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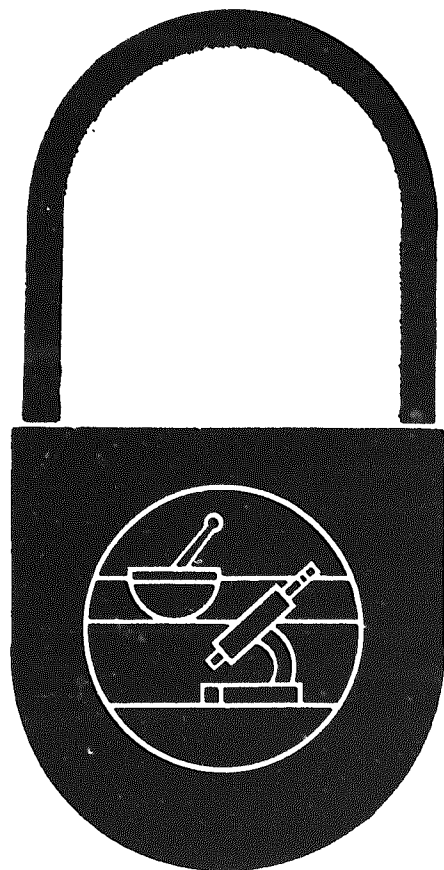
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**CUMULATIVE  
SUPPLEMENT 8**

**JAN'88-AUG'88**

CONTIN



# **APPROVED DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**8<sup>TH</sup> 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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**Prepared By  
Division of Drug Information Resources  
Office of Management  
Center for Drug Evaluation and Research, FDA**

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS  
8TH EDITION  
CUMULATIVE SUPPLEMENT 8  
AUGUST 1988

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**APPROVED DRUG PRODUCTS**  
**with**  
**THERAPEUTIC EQUIVALENCE EVALUATIONS**  
**8th EDITION**  
**CUMULATIVE SUPPLEMENT 8**  
**AUGUST 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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 "a" symbol to designate their non-marketed status. All products having a "a" 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.

| <u>Products</u>                                   | <u>Federal Register Reference</u> |
|---------------------------------------------------|-----------------------------------|
| 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.

### APPLICANT (NAME) CHANGES

| <u>FORMER APPLICANT (NAME)</u>                | <u>NEW APPLICANT (NAME)</u> | <u>NEW ABBREVIATED NAME</u> |
|-----------------------------------------------|-----------------------------|-----------------------------|
| NOVOCOL CHEMICAL MANUFACTURING<br>COMPANY INC | NOVOCOL PHARMACEUTICAL INC  | NOVOCOL PHARM               |

## 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<sup>1</sup>

| <u>CATEGORIES COUNTED</u>       | <u>DEC 1987</u> | <u>MAR 1988</u> | <u>JUN 1988</u> |
|---------------------------------|-----------------|-----------------|-----------------|
| 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 <sup>2</sup>         | 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 August 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 1-8 of the List).



ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

AP QUAD PHARMS 500MG/VIALM

N89619 001  
JAN 13, 1988~~BIAMON~~

AP LEDERLE LABS 500MG/VIAL

N09388 001

ACETOHYDROXAMIC ACID

TABLET; ORAL

LITHOSTAT

MISSION PHARMA

250MG

N18749 001  
MAY 31, 1983> ADD >  
> ADD >  
> DLT >  
> DLT >~~/MID/RES/~~~~/250MG/~~~~/N18749/001/~~  
~~/MAY/31/1983/~~ALBUTEROL SULFATE

CAPSULE; INHALATION

VENTOLIN ROTACAPS

GLAXO

EQ 0.2MG BASEM

N19489 001  
MAY 04, 1988ALSEROXYLON

TABLET; ORAL

~~/RAUTENSIN/~~~~/BP/ /DORSEY/ LABS/~~

3 DORSEY LABS

~~/2MG/~~  
2MG~~/N09215/001/~~  
N09215 001AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

~~/AMANTADINE HCL/~~~~/AM/ /REID/ROWELL/~~~~/100MG/~~~~/100MG/~~~~/N71000/001/~~  
~~/SEP/04/1986/~~~~SYNARTINE~~

AP REID ROWELL 100MG

N71000 001  
SEP 04, 1986AMCINONIDE

LOTION; TOPICAL

CYCLOCORT

LEDERLE LABS

0.1%M

N19729 001  
JUN 13, 1988AMLORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMLORIDE HCL AND HYDROCHLOROTHIAZIDE

AP BARR LABS 5MG;50MG

N71111 001  
MAY 10, 1988AMINO ACIDS

INJECTABLE; INJECTION

~~NEOPHAM/6.4%/~~~~/KABIVITRUM/~~~~/6.4%/~~~~/N18792/001/~~  
~~/JAN/17/1984/~~

3 KABIVITRUM

6.4%

N18792 001  
JAN 17, 1984

TRAVASOL 10% IN PLASTIC CONTAINER

BAXTER

10%M

N18931 004  
APR 27, 1988AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE

INJECTABLE; INJECTION

FREAMINE III 8.5% W/ ELECTROLYTES

KENDALL MCGAW

8.5%;110MG/100ML;230MG/100ML;

10MG/100ML;440MG/100ML;

690MG/100MLM

N16822 007  
JUL 01, 1988AMINOCAPROIC ACID

INJECTABLE; INJECTION

AMINOCAPROIC ACID

AP ABBOTT LABS 250MG/MLM

N70888 001  
JUN 16, 1988AMINOHIPPURATE SODIUM

INJECTABLE; INJECTION

AMINOHIPPURATE SODIUMAP MS&D 20%  
AP QUAD PHARMS 20%MN05619 001  
N89821 001  
JUL 14, 1988

AMINOPHYLLINETABLET; ORAL  
AMINOPHYLLINE

|         |                |         |
|---------|----------------|---------|
| /60/    | /BARR/LABS/    | /100MG/ |
| /60/    |                | /200MG/ |
|         | 3 BARR LABS    | 100MG   |
|         | 3              | 200MG   |
| > ADD > | BD HALSEY DRUG | 100MG   |
| > DLT > | /3/            | /100MG/ |
|         | /3/VALE/CHEM/  | /100MG/ |
|         | VALE CHEM      | 100MG   |

AMINOSALICYLATE SODIUMTABLET; ORAL  
/FEEDACIN/

|      |                 |         |
|------|-----------------|---------|
| /60/ | /CNSOL MIDLAND/ | /500MG/ |
|      | 3 CNSOL MIDLAND | 500MG   |

ANITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

|      |                 |         |
|------|-----------------|---------|
| /60/ | AMITRIPTIL      | /10MG/  |
| /60/ | /PARKE/DAVIS/   | /25MG/  |
| /60/ |                 | /50MG/  |
| /60/ |                 | /75MG/  |
| /60/ |                 | /100MG/ |
| /60/ |                 | /150MG/ |
| AR   | MARNER CHILCOTT | 10MG    |
| AR   |                 | 25MG    |
| AR   |                 | 50MG    |
| AR   |                 | 75MG    |
| AR   |                 | 100MG   |
| AR   |                 | 150MG   |

ANITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

|    |                                        |                     |
|----|----------------------------------------|---------------------|
| AR | CHLORDIAZEPOXIDE AND ANITRIPTYLINE HCL | EQ 12.5MG BASE; 5MG |
|    | PAR PHARM                              |                     |
| AR |                                        | 25MG; 10MG          |

|               |
|---------------|
| /N64497/001/  |
| /AUG/19/1983/ |
| /N64498/001/  |
| /AUG/19/1983/ |
| N68297 001    |
| AUG 19, 1983  |
| N68298 001    |
| AUG 19, 1983  |
| N64674 001    |
| /N64674/001/  |
| /N64533/001/  |
| N64533 001    |

|            |
|------------|
| N63937 001 |
| N63938 002 |
| N64957 001 |
| N65093 001 |
| N66295 001 |

ANITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

|    |                                        |                     |
|----|----------------------------------------|---------------------|
| AR | CHLORDIAZEPOXIDE AND ANITRIPTYLINE HCL | EQ 12.5MG BASE; 5MG |
|    | PHARM BASICS                           |                     |
| AR |                                        | EQ 25MG BASE; 10MG  |

|              |
|--------------|
| N70477 001   |
| JAN 12, 1988 |
| N70478 001   |
| JAN 12, 1988 |

AMOXICILLIN

CAPSULE; ORAL

|    |              |       |
|----|--------------|-------|
| AR | AMOXICILLIN  | 250MG |
|    | CLOMEL CHEMS |       |
| AR |              | 500MG |

|              |
|--------------|
| N62884 001   |
| FEB 25, 1988 |
| N62881 001   |
| FEB 25, 1988 |

POWDER FOR RECONSTITUTION; ORAL

|    |                |           |
|----|----------------|-----------|
| AR | POLYMER        | 125MG/5ML |
|    | BRSTL MYRS IND |           |
| AR |                | 250MG/5ML |

|              |
|--------------|
| N62885 001   |
| MAR 08, 1988 |
| N62885 002   |
| MAR 08, 1988 |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

|    |              |               |
|----|--------------|---------------|
| AR | AMPICILLIN   | EQ 250MG BASE |
|    | CLOMEL CHEMS |               |
| AR |              | EQ 500MG BASE |

|              |
|--------------|
| N62883 001   |
| FEB 25, 1988 |
| N62882 001   |
| FEB 25, 1988 |

|         |      |                |                 |
|---------|------|----------------|-----------------|
| > DLT > | /60/ | /LEDERLE/LABS/ | /EQ 250MG BASE/ |
| > DLT > | /60/ |                | /EQ 500MG BASE/ |
| > ADD > |      | 3 LEDERLE LABS | EQ 250MG BASE   |
| > ADD > |      | 3              | EQ 500MG BASE   |

|             |
|-------------|
| N62208/001/ |
| N62208/002/ |
| N62208 001  |
| N62208 002  |

|    |                |               |
|----|----------------|---------------|
| AR | POLYCELLIN     | EQ 250MG BASE |
|    | BRSTL MYRS IND |               |
| AR |                | EQ 500MG BASE |

|              |
|--------------|
| N62888 001   |
| MAR 04, 1988 |
| N62888 002   |
| MAR 04, 1988 |

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

|    |                       |                   |
|----|-----------------------|-------------------|
| AR | ORPHENADRINE COMPOUND | 385MG; 30MG; 25MG |
|    | VITARINE              |                   |

|              |
|--------------|
| N71564 001   |
| JUN 23, 1988 |

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE COMPOUND DOUBLE STRENGTH

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

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND / 65 /

|      |                 |                     |              |
|------|-----------------|---------------------|--------------|
| /BP/ | BANMAX PHARMS/  | /339MG;32.4MG;65MG/ | /N84553/002/ |
|      |                 |                     | AUG 17, 1983 |
|      | 2 BANMAX PHARMS | 339MG;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

ATENOLOL

|    |                 |       |              |
|----|-----------------|-------|--------------|
| AB | ICI PHARMS      | 50MG  | N72303 001   |
|    |                 |       | JUL 15, 1988 |
| AB |                 | 100MG | N72304 001   |
|    |                 |       | JUL 15, 1988 |
| AB | <u>TENDOMIN</u> | 50MG  | N18240 001   |
| AB | STUART PHARMS   | 100MG | N18240 002   |

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL

ATROPINE3/CARRICK LABS/

CARRICK LABS

/0.025MG;1MG/  
0.025MG;1MG

/N17744/002/  
N17744 002

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

AZATHIOPRINE

|    |             |                    |              |
|----|-------------|--------------------|--------------|
| AP | QUAD PHARMS | EQ 100MG BASE/VIAL | N71056 001   |
|    |             |                    | JUN 08, 1988 |

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

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 |
| AB | ZENITH LABS        | 10MG | N72234 001   |
|    |                    |      | JUL 21, 1988 |
| AB |                    | 20MG | N72235 001   |
|    |                    |      | JUL 21, 1988 |
| AB | <u>LTORISAL</u>    | 10MG | N17851 001   |
|    | GEIGY PHARMS       |      |              |
| AB | <u>LTORISAL DS</u> | 20MG | N17851 003   |
|    | GEIGY PHARMS       |      | JAN 20, 1982 |

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

|      |                  |        |              |
|------|------------------|--------|--------------|
| /BP/ | /PRIVATE/FMLTNS/ | /50MG/ | /N83206/001/ |
|      | 3 PRIVATE FMLTNS | 50MG   | N83206 001   |

**BETAMETHASONE DIPROPIONATE**

**LOTION; TOPICAL**

**DETAMETHASONE DIPROPIONATE**

N88877 001  
APR 11, 1985  
N88894 001  
APR 11, 1985  
N88895 001  
APR 11, 1985  
/N88877/001/  
/APR/11/1985/  
/N88894/001/  
/APR/11/1985/  
/N88895/001/  
/APR/11/1985/  
N89211 001  
JUN 14, 1988  
N89212 001  
JUN 14, 1988  
N89213 001  
JUN 14, 1988  
N89514 001  
JAN 31, 1984  
N89510 001  
JAN 31, 1984  
N89511 001  
JAN 31, 1984  
/N89514/001/  
/JAN/31/1984/  
/N89510/001/  
/JAN/31/1984/  
/N89511/001/  
/JAN/31/1984/  
N89058 001  
AUG 10, 1988  
N89059 001  
AUG 10, 1988  
N89060 001  
AUG 10, 1988  
  
N09193 004  
N09193 003  
N09193 002  
/N09193/004/  
/N09193/003/  
/N09193/002/

|                                   |                                                   |                       |                            |
|-----------------------------------|---------------------------------------------------|-----------------------|----------------------------|
| AB                                | <del>BETAMETHASONE VALERATE</del><br>COPLEY PHARM | <u>EQ 0.05% BASEM</u> | N71882 001<br>JUN 06, 1988 |
| > <u>ADD</u> >                    | AB THAMES PHARMA                                  | <u>EQ 0.05% BASEM</u> | N72276 001                 |
| > <u>ADD</u> >                    |                                                   |                       | AUG 24, 1988               |
| > <u>ADD</u> >                    | DIPROLENE                                         |                       |                            |
| > <u>ADD</u> >                    | BX SCHERING                                       | <u>EQ 0.05% BASEM</u> | N19716 001                 |
| > <u>ADD</u> >                    |                                                   |                       | AUG 01, 1988               |
| <br><u>BETAMETHASONE VALERATE</u> |                                                   |                       |                            |
| CREAM; TOPICAL                    |                                                   |                       |                            |
|                                   | <u>DERMABET</u>                                   |                       |                            |
| AB                                | TARO PHARMS                                       | <u>EQ 0.1% BASEM</u>  | N72041 001<br>JAN 06, 1988 |
| <br>LOTION; TOPICAL               |                                                   |                       |                            |
|                                   | <u>BETAMETHASONE VALERATE</u>                     |                       |                            |
| AB                                | COPLEY PHARM                                      | <u>EQ 0.1% BASEM</u>  | N71883 001<br>APR 22, 1988 |
| <br><u>BETAZOLE HYDROCHLORIDE</u> |                                                   |                       |                            |
| INJECTABLE; INJECTION             |                                                   |                       |                            |
|                                   | <u>MISTALOG/</u>                                  |                       |                            |
|                                   | <u>/LILLY/</u>                                    | <u>/50MG/ML/</u>      | <u>/N09344/001/</u>        |
|                                   | 2 LILLY                                           | 50MG/ML               | N09344 001                 |
| <br><u>BETHANECHOL CHLORIDE</u>   |                                                   |                       |                            |
| INJECTABLE; INJECTION             |                                                   |                       |                            |
|                                   | <u>BETHANECHOL CHLORIDE</u>                       |                       |                            |
| AP                                | QUAD PHARMS                                       | <u>5MG/MLM</u>        | N89815 001<br>APR 12, 1988 |
|                                   | <u>URECHOLINE</u>                                 |                       |                            |
| AP                                | MS&D                                              | <u>5MG/ML</u>         | N06536 001                 |
| <br><u>BRETYLIUM TOSYLATE</u>     |                                                   |                       |                            |
| INJECTABLE; INJECTION             |                                                   |                       |                            |
|                                   | <u>BRETYLIUM TOSYLATE</u>                         |                       |                            |
| AP                                | LUITPOLD PHARMS                                   | <u>50MG/MLM</u>       | N70891 001<br>JUL 26, 1988 |
| AP                                | QUAD PHARMS                                       | <u>50MG/MLM</u>       | N71181 001<br>FEB 16, 1988 |

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE  
/AA/ /BARR LABS/ /4MG/  
3 BARR LABS 4MG

/N4444/001/  
N84468 001

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HCL AND EPINEPHRINE

ABBOTT LABS

0.25%;0.005MG/MLM

N71165 001

JUN 16, 1988

0.25%;0.005MG/MLM

N71166 001

JUN 16, 1988

0.25%;0.005MG/MLM

N71167 001

JUN 16, 1988

0.5%;0.005MG/MLM

N71168 001

JUN 16, 1988

0.5%;0.005MG/MLM

N71169 001

JUN 16, 1988

0.5%;0.005MG/MLM

N71170 001

JUN 16, 1988

0.75%;0.005MG/MLM

N71171 001

JUN 16, 1988

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

SOLUTION; INTRAPERITONEAL

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

AI BAXTER

25.7MG/100ML;3.5GM/100ML;

15.2MG/100ML;567MG/100ML;

392MG/100MLM

N17512 010

NOV 18, 1985

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

AI BAXTER

25.7MG/100ML;3.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N17512 011

NOV 18, 1985

INPEROL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AI ABBOTT LABS

25.7MG/100ML;3.5GM/100ML;

15.2MG/100ML;567MG/100ML;

392MG/100MLM

N18379 007

JUN 24, 1988

INPEROL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AI ABBOTT LABS

25.7MG/100ML;3.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

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/100MLM

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/100MLM

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/100MLM

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/100MLM

N19632 001

FEB 29, 1988

CARBAMAZEPINE

TABLET; CHEWABLE; ORAL

CARBAMAZEPINE

AP

WARNER CHILCOTT

100MG

N71940 001

FEB 01, 1988

TEBETOL

AP

GEIGY PHARMS

100MG

N18281 001

CARISOPRODOL

TABLET; ORAL

CARTISOPRODOL

VITARINE

350MG

N89566 001

AUG 30, 1988

>\_ADD> AA  
>\_ADD>

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RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'88 - AUG'88

7

CEFACTOR

## POWDER FOR RECONSTITUTION; ORAL

CECLOR  
LILLY

EQ 187MG BASE/5MLM N62206 003  
APR 20, 1988  
EQ 375MG BASE/5MLM N62206 004  
APR 20, 1988

CEFAZOLIN SODIUM

## INJECTABLE; INJECTION

ANCEF

AP SK&F LABS EQ 5GM BASE/VIAL N50461 004  
AP CEFAZOLIN SODIUM EQ 250MG BASE/VIALM N62894 001  
BEN VENUE LABS JUL 21, 1988  
AP EQ 500MG BASE/VIALM N62894 002  
JUL 21, 1988  
AP EQ 1GM BASE/VIALM N62894 003  
JUL 21, 1988  
AP EQ 5GM BASE/VIALM N62894 004  
JUL 21, 1988  
AP EQ 10GM BASE/VIALM N62894 005  
JUL 21, 1988  
AP ELKINS SINN EQ 250MG BASE/VIALM N62807 001  
JAN 12, 1988  
AP EQ 500MG BASE/VIALM N62807 002  
JAN 12, 1988  
AP EQ 1GM BASE/VIALM N62807 003  
JAN 12, 1988  
AP EQ 5GM BASE/VIALM N62807 004  
JAN 12, 1988  
AP EQ 10GM BASE/VIALM N62807 005  
JAN 12, 1988  
AP EQ 20GM BASE/VIALM N62807 006  
JAN 12, 1988

CEFOTETAN DISODIUM

## INJECTABLE; INJECTION

CEFOTAN

STUART PHARMS

EQ 10GM BASE/VIALM N50588 003  
APR 25, 1988

CEPHALEXIN

## CAPSULE; ORAL

CEPHALEXIN

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

## POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

AB TAG PHARMS EQ 125MG BASE/5MLM N62873 001  
MAY 23, 1988  
AB EQ 250MG BASE/5MLM N62867 001  
APR 15, 1988

## TABLET; ORAL

CEPHALEXIN

VITARINE

> ADD > AB EQ 250MG BASEM N62863 001  
> ADD > AB EQ 500MG BASEM N62863 002  
> ADD > AB EQ 1GM BASEM N62863 003  
> ADD > AB EQ 1GM BASE N50440 002

KEFLET  
LILLYCEPHALEXIN HYDROCHLORIDE

## TABLET; ORAL

KEFTAB  
LILLY

EQ 333MG BASEM N50614 003  
MAY 16, 1988

CEPHRADINE

## CAPSULE; ORAL

CEPHRADINE

AB BARR LABS 250MG  
 AB 500MG  
 AB VITARINE 250MG  
 AB 500MG

N62850 001  
 APR 22, 1988  
 N62851 001  
 APR 22, 1988  
 N62813 001  
 FEB 25, 1988  
 N62813 002  
 FEB 25, 1988

> ADD > AA  
 > ADD >  
 > DLT > /66/  
 > DLT >

CHLOROQUINE PHOSPHATE

## TABLET; ORAL

CHLOROQUINE PHOSPHATE

DANBURY PHARMA EQ 300MG BASE

N88030 001  
 DEC 21, 1982  
 /N88030/001/  
 /DEC/21/1982/

/66/00000/0000/

CHLOROTHIAZIDE; RESERPINE

## TABLET; ORAL

CHLOROTHIAZIDE W/ RESERPINE

/BP/ /BOLAR/PHARM/ 250MG;0.125MG/  
 3 BOLAR PHARM 250MG;0.125MG

/N84853/001/  
 N84853 001

CHLORPHENIRAMINE MALEATE

## TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/66/ /BARR/LABS/ 4MG/  
 3 BARR LABS 4MG

/N80700/001/  
 N80700 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

## CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

AB PIONEER PHARMS 10MG  
 AB 25MG  
 /66/ /PUREPAC/PHARM/ 5MG/  
 /66/ 10MG/  
 /66/ 25MG/  
 3 PUREPAC PHARM 5MG  
 3 10MG  
 3 25MG  
 /66/ /LYNN/ 5MG/  
 /66/ /BANMAX/PHARMS/ 10MG/  
 /66/ 25MG/  
 3 BANMAX PHARMS 5MG  
 3 10MG  
 3 25MG

N89533 001  
 JUL 15, 1988  
 N89558 001  
 JUL 15, 1988  
 /N85155/001/  
 /N84939/002/  
 /N85144/001/  
 N85155 001  
 N84939 002  
 N85144 001

CHLORPROMAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

CHLORPROMAZINE HCL

AP MARSAM PHARMS 25MG/ML

N89563 001  
 APR 15, 1988

CHLORTHALIDONE

## TABLET; ORAL

CHLORTHALIDONE

AB 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

CHLOROQUINE PHOSPHATE

## TABLET; ORAL

ARALEN

> ADD > AA STERLING DRUG EQ 300MG BASE

N06002 001

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

|    |        |              |              |
|----|--------|--------------|--------------|
| AA | LEHMON | <u>500MG</u> | N89859 001   |
|    |        |              | MAY 04, 1988 |

PARAFON FORTE 030

|    |              |              |              |
|----|--------------|--------------|--------------|
| AA | MCNEIL PHARM | <u>500MG</u> | N11529 002   |
|    |              |              | JUN 15, 1987 |

CHOLESTYRAMINE

BAR, CHEMABLE; 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

|    |            |                     |            |
|----|------------|---------------------|------------|
| AB | UPJOHN MFG | <u>EQ 75MG BASE</u> | N61809 001 |
|----|------------|---------------------|------------|

|    |  |                      |            |
|----|--|----------------------|------------|
| AB |  | <u>EQ 150MG BASE</u> | N61809 002 |
|----|--|----------------------|------------|

CLEOCIN HCL

UPJOHN

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

CLINDAMYCIN HCL

VITARINE

|  |                     |              |
|--|---------------------|--------------|
|  | <u>EQ 75MG BASE</u> | N62910 001   |
|  |                     | JUL 05, 1988 |

|  |                      |              |
|--|----------------------|--------------|
|  | <u>EQ 150MG BASE</u> | N62910 002   |
|  |                      | JUL 05, 1988 |

CLINDAMYCIN PHOSPHATE

INJECTABLE; IM-IV

CLINDAMYCIN PHOSPHATE

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

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

|    |             |                         |              |
|----|-------------|-------------------------|--------------|
| AP | ELKINS SINN | <u>EQ 150MG BASE/ML</u> | N62953 001   |
|    |             |                         | APR 21, 1988 |

|    |                 |                         |              |
|----|-----------------|-------------------------|--------------|
| AP | LEDERLE PARNTLS | <u>EQ 150MG BASE/ML</u> | N62889 001   |
|    |                 |                         | APR 25, 1988 |

|    |        |                         |              |
|----|--------|-------------------------|--------------|
| AP | LEHMON | <u>EQ 150MG BASE/ML</u> | N62900 001   |
|    |        |                         | JUN 08, 1988 |

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

|    |          |                         |              |
|----|----------|-------------------------|--------------|
| AP | LYPHONED | <u>EQ 150MG BASE/ML</u> | N62747 001   |
|    |          |                         | JUN 03, 1988 |

|    |             |                         |              |
|----|-------------|-------------------------|--------------|
| AP | QUAD PHARMS | <u>EQ 150MG BASE/ML</u> | N62877 001   |
|    |             |                         | MAR 15, 1988 |

|    |              |                         |              |
|----|--------------|-------------------------|--------------|
| AP | SOLOPAK LABS | <u>EQ 150MG BASE/ML</u> | N62819 001   |
|    |              |                         | MAR 15, 1988 |

|    |  |                         |              |
|----|--|-------------------------|--------------|
| AP |  | <u>EQ 150MG BASE/ML</u> | N62852 001   |
|    |  |                         | MAR 17, 1988 |

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

|    |           |              |              |
|----|-----------|--------------|--------------|
| AB | CORD LABS | <u>500MG</u> | N72191 001   |
|    |           |              | MAY 02, 1988 |

CLONIPHENE CITRATE

TABLET; ORAL

CLONIPHENE CITRATE

|    |         |             |              |
|----|---------|-------------|--------------|
| AB | PLANTER | <u>50MG</u> | N18161 001   |
|    |         |             | MAR 22, 1982 |

SEROPHENE

|    |             |             |              |
|----|-------------|-------------|--------------|
| AB | SERONO LABS | <u>50MG</u> | N18361 001   |
|    |             |             | MAR 22, 1982 |

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

|         |    |           |              |              |
|---------|----|-----------|--------------|--------------|
| > ADD > | AB | CORD LABS | <u>0.1MG</u> | N70887 001   |
| > ADD > |    |           |              | AUG 31, 1988 |

|         |    |  |              |              |
|---------|----|--|--------------|--------------|
| > ADD > | AB |  | <u>0.2MG</u> | N70886 001   |
| > ADD > |    |  |              | AUG 31, 1988 |

|         |    |  |              |              |
|---------|----|--|--------------|--------------|
| > ADD > | AB |  | <u>0.3MG</u> | N71294 001   |
| > ADD > |    |  |              | AUG 31, 1988 |

|         |    |              |              |              |
|---------|----|--------------|--------------|--------------|
| > ADD > | AB | LEDERLE LABS | <u>0.1MG</u> | N71783 001   |
| > ADD > |    |              |              | APR 05, 1988 |

|         |    |  |              |              |
|---------|----|--|--------------|--------------|
| > ADD > | AB |  | <u>0.2MG</u> | N71784 001   |
| > ADD > |    |  |              | APR 05, 1988 |

|         |    |  |              |              |
|---------|----|--|--------------|--------------|
| > ADD > | AB |  | <u>0.3MG</u> | N71785 001   |
| > ADD > |    |  |              | APR 05, 1988 |

CLONIDINE HYDROCHLORIDE

## TABLET; ORAL

CLONIDINE HCL

|    |                 |       |              |
|----|-----------------|-------|--------------|
| AB | WARNER CHILCOTT | 0.1MG | N72138 001   |
|    |                 |       | JUN 15, 1988 |
| AB |                 | 0.2MG | N72139 001   |
|    |                 |       | JUN 15, 1988 |
| AB |                 | 0.3MG | N72140 001   |
|    |                 |       | JUN 15, 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 |
| > ADD > AB | CORD LABS       | 3.75MG | N72219 001   |
| > ADD >    |                 |        | AUG 26, 1988 |
| > ADD > AB |                 | 7.5MG  | N72220 001   |
| > ADD >    |                 |        | AUG 26, 1988 |
| > ADD > AB |                 | 15MG   | N72112 001   |
| > ADD >    |                 |        | AUG 26, 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 |
| 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

|            |               |        |              |
|------------|---------------|--------|--------------|
| > ADD > AB | PUREPAC PHARM | 3.75MG | N72330 001   |
| > ADD >    |               |        | AUG 08, 1988 |
| > ADD > AB |               | 7.5MG  | N72331 001   |
| > ADD >    |               |        | AUG 08, 1988 |
| > ADD > AB |               | 15MG   | N72332 001   |
| > ADD >    |               |        | AUG 08, 1988 |

CLORAZEPATE DIPOTASSIUM

## 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 |
| AB | GEN-MEN         |        |              |
| 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   |
| /AA/ |               | /EQ 125MG BASE/5ML/ | /N62268/001/ |
| AA   | BRISTOL LABS  | EQ 125MG BASE/5ML   | N50192 001   |
| AA   |               | EQ 125MG BASE/5ML   | N61453 001   |
| /AA/ |               | /EQ 125MG BASE/5ML/ | /N50192/001/ |
| /AA/ |               | /EQ 125MG BASE/5ML/ | /N61453/001/ |

COLCHICINE; PROBENECID

## TABLET; ORAL

## PROBENECID AND COLCHICINE

|      |                |               |              |
|------|----------------|---------------|--------------|
| /BP/ | BEECHAM/LABS/  | /0.5MG;500MG/ | /N44321/001/ |
|      | 3 BEECHAM LABS | 0.5MG;500MG   | N84321 001   |
| /BP/ | LEDERLE/LABS/  | /0.5MG;500MG/ | /N86954/001/ |
|      | 3 LEDERLE LABS | 0.5MG;500MG   | N86954 001   |

COPPER

INTRAUTERINE DEVICE; INTRAUTERINE  
INTRAUTERINE COPPER CONTRACEPTIVE  
POP COUNCIL CBR APPROX 176MG COPPERM N18680 002  
APR 29, 1988

CYCLACILLIN

TABLET; ORAL  
> ADD > CYCLACILLIN  
> ADD > AB BIOCRRAFT LABS 250MG N62895 001  
> ADD > AUG 04, 1988  
> ADD > AB 500MG N62895 002  
> ADD > AUG 04, 1988  
  
> ADD > AB CYCLAPEN-N  
> ADD > AB NYETH AYERST LABS 250MG N50509 001  
500MG N50509 002

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL  
AB CYCLOBENZAPRINE HCL 10MG N71611 001  
DANBURY PHARMA MAY 03, 1989 : FEB 29, 1988  
  
AB FLEXERIL 10MG N17821 002  
MS&D

CYTARABINE

INJECTABLE; INJECTION  
CYTOSAR-U  
> ADD > UPJOHN 1GM/VIAL N16793 003  
> ADD > DEC 21, 1987  
> ADD > 2GM/VIAL N16793 004  
> ADD > DEC 21, 1987

DACARBAZINE

INJECTABLE; INJECTION  
DACARBAZINE  
QUAD PHARMS 500MG/VIALM N71563 001  
MAY 06, 1988

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL  
AB DESIPRAMINE HCL 10MG N72099 001  
CORD LABS MAY 24, 1988  
AB 25MG N72100 001  
AB 50MG N72101 001  
AB 75MG N72102 001  
AB 100MG N72103 001  
AB 150MG N72104 001  
AB VITARINE 10MG N72167 001  
AB 150MG FEB 03, 1988  
N72254 001  
FEB 03, 1988  
  
AB NORPRAMIN 10MG N14399 007  
AB MERRELL DON 150MG FEB 11, 1982  
N14399 006

DESONIDE

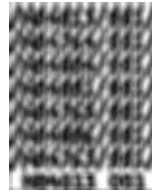
ointment; TOPICAL  
AB DESONEN 0.05% N71425 001  
OWEN LABS JUN 15, 1988  
AB TRIDESTION 0.05% N17426 001  
MILES PHARM

DESOXYCORTICOSTERONE ACETATE

PELLET; IMPLANTATION  
/PERCORTEN/  
/CIBA/PHARM/ 125MG /N05151/001/  
a CIBA PHARM 125MG N05151 001

DEXAMETHASONETABLET; ORAL  
DEXAMETHASONE

|      |             |          |
|------|-------------|----------|
| /BP/ | /BARR/LABS/ | /0.25MG/ |
| /BP/ |             | /0.25MG/ |
| /BP/ |             | /0.5MG/  |
| /BP/ |             | /0.5MG/  |
| /BP/ |             | /0.75MG/ |
| /BP/ |             | /0.75MG/ |
| /BP/ |             | /1.5MG/  |
| /BP/ |             | /1.5MG/  |
| 3    | BARR LABS   | 0.25MG   |
| 3    |             | 0.25MG   |
| 3    |             | 0.5MG    |
| 3    |             | 0.75MG   |
| 3    |             | 0.75MG   |
| 3    |             | 1.5MG    |
| 3    |             | 1.5MG    |



N84764 001  
N84084 001  
N84081 001  
N84765 001  
N84086 001  
N84763 001

> ADD > DEXAMETHASONE; TOBRAMYCIN

## &gt; ADD &gt; SUSPENSION/DROPS; OPHTHALMIC

## &gt; ADD &gt; TOBRADAX

&gt; ADD &gt; ALCON LABS 0.1%;0.3%

N50592 001  
AUG 18, 1988

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

## SYRUP; ORAL

|         |             |                    |                        |
|---------|-------------|--------------------|------------------------|
| > DLT > | /PHEMCO/N/  | /DEXTROMETHORPHAN/ |                        |
| > DLT > | /AFTN/AFTN/ | /LABS/             | /1.0MG/5ML;0.25MG/5ML/ |
| > DLT > |             |                    | /N11265/001/           |
|         |             |                    | /APR/02/1984/          |

DEXTROSE

## INJECTABLE; INJECTION

|    |               |                                    |              |
|----|---------------|------------------------------------|--------------|
| AP | KENDALL MCGAM | 10GM/100MLM                        | N19626 004   |
|    |               |                                    | FEB 02, 1988 |
|    |               | DEXTROSE 2.5% IN PLASTIC CONTAINER |              |
|    | KENDALL MCGAM | 2.5GM/100MLM                       | N19626 001   |
|    |               |                                    | FEB 02, 1988 |
| AP | KENDALL MCGAM | 5GM/100MLM                         | N19626 002   |
|    |               |                                    | FEB 02, 1988 |
|    |               | DEXTROSE 7.7% IN PLASTIC CONTAINER |              |
|    | KENDALL MCGAM | 7.7GM/100MLM                       | N19626 003   |
|    |               |                                    | FEB 02, 1988 |

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

|                                                              |                          |
|--------------------------------------------------------------|--------------------------|
| /DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/N//POTASSIUM/CHLORIDE/ |                          |
| /0.475%/IN/PLASTIC/CONTAINER/                                |                          |
| /ABBOTT/LABS/                                                | /5GM/100ML;17.5MG/100ML/ |
|                                                              | /300MG/100ML/            |
|                                                              | N18876/001/              |
|                                                              | JAN/17/1986/             |
| /DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/N//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%/N//POTASSIUM/CHLORIDE/ |                          |
| /0.224%/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;15.0MG/100ML/ |
|                                                              | /225MG/100ML/            |
|                                                              | N18365/001/              |
| /DEXTROSE/5%;SODIUM/CHLORIDE/0.45%AND/POTASSIUM/CHLORIDE/    |                          |
| /0.334%IN/PLASTIC/CONTAINER/                                 |                          |
| /ABBOTT/LABS/                                                | /5GM/100ML;44.4MG/100ML/ |
|                                                              | /450MG/100ML/            |
|                                                              | N18362/002/              |
| /DEXTROSE/5%;SODIUM/CHLORIDE/0.45%AND/POTASSIUM/CHLORIDE/    |                          |
| /0.3%IN/PLASTIC/CONTAINER/                                   |                          |
| /ABBOTT/LABS/                                                | /5GM/100ML;44.4MG/100ML/ |
|                                                              | /450MG/100ML/            |
|                                                              | N18362/003/              |
|                                                              |                          |
| POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM         |                          |
| CHLORIDE 0.2% IN PLASTIC CONTAINER                           |                          |
| KENDALL MCGAM                                                | 10GM/100ML;37MG/100ML;   |
|                                                              | 200MG/100MLM             |
|                                                              | N19630 031               |
|                                                              | FEB 17, 1988             |
| POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM         |                          |
| CHLORIDE 0.45% IN PLASTIC CONTAINER                          |                          |
| KENDALL MCGAM                                                | 10GM/100ML;37MG/100ML;   |
|                                                              | 450MG/100MLM             |
|                                                              | N19630 037               |
|                                                              | FEB 17, 1988             |
| POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM         |                          |
| CHLORIDE 0.9% IN PLASTIC CONTAINER                           |                          |
| KENDALL MCGAM                                                | 10GM/100ML;37MG/100ML;   |
|                                                              | 900MG/100MLM             |
|                                                              | N19630 043               |
|                                                              | FEB 17, 1988             |
| POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM          |                          |
| CHLORIDE 0.11% IN PLASTIC CONTAINER                          |                          |
| KENDALL MCGAM                                                | 5GM/100ML;37MG/100ML;    |
|                                                              | 110MG/100MLM             |
|                                                              | N19630 001               |
|                                                              | FEB 17, 1988             |

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM  
CHLORIDE 0.2% IN PLASTIC CONTAINER  
KENDALL MCGAW 5GM/100ML; 37MG/100ML;  
200MG/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM N19630 044  
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM  
CHLORIDE 0.2% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML; 75MG/100ML;  
200MG/100MLM 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/100MLM 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/100MLM N19630 020  
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM  
CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML; 75MG/100ML;  
900MG/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM N19630 009  
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM  
CHLORIDE 0.33% IN PLASTIC CONTAINER  
KENDALL MCGAW 5GM/100ML; 110MG/100ML;  
330MG/100MLM 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/100MLM N19630 021  
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM  
CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;110MG/100ML;  
900MG/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM N19630 022  
FEB 17, 1988

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

AP KENDALL MCGAW 5GM/100ML;150MG/100ML;  
900MG/100MLM 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/100MLM 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/100MLM N19630 035  
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTION

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

KENDALL MCGAW 10GM/100ML;220MG/100ML;  
450MG/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM N19630 029  
FEB 17, 1988

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

KENDALL MCGAW 10GM/100ML;300MG/100ML;  
200MG/100MLM 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/100MLM 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/100MLM N19630 048  
FEB 17, 1988

BEST COPY AVAILABLE

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

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

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

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

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.4% IN PLASTIC CONTAINER

AP KENDALL MCGAN 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 MCGAN 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 MCGAN 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

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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 SODIUMCHLORIDE 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 SODIUMCHLORIDE 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 SODIUMCHLORIDE 0.45% IN PLASTIC CONTAINER

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

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

ABBOTT LABS 5GM/100ML;224MG/100ML;  
225MG/100ML N18365 003

JUL 05, 1983

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

AP TRAVENOL LABS 5GM/100ML;224MG/100ML;  
900MG/100ML N19308 006

APR 05, 1985

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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 SODIUMCHLORIDE 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 SODIUMCHLORIDE 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 SODIUMCHLORIDE 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 CHLORIDE0.45% 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 CHLORIDE0.9% 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

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE0.225% 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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE  
0.5% IN PLASTIC CONTAINER  
ABBOTT LABS

5GM/100ML;74.5MG/100ML;  
300MG/100MLM N18876 005  
MAR 28, 1988

5GM/100ML;149MG/100ML;  
300MG/100MLM 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/100MLM N19631 011  
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER  
KENDALL MCGAW 10GM/100ML;200MG/100MLM N19631 012  
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC  
CONTAINER

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

DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC  
CONTAINER

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

DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC  
CONTAINER

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

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC  
CONTAINER

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

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.33% IN PLASTIC  
CONTAINER

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

DEXTROSE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC  
CONTAINER

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

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC  
CONTAINER

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

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER  
KENDALL MCGAW 5GM/100ML;110MG/100MLM N19631 006  
FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

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

DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

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

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

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

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

DIATRIZOATE MEGGLUMINE; DIATRIZOATE SODIUM

## INJECTABLE; INJECTION

RENOCAL-74

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

DIAZEPAM

## TABLET; ORAL

DIAZEPAM

PIONEER PHARMS

> ADD > AB 2MG N70787 001  
> ADD > AB 5MG N70788 001  
> ADD > AB 10MG N70776 001  
> ADD > AB AUG 02, 1988

DIAZEPAM

TABLET; ORAL  
5-PAM  
 AB QUANTUM PHARMS 2MG N72431 001  
 APR 29, 1988  
 AB 5MG N72432 001  
 APR 29, 1988  
 AB 10MG N72433 001  
 APR 29, 1988

DIAZOXIDE

CAPSULE; ORAL  
 PROGLYCEM  
 MED MKTG SPEC 50MG N17425 001  
 3 100MG N17425 002  
 /2/5CHERINE/ /50MG/ /N17425/001/

INJECTABLE; INJECTION  
DIAZOXIDE  
 AP QUAD PHARMS 15MG/ML N71908 001  
 JAN 26, 1988

SUSPENSION; ORAL  
 PROGLYCEM  
 MED MKTG SPEC 50MG/ML N17453 001  
 /2/5CHERINE/ /50MG/ML/ /N17453/001/

DICLOFENAC SODIUM

TABLET, ENTERIC COATED; ORAL  
 VOLTAREN  
 CIBA PHARM 25MG N19201 001  
 JUL 28, 1988  
 50MG N19201 002  
 JUL 28, 1988  
 75MG N19201 003  
 JUL 28, 1988

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL  
 HETRAZAN  
 /LEDERLE/LABS/ /50MG/ N06459/001/  
 3 LEDERLE LABS 50MG N06459 001

DIFLORASONE DIACETATE

CREAM; TOPICAL  
 /DIFLORASONE/DIACETATE/  
 /UPJOHN/ /0.05%/ N19259/001/  
 /AUG/28/1988/  
 > DLT >  
 > DLT >  
 > DLT >  
 > ADD > 3 UPJOHN 0.05% N19259 001  
 > ADD > AUG 28, 1988

DISOPYRAMIDE PHOSPHATE

CAPSULE, CONTROLLED RELEASE; ORAL  
DISOPYRAMIDE PHOSPHATE  
 > ADD > AB KV PHARM EQ 100MG BASEM N71929 001  
 > ADD > AUG 19, 1988  
 > ADD > AB NORPACE CR EQ 100MG BASE N18655 001  
 > ADD > SEARLE EQ 100MG BASE JUL 20, 1982

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

DOXEPIN HYDROCHLORIDE

## CAPSULE; ORAL

ADAPIN

|    |          |                      |                            |
|----|----------|----------------------|----------------------------|
| AB | PENNMALT | <u>EQ 150MG BASE</u> | N16987 007<br>APR 13, 1987 |
|----|----------|----------------------|----------------------------|

DOXEPIN HCL

|    |              |                       |                            |
|----|--------------|-----------------------|----------------------------|
| AB | BARR LABS    | <u>EQ 25MG BASEM</u>  | N71502 001<br>FEB 18, 1988 |
| AB |              | <u>EQ 50MG BASEM</u>  | N71653 001<br>FEB 18, 1988 |
| AB |              | <u>EQ 75MG BASEM</u>  | N71654 001<br>FEB 18, 1988 |
| AB |              | <u>EQ 100MG BASEM</u> | N71521 001<br>FEB 18, 1988 |
| AB | CHELSEA LABS | <u>EQ 75MG BASEM</u>  | N71763 001<br>FEB 09, 1988 |
| AB |              | <u>EQ 150MG BASEM</u> | N71764 001<br>FEB 09, 1988 |
| AB | LEDERLE LABS | <u>EQ 10MG BASEM</u>  | N71685 001<br>JAN 05, 1988 |
| AB |              | <u>EQ 25MG BASEM</u>  | N71686 001<br>JAN 05, 1988 |
| AB |              | <u>EQ 50MG BASEM</u>  | N71673 001<br>JAN 05, 1988 |
| AB |              | <u>EQ 75MG BASEM</u>  | N71674 001<br>JAN 05, 1988 |
| AB |              | <u>EQ 100MG BASEM</u> | N71675 001<br>JAN 05, 1988 |
| AB |              | <u>EQ 150MG BASEM</u> | N71676 001<br>JAN 05, 1988 |

## CONCENTRATE; ORAL

DOXEPIN HCL

|    |           |                         |                            |
|----|-----------|-------------------------|----------------------------|
| AA | MY K LABS | <u>EQ 10MG BASE/MLM</u> | N71918 001<br>JUL 20, 1988 |
|----|-----------|-------------------------|----------------------------|

DOXYCYCLINE HYCLATE

## CAPSULE; ORAL

DOXYCYCLINE HYCLATE

|    |          |                      |                            |
|----|----------|----------------------|----------------------------|
| AB | VITARINE | <u>EQ 50MG BASEM</u> | N62780 001<br>APR 12, 1988 |
|----|----------|----------------------|----------------------------|

## INJECTABLE; INJECTION

DOXYCYCLINE

|    |                |                            |                            |
|----|----------------|----------------------------|----------------------------|
| AP | BEN VENUE LABS | <u>EQ 100MG BASE/VIALM</u> | N62569 001<br>MAR 09, 1988 |
| AP |                | <u>EQ 200MG BASE/VIALM</u> | N62569 002<br>MAR 09, 1988 |

DROPERIDOL

## INJECTABLE; INJECTION

DROPERIDOL

|         |                 |                  |                                                |
|---------|-----------------|------------------|------------------------------------------------|
| AP      | ABBOTT LABS     | <u>2.5MG/MLM</u> | N71981 001<br>FEB 29, 1988                     |
| AP      | DUPONT CRI CARE | <u>2.5MG/MLM</u> | N71645 001<br>APR 07, 1988                     |
| > ADD > | AP              | QUAD PHARMS      | <u>2.5MG/MLM</u><br>N71941 001<br>AUG 17, 1988 |
| > ADD > | AP              |                  | <u>2.5MG/MLM</u><br>N71942 001<br>AUG 17, 1988 |

DROPERIDOL; FENTANYL CITRATE

## INJECTABLE; INJECTION

FENTANYL CITRATE AND DROPERIDOL

|    |               |                                               |                            |
|----|---------------|-----------------------------------------------|----------------------------|
| AP | ABBOTT LABS   | <u>2.5MG/ML;</u><br><u>EQ 0.05MG BASE/MLM</u> | N71982 001<br>MAY 04, 1988 |
| AP | JANSEN PHARMA | <u>2.5MG/ML;</u><br><u>EQ 0.05MG BASE/MLM</u> | N16049 001                 |

EDROPHONIUM CHLORIDE

## INJECTABLE; INJECTION

REVERSOLO

|    |         |                 |                            |
|----|---------|-----------------|----------------------------|
| AP | ORGANON | <u>10MG/MLM</u> | N89624 001<br>MAY 13, 1988 |
|----|---------|-----------------|----------------------------|

ENALAPRILAT

## INJECTABLE; INJECTION

## VASOTEC

|               |                   |                            |
|---------------|-------------------|----------------------------|
| MS&D RES LABS | <u>1.25MG/MLM</u> | N19309 001<br>FEB 09, 1988 |
|---------------|-------------------|----------------------------|

ENALAPRIL MALEATE

## TABLET; ORAL

## VASOTEC

|               |              |                            |
|---------------|--------------|----------------------------|
| MS&D RES LABS | <u>2.5MG</u> | N18998 005<br>JUL 26, 1988 |
|---------------|--------------|----------------------------|

EPINEPHRINE; LIDOCAINE HYDROCHLORIDEINJECTABLE; INJECTIONLIDOCAINE 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 |

LIDOCAINE HCL W/ EPINEPHRINE

|              |         |              |              |
|--------------|---------|--------------|--------------|
| > DLT > /AA/ | /LEMON/ | 0.01MG/ML;1% | /N85463/001/ |
| > ADD >      | 3 LEMON | 0.01MG/ML;1% | N85463 001   |

HYLOCAINE 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 MESYLATESTABLET; ORAL

|      |                      |       |               |
|------|----------------------|-------|---------------|
| /AA/ | /ERGOLOID MESYLATES/ | /1MG/ | /N88207/001/  |
| /AA/ | /CHELSEA LABS/       | /1MG/ | /MAR/22/1984/ |
| AB   | CHLSEAL              | 1MG   | N88207 001    |
|      |                      |       | MAR 22, 1984  |

TABLET; SUBLINGUAL

|      |                      |         |              |
|------|----------------------|---------|--------------|
| /AA/ | /ERGOLOID MESYLATES/ | /0.5MG/ | /N84868/001/ |
| /AA/ | /RIKER LABS/         | /1MG/   | /N85809/001/ |
|      | 3 RIKER LABS         | 0.5MG   | N84868 001   |
|      | 3                    | 1MG     | N85809 001   |
| /AA/ | /ERGOLOID MESYLATES/ | /0.5MG/ | /N86189/001/ |
| /AA/ | /CHELSEA LABS/       | /1MG/   | /N86188/001/ |
| AA   | CHLSEAL              | 0.5MG   | N86189 001   |
| AA   |                      | 1MG     | N86188 001   |

ERYTHROMYCINSOLUTION; TOPICALERYTHROMYCIN

|    |              |    |              |
|----|--------------|----|--------------|
| AT | NASKA PHARMA | 2% | N62957 001   |
|    |              |    | JUL 21, 1988 |
| AT | ETS-22       | 2% | N62687 001   |
|    | PADDOCK LABS |    | FEB 05, 1988 |

ERYTHROMYCIN ETHYLSUCCINATETABLET, CHENABLE; ORALERYPED

|    |             |                |              |
|----|-------------|----------------|--------------|
| AB | ABBOTT LABS | EQ 200MG BASEM | N50297 003   |
|    |             |                | JUL 05, 1988 |

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYLGRANULE; ORALERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL

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

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

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

ERYTHROMYCIN LACTOBIONATEINJECTABLE; INJECTIONERYTHROGIN

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

ERYTHROMYCIN STEARATETABLET; ORALERYTHROMYCIN

|      |                |                 |              |
|------|----------------|-----------------|--------------|
| /AA/ | /ERYTHROMYCIN/ | /EQ 250MG BASE/ | /N61304/001/ |
| /AA/ | /BRISTOL LABS/ | /EQ 250MG BASE/ | /N61304/001/ |
|      | 3 BRISTOL LABS | EQ 250MG BASE   | N61304 001   |
|      | 3              | EQ 250MG BASE   | N61887 001   |

ERYTHROMYCIN STEARATE

## TABLET; ORAL

|                              |                |                 |              |
|------------------------------|----------------|-----------------|--------------|
| <u>ERYPAR</u>                |                |                 |              |
| /66/                         | /PARKE/DAVIS/  | /EQ 250MG BASE/ | /N62032/001/ |
| /66/                         |                | /EQ 500MG BASE/ | /N62032/002/ |
|                              | 3 PARKE DAVIS  | EQ 250MG BASE   | N62032 001   |
|                              | 3              | EQ 500MG BASE   | N62032 002   |
| <u>ERYTHROCIN STEARATE</u>   |                |                 |              |
| /66/                         | /ABBOTT/LABS/  | /EQ 125MG BASE/ | /N60359/001/ |
|                              | 3 ABBOTT LABS  | EQ 125MG BASE   | N60359 002   |
| <u>ERYTHROMYCIN STEARATE</u> |                |                 |              |
| /66/                         | /LEDERLE/LABS/ | /EQ 250MG BASE/ | /N62089/001/ |
| /66/                         |                | /EQ 500MG BASE/ | /N62089/002/ |
|                              | 3 LEDERLE LABS | EQ 250MG BASE   | N62089 001   |
|                              | 3              | EQ 500MG BASE   | N62089 002   |
| <u>PFIZER-L/</u>             |                |                 |              |
| /66/                         | /PFIZER/LABS/  | /EQ 500MG BASE/ | /N61791/001/ |
|                              | 3 PFIZER LABS  | EQ 500MG BASE   | N61791 002   |

ESMOLOL HYDROCHLORIDEINJECTABLE; INJECTION  
BREVIBLOC

|         |                 |          |              |
|---------|-----------------|----------|--------------|
| > ADD > | DUPONT CRI CARE | 10MG/MLM | N19386 001   |
| > ADD > |                 |          | AUG 15, 1988 |

ESTRONE

## INJECTABLE; INJECTION

|                |               |          |              |
|----------------|---------------|----------|--------------|
| <u>ESTRONE</u> |               |          |              |
| /66/           | /STERIS/LABS/ | /5MG/ML/ | /N85239/001/ |
|                | STERIS LABS   | 5MG/ML   | N85239 001   |
| <u>THEELIN</u> |               |          |              |
| /66/           | /PARKE/DAVIS/ | /1MG/ML/ | /N03977/001/ |
| /66/           |               | /5MG/ML/ | /N03977/003/ |
|                | 3 PARKE DAVIS | 1MG/ML   | N03977 001   |
|                | 3             | 5MG/ML   | N03977 003   |

ETHINYL ESTRADIOL; NORETHINDRONE

## TABLET; ORAL-21

|                                            |               |                       |              |
|--------------------------------------------|---------------|-----------------------|--------------|
| <u>NORETHIN 1/35E-21</u>                   |               |                       |              |
| AB                                         | SEARLE PHARMS | 0.035MG;1MG           | N71480 001   |
|                                            |               |                       | APR 12, 1988 |
| <u>NORETHINDRONE AND ETHINYL ESTRADIOL</u> |               |                       |              |
| AB                                         | WATSON LABS   | 0.035MG;0.5MG AND 1MG | N71043 001   |
|                                            |               |                       | APR 01, 1988 |

ETHINYL ESTRADIOL; NORETHINDRONE

## TABLET; ORAL-21

|                             |             |                       |              |
|-----------------------------|-------------|-----------------------|--------------|
| <u>ORTHO-NOVUM 10/11-21</u> |             |                       |              |
| AB                          | ORTHO PHARM | 0.035MG;0.5MG AND 1MG | N18354 001   |
|                             |             |                       | JAN 11, 1982 |

## TABLET; ORAL-28

|                          |               |             |              |
|--------------------------|---------------|-------------|--------------|
| <u>NORETHIN 1/35E-28</u> |               |             |              |
| AB                       | SEARLE PHARMS | 0.035MG;1MG | N71481 001   |
|                          |               |             | APR 12, 1988 |

|                                            |             |                       |              |
|--------------------------------------------|-------------|-----------------------|--------------|
| <u>NORETHINDRONE AND ETHINYL ESTRADIOL</u> |             |                       |              |
| AB                                         | WATSON LABS | 0.035MG;0.5MG AND 1MG | N71044 001   |
|                                            |             |                       | APR 01, 1988 |

|                             |             |                       |              |
|-----------------------------|-------------|-----------------------|--------------|
| <u>ORTHO-NOVUM 10/11-28</u> |             |                       |              |
| AB                          | ORTHO PHARM | 0.035MG;0.5MG AND 1MG | N18354 002   |
|                             |             |                       | JAN 11, 1982 |

ETHIODIZED OIL

/INJECTABLE/INJECTION/  
/ETHIODOL/  
/FOUGERA/

/99%/

/N09190/001/

OIL; INTRALYMPHATIC, INTRAUTERINE  
ETHIODOL  
FOUGERA

99%

N09190 001

FENOPROFEN CALCIUM

## CAPSULE; ORAL

|                           |    |                |                             |
|---------------------------|----|----------------|-----------------------------|
| <u>FENOPROFEN CALCIUM</u> |    |                |                             |
| > ADD >                   | AB | AM THERPTCS    | EQ 200MG BASEM              |
| > ADD >                   |    |                | N72307 001                  |
| > ADD >                   |    |                | AUG 22, 1988                |
| > ADD >                   | AB |                | EQ 300MG BASEM              |
|                           |    |                | N72308 001                  |
|                           |    |                | AUG 22, 1988                |
|                           | AB | HALSEY DRUG    | EQ 200MG BASEM              |
|                           |    |                | N72355 001                  |
|                           |    |                | AUG 17, 1988 : JUL 05, 1988 |
|                           | AB |                | EQ 300MG BASEM              |
|                           |    |                | N72356 001                  |
|                           |    |                | AUG 17, 1988 : JUL 05, 1988 |
| > ADD >                   | AB | PAR PHARM      | EQ 200MG BASEM              |
| > ADD >                   |    |                | N72437 001                  |
| > ADD >                   |    |                | AUG 22, 1988                |
| > ADD >                   | AB |                | EQ 300MG BASEM              |
|                           |    |                | N72438 001                  |
|                           |    |                | AUG 22, 1988                |
|                           | AB | QUANTUM PHARMS | EQ 200MG BASEM              |
|                           |    |                | N72214 001                  |
|                           |    |                | AUG 17, 1988 : APR 14, 1988 |
|                           |    |                | EQ 300MG BASEM              |
|                           |    |                | N71738 001                  |
|                           |    |                | AUG 17, 1988 : APR 14, 1988 |

FENOPROFEN CALCIUM

## CAPSULE; ORAL

FENOPROFEN CALCIUM

|    |                    |                       |              |
|----|--------------------|-----------------------|--------------|
| AB | <u>WATSON LABS</u> | <u>EQ 200MG BASEM</u> | N72294 001   |
|    |                    | AUG 17, 1988 :        | JUL 08, 1988 |
| AB |                    | <u>EQ 300MG BASEM</u> | N72293 001   |
|    |                    | AUG 17, 1988 :        | JUL 08, 1988 |

NALFON

|    |                    |                      |            |
|----|--------------------|----------------------|------------|
| AB | <u>DISTA PRODS</u> | <u>EQ 300MG BASE</u> | N17604 002 |
| AB | <u>NALFON 300</u>  | <u>EQ 200MG BASE</u> | N17604 003 |

## TABLET; ORAL

FENOPROFEN CALCIUM

|            |                        |                       |              |
|------------|------------------------|-----------------------|--------------|
| AB         | <u>AM THERPTCS</u>     | <u>EQ 600MG BASEM</u> | N72309 001   |
|            |                        | AUG 17, 1988 :        | JUN 16, 1988 |
| AB         | <u>CHELSEA LABS</u>    | <u>EQ 600MG BASEM</u> | N72407 001   |
|            |                        | AUG 17, 1988 :        | JUN 13, 1988 |
| AB         | <u>HALSEY DRUG</u>     | <u>EQ 600MG BASEM</u> | N72357 001   |
|            |                        | AUG 17, 1988 :        | JUL 05, 1988 |
| AB         | <u>LEDERLE LABS</u>    | <u>EQ 600MG BASEM</u> | N72326 001   |
|            |                        | AUG 17, 1988 :        | APR 20, 1988 |
| AB         | <u>MYLAN PHARMS</u>    | <u>EQ 600MG BASEM</u> | N72267 001   |
|            |                        | AUG 17, 1988 :        | JUN 08, 1988 |
| AB         | <u>PAR PHARM</u>       | <u>EQ 600MG BASEM</u> | N72429 001   |
|            |                        | AUG 17, 1988 :        | JUL 19, 1988 |
| AB         | <u>PHARM BASICS</u>    | <u>EQ 600MG BASEM</u> | N72362 001   |
|            |                        | AUG 17, 1988 :        | JUN 16, 1988 |
| AB         | <u>PUREPAC PHARM</u>   | <u>EQ 600MG BASEM</u> | N72274 001   |
|            |                        | MAY 02, 1988          |              |
| AB         | <u>QUANTUM PHARMCS</u> | <u>EQ 600MG BASEM</u> | N72194 001   |
|            |                        | AUG 17, 1988 :        | APR 14, 1988 |
| AB         | <u>WATSON LABS</u>     | <u>EQ 600MG BASEM</u> | N72165 001   |
|            |                        | AUG 17, 1988 :        | JUL 08, 1988 |
| > ADD > AB | <u>ZENITH LABS</u>     | <u>EQ 600MG BASEM</u> | N72557 001   |
| > ADD >    |                        |                       | AUG 29, 1988 |

NALFON

|    |                    |                      |            |
|----|--------------------|----------------------|------------|
| AB | <u>DISTA PRODS</u> | <u>EQ 600MG BASE</u> | N17710 001 |
|----|--------------------|----------------------|------------|

FLECAINIDE ACETATE

## TABLET; ORAL

TAMBOCOR

|         |    |                   |        |              |
|---------|----|-------------------|--------|--------------|
| > ADD > | AB | <u>RIKER LABS</u> | 50MGm  | N18830 004   |
| > ADD > |    |                   |        | AUG 23, 1988 |
|         |    |                   | 150MGm | N18830 003   |
|         |    |                   |        | JUN 03, 1988 |

FLUOCINOLONE ACETONIDE

## CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

|    |                     |                           |              |
|----|---------------------|---------------------------|--------------|
| AT | <u>G&amp;N LABS</u> | <u>0.01%<sub>m</sub></u>  | N89526 001   |
|    |                     |                           | JUL 26, 1988 |
| AT |                     | <u>0.025%<sub>m</sub></u> | N89525 001   |
|    |                     |                           | JUL 26, 1988 |

## OIL; TOPICAL

DERMA-SMOOTH/FS  
HILL DERM

|                    |              |
|--------------------|--------------|
| 0.01% <sub>m</sub> | N19452 001   |
|                    | FEB 03, 1988 |

## OINTMENT; TOPICAL

FLUOCINOLONE ACETONIDE

|    |                     |                           |              |
|----|---------------------|---------------------------|--------------|
| AT | <u>G&amp;N LABS</u> | <u>0.025%<sub>m</sub></u> | N89524 001   |
|    |                     |                           | JUL 26, 1988 |

FLUOCINONIDE

## CREAM; TOPICAL

FLUOCINONIDE

|    |                       |                          |                             |
|----|-----------------------|--------------------------|-----------------------------|
| AB | <u>CLAY PARK LABS</u> | <u>0.05%<sub>m</sub></u> | N71790 001                  |
|    |                       |                          | JUL 13, 1988 : APR 25, 1988 |

FLUOROURACIL

## INJECTABLE; INJECTION

FLUOROURACIL

|    |                       |                 |              |
|----|-----------------------|-----------------|--------------|
| AP | <u>BEN VENUE LABS</u> | <u>50MG/MLm</u> | N89508 001   |
|    |                       |                 | JAN 26, 1988 |

FLUPHENAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

FLUPHENAZINE HCL

|    |                    |                  |              |
|----|--------------------|------------------|--------------|
| AP | <u>QUAD PHARMS</u> | <u>2.5MG/MLm</u> | N89800 001   |
|    |                    |                  | JUN 08, 1988 |

## TABLET; ORAL

FLUPHENAZINE HCL

|            |                     |               |              |
|------------|---------------------|---------------|--------------|
| > ADD > AB | <u>MYLAN PHARMS</u> | <u>1MGm</u>   | N89801 001   |
| > ADD >    |                     |               | AUG 12, 1988 |
| > ADD > AB |                     | <u>2.5MGm</u> | N89802 001   |
| > ADD >    |                     |               | AUG 12, 1988 |
| > ADD > AB |                     | <u>5MGm</u>   | N89803 001   |
| > ADD >    |                     |               | AUG 12, 1988 |
| > ADD > AB |                     | <u>10MGm</u>  | N89804 001   |
| > ADD >    |                     |               | AUG 12, 1988 |

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FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL

FLUPHENAZINE HCL

|            |           |         |              |
|------------|-----------|---------|--------------|
| > ADD > AB | PAR PHARM | 1MG     | N89740 001   |
| > ADD >    |           |         | AUG 25, 1988 |
| > ADD > AB |           | 2.5MG   | N89741 001   |
| > ADD >    |           |         | AUG 25, 1988 |
| > ADD > AB |           | 5MG     | N89742 001   |
| > ADD >    |           |         | AUG 25, 1988 |
| > ADD > AB |           | 10MG    | N89743 001   |
| > ADD >    |           |         | AUG 25, 1988 |
|            | PERMITIL  |         |              |
| BP         | SCHERING  | 2.5MG   | N12034 004   |
| BP         |           | 5MG     | N12034 005   |
| BP         |           | 10MG    | N12034 006   |
| /2/        |           | /2.5MG/ | /N12034/004/ |
| /2/        |           | /5MG/   | /N12034/005/ |
| /2/        |           | /10MG/  | /N12034/006/ |

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

|            |             |      |              |
|------------|-------------|------|--------------|
| AB         | HALSEY DRUG | 15MG | N71808 001   |
|            |             |      | JAN 07, 1988 |
| AB         |             | 30MG | N71809 001   |
|            |             |      | JAN 07, 1988 |
| > ADD > AB | SUPERPHARM  | 15MG | N71659 001   |
| > ADD >    |             |      | AUG 04, 1988 |
| > ADD > AB |             | 30MG | N71660 001   |
| > ADD >    |             |      | AUG 04, 1988 |

FOLIC ACID

TABLET; ORAL

FOLIC ACID

|      |             |       |               |
|------|-------------|-------|---------------|
| /66/ | /BARR LABS/ | /1MG/ | /N89177/001/  |
|      |             |       | /JAN/08/1986/ |
|      | 3 BARR LABS | 1MG   | N89177 001    |
|      |             |       | JAN 08, 1986  |

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

|      |                 |           |               |
|------|-----------------|-----------|---------------|
| /66/ | /PARKE/DAVIS/   | /10MG/ML/ | /N18420/001/  |
|      |                 |           | /FEB/26/1982/ |
| AP   | WARNER CHILCOTT | 10MG/ML   | N18420 001    |
|      |                 |           | FEB 26, 1982  |

FUROSEMIDE

TABLET; ORAL

FUROSEMIDE

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

GADOPENTETATE DIMESGLUMINE

INJECTABLE; INJECTION

MAGNEVIST

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

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

GALLIUM CITRATE GA 67

|                |           |              |
|----------------|-----------|--------------|
| /MEDI/PHYSICS/ | /1MCI/ML/ | /N17700/001/ |
| 3 MEDI PHYSICS | 1MCI/ML   | N17700 001   |

GENTAMICIN SULFATE; PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

PRED-G

|                 |                    |              |
|-----------------|--------------------|--------------|
| ALLERGAN PHARMS | EQ 0.3% BASE; 1/2M | N50586 001   |
|                 |                    | JUN 10, 1988 |

GLYCOPYRROLATE

INJECTABLE; INJECTION

GLYCOPYRROLATE

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

HALOPERIDOL

TABLET; ORAL

HALDOL SOLUTAB

|                 |       |              |
|-----------------|-------|--------------|
| /3/MCNEIL/LABS/ | /1MG/ | /N17079/001/ |
| 3 MCNEIL PHARM  | 1MG   | N17079 001   |

HALOPERIDOL

## TABLET; ORAL

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

|      |                      |                  |              |
|------|----------------------|------------------|--------------|
| /66/ | /MCNEIL/LABS/        | /EQ 2MG BASE/ML/ | /N15022/001/ |
| AA   | MCNEIL PHARM         | EQ 2MG BASE/ML   | N15922 001   |
| AA   | HALOPERIDOL INTENSOL | EQ 2MG BASE/MLM  | N72045 001   |
|      | ROXANE LABS          |                  | APR 12, 1988 |

## INJECTABLE; INJECTION

HALOPERIDOL

|    |        |                 |              |
|----|--------|-----------------|--------------|
| AP | LEHMAN | EQ 5MG BASE/MLM | N70713 001   |
|    |        |                 | MAY 17, 1988 |
| AP |        | EQ 5MG BASE/MLM | N70714 001   |
|    |        |                 | MAY 17, 1988 |
| AP |        | EQ 5MG BASE/MLM | N70744 001   |
|    |        |                 | MAY 17, 1988 |

HEPARIN SODIUM

## INJECTABLE; INJECTION

HEPARIN LOCK FLUEN

|      |               |                |              |
|------|---------------|----------------|--------------|
| /66/ | /ABBOTT/LABS/ | /100 UNITS/ML/ | /N05264/010/ |
|      | 3 ABBOTT LABS | 100 UNITS/ML   | N05264 010   |

HEPARIN LOCK FLUEN IN PLASTIC CONTAINER

|    |             |              |              |
|----|-------------|--------------|--------------|
| AP | ABBOTT LABS | 10 UNITS/ML  | N05264 015   |
|    |             |              | MAY 21, 1985 |
| AP |             | 100 UNITS/ML | N05264 016   |
|    |             |              | MAY 21, 1985 |

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

|      |               |                      |              |
|------|---------------|----------------------|--------------|
| /66/ | /ABBOTT/LABS/ | /10,000 UNITS/100ML/ | /N19339/003/ |
|      | 3 ABBOTT LABS | 10,000 UNITS/100ML   | N19339 003   |
|      |               |                      | MAR 27, 1985 |

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

|      |                 |                   |              |
|------|-----------------|-------------------|--------------|
| AP   | BAXTER          | 200 UNITS/100ML   | N18609 001   |
|      |                 |                   | APR 28, 1982 |
| /66/ | /TRAVENOL/LABS/ | /200 UNITS/100ML/ | /N18609/001/ |
|      |                 |                   | APR 28, 1982 |

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

|      |               |                     |              |
|------|---------------|---------------------|--------------|
| /66/ | /ABBOTT/LABS/ | /5,000 UNITS/100ML/ | /N19339/001/ |
|      | 3 ABBOTT LABS | 5,000 UNITS/100ML   | N19339 001   |
|      |               |                     | MAR 27, 1985 |

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

|      |                 |                   |              |
|------|-----------------|-------------------|--------------|
| AP   | BAXTER          | 200 UNITS/100ML   | N18609 002   |
|      |                 |                   | APR 28, 1982 |
| /66/ | /TRAVENOL/LABS/ | /200 UNITS/100ML/ | /N18609/002/ |
|      |                 |                   | APR 28, 1982 |

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

|      |               |                      |              |
|------|---------------|----------------------|--------------|
| /66/ | /ABBOTT/LABS/ | /5,000 UNITS/100ML/  | /N19339/004/ |
|      |               |                      | MAR 27, 1985 |
| /66/ | /ABBOTT/LABS/ | /10,000 UNITS/100ML/ | /N19339/002/ |
|      |               |                      | MAR 27, 1985 |

HEPARIN SODIUM 5,000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

|   |             |                    |              |
|---|-------------|--------------------|--------------|
| 3 | ABBOTT LABS | 5,000 UNITS/100ML  | N19339 004   |
|   |             |                    | MAR 27, 1985 |
| 3 |             | 10,000 UNITS/100ML | N19339 002   |
|   |             |                    | MAR 27, 1985 |

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

|      |                 |                   |              |
|------|-----------------|-------------------|--------------|
| AP   | BAXTER          | 500 UNITS/100ML   | N18609 003   |
|      |                 |                   | APR 28, 1982 |
| /66/ | /TRAVENOL/LABS/ | /500 UNITS/100ML/ | /N18609/003/ |
|      |                 |                   | APR 28, 1982 |

HEPARIN SODIUMINJECTABLE; INJECTION

|         |                                    |                   |                |
|---------|------------------------------------|-------------------|----------------|
| > DLT > | /LIDAZEN SODIUM PRESERVATIVE FREE/ |                   | /N00552/011/   |
| > DLT > | /62/ /ORGANON/                     | /1.000 UNITS/ML/  | /APR/11./1986/ |
| > DLT > |                                    |                   | /N00552/012/   |
| > DLT > | /62/                               | /5.000 UNITS/ML/  | /APR/11./1986/ |
| > DLT > |                                    |                   | /N00552/013/   |
| > DLT > | /62/                               | /10.000 UNITS/ML/ | /APR/11./1986/ |
| > DLT > |                                    |                   |                |
| > ADD > | 3 ORGANON                          | 1,000 UNITS/ML    | N00552 011     |
| > ADD > |                                    |                   | APR 11, 1986   |
| > ADD > | 3                                  | 5,000 UNITS/ML    | N00552 012     |
| > ADD > |                                    |                   | APR 11, 1986   |
| > ADD > | 3                                  | 10,000 UNITS/ML   | N00552 013     |
| > ADD > |                                    |                   | APR 11, 1986   |

HYDRALAZINE HYDROCHLORIDETABLET; ORAL

|      |                        |        |                |
|------|------------------------|--------|----------------|
|      | <u>HYDRALAZINE HCL</u> |        |                |
| /66/ | /PUREPAC/PHARM/        | /50MG/ | /N88178/001/   |
|      |                        |        | /AUG/15./1983/ |
|      | 3 PUREPAC PHARM        | 50MG   | N88178 001     |
|      |                        |        | AUG 15, 1983   |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDECAPSULE; ORAL

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINETABLET; ORAL

|      |                                                           |                   |                |
|------|-----------------------------------------------------------|-------------------|----------------|
|      | <u>RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE</u> |                   |                |
| /67/ | /REID/ROWELL/                                             | /25MG;15MG;0.1MG/ | /N87210/001/   |
| BP   | REID ROWELL                                               | 25MG;15MG;0.1MG   | N88376 001     |
|      |                                                           |                   | OCT 28, 1983   |
|      | 3                                                         | 25MG;15MG;0.1MG   | N87210 001     |
| /3/  |                                                           | /25MG;15MG;0.1MG/ | /N88376/001/   |
|      |                                                           |                   | /OCT/28./1983/ |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINETABLET; ORAL

|         |                                                       |                   |                |
|---------|-------------------------------------------------------|-------------------|----------------|
| > DLT > | /RESERPINE, HYDROCHLOROTHIAZIDE, AND HYDRALAZINE/HCL/ |                   |                |
| > DLT > | /67/ /LEDERLE/LABS/                                   | /25MG;15MG;0.1MG/ | /N87789/001/   |
| > DLT > |                                                       |                   | /MAY/13./1982/ |
| > ADD > | 3 LEDERLE LABS                                        | 25MG;15MG;0.1MG   | N87709 001     |
| > ADD > |                                                       |                   | MAY 13, 1982   |

HYDROCHLOROTHIAZIDESOLUTION; ORAL

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

TABLET; ORAL

|      |                            |        |              |
|------|----------------------------|--------|--------------|
|      | <u>HYDROCHLOROTHIAZIDE</u> |        |              |
| /68/ | /BANMAX/PHARMS/            | /25MG/ | /N86369/001/ |
| /68/ |                            | /50MG/ | /N83554/001/ |
|      | 3 BANMAX PHARMS            | 25MG   | N86369 001   |
|      | 3                          | 50MG   | N83554 001   |

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDETABLET; ORAL

|      |                     |              |                |
|------|---------------------|--------------|----------------|
|      | <u>NORMOZIDE</u>    |              |                |
|      | /SCHERING/          | /25MG;400MG/ | /N19046/004/   |
|      |                     |              | /APR/06./1987/ |
|      | 3 SCHERING          | 25MG;400MG   | N19046 004     |
|      |                     |              | APR 06, 1987   |
|      | <u>TRANDATE HCT</u> |              |                |
| AB   | GLAXO               | 25MG;100MG   | N19174 001     |
|      |                     |              | APR 10, 1987   |
| AB   |                     | 25MG;200MG   | N19174 002     |
|      |                     |              | APR 10, 1987   |
| AB   |                     | 25MG;300MG   | N19174 003     |
|      |                     |              | APR 10, 1987   |
| AB   |                     | 25MG;400MG   | N19174 004     |
|      |                     |              | APR 10, 1987   |
|      | <u>TRANDATE HCT</u> |              |                |
| /69/ | /GLAXO/             | /25MG;100MG/ | /N19174/001/   |
|      |                     |              | /APR/10./1987/ |
| /69/ |                     | /25MG;200MG/ | /N19174/002/   |
|      |                     |              | /APR/10./1987/ |
| /69/ |                     | /25MG;300MG/ | /N19174/003/   |
|      |                     |              | /APR/10./1987/ |
| /69/ |                     | /25MG;400MG/ | /N19174/004/   |
|      |                     |              | /APR/10./1987/ |

HYDROCHLOROTHIAZIDE; METHYLDOPA

## TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

|         |                 |              |
|---------|-----------------|--------------|
| AB      | NOVOPHARM       | 15MG;250MG   |
| AB      |                 | 25MG;250MG   |
| AB      |                 | 30MG;500MG   |
| AB      |                 | 50MG;500MG   |
| /AB/    | /PUREPAC/PHARM/ | /50MG;500MG/ |
|         | 3 PUREPAC PHARM | 50MG;500MG   |
| > ADD > | AB              | WATSON LABS  |
| > ADD > |                 | 15MG;250MG   |
| > ADD > | AB              | 25MG;250MG   |
| > ADD > | AB              | 30MG;500MG   |
| > ADD > | AB              | 50MG;500MG   |
| > ADD > | AB              | ZENITH LABS  |
|         |                 | 15MG;250MG   |
| AB      |                 | 25MG;250MG   |
| AB      |                 | 30MG;500MG   |
| AB      |                 | 50MG;500MG   |

N71819 001  
APR 08, 1988  
N71820 001  
APR 08, 1988  
N71821 001  
APR 08, 1988  
N71822 001  
APR 08, 1988  
/N70689/001/  
/APR/24/1986/  
N70689 001  
APR 24, 1986  
N71920 001  
AUG 29, 1988  
N71921 001  
AUG 29, 1988  
N71922 001  
AUG 29, 1988  
N71923 001  
AUG 29, 1988  
N71458 001  
MAR 08, 1988  
N71459 001  
MAR 08, 1988  
N71460 001  
MAR 08, 1988  
N71461 001  
MAR 08, 1988

HYDROCHLOROTHIAZIDE; PINDOLOL

## TABLET; ORAL

PINDOLOL AND HYDROCHLOROTHIAZIDE

3 SANDOZ PHARMS

/25MG;5MG/

/25MG;10MG/

25MG;10MG

/N18872/001/  
/JUL/22/1987/  
N18872 001  
JUL 22, 1987  
/N18872/002/  
/JUL/22/1987/  
N18872 002  
JUL 22, 1987

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

## TABLET; ORAL

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

|    |                 |           |
|----|-----------------|-----------|
| AB | SIDMAK LABS     | 25MG;40MG |
| AB |                 | 25MG;80MG |
| AB | WARNER CHILCOTT | 25MG;40MG |
| AB |                 | 25MG;80MG |

N72042 001  
MAR 14, 1988  
N72043 001  
MAR 14, 1988  
N71771 001  
JAN 26, 1988  
N71772 001  
JAN 26, 1988

HYDROCHLOROTHIAZIDE; RESERPINE

## TABLET; ORAL

HYDROCHLOROTHIAZIDE W/ RESERPINE

|         |                                   |                |              |
|---------|-----------------------------------|----------------|--------------|
| > DLT > | /3/0003/PHARMS/                   | /25MG;0.125MG/ | /N85421/001/ |
| > ADD > | 3 PHARMAFAIR                      | 25MG;0.125MG   | N85421 001   |
|         | RESERPINE AND HYDROCHLOROTHIAZIDE |                |              |
| /BP/    | /BARR/LABS/                       | /25MG;0.125MG/ | /N84580/001/ |
| /BP/    |                                   | /50MG;0.125MG/ | /N84579/001/ |
|         | 3 BARR LABS                       | 25MG;0.125MG   | N84580 001   |
|         | 3                                 | 50MG;0.125MG   | N84579 001   |

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

## TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

|         |      |                |             |              |
|---------|------|----------------|-------------|--------------|
| > DLT > | /AB/ | /LEDERLE/LABS/ | /25MG;25MG/ | /N87511/001/ |
| > ADD > |      | 3 LEDERLE LABS | 25MG;25MG   | N87511 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

|    |           |           |
|----|-----------|-----------|
| AB | PAR PHARM | 50MG;75MG |
|----|-----------|-----------|

JAN 15, 1988  
N72337 001  
MAY 11, 1988

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AT QUANTUM PHARMS 50MG;75MG N71980 001  
APR 17, 1988 : FEB 01, 1988

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

AT NASKA PHARMA 12M N89706 001  
MAR 10, 1988  
AT 2.52M N89682 001  
MAR 10, 1988  
AT NMC LABS 12 N87795 001  
MAY 03, 1983

HYDROGEN

AT SYOSSET LABS 12M N87427 001  
APR 04, 1988

/AT/ /NMC/ /LABS/ /12/ /N87795/001/ > DLT > /66/ /BOLAR/PHARM/ /50MG/ /N88031/001/ > DLT > /APR/06/1983/ > ADD > 3 BOLAR PHARM 50MG N88031 001 > ADD > APR 06, 1983

LOTION; TOPICAL

BETA-HC

AT BETA DERM 12M N89495 001  
JAN 25, 1988

HYDROCORTISONE

AT NASKA PHARMA 12M N89705 001  
APR 25, 1988

OINTMENT; TOPICAL

HC (HYDROCORTISONE)

3/C&M/PHARMA/

AT C&M PHARMA 12 N88481/001/ > DLT > /N88481/002/ > ADD > 3 ALTANA 25MG/ML N87273 001 > ADD > 3 50MG/ML N87273 002

HYDROCORTISONE

AT NASKA PHARMA 12M N89704 001  
MAR 10, 1988

TABLET; ORAL

HYDROCORTISONE

/BP/ /BARR/LABS/ /20MG/ /N83999/001/ > DLT > /N83999/001/ > ADD > 3 BARR LABS 20MG N83999 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT STERIS LABS 12;EQ 3.5MG BASE/ML; 10,000 UNITS/ML N62874 001  
MAY 11, 1988

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

AT THAMES PHARMA 12M N89472 001  
JUN 13, 1988

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL

SPRFOAM

AT REED & CARNICK 12;12 N86457 001  
AT HYDROCORTISONE ACETATE 12 AND PRAMOXINE HCL 12 N89440 001  
COPLEY PHARM 12;12M MAY 17, 1988

HYDROFLUMETHIAZIDE

TABLET; ORAL

HYDROFLUMETHIAZIDE

> DLT > /66/ /BOLAR/PHARM/ /50MG/ /N88031/001/ > DLT > /APR/06/1983/ > ADD > 3 BOLAR PHARM 50MG N88031 001 > ADD > APR 06, 1983

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

/AP/ /ALTANA/ /25MG/ML/ /N87273/001/ > DLT > /APR/20/1982/ > ADD > 3 ALTANA 25MG/ML N87273 001 > ADD > 3 50MG/ML N87273 002

3 ALTANA

3

25MG/ML

50MG/ML

SYRUP; ORAL

HYDROXYZINE HCL

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

HYDROXYZINE HYDROCHLORIDE

## TABLET; ORAL

HYDROXYZINE HCL

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

IBUPROFEN

## TABLET; ORAL

IBU-TAB

|         |    |                |       |              |
|---------|----|----------------|-------|--------------|
| > ADD > | AB | ALRA LABS      | 400MG | N71058 001   |
| > ADD > |    |                |       | AUG 11, 1988 |
| > ADD > | AB |                | 600MG | N71059 001   |
| > ADD > |    |                |       | AUG 11, 1988 |
| > ADD > | AB |                | 800MG | N71965 001   |
| > ADD > |    |                |       | AUG 11, 1988 |
|         | AB | HALSEY DRUG    | 800MG | N72137 001   |
|         |    |                |       | FEB 05, 1988 |
|         | 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 PHLTNS | 800MG | N72300 001   |
|         |    |                |       | JUL 01, 1988 |
|         | AB | PUREPAC PHARM  | 800MG | N71964 001   |
|         |    |                |       | FEB 01, 1988 |

IMIPRAMINE HYDROCHLORIDE

## TABLET; ORAL

IMIPRAMINE

|      |                 |        |              |
|------|-----------------|--------|--------------|
| /66/ | /BANMAX/PHARMS/ | /10MG/ | /N83827/001/ |
| /66/ |                 | /25MG/ | /N83827/002/ |
| /66/ |                 | /50MG/ | /N83827/003/ |
|      | 3 BANMAX PHARMS | 10MG   | N83827 001   |
|      | 3               | 25MG   | N83827 002   |
|      | 3               | 50MG   | N83827 003   |

INDIUM IN-111 OXYQUINOLINE

/INJECTABLE/ INJECTION/  
/INDIUM/IN-111/OXYQUINOLINE/  
/AMERSHAM/ /N/A/

/N19044/001/  
/DEC/23/1985/

INJECTABLE; INTRATHECAL  
INDIUM IN-111 OXYQUINOLINE  
AMERSHAM INCI/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  | 25MG | N71711 001   |
|    |           |      | JUL 05, 1988 |
| AB |           | 50MG | N71712 001   |
|    |           |      | JUL 05, 1988 |

INSULIN PORK

## INJECTABLE; INJECTION

/ILETIN/  
/LILLY/

/500/UNITS/ML/

/N17931/001/

ILETIN I  
LILLY

500 UNITS/ML

N17931 001

IONEXOL

## INJECTABLE; INJECTION

IONEXOL 100

|     |               |         |
|-----|---------------|---------|
| AP  | STERLING DRUG | 30.8%   |
|     |               |         |
| /3/ |               | /30.8%/ |

N18956 001  
DEC 26, 1985  
/N18956/001/  
/DEC/26/1985/

IOTHALAMATE MEGLIUMINE

SOLUTION; INTRAVESICAL  
CYSTO-CONRAY II  
MALLINCKRODT

17.2%

N17057 002

IOTHALAMATE MEGLUMINE

> ADD > SOLUTION; INTRAVESICAL, URETERAL  
 > ADD > CYSTO-CONRAY  
 > ADD > MALLINCKRODT 43% N17057 001  
 > DLT > /SOLUTION; URETERAL/  
 > DLT > /CYSTO-CONRAY/  
 > DLT > /MALLINCKRODT/ /43%/ /N17057/001/  
 > DLT > /CYSTO-CONRAY/ /11/ /N17057/001/  
 > DLT > /MALLINCKRODT/ /11.4%/ /N17057/001/

IRON DEXTRAN

INJECTABLE; INJECTION  
 /AB/ /PROFERON/  
 /AB/ /FISONS/ /EQ 50MG IRON/ML/ /N17807/001/  
 EQ 50MG IRON/ML N17807 001

ISONIAZID

TABLET; ORAL  
 LANTAZID  
 AA LANNETT 300MG N89776 001  
 JUN 13, 1988

ISOSORBIDE DINITRATE

CAPSULE, CONTROLLED RELEASE; ORAL  
 ISORDIL  
 NYETH AYERST LABS 40MG N12882 002  
 JUL 29, 1988

## TABLET; ORAL

ISORDIL  
 AB NYETH AYERST LABS 5MG N12093 007  
 JUL 29, 1988  
 AB 10MG N12093 002  
 JUL 29, 1988  
 AB 20MG N12093 006  
 JUL 29, 1988  
 AB 30MG N12093 005  
 JUL 29, 1988  
 40MG N12093 001  
 JUL 29, 1988  
 N87564 001  
 SEP 18, 1986  
ISOSORBIDE DINITRATE  
 AB BARR LABS 30MG

ISOSORBIDE DINITRATE

## TABLET; ORAL

ISOSORBIDE DINITRATE  
 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

ISORDIL  
 AB NYETH AYERST LABS 2.5MG N12940 004  
 JUL 29, 1988  
 AB 5MG N12940 003  
 JUL 29, 1988  
 AB 10MG N12940 005  
 JUL 29, 1988

ISOSORBIDE DINITRATE  
 AB BARR LABS 10MG N87545 001  
 SEP 18, 1986  
 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

## TABLET, CONTROLLED RELEASE; ORAL

ISORDIL  
 NYETH AYERST LABS 40MG N12882 001  
 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 HYDROCHLORIDEINJECTABLE; INJECTION

|                     |                          |              |
|---------------------|--------------------------|--------------|
| <u>KETAMINE HCL</u> |                          |              |
| AP QUAD PHARMS      | <u>EQ 10MG BASE/MLM</u>  | N71949 001   |
|                     |                          | APR 11, 1988 |
| AP                  | <u>EQ 50MG BASE/MLM</u>  | N71950 001   |
|                     |                          | APR 11, 1988 |
| AP                  | <u>EQ 100MG BASE/MLM</u> | N71951 001   |
|                     |                          | APR 11, 1988 |

LACTULOSESYRUP; ORAL

|                           |                   |              |
|---------------------------|-------------------|--------------|
| <u>CHRONULAC</u>          |                   |              |
| AA MERRELL DOW            | <u>10GM/15ML</u>  | N17884 001   |
| <u>CONSTILAC</u>          |                   |              |
| AA ALRA LABS              | <u>10GM/15MLM</u> | N71054 001   |
|                           |                   | JUL 26, 1988 |
| > ADD > <u>CONSTULOSE</u> |                   |              |
| > ADD > AA BARRE NATL     | <u>10GM/15MLM</u> | N70288 001   |
| > ADD >                   |                   | AUG 15, 1988 |

|                       |                  |             |
|-----------------------|------------------|-------------|
| /66/ <u>CEPHULAC</u>  |                  |             |
| /66/ MERRELL/DOW/     | <u>10GM/15ML</u> | N17657/001/ |
| /66/ <u>LACTULOSE</u> |                  |             |
| /66/ ROTANE/LABS/     | <u>10GM/15ML</u> | N17946/001/ |

SYRUP; ORAL, RECTAL

|                        |                   |              |
|------------------------|-------------------|--------------|
| <u>CEPHULAC</u>        |                   |              |
| AA MERRELL DOW         | <u>10GM/15ML</u>  | N17657 001   |
| <u>CHOLAC</u>          |                   |              |
| AA ALRA LABS           | <u>10GM/15MLM</u> | N71331 001   |
|                        |                   | JUL 26, 1988 |
| > ADD > <u>ENULOSE</u> |                   |              |
| > ADD > AA BARRE NATL  | <u>10GM/15MLM</u> | N71548 001   |
| > ADD >                |                   | AUG 15, 1988 |
| <u>LACTULOSE</u>       |                   |              |
| AA KALI DUPHAR         | <u>10GM/15ML</u>  | N17906 001   |

LEUCOVORIN CALCIUMINJECTABLE; INJECTION

|                           |                            |              |
|---------------------------|----------------------------|--------------|
| <u>LEUCOVORIN CALCIUM</u> |                            |              |
| AP BEN VENUE LABS         | <u>EQ 100MG BASE/VIALM</u> | N89717 001   |
|                           |                            | MAR 28, 1988 |

LEUCOVORIN CALCIUMINJECTABLE; INJECTION

|                           |                            |              |
|---------------------------|----------------------------|--------------|
| <u>LEUCOVORIN CALCIUM</u> |                            |              |
| AP INTL PHARM             | <u>EQ 3MG BASE/MLM</u>     | N89352 001   |
|                           |                            | JUN 01, 1988 |
| AP                        | <u>EQ 50MG BASE/VIALM</u>  | N89353 001   |
|                           |                            | JUN 01, 1988 |
| AP LEDERLE LABS           | <u>EQ 3MG BASE/ML</u>      | N08107 001   |
| AP                        | <u>EQ 100MG BASE/VIALM</u> | N08107 004   |
|                           |                            | MAY 23, 1988 |
| AP QUAD PHARMS            | <u>EQ 100MG BASE/VIAL</u>  | N89636 001   |
|                           |                            | DEC 24, 1987 |

LEVODOPACAPSULE; ORAL

|                        |              |             |
|------------------------|--------------|-------------|
| <u>LEVODOPA</u>        |              |             |
| /66/ <u>ICN PHARMS</u> | <u>100MG</u> | N16948/001/ |
| /66/                   | <u>250MG</u> | N16948/001/ |
| /66/                   | <u>500MG</u> | N16948/002/ |
| 3 ICN PHARMS           | 100MG        | N16948 003  |
| 3                      | 250MG        | N16948 001  |
| 3                      | 500MG        | N16948 002  |

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDEINJECTABLE; INJECTION

|                                    |                       |              |
|------------------------------------|-----------------------|--------------|
| <u>POLOCATINE H/ LEVONORDEFRIN</u> |                       |              |
| AP ASTRA PHARM PRODS               | <u>0.05MG/ML; 2%M</u> | N89517 001   |
|                                    |                       | APR 14, 1988 |

LIDOCAINE HYDROCHLORIDEINJECTABLE; INJECTION

|                      |             |              |
|----------------------|-------------|--------------|
| <u>LIDOCAINE HCL</u> |             |              |
| AP ABBOTT LABS       | <u>20%M</u> | N89362 001   |
|                      |             | MAY 25, 1988 |
| /66/ <u>LEMON</u>    | <u>1%</u>   | N83627/001/  |
| /66/                 | <u>2%</u>   | N83627/002/  |
| 3 LEMON              | 1%          | N83627 001   |
| 3                    | 2%          | N83627 002   |

LINCOMYCIN HYDROCHLORIDEINJECTABLE; INJECTION

|                   |                         |            |
|-------------------|-------------------------|------------|
| <u>LINCOMYCIN</u> |                         |            |
| AP UPJOHN         | <u>EQ 300MG BASE/ML</u> | N50317 001 |

LINCOMYCIN HYDROCHLORIDE

## INJECTABLE; INJECTION

LINCOMYCIN HCL

|    |             |                         |                            |
|----|-------------|-------------------------|----------------------------|
| AP | QUAD PHARMS | <u>EQ 300MG BASE/ML</u> | N62784 001<br>MAR 14, 1988 |
|----|-------------|-------------------------|----------------------------|

LISINAPRIL

## TABLET; ORAL

PRINIVIL

|    |               |             |                            |
|----|---------------|-------------|----------------------------|
| AB | MS&D RES LABS | <u>5MG</u>  | N19558 001<br>DEC 29, 1987 |
| AB |               | <u>10MG</u> | N19558 002<br>DEC 29, 1987 |
| AB |               | <u>20MG</u> | N19558 003<br>DEC 29, 1987 |

ZESTRIL

|    |               |             |                            |
|----|---------------|-------------|----------------------------|
| AB | IMPERIAL CHEM | <u>5MG</u>  | N19777 001<br>MAY 19, 1988 |
| AB |               | <u>10MG</u> | N19777 002<br>MAY 19, 1988 |
| AB |               | <u>20MG</u> | N19777 003<br>MAY 19, 1988 |

LOPERAMIDE HYDROCHLORIDE/SOLUTION; ORAL/  
/INJECTION/JANSSEN PHARMA

|  |  |                |  |
|--|--|----------------|--|
|  |  | <u>1MG/5ML</u> |  |
|--|--|----------------|--|

|                  |                |  |
|------------------|----------------|--|
| 2 JANSSEN PHARMA | <u>1MG/5ML</u> |  |
|------------------|----------------|--|

|                     |
|---------------------|
| <u>N19037 001</u>   |
| <u>1ML/5ML/1984</u> |
| N19037 001          |
| JUL 31, 1984        |

LORAZEPAM

## TABLET; ORAL

LORAZEPAM

|    |                 |              |                            |
|----|-----------------|--------------|----------------------------|
| AB | CORD LABS       | <u>0.5MG</u> | N71193 001<br>APR 15, 1988 |
| AB |                 | <u>1MG</u>   | N71194 001<br>APR 15, 1988 |
| AB |                 | <u>2MG</u>   | N71195 001<br>APR 15, 1988 |
| AB | WARNER CHILCOTT | <u>1MG</u>   | N71038 001<br>JAN 12, 1988 |
| AB |                 | <u>2MG</u>   | N71039 001<br>JAN 12, 1988 |

LOXAPINE SUCCINATE

## CAPSULE; ORAL

LOXAPINE SUCCINATE

|    |             |                     |                            |
|----|-------------|---------------------|----------------------------|
| AB | WATSON LABS | <u>EQ 5MG BASE</u>  | N72204 001<br>JUN 15, 1988 |
| AB |             | <u>EQ 10MG BASE</u> | N72205 001<br>JUN 15, 1988 |
| AB |             | <u>EQ 25MG BASE</u> | N72206 001<br>JUN 15, 1988 |
| AB |             | <u>EQ 50MG BASE</u> | N72062 001<br>JUN 15, 1988 |

LOMETANE

## LEDERLE LABS

|    |  |                     |            |
|----|--|---------------------|------------|
| AB |  | <u>EQ 5MG BASE</u>  | N17525 001 |
| AB |  | <u>EQ 10MG BASE</u> | N17525 002 |
| AB |  | <u>EQ 25MG BASE</u> | N17525 003 |
| AB |  | <u>EQ 50MG BASE</u> | N17525 004 |

MAPROTILINE HYDROCHLORIDE

## TABLET; ORAL

MAPROTILINE HCL

|    |             |             |                            |
|----|-------------|-------------|----------------------------|
| AB | AM THERPTCS | <u>25MG</u> | N72129 001<br>JAN 14, 1988 |
| AB |             | <u>50MG</u> | N72130 001<br>JAN 14, 1988 |
| AB |             | <u>75MG</u> | N72131 001<br>JAN 14, 1988 |
| AB | WATSON LABS | <u>25MG</u> | N72162 001<br>JUN 01, 1988 |
| AB |             | <u>50MG</u> | N72163 001<br>JUN 01, 1988 |
| AB |             | <u>75MG</u> | N72164 001<br>JUN 01, 1988 |

MECLIZINE HYDROCHLORIDE

## TABLET; ORAL

ANTIEMET

## ROERIG

|    |  |             |                            |
|----|--|-------------|----------------------------|
| AA |  | <u>50MG</u> | N10721 001<br>JAN 20, 1982 |
|----|--|-------------|----------------------------|

MECLIZINE HCL

## PAR PHARM

|    |  |             |                            |
|----|--|-------------|----------------------------|
| AA |  | <u>50MG</u> | N89674 001<br>MAR 31, 1988 |
|----|--|-------------|----------------------------|

MECLOFENAMATE SODIUM

CAPSULE; ORAL  
MECLOFENAMATE SODIUM  
 AB PAR PHARM EQ 50MG BASEM N72077 001  
 MAR 10, 1988  
 AB EQ 100MG BASEM N72078 001  
 MAR 10, 1988  
 AB PHARM BASICS EQ 50MG BASEM N71007 001  
 MAR 25, 1988  
 AB EQ 100MG BASEM N71008 001  
 MAR 25, 1988  
 AB VITARINE EQ 50MG BASEM N71710 001  
 JUN 15, 1988  
 AB EQ 100MG BASEM N71684 001  
 JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL  
MEFENAMIC ACID  
 AB VITARINE 250MG N72179 001  
 APR 21, 1988  
 AB PONTREL PARKE DAVIS PR 250MG N15034 003

MEGESTROL ACETATE

TABLET; ORAL  
MEGESTROL ACETATE  
 > ADD > AB PAR PHARM 20MG N72422 001  
 > ADD > AUG 08, 1988  
 > ADD > AB 40MG N72423 001  
 > ADD > AUG 08, 1988

MEPENZOLATE BROMIDE

> DLT > /SOLUTION; ORAL/  
 > DLT > /CANTIL/  
 > DLT > /MERRELL/DON/  
 > ADD > 3 MERRELL DON 25MG/5ML N10679 004  
 N10679 004

MEPROBAMATE

TABLET; ORAL  
MEPROBAMATE  
 /66/ /MALLARD/ 400MG N15072 002  
 3 MALLARD

MEPROBAMATE

TABLET; ORAL  
MEPROBAMATE  
 /66/ /PHARM BASICS/ 400MG N87825 001  
 /66/ /400MG/ N87826 001  
 3 PHARM BASICS 200MG N87825 001  
 3 400MG N87826 001  
 MAR 18, 1982  
 MAR 18, 1982

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21  
NORETHIN 1/50M-21  
 AB SEARLE PHARMS 0.05MG; 1MG N71539 001  
 APR 12, 1988  
 AB NORETHINDRONE AND MESTRANOL  
 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  
 AB NORETHINDRONE AND MESTRANOL  
 WATSON LABS 0.05MG; 1MG N70759 001  
 JUL 01, 1988

MESTRANOL; NORETHYNODREL

TABLET; ORAL-20  
ENOVED  
 /66/ /SEARLE/ 0.075MG; 5MG N10976 004  
 3 SEARLE 0.075MG; 5MG  
 /66/ /ENOVED-1/ 0.1MG; 2.5MG N10976 006  
 /66/ /SEARLE/ 0.1MG; 2.5MG  
 3 SEARLE

METAPROTERENOL SULFATE

SOLUTION; INHALATION  
ALUPENT  
 AN BOEHR INGEL 0.4% N18761 002  
 OCT 10, 1986  
 > ADD > AN DEY-209E  
 > ADD > DEY LABS 5% N70805 001  
 AUG 17, 1987

METAPROTERENOL SULFATE

## SOLUTION; INHALATION

> ADD >  
 > ADD > AN DEY LABS 0.42M  
 > ADD >  
 > ADD > AN 0.6%  
 > ADD >  
 > ADD > 0.332M  
 > ADD >  
 > ADD > 0.52M  
 > ADD >

METAPROTERENOL SULFATE

AN ARNOUR PHARM 0.42M  
 AN 0.62M  
 > DLT > /AN/ /DEY LABS/ /0.62/  
 > DLT >  
 > DLT > /AN/ /52/  
 > DLT >  
 AN MY K LABS 52M  
 AN PACO RES 0.42M  
 AN 0.62M

## TABLET; ORAL

ALUPENT

AB BOEHR INGEL 10MG  
 AB 20MG  
METAPROTERENOL SULFATE  
 AB AM THERPTCS 10MG  
 AB 20MG  
 AB PAR PHARM 10MG  
 AB 20MG  
 AB PHARM BASICS 10MG  
 AB 20MG

METHOCARBAMOL

## TABLET; ORAL

METHOCARBAMOL  
 /AA/ /BARR LABS/ /500MG/  
 3 BARR LABS 500MG

N71786 001  
 AUG 05, 1988  
 N70804 001  
 AUG 17, 1987  
 N71806 001  
 AUG 05, 1988  
 N71805 001  
 AUG 05, 1988

N71275 001  
 JUL 27, 1988  
 N71018 001  
 JUL 27, 1988  
 /N70804/001/  
 /AUG/17/1987/  
 /N70805/001/  
 /AUG/17/1987/  
 N72190 001  
 JUN 07, 1988  
 N71855 001  
 JUL 14, 1988  
 N71726 001  
 JUL 14, 1988

N15874 002  
 N15874 001  
 N72054 001  
 JUN 23, 1988  
 N72055 001  
 JUN 23, 1988  
 N72024 001  
 JUN 28, 1988  
 N72025 001  
 JUN 28, 1988  
 N71013 001  
 JAN 25, 1988  
 N71014 001  
 JAN 25, 1988

/N84488/001/  
 N84488 001

METHOTREXATE SODIUM

## INJECTABLE; INJECTION

METHOTREXATE

LEDERLE LABS EQ 1GM BASE/VIALM  
 N11719 009  
 APR 07, 1988  
METHOTREXATE SODIUM  
 AP PHARMACHEMIE EQ 25MG BASE/MLM  
 N89158 001  
 JUL 08, 1988

METHOXSALEN

## CAPSULE; ORAL

/OXSORALEN/  
 /BP/ /ELDER PHARMS/ /10MG/ /N89048/001/  
 8-HOP  
 ELDER PHARMS 10MG  
 N89048 001

METHYCLOTHIAZIDE

## TABLET; ORAL

METHYCLOTHIAZIDE  
 > ADD > AB CORD LABS 2.5MG  
 > ADD >  
 > ADD > AB 5MG  
 > ADD >  
 N89835 001  
 AUG 18, 1988  
 N89837 001  
 AUG 18, 1988

METHYLDOPA

## TABLET; ORAL

METHYLDOPA  
 AB CORD LABS 125MG  
 N71700 001  
 MAR 02, 1988  
 AB HALSEY DRUG 125MG  
 N71751 001  
 MAR 28, 1988  
 AB 250MG  
 N71752 001  
 MAR 28, 1988  
 AB 500MG  
 N71753 001  
 MAR 28, 1988  
 AB 125MG  
 N72126 001  
 JUL 07, 1988  
 AB 250MG  
 N72127 001  
 JUL 07, 1988  
 AB 500MG  
 N72128 001  
 JUL 07, 1988

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL

|    |                            |             |              |
|----|----------------------------|-------------|--------------|
| AB | <u>METHYLPHENIDATE HCL</u> | <u>20MG</u> | N89601 001   |
|    | MD PHARM                   |             | JUN 01, 1988 |
| AB | <u>RITALIN-SR</u>          | <u>20MG</u> | N18029 001   |
|    | CIBA PHARM                 |             | MAR 30, 1982 |

METHYLPREDNISOLONE

TABLET; ORAL

|    |                           |             |              |
|----|---------------------------|-------------|--------------|
| AB | <u>MEDROL</u>             | <u>24MG</u> | N11153 005   |
| AB | UPJOHN                    | <u>32MG</u> | N11153 006   |
| AB | <u>METHYLPREDNISOLONE</u> | <u>16MG</u> | N89207 001   |
|    | PAR PHARM                 |             | APR 25, 1988 |
| AB |                           | <u>24MG</u> | N89208 001   |
|    |                           |             | APR 25, 1988 |
| AB |                           | <u>32MG</u> | N89209 001   |
|    |                           |             | APR 25, 1988 |

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

|         |    |                           |                         |              |
|---------|----|---------------------------|-------------------------|--------------|
| > ADD > | AP | <u>METOCLOPRAMIDE HCL</u> | <u>EQ 10MG BASE/2ML</u> | N70892 001   |
| > ADD > |    | MAURRY BIOL               |                         | AUG 26, 1988 |

SYRUP; ORAL

|         |    |                           |                        |              |
|---------|----|---------------------------|------------------------|--------------|
| > ADD > | AA | <u>METOCLOPRAMIDE HCL</u> | <u>EQ 5MG BASE/5ML</u> | N71340 001   |
| > ADD > |    | BARRE NATL                |                        | AUG 18, 1988 |

TABLET; ORAL

|    |                           |                     |              |
|----|---------------------------|---------------------|--------------|
| AB | <u>CLOFRA</u>             | <u>EQ 5MG BASE</u>  | N72384 001   |
|    | QUANTUM PHARMCS           |                     | JUN 02, 1988 |
| AB | <u>METOCLOPRAMIDE HCL</u> | <u>EQ 10MG BASE</u> | N71250 001   |
|    | SIDMAK LABS               |                     | FEB 03, 1988 |
| AB | <u>REGLAN</u>             | <u>EQ 5MG BASE</u>  | N17854 002   |
|    | ROBINS                    |                     | MAY 05, 1987 |

METOCURINE IODIDE

INJECTABLE; INJECTION

|    |                          |               |              |
|----|--------------------------|---------------|--------------|
| AP | <u>METOCURINE IODIDE</u> | <u>2MG/ML</u> | N89443 001   |
|    | QUAD PHARMS              |               | JUN 01, 1988 |
| AP | <u>METURINE IODIDE</u>   | <u>2MG/ML</u> | N06632 003   |
|    | LILLY                    |               |              |

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION

|  |             |                   |              |
|--|-------------|-------------------|--------------|
|  | MEZLIN      | EQ 20GM BASE/VIAL | N50549 005   |
|  | MILES PHARM |                   | MAR 02, 1988 |
|  |             | EQ 20GM BASE/VIAL | N62372 004   |
|  |             |                   | MAR 02, 1988 |

MINOXIDIL

|         |                   |                 |              |
|---------|-------------------|-----------------|--------------|
| > ADD > | SOLUTION; TOPICAL |                 |              |
| > ADD > | ROGAINE           |                 |              |
| > ADD > | UPJOHN            | 2% <sup>m</sup> | N19501 001   |
| > ADD > |                   |                 | AUG 17, 1988 |

TABLET; ORAL

|    |                 |              |              |
|----|-----------------|--------------|--------------|
| AB | <u>MENODYL</u>  | <u>2.5MG</u> | N72153 001   |
|    | QUANTUM PHARMCS |              | JUL 13, 1988 |

NITOMYCIN

INJECTABLE; INJECTION

|  |               |           |              |
|--|---------------|-----------|--------------|
|  | MUTAMYCIN     | 40MG/VIAL | N62336 003   |
|  | BRISTOL MYERS |           | MAR 10, 1988 |

MORPHINE SULFATE

INJECTABLE; INJECTION

|    |                         |                 |              |
|----|-------------------------|-----------------|--------------|
| AP | <u>MORPHINE SULFATE</u> | <u>0.5MG/ML</u> | N71849 001   |
|    | ABBOTT LABS             |                 | MAY 11, 1988 |
| AP |                         | <u>1MG/ML</u>   | N71850 001   |
|    |                         |                 | MAY 11, 1988 |

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MORPHINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL  
MS CONTIN  
PURDUE FRDRK

60MG

N19516 002  
APR 08, 1988

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL  
NAFTIN  
HERBERT LABS

1%  
1/2

N19599 001  
FEB 29, 1988

NALIDIXIC ACID

TABLET; ORAL

NALIDIXIC ACID

AB DANDURY 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

AP

MARSAN PHARMS

0.4MG/ML

N71811 001  
JUL 19, 1988

AP

MARGAN

DUPONT CRI CARE

0.4MG/ML

N71083 001  
JUL 28, 1988

AP

1MG/ML

N71084 001  
JUL 28, 1988

AP

1MG/ML

N71311 001  
JUL 28, 1988

NITROFURANTOIN

> DLT >

/CAPSULE; ORAL/

> DLT >

/NITROFURANTOIN/

> DLT >

/BOLAR PHARM/

> ADD >

3 BOLAR PHARM

/50MG/

50MG

/100MG/

100MG

/N84326/001/

N84326 001

/N84326/002/

N84326 002

> DLT >

> ADD >

3

TABLET; ORAL

NITROFURANTOIN

/AB/

/BOLAR PHARM/

/100MG/

100MG

/N80447/001/

N80447 002

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

MACRODANTIN

AB

NORNICH 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

OINTMENT; TOPICAL

NITROGLYCERIN

ALTANA

2%  
2/2

N87355 001

JUL 08, 1988

NIZATIDINE

CAPSULE; ORAL

AXID

LILLY

150MG

N19508 001

APR 12, 1988

300MG

N19508 002

APR 12, 1988

NORTRIPTYLINE HYDROCHLORIDECAPSULE; 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 |

|         |      |           |        |                |
|---------|------|-----------|--------|----------------|
| > ADD > | AB   | BARR LABS | 15MG   | N71025 001     |
| > ADD > |      |           |        | AUG 10, 1987   |
| > ADD > | AB   |           | 30MG   | N71026 001     |
| > ADD > |      |           |        | AUG 10, 1987   |
| > DLT > | /BP/ |           | /15MG/ | /N71025/001/   |
| > DLT > |      |           |        | /AUG/10./1987/ |
| > DLT > | /BP/ |           | /30MG/ | /N71026/001/   |
| > DLT > |      |           |        | /AUG/10./1987/ |

|    |              |      |              |
|----|--------------|------|--------------|
| AB | CHELSEA LABS | 10MG | N71661 001   |
|    |              |      | MAR 02, 1988 |
| AB |              | 15MG | N71662 001   |
|    |              |      | MAR 02, 1988 |
| AB |              | 30MG | N71663 001   |
|    |              |      | MAR 02, 1988 |

OXAZEPAM

## CAPSULE; ORAL

OXAZEPAM

|      |              |        |                |
|------|--------------|--------|----------------|
| AB   | CORD LABS    | 10MG   | N71813 001     |
|      |              |        | APR 19, 1988   |
| AB   |              | 15MG   | N71756 001     |
|      |              |        | APR 19, 1988   |
| AB   |              | 30MG   | N71814 001     |
|      |              |        | APR 19, 1988   |
| /BP/ | MYLAN PHARMS | /10MG/ | /N71713/001/   |
| /BP/ |              | /15MG/ | /OCT/20./1987/ |
| /BP/ |              | /30MG/ | /N71714/001/   |
|      |              |        | /OCT/20./1987/ |
|      |              |        | /N71715/001/   |
|      |              |        | /OCT/20./1987/ |

## a MYLAN PHARMS

|  |      |              |
|--|------|--------------|
|  | 10MG | N71713 001   |
|  | 15MG | OCT 20, 1987 |
|  | 30MG | N71714 001   |
|  |      | OCT 20, 1987 |
|  |      | N71715 001   |
|  |      | OCT 20, 1987 |

## AB PUREPAC PHARM

|    |      |              |
|----|------|--------------|
|    | 10MG | N72251 001   |
| AB | 15MG | APR 14, 1988 |
|    |      | N72252 001   |
| AB | 30MG | APR 14, 1988 |
|    |      | N72253 001   |

## AB ZENITH LABS

|      |        |                |
|------|--------|----------------|
|      | 10MG   | APR 14, 1988   |
| AB   | 15MG   | N70943 001     |
|      |        | AUG 03, 1987   |
| AB   | 30MG   | N70944 001     |
|      |        | AUG 03, 1987   |
|      |        | N70945 001     |
|      |        | AUG 03, 1987   |
| /BP/ | /10MG/ | /N70943/001/   |
| /BP/ | /15MG/ | /AUG/03./1987/ |
| /BP/ | /30MG/ | /N70944/001/   |
|      |        | /AUG/03./1987/ |
|      |        | /N70945/001/   |
|      |        | /AUG/03./1987/ |

SERAX

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

OXAZEPAM

CAPSULE; ORAL  
ZANOPAM  
 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  
 AB OXYBUTYNIN CHLORIDE  
 PHARM BASICS 5MG N70746 001  
 MAR 10, 1988

OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL  
OXYTETRACYCLINE HCL  
 /AA/ /PUREPAC/PHARM/ /EQ 250MG BASE/ /N60634/001/  
 3 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

PANCURONIUM BROMIDE

INJECTABLE; INJECTION  
PAVULON  
 AP ORGANON 1MG/ML N17015 002  
 AP 2MG/ML N17015 001

PARAMETHADIONE

/CONCENTRATE//ORAL/  
 /PARADIONE/  
 /AA/ /ABBOTT/LABS/ /300MG/ML/ /N06800/002/

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

PENICILLAMINE

CAPSULE; ORAL  
 CUPRIMINE  
 MS&D 125MG N19853 002  
 > ADD > /125MG/ /N50376/002/  
 > DLT > 250MG N19853 001  
 > ADD > /250MG/ /N50376/001/  
 > DLT >

TABLET; ORAL  
 DEPEN 250  
 WALLACE LABS 250MG N19854 001  
 > ADD > /250MG/ /N50491/001/  
 > DLT >

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL  
PENICILLIN G POTASSIUM  
 /AA/ /PUREPAC/PHARM/ /400,000 UNITS/5ML/ /N61740/002/  
 3 PUREPAC PHARM 400,000 UNITS/5ML N61740 002

TABLET; ORAL  
PENICILLIN G POTASSIUM  
 /AA/ /PUREPAC/PHARM/ /250,000 UNITS/ /N61588/002/  
 /AA/ /PUREPAC/PHARM/ /400,000 UNITS/ /N61588/003/  
 3 PUREPAC PHARM 250,000 UNITS N61588 002  
 3 400,000 UNITS N61588 003

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

|      |                               |                     |              |
|------|-------------------------------|---------------------|--------------|
| /AA/ | <u>PENICILLIN V POTASSIUM</u> | /EQ 250MG BASE/5ML/ | /N61758/002/ |
| /AA/ | /PUREPAC/PHARM/               | /EQ 250MG BASE/5ML/ | /N61758/002/ |
|      | 3 PUREPAC PHARM               | EQ 250MG BASE/5ML   | N61758 002   |

TABLET; ORAL

|      |                               |                 |              |
|------|-------------------------------|-----------------|--------------|
| /AA/ | <u>PENICILLIN V POTASSIUM</u> | /EQ 250MG BASE/ | /N61571/002/ |
| /AA/ | /PUREPAC/PHARM/               | /EQ 500MG BASE/ | /N61571/003/ |
|      | 3 PUREPAC PHARM               | EQ 250MG BASE   | N61571 002   |
|      | 3                             | EQ 500MG BASE   | N61571 003   |

PERPHENAZINE

|               |           |              |  |
|---------------|-----------|--------------|--|
| /SYRUP;/ORAL/ |           |              |  |
| /TRILAFON/    |           |              |  |
| /SCHERING/    | /2MG/5ML/ | /N11294/002/ |  |
| 3 SCHERING    | 2MG/5ML   | N11294 002   |  |

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

|      |                                 |        |              |
|------|---------------------------------|--------|--------------|
| /AA/ | <u>PHENDIMETRAZINE TARTRATE</u> | /35MG/ | /N83644/001/ |
| /AA/ | /BARR/LABS/                     | /35MG/ | /N83644/001/ |
| /AA/ |                                 | /35MG/ | /N83686/001/ |
| /AA/ |                                 | /35MG/ | /N83687/001/ |
| /AA/ |                                 | /35MG/ | /N84831/001/ |
| /AA/ |                                 | /35MG/ | /N84834/001/ |
| /AA/ |                                 | /35MG/ | /N84835/001/ |
|      | 3 BARR LABS                     | 35MG   | N83644 001   |
|      | 3                               | 35MG   | N83684 001   |
|      | 3                               | 35MG   | N83686 001   |
|      | 3                               | 35MG   | N83687 001   |
|      | 3                               | 35MG   | N84831 001   |
|      | 3                               | 35MG   | N84834 001   |
|      | 3                               | 35MG   | N84835 001   |

PHENTERMINE RESIN COMPLEX

CAPSULE, CONTROLLED RELEASE; ORAL

|    |                             |                |              |
|----|-----------------------------|----------------|--------------|
| AB | <u>ZONAPRON-30</u>          | /EQ 30MG BASE/ | N11613 902   |
|    | PENNAULT                    | EQ 30MG BASE   |              |
| AB | <u>PHENTERMINE RESIN 30</u> |                | N89120 001   |
|    | QUANTUM PHARMCS             | EQ 30MG BASE   | FEB 04, 1988 |

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

|             |                   |                      |                |
|-------------|-------------------|----------------------|----------------|
| > DLT >     | /PHENERGAN/30/    |                      |                |
| > DLT >/AA/ | /WYETH/AT&T/LABS/ | /2MG/5ML/6.25MG/5ML/ | /N00604/003/   |
| > DLT >     |                   |                      | /APR/02./1984/ |

/PIPERACETAZINE//TABLET;/ORAL//GUIDE//DOM/PHARMS/

3 DOM PHARMS

/10MG/

10MG

/25MG/

25MG

/N13615/001/

N13615 001

/N13615/002/

N13615 002

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

SOLUTION; ORAL

OCL

/3/ABBOTT/LABS//65M/100ML;75MG/100ML;168MG/100ML;//146MG/100ML;//1.29GM/100ML/

/N19284/001/

/APR/30./1986/

ABBOTT LABS

65M/100ML;75MG/100ML;168MG/100ML;

146MG/100ML;

1.29GM/100ML

N19284 001

APR 30, 1986

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

POWDER FOR RECONSTITUTION; ORAL

|             |             |                                 |                |
|-------------|-------------|---------------------------------|----------------|
| > DLT >     | /COLONYTE/  |                                 |                |
| > DLT >/AA/ | /DYNAPHARM/ | /227.1GM/PACKET;2.82GM/PACKET;/ |                |
| > DLT >     |             | /6.36GM/PACKET;5.53GM/PACKET;/  |                |
| > DLT >     |             | /21.5GM/PACKET/                 | /N71320/001/   |
| > DLT >     |             |                                 | /APR/20./1988/ |

&gt; ADD &gt;

COLOVARE

&gt; ADD &gt;

AA

DYNAPHARM

&gt; ADD &gt;

227.1GM/PACKET;2.82GM/PACKET;

6.36GM/PACKET;5.53GM/PACKET;

21.5GM/PACKET

N71320 001

APR 20, 1988

&gt; ADD &gt;

COLYTE

AB

REED &amp; CARRICK

227.1GM/PACKET;2.82GM/PACKET;

6.36GM/PACKET;5.53GM/PACKET;

21.5GM/PACKET

N18983 004

OCT 26, 1984

POTASSIUM CHLORIDE

> ADD > GRANULE FOR RECONSTITUTION, CR; ORAL  
 > ADD > MICRO-K LS  
 > ADD > ROBINS 20MEQ/PACKETM N19561 003  
 > ADD > AUG 26, 1988

INJECTABLE; INJECTION

AP POTASSIUM CHLORIDE  
 STERIS LABS 2MEQ/MLM N89163 001  
 MAR 10, 1988

TABLET, CONTROLLED RELEASE; ORAL

POTASSIUM CHLORIDE  
 > ADD > BC ABBOTT LABS 8MEQM N18279 002  
 > ADD > AUG 01, 1988

PREDNISOLONETABLET; ORAL  
PREDNISOLONE

/BX/ /BARR LABS/ /5MG/ /N84426/002/  
 3 BARR LABS 5MG N84426 002  
 > DLT > /STERANE/  
 > DLT > /BX/ /PFIZER LABS/ /5MG/ /N89996/001/  
 > ADD > 3 PFIZER LABS 5MG N89996 001

> ADD > PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

> ADD > SOLUTION/DROPS; OPHTHALMIC  
 > ADD > VASOCIDIN  
 > ADD > IOLAB PHARMS EQ 0.23% PHOSPHATE;10% N18988 001  
 > ADD > AUG 26, 1988

PREDNISONESOLUTION; ORAL

PREDNISONE  
 > ADD > AA MY K LABS 5MG/5MLM N89726 001  
 > ADD > AUG 02, 1988  
 > ADD > AA ROXANE LABS 5MG/5ML N88703 001  
 > ADD > NOV 08, 1984

PREDNISONETABLET; 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/

PROBUCOLTABLET; ORAL

LORELCO  
 MERRELL DOW 500MG N17535 002  
 JUL 06, 1988

PROCAINAMIDE HYDROCHLORIDEINJECTABLE; INJECTION

PROCAINAMIDE HCL  
 AP WARNER CHILCOTT 100MG/MLM N89528 001  
 MAY 03, 1988  
 AP 500MG/MLM N89529 001  
 MAY 03, 1988

PROCHLORPERAZINE EDISYLATEINJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE  
 AP ELKINS SINN EQ 5MG BASE/MLM N89523 001  
 MAY 03, 1988  
 AP QUAD PHARMS EQ 5MG BASE/MLM N89637 001  
 FEB 01, 1988  
 AP EQ 5MG BASE/MLM N89638 001  
 FEB 01, 1988  
 AP STERLING DRUG EQ 5MG BASE/MLM N89703 001  
 APR 07, 1988

PROMETHAZINE HYDROCHLORIDEINJECTABLE; INJECTION

|           |                         |                 |
|-----------|-------------------------|-----------------|
| <u>AP</u> | <u>PROMETHAZINE HCL</u> | <u>25MG/MLM</u> |
|           | MARSAM PHARMS           |                 |
| <u>AP</u> |                         | <u>50MG/MLM</u> |

TABLET; ORAL

|             |                         |                 |
|-------------|-------------------------|-----------------|
|             | <u>PROMETHAZINE HCL</u> |                 |
| <u>/BP/</u> | <u>/BARR/LABS/</u>      | <u>/12.5MG/</u> |
| <u>/BP/</u> |                         | <u>/25MG/</u>   |
| <u>/BP/</u> |                         | <u>/50MG/</u>   |
|             | 2 BARR LABS             | 12.5MG          |
|             | 2                       | 25MG            |
|             | 2                       | 50MG            |

> ADD > PROPIOLACTONE> ADD > SOLUTION; IRRIGATION> ADD > BETAPRONE> ADD > FOREST PHARM N/APROPOXYPHENE HYDROCHLORIDECAPSULE; ORAL

|             |                         |               |
|-------------|-------------------------|---------------|
|             | <u>PROPOXYPHENE HCL</u> |               |
| <u>/BP/</u> | <u>/BANMAX/PHARMS/</u>  | <u>/65MG/</u> |
|             | 2 BANMAX PHARMS         | 65MG          |
| <u>/BP/</u> | <u>/BARR/LABS/</u>      | <u>/65MG/</u> |
|             | 2 BARR LABS             | 65MG          |

PROPRANOLOL HYDROCHLORIDETABLET; ORAL

|           |                        |             |
|-----------|------------------------|-------------|
| <u>AB</u> | <u>PROPRANOLOL HCL</u> | <u>10MG</u> |
|           | INVAMED                |             |
| <u>AB</u> |                        | <u>20MG</u> |
| <u>AB</u> |                        | <u>40MG</u> |
| <u>AB</u> |                        | <u>60MG</u> |
| <u>AB</u> |                        | <u>80MG</u> |
| <u>AB</u> |                        | <u>90MG</u> |

N89463 001  
MAY 02, 1988  
N89477 001  
MAY 02, 1988

/N84555/001/  
/N84554/001/  
/N84557/001/  
N84555 001  
N84554 001  
N84557 001

N11657 001

N71658 001  
JUL 05, 1988  
N71687 001  
JUL 05, 1988  
N71688 001  
JUL 05, 1988  
N72197 001  
JUL 05, 1988  
N71689 001  
JUL 05, 1988  
N72198 001  
JUL 05, 1988

PROPRANOLOL HYDROCHLORIDETABLET; ORAL

|             |                        |               |
|-------------|------------------------|---------------|
| <u>AB</u>   | <u>PROPRANOLOL HCL</u> | <u>10MG</u>   |
|             | LEDERLE LABS           |               |
| <u>AB</u>   |                        | <u>20MG</u>   |
| <u>AB</u>   |                        | <u>40MG</u>   |
| <u>AB</u>   |                        | <u>80MG</u>   |
| <u>/BP/</u> | <u>/LEMMON/</u>        | <u>/10MG/</u> |
|             | 2 LEMMON               | 10MG          |
| <u>/BP/</u> | <u>/PARKE/DAVIS/</u>   | <u>/10MG/</u> |
| <u>AB</u>   |                        | <u>10MG</u>   |
| <u>AB</u>   |                        | <u>20MG</u>   |
| <u>AB</u>   |                        | <u>40MG</u>   |
| <u>AB</u>   |                        | <u>60MG</u>   |
| <u>AB</u>   |                        | <u>80MG</u>   |
| <u>AB</u>   |                        | <u>90MG</u>   |
| <u>AB</u>   | SUPERPHARM             | <u>10MG</u>   |
| <u>AB</u>   |                        | <u>20MG</u>   |
| <u>AB</u>   |                        | <u>40MG</u>   |
| <u>AB</u>   |                        | <u>80MG</u>   |
| <u>AB</u>   | WARNER CHILCOTT        | <u>10MG</u>   |
| <u>AB</u>   | ZENITH LABS            | <u>10MG</u>   |
| <u>AB</u>   |                        | <u>20MG</u>   |
| <u>AB</u>   |                        | <u>40MG</u>   |
| <u>AB</u>   |                        | <u>60MG</u>   |
| <u>AB</u>   |                        | <u>80MG</u>   |

N72117 001  
JUN 23, 1988  
N72113 001  
JUN 23, 1988  
N72119 001  
JUN 23, 1988  
N72120 001  
JUN 23, 1988  
/N70232/001/  
/OCT/07/1988/  
N70232 001  
OCT 07, 1987  
/N70438/001/  
/SEP/15/1988/  
N71972 001  
APR 06, 1988  
N71973 001  
APR 06, 1988  
N71974 001  
APR 06, 1988  
N71975 001  
APR 06, 1988  
N71976 001  
APR 06, 1988  
N71977 001  
APR 06, 1988  
N71515 001  
JUN 08, 1988  
N71516 001  
JUN 08, 1988  
N71517 001  
JUN 08, 1988  
N71518 001  
JUN 08, 1988  
N70438 001  
SEP 15, 1986  
N72063 001  
JUL 29, 1988  
N72066 001  
JUL 29, 1988  
N72067 001  
JUL 29, 1988  
N72068 001  
JUL 29, 1988  
N72069 001  
JUL 29, 1988

RES: 001/001/001

PROTAMINE SULFATE

INJECTABLE; INJECTION

PROTAMINE SULFATE

/BP/ /UPJOHN/ /50MG/VIAL/ /N07413/001/  
/BP/ /250MG/VIAL/ /N07413/002/  
/BP/ /AUG/02/1984/  
2 UPJOHN 50MG/VIAL N07413 001  
2 250MG/VIAL N07413 002  
AUG 02, 1984

QUINESTROL

/TABLET;/ORAL/  
/ESTROVIS/  
/PARKE/DAVIS/  
2 PARKE DAVIS  
2

/0.1MG/ /N16768/002/  
0.1MG N16768 002  
/0.2MG/ /N16768/003/  
0.2MG N16768 003

RAUWOLFIA SERPENTINA

TABLET; ORAL  
RAUVAL  
BP VALE CHEM  
/2/  
BP /2/

50MG N09108 002  
/100MG/ /N09108/004/  
100MG N09108 004  
/50MG/ /N09108/002/

RESERPINE

TABLET; ORAL  
RESERPINE  
/BP/ /BARR/LABS/  
2 BARR LABS

/0.25MG/ /N08721/002/  
0.25MG N08721 002

RESERPINE; TRICHLORMETHIAZIDE

TABLET; ORAL  
/TRICHLORMETHIAZIDE/N/RESERPINE/  
/BP/ /BOLAR/PHARM/ /0.1MG;4MG/  
/ADD/ 2 BOLAR PHARM 0.1MG;4MG

/N08248/001/  
N08248 001

SECOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM SECOBARBITAL

/BP/ /BARR/LABS/ /100MG/ /N04225/001/  
2 BARR LABS 100MG N04225 001

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL

BAROS

> ADD > LAFAYETTE 460MG/GM;420MG/GM N18509 001  
> ADD > /NALLINX/RODT/ /460MG/GM;420MG/GM/ N18509/001/  
> DLT > /AUG/07/1985/  
> DLT > /AUG/07/1985/

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAM 900MG/100MLM N19635 002  
MAR 09, 1988

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP ABBOTT LABS 450MG/100MLM N19759 001  
JUN 08, 1988

AP KENDALL MCGAM 450MG/100MLM N19635 001  
MAR 09, 1988

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

AP KENDALL MCGAM 3GM/100MLM N19635 003  
MAR 09, 1988

AP TRAVENOL LABS 3GM/100ML N19022 001  
NOV 01, 1983

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100MLM N19635 004  
MAR 09, 1988

AP TRAVENOL LABS 5GM/100ML N19022 002  
NOV 01, 1983

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION

NITROPRESS

> ADD > ABBOTT LABS 25MG/MLM N71961 001  
> ADD > AUG 01, 1988

SODIUM SUCCINATEINJECTABLE; INJECTION  
SODIUM SUCCINATE/ELKINS/SINN/  
2 ELKINS SINN/30%/  
30%/N80516/001/  
N80516 001SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE/LEDERLE/LABS/  
2 LEDERLE LABS/25MG/  
25MG/N87634/001/  
N87634 001> DLT > /66/  
> ADD >SULINDAC

TABLET; ORAL

CLINORIL

AB

MS&amp;D

150MG

N17911 001

AB

200MG

N17911 002

SULINDAC

AB

AM THERPTCS

150MG

N72171 001

AB

200MG

MAY 23, 1988

AB

DANBURY PHARMA

150MG

MAY 23, 1988

AB

200MG

N71891 001

APR 03, 1990 : MAR 03, 1988

N71795 001

APR 03, 1990 : MAR 03, 1988

SULFAMETHOXAZOLE

TABLET; ORAL

SULFAMETHOXAZOLE

/BARR/LABS/

/500MG/

2 BARR LABS

500MG

/N87189/001/  
/JUL 25, 1983/  
N87189 001  
JUL 25, 1983

&gt; DLT &gt;

&gt; DLT &gt; /66/

&gt; ADD &gt;

&gt; DLT &gt;

&gt; DLT &gt; /66/

&gt; ADD &gt;

&gt; ADD &gt;

INJECTABLE; INJECTION

Na<sup>235</sup> stable stannous stannate

/MEDI/PHYSICS/

/N/A/

/N17667/001/

2 MEDI PHYSICS

N/A

N17667 001

OSTEOSCAN

/MALLINCKRODT/

/N/A/

/N17454 001/

OSTEOSCAN

MALLINCKRODT

N/A

N17454 001

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

TRIMETH/SULFA

AB NASKA PHARMA

200MG/5ML; 40MG/5ML

N72289 001

AB

200MG/5ML; 40MG/5ML

MAY 23, 1988

AB

200MG/5ML; 40MG/5ML

N72398 001

MAY 23, 1988

AB

200MG/5ML; 40MG/5ML

N72399 001

MAY 23, 1988

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

AB

CORD LABS

15MG

N71427 001

AB

30MG

JAN 12, 1988

N71428 001

JAN 12, 1988

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/BARR/LABS/

/500MG/

2 BARR LABS

500MG

/N84031/001/

N84031 001

/N87649/001/

N87649 001

> DLT > /66/  
> ADD >

/LEDERLE/LABS/

/500MG/

2 LEDERLE LABS

500MG

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL

HYTRIN

/2/ABBOTT/LABS/

/10MG/

ABBOTT LABS

10MG

/N19057/004/

/AUG 07, 1987/

N19057 004

AUG 07, 1987

TERCONAZOLE

SUPPOSITORY; VAGINAL  
TERAZOL 3  
ORTHO PHARM

80MG

N19641 001  
MAY 24, 1988

TIIOCONAZOLE

/OINTMENT; VAGINAL/  
/VAGISTAT/  
/ROERIG/

/6.5%/

3 ROERIG

6.5%

/N19355/001/  
/DEC 30, 1986/  
N19355 001  
DEC 30, 1986

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

&gt; ADD &gt; AB

LABROS ATRAL

250MG

N62752 001  
AUG 12, 1988

&gt; ADD &gt;

&gt; ADD &gt; AB

500MG

N62752 002  
AUG 12, 1988

&gt; ADD &gt;

AB

VITARINE

250MG

N61471 001

> ADD > TIOPRONIN

&gt; ADD &gt;

TABLET; ORAL

&gt; ADD &gt;

TIOPRONIN

&gt; ADD &gt;

UNIV TEXAS

100MG

N19569 001  
AUG 11, 1988

&gt; ADD &gt;

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

AB

PHARM BASICS

100MG

N71355 001  
JAN 11, 1988

THEOPHYLLINE

ELIXIR; ORAL

THEOPHYLLINE

AA

NASKA PHARMA

80MG/15ML

N89223 001  
MAY 27, 1988

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

/66/

/BANMAX PHARMS/

/500MG/

3 BANMAX PHARMS

500MG

/N86141/001/  
N86141 001

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

RIKFR LABS

250MG

/250MG/

N86363 002  
JUL 16, 1987  
/N86363/002/  
/JUL 16, 1987/

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

&gt; ADD &gt;

TRAZODONE HCL

&gt; ADD &gt; AB

SIDMAK LABS

50MG

N71523 001  
DEC 11, 1987

&gt; ADD &gt;

&gt; ADD &gt; AB

100MG

N71524 001  
DEC 11, 1987

&gt; ADD &gt;

&gt; DLT &gt;

/N71524/001/

&gt; DLT &gt; /66/

/SIDMAK LABS/

/100MG/

/N71524/001/  
/DEC 11, 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

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZON-150

AB SIDMAK LABS 150MG

N71525 001  
MAR 09, 1988> DLT > /TRAZON-150/  
> DLT > /SIDMAK LABS/  
> DLT > /150MG//N71525/001/  
/DEC/11./1983/TRIAMCINOLONE

TABLET; ORAL

TRIAMCINOLONE/BP/ /BARR LABS/ /2MG/  
/BP/ /2MG/  
/BP/ /4MG/  
/BP/ /4MG/  
/BP/ /8MG/  
/BP/ /8MG/  
3 BARR LABS 2MG  
3 2MG  
3 4MG  
3 4MG  
3 8MG  
3 8MGN84318 001  
N84267 001  
N84319 001  
N84268 001  
N84320 001TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRYMED> DLT > /1/ /SAVAGE LABS/ /0.5%/  
> DLT > /0.5%/  
> ADD > 3 SAVAGE LABS 0.5%  
> ADD >/N88198/001/  
/MAR/25./1983/  
N88198 001  
MAR 25, 1983TRIAZOLAM

TABLET; ORAL

HALCION/UPJOHN/ /0.5MG/  
3 UPJOHN 0.5MG/N17892/002/  
/NOV/15./1982/  
N17892 002  
NOV 15, 1982/TRICLOFOS/SODIUM/

/SOLUTION;/ORAL/

/TRICLOS//MERRELL/DON/  
3 MERRELL DON/1.5GM/15ML/  
1.5GM/15ML/N16830/001/  
N16830 001

/TABLET;/ORAL/

/TRICLOS//MERRELL/DON/  
3 MERRELL DON/750MG/  
750MG/N16809/002/  
N16809 002TRIDINEXETHYL CHLORIDE

/INJECTABLE;/INJECTION/

/PATRILON//LEDERLE LABS/  
3 LEDERLE LABS/10MG/ML/  
10MG/ML/N09729/001/  
N09729 001TRIFLUOPRAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPRAZINE HCLAB BOLAR PHARM EQ 1MG BASEM  
AB EQ 2MG BASEM  
AB EQ 5MG BASEM  
AB EQ 10MG BASEMN85975 001  
JUN 23, 1988  
N85976 001  
JUN 23, 1988  
N85973 001  
JUN 23, 1988  
N88710 001  
JUN 23, 1988TRIMETHOPRIM

TABLET; ORAL

TRIMETHOPRIMAB BARR LABS 100MG  
/68/ /200MG/  
/3/ /100MG/  
3 200MGN70494 001  
JAN 22, 1986  
/N70495/001/  
/MAR/14./1986/  
/N70494/001/  
/JAN/22./1986/  
N70495 001  
MAR 14, 1986

TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL

TRIPLENNAMINE HCL  
 /AA/ /BARR LABS/ /50MG/  
 @ BARR LABS 50MG

/N80744/881/  
 N80744 001

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION

TUBOCURARINE CHLORIDE  
 > ADD > AP QUAD PHARMS 3MG/MLM  
 > ADD >

N89442 001  
 AUG 12, 1988

URSODIOL

CAPSULE; ORAL

ACTIGALL  
 @ CIBA PHARM

150MG

300MG

N19594 001  
 DEC 31, 1987  
 N19594 002  
 DEC 31, 1987

/DEURSIL/  
 /SIPHARMEX/

/150MG/  
 /300MG/

/N19594/881/  
 /DEC/31/1987/  
 /N19594/882/  
 /DEC/31/1987/

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

LYPHOCIN

AP LYPHOMED EQ 1GM BASE/VIAL

N62663 002  
 JUL 31, 1987

AP EQ 5GM BASE/VIALM

N62663 003  
 JUN 03, 1988

VANOCOCTIN 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

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOLEB

AP LEDERLE LABS

EQ 1GM BASE/VIALM

N62682 002

AP

EQ 5GM BASE/VIAL

MAR 30, 1988

N62682 004

AP

EQ 10GM BASE/VIALM

MAY 11, 1988

N62682 005

EQ 2GM BASE/VIALM

MAY 11, 1988

N62682 003

MAY 11, 1988

VANCOMYCIN HCL

&gt; ADD &gt; AP ABBOTT LABS

EQ 500MG BASE/VIALM

N62911 001

&gt; ADD &gt;

AUG 04, 1988

&gt; ADD &gt;

EQ 1GM BASE/VIALM

N62912 001

&gt; ADD &gt;

AUG 04, 1988

&gt; ADD &gt;

EQ 500MG BASE/VIALM

N62879 001

&gt; ADD &gt;

AUG 02, 1988

&gt; ADD &gt;

EQ 1GM BASE/VIALM

N62879 002

&gt; ADD &gt;

AUG 02, 1988

AP QUAD PHARMS

EQ 500MG BASE/VIALM

N62845 001

AP

EQ 1GM BASE/VIALM

JUL 15, 1988

N62845 002

JUL 15, 1988

VANCOR

&gt; ADD &gt; AP ADRIA LABS

EQ 500MG BASE/VIALM

N62956 001

&gt; ADD &gt;

AUG 01, 1988

&gt; ADD &gt;

EQ 1GM BASE/VIALM

N62956 002

&gt; ADD &gt;

AUG 01, 1988

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

GALAN

/SEARLE/

/160MG/

/N18817/881/

AB SEARLE PHARMS

40MG

/FEB/23/1988/

N18817 003

@

160MG

FEB 23, 1988

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

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

|                      |              |            |              |
|----------------------|--------------|------------|--------------|
| <u>VERAPAMIL HCL</u> |              |            |              |
| AB LEDERLE LABS      | <u>80MG</u>  | N71880 001 | APR 05, 1988 |
| AB                   | <u>120MG</u> | N71881 001 | APR 05, 1988 |
| AB MUTUAL PHARM      | <u>80MG</u>  | N71488 001 | JAN 13, 1988 |
| AB                   | <u>120MG</u> | N71489 001 | JAN 13, 1988 |

XYLOSE

POWDER; ORAL

|               |             |           |
|---------------|-------------|-----------|
| <u>XYLOSE</u> |             |           |
| /AA/          | /LYNE/LABS/ | /25G/BOT/ |
|               | 3 LYNE LABS | 25G/BOT   |

/N18856/001/  
 /MAR/26./1987/  
 N18856 001  
 MAR 26, 1987

VINCRIStINE SULFATE

INJECTABLE; INJECTION

|                                |                 |            |              |
|--------------------------------|-----------------|------------|--------------|
| <u>VINCRIStINE</u>             |                 |            |              |
| AP BRISTOL LABS                | <u>5MG/VIAL</u> | N70867 001 | JUL 12, 1988 |
| <u>VINCRIStINE SULFATE</u>     |                 |            |              |
| AP BULL LABS                   | <u>1MG/VIAL</u> | N71559 001 | APR 11, 1988 |
| AP                             | <u>2MG/VIAL</u> | N71560 001 | APR 11, 1988 |
| AP                             | <u>5MG/VIAL</u> | N71561 001 | APR 11, 1988 |
| AP QUAD PHARMS                 | <u>1MG/VIAL</u> | N71222 001 | MAR 07, 1988 |
| AP                             | <u>2MG/VIAL</u> | N71223 001 | MAR 07, 1988 |
| AP                             | <u>5MG/VIAL</u> | N71937 001 | MAR 07, 1988 |
| <u>VINCRIStINE SULFATE PFS</u> |                 |            |              |
| AP BULL LABS                   | <u>1MG/ML</u>   | N71484 001 | APR 19, 1988 |

WATER FOR INJECTION, STERILE

LIQUID; N/A

STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

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

ACETAMINOPHEN

SUPPOSITORY; RECTAL  
TYLENOL

MCNEIL CONSUMER

120MG  
650MG

/MCNEIL/LABS/

/120MG/  
/650MG/

N17756 002  
N17756 001

/N17756/002/  
/N17756/001/

> DLT > /BROMPHENIRAMINE/MALEATE;/PHENYLPROPANOLAMINE/

> DLT > /TABLET;/CONTROLLED/RELEASE;/ORAL/

> DLT > /BROMATAPP/

> DLT > /COPLY/PHARM/

> DLT >

/12MG;75MG/

/N71099/001/  
/JUL/02;/1987/

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL

BROMATAPP

COPLY PHARM

12MG;75MG

N71099 001

JUL 02, 1987

> ADD >

> ADD >

> ADD >

CHLORPHENIRAMINE MALEATE

CAPSULE, CONTROLLED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE

CORD LABS

12MG

N70797 001

AUG 12, 1988

> ADD >

> ADD >

> ADD >

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL

PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE

CENTRAL PHARMS

8MG;120MG

N19428 001

AUG 02, 1988

> ADD >

> ADD >

> ADD >

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL

RESPORAL

PIONEER PHARMS

6MG;120MG

N89139 001

JUN 16, 1988

> ADD > DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

> ADD >

> ADD >

> ADD >

> ADD >

SYRUP; ORAL

PHENERGAN DM

WYETH AYERST LABS

15MG/5ML;6.25MG/5ML

N11265 003

AUG 11, 1988

HYDROCORTISONE

OINTMENT; TOPICAL

HC (HYDROCORTISONE)

C&M PHARMA

0.5%

N80481 001

IBUPROFEN

TABLET; ORAL

IBU-TAB 200

ALRA LABS

200MG

N71057 001

AUG 11, 1988

> ADD >

> ADD >

> ADD >

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

PRIVATE FMTNS

200MG

N72299 001

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

/JUL/02/

/200MG/

/N19428/001/

/MAY/18;/1988/

/200MG/

/N19428/003/

/JUL/29;/1988/

2 UPJOHN

200MG

N19012 001

MAY 18, 1984

2

200MG

N19012 003

JUL 29, 1987

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE  
SEMISYNTHETIC PURIFIED HUMANINJECTABLE; INJECTION  
MIXTARD HUMAN 70/30  
NORDISK USA30 UNITS/ML;  
70 UNITS/MLMN19585 001  
MAR 11, 1988INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMANINJECTABLE; INJECTION  
HUMULIN U  
/Lilly/

/40 UNITS/ML/

3 LILLY

40 UNITS/ML

/N19571/001/  
/JUN/10/1987/  
N19571 001  
JUN 10, 1987LOPERAMIDE HYDROCHLORIDESOLUTION; ORAL  
IMODIUM A-D  
MCNEIL CONSUMER

1MG/5MLM

N19487 001  
MAR 01, 1988NONOXYNOL-9SPONGE; VAGINAL  
TODAY  
/NLT/

/1GM/

WHITEHALL LABS

1GM

/N18683/001/  
/APR/01/1983/  
N18683 001  
APR 01, 1983> ADD > PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE> ADD > SYRUP; ORAL  
> ADD > PHENERGAN VC> ADD > MYETH AYERST LABS

10MG/5ML; 6.25MG/5MLM

N08604 004  
AUG 11, 1988

DEXTRAN 70, 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION

MACRODEX(R)

PHARMACIA INC

6GM/100ML;0.9GM/100ML

N 06826

> DLT > /PEDIOLACTONE/99%/

> DLT > /SOLUTION/;CHEMICAL/STERILIZING/AGENT/

> DLT > /BETAPRONE/

> DLT > /ONEAL/JONES/FEIDMAN//9954/100ML/

/N/11657/

## 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 MARKETING 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         |
|------------------------------------------|----------------------------------------------------------|--------------|------------------------------|----------------------------------|
| LEUCOVORIN CALCIUM<br>EQ 3MG BASE/ML     | LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION              | LEDERLE LABS | 08107 001<br>AUG 31, 1988    | ODE <sup>1</sup><br>AUG 31, 1995 |
| LEUCOVORIN CALCIUM<br>EQ 50MG BASE/VIAL  | LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION              | LEDERLE LABS | 08107 002<br>AUG 31, 1988    | ODE <sup>1</sup><br>AUG 31, 1995 |
| LEUCOVORIN CALCIUM<br>EQ 100MG BASE/VIAL | LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION              | LEDERLE LABS | 08107 004<br>AUG 31, 1988    | ODE <sup>1</sup><br>AUG 31, 1995 |
| LEUCOVORIN CALCIUM<br>EQ 60MG BASE/VIAL  | LEUCOVORIN CALCIUM<br>POWDER FOR<br>RECONSTITUTION; ORAL | LEDERLE LABS | 08107 003<br>AUG 31, 1988    | ODE <sup>1</sup><br>AUG 31, 1995 |
| METHOTREXATE SODIUM<br>EQ 2.5MG BASE/ML  | METHOTREXATE<br>INJECTABLE; INJECTION                    | LEDERLE LABS | 11719 004<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |
| METHOTREXATE SODIUM<br>EQ 20MG BASE/VIAL | METHOTREXATE<br>INJECTABLE; INJECTION                    | LEDERLE LABS | 11719 001<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |

<sup>1</sup>ODE PERTAINS ONLY TO INDICATION I-79 (SEE EXCLUSIVITY TERMS)

<sup>2</sup>ODE PERTAINS ONLY TO INDICATION I-78 (SEE EXCLUSIVITY TERMS)

## 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 25MG BASE/ML    | METHOTREXATE<br>INJECTABLE; INJECTION     | LEDERLE LABS | 11719 005<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |
| METHOTREXATE SODIUM<br>EQ 50MG BASE/VIAL  | METHOTREXATE<br>INJECTABLE; INJECTION     | LEDERLE LABS | 11719 003<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |
| METHOTREXATE SODIUM<br>EQ 100MG BASE/VIAL | METHOTREXATE<br>INJECTABLE; INJECTION     | LEDERLE LABS | 11719 006<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |
| METHOTREXATE SODIUM<br>EQ 1GM BASE/VIAL   | METHOTREXATE<br>INJECTABLE; INJECTION     | LEDERLE LABS | 11719 009<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |
| METHOTREXATE SODIUM<br>EQ 25MG BASE/ML    | METHOTREXATE LPF<br>INJECTABLE; INJECTION | LEDERLE LABS | 11719 007<br>APR 07, 1988    | ODE <sup>2</sup><br>APR 07, 1995 |
| TIOPRONIN<br>100MG                        | TIOPRONIN<br>TABLET; ORAL                 | UNIV TEXAS   | 19569 001<br>AUG 11, 1988    | ODE<br>AUG 11, 1995              |

<sup>2</sup>ODE PERTAINS ONLY TO INDICATION I-78 (SEE EXCLUSIVITY TERMS)

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

NO AUGUST 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.

| DRUG NAME (DOSAGE FORM)                                  | DATE                    | REVISED DATE |
|----------------------------------------------------------|-------------------------|--------------|
| ACETOHEXAMIDE (TABLET)                                   | NOV 15, 1985            | AUG 01, 1988 |
| ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER) | AUG 25, 1988            |              |
| AMOXAPINE (TABLET)                                       | SEP 10, 1987            | AUG 05, 1988 |
| CARBAMAZEPINE (TABLET)                                   | JAN 01, 1988            |              |
| CLINDAMYCIN (CAPSULE)                                    | MAY 31, 1988            |              |
| <del>CONJUGATED ESTROGEN (TABLET)*</del>                 | <del>DEC 17, 1988</del> |              |
| 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            |              |
| LEUCOVORIN CALCIUM (TABLET)                              | APR 28, 1987            | AUG 04, 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            |              |
| TIMOLOL MALEATE (TABLET)                                 | AUG 09, 1988            |              |

\*The methodology in the Biopharmaceutical Availability Guidance is no longer accepted by the Agency.

# 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 |
| CHLORHEXIDINE GLUCONATE<br>SPRAY; TOPICAL          | 0.5%                         | 88 P-0036/CP         | ARENT, FOX, KINTNER,<br>PLOTKIN & KAHN | NEW DOSAGE<br>FORM     | APPROVED<br>AUG 19, 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<br>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<br>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<br>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<br>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<br>AND BECKER         | NEW DOSAGE<br>FORM                 | APPROVED<br>MAY 12, 1988 |
| HYDROCHLOROTHIAZIDE;<br>PROPRANOLOL HYDROCHLORIDE<br>SOLUTION; ORAL                   | 25MG/5ML<br>40MG/5ML                                 | 87 P-0399/CP  | BURDITT, BOWLES,<br>RADZIUS AND RUBERRY | NEW DOSAGE<br>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<br>PETITION | STATUS                   |
|---------------------------------------------------------------------|------------------------------|----------------------|-----------------------------------------|------------------------|--------------------------|
| HYDROCHLOROTHIAZIDE;<br>PROPRANOLOL HYDROCHLORIDE<br>SOLUTION; ORAL | 25MG/5ML<br>80MG/5ML         | 87 P-0399/CP         | BURDITT, BOWLES,<br>RADZIUS AND RUBERRY | NEW DOSAGE<br>FORM     | APPROVED<br>FEB 16, 1988 |
| HYDROCHLOROTHIAZIDE;<br>TRIAMTERENE<br>TABLET; ORAL                 | 25MG<br>50MG                 | 87 P-0335/CP         | PAR PHARM                               | NEW DOSAGE<br>FORM     | APPROVED<br>FEB 26, 1988 |
| LEUCOVORIN CALCIUM<br>SOLUTION; ORAL                                | EQ 1MG BASE/ML               | 88 P-0149/CP         | ROXANE LABS                             | NEW DOSAGE<br>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<br>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<br>FORM     | APPROVED<br>MAY 11, 1988 |
| NIFEDIPINE<br>CAPSULE; ORAL                                         | 20MG                         | 88 P-0072/CP         | MARTEC PHARMS                           | NEW DOSAGE<br>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<br>250MG/VIAL         | 87 P-0367/CP  | LYPHOMED      | NEW DOSAGE<br>FORM     | APPROVED<br>FEB 16, 1988 |
| PREDNISOLONE SODIUM PHOSPHATE<br>SOLUTION; ORAL                       | EQ 5MG BASE/ML                   | 88 P-0235/CP  | PAN AM PHARMS | NEW STRENGTH           | APPROVED<br>AUG 24, 1988 |
| SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>INJECTABLE; INJECTION | 900MG/100ML<br>(100ML/CONTAINER) | 87 P-0391/CP  | LYPHOMED      | NEW STRENGTH           | APPROVED<br>AUG 11, 1988 |
| STERILE WATER<br>IN PLASTIC CONTAINER<br>INJECTABLE; INJECTION        | 100%<br>(100ML/CONTAINER)        | 87 P-0392/CP  | LYPHOMED      | NEW STRENGTH           | APPROVED<br>AUG 11, 1988 |
| THEOPHYLLINE<br>CAPSULE, CONTROLLED<br>RELEASE; ORAL                  | 450MG                            | 88 P-0119/CP  | RIKER LABS    | NEW STRENGTH           | APPROVED<br>MAY 11, 1988 |
| THEOPHYLLINE<br>CAPSULE, CONTROLLED<br>RELEASE; ORAL                  | 500MG                            | 88 P-0226/CP  | SAVAGE LABS   | NEW STRENGTH           | APPROVED<br>AUG 25, 1988 |

## ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE                                 | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION             | STATUS                   |
|-----------------------------------------------------------------|------------------------------|---------------|------------|------------------------------------|--------------------------|
| 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 INGREDIENT<br>(NEW ESTER)      | DENIED<br>MAR 19, 1986 |
| BROMPHENIRAMINE<br>MALEATE;<br>HYDROCODONE BITARTRATE;<br>PHENYLPROPANOLAMINE<br>HYDROCHLORIDE<br>SYRUP; ORAL | 2MG/5ML<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>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>2.5MG/5ML              | 85 P-0255/CP  | MIKART         | NEW<br>COMBINATION                 | DENIED<br>MAY 11, 1988 |
| CYCLOBENZAPRINE<br>HYDROCHLORIDE<br>TABLET; ORAL                                                              | 15MG                                 | 86 P-0386/CP  | CENTRAL PHARMS | NEW STRENGTH                       | DENIED<br>AUG 15, 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 |

## ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

| DRUG NAME<br>DOSAGE FORM; ROUTE                                                                         | STRENGTH<br>(CONTAINER SIZE)                       | DOCKET NUMBER | PETITIONER     | REASON FOR<br>PETITION             | STATUS                 |
|---------------------------------------------------------------------------------------------------------|----------------------------------------------------|---------------|----------------|------------------------------------|------------------------|
| 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 |
| DIPHENHYDRAMINE<br>HYDROCHLORIDE<br>CAPSULE, SUSTAINED<br>RELEASE; ORAL                                 | 75MG                                               | 87 P-0355/CP  | PARKE DAVIS    | NEW DOSAGE<br>FORM<br>NEW STRENGTH | DENIED<br>MAY 11, 1988 |
| HYDROCODONE BITARTRATE;<br>PHENYLEPHRINE<br>HYDROCHLORIDE;<br>PROMETHAZINE HYDROCHLORIDE<br>SYRUP; ORAL | 1.66MG/5ML<br>5MG/5ML<br>6.25MG/5ML                | 85 P-0389/CP  | UAD LABS       | NEW<br>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<br>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 |

## 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>(50ML/VIAL)        | 87 P-0090/CP  | INTL MEDTN SYS | NEW STRENGTH           | DENIED<br>FEB 08, 1988 |
| 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-79~~ ~~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  
 I-78 HIGH DOSE METHOTREXATE WITH LEUCOVORIN RESCUE IN COMBINATION WITH OTHER CHEMOTHERAPEUTIC AGENTS  
       TO DELAY RECURRENCE IN PATIENTS WITH NONMETASTATIC OSTEOSARCOMA WHO HAVE UNDERGONE SURGICAL  
       RESECTION OR AMPUTATION FOR THE PRIMARY TUMOR  
 I-79 RESCUE AFTER HIGH-DOSE METHOTREXATE THERAPY IN OSTEOSARCOMA

## 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                                               |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD       | INGREDIENT NAME; TRADE NAME           | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|-----------------|---------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 19489 001       | ALBUTEROL SULFATE; VENTOLIN ROTACAPS  | 3705233          | DEC 05, 1989      |             |                |                   |
| 18116 002       | AMCINONIDE; CYCLOCORT                 | 3644353          | FEB 22, 1989      |             | NDF            | MAY 04, 1991      |
| 18498 001       | AMCINONIDE; CYCLOCORT                 | 4158055          | JUN 12, 1996      | U-34        |                |                   |
| >ADD> 19716 001 | BETAMETHASONE DIPROPIONATE; DIPROLENE | 4158055          | JUN 12, 1996      | U-34        |                |                   |
| 18644 001       | BUPROPION HYDROCHLORIDE; WELLBUTRIN   |                  |                   |             | NP             | AUG 01, 1991      |
| 18644 002       | BUPROPION HYDROCHLORIDE; WELLBUTRIN   | 4507323          | MAR 26, 2002      |             |                |                   |
| 18644 003       | BUPROPION HYDROCHLORIDE; WELLBUTRIN   | 4507323          | MAR 26, 2002      |             |                |                   |
| 17920 002       | CIMETIDINE; TAGAMET                   | 4507323          | MAR 26, 2002      |             |                |                   |
|                 |                                       | 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      |
| 19201 001       | DICLOFENAC SODIUM; VOLTAREN           | 3652762          | MAR 28, 1989      |             | NCE            | JUL 28, 1993      |
| 19201 002       | DICLOFENAC SODIUM; VOLTAREN           | 3652762          | MAR 28, 1989      |             | NCE            | JUL 28, 1993      |
| 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      |
| 18998 005       | ENALAPRIL MALEATE; VASOTEC            | 4374829          | FEB 22, 2000      |             | NCE            | DEC 24, 1990      |
|                 |                                       |                  |                   |             | 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        |                |                   |
| >ADD> 19386 001 | ESMOLOL HYDROCHLORIDE; BREVIBLOC      | 4593119          | JUN 03, 2003      |             | NCE            | DEC 31, 1991      |
| >ADD> 18830 003 | FLECAINIDE ACETATE; TAMBOCOR          | 4387103          | JUN 07, 2000      | U-16        |                |                   |
|                 |                                       | 4005209          | JAN 25, 1996      |             | NS             | JUN 03, 1991      |
|                 |                                       | 3900481          | AUG 19, 1992      |             | NCE            | OCT 31, 1990      |
| >ADD> 18830 004 | FLECAINIDE ACETATE; TAMBOCOR          | 4005209          | JAN 25, 1996      |             |                |                   |
| >ADD> 18830 004 | FLECAINIDE ACETATE; TAMBOCOR          | 3900481          | AUG 19, 1992      |             | NCE            | OCT 31, 1990      |

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PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD | INGREDIENT NAME; TRADE NAME               | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|-----------|-------------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 19452 001 | FLUOCINOLONE ACETONIDE; DERMA-SMOOTHIE/FS | 4683235          | JUL 28, 2004      | U-30        | NDF            | FEB 03, 1991      |
| 18936 001 | FLUOXETINE HYDROCHLORIDE; PROZAC          | 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      |             |                |                   |
| 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           |                  |                   |             | D-15           | MAY 13, 1991      |
| 18956 002 | IOHEXOL; OMNIPAQUE 240                    |                  |                   |             | I-19           | JUL 29, 1991      |
|           |                                           |                  |                   |             | I-60           | JUL 29, 1991      |
|           |                                           |                  |                   |             | I-75           | JUL 29, 1991      |
|           |                                           |                  |                   |             | I-76           | JUL 29, 1991      |
|           |                                           |                  |                   |             | I-77           | JUL 29, 1991      |
| 18956 003 | IOHEXOL; OMNIPAQUE 300                    | 4021481          | MAY 03, 1994      |             | I-55           | FEB 01, 1988      |
|           |                                           |                  |                   |             | I-58           | FEB 01, 1988      |
|           |                                           |                  |                   |             | I-60           | JUL 29, 1991      |
|           |                                           |                  |                   |             | I-77           | JUL 29, 1991      |
| 18956 004 | IOHEXOL; OMNIPAQUE 350                    |                  |                   |             | I-56           | MAY 24, 1991      |
|           |                                           |                  |                   |             | I-77           | JUL 29, 1991      |
| 19085 001 | IPRATROPIUM BROMIDE; ATROVENT             | 3681500          | AUG 01, 1991      |             | NCE            | DEC 29, 1991      |
| >ADD>     | 08107 001                                 |                  |                   |             | ODE            | AUG 31, 1995      |
| >ADD>     |                                           |                  |                   |             | I-79           | AUG 31, 1995      |
| >ADD>     | 08107 002                                 |                  |                   |             | ODE            | AUG 31, 1995      |
| >ADD>     |                                           |                  |                   |             | I-79           | AUG 31, 1995      |
| >ADD>     | 08107 003                                 |                  |                   |             | ODE            | AUG 31, 1995      |
| >ADD>     |                                           |                  |                   |             | I-79           | AUG 31, 1995      |
| >ADD>     | 08107 004                                 |                  |                   |             | ODE            | AUG 31, 1995      |
| >ADD>     |                                           |                  |                   |             | I-79           | AUG 31, 1995      |
| 19777 001 | LISINAPRIL; ZESTRIL                       | 4374829          | FEB 22, 2000      |             | NCE            | DEC 29, 1992      |
| 19777 002 | LISINAPRIL; ZESTRIL                       | 4374829          | FEB 22, 2000      |             | NCE            | DEC 29, 1992      |
| 19777 003 | LISINAPRIL; ZESTRIL                       | 4374829          | FEB 22, 2000      |             | NCE            | DEC 29, 1992      |
| 19487 001 | LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D     | 3714159          | JAN 30, 1990      |             |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

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| APPL/PROD       | INGREDIENT NAME; TRADE NAME           | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|-----------------|---------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| >DLT> 79643 003 | LOVASTATIN; MEVACOR                   | 4237938          | NOV 04, 1997      |             | NCE            | AUG 31, 1992      |
| >ADD> 19643 003 | LOVASTATIN; MEVACOR                   | 4231938          | NOV 04, 1999      |             | NCE            | AUG 31, 1992      |
| >ADD> 18006 001 | MECLOFENAMATE SODIUM; MECLOMEN        |                  |                   |             | I-68           | AUG 30, 1991      |
| >ADD> 18006 002 | MECLOFENAMATE SODIUM; MECLOMEN        |                  |                   |             | I-68           | AUG 30, 1991      |
| >ADD> 11719 001 | METHOTREXATE SODIUM; METHOTREXATE     |                  |                   |             | ODE            | APR 07, 1995      |
| >ADD> 11719 003 | METHOTREXATE SODIUM; METHOTREXATE     |                  |                   |             | I-78           | APR 07, 1995      |
| >ADD> 11719 004 | METHOTREXATE SODIUM; METHOTREXATE     |                  |                   |             | ODE            | APR 07, 1995      |
| >ADD> 11719 005 | METHOTREXATE SODIUM; METHOTREXATE     |                  |                   |             | I-78           | APR 07, 1995      |
| >ADD> 11719 006 | METHOTREXATE SODIUM; METHOTREXATE     |                  |                   |             | ODE            | APR 07, 1995      |
| >ADD> 11719 009 | METHOTREXATE SODIUM; METHOTREXATE     |                  |                   |             | I-78           | APR 07, 1995      |
| >ADD> 11719 007 | METHOTREXATE SODIUM; METHOTREXATE LPF |                  |                   |             | ODE            | APR 07, 1995      |
| >ADD> 09048 001 | METHOXSALEN; 8-MOP                    |                  |                   |             | I-78           | APR 07, 1995      |
| >DLT> 78654 001 | MIDAZOLAM HYDROCHLORIDE; VERSED       | 4280957          | JUL 28, 1998      |             | I-72           | MAR 23, 1991      |
| >ADD> 18654 001 | MIDAZOLAM HYDROCHLORIDE; VERSED       | 4280957          | DEC 20, 1999      |             | NCE            | DEC 20, 1990      |
| >DLT> 78654 002 | MIDAZOLAM HYDROCHLORIDE; VERSED       | 4280957          | JUL 28, 1998      |             | NCE            | DEC 20, 1990      |
| >ADD> 18654 002 | MIDAZOLAM HYDROCHLORIDE; VERSED       | 4280957          | DEC 20, 1999      |             | NCE            | DEC 20, 1990      |
| >ADD> 19501 001 | MINOXIDIL; ROGAINE                    | 4139619          | FEB 13, 1996      |             | NDF            | AUG 17, 1991      |
| >ADD> 19516 002 | MORPHINE SULFATE; MS CONTIN           |                  |                   |             | NDF            | MAY 29, 1990      |
| >ADD> 18677 001 | NABILONE; CESAMET                     | 4087545          | MAY 02, 1997      | U-7         |                |                   |
| >ADD> 19599 001 | NAFTIFINE HYDROCHLORIDE; NAFTIN       | 4282251          | AUG 04, 1998      |             | NCE            | MAR 01, 1993      |
| >ADD> 19508 001 | NIZATIDINE; AXID                      | 4760075          | MAY 03, 2000      | U-33        |                |                   |
| >ADD> 19508 002 | NIZATIDINE; AXID                      | 4382090          | MAY 03, 2000      | U-33        |                |                   |
| >ADD> 19508 002 | NIZATIDINE; AXID                      | 4375547          | MAR 01, 2000      |             | NCE            | APR 12, 1993      |
| >ADD> 19508 002 | NIZATIDINE; AXID                      | 4760075          | MAY 03, 2000      | U-33        |                |                   |
| >ADD> 19508 002 | NIZATIDINE; AXID                      | 4382090          | MAY 03, 2000      | U-33        |                |                   |
| >ADD> 19508 002 | NIZATIDINE; AXID                      | 4375547          | MAR 01, 2000      |             | NCE            | APR 12, 1993      |
| >ADD> 19009 001 | PIRBUTEROL ACETATE; EXIREL            | 4175128          | NOV 20, 1996      |             |                |                   |
| >ADD> 19009 001 | PIRBUTEROL ACETATE; EXIREL            | 3786160          | JAN 15, 1993      |             |                |                   |
| >ADD> 19009 001 | PIRBUTEROL ACETATE; EXIREL            | 3700681          | OCT 24, 1989      |             | NCE            | DEC 30, 1991      |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

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| APPL/PROD       | INGREDIENT NAME; TRADE NAME                                 | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|-----------------|-------------------------------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| >ADD> 19561 003 | POTASSIUM CHLORIDE; MICRO-K LS                              | 4259315          | MAR 31, 1998      |             |                |                   |
| 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        |                |                   |
| >DLT> 19057 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4251532          | FEB 17, 2000      | U-5         | NCE            | AUG 07, 1992      |
| >ADD> 19057 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4112097          | SEP 05, 1995      | U-5         |                |                   |
|                 |                                                             | 4026894          | MAY 31, 1994      |             |                |                   |
| >DLT> 19057 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4251532          | FEB 17, 2000      | U-5         | NCE            | AUG 07, 1992      |
| >ADD> 19057 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4112097          | SEP 05, 1995      | U-5         |                |                   |
|                 |                                                             | 4026894          | MAY 31, 1994      |             |                |                   |
| >DLT> 19057 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4251532          | FEB 17, 2000      | U-5         | NCE            | AUG 07, 1992      |
| >ADD> 19057 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4112097          | SEP 05, 1995      | U-5         |                |                   |
|                 |                                                             | 4026894          | MAY 31, 1994      |             |                |                   |
| >DLT> 19057 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 4251532          | FEB 17, 2000      | U-5         | NCE            | AUG 07, 1992      |
| >ADD> 19057 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN                             | 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      |
| >ADD> 19569 001 | TIOPRONIN; TIOPRONIN                                        |                  |                   |             | NCE            | AUG 11, 1993      |
| >ADD> 18207 003 | TRAZODONE HYDROCHLORIDE; DESYREL                            | 4258027          | MAR 24, 1998      |             | ODE            | AUG 11, 1995      |
|                 |                                                             | 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      |



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