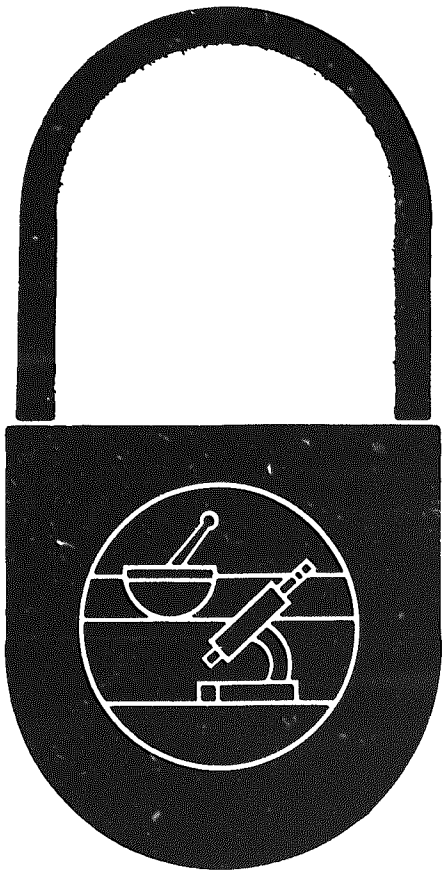
**CUMULATIVE SUPPLEMENT 7**
**JAN'88-JUL'88**



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 8TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT

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## JULY 1988

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JULY 1988

# 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, 8th 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 in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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, along with the application number and product number (FDA's internal file number). 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 effective date for the approved drug product (the earliest date a product may be marketed) appears, when appropriate, to the left of the approval date.

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, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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. A newly approved product is also identified by a lozenge ( ◆ ) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 will remain in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act and the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the " ə " symbol to designate their non-marketed status. All products having a " ə " symbol in the 12th Cumulative Supplement of the 8th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 9th 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 7, 1984 (49 FR 35428) |
| Nitroglycerin (tablet, controlled release;oral) | SEP 7, 1984 (49 FR 35428) |
| Nitroglycerin (tablet, controlled release;buccal) | JUL 5, 1985 (50 FR 27688) |
| Tranylcypromine Sulfate | MAR 22, 1984 (49 FR 10708) |

## 1.3 APPLICANT (NAME) CHANGES

Because 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, 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.

## 1.4 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1987) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product, provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

#### New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

## COUNTS CUMULATIVE BY QUARTER[1]

| CATEGORIES COUNTED | DEC 1987 | MAR 1988 | JUN 1988 |
|---|---|---|---|
| DRUG PRODUCTS LISTED | 9709 | 9528 | 9769* |
| SINGLE SOURCE | 2096 (21.6%) | 1997 (21.0%) | 1975 (20.2%) |
| MULTISOURCE | 7613 (78.4%) | 7531 (79.0%) | 7794 (79.8%) |
| THERAPEUTICALLY EQUIVALENT | 6691 (68.9%) | 6660 (69.9%) | 6937 (71.0%) |
| NOT THERAPEUTICALLY EQUIVALENT | 848 ( 8.7%) | 770 ( 8.1%) | 757 ( 7.8%) |
| EXCEPTIONS[2] | 74 ( 0.8%) | 101 ( 1.0) | 100 ( 1.0%) |
| NEW MOLECULAR ENTITIES APPROVED | -- | 1 | 2 |
| NUMBER OF APPLICANTS | 349 | 361 | 378 |

*This number is inclusive of products discontinued since December 1987, and any products approved or discontinued through July 1988.

(1) Cumulative counts are calculated from January 1, 1988 to, and including, the month indicated.

(2) Amino acid-containing products of varying composition (see Introduction, page I-8 of the List).

**ACETAMINOPHEN; BUTALBITAL; CAFFEINE**

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

| | | | |
|---|---|---|---|
| | MIKART | 50MG;50MG;40MG™ | N89451 001 MAY 23, 1988 |

BUTALBITAL, APAP, AND CAFFEINE

| | | | |
|---|---|---|---|
| AB | HALSEY DRUG | 325MG;50MG;40MG™ | N89536 001 FEB 16, 1988 |

**ACETAMINOPHEN; CODEINE PHOSPHATE**

ELIXIR; ORAL

MYAPAP AND CODEINE

| | | | |
|---|---|---|---|
| AA | MY K LABS | 120MG/5ML;12MG/5ML | N87006 001 |

TYLENOL W/ CODEINE

| | | | |
|---|---|---|---|
| AA | MCNEIL PHARM | 120MG/5ML;12MG/5ML | N85057 001 |

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

| | | | |
|---|---|---|---|
| AA | BOOTS LABS | 300MG;30MG | N87762 001 DEC 10, 1982 |
| > ADD > | ACETAMINOPHEN AND CODEINE PHOSPHATE | | |
| > ADD > AA | HALSEY DRUG | 300MG;60MG | N86549 001 |

ACETAMINOPHEN AND CODEINE PHOSPHATE

| | | | |
|---|---|---|---|
| AA | MUTUAL PHARM | 300MG;15MG™ | N89671 001 FEB 10, 1988 |
| AA | | 300MG;30MG™ | N89672 001 FEB 10, 1988 |
| AA | | 300MG;60MG™ | N89673 001 FEB 10, 1988 |
| AA | PHARMAFAIR | 300MG;30MG | N87762 001 DEC 10, 1982 |
| > DLT > | ACETAMINOPHEN W/ CODEINE PHOSPHATE | | |
| > DLT > AA | HALSEY DRUG | 300MG;60MG | N86549 001 |

TYLENOL W/ CODEINE

| | | | |
|---|---|---|---|
| AA | MCNEIL PHARM | 325MG;7.5MG | N85056 001 |
| AA | | 325MG;15MG | N85056 002 |
| AA | | 325MG;30MG | N85056 003 |
| AA | | 325MG;60MG | N85056 004 |

TYLENOL W/ CODEINE NO. 1

| | | | |
|---|---|---|---|
| AA | MCNEIL PHARM | 300MG;7.5MG | N85055 001 |

TYLENOL W/ CODEINE NO. 2

| | | | |
|---|---|---|---|
| AA | MCNEIL PHARM | 300MG;15MG | N85055 002 |

TYLENOL W/ CODEINE NO. 3

| | | | |
|---|---|---|---|
| AA | MCNEIL PHARM | 300MG;30MG | N85055 003 |

TYLENOL W/ CODEINE NO. 4

| | | | |
|---|---|---|---|
| AA | MCNEIL PHARM | 300MG;60MG | N85055 004 |

**ACETAMINOPHEN; HYDROCODONE BITARTRATE**

CAPSULE; ORAL

CO-GESIC

| | | | |
|---|---|---|---|
| AA | CENTRAL PHARMS | 500MG;5MG™ | N89360 001 MAR 02, 1988 |

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | |
|---|---|---|---|
| AA | BEECHAM LABS | 650MG;7.5MG | N89725 001 SEP 30, 1987 |
| AA | LUCHEM PHARMS | 500MG;5MG™ | N89696 001 APR 21, 1988 |
| AA | MIKART | 650MG;7.5MG™ | N89689 001 JUN 29, 1988 |

**ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE**

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

| | | | |
|---|---|---|---|
| AB | HALSEY DRUG | 325MG;50MG™ | N72105 001 MAY 13, 1988 |
| AB | | 650MG;100MG™ | N72106 001 MAY 13, 1988 |
| AB | MYLAN PHARMS | 650MG;100MG™ | N72195 001 FEB 16, 1988 |

**ACETAZOLAMIDE**

TABLET; ORAL

ACETAZOLAMIDE

| | | | |
|---|---|---|---|
| AB | MUTUAL PHARM | 125MG™ | N89752 001 JUN 22, 1988 |
| AB | | 250MG™ | N89753 001 JUN 22, 1988 |

DIAMOX

| | | | |
|---|---|---|---|
| AB | LEDERLE LABS | 125MG | N08943 001 |

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION
ACETAZOLAMIDE SODIUM

| | | | |
|---|---|---|---|
| AP | QUAD PHARMS | 500MG/VIAL | N89619 001<br>JAN 13, 1988 |

DIAMOX

| | | | |
|---|---|---|---|
| AP | LEDERLE LABS | 500MG/VIAL | N09388 001 |

ALBUTEROL SULFATE

CAPSULE; INHALATION
VENTOLIN ROTACAPS

| | | | |
|---|---|---|---|
| | GLAXO | EQ 0.2MG BASE | N19489 001<br>MAY 04, 1988 |

ALSEROXYLON

TABLET; ORAL
RAUTENSIN

| | | | |
|---|---|---|---|
| /BP/ | /DORSEY LABS/ | /2MG/ | /N09215/001/ |
| | ∂ DORSEY LABS | 2MG | N09215 001 |

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
> DLT > /AMANTADINE HCL/
> DLT > /AB/ /REID ROWELL/ /100MG/ /N71000/001/
> DLT > /SEP 04 1986/
> ADD > SYMADINE

| | | | |
|---|---|---|---|
| > ADD > AB | REID ROWELL | 100MG | N71000 001<br>SEP 04, 1986 |

> ADD >

AMCINONIDE

LOTION; TOPICAL
CYCLOCORT

| | | | |
|---|---|---|---|
| | LEDERLE LABS | 0.1% | N19729 001<br>JUN 13, 1988 |

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| AB | BARR LABS | 5MG;50MG | N71111 001<br>MAY 10, 1988 |

AMINO ACIDS

INJECTABLE; INJECTION
NEOPHAM 6.4%

| | | | |
|---|---|---|---|
| /KABIVITRUM/ | | /6.4%/ | /N18792/001/<br>/JAN 17 1984/ |
| ∂ KABIVITRUM | | 6.4% | N18792 001<br>JAN 17, 1984 |

TRAVASOL 10% IN PLASTIC CONTAINER

| | | |
|---|---|---|
| BAXTER | 10% | N18931 004<br>APR 27, 1988 |

> ADD > AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM
> ADD > ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE

> ADD > INJECTABLE; INJECTION
> ADD > FREAMINE III 8.5% W/ ELECTROLYTES

| | | |
|---|---|---|
| > ADD > | KENDALL MCGAW | 8.5%;110MG/100ML;230MG/100ML;<br>10MG/100ML;440MG/100ML;<br>690MG/100ML |
| > ADD > | | N16822 007<br>JUL 01, 1988 |

AMINOCAPROIC ACID

INJECTABLE; INJECTION
AMINOCAPROIC ACID

| | | | |
|---|---|---|---|
| AP | ABBOTT LABS | 250MG/ML | N70888 001<br>JUN 16, 1988 |

AMINOHIPPURATE SODIUM

INJECTABLE; INJECTION
AMINOHIPPURATE SODIUM

| | | | |
|---|---|---|---|
| > ADD > AP | MS&D | 20% | N05619 001 |
| > ADD > AP | QUAD PHARMS | 20% | N89821 001<br>JUL 14, 1988 |

> ADD >

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

| | | | |
|---|---|---|---|
| /BP/ | /BARR LABS/ | /100MG/ | /N88297/001/<br>/AUG 19 1983/ |
| /BP/ | | /200MG/ | /N88298/001/<br>/AUG 19 1983/ |
| | ∂ BARR LABS | 100MG | N88297 001<br>AUG 19, 1983 |
| | ∂ | 200MG | N88298 001<br>AUG 19, 1983 |

**AMINOPHYLLINE**

TABLET; ORAL
AMINOPHYLLINE

| | | | |
|---|---|---|---|
| /BP/ | /3/VALE/CHEM/ | /100MG/ | /N84533/001/ |
| | VALE CHEM | 100MG | N84533 001 |

**AMINOSALICYLATE SODIUM**

TABLET; ORAL
TEEBACIN

| | | | |
|---|---|---|---|
| /BP/ | /CNSOL/MIDLAND/ | /500MG/ | /N07320/002/ |
| | ə CNSOL MIDLAND | 500MG | N07320 002 |

**AMITRIPTYLINE HYDROCHLORIDE**

TABLET; ORAL
AMITRIL

| | | | |
|---|---|---|---|
| /AB/ | /PARKE/DAVIS/ | /10MG/ | |
| /AB/ | | /25MG/ | |
| /AB/ | | /50MG/ | |
| /AB/ | | /75MG/ | |
| /AB/ | | /100MG/ | |
| /AB/ | | /150MG/ | |
| AB | MARNER CHILCOTT | 10MG | |
| AB | | 25MG | N83937 001 |
| AB | | 50MG | N83938 002 |
| AB | | 75MG | N84957 001 |
| AB | | 100MG | N85093 001 |
| AB | | 150MG | N86295 001 |

**AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE**

TABLET; ORAL
CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

| | | | |
|---|---|---|---|
| AB | PAR PHARM | EQ 12.5MG BASE;5MG | N72277 001 MAY 09, 1988 |
| AB | | 25MG;10MG | N72278 001 MAY 09, 1988 |
| AB | PHARM BASICS | EQ 12.5MG BASE;5MG | N70477 001 JAN 12, 1988 |
| AB | | EQ 25MG BASE;10MG | N70478 001 JAN 12, 1988 |

**AMOXICILLIN**

CAPSULE; ORAL
AMOXICILLIN

| | | | |
|---|---|---|---|
| AB | CLONMEL CHEMS | 250MG | N62884 001 FEB 25, 1988 |
| AB | | 500MG | N62881 001 FEB 25, 1988 |

POWDER FOR RECONSTITUTION; ORAL
POLYMOX

| | | | |
|---|---|---|---|
| AB | BRSTL MYRS IND | 125MG/5ML | N62885 001 MAR 08, 1988 |
| AB | | 250MG/5ML | N62885 002 MAR 08, 1988 |

**AMPICILLIN/AMPICILLIN TRIHYDRATE**

CAPSULE; ORAL
AMPICILLIN

| | | | |
|---|---|---|---|
| AB | CLONMEL CHEMS | EQ 250MG BASE | N62883 001 FEB 25, 1988 |
| AB | | EQ 500MG BASE | N62882 001 FEB 25, 1988 |

POLYCILLIN

| | | | |
|---|---|---|---|
| AB | BRSTL MYRS IND | EQ 250MG BASE | N62888 001 MAR 04, 1988 |
| AB | | EQ 500MG BASE | N62888 002 MAR 04, 1988 |

**ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE**

TABLET; ORAL
ORPHENADRINE COMPOUND

| | | | |
|---|---|---|---|
| AB | VITARINE | 385MG;30MG;25MG | N71564 001 JUN 23, 1988 |

ORPHENADRINE COMPOUND DOUBLE STRENGTH

| | | | |
|---|---|---|---|
| AB | VITARINE | 770MG;60MG;50MG | N71565 001 JUN 23, 1988 |

**ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE**

CAPSULE; ORAL
COMPOUND 65

| | | | |
|---|---|---|---|
| /AA/ | /BANMAX/PHARMS/ | /389MG;32.4MG;65MG/ | /N84553/002/ /AUG 17, 1983/ |
| | ə BANMAX PHARMS | 389MG;32.4MG;65MG | N84553 002 AUG 17, 1983 |

**ASPIRIN; HYDROCODONE BITARTRATE**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | AZDONE | | | |
| | CENTRAL PHARMS | 500MG;5MG™ | N89420 001 | JAN 25, 1988 |

**ATENOLOL**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| >ADD> | ATENOLOL | | | |
| >ADD> AB | ICI PHARMS | 50MG™ | N72303 001 | JUL 15, 1988 |
| >ADD> AB | | 100MG™ | N72304 001 | JUL 15, 1988 |
| | TENORMIN | | | |
| >ADD> AB | STUART PHARMS | 50MG | N18240 001 | |
| >ADD> AB | | 100MG | N18240 002 | |

**ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE**

TABLET; ORAL

| | | | |
|---|---|---|---|
| >DLT> | /MOTOFEN/ | | |
| >DLT> | /J/CARNRICK/LABS/ | /0.025MG;1MG/ | /N17744/002/ |
| >ADD> | CARNRICK LABS | 0.025MG;1MG | N17744 002 |

**AZATHIOPRINE SODIUM**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | AZATHIOPRINE | | | |
| AP | QUAD PHARMS | EQ 100MG BASE/VIAL™ | N71056 001 | JUN 08, 1988 |
| | IMURAN | | | |
| AP | BURROUGHS WELLC | EQ 100MG BASE/VIAL | N17391 001 | |

**BACLOFEN**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | BACLOFEN | | | |
| AB | PHARM BASICS | 10MG™ | N71260 001 | MAY 06, 1988 |
| AB | | 20MG™ | N71261 001 | MAY 06, 1988 |
| AB | VITARINE | 10MG™ | N71901 001 | APR 13, 1988 |
| AB | | 20MG™ | N71902 001 | APR 13, 1988 |

**BACLOFEN**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | BACLOFEN | | | |
| >ADD> AB | ZENITH LABS | 10MG™ | N72234 001 | JUL 21, 1988 |
| >ADD> AB | | 20MG™ | N72235 001 | JUL 21, 1988 |
| | LIORESAL | | | |
| AB | GEIGY PHARMS | 10MG | N17851 001 | |
| | LIORESAL DS | | | |
| AB | GEIGY PHARMS | 20MG | N17851 003 | JAN 20, 1982 |

**BENZTHIAZIDE**

TABLET; ORAL

| | | | |
|---|---|---|---|
| | BENZTHIAZIDE | | |
| /BP/ | /PRIVATE FMLTNS/ | /50MG/ | /N83206/001/ |
| | ∂ PRIVATE FMLTNS | 50MG | N83206 001 |

**BENZTROPINE MESYLATE**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | BENZTROPINE MESYLATE | | | |
| AA | PAR PHARM | 0.5MG | N88877 001 | APR 11, 1985 |
| AA | | 1MG | N88894 001 | APR 11, 1985 |
| AA | | 2MG | N88895 001 | APR 11, 1985 |
| /BP/ | | /0.5MG/ | /N88877/001/ | /APR/11,/1985/ |
| /BP/ | | /1MG/ | /N88894/001/ | /APR/11,/1985/ |
| /BP/ | | /2MG/ | /N88895/001/ | /APR/11,/1985/ |
| AA | PHARM BASICS | 0.5MG™ | N89211 001 | JUN 14, 1988 |
| AA | | 1MG™ | N89212 001 | JUN 14, 1988 |
| AA | | 2MG™ | N89213 001 | JUN 14, 1988 |

**BENZTROPINE MESYLATE**

TABLET; ORAL

| | | | |
|---|---|---|---|
| | BENZTROPINE MESYLATE | | |
| AA | QUANTUM PHARMCS | 0.5MG | N88514 001<br>JAN 31, 1984 |
| AA | | 1MG | N88510 001<br>JAN 31, 1984 |
| AA | | 2MG | N88511 001<br>JAN 31, 1984 |
| /BP/ | | /0.5MG/ | /N88514/001/ |
| /BP/ | | /1MG/ | /N88510/001/ |
| /BP/ | | /2MG/ | /N88511/001/ |
| | COGENTIN | | |
| AA | MS&D | 0.5MG | N09193 004 |
| AA | | 1MG | N09193 003 |
| AA | | 2MG | N09193 002 |
| /BP/ | | /0.5MG/ | /N09193/004/ |
| /BP/ | | /1MG/ | /N09193/003/ |
| /BP/ | | /2MG/ | /N09193/002/ |

**BETAMETHASONE DIPROPIONATE**

LOTION; TOPICAL

| | | | |
|---|---|---|---|
| | BETAMETHASONE DIPROPIONATE | | |
| AB | COPLEY PHARM | EQ 0.05% BASE‡ | N71882 001<br>JUN 06, 1988 |

**BETAMETHASONE VALERATE**

CREAM; TOPICAL

| | | | |
|---|---|---|---|
| | DERMABET | | |
| AB | TARO PHARMS | EQ 0.1% BASE‡ | N72041 001<br>JAN 06, 1988 |

LOTION; TOPICAL

| | | | |
|---|---|---|---|
| | BETAMETHASONE VALERATE | | |
| AB | COPLEY PHARM | EQ 0.1% BASE‡ | N71883 001<br>APR 22, 1988 |

**BETAZOLE HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | HISTALOG | | | |
| >DLT> | /LILLY/ | /50MG/ML/ | /N09344/001/ | |
| >ADD> | ∂ LILLY | 50MG/ML | N09344 001 | |

**BETHANECHOL CHLORIDE**

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | BETHANECHOL CHLORIDE | | |
| AP | QUAD PHARMS | 5MG/ML‡ | N89815 001<br>APR 12, 1988 |
| | URECHOLINE | | |
| AP | MS&D | 5MG/ML | N06536 001 |

**BRETYLIUM TOSYLATE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | BRETYLIUM TOSYLATE | | | |
| >ADD> | AP | LUITPOLD PHARMS | 50MG/ML‡ | N70891 001<br>JUL 26, 1988 |
| >ADD> | AP | QUAD PHARMS | 50MG/ML‡ | N71181 001<br>FEB 16, 1988 |

**BROMPHENIRAMINE MALEATE**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | BROMPHENIRAMINE MALEATE | | | |
| /AA/ | /BARR LABS/ | /4MG/ | /N84468/001/ | |
| | ∂ BARR LABS | 4MG | N84468 001 | |

**BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE**

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | BUPIVACAINE HCL AND EPINEPHRINE | | |
| | ABBOTT LABS | 0.25%;0.005MG/ML‡ | N71166 001<br>JUN 16, 1988 |
| | | 0.25%;0.005MG/ML‡ | N71165 001<br>JUN 16, 1988 |
| | | 0.25%;0.005MG/ML‡ | N71167 001<br>JUN 16, 1988 |
| | | 0.5%;0.005MG/ML‡ | N71168 001<br>JUN 16, 1988 |
| | | 0.5%;0.005MG/ML‡ | N71169 001<br>JUN 16, 1988 |
| | | 0.5%;0.005MG/ML‡ | N71170 001<br>JUN 16, 1988 |
| | | 0.75%;0.005MG/ML‡ | N71171 001<br>JUN 16, 1988 |

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

SOLUTION; INTRAPERITONEAL

DIANEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | BAXTER | 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML‡ | N17512 010 NOV 18, 1985 |

DIANEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | BAXTER | 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML‡ | N17512 011 NOV 18, 1985 |

INPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT LABS | 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML‡ | N18379 007 JUN 24, 1988 |

INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT LABS | 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML‡ | N18379 008 JUN 24, 1988 |

**CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE**

INJECTABLE; INJECTION

DEXTROSE 2.5% IN HALF-STRENGTH LACTATED RINGER'S IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAN | 10MG/100ML;2.5GM/100ML;15MG/100ML; 300MG/100ML; 160MG/100ML‡ | N19634 001 FEB 24, 1988 |

DEXTROSE 4% IN MODIFIED LACTATED RINGER'S IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAN | 4MG/100ML;4GM/100ML;6MG/100ML; 120MG/100ML;62MG/100ML‡ | N19634 002 FEB 24, 1988 |

DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAN | 20MG/100ML;5GM/100ML;30MG/100ML; 600MG/100ML; 310MG/100ML‡ | N19634 003 FEB 24, 1988 |

**CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE**

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAN | 20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML‡ | N19632 001 FEB 29, 1988 |

**CARBAMAZEPINE**

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

| | | | |
|---|---|---|---|
| AB | WARNER CHILCOTT | 100MG‡ | N71940 001 FEB 01, 1988 |

TEGRETOL

| | | | |
|---|---|---|---|
| AB | GEIGY PHARMS | 100MG | N18281 001 |

**CEFACLOR**

POWDER FOR RECONSTITUTION; ORAL

CECLOR

| | | | |
|---|---|---|---|
| | LILLY | EQ 187MG BASE/5ML‡ | N62206 003 APR 20, 1988 |
| | | EQ 375MG BASE/5ML‡ | N62206 004 APR 20, 1988 |

**CEFAZOLIN SODIUM**

INJECTABLE; INJECTION

ANCEF

| | | | |
|---|---|---|---|
| AP | SK&F LABS | EQ 5GM BASE/VIAL | N50461 004 |

CEFAZOLIN SODIUM

| | | | |
|---|---|---|---|
| > ADD > AP | BEN VENUE LABS | EQ 250MG BASE/VIAL‡ | N62894 001 JUL 21, 1988 |
| > ADD > AP | | EQ 500MG BASE/VIAL‡ | N62894 002 JUL 21, 1988 |
| > ADD > AP | | EQ 1GM BASE/VIAL‡ | N62894 003 JUL 21, 1988 |
| > ADD > AP | | EQ 5GM BASE/VIAL‡ | N62894 004 JUL 21, 1988 |
| > ADD > AP | | EQ 10GM BASE/VIAL‡ | N62894 005 JUL 21, 1988 |

**CEFAZOLIN SODIUM**

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

| | | | | |
|---|---|---|---|---|
| AP | ELKINS SINN | EQ 250MG BASE/VIAL‡ | N62807 001 | JAN 12, 1988 |
| AP | | EQ 500MG BASE/VIAL‡ | N62807 002 | JAN 12, 1988 |
| AP | | EQ 1GM BASE/VIAL‡ | N62807 003 | JAN 12, 1988 |
| AP | | EQ 5GM BASE/VIAL‡ | N62807 004 | JAN 12, 1988 |
| AP | | EQ 10GM BASE/VIAL‡ | N62807 005 | JAN 12, 1988 |
| AP | | EQ 20GM BASE/VIAL‡ | N62807 006 | JAN 12, 1988 |

**CEFOTETAN DISODIUM**

INJECTABLE; INJECTION
CEFOTAN

| | | | | |
|---|---|---|---|---|
| | STUART PHARMS | EQ 10GM BASE/VIAL‡ | N50588 003 | APR 25, 1988 |

**CEPHALEXIN**

CAPSULE; ORAL
CEPHALEXIN

| | | | | |
|---|---|---|---|---|
| >ADD> AB | LABROS ATRAL | EQ 250MG BASE‡ | N62713 001 | JUL 15, 1988 |
| >ADD> AB | | EQ 500MG BASE‡ | N62713 002 | JUL 15, 1988 |
| AB | JEROME STEVENS | EQ 250MG BASE‡ | N62870 001 | MAR 17, 1988 |
| AB | | EQ 500MG BASE‡ | N62869 001 | MAR 17, 1988 |
| AB | TAG PHARMS | EQ 250MG BASE‡ | N62821 001 | FEB 05, 1988 |
| AB | | EQ 500MG BASE‡ | N62823 001 | FEB 05, 1988 |
| AB | YOSHITOMI PHARM | EQ 250MG BASE‡ | N62872 001 | JUN 20, 1988 |
| >ADD> AB | | EQ 500MG BASE‡ | N62871 001 | JUL 05, 1988 |

PONDER FOR RECONSTITUTION; ORAL
CEPHALEXIN

| | | | | |
|---|---|---|---|---|
| AB | TAG PHARMS | EQ 125MG BASE/5ML‡ | N62873 001 | MAY 23, 1988 |
| AB | | EQ 250MG BASE/5ML‡ | N62867 001 | APR 15, 1988 |

**CEPHALEXIN HYDROCHLORIDE**

TABLET; ORAL
KEFTAB

| | | | | |
|---|---|---|---|---|
| | LILLY | EQ 333MG BASE‡ | N50614 003 | MAY 16, 1988 |

**CEPHRADINE**

CAPSULE; ORAL
CEPHRADINE

| | | | | |
|---|---|---|---|---|
| AB | BARR LABS | 250MG‡ | N62850 001 | APR 22, 1988 |
| AB | | 500MG‡ | N62851 001 | APR 22, 1988 |
| AB | VITARINE | 250MG‡ | N62813 001 | FEB 25, 1988 |
| AB | | 500MG‡ | N62813 002 | FEB 25, 1988 |

POWDER FOR RECONSTITUTION; ORAL
CEPHRADINE

| | | | | |
|---|---|---|---|---|
| AB | BARR LABS | 125MG/5ML‡ | N62858 001 | MAY 19, 1988 |
| AB | | 250MG/5ML‡ | N62859 001 | MAY 19, 1988 |

**CHLORDIAZEPOXIDE HYDROCHLORIDE**

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

| | | | | |
|---|---|---|---|---|
| >ADD> AB | PIONEER PHARMS | 10MG‡ | N89533 001 | JUL 15, 1988 |
| >ADD> AB | | 25MG‡ | N89558 001 | JUL 15, 1988 |
| /AB/ | /PUREPAC/PHARM/ | /5MG/ | /N85155/001/ | |
| /AB/ | | /10MG/ | /N84939/002/ | |
| /AB/ | | /25MG/ | /N85144/001/ | |
| | ə PUREPAC PHARM | 5MG | N85155 001 | |
| | ə | 10MG | N84939 002 | |
| | ə | 25MG | N85144 001 | |
| | LYGEN | | | |
| /AB/ | /BANMAX/PHARMS/ | /5MG/ | /N85107/002/ | |
| /AB/ | | /10MG/ | /N85009/001/ | |
| /AB/ | | /25MG/ | /N85108/001/ | |
| | ə BANMAX PHARMS | 5MG | N85107 002 | |
| | ə | 10MG | N85009 001 | |
| | ə | 25MG | N85108 001 | |

**CHLOROTHIAZIDE; RESERPINE**

TABLET; ORAL
CHLOROTHIAZIDE W/ RESERPINE

| | | | | |
|---|---|---|---|---|
| BP | BOLAR PHARM | 250MG;0.125MG | N84853 001 | |
| | @ BOLAR PHARM | | | |

**CHLORPHENIRAMINE MALEATE**

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

| | | | | |
|---|---|---|---|---|
| AA | BARR LABS | 4MG | N80700 001 | |
| | @ BARR LABS | | | |

**CHLORPROMAZINE HYDROCHLORIDE**

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

| | | | | |
|---|---|---|---|---|
| AP | MARSAM PHARMS | 25MG/ML | N89563 001 | APR 15, 1988 |

**CHLORTHALIDONE**

TABLET; ORAL
CHLORTHALIDONE

| | | | | |
|---|---|---|---|---|
| > ADD > AB > ADD > | PIONEER PHARMS | 50MG | N89591 001 | JUL 21, 1988 |

**CHLORZOXAZONE**

TABLET; ORAL
CHLORZOXAZONE

| | | | | |
|---|---|---|---|---|
| AA | BARR LABS | 500MG | N89895 001 | MAY 04, 1988 |
| AA | CORD LABS | 250MG | N89852 001 | MAY 04, 1988 |
| AA | | 500MG | N89853 001 | MAY 04, 1988 |
| AA | LEMMON | 500MG | N89859 001 | MAY 04, 1988 |

PARAFON FORTE DSC

| | | | | |
|---|---|---|---|---|
| AA | MCNEIL PHARM | 500MG | N11529 002 | JUN 15, 1987 |

**CHOLESTYRAMINE**

BAR, CHEWABLE; ORAL
CHOLYBAR

| | | | | |
|---|---|---|---|---|
| | PARKE DAVIS | EQ 4GM RESIN/BAR | N71621 001 | MAY 26, 1988 |
| | | EQ 4GM RESIN/BAR | N71739 001 | MAY 26, 1988 |

**CLINDAMYCIN HYDROCHLORIDE**

CAPSULE; ORAL
CLEOCIN

| | | | | |
|---|---|---|---|---|
| > ADD > AB | UPJOHN MFG | EQ 75MG BASE | N61809 001 | |
| > ADD > AB | | EQ 150MG BASE | N61809 002 | |

CLEOCIN HCL

| | | | | |
|---|---|---|---|---|
| | UPJOHN | EQ 300MG BASE | N50162 003 | APR 14, 1988 |

> ADD >
CLINDAMYCIN HCL

| | | | | |
|---|---|---|---|---|
| > ADD > AB | VITARINE | EQ 75MG BASE | N62910 001 | JUL 05, 1988 |
| > ADD > AB > ADD > | | EQ 150MG BASE | N62910 002 | JUL 05, 1988 |

**CLINDAMYCIN PHOSPHATE**

INJECTABLE; IM-IV
CLINDAMYCIN PHOSPHATE

| | | | | |
|---|---|---|---|---|
| AP | LOCH PHARMS | EQ 150MG BASE/ML | N62905 001 | MAY 09, 1988 |

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

| | | | | |
|---|---|---|---|---|
| AP | ELKINS SINN | EQ 150MG BASE/ML | N62953 001 | APR 21, 1988 |
| AP | LEDERLE PARNTLS | EQ 150MG BASE/ML | N62889 001 | APR 25, 1988 |
| AP | LEMMON | EQ 150MG BASE/ML | N62900 001 | JUN 08, 1988 |
| AP | LYPHOMED | EQ 150MG BASE/ML | N62747 001 | JUN 03, 1988 |
| AP | QUAD PHARMS | EQ 150MG BASE/ML | N62877 001 | MAR 15, 1988 |
| AP | SOLOPAK LABS | EQ 150MG BASE/ML | N62819 001 | MAR 15, 1988 |
| AP | | EQ 150MG BASE/ML | N62852 001 | MAR 17, 1988 |

## CLOFIBRATE

CAPSULE; ORAL
CLOFIBRATE

| | | | | |
|---|---|---|---|---|
| AB | CORD LABS | 500MG | N72191 001 | MAY 02, 1988 |

## CLOMIPHENE CITRATE

TABLET; ORAL
CLOMIPHENE CITRATE

| | | | | |
|---|---|---|---|---|
| DLT | | | | |
| DLT | AB | PLANTEX | 50MG | N18361 001 MAR 22, 1982 |
| DLT | | | | |
| ADD | | | | |
| ADD | | SEROPHENE | | |
| ADD | AB | SERONO LABS | 50MG | N18361 001 MAR 22, 1982 |
| ADD | | | | |

## CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

| | | | | |
|---|---|---|---|---|
| AB | LEDERLE LABS | 0.1MG | N71783 001 | APR 05, 1988 |
| AB | | 0.2MG | N71784 001 | APR 05, 1988 |
| AB | | 0.3MG | N71785 001 | APR 05, 1988 |
| AB | WARNER CHILCOTT | 0.1MG | N72138 001 | JUN 13, 1988 |
| AB | | 0.2MG | N72139 001 | JUN 13, 1988 |
| AB | | 0.3MG | N72140 001 | JUN 13, 1988 |

## CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

| | | | | |
|---|---|---|---|---|
| AB | CHELSEA LABS | 3.75MG | N71878 001 | MAR 15, 1988 |
| AB | | 7.5MG | N71879 001 | MAR 15, 1988 |
| AB | | 15MG | N71860 001 | MAR 15, 1988 |
| AB | PUREPAC PHARM | 3.75MG | N71924 001 | APR 25, 1988 |
| AB | | 7.5MG | N71925 001 | APR 25, 1988 |
| AB | | 15MG | N71926 001 | APR 25, 1988 |

## CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

| | | | | |
|---|---|---|---|---|
| AB | WARNER CHILCOTT | 3.75MG | N71774 001 | MAR 01, 1988 |
| AB | | 7.5MG | N71775 001 | MAR 01, 1988 |
| AB | | 15MG | N71776 001 | MAR 01, 1988 |

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

| | | | | |
|---|---|---|---|---|
| AB | WARNER CHILCOTT | 3.75MG | N71828 001 | MAR 03, 1988 |
| AB | | 7.5MG | N71829 001 | MAR 03, 1988 |
| AB | | 15MG | N71830 001 | MAR 03, 1988 |
| AB | WATSON LABS | 3.75MG | N71852 001 | FEB 09, 1988 |
| AB | | 7.5MG | N71853 001 | FEB 09, 1988 |
| AB | | 15MG | N71854 001 | FEB 09, 1988 |
| | GEN-XENE | | | |
| AB | ALRA LABS | 3.75MG | N71787 001 | APR 26, 1988 |
| AB | | 7.5MG | N71788 001 | APR 26, 1988 |
| AB | | 15MG | N71789 001 | APR 26, 1988 |

## CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM

| | | | |
|---|---|---|---|
| AA | BIOCRAFT LABS | EQ 125MG BASE/5ML | N62268 001 |
| AB | | EQ 125MG BASE/5ML | N62268 001 |
| | TEGOPEN | | |
| AA | BRISTOL LABS | EQ 125MG BASE/5ML | N50192 001 |
| AA | | EQ 125MG BASE/5ML | N61453 001 |
| AB | | EQ 125MG BASE/5ML | N50192 001 |
| AB | | EQ 125MG BASE/5ML | N61453 001 |

## COLCHICINE; PROBENECID

TABLET; ORAL
PROBENECID AND COLCHICINE

| | | | |
|---|---|---|---|
| BP | BEECHAM LABS | 0.5MG;500MG | N84321 001 |
| | BEECHAM LABS | 0.5MG;500MG | N84321 001 |

**COLCHICINE; PROBENECID**

TABLET; ORAL
PROBENECID W/ COLCHICINE

| | | | | |
|---|---|---|---|---|
| /BP/ | /LEDERLE/LABS/ | /0.5MG;500MG/ | | /N86954/001/ |
| | a LEDERLE LABS | 0.5MG;500MG | | N86954 001 |

DD > **COPPER**

DD > INTRAUTERINE DEVICE; INTRAUTERINE
DD > INTRAUTERINE COPPER CONTRACEPTIVE

| | | | |
|---|---|---|---|
| DD > | POPULATION COUNCIL | APPROX 176MG COPPER(M) | N18680 002 |
| DD > | | | APR 29, 1988 |

**CYCLOBENZAPRINE HYDROCHLORIDE**

TABLET; ORAL
CYCLOBENZAPRINE HCL

| | | | | |
|---|---|---|---|---|
| AB | DANBURY PHARMA | 10MG(M) | | N71611 001 |
| | | | MAY 03, 1989 : | FEB 29, 1988 |

FLEXERIL

| | | | |
|---|---|---|---|
| AB | MSD | 10MG | N17821 002 |

**DACARBAZINE**

INJECTABLE; INJECTION
DACARBAZINE

| | | | |
|---|---|---|---|
| | QUAD PHARMS | 500MG/VIAL(M) | N71563 001 |
| | | | MAY 06, 1988 |

**DESIPRAMINE HYDROCHLORIDE**

TABLET; ORAL
DESIPRAMINE HCL

| | | | | |
|---|---|---|---|---|
| AB | CORD LABS | 10MG(M) | | N72099 001 |
| | | | | MAY 24, 1988 |
| AB | | 25MG(M) | | N72100 001 |
| | | | | MAY 24, 1988 |
| AB | | 50MG(M) | | N72101 001 |
| | | | | MAY 24, 1988 |
| AB | | 75MG(M) | | N72102 001 |
| | | | | JUN 20, 1988 |
| AB | | 100MG(M) | | N72103 001 |
| | | | | JUN 20, 1988 |
| AB | | 150MG(M) | | N72104 001 |
| | | | | JUN 20, 1988 |

**DESIPRAMINE HYDROCHLORIDE**

TABLET; ORAL
DESIPRAMINE HCL

| | | | | |
|---|---|---|---|---|
| AB | VITARINE | 10MG(M) | | N72167 001 |
| | | | | FEB 03, 1988 |
| AB | | 150MG(M) | | N72254 001 |
| | | | | FEB 03, 1988 |

NORPRAMIN

| | | | | |
|---|---|---|---|---|
| AB | MERRELL DON | 10MG | | N14399 007 |
| | | | | FEB 11, 1982 |
| AB | | 150MG | | N14399 006 |

**DESONIDE**

OINTMENT; TOPICAL
DESONEN

| | | | |
|---|---|---|---|
| AB | OWEN LABS | 0.05%(M) | N71425 001 |
| | | | JUN 15, 1988 |

TRIDESILON

| | | | |
|---|---|---|---|
| AB | MILES PHARM | 0.05% | N17426 001 |

**DESOXYCORTICOSTERONE ACETATE**

PELLET; IMPLANTATION
PERCORTEN

| | | | | |
|---|---|---|---|---|
| > DLT > | /CIBA/PHARM/ | /125MG/ | | /N05151/001/ |
| > ADD > | a CIBA PHARM | 125MG | | N05151 001 |

**DEXAMETHASONE**

TABLET; ORAL
DEXAMETHASONE

| | | | | |
|---|---|---|---|---|
| /BP/ | /BARR/LABS/ | /0.25MG/ | | /N84013/001/ |
| /BP/ | | /0.25MG/ | | /N84764/001/ |
| /BP/ | | /0.5MG/ | | /N84084/001/ |
| /BP/ | | /0.75MG/ | | /N84081/001/ |
| /BP/ | | /0.75MG/ | | /N84765/001/ |
| /BP/ | | /1.5MG/ | | /N84086/001/ |
| /BP/ | | /1.5MG/ | | /N84763/001/ |
| | a BARR LABS | 0.25MG | | N84013 001 |
| | a | 0.25MG | | N84764 001 |
| | a | 0.5MG | | N84084 001 |
| | a | 0.75MG | | N84081 001 |
| | a | 0.75MG | | N84765 001 |
| | a | 1.5MG | | N84086 001 |
| | a | 1.5MG | | N84763 001 |

**DEXTROSE**

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW | 10GM/100ML | N19626 004 FEB 02, 1988 |

DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 2.5GM/100ML | N19626 001 FEB 02, 1988 |

DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW | 5GM/100ML | N19626 002 FEB 02, 1988 |

DEXTROSE 7.7% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 7.7GM/100ML | N19626 003 FEB 02, 1988 |

**DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE**

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;14.5MG/100ML; 300MG/100ML | N18876 001 JAN 17, 1986 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;14.9MG/100ML; 300MG/100ML | N18876 002 JAN 17, 1986 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% AND POTASSIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;22.4MG/100ML; 300MG/100ML | N18876 003 JAN 17, 1986 |

DEXTROSE 5%; SODIUM CHLORIDE 0.225%; POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;15MG/100ML; 225MG/100ML | N18365 001 |

DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.2242 IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABS | 5GM/100ML;22.4MG/100ML; 450MG/100ML | N18362 002 |

DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABS | 5GM/100ML;22.4MG/100ML; 450MG/100ML | N18362 003 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;37MG/100ML; 200MG/100ML | N19630 031 FEB 17, 1988 |

**DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE**

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;37MG/100ML; 450MG/100ML | N19630 037 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;37MG/100ML; 900MG/100ML | N19630 043 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 5GM/100ML;37MG/100ML; 110MG/100ML | N19630 001 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 5GM/100ML;37MG/100ML; 200MG/100ML | N19630 007 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 5GM/100ML;37MG/100ML; 330MG/100ML | N19630 013 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 5GM/100ML;37MG/100ML; 450MG/100ML | N19630 019 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 5GM/100ML;37MG/100ML; 900MG/100ML | N19630 025 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;75MG/100ML; 200MG/100ML | N19630 032 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;75MG/100ML; 450MG/100ML | N19630 038 FEB 17, 1988 |

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;75MG/100ML; 900MG/100ML | N19630 044 FEB 17, 1988 |

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 200MG/100ML‡ N19630 008 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 330MG/100ML‡ N19630 014 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 450MG/100ML‡ N19630 020 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;75MG/100ML; 900MG/100ML‡ N19630 026 FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;75MG/100ML; 110MG/100ML‡ N19630 002 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100ML; 200MG/100ML‡ N19630 033 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100ML; 450MG/100ML‡ N19630 039 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100ML; 900MG/100ML‡ N19630 045 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 110MG/100ML‡ N19630 003 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 200MG/100ML‡ N19630 009 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 330MG/100ML‡ N19630 015 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 450MG/100ML‡ N19630 021 FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100ML; 900MG/100ML‡ N19630 027 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 200MG/100ML‡ N19630 034 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 450MG/100ML‡ N19630 040 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;150MG/100ML; 900MG/100ML‡ N19630 046 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;150MG/100ML; 200MG/100ML‡ N19630 010 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;150MG/100ML; 330MG/100ML‡ N19630 016 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;150MG/100ML; 450MG/100ML‡ N19630 022 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;150MG/100ML; 900MG/100ML‡ N19630 028 FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;150MG/100ML; 110MG/100ML‡ N19630 004 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAW 10GM/100ML;220MG/100ML; 200MG/100ML‡ N19630 035 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

KENDALL MCGAW 10GM/100ML;220MG/100ML; 450MG/100ML‡ N19630 041 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 10GM/100ML;220MG/100ML; 900MG/100ML‡ N19630 047 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;220MG/100ML; 110MG/100ML‡ N19630 005 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;220MG/100ML; 200MG/100ML‡ N19630 011 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;220MG/100ML; 330MG/100ML‡ N19630 017 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;220MG/100ML; 450MG/100ML‡ N19630 023 FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;220MG/100ML; 900MG/100ML‡ N19630 029 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAW 10GM/100ML;300MG/100ML; 200MG/100ML‡ N19630 036 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

KENDALL MCGAW 10GM/100ML;300MG/100ML; 450MG/100ML‡ N19630 042 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 10GM/100ML;300MG/100ML; 900MG/100ML‡ N19630 048 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 200MG/100ML‡ N19630 012 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 330MG/100ML‡ N19630 018 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 450MG/100ML‡ N19630 024 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML; 900MG/100ML‡ N19630 030 FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;300MG/100ML; 110MG/100ML‡ N19630 006 FEB 17, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 450MG/100ML‡ N18362 009 JUL 05, 1983

AP 5GM/100ML;149MG/100ML; 450MG/100ML‡ N18362 005 MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;74.5MG/100ML; 900MG/100ML‡ N19691 002 MAR 24, 1988

AP 5GM/100ML;149MG/100ML; 900MG/100ML‡ N19691 004 MAR 24, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;74.5MG/100ML; 225MG/100ML‡ N18365 002 JUL 05, 1983

5GM/100ML;149MG/100ML; 225MG/100ML‡ N18365 006 MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;74.5MG/100ML; 300MG/100ML N18876 001 JAN 17, 1986

5GM/100ML;149MG/100ML; 300MG/100ML‡ N18876 006 MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP TRAVENOL LABS 5GM/100ML;75MG/100ML; 900MG/100ML‡ N19308 004 APR 05, 1985

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;224MG/100ML; 450MG/100ML‡ N18362 006 MAR 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;224MG/100ML; 900MG/100ML‡ N19691 006 MAR 24, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML; 225MG/100ML‡ N18365 008 MAR 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML; 300MG/100ML‡ N18876 007 MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;149MG/100ML; 450MG/100ML‡ N18362 010 JUL 05, 1983

AP 5GM/100ML;298MG/100ML; 450MG/100ML‡ N18362 007 MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;149MG/100ML; 900MG/100ML‡ N19691 005 MAR 24, 1988

AP 5GM/100ML;298MG/100ML; 900MG/100ML‡ N19691 008 MAR 24, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;149MG/100ML; 225MG/100ML N18365 001

5GM/100ML;298MG/100ML; 225MG/100ML‡ N18365 009 MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;298MG/100ML; 300MG/100ML‡ N18876 008 MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% IN SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;149MG/100ML; 300MG/100ML N18876 002 JAN 17, 1986

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;224MG/100ML; 450MG/100ML N18362 002

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;224MG/100ML; 900MG/100ML‡ N19691 007 MAR 24, 1988

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML; 225MG/100ML‡ N18365 003 JUL 05, 1983

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;224MG/100ML; 300MG/100ML | N18876 003 | JAN 17, 1986 |

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | TRAVENOL LABS | 5GM/100ML;224MG/100ML; 900MG/100ML‡ | N19308 006 | APR 05, 1985 |

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABS | 5GM/100ML;298MG/100ML; 450MG/100ML | N18362 003 | |

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABS | 5GM/100ML;298MG/100ML; 900MG/100ML‡ | N19691 009 | MAR 24, 1988 |

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;298MG/100ML; 225MG/100ML‡ | N18365 004 | JUL 05, 1983 |

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;298MG/100ML; 300MG/100ML‡ | N18876 004 | MAR 28, 1988 |

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABS | 5GM/100ML;74.5MG/100ML; 450MG/100ML‡ | N18362 008 | MAR 28, 1988 |
| AP | | 5GM/100ML;149MG/100ML; 450MG/100ML‡ | N18362 004 | MAR 28, 1988 |

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABS | 5GM/100ML;74.5MG/100ML; 900MG/100ML‡ | N19691 001 | MAR 24, 1988 |
| AP | | 5GM/100ML;149MG/100ML; 900MG/100ML‡ | N19691 003 | MAR 24, 1988 |

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;74.5MG/100ML; 225MG/100ML‡ | N18365 005 | MAR 28, 1988 |
| | | 5GM/100ML;149MG/100ML; 225MG/100ML‡ | N18365 007 | MAR 28, 1988 |

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | ABBOTT LABS | 5GM/100ML;74.5MG/100ML; 300MG/100ML‡ | N18876 005 | MAR 28, 1988 |
| | | 5GM/100ML;149MG/100ML; 300MG/100ML‡ | N18876 009 | MAR 28, 1988 |

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;110MG/100ML‡ | N19631 011 | FEB 24, 1988 |

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;200MG/100ML‡ | N19631 012 | FEB 24, 1988 |

DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;330MG/100ML‡ | N19631 013 | FEB 24, 1988 |

DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 10GM/100ML;450MG/100ML‡ | N19631 014 | FEB 24, 1988 |

DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | KENDALL MCGAW | 10GM/100ML;900MG/100ML‡ | N19631 015 | FEB 24, 1988 |

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 2.5GM/100ML; 110MG/100ML‡ | N19631 001 | FEB 24, 1988 |

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 2.5GM/100ML; 200MG/100ML‡ | N19631 002 | FEB 24, 1988 |

**DEXTROSE; SODIUM CHLORIDE**

INJECTABLE; INJECTION

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 2.5GM/100ML; 330MG/100ML‡ | N19631 003 | FEB 24, 1988 |

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | KENDALL MCGAW | 2.5GM/100ML; 450MG/100ML‡ | N19631 004 | FEB 24, 1988 |

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 2.5GM/100ML; 900MG/100ML‡ | N19631 005 | FEB 24, 1988 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | KENDALL MCGAW | 5GM/100ML;110MG/100ML‡ | N19631 006 | FEB 24, 1988 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | KENDALL MCGAW | 5GM/100ML;200MG/100ML‡ | N19631 007 | FEB 24, 1988 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | KENDALL MCGAW | 5GM/100ML;330MG/100ML‡ | N19631 008 | FEB 24, 1988 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | KENDALL MCGAW | 5GM/100ML;450MG/100ML‡ | N19631 009 | FEB 24, 1988 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | KENDALL MCGAW | 5GM/100ML;900MG/100ML‡ | N19631 010 | FEB 24, 1988 |

**DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM**

INJECTABLE; INJECTION

RENOCAL-76

| | | | | |
|---|---|---|---|---|
| AP | SQUIBB DIAGS | 66%;10%‡ | N89347 001 | JUN 01, 1988 |

**DIAZEPAM**

TABLET; ORAL

G-PAM

| | | | | |
|---|---|---|---|---|
| AB | QUANTUM PHARMCS | 2MG‡ | N72431 001 | APR 29, 1988 |
| AB | | 5MG‡ | N72432 001 | APR 29, 1988 |
| AB | | 10MG‡ | N72433 001 | APR 29, 1988 |

**DIAZOXIDE**

CAPSULE; ORAL

PROGLYCEM

| | | | | |
|---|---|---|---|---|
| >ADD> | MED MRKTG SPECLTIES | 50MG | N17425 001 | |
| >ADD> | a | 100MG | N17425 002 | |
| >DLT> | /S/SCHERING/ | /50MG/ | /N17425/001/ | |

INJECTABLE; INJECTION

DIAZOXIDE

| | | | | |
|---|---|---|---|---|
| AP | QUAD PHARMS | 15MG/ML‡ | N71908 001 | JAN 26, 1988 |

SUSPENSION; ORAL

PROGLYCEM

| | | | | |
|---|---|---|---|---|
| >ADD> | MED MRKTG SPECLTIES | 50MG/ML | N17453 001 | |
| >DLT> | /S/SCHERING/ | /50MG/ML/ | /N17453/001/ | |

**DICLOFENAC SODIUM**

>ADD> TABLET, ENTERIC COATED; ORAL

>ADD> VOLTAREN

| | | | |
|---|---|---|---|
| >ADD> | CIBA PHARM | 25MG‡ | N19201 001 JUL 28, 1988 |
| >ADD> | | 50MG‡ | N19201 002 JUL 28, 1988 |
| >ADD> | | 75MG‡ | N19201 003 JUL 28, 1988 |

**DIETHYLCARBAMAZINE CITRATE**

TABLET; ORAL

HETRAZAN

| | | | | |
|---|---|---|---|---|
| >DLT> | /LEDERLE/LABS/ | /50MG/ | /N06459/001/ | |
| >ADD> | a LEDERLE LABS | 50MG | N06459 001 | |

**DOPAMINE HYDROCHLORIDE**

INJECTABLE; INJECTION

DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | BAXTER | 80MG/100ML | N19615 001 | MAR 27, 1987 |
| AP | | 160MG/100ML | N19615 002 | MAR 27, 1987 |
| AP | | 320MG/100ML | N19615 003 | MAR 27, 1987 |
| | | 640MG/100ML | N19615 004 | MAR 27, 1987 |

**DOPAMINE HYDROCHLORIDE**

INJECTABLE; INJECTION
DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| /AP/ | /TRAVENOL LABS/ | /80MG/100ML/ | /N19615/001/ | /MAR/27/1987/ |
| /AP/ | | /160MG/100ML/ | /N19615/002/ | /MAR/27/1987/ |
| /AP/ | | /320MG/100ML/ | /N19615/003/ | /MAR/27/1987/ |
| | | /640MG/100ML/ | /N19615/004/ | /MAR/27/1987/ |

**DOXEPIN HYDROCHLORIDE**

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | ADAPIN | | | |
| AB | PENNWALT | EQ 150MG BASE | N16987 007 | APR 13, 1987 |
| | DOXEPIN HCL | | | |
| AB | BARR LABS | EQ 25MG BASE | N71502 001 | FEB 18, 1988 |
| AB | | EQ 50MG BASE | N71653 001 | FEB 18, 1988 |
| AB | | EQ 75MG BASE | N71654 001 | FEB 18, 1988 |
| AB | | EQ 100MG BASE | N71521 001 | FEB 18, 1988 |
| AB | CHELSEA LABS | EQ 75MG BASE | N71763 001 | FEB 09, 1988 |
| AB | | EQ 150MG BASE | N71764 001 | FEB 09, 1988 |
| AB | LEDERLE LABS | EQ 10MG BASE | N71685 001 | JAN 05, 1988 |
| AB | | EQ 25MG BASE | N71686 001 | JAN 05, 1988 |
| AB | | EQ 50MG BASE | N71673 001 | JAN 05, 1988 |
| AB | | EQ 75MG BASE | N71674 001 | JAN 05, 1988 |
| AB | | EQ 100MG BASE | N71675 001 | JAN 05, 1988 |
| AB | | EQ 150MG BASE | N71676 001 | JAN 05, 1988 |

CONCENTRATE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | DOXEPIN HCL | | | |
| >ADD> | AA | MY K LABS | EQ 10MG BASE/ML | N71918 001 | JUL 20, 1988 |
| >ADD> | | | | | |

**DOXYCYCLINE HYCLATE**

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | DOXYCYCLINE HYCLATE | | | |
| AB | VITARINE | EQ 50MG BASE | N62780 001 | APR 12, 1988 |

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | DOXYCYCLINE | | | |
| AP | BEN VENUE LABS | EQ 100MG BASE/VIAL | N62569 001 | MAR 09, 1988 |
| AP | | EQ 200MG BASE/VIAL | N62569 002 | MAR 09, 1988 |

**DROPERIDOL**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | DROPERIDOL | | | |
| AP | ABBOTT LABS | 2.5MG/ML | N71981 001 | FEB 29, 1988 |
| AP | DUPONT CRI CARE | 2.5MG/ML | N71645 001 | APR 07, 1988 |

**DROPERIDOL; FENTANYL CITRATE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | FENTANYL CITRATE AND DROPERIDOL | | | |
| AP | ABBOTT LABS | 2.5MG/ML; EQ 0.05MG BASE/ML | N71982 001 | MAY 04, 1988 |
| | INNOVAR | | | |
| AP | JANSSEN PHARMA | 2.5MG/ML; EQ 0.05MG BASE/ML | N16049 001 | |

**EDROPHONIUM CHLORIDE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | REVERSOL | | | |
| AP | ORGANON | 10MG/ML | N89624 001 | MAY 13, 1988 |

**ENALAPRIL MALEATE**

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | VASOTEC | | | |
| >ADD> | | MS&D RES LABS | 2.5MG | N18998 005 | JUL 26, 1988 |
| >ADD> | | | | | |

**ENALAPRILAT**

INJECTABLE; INJECTION
VASOTEC

| | | | |
|---|---|---|---|
| | MS&D RES LABS | 1.25MG/ML | N19309 001 FEB 09, 1988 |

**EPINEPHRINE; LIDOCAINE HYDROCHLORIDE**

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE

| | | | |
|---|---|---|---|
| AP | ABBOTT LABS | 0.005MG/ML;0.5% | N89635 001 JUN 21, 1988 |
| AP | | 0.005MG/ML;1% | N89649 001 JUN 21, 1988 |
| AP | | 0.005MG/ML;1.5% | N89645 001 JUN 21, 1988 |
| AP | | 0.005MG/ML;1.5% | N89650 001 JUN 21, 1988 |
| AP | | 0.005MG/ML;2% | N89651 001 JUN 21, 1988 |
| AP | | 0.01MG/ML;1% | N89644 001 JUN 21, 1988 |
| AP | | 0.01MG/ML;2% | N89646 001 JUN 21, 1988 |

OCTOCAINE

| | | | |
|---|---|---|---|
| AP | NOVOCOL PHARM | 0.01MG/ML;2% | N84048 001 |
| AP | | 0.02MG/ML;2% | N84048 002 |

XYLOCAINE W/ EPINEPHRINE

| | | | |
|---|---|---|---|
| AP | ASTRA PHARM PRODS | 0.005MG/ML;0.5% | N06488 013 |
| AP | | 0.005MG/ML;1% | N06488 018 NOV 13, 1986 |
| AP | | 0.005MG/ML;2% | N06488 019 NOV 13, 1986 |

**ERGOLOID MESYLATES**

TABLET; ORAL
ERGOLOID MESYLATES

| | | | |
|---|---|---|---|
| AB | CHELSEA LABS | 1MG | N88207 001 MAR 22, 1984 |

GERIMAL

| | | | |
|---|---|---|---|
| AB | CHELSEA LABS | 1MG | N88207 001 MAR 22, 1984 |

**ERGOLOID MESYLATES**

TABLET; SUBLINGUAL
CIRCANOL

| | | | |
|---|---|---|---|
| AA | RIKER LABS | 0.5MG | N84868 001 |
| AA | | 1MG | N85809 001 |

ERGOLOID MESYLATES

| | | | |
|---|---|---|---|
| AA | CHELSEA LABS | 0.5MG | N86189 001 |
| AA | | 1MG | N86188 001 |

**ERYTHROMYCIN**

SOLUTION; TOPICAL
ETS-2%

| | | | |
|---|---|---|---|
| AT | PADDOCK LABS | 2% | N62687 001 FEB 05, 1988 |

ERYTHROMYCIN

| | | | |
|---|---|---|---|
| >ADD> AT | NASKA PHARMA | 2% | N62957 001 JUL 21, 1988 |

**ERYTHROMYCIN ETHYLSUCCINATE**

TABLET, CHEWABLE; ORAL
ERYPED

| | | | |
|---|---|---|---|
| >ADD> AB | ABBOTT LABS | EQ 200MG BASE | N50297 003 JUL 05, 1988 |

**ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL**

GRANULE; ORAL
ERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL

| | | | |
|---|---|---|---|
| AB | BARR LABS | EQ 200MG BASE/5 ML; EQ 600MG BASE/5ML | N62759 001 MAY 20, 1988 |

ERYZOLE

| | | | |
|---|---|---|---|
| AB | ALRA LABS | EQ 200MG BASE/5ML; EQ 600MG BASE/5ML | N62758 001 JUN 15, 1988 |

PEDIAZOLE

| | | | |
|---|---|---|---|
| AB | ROSS LABS | EQ 200MG BASE/5ML; EQ 600MG BASE/5ML | N50529 001 |

**ERYTHROMYCIN LACTOBIONATE**

INJECTABLE; INJECTION

ERYTHROCIN

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABS | EQ 500MG BASE/VIAL* | N62586 001 | JAN 04, 1988 |
| AP | | EQ 1GM BASE/VIAL* | N62586 002 | JAN 04, 1988 |

**ERYTHROMYCIN STEARATE**

TABLET; ORAL

BRISTAMYCIN

| | | | | |
|---|---|---|---|---|
| AB | BRISTOL LABS | EQ 250MG BASE | N61304 001 | |
| AB | ∂ | EQ 250MG BASE | N61887 001 | |

ERYPAR

| | | | | |
|---|---|---|---|---|
| AB | PARKE DAVIS | EQ 250MG BASE | N62032 001 | |
| AB | ∂ | EQ 500MG BASE | N62032 002 | |

ERYTHROCIN STEARATE

| | | | | |
|---|---|---|---|---|
| AB | ABBOTT LABS | EQ 125MG BASE | N60359 002 | |

ERYTHROMYCIN STEARATE

| | | | | |
|---|---|---|---|---|
| AB | LEDERLE LABS | EQ 250MG BASE | N62089 001 | |
| AB | ∂ | EQ 500MG BASE | N62089 002 | |

PFIZER-E

| | | | | |
|---|---|---|---|---|
| AB | PFIZER LABS | EQ 500MG BASE | N61791 002 | |

**ESTRONE**

INJECTABLE; INJECTION

ESTRONE

| | | | | | |
|---|---|---|---|---|---|
| >DLT> | BP | STERIS LABS | 5MG/ML | N85239 001 | |
| >ADD> | | | | | |

THEELIN

| | | | | | |
|---|---|---|---|---|---|
| >DLT> | BP | PARKE/DAVIS | 1MG/ML | N03977 001 | |
| >DLT> | BP | | 5MG/ML | N03977 003 | |
| >ADD> | | ∂ PARKE DAVIS | 1MG/ML | N03977 001 | |
| >ADD> | | ∂ | 5MG/ML | N03977 003 | |

**ETHINYL ESTRADIOL; NORETHINDRONE**

TABLET; ORAL-21

NORETHIN 1/35E-21

| | | | | |
|---|---|---|---|---|
| AB | SEARLE PHARMS | 0.035MG;1MG* | N71480 001 | APR 12, 1988 |

NORETHINDRONE AND ETHINYL ESTRADIOL

| | | | | |
|---|---|---|---|---|
| AB | WATSON LABS | 0.035MG;0.5MG AND 1MG* | N71043 001 | APR 01, 1988 |

ORTHO-NOVUM 10/11-21

| | | | | |
|---|---|---|---|---|
| AB | ORTHO PHARM | 0.035MG;0.5MG AND 1MG | N18354 001 | JAN 11, 1982 |

TABLET; ORAL-28

NORETHIN 1/35E-28

| | | | | |
|---|---|---|---|---|
| AB | SEARLE PHARMS | 0.035MG;1MG* | N71481 001 | APR 12, 1988 |

NORETHINDRONE AND ETHINYL ESTRADIOL

| | | | | |
|---|---|---|---|---|
| AB | WATSON LABS | 0.035MG;0.5MG AND 1MG* | N71044 001 | APR 01, 1988 |

ORTHO-NOVUM 10/11-28

| | | | | |
|---|---|---|---|---|
| AB | ORTHO PHARM | 0.035MG;0.5MG AND 1MG | N18354 002 | JAN 11, 1982 |

**ETHIODIZED OIL**

| | | | | |
|---|---|---|---|---|
| >DLT> | INJECTABLE;INJECTION | | | |
| >DLT> | ETHIODOL | | | |
| >DLT> | FOUGERA | 99% | N09196 001 | |

>ADD> OIL; INTRALYMPHATIC, INTRAUTERINE

ETHIODOL

| | | | | |
|---|---|---|---|---|
| >ADD> | FOUGERA | 99% | N09190 001 | |

**FENOPROFEN CALCIUM**

CAPSULE; ORAL

FENOPROFEN CALCIUM

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | AB | HALSEY DRUG | EQ 200MG BASE* | N72355 001 | |
| >ADD> | | | AUG 17, 1988 : | JUL 05, 1988 | |
| >ADD> | AB | | EQ 300MG BASE* | N72356 001 | |
| >ADD> | | | AUG 17, 1988 : | JUL 05, 1988 | |
| | AB | QUANTUM PHARMCS | EQ 200MG BASE* | N72214 001 | |
| | | | AUG 17, 1988 : | APR 14, 1988 | |
| | AB | | EQ 300MG BASE* | N71738 001 | |
| | | | AUG 17, 1988 : | APR 14, 1988 | |

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM

| | | | | | |
|---|---|---|---|---|---|
| >ADD > | AB | WATSON LABS | EQ 200MG BASE‡ | N72294 001 | |
| >ADD > | | | AUG 17, 1988 : JUL 08, 1988 | | |
| >ADD > | AB | | EQ 300MG BASE‡ | N72293 001 | |
| >ADD > | | | AUG 17, 1988 : JUL 08, 1988 | | |

NALFON

| | | | | |
|---|---|---|---|---|
| | AB | DISTA PRODS | EQ 300MG BASE | N17604 002 |

NALFON 200

| | | | | |
|---|---|---|---|---|
| | AB | DISTA PRODS | EQ 200MG BASE | N17604 003 |

TABLET; ORAL
FENOPROFEN CALCIUM

| | | | | |
|---|---|---|---|---|
| | AB | AM THERPTCS | EQ 600MG BASE‡ | N72309 001 |
| | | | AUG 17, 1988 : JUN 16, 1988 | |
| | AB | CHELSEA LABS | EQ 600MG BASE‡ | N72407 001 |
| | | | AUG 17, 1988 : JUN 13, 1988 | |
| >ADD > | AB | HALSEY DRUG | EQ 600MG BASE‡ | N72357 001 |
| >ADD > | | | AUG 17, 1988 : JUL 05, 1988 | |
| | AB | LEDERLE LABS | EQ 600MG BASE‡ | N72326 001 |
| | | | AUG 17, 1988 : APR 20, 1988 | |
| | AB | MYLAN PHARMS | EQ 600MG BASE‡ | N72267 001 |
| | | | AUG 17, 1988 : JUN 08, 1988 | |
| >ADD > | AB | PAR PHARM | EQ 600MG BASE‡ | N72429 001 |
| >ADD > | | | AUG 17, 1988 : JUL 19, 1988 | |
| | AB | PHARM BASICS | EQ 600MG BASE‡ | N72362 001 |
| | | | AUG 17, 1988 : JUN 16, 1988 | |
| | AB | PUREPAC PHARM | EQ 600MG BASE‡ | N72274 001 |
| | | | | MAY 02, 1988 |
| | AB | QUANTUM PHARMCS | EQ 600MG BASE‡ | N72194 001 |
| | | | AUG 17, 1988 : APR 14, 1988 | |
| >ADD > | AB | WATSON LABS | EQ 600MG BASE‡ | N72165 001 |
| >ADD > | | | AUG 17, 1988 : JUL 08, 1988 | |

NALFON

| | | | | |
|---|---|---|---|---|
| | AB | DISTA PRODS | EQ 600MG BASE | N17710 001 |

FLECAINIDE ACETATE

TABLET; ORAL
TAMBOCOR

| | | | | |
|---|---|---|---|---|
| | | RIKER LABS | 150MG‡ | N18830 003 |
| | | | | JUN 03, 1988 |

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| >ADD > | AT | G&W LABS | 0.025%‡ | N89525 001 |
| >ADD > | | | | JUL 26, 1988 |

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| >ADD > | AT | G&W LABS | 0.01%‡ | N89526 001 |
| >ADD > | | | | JUL 26, 1988 |

OIL; TOPICAL
DERMA-SMOOTHE/FS

| | | | | |
|---|---|---|---|---|
| | | HILL DERM | 0.01%‡ | N19452 001 |
| | | | | FEB 03, 1988 |

OINTMENT; TOPICAL
FLUOCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| >ADD > | AT | G&W LABS | 0.025%‡ | N89524 001 |
| >ADD > | | | | JUL 26, 1988 |

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

| | | | | |
|---|---|---|---|---|
| | AB | CLAY PARK LABS | 0.05%‡ | N71790 001 |
| | | | JUL 13, 1988 : APR 25, 1988 | |

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

| | | | | |
|---|---|---|---|---|
| | AP | BEN VENUE LABS | 50MG/ML‡ | N89508 001 |
| | | | | JAN 26, 1988 |

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
FLUPHENAZINE HCL

| | | | | |
|---|---|---|---|---|
| | AP | QUAD PHARMS | 2.5MG/ML‡ | N89800 001 |
| | | | | JUN 08, 1988 |

TABLET; ORAL
PERMITIL

| | | | | |
|---|---|---|---|---|
| | /3/ | SCHERING | 2.5MG | N12034 004 |
| | /3/ | | 5MG | N12034 005 |
| | /3/ | | 10MG | N12034 006 |

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**FLURAZEPAM HYDROCHLORIDE**

CAPSULE; ORAL
FLURAZEPAM HCL

| | | | |
|---|---|---|---|
| AB | HALSEY DRUG | 15MG | N71808 001 JAN 07, 1988 |
| AB | | 30MG | N71809 001 JAN 07, 1988 |

**FOLIC ACID**

TABLET; ORAL
FOLIC ACID

| | | | |
|---|---|---|---|
| ~~AA~~ | ~~BARR LABS~~ | ~~1MG~~ | ~~N89177 001 JAN 08, 1986~~ |
| ∂ | BARR LABS | 1MG | N89177 001 JAN 08, 1986 |

**FUROSEMIDE**

INJECTABLE; INJECTION
FUROSEMIDE

| | | | |
|---|---|---|---|
| ~~AP~~ | ~~PARKE/DAVIS~~ | ~~10MG/ML~~ | ~~N18420 001 FEB 26, 1982~~ |
| AP | NARNER CHILCOTT | 10MG/ML | N18420 001 FEB 26, 1982 |

TABLET; ORAL
FUROSEMIDE

| | | | |
|---|---|---|---|
| AB | BARR LABS | 80MG | N70100 001 JAN 26, 1988 |
| AB | DANBURY PHARMA | 80MG | N71594 001 FEB 09, 1988 |

**GADOPENTETATE DIMEGLUMINE**

INJECTABLE; INJECTION
MAGNEVIST

| | | | |
|---|---|---|---|
| | BERLEX LABS | 469.01MG/ML | N19596 001 JUN 02, 1988 |

**GALLIUM CITRATE, GA-67**

INJECTABLE; INJECTION
GALLIUM CITRATE GA 67

| | | | |
|---|---|---|---|
| ~~AA~~ | ~~MEDI PHYSICS~~ | ~~1MCI/ML~~ | ~~N17700 001~~ |
| ∂ | MEDI PHYSICS | 1MCI/ML | N17700 001 |

**GENTAMICIN SULFATE; PREDNISOLONE ACETATE**

SUSPENSION/DROPS; OPHTHALMIC
PRED-G

| | | | |
|---|---|---|---|
| | ALLERGAN PHARMS | EQ 0.3% BASE;1% | N50586 001 JUN 10, 1988 |

**GLYCOPYRROLATE**

INJECTABLE; INJECTION
GLYCOPYRROLATE

| | | | |
|---|---|---|---|
| ~~AA~~ | ~~ABBOTT LABS~~ | ~~0.2MG/ML~~ | ~~N89393 001 JUN 15, 1988~~ |
| AP | ABBOTT LABS | 0.2MG/ML | N89393 001 JUN 15, 1988 |

**HALOPERIDOL**

TABLET; ORAL
HALDOL SOLUTAB

| | | | |
|---|---|---|---|
| ~~AA~~ | ~~MCNEIL LABS~~ | ~~1MG~~ | ~~N17079 001~~ |
| ∂ | MCNEIL PHARM | 1MG | N17079 001 |

HALOPERIDOL

| | | | |
|---|---|---|---|
| AB | BARR LABS | 5MG | N71212 001 JAN 07, 1988 |
| AB | | 10MG | N71173 001 JAN 07, 1988 |
| AB | | 20MG | N71177 001 JAN 07, 1988 |
| AB | BOLAR PHARM | 0.5MG | N71571 001 JUN 03, 1988 |
| AB | | 1MG | N71572 001 JUN 03, 1988 |
| AB | | 2MG | N71573 001 JUN 03, 1988 |
| AB | | 5MG | N71374 001 JUN 03, 1988 |
| AB | | 10MG | N71375 001 JUN 03, 1988 |
| AB | | 20MG | N71376 001 JUN 03, 1988 |
| AB | CORD LABS | 10MG | N71210 001 MAR 11, 1988 |
| AB | | 20MG | N71211 001 MAR 11, 1988 |

**HALOPERIDOL LACTATE**

CONCENTRATE; ORAL
HALDOL

| | | | |
|---|---|---|---|
| ~~AA~~ | ~~MCNEIL LABS~~ | ~~EQ 2MG BASE/ML~~ | ~~N15922 001~~ |
| AA | MCNEIL PHARM | EQ 2MG BASE/ML | N15922 001 |

HALOPERIDOL LACTATE

CONCENTRATE; ORAL
HALOPERIDOL INTENSOL

| | | | |
|---|---|---|---|
| AA | ROXANE LABS | EQ 2MG BASE/ML | N72045 001<br>APR 12, 1988 |

INJECTABLE; INJECTION
HALOPERIDOL

| | | | |
|---|---|---|---|
| AP | LEMMON | EQ 5MG BASE/ML | N70713 001<br>MAY 17, 1988 |
| AP | | EQ 5MG BASE/ML | N70714 001<br>MAY 17, 1988 |
| AP | | EQ 5MG BASE/ML | N70744 001<br>MAY 17, 1988 |

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

| | | | |
|---|---|---|---|
| > DLT > /AP/ | /ABBOTT/LABS/ | /100 UNITS/ML/ | /N05264/010/ |
| > ADD > | ə ABBOTT LABS | 100 UNITS/ML | N05264 010 |
| > ADD > | HEPARIN LOCK FLUSH IN PLASTIC CONTAINER | | |
| > ADD > AP | ABBOTT LABS | 10 UNITS/ML | N05264 015<br>MAY 21, 1985 |
| > ADD > | | | |
| > ADD > AP | | 100 UNITS/ML | N05264 016<br>MAY 21, 1985 |
| > ADD > | | | |

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| /AP/ | /ABBOTT/LABS/ | /10,000 UNITS/100ML/ | /N19339/003/<br>/MAR/27,/1985/ |
| | ə ABBOTT LABS | 10,000 UNITS/100ML | N19339 003<br>MAR 27, 1985 |

HEPARIN SODIUM 1000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | BAXTER | 200 UNITS/100ML | N18609 001<br>APR 28, 1982 |
| /AP/ | /TRAVENOL/LABS/ | /200 UNITS/100ML/ | /N18609/001/<br>/APR/28,/1982/ |

HEPARIN SODIUM 12,500 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| /AP/ | /ABBOTT/LABS/ | /5,000 UNITS/100ML/ | /N19339/001/<br>/MAR/27,/1985/ |
| | ə ABBOTT LABS | 5,000 UNITS/100ML | N19339 001<br>MAR 27, 1985 |

HEPARIN SODIUM 2000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | BAXTER | 200 UNITS/100ML | N18609 002<br>APR 28, 1982 |

HEPARIN SODIUM

INJECTABLE; INJECTION
/HEPARIN SODIUM 20000 UNITS AND SODIUM CHLORIDE 0.9% IN/
/PLASTIC CONTAINER/

| | | | |
|---|---|---|---|
| /AP/ | /TRAVENOL/LABS/ | /200 UNITS/100ML/ | /N18609/002/<br>/APR/28,/1982/ |

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| /AP/ | /ABBOTT/LABS/ | /5,000 UNITS/100ML/ | /N19339/004/<br>/MAR/27,/1985/ |
| /AP/ | | /10,000 UNITS/100ML/ | /N19339/002/<br>/MAR/27,/1985/ |
| | ə ABBOTT LABS | 5,000 UNITS/100ML | N19339 004<br>MAR 27, 1985 |
| | ə | 10,000 UNITS/100ML | N19339 002<br>MAR 27, 1985 |

HEPARIN SODIUM 5000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | BAXTER | 500 UNITS/100ML | N18609 003<br>APR 28, 1982 |
| /AP/ | /TRAVENOL/LABS/ | /500 UNITS/100ML/ | /N18609/003/<br>/APR/28,/1982/ |

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

| | | | |
|---|---|---|---|
| /AA/ | /PUREPAC/PHARM/ | /50MG/ | /N88178/001/<br>/AUG/15,/1983/ |
| | ə PUREPAC PHARM | 50MG | N88178 001<br>AUG 15, 1983 |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDRAL

| | | | |
|---|---|---|---|
| AB | REID ROWELL | 25MG;25MG | N87608 001<br>FEB 08, 1982 |
| AB | | 50MG;50MG | N87213 001<br>FEB 08, 1982 |
| /3/ | | /25MG;25MG/ | /N87608/001/<br>/FEB/08,/1982/ |
| /3/ | | /50MG;50MG/ | /N87213/001/<br>/FEB/08,/1982/ |

## HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| /BP/ | /REID/RONELL/ | /25MG;15MG;0.1MG/ | /N87210/001/ |
| BP | REID RONELL | 25MG;15MG;0.1MG | N88376 001<br>OCT 28, 1983 |
| | ∂ | 25MG;15MG;0.1MG | N87210 001 |
| /∂/ | | /25MG;15MG;0.1MG/ | /N88376/001/<br>/OCT/28./1983/ |

## HYDROCHLOROTHIAZIDE

SOLUTION; ORAL
HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| AA | MY K LABS | 50MG/5ML* | N89661 001<br>JUN 20, 1988 |
| AA | ROXANE LABS | 50MG/5ML | N88587 001<br>JUL 02, 1984 |

TABLET; ORAL
HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| /AB/ | /BANMAX/PHARMS/ | /25MG/ | /N86369/001/ |
| /AB/ | | /50MG/ | /N83554/001/ |
| | ∂ BANMAX PHARMS | 25MG | N86369 001 |
| | ∂ | 50MG | N83554 001 |

## HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL
NORMOZIDE

| | | | |
|---|---|---|---|
| | /SCHERING/ | /25MG;400MG/ | /N19046/004/<br>/APR/06./1987/ |
| | ∂ SCHERING | 25MG;400MG | N19046 004<br>APR 06, 1987 |

TRANDATE HCT

| | | | |
|---|---|---|---|
| AB | GLAXO | 25MG;100MG | N19174 001<br>APR 10, 1987 |
| AB | | 25MG;200MG | N19174 002<br>APR 10, 1987 |
| AB | | 25MG;300MG | N19174 003<br>APR 10, 1987 |
| AB | | 25MG;400MG | N19174 004<br>APR 10, 1987 |

## HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL
/LABETALOL HCL/

| | | | |
|---|---|---|---|
| /AB/ | /GLAXO/ | /25MG;100MG/ | /N19174/001/<br>/APR/10./1987/ |
| /AB/ | | /25MG;200MG/ | /N19174/002/<br>/APR/10./1987/ |
| /AB/ | | /25MG;300MG/ | /N19174/003/<br>/APR/10./1987/ |
| /AB/ | | /25MG;400MG/ | /N19174/004/<br>/APR/10./1987/ |

## HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| AB | NOVOPHARM | 15MG;250MG* | N71819 001<br>APR 08, 1988 |
| AB | | 25MG;250MG* | N71820 001<br>APR 08, 1988 |
| AB | | 30MG;500MG* | N71821 001<br>APR 08, 1988 |
| AB | | 50MG;500MG* | N71822 001<br>APR 08, 1988 |
| /AB/ | /PUREPAC/PHARM/ | /50MG;500MG/ | /N70689/001/<br>/APR/24./1986/ |
| | ∂ PUREPAC PHARM | 50MG;500MG | N70689 001<br>APR 24, 1986 |
| AB | ZENITH LABS | 15MG;250MG* | N71458 001<br>MAR 08, 1988 |
| AB | | 25MG;250MG* | N71459 001<br>MAR 08, 1988 |
| AB | | 30MG;500MG* | N71460 001<br>MAR 08, 1988 |
| AB | | 50MG;500MG* | N71461 001<br>MAR 08, 1988 |

## HYDROCHLOROTHIAZIDE; PINDOLOL

TABLET; ORAL
VISKAZIDE

| | | | | |
|---|---|---|---|---|
| >DLT< | /SANDOZ/PHARMS/ | /25MG;5MG/ | | /N18872/001/<br>/JUL/22./1987/ |
| >DLT< | | | | |
| >ADD< | ∂ SANDOZ PHARMS | 25MG;5MG | | N18872 001<br>JUL 22, 1987 |
| >ADD< | | | | |
| >DLT< | | /25MG;10MG/ | | /N18872/002/<br>/JUL/22./1987/ |
| >DLT< | | | | |
| >ADD< | ∂ | 25MG;10MG | | N18872 002<br>JUL 22, 1987 |
| >ADD< | | | | |

## HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| AB | SIDMAK LABS | 25MG;40MG | N72042 001 | MAR 14, 1988 |
| AB | | 25MG;80MG | N72043 001 | MAR 14, 1988 |
| AB | WARNER CHILCOTT | 25MG;40MG | N71771 001 | JAN 26, 1988 |
| AB | | 25MG;80MG | N71772 001 | JAN 26, 1988 |

## HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| /BP/ | /BARR/LABS/ | /25MG;0.125MG/ | /N84580 001/ | |
| /BP/ | | /50MG;0.125MG/ | /N84579 001/ | |
| | ∂ BARR LABS | 25MG;0.125MG | N84580 001 | |
| | ∂ | 50MG;0.125MG | N84579 001 | |

## HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| AB | VITARINE | 25MG;50MG | N71737 001 | FEB 12, 1988 |

TABLET; ORAL
MAXZIDE-25MG

| | | | | |
|---|---|---|---|---|
| | MYLAN PHARMS | 25MG;37.5MG | N19129 003 | MAY 13, 1988 |

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| AB | CORD LABS | 50MG;75MG | N72011 001 | JUN 17, 1988 |
| AB | DANBURY PHARMA | 50MG;75MG | N71969 001 | APR 17, 1988 : JAN 15, 1988 |
| AB | PAR PHARM | 50MG;75MG | N72337 001 | MAY 11, 1988 |
| AB | QUANTUM PHARMCS | 50MG;75MG | N71980 001 | APR 17, 1988 : FEB 01, 1988 |

## HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| AT | NASKA PHARMA | 1% | N89706 001 | MAR 10, 1988 |
| AT | | 2.5% | N89682 001 | MAR 10, 1988 |
| AT | NMC LABS | 1% | N87795 001 | MAY 03, 1983 |

HYDROTEX

| | | | | |
|---|---|---|---|---|
| AT | SYOSSET LABS | 1% | N87427 001 | APR 04, 1988 |
| /AT/ | /HYNAC/ /NMC LABS/ | /1%/ | /N87795/001/ /MAY 03, 1983/ | |

LOTION; TOPICAL
BETA-HC

| | | | | |
|---|---|---|---|---|
| AT | BETA DERM | 1% | N89495 001 | JAN 25, 1988 |

HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| AT | NASKA PHARMA | 1% | N89705 001 | APR 25, 1988 |

OINTMENT; TOPICAL
HC (HYDROCORTISONE)

| | | | | |
|---|---|---|---|---|
| /AT/ | /C&M PHARMA/ | /0.5%/ | /N80481/001/ | |
| /$/ | | /1%/ | /N80481/002/ | |
| AT | C&M PHARMA | 1% | N80481 002 | |

HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| AT | NASKA PHARMA | 1% | N89704 001 | MAR 10, 1988 |

TABLET; ORAL
HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| /BP/ | /BARR/LABS/ | /20MG/ | /N83999/001/ | |
| | ∂ BARR LABS | 20MG | N83999 001 | |

## HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

| | | | | |
|---|---|---|---|---|
| AT | THAMES PHARMA | 1% | N89472 001 | JUN 13, 1988 |

## HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL
EPIFOAM

| | | | | |
|---|---|---|---|---|
| AT | REED & CARNRICK | 1%;1% | N86457 001 | |

**HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE**

AEROSOL; TOPICAL
HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%

| | | | | |
|---|---|---|---|---|
| AT | COPLEY PHARM | 1%;1% | N89440 001 | MAY 17, 1988 |

**HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE**

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

| | | | | | |
|---|---|---|---|---|---|
| AT | STERIS LABS | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62874 001 | > ADD > > ADD > | MAY 11, 1988 |

**HYDROXYZINE HYDROCHLORIDE**

INJECTABLE; INJECTION
HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| /AP/ | /ALTANA/ | /25MG/ML/ | /N87273/001/ | /APR/20./1982/ |
| /AP/ | | /50MG/ML/ | /N87273/002/ | /APR/20./1982/ |
| | ə ALTANA | 25MG/ML | N87273 001 | APR 20, 1982 |
| | ə | 50MG/ML | N87273 002 | APR 20, 1982 |

SYRUP; ORAL
HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| AA | NASKA PHARMA | 10MG/5ML | N88785 001 | FEB 03, 1988 |

TABLET; ORAL
HYDROXYZINE HCL

| | | | | | |
|---|---|---|---|---|---|
| AB | HALSEY DRUG | 10MG | N89366 001 | > DLT > > DLT > > ADD > > ADD > | MAY 02, 1988 |
| AB | | 25MG | N89117 001 | | MAY 02, 1988 |
| AB | | 50MG | N89396 001 | | MAY 02, 1988 |

**IBUPROFEN**

TABLET; ORAL
IBUPROFEN

| | | | | | |
|---|---|---|---|---|---|
| AB | HALSEY DRUG | 800MG | N72137 001 | > ADD > > ADD > > ADD > > ADD > | FEB 05, 1988 |

**IBUPROFEN**

TABLET; ORAL
IBUPROFEN

| | | | | | |
|---|---|---|---|---|---|
| AB | INVAMED | 400MG | N72064 001 | | JAN 14, 1988 |
| AB | | 600MG | N72065 001 | | JAN 14, 1988 |
| AB | | 800MG | N71938 001 | | JAN 14, 1988 |
| AB | MEDICOPHARMA | 400MG | N71644 001 | | FEB 01, 1988 |
| AB | PRIVATE FMLTNS | 800MG | N72300 001 | | JUL 01, 1988 |
| AB | PUREPAC PHARM | 800MG | N71964 001 | | FEB 01, 1988 |

**IMIPRAMINE HYDROCHLORIDE**

TABLET; ORAL
PRAMINE

| | | | | |
|---|---|---|---|---|
| /AB/ | /BANMAX/PHARMS/ | /10MG/ | /N83827/001/ | |
| /AB/ | | /25MG/ | /N83827/002/ | |
| /AB/ | | /50MG/ | /N83827/003/ | |
| | ə BANMAX PHARMS | 50MG | N83827 003 | |
| | ə | 10MG | N83827 001 | |
| | ə | 25MG | N83827 002 | |

**INDIUM IN-111 OXYQUINOLINE**

INJECTABLE; INTRATHECAL
INDIUM IN-111 OXYQUINOLINE

| | | | | | |
|---|---|---|---|---|---|
| | /AMERSHAM/ | /N/A/ | /N19044/001/ | | /DEC/23./1985/ |
| | AMERSHAM | 1MCI/ML | N19044 001 | | DEC 23, 1985 |

**INDOMETHACIN**

CAPSULE; ORAL
INDOMETHACIN

| | | | | | |
|---|---|---|---|---|---|
| AB | NOVOPHARM | 25MG | N71342 001 | | APR 18, 1988 |
| AB | | 50MG | N71343 001 | | APR 18, 1988 |
| AB | VITARINE PHARMS | 25MG | N71711 001 | | JUL 05, 1988 |
| AB | | 50MG | N71712 001 | | JUL 05, 1988 |

**INSULIN PORK**

INJECTABLE; INJECTION

> DLT > /ILETIN/
> DLT > /LILLY/ /500 UNITS/ML/ /N17931/001/
> ADD > ILETIN I
> ADD > LILLY 500 UNITS/ML N17931 001

**IOHEXOL**

INJECTABLE; INJECTION

OMNIPAQUE 180
/S/STERLING/DRUG/ /38.8%/ /N18956/001/ /DEC/26,/1985/
AP STERLING DRUG 38.8% N18956 001 DEC 26, 1985

**IRON DEXTRAN**

INJECTABLE; INJECTION

PROFERDEX
> DLT >/AP/ /FISONS/ /EQ 50MG IRON/ML/ /N17807/001/
> ADD > 3 FISONS EQ 50MG IRON/ML N17807 001

**ISONIAZID**

TABLET; ORAL

LANIAZID
AA LANNETT 300MG* N89776 001 JUN 13, 1988

**ISOSORBIDE DINITRATE**

> ADD > CAPSULE, CONTROLLED RELEASE; ORAL
> ADD > ISORDIL
> ADD > NYETH-AYERST 40MG* N12882 002 JUL 29, 1988
> ADD >

**ISOSORBIDE DINITRATE**

TABLET; ORAL

> ADD >
> ADD > AB ISORDIL NYETH-AYERST 5MG* N12093 007 JUL 29, 1988
> ADD >
> ADD > AB 10MG* N12093 002 JUL 29, 1988
> ADD >
> ADD > AB 20MG* N12093 006 JUL 29, 1988
> ADD >
> ADD > AB 30MG* N12093 005 JUL 29, 1988
> ADD >
> ADD > 40MG* N12093 001 JUL 29, 1988
> ADD >

**ISOSORBIDE DINITRATE**

AB BARR LABS 30MG* N87564 001 SEP 18, 1986
AB CORD LABS 5MG* N86221 001 JAN 07, 1988
AB 10MG* N86223 001 JAN 07, 1988
AB 20MG* N89367 001 APR 07, 1988
AB DANBURY PHARMA 5MG* N86034 001 JAN 06, 1988
AB 10MG* N86032 001 JAN 07, 1988
AB PAR PHARM 30MG* N87946 001 JAN 12, 1988

TABLET; SUBLINGUAL

> ADD >
> ADD > AB ISORDIL NYETH-AYERST 2.5MG* N12940 004 JUL 29, 1988
> ADD >
> ADD > AB 5MG* N12940 003 JUL 29, 1988
> ADD >
> ADD > AB 10MG* N12940 005 JUL 29, 1988
> ADD >

**ISOSORBIDE DINITRATE**

> ADD > AB BARR LABS 10MG N87545 001 SEP 18, 1986
> ADD >
AB CORD LABS 2.5MG* N86225 001 FEB 19, 1988
AB 5MG* N86222 001 FEB 19, 1988
AB DANBURY PHARMA 2.5MG* N86033 001 FEB 26, 1988
AB 5MG N86031 001 SEP 29, 1987

**ISOSORBIDE DINITRATE**

TABLET, CONTROLLED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | | ISORDIL | | | |
| >ADD> | | MYETH-AYERST | 40MGM | | N12882 001 |
| >ADD> | | | | | JUL 29, 1988 |

**KETAMINE HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | KETALAR | | | |
| AP | PARKE DAVIS | EQ 10MG BASE/ML | | N16812 001 |
| AP | | EQ 50MG BASE/ML | | N16812 002 |
| AP | | EQ 100MG BASE/ML | | N16812 003 |
| | KETAMINE HCL | | | |
| AP | QUAD PHARMS | EQ 10MG BASE/MLM | | N71949 001 |
| | | | | APR 11, 1988 |
| AP | | EQ 50MG BASE/MLM | | N71950 001 |
| | | | | APR 11, 1988 |
| AP | | EQ 100MG BASE/MLM | | N71951 001 |
| | | | | APR 11, 1988 |

**LACTULOSE**

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | | CHRONULAC | | |
| >ADD> | AA | MERRELL DOW | 10GM/15ML | N17884 001 |
| >ADD> | | CONSTILAC | | |
| >ADD> | AA | ALRA LABS | 10GM/15MLM | N71054 001 |
| >ADD> | | | | JUL 26, 1988 |
| >DLT> | | /CEPHULAC/ | | |
| >DLT>/AA/ | | /MERRELL/DOW/ | /10GM/15ML/ | /N17657/001/ |
| >DLT> | | /LACTULOSE/ | | |
| >DLT>/AA/ | | /ROXANE/LABS/ | /10GM/15ML/ | /N17906/001/ |

SYRUP; ORAL, RECTAL

| | | | | |
|---|---|---|---|---|
| >ADD> | | CEPHULAC | | |
| >ADD> | AA | MERRELL DOW | 10GM/15ML | N17657 001 |
| >ADD> | | CHOLAC | | |
| >ADD> | AA | ALRA LABS | 10GM/15MLM | N71331 001 |
| >ADD> | | | | JUL 26, 1988 |
| >ADD> | | LACTULOSE | | |
| >ADD> | AA | KALI DUPHAR | 10GM/15ML | N17906 001 |

**LEUCOVORIN CALCIUM**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | LEUCOVORIN CALCIUM | | | |
| AP | BEN VENUE LABS | EQ 100MG BASE/VIALM | | N89717 001 |
| | | | | MAR 28, 1988 |
| AP | INTL PHARM | EQ 3MG BASE/ML | M | N89352 001 |
| | | | | JUN 01, 1988 |
| AP | | EQ 50MG BASE/VIALM | | N89353 001 |
| | | | | JUN 01, 1988 |
| AP | LEDERLE LABS | EQ 3MG BASE/ML | | N08107 001 |
| AP | | EQ 100MG BASE/VIALM | | N08107 004 |
| | | | | MAY 23, 1988 |
| AP | QUAD PHARMS | EQ 100MG BASE/VIAL | | N89636 001 |
| | | | | DEC 24, 1987 |

**LEVODOPA**

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | BENDOPA | | |
| /BO/ | /ICN/PHARMS/ | /100MG/ | /N16948/001/ |
| /BO/ | | /250MG/ | /N16948/001/ |
| /BO/ | | /500MG/ | /N16948/002/ |
| | ∂ ICN PHARMS | 100MG | N16948 003 |
| | ∂ | 250MG | N16948 001 |
| | ∂ | 500MG | N16948 002 |

**LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | ISOCAINE HCL W/ LEVONORDEFRIN | | |
| /AP/ | /NOVOCOL/CHEM/ | /0.05MG/ML;2%/ | /N84697/001/ |
| AP | NOVOCOL PHARM | 0.05MG/ML;2% | N84697 001 |
| | POLOCAINE W/ LEVONORDEFRIN | | |
| AP | ASTRA PHARM PRODS | 0.05MG/ML;2%M | N89517 001 |
| | | | APR 14, 1988 |

**LIDOCAINE HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | LIDOCAINE HCL | | | |
| AP | ABBOTT LABS | 20%M | | N89362 001 |
| | | | | MAY 25, 1988 |
| /AP/ | /LEMMON/ | /1%/ | | /N83627/001/ |
| /AP/ | | /2%/ | | /N83627/002/ |
| | ∂ LEMMON | 1% | | N83627 001 |
| | ∂ | 2% | | N83627 002 |

**LINCOMYCIN HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | LINCOCIN | | | |
| AP | UPJOHN | EQ 300MG BASE/ML | N50317 001 | |
| | LINCOMYCIN HCL | | | |
| AP | QUAD PHARMS | EQ 300MG BASE/ML‡ | N62784 001 | MAR 14, 1988 |

**LISINOPRIL**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PRINIVIL | | | |
| AB | MS&D RES LABS | 5MG | N19558 001 | DEC 29, 1987 |
| AB | | 10MG | N19558 002 | DEC 29, 1987 |
| AB | | 20MG | N19558 003 | DEC 29, 1987 |
| | ZESTRIL | | | |
| AB | IMPERIAL CHEM | 5MG‡ | N19777 001 | MAY 19, 1988 |
| AB | | 10MG‡ | N19777 002 | MAY 19, 1988 |
| AB | | 20MG‡ | N19777 003 | MAY 19, 1988 |

**LOPERAMIDE HYDROCHLORIDE**

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | IMODIUM | | | |
| | /JANSSEN/PHARMA/ | /1MG/5ML/ | /N19037/001/ | /JUL/31/1984/ |
| | ∂ JANSSEN PHARMA | 1MG/5ML | N19037 001 | JUL 31, 1984 |

**LORAZEPAM**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | LORAZEPAM | | | |
| AB | CORD LABS | 0.5MG‡ | N71193 001 | APR 15, 1988 |
| AB | | 1MG‡ | N71194 001 | APR 15, 1988 |
| AB | | 2MG‡ | N71195 001 | APR 15, 1988 |
| AB | MARNER CHILCOTT | 1MG‡ | N71038 001 | JAN 12, 1988 |
| AB | | 2MG‡ | N71039 001 | JAN 12, 1988 |

**LOXAPINE SUCCINATE**

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | LOXAPINE SUCCINATE | | | |
| AB | NATSON LABS | EQ 5MG BASE‡ | N72204 001 | JUN 15, 1988 |
| AB | | EQ 10MG BASE‡ | N72205 001 | JUN 15, 1988 |
| AB | | EQ 25MG BASE‡ | N72206 001 | JUN 15, 1988 |
| AB | | EQ 50MG BASE‡ | N72062 001 | JUN 15, 1988 |
| | LOXITANE | | | |
| AB | LEDERLE LABS | EQ 5MG BASE | N17525 001 | |
| AB | | EQ 10MG BASE | N17525 002 | |
| AB | | EQ 25MG BASE | N17525 003 | |
| AB | | EQ 50MG BASE | N17525 004 | |

**MAPROTILINE HYDROCHLORIDE**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | MAPROTILINE HCL | | | |
| AB | AM THERPTCS | 25MG‡ | N72129 001 | JAN 14, 1988 |
| AB | | 50MG‡ | N72130 001 | JAN 14, 1988 |
| AB | | 75MG‡ | N72131 001 | JAN 14, 1988 |
| AB | NATSON LABS | 25MG‡ | N72162 001 | JUN 01, 1988 |
| AB | | 50MG‡ | N72163 001 | JUN 01, 1988 |
| AB | | 75MG‡ | N72164 001 | JUN 01, 1988 |

**MECLIZINE HYDROCHLORIDE**

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ANTIVERT | | | |
| AA | ROERIG | 50MG | N10721 001 | JAN 20, 1982 |
| | MECLIZINE HCL | | | |
| AA | PAR PHARM | 50MG‡ | N89674 001 | MAR 31, 1988 |

## MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

| | | | | |
|---|---|---|---|---|
| AB | PAR PHARM | EQ 50MG BASE‡ | N72077 001 | MAR 10, 1988 |
| AB | | EQ 100MG BASE‡ | N72078 001 | MAR 10, 1988 |
| AB | PHARM BASICS | EQ 50MG BASE‡ | N71007 001 | MAR 25, 1988 |
| AB | | EQ 100MG BASE‡ | N71008 001 | MAR 25, 1988 |
| AB | VITARINE | EQ 50MG BASE‡ | N71710 001 | JUN 15, 1988 |
| AB | | EQ 100MG BASE‡ | N71684 001 | JUN 15, 1988 |

## MEFENAMIC ACID

CAPSULE; ORAL

MEFENAMIC ACID

| | | | |
|---|---|---|---|
| AB | VITARINE | 250MG‡ | N72179 001 APR 21, 1988 |

PONSTEL

| | | | |
|---|---|---|---|
| AB | PARKE DAVIS PR | 250MG | N15034 003 |

## MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

ISOCAINE HCL

| | | | |
|---|---|---|---|
| AP | NOVOCOL PHARM | 3% | N80925 001 |

## MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

| | | | |
|---|---|---|---|
| | ∂ MALLARD | 400MG | N15072 002 |
| | ∂ PHARM BASICS | 200MG | N87825 001 MAR 18, 1982 |
| | ∂ | 400MG | N87826 001 MAR 18, 1982 |

## MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

NORETHIN 1/50M-21

| | | | |
|---|---|---|---|
| AB | SEARLE PHARMS | 0.05MG;1MG‡ | N71539 001 APR 12, 1988 |

NORETHINDRONE AND MESTRANOL

| | | | |
|---|---|---|---|
| AB | WATSON LABS | 0.05MG;1MG‡ | N70758 001 JUL 01, 1988 |

TABLET; ORAL-28

NORETHIN 1/50M-28

| | | | |
|---|---|---|---|
| AB | SEARLE PHARMS | 0.05MG;1MG‡ | N71540 001 APR 12, 1988 |

NORETHINDRONE AND MESTRANOL

| | | | |
|---|---|---|---|
| AB | WATSON LABS | 0.05MG;1MG‡ | N70759 001 JUL 01, 1988 |

## MESTRANOL; NORETHYNODREL

TABLET; ORAL-20

ENOVID

| | | | |
|---|---|---|---|
| | ∂ SEARLE | 0.075MG;5MG | N10976 004 |

ENOVID-E

| | | | |
|---|---|---|---|
| | ∂ SEARLE | 0.1MG;2.5MG | N10976 006 |

## METAPROTERENOL SULFATE

SOLUTION; INHALATION

ALUPENT

| | | | |
|---|---|---|---|
| AN | BOEHR INGEL | 0.4% | N18761 002 OCT 10, 1986 |

METAPROTERENOL SULFATE

| | | | |
|---|---|---|---|
| AN | ARMOUR PHARM | 0.4%‡ | N71275 001 JUL 27, 1988 |
| AN | | 0.6%‡ | N71018 001 JUL 27, 1988 |
| AN | MY K LABS | 5%‡ | N72190 001 JUN 07, 1988 |
| AN | PACO RES | 0.4%‡ | N71855 001 JUL 14, 1988 |
| AN | | 0.6%‡ | N71726 001 JUL 14, 1988 |

TABLET; ORAL

ALUPENT

| | | | |
|---|---|---|---|
| AB | BOEHR INGEL | 10MG | N15874 002 |
| AB | | 20MG | N15874 001 |

METAPROTERENOL SULFATE

TABLET; ORAL

METAPROTERENOL SULFATE

| | | | | |
|---|---|---|---|---|
| AB | AM THERPTCS | 10MG | N72054 001 | JUN 23, 1988 |
| AB | | 20MG | N72055 001 | JUN 23, 1988 |
| AB | PAR PHARM | 10MG | N72024 001 | JUN 28, 1988 |
| AB | | 20MG | N72025 001 | JUN 28, 1988 |
| AB | PHARM BASICS | 10MG | N71013 001 | JAN 25, 1988 |
| AB | | 20MG | N71014 001 | JAN 25, 1988 |

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

| | | | | |
|---|---|---|---|---|
| ~~AA~~ | ~~BARR LABS~~ | ~~500MG~~ | ~~N84446 001~~ | |
| a | BARR LABS | 500MG | N84488 001 | |

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE

| | | | | |
|---|---|---|---|---|
| | LEDERLE LABS | EQ 1GM BASE/VIAL | N11719 009 | APR 07, 1988 |

METHOTREXATE SODIUM

| | | | | |
|---|---|---|---|---|
| > ADD > AP > ADD > | PHARMACHEMIE | EQ 25MG BASE/ML | N89158 001 | JUL 08, 1988 |

METHOXSALEN

CAPSULE; ORAL

~~OXSORALEN~~

| | | | | |
|---|---|---|---|---|
| ~~BP~~ | ~~ELDER PHARMS~~ | ~~10MG~~ | ~~N09046 001~~ | |

8-MOP

| | | | | |
|---|---|---|---|---|
| | ELDER PHARMS | 10MG | N09048 001 | |

METHYLDOPA

TABLET; ORAL

METHYLDOPA

| | | | | |
|---|---|---|---|---|
| AB | CORD LABS | 125MG | N71700 001 | MAR 02, 1988 |

METHYLDOPA

TABLET; ORAL

METHYLDOPA

| | | | | |
|---|---|---|---|---|
| AB | HALSEY DRUG | 125MG | N71751 001 | MAR 28, 1988 |
| AB | | 250MG | N71752 001 | MAR 28, 1988 |
| AB | | 500MG | N71753 001 | MAR 28, 1988 |
| > ADD > AB > ADD > | SIDMAK LABS | 125MG | N72126 001 | JUL 07, 1988 |
| > ADD > AB > ADD > | | 250MG | N72127 001 | JUL 07, 1988 |
| > ADD > AB > ADD > | | 500MG | N72128 001 | JUL 07, 1988 |

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL

METHYLPHENIDATE HCL

| | | | | |
|---|---|---|---|---|
| AB | MD PHARM | 20MG | N89601 001 | JUN 01, 1988 |

RITALIN-SR

| | | | | |
|---|---|---|---|---|
| AB | CIBA PHARM | 20MG | N18029 001 | MAR 30, 1982 |

METHYLPREDNISOLONE

TABLET; ORAL

MEDROL

| | | | | |
|---|---|---|---|---|
| AB | UPJOHN | 24MG | N11153 005 | |
| AB | | 32MG | N11153 006 | |

METHYLPREDNISOLONE

| | | | | |
|---|---|---|---|---|
| AB | PAR PHARM | 16MG | N89207 001 | APR 25, 1988 |
| AB | | 24MG | N89208 001 | APR 25, 1988 |
| AB | | 32MG | N89209 001 | APR 25, 1988 |

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

CLOPRA

| | | | | |
|---|---|---|---|---|
| AB | QUANTUM PHARMCS | EQ 5MG BASE | N72384 001 | JUN 02, 1988 |

METOCLOPRAMIDE HCL

| | | | | |
|---|---|---|---|---|
| AB | SIDMAK LABS | EQ 10MG BASE | N71250 001 | FEB 03, 1988 |

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
REGLAN
AB ROBINS EQ 5MG BASE N17854 002 MAY 05, 1987

METOCURINE IODIDE

INJECTABLE; INJECTION
METOCURINE IODIDE
AP QUAD PHARMS 2MG/ML N89443 001 JUN 01, 1988

METUBINE IODIDE
AP LILLY 2MG/ML N06632 003

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION
MEZLIN
MILES PHARM EQ 20GM BASE/VIAL N50549 005 MAR 02, 1988
EQ 20GM BASE/VIAL N62372 004 MAR 02, 1988

MINOXIDIL

TABLET; ORAL
MINODYL
>ADD> >ADD> AB QUANTUM PHARMCS 2.5MG N72153 001 JUL 13, 1988

MITOMYCIN

INJECTABLE; INJECTION
MUTAMYCIN
BRISTOL MYERS 40MG/VIAL N62336 003 MAR 10, 1988

MORPHINE SULFATE

INJECTABLE; INJECTION
MORPHINE SULFATE
AP ABBOTT LABS 0.5MG/ML N71849 001 MAY 11, 1988
AP 1MG/ML N71850 001 MAY 11, 1988

MORPHINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL
MS CONTIN
PURDUE FRDRK 60MG N19516 002 APR 08, 1988

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL
NAFTIN
HERBERT LABS 1% N19599 001 FEB 29, 1988

NALIDIXIC ACID

TABLET; ORAL
NALIDIXIC ACID
AB DANBURY PHARMA 250MG N71936 001 JUN 29, 1988 : JUN 28, 1988
AB 500MG N72061 001 JUN 29, 1988 : JUN 28, 1988
AB 1GM N71919 001 JUN 29, 1988 : JUN 28, 1988

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL
AP ELKINS SINN 0.02MG/ML N71272 001 MAY 24, 1988
AP 1MG/ML N71273 001 MAY 24, 1988
AP 1MG/ML N71274 001 MAY 24, 1988
AP 1MG/ML N71287 001 MAY 24, 1988
AP INTL MEDTN SYS 1MG/ML N72076 001 MAR 24, 1988
AP 1MG/ML N72115 001 APR 27, 1988
>ADD> >ADD> AP MARSAM PHARMS 0.4MG/ML N71811 001 JUL 19, 1988

NARCAN
>ADD> >ADD> AP DUPONT CRI CARE 0.4MG/ML N71083 001 JUL 28, 1988
>ADD> >ADD> AP 1MG/ML N71084 001 JUL 28, 1988
>ADD> >ADD> AP 1MG/ML N71311 001 JUL 28, 1988

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN
/AA/ /BOLAR PHARM/ /100MG/ /N80447/002/
∂ BOLAR PHARM 100MG N80447 002

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
MACRODANTIN
AB NORWICH EATON 50MG N16620 001
AB 100MG N16620 002
NITROFURANTOIN MACROCRYSTALLINE
AB BOLAR PHARM 50MG∅ N70248 001 JUN 24, 1988
AB 100MG∅ N70249 001 JUN 24, 1988

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN
AP LUITPOLD PHARMS 5MG/ML∅ N71492 001 MAY 24, 1988
AP 5MG/ML∅ N72034 001 MAY 24, 1988

>ADD> OINTMENT; TOPICAL
>ADD> NITROGLYCERIN
>ADD> ALTANA 2%∅ N87355 001 JUL 08, 1988
>ADD>

NIZATIDINE

CAPSULE; ORAL
AXID
LILLY 150MG∅ N19508 001 APR 12, 1988
300MG∅ N19508 002 APR 12, 1988

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
AVENTYL HCL
BD LILLY EQ 10MG BASE N14684 001
BD EQ 25MG BASE N14684 002
/BP/ /EQ/10MG/BASE/ /N14684/001/
/BP/ /EQ/25MG/BASE/ /N14684/002/
PAMELOR
BD SANDOZ PHARMS EQ 10MG BASE N18013 001
BD EQ 25MG BASE N18013 002
/BP/ /EQ/10MG/BASE/ /N18013/001/
/BP/ /EQ/25MG/BASE/ /N18013/002/

NYSTATIN

CREAM; TOPICAL
NYSTATIN
AT NASKA PHARMA 100,000 UNITS/GM∅ N62949 001 JUN 13, 1988

SUSPENSION; ORAL
NYSTATIN
AA THAMES PHARMA 100,000 UNITS/ML∅ N62876 001 FEB 29, 1988

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM
AB AM THERPTCS 10MG∅ N71955 001 MAR 03, 1988
AB 15MG∅ N71956 001 MAR 03, 1988
AB 30MG∅ N71957 001 MAR 03, 1988
AB CHELSEA LABS 10MG∅ N71661 001 MAR 02, 1988
AB 15MG∅ N71662 001 MAR 02, 1988
AB 30MG∅ N71663 001 MAR 02, 1988
AB CORD LABS 10MG∅ N71813 001 APR 19, 1988
AB 15MG∅ N71756 001 APR 19, 1988
AB 30MG∅ N71814 001 APR 19, 1988

**OXAZEPAN**

CAPSULE; ORAL

OXAZEPAM

| | | | | | |
|---|---|---|---|---|---|
| /BP/ | /MYLAN PHARMS/ | /10MG/ | /N71713/001/ /OCT 20, 1987/ | | |
| /BP/ | | /15MG/ | /N71714/001/ /OCT 20, 1987/ | | |
| /BP/ | | /30MG/ | /N71715/001/ /OCT 20, 1987/ | | |
| | ə MYLAN PHARMS | 10MG | N71713 001 OCT 20, 1987 | | |
| | ə | 15MG | N71714 001 OCT 20, 1987 | | |
| | ə | 30MG | N71715 001 OCT 20, 1987 | | |
| AB | PUREPAC PHARM | 10MG | N72251 001 APR 14, 1988 | | |
| AB | | 15MG | N72252 001 APR 14, 1988 | | |
| AB | | 30MG | N72253 001 APR 14, 1988 | | |
| > ADD > AB | ZENITH LABS | 10MG | N70943 001 AUG 03, 1987 | | |
| > ADD > AB | | 15MG | N70944 001 AUG 03, 1987 | | |
| > ADD > AB | | 30MG | N70945 001 AUG 03, 1987 | | |
| > DLT > /BP/ | | /10MG/ | /N70943/001/ /AUG 03, 1987/ | | |
| > DLT > /BP/ | | /15MG/ | /N70944/001/ /AUG 03, 1987/ | | |
| > DLT > /BP/ | | /30MG/ | /N70945/001/ /AUG 03, 1987/ | | |

SERAX

| | | | |
|---|---|---|---|
| AB | WYETH | 10MG | N15539 002 |
| AB | | 15MG | N15539 004 |
| AB | | 30MG | N15539 006 |
| /BP/ | | /10MG/ | /N15539/002/ |
| /BP/ | | /15MG/ | /N15539/004/ |
| /BP/ | | /30MG/ | /N15539/006/ |

ZAMOPAM

| | | | | |
|---|---|---|---|---|
| AB | QUANTUM PHARMCS | 10MG | N70650 001 MAR 01, 1988 | |
| AB | | 15MG | N70640 001 MAR 01, 1988 | |
| AB | | 30MG | N70641 001 MAR 01, 1988 | |

**OXYBUTYNIN CHLORIDE**

TABLET; ORAL

DITROPAN

| | | | |
|---|---|---|---|
| AB | MARION LABS | 5MG | N17577 001 |

OXYBUTYNIN CHLORIDE

| | | | |
|---|---|---|---|
| AB | PHARM BASICS | 5MG | N70746 001 MAR 10, 1988 |

**OXYTETRACYCLINE HYDROCHLORIDE**

CAPSULE; ORAL

OXYTETRACYCLINE HCL

| | | | |
|---|---|---|---|
| /AA/ | /PUREPAC PHARM/ | /EQ 250MG BASE/ | /N60634/001/ |
| | ə PUREPAC PHARM | EQ 250MG BASE | N60634 001 |

**PANCURONIUM BROMIDE**

INJECTABLE; INJECTION

PANCURONIUM

| | | | |
|---|---|---|---|
| AP | ELKINS SINN | 1MG/ML | N72058 001 MAR 23, 1988 |
| AP | | 2MG/ML | N72059 001 MAR 23, 1988 |
| AP | | 2MG/ML | N72060 001 MAR 23, 1988 |

PANCURONIUM BROMIDE

| | | | |
|---|---|---|---|
| AP | ASTRA PHARM PRODS | 1MG/ML | N72210 001 MAR 31, 1988 |
| AP | | 2MG/ML | N72211 001 MAR 31, 1988 |
| AP | | 2MG/ML | N72212 001 MAR 31, 1988 |
| AP | | 2MG/ML | N72213 001 MAR 31, 1988 |
| AP | QUAD PHARMS | 1MG/ML | N72209 001 JUN 03, 1988 |
| AP | | 2MG/ML | N72208 001 JUN 03, 1988 |

PAVULON

| | | | |
|---|---|---|---|
| AP | ORGANON | 1MG/ML | N17015 002 |
| AP | | 2MG/ML | N17015 001 |

**PARAMETHADIONE**

| | | | |
|---|---|---|---|
| > DLT > | /CONCENTRATE;ORAL/ | | |
| > DLT > | /PARADIONE/ | | |
| > DLT > /AA/ | /ABBOTT LABS/ | /300MG/ML/ | /N06800/002/ |

**PARAMETHADIONE**

> ADD > SOLUTION; ORAL
> ADD > PARADIONE
> ADD > AA ABBOTT LABS 300MG/ML N06800 002

**PENICILLIN G POTASSIUM**

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN G POTASSIUM

| | | | |
|---|---|---|---|
| /AA/ | /PUREPAC PHARM/ | /400,000 UNITS/5ML/ | /N61740/002/ |
| ə | PUREPAC PHARM | 400,000 UNITS/5ML | N61740 002 |

TABLET; ORAL
PENICILLIN G POTASSIUM

| | | | |
|---|---|---|---|
| /AB/ | /PUREPAC PHARM/ | /250,000 UNITS/ | /N61588/002/ |
| /AB/ | | /400,000 UNITS/ | /N61588/003/ |
| ə | PUREPAC PHARM | 250,000 UNITS | N61588 002 |
| ə | | 400,000 UNITS | N61588 003 |

**PENICILLIN V POTASSIUM**

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN V POTASSIUM

| | | | |
|---|---|---|---|
| /AA/ | /PUREPAC PHARM/ | /EQ 250MG BASE/5ML/ | /N61758/002/ |
| ə | PUREPAC PHARM | EQ 250MG BASE/5ML | N61758 002 |

TABLET; ORAL
PENICILLIN V POTASSIUM

| | | | |
|---|---|---|---|
| /AB/ | /PUREPAC PHARM/ | /EQ 250MG BASE/ | /N61571/002/ |
| /AB/ | | /EQ 500MG BASE/ | /N61571/003/ |
| ə | PUREPAC PHARM | EQ 250MG BASE | N61571 002 |
| ə | | EQ 500MG BASE | N61571 003 |

**PERPHENAZINE**

SYRUP; ORAL
TRILAFON

| | | | |
|---|---|---|---|
| | /SCHERING/ | /2MG/5ML/ | /N11294/002/ |
| ə | SCHERING | 2MG/5ML | N11294 002 |

**PHENDIMETRAZINE TARTRATE**

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

| | | | |
|---|---|---|---|
| /AA/ | /BARR LABS/ | /35MG/ | /N83644/001/ |
| /AA/ | | /35MG/ | /N83684/001/ |
| /AA/ | | /35MG/ | /N83686/001/ |
| /AA/ | | /35MG/ | /N83687/001/ |
| /AA/ | | /35MG/ | /N84831/001/ |
| /AA/ | | /35MG/ | /N84834/001/ |
| /AA/ | | /35MG/ | /N84835/001/ |
| ə | BARR LABS | 35MG | N83644 001 |
| ə | | 35MG | N83684 001 |
| ə | | 35MG | N83686 001 |
| ə | | 35MG | N83687 001 |
| ə | | 35MG | N84831 001 |
| ə | | 35MG | N84834 001 |
| ə | | 35MG | N84835 001 |

**PHENTERMINE RESIN COMPLEX**

CAPSULE, CONTROLLED RELEASE; ORAL
IONAMIN-30

| | | | |
|---|---|---|---|
| AB | PENNWALT | EQ 30MG BASE | N11613 002 |

PHENTERMINE RESIN 30

| | | | |
|---|---|---|---|
| AB | QUANTUM PHARMCS | EQ 30MG BASE‡ | N89120 001 |
| | | | FEB 04, 1988 |

**PIPERACETAZINE**

TABLET; ORAL
QUIDE

| | | | |
|---|---|---|---|
| | /DOW PHARMS/ | /10MG/ | /N13615/001/ |
| | DOW PHARMS | 10MG | N13615 001 |
| | | /25MG/ | /N13615/002/ |
| | | 25MG | N13615 002 |

**POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS**

POWDER FOR RECONSTITUTION; ORAL
COLONLITE

| | | | |
|---|---|---|---|
| AA | DYNAPHARM | 227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET‡ | N71320 001 |
| | | | APR 20, 1988 |

**POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS**

PONDER FOR RECONSTITUTION; ORAL

COLYTE

| | | | | |
|---|---|---|---|---|
| AB | REED & CARNRICK | 227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET‡ | N18983 004 OCT 26, 1984 | |

**POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE**

SOLUTION; ORAL

OCL

| | | | | |
|---|---|---|---|---|
| /A/ | /ABBOTT/LABS/ | /6GM/100ML;75MG/100ML;168MG/100ML; 146MG/100ML; 1.29GM/100ML/ | /N19284/001/ /APR 30, 1986/ | |
| | ABBOTT LABS | 6GM/100ML;75MG/100ML;168MG/100ML; 146MG/100ML; 1.29GM/100ML | N19284 001 APR 30, 1986 | >ADD< >ADD< |

**POTASSIUM CHLORIDE**

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

| | | | | |
|---|---|---|---|---|
| AP | STERIS LABS | 2MEQ/ML‡ | N89163 001 MAR 10, 1988 | |

**PREDNISOLONE**

TABLET; ORAL

PREDNISOLONE

| | | | | |
|---|---|---|---|---|
| /BX/ | /BARR LABS/ | /5MG/ | /N84426/002/ | |
| | ∋ BARR LABS | 5MG | N84426 002 | |

**PREDNISONE**

TABLET; ORAL

PREDNISONE

| | | | | |
|---|---|---|---|---|
| AB | SUPERPHARM | 5MG | N88865 001 OCT 25, 1984 | |
| AB | | 10MG | N88866 001 OCT 25, 1984 | |
| AB | | 20MG | N88867 001 OCT 25, 1984 | |
| /BX/ | | /5MG/ | /N88865/001/ /OCT 25, 1984/ | |
| /BX/ | | /10MG/ | /N88866/001/ /OCT 25, 1984/ | |
| /BX/ | | /20MG/ | /N88867/001/ /OCT 25, 1984/ | |

**PROBUCOL**

TABLET; ORAL

LORELCO

| | | | | |
|---|---|---|---|---|
| | MERRELL DOW | 500MG‡ | N17535 002 JUL 06, 1988 | |

**PROCAINAMIDE HYDROCHLORIDE**

INJECTABLE; INJECTION

PROCAINAMIDE HCL

| | | | | |
|---|---|---|---|---|
| AP | WARNER CHILCOTT | 100MG/ML‡ | N89528 001 MAY 03, 1988 | |
| AP | | 500MG/ML‡ | N89529 001 MAY 03, 1988 | |

**PROCHLORPERAZINE EDISYLATE**

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

| | | | | |
|---|---|---|---|---|
| AP | ELKINS SINN | EQ 5MG BASE/ML‡ | N89523 001 MAY 03, 1988 | |
| AP | QUAD PHARMS | EQ 5MG BASE/ML‡ | N89637 001 FEB 01, 1988 | |
| AP | | EQ 5MG BASE/ML‡ | N89638 001 FEB 01, 1988 | |
| AP | STERLING DRUG | EQ 5MG BASE/ML‡ | N89703 001 APR 07, 1988 | |

## PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HCL

| | | | | |
|---|---|---|---|---|
| AP | MARSAM PHARMS | 25MG/ML | N89463 001 | MAY 02, 1988 |
| AP | | 50MG/ML | N89477 001 | MAY 02, 1988 |

TABLET; ORAL

PROMETHAZINE HCL

| | | | | |
|---|---|---|---|---|
| /BP/ | /BARR LABS/ | /12.5MG/ | /N84555/001/ | |
| /BP/ | | /25MG/ | /N84554/001/ | |
| /BP/ | | /50MG/ | /N84557/001/ | |
| | ∂ BARR LABS | 12.5MG | N84555 001 | |
| | ∂ | 25MG | N84554 001 | |
| | ∂ | 50MG | N84557 001 | |

## PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

| | | | | |
|---|---|---|---|---|
| /AA/ | /BANMAX PHARMS/ | /65MG/ | /N83184/001/ | |
| | ∂ BANMAX PHARMS | 65MG | N83184 001 | |
| /AA/ | /BARR LABS/ | /65MG/ | /N83186/001/ | |
| | ∂ BARR LABS | 65MG | N83186 001 | |

## PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | INVAMED | 10MG | N71658 001 | JUL 05, 1988 |
| > ADD > | AB | | 20MG | N71687 001 | JUL 05, 1988 |
| > ADD > | AB | | 40MG | N71688 001 | JUL 05, 1988 |
| > ADD > | AB | | 60MG | N72197 001 | JUL 05, 1988 |
| > ADD > | AB | | 80MG | N71689 001 | JUL 05, 1988 |
| > ADD > | AB | | 90MG | N72198 001 | JUL 05, 1988 |
| | AB | LEDERLE LABS | 10MG | N72117 001 | JUN 23, 1988 |
| | AB | | 20MG | N72118 001 | JUN 23, 1988 |
| | AB | | 40MG | N72119 001 | JUN 23, 1988 |
| | AB | | 80MG | N72120 001 | JUN 23, 1988 |

## PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AA/ | /LEMMON/ | /10MG/ | /N70232/001/ | /OCT 07, 1987/ |
| > DLT > | | | | | |
| > ADD > | | ∂ LEMMON | 10MG | N70232 001 | OCT 07, 1987 |
| > ADD > | /AA/ | /PARKE/DAVIS/ | /10MG/ | /N70438/001/ | /SEP 15, 1986/ |
| | AB | SIDMAK LABS | 10MG | N71972 001 | APR 06, 1988 |
| | AB | | 20MG | N71973 001 | APR 06, 1988 |
| | AB | | 40MG | N71974 001 | APR 06, 1988 |
| | AB | | 60MG | N71975 001 | APR 06, 1988 |
| | AB | | 80MG | N71976 001 | APR 06, 1988 |
| | AB | | 90MG | N71977 001 | APR 06, 1988 |
| | AB | SUPERPHARM | 10MG | N71515 001 | JUN 08, 1988 |
| | AB | | 20MG | N71516 001 | JUN 08, 1988 |
| | AB | | 40MG | N71517 001 | JUN 08, 1988 |
| | AB | | 80MG | N71518 001 | JUN 08, 1988 |
| | AB | WARNER CHILCOTT | 10MG | N70438 001 | SEP 15, 1986 |
| > ADD > | AB | ZENITH LABS | 10MG | N72063 001 | JUL 29, 1988 |
| > ADD > | AB | | 20MG | N72066 001 | JUL 29, 1988 |
| > ADD > | AB | | 40MG | N72067 001 | JUL 29, 1988 |
| > ADD > | AB | | 60MG | N72068 001 | JUL 29, 1988 |
| > ADD > | AB | | 80MG | N72069 001 | JUL 29, 1988 |

**PROTAMINE SULFATE**

INJECTABLE; INJECTION
PROTAMINE SULFATE

| | | | |
|---|---|---|---|
| /AP/ | /UPJOHN/ | /50MG/VIAL/ | /N07413/001/ |
| /AP/ | | /250MG/VIAL/ | /N07413/002/ |
| | | | /AUG 02, 1984/ |
| | ∂ UPJOHN | 50MG/VIAL | N07413 001 |
| | ∂ | 250MG/VIAL | N07413 002 |
| | | | AUG 02, 1984 |

**QUINESTROL**

TABLET; ORAL
ESTROVIS

| | | | |
|---|---|---|---|
| | /PARKE/DAVIS/ | /0.1MG/ | /N16768/002/ |
| | ∂ PARKE DAVIS | 0.1MG | N16768 002 |
| | | /0.2MG/ | /N16768/003/ |
| | ∂ | 0.2MG | N16768 003 |

**RAUWOLFIA SERPENTINA**

TABLET; ORAL
RAUVAL

| | | | |
|---|---|---|---|
| | /3/VALE/CHEM/ | /50MG/ | /N09108/002/ |
| | /3/ | /100MG/ | /N09108/004/ |
| BP | VALE CHEM | 50MG | N09108 002 |
| BP | | 100MG | N09108 004 |

**RESERPINE**

TABLET; ORAL
RESERPINE

| | | | |
|---|---|---|---|
| /BP/ | /BARR/LABS/ | /0.25MG/ | /N80721/002/ |
| | ∂ BARR LABS | 0.25MG | N80721 002 |

**SECOBARBITAL SODIUM**

CAPSULE; ORAL
SODIUM SECOBARBITAL

| | | | |
|---|---|---|---|
| /AA/ | /BARR/LABS/ | /100MG/ | /N84225/001/ |
| | ∂ BARR LABS | 100MG | N84225 001 |

**SODIUM CHLORIDE**

INJECTABLE; INJECTION
SODIUM CHLODIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW | 900MG/100ML | N19635 002 MAR 09, 1988 |

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABS | 450MG/100ML | N19759 001 JUN 08, 1988 |
| AP | KENDALL MCGAW | 450MG/100ML | N19635 001 MAR 09, 1988 |

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW | 3GM/100ML | N19635 003 MAR 09, 1988 |
| AP | TRAVENOL LABS | 3GM/100ML | N19022 001 NOV 01, 1983 |

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW | 5GM/100ML | N19635 004 MAR 09, 1988 |
| AP | TRAVENOL LABS | 5GM/100ML | N19022 002 NOV 01, 1983 |

**SODIUM SUCCINATE**

INJECTABLE; INJECTION
SODIUM SUCCINATE

| | | | |
|---|---|---|---|
| | /ELKINS/SINN/ | /30%/ | /N80516/001/ |
| | ∂ ELKINS SINN | 30% | N80516 001 |

**SULFAMETHOXAZOLE**

TABLET; ORAL
SULFAMETHOXAZOLE

| | | | |
|---|---|---|---|
| /AA/ | /BARR/LABS/ | /500MG/ | /N87189/001/ |
| | | | /JUL 25, 1983/ |
| | ∂ BARR LABS | 500MG | N87189 001 JUL 25, 1983 |

**SULFAMETHOXAZOLE; TRIMETHOPRIM**

SUSPENSION; ORAL
TRIMETH/SULFA

| | | | |
|---|---|---|---|
| AB | NASKA PHARMA | 200MG/5ML;40MG/5ML | N72289 001 MAY 23, 1988 |
| AB | | 200MG/5ML;40MG/5ML | N72398 001 MAY 23, 1988 |
| AB | | 200MG/5ML;40MG/5ML | N72399 001 MAY 23, 1988 |

**SULFISOXAZOLE**

TABLET; ORAL
SULFISOXAZOLE
/AB/ /BARR LABS/ /500MG/ /N84031/001/
∂ BARR LABS 500MG N84031 001

**SULINDAC**

TABLET; ORAL
CLINORIL
AB MS&D 150MG N17911 001
AB 200MG N17911 002
SULINDAC
AB AM THERPTCS 150MG N72171 001 MAY 23, 1988
AB 200MG N72172 001 MAY 23, 1988
AB DANBURY PHARMA 150MG N71891 001 APR 03, 1990 : MAR 03, 1988
AB 200MG N71795 001 APR 03, 1990 : MAR 03, 1988

**TEMAZEPAM**

CAPSULE; ORAL
TEMAZEPAM
AB CORD LABS 15MG N71427 001 JAN 12, 1988
AB 30MG N71428 001 JAN 12, 1988

**TERAZOSIN HYDROCHLORIDE**

TABLET; ORAL
HYTRIN
> DLT > /ABBOTT LABS/ /10MG/ /N19057/004/ /AUG 07, 1987/
> DLT >
> ADD > ABBOTT LABS 10MG N19057 004 AUG 07, 1987
> ADD >

**TERCONAZOLE**

SUPPOSITORY; VAGINAL
TERAZOL 3
ORTHO PHARM 80MG N19641 001 MAY 24, 1988

**TETRACYCLINE HYDROCHLORIDE**

CAPSULE; ORAL
TETRACYCLINE HCL
AB VITARINE 250MG N61471 001

**THEOPHYLLINE**

ELIXIR; ORAL
THEOPHYLLINE
AA NASKA PHARMA 80MG/15ML N89223 001 MAY 27, 1988

INJECTABLE; INJECTION
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER
AP TRAVENOL LABS 320MG/100ML N18649 006 NOV 13, 1985
THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 320MG/100ML N19211 006 JAN 20, 1988

TABLET, CONTROLLED RELEASE; ORAL
THEOLAIR-SR
BC RIKER LABS 250MG N86363 002 JUL 16, 1987
/250MG/ /N86363/002/ /JUL/16/1987/

**THIORIDAZINE HYDROCHLORIDE**

TABLET; ORAL
THIORIDAZINE HCL
AB PAR PHARM 150MG N89764 001 FEB 09, 1988
AB 200MG N89765 001 FEB 09, 1988
AB ROXANE LABS 25MG N88664 001 MAR 15, 1984

**TIOCONAZOLE**

OINTMENT; VAGINAL
VAGISTAT
/ROERIG/ /6.5%/ /N19355/001/ /DEC/30/1986/
∂ ROERIG 6.5% N19355 001 DEC 30, 1986

**TOLAZAMIDE**

TABLET; ORAL
TOLAZAMIDE

| | | | | |
|---|---|---|---|---|
| AB | PHARM BASICS | 100MG | N71355 001 JAN 11, 1988 | |

**TOLBUTAMIDE**

TABLET; ORAL
TOLBUTAMIDE

| | | | | |
|---|---|---|---|---|
| /AB/ | /BANMAX/PHARMS/ | /500MG/ | /N86141/001/ | |
| | ə BANMAX PHARMS | 500MG | N86141 001 | |

**TRAZODONE HYDROCHLORIDE**

TABLET; ORAL
DESYREL

| | | | | |
|---|---|---|---|---|
| AB | MEAD JOHNSON | 150MG | N18207 003 MAR 25, 1985 | |

TRAZODONE HCL

| | | | | |
|---|---|---|---|---|
| AB | PUREPAC PHARM | 50MG | N71636 001 APR 18, 1988 | |
| AB | | 100MG | N71514 001 APR 18, 1988 | |

TRAZON-150

| | | | | |
|---|---|---|---|---|
| AB | SIDMAK LABS | 150MG | N71525 001 MAR 09, 1988 | |

**TRIAMCINOLONE**

TABLET; ORAL
TRIAMCINOLONE

| | | | | |
|---|---|---|---|---|
| /BP/ | /BARR/LABS/ | /2MG/ | /N84286/001/ | |
| /BP/ | | /2MG/ | /N84318/001/ | |
| /BP/ | | /4MG/ | /N84267/001/ | |
| /BP/ | | /4MG/ | /N84319/001/ | |
| /BP/ | | /8MG/ | /N84268/001/ | |
| /BP/ | | /8MG/ | /N84320/001/ | |
| | ə BARR LABS | 2MG | N84286 001 | |
| | ə | 2MG | N84318 001 | |
| | ə | 4MG | N84267 001 | |
| | ə | 4MG | N84319 001 | |
| | ə | 8MG | N84268 001 | |
| | ə | 8MG | N84320 001 | |

**TRIAZOLAM**

TABLET; ORAL
HALCION

| | | | |
|---|---|---|---|
| /UPJOHN/ | /0.5MG/ | /N17892/002/ /NOV/15,/1982/ |
| ə UPJOHN | 0.5MG | N17892 002 NOV 15, 1982 |

**TRICLOFOS SODIUM**

SOLUTION; ORAL
TRICLOS

| | | | | |
|---|---|---|---|---|
| > DLT > | /MERRELL/DOW/ | /1.5GM/15ML/ | /N16830/001/ | |
| > ADD > | ə MERRELL DOW | 1.5GM/15ML | N16830 001 | |

TABLET; ORAL
TRICLOS

| | | | | |
|---|---|---|---|---|
| > DLT > | /MERRELL/DOW/ | /750MG/ | /N16809/002/ | |
| > ADD > | ə MERRELL DOW | 750MG | N16809 002 | |

**TRIDIHEXETHYL CHLORIDE**

INJECTABLE; INJECTION
PATHILON

| | | | |
|---|---|---|---|
| /LEDERLE/LABS/ | /10MG/ML/ | /N09729/001/ |
| ə LEDERLE LABS | 10MG/ML | N09729 001 |

**TRIFLUOPERAZINE HYDROCHLORIDE**

TABLET; ORAL
TRIFLUOPERAZINE HCL

| | | | |
|---|---|---|---|
| AB | BOLAR PHARM | EQ 1MG BASE | N85975 001 JUN 23, 1988 |
| AB | | EQ 2MG BASE | N85976 001 JUN 23, 1988 |
| AB | | EQ 5MG BASE | N85973 001 JUN 23, 1988 |
| AB | | EQ 10MG BASE | N88710 001 JUN 23, 1988 |

**TRIMETHOPRIM**

TABLET; ORAL

| | | | |
|---|---|---|---|
| | TRIMETHOPRIM | | |
| AB | BARR LABS | 100MG | N70494 001 JAN 22, 1986 |
| /AB/ | | /100MG/ | /N70495/001/ /MAR/14,/1986/ |
| /A/ | | /100MG/ | /N70494/001/ /JAN/22,/1986/ |
| ə | | 200MG | N70495 001 MAR 14, 1986 |

**TRIPELENNAMINE HYDROCHLORIDE**

TABLET; ORAL

| | | | |
|---|---|---|---|
| | TRIPELENNAMINE HCL | | |
| /AB/ | /BARR LABS/ | /50MG/ | /N80744/001/ |
| ə | BARR LABS | 50MG | N80744 001 |

**URSODIOL**

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| ADD > | ACTIGALL | | |
| ADD > | ə CIBA PHARM | 150MG | N19594 001 DEC 31, 1987 |
| ADD > | | 300MG | N19594 002 DEC 31, 1987 |
| ADD > | | | |
| ADD > | /DEURSIL/ /SIPHARMEX/ | /150MG/ | /N19594/001/ /DEC/31,/1987/ |
| | | /300MG/ | /N19594/002/ /DEC/31,/1987/ |

**VANCOMYCIN HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | LYPHOCIN | | |
| AP | LYPHOMED | EQ 1GM BASE/VIAL | N62667 002 JUL 31, 1987 |
| AP | | EQ 5GM BASE/VIAL* | N62663 003 JUN 03, 1988 |

**VANCOMYCIN HYDROCHLORIDE**

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | VANCOCIN HCL | | |
| AP | LILLY | EQ 1GM BASE/VIAL | N60180 002 MAR 21, 1986 |
| AP | | EQ 1GM BASE/VIAL | N62476 002 MAR 21, 1986 |
| AP | | EQ 1GM BASE/VIAL | N62716 002 MAR 13, 1987 |
| AP | | EQ 1GM BASE/VIAL | N62812 002 NOV 17, 1987 |
| AP | | EQ 10GM BASE/VIAL | N62812 003 NOV 17, 1987 |
| | VANCOLED | | |
| AP | LEDERLE LABS | EQ 1GM BASE/VIAL* | N62682 002 MAR 30, 1988 |
| AP | | EQ 5GM BASE/VIAL | N62682 004 MAY 11, 1988 |
| AP | | EQ 10GM BASE/VIAL* | N62682 005 MAY 11, 1988 |
| | | EQ 2GM BASE/VIAL* | N62682 003 MAY 11, 1988 |
| | VANCOMYCIN HCL | | |
| > ADD > AP | QUAD PHARMS | EQ 500MG BASE/VIAL* | N62845 001 JUL 15, 1988 |
| > ADD > AP | | EQ 1GM BASE/VIAL* | N62845 002 JUL 15, 1988 |

**VERAPAMIL HYDROCHLORIDE**

TABLET; ORAL

| | | | |
|---|---|---|---|
| | CALAN | | |
| | /SEARLE/ | /160MG/ | /N18817/004/ /FEB/23,/1988/ |
| AB | SEARLE PHARMS | 40MG* | N18817 003 FEB 23, 1988 |
| | ə | 160MG | N18817 004 FEB 23, 1988 |
| | ISOPTIN | | |
| AB | KNOLL PHARM | 40MG | N18593 003 NOV 23, 1987 |
| | VERAPAMIL HCL | | |
| AB | CORD LABS | 80MG* | N71423 001 MAY 24, 1988 |
| AB | | 120MG* | N71424 001 MAY 25, 1988 |
| AB | LEDERLE LABS | 80MG* | N71880 001 APR 05, 1988 |
| AB | | 120MG* | N71881 001 APR 05, 1988 |

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

VERAPAMIL HCL

| | | | |
|---|---|---|---|
| AB | MUTUAL PHARM | 80MG | N71488 001<br>JAN 13, 1988 |
| AB | | 120MG | N71489 001<br>JAN 13, 1988 |

VINCRISTINE SULFATE

INJECTABLE; INJECTION

VINCREX

| | | | |
|---|---|---|---|
| > ADD > AP | BRISTOL LABS | 5MG/VIAL | N70867 001<br>JUL 12, 1988 |

VINCRISTINE SULFATE

| | | | |
|---|---|---|---|
| AP | BULL LABS | 1MG/VIAL | N71559 001<br>APR 11, 1988 |
| AP | | 2MG/VIAL | N71560 001<br>APR 11, 1988 |
| AP | | 5MG/VIAL | N71561 001<br>APR 11, 1988 |
| AP | QUAD PHARMS | 1MG/VIAL | N71222 001<br>MAR 07, 1988 |
| AP | | 2MG/VIAL | N71223 001<br>MAR 07, 1988 |
| AP | | 5MG/VIAL | N71937 001<br>MAR 07, 1988 |

VINCRISTINE SULFATE PFS

| | | | |
|---|---|---|---|
| AP | BULL LABS | 1MG/ML | N71484 001<br>APR 19, 1988 |

WATER FOR INJECTION, STERILE

LIQUID; N/A

STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | BAXTER | 100% | N18632 002<br>APR 19, 1988 |
| AP | KENDALL MCGAW | 100% | N19633 001<br>FEB 29, 1988 |

XYLOSE

POWDER; ORAL

XYLOSE

| | | | |
|---|---|---|---|
| /AB/ | /LYNE LABS/ | /25GM/BOT/ | /N18856/001/<br>/MAR 26, 1987/ |
| | ∂ LYNE LABS | 25GM/BOT | N18856 001<br>MAR 26, 1987 |

**ACETAMINOPHEN**

SUPPOSITORY; RECTAL

| | | |
|---|---|---|
| TYLENOL | | |
| MCNEIL CONSUMER | 120MG | N17756 002 |
| | 650MG | N17756 001 |
| /MCNEIL/LABS/ | /120MG/ | /N17756/002/ |
| | /650MG/ | /N17756/001/ |

**DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE**

TABLET, CONTROLLED RELEASE; ORAL

| | | |
|---|---|---|
| RESPORAL | | |
| PIONEER PHARMS | 6MG;120MG‡ | N89139 001 |
| | | JUN 16, 1988 |

**HYDROCORTISONE**

OINTMENT; TOPICAL

| | | |
|---|---|---|
| HC (HYDROCORTISONE) | | |
| C&M PHARMA | 0.5% | N80481 001 |

**IBUPROFEN**

TABLET; ORAL

| | | |
|---|---|---|
| IBUPROFEN | | |
| DANBURY PHARMA | 200MG‡ | N71905 001 |
| | | MAR 08, 1988 |
| INTERPHARM | 200MG‡ | N72199 001 |
| | | MAY 23, 1988 |
| INVAMED | 200MG‡ | N71807 001 |
| | | FEB 25, 1988 |
| MEDICOPHARMA | 200MG‡ | N71639 001 |
| | | FEB 02, 1988 |
| MYLAN PHARMS | 200MG‡ | N71870 001 |
| | | MAY 05, 1988 |
| >ADD< PRIVATE FMLTNS | 200MG‡ | N72299 001 |
| >ADD< | | JUL 01, 1988 |
| ZENITH LABS | 200MG‡ | N72040 001 |
| | | APR 29, 1988 |
| NUPRIN | | |
| BRISTOL MYERS | 200MG‡ | N72035 001 |
| | | FEB 16, 1988 |
| | 200MG‡ | N72036 001 |
| | | FEB 16, 1988 |

**IBUPROFEN**

TABLET; ORAL

| | | |
|---|---|---|
| NUPRIN | | |
| /UPJOHN/ | /200MG/ | /N19012/003/ |
| | | /JUL/29,/1987/ |
| | /200MG/ | /N19012/001/ |
| | | /MAY/18,/1984/ |
| a UPJOHN | 200MG | N19012 001 |
| | | MAY 18, 1984 |
| a | 200MG | N19012 003 |
| | | JUL 29, 1987 |

**INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN**

INJECTABLE; INJECTION

| | | |
|---|---|---|
| MIXTARD HUMAN 70/30 | | |
| NORDISK USA | 30 UNITS/ML; | |
| | 70 UNITS/ML‡ | N19585 001 |
| | | MAR 11, 1988 |

**INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN**

INJECTABLE; INJECTION

| | | |
|---|---|---|
| HUMULIN U | | |
| /LILLY/ | /40/UNITS/ML/ | /N19571/001/ |
| | | /JUN/10,/1987/ |
| a LILLY | 40 UNITS/ML | N19571 001 |
| | | JUN 10, 1987 |

**LOPERAMIDE HYDROCHLORIDE**

SOLUTION; ORAL

| | | |
|---|---|---|
| IMODIUM A-D | | |
| MCNEIL CONSUMER | 1MG/5ML‡ | N19487 001 |
| | | MAR 01, 1988 |

**NONOXYNOL-9**

SPONGE; VAGINAL

| | | |
|---|---|---|
| TODAY | | |
| /WLI/ | /1GM/ | /N18683/001/ |
| | | /APR/01,/1983/ |
| WHITEHALL LABS | 1GM | N18683 001 |
| | | APR 01, 1983 |

DEXTRAN 70, 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
MACRODEX(R)
PHARMACIA INC 6GM/100ML;0.9GM/100ML N 06826

# ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG". SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

ORPHAN DRUG EXCLUSIVE APPROVAL STATUS (CODED ODE) APPLIES ONLY TO THE APPROVED OR LICENSED INDICATION(S) FOR WHICH ORPHAN DRUG DESIGNATION HAS BEEN GRANTED PURSUANT TO SECTION 526 OF THE ACT.

FOR THE FOLLOWING DRUG PRODUCTS WITH ORPHAN DRUG EXCLUSIVE APPROVAL STATUS, THE SPONSOR HAS SEVEN YEARS OF EXCLUSIVE APPROVAL FOR THE APPROVED INDICATION BEGINNING ON THE DATE OF NDA, ANTIBIOTIC APPLICATION, OR BIOLOGICAL LICENSE APPROVAL FOR THE DRUG. NO SUBSEQUENT SPONSOR MAY RECEIVE APPROVAL OF AN NDA, BIOLOGICAL LICENSE, PAPER NDA, ANTIBIOTIC APPLICATION, ANDA, OR ABBREVIATED ANTIBIOTIC APPLICATION DURING THE SEVEN YEAR PERIOD FOR THE DRUG AND INDICATION(S) FOR WHICH ODE STATUS IS MAINTAINED UNLESS THE EXCLUSIVE APPROVAL HAS BEEN REVOKED AS DESCRIBED ABOVE OR THE SUBSEQUENT SPONSOR HAS OBTAINED WRITTEN CONSENT FROM THE SPONSOR WHO HAS RECEIVED EXCLUSIVE APPROVAL.

BIOLOGICAL PRODUCTS, ANTIBIOTICS, AND DRUGS THAT HAVE BEEN APPROVED UNDER SECTION 505 OR 507 OF THE ACT OR UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT FOR MARKETING AND HAVE BEEN GIVEN ORPHAN DRUG EXCLUSIVE APPROVAL WILL BE NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. DRUG PRODUCTS THAT HAVE RECEIVED THE WRITTEN PERMISSION OF THE SPONSOR THAT HAS ORPHAN DRUG EXCLUSIVE APPROVAL TO BE APPROVED UNDER SECTION 527(b)(2) OF THE ACT ARE ALSO NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. THESE DRUG PRODUCTS DO NOT HAVE ANY EXCLUSIVE APPROVAL RIGHTS OF THEIR OWN, BUT CAN BE MARKETED BECAUSE OF THE CONSENT GIVEN BY THE SPONSOR THAT HAS EXCLUSIVE APPROVAL. THESE PRODUCTS ARE MARKED BY AN (*) NEXT TO THE APPLICANT'S NAME.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

# ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

## DRUG PRODUCTS

| ACTIVE INGREDIENT(S)<br>STRENGTH(S) | TRADE NAME<br>DOSAGE FORM; ROUTE | APPLICANT | APPL. PROD.<br>APPROVAL DATE | EXCLUSIVITY<br>EXP. DATE |
|---|---|---|---|---|
| METHOTREXATE SODIUM<br>EQ 1GM BASE/VIAL | METHOTREXATE SODIUM<br>INJECTABLE; INJECTION | LEDERLE LABS | 11719 009<br>APR 07, 1988 | ODE<br>APR 07, 1995 |

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

NO JULY 1988 ADDITIONS

## BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFN-250, ROOM 17B-06, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| NAME OF DRUG (DOSAGE FORM) | DATE | REVISED DATE |
|---|---|---|
| CARBAMAZEPINE (TABLET) | JAN 01, 1988 | |
| CLINDAMYCIN (CAPSULE) | MAY 31, 1988 | |
| CYCLOBENZAPRINE HYDROCHLORIDE (TABLET) | JAN 25, 1988 | |
| DOXYCYCLINE HYCLATE (CAPSULE AND TABLET) | APR 11, 1988 | |
| FENOPROFEN (CAPSULE AND TABLET) | AUG 27, 1987 | FEB 03, 1988 |
| INDOMETHACIN (CAPSULE) | JAN 27, 1988 | |
| MESTRANOL; NORETHYNODREL (TABLET) | MAY 13, 1988 | |
| METAPROTERENOL SULFATE (TABLET) | MAR 18, 1988 | |
| NORETHINDRONE; ETHINYL ESTRADIOL (TABLET) | MAR 18, 1988 | |
| PRAZEPAM (CAPSULE AND TABLET) | JUL 26, 1988 | |

## ANDA SUITABILITY PETITIONS

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

### PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| ASPIRIN;<br>HYDROCODONE BITARTRATE<br>TABLET; ORAL | 325MG<br>5MG | 87 P-0376/<br>CP0002 | ANABOLIC | NEW STRENGTH | APPROVED<br>FEB 12, 1988 |
| ASPIRIN;<br>HYDROCODONE BITARTRATE<br>TABLET; ORAL | 650MG<br>5MG | 87 P-0376/CP | ANABOLIC | NEW STRENGTH | APPROVED<br>FEB 12, 1988 |
| CHLORZOXAZONE<br>CAPSULE; ORAL | 500MG | 82 N-0032/<br>CP0006 | MIKART | NEW DOSAGE<br>FORM | APPROVED<br>JAN 13, 1988 |

# ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|---|---|---|---|---|---|
| CISPLATIN<br>INJECTABLE; INJECTION | 1MG/ML<br>(10ML/VIAL)<br>(50ML/VIAL)<br>(100ML/VIAL) | 87 P-0421/CP | BULL LABS | NEW DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>FEB 29, 1988 |
| CISPLATIN<br>INJECTABLE; INJECTION | 1MG/ML<br>(20ML/VIAL) | 88 P-0010/CP | LYPHOMED | NEW DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>APR 01, 1988 |
| CYCLOPHOSPHAMIDE<br>INJECTABLE; INJECTION | 20MG/ML<br>(500ML/CONTAINER) | 88 P-0011/CP | BAXTER HLTHCARE | NEW DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>JUN 10, 1988 |
| FLUOROURACIL<br>INJECTABLE; INJECTION | 50MG/ML<br>(5ML/VIAL) | 88 P-0052/CP | BEN VENUE LABS | NEW STRENGTH | APPROVED<br>MAR 21, 1988 |
| HOMATROPINE METHYLBROMIDE;<br>HYDROCODONE BITARTRATE<br>SOFT GELATIN<br>CAPSULE; ORAL | 1.5MG<br>5MG | 88 P-0061/CP | KLEINFELD, KAPLAN AND BECKER | NEW DOSAGE FORM | APPROVED<br>MAY 12, 1988 |
| HYDROCHLOROTHIAZIDE;<br>PROPRANOLOL HYDROCHLORIDE<br>SOLUTION; ORAL | 25MG/5ML<br>40MG/5ML | 87 P-0399/CP | BURDITT, BOWLES, RADZIUS AND RUBERRY | NEW DOSAGE FORM | APPROVED<br>FEB 16, 1988 |

# ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|---|---|---|---|---|---|
| HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE<br>SOLUTION; ORAL | 25MG/5ML<br>80MG/5ML | 87 P-0399/CP | BURDITT, BOWLES, RADZIUS AND RUBERRY | NEW DOSAGE FORM | APPROVED<br>FEB 16, 1988 |
| HYDROCHLOROTHIAZIDE; TRIAMTERENE<br>TABLET; ORAL | 25MG<br>50MG | 87 P-0335/CP | PAR PHARM | NEW DOSAGE FORM | APPROVED<br>FEB 26, 1988 |
| LEUCOVORIN CALCIUM<br>SOLUTION; ORAL | EQ 1MG BASE/ML | 88 P-0149/CP | ROXANE LABS | NEW DOSAGE FORM | APPROVED<br>JUL 25, 1988 |
| MEPERIDINE HYDROCHLORIDE<br>INJECTABLE; INJECTION | 10MG/ML<br>(50ML/CONTAINER) | 88 P-0008/CP | LYPHOMED | NEW STRENGTH | APPROVED<br>APR 01, 1988 |
| METOCLOPRAMIDE HYDROCHLORIDE INTENSOL<br>CONCENTRATE; ORAL | 10MG/ML | 88 P-0164/CP | ROXANE LABS | NEW STRENGTH | APPROVED<br>JUN 28, 1988 |
| NIFEDIPINE<br>CAPSULE; ORAL | 10MG | 88 P-0072/<br>CP0002 | MARTEC PHARMS | NEW DOSAGE FORM | APPROVED<br>MAY 11, 1988 |
| NIFEDIPINE<br>CAPSULE; ORAL | 20MG | 88 P-0072/CP | MARTEC PHARMS | NEW DOSAGE FORM | APPROVED<br>MAY 11, 1988 |

# ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| PHENYTOIN SODIUM<br>INJECTABLE; INJECTION | 100MG/VIAL | 87 P-0367/CP | LYPHOMED | NEW DOSAGE<br>FORM | APPROVED<br>FEB 16, 1988 |
| PHENYTOIN SODIUM<br>INJECTABLE; INJECTION | 250MG/VIAL | 87 P-0367/CP | LYPHOMED | NEW DOSAGE<br>FORM | APPROVED<br>FEB 16, 1988 |
| THEOPHYLLINE<br>CAPSULE, CONTROLLED<br>RELEASE; ORAL | 450MG | 88 P-0119/CP | RIKER LABS | NEW STRENGTH | APPROVED<br>MAY 11, 1988 |
| THIOTEPA (WITH DILUENT)<br>INJECTABLE; INJECTION | 15MG/VIAL | 87 P-0382/CP | LYPHOMED | NEW DOSAGE<br>FORM | APPROVED<br>MAY 12, 1988 |
| VERAPAMIL HYDROCHLORIDE<br>CAPSULE, CONTROLLED<br>RELEASE; ORAL | 120MG<br>240MG | 87 P-0233/CP | SEARLE | NEW DOSAGE<br>FORM<br>NEW STRENGTH | APPROVED<br>FEB 26, 1988 |

# ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| BENZOYL METRONIDAZOLE<br>SUSPENSION; ORAL | 200MG/5ML | 85 P-0258/CP | APKON LABS | NEW ESTER<br>NEW INGREDIENT | DENIED<br>MAR 19, 1986 |
| BROMPHENIRAMINE<br>MALEATE;<br>HYDROCODONE BITARTRATE;<br>PHENYLPROPANOLAMINE<br>HYDROCHLORIDE<br>SYRUP; ORAL | 2MG/5ML<br><br>2.5MG/5ML<br>12.5MG/5ML | 85 P-0237/CP | MIKART | NEW<br>COMBINATION | DENIED<br>MAY 11, 1988 |
| BROMDIPHENHYDRAMINE<br>HYDROCHLORIDE;<br>HYDROCODONE BITARTRATE<br>SOLUTION; ORAL | 12.5MG/5ML<br><br>2.5MG/5ML | 85 P-0255/CP | MIKART | NEW<br>COMBINATION | DENIED<br>MAY 11, 1988 |
| BROMDIPHENHYDRAMINE<br>HYDROCHLORIDE;<br>HYDROCODONE BITARTRATE<br>SYRUP; ORAL | 12.5MG/5ML<br><br>2.5MG/5ML | 85 P-0255/CP | MIKART | NEW<br>COMBINATION | DENIED<br>MAY 11, 1988 |
| CYCLOPHOSPHAMIDE<br>INJECTABLE; INJECTION | 100MG/ML<br>(1ML/VIAL)<br>(2ML/VIAL) | 87 P-0283/CP | LYPHOMED | NEW DOSAGE<br>FORM<br>NEW STRENGTH | DENIED<br>JAN 21, 1988 |
| CYCLOPHOSPHAMIDE<br>INJECTABLE; INJECTION | 500MG/ML<br>(1ML/VIAL)<br>(2ML/VIAL)<br>(4ML/VIAL) | 87 P-0283/CP | LYPHOMED | NEW DOSAGE<br>FORM<br>NEW STRENGTH | DENIED<br>JAN 21, 1988 |

# ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| DIPHENHYDRAMINE HYDROCHLORIDE<br>CAPSULE, SUSTAINED RELEASE; ORAL | 75MG | 87 P-0355/CP | PARKE DAVIS | NEW DOSAGE FORM<br>NEW STRENGTH | DENIED<br>MAY 11, 1988 |
| HYDROCODONE BITARTRATE;<br>PHENYLEPHRINE HYDROCHLORIDE;<br>PROMETHAZINE HYDROCHLORIDE<br>SYRUP; ORAL | 1.66MG/5ML<br>5MG/5ML<br>6.25MG/5ML | 85 P-0389/CP | UAD LABS | NEW COMBINATION | DENIED<br>MAY 11, 1988 |
| HYDROCODONE BITARTRATE;<br>PROMETHAZINE HYDROCHLORIDE<br>SYRUP; ORAL | 2.5MG/5ML<br>6.25MG/5ML | 85 P-0256/CP | MIKART | NEW COMBINATION | DENIED<br>MAY 11, 1988 |
| MAGNESIUM ASCORBATE<br>INJECTABLE; INJECTION | 10%<br>20% | 88 P-0200/CP | RIM CONSULTING | NEW INGREDIENT | DENIED<br>JUN 10, 1988 |
| METOCLOPRAMIDE HYDROCHLORIDE<br>INJECTABLE; INJECTION | 1MG/ML<br>(50ML/VIAL) | 87 P-0090/CP | INTL MEDTN SYS | NEW STRENGTH | DENIED<br>FEB 08, 1988 |

# ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| METOCLOPRAMIDE<br>HYDROCHLORIDE<br>INJECTABLE; INJECTION | 1MG/ML<br>(75ML/VIAL) | 87 P-0090/CP | INTL MEDTN SYS | NEW STRENGTH | DENIED<br>FEB 08, 1988 |
| METOCLOPRAMIDE<br>HYDROCHLORIDE<br>INJECTABLE; INJECTION | 1MG/ML<br>(100ML/VIAL) | 87 P-0090/CP | INTL MEDTN SYS | NEW STRENGTH | DENIED<br>FEB 08, 1988 |

## EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

## REFERENCES

### NEW DOSING SCHEDULE

D-12 BEDTIME DOSING OF 800MG FOR TREATMENT
D-12 BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE DUODENAL ULCER
D-13 INCREASED MAXIMUM DAILY DOSAGE RECOMMENDATION
D-14 BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE BENIGN GASTRIC ULCER
D-15 SINGLE DAILY DOSE OF 25MG/37.5MG

### NEW INDICATION

I-19 ANTIDOTE/FOR/ACETAMINOPHEN/OVERDOSAGE
I-19 CHOLANGIOPANCREATOGRAPHY
I-72 PHOTOPHERESIS IN THE PALLIATIVE TREATMENT OF SKIN MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA IN PERSONS NOT RESPONSIVE TO OTHER TREATMENT
I-73 FOLLICULAR STIMULATION IN IN VITRO FERTILIZATION
I-74 MANAGEMENT OF CONGESTIVE HEART FAILURE
I-75 ENDOSCOPIC RETROGRADE PANCREATOGRAPHY
I-76 HERNIOGRAPHY
I-77 KNEE ARTHROGRAPHY

EXCLUSIVITY TERMS

REFERENCES

PATENT USE CODE

| | |
|---|---|
| U-26 | METHOD OF TREATING ANIMALS SUFFERING FROM AN APPETITE DISORDER |
| U-27 | METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS |
| U-28 | METHOD FOR IMPROVING MEMORY IN MAMMALS |
| U-29 | METHOD FOR TREATING AMNESIA |
| U-30 | METHOD OF POTENTIATING CODEINE ANALGESIA IN MAMMALS |
| U-31 | USE IN LUNG SCANNING PROCEDURES |
| U-32 | TREATMENT OF VENTRICULAR AND SUPRAVENTRICULAR ARRHYTHMIAS |
| U-33 | METHOD FOR INHIBITING GASTRIC SECRETION IN MAMMALS |
| U-34 | TREATMENT OF INFLAMMATION |

| | APPL/PROD | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 19489 001 | ALBUTEROL SULFATE; VENTOLIN ROTACAPS | 3705233 | DEC 05, 1989 | | | |
| | | | 3644353 | FEB 22, 1989 | | NDF | MAY 04, 1991 |
| | 18116 002 | AMCINONIDE; CYCLOCORT | 4158055 | JUN 12, 1996 | U-34 | | |
| | 18498 001 | AMCINONIDE; CYCLOCORT | 4158055 | JUN 12, 1996 | U-34 | | |
| | 18644 001 | BUPROPION HYDROCHLORIDE; WELLBUTRIN | 4507323 | MAR 26, 2002 | | | |
| | 18644 002 | BUPROPION HYDROCHLORIDE; WELLBUTRIN | 4507323 | MAR 26, 2002 | | | |
| | 18644 003 | BUPROPION HYDROCHLORIDE; WELLBUTRIN | 4507323 | MAR 26, 2002 | | | |
| | 17920 002 | CIMETIDINE; TAGAMET | 4024271 | MAY 17, 1994 | | D-14 | MAR 31, 1991 |
| | | | 3950333 | APR 13, 1993 | | D-12 | APR 30, 1989 |
| | 17920 003 | CIMETIDINE; TAGAMET | 4024271 | MAY 17, 1994 | | D-14 | MAR 31, 1991 |
| | | | 3950333 | APR 13, 1993 | | D-12 | APR 30, 1989 |
| | 17920 004 | CIMETIDINE; TAGAMET | 4024271 | MAY 17, 1994 | | D-14 | MAR 31, 1991 |
| | | | 3950333 | APR 13, 1993 | | D-12 | APR 30, 1989 |
| | 17920 005 | CIMETIDINE; TAGAMET | 4024271 | MAY 17, 1994 | | D-14 | MAR 31, 1991 |
| | | | 3950333 | APR 13, 1993 | | D-12 | APR 30, 1989 |
| | 17924 001 | CIMETIDINE HYDROCHLORIDE; TAGAMET | 4024271 | MAY 17, 1994 | | D-14 | MAR 31, 1991 |
| | | | 3950333 | APR 13, 1993 | | D-12 | APR 30, 1989 |
| >ADD> | 19201 001 | DICLOFENAC SODIUM; VOLTAREN | 3652762 | MAR 28, 1989 | | NCE | JUL 28, 1993 |
| >ADD> | 19201 002 | DICLOFENAC SODIUM; VOLTAREN | 3652762 | MAR 28, 1989 | | NCE | JUL 28, 1993 |
| >ADD> | 19201 003 | DICLOFENAC SODIUM; VOLTAREN | 3652762 | MAR 28, 1989 | | NCE | JUL 28, 1993 |
| | 18998 001 | ENALAPRIL MALEATE; VASOTEC | | | | I-74 | JUN 24, 1991 |
| | 18998 002 | ENALAPRIL MALEATE; VASOTEC | | | | I-74 | JUN 24, 1991 |
| | 18998 003 | ENALAPRIL MALEATE; VASOTEC | | | | I-74 | JUN 24, 1991 |
| >ADD> | 18998 005 | ENALAPRIL MALEATE; VASOTEC | 4374829 | FEB 22, 2000 | | NCE | DEC 24, 1990 |
| >ADD> | | | | | | I-74 | JUN 24, 1991 |
| | 19309 001 | ENALAPRILAT; VASOTEC | 4374829 | FEB 22, 2000 | | NDF | FEB 09, 1991 |
| | 18981 002 | ENCAINIDE HYDROCHLORIDE; ENKAID | RE30811 | DEC 20, 1996 | U-32 | | |
| | 18981 003 | ENCAINIDE HYDROCHLORIDE; ENKAID | RE30811 | DEC 20, 1996 | U-32 | | |
| | 18981 004 | ENCAINIDE HYDROCHLORIDE; ENKAID | RE30811 | DEC 20, 1996 | U-32 | | |
| | 18830 003 | FLECAINIDE ACETATE; TAMBOCOR | 4005209 | JAN 25, 1996 | | NS | JUN 03, 1991 |
| | | | 3900481 | AUG 19, 1992 | | NCE | OCT 31, 1990 |
| | 19452 001 | FLUOCINOLONE ACETONIDE; DERMA-SMOOTHE/FS | | | | NDF | FEB 03, 1991 |
| | 18936 001 | FLUOXETINE HYDROCHLORIDE; PROZAC | 4683235 | JUL 28, 2004 | U-30 | | |
| | | | 4647591 | MAR 03, 2004 | U-28 | | |
| | | | 4647591 | MAR 03, 2004 | U-29 | | |
| | | | 4626549 | DEC 02, 2003 | U-26 | | |
| | | | 4626549 | DEC 02, 2003 | U-27 | | |
| | | | 4194009 | APR 19, 1994 | | | |

| | APPL/PROD | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 19404 001 | FLURBIPROFEN SODIUM; OCUFEN | 3793457 | FEB 19, 1993 | | | |
| | 19596 001 | GADOPENTETATE DIMEGLUMINE; MAGNEVIST | 4647447 | MAR 03, 2004 | | NCE | JUN 02, 1993 |
| | 18061 001 | HYDROCHLOROTHIAZIDE; TIMOLIDE 10-25 | 3655663 | APR 11, 1989 | | D-2 | FEB 03, 1991 |
| | 19129 003 | HYDROCHLOROTHIAZIDE; MAXZIDE-25 | 4444769 | APR 24, 2001 | | NS | MAY 13, 1991 |
| | | | | | | D-15 | MAY 13, 1991 |
| >ADD> | | | | | | | |
| >ADD> | 18956 002 | IOHEXOL; OMNIPAQUE 240 | | | | I-19 | JUL 29, 1991 |
| >ADD> | | | | | | I-60 | JUL 29, 1991 |
| >ADD> | | | | | | I-75 | JUL 29, 1991 |
| >ADD> | | | | | | I-76 | JUL 29, 1991 |
| >ADD> | | | | | | I-77 | JUL 29, 1991 |
| | 18956 003 | IOHEXOL; OMNIPAQUE 300 | 4021481 | MAY 03, 1994 | | I-55 | FEB 01, 1988 |
| | | | | | | I-58 | FEB 01, 1988 |
| >ADD> | | | | | | I-60 | JUL 29, 1991 |
| >ADD> | | | | | | I-77 | JUL 29, 1991 |
| | 18956 004 | IOHEXOL; OMNIPAQUE 350 | | | | I-56 | MAY 24, 1991 |
| >ADD> | | | | | | I-77 | JUL 29, 1991 |
| | 19085 001 | IPRATROPIUM BROMIDE; ATROVENT | 3681500 | AUG 01, 1991 | | NCE | DEC 29, 1991 |
| | 19777 001 | LISINOPRIL; ZESTRIL | 4374829 | FEB 22, 2000 | | NCE | DEC 29, 1992 |
| | 19777 002 | LISINOPRIL; ZESTRIL | 4374829 | FEB 22, 2000 | | NCE | DEC 29, 1992 |
| | 19777 003 | LISINOPRIL; ZESTRIL | 4374829 | FEB 22, 2000 | | NCE | DEC 29, 1992 |
| | 19487 001 | LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D | 3714159 | JAN 30, 1990 | | | |
| | 11719 009 | METHOTREXATE SODIUM; METHOTREXATE | | | | ODE | APR 07, 1995 |
| | 09048 001 | METHOXSALEN; 8-MOP | | | | I-72 | MAR 23, 1991 |
| | 19516 002 | MORPHINE SULFATE; MS CONTIN | | | | NDF | MAY 29, 1990 |
| | 18677 001 | NABILONE; CESAMET | 4087545 | MAY 02, 1997 | U-7 | | |
| | 19599 001 | NAFTIFINE HYDROCHLORIDE; NAFTIN | 4282251 | AUG 04, 1998 | | NCE | MAR 01, 1993 |
| | 19508 001 | NIZATIDINE; AXID | 4382090 | MAY 03, 2000 | U-33 | | |
| | | | 4375547 | MAR 01, 2000 | | NCE | APR 12, 1993 |
| | 19508 002 | NIZATIDINE; AXID | 4382090 | MAY 03, 2000 | U-33 | | |
| | | | 4375547 | MAR 01, 2000 | | NCE | APR 12, 1993 |
| | 19009 001 | PIRBUTEROL ACETATE; EXIREL | 4175128 | NOV 20, 1996 | | | |
| | | | 3786160 | JAN 15, 1993 | | | |
| | | | 3700681 | OCT 24, 1989 | | NCE | DEC 30, 1991 |
| >ADD> | 17535 002 | PROBUCOL; LORELCO | 3862332 | JAN 21, 1992 | | | |
| | 17881 001 | TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT; TECHNETIUM TC 99M | 3872226 | MAR 18, 1992 | | | |
| | | | 3863004 | JAN 28, 1992 | U-31 | | |

| APPL/PROD | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 19057 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 1998 | U-5 | NCE | AUG 07, 1992 |
| | | 4112097 | SEP 05, 1995 | U-5 | | |
| | | 4026894 | MAY 31, 1994 | | | |
| 19057 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 1998 | U-5 | NCE | AUG 07, 1992 |
| | | 4112097 | SEP 05, 1995 | U-5 | | |
| | | 4026894 | MAY 31, 1994 | | | |
| 19057 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 1998 | U-5 | NCE | AUG 07, 1992 |
| | | 4112097 | SEP 05, 1995 | U-5 | | |
| | | 4026894 | MAY 31, 1994 | | | |
| 19057 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 1998 | U-5 | NCE | AUG 07, 1992 |
| | | 4112097 | SEP 05, 1995 | U-5 | | |
| | | 4026894 | MAY 31, 1994 | | | |
| 19641 001 | TERCONAZOLE; TERAZOL 3 | 4358449 | NOV 09, 1999 | | NCE | DEC 31, 1992 |
| | | | | | NDF | MAY 24, 1991 |
| 18207 003 | TRAZODONE HYDROCHLORIDE; DESYREL | 4258027 | MAR 24, 1998 | | | |
| | | 4215104 | JUL 29, 1997 | | | |
| 19415 002 | UROFOLLITROPIN; METRODIN | | | | I-73 | MAR 01, 1991 |
| 18817 003 | VERAPAMIL HYDROCHLORIDE; CALAN | | | | I-50 | DEC 16, 1989 |
| | | | | | I-51 | DEC 16, 1989 |
| 18817 004 | VERAPAMIL HYDROCHLORIDE; CALAN | | | | I-50 | DEC 16, 1989 |
| | | | | | I-51 | DEC 16, 1989 |

# SUBSCRIPTION FORM

## APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 8TH EDITION (1988)

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