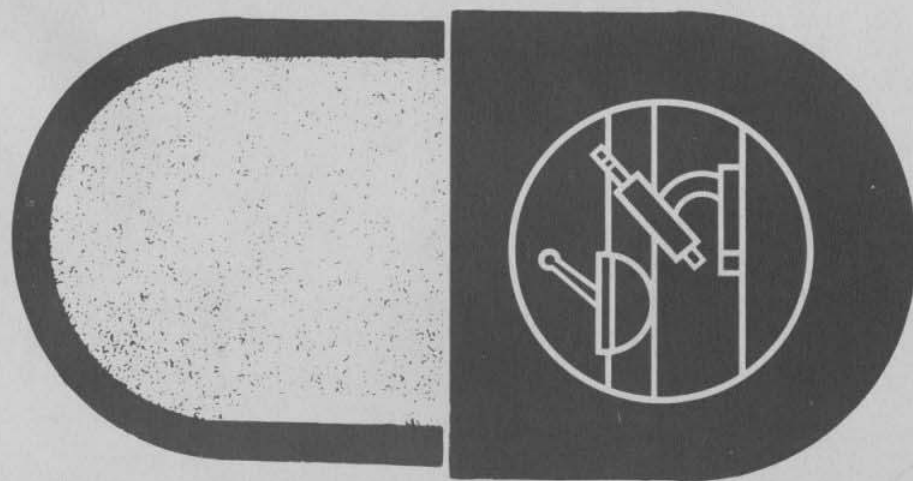


MED  
HE 20.4210  
985/supp.

**CUMULATIVE  
SUPPLEMENT 16**

**AUG'85-DEC'86**



# **APPROVED DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**6<sup>TH</sup> EDITION**



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUGS AND BIOLOGICS

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS  
6TH EDITION

CUMULATIVE SUPPLEMENT

DECEMBER 1986

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## A. INTRODUCTION

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4. OTC Drug Products
5. Products Requiring Revised Labeling for Full Approval
6. Injectable Product Package Size Designation
7. Report of Counts for the Prescription Drug Product List

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS

6th EDITION

CUMULATIVE SUPPLEMENT

DECEMBER 1986

A. INTRODUCTION

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, 6th Edition (the List). The List is comprised of three drug product lists: The Prescription Drug Product list, the OTC Drug Product list, and the Drug Products Approved Under Section 505 of the Act by the Division of Blood and Blood Products list. 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.

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.

Information in the Cumulative Supplement follows the format of the drug product lists. 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.)

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the drug product lists for the revision. [Strength(s) which already exist in the publication will not be repeated for context.] A page number in parentheses, located to the right of the ingredient(s), refers to the related page in the drug product lists. The effective (marketing) date (the date a product may be marketed), when appropriate, will appear to the left of the approval date.

Additions to the drug product lists and the Appendices are indicated by new information in the Cumulative Supplement. Additions new to the current Cumulative Supplement are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is dropped in subsequent Cumulative Supplements for that item.

A newly approved product is identified by the lozenge (≡) to the right of its strength. This identifier remains throughout all Cumulative Supplements for this edition.

Deletions from the drug product lists and the Appendices are indicated by overstruck print in the Cumulative Supplement. Deletions new to the current Cumulative Supplement are indicated by the symbol >DLT> (DELETE) to the left of the line containing the overstruck print. The symbol is dropped in subsequent Cumulative Supplements for that item.

Products discontinued from marketing will be flagged in this Cumulative Supplement with the "•" symbol to designate their non-marketed status until such time that the Agency is notified that they are being marketed.

The Appendices of the Cumulative Supplement provide, among other things, updated information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984."

## 2. 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 Special Notes 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. The current list of applicant holder changes follows.

### APPLICANT (NAME) CHANGES

| <u>Former Applicant (Name)</u> | <u>New Applicant (Name)</u>                                                 | <u>New Abbreviated Name</u> |
|--------------------------------|-----------------------------------------------------------------------------|-----------------------------|
| VITARINE/PHOENIX               | VITARINE<br>PHARMACEUTICALS, INC                                            | VITARINE PHARMS             |
| DRUMMER/PHOENIX                | VITARINE<br>PHARMACEUTICALS, INC                                            | VITARINE PHARMS             |
| INVENEX LABS/LIFE              | LYPHOMED, INC                                                               | LYPHOMED                    |
| ONEAL JONES&FELDMAN            | FOREST<br>PHARMACEUTICALS, INC<br>SUBSIDIARY OF FOREST<br>LABORATORIES, INC | FOREST PHARMS/FOREST        |
| AM MCGAW/AM HOSP               | KENDALL MCGAW<br>LABORATORIES, INC                                          | KENDALL MCGAW LABS          |

(continued)

### APPLICANT (NAME) CHANGES

(continued)

| <u>Former Applicant (Name)</u>                          | <u>New Applicant (Name)</u>                                           | <u>New Abbreviated Name</u> |
|---------------------------------------------------------|-----------------------------------------------------------------------|-----------------------------|
| IVES LABS/AMHO                                          | WYETH LABORATORIES, INC<br>DIVISION OF AMERICAN<br>HOME PRODUCTS CORP | WYETH LABS/AMHO             |
| REID PROVIDENT LABS<br>AND<br>ROWELL LABORATORIES       | REID-ROWELL                                                           | REID-ROWELL                 |
| BAY LABORATORIES                                        | MY-K LABORATORIES, INC                                                | MY-K LABS                   |
| AMERICAN CRITICAL CARE<br>DIV AMERICAN HOSP SUPPLY CORP | AM CRITICAL CARE/AHS                                                  | DUPONT CRIT CRE             |

### 3. PREDNISONE BIOEQUIVALENCE

The Agency has determined that in vitro data are sufficient to demonstrate bioequivalence of prednisone products. This decision is based on past bioavailability studies on a variety of prednisone products sponsored under FDA contract which established an in vitro and in vivo correlation with a variety of in vitro apparatus and media. The studies demonstrated that the dissolution rate using apparatus such as the spin filter, USP basket, and paddle correlated with the rate of drug absorption. The initial paddle used in the above studies was a tilting blade paddle. When the USP adopted a fixed blade paddle method, it raised the issue of whether the same correlation existed for the tilting blade paddle. Following the October 15, 1977, effective date of the new USP prednisone table dissolution specification, the Agency initiated an extensive voluntary dissolution certification program for all marketed prednisone tablet products. This program continued until each firm demonstrated that every prednisone product could consistently meet the new USP standard. Firms failing to meet the new standard were required to remove their product from the market or reformulate to an acceptable product.

As a result of this program, when marketed prednisone table products were resurveyed in 1980, all met the USP standard.

A selected sample of the products in an Agency bioavailability study conducted in 1982 on marketed prednisone tablets revealed no statistically significant differences in the key bioavailability parameters (AUC, Cmax, Tmax) for prednisone tablets.

Therefore, FDA will change the therapeutic equivalence code from BX to AB on any approved prednisone tablets if the application is supplemented with an acceptable comparative in vitro dissolution study. (See Appendix 3 of this Supplement for available guidance from the Division of Bioequivalence.)

#### 4. OTC DRUG PRODUCTS

The following drug products identified in the "OTC Drug Product List" of this publication as requiring approved applications may be marketed on the firm's own responsibility without an application under the Agency's existing OTC drug marketing policies so long as applicable proposed or tentative final monographs are followed (see 21 CFR 330.13).

|                            |            |
|----------------------------|------------|
| Dexbrompheniramine Maleate | 2mg        |
| Pseudoephedrine Sulfate    | 60mg       |
| Tablet; Oral               |            |
| Pseudoephedrine HCl        | 60mg       |
| Triprolidine HCl           | 2.5mg      |
| Tablet or Capsule; Oral    |            |
| Pseudoephedrine HCl        | 30mg/5ml   |
| Triprolidine HCl           | 1.25mg/5ml |
| Syrup; Oral                |            |
| Triprolidine HCl           | 1.25mg/5ml |
| Syrup; Oral                |            |
| Triprolidine HCl           | 2.5mg      |
| Tablet; Oral               |            |

## 5. PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

### Products

### Federal Register Reference

MAR 26, 1984 (49 FR 11888)

neomycin sulfate with either:  
 dexamethasone sodium phosphate,  
 fluocinolone acetonide,  
 flurandrenolide,  
 hydrocortisone, or  
 methylprednisolone acetate  
 [topical anti-infectives for  
 dermatologic use]  
 nitroglycerin (capsule, controlled release;oral)  
 nitroglycerin (ointment;topical)  
 nitroglycerin (tablet, controlled release;oral)  
 nitroglycerin (tablet, controlled release;buccal)  
 phenazopyridine hydrochloride and  
 sulfamethoxazole  
 tranilcypromine sulfate

SEP 7, 1984 (49 FR 35428)  
 SEP 3, 1986 (51 FR 31371)  
 SEP 7, 1984 (49 FR 35428)  
 JUL 5, 1985 (50 FR 27688)  
 JUL 29, 1983 (48 FR 34516)  
 MAR 22, 1984 (49 FR 10708)

6. INJECTABLE PRODUCT PACKAGE SIZE DESIGNATION

When a new drug product (usually injectable) is approved for the same concentration but a different package size than the listed drug, and it has received a period of exclusivity by the Agency, the product will appear as single source (no therapeutic equivalence code displayed) and the potency will reflect the unique package size. Once the period of exclusivity has ended, the product will then conform to the standard ADP format of reflecting "collapsed" package sizes. The current standard is to display package sizes of all small volume parenterals within an NDA as a per ml concentration and large volume parenterals as per 100ml.

## 7. 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. Thus, 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 those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

The counts appear in two sections. Section A. provides baseline and quarterly data. The baseline column refers to the products in the List. For each three-month period following July '85, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count. Section B. refers to products in the Cumulative Supplements and provides monthly activity with a cumulative count for the current quarter.

### 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 part of a combination.

### USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval and changes from prescription to over-the-counter status; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category changes is reflected in the quarterly counts for multisource and single source products.

# REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

## A. COUNTS CUMULATIVE BY QUARTERS

| CATEGORIES COUNTED              | JULY '85 (BASELINE) | JUL '86      | OCT '86      |
|---------------------------------|---------------------|--------------|--------------|
| DRUG PRODUCTS LISTED            | 8048                | 8860         | 9066         |
| SINGLE SOURCE                   | 2096 (26.0%)        | 2137 (24.1%) | 2128 (23.5%) |
| MULTISOURCE(1)                  | 5952 (74.0%)        | 6723 (75.9%) | 6938 (76.5%) |
| THERAPEUTICALLY EQUIVALENT      | 4864 (60.5%)        | 5619 (63.4%) | 5850 (64.5%) |
| NOT THERAPEUTICALLY EQUIVALENT  | 1054 (13.1%)        | 1062 (12.1%) | 1039 (11.5%) |
| EXCEPTIONS(2)                   | 34 ( 0.4%)          | 42 ( 0.4%)   | 49 ( 0.5%)   |
| NEW MOLECULAR ENTITIES APPROVED | -                   | 27           | 8            |
| NUMBER OF APPLICANTS            | 306                 | 327          | 330          |

## B. ACTIVITY FOR SUPPLEMENT NUMBER 16

|                                    | NOV '86 | DEC '86 | CUMULATIVE |
|------------------------------------|---------|---------|------------|
| DRUG PRODUCTS ADDED:               |         |         |            |
| NEWLY APPROVED                     | 81      | 108     | 189        |
| DESI EFFECTIVE                     | 80      | 107     | 187        |
| REMARKETED                         | 0       | 1       | 1          |
| DRUG PRODUCTS REMOVED:             |         |         |            |
| WITHDRAWN APPROVAL                 | 0       | 0       | 0          |
| RX TO OTC SWITCH                   | 0       | 0       | 0          |
| NET GAIN IN DRUG PRODUCTS          | 81      | 108     | 189        |
| SINGLE SOURCE PRODUCTS APPROVED    | 7       | 36      | 43         |
| MULTISOURCE DRUG PRODUCTS APPROVED | 74      | 72      | 146        |
| NEW MOLECULAR ENTITIES APPROVED:   | 0       | 10      | 10         |
| AS THE ENTITY                      | 0       | 3       | 3          |
| AS A SALT, ESTER OR DERIVATIVE     | 0       | 7       | 7          |
| OF THE ENTITY                      |         |         |            |

(1) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (I.E., AVAILABLE FROM MORE THAN ONE APPLICANT)

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-8 OF THE LIST)

B. DRUG PRODUCT LISTS

1. Prescription Drug Product List
2. OTC Drug Product List
3. Drug Products Approved Under Section 505 of the Act  
by the Division of Blood and Blood Products List



ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

capsule; oral  
BANCAP HC

AA FOREST PHARM/FOREST 500MG;5MG  
/AA/ JONES & JONES/FOREST/500MG;5MG/  
/MAR 17, 1983/

AA HYDROCODONE BITARTRATE AND ACETAMINOPHEN  
MIKART 500MG;5MG

TABLET; ORAL  
DURADYNE DHC

AA FOREST PHARM/FOREST 500MG;5MG

AA HYDROCODONE BITARTRATE AND ACETAMINOPHEN  
MIKART 500MG;5MG

AA HOLLOWAY PHARMS  
HOLCET

AA HOLLOWAY PHARMS 500MG;5MG

AA MCNEIL PHARM  
TYCODONE

AA MCNEIL PHARM 500MG;5MG

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; (PAGE 3-3)

SOLUTION; ORAL  
ROXICET

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

N89351 001  
DEC 03, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL  
/PROXYPHENE 100/  
PROXACET 100  
LEMMON

AB 650MG;100MG

AB PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN  
BARR LABORATORIES 650MG;100MG

AB 650MG;100MG

AB 650MG;100MG

N70107 001  
JUN 12, 1985

N70615 001  
MAR 21, 1986

N70771 001  
MAR 21, 1986

N70775 001  
MAR 21, 1986

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN  
BOLAR PHARMACEUTICAL 325MG;50MG

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

650MG;100MG

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

650MG;100MG

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

650MG;100MG

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

650MG;100MG

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

650MG;100MG

N70398 001  
DEC 18, 1986

N70399 001  
DEC 18, 1986

N71336 001  
DEC 11, 1986

N71337 001  
DEC 11, 1986

N70443 001  
JAN 23, 1986

N70732 001  
JAN 03, 1986

N70146 001  
AUG 02, 1985

ACETAZOLAMIDE (PAGE 3-4)

TABLET; ORAL  
ACETAZOLAMIDE

AB DANBURY PHARMACAL 250MG

N88882 001  
OCT 22, 1985

ACETIC ACID, GLACIAL (PAGE 3-4)

SOLUTION/DROPS; OTIC  
BOROFAIR

AT PHARMAFAIR 2/4

N88606 001  
AUG 21, 1985

ACETOHEXAMIDE (PAGE 3-4)

TABLET; ORAL  
ACETOHEXAMIDE

AB COLMED LABORATORIES 250MG

AB 500MG

N70753 001  
NOV 03, 1986

N70754 001  
NOV 03, 1986

DIYEMELOR

AB ELI LILLY INDSTRS/PR 250MG

AB 500MG

N13378 002  
N13378 001

ACETYLCYSTEINE (PAGE 3-5)

SOLUTION; INHALATION  
MUCOMYST

AN MEAD JOHNSON/B-M 10%  
AN 20%

N13601 002  
N13601 001



AMINO ACIDS (PAGE 3-7)INJECTABLE; INJECTIONAMINOSYN-HBC 7% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 7/MN19400 001  
JUL 23, 1986

AMINOSYN-PF 7%

ABBOTT LABORATORIES 7/M

N19398 001  
SEP 06, 1985

AMINOSYN-PF 10%

ABBOTT LABORATORIES 10/M

N19492 001  
OCT 17, 1986

AMINOSYN II 3.5%

ABBOTT LABORATORIES 3.5/M

N19438 001  
APR 03, 1986

AMINOSYN II 3.5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 3.5/M

N19491 001  
OCT 10, 1986

AMINOSYN II 5%

ABBOTT LABORATORIES 5/M

N19438 002  
APR 03, 1986

AMINOSYN II 7%

ABBOTT LABORATORIES 7/M

N19438 003  
APR 03, 1986

AMINOSYN II 8.5%

ABBOTT LABORATORIES 8.5/M

N19438 004  
APR 03, 1986

AMINOSYN II 10%

ABBOTT LABORATORIES 10/M

N19438 005  
APR 03, 1986/NEOPHAM 6.4%/  
/KABIVITRUM/> DLT >  
> DLT >  
> DLT >  
> ADD >  
> ADD >  
> ADD >

NEOPHAM 6.4%

KABIVITRUM

6.4%

N18792 001  
JAN 17, 1984

NOVAMINE 15%

KABIVITRUM

15/M

N17957 004  
NOV 28, 1986AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE;  
PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM  
CHLORIDE (PAGE 3-8)INJECTABLE; INJECTION/PERITHAMINE/  
PROCALAMINE

KENDALL MCGAW LABS

3%; 26MG/100ML; 3GM/100ML; 54MG/100ML;  
41MG/100ML; 150MG/100ML; 200MG/100ML;  
120MG/100ML  
N18582 001  
MAY 08, 1982AMINO ACIDS; DEXTROSE (PAGE 3-8)INJECTABLE; INJECTIONAMINOSYN II 3.5% IN DEXTROSE 5% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 3.5%; 5GM/100MLMN19506 001  
NOV 07, 1986AMINOSYN II 3.5% IN DEXTROSE 25% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 3.5%; 25GM/100MLMN19505 001  
NOV 07, 1986AMINOSYN II 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 4.25%; 25GM/100MLMN19504 002  
NOV 07, 1986AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 5%; 25GM/100MLMN19565 001  
DEC 17, 1986AMINO ACIDS; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;  
POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE (PAGE 3-8)INJECTABLE; INJECTIONAMINOSYN II 3.5% W/ ELECTROLYTES IN DEXTROSE 25% IN PLASTIC  
CONTAINER

ABBOTT LABS

3.5%; 25GM/100ML; 51MG/100ML;  
22.4MG/100ML; 261MG/100ML;  
205MG/100ML  
N19564 002  
DEC 16, 1986AMINOSYN II 4.25% W/ ELECTROLYTES IN DEXTROSE 25% IN  
PLASTIC CONTAINER

ABBOTT LABS

4.25%; 25GM/100ML; 51MG/100ML;  
22.4MG/100ML; 261MG/100ML;  
205MG/100ML  
N19564 004  
DEC 16, 1986AMINO ACIDS; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;  
SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC (PAGE 3-8)INJECTABLE; INJECTIONAMINOSYN II 3.5% M IN DEXTROSE 5% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 3.5%; 5GM/100ML; 30MG/100ML;  
97MG/100ML; 120MG/100ML;  
49.3MG/100MLMN19564 001  
DEC 16, 1986AMINOSYN II 4.25% M IN DEXTROSE 10% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 4.25%; 10GM/100ML; 30MG/100ML;  
97MG/100ML; 120MG/100ML;  
49.3MG/100MLMN19564 003  
DEC 16, 1986

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC (PAGE 3-9)INJECTABLE; INJECTION

> DLT >  
> DLT >  
> DLT >  
> DLT >

AMINOSYN II 3.5% W/  
/ABBOTT LABORATORIES//1.5%:3.5%:100ML;128MG/100ML;  
/2.2%:100ML;49MG/100ML;119437 001  
/APR 03, 1986/

AMINOSYN II 3.5% M IN PLASTIC CONTAINER

ABBOTT LABORATORIES 3.5%:32MG/100ML;128MG/100ML;  
222MG/100ML;49MG/100ML N19493 001  
OCT 16, 1986

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE (PAGE 3-9)INJECTABLE; INJECTIONAMINOSYN II 7% W/ ELECTROLYTES

ABBOTT LABORATORIES 7%:102MG/100ML;45MG/100ML;  
522MG/100ML;410MG/100ML N19437 006  
APR 03, 1986

AMINOSYN II 8.5% W/ ELECTROLYTES

ABBOTT LABORATORIES 8.5%:102MG/100ML;45MG/100ML;  
522MG/100ML;410MG/100ML N19437 005  
APR 03, 1986

AMINOSYN II 10% W/ ELECTROLYTES

ABBOTT LABORATORIES 10%:102MG/100ML;45MG/100ML;  
522MG/100ML;410MG/100ML N19437 004  
APR 03, 1986

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-9)INJECTABLE; INJECTIONTRAVASOL M 3.5% W/ ELECTROLYTES

TRAVENOL LABS 3.5%:51MG/100ML;131MG/100ML;  
218MG/100ML;35MG/100ML N17493 003

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC; (PAGE 3-9)INJECTABLE; INJECTIONAMINOSYN II 3.5% M

ABBOTT LABORATORIES 3.5%:30MG/100ML;97MG/100ML;  
120MG/100ML;49MG/100ML N19437 007  
APR 03, 1986

AMINOCAPROIC ACID (PAGE 3-9)INJECTABLE; INJECTIONAMINOCAPROIC ACID

AP

LYPHOMED 250MG/ML

N70522 001  
JUN 17, 1986  
N70694 001  
MAR 04, 1986

AP

QUAD PHARMS 250MG/ML

AMINOPHYLLINE (PAGE 3-10)TABLET; ORALAMINOPHYLLINE

AB

CORD LABORATORIES 100MG

/BIO/ /CORD LABORATORIES/ /100MG/

N85262 002  
/N85262 002/

AMTODARONE HYDROCHLORIDE (PAGE 3-11)TABLET; ORAL

CORDARONE

IVES LABS/AMHO 200MG

N18972 001  
DEC 24, 1985

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE (PAGE 3-14)TABLET; ORALCHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

BARR LABORATORIES EQ 12.5MG BASE; 5MG

N70765 001  
DEC 10, 1986

BARR LABORATORIES EQ 25MG BASE; 10MG

N70766 001  
DEC 10, 1986

MYLAN PHARMS EQ 12.5MG BASE; 5MG

N71296 001  
DEC 10, 1986

MYLAN PHARMS EQ 25MG BASE; 10MG

N71297 001  
DEC 10, 1986

LITHBITROL

/HOFFMANN-LA ROCHE

HOFFMANN-LA ROCHE EQ 12.5MG BASE; 5MG

N16949 001  
DEC 10, 1986

HOFFMANN-LA ROCHE EQ 25MG BASE; 10MG

N16949 002

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE (PAGE 3-14)TABLET; ORALPERPHENAZINE AND AMITRIPTYLINE HCL

BARR LABORATORIES 10MG; 2MG

N71077 001  
NOV 12, 1986

BARR LABORATORIES 25MG; 2MG

N70297 001  
NOV 12, 1986

BARR LABORATORIES 10MG; 4MG

N71078 001  
NOV 12, 1986

BARR LABORATORIES 25MG; 4MG

N71079 001  
NOV 12, 1986

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE (PAGE 3-14)AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE (PAGE 3-14)TABLET; ORALPERPHENAZINE AND AMITRIPTYLINE HCL

|    |              |            |    |            |          |            |
|----|--------------|------------|----|------------|----------|------------|
| AB | TRIAXIL 2-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;2MG | N14715 004 |
| AB | TRIAXIL 2-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;2MG | N14715 002 |
| AB | TRIAXIL 4-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;4MG | N14715 003 |
| AB | TRIAXIL 4-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;4MG | N14715 005 |
| AB | TRIAXIL 4-50 | MS&D/MERCK | AB | MS&D/MERCK | 50MG;4MG | N14715 006 |

CHELSEA LABORATORIES

|    |              |            |    |            |          |            |
|----|--------------|------------|----|------------|----------|------------|
| AB | TRIAXIL 2-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;2MG | N14715 004 |
| AB | TRIAXIL 2-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;2MG | N14715 002 |
| AB | TRIAXIL 4-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;4MG | N14715 003 |
| AB | TRIAXIL 4-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;4MG | N14715 005 |
| AB | TRIAXIL 4-50 | MS&D/MERCK | AB | MS&D/MERCK | 50MG;4MG | N14715 006 |

PAR PHARMACEUTICAL

|    |              |            |    |            |          |            |
|----|--------------|------------|----|------------|----------|------------|
| AB | TRIAXIL 2-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;2MG | N14715 004 |
| AB | TRIAXIL 2-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;2MG | N14715 002 |
| AB | TRIAXIL 4-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;4MG | N14715 003 |
| AB | TRIAXIL 4-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;4MG | N14715 005 |
| AB | TRIAXIL 4-50 | MS&D/MERCK | AB | MS&D/MERCK | 50MG;4MG | N14715 006 |

ZENITH LABORATORIES

|    |              |            |    |            |          |            |
|----|--------------|------------|----|------------|----------|------------|
| AB | TRIAXIL 2-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;2MG | N14715 004 |
| AB | TRIAXIL 2-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;2MG | N14715 002 |
| AB | TRIAXIL 4-10 | MS&D/MERCK | AB | MS&D/MERCK | 10MG;4MG | N14715 003 |
| AB | TRIAXIL 4-25 | MS&D/MERCK | AB | MS&D/MERCK | 25MG;4MG | N14715 005 |
| AB | TRIAXIL 4-50 | MS&D/MERCK | AB | MS&D/MERCK | 50MG;4MG | N14715 006 |

TRIAXIL 2-10

|    |              |            |    |              |            |          |            |
|----|--------------|------------|----|--------------|------------|----------|------------|
| BP | TRIAXIL 2-10 | MS&D/MERCK | BP | TRIAXIL 2-10 | MS&D/MERCK | 10MG;2MG | N14715 004 |
| BP | TRIAXIL 2-25 | MS&D/MERCK | BP | TRIAXIL 2-25 | MS&D/MERCK | 25MG;2MG | N14715 002 |
| BP | TRIAXIL 4-10 | MS&D/MERCK | BP | TRIAXIL 4-10 | MS&D/MERCK | 10MG;4MG | N14715 003 |
| BP | TRIAXIL 4-25 | MS&D/MERCK | BP | TRIAXIL 4-25 | MS&D/MERCK | 25MG;4MG | N14715 005 |
| BP | TRIAXIL 4-50 | MS&D/MERCK | BP | TRIAXIL 4-50 | MS&D/MERCK | 50MG;4MG | N14715 006 |

AMOXICILLIN (PAGE 3-15)CAPSULE; ORALAMOXICILLINLABORATORIOS ATRAL

|    |             |       |            |
|----|-------------|-------|------------|
| AB | AMOXICILLIN | 250MG | N62528 001 |
| AB | AMOXICILLIN | 500MG | N62528 002 |
| AB | AMOXICILLIN | 500MG | N62528 002 |
| AB | AMOXICILLIN | 500MG | N62528 002 |

UTIMOXPARKE-DAVIS/M-LPOWDER FOR RECONSTITUTION; ORALUTIMOXPARKE-DAVIS/M-L

|    |        |           |            |
|----|--------|-----------|------------|
| AB | UTIMOX | 125MG/5ML | N62127 001 |
| AB | UTIMOX | 250MG/5ML | N62127 002 |
| AB | UTIMOX | 250MG/5ML | N62127 002 |
| AB | UTIMOX | 250MG/5ML | N62127 002 |

AMPICILLIN SODIUM (PAGE 3-17)INJECTABLE; INJECTIONAMPICILLIN SODIUMELI LILLY

|    |                   |                    |            |
|----|-------------------|--------------------|------------|
| AP | AMPICILLIN SODIUM | EQ 2GM BASE/VIAL   | N62565 003 |
| AP | AMPICILLIN SODIUM | EQ 125MG BASE/VIAL | N62692 001 |
| AP | AMPICILLIN SODIUM | EQ 250MG BASE/VIAL | N62692 002 |
| AP | AMPICILLIN SODIUM | EQ 500MG BASE/VIAL | N62692 003 |
| AP | AMPICILLIN SODIUM | EQ 1GM BASE/VIAL   | N62692 004 |
| AP | AMPICILLIN SODIUM | EQ 2GM BASE/VIAL   | N62692 005 |
| AP | AMPICILLIN SODIUM | EQ 10GM BASE/VIAL  | N62692 006 |

ELKINS-SINN/AHROBINSEQ 125MG BASE/VIALEQ 250MG BASE/VIALEQ 500MG BASE/VIALEQ 1GM BASE/VIALEQ 2GM BASE/VIALEQ 10GM BASE/VIALEQ 125MG BASE/VIALEQ 250MG BASE/VIALEQ 500MG BASE/VIALEQ 1GM BASE/VIALEQ 2GM BASE/VIALEQ 10GM BASE/VIAL

AMPICILLIN SODIUM (PAGE 3-17)INJECTABLE; INJECTIONOMITIPEN-NWYETH LABS/AMHO

> ADD > AP EQ 125MG BASE/VIALM N62718 001  
 > ADD > DEC 16, 1986  
 > ADD > AP EQ 250MG BASE/VIALM N62718 002  
 > ADD > DEC 16, 1986  
 > ADD > AP EQ 500MG BASE/VIALM N62718 003  
 > ADD > DEC 16, 1986  
 > ADD > AP EQ 1GM BASE/VIALM N62718 004  
 > ADD > DEC 16, 1986  
 > ADD > AP EQ 2GM BASE/VIALM N62718 005  
 > ADD > DEC 16, 1986

TOTACILLIN-NBEECHAM LABS/BEECHAM

> ADD > AP EQ 1GM BASE/VIALM N62727 001  
 > ADD > DEC 19, 1986  
 > ADD > AP EQ 2GM BASE/VIALM N62727 002  
 > ADD > DEC 19, 1986  
 > ADD > AP EQ 10GM BASE/VIAL N60677 006

> ADD > AMPICILLIN SODIUM; SULBACTAM SODIUM (PAGE 3-18)INJECTABLE; INJECTIONUNASYNPFIZER LABS/PFIZER

> ADD > EQ 500MG BASE/VIAL; N50608 003  
 > ADD > EQ 250MG BASE/VIAL DEC 31, 1986  
 > ADD > EQ 1GM BASE/VIAL; N50608 002  
 > ADD > EQ 500MG BASE/VIAL DEC 31, 1986  
 > ADD > EQ 2GM BASE/VIAL; N50608 001  
 > ADD > EQ 1GM BASE/VIAL DEC 31, 1986

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;  
 ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;  
 RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE;  
 VITAMIN A; VITAMINE E (PAGE 3-19)

INJECTABLE; INJECTIONM.V.I.-12 LYOPHILIZEDUSV PHARMACEUTICAL

100MG/VIAL; 0.06MG/VIAL; 0.05MG/VIAL  
 15MG/VIAL; 200 IU/VIAL; 0.4MG/VIAL;  
 40MG/VIAL; 4MG/VIAL; 3.6MG/VIAL;  
 3MG/VIAL; 3,300 IU/VIAL; 10 IU/VIALM  
 N18933 002  
 AUG 08, 1985

INJECTABLE; INJECTIONM.V.C. 9+3LYPHOMED

AP 10MG/MIL; 0.006MG/MIL; 0.5UGM/MIL;  
 1.5MG/MIL; 20 IU/MIL; 0.04MG/MIL; 4MG/MIL;  
 0.4MG/MIL; 0.36MG/MIL; 0.3MG/MIL;  
 330 IU/MIL; 1 IU/MILM N18440 002  
 AUG 08, 1985

M.V.I.-12USV PHARMACEUTICAL

AP 10MG/MIL; 0.006MG/MIL; 0.5UGM/MIL;  
 1.5MG/MIL; 20 IU/MIL; 0.04MG/MIL; 4MG/MIL;  
 0.4MG/MIL; 0.36MG/MIL; 0.3MG/MIL;  
 330 IU/MIL; 1 IU/MILM N08809 004  
 AUG 08, 1985

MVC PLUSASCOT HOSP PHARMS

AP 10MG/MIL; 0.006MG/MIL; 0.5UGM/MIL;  
 1.5MG/MIL; 20 IU/MIL; 0.04MG/MIL; 4MG/MIL;  
 0.4MG/MIL; 0.36MG/MIL; 0.3MG/MIL;  
 330 IU/MIL; 1 IU/MILM N18439 002  
 AUG 08, 1985

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;  
 ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;  
 HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE  
 HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN E (PAGE 3-19)

INJECTABLE; INJECTIONBEROCCA PNHOFFMANN-LA ROCHE

50MG/MIL; 0.03MG/MIL; 0.0025MG/MIL;  
 7.5MG/MIL; 100 IU/MIL; 0.2MG/MIL; 20MG/MIL;  
 2MG/MIL; 1.8MG/MIL; 1.5MG/MIL; 1.650 IU/MIL;  
 5 IU/MILM N06071 003  
 OCT 10, 1985

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)CAPSULE; ORALBUTALBITAL W/ ASPIRIN AND CAFFEINECHELSEA LABORATORIES 325MG; 50MG; 40MG

AB N86231 002  
 FEB 12, 1985

FIORINALSANDOZ PHARMS/SANDOZ 325MG; 50MG; 40MG

AB N17534 005  
 APR 16, 1986

LAMORINALLANNETT 325MG; 50MG; 40MG

AB N86996 002  
 OCT 11, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

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ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

TABLET; ORAL

BUTALBITAL W/ ASPIRIN AND CAFFEINE  
WEST-WARD 325MG;50MG;40MG

AB

N86162 002  
FEB 16, 1984

> ADD >  
> ADD >  
> ADD >

BUTALBITAL, ASPIRIN & CAFFEINE  
HALSEY DRUG 325MG;50MG;40MG

AB

N89448 001  
DEC 01, 1986

FLORINAL

SANDOZ PHARMS/SANDOZ 325MG;50MG;40MG

AB

N17534 003  
APR 16, 1986

LAHORINAL  
LANNETT 325MG;50MG;40MG

AB

N86986 002  
OCT 18, 1985

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL

CARISOPRODOL COMPOUND  
BOLAR PHARMACEUTICAL 325MG;200MG

AB

N88809 001  
OCT 03, 1985

SOMA COMPOUND

WALLACE PHARMS/C-W 325MG;200MG

AB

N12365 005  
JUL 11, 1983

ASPIRIN; MEPROBAMATE (PAGE 3-20)

TABLET; ORAL

MEPROBAMATE AND ASPIRIN  
PAR PHARMACEUTICAL 325MG;200MG

AB

N89126 001  
AUG 19, 1986

ASPIRIN; METHOCARBAMOL (PAGE 3-20)

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN  
MCNEIL CONSUMER PROD 325MG;400MG

AB

N89193 001  
FEB 12, 1986

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE (PAGE 3-20)

TABLET; ORAL

/OXYCODONE AND ASPIRIN (FULL-STRENGTH)  
ROXIAPRIN

AA

ROXANE LABORATORIES 325MG;4.5MG;0.38MG  
JUN 04, 1982

> ADD > AZTREONAM (PAGE 3-22)

> ADD > INJECTABLE; INJECTION  
> ADD > AZACTAM  
> ADD > ER SQUIBB AND SONS  
> ADD > 500MG/VIALM

500MG/VIALM

N50580 001  
DEC 31, 1986

1GM/VIALM

N50580 002  
DEC 31, 1986

2GM/VIALM

N50580 003  
DEC 31, 1986

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-23)

ointment; TOPICAL

CORTISPORIN  
BURROUGHS WELLCOME 400 UNITS/GM;12;EQ 3.5MG BASE/GM;  
5,000 UNITS/GM N50168 002  
MAY 04, 1985

AI

NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE  
PHARMAFAIR 400 UNITS/GM;12;EQ 3.5MG BASE/GM;  
5,000 UNITS/GM N62381 001  
SEP 06, 1985

AI

BENZYL PENICILLOYL-POLYLYSINE (PAGE 3-25)

INJECTABLE; INJECTION

PRE-PEN  
/KREMER-SUREAN/  
SCHWARZ PHARMS 60 UMOLAR  
/N50114;001/  
N50114 001

BETAMETHASONE BENZOATE (PAGE 3-25)

CREAM; TOPICAL

/BENSONE/  
/PARKE-DAVIS/M-L/  
UTICORT 0.025%  
PARKE-DAVIS/M-L  
/N16998;001/  
N16998 002

GEL; TOPICAL

/BENSONE/  
UTICORT

ointment; TOPICAL

/BENSONE/  
UTICORT

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL

BX DIPROLENE

SCHERING EQ 0.05% BASEM

N19408 001  
JAN 31, 1986

LOTION; TOPICAL

AB ALPHATREX

SAVAGE LABS/ALTANA EQ 0.05% BASEM

N70273 001  
AUG 12, 1985

BETAMETHASONE DIPROPIONATE

AB E FOUGERA/ALTANA EQ 0.05% BASEM

N70275 001  
AUG 12, 1985

AB PHARMADERM/ALTANA EQ 0.05% BASEM

N70274 001  
AUG 12, 1985

BETAMETHASONE VALERATE (PAGE 3-26)

CREAM; TOPICAL

AB BETAMETHASONE VALERATE

CLAY-PARK LABS EQ 0.1% BASEM

N70053 001  
JUN 10, 1986

ointment; TOPICAL

AB BETA-VAL

LEMMON EQ 0.1% BASEM

N70069 001  
DEC 19, 1985

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC

BETOPTIC

ALCON LABORATORIES EQ 0.5% BASEM

N19270 001  
AUG 30, 1985

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL

AA BETHANECHOL CHLORIDE

SIDMAK LABORATORIES 5MGM

N89095 001  
DEC 19, 1985

AA 50MGM

N89096 001  
DEC 19, 1985

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

AP ABBOTT LABORATORIES 50MG/MLM

N19033 001  
APR 29, 1986 : APR 16, 1986

AP ELKINS-SINN/AHROBINS 50MG/MLM

MAY 14, 1986  
N70545 001

AP 50MG/MLM

MAY 14, 1986  
N70546 001

AP INTL MEDICATION SYS 50MG/MLM

N70119 001  
APR 29, 1986 : MAR 06, 1986

AP LYPHOMED 50MG/MLM

N70134 001  
APR 29, 1986 : FEB 12, 1986

BRETYLIUM TOSYLATE IN PLASTIC CONTAINER

AP ABBOTT LABORATORIES 50MG/MLM

N19030 001  
APR 29, 1986 : APR 16, 1986

BRETYLOL

AP AM CRITICAL CARE/AHS 50MG/ML

N17954 001

BRETYLIUM TOSYLATE; DEXTROSE (PAGE 3-28)

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE IN DEXTROSE 5%

AP ABBOTT LABORATORIES 200MG/100ML; 5GM/100MLM

N19005 002  
APR 29, 1986 : APR 16, 1986

AP 400MG/100ML; 5GM/100MLM

N19005 003  
APR 29, 1986 : APR 16, 1986

AP 800MG/100MG; 5GM/100MLM

N19005 001  
APR 29, 1986 : APR 16, 1986

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT LABORATORIES 200MG/100ML; 5GM/100MLM

N19008 002  
APR 29, 1986 : APR 16, 1986

AP 400MG/100ML; 5GM/100MLM

N19008 003  
APR 29, 1986 : APR 16, 1986

AP 800MG/100MG; 5GM/100MLM

N19008 001  
APR 29, 1986 : APR 16, 1986

KENDALL MCGAW LABS

100MG/100ML; 5GM/100MLM

N19121 001  
APR 29, 1986

AP 200MG/100ML; 5GM/100MLM

N19121 002  
APR 29, 1986

AP 400MG/100ML; 5GM/100MLM

APR 29, 1986  
N19121 003

APR 29, 1986

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE  
(PAGE 3-28)

SYRUP; ORAL

AMBENYL

/AA/ /MARION LABORATORIES//12.5MG/5ML;10MG/5ML/

/N09319,006/

/JAN 10, 1984/

N09319 006

JAN 10, 1984

AA FOREST LABORATORIES 12.5MG/5ML;10MG/5ML

TABLET; ORAL

BUSPAR

BRISTOL LABS/B-M

5MG

N18731 001

SEP 29, 1986

N18731 002

SEP 29, 1986

10MG

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE  
(PAGE 3-29)

/TABLET; CONTROLLED RELEASE; ORAL

/DINE-TAPP/

/MR. ROBINS/

/12MG;75MG/

/N18436,001/

/APR 02, 1984/

BUPIVACAINE HYDROCHLORIDE (PAGE 3-29)

INJECTABLE; INJECTION

SENSORCAINE

ASTRA PHARM PRODS

0.25/M

N70552 001

MAY 21, 1986

0.5/M

N70553 001

MAY 21, 1986

0.75/M

N70554 001

MAY 21, 1986

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION

MARCINE SPINAL

3 WINTHROP-BREON/STERL 0.75%;8.25%

N18692 001

MAY 04, 1984

BUPROPION HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL

WELLBUTRIN

3 BURROUGHS WELLCOME

50MG

N18644 001

DEC 30, 1985

75MG

N18644 002

DEC 30, 1985

100MG

N18644 003

DEC 30, 1985

BUSPIRONE HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL

BUSPAR

BRISTOL LABS/B-M

5MG

N18731 001

SEP 29, 1986

N18731 002

SEP 29, 1986

10MG

BUTOCONAZOLE NITRATE (PAGE 3-31)

CREAM; VAGINAL

FEMSTAT

SYNTEX LABS/SYNTEX

2/M

N19215 001

NOV 25, 1985

SUPPOSITORY; VAGINAL

FEMSTAT

SYNTEX LABS/SYNTEX

100MG

N19359 001

NOV 25, 1985

/CALCIFEDIOL; ANHYDROUS (PAGE 3-31)

CALCIFEDIOL; ANHYDROUS (PAGE 3-31)

CALCITONIN, HUMAN (PAGE 3-31)

INJECTABLE; INJECTION

CIBACALCIN

CIBA/CIBA-GEIGY

0.5MG/VIAL

N18470 001

OCT 31, 1986

CALCITONIN, SALMON (PAGE 3-31)

INJECTABLE; INJECTION

MICALCIN

SANDOZ PHARMS/SANDOZ

100 IU/ML

N17808 001

JUL 03, 1986

CALCITROL (PAGE 3-31)

INJECTABLE; INJECTION

CALCIJEX

ABBOTT LABORATORIES

0.001MG/ML

N18874 001

SEP 25, 1986

0.002MG/ML

N18874 002

SEP 25, 1986

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL  
DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER  
KENDALL MCGAW LABS 29MG/100ML; 2.5GM/100ML;  
15MG/100ML; 610MG/100ML;  
560MG/100MLM N18460 006  
JAN 29, 1986

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL  
DIALYTE W/ DEXTROSE 1.5% IN PLASTIC CONTAINER  
KENDALL MCGAW LABS 26MG/100ML; 1.5GM/100ML;  
5MG/100ML; 530MG/100ML;  
450MG/100MLM N18460 007  
JAN 29, 1986

DIALYTE W/ DEXTROSE 2.5% IN PLASTIC CONTAINER  
KENDALL MCGAW LABS 26MG/100ML; 2.5GM/100ML;  
5MG/100ML; 530MG/100ML;  
450MG/100MLM N18460 008  
JAN 29, 1986

DIALYTE W/ DEXTROSE 4.25% IN PLASTIC CONTAINER  
KENDALL MCGAW LABS 26MG/100ML; 4.25GM/100ML;  
5MG/100ML; 530MG/100ML;  
450MG/100MLM N18460 009  
JAN 29, 1986

DIANEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER  
TRAVENOL LABS 25.7MG/100ML; 3.5GM/100ML;  
15.2MG/100ML; 567MG/100ML;  
392MG/100MLM N17512 010  
NOV 18, 1985

DIANEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER  
TRAVENOL LABS 25.7MG/100ML; 3.5GM/100ML;  
5.08MG/100ML; 538/100ML;  
448MG/100MLM N17512 011  
NOV 18, 1985

CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL  
INPERSOL-ZM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 25.7MG/100ML; 1.5GM/100ML;  
538MG/100ML; 448MG/100MLM N19395 001  
MAR 26, 1986

INPERSOL-ZM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 25.7MG/100ML; 2.5GM/100ML;  
538MG/100ML; 448MG/100MLM N19395 002  
MAR 26, 1986

CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-32)

SOLUTION; INTRAPERITONEAL  
INPERSOL-ZM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 25.7MG/100ML; 4.25GM/100ML;  
538MG/100ML; 448MG/100MLM N19395 003  
MAR 26, 1986

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE SODIUM ACETATE; SODIUM CHLORIDE (PAGE 3-34)

INJECTABLE; INJECTION  
TPN ELECTROLYTES IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 16.5MG/ML; 25.4MG/ML; 74.6MG/ML;  
121MG/ML; 16.1MG/MLM N19399 001  
JUN 16, 1986  
16.5MG/ML; 25.4MG/ML; 74.6MG/ML;  
121MG/ML; 16.1MG/ML N18895 001  
JUL 20, 1986

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE (PAGE 3-35)

INJECTABLE; INJECTION  
LACTATED RINGER'S IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 20MG/100ML; 30MG/100ML; 600MG/100ML;  
310MG/100MLM N19485 001  
OCT 24, 1985

SOLUTION; IRRIGATION  
LACTATED RINGER'S IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 20MG/100ML; 30MG/100ML; 600MG/100ML;  
310MG/100MLM N19416 001  
JAN 17, 1986

CAPTOPRIL (PAGE 3-36)

TABLET; ORAL  
CAPOTEN  
ER SQUIBB AND SONS 37.5MGM N18343 006  
SEP 17, 1986

CARBACHOL (PAGE 3-36)

INJECTABLE; INJECTION

AP CARBACHOL  
PHARMAFAIR 0.01% N70292 001  
MAY 21, 1986

AP MIOSTAT  
ALCON LABORATORIES 0.01% N16968 001

CARBAMAZEPINE (PAGE 3-36)

## TABLET; ORAL

CARBAMAZEPINE

AB COLMED LABORATORIES 200MG

AB INWOOD LABS/FOREST 200MG

EPITOL

AB LEMMON 200MG

TEGRETOL

AB GEIGY/CIBA-GEIGY 200MG

CARNITINE, L- (PAGE 3-37)

## SOLUTION; ORAL

VITACARN

KENDALL MCGAW LABS 1GM/10ML

## TABLET; ORAL

L-CARNITINE/CARNITOR

SIGMA-TAU 330MG

CEFAMANDOLE NAFATE (PAGE 3-37)

## INJECTABLE; INJECTION

MANDOLELI LILLY

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

CEFAZOLIN SODIUM (PAGE 3-38)

## INJECTABLE; INJECTION

CEFAZOLIN SODIUMLYPHOMED

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 10GM BASE/VIAL

CEFAZOLIN SODIUM (PAGE 3-38)

## INJECTABLE; INJECTION

KEFZOLELI LILLY

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

N62557 001  
SEP 10, 1985  
N62557 002  
SEP 10, 1985CEFOPERAZONE SODIUM; DEXTROSE (PAGE 3-38)

## INJECTABLE; INJECTION

CEFOBID IN PLASTIC CONTAINERROERIG/PFIZEREQ 40MG BASE/ML; 36MG/ML  
N50613 001  
JUL 23, 1986CEFOTETAN DISODIUM (PAGE 3-38)

## INJECTABLE; INJECTION

CEFOTANSTUART PHARMS/ICI

EQ 1GM BASE/VIAL

N50588 001  
DEC 27, 1985  
N50588 002  
DEC 27, 1985CEFTAZIDIME (PAGE 3-39)

## INJECTABLE; INJECTION

FORTAZGLAXO

EQ 500MG/VIAL

EQ 1GM/VIAL

EQ 2GM/VIAL

EQ 6GM/VIAL

N50578 001  
JUL 19, 1985  
N50578 002  
JUL 19, 1985  
N50578 003  
JUL 19, 1985  
N50578 004  
JUL 19, 1985TAZICEF

## INJECTABLE; INJECTION

SK&F LABORATORIES

EQ 500MG/VIAL

EQ 1GM/VIAL

EQ 2GM/VIAL

EQ 6GM/VIAL

N62662 001  
MAR 06, 1986  
N62662 002  
MAR 06, 1986  
N62662 003  
MAR 06, 1986  
N62662 004  
MAR 06, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

## CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION

|    |           |             |              |    |                       |                   |              |
|----|-----------|-------------|--------------|----|-----------------------|-------------------|--------------|
| AP | ELI LILLY | 500MG/VIALM | N62640 001   | AP | INJECTABLE; INJECTION | EQ 1GM BASE/VIALM | N62547 001   |
| AP |           | 1GM/VIALM   | NOV 20, 1985 | AP | CEPHALOTHIN SODIUM    | EQ 1GM BASE/VIALM | SEP 11, 1985 |
| AP |           | 1GM/VIALM   | NOV 20, 1985 | AP | ABBOTT LABORATORIES   | EQ 1GM BASE/VIALM | N62548 001   |
| AP |           | 2GM/VIALM   | NOV 20, 1985 | AP |                       | EQ 2GM BASE/VIALM | SEP 11, 1985 |
| AP |           | 2GM/VIALM   | NOV 20, 1985 | AP |                       | EQ 2GM BASE/VIALM | N62547 002   |
| AP |           | 2GM/VIALM   | NOV 20, 1985 | AP |                       | EQ 2GM BASE/VIALM | SEP 11, 1985 |
| AP |           | 2GM/VIALM   | NOV 20, 1985 | AP |                       | EQ 2GM BASE/VIALM | N62548 002   |
| AP |           | 2GM/VIALM   | NOV 20, 1985 | AP |                       | EQ 2GM BASE/VIALM | SEP 11, 1985 |

TAXIDIME IN PLASTIC CONTAINER

|    |           |           |              |    |                             |                   |              |
|----|-----------|-----------|--------------|----|-----------------------------|-------------------|--------------|
| AP | ELI LILLY | 1GM/VIALM | N62739 001   | AP | KEFLIN IN PLASTIC CONTAINER | EQ 1GM BASE/VIALM | N62549 001   |
| AP |           | 2GM/VIALM | JUL 10, 1986 | AP | ELI LILLY                   | EQ 1GM BASE/VIALM | SEP 10, 1985 |
| AP |           | 2GM/VIALM | N62739 002   | AP |                             | EQ 2GM BASE/VIALM | N62549 002   |
| AP |           | 2GM/VIALM | JUL 10, 1986 | AP |                             | EQ 2GM BASE/VIALM | SEP 10, 1985 |

## CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

|    |           |                     |              |    |                       |                     |              |
|----|-----------|---------------------|--------------|----|-----------------------|---------------------|--------------|
| AP | ELI LILLY | EQ 750MG BASE/VIALM | N62591 001   | AP | INJECTABLE; INJECTION | EQ 500MG BASE/VIALM | N50446 005   |
| AP |           | EQ 750MG BASE/VIALM | JAN 10, 1986 | AP | CEFADYL               | EQ 1GM BASE/VIALM   | N50446 001   |
| AP |           | EQ 1.5GM BASE/VIALM | N62592 001   | AP | BRISTOL LABS/B-M      | EQ 1GM BASE/VIALM   | N61769 001   |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                       | EQ 1GM BASE/VIALM   | N62724 001   |
| AP |           | EQ 1.5GM BASE/VIALM | N62591 002   | AP |                       | EQ 2GM BASE/VIALM   | DEC 23, 1986 |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                       | EQ 2GM BASE/VIALM   | N50446 002   |
| AP |           | EQ 1.5GM BASE/VIALM | N62592 002   | AP |                       | EQ 2GM BASE/VIALM   | N61769 002   |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                       | EQ 2GM BASE/VIALM   | N62724 002   |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                       | EQ 4GM BASE/VIALM   | DEC 23, 1986 |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                       | EQ 20GM BASE/VIALM  | N50446 003   |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                       | EQ 20GM BASE/VIALM  | N50446 004   |

KEFUROX IN PLASTIC CONTAINER

|    |           |                     |              |    |                   |                     |              |
|----|-----------|---------------------|--------------|----|-------------------|---------------------|--------------|
| AP | ELI LILLY | EQ 750MG BASE/VIALM | N62590 001   | AP | CEPHAPIRIN SODIUM | EQ 500MG BASE/VIALM | N62723 001   |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP | LYPHOMED          | EQ 1GM BASE/VIALM   | NOV 17, 1986 |
| AP |           | EQ 1.5GM BASE/VIALM | N62590 002   | AP |                   | EQ 2GM BASE/VIALM   | N62723 002   |
| AP |           | EQ 1.5GM BASE/VIALM | JAN 10, 1986 | AP |                   | EQ 2GM BASE/VIALM   | NOV 17, 1986 |
| AP |           | EQ 1.5GM BASE/VIALM | N50558 002   | AP |                   | EQ 4GM BASE/VIALM   | N62723 003   |
| AP |           | EQ 1.5GM BASE/VIALM | OCT 19, 1983 | AP |                   | EQ 4GM BASE/VIALM   | NOV 17, 1986 |
| AP |           | EQ 1.5GM BASE/VIALM | N50558 003   | AP |                   | EQ 20GM BASE/VIALM  | N62723 004   |
| AP |           | EQ 1.5GM BASE/VIALM | OCT 19, 1986 | AP |                   | EQ 20GM BASE/VIALM  | NOV 17, 1986 |
| AP |           | EQ 1.5GM BASE/VIALM | OCT 19, 1986 | AP |                   | EQ 20GM BASE/VIALM  | N62723 005   |
| AP |           | EQ 1.5GM BASE/VIALM | OCT 19, 1986 | AP |                   | EQ 20GM BASE/VIALM  | NOV 17, 1986 |

## CEPHALEXIN (PAGE 3-40)

TABLET; ORAL

|         |           |                |              |         |
|---------|-----------|----------------|--------------|---------|
| > ADD > | KEFLET    | EQ 250MG BASEM | N62745 001   | > ADD > |
| > ADD > | ELI LILLY | EQ 500MG BASEM | DEC 01, 1986 | > ADD > |
| > ADD > |           |                | N62745 002   | > ADD > |
| > ADD > |           |                | DEC 01, 1986 | > ADD > |

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC

CHLORAMPHENICOL  
CARTER-GLOGAU LABS 0.5%M

N62628 001  
SEP 25, 1985

N89139 001  
JUL 16, 1986  
N88902 001  
SEP 19, 1985  
N88903 001  
SEP 19, 1985

CHLORHEXIDINE GLUCONATE (PAGE 3-44)

SOLUTION; DENTAL

PERIDEX  
PROCTER AND GAMBLE 0.12%M

N19028 001  
AUG 13, 1986

CHROMIC CHLORIDE (PAGE 3-50)

INJECTABLE; INJECTION  
CHROMIC CHLORIDE IN PLASTIC CONTAINER  
ABBOTT LABORATORIES EQ 0.004MG CHROMIUM/MLM

CHLORPHENTRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE  
(PAGE 3-46)

CAPSULE, CONTROLLED RELEASE; ORAL  
DRIZE

BC BF ASCHER 12MG;75MGM

N88359 001  
FEB 13, 1986

BC ORNADE SK&F LABORATORIES 12MG;75MG

N12152 004

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL

CHLORPROPAMIDE  
BARR LABORATORIES 100MGM

N89446 001

NOV 17, 1986

AB N89447 001 250MGM

NOV 17, 1986

AB N89321 001 100MGM

JAN 16, 1986

AB N88662 001 250MGM

JAN 09, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL

CHLORTHALIDONE  
MUTUAL PHARM 25MGM

N89285 001

JUL 21, 1986

AB N89286 001 50MGM

JUL 21, 1986

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL

CHLORTHALIDONE  
PUREPAC/KALIPHARMA 25MGM

AB

AB SIDMAK LABORATORIES 25MGM

AB 50MGM

INJECTABLE; INJECTION  
CHROMIC CHLORIDE IN PLASTIC CONTAINER  
ABBOTT LABORATORIES EQ 0.004MG CHROMIUM/MLM

N18961 001  
JUN 26, 1986

CHYMOPAPAIN (PAGE 3-50)

INJECTABLE; INJECTION  
CHYMOTRYPSIN

/SWIFT LABORATORIES/ 1/4,000 UNITS/VIAL/  
/10,000 UNITS/VIAL/

TRAVENOL LABS 4,000 UNITS/VIAL  
10,000 UNITS/VIAL

/N18663,002/  
/AUG 21, 1984/  
/N18663,001/  
/NOV 10, 1982/  
N18663 002  
AUG 21, 1984  
N18663 001  
NOV 10, 1982

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION  
PRIMAXIN

MS&D RES LABS/MERCK EQ 250MG BASE/VIAL;  
250MG/VIALM

N50587 001  
NOV 26, 1985

EQ 500MG BASE/VIAL;  
500MG/VIALM

N50587 002  
NOV 26, 1985

CIMETIDINE (PAGE 3-50)

TABLET; ORAL

TAGAMET  
SK&F LAB

800MGM

N17920 005  
APR 30, 1986

CIMETIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-50)INJECTABLE; INJECTION

TAGAMET IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
SK&F LAB  
EQ 6MG BASE/ML; 9MG/ML  
N19434 001  
OCT 31, 1985

CLONIDINE HYDROCHLORIDE (PAGE 3-52)TABLET; ORAL

CATAPRES  
BOEHRINGER INGELHEIM  
0.1MG  
0.2MG  
0.3MG  
N17407 001  
N17407 002  
N17407 003

CLONIDINE HCL  
AM THERAPEUTICS  
0.1MG  
0.2MG  
0.3MG  
N70881 001  
JUL 08, 1986 : MAY 27, 1986  
N70882 001  
JUL 08, 1986 : MAY 27, 1986  
N70883 001  
JUL 08, 1986 : MAY 27, 1986  
N70747 001  
JUL 08, 1986 : MAR 20, 1986  
N70702 001  
JUL 08, 1986 : MAR 20, 1986  
N70659 001  
JUL 08, 1986 : MAR 20, 1986  
N70965 001  
JUL 08, 1986 : JUL 01, 1986  
N70964 001  
JUL 08, 1986 : JUL 01, 1986  
N70963 001  
JUL 08, 1986 : JUL 01, 1986  
N71103 001  
AUG 14, 1986  
N71102 001  
AUG 14, 1986  
N71101 001  
AUG 14, 1986  
N71252 001  
OCT 01, 1986  
N71253 001  
OCT 01, 1986  
N71254 001  
OCT 01, 1986  
N70461 001  
JUL 08, 1986 : NOV 22, 1985  
N70460 001  
JUL 08, 1986 : NOV 22, 1985  
N70459 001  
JUL 08, 1986 : NOV 22, 1985  
N70974 001  
DEC 16, 1986  
N70975 001  
DEC 16, 1986  
N70976 001  
DEC 16, 1986

CLINDAMYCIN PALMITATE HYDROCHLORIDE (PAGE 3-51)POWDER FOR RECONSTITUTION; ORAL

CLEOCIN  
UP JOHN  
EQ 75MG BASE/5ML  
N62644 001  
APR 07, 1986  
N61827 001

CLOBETASOL PROPIONATE (PAGE 3-51)CREAM; TOPICAL

TEMOVATE  
GLAXO  
0.05%  
N19322 001  
DEC 27, 1985

ointment; TOPICAL

TEMOVATE  
GLAXO  
0.05%  
N19323 001  
DEC 27, 1985

> ADD > CLOFAZIMINE (PAGE 3-51)CAPSULE; ORAL

LAMPRENE  
GEIGY/CIBA-GEIGY  
50MG  
100MG  
N19500 002  
DEC 15, 1986  
N19500 001  
DEC 15, 1986

CLOFIBRATE (PAGE 3-51)CAPSULE; ORAL

ATROMID-S  
AYERST LABS/AMHO  
CLOFIBRATE  
FORMUTEC  
500MG  
500MG  
N16099 002  
N70531 001  
JUN 16, 1986

CLONAZEPAM (PAGE 3-52)TABLET; ORAL

CLONOPIN  
KLOPIN  
HOFFMANN-LA ROCHE  
0.5MG  
1MG  
2MG  
N17533 001  
N17533 002  
N17533 003

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)

|                                                                                          |                            |                                   |                            |
|------------------------------------------------------------------------------------------|----------------------------|-----------------------------------|----------------------------|
| SYRUP; ORAL                                                                              |                            |                                   |                            |
| AA                                                                                       | PROMETHAZINE VC W/ CODEINE |                                   |                            |
|                                                                                          | HR CENCI LABS              | 10MG/5ML; 5MG/5ML;<br>6.25MG/5ML  | N88816 001<br>NOV 22, 1985 |
| CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)                                |                            |                                   |                            |
| SYRUP; ORAL                                                                              |                            |                                   |                            |
| AA                                                                                       | PROMETHAZINE W/ CODEINE    |                                   |                            |
|                                                                                          | HR CENCI LABS              | 10MG/5ML; 6.25MG/5ML              | N88814 001<br>NOV 22, 1985 |
| CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-53) |                            |                                   |                            |
| SYRUP; ORAL                                                                              |                            |                                   |                            |
| AA                                                                                       | HISTAFED C                 |                                   |                            |
|                                                                                          | LIFE LABORATORIES          | 10MG/5ML; 30MG/5ML;<br>1.25MG/5ML | N89018 001<br>JUL 23, 1986 |
| COPPER (PAGE 3-54)                                                                       |                            |                                   |                            |
| INTRAUTERINE DEVICE; INTRAUTERINE                                                        |                            |                                   |                            |
| CU-7                                                                                     | SEARLE PHARMS              | 89MG                              | N17408 001                 |
|                                                                                          | TATUM-T                    |                                   |                            |
| SEARLE PHARMS                                                                            |                            | 120MG                             | N18205 001                 |
|                                                                                          |                            |                                   |                            |
| CROMOLYN SODIUM (PAGE 3-55)                                                              |                            |                                   |                            |
| AEROSOL; INHALATION                                                                      |                            |                                   |                            |
| INTAL                                                                                    |                            |                                   |                            |
|                                                                                          | FISONS                     | 0.8MG/INH                         | N18887 001<br>DEC 05, 1985 |
| CUPRIC CHLORIDE (PAGE 3-55)                                                              |                            |                                   |                            |
| INJECTABLE; INJECTION                                                                    |                            |                                   |                            |
| CUPRIC CHLORIDE IN PLASTIC CONTAINER                                                     |                            |                                   |                            |
|                                                                                          | ABBOTT LABORATORIES        | EQ 0.4MG COPPER/ML                | N18960 001<br>JUN 26, 1986 |

CYCLOPHOSPHAMIDE (PAGE 3-57)

|                              |                      |            |                                           |
|------------------------------|----------------------|------------|-------------------------------------------|
| INJECTABLE; INJECTION        |                      |            |                                           |
| CYCLOPHOSPHAMIDE             |                      |            |                                           |
| AP                           | ELKINS-SINN/AHROBINS | 100MG/VIAL | N88371 001<br>JUL 03, 1986                |
|                              |                      |            | N88372 001<br>JUL 03, 1986                |
| AP                           |                      | 200MG/VIAL | N88373 001<br>JUL 03, 1986                |
|                              |                      |            | N88374 001<br>JUL 03, 1986                |
| AP                           |                      | 1GM/VIAL   | N88374 001<br>SEP 24, 1986 : JUL 03, 1986 |
|                              |                      |            |                                           |
| CYTOSAN                      |                      |            |                                           |
| AP                           | BRISTOL LABS/B-M     | 2GM/VIAL   | N12142 005<br>AUG 30, 1982                |
|                              |                      |            |                                           |
| LYOPHILIZED CYCLOPHOSPHAMIDE |                      |            |                                           |
| AP                           | LYPHOMED             | 100MG/VIAL | N89194 001<br>AUG 27, 2002 : JUL 07, 1986 |
|                              |                      |            | N89195 001<br>AUG 27, 2002 : JUL 07, 1986 |
| AP                           |                      | 200MG/VIAL | N89196 001<br>AUG 27, 2002 : JUL 07, 1986 |
|                              |                      |            |                                           |
| LYOPHILIZED CYTOSAN          |                      |            |                                           |
| AP                           | BRISTOL LABS/B-M     | 100MG/VIAL | N12142 006<br>DEC 05, 1985                |
|                              |                      |            | N12142 007<br>DEC 10, 1985                |
| AP                           |                      | 200MG/VIAL | N12142 008<br>JAN 04, 1984                |
|                              |                      |            | N12142 010<br>SEP 24, 1985                |
| AP                           |                      | 1GM/VIAL   | N12142 009<br>DEC 10, 1984                |
|                              |                      |            |                                           |

CYPROHEPTADINE HYDROCHLORIDE (PAGE 3-58)

|              |                    |         |                            |
|--------------|--------------------|---------|----------------------------|
| SYRUP; ORAL  |                    |         |                            |
| AA           | CYPROHEPTADINE HCL |         |                            |
|              | HALSEY DRUG        | 2MG/5ML | N89199 001<br>JUL 03, 1986 |
| TABLET; ORAL |                    |         |                            |
| AA           | CYPROHEPTADINE HCL |         |                            |
|              | HALSEY DRUG        | 4MG     | N89057 001<br>JUL 03, 1986 |

CYSTEINE HYDROCHLORIDE (PAGE 3-58)

|                       |            |        |                            |
|-----------------------|------------|--------|----------------------------|
| INJECTABLE; INJECTION |            |        |                            |
| CYSTEINE HCL          |            |        |                            |
|                       | KABIVITRUM | 7.25/M | N19523 001<br>OCT 22, 1986 |

DACARBAZINE (PAGE 3-58)INJECTABLE; INJECTION

DACARBAZINE  
LYPHOMED

100MG/VIALM

N70962 001  
AUG 28, 1986

200MG/VIALM

N70990 001  
AUG 28, 1986

100MG/VIALM

N70821 001  
OCT 09, 1986

200MG/VIALM

N70822 001  
OCT 09, 1986

DTIC-DOME

MILES PHARMS/MILES

100MG/VIAL

N17575 001

200MG/VIAL

N17575 002

DEXAMETHASONE (PAGE 3-60)ELIXIR; ORAL

DEXAMETHASONE

NASKA PHARMACAL

0.5MG/5MLM

N88997 001  
OCT 10, 1986

DEXAMETHASONE SODIUM PHOSPHATE (PAGE 3-62)INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

CARTER-GLOGAU LABS

EQ 4MG PHOSPHATE/MLM

N89169 001

APR 09, 1986

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE (PAGE 3-63)SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

CARTER-GLOGAU LABS

EQ 0.1% PHOSPHATE;  
EQ 3.5MG BASE/MLM

N62714 001

JUL 21, 1986

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-62)SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

CARTER-GLOGAU LABS

0.1%; EQ 3.5MG BASE/ML;  
10,000 UNITS/MLM

N62721 001

NOV 17, 1986

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)TABLET; ORAL

DEXCHLORPHENIRAMINE MALEATE

SIDHAK LABORATORIES

2MG

N88682 001  
JAN 17, 1986

POLARAMINE

SCHERING

2MG

N86835 001

DEXTROSE (PAGE 3-64)INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES

5GM/100MLM

N19479 001  
SEP 17, 1985

N16673 003  
OCT 30, 1985

TRAVENOL LABS

50MG/MLM

N19445 001  
JUN 03, 1986

DEXTROSE 50% IN PLASTIC CONTAINER

ABBOTT LABORATORIES

500MG/MLM

DEXTROSE; DOPAMINE HYDROCHLORIDE (PAGE 3-65)INJECTABLE; INJECTION

DOPAMINE HCL IN DEXTROSE 5%

KENDALL MCGAW LABS

5GM/100ML; 40MG/100MLM

N19099 001

OCT 15, 1986

N19099 002

OCT 15, 1986

N19099 003

OCT 15, 1986

190990 004

OCT 15, 1986

DOPAMINE HCL IN PLASTIC CONTAINER

ABBOTT LABORATORIES

5GM/100ML; 320MG/100ML

N18826 003

SEP 30, 1983

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)INJECTABLE; INJECTION

LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES

5GM/100ML; 200MG/100MLM

N18954 001

JUL 09, 1985

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM

PHOSPHATE, DIBASIC; SODIUM CHLORIDE; SODIUM LACTATE;

SODIUM PHOSPHATE, MONOBASIC (PAGE 3-66)

INJECTABLE; INJECTION

IONOSOL B AND DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES

5GM/100ML; 53MG/100ML; 100MG/100ML;

100MG/100ML; 180MG/100ML;

280MG/100ML; 16MG/100MLM

N19515 001

MAY 08, 1986

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC (PAGE 3-66)

INJECTABLE; INJECTION  
 IONOSOL MB AND DEXTROSE 5% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 30MG/100ML; 141MG/100ML;  
 15MG/100ML; 260MG/100ML; 25MG/100ML  
 N19513 001  
 MAY 08, 1986

DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM LACTATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, MONOBASIC (PAGE 3-66)

INJECTABLE; INJECTION  
 IONOSOL T AND DEXTROSE 5% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 111MG/100ML; 256MG/100ML;  
 146MG/100ML; 207MG/100ML; 19514 001  
 MAY 08, 1986

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-68)

INJECTABLE; INJECTION  
 DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE  
 0.075% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 74.5MG/100ML;  
 300MG/100ML  
 N18876 001  
 JAN 17, 1986  
 DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE  
 0.15% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 149MG/100ML;  
 300MG/100ML  
 N18876 002  
 JAN 17, 1986  
 DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE  
 0.224% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 224MG/100ML;  
 300MG/100ML  
 N18876 003  
 JAN 17, 1986

DEXTROSE 5%; SODIUM CHLORIDE 0.3% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER  
 KENDALL MCGAW LABS 5GM/100ML; 75MG/100ML;  
 330MG/100ML  
 N18268 011  
 JAN 18, 1986

DEXTROSE 5%; SODIUM CHLORIDE 0.3% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER  
 KENDALL MCGAW LABS 5GM/100ML; 150MG/100ML;  
 330MG/100ML  
 N18268 012  
 JAN 18, 1986

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE (PAGE 3-68)

INJECTABLE; INJECTION  
 DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE  
 0.22% IN PLASTIC CONTAINER  
 KENDALL MCGAW LABS 5GM/100ML; 220MG/100ML;  
 330MG/100ML  
 N18268 013  
 JAN 18, 1986  
DEXTROSE 5%; SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.30% IN PLASTIC CONTAINER  
 KENDALL MCGAW LABS 5GM/100ML; 300MG/100ML;  
 330MG/100ML  
 N18268 014  
 JAN 18, 1986

DEXTROSE; SODIUM CHLORIDE (PAGE 3-70)

INJECTABLE; INJECTION  
DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 225MG/100ML  
 N17606 001  
 5GM/100ML; 225MG/100ML  
 N19482 001  
 OCT 04, 1985  
DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 300MG/100ML  
 N19486 001  
 OCT 04, 1985  
DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 450MG/100ML  
 N19484 001  
 OCT 04, 1985  
DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5GM/100ML; 900MG/100ML  
 N19483 001  
 OCT 04, 1985

DEXTROSE; THEOPHYLLINE (PAGE 3-70)

INJECTABLE; INJECTION  
THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER  
 TRAVENOL LABS 5GM/100ML; 320MG/100ML  
 N18649 006  
 NOV 13, 1985

DIAZEPAM (PAGE 3-72)

INJECTABLE; INJECTION  
DIAZEPAM  
 AP CARTER-GLOGAU LABS 5MG/ML  
 N70296 001  
 FEB 12, 1986  
 AP ELKINS-SINN/AHROBINS 5MG/ML  
 N70311 001  
 DEC 16, 1985  
 AP 5MG/ML  
 N70312 001  
 DEC 16, 1985  
 AP 5MG/ML  
 N70313 001  
 DEC 16, 1985

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

DIAZEPAM (PAGE 3-72)DIAZEPAM (PAGE 3-72)

## INJECTABLE; INJECTION

DIAZEPAM

## LEMMON

AP

5MG/ML

N70911 001

AB

MYLAN PHARMS

2MG

N70323 001  
SEP 04, 1985

AP

5MG/ML

N70912 001

AB

MYLAN PHARMS

5MG

N70324 001  
SEP 04, 1985

&gt; ADD &gt; AP

5MG/ML

AUG 28, 1986

AB

MYLAN PHARMS

10MG

N70325 001  
SEP 04, 1985

&gt; ADD &gt; AP

5MG/ML

DEC 01, 1986

AB

PAR PHARMACEUTICAL

2MG

N70462 001  
FEB 25, 1986

AP

5MG/ML

JUN 25, 1986

AB

PAR PHARMACEUTICAL

5MG

N70463 001  
FEB 25, 1986

AP

5MG/ML

N16087 001

AB

PARKE-DAVIS/W-L

10MG

N70464 001  
FEB 25, 1986

AP

5MG/ML

N70152 001

AB

PARKE-DAVIS/W-L

2MG

N70209 001  
SEP 04, 1985

AP

2MG

NOV 01, 1985

AB

PARKE-DAVIS/W-L

5MG

N70210 001  
SEP 04, 1985

AP

5MG

NOV 01, 1985

AB

PARKE-DAVIS/W-L

10MG

N70222 001  
SEP 04, 1985

AP

10MG

NOV 01, 1985

AB

PUREPAC/KALIPHARMA

2MG

N70781 001  
MAR 19, 1986

AP

2MG

NOV 01, 1985

AB

PUREPAC/KALIPHARMA

5MG

N70706 001  
MAR 19, 1986

AP

5MG

NOV 01, 1985

AB

PUREPAC/KALIPHARMA

10MG

N70707 001  
MAR 19, 1986

AP

10MG

NOV 01, 1985

AB

PUREPAC/KALIPHARMA

2MG

N70356 001  
JUN 17, 1986

AP

2MG

DEC 20, 1985

AB

ROXANE LABORATORIES

5MG

N70357 001  
JUN 17, 1986

AP

5MG

DEC 20, 1985

AB

ROXANE LABORATORIES

10MG

N70358 001  
JUN 17, 1986

AP

2MG

DEC 20, 1985

AB

ROXANE LABORATORIES

2MG

N70642 001  
DEC 11, 1985

AP

5MG

AUG 27, 1986

AB

SUPERPHARM

5MG

N70643 001  
DEC 11, 1985

AP

10MG

AUG 27, 1986

AB

SUPERPHARM

10MG

N70644 001  
DEC 11, 1985

AP

2MG

AUG 27, 1986

AB

ZENITH LABORATORIES

2MG

N70360 001  
SEP 04, 1985

AP

2MG

AUG 15, 1986

AB

ZENITH LABORATORIES

2MG

N71307 001  
DEC 10, 1986

AP

5MG

AUG 15, 1986

AB

ZENITH LABORATORIES

5MG

N70361 001  
SEP 04, 1985

AP

10MG

AUG 15, 1986

AB

ZENITH LABORATORIES

10MG

N71321 001  
DEC 10, 1986

AP

5MG

SEP 26, 1985

AB

ZENITH LABORATORIES

5MG

N70362 001  
SEP 04, 1985

AP

10MG

SEP 26, 1985

AB

ZENITH LABORATORIES

10MG

N71322 001  
DEC 10, 1986

AP

10MG

SEP 26, 1985

AB

ZENITH LABORATORIES

10MG

N70363 001  
DEC 10, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

AB 9-PAM QUANTUM PHARMICS

2MG

5MG

10MG

N70423 001  
DEC 12, 1985  
N70424 001  
DEC 12, 1985  
N70425 001  
DEC 12, 1985

VALIUM

AB HOFFMANN-LA ROCHE

2MG

5MG

10MG

N13263 002  
N13263 004  
N13263 006

DICYCLONINE HYDROCHLORIDE (PAGE 3-73)

CAPSULE; ORAL

BENTYL

AB MERRELL DOW/DOW CHEM 10MG

DICYCLONINE HCL

AB BOLAR PHARMACEUTICAL 10MG

AB CHELSEA LABORATORIES 10MG

INJECTABLE; INJECTION

BENTYL

AP MERRELL DOW/DOW CHEM 10MG/ML

DICYCLONINE HCL

AP CARTER-GLOGAU LABS 10MG/ML

TABLET; ORAL

BENTYL

AB MERRELL DOW/DOW CHEM 20MG

DICYCLONINE HCL

AB BARR LABORATORIES 20MG

AB BOLAR PHARMACEUTICAL 20MG

AB PIONEER PHARMS 20MG

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL

BX DIFLORASONE DIACETATE

0.05%

FLORONE

BX UPJOHN 0.05%

DIFLORASONE DIACETATE (PAGE 3-74)

OINTMENT; TOPICAL

BX DIFLORASONE DIACETATE

0.05%

FLORONE

BX UPJOHN

0.05%

N19260 001  
AUG 28, 1985

N17994 001

DILTIAZEM HYDROCHLORIDE (PAGE 3-75)

TABLET; ORAL

CARDIZEM

MARION LABORATORIES 90MG

120MG

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

N18602 003  
DEC 08, 1986  
N18602 004  
DEC 08, 1986

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-76)

CAPSULE; ORAL

AA DIPHENHYDRAMINE HCL

PIONEER PHARMS

25MG

50MG

N89101 001  
DEC 20, 1985  
N88880 001  
DEC 20, 1985

DIPYRIDAMOLE (PAGE 3-77)

TABLET; ORAL

PERSANTINE

BOEHRINGER INGELHEIM 25MG

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

N08370 001  
OCT 15, 1984

N80614 001  
FEB 11, 1986

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL

AB DISOPYRAMIDE PHOSPHATE

BARR LABORATORIES

EQ 100MG BASE

EQ 150MG BASE

EQ 100MG BASE

EQ 150MG BASE

N70351 001  
DEC 17, 1985  
N70352 001  
DEC 17, 1985  
N70240 001  
FEB 02, 1986  
N70241 001  
FEB 02, 1986

N19259 001  
AUG 28, 1985

N17741 001



DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE, COATED PELLETS; ORAL

AB DORYX

FAULDING

EQ 100MG BASE

N50582 001

JUL 22, 1985

N62653 001

OCT 30, 1985

EQ 100MG BASEM

AB PARKE-DAVIS/W-L

INJECTABLE; INJECTION

DOXYCYCLINE

/MEDICOPHARMA/

/EQ 100MG BASEM

/N62538 001

/APR 07, 1986

AB DOXYCYCLINE HYCLATE

QUAD PHARMS

EQ 100MG BASE/VIALM

N62643 001

FEB 13, 1986

N62643 002

FEB 13, 1986

EQ 200MG BASE/VIALM

AB

TABLET; ORAL

DOXYCYCLINE HYCLATE

MEDICOPHARMA

EQ 100MG BASEM

N62538 001

APR 07, 1986

N62677 001

JUL 10, 1986

EQ 100MG BASEM

AB MUTUAL PHARM

AB PARKE-DAVIS/W-L

EQ 100MG BASEM

AUG 28, 1985

N62593 001

/N62594 001

/DEC 05, 1985

/N62594 002

/DEC 05, 1985

/EQ 50MG BASEM

/AB

DOXYLAMINE SUCCINATE (PAGE 3-80)

TABLET; ORAL

DOXYLAMINE SUCCINATE

COPLY PHARM

25MGH

N88900 001

OCT 08, 1985

PROPERIDOL (PAGE 3-80)

INJECTABLE; INJECTION

PROPERIDOL

LYPHOMED

2.5MG/MLM

N70993 001

NOV 17, 1986

N70992 001

NOV 17, 1986

2.5MG/MLM

AB INAPISINE

JANSSEN PHARMA

2.5MG/ML

N16796 001

EDROPHONIUM CHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION

ENLON

AP ANAQUEST/BOC

10MG/MLM

N88873 001

AUG 06, 1985

AP TENSILON

HOFFMANN-LA ROCHE

10MG/ML

N07959 001

ENALAPRIL MALEATE (PAGE 3-81)

TABLET; ORAL

VASOTEC

MS&D RES LABS/MERCK

5MGH

N18998 001

DEC 24, 1985

10MGH

N18998 002

DEC 24, 1985

20MGH

N18998 003

DEC 24, 1985

ENALAPRIL MALEATE; HYDROCHLOROTHAZIDE (PAGE 3-81)

TABLET; ORAL

VASERETIC

MS&D RES LABS/MERCK

10MG;25MGH

N19221 001

OCT 31, 1986

ENCAINIDE HYDROCHLORIDE (PAGE 3-81)

CAPSULE; ORAL

ENKAID

BRISTOL LABS/B-M

25MGH

N18981 002

DEC 24, 1986

35MGH

N18981 003

DEC 24, 1986

50MGH

N18981 004

DEC 24, 1986

EPINEPHRINE (PAGE 3-81)

INJECTABLE; INJECTION

SUS-PHRINE

/BERLEX/SCHERING/

5MG/ML

/N07942 001

FOREST LABORATORIES

5MG/ML

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

ERYTHROMYCIN (PAGE 3-83)EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-81)INJECTABLE; INJECTIONLIDOCAINE HCL AND EPINEPHRINE

AP ABBOTT LABORATORIES 0.005MG/ML; 1.5%~~M~~ N88571 001  
SEP 13, 1985

XYLOCAINE W/ EPINEPHRINE

AP ASTRA PHARM PRODS 0.005MG/ML; 1.5% N10418 010  
AP 0.005MG/ML; 1.5% N06488 017  
AUG 29, 1986

ERGOLOID MESYLATES (PAGE 3-82)TABLET; ORALERGOLOID MESYLATES

AB BARR LABORATORIES 1MG~~M~~ N88891 001  
NOV 01, 1985

TABLET; SUBLINGUALERGOLOID MESYLATES

AA SUPERPHARM 0.5MG~~M~~ N89233 001  
SEP 23, 1986

AA 1MG~~M~~ N89234 001  
SEP 23, 1986

ERYTHROMYCIN (PAGE 3-83)CAPSULE, ENTERIC-COATED PELLETS; ORALERYC

> ADD > AB PARKE-DAVIS/M-L 250MG~~M~~ N62618 001  
SEP 25, 1985

ERYC 125

PARKE-DAVIS/M-L 125MG~~M~~ N62648 001  
OCT 24, 1985

ERYTHROMYCIN

> ADD > AB ABBOTT LABORATORIES 250MG~~M~~ N62746 001  
DEC 22, 1986

POWDER; FOR RX COMPOUNDINGERYTHROMYCIN

PADDOCK LABORATORIES 100%~~M~~ N50610 001  
NOV 07, 1986

N50611 001  
SEP 09, 1986

/TABLET; ENTERIC-COATED PARTICLES; ORAL/  
TABLET, COATED PARTICLES; ORALPCE

ABBOTT LABORATORIES 333MG~~M~~

ERYTHROMYCIN LACTOBIONATE (PAGE 3-85)INJECTABLE; INJECTIONERYTHROCIN LACTOBIONATE

AP ABBOTT LABORATORIES EQ 500MG BASE/VIAL~~M~~ N50609 001  
SEP 24, 1986

AP EQ 1GM BASE/VIAL~~M~~ N50609 002  
SEP 24, 1986

AP EQ 500MG BASE/VIAL~~M~~ N62638 001  
OCT 31, 1986

AP EQ 1GM BASE/VIAL~~M~~ N62638 002  
OCT 31, 1986

AP EQ 500MG BASE/VIAL~~M~~ N62604 001  
NOV 24, 1986

AP EQ 1GM BASE/VIAL~~M~~ N62604 002  
NOV 24, 1986

AP EQ 500MG BASE/VIAL~~M~~ N62660 001  
NOV 24, 1986

AP EQ 1GM BASE/VIAL~~M~~ N62660 003  
NOV 24, 1986

> ADD > ESMOLOL HYDROCHLORIDE (PAGE 3-86)> ADD > INJECTABLE; INJECTIONBREVIBLOC

> ADD > DUPONT CRIT CRE 250MG/ML~~M~~ N19386 001  
DEC 31, 1986

ESTRADIOL (PAGE 3-86)FILM, CONTROLLED RELEASE; PERCUTANEOUSESTRADERM

CIBA/CIBA-GEIGY 4MG~~M~~ N19081 002  
SEP 10, 1986

8MG~~M~~ N19081 003  
SEP 10, 1986

ESTRADIOL CYPIONATE; TESTOSTERONE CYPIONATE (PAGE 3-86)INJECTABLE; INJECTIONDEPO-TESTADIOL

AO UP-JOHN 2MG/ML; 50MG/ML N17968 001

AO TESTOSTERONE CYPIONATE-ESTRADIOL CYPIONATE 2MG/ML; 50MG/ML~~M~~ N85603 001  
MAR 13, 1986

AO CARTER-GLOGAU LABS 2MG/ML; 50MG/ML~~M~~



## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

FLUOCINOLONE ACETONIDE (PAGE 3-92)

SOLUTION; TOPICAL  
FLUOCINOLONE ACETONIDE  
 AT THAMES PHARMACAL 0.01%  
 N89124 001  
 SEP 11, 1985

CONCENTRATE; ORAL

PERMITIL  
 AA SCHERING 5MG/ML  
 PROLOXIN  
 AA ER SQUIBB AND SONS 5MG/ML

N16008 001  
 N70533 001  
 NOV 07, 1985

FLUOROMETHOLONE (PAGE 3-93)

OINTMENT; OPHTHALMIC

FML  
 ALLERGAN PHARMS 0.1%  
 N17760 001  
 SEP 04, 1985

SUSPENSION/DROPS; OPHTHALMIC

FLUOR-OP  
 AB COOPERVISION PHARMS 0.1%  
 N70185 001  
 FEB 27, 1986

FML  
 AB ALLERGAN PHARMS 0.1%  
 N16851 002  
 JUL 28, 1982

FML FORTE  
 ALLERGAN PHARMS 0.25%  
 N19216 001  
 APR 23, 1986

FLUOROMETHOLONE ACETATE (PAGE 3-93)

SUSPENSION/DROPS; OPHTHALMIC

OMNITROL  
 ALCON LABORATORIES 0.1%  
 N19079 001  
 FEB 11, 1986

FLUOROURACIL (PAGE 3-93)

INJECTABLE; INJECTION

FLUOROURACIL  
 AP INTL PHARM PROD 50MG/ML

AP LYPHOMED 50MG/ML

FLUPHENAZINE DECANOATE (PAGE 3-94)

INJECTABLE; INJECTION

FLUPHENAZINE  
 AO QUAD PHARMS 25MG/ML

PROLOXIN DECANOATE  
 AO ER SQUIBB AND SONS 25MG/ML

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-94)

CONCENTRATE; ORAL

PERMITIL  
 AA SCHERING 5MG/ML  
 PROLOXIN  
 AA ER SQUIBB AND SONS 5MG/ML

FLURAZEPAM HYDROCHLORIDE (PAGE 3-95)

CAPSULE; ORAL

DALMANE  
 AB ROCHE PRODUCTS 15MG  
 AB 30MG

FLURAZEPAM HCL  
 AB BARR LABORATORIES 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

AB 30MG

AB 15MG

N19404 001  
 DEC 31, 1986

FOLATE SODIUM (PAGE 3-95)

INJECTABLE; INJECTION

FOLVITE  
 /FOLVITE/  
 /FEDERLE LABS/AM CYAN/AM/ BASE/ML/

N70762 001  
 FEB 20, 1986

N16727 001

N055597.0001

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

FOLIC ACID (PAGE 3-95)INJECTABLE; INJECTION

FOLIC ACID  
LYPHONED

5MG/MLM

N89202 001  
FEB 18, 1986

GENTAFAIR  
PHARMAFAIR

EQ 40MG BASE/MLM

N62493 001  
AUG 28, 1985

FOLVITE

LEDERLE LABS/AM CYAN 5MG/ML

N05897 008

GENTAMICIN SULFATE  
ABBOTT LABORATORIES

EQ 10MG BASE/MLM

N62612 004  
FEB 20, 1986

TABLET; ORAL

FOLIC ACID

BARR LABORATORIES

1MGH

N89177 001  
JAN 08, 1986

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

EQ 3MG BASE/MLM

N62523 001  
NOV 25, 1985

PIONEER PHARMS

1MGH

N88949 001  
SEP 13, 1985

GENTAMICIN SULFATE; SODIUM CHLORIDE (PAGE 3-98)FUROSEMIDE (PAGE 3-96)INJECTABLE; INJECTION

FUROSEMIDE

ASTRA PHARM PRODS

10MG/MLM

N70014 001  
SEP 09, 1985

10MG/MLM

N70095 001  
SEP 09, 1985

10MG/MLM

N70096 001  
SEP 09, 1985

10MG/MLM

N70019 001  
SEP 22, 1986

10MG/MLM

N70017 001  
DEC 15, 1986

10MG/MLM

N70023 001  
FEB 05, 1986

10MG/MLM

N70078 001  
FEB 05, 1986

10MG/MLM

TABLET; ORAL

FUROSEMIDE

BARR LABORATORIES

20MGH

N70043 001  
SEP 26, 1985

DANBURY PHARMACAL

20MGH

N70412 001  
FEB 26, 1986

40MGH

N70413 001  
FEB 26, 1986

80MGH

N70082 001  
OCT 29, 1986

80MGH

N70086 001  
JAN 24, 1986

80MGH

N70449 001  
NOV 22, 1985

20MGH

N70450 001  
NOV 22, 1985

40MGH

N70528 001  
JAN 07, 1986

80MGH

GENTAMICIN SULFATE (PAGE 3-97)INJECTABLE; INJECTION

GENTAFAIR

PHARMAFAIR

EQ 40MG BASE/MLM

N62493 001  
AUG 28, 1985

GENTAMICIN SULFATE

EQ 10MG BASE/MLM

N62612 004  
FEB 20, 1986

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

EQ 3MG BASE/MLM

N62523 001  
NOV 25, 1985

GENTAMICIN SULFATE; SODIUM CHLORIDE (PAGE 3-98)INJECTABLE; INJECTION

GENTAMICIN SULFATE IN PLASTIC CONTAINER

ABBOTT LABORATORIES

EQ 60MG BASE/100ML;

900MG/100MLM

N62588 006  
JAN 06, 1986

EQ 70MG BASE/100ML;

900MG/100MLM

N62588 007  
JAN 06, 1986

EQ 80MG BASE/100ML;

900MG/100MLM

N62588 008  
JAN 06, 1986

EQ 90MG BASE/100ML;

900MG/100MLM

N62588 009  
JAN 06, 1986

EQ 100MG BASE/100ML;

900MG/100MLM

N62588 010  
JAN 06, 1986

EQ 1.2MG BASE/ML;

9MG/MLM

N62588 001  
JAN 06, 1986

EQ 1.4MG BASE/ML;

9MG/MLM

N62588 002  
JAN 06, 1986

EQ 1.6MG BASE/ML;

9MG/MLM

N62588 003  
JAN 06, 1986

EQ 1.8MG BASE/ML;

9MG/MLM

N62588 004  
JAN 06, 1986

EQ 2MG BASE/ML;

9MG/MLM

N62588 005  
JAN 06, 1986

GLUTETHIMIDE (PAGE 3-100)TABLET; ORAL

GLUTETHIMIDE

HALSEY DRUG

250MGH

N89458 001  
OCT 10, 1986

500MGH

N89459 001  
OCT 10, 1986

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

GLYCINE (PAGE 3-100)

SOLUTION; IRRIGATION

/AT/ AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER  
/TRAVENOL LABS/ /1.5GM/100ML/AT GLYCINE 1.5% IN PLASTIC CONTAINER  
TRAVENOL LABS 1.5GM/100MLN18522 001  
FEB 19, 1982

TABLET; ORAL

HALDOL  
MCNEIL PHARM0.5MG  
1MG  
2MG  
5MG  
10MG  
20MGN15921 001  
N15921 002  
N15921 003  
N15921 004  
N15921 005  
N15921 006  
FEB 02, 1982GLYCOPYRROLATE (PAGE 3-100)

INJECTABLE; INJECTION

GLYCOPYRROLATE

LUITPOLD PHARMS 0.2MG/ML

AP QUAD PHARMS

0.2MG/ML

N89335 001  
JUL 23, 1986  
N89397 001  
DEC 09, 1986> ADD >  
> ADD >GONADOTROPIN, CHORIONIC (PAGE 3-101)

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

QUAD PHARMS

5,000 UNITS/VIAL

&gt; ADD &gt; AP

&gt; ADD &gt;

&gt; ADD &gt; AP

&gt; ADD &gt;

&gt; ADD &gt; AP

&gt; ADD &gt;

&gt; ADD &gt; AP

&gt; ADD &gt;

&gt; ADD &gt;

N89312 001  
DEC 04, 1986  
N89313 001  
DEC 04, 1986  
N89314 001  
DEC 04, 1986  
N89315 001  
DEC 04, 1986  
N89316 001  
DEC 04, 1986GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL

WYTHENIN

WYETH LABS/AMHO

EQ 16MG BASEM

N18587 003  
SEP 07, 1982GUANFACINE HYDROCHLORIDE (PAGE 3-102)

TABLET; ORAL

TENEX

AH ROBINS

1MG

N19032 001  
OCT 27, 1986HALOPERIDOL

CORD LABORATORIES

0.5MG

N71206 001

NOV 17, 1986

N71207 001

NOV 17, 1986

N71208 001

NOV 17, 1986

N71209 001

NOV 17, 1986

N71210 001

DEC 04, 1986

N71211 001

DEC 04, 1986

N71212 001

DEC 04, 1986

N71213 001

DEC 04, 1986

N71214 001

DEC 04, 1986

N71215 001

JUN 10, 1986

N71216 001

JUN 10, 1986

N71217 001

JUN 10, 1986

N71218 001

JUN 10, 1986

N71219 001

JUN 10, 1986

N71220 001

JUN 10, 1986

N71221 001

JUN 10, 1986

N71222 001

JUN 10, 1986

N71223 001

NOV 03, 1986

N71224 001

NOV 03, 1986

N71225 001

NOV 03, 1986

N71226 001

NOV 03, 1986

N71227 001

NOV 03, 1986

N71228 001

NOV 03, 1986

N71229 001

NOV 03, 1986

N71230 001

NOV 03, 1986

N71231 001

NOV 03, 1986

N71232 001

NOV 03, 1986

HALOPERIDOL (PAGE 3-102)

TABLET; ORAL

**AB** **HALOPERIDOL** **SEARLE PHARMS**

| <u>AB</u> | <u>SEARLE PHARMS</u> | <u>0.5MG</u> | <u>N70720 001</u>           |
|-----------|----------------------|--------------|-----------------------------|
| <u>AB</u> |                      | <u>1MG</u>   | JUN 10, 1986                |
| <u>AB</u> |                      | <u>2MG</u>   | JUN 10, 1986                |
| <u>AB</u> |                      | <u>5MG</u>   | JUN 10, 1986                |
| <u>AB</u> |                      | <u>10MG</u>  | JUN 10, 1986                |
| <u>AB</u> |                      | <u>20MG</u>  | JUN 10, 1986                |
|           |                      |              | N70725 001                  |
|           |                      |              | SEP 24, 1986 : JUN 10, 1986 |

HALOPERIDOL DECANOATE (PAGE 3-102)

INJECTABLE; INJECTION  
HALDOL DECANOATE  
MCNEIL PHARM

EQ 50MG BASE/MLM  
N18701 001  
JAN 14, 1986

HALOPERIDOL LACTATE (PAGE 3-102)

CONCENTRATE; ORAL

|           |        |                      |                       |              |
|-----------|--------|----------------------|-----------------------|--------------|
| <u>AA</u> | HALDOL | MCNEIL LABORATORIES  | <u>EQ 2MG BASE/ML</u> | N15922 001   |
| <u>AA</u> |        | HALOPERIDOL          |                       |              |
| <u>AA</u> |        | BAY LABORATORIES     | <u>EQ 2MG BASE/ML</u> | N70710 001   |
| <u>AA</u> |        | NATL PHARM MFG/BARRE | <u>EQ 2MG BASE/ML</u> | APR 15, 1986 |
| <u>AA</u> |        | SEARLE PHARMS        | <u>EQ 2MG BASE/ML</u> | N70318 001   |
|           |        |                      |                       | APR 11, 1986 |
|           |        |                      |                       | N70726 001   |
|           |        |                      |                       | JN 10, 1986  |

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

/AD/  
 /ELKINS: SINN/ALPHABETICS/10 UNITS/ML/  
 /HEP-LOCK: PF/  
 /AD/  
 /100' UNITS/ML/  
 /AD/

**HER-LOCK U/P**

| AP | ELKINS-SINN/AHROBINS | <u>10 UNITS/ML</u>  | N17037 010   |
|----|----------------------|---------------------|--------------|
|    |                      |                     | JUN 10, 1983 |
| AP |                      | <u>100 UNITS/ML</u> | N17037 011   |
|    |                      |                     | JUN 10, 1983 |

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION  
HEPARIN LOCK FLUSH

| <u>HEPARIN LOCK FLUSH</u> |                     |
|---------------------------|---------------------|
| CARTER-GLOGAU LABS        |                     |
| LUITPOLD PHARMS           |                     |
| <u>AP</u>                 | <u>100 UNITS/ML</u> |
| <u>AP</u>                 | <u>10 UNITS/ML</u>  |
| <u>AP</u>                 | <u>100 UNITS/ML</u> |

**HEPARIN SODIUM**  
ABBOTT LABORATORIES 2,000 UNITS/ML

| AP/<br>AP<br>AP<br>AP | CARTER-GLOGAU LABS   | /100 UNITS/ML/<br>2,500 UNITS/ML<br>7,500 UNITS/ML<br>3,000 UNITS/ML<br>4,000 UNITS/ML<br>6,000 UNITS/ML<br>5,000 UNITS/0.5ML |
|-----------------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------|
| AP                    | ELKINS-SINN/AHROBTNS |                                                                                                                               |

|                                  |                |
|----------------------------------|----------------|
| HEPARIN SODIUM PRESERVATIVE FREE | 1,000 UNITS/ML |
| INVENEX/LYPHOMED                 |                |

MARSAM  
1,000 UNITS/ML

**LIQUAEMIN SODIUM PRESERVATIVE FREE**  
ORGANON/AKZONA 1,000 UNITS/ML

| AP | 5,000 UNITS/MLH  |
|----|------------------|
| AP | 10,000 UNITS/MLH |

**SODIUM HEPARIN**  
/CARTER-BLOOM LABS/  
/45/ 1/2,500 UNITS/ML/  
/46/ 1/500 UNITS/ML/  
1/3,000 UNITS/ML/  
1/4,000 UNITS/ML/  
1/5,000 UNITS/ML/  
1/6,000 UNITS/ML/

HEXACHLOROPHENE (PAGE 3-106)

**S-P-100**  
SPONGE; TOPICAL  
/E-Z SCRUB, SURGICAL/  
/PARKER-PAYSON, W-L/  
E-Z SCRUB

DESERET/P-D  
450MG

N17452 001

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)INJECTABLE; INJECTION

AP HYDRALAZINE HCL  
SOLOPAK LABORATORIES 20MG/ML

TABLET; ORAL

AA HYDRALAZINE HCL  
HALSEY DRUG

|           |              |              |              |
|-----------|--------------|--------------|--------------|
| <u>AA</u> | <u>10MG</u>  | N89218 001   | <u>10MG</u>  |
|           |              | JAN 22, 1986 |              |
| <u>AA</u> | <u>25MG</u>  | N89130 001   | <u>25MG</u>  |
|           |              | JAN 15, 1986 |              |
| <u>AA</u> | <u>50MG</u>  | N89222 001   | <u>50MG</u>  |
|           |              | JAN 22, 1986 |              |
| <u>AA</u> | <u>100MG</u> | N89178 001   | <u>100MG</u> |
|           |              | JAN 15, 1986 |              |
| <u>AA</u> | <u>10MG</u>  | N89359 001   | <u>10MG</u>  |
|           |              | JUL 25, 1986 |              |
| <u>AA</u> | <u>25MG</u>  | N89258 001   | <u>25MG</u>  |
|           |              | MAY 05, 1986 |              |
| <u>AA</u> | <u>50MG</u>  | N89259 001   | <u>50MG</u>  |
|           |              | MAY 05, 1986 |              |
| <u>AA</u> | <u>10MG</u>  | N89097 001   | <u>10MG</u>  |
|           |              | DEC 18, 1985 |              |
| <u>AA</u> | <u>100MG</u> | N89098 001   | <u>100MG</u> |
|           |              | DEC 18, 1985 |              |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)CAPSULE; ORAL

AB HYDRA-ZIDE

|           |                    |              |                    |
|-----------|--------------------|--------------|--------------------|
| <u>AB</u> | <u>25MG; 25MG</u>  | N88957 001   | <u>25MG; 25MG</u>  |
|           |                    | OCT 21, 1985 |                    |
| <u>AB</u> | <u>50MG; 50MG</u>  | N88946 001   | <u>50MG; 50MG</u>  |
|           |                    | OCT 21, 1985 |                    |
| <u>AB</u> | <u>100MG; 50MG</u> | N88961 001   | <u>100MG; 50MG</u> |
|           |                    | OCT 21, 1985 |                    |

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)TABLET; ORAL

AB ALDORIL D30

|           |                    |            |                    |
|-----------|--------------------|------------|--------------------|
| <u>AB</u> | <u>30MG; 500MG</u> | N13402 003 | <u>30MG; 500MG</u> |
|           |                    |            |                    |
| <u>AB</u> | <u>50MG; 500MG</u> | N13402 004 | <u>50MG; 500MG</u> |
|           |                    |            |                    |
| <u>AB</u> | <u>15MG; 250MG</u> | N13402 001 | <u>15MG; 250MG</u> |
|           |                    |            |                    |
| <u>AB</u> | <u>25MG; 250MG</u> | N13402 002 | <u>25MG; 250MG</u> |
|           |                    |            |                    |

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)TABLET; ORAL

AB METHYLDOPA AND HYDROCHLOROTHIAZIDE  
BOLAR PHARMACEUTICAL 15MG; 250MG

|           |                    |              |                    |
|-----------|--------------------|--------------|--------------------|
| <u>AB</u> | <u>25MG; 250MG</u> | N70366 001   | <u>25MG; 250MG</u> |
|           |                    | MAR 19, 1986 |                    |
| <u>AB</u> | <u>30MG; 500MG</u> | N70367 001   | <u>30MG; 500MG</u> |
|           |                    | APR 16, 1986 |                    |
| <u>AB</u> | <u>50MG; 500MG</u> | N70368 001   | <u>50MG; 500MG</u> |
|           |                    | MAR 19, 1986 |                    |
| <u>AB</u> | <u>15MG; 250MG</u> | N70182 001   | <u>15MG; 250MG</u> |
|           |                    | APR 16, 1986 |                    |
| <u>AB</u> | <u>25MG; 250MG</u> | N70183 001   | <u>25MG; 250MG</u> |
|           |                    | JAN 15, 1986 |                    |
| <u>AB</u> | <u>30MG; 500MG</u> | N70543 001   | <u>30MG; 500MG</u> |
|           |                    | JAN 15, 1986 |                    |
| <u>AB</u> | <u>50MG; 500MG</u> | N70544 001   | <u>50MG; 500MG</u> |
|           |                    | JAN 15, 1986 |                    |
| <u>AB</u> | <u>15MG; 250MG</u> | N70264 001   | <u>15MG; 250MG</u> |
|           |                    | JAN 23, 1986 |                    |
| <u>AB</u> | <u>25MG; 250MG</u> | N70265 001   | <u>25MG; 250MG</u> |
|           |                    | JAN 23, 1986 |                    |
| <u>AB</u> | <u>15MG; 250MG</u> | N70853 001   | <u>15MG; 250MG</u> |
|           |                    | OCT 08, 1986 |                    |
| <u>AB</u> | <u>25MG; 250MG</u> | N70688 001   | <u>25MG; 250MG</u> |
|           |                    | APR 24, 1986 |                    |
| <u>AB</u> | <u>30MG; 500MG</u> | N70854 001   | <u>30MG; 500MG</u> |
|           |                    | OCT 08, 1986 |                    |
| <u>AB</u> | <u>50MG; 500MG</u> | N70689 001   | <u>50MG; 500MG</u> |
|           |                    | APR 24, 1986 |                    |

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE (PAGE 3-111)TABLET; ORAL

AB INDERIDE-60/25

|           |                   |            |                   |
|-----------|-------------------|------------|-------------------|
| <u>AB</u> | <u>25MG; 40MG</u> | N18031 001 | <u>25MG; 40MG</u> |
|           |                   |            |                   |

AB INDERIDE-80/25

|           |                   |            |                   |
|-----------|-------------------|------------|-------------------|
| <u>AB</u> | <u>25MG; 80MG</u> | N18031 002 | <u>25MG; 80MG</u> |
|           |                   |            |                   |

AB PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE  
BARR LABORATORIES 25MG; 40MG

|           |                   |              |                   |
|-----------|-------------------|--------------|-------------------|
| <u>AB</u> | <u>25MG; 80MG</u> | N70704 001   | <u>25MG; 80MG</u> |
|           |                   | OCT 01, 1986 |                   |
| <u>AB</u> | <u>25MG; 80MG</u> | N70705 001   | <u>25MG; 80MG</u> |
|           |                   | OCT 01, 1986 |                   |
| <u>AB</u> | <u>25MG; 40MG</u> | N70301 001   | <u>25MG; 40MG</u> |
|           |                   | APR 18, 1986 |                   |
| <u>AB</u> | <u>25MG; 80MG</u> | N70305 001   | <u>25MG; 80MG</u> |
|           |                   | APR 18, 1986 |                   |
| <u>AB</u> | <u>25MG; 40MG</u> | N70851 001   | <u>25MG; 40MG</u> |
|           |                   | MAY 15, 1986 |                   |
| <u>AB</u> | <u>25MG; 80MG</u> | N70852 001   | <u>25MG; 80MG</u> |
|           |                   | MAY 15, 1986 |                   |

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL

AB SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE  
PUREPAC/KALIPHARMA 25MG;25MG

AB SUPERPHARM 25MG;25MG

N87999 001  
NOV 06, 1985  
N89137 001  
AUG 26, 1985

/HYDROCODONE; PHENYLETHANAMINE/ (PAGE 3-112)

/SUSPENSION; ORAL/  
TUSSIONE/  
/PENWALT PHARM/  
/EQ 5MG BASE/5ML/  
/EQ 10MG BASE/5ML/

N10768 006/  
/N10768 006/

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL

ALA-CORT

AT DEL-RAY LABORATORIES 1%  
E FOUGERA/ALTANA 2.5%  
PHARMADERM/ALTANA 1%  
2.5%

> ADD > AT  
> ADD >  
> ADD > AT  
> ADD >

N80706 001  
N89414 001  
DEC 16, 1986  
N88845 001  
FEB 27, 1986  
N89413 001  
DEC 16, 1986

LOTION; TOPICAL

ALA-CORT

AT DEL-RAY LABORATORIES 1%  
ALA-SCALP 2%  
THAMES PHARMACAL 1%  
STIEFEL LABORATORIES 1%  
2.5%

> ADD > AT  
> ADD >  
> ADD > AT  
> ADD >

N83201 001  
N83231 001  
N89024 001  
FEB 12, 1986  
N89066 001  
NOV 25, 1985  
N89074 001  
NOV 26, 1985

ointment; TOPICAL

AT HYDROCORTISONE IN ABSORBABLE  
CAROLINA MED PRODS 1%  
1%

N88138 001  
SEP 06, 1985

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-115)

SUSPENSION; OTIC

AT NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE  
CARTER-GLOGAU LABS 1%;EQ 3.5MG BASE/ML;  
10,000 UNITS/ML

N62488 001  
NOV 06, 1985

AT NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE  
PHARMAFAIR 1%;EQ 3.5MG BASE/ML;  
10,000 UNITS/ML

N62617 001  
SEP 18, 1985

SUSPENSION/DROPS; OPHTHALMIC

CORTISPORIN

AT BURROUGHS WELLCOME 1%;EQ 3.5MG BASE/ML;  
10,000 UNITS/ML

N50169 001

AT NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE  
PHARMAFAIR 1%;EQ 3.5MG BASE/ML;  
10,000 UNITS/ML

N62623 001  
SEP 24, 1985

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-116)

CREAM; TOPICAL

CORTISPORIN

BURROUGHS WELLCOME 0.5%;EQ 3.5MG BASE/GM;  
10,000 UNITS/GM

N50218 001  
AUG 09, 1985

HYDROCORTISONE BUTYRATE (PAGE 3-116)

CREAM; TOPICAL

HYDROCORTISONE BUTYRATE

BX @ GIST-BROCADES 0.1%

N18514 001  
MAY 31, 1982

LOCOID

BX OMEN LABS/DERM PRODS 0.1%

N18795 001  
JAN 07, 1983

ointment; TOPICAL

HYDROCORTISONE BUTYRATE

BX @ GIST-BROCADES 0.1%

N18652 001  
OCT 29, 1982

LOCOID

BX OMEN LABS/DERM PRODS 0.1%

N19106 001  
JUL 03, 1984



RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

IBUPROFEN (PAGE 3-120)

TABLET; ORAL

|    |                                 |       |                            |    |                                                    |          |                            |
|----|---------------------------------|-------|----------------------------|----|----------------------------------------------------|----------|----------------------------|
| AB | IBUPROFEN<br>OHM LABORATORIES   | 400MG | N70818 001<br>DEC 26, 1985 | AB | INDOMETHACIN<br>LEMMON                             | 25MG     | N70266 001<br>NOV 07, 1985 |
| AB | IBUPROFEN<br>PAR PHARMACEUTICAL | 300MG | N70328 001<br>AUG 06, 1985 | AB |                                                    | 50MG     | N70267 001<br>NOV 07, 1985 |
| AB |                                 | 400MG | N70329 001                 | AB | INDOMETHACIN<br>BARR LABORATORIES                  | 25MG     | N70067 001<br>OCT 03, 1986 |
| AB |                                 | 600MG | AUG 06, 1985               | AB |                                                    | 50MG     | N70068 001<br>OCT 03, 1986 |
| AB |                                 | 800MG | N70330 001                 | AB | BOLAR PHARMACEUTICAL                               | 25MG     | N70784 001<br>AUG 20, 1986 |
| AB | PRIVATE FORMULATIONS            | 300MG | N70986 001<br>JUL 25, 1986 | AB |                                                    | 50MG     | N70785 001<br>AUG 20, 1986 |
| AB |                                 | 400MG | N71266 001<br>OCT 15, 1986 | AB | DURAMED PHARMS                                     | 25MG     | N70326 001<br>OCT 18, 1985 |
| AB |                                 | 600MG | N71267 001                 | AB |                                                    | 50MG     | N70327 001<br>OCT 18, 1985 |
| AB | PUREPAC/KALIPHARMA              | 300MG | N71268 001                 | AB | MYLAN PHARMS                                       | 50MG     | N70624 001<br>SEP 04, 1985 |
| AB |                                 | 400MG | OCT 15, 1986               | AB | PAR PHARMACEUTICAL                                 | 50MG     | N70651 001<br>MAR 05, 1986 |
| AB |                                 | 600MG | N71123 001<br>SEP 19, 1986 | AB | PIONEER PHARMS                                     | 25MG     | N70813 001<br>AUG 11, 1986 |
| AB | SUPERPHARM                      | 400MG | N71124 001                 | AB | SUPERPHARM                                         | 25MG     | N70592 001<br>AUG 11, 1986 |
| AB |                                 | 600MG | N71125 001                 | AB |                                                    | 50MG     | N70487 001<br>OCT 10, 1986 |
| AB |                                 | 800MG | SEP 19, 1986               | AB | WATSON LABORATORIES                                | 25MG     | N70488 001<br>OCT 10, 1986 |
| AB | IBUPROFEN<br>OHM LABORATORIES   | 400MG | N70708 001                 | AB |                                                    | 50MG     | N70529 001<br>OCT 18, 1985 |
| AB | IFEN                            | 400MG | APR 25, 1986               | AB | ZENITH LABORATORIES                                | 25MG     | N70530 001<br>OCT 18, 1985 |
| AB |                                 | 600MG | N70709 001                 | AB |                                                    | 50MG     | N70719 001<br>FEB 12, 1986 |
| AB |                                 | 800MG | APR 25, 1986               | AB |                                                    | 50MG     | N70756 001<br>FEB 12, 1986 |
| AB | IBUPROFEN<br>OHM LABORATORIES   | 400MG | N70469 001<br>AUG 29, 1985 |    | SUSPENSION; ORAL<br>INDOCIN<br>MS&D RES LABS/MERCK | 25MG/5ML | N18332 001<br>OCT 10, 1985 |
| AB | IFEN                            | 400MG | N71145 001                 |    |                                                    |          |                            |
| AB | LUCHEM PHARMS                   | 600MG | SEP 23, 1986               |    |                                                    |          |                            |
| AB |                                 | 800MG | N71146 001                 |    |                                                    |          |                            |
| AB | MOTRIN<br>UPJOHN                | 300MG | SEP 23, 1986               |    |                                                    |          |                            |
| AB |                                 | 800MG | N17463 003                 |    |                                                    |          |                            |
| AB | RUFEN                           | 800MG | N17463 005                 |    |                                                    |          |                            |
| AB | BOOT PHARMACEUTICAL             | 800MG | MAY 22, 1985               |    |                                                    |          |                            |
| AB |                                 |       | N70745 001<br>JUL 23, 1986 |    |                                                    |          |                            |

INDIUM IN-111 OXYQUINOLINE (PAGE 3-121)

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

N19044 001  
DEC 23, 1985

INJECTABLE; INJECTION  
OMNIPAGUE 180  
WINTHROP-BREON/STERL 38.8/M

N18956 001  
DEC 26, 1985

IOHEXOL (PAGE 3-123)

## INJECTABLE; INJECTION

OMNIPAQUE 240  
WINTHROP-BREON/STERL 51.8/MN18956 002  
DEC 26, 1985OMNIPAQUE 300  
WINTHROP-BREON/STERL 64.7/MN18956 003  
DEC 26, 1985OMNIPAQUE 350  
WINTHROP-BREON/STERL 75.5/MN18956 004  
DEC 26, 1985

## TABLET; ORAL

ISOSORBIDE DINITRATE  
BARR LABORATORIES

5MG

N86166 001  
SEP 19, 1986N86169 001  
SEP 19, 1986N86167 001  
SEP 19, 1986N87564 001  
SEP 18, 1986N87564 001  
SEP 18, 1986IOPAMIDOL (PAGE 3-123)

## INJECTABLE; INJECTION

ISOVUE-300  
ER SQUIBB AND SONS 61/MN18735 002  
DEC 31, 1985ISOVUE-370  
ER SQUIBB AND SONS 76/MN18735 003  
DEC 31, 1985ISOVUE-M 200  
ER SQUIBB AND SONS 41/MN18735 001  
DEC 31, 1985ISOVUE-M 300  
ER SQUIBB AND SONS 61/MN18735 004  
DEC 31, 1985

## TABLET; SUBLINGUAL

ISOSORBIDE DINITRATE  
BARR LABORATORIES

2.5MG

N84204 001  
SEP 18, 1986N86168 001  
SEP 18, 1986N87545 001  
SEP 18, 1986KANAMYCIN SULFATE (PAGE 3-126)

## INJECTABLE; INJECTION

KANAMYCIN SULFATE  
QUAD PHARMS

EQ 75MG BASE/2ML

N62642 001  
FEB 03, 1986

EQ 500MG BASE/2ML

N62642 002  
FEB 03, 1986

EQ 1GM BASE/3ML

N62642 003  
FEB 03, 1986

EQ 75MG BASE/2ML

N62605 003  
FEB 26, 1986

EQ 500MG BASE/2ML

N62605 001  
FEB 26, 1986

EQ 1GM BASE/3ML

N62605 002  
FEB 26, 1986> ADD > IPRATROPIUM BROMIDE (PAGE 3-124)

## AEROSOL; INHALATION

ATROVENT  
BOEHRINGER INGELHEIM 0.018MG/INH

&gt; ADD &gt;

&gt; ADD &gt;

&gt; ADD &gt;

&gt; ADD &gt;

ISOETHARINE HYDROCHLORIDE (PAGE 3-124)

## SOLUTION; INHALATION

ISOETHARINE HCL S/F  
DEY LABORATORIES 1/MN89252 001  
SEP 15, 1986

2/M

N19084 001  
DEC 31, 1985ISONIAZID (PAGE 3-125)

## SYRUP; ORAL

LANNAZID  
LANNETT 50MG/5MLN89243 001  
FEB 03, 1986

100MG/5ML

N70767 001  
NOV 07, 1986KETOCONAZOLE (PAGE 3-127)

## CREAM; TOPICAL

NIZORAL  
JANSSEN PHARMA

2/M

## SUSPENSION; ORAL

NIZORAL  
JANSSEN PHARM

100MG/5ML

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

KETOPROFEN (PAGE 3-127)

CAPSULE; ORAL  
 ORUDIS  
 MYETH LABS/AMHO 50MG  
 75MG

N18754 002  
 JAN 09, 1986  
 N18754 003  
 JAN 09, 1986

LITHIUM CITRATE (PAGE 3-132)

SYRUP; ORAL

AA  
LITHIUM CITRATE  
 MY-K LABS

EQ 300MG CARBONATE/5ML  
 N70755 001  
 MAY 21, 1986

LABETALOL HYDROCHLORIDE (PAGE 3-127)

INJECTABLE; INJECTION  
 HORMODYNE  
 AP SCHERING

AP 5MG/ML

N18686 001  
 AUG 01, 1984

AP  
 TRANDATE  
 GLAXO

AP 5MG/ML

N19425 001  
 DEC 31, 1985

LACTULOSE (PAGE 3-127)

SYRUP; ORAL  
 LACTULOSE  
 AA ROXANE LABORATORIES

AA 10GM/15ML

N17906 001

LEUCOVORIN CALCIUM (PAGE 3-127)

INJECTABLE; INJECTION  
 LEUCOVORIN CALCIUM

> ADD > AP  
 > ADD > AP  
 > ADD > AP  
 LEIDERLE LABS/AM CYAN EQ 50MG BASE/VIAL  
 LYPHOMED EQ 50MG BASE/VIAL

N08107 002  
 N88939 001  
 DEC 01, 1986

TABLET; ORAL

BX LEUCOVORIN CALCIUM

BX LEIDERLE LABS/AM CYAN EQ 5MG BASE

WELLCOVORIN

BX BURROUGHS WELLCOME EQ 5MG BASE

N18459 001  
 JAN 30, 1986

N18342 001  
 JUL 08, 1983

LEVONUNOLOL HYDROCHLORIDE (PAGE 3-128)

SOLUTION/DROPS; OPHTHALMIC  
 BETAGAN

ALLERGAN PHARMS 0.5%

N19219 002  
 DEC 19, 1985

LORAZEPAM (PAGE 3-132)

TABLET; ORAL

AB  
 AB  
 AB  
 ATIVAN  
 MYETH LABS/AMHO

0.5MG

1MG

2MG

N17794 001  
 N17794 002  
 N17794 003

AB  
 AB  
 AB  
 LORAZEPAM  
 AM THERAPEUTIC

0.5MG

1MG

2MG

N70727 001  
 MAR 07, 1986  
 N70728 001  
 MAR 07, 1986  
 N70729 001  
 MAR 07, 1986

AB  
 AB  
 AB  
 LORAZEPAM  
 BARR LABORATORIES

0.5MG

1MG

2MG

N70472 001  
 DEC 10, 1985  
 N70473 001  
 DEC 10, 1985  
 N70474 001  
 DEC 10, 1985

> ADD > AB  
 > ADD > AB  
 > ADD > AB  
 COLMED LABORATORIES

1MG

2MG

N70539 001  
 DEC 22, 1986  
 N70540 001  
 DEC 22, 1986

0.5MG

1MG

2MG

N71117 001  
 JUL 24, 1986  
 N71118 001  
 JUL 24, 1986

2MG

0.5MG

1MG

2MG

N71110 001  
 JUL 24, 1986  
 N70675 001  
 DEC 01, 1986

1MG

2MG

0.5MG

1MG

2MG

N70677 001  
 DEC 01, 1986  
 N70200 001  
 AUG 09, 1985

0.5MG

1MG

2MG

N70201 001  
 AUG 09, 1985  
 N70202 001  
 AUG 09, 1985

LOXAPINE SUCCINATE (PAGE 3-132)

## TABLET; ORAL

LOXITANE

3 LEDERLE LABS/AM CYAN EQ 10MG BASE  
3 EQ 25MG BASE  
3 EQ 50MG BASE

N17525 006  
N17525 007  
N17525 008

## CAPSULE; ORAL

MECLOFENAMATE SODIUM

AB BOLAR PHARMACEUTICAL EQ 50MG BASE  
AB EQ 100MG BASE  
AB MYLAN PHARMS EQ 50MG BASE  
AB EQ 100MG BASE

N70400 001  
NOV 25, 1986  
N70401 001  
NOV 25, 1986  
N71080 001  
SEP 03, 1986  
N71081 001  
SEP 03, 1986

MAGNESIUM SULFATE (PAGE 3-134)

INJECTABLE; INJECTION

MAGNESIUM SULFATE

LYPHOMED

N19316 001  
SEP 08, 1986

MANGANESE CHLORIDE (PAGE 3-134)

INJECTABLE; INJECTION

MANGANESE CHLORIDE IN PLASTIC CONTAINER

ABBOTT LABORATORIES EQ 0.1MG MANGANESE/ML

N18962 001  
JUN 26, 1986

MANNITOL (PAGE 3-134)

SOLUTION; IRRIGATION

RESECTISOL

AM MCGAM/AM HOSP /50M/100ML/  
RESECTISOL IN PLASTIC CONTAINER  
AM MCGAM/AM HOSP 50M/100ML

N16772 002

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

## TABLET; ORAL

MECLIZINE HCL

AA SIDMAK LABORATORIES 12.5MG

AA 25MG

AA SUPERPHARM 12.5MG

AA 25MG

TABLET, CHEWABLE; ORAL

MECLIZINE HCL

AA SIDMAK LABORATORIES 25MG

N88733 001  
DEC 11, 1985

MECLOFENAMATE SODIUM (PAGE 3-136)

## CAPSULE; ORAL

MECLOFENAMATE SODIUM

AB BOLAR PHARMACEUTICAL EQ 50MG BASE  
AB EQ 100MG BASE  
AB MYLAN PHARMS EQ 50MG BASE  
AB EQ 100MG BASE

N70400 001  
NOV 25, 1986  
N70401 001  
NOV 25, 1986  
N71080 001  
SEP 03, 1986  
N71081 001  
SEP 03, 1986

MECLOFEN

PARKE-DAVIS/W-L

AB EQ 50MG BASE  
AB EQ 100MG BASE

N18006 001  
N18006 002

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

## TABLET; ORAL

PROVERA

UPJOHN

5MG

N11839 003

MENOTROPINS (PAGE 1-137)

INJECTABLE; INJECTION

PERGONAL

/SERONO LABS/

/150 IU/AMP/

/300 IU/AMP/

SERONO LABS

75 IU/AMP

150 IU/AMP

MAY 20, 1985

/N17646 001/  
/N17646 002/  
N17646 001  
N17646 002

MEPHENYTOIN (PAGE 3-138)

## TABLET; ORAL

MESANTOIN

SANDOZ PHARMS/SANDOZ 100MG

N06008 001

MEPIVACAINES HYDROCHLORIDE (PAGE 3-138)

INJECTABLE; INJECTION

CARBOCAINE

WINTHROP-BREON/STERIL 1.5%

POLOCAINE

ASTRA PHARM PRODS

1.5%

N12250 005

1.5%

1.5%

1.5%

2%

2%

2%

2%

2%

2%

2%

2%

2%

2%

2%

2%

N89406 001

DEC 01, 1986

N89407 001

DEC 01, 1986

N89408 001

DEC 01, 1986

N89409 001

DEC 01, 1986

N89410 001

DEC 01, 1986

N89411 001

DEC 01, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

METAPROTERENOL SULFATE (PAGE 3-140)

SOLUTION; INHALATION  
ALUPENT  
BOEHRINGER INGELHEIM 0.4%M

N18761 002  
OCT 10, 1986

METHACHOLINE CHLORIDE (PAGE 3-140)

POWDER FOR RECONSTITUTION; INHALATION  
PROVOCHOLINE  
HOFFMANN-LA ROCHE 100MG/VIALM

N19193 001  
OCT 31, 1986

METHOCARBAMOL (PAGE 3-142)

TABLET; ORAL

METHOCARBAMOL

AA PIONEER PHARMS 500MGM

AA 750MGM

N88731 001  
DEC 13, 1985  
N89082 001  
DEC 13, 1985

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

FOLEX

AP ADRIA LABS/ERBAMONT EQ 250MG BASE/VIALM

FOLEX PFS

AP ADRIA LABS/ERBAMONT EQ 25MG BASE/MLM

/AP/ EQ 25MG BASE/MLM

/AP/ EQ 25MG BASE/MLM

METHOTREXATE LPF

AP LEDERLE LABS/AM CYAN EQ 25MG BASE/ML

METHOTREXATE SODIUM

AP BEN VENUE LABS EQ 25MG BASE/MLM

AP EQ 25MG BASE/MLM

AP EQ 25MG BASE/MLM

AP EQ 25MG BASE/MLM

AP EQ 25MG BASE/MLM

N11719 007  
MAR 31, 1982

N89340 001  
SEP 16, 1986

N89341 001  
SEP 16, 1986

N89342 001  
SEP 16, 1986

N89343 001  
SEP 16, 1986

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

METHOTREXATE SODIUM

AP INTL PHARM PRODS EQ 25MG BASE/MLM

AP LYPHOMED EQ 2.5MG BASE/MLM

AP EQ 20MG BASE/VIALM

AP EQ 25MG BASE/MLM

AP EQ 25MG BASE/MLM

AP EQ 50MG BASE/VIALM

AP EQ 100MG BASE/VIALM

AP QUAD PHARMS EQ 25MG BASE/MLM

AP EQ 25MG BASE/MLM

AP EQ 20MG BASE/VIALM

AP EQ 50MG BASE/VIALM

AP EQ 100MG BASE/VIALM

AP EQ 250MG BASE/VIALM

METHOTREXATE

AP LEDERLE LABS/AM CYAN EQ 2.5MG BASE/ML

MEKATE

AP BRISTOL LABS/B-M EQ 250MG BASE/VIAL

METHOXSALEN (PAGE 3-143)

CAPSULE, LIQUID FILLED; ORAL  
OXSORALEN-ULTRA

ELDER PHARMS 10MGM

METHYLCLOTHIAZIDE (PAGE 3-143)

TABLET; ORAL

METHYLCLOTHIAZIDE

AB PAR PHARMACEUTICAL 2.5MGM

AB 5MGM

N88648 001  
MAY 09, 1986  
N89323 001  
JUN 13, 1986  
N88935 001  
OCT 11, 1985  
N89322 001  
JUN 13, 1986  
N89263 001  
JUN 13, 1986  
N88936 001  
OCT 11, 1985  
N89937 001  
OCT 11, 1985  
N89308 001  
JUL 10, 1986  
N89309 001  
JUL 10, 1986  
N89293 001  
JUL 10, 1986  
N89294 001  
JUL 10, 1986  
N89295 001  
JUL 10, 1986  
N89296 001  
JUL 10, 1986  
N11719 004  
N86358 004

N19600 001  
OCT 30, 1986

N89135 001  
FEB 12, 1986  
N89136 001  
FEB 12, 1986

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

## METHYLDOPA (PAGE 3-144)

## TABLET; ORAL

## METHYLDOPA

|         |                      |       |              |
|---------|----------------------|-------|--------------|
| AB      | BARR LABORATORIES    | 125MG | N70073 001   |
| AB      |                      | 250MG | OCT 09, 1986 |
| AB      |                      | 500MG | N70060 001   |
| AB      |                      |       | OCT 09, 1986 |
| AB      | BOLAR PHARMACEUTICAL | 125MG | N70074 001   |
| AB      |                      | 250MG | OCT 09, 1986 |
| AB      |                      | 500MG | N70245 001   |
| AB      |                      |       | FEB 25, 1986 |
| AB      |                      | 250MG | N70246 001   |
| AB      |                      | 500MG | FEB 25, 1986 |
| AB      | DANBURY PHARMACAL    | 250MG | N70247 001   |
| AB      |                      | 500MG | FEB 25, 1986 |
| AB      |                      | 250MG | N70703 001   |
| AB      |                      | 500MG | JUN 06, 1986 |
| AB      |                      | 250MG | N70625 001   |
| AB      |                      | 500MG | JUN 06, 1986 |
| > ADD > | DURAMED PHARMS       | 250MG | N71006 001   |
| > ADD > |                      | 500MG | DEC 16, 1986 |
| > ADD > |                      | 500MG | N71009 001   |
| > ADD > | LEDERLE LABS/AM CYAN | 125MG | DEC 16, 1986 |
| AB      |                      | 250MG | OCT 15, 1985 |
| AB      |                      | 500MG | N70084 001   |
| AB      |                      | 125MG | OCT 15, 1985 |
| > ADD > | NOVOPHARM            | 250MG | N70085 001   |
| > ADD > |                      | 500MG | OCT 15, 1985 |
| > ADD > |                      | 125MG | N71105 001   |
| > ADD > |                      | 250MG | DEC 05, 1986 |
| > ADD > |                      | 500MG | N71106 001   |
| > ADD > |                      | 125MG | DEC 05, 1986 |
| > ADD > | PARKE-DAVIS/M-L      | 250MG | N71067 001   |
| AB      |                      | 500MG | DEC 05, 1986 |
| AB      |                      | 125MG | N70331 001   |
| AB      |                      | 500MG | APR 15, 1986 |
| AB      | PUREPAC/KALIPHARMA   | 125MG | N70332 001   |
| AB      |                      | 250MG | APR 15, 1986 |
| AB      |                      | 500MG | N70333 001   |
| AB      |                      | 125MG | APR 15, 1986 |
| AB      |                      | 250MG | N70749 001   |
| AB      |                      | 500MG | FEB 07, 1986 |
| AB      |                      | 125MG | N70750 001   |
| AB      |                      | 250MG | FEB 07, 1986 |
| AB      |                      | 500MG | N70452 001   |
| AB      | ROXANE LABORATORIES  | 125MG | FEB 07, 1986 |
| AB      |                      | 250MG | N70192 001   |
| AB      |                      | 500MG | APR 25, 1986 |
| AB      |                      |       | N70193 001   |
| AB      |                      |       | APR 25, 1986 |
| AB      |                      |       | N70194 001   |
| AB      |                      |       | APR 25, 1986 |

## METHYLDOPA (PAGE 3-144)

## TABLET; ORAL

## METHYLDOPA

|    |                                         |         |              |
|----|-----------------------------------------|---------|--------------|
| AB | ZENITH LABORATORIES                     | 250MG   | N70098 001   |
| AB |                                         | 500MG   | FEB 20, 1986 |
| AB |                                         |         | N70343 001   |
| AB |                                         |         | FEB 20, 1986 |
| AB | METHYLDOPATE HYDROCHLORIDE (PAGE 3-144) |         |              |
| AB | INJECTABLE; INJECTION                   |         |              |
| AB | ALDOMET                                 | 50MG/ML | N13401 001   |
| AB | MS&D/MERCK                              | 50MG/ML |              |
| AB | METHYLDOPATE HCL                        | 50MG/ML | N70291 001   |
| AB | ELKINS-SINN/AHROBINS                    | 50MG/ML | JUL 01, 1986 |
| AB |                                         | 50MG/ML | N70652 001   |
| AB |                                         | 50MG/ML | JUN 03, 1986 |
| AB | LYPHOMED                                | 50MG/ML | N71024 001   |
| AB | QUAD PHARM                              | 50MG/ML | SEP 18, 1986 |

## METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

## INJECTABLE; INJECTION

## METHYLPREDNISOLONE SODIUM SUCCINATE

|    |             |                    |              |
|----|-------------|--------------------|--------------|
| AP | LYPHOMED    | EQ 40MG BASE/VIAL  | N89143 001   |
| AP |             | EQ 125MG BASE/VIAL | MAR 28, 1986 |
| AP |             | EQ 500MG BASE/VIAL | N89144 001   |
| AP |             | EQ 500MG BASE/VIAL | MAR 28, 1986 |
| AP |             | EQ 500MG BASE/VIAL | N89186 001   |
| AP |             | EQ 1GM BASE/VIAL   | MAR 28, 1986 |
| AP |             | EQ 1GM BASE/VIAL   | N89187 001   |
| AP |             | EQ 1GM BASE/VIAL   | MAR 28, 1986 |
| AP |             | EQ 1GM BASE/VIAL   | N89188 001   |
| AP |             | EQ 40MG BASE/VIAL  | MAR 28, 1986 |
| AP | QUAD PHARMS | EQ 125MG BASE/VIAL | N89189 001   |
| AP |             | EQ 500MG BASE/VIAL | MAR 28, 1986 |
| AP |             | EQ 500MG BASE/VIAL | N89264 001   |
| AP |             | EQ 1GM BASE/VIAL   | JAN 22, 1986 |
| AP |             | EQ 125MG BASE/VIAL | N89265 001   |
| AP |             | EQ 500MG BASE/VIAL | JAN 22, 1986 |
| AP |             | EQ 1GM BASE/VIAL   | N89266 001   |
| AP |             | EQ 1GM BASE/VIAL   | JAN 22, 1986 |
| AP |             | EQ 1GM BASE/VIAL   | N89267 001   |
| AP |             | EQ 1GM BASE/VIAL   | JAN 22, 1986 |

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION  
METOCLOPRAMIDE HCL

AP LYPHOMED EQ 10MG BASE/2MLM

N70293 001  
JAN 24, 1986  
N70671 001  
MAY 27, 1986

AP QUAD PHARMS EQ 10MG BASE/2MLM

AP REGLAN

EQ 10MG BASE/2ML  
EQ 50MG BASE/10ML  
EQ 150MG BASE/30ML

N17862 001  
N17862 003  
AUG 03, 1984  
N17862 002  
AUG 03, 1984

TABLET; ORAL  
CLOPRA-YELLOW  
AP QUANTUM PHARMICS

EQ 10MG BASEM

N70632 001  
OCT 28, 1985

AP MAXOLON

EQ 10MG BASEM

N70106 001  
MAR 04, 1986

AP METOCLOPRAMIDE HCL  
CHELSEA LABORATORIES

EQ 10MG BASEM

N70453 001  
JUN 06, 1986  
N70511 001  
JAN 22, 1986

AP DANBURY PHARMACAL

EQ 10MG BASEM

N70906 001  
OCT 28, 1986

AP HALSEY DRUG

EQ 10MG BASEM

N71213 001  
SEP 24, 1986

AP INTERPHARM

EQ 10MG BASEM

N70342 001  
MAR 25, 1986

AP PAR PHARMACEUTICAL

EQ 10MG BASEM

N70581 001  
OCT 17, 1985

AP PUREPAC/KALIPHARMA

EQ 10MG BASEM

METRONIDAZOLE (PAGE 3-148)

INJECTABLE; INJECTION  
METRONIDAZOLE

AP CARTER-GLOGAU LABS 500MG/100MLM

N70170 001  
APR 01, 1986

TABLET; ORAL

AP METRONIDAZOLE  
HALSEY DRUG

500MG

N70593 001  
FEB 27, 1986

AP MUTUAL PHARM

250MG

N70772 001  
JUL 16, 1986

AP VITARINE

250MG

N70773 001  
JUL 16, 1986

AP VITARINE

250MG

N18620 001  
MAR 04, 1982

500MG

N18620 002  
JUN 02, 1983

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL

AP METRYL  
VITAPHARM

EQ 500MG

N18873 001  
DEC 30, 1985

AP METRYL 500  
VITAPHARM

EQ 500MG

N18873 003  
DEC 30, 1985

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION

AP SEARLE PHARMS

EQ 500MG BASE/VIAL

N18353 001

AP METRONIDAZOLE HCL

EQ 500MG BASE/VIALM

N70295 001  
OCT 15, 1985

MEXILETINE HYDROCHLORIDE (PAGE 3-149)

AP MEXITIL

BOEHRINGER INGELHEIM 150MG

N18873 002  
DEC 30, 1985

AP MEXITIL

200MG

N18873 003  
DEC 30, 1985

AP MEXITIL

250MG

N18873 004  
DEC 30, 1985

MIDAZOLAM HYDROCHLORIDE (PAGE 3-149)

INJECTABLE; INJECTION  
VERSED

HOFFMANN-LA ROCHE

EQ 5MG BASE/MLM

N18654 001  
DEC 20, 1985

MONOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY  
MOCTANIN

ETHITEK PHARMS 100/M

N19368 001  
OCT 29, 1985



NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION  
NALOXONE HCL  
LYPHOMED

|    |           |              |
|----|-----------|--------------|
| AP | 0.02MG/ML | N70648 001   |
| AP | 0.02MG/ML | NOV 17, 1986 |
| AP | 0.02MG/ML | N70661 001   |
| AP | 0.02MG/ML | NOV 17, 1986 |
| AP | 0.04MG/ML | N70649 001   |
| AP | 0.04MG/ML | NOV 17, 1986 |
| AP | 0.02MG/ML | N70678 001   |
| AP | 0.02MG/ML | DEC 18, 1986 |
| AP | 0.04MG/ML | N70679 001   |
| AP | 0.04MG/ML | DEC 18, 1986 |
| AP | 1MG/ML    | N70680 001   |
| AP | 1MG/ML    | DEC 18, 1986 |
| AP | 0.02MG/ML | N70171 001   |
| AP | 0.02MG/ML | SEP 24, 1986 |
| AP | 0.04MG/ML | N70172 001   |
| AP | 0.04MG/ML | SEP 24, 1986 |
| AP | 0.02MG/ML | N16636 002   |
| AP | 0.02MG/ML | NOV 17, 1986 |
| AP | 0.04MG/ML | N16636 001   |
| AP | 0.04MG/ML | NOV 17, 1986 |
| AP | 0.04MG/ML | N16636 003   |
| AP | 0.04MG/ML | JUN 14, 1982 |

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

TABLET; ORAL  
TALWIN NX

WINTHROP-BREON/STERL EQ 0.5MG BASE;  
EQ 50MG BASE  
/WINTHROP-BREON/STERL/0.5 MG; EQ 50MG BASE/  
/DEC 16, 1982/  
N18733 001  
DEC 16, 1982

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION  
DECA-DURABOLIN  
ORGANON/AKZONA

|    |          |              |
|----|----------|--------------|
| AO | 50MG/ML  | N13132 001   |
| AO | 50MG/ML  | JUN 12, 1986 |
| AO | 100MG/ML | N13132 002   |
| AO | 100MG/ML | JUN 12, 1986 |
| AO | 200MG/ML | N13132 003   |
| AO | 200MG/ML | JUN 12, 1986 |

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION  
NANDROLONE DECANOATE  
CARTER-GLOGAU LABS

|    |          |              |
|----|----------|--------------|
| AO | 50M/ML   | N86385 001   |
| AO | 50M/ML   | JAN 13, 1984 |
| AO | 100MG/ML | N86598 001   |
| AO | 100MG/ML | JAN 13, 1984 |
| AO | 50MG/ML  | N88554 001   |
| AO | 50MG/ML  | FEB 10, 1986 |
| AO | 50MG/ML  | N87598 001   |
| AO | 50MG/ML  | OCT 06, 1983 |
| AO | 50MG/ML  | N89248 001   |
| AO | 50MG/ML  | JUN 25, 1986 |
| AO | 100MG/ML | N89249 001   |
| AO | 100MG/ML | JUN 25, 1986 |
| AO | 200MG/ML | N89250 001   |
| AO | 200MG/ML | JUN 25, 1986 |

NANDROLONE PHENPROPIONATE (PAGE 3-151)

INJECTABLE; INJECTION  
NANDROLONE PHENPROPIONATE  
QUAD PHARMS

|    |         |              |
|----|---------|--------------|
| AO | 25MG/ML | N89297 001   |
| AO | 25MG/ML | OCT 01, 1986 |
| AO | 50MG/ML | N89298 001   |
| AO | 50MG/ML | OCT 01, 1986 |

NEOMYCIN SULFATE; POLYMYXIN B SULFATE (PAGE 3-153)

SOLUTION; IRRIGATION

NEOMYCIN AND POLYMYXIN B SULFATES

|    |                                      |              |
|----|--------------------------------------|--------------|
| AI | EQ 40MG BASE/ML;<br>200,000 UNITS/ML | N62664 001   |
| AI | EQ 40MG BASE/ML;<br>200,000 UNITS/ML | APR 08, 1986 |

NEOSPORIN G.U. IRRIGANT

|    |                                      |            |
|----|--------------------------------------|------------|
| AI | BURROUGHS WELLCOME                   | N60707 001 |
| AI | EQ 40MG BASE/ML;<br>200,000 UNITS/ML |            |

NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

CREAM; TOPICAL

MYTRET A

|    |                                          |                        |              |
|----|------------------------------------------|------------------------|--------------|
| AI | SAVAGE LABS/ALTANA                       | EQ 3.5MG BASE/GH;0.12M | N62598 001   |
| AI | EQ 3.5MG BASE/GH;0.12M                   |                        | JUL 21, 1986 |
| AI | NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE |                        |              |
| AI | E FOUGERA/ALTANA                         | EQ 3.5MG BASE/GH;0.12M | N62600 001   |
| AI | EQ 3.5MG BASE/GH;0.12M                   |                        | JUL 21, 1986 |
| AI | PHARMADERM/ALTANA                        | EQ 3.5MG BASE/GH;0.12M | N62595 001   |
| AI | EQ 3.5MG BASE/GH;0.12M                   |                        | JUL 21, 1986 |

## NEOMYCIN SULFATE; TRIAMCINOLONE ACETONIDE (3-153)

## OINTMENT; TOPICAL

|    |                                                              |                                        |                            |
|----|--------------------------------------------------------------|----------------------------------------|----------------------------|
| AT | MYTREX A<br>Savage Labs/Altana                               | EQ 3.5MG BASE/GM; 0.1%<br>MAY 23, 1986 | N62609 001<br>MAY 23, 1986 |
| AT | NEOMYCIN SULFATE-TRIAMCINOLONE ACETONIDE<br>E FOUGERA/ALTANA | EQ 3.5MG BASE/GM; 0.1%<br>MAY 23, 1986 | N62608 001<br>MAY 23, 1986 |
| AT | PHARMADERM/ALTANA                                            | EQ 3.5MG BASE/GM; 0.1%<br>MAY 23, 1986 | N62607 001<br>MAY 23, 1986 |

## NIFEDIPINE (PAGE 3-154)

## CAPSULE; ORAL

|    |                                 |                      |                            |
|----|---------------------------------|----------------------|----------------------------|
| AB | ADALAT<br>Miles Pharm/Miles     | 10MG<br>NOV 27, 1985 | N19478 001<br>NOV 27, 1985 |
| AB |                                 | 20MG<br>SEP 17, 1986 | N19478 002<br>SEP 17, 1986 |
| AB | PROCARDIA<br>Pfizer Labs/Pfizer | 10MG<br>JUL 24, 1986 | N18482 001<br>JUL 24, 1986 |
| AB |                                 | 20MG                 | N18482 002<br>JUL 24, 1986 |

## NITROGLYCERIN (PAGE 3-154)

AEROSOL; ORAL  
NITROLINGUAL  
G POHL-BOSKAMP

0.4MG/SPRAY

N18705 001  
OCT 31, 1985

## INJECTABLE; INJECTION

## NITROGLYCERIN

|    |                      |                        |                            |
|----|----------------------|------------------------|----------------------------|
| AP | INTL MEDICATION SYS  | 5MG/ML<br>SEP 10, 1985 | N70026 001<br>SEP 10, 1985 |
| AP | LYPHONED             | 5MG/ML<br>DEC 13, 1985 | N70077 001<br>DEC 13, 1985 |
| AP | SOLOPAK LABORATORIES | 5MG/ML<br>JUN 19, 1986 | N70633 001<br>JUN 19, 1986 |
| AP |                      | 5MG/ML<br>JUN 19, 1986 | N70634 001<br>JUN 19, 1986 |

## NORFLOXACIN (PAGE 3-155)

## NORFLOXACIN

/MERITAC/  
/S/HOECHST-ROUSSEL/  
/S/  
/N18824, 001/  
/DEC 31, 1984/  
/N18824, 002/  
/DEC 31, 1984/  
/N18824, 003/  
/DEC 31, 1984/

## NORFLOXACIN (PAGE 3-155)

## TABLET; ORAL

|              |       |                            |
|--------------|-------|----------------------------|
| MSD RES LABS | 400MG | N19384 002<br>OCT 31, 1986 |
|--------------|-------|----------------------------|

## NYSTATIN (PAGE 3-156)

## OINTMENT; TOPICAL

## MYKINAC

|    |                  |                  |                            |
|----|------------------|------------------|----------------------------|
| AT | NMC LABORATORIES | 100,000 UNITS/GM | N62731 001<br>SEP 22, 1986 |
|----|------------------|------------------|----------------------------|

## POWDER; ORAL

## MILSTAT

|    |                      |      |                            |
|----|----------------------|------|----------------------------|
| AA | LEDERLE LABS/AM CYAN | 100% | N50576 001<br>DEC 22, 1983 |
|----|----------------------|------|----------------------------|

## NYSTATIN

|    |                      |      |                            |
|----|----------------------|------|----------------------------|
| AA | PADDUCK LABORATORIES | 100% | N62613 001<br>NOV 26, 1985 |
|----|----------------------|------|----------------------------|

## SUSPENSION; ORAL

## NYSTATIN

|    |                 |                  |                            |
|----|-----------------|------------------|----------------------------|
| AA | NASKA PHARMACAL | 100,000 UNITS/ML | N62571 001<br>OCT 29, 1985 |
|----|-----------------|------------------|----------------------------|

## TABLET; ORAL

## NYSTATIN

|    |        |               |                            |
|----|--------|---------------|----------------------------|
| AA | LEMMON | 500,000 UNITS | N62506 001<br>JAN 16, 1984 |
|----|--------|---------------|----------------------------|

## PHARM BASICS

|    |  |               |                            |
|----|--|---------------|----------------------------|
| AA |  | 500,000 UNITS | N62524 001<br>NOV 26, 1985 |
|----|--|---------------|----------------------------|

## TABLET; VAGINAL

## NYSTATIN

|    |                     |               |                            |
|----|---------------------|---------------|----------------------------|
| AT | SIDMAK LABORATORIES | 100,000 UNITS | N62615 001<br>OCT 17, 1985 |
|----|---------------------|---------------|----------------------------|

## NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

## CREAM; TOPICAL

## MYCO-TRIACET II

|    |        |                        |                            |
|----|--------|------------------------|----------------------------|
| AT | LEMMON | 100,000 UNITS/GM; 0.1% | N61954 002<br>SEP 20, 1985 |
|----|--------|------------------------|----------------------------|

## MYTREX F

|    |                    |                        |                            |
|----|--------------------|------------------------|----------------------------|
| AT | SAVAGE LABS/ALTANA | 100,000 UNITS/GM; 0.1% | N62597 001<br>OCT 08, 1985 |
|----|--------------------|------------------------|----------------------------|

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL  
NYSTATIN-TRIAMCINOLONE ACETONIDE  
 AI E FOUGERA/ALTANA 100,000 UNITS/GM;0.1%<sup>m</sup> N62599 001 OCT 08, 1985  
 AI PHARMADERM/ALTANA 100,000 UNITS/GM;0.1%<sup>m</sup> N62596 001 OCT 08, 1985  
 AI NYSTATIN AND TRIAMCINOLONE ACETONIDE  
 AI PHARMAFAIR 100,000 UNITS/GM;0.1%<sup>m</sup> N62657 001 JUL 30, 1986

OINTMENT; TOPICAL  
MYCO-TRIZACET II

AI LEMMON 100,000 UNITS/GM;0.1%<sup>m</sup> N62045 002 NOV 26, 1985  
 AI MYCOLOG-II  
 AI ER SQUIBB AND SONS 100,000 UNITS/GM;0.1%<sup>m</sup> N60572 001 JUN 28, 1985  
 AI MYTRET F  
 AI SAVAGE LABS/ALTANA 100,000 UNITS/GM;0.1%<sup>m</sup> N62601 001 OCT 09, 1985

NYSTATIN-TRIAMCINOLONE ACETONIDE

AI E FOUGERA/ALTANA 100,000 UNITS/GM;0.1%<sup>m</sup> N62602 001 OCT 09, 1985  
 AI PHARMADERM/ALTANA 100,000 UNITS/GM;0.1%<sup>m</sup> N62603 001 OCT 09, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AI CLAY-PARK LABS 100,000 UNITS/GM;0.1%<sup>m</sup> N62280 002 OCT 10, 1985  
 AI PHARMAFAIR 100,000 UNITS/GM;0.1%<sup>m</sup> N62656 002 JUL 30, 1986

OXACILLIN SODIUM (PAGE 3-157)

## INJECTABLE; INJECTION

BACTOCILL

> ADD > AP BEECHAM LABS/BEECHAM EQ 1GM BASE/VIAL<sup>m</sup> N62736 001 DEC 19, 1986  
 > ADD > AP EQ 2GM BASE/VIAL<sup>m</sup> N62736 002 DEC 19, 1986  
 > ADD > AP

PROSTAPHLIN

> ADD > AP BRISTOL LABS/B-M EQ 1GM BASE/VIAL<sup>m</sup> N62737 001 DEC 23, 1986  
 > ADD > AP EQ 2GM BASE/VIAL<sup>m</sup> N62737 002 DEC 23, 1986  
 > ADD > AP

OXYPHENBUTAZONE (PAGE 3-159)

## TABLET; ORAL

OXYPHENBUTAZONE

AB @ BOLAR PHARMACEUTICAL 100MG N88399 001 SEP 17, 1984

PARGYLINE HYDROCHLORIDE (PAGE 3-160)

## TABLET; ORAL

EUTONYL  
 @ ABBOTT LABORATORIES 50MG N13448 004

PENCILLIN G POTASSIUM (PAGE 3-161)

## POWDER FOR RECONSTITUTION; ORAL

PENCILLIN G POTASSIUM  
 AA @ MYLAN PHARMS 200,000 UNITS/5ML N60752 003  
 AA @ 250,000 UNITS/5ML N60752 002  
 AA @ 400,000 UNITS/5ML N60752 001

PERMETHRIN (PAGE 3-164)

## LOTION; TOPICAL

NIX  
 BURROUGHS WELLCOME 1%<sup>m</sup> N19435 001 MAR 31, 1986

PHENTERMINE HYDROCHLORIDE (PAGE 3-167)

## CAPSULE; ORAL

ADIPEX/LEMMON  
 /AA/ /LEMMON/ 30MG<sup>m</sup> N87126 001  
 /AA/ PHENTERMINE HCL 30MG<sup>m</sup> N88948 001 APR 25, 1986  
 AA DURAMED PHARMS 30MG<sup>m</sup> N87777 001 NOV 01, 1985  
 AA LEMMON 30MG<sup>m</sup> N87126 001  
 AA 30MG

PHENYLBUTAZONE (PAGE 3-168)

## CAPSULE; ORAL

PHENYLBUTAZONE  
 AB BARR LABORATORIES 100MG<sup>m</sup> N88994 001 DEC 04, 1985

## TABLET; ORAL

PHENYLBUTAZONE  
 AB BARR LABORATORIES 100MG<sup>m</sup> N88863 001 DEC 04, 1985

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM  
BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE (PAGE 3-170)

SOLUTION; ORAL

OC

ABBOTT LABORATORIES

6GM/100ML; 75MG/100ML; 168MG/100ML;  
146MG/100ML;  
1.29GM/100MLM

N19284 001  
APR 30, 1986

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE  
(PAGE 3-168)

SYRUP; ORAL

PROMETHAZINE VC PLAIN

HR CENCL LABS

N88815 001  
NOV 22, 1985

5MG/5ML; 6.25MG/5MLM

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

SIDHAK LABORATORIES 100MG

N89441 001  
DEC 18, 1986

EXTENDED PHENYTOIN SODIUM

BOLAR PHARMACEUTICAL 100MG

N88711 001  
DEC 21, 1984

SEITZ

PHENYTOIN

BOLAR PHARMACEUTICAL 100MG

N88711 001  
DEC 21, 1984

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

CAPSULE; ORAL

PHENYTOIN SODIUM

DANBURY PHARMACAL 100MG

ZENITH LABORATORIES 100MG

PROMPT PHENYTOIN SODIUM

DANBURY PHARMACAL 100MG

ZENITH LABORATORIES 100MG

PIPERAZINE CITRATE (PAGE 3-170)

TABLET; ORAL

ANTEPAR

BURROUGHS WELLCOME EQ 500MG BASE

N09102 003

ADD > PIRBUTEROL ACETATE (PAGE 3-170)

AEROSOL; INHALATION

EXTREL

PFIZER LABS/PFIZER EQ 0.2MG BASE/INH

N19009 001  
DEC 30, 1986

N19071 001  
AUG 30, 1985

POTASSIUM CHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

MAURRY BIOLOGICAL 2MEQ/MLM

N88286 001  
SEP 05, 1985

TABLET, CONTROLLED RELEASE; ORAL

K-DUR 10

KEY PHARMACEUTICALS 10MEQ

N19439 002  
JUN 13, 1986

K-DUR 20

KEY PHARMACEUTICALS 20MEQ

N19439 001  
JUN 13, 1986

> DLT >  
> ADD >

KALINORM

TEN-K

A/S BENZON

BC CIBA/CIBA-GEIGY 10MEQ

N19381 001  
APR 16, 1986

KLOR-CON

UPSHER-SMITH LABS 8MEQ

N19123 001  
APR 17, 1986

BC

10MEQ

N19123 002  
APR 17, 1986

SLOW-K

CIBA-GEIGY 8MEQ

N17476 002

POTASSIUM CITRATE (PAGE 3-173)

TABLET; ORAL

TABLET, CONTROLLED RELEASE; ORAL

POTASSIUM CITRATE

UROCI-K

UNIV TX HLTH SCI CTR 5MEQ

POTASSIUM CLAVULANATE; TICARCILLIN DISODIUM (PAGE 3-173)INJECTABLE; INJECTION  
TIMENTINBEECHAM LABS/BEECHAM EQ 100MG ACID/VIAL;  
EQ 3GM BASE/VIALMN62691 001  
DEC 19, 1986SOLUTION; ORAL  
PEDIAPRED  
FISONS

EQ 5MG BASE/5MLM

N19157 001  
MAY 28, 1986PREDNISOLONE SODIUM PHOSPHATE (PAGE 3-176)> ADD >  
> ADD >  
> ADD >  
> ADD >  
> ADD >POVIDONE-IODINE (PAGE 3-174)SOLUTION/DROPS; OPHTHALMIC  
BETADINE

PURDUE FREDERICK 5/M

N18634 001  
DEC 17, 1986TABLET; ORAL  
DELTASONE  
UPJOHN5MG  
10MG  
20MGN09986 002  
N09986 006  
N09986 007PRALIDOXIME CHLORIDE (PAGE 3-174)INJECTABLE; INJECTION  
PRALIDOXIME CHLORIDE

AP SURVIVAL TECHNOLOGY 300MG/ML

N18986 001  
APR 26, 1983/AP/ /PREDTODAM/  
/SURVIVAL TECHNOLOGY/ /300MG/ML/

ORASONE

/REID-ROWELL LABS/

/1MG/  
/5MG/  
/10MG/  
/20MG/  
/50MG//N83009 001  
/N83009 002  
/N83009 003  
/N83009 004  
/N85999 001

REID-ROWELL LABS

1MG  
5MG  
10MG  
20MG  
50MGN83009 001  
N83009 002  
N83009 003  
N83009 004  
N85999 001PREDNISONE  
AM THERAPEUTICS

5MG

N89387 001

PREDNISOLONE (PAGE 3-174)

SYRUP; ORAL

PRELONE

MURO PHARMACEUTICAL 15MG/5MLM

N89081 001  
FEB 04, 1986

5MG

N89387 001

10MG

N89388 001

20MG

N89389 001

5MG

N89387 001

10MG

N89388 001

20MG

N89389 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-175)

OINTMENT; OPHTHALMIC

BLEPHAMIDE S.O.P.

ALLERGAN PHARMS

0.2%; 10/M

N87748 001  
DEC 03, 1986

5MG

N80701 001

10MG

N86595 001

20MG

N86634 001

5MG

N80336 001

20MG

N85813 001

5MG

N86336 001

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N86336 001

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20MG

N86336 001

## PREDNISONE (PAGE 3-176)

## TABLET; ORAL

## PREDNISONE

## DANBURY PHARMACAL

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## TABLET; ORAL

## PREDNISONE

## DANBURY PHARMACAL

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5MG

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

PROCHLORPERAZINE EDISYLATE (PAGE 3-180)

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

> ADD > AP SOLOPAK LABORATORIES EQ 5MG BASE/ML

> ADD >

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL

PROMETHAZINE

AA LIFE LABORATORIES 6.25MG/5ML

TABLET; ORAL

PROMETHAZINE HCL

BP LEMMON 25MG

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

INJECTABLE; INJECTION

INDERAL

AYERST LABS/AMHO

AP PROPRANOLOL HCL 1MG/ML

AP SOLOPAK LABORATORIES 1MG/ML

AP 1MG/ML

AP 1MG/ML

SUSPENSION; ORAL

INDERAL

AYERST LABS/AMHO

> ADD > 10MG/ML

> ADD >

> ADD >

> ADD >

TABLET; ORAL

INDERAL

AYERST LABS/AMHO

AB 60MG

AB 90MG

PROPRANOLOL

MYLAN PHARMS

AB 10MG

AB 20MG

AB 40MG

AB 80MG

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

PROPRANOLOL HCL

BARR LABORATORIES

AB 10MG

AB 20MG

AB 40MG

AB 60MG

AB 80MG

AB 10MG

AB 20MG

AB 40MG

AB 60MG

AB 80MG

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AB 80MG

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AB 40MG

AB 60MG

AB 80MG

N70319 001  
OCT 22, 1985  
N70320 001  
OCT 22, 1985  
N70103 001  
OCT 22, 1985  
N70321 001  
SEP 24, 1986  
N70322 001  
AUG 04, 1986  
N70663 001  
JUN 13, 1986  
N70664 001  
JUN 13, 1986  
N70665 001  
JUN 13, 1986  
N70666 001  
OCT 10, 1986  
N70667 001  
JUN 13, 1986  
N70175 001  
MAY 13, 1986  
N70176 001  
MAY 13, 1986  
N70177 001  
MAY 13, 1986  
N71098 001  
OCT 06, 1986  
N70178 001  
MAY 13, 1986  
N71183 001  
OCT 06, 1986  
N70306 001  
SEP 09, 1985  
N70307 001  
SEP 09, 1985  
N70308 001  
SEP 09, 1985  
N70309 001  
OCT 01, 1986  
N70310 001  
SEP 09, 1985  
N71327 001  
OCT 01, 1986  
N70233 001  
JUN 23, 1986  
N70234 001  
JUN 23, 1986

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

## TABLET; ORAL

PROPRANOLOL HCL  
MARTEC PHARMS

AB 10MG N70120 001  
 AB 20MG AUG 06, 1985  
 AB 40MG N70121 001  
 AB 60MG AUG 06, 1985  
 AB 80MG N70122 001  
 AB 10MG N70123 001  
 AB 20MG AUG 06, 1985  
 AB 40MG OCT 29, 1986  
 AB 60MG N70124 001  
 AB 80MG N70125 001  
 AB 10MG AUG 06, 1985  
 AB 20MG N70217 001  
 AB 40MG AUG 01, 1986  
 AB 60MG N70218 001  
 AB 80MG AUG 01, 1986  
 AB 10MG N70219 001  
 AB 20MG AUG 01, 1986  
 AB 40MG N70220 001  
 AB 60MG SEP 24, 1986 : JUN 05, 1986  
 AB 80MG N70221 001  
 AB 10MG APR 14, 1986  
 AB 20MG N71288 001  
 AB 40MG OCT 22, 1986  
 AB 60MG N70438 001  
 AB 80MG SEP 15, 1986  
 AB 10MG N70439 001  
 AB 20MG SEP 15, 1986  
 AB 40MG N70440 001  
 AB 60MG SEP 15, 1986  
 AB 80MG N70441 001  
 AB 10MG SEP 24, 1986 : SEP 15, 1986  
 AB 20MG N70442 001  
 AB 40MG SEP 15, 1986  
 AB 60MG N70814 001  
 AB 80MG NOV 03, 1986  
 AB 10MG N70815 001  
 AB 20MG NOV 03, 1986  
 AB 40MG N70816 001  
 AB 60MG NOV 03, 1986  
 AB 80MG N70817 001  
 AB 10MG NOV 03, 1986  
 AB 20MG N70757 001  
 AB 40MG NOV 03, 1986  
 AB 60MG NOV 03, 1986  
 AB 80MG NOV 03, 1986

## PAR PHARMACEUTICAL

## PARKE-DAVIS/M-L

## PUREPAC/KALIPHARMA

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

## TABLET; ORAL

PROPRANOLOL HCL  
ROXANE LABORATORIES

AB 10MG N70516 001  
 AB 20MG JUL 07, 1986  
 AB 40MG N70517 001  
 AB 60MG JUL 07, 1986  
 AB 80MG N70518 001  
 AB 10MG JUL 07, 1986  
 AB 20MG N70519 001  
 AB 40MG SEP 24, 1986 : SEP 11, 1986  
 AB 60MG N70520 001  
 AB 80MG JUL 07, 1986  
 AB 10MG N70521 001  
 AB 20MG SEP 24, 1986 : SEP 11, 1986  
 AB 40MG N70548 001  
 AB 60MG JUL 10, 1986  
 AB 80MG N70549 001  
 AB 10MG APR 11, 1986  
 AB 20MG N70550 001  
 AB 40MG APR 11, 1986  
 AB 60MG N70551 001  
 AB 80MG JUL 10, 1986

## WATSON LABS

PROTAMINE SULFATE (PAGE 3-184)

## INJECTABLE; INJECTION

PROTAMINE SULFATE

AP 10MG/ML ELI LILLY  
 AP 20MG/ML ELKINS-SINN/AHROBINS  
 AP 40MG/ML ELI LILLY  
 AP 60MG/ML ELKINS-SINN/AHROBINS  
 AP 80MG/ML ELI LILLY  
 AP 10MG/VIAL ELKINS-SINN/AHROBINS  
 AP 20MG/VIAL ELI LILLY  
 AP 40MG/VIAL ELKINS-SINN/AHROBINS  
 AP 60MG/VIAL ELI LILLY  
 AP 80MG/VIAL ELKINS-SINN/AHROBINS

PROTEIN HYDROLYSATE (PAGE 3-184)

## INJECTABLE; INJECTION

## HYPROTIGEN 5%

KENDALL MCGAW LABS 5%

N06170 003  
JAN 10, 1984QUAZEPAM (PAGE 3-186)

## TABLET; ORAL

## DORMALIN

## SCHERING

15MG

N18708 001  
DEC 27, 1985

QUINIDINE GLUCONATE (PAGE 3-186)

TABLET, CONTROLLED RELEASE; ORAL

QUINALAN

BC LANNETT

324MG

N88081 001

FEB 10, 1986

QUINIDINE GLUCONATE

AB SUPERPHARM

324MG

N89164 001

NOV 21, 1985

INJECTABLE; INJECTION  
SECRETIN-KABI  
/KABI/ITRUM/  
PHARMACIA/PHARMACIA 75CU/VIAL/  
/75CU/VIAL/  
/N18290, 001/  
N18290 001SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL

SILVADENE/AT/  
AB /MARION LABORATORIES//12/  
MARION LABORATORIES 12/N17381, 001/  
N17381 001/AT/  
SSD /TRAVENOL LABS/  
/12/  
/N18578, 001/  
/FEB 25, 1982/  
N18578 001  
FEB 25, 1982

AB TRAVENOL LABS 12

/N18578, 001/  
/FEB 25, 1982/  
N18578 001  
FEB 25, 1982AB ULTRA DERM

AB CHESEBROUGH-PONDS 12M

N18810 001  
DEC 23, 1985> ADD > RANITIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-187)

INJECTABLE; INJECTION

ZANTAC IN PLASTIC CONTAINER

GLAXO

EQ 50MG BASE/100ML;

450MG/100MLM

N19593 001

DEC 17, 1986

INJECTABLE; INJECTION

SODIUM BICARBONATE IN PLASTIC CONTAINER

ABBOTT LABORATORIES 0.9MEQ/MLM

1MEQ/MLM

N19443 001  
JUN 03, 1986  
N19443 002  
JUN 03, 1986RIBAVIRIN (PAGE 3-189)

POWDER FOR RECONSTITUTION; INHALATION

VIRAZOLE

VIRATEK

6GM/VIALM

N18859 001

DEC 31, 1985

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL

BAROS

MALLINCKRODT

460MG/GM; 420MG/GM

N18509 001  
AUG 07, 1985RITODRINE HYDROCHLORIDE (PAGE 3-189)

INJECTABLE; INJECTION

RITODRINE HCL

QUAD PHARMS

10MG/MLM

N70700 001

OCT 06, 1986

15MG/MLM

N70701 001

OCT 06, 1986

YUTOPAR

ASTRA PHARM PRODS

10MG/ML

15MG/ML

N18580 001

N18580 002

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 900MG/100MLM

9MG/MLM

N19480 001  
SEP 17, 1985  
N16677 004  
OCT 30, 1985

SODIUM IODIDE, I-123 (PAGE 3-193)

CAPSULE; ORAL  
SODIUM IODIDE I-123  
 @ BENEDICT NUCLR PHARM 400 UCI

N18671 003  
 MAY 27, 1982

TABLET; ORAL  
 WINSTROL  
 WINTHROP-BREON/STERL 2MG

N12885 001  
 MAY 14, 1984

SODIUM NITROPRUSSIDE (PAGE 3-194)

INJECTABLE; INJECTION  
NITROPRESS  
 @ ABBOTT LABORATORIES 50MG/VIAL

N70566 001  
 JUN 09, 1986

SOLUTION; TOPICAL  
 SULCOSYN  
 SYNTEX LABS/SYNTEX 1/4

N18738 001  
 AUG 30, 1985

SODIUM POLYSTYRENE SULFONATE (PAGE 3-195)

SUSPENSION; ORAL, RECTAL  
SODIUM POLYSTYRENE SULFONATE  
 @ ROXANE LABORATORIES 15GM/60ML

N89049 001  
 NOV 17, 1986

CREAM; VAGINAL  
 GYNE-SULF  
 G AND W LABORATORIES 3.7%; 2.86%; 3.42%; 0.64%

AT N88607 001  
 JUN 09, 1986

SOMATREM (PAGE 3-195)

INJECTABLE; INJECTION  
 PROTROPIN  
 GENENTECH 5MG/VIAL

N19107 001  
 OCT 17, 1985

SUSPENSION; ORAL  
 SEPTRA GRAPE  
 BURROUGHS WELLCOME 200MG/5ML; 40MG/5ML

N17598 002  
 FEB 12, 1986

SOMATROPIN (PAGE 3-195)

INJECTABLE; INJECTION  
 ASELLACRIN 10  
 @ SERONO LABS  
 ASELLACRIN 2  
 @ SERONO LABS

10 IU/VIAL  
 2 IU/VIAL

N17726 001  
 JUL 21, 1983

SULFAMETHOXAZOLE AND TRIMETHOPRIM  
 PLANTEX/IKAPHARM 200MG/5ML; 40MG/5ML  
 JUN 02, 1987

N70028 001  
 OCT 29, 1985

CRESCORMON  
 @ KABIVITRUM 4 IU/VIAL

N17992 001

SULMEPRIM PEDIATRIC  
 MY-K LABS 200MG/5ML; 40MG/5ML

N70063 001  
 AUG 01, 1986

SULMEPRIM PEDIATRIC  
 MY-K LABS 200MG/5ML; 40MG/5ML

N70064 001  
 AUG 01, 1986

SPIRONOLACTONE (PAGE 3-196)

TABLET; ORAL  
SPIRONOLACTONE  
 @ MUTUAL PHARMACAL 25MG

N89424 001  
 JUL 23, 1986  
 N89364 001  
 NOV 07, 1986

TABLET; ORAL  
SULFAMETHOXAZOLE AND TRIMETHOPRIM  
 CORD LABORATORIES 400MG; 80MG

N70889 001  
 NOV 13, 1986

800MG; 160MG

N70890 001  
 NOV 13, 1986

400MG; 80MG

N71016 001  
 AUG 25, 1986

800MG; 160MG

N71017 001  
 AUG 25, 1986

400MG; 80MG

N70203 001  
 NOV 08, 1985

800MG; 160MG

N70204 001  
 NOV 08, 1985



## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL

TEM  
MAZ  
QUANTUM PHARMICSAB 15MGAB 30MGTEM  
APAM  
BARR LABORATORIESAB 15MGAB 30MGAB 15MGAB 30MGAB 15MGAB 30MGTESTOSTERONE ENANTHATE (PAGE 3-204)

INJECTABLE; INJECTION

TESTOSTERONE ENANTHATEAO 100MG/MLAO 200MG/MLTESTOSTERONE PROPIONATE (PAGE 3-204)

INJECTABLE; INJECTION

TESTOSTERONE PROPIONATEAO 100MG/MLTETRACYCLINE HYDROCHLORIDE (PAGE 3-205)

CAPSULE; ORAL

TETRACYCLINE HCLAB 250MGAB 500MGTHEOPHYLLINE (PAGE 3-206)

CAPSULE; ORAL

EL  
THO  
PHYLLINAB BERLEX/SCHERINGAB 100MGAB 200MGSOM  
OPHYLLIN-T  
FISONSBP 100MGBP 200MG

BX BERLEX/SCHERING

BX

BX

BX

THEOPHYLLINE  
RP SCHERERBX 100MGBX 200MGBX 250MG

CAPSULE, CONTROLLED RELEASE; ORAL

AEROLATE III

FLEMING

BC

AEROLATE JR

FLEMING

BC

AEROLATE SR

FLEMING

BC

THEO-DUR SPRINKLE

KEY PHARMACEUTICALS

BC

BC

BC

BC

BC

BC

BC

BC

BC

BC

BC

BC

BC

BC

/N85545 '001/  
/JUL 15, 1985/  
/N83921 '001/  
/JUL 31, 1984/  
/N87155 '001/  
/FEB 25, 1985/  
/N87155 '002/  
/FEB 25, 1985/  
/N85545 '001/  
/JUL 31, 1984/  
/N83921 '001/  
/JUL 31, 1984/  
/N87155 '001/  
/FEB 25, 1985/  
/N87155 '002/  
/FEB 25, 1985/  
/N87155 '003/  
/FEB 25, 1985/  
/N87155 '001/  
/NOV 07, 1986/  
/N84731 '001/  
/NOV 07, 1986/  
/N84731 '003/  
/NOV 07, 1986/  
/N85075 '003/  
/NOV 24, 1986/  
/N85075 '002/  
/NOV 24, 1986/  
/N85075 '001/  
/NOV 24, 1986/  
/N88022 '001/  
/SEP 10, 1985/  
/N88016 '001/  
/SEP 10, 1985/  
/N87995 '001/  
/SEP 10, 1985/  
/N88015 '001/  
/SEP 10, 1985/  
/N88255 '001/  
/JUN 12, 1986

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG'85 - DEC'86

THEOPHYLLINE (PAGE 3-206)

## ELIXIR; ORAL

## THEOPHYL 225

/N00L PHARMACEUTICAL/112.5MG/15ML/  
MCNEIL PHARM

## SOLUTION; ORAL

## AEROLATE

## FLEMING

>\_ADD\_>  
>\_ADD\_>  
>\_ADD\_>

112.5MG/15ML

## SYRUP; ORAL

## ACCURBON

MERRELL DOW/DOW CHEM 150MG/15ML

AA

THEOPHYLLINE

NATL PHARM MFG/BARRE 150MG/15ML

AA

## TABLET; ORAL

## QUITRON-T

MEAD JOHNSON/B-M

300MG

## SLO-PHYLLIN

/WILLIAM H. RORER/

100MG

200MG

225MG

## THEOPHYL-225

/N00L PHARMACEUTICAL/225MG/

225MG

225MG

## TABLET, CHEWABLE; ORAL

## THEOPHYL

MCNEIL PHARM

100MG

## TABLET, CONTROLLED RELEASE; ORAL

## THEO-DUR

KEY PHARMACEUTICALS 450MG

THIOTIDAZINE HYDROCHLORIDE (PAGE 3-209)

## CONCENTRATE; ORAL

THIOTIDAZINE HCL INTENSOL

ROXANE LABORATORIES 30MG/ML

100MG/ML

AA

AA

THIOTIDAZINE HYDROCHLORIDE (PAGE 3-209)

## TABLET; ORAL

THIOTIDAZINE HCL

CORD LABORATORIES

150MG

N88136 001

SEP 17, 1986

N88137 001

SEP 17, 1986

N89431 001

AUG 01, 1986

N89432 001

AUG 01, 1986

N89433 001

AUG 01, 1986

## TABLET; ORAL

THIOTIDAZINE HCL

CORD LABORATORIES

150MG

N88136 001

SEP 17, 1986

N88137 001

SEP 17, 1986

N89431 001

AUG 01, 1986

N89432 001

AUG 01, 1986

N89433 001

AUG 01, 1986

TICARCILLIN DISODIUM (PAGE 3-211)

## INJECTABLE; INJECTION

## TICAR

BEECHAM LABS/BEECHAM EQ 3GM BASE/VIAL

&gt;\_ADD\_&gt;

&gt;\_ADD\_&gt;

N62690 001

DEC 19, 1986

TIMOLOL MALEATE (PAGE 3-211)

## SOLUTION/DROPS; OPHTHALMIC

TIMOPTIC IN OCULOSE

MSD RES LABS

EQ 0.25% BASE

N19463 001

NOV 05, 1986

N19463 002

NOV 05, 1986

EQ 0.5% BASE

## &gt;\_ADD\_&gt;

## &gt;\_ADD\_&gt;

## &gt;\_ADD\_&gt;

## &gt;\_ADD\_&gt;

## &gt;\_ADD\_&gt;

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## &gt;\_ADD\_&gt;

## &gt;\_ADD\_&gt;

## TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL  
TOLAZAMIDE

AB BOLAR PHARMACEUTICAL 100MG

AB 250MG

AB 500MG

AB CHELSEA LABORATORIES 100MG

AB 250MG

AB 500MG

AB COLMED LABORATORIES 250MG

AB 500MG

AB CORD LABORATORIES 250MG

AB 500MG

AB DANBURY PHARMACAL 100MG

AB 250MG

AB 500MG

AB DURAMED PHARMS 100MG

AB 250MG

AB 500MG

AB INTERPHARM 250MG

AB 500MG

AB MYLAN PHARMS 250MG

AB 500MG

AB PAR PHARMACEUTICAL 100MG

AB 250MG

AB 500MG

AB SUPERPHARM 250MG

AB 500MG

N70242 001  
AUG 01, 1986

N70243 001

AUG 01, 1986

N70244 001

AUG 01, 1986

N70285 001

JAN 09, 1986

N70286 001

JAN 09, 1986

N70287 001

JAN 09, 1986

N70168 001

APR 02, 1986

N70169 001

APR 02, 1986

N70289 001

MAR 13, 1986

N70290 001

MAR 13, 1986

N70513 001

JAN 09, 1986

N70514 001

JAN 09, 1986

N70515 001

JAN 09, 1986

N70165 001

JAN 10, 1986

N70166 001

JAN 10, 1986

N70167 001

JAN 10, 1986

N71270 001

SEP 23, 1986

N71271 001

SEP 23, 1986

N70259 001

JAN 02, 1986

N70913 001

MAR 17, 1986

N70159 001

JAN 06, 1986

N70160 001

JAN 06, 1986

N70161 001

JAN 06, 1986

N70763 001

JUN 16, 1986

N70764 001

JUN 16, 1986

## &gt; ADD &gt; TRANEXAMIC ACID (PAGE 3-212)

> ADD > INJECTABLE; INJECTION  
> ADD > CYKLOKAPRON  
> ADD > KABIVITRUM

100MG/ML

> ADD > TABLET; ORAL  
> ADD > CYKLOKAPRON  
> ADD > KABIVITRUM

500MG

## TRAZODONE HYDROCHLORIDE (PAGE 3-212)

TABLET; ORAL

DESTREL

AB MEAD JOHNSON/B-M

50MG

100MG

TRAZODONE HCL

AB AM THERAPEUTICS

50MG

100MG

AB BOLAR PHARMACEUTICAL

50MG

100MG

AB CHELSEA LABORATORIES

50MG

100MG

AB DANBURY PHARMACAL

50MG

100MG

AB QUANTUM PHARMICS

50MG

100MG

## TRIAMCINOLONE ACETONIDE (PAGE 3-213)

LOTION; TOPICAL

AT TRIAMCINOLONE ACETONIDE

0.1%

0.1%

PASTE; DENTAL

AT KENALOG IN ORABASE

0.1%

0.1%

AT ER SQUIBB AND SONS

0.1%

0.1%

AT TARO PHARMS

N19281 001  
DEC 30, 1986

N19280 001  
DEC 30, 1986

N18207 001  
N18207 002

N71139 001  
OCT 29, 1986

N71140 001  
OCT 29, 1986

N71112 001  
NOV 17, 1986

N71113 001  
NOV 17, 1986

N70568 001  
OCT 10, 1986

N70569 001  
OCT 10, 1986

N70857 001  
OCT 10, 1986

N70858 001  
OCT 10, 1986

N70942 001  
DEC 01, 1986

N70921 001  
DEC 01, 1986

N89129 001  
AUG 14, 1986

N12097 001

N70730 001  
OCT 01, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

CAPSULE; ORAL

CUPRID

MS&D RES LABS/MERCK 250MG

N19194 001  
NOV 08, 1985

TRIMETHOBENZAMIDE HYDROCHLORIDE (PAGE 3-217)

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

SOLOPAK LABORATORIES 100MG/ML

N88960 001  
APR 04, 1986

100MG/ML

N89043 001  
APR 04, 1986

100MG/ML

N89094 001  
APR 04, 1986

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL

TRIMETHOPRIM

BARR LABORATORIES 100MG

N70494 001  
JAN 22, 1986

200MG

SEP 24, 1986 : MAR 14, 1986

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC

TROPICAMIDE

MAURRY BIOLOGICAL 1/2

UROFOLLITROPIN (PAGE 3-220)

INJECTABLE; INJECTION

METRODIN

SERONO LABS

75IU/AMPH

N19415 001  
SEP 18, 1986

VALPROATE SODIUM (PAGE 3-220)

SYRUP; ORAL

DEPAKENE

ABBOTT LABORATORIES EQ 250MG BASE/5ML

MYPROIC ACID

MY-K LABS EQ 250MG BASE/5ML

N18082 001

N70868 001  
JUL 01, 1986

VALPROIC ACID (PAGE 3-220)

CAPSULE; ORAL

DEPAKENE

ABBOTT LABORATORIES 250MG

VALPROIC ACID

PAR PHARMACEUTICAL 250MG

N18081 001

N70431 001  
FEB 28, 1986

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

CAPSULE; ORAL

VANCOCIN HCL

ELI LILLY

EQ 125MG BASE

EQ 250MG BASE

N50606 001  
APR 15, 1986  
N50606 002  
APR 15, 1986

INJECTABLE; INJECTION

VANCOCIN HCL

ELI LILLY

EQ 500MG BASE/VIAL

EQ 500MG BASE/VIAL

N60180 001  
MAR 15, 1986

N62476 001  
MAR 15, 1986

N62476 002  
MAR 21, 1986

N60180 002  
MAR 21, 1986

VANCOLED

LEDERLE PARENTERALS

EQ 500MG BASE/VIAL

N62682 001  
JUL 22, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION

VERAPAMIL HCL

INTL MEDICATION SYS 2.5MG/ML

N70451 001  
DEC 16, 1985

N70225 001  
NOV 12, 1985

N70617 001  
NOV 12, 1985

N70348 001  
MAY 01, 1986

N70672 001  
MAR 07, 1986

QUAD PHARMS

2.5MG/ML

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

TABLET; ORAL

VERAPAMIL HCL

AB BARR LABORATORIES 80MG

AB 120MG

AB CHELSEA LABORATORIES 80MG

AB 120MG

AB DANBURY PHARMACAL 80MG

AB 120MG

AB PARKE-DAVIS/M-L 80MG

AB 120MG

AB PUREPAC/KALIPHARMA 80MG

AB 120MG

AB WATSON LABS 80MG

AB 80MG

AB 120MG

AB 120MG

>\_ADD\_>  
>\_ADD\_>  
>\_ADD\_>  
>\_ADD\_>

TABLET, CONTROLLED RELEASE; ORAL  
ISOPTIN SR  
KNOLL PHARMACEUTICAL 240MG

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION

VELBAN

AP 10MG/AMP

AP 10MG/VIAL

AP VINBLASTINE SULFATE

AP 10MG/VIAL

AP 10MG/VIAL

/N12665.001/

N12665 001

N89011 001

NOV 18, 1985

N89365 001

AUG 07, 1986

VINCRISTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION

ONCOCVIN

AP ELI LILLY 1MG/ML

AP VINCRISTINE SULFATE

AP LYPHOMED 1MG/ML

AP QUAD PHARMS 1MG/ML

AP 1MG/ML

N14103 003  
MAR 07, 1984

N70411 001  
SEP 10, 1986

N70777 001  
APR 29, 1986

N70778 001  
MAY 01, 1986

MARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL

COJUMADIN

AB DUPONT PHARMS/DUPONT 2.5MG

AB DUPONT PHARMS/DUPONT 2.5MG

AB MARFARIN SODIUM

AB COLMED LABORATORIES 2.5MG

/N89218.018/  
N89218 018

N88720 001  
AUG 06, 1985

ZINC CHLORIDE (PAGE 3-223)

INJECTABLE; INJECTION

ZINC CHLORIDE IN PLASTIC CONTAINER  
ABBOTT LABORATORIES EQ 1MG ZINC/ML

N18959 001  
JUN 26, 1986

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86  
(ALL PRODUCTS - SEE INTRODUCTION)

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ACETAMINOPHEN (PAGE 3-224)

SUPPOSITORY; RECTAL  
ACETAMINOPHEN  
SUPPOSITORY

650MG

N70608 001  
DEC 01, 1986

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX (PAGE 3-225)

SYRUP; ORAL  
PENNTUSS  
PENNWALT PHARM  
EQ 4MG MALEATE/5ML;  
EQ 10MG BASE/5ML

N18928 001  
AUG 14, 1985

BACITRACIN; POLYMYXIN B SULFATE (PAGE 3-224)

AEROSOL; TOPICAL  
LANABIOTIC  
COMBE

500 UNITS/GM;  
5,000 UNITS/GM

N50598 001  
SEP 22, 1986

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

SYRUP; ORAL  
BELDIN  
HALSEY DRUG  
12.5MG/5ML  
DIPHEN  
BAY LABORATORIES  
12.5MG/5ML  
HYDRAMINE  
NATL PHARM MFG/BARRE  
12.5MG/5ML

N89179 001  
JUN 05, 1986  
N70118 001  
OCT 01, 1985  
N70205 001  
JAN 28, 1986

CHLORHEXIDINE GLUCONATE (PAGE 3-224)

SOLUTION; TOPICAL  
CIDA-STAT  
HUNTINGTON LABS

2/M

N19258 001  
JUL 22, 1986

CHG SCRUB  
HUNTINGTON LABS

4/M

N19258 002  
JUL 22, 1986

EXIDINE  
XTTRIUM LABS

2/M

N19422 001  
DEC 17, 1985  
N19421 001  
DEC 17, 1985

STERI-STAT  
MEDICAL SYS RES

4/M

N70104 001  
JUL 24, 1986

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-225)

TABLET, CONTROLLED RELEASE; ORAL  
PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE  
DORSEY LABS/SANDOZ 12MG;75MG

N19613 001  
JUN 16, 1986

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-225)

CAPSULE, CONTROLLED RELEASE; ORAL  
ISOCLOM  
AM CRITICAL CARE/AHS 8MG;120MG

N18747 001

DOXYLAMINE SUCCINATE (PAGE 3-225)

CAPSULE; ORAL  
UNISON  
PFIZER LABS/PFIZER 25MG

N19440 001  
FEB 05, 1986

EPINEPHRINE (PAGE 3-225)

AEROSOL; INHALATION  
BRONKAID MIST  
WINTHROP-BREON/STERL 0.25MG/INH  
EPINEPHRINE MIST  
NATL PHARM MFG/BARRE 0.2MG/INH  
PRIMATENE MIST  
WHITEHALL LABS/AMHO 0.2MG/INH

N16803 001  
N87907 001  
MAY 23, 1984  
N16126 001

EPINEPHRINE BITARTRATE (PAGE 3-225)

AEROSOL; INHALATION  
BRONITIN MIST  
WHITEHALL LABS/AMHO 0.3MG/INH  
MEDIALER EPI  
RIKER LABS/3M 0.3MG/INH

N16126 002  
N10374 003

IBUPROFEN (PAGE 3-225)

TABLET; ORAL

IBUPROFEN  
BARR LABORATORIES

200MG  
SEP 24, 1986 : DEC 24, 1985

200MG  
SEP 26, 1986 : SEP 26, 1986

200MG  
OCT 02, 1986 : OCT 02, 1986

200MG  
SEP 24, 1986 : MAY 07, 1986

200MG  
SEP 24, 1986 : SEP 19, 1986

200MG  
SEP 24, 1986 : MAR 05, 1986

200MG  
SEP 24, 1986 : JUL 15, 1986

200MG  
DEC 01, 1986 : DEC 01, 1986

200MG  
SEP 24, 1986 : OCT 18, 1985

200MG  
OCT 03, 1986 : OCT 03, 1986

200MG  
SEP 24, 1986 : FEB 06, 1986

200MG  
SEP 24, 1986 : JUN 26, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

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OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

200MG  
OCT 15, 1986 : OCT 15, 1986

> ADD >  
> ADD >

INSULIN SUSPENSION, ISOPHANE, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

HUMULIN N

ELI LILLY

100 UNITS/ML

N18781 001  
OCT 28, 1982

INSULIN SUSPENSION, ISOPHANE, PURIFIED HUMAN (SEMITSYNTHETIC) (PAGE 3-226)

INJECTABLE; INJECTION

INSULATARD NPH HUMAN

NORDISK USA

100 UNITS/MLM

N19449 001  
MAY 30, 1986

INSULIN ZINC SUSPENSION, BIOSYNTHETIC HUMAN (PAGE 3-226)

INJECTABLE; INJECTION

HUMULIN L

ELI LILLY

100 UNITS/MLM

N19377 002  
SEP 30, 1985

INSULIN, PURIFIED, HUMAN, SEMISYNTHETIC (PAGE 3-227)

INJECTABLE; INJECTION

VELOSULIN HUMAN

NORDISK USA

100 UNITS/MLM

N19450 001  
MAY 30, 1986

OXYMETAZOLINE HYDROCHLORIDE (PAGE 3-228)

SOLUTION/DROPS; OPHTHALMIC

OCUCLEAR

SCHERING

0.025/M

N18471 001  
MAY 30, 1986

POVIDONE-IODINE (PAGE 3-228)

SPONGE; TOPICAL

POVIDONE-IODINE

PARKE-DAVIS/DESERET

20/M

N19240 001  
NOV 29, 1985

PSEUDOPHEDRINE HYDROCHLORIDE (PAGE 3-228)

CAPSULE, CONTROLLED RELEASE; ORAL

/SUDAFED S.A./

SUDAFED 12 HOUR

INJECTABLE; INJECTION

HUMULIN BR

ELI LILLY

100 UNITS/MLM

N19529 001  
APR 28, 1986

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 16 / AUG '85 - DEC '86  
(ALL PRODUCTS - SEE INTRODUCTION)

PYRITHIONE ZINC (PAGE 3-228)

LOTION; TOPICAL  
HEAD & SHOULDERS CONDITIONER  
PROCTER AND GAMBLE 0.3%  
0.3%  
0.3%  
0.3%

N19412 001  
MAR 10, 1986  
N19412 002  
MAR 10, 1986  
N19412 003  
MAR 10, 1986  
N19412 004  
MAR 10, 1986

SODIUM MONOFLUOROPHOSPHATE (PAGE 3-229)

GEL; DENTAL  
EXTRA-STRENGTH AIM  
LEVER BROTHERS 1.2%

N19518 001  
AUG 06, 1986

NO SEPTEMBER 1985 - DECEMBER 1986 APPROVALS

C. APPENDICES

1. Orphan Drug Products with Exclusive Approval
2. List of Drug Products Which Must Demonstrate in vivo  
Bioavailability Only if Product Fails to Achieve  
Adequate Dissolution
3. Biopharmaceutic Guidance Availability List
4. ANDA Suitability Petitions
5. Exclusivity Terms
6. Prescription and OTC Drug Product Patent and  
Exclusivity Data

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 a person maintains ODE status 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 Data Appendix. 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 Data Appendix. These drug products do not have any exclusive approval rights of their own, but can be marketed because of the consent given by the sponsor that has exclusive approval. These products are marked by an (\*) next to the applicant's name.

## APPENDIX 1

BIOLOGICAL PRODUCTS

| <u>Active Ingrid.(s)</u><br><u>Strength</u> | <u>Trade Name</u><br><u>Dosage Form; Route</u> | <u>Applicant</u>       | <u>License Number</u><br><u>Approval Date</u> | <u>Exclusivity</u><br><u>Exp.Date</u> |
|---------------------------------------------|------------------------------------------------|------------------------|-----------------------------------------------|---------------------------------------|
| Hemin<br>313mg/amp                          | Panhematin<br>Injectable; Injection            | Abbott<br>Laboratories | 43<br>Jul 20, 1983                            | ODE<br>Jul 20, 1990                   |
| Digoxin Immune<br>Fab (OVINE)               | Digibind<br>Injectable; Injection              | Burroughs Wellcome     | 129<br>Apr 22, 1986                           | ODE<br>Apr 22, 1993                   |

## APPENDIX 1

DRUG PRODUCTS

| <u>Active Ingrid.(s)</u><br><u>Strength(s)</u> | <u>Trade Name</u><br><u>Dosage Form; Route</u> | <u>Applicant</u>       | <u>Appl. Prod.</u><br><u>Approval Date</u> | <u>Exclusivity</u><br><u>Exp. Date</u> |
|------------------------------------------------|------------------------------------------------|------------------------|--------------------------------------------|----------------------------------------|
| Chenodiol<br>250mg                             | Chenix<br>Tablet; Oral                         | Rowell<br>Laboratories | 18513 002<br>Jul 28, 1983                  | ODE<br>Jul 28, 1990                    |
| Cromolyn Sodium<br>4%                          | Opticrom<br>Solution/Drops;<br>Ophthalmic      | Fisons                 | 18155 001<br>Oct 3, 1984                   | ODE<br>Oct 3, 1991                     |
| Carnitine, L-<br>330mg                         | L-Carnitine<br>Tablet; Oral                    | Sigma-Tau              | 18948 001<br>Dec 27, 1985                  | ODE<br>Dec 27, 1992                    |
| Carnitine, L-<br>1gm/10ml                      | Vitacarn<br>Solution; Oral                     | Kendall McGaw<br>Labs* | 19257 001<br>Apr 10, 1986                  |                                        |
| Clofazimine<br>50mg                            | Lampreme<br>Capsule; Oral                      | Geigy/Ciba-Geigy       | 19500 002<br>Dec 15, 1986                  | ODE<br>Dec 15, 1993                    |
| Clofazimine<br>100mg                           | Lampreme<br>Capsule; Oral                      | Geigy/Ciba-Geigy       | 19500 001<br>Dec 15, 1986                  | ODE<br>Dec 15, 1993                    |

(continued)

\*Refer to Appendix I narrative

## APPENDIX 1

## APPENDIX 1

DRUG PRODUCTS

(continued)

| <u>Active Ingrid.(s)</u><br><u>Strength(s)</u> | <u>Trade Name</u><br><u>Dosage Form; Route</u> | <u>Applicant</u>           | <u>Appl. Prod.</u><br><u>Approval Date</u> | <u>Exclusivity</u><br><u>Exp. Date</u> |
|------------------------------------------------|------------------------------------------------|----------------------------|--------------------------------------------|----------------------------------------|
| Naltrexone<br>Hydrochloride<br>50mg            | Trexan<br>Tablet; Oral                         | Dupont Pharms              | 18932 001<br>Nov 20, 1984                  | ODE<br>Nov 20, 1991                    |
| Monooctanooin<br>100%                          | Moctanin<br>Liquid;<br>Perfusion<br>Biliary    | Ascot Hosp<br>Pharms       | 19368 001<br>Oct 29, 1985                  | ODE<br>Oct 29, 1992                    |
| Pentamidine<br>Isethionate<br>300mg/ml         | Pentam 300<br>Injectable;<br>Injection         | LyphoMed                   | 19264 001<br>Oct 16, 1984                  | ODE<br>Oct 16, 1991                    |
| Potassium<br>Citrate<br>5meq                   | Urocit-K<br>Tablet; Oral                       | Univ of Tx Hlth<br>Sci Ctr | 19071 001<br>Aug 30, 1985                  | ODE<br>Aug 30, 1992                    |
| Somatrem<br>5mg/vial                           | Protropin<br>Injectable;<br>Injection          | Genentech                  | 19107 001<br>Oct 17, 1985                  | ODE<br>Oct 17, 1992                    |

(continued)

## APPENDIX 1

DRUG PRODUCTS

(continued)

| <u>Active Ingrid.(s)</u><br><u>Strength(s)</u> | <u>Trade Name</u><br><u>Dosage Form; Route</u> | <u>Applicant</u>                  | <u>Appl. Prod.</u><br><u>Approval Date</u> | <u>Exclusivity</u><br><u>Exp. Date</u> |
|------------------------------------------------|------------------------------------------------|-----------------------------------|--------------------------------------------|----------------------------------------|
| Trientine<br>Hydrochloride<br>250mg            | Cuprid<br>Capsule; Oral                        | Merck Sharp and<br>Dohme Res Labs | 19194 001<br>Nov 8, 1985                   | ODE<br>Nov 08, 1992                    |
| Tranexamic Acid<br>500mg                       | Cyklokapron<br>Tablet; Oral                    | Kabivitrum                        | 19280 001<br>Dec 30, 1986                  | ODE<br>Dec 30, 1993                    |
| Tranexamic Acid<br>100mg/ml                    | Cyklokapron<br>Injectable; Injection           | Kabivitrum                        | 19281 001<br>Dec 30, 1986                  | ODE<br>Dec 30, 1993                    |

## APPENDIX 2

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

|                                                                                                                |                                                                                                      |                                                                                   |
|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Acetaminophen; Aspirin;<br>Butalbital<br>Capsule or Tablet; Oral<br>160-165mg; 160-165mg; 50mg                 | Aminophylline<br>Tablet; Oral<br>100mg<br>200mg                                                      | Aspirin; Carisoprodol;<br>Codeine Phosphate<br>Tablet; Oral<br>325mg; 200mg; 10mg |
| Acetaminophen; Aspirin;<br>Butalbital<br>Capsule or Tablet; Oral<br>325mg; 325mg; 50mg                         | Aspirin; Butalbital<br>Capsule or Tablet; Oral<br>325mg; 50mg<br>650mg; 50mg                         | Aspirin; Meproamate<br>Tablet; Oral<br>325mg; 200mg                               |
| Acetaminophen; Aspirin;<br>Butalbital; Caffeine<br>Capsule or Tablet; Oral<br>160-165mg; 160-165mg; 50mg; 40mg | Aspirin; Butalbital; Caffeine<br>Capsule or Tablet; Oral<br>325mg; 50mg; 40mg;<br>650mg; 50mg; 40mg; | Aspirin; Methocarbamol<br>Tablet; Oral<br>325mg; 200mg                            |
| Acetaminophen; Aspirin;<br>Butalbital; Caffeine<br>Capsule or Tablet; Oral<br>325mg; 325mg; 50mg; 40mg         | Aspirin; Caffeine;<br>Carisoprodol<br>Tablet; Oral<br>160mg; 32mg; 200mg                             | Chlorothiazide<br>Tablet; Oral<br>250mg                                           |
| Acetaminophen; Butalbital<br>Capsule or Tablet; Oral<br>325mg; 50mg<br>650mg; 50mg                             | Aspirin; Caffeine;<br>Carisoprodol; Codeine Phosphate<br>Tablet; Oral<br>160mg; 32mg; 200mg; 16mg    | Estrogens, Conjugated; Meproamate<br>Tablet; Oral<br>0.4mg; 200mg<br>0.4mg; 400mg |
| Acetaminophen; Butalbital;<br>Caffeine<br>Capsule or Tablet; Oral<br>325mg; 50mg; 40mg<br>650mg; 50mg; 40mg    | Aspirin; Carisoprodol<br>Tablet; Oral<br>325mg; 200mg                                                | Hydroxyzine Hydrochloride<br>Tablet; Oral<br>10mg<br>25mg<br>50mg<br>100mg        |

## APPENDIX 3

BIOPHARMACEUTIC GUIDANCE AVAILABILITY LIST

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.

| <u>Name of Drug</u>                        | <u>Date</u>  | <u>Revised Date</u> |
|--------------------------------------------|--------------|---------------------|
| Acetohexamide                              | Nov 15, 1985 |                     |
| Allopurinol                                | Jul 15, 1985 |                     |
| Amiloride Hydrochloride                    | Mar 29, 1985 |                     |
| Aminophylline Suppositories                | Jul 05, 1983 |                     |
| Amitriptyline Hydrochloride                | Jul 05, 1983 |                     |
| Anticholinergic Drugs (Controlled Release) | Nov 07, 1980 |                     |
| Baclofen                                   | May 05, 1986 |                     |
| Carbamazepine                              | Dec 05, 1984 | Aug 04, 1986        |
| Cefadroxil                                 | Oct 07, 1986 |                     |
| Cephadrine (Capsule and Suspension)        | Sep 10, 1986 |                     |
| Cephalexin (Tablet and Capsule)            | Aug 13, 1986 |                     |
| *Cholestyramine Resin                      | Dec 24, 1986 | Oct 27, 1986        |
| Chlordiazepoxide Hydrochloride             | Jul 05, 1983 |                     |
| Chlorpropamide                             | Jul 05, 1983 |                     |
| Chlorthalidone                             | Jul 05, 1983 |                     |
| Clofibrate                                 | Apr 07, 1986 |                     |
| Clonidine Hydrochloride                    | Dec 05, 1984 |                     |
| Clorazepate Dipotassium                    | Mar 10, 1986 |                     |
| *Conjugated Estrogen (Tablet)              | Dec 17, 1986 |                     |

(continued)

\*New Addition

## APPENDIX 3

(continued)

| <u>Name of Drug</u>                                | <u>Date</u>  | <u>Revised Date</u> |
|----------------------------------------------------|--------------|---------------------|
| Diazepam (revised)                                 | Jul 08, 1985 |                     |
| Dicyclomine Hydrochloride                          | Aug 10, 1984 |                     |
| Dipyridamole                                       | Jul 05, 1983 |                     |
| Disopyramide Phosphate                             | Jul 09, 1985 |                     |
| Dissolution Testing (General)                      | Apr 19, 1985 |                     |
| Doxepin Hydrochloride                              | Apr 02, 1985 |                     |
| Erythromycin                                       | Apr 05, 1977 |                     |
| Flurazepam                                         | Oct 15, 1985 |                     |
| Hydrochlorothiazide                                | Jul 25, 1983 |                     |
| Hydroxyzine Hydrochloride (Dissolution Only)       | Jan 27, 1981 |                     |
| Hydroxyzine Pamoate                                | Jul 26, 1983 |                     |
| Indomethacin                                       | Apr 06, 1985 |                     |
| Isosorbide Dinitrate                               | Jun 04, 1985 |                     |
| Isosorbide Dinitrate (Controlled Release Products) | Sep 19, 1985 |                     |
| Lorazepam                                          | Dec 03, 1984 |                     |
| Meclofenamate Sodium                               | Nov 12, 1986 |                     |
| *Medroxyprogesterone Acetate (Tablet)              | Dec 24, 1986 |                     |
| Methylprednisolone                                 | Jun 12, 1986 |                     |
| Methyltestosterone                                 | Nov 16, 1979 |                     |
| Metoclopramide                                     | Dec 27, 1984 |                     |
| Minoxidil                                          | Apr 02, 1986 |                     |
| Nitrofurantoin (Macrocrystalline)                  | Oct 29, 1985 |                     |
| *Nitroglycerin (Ointment)                          | Dec 17, 1986 |                     |
|                                                    |              | Oct 09, 1986        |

(continued)

\*New Addition

APPENDIX 3  
(continued)

| <u>Name of Drug</u>                                         | <u>Date</u>  | <u>Revised Date</u> |
|-------------------------------------------------------------|--------------|---------------------|
| Phentermine Hydrochloride (Dissolution)                     | Nov 21, 1980 |                     |
| Phentermine Hydrochloride (Slow Dissolving;<br>Dissolution) | Nov 21, 1980 |                     |
| Phenylbutazone & Oxyphenbutazone                            | Jul 26, 1983 |                     |
| Prednisone (Dissolution Only)                               | Jul 10, 1985 |                     |
| Probenecid                                                  | Jul 26, 1983 |                     |
| Procainamide                                                | Jul 25, 1983 |                     |
| Propranolol                                                 | May 19, 1984 |                     |
| Propylthiouracil                                            | Aug 13, 1986 |                     |
| Quinidine Gluconate (Controlled Release)                    | Jun 15, 1981 |                     |
| Spiroinolactone                                             | Jul 25, 1983 |                     |
| Sulfinpyrazone                                              | Jul 15, 1983 |                     |
| Temazepam                                                   | Aug 1985     |                     |
| Theophylline (Controlled Release)                           | Apr 1984     |                     |
| Theophylline (Immediate Release)                            | Nov 02, 1983 |                     |
| Tolazamide                                                  | Aug 22, 1984 |                     |
| Tolbutamide                                                 | Jan 1982     |                     |
| Trazodone                                                   | Nov 15, 1985 | Apr 30, 1986        |
| Trimipramine                                                | Nov 03, 1986 |                     |
| Verapamil                                                   | Jul 1985     |                     |

# APPENDIX 4

## 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 (List I., Petitions Approved) and (2) is not suitable for submission as an ANDA (List II., 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.

### I. Petitions Approved

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                        | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u> | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|----------------------------------------------------------------------|--------------------------------------------|----------------------|-------------------|--------------------------------------|--------------------------|
| Acetaminophen;<br>Codeine Phosphate<br>Capsule; Oral                 | 500mg<br>30mg                              | 84 P-0228/CP         | McNeil Pharm      | New Dosage<br>Form<br>New Strength   | Approved<br>Jun 02, 1986 |
| Acetaminophen;<br>Codeine Phosphate<br>Capsule; Oral                 | 500mg<br>60mg                              | 84 P-0228/CP         | McNeil Pharm      | New Dosage<br>Form<br>New Strength   | Approved<br>Jun 02, 1986 |
| Acetaminophen;<br>Codeine Phosphate<br>Capsule; Oral                 | 650mg<br>15mg                              | 86 P-0200/CP         | Mikart, Inc       | New Strength<br>New Dosage<br>Form   | Approved<br>Oct 3, 1986  |
| Acetaminophen;<br>Codeine Phosphate<br>Soft Gelatin<br>Capsule; Oral | 300mg<br>30mg                              | 85 P-0543/CP         | Softan            | New Dosage<br>Form                   | Approved<br>Mar 18, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                        | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>               | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|----------------------------------------------------------------------|--------------------------------------------|----------------------|---------------------------------|--------------------------------------|--------------------------|
| Acetaminophen;<br>Codeine Phosphate<br>Soft Gelatin<br>Capsule; Oral | 500mg<br>7.5mg                             | 85 P-0543/<br>CP0002 | Softan                          | New Dosage<br>Form<br>New Strength   | Approved<br>Mar 19, 1986 |
| Acetaminophen;<br>Codeine Phosphate<br>Soft Gelatin<br>Capsule; Oral | 500mg<br>15mg                              | 85 P-0543/<br>CP0002 | Softan                          | New Dosage<br>Form<br>New Strength   | Approved<br>Mar 19, 1986 |
| Acetaminophen;<br>Codeine Phosphate<br>Elixir; Oral                  | 160mg/5ml<br>6mg/5ml                       | 86 P-0133/CP         | Kleinfeld, Kaplan and<br>Becker | New Strength                         | Approved<br>May 21, 1986 |
| Acetaminophen;<br>Codeine Phosphate<br>Tablet; Oral                  | 500mg<br>15mg                              | 86 P-0161/CP         | Roxane Laboratories             | New Strength                         | Approved<br>May 8, 1986  |
| Acetaminophen;<br>Codeine Phosphate<br>Tablet; Oral                  | 500mg<br>30mg                              | 86 P-0161/CP         | Roxane Laboratories             | New Strength                         | Approved<br>May 8, 1986  |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                 | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|-------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------------|--------------------------------------|--------------------------|
| Acetaminophen;<br>Codeine Phosphate<br>Tablet; Oral                           | 500mg<br>60mg                              | 86 P-0161/CP         | Roxane Laboratories | New Strength                         | Approved<br>May 8, 1986  |
| Acetaminophen;<br>Codeine Phosphate<br>Tablet; Oral                           | 650mg<br>15mg                              | 86 P-0200/CP         | Mikart, Inc         | New Strength                         | Approved<br>Oct 3, 1986  |
| Acetaminophen;<br>Hydrocodone Bitartrate<br>Solution; Oral                    | 500mg/15ml<br>5mg/15ml                     | 84 P-0391/CP         | UAD Laboratories    | New Dosage<br>Form                   | Approved<br>Jul 2, 1985  |
| Acetaminophen;<br>Oxycodone Hydrochloride<br>Solution; Oral                   | 325mg/5ml<br>5mg/5ml                       | 85 P-0085/CP         | Roxane Laboratories | New Dosage<br>Form                   | Approved<br>Aug 23, 1985 |
| Acetaminophen;<br>Oxycodone Hydrochloride<br>Soft Gelatin<br>Capsule; Oral    | 500mg<br>5mg                               | 85 P-0543/<br>CP0003 | Softan              | New Dosage<br>Form                   | Approved<br>Mar 18, 1986 |
| Acetaminophen;<br>Propoxyphene Hydrochloride<br>Soft Gelatin<br>Capsule; Oral | 500mg<br>32mg                              | 85 P-0581/CP         | Softan              | New Dosage<br>Form<br>New Strength   | Approved<br>Mar 18, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                                    | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u>     | <u>Status</u>            |
|--------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------------|------------------------------------------|--------------------------|
| Acetaminophen<br>Suppository; Rectal                                                             | 80mg                                       | 85 P-0403/CP         | Upsher-Smith Labs   | New Dosage<br>Form<br>(Pediatric)        | Approved<br>Oct 16, 1985 |
| Aminocaproic Acid<br>Injectable; Injection                                                       | 500mg/ml<br>(10ml/vial)                    | 85 P-0308/CP         | Abbott Laboratories | New Strength                             | Approved<br>Feb 12, 1986 |
| Aminophylline<br>Injectable; Injection                                                           | 10mg/ml<br>(10ml/vial)                     | 85 P-0459/CP         | Abbott Laboratories | New Strength                             | Approved<br>Feb 12, 1986 |
| Aminophylline<br>Injectable; Injection                                                           | 50mg/ml<br>(20ml/vial)                     | 85 P-0459/CP         | Abbott Laboratories | New Strength                             | Approved<br>Feb 12, 1986 |
| Aspirin;<br>Caffeine;<br>Dihydrocodeine Bitartrate<br>Tablet; Oral                               | 356.4mg<br>30mg<br>16mg                    | 86 P-0359/CP         | Central Pharms      | New Dosage<br>Form                       | Approved<br>Sep 29, 1986 |
| Azatadine Maleate;<br>Phenylpropanolamine<br>Hydrochloride<br>Sustained Release<br>Capsule; Oral | 1mg<br>75mg                                | 85 P-0492/CP         | SK&F Laboratories   | New<br>Combination<br>New Dosage<br>Form | Approved<br>Jan 28, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                                            | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u>     | <u>Status</u>            |
|----------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|----------------------|------------------------------------------|--------------------------|
| Benztropine Mesylate<br>Syrup; Oral                                                                      | 0.5mg/5ml                                  | 85 P-0423/CP         | RIM Consulting       | New Dosage<br>Form                       | Approved<br>Oct 16, 1985 |
| Bretylium Tosylate<br>Injectable; Injection                                                              | 100mg/ml                                   | 86 P-0157/CP         | Lyphomed             | New Strength                             | Approved<br>May 8, 1986  |
| Brompheniramine Maleate;<br>Pseudoephedrine<br>Hydrochloride<br>Sustained Release<br>Capsule; Oral       | 12mg<br>120mg                              | 85 P-0095/CP         | UAD Laboratories     | New<br>Combination<br>New Dosage<br>Form | Approved<br>Dec 13, 1985 |
| Cholestyramine<br>Tablet, Chewable;<br>Oral                                                              | Eq 4gm<br>Resin                            | 86 P-0123/CP         | Parke-Davis Labs/W-L | New Dosage<br>Form                       | Approved<br>Jun 20, 1986 |
| Chlorpheniramine Maleate;<br>Phenylpropanolamine<br>Hydrochloride<br>Controlled-release<br>Capsule; Oral | 10mg<br>75mg                               | 85 P-0149/CP         | Dura Pharmaceuticals | New<br>Strength                          | Approved<br>Dec 13, 1985 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                                             | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u> | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|-------------------|--------------------------------------|--------------------------|
| Chlorhexidine Gluconate<br>Solution; Topical                                                              | 1.5%                                       | 84 P-0417/CP         | Parke-Davis       | New Strength                         | Approved<br>Sep 18, 1985 |
| Cisplatin<br>Injectable, Injection                                                                        | 100mg/vial                                 | 86 P-0395/CP         | Ben Venue Labs    | New<br>Strength                      | Approved<br>Dec 8, 1986  |
| Codeine Phosphate;<br>Dextbrompheniramine Maleate;<br>Phenylpropanolamine<br>Hydrochloride<br>Syrup; Oral | 10mg/5ml<br>1mg/5ml<br>12.5mg/5ml          | 85 P-0269/CP         | Bock Pharmacal    | New<br>Combination                   | Approved<br>Dec 6, 1985  |
| Cytarabine<br>Injectable; Injection                                                                       | 20mg/ml<br>(5ml/vial)                      | 86 P-0130/CP         | Quad Pharms       | New Dosage<br>Form                   | Approved<br>Aug 21, 1986 |
| Cytarabine<br>Injectable; Injection                                                                       | 20mg/ml<br>(25ml/vial)                     | 86 P-0130/CP         | Quad Pharms       | New Dosage<br>Form                   | Approved<br>Aug 21, 1986 |
| Dacarbazine<br>Injectable; Injection                                                                      | 500mg/vial                                 | 86 P-0300/CP         | Quad Pharms       | New Strength                         | Approved<br>Aug 15, 1986 |

(continued)

## APPENDIX 4

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                                         | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u>     | <u>Status</u>            |
|-------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------------|------------------------------------------|--------------------------|
| Dexbrompheniramine Maleate;<br>phenylpropanolamine<br>Hydrochloride<br>Time Release Capsule;<br>Oral  | 6mg<br>75mg                                | 85 P-0238/<br>CP0002 | Bock Pharmacal      | New<br>Combination                       | Approved<br>Dec 13, 1985 |
| Dexbrompheniramine Maleate;<br>Pseudoephedrine<br>Hydrochloride<br>Sustained Release<br>Capsule; Oral | 6mg<br>120mg                               | 85 P-0140/CP         | Central Pharms      | New<br>Combination<br>New Dosage<br>Form | Approved<br>Dec 13, 1985 |
| Dexbrompheniramine Maleate;<br>Pseudoephedrine<br>Sulfate<br>Sustained Release<br>Capsule; Oral       | 6mg<br>120mg                               | 85 P-0140/<br>CP0002 | Central Pharms      | New<br>Dosage Form                       | Approved<br>Jan 22, 1986 |
| Diazepam<br>Solution; Oral                                                                            | 5mg/5ml                                    | 85 P-0090/CP         | Roxane Laboratories | New Dosage<br>Form                       | Approved<br>Sep 19, 1985 |
| Diazepam<br>Syrup; Oral                                                                               | 2mg/5ml                                    | 85 P-0499/CP         | Carolina Med Prods  | New Dosage<br>Form                       | Approved<br>Feb 28, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                 | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|---------------------------------------------------------------|--------------------------------------------|----------------------|----------------------|--------------------------------------|--------------------------|
| Diazepam<br>Intensol<br>Solution (Concentrate);<br>Oral       | 5mg/ml                                     | 85 P-0566/CP         | Roxane Laboratories  | New Dosage<br>Form                   | Approved<br>Mar 18, 1986 |
| Diphenhydramine<br>Hydrochloride<br>Concentrate; Oral         | 50mg/ml                                    | 84 P-0174/CP         | Roxane Laboratories  | New Strength                         | Approved<br>Sep 11, 1985 |
| Disopyramide Phosphate<br>Tablet, Controlled<br>Release; Oral | 200mg<br>300mg                             | 84 N-0116/CP         | Biocraft Labs        | New Dosage<br>Form<br>New Strength   | Approved<br>Jun 03, 1986 |
| Disulfiram<br>Suspension; Oral                                | 500mg/30ml                                 | 85 P-0215/CP         | Paddock Laboratories | New Dosage<br>Form                   | Approved<br>Oct 8, 1985  |
| Estradiol<br>Tablet; Oral                                     | 0.5mg                                      | 84 P-0308/CP         | Key Pharmaceuticals  | New Strength                         | Approved<br>Mar 24, 1986 |
| Floxuridine<br>Injectable; Injection                          | 500mg/5ml                                  | 86 P-0242/CP         | Quad Pharms          | New Dosage<br>Form                   | Approved<br>Aug 15, 1986 |
| Fluorouracil<br>Injectable; Injection                         | 25mg/ml                                    | 85 P-0208/CP         | Intl Pharm Prods     | New Strength                         | Approved<br>Oct 8, 1985  |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>    | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for<br/>Petition</u> | <u>Status</u>            |
|--------------------------------------------|--------------------------------------|----------------------|---------------------|--------------------------------|--------------------------|
| Fluorouracil<br>Injectable; Injection      | 50mg/ml<br>(100ml/vial)              | 85 P-0221/CP         | LyphoMed            | New Strength                   | Approved<br>Feb 18, 1986 |
| Fluorouracil<br>Injectable; Injection      | 50mg/ml<br>(20ml/vial)               | 86 P-0080/CP         | Ben Venue Labs      | New Strength                   | Approved<br>Apr 2, 1986  |
| Flurazepam<br>Concentrate; Oral            | 30mg/ml                              | 85 P-0081/CP         | Roxane Laboratories | New Dosage<br>Form             | Approved<br>Jul 10, 1985 |
| Flurazepam Hydrochloride<br>Solution; Oral | 15mg/5ml                             | 85 P-0091/CP         | Roxane Laboratories | New Dosage<br>Form             | Approved<br>Oct 25, 1985 |
| Furosemide<br>Solution; Oral               | 40mg/5ml                             | 85 P-0106/<br>CP0002 | Roxane Laboratories | New Strength                   | Approved<br>Sep 19, 1985 |
| Furosemide<br>Concentrate; Oral            | 80mg/ml                              | 85 P-0106/CP         | Roxane Laboratories | New Strength                   | Approved<br>Sep 19, 1985 |
| Glucagon<br>Injectable; Injection          | Eq 2mg Base/Amp                      | 86 P-0411/CP         | King and Spaulding  | New Strength                   | Approved<br>Oct 30, 1986 |
| Haloperidol<br>Solution; Oral              | 2mg/5ml                              | 85 P-0076/<br>CP0002 | Roxane Laboratories | New Strength                   | Approved<br>Mar 26, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>        | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|------------------------------------------------------|--------------------------------------------|----------------------|---------------------|--------------------------------------|--------------------------|
| Haloperidol Lactate<br>Intenol<br>Concentrate; Oral  | Eq 5mg Base/ml                             | 85 P-0076/CP         | Roxane Laboratories | New Strength                         | Approved<br>Dec 8, 1986  |
| Haloperidol<br>Solution; Oral                        | 5mg/5ml                                    | 85 P-0080/CP         | Roxane Laboratories | New Strength                         | Approved<br>Sep 19, 1985 |
| Hydralazine Hydrochloride<br>Solution; Oral          | 25mg/5ml                                   | 85 P-0074/CP         | Roxane Laboratories | New Dosage<br>Form                   | Approved<br>Jul 3, 1985  |
| Hydrochlorothiazide;<br>Triamterene<br>Capsule; Oral | 50mg<br>75mg                               | 86 P-0427/CP         | Par Pharmaceutical  | New Dosage<br>Form                   | Approved<br>Dec 11, 1986 |
| Ibuprofen<br>Capsule; Oral                           | 200mg                                      | 84 P-0383/CP         | Sterling Drug       | New Dosage<br>Form                   | Approved<br>Jun 25, 1985 |
| Ibuprofen<br>Soft Gelatin<br>Capsule; Oral           | 300mg<br>400mg<br>600mg                    | 85 P-0563/CP         | Softan              | New Dosage<br>Form                   | Approved<br>Mar 19, 1986 |
| Indomethacin<br>Suspension; Oral                     | 25mg/5ml                                   | 85 P-0077/<br>CP0002 | Roxane Laboratories | New Dosage<br>Form                   | Approved<br>Jul 19, 1985 |

(continued)

## APPENDIX 4

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I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>  | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|------------------------------------------------|--------------------------------------------|----------------------|----------------------|--------------------------------------|--------------------------|
| Isoniazid<br>Concentrate; Oral                 | 50mg/ml                                    | 85 P-0468/CP         | Carolina Med Prods   | New Strength                         | Approved<br>Dec 13, 1985 |
| Ketoconazole<br>Suspension; Oral               | 20mg/ml                                    | 85 P-0147/CP         | Janssen Pharma       | New Dosage<br>Form                   | Approved<br>Sep 27, 1985 |
| Leucovorin Calcium<br>Tablet; Oral             | 15mg                                       | 85 P-0487/CP         | Lederle Labs/AM Cyan | New Strength                         | Approved<br>Jan 28, 1986 |
| Lorazepam<br>Oral; Solution                    | 1mg/5ml                                    | 86 P-0292/CP         | Roxane Laboratories  | New Dosage<br>Form                   | Approved<br>Oct 15, 1986 |
| Lorazepam<br>Solution (Concentrate);<br>Oral   | 2mg/ml                                     | 86 P-0291/CP         | Roxane Laboratories  | New Dosage<br>Form                   | Approved<br>Oct 15, 1986 |
| Meperidine Hydrochloride<br>Concentrate; Oral  | 100mg/ml                                   | 84 P-0175/CP         | Roxane Laboratories  | New Strength                         | Approved<br>Jun 7, 1985  |
| Metaproterenol Sulfate<br>Solution; Inhalation | 10mg/2.5ml                                 | 85 P-0509/CP         | Armour Pharm         | New Strength                         | Approved<br>Feb 28, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>         | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|-------------------------------------------------------|--------------------------------------------|----------------------|----------------------|--------------------------------------|--------------------------|
| Metaproterenol Sulfate<br>Solution; Inhalation        | 10mg/3ml                                   | 85 P-0429/<br>CP0002 | Dey Laboratories     | New Strength                         | Approved<br>Feb 28, 1986 |
| Metaproterenol Sulfate<br>Solution; Inhalation        | 15mg/3ml                                   | 85 P-0429/CP         | Dey Laboratories     | New Strength                         | Approved<br>Feb 28, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>(20ml/vial)                      | 86 P-0036/CP         | AM Critical Care/AHS | New Strength                         | Approved<br>Mar 18, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>(50ml/vial)                      | 85 P-0545/CP         | Lyphomed             | New Strength                         | Approved<br>Feb 28, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>(50ml/vial)                      | 85 P-0540/CP         | Quad Pharms          | New Strength                         | Approved<br>Feb 28, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>(100ml/vial)                     | 85 P-0540/CP         | Quad Pharms          | New Strength                         | Approved<br>Feb 28, 1986 |
| Methyldopate Hydrochloride<br>Injectable; Injection   | 50mg/ml<br>(10ml/vial)                     | 85 P-0404/CP         | AM Critical Care/AHS | New Strength                         | Approved<br>Oct 25, 1985 |
| Methyltestosterone<br>Capsule; Oral                   | 25mg                                       | 85 P-0067/CP         | Star Pharmaceuticals | New Dosage<br>Form                   | Approved<br>Aug 23, 1985 |

(continued)

## APPENDIX 4

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                  | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for<br/>Petition</u> | <u>Status</u>            |
|----------------------------------------------------------|--------------------------------------|----------------------|----------------------|--------------------------------|--------------------------|
| Miconazole Nitrate<br>Cream; Vaginal                     | 4%                                   | 84 P-0398/CP         | Ortho Pharmaceutical | New Strength                   | Approved<br>Mar 31, 1986 |
| Naloxone Hydrochloride<br>Injectable; Injection          | 1mg/ml<br>(5ml/vial)                 | 86 P-0079/CP         | AM Critical Care/AHS | New Strength                   | Approved<br>May 7, 1986  |
| Naloxone Hydrochloride<br>Injectable; Injection          | 1mg/ml<br>(10ml/vial)                | 86 P-0079/CP         | AM Critical Care/AHS | New Strength                   | Approved<br>May 7, 1986  |
| Nitroglycerin<br>Injectable; Injection                   | 5mg/ml                               | 86 P-0025/CP         | Lyphomed             | New Strength                   | Approved<br>Apr 1, 1986  |
| Nitroglycerin<br>Injectable; Injection                   | 10mg/ml                              | 85 P-0134/CP         | Marion Laboratories  | New Strength                   | Approved<br>Sep 19, 1985 |
| Nitroglycerin in<br>5% Dextrose<br>Injectable; Injection | 10mg/100ml<br>(500ml Container)      | 86 P-0099/CP         | Abbott Laboratories  | New Strength                   | Approved<br>Apr 1, 1986  |
| Nitroglycerin<br>in 5% Dextrose<br>Injectable; Injection | 20mg/100ml<br>(250ml Container)      | 86 P-0099/<br>CP0002 | Abbott Laboratories  | New Strength                   | Approved<br>Apr 1, 1986  |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                  | <u>Strength<br/>(Container Size)</u>          | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for<br/>Petition</u> | <u>Status</u>            |
|----------------------------------------------------------|-----------------------------------------------|----------------------|----------------------|--------------------------------|--------------------------|
| Nitroglycerin<br>in 5% Dextrose<br>Injectable; Injection | 40mg/100ml<br>(250ml and 500ml<br>Containers) | 86 P-0099/<br>CP0003 | Abbott Laboratories  | New Strength                   | Approved<br>Apr 1, 1986  |
| Prednisolone<br>Syrup; Oral                              | 5mg/5ml                                       | 86 P-0399/CP         | Muro Pharmaceutical  | New Strength                   | Approved<br>Dec 8, 1986  |
| Probuco1<br>Tablet; Oral                                 | 500mg                                         | 85 P-0337/CP         | Merrell Dow/Dow Chem | New Strength                   | Approved<br>Oct 25, 1985 |
| Procainamide Hydrochloride<br>Tablet; Oral               | 375mg                                         | 85 P-0125/CP         | Key Pharmaceuticals  | New Strength                   | Approved<br>Sep 19, 1985 |
| Propranolol Hydrochloride<br>Capsule; Oral               | 10mg<br>20mg<br>40mg<br>60mg<br>80mg<br>90mg  | 86 P-0045/CP         | Nutripharm Labs      | New Dosage<br>Form             | Approved<br>Mar 19, 1986 |
| Propranolol Hydrochloride<br>Solution; Oral              | 40mg/5ml                                      | 85 P-0073/CP         | Roxane Laboratories  | New Dosage<br>Form             | Approved<br>Jul 8, 1985  |

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## APPENDIX 4

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                                                | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for<br/>Petition</u>       | <u>Status</u>            |
|----------------------------------------------------------------------------------------|--------------------------------------|----------------------|----------------------|--------------------------------------|--------------------------|
| Propranolol Hydrochloride<br>Concentrate; Oral                                         | 80mg/ml                              | 85 P-0073/<br>CP0002 | Roxane Laboratories  | New Dosage<br>Form                   | Approved<br>Jul 19, 1985 |
| Propranolol Hydrochloride<br>Solution; Oral                                            | 20mg/5ml                             | 85 P-0073/<br>CP0003 | Roxane Laboratories  | New Dosage<br>Form                   | Approved<br>Sep 24, 1985 |
| Propranolol Hydrochloride<br>Tablet, Constant-Release;<br>Oral                         | 160mg                                | 85 P-0129/CP         | Verex Laboratories   | New Dosage<br>Form                   | Approved<br>Sep 25, 1985 |
| Propranolol Hydrochloride<br>Tablet, Controlled Release;<br>Oral                       | 80mg<br>120mg<br>160mg               | 85 P-0197/CP         | Forest Laboratories  | New Dosage<br>Form                   | Approved<br>Sep 27, 1985 |
| Pyridostigmine<br>Bromide<br>Tablet; Oral                                              | 30mg                                 | 85 P-0412/CP         | Kali-Duphar Labs     | New Strength                         | Approved<br>Jan 22, 1986 |
| Ritodrine Hydrochloride<br>in Dextrose 5%<br>Injectable; Injection                     | 30mg/100ml<br>(500ml Container)      | 86 P-0100/CP         | Abbott Laboratories  | New Strength                         | Approved<br>May 7, 1986  |
| Scopolamine Transdermal<br>System/24 Hour<br>Film, Controlled Release;<br>Percutaneous | 1mg                                  | 85 P-0168/CP         | Ciba Consumer Pharms | New Strength<br>(Dosing<br>Interval) | Approved<br>Sep 27, 1985 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>       | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|-----------------------------------------------------|--------------------------------------------|----------------------|----------------------|--------------------------------------|--------------------------|
| Spiroinolactone<br>Syrup; Oral                      | 25mg/5ml                                   | 85 P-0510/CP         | Carolina Med Prods   | New Dosage<br>Form                   | Approved<br>Jan 22, 1986 |
| Spiroinolactone<br>Oral; Injection                  | 25mg/5ml                                   | 86 P-0055/CP         | Carolina Med Prods   | New Dosage<br>Form                   | Approved<br>Mar 28, 1986 |
| Theophylline<br>Capsule; Oral                       | 150mg<br>300mg                             | 85 P-0175/CP         | Mead Johnson/B-M     | New Strength                         | Approved<br>Oct 8, 1985  |
| Theophylline<br>Tablet, Controlled-release;<br>Oral | 600mg                                      | 85 P-0580/CP         | Purdue Frederick     | New Strength                         | Approved<br>Oct 15, 1986 |
| Thiothixene Hydrochloride<br>Solution; Oral         | 5mg/5ml                                    | 86 P-0178/CP         | Ellis Pharmaceutical | New Strength                         | Approved<br>Jun 04, 1986 |
| Triamcinolone<br>Acetonide<br>Cream; Topical        | 0.05%                                      | 86 P-0360/CP         | Carolina Med Prods   | New Strength                         | Approved<br>Oct 15, 1986 |
| Triamcinolone<br>Acetonide<br>Ointment; Topical     | 0.05%                                      | 86 P-0360/CP         | Carolina Med Prods   | New Strength                         | Approved<br>Oct 15, 1986 |

(continued)

## APPENDIX 4

I. Petitions Approved

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u> | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>      | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>            |
|-----------------------------------------------|--------------------------------------------|----------------------|------------------------|--------------------------------------|--------------------------|
| Vinblastine Sulfate<br>Injectable; Injection  | 1mg/ml                                     | 86 P-0056/CP         | Quad Pharms            | New Dosage<br>Form                   | Approved<br>Mar 28, 1986 |
| Vincristine Sulfate<br>Injectable; Injection  | 2mg/vial                                   | 85 P-0016/CP         | Bristol Labs/B-M       | New Dosage<br>Form                   | Approved<br>Nov 8, 1985  |
| Xenon XE 133<br>Gas; Inhalation               | 150mCi/vial<br>250mCi/vial                 | 86 P-0041/CP         | Medi Nuclear Corp, Inc | New Strength                         | Approved<br>Oct 15, 1986 |

## APPENDIX 4

II. Petitions Denied

| <u>Drug Name<br/>Dosage Form; Route</u>                     | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for<br/>Petition</u> | <u>Status</u>          |
|-------------------------------------------------------------|--------------------------------------|----------------------|----------------------|--------------------------------|------------------------|
| Acetaminophen;<br>Hydrocodone<br>Bitartrate<br>Tablet; Oral | 650mg<br>10mg                        | 85 P-0015/CP         | Applied Labs         | New Strength                   | Denied<br>Nov 7, 1985  |
| Acetaminophen;<br>Hydrocodone<br>Bitartrate<br>Tablet; Oral | 750mg<br>7.5mg                       | 85 P-0169/CP         | Knoll Pharmaceutical | New Strength                   | Denied<br>Nov 7, 1985  |
| Aminocaproic Acid<br>Injectable; Injection                  | 500mg/ml                             | 85 P-0064/CP         | Abbott Laboratories  | New Strength                   | Denied<br>May 29, 1985 |
| Aminophylline<br>Injectable; Injection                      | 10mg/ml                              | 85 P-0066/CP         | Abbott Laboratories  | New Strength                   | Denied<br>May 3, 1985  |
| Aminophylline<br>Injectable; Injection                      | 50mg/ml                              | 85 P-0066/CP         | Abbott Laboratories  | New Strength                   | Denied<br>May 3, 1985  |
| 5-Aminosalicylic Acid<br>Suppository; Rectal                | 500mg                                | 84 P-0425/CP         | Reid-Rowell          | New Ingredient                 | Denied<br>Jun 05, 1986 |

(continued)

## APPENDIX 4

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                              | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>          |
|----------------------------------------------------------------------------|--------------------------------------------|----------------------|----------------------|--------------------------------------|------------------------|
| Aspirin;<br>Chlorzoxazone<br>Tablet; Oral                                  | 325mg<br>250mg                             | 85 P-0071/CP         | McNeil Pharm         | New<br>Combination                   | Denied<br>Sep 3, 1985  |
| Aspirin;<br>Butalbital;<br>Caffeine;<br>Codeine Phosphate<br>Capsule; Oral | 325mg<br>50mg<br>40mg<br>7.5mg             | 85 P-0101/CP         | Sandoz Pharms/Sandoz | New<br>Combination                   | Denied<br>Sep 11, 1985 |
| Aspirin;<br>Butalbital;<br>Caffeine;<br>Codeine Phosphate<br>Capsule; Oral | 325mg<br>50mg<br>40mg<br>15mg              | 85 P-0101/CP         | Sandoz Pharms/Sandoz | New<br>Combination                   | Denied<br>Sep 11, 1985 |

(continued)

# APPENDIX 4

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## II. Petitions Denied

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                                    | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for<br/>Petition</u> | <u>Status</u>          |
|----------------------------------------------------------------------------|--------------------------------------|----------------------|----------------------|--------------------------------|------------------------|
| Aspirin;<br>Butalbital;<br>Caffeine;<br>Codeine Phosphate<br>Capsule; Oral | 325mg<br>50mg<br>40mg<br>30mg        | 85 P-0101/CP         | Sandoz Pharms/Sandoz | New<br>Combination             | Denied<br>Sep 11, 1985 |
| Aspirin;<br>Butalbital;<br>Caffeine;<br>Codeine Phosphate<br>Capsule; Oral | 325mg<br>50mg<br>40mg<br>60mg        | 85 P-0101/<br>CP0002 | Sandoz Pharms/Sandoz | New<br>Combination             | Denied<br>Sep 11, 1985 |
| Benzoyl Metronidazole<br>Suspension; Injection                             | 200mg/5ml                            | 85 P-0258/CP         | Apkon Laboratories   | New Ester<br>New Ingredient    | Denied<br>Mar 19, 1986 |
| Betamethasone Dipropionate<br>Miconazole Nitrate<br>Cream; Topical         | 0.05%<br>2%                          | 85 P-0271/CP         | Ortho Pharmaceutical | New<br>Combination             | Denied<br>Apr 18, 1986 |

(continued)

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                                             | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for<br/>Petition</u> | <u>Status</u>          |
|-------------------------------------------------------------------------------------|--------------------------------------|----------------------|----------------------|--------------------------------|------------------------|
| Bretylium Tosylate<br>Injectable; Injection                                         | 2mg/ml                               | 85 P-0063/CP         | Abbott Laboratories  | New Strength                   | Denied<br>May 29, 1985 |
| Bretylium Tosylate<br>Injectable; Injection                                         | 4mg/ml                               | 85 P-0063/<br>CP0002 | Abbott Laboratories  | New Strength                   | Denied<br>May 29, 1985 |
| Bretylium Tosylate<br>Injectable; Injection                                         | 8mg/ml                               | 85 P-0063/<br>CP0003 | Abbott Laboratories  | New Strength                   | Denied<br>May 29, 1985 |
| Bretylium Tosylate<br>Injectable; Injection                                         | 10mg/ml                              | 85 P-0063/<br>CP0004 | Abbott Laboratories  | New Strength                   | Denied<br>May 29, 1985 |
| Caffeine;<br>Ergotamine Tartrate;<br>Pentobarbital<br>Tablet; Oral                  | 100mg<br>1mg<br>30mg                 | 85 P-0433/CP         | Sandoz Pharms/Sandoz | New<br>Combination             | Denied<br>Nov 8, 1985  |
| Caffeine;<br>Ergotamine Tartrate;<br>Pentobarbital<br>Sodium<br>Suppository; Rectal | 200mg<br>2mg<br>60mg                 | 85 P-0433/<br>CP0002 | Sandoz Pharms/Sandoz | New<br>Combination             | Denied<br>Nov 8, 1985  |

(continued)

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                                 | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u> | <u>Reason for<br/>Petition</u> | <u>Status</u>          |
|-------------------------------------------------------------------------|--------------------------------------|----------------------|-------------------|--------------------------------|------------------------|
| Cholecalciferol<br>Capsule; Oral                                        | 1.25mg                               | 84 P-0161/CP         | Pharmacaps        | New Active<br>Ingredient       | Denied<br>Feb 13, 1986 |
| Codeine Phosphate;<br>Ibuprofen<br>Capsule; Oral                        | 30mg<br>200mg                        | 84 P-0388/CP         | McNeil Pharm      | New<br>Combination             | Denied<br>Sep 16, 1985 |
| Codeine Phosphate;<br>Ibuprofen<br>Capsule; Oral                        | 60mg<br>200mg                        | 84 P-0388/CP         | McNeil Pharm      | New<br>Combination             | Denied<br>Sep 16, 1985 |
| Codeine Phosphate;<br>Ibuprofen<br>Tablet; Oral                         | 30mg<br>200mg                        | 84 P-0388/CP         | McNeil Pharm      | New<br>Combination             | Denied<br>Sep 16, 1985 |
| Codeine Phosphate;<br>Ibuprofen<br>Tablet; Oral                         | 60mg<br>200mg                        | 84 P-0388/CP         | McNeil Pharm      | New<br>Combination             | Denied<br>Sep 16, 1985 |
| Choline Magnesium<br>Trisalicylate<br>Codeine Phosphate<br>Tablet; Oral | 500mg<br>30mg                        | 85 P-0142/CP         | Purdue Frederick  | New<br>Combination             | Denied<br>Jul 21, 1986 |

(continued)

## APPENDIX 4

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                                   | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>          |
|-------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------|----------------------|--------------------------------------|------------------------|
| Choline Magnesium<br>Trisalicylate;<br>Codeine Phosphate<br>Tablet; Oral                        | 500mg<br>60mg                              | 85 P-0142/CP         | Purdue Frederick     | New<br>Combination                   | Denied<br>Jul 21, 1986 |
| Dextromethorphan<br>Hydrobromide<br>Tablet, Controlled Release;<br>Oral                         | 60mg                                       | 85 P-0135/CP         | Ciba Consumer Pharms | New Salt<br>New Ingredient           | Denied<br>Jul 17, 1986 |
| Diatrizoate Meglumine;<br>Lidocaine Hydrochloride<br>Injectable; Injection                      | 60%<br>1.5mg/ml                            | 84 P-0325/CP         | Cook Imaging         | New<br>Combination                   | Denied<br>Sep 3, 1985  |
| Diazepam Intenol<br>Concentrate; Oral                                                           | 10mg/ml                                    | 85 P-0075/CP         | Roxane Laboratories  | New Dosage<br>Form                   | Denied<br>Sep 24, 1985 |
| Tri-Phasic Contraceptive<br>Tablet; Oral (21 and 28 days)<br>Ethinyl Estradiol<br>Norethindrone | 0.05mg<br>0.5mg                            | 84 P-0443/CP         | Ortho Pharmaceutical | New Strength<br>(Dose Schedule)      | Denied<br>Sep 3, 1985  |
| Ethinyl Estradiol<br>Norethindrone                                                              | 0.05mg<br>0.75mg                           |                      |                      |                                      |                        |
| Ethinyl Estradiol<br>Norethindrone                                                              | 0.05mg<br>1.0mg                            |                      |                      |                                      |                        |

(continued)

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name<br/>Dosage Form; Route</u>                                                                   | <u>Strength<br/>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for<br/>Petition</u> | <u>Status</u>          |
|-----------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------|---------------------|--------------------------------|------------------------|
| Fluphenazine Hydrochloride<br>Injectable; Injection                                                       | 5mg/ml                               | 85 P-0019/CP         | ER Squibb and Sons  | New Strength                   | Denied<br>Oct 25, 1985 |
| Heparin Sodium<br>Injectable; Injection                                                                   | 2000 Units/ml                        | 85 P-0065/CP         | Abbott Laboratories | New Strength                   | Denied<br>May 29, 1985 |
| Heparin Sodium<br>Injectable; Injection                                                                   | 4000 Units/ml                        | 85 P-0065/CP         | Abbott Laboratories | New Strength                   | Denied<br>May 29, 1985 |
| Hydrochlorothiazide;<br>Propranolol Hydrochloride;<br>Triamterene<br>Capsule, Controlled Release;<br>Oral | 50mg<br>80mg<br>75mg                 | 85 P-0571/CP         | Ayerst Labs/AMHO    | New<br>Combination             | Denied<br>May 16, 1986 |
| Hydrochlorothiazide;<br>Propranolol Hydrochloride;<br>Triamterene<br>Capsule, Controlled Release;<br>Oral | 50mg<br>120mg<br>75mg                | 85 P-0571/CP         | Ayerst Labs/AMHO    | New<br>Combination             | Denied<br>May 16, 1986 |
| Hydrochlorothiazide;<br>Propranolol Hydrochloride;<br>Triamterene<br>Capsule, Controlled Release;<br>Oral | 50mg<br>160mg<br>75mg                | 85 P-0571/CP         | Ayerst Labs/AMHO    | New<br>Combination             | Denied<br>May 16, 1986 |

(continued)

## APPENDIX 4

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>               | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>    | <u>Reason for</u><br><u>Petition</u>                                                   | <u>Status</u>          |
|-------------------------------------------------------------|--------------------------------------------|----------------------|----------------------|----------------------------------------------------------------------------------------|------------------------|
| Hydrocortisone Acetate<br>Suppository; Rectal               | 1%                                         | 85 P-0088/CP         | Parke-Davis Labs/W-L | New Dosage<br>Form<br>New Route of<br>Administration<br>New Strength<br>New Ingredient | Denied<br>Sep 16, 1986 |
| Ibuprofen;<br>Oxycodone Hydrochloride<br>Capsule; Oral      | 200mg<br>5mg                               | 85 P-0141/CP         | Dupont Pharms/Dupont | New<br>Combination                                                                     | Denied<br>Sep 27, 1985 |
| Ibuprofen;<br>Oxycodone Hydrochloride<br>Tablet; Oral       | 200mg<br>5mg                               | 85 P-0141/CP         | Dupont Pharms/Dupont | New<br>Combination                                                                     | Denied<br>Sep 27, 1985 |
| Indomethacin<br>Tablet; Oral                                | 25mg                                       | 85 P-0025/CP         | Verex Laboratories   | New Dosage<br>Form                                                                     | Denied<br>Mar 31, 1986 |
| Indomethacin<br>Tablet; Oral                                | 50mg                                       | 85 P-0025/CP         | Verex Laboratories   | New Dosage<br>Form                                                                     | Denied<br>Mar 31, 1986 |
| Indomethacin<br>Intensol<br>Solution (Concentrate);<br>Oral | 50mg/ml                                    | 85 P-0077/CP         | Roxane Laboratories  | New Dosage<br>Form<br>New Strength                                                     | Denied<br>Apr 7, 1986  |

(continued)

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>         | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>          |
|-------------------------------------------------------|--------------------------------------------|----------------------|---------------------|--------------------------------------|------------------------|
| Indomethacin<br>Tablet, Constant<br>Release; Oral     | 75mg                                       | 85 P-0026/CP         | Verex Laboratories  | New Dosage<br>Form                   | Denied<br>Sep 16, 1985 |
| Indomethacin<br>Tablet, Controlled<br>Release; Oral   | 75mg                                       | 85 P-0180/CP         | Forest Laboratories | New Dosage<br>Form                   | Denied<br>Apr 7, 1986  |
| Methocarbamol;<br>Acetaminophen<br>Tablet; Oral       | 400mg<br>325mg                             | 85 P-0102/CP         | McNeil Pharm        | New<br>Combination                   | Denied<br>Jun 24, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 1mg/ml<br>(50ml/vial)                      | 86 P-0015/CP         | Intl Medication Sys | New Strength                         | Denied<br>Apr 25, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 1mg/ml<br>(75ml/vial)                      | 86 P-0015/CP         | Intl Medication Sys | New Strength                         | Denied<br>Apr 25, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 1mg/ml<br>(100ml/vial)                     | 86 P-0015/CP         | Intl Medication Sys | New Strength                         | Denied<br>Apr 25, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 10mg/ml                                    | 85 P-0062/CP         | Abbott Laboratories | New Strength                         | Denied<br>May 29, 1985 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 10mg/ml                                    | 85 P-0457/CP         | Abbott Laboratories | New Strength                         | Denied<br>Apr 18, 1986 |

(continued)

## APPENDIX 4

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>                                      | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u>     | <u>Status</u>          |
|------------------------------------------------------------------------------------|--------------------------------------------|----------------------|---------------------|------------------------------------------|------------------------|
| Metoclopramide Hydrochloride 20mg/ml<br>Injectable; Injection                      | 20mg/ml                                    | 85 P-0062/<br>CP0002 | Abbott Laboratories | New Strength                             | Denied<br>May 29, 1985 |
| Metoclopramide Hydrochloride 20mg/ml<br>Injectable; Injection                      | 20mg/ml                                    | 85 P-0457/<br>CP0002 | Abbott Laboratories | New Strength                             | Denied<br>Apr 18, 1986 |
| Metronidazole<br>Sponge; Vaginal                                                   | 50-125mg/<br>Sponge                        | 85 P-0117/CP         | VLI                 | New Dosage<br>Form                       | Denied<br>Oct 8, 1985  |
| Nitroglycerin<br>Film, Controlled<br>Release; Percutaneous                         | None<br>Given                              | 84 P-0302/CP         | Key Pharmaceuticals | New Dosage<br>Form<br>(New Matrix)       | Denied<br>Jul 29, 1985 |
| Phenylephrine Hydrochloride; 0.5%<br>Sulfathiazole<br>Nasal Suspension;<br>Topical | 0.5%<br>5%                                 | 85 P-0205/CP         | Tanya W Ross        | New Dosage<br>Form<br>New<br>Combination | Denied<br>Nov 14, 1985 |
| Pseudoephedrine Polisterex<br>Capsule, Controlled<br>Release; Oral                 | 60mg                                       | 85 P-0334/CP         | Pennwalt Pharm      | New Salt<br>New Ingredient               | Denied<br>Mar 19, 1986 |
| Temazepam<br>Soft Gelatin<br>Capsule; Oral                                         | 10mg<br>20mg                               | 85 P-0016/CP         | Wyeth/AMHO          | New Strength                             | Denied<br>Sep 29, 1986 |

(continued)

## APPENDIX 4

II. Petitions Denied

(continued)

| <u>Drug Name</u><br><u>Dosage Form; Route</u>    | <u>Strength</u><br><u>(Container Size)</u> | <u>Docket Number</u> | <u>Petitioner</u>   | <u>Reason for</u><br><u>Petition</u> | <u>Status</u>         |
|--------------------------------------------------|--------------------------------------------|----------------------|---------------------|--------------------------------------|-----------------------|
| Triamcinolone Acetonide<br>Suspension; Injection | 2.5mg/ml                                   | 85 P-0001/CP         | GenDerm             | New Strength                         | Denied<br>Mar 4, 1985 |
| Triamcinolone Acetonide<br>Suspension; Injection | 3mg/ml                                     | 84 P-0240/CP         | Bay Pharmaceuticals | New Strength                         | Denied<br>Mar 4, 1985 |

## APPENDIX 5

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, THE FOLLOWING ABBREVIATIONS HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THIS PAGE FOR AN EXPLANATION OF THE EXCLUSIVITY ABBREVIATIONS FOUND IN THE ADDENDUM.

ABBREVIATIONS

|     |                                            |
|-----|--------------------------------------------|
| NC  | NEW COMBINATION                            |
| NCE | NEW CHEMICAL ENTITY                        |
| NDF | NEW DOSAGE FORM                            |
| NE  | NEW ESTER OR SALT OF AN ACTIVE INGREDIENT  |
| NP  | NEW PRODUCT                                |
| NR  | NEW ROUTE                                  |
| PP  | PARENTERAL IN PLASTIC CONTAINER            |
| RT0 | PRESCRIPTION TO OTC STATUS CHANGE          |
| NS  | NEW STRENGTH                               |
| D   | NEW DOSING SCHEDULE (SEE REFERENCE, BELOW) |
| I   | NEW INDICATION (SEE REFERENCE, BELOW)      |
| ODE | ORPHAN DRUG EXCLUSIVITY                    |

REFERENCESNEW DOSING SCHEDULE

|     |                                                  |
|-----|--------------------------------------------------|
| D-1 | ONCE A DAY APPLICATION                           |
| D-2 | ONCE DAILY DOSING                                |
| D-3 | SEVEN DAYS/SEVEN DAYS/SEVEN DAYS DOSING SCHEDULE |
| D-4 | SEVEN DAYS/FOURTEEN DAYS DOSING SCHEDULE         |
| D-5 | TEN DAYS/ELEVEN DAYS DOSING SCHEDULE             |

(continued)

## APPENDIX 5

(continued)

NEW DOSING SCHEDULE

|      |                                                |
|------|------------------------------------------------|
| D-6  | SEVEN DAYS/NINE DAYS/FIVE DAYS DOSING SCHEDULE |
| D-7  | BID DOSING                                     |
| D-8  | INTRAVENOUS, EPIDURAL AND INTRATHECAL DOSING   |
| D-9  | NARCOTIC OVERDOSE IN ADULTS                    |
| D-10 | NARCOTIC OVERDOSE IN CHILDREN                  |
| D-11 | POSTOPERATIVE NARCOTIC DEPRESSION IN CHILDREN  |
| D-12 | BEDTIME DOSING OF 800MG FOR TREATMENT          |

NEW INDICATION

|      |                                                                    |
|------|--------------------------------------------------------------------|
| I-1  | SEVERE HYPERTENSION IN PEDIATRICS AND NON-MALIGNANT HYPERTENSION   |
| I-2  | DYSMENORRHEA                                                       |
| I-3  | TREATMENT OF TINEA VERSICOLOR                                      |
| I-4  | SYMPTOMATIC GASTROESOPHAGEAL REFLUX                                |
| I-5  | NEPHROTOMOGRAPHY                                                   |
| I-6  | CONTRAST ENHANCEMENT IN CRANIAL COMPUTED TOMOGRAPHY                |
| I-7  | VENOGRAPHY OF LOWER EXTREMITIES                                    |
| I-8  | WHOLE-BODY COMPUTED TOMOGRAPHY                                     |
| I-9  | GATED CARDIAC POOL IMAGING                                         |
| I-10 | POST-MYOCARDIAL INFARCTION                                         |
| I-11 | COLORECTAL SURGERY                                                 |
| I-12 | NAUSEA AND VOMITING ASSOCIATED WITH EMETOGENIC CANCER CHEMOTHERAPY |
| I-13 | CISPLATIN INDUCED EMESIS                                           |
| I-14 | DIABETIC GASTROPARESIS                                             |
| I-15 | SHORT TERM TREATMENT OF GASTRIC ULCER DISEASE                      |
| I-16 | ACROMEGALY                                                         |

(continued)

## APPENDIX 5

(continued)

NEW INDICATION

|              |                                                                       |
|--------------|-----------------------------------------------------------------------|
| I-17         | PITUITARY TUMORS                                                      |
| I-18         | POSTMENOPAUSAL OSTEOPOROSIS                                           |
| I-19         | ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE                                 |
| I-20         | CONGESTIVE HEART FAILURE BID DOSAGE SCHEDULE                          |
| I-21         | ACUTE/CHRONIC/HEPATIC                                                 |
| I-22         | EXERCISE INDUCED BRONCHOSPASMS                                        |
| I-23         | MYOCARDIAL INFARCTION OR STROKE                                       |
| I-24         | COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL           |
| I-25         | BLASTOMYCOSES DERMATITIDES                                            |
| I-26         | PEDIATRIC SUBARACHNOID VASCULAR                                       |
| I-27         | PETRIELLIDIUM BOYDII INFECTION                                        |
| I-28         | HEREDITARY ANGIOEDEMA                                                 |
| I-29         | INTRACORONARY USE                                                     |
| I-30         | PEDIATRIC USE                                                         |
| I-31         | DIRECT ISOTOPIC CYSTOGRAPHY                                           |
| I-32         | POSTPARTUM HEMORRHAGE                                                 |
| I-33         | USE IN METHUONE INDUCED RESPIRATORY DEPRESSION                        |
| I-34         | PROLACTIN SECRETING ADENOMAS                                          |
| I-35         | ANGINA PECTORIS DUE TO CORONARY ATHEROSCLEROSIS                       |
| I-36         | ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY                              |
| I-37         | SPINAL ANESTHESIA                                                     |
| I-38         | PATIENT PREOPERATIVE SKIN PREPARATION                                 |
| I-39         | ADJUVANT/THERAPY/POST-TREATMENT/OF/BREAST/CANCER/FOLLOWING/MASTECTOMY |
| > DLI > I-40 | ANTIDOTE FOR ACETAMINOPHEN OVERDOSE                                   |

(continued)

## APPENDIX 5

(continued)

NEW INDICATION

|                |                                                                                                |
|----------------|------------------------------------------------------------------------------------------------|
| I-41           | MANAGEMENT OF HYPOCALCEMIA AND RESULTANT METABOLIC BONE DISEASE IN RENAL DIALYSIS PATIENTS     |
| I-42           | MAINTENANCE THERAPY AT REDUCED DOSE FOLLOWING HEALING OF ACUTE DUODENAL ULCER                  |
| I-43           | TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE                                                   |
| I-44           | TREATMENT OF SEVERE RECALCITRANT DERMATOPHYTE INFECTIONS                                       |
| I-45           | ACCELERATE BARIUM TRANSIT THEREBY DECREASING TIME AND EXTENT OF RADIATION TO INTESTINAL TRACT  |
| I-46           | TREATMENT OF SMALL CELL LUNG CANCER IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC DRUGS  |
| I-47           | USE IN BALANCED ANESTHESIA                                                                     |
| I-48           | MANAGEMENT OF FAMILIAL OR HEREDITARY ESSENTIAL TREMOR                                          |
| I-49           | ADJUNCT TO COUMARIN ANTICOAGULANTS IN PREVENTION OF POSTOPERATIVE THROMBOEMBOLIC COMPLICATIONS |
| > <u>ADD</u> > | OF CARDIAC VALVE REPLACEMENTS                                                                  |
| > <u>ADD</u> > | TREATMENT OF ARRHYTHMIAS                                                                       |
| > <u>ADD</u> > | MANAGEMENT OF ESSENTIAL HYPERTENSION                                                           |
| > <u>ADD</u> > | CERVICAL MYELOGRAPHY                                                                           |
| > <u>ADD</u> > | USE AS SINGLE AGENT TO DELAY BREAST CANCER RECURRENCE FOLLOWING TOTAL MASTECTOMY AND           |
|                | AXILLARY DISSECTION IN POSTMENOPAUSAL WOMEN                                                    |

DRUG PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT  
BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST

NO SEPTEMBER 1985 - DECEMBER 1986 ACTIONS

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

[illegible]

(continued)

APPENDIX 6  
PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

[illegible]

(continued)

APPENDIX 6  
PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

[illegible]

(continued)

(continued)

(continued)

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APPENDIX 6  
PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

| APPL/PROD | PATENT<br>NUMBER | PATENT<br>EXPIRES | EXCLUSIVITY<br>CODE | EXCLUSIVITY<br>EXPIRES | APPL/PROD | PATENT<br>NUMBER | PATENT<br>EXPIRES | EXCLUSIVITY<br>CODE | EXCLUSIVITY<br>EXPIRES |
|-----------|------------------|-------------------|---------------------|------------------------|-----------|------------------|-------------------|---------------------|------------------------|
| 19081 003 | 4379454          | APR 12, 2000      | NDF                 | SEP 10, 1989           | 19369 001 | 4215215          | JUL 29, 1997      | NCE                 | SEP 30, 1991           |
|           | 4144317          | SEP 09, 1992      |                     |                        |           | 4200647          | APR 29, 1997      |                     |                        |
|           | 3948262          | JUL 29, 1992      |                     |                        | 19369 002 | 4215215          | JUL 29, 1997      | NCE                 | SEP 30, 1991           |
|           | 4335125          | JUN 15, 1999      | NDF                 | DEC 31, 1988           |           | 4200647          | APR 29, 1997      |                     |                        |
| > ADD >   | 3681500          | AUG 01, 1989      | NCE                 | DEC 29, 1991           |           | 4146719          | MAR 27, 1996      | NCE                 | OCT 31, 1991           |
|           | 4585790          | APR 29, 2003      |                     |                        |           |                  |                   | NCE                 | DEC 31, 1991           |
|           | 19107 001        |                   | NCE                 | OCT 17, 1990           | > ADD >   |                  |                   | NCE                 | DEC 31, 1991           |
|           | 19107 001        |                   | ODE                 | OCT 17, 1992           | > ADD >   |                  |                   | NS                  | MAR 10, 1989           |
| > ADD >   | 19152 001        |                   | NDF                 | DEC 16, 1989           |           |                  |                   | NS                  | MAR 10, 1989           |
|           | 19193 001        |                   | NCE                 | OCT 31, 1991           |           |                  |                   | NS                  | MAR 10, 1989           |
| 19194 001 |                  |                   | NCE                 | NOV 11, 1990           |           |                  |                   | NS                  | MAR 10, 1989           |
|           |                  |                   | ODE                 | NOV 11, 1992           |           |                  |                   | NE                  | SEP 18, 1989           |
| 19215 001 | 4078071          | MAR 07, 1995      | NCE                 | NOV 25, 1990           |           | 4012444          | MAR 15, 1994      | NCE                 | AUG 01, 1994           |
| 19219 002 | 3641152          | FEB 08, 1989      | NCE                 | DEC 19, 1990           |           | 4066755          | JAN 03, 1995      |                     |                        |
| 19221 001 | 4374829          | FEB 22, 2000      | NC                  | OCT 31, 1989           | 19434 001 | 3950333          | APR 13, 1993      |                     |                        |
|           | 4472380          | SEP 18, 2001      |                     |                        |           | 4024271          | MAY 17, 1994      |                     |                        |
| 19257 001 |                  |                   | NDF                 | APR 10, 1989           |           | 4024163          | MAY 17, 1994      | NCE                 | MAR 31, 1991           |
|           |                  |                   | ODE*                | DEC 27, 1992           |           |                  |                   | NS                  | JUN 13, 1989           |
| 19259 001 | 3980778          | SEP 14, 1993      |                     |                        |           |                  |                   | NC                  | JUL 11, 1989           |
| 19260 001 | 3980778          | SEP 14, 1993      |                     |                        |           |                  |                   | NCE                 | OCT 15, 1991           |
| 19264 001 |                  |                   | ODE                 | OCT 16, 1991           |           | 4283408          | AUG 11, 1998      | NCE                 | OCT 15, 1991           |
| 19270 001 | 4252984          | FEB 24, 1998      | NCE                 | AUG 30, 1990           |           | 3655663          | APR 11, 1989      | NP                  | NOV 05, 1989           |
|           | 4311708          | JAN 19, 1999      |                     |                        |           | 4195085          | MAR 25, 1997      |                     |                        |
|           | 4342783          | AUG 03, 1999      |                     |                        |           | 3655663          | APR 11, 1989      | NP                  | NOV 05, 1989           |
| > ADD >   | 3950405          | APR 13, 1993      | NCE                 | DEC 30, 1991           |           | 4195085          | MAR 25, 1997      |                     |                        |
| > ADD >   |                  |                   | ODE                 | DEC 30, 1993           |           | 3644627          | FEB 22, 1989      |                     |                        |
| > ADD >   |                  |                   | ODE                 | DEC 30, 1990           |           | 3784684          | JAN 08, 1991      |                     |                        |
| 19281 001 | 3950405          | APR 13, 1993      | NCE                 | DEC 27, 1990           | 19478 001 | 3644627          | FEB 22, 1989      |                     |                        |
|           |                  |                   | NCE                 | DEC 27, 1991           |           | 3784684          | JAN 08, 1991      | NCE                 | DEC 15, 1991           |
| 19322 001 | 3721687          | MAR 20, 1990      | NCE                 | DEC 29, 1991           | > ADD >   |                  |                   | ODE                 | DEC 15, 1993           |
| 19323 001 | 3721687          | MAR 20, 1990      | NCE                 | DEC 29, 1991           | > ADD >   |                  |                   | NCE                 | DEC 15, 1991           |
| > ADD >   |                  |                   | NCE                 | FEB 18, 1993           | > ADD >   |                  |                   | ODE                 | DEC 15, 1993           |
| > ADD >   | 4062966          | DEC 13, 1994      | NCE                 | NOV 25, 1990           | > ADD >   |                  |                   | NCE                 | OCT 15, 1991           |
|           | 4078071          | MAR 07, 1995      | NCE                 | OCT 29, 1990           |           | 4283408          | AUG 11, 1998      | NS                  | AUG 06, 1989           |
| 19368 001 | 4205086          | MAY 27, 1997      | ODE                 | OCT 29, 1992           |           |                  |                   |                     |                        |

\*REFER TO APPENDIX I NARRATIVE

(continued)

APPENDIX 6  
 PRESCRIPTION AND OTC DRUG PRODUCT  
 PATENT AND EXCLUSIVITY DATA

| APPL/PROD | PATENT<br>NUMBER | PATENT<br>EXPIRES | EXCLUSIVITY<br>CODE | EXCLUSIVITY<br>EXPIRES |
|-----------|------------------|-------------------|---------------------|------------------------|
| > ADD >   | 19536 001        |                   |                     |                        |
| > ADD >   |                  |                   | D-7                 | OCT 31, 1989           |
| > ADD >   |                  |                   | I-48                | OCT 31, 1989           |
| > ADD >   | 3524844          | AUG 18, 1987      | NCE                 | NOV 10, 1993           |
| > ADD >   | 3524844          | AUG 18, 1987      | NCE                 | NOV 10, 1993           |
| > ADD >   | 4128658          | DEC 05, 1995      | NCE                 | JUN 09, 1993           |
| > ADD >   | 4521431          | JUN 04, 2002      |                     |                        |
| > ADD >   | 4585790          | APR 29, 2003      |                     |                        |
| > ADD >   | 4454152          | JUN 12, 2001      | NDF                 | OCT 30, 1989           |