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

REFERENCES

NEW DOSING SCHEDULE

SINGLE 32MG DOSE

REFERENCES

NEW INDICATION

RENAL IMAGING AGENT FOR USE IN CHILDREN
 MANAGEMENT OF ENDOMETRIOSIS
 EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE
 INTENSIVE CARE UNIT SEDATION
 MONOTHERAPY USE FOR HYPERTENSION
 ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE
 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS
 USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITATE VISUALIZATION OF LESIONS IN THE BODY [EXCLUDING THE HEART]
 TREATMENT OF LEFT VENTRICULAR DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION
 TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA

REFERENCES

PATENT USE CODE

METHOD OF PROVIDING HYPNOTIC EFFECT
 RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
 USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM
 TREATMENT OF SYMPTOMS OF SEASONAL ALLERGIC RHINITIS
 ULCERATIVE COLITIS
 SYMPTOMATIC TREATMENT OF PATIENTS WITH NOCTURNAL HEARTBURN DUE TO GERD
 METHOD OF TREATING OCULAR BACTERIAL INFECTIONS
 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS
 TREATMENT FOR DEMENTIA IN PATIENTS WITH ALZHEIMER'S DISEASE
 TREATMENT OF SEIZURES

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

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				ODE	DEC 22, 1999
18651 002	DRONABINOL; MARINOL				ODE	DEC 22, 1999
18651 003	DRONABINOL; MARINOL				ODE	DEC 22, 1999
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	ODE	JUL 29, 2000
>ADD>						
>ADD>						
>ADD>						
20189 002	FELBAMATE; FELBATOL	4978680	DEC 18, 2007	U-83	NCE	JUL 29, 1998
>ADD>		5082861	JAN 21, 2009	U-83	ODE	JUL 29, 2000
>ADD>		4978680	DEC 18, 2007	U-83	NCE	JUL 29, 1998
20189 003	FELBAMATE; FELBATOL	5082861	JAN 21, 2009	U-83	ODE	JUL 29, 2000
>ADD>		4978680	DEC 18, 2007	U-83	NCE	JUL 29, 1998
>ADD>		4316839	MAR 03, 2003		NCE	DEC 20, 1996
20073 001	FLUMAZENIL; MAZICON	4626549	DEC 02, 2003			
18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003			
18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
>ADD>		4194009	APR 19, 1994			
20068 001	FOSCARNET SODIUM; FOSCAVIR	4018895	APR 19, 1994	U-12		
20123 001	GADODIAMIDE; OMNISCAN	4215113	JUN 06, 2000	U-64	NCE	SEP 27, 1996
19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4687659	AUG 18, 2004	U-76	NCE	JAN 08, 1998
17783 003	GLIPIZIDE; GLUCOTROL	4957939	MAR 03, 2004		I-94	AUG 17, 1996
20051 003	GLYBURIDE; GLYNASE				NCE	MAY 08, 1994
20051 004	GLYBURIDE; GLYNASE	4735805	APR 05, 2005		NP	MAR 04, 1995
>ADD>		4916163	APR 10, 2007		NCE	MAY 01, 1994
>ADD>		4735805	APR 05, 2005		NP	MAR 04, 1995
>ADD>		4916163	APR 10, 2007		NCE	MAY 01, 1994
19726 001	GOSERELIN ACETATE; ZOLADEX				1-88	FEB 02, 1996
19032 001	GUANFACINE HYDROCHLORIDE; TENEX				1-91	MAY 11, 1996
19032 002	GUANFACINE HYDROCHLORIDE; TENEX				1-91	MAY 11, 1996
19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NCE	JAN 11, 1994
19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID				NDF	DEC 07, 1995
18538 002	INDAPAMIDE; LOZOL				NCE	JAN 11, 1994
19710 005	IOVERSOL; OPTIRAY 350				NDF	DEC 07, 1995
					NS	APR 29, 1996
					NCE	JUL 06, 1993
					1-48	JUL 27, 1996

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20215 001	ISOSORBIDE MONONITRATE; MONOKET	4335125	JUN 15, 1999		NCE	DEC 30, 1996
20215 002	ISOSORBIDE MONONITRATE; MONOKET	5110493	MAY 05, 2009		NCE	DEC 30, 1996
20225 001	ISOSORBIDE MONONITRATE; IMDUR	4454151	JUN 12, 2001		NS	JUN 30, 1996
20225 002	ISOSORBIDE MONONITRATE; IMDUR	4089969	MAY 16, 1997		NCE	DEC 30, 1996
19084 001	KETOCONAZOLE; NIZORAL	4917893	MAR 24, 2004		NDF	AUG 12, 1996
19700 001	KETOROLAC TROMETHAMINE; ACULAR	4849228	JUL 18, 2006		NCE	DEC 30, 1996
20263 001	LEUPROLIDE ACETATE; LUPRON	4728721	MAR 01, 2005		NDF	AUG 12, 1996
		4677191	JUN 30, 2004		I-30	JAN 27, 1996
		4652441	MAR 24, 2004		NCE	NOV 30, 1994
		4005063	JAN 25, 1996		NDF	NOV 09, 1995
20263 002	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004		NP	APR 16, 1996
		4849228	JUL 18, 2006		ODE	APR 16, 2000
		4728721	MAR 01, 2005		NP	APR 16, 1996
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004		ODE	APR 16, 2000
20263 003	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4005063	JAN 25, 1996		NP	APR 16, 1996
		4917893	MAR 24, 2004			
		4849228	JUL 18, 2006		ODE	APR 16, 2000
		4728721	MAR 01, 2005		NP	APR 16, 1996
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004		ODE	APR 16, 2000
20263 004	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4005063	JAN 25, 1996		NP	APR 16, 1996
		4917893	MAR 24, 2004			
		4849228	JUL 18, 2006		ODE	APR 16, 2000
		4728721	MAR 01, 2005		NP	APR 16, 1996
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004		ODE	APR 16, 2000
		4005063	JAN 25, 1996			

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME
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APPL/PROD NUMBER	INGREDIENT NAME: TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18948 001	LEVOCARNITINE; CARNITOR				1-86	DEC 16, 1995
18948 002	LEVOCARNITINE; CARNITOR				ODE	DEC 16, 1999
20315 001	LEVOMETHADYL ACETATE HYDROCHLORIDE; ORLAAM				ODE	DEC 16, 1995
19558 001	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		ODE	DEC 16, 1999
19558 002	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	JUL 09, 1998
19558 003	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
19558 004	LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
19777 001	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
19777 002	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
19777 003	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
19777 004	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
19777 005	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		ODE	JUL 09, 2000
20191 001	LODOXAMIDE TROMETHAMINE; ALOMIDE				ODE	JUL 09, 2000
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN				ODE	JUL 09, 2000
19658 001	LORATADINE; CLARITIN				ODE	JUL 09, 2000
20049 001	MESALAMINE; PENTASA				ODE	JUL 09, 2000
20098 001	MIVACURIUM CHLORIDE; MIVACRON				ODE	JUL 09, 2000
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%				ODE	JUL 09, 2000
19583 001	NABUMETONE; RELAFEN				ODE	JUL 09, 2000
19583 002	NABUMETONE; RELAFEN				ODE	JUL 09, 2000
20109 001	NAFARELIN ACETATE; SYNAREL				ODE	JUL 09, 2000
19356 001	NAFTIFINE HYDROCHLORIDE; NAFTIN				ODE	JUL 09, 2000
20150 001	NICOTINE; NICOTROL				ODE	JUL 09, 2000
20150 002	NICOTINE; NICOTROL				ODE	JUL 09, 2000
20150 003	NICOTINE; NICOTROL				ODE	JUL 09, 2000
20666 001	NICOTINE POLACRILEX; NICORETTE DS				ODE	JUL 09, 2000
20198 001	NIFEDIPINE; ADALAT CC				ODE	JUL 09, 2000
20198 002	NIFEDIPINE; ADALAT CC				ODE	JUL 09, 2000
20198 003	NIFEDIPINE; ADALAT CC				ODE	JUL 09, 2000
19921 001	OFLOXACIN; OCUFLOX				ODE	JUL 09, 2000
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN				ODE	JUL 09, 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
20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAM	4695578	SEP 22, 2004		NCE	JAN 04, 1996
20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAM	4695578	SEP 22, 2004		NCE	JAN 04, 1996
20036 001	PAMIDRONATE DISODIUM; AREDIA	3962432	JUL 16, 1996	U-53		
20036 003	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			
		3962432	JUL 16, 1996	U-53	NCE	OCT 31, 1996
20036 004	PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			
		3962432	JUL 16, 1996	U-53	NCE	OCT 31, 1996
20091 001	PERFLUBRON; IMAGENT	4664107	MAY 12, 2004		NCE	AUG 13, 1998
20014 001	PIRBUTEROL ACETATE; MAXAIR					
19795 001	PODOFILOX; CONDYLOX	4346227	AUG 24, 1999		NCE	DEC 13, 1995
19898 004	PRAVASTATIN SODIUM; PRAVACHOL	4242334	DEC 30, 1999	U-50	NCE	OCT 31, 1996
19568 001	PREDNICARBATE; DERMATOP				NE	SEP 23, 1994
19627 001	PROPOFOL; DIPRIVAN	4996061	FEB 26, 2008		I-90	MAR 08, 1996
19664 001	PSEUDOPHEDRINE HYDROCHLORIDE; SELDANE-D	4929605	MAY 29, 2007	U-81		
		4254129	MAR 03, 1998	U-81		
50689 001	RIFABUTIN; MYCOBUTIN				ODE	DEC 23, 1999
19650 001	RIMANTADINE HYDROCHLORIDE; FLUMADINE				NCE	SEP 17, 1998
19649 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
20134 001	STRONTIUM CHLORIDE, SR-89; METASTRON				NCE	JUN 18, 1998
19050 001	SUFENTANIL CITRATE; SUFENTA	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
20080 001	SUMATRIPTAN SUCCINATE; IMITREX				I-89	MAR 19, 1996
>ADD>		4816470	MAR 28, 2006	U-72		
>ADD>	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
>ADD>	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
>ADD>	TACRINE HYDROCHLORIDE; COGNEX	4816456	MAR 28, 2006	U-82	NCE	SEP 09, 1998
>ADD>	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

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
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			
		5030632	JUL 09, 2008	U-70	NS	OCT 25, 1994
20223 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000			
		4112097	SEP 05, 1995			
20223 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994		I-96	SEP 29, 1996
		4251532	FEB 17, 2000			
		4112097	SEP 05, 1995			
20223 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994		I-96	SEP 29, 1996
		4251532	FEB 17, 2000			
		4112097	SEP 05, 1995			
20223 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994		I-96	SEP 29, 1996
		4251532	FEB 17, 2000			
		4112097	SEP 05, 1995			
18949 001	TERFENADINE; SELDANE	4254129	MAR 03, 1998	U-81		
19979 001	TICLOPIDINE HYDROCHLORIDE; TICLID	4026894	MAY 31, 1994			
		4254129	MAR 03, 1998			
19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4591592	NOV 01, 2005		NCE	OCT 31, 1996
		4051141	SEP 27, 1996			
20136 001	TORSEMIDE; DEMADEX	4051141	SEP 27, 1996		NCE	OCT 31, 1996
		4822807	APR 18, 2006			
		4018929	APR 19, 1994		NCE	AUG 23, 1998
20136 002	TORSEMIDE; DEMADEX	RE30633	APR 19, 1994			
		4822807	APR 18, 2006			
		4018929	APR 19, 1994		NCE	AUG 23, 1998
20136 003	TORSEMIDE; DEMADEX	RE30633	APR 19, 1994			
		4822807	APR 18, 2006		NCE	AUG 23, 1998
		4018929	APR 19, 1994			
20136 004	TORSEMIDE; DEMADEX	RE30633	APR 19, 1994			
		4822807	APR 18, 2006		NCE	AUG 23, 1998
		4018929	APR 19, 1994			
20137 002	TORSEMIDE; DEMADEX	RE30633	APR 19, 1994			
		4822807	APR 18, 2006		NCE	AUG 23, 1998
		4018929	APR 19, 1994			
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