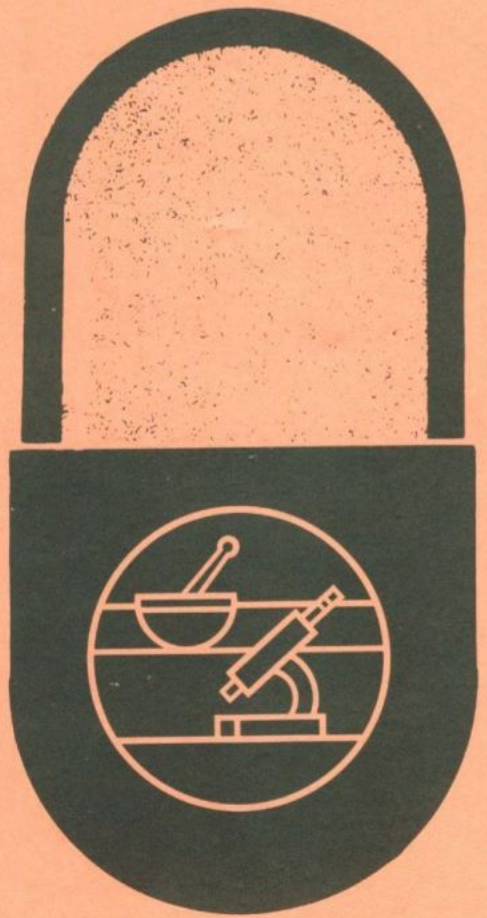
CUMULATIVE

SUPPLEMENT 7

AUG'85-MAR'86





# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 6TH 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

## MARCH 1986

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# 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 drug product lists 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

| Former Applicant (Name) | New Applicant (Name) | New Abbreviated Name |
|---|---|---|
| VITARINE/PHOENIX | VITARINE PHARMACEUTICALS, INC | VITARINE PHARMS |
| DRUMMER/PHOENIX | VITARINE PHARMACEUTICALS, INC | VITARINE PHARMS |
| INVENEX LABS/LIFE | LYPHOMED, INC | LYPHOMED |
| ONEAL JONES&FELDMAN | FOREST PHARMACEUTICALS, INC SUBSIDIARY OF FOREST LABORATORIES, INC | FOREST PHARMS/FOREST |

(continued)

## APPLICANT (NAME) CHANGES

(continued)

| Former Applicant (Name) | New Applicant (Name) | New Abbreviated Name |
|---|---|---|
| AM MCGAW/AM HOSP | KENDALL MCGAW LABORATORIES, INC | KENDALL MCGAW LABS |
| IVES LABS/AMHO | WYETH LABORATORIES, INC DIVISION OF AMERICAN HOME PRODUCTS CORP | WYETH LABS/AMHO |
| REID PROVIDENT LABS AND ROWELL LABORATORIES | REID-ROWELL | REID-ROWELL |

### 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 |
|---|---|
| isosorbide dinitrate | AUG 3, 1984 (49 FR 31151) |
| nandrolone decanoate | JUL 15, 1983 (48 FR 32395) |
| neomycin sulfate with either: dexamethasone sodium phosphate, fluocinolone acetonide, flurandrenolide, hydrocortisone, or methylprednisolone acetate [topical anti-infectives for dermatologic use] | MAR 26, 1984 (49 FR 11888) |
| neomycin sulfate, polymyxin B sulfate, bacitracin zinc, and hydrocortisone [topical ointment] | MAY 4, 1984 (49 FR 19147) |
| nitroglycerin (capsule, controlled release;oral) | SEP 7, 1984 (49 FR 35428) |
| nitroglycerin (tablet, controlled release;oral) | SEP 7, 1984 (49 FR 35428) |
| nitroglycerin (tablet, controlled release;buccal) | JUL 5, 1985 (50 FR 27688) |
| phenazopyridine hydrochloride and sulfamethoxazole | JUL 29, 1983 (48 FR 34516) |
| sulfanilamide and aminacrine | AUG 22, 1983 (48 FR 38097) |
| tranylcypromine sulfate | MAR 22, 1984 (49 FR 10708) |

## 6. 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) | OCT '85 | JAN '86 |
|---|---|---|---|
| DRUG PRODUCTS LISTED | 8048 | 8230 | 8515 |
| SINGLE SOURCE | 2096 (26.0%) | 2100 (25.5%) | 2144 (25.1%) |
| MULTISOURCE(1) | 5952 (74.0%) | 6130 (74.5%) | 6371 (74.9%) |
| THERAPEUTICALLY EQUIVALENT | 4864 (60.5%) | 5034 (61.2%) | 5263 (61.8%) |
| NOT THERAPEUTICALLY EQUIVALENT | 1054 (13.1%) | 1058 (12.9%) | 1070 (12.6%) |
| EXCEPTIONS(2) | 34 ( 0.4%) | 38 ( 0.4%) | 38 ( 0.5%) |
| NEW MOLECULAR ENTITIES APPROVED | - | 5 | 21 |
| NUMBER OF APPLICANTS | 306 | 313 | 322 |

### B. ACTIVITY FOR SUPPLEMENT NUMBER 7

| | FEB '86 | MAR '86 | CUMULATIVE |
|---|---|---|---|
| DRUG PRODUCTS ADDED: | 59 | 61 | 120 |
| NEWLY APPROVED | 59 | 61 | 120 |
| DESI EFFECTIVE | 0 | 0 | 0 |
| REMARKETED | 0 | 0 | 0 |
| DRUG PRODUCTS REMOVED: | 0 | 0 | 0 |
| WITHDRAWN APPROVAL | 0 | 0 | 0 |
| RX TO OTC SWITCH | 0 | 0 | 0 |
| NET GAIN IN DRUG PRODUCTS | 59 | 61 | 120 |
| SINGLE SOURCE PRODUCTS APPROVED | 6 | 9 | 15 |
| MULTISOURCE DRUG PRODUCTS APPROVED | 53 | 52 | 105 |
| NEW MOLECULAR ENTITIES APPROVED: | 0 | 1 | 1 |
| AS THE ENTITY | 0 | 1 | 1 |
| AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY | 0 | 0 | 0 |

(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 I-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

>ADD> ACETAMINOPHEN (PAGE 3-1)

>ADD> INJECTABLE; INJECTION
>ADD> INJECTAPAP
>ADD> MCNEIL PHARM 100MG/ML* N17785 001
>ADD> MAR 07, 1986

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

CAPSULE; ORAL
BANCAP
FOREST PHARM/FOREST 325MG;50MG* N88989 001
JAN 16, 1986

TABLET; ORAL
SEDAPAP-10
MAYRAND 650MG;50MG* N88944 001
OCT 17, 1985

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL
>ADD> ACETAMINOPHEN, BUTALBITAL, AND CAFFEINE
>ADD> AB MIKART 325MG;50MG;40MG* N89007 001
>ADD> MAR 17, 1986
MEDIGESIC PLUS
AB US CHEM MKTG GROUP 325MG;50MG;40MG* N89115 001
JAN 14, 1986

>ADD> ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE (PAGE 3-1)

>ADD> CAPSULE; ORAL
>ADD> COMPAL
>ADD> REID-ROWELL 356.4MG;30MG;16MG* N88584 001
>ADD> MAR 04, 1986

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL
ACETAMINOPHEN AND CODEINE
AA VITARINE 300MG;15MG N87433 001
AA 300MG;30MG N85917 001
AA 300MG;60MG N87423 001
>ADD> ACETAMINOPHEN AND CODEINE PHOSPHATE
>ADD> AA MIKART 650MG;30MG* N89231 001
>ADD> MAR 03, 1986

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE #2
AA SUPERPHARM 300MG;15MG* N89183 001
OCT 18, 1985
ACETAMINOPHEN AND CODEINE PHOSPHATE #3
AA MIKART 300MG;30MG* N89238 001
FEB 25, 1986
AA SUPERPHARM 300MG;30MG* N89184 001
OCT 18, 1985
ACETAMINOPHEN AND CODEINE PHOSPHATE #4
AA MIKART 300MG;60MG* N89244 001
FEB 25, 1986
AA SUPERPHARM 300MG;60MG* N89185 001
OCT 18, 1985
ACETAMINOPHEN W/ CODEINE
/AA/ /VITARINE/ /300MG;30MG/ /N85917.001/
ACETAMINOPHEN W/ CODEINE #2
/AA/ /VITARINE/ /300MG;15MG/ /N87433.001/
ACETAMINOPHEN W/ CODEINE #4
/AA/ /VITARINE /300MG;60MG/ /N87423.001/
PHENAPHEN-650 W/ CODEINE
>ADD> AA AH ROBINS 650MG;30MG N85856 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-3)

CAPSULE; ORAL
ACETAMINOPHEN AND HYDROCODONE BITARTRATE
AA DM GRAHAM LABS 500MG;5MG* N89006 001
AUG 09, 1985
BANCAP HC
AA FOREST PHARM/FOREST 500MG;5MG N87961 001
MAR 17, 1983
/AA/ /ONEAL,JONES&FELDMAN//500MG;5MG/ /N87961.001/
/MAR.17,.1983/
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA MIKART 500MG;5MG* N89008 001
FEB 21, 1986

TABLET; ORAL
DURADYNE DHC
AA FOREST PHARM/FOREST 500MG;5MG N87809 001
MAR 17, 1983

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE (PAGE 3-3)

TABLET; ORAL
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | BARR LABORATORIES | 650MG;100MG¤ | N70615 001 | MAR 21, 1986 |
| > ADD > | | | | | |
| > ADD > | AB | | 650MG;100MG¤ | N70771 001 | MAR 21, 1986 |
| > ADD > | | | | | |
| > ADD > | AB | | 650MG;100MG¤ | N70775 001 | MAR 21, 1986 |
| > ADD > | | | | | |
| | AB | CORD LABORATORIES | 650MG;100MG¤ | N70443 001 | JAN 23, 1986 |
| | AB | LEMMON | 650MG;100MG¤ | N70732 001 | JAN 03, 1986 |
| | AB | ZENITH LABORATORIES | 650MG;100MG¤ | 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%¤ | N88606 001 | AUG 21, 1985 |

ACYCLOVIR (PAGE 3-5)

CAPSULE; ORAL
ZOVIRAX

| | | | | |
|---|---|---|---|---|
| | BURROUGHS WELLCOME | 200MG | N18828 001 | /JAN/28,/1985/ JAN 25, 1985 |

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL
ALLOPURINOL

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 100MG¤ | N70466 001 | NOV 30, 1988 : DEC 24, 1985 |
| AB | | 300MG¤ | N70467 001 | NOV 30, 1988 : DEC 24, 1985 |
| AB | CORD LABORATORIES | 100MG¤ | N70263 001 | /NOV/30,/1988/:/DEC 31, 1985 |
| > DLT > | | | | |
| AB | | 300MG¤ | N70269 001 | /NOV/30,/1988/:/DEC 31, 1985 |
| > DLT > | | | | |

ALLOPURINOL (PAGE 3-6)

TABLET; ORAL
ALLOPURINOL

| | | | | |
|---|---|---|---|---|
| AB | PAR PHARMACEUTICAL | 100MG¤ | N70150 001 | /NOV/30,/1988/:/DEC 10, 1985 |
| AB | | 300MG¤ | N70147 001 | /NOV/30,/1988/:/DEC 10, 1985 |

AMILORIDE HYDROCHLORIDE (PAGE 3-7)

TABLET; ORAL
MIDAMOR

| | | | |
|---|---|---|---|
| AB | MS&D/MERCK | 5MG | N18200 001 |

AMILORIDE HCL

| | | | | |
|---|---|---|---|---|
| AB | PAR PHARMACEUTICAL | 5MG¤ | N70346 001 | JAN 22, 1986 |

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN-PF 7%

| | | | |
|---|---|---|---|
| | ABBOTT LABORATORIES | 7%¤ | N19398 001 SEP 06, 1985 |

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

INJECTABLE; INJECTION
/TRAVASOL/M/3.5%/W/ELECTROLYTE/45/
TRAVASOL 3.5% W/ ELECTROLYTES

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

AMINOCAPROIC ACID (PAGE 3-9)

INJECTABLE; INJECTION
AMINOCAPROIC ACID

| | | | | |
|---|---|---|---|---|
| > ADD > | AP | QUAD PHARMS | 250MG/ML¤ | N70694 001 MAR 04, 1986 |
| > ADD > | | | | |

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL
AMINOPHYLLINE

| | | | | |
|---|---|---|---|---|
| AB | CORD LABORATORIES | 100MG | N85262 002 | /N85262/002/ |
| /BD/ | /CORD LABORATORIES/ | /100MG/ | | |

AMIODARONE HYDROCHLORIDE (PAGE 3-11)

TABLET; ORAL
CORDARONE

| | | | | |
|---|---|---|---|---|
| | IVES LABS/AMHO | 200MG* | N18972 001 DEC 24, 1985 |

AMITRIPTYLINE HYROCHLORIDE; PERPHENAZINE (PAGE 3-14)

TABLET; ORAL
TRIAVIL 4-10

| | | | | |
|---|---|---|---|---|
| > DLT > | /BP/ | /MS&D/MERCK/ | /10MG;4MG/ | /N14715 001/ |
| > ADD > | BP | MS&D/MERCK | 10MG;4MG | N14715 003 |

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL
AMOXICILLIN

| | | | | |
|---|---|---|---|---|
| AB | LABORATORIOS ATRAL | 250MG* | N62528 001 AUG 07, 1985 |
| AB | | 500MG* | N62528 002 AUG 07, 1985 |

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

INJECTABLE; INJECTION
M.V.I.-12 LYOPHILIZED

| | | | |
|---|---|---|---|
| | USV PHARMACEUTICAL | 100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL 15MG/VIAL;200 IU/VIAL;0.4MG/VIAL; 40MG/VIAL;4MG/VIAL;3.6MG/VIAL; 3MG/VIAL;3,300 IU/VIAL;10 IU/VIAL* | N18933 002 AUG 08, 1985 |

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

INJECTABLE; INJECTION
M.V.C. 9+3

| | | | | |
|---|---|---|---|---|
| AP | LYPHOMED | 10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 IU/ML;1 IU/ML* | N18440 002 AUG 08, 1985 |

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

INJECTABLE; INJECTION
M.V.I.-12

| | | | | |
|---|---|---|---|---|
| AP | USV PHARMACEUTICAL | 10MG/ML;0.006MG/ML;0.5UGM/ML 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 IU/ML;1 IU/ML* | N08809 004 AUG 08, 1985 |

MVC PLUS

| | | | | |
|---|---|---|---|---|
| AP | ASCOT HOSP PHARMS | 10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 IU/ML;1 IU/ML* | 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; INJECTION
BEROCCA PN

| | | | |
|---|---|---|---|
| | HOFFMANN-LA ROCHE | 50MG/ML;0.03MG/ML;0.0025MG/ML; 7.5MG/ML;100 IU/ML;0.2MG/ML;20MG/ML; 2MG/ML;1.8MG/ML;1.5MG/ML;1,650 IU/ML; 5 IU/ML* | N06071 003 OCT 10, 1985 |

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

CAPSULE; ORAL
LANORINAL

| | | | | |
|---|---|---|---|---|
| AB | LANNETT | 325MG;50MG;40MG* | N86996 002 OCT 11, 1985 |

TABLET; ORAL
LANORINAL

| | | | | |
|---|---|---|---|---|
| AB | LANNETT | 325MG;50MG;40MG* | N86986 002 OCT 18, 1985 |

ASPIRIN; CARISOPRODOL (PAGE 3-20)

TABLET; ORAL
CARISOPRODOL COMPOUND

| | | | | |
|---|---|---|---|---|
| AB | BOLAR PHARMACEUTICAL | 325MG;200MG* | N88809 001 OCT 03, 1985 |

SOMA COMPOUND

| | | | | |
|---|---|---|---|---|
| AB | WALLACE PHARMS/C-W | 325MG;200MG | N12365 005 JUL 11, 1983 |

ASPIRIN; METHOCARBAMOL (PAGE 3-20)

TABLET; ORAL
METHOCARBAMOL AND ASPIRIN

| | | | | |
|---|---|---|---|---|
| AB | MCNEIL CONSUMER PROD | 325MG;400MG¤ | N89193 001 | FEB 12, 1986 |

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

OINTMENT; TOPICAL
CORTISPORIN

| | | | | |
|---|---|---|---|---|
| AT | BURROUGHS WELLCOME | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM | N50168 002 | MAY 04, 1985 |

NEOMYCIN & POLYMYXIN B SULFATES & BACITRACIN ZINC & HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| AT | PHARMAFAIR | 400 UNITS/GM;1%;EQ 3.5MG BASE/GM; 5,000 UNITS/GM¤ | N62381 001 | SEP 06, 1985 |

BETAMETHASONE DIPROPIONATE (PAGE 3-25)

CREAM; TOPICAL
DIPROLENE

| | | | | |
|---|---|---|---|---|
| BX | SCHERING | EQ 0.05% BASE¤ | N19408 001 | JAN 31, 1986 |

LOTION; TOPICAL
ALPHATREX

| | | | | |
|---|---|---|---|---|
| AB | SAVAGE LABS/ALTANA | EQ 0.05% BASE¤ | N70273 001 | AUG 12, 1985 |

BETAMETHASONE DIPROPIONATE

| | | | | |
|---|---|---|---|---|
| AB | E FOUGERA/ALTANA | EQ 0.05% BASE¤ | N70275 001 | AUG 12, 1985 |
| AB | PHARMADERM/ALTANA | EQ 0.05% BASE¤ | N70274 001 | AUG 12, 1985 |

BETAMETHASONE VALERATE (PAGE 3-26)

OINTMENT; TOPICAL
BETA-VAL

| | | | | |
|---|---|---|---|---|
| AB | LEMMON | EQ 0.1% BASE¤ | N70069 001 | DEC 19, 1985 |

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC
BETOPTIC

| | | | | |
|---|---|---|---|---|
| | ALCON LABORATORIES | EQ 0.5% BASE¤ | N19270 001 | AUG 30, 1985 |

BETHANECHOL CHLORIDE (PAGE 3-27)

TABLET; ORAL
BETHANECHOL CHLORIDE

| | | | | |
|---|---|---|---|---|
| AA | SIDMAK LABORATORIES | 5MG¤ | N89095 001 | DEC 19, 1985 |
| AA | | 50MG¤ | N89096 001 | DEC 19, 1985 |

BRETYLIUM TOSYLATE (PAGE 3-28)

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

| | | | | |
|---|---|---|---|---|
| > ADD > AP | INTL MEDICATION SYS | 50MG/ML¤ | N70119 001 | APR 29, 1986 : MAR 06, 1986 |
| > ADD > AP | LYPHOMED | 50MG/ML¤ | N70134 001 | APR 29, 1986 : FEB 12, 1986 |

BRETYLOL

| | | | | |
|---|---|---|---|---|
| AP | AM CRITICAL CARE/AHS | 50MG/ML | N17954 001 | |

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION
MARCAINE SPINAL

| | | | | |
|---|---|---|---|---|
| | ⊛ WINTHROP-BREON/STERL | 0.75%;8.25% | N18692 001 | MAY 04, 1984 |

BUPROPION HYDROCHLORIDE (PAGE 3-30)

TABLET; ORAL
WELLBUTRIN

| | | | | |
|---|---|---|---|---|
| > ADD > | ⊛ BURROUGHS WELLCOME | 50MG¤ | N18644 001 | DEC 30, 1985 |
| > ADD > | ⊛ | 75MG¤ | N18644 002 | DEC 30, 1985 |
| > ADD > | ⊛ | 100MG¤ | N18644 003 | DEC 30, 1985 |

BUTOCONAZOLE NITRATE (PAGE 3-31)

CREAM; VAGINAL
FEMSTAT

| | | | | |
|---|---|---|---|---|
| | SYNTEX LABS/SYNTEX | 2%¤ | N19215 001 | NOV 25, 1985 |

SUPPOSITORY; VAGINAL
FEMSTAT

| | | | | |
|---|---|---|---|---|
| | SYNTEX LABS/SYNTEX | 100MG¤ | N19359 001 | NOV 25, 1985 |

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/100ML¤ 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/100ML¤ 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/100ML¤ 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/100ML¤ 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/100ML¤ N17512 010 NOV 16, 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/100ML¤ N17512 011 NOV 18, 1985

>ADD> CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE
>ADD> (PAGE 3-34)

>ADD> SOLUTION; INTRAPERITONEAL
>ADD> INPERSOL-ZM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
>ADD> ABBOTT LABORATORIES 25.7MG/100ML;1.5GM/100ML; 538MG/100ML;448MG/100ML¤ N19395 001 MAR 26, 1986
>ADD> INPERSOL-ZM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
>ADD> ABBOTT LABORATORIES 25.7MG/100ML;2.5GM/100ML; 538MG/100ML;448MG/100ML¤ N19395 002 MAR 26, 1986
>ADD> INPERSOL-ZM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
>ADD> ABBOTT LABORATORIES 25.7MG/100ML;4.25GM/100ML; 538MG/100ML;448MG/100ML¤ N19395 003 MAR 26, 1986

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

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

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

CARNITINE, L- (PAGE 3-37)

TABLET; ORAL
L-CARNITINE
SIGMA-TAU 330MG¤ N18948 001 DEC 27, 1985

CEFAMANDOLE NAFATE (PAGE 3-37)

INJECTABLE; INJECTION
MANDOL
ELI LILLY EQ 1GM BASE/VIAL¤ N62560 001 SEP 10, 1985
EQ 2GM BASE/VIAL¤ N62560 002 SEP 10, 1985

CEFAZOLIN SODIUM (PAGE 3-38)

INJECTABLE; INJECTION
KEFZOL
AP ELI LILLY EQ 500MG BASE/VIAL¤ N62557 001 SEP 10, 1985
AP EQ 1GM BASE/VIAL¤ N62557 002 SEP 10, 1985

CEFOTETAN DISODIUM (PAGE 3-38)

INJECTABLE; INJECTION
CEFOTAN
STUART PHARMS/ICI EQ 1GM BASE/VIAL¤ N50588 001 DEC 27, 1985
EQ 2GM BASE/VIAL¤ N50588 002 DEC 27, 1985

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | FORTAZ | | |
| | AP | GLAXO | 500MG/VIAL | N50578 001 JUL 19, 1985 |
| | AP | | 1GM/VIAL | N50578 002 JUL 19, 1985 |
| | AP | | 2GM/VIAL | N50578 003 JUL 19, 1985 |
| > ADD > | AP | | 6GM/VIAL | N50578 004 JUL 19, 1985 |
| > ADD > | | TAZICEF | | |
| > ADD > | AP | SK&F LABORATORIES | 500MG/VIAL* | N62662 001 MAR 06, 1986 |
| > ADD > | AP | | 1GM/VIAL* | N62662 002 MAR 06, 1986 |
| > ADD > | AP | | 2GM/VIAL* | N62662 003 MAR 06, 1986 |
| > ADD > | AP | | 6GM/VIAL* | N62662 004 MAR 06, 1986 |
| | | TAZIDIME | | |
| | AP | ELI LILLY | 500MG/VIAL* | N62640 001 NOV 20, 1985 |
| | AP | | 1GM/VIAL* | N62640 002 NOV 20, 1985 |
| | AP | | 1GM/VIAL* | N62655 001 NOV 20, 1985 |
| | AP | | 2GM/VIAL* | N62655 002 NOV 20, 1985 |
| | AP | | 2GM/VIAL* | N62640 003 NOV 20, 1985 |

CEFUROXIME SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | ZINACEF | | |
| | AP | GLAXO | EQ 750MG BASE/VIAL | N50558 002 OCT 19, 1983 |
| | AP | | EQ 1.5 GM BASE/VIAL | N50558 003 OCT 19, 1986 |
| | | KEFUROX | | |
| | AP | ELI LILLY | EQ 750MG BASE/VIAL* | N62591 001 JAN 10, 1986 |
| | AP | | EQ 750MG BASE/VIAL* | N62592 001 JAN 10, 1986 |
| | AP | | EQ 1.5GM BASE/VIAL* | N62591 002 JAN 10, 1986 |
| | AP | | EQ 1.5GM BASE/VIAL* | N62592 002 JAN 10, 1986 |
| | | KEFUROX IN PLASTIC CONTAINER | | |
| | AP | ELI LILLY | EQ 750MG BASE/VIAL* | N62590 001 JAN 10, 1986 |
| | AP | | EQ 1.5GM BASE/VIAL* | N62590 002 JAN 10, 1986 |

CEPHALOTHIN SODIUM (PAGE 3-40)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | CEPHALOTHIN SODIUM | | |
| | AP | ABBOTT LABORATORIES | EQ 1GM BASE/VIAL* | N62547 001 SEP 11, 1985 |
| | AP | | EQ 1GM BASE/VIAL* | N62548 001 SEP 11, 1985 |
| | AP | | EQ 2GM BASE/VIAL* | N62547 002 SEP 11, 1985 |
| | AP | | EQ 2GM BASE/VIAL* | N62548 002 SEP 11, 1985 |
| | | KEFLIN IN PLASTIC CONTAINER | | |
| | AP | ELI LILLY | EQ 1GM BASE/VIAL* | N62549 001 SEP 10, 1985 |
| | AP | | EQ 2GM BASE/VIAL* | N62549 002 SEP 10, 1985 |

CHLORAMPHENICOL (PAGE 3-42)

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | | CHLORAMPHENICOL | | |
| | AT | CARTER-GLOGAU LABS | 0.5%* | N62628 001 SEP 25, 1985 |

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-46)

CAPSULE, CONTROLLED RELEASE ORAL

| | | | | |
|---|---|---|---|---|
| | | DRIZE | | |
| | BC | BF ASCHER | 12MG;75MG* | N88359 001 FEB 13, 1986 |
| | | ORNADE | | |
| | BC | SK&F LABORATORIES | 12MG;75MG | N12152 004 |

CHLORPROPAMIDE (PAGE 3-48)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | CHLORPROPAMIDE | | |
| | AB | HALSEY DRUG | 100MG* | N89321 001 JAN 16, 1986 |
| | AB | | 250MG* | N88662 001 JAN 09, 1986 |

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | CHLORTHALIDONE | | |
| | AB | SIDMAK LABORATORIES | 25MG* | N88902 001 SEP 19, 1985 |
| | AB | | 50MG* | N88903 001 SEP 19, 1985 |

CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

INJECTABLE; INJECTION
PRIMAXIN
MS&D RES LABS/MERCK — EQ 250MG BASE/VIAL; 250MG/VIAL¤ — N50587 001 NOV 26, 1985
EQ 500MG BASE/VIAL; 500MG/VIAL¤ — N50587 002 NOV 26, 1985

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

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

CLONAZEPAM (PAGE 3-52)

TABLET; ORAL
> DLT > /CLONOPIN/
> ADD > KLONOPIN
HOFFMANN-LA ROCHE — 0.5MG — N17533 001
1MG — N17533 002
2MG — N17533 003

CLONIDINE HYDROCHLORIDE (PAGE 3-52)

TABLET; ORAL
CATAPRES
AB BOEHRINGER INGELHEIM — 0.1MG — N17407 001
AB — 0.2MG — N17407 002
AB — 0.3MG — N17407 003
CLONIDINE HCL
> ADD > AB BIOCRAFT LABS — 0.1MG¤ — N70747 001
> ADD > JUL 08, 1986 : MAR 20, 1986
> ADD > AB 0.2MG¤ N70702 001
> ADD > JUL 08, 1986 : MAR 20, 1986
> ADD > AB 0.3MG¤ N70659 001
> ADD > JUL 08, 1986 : MAR 20, 1986

CLONIDINE HYDROCHLORIDE (PAGE 3-52)

TABLET; ORAL
CLONIDINE HCL
AB PAR PHARMACEUTICAL — 0.1MG¤ — N70461 001 JUL 08, 1986 : NOV 22, 1985
AB — 0.2MG¤ — N70460 001 JUL 08, 1986 : NOV 22, 1985
AB — 0.3MG¤ — N70459 001 JUL 08, 1986 : NOV 22, 1985

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

SYRUP; ORAL
PROMETHAZINE VC W/ CODEINE
AA HR CENCI LABS — 10MG/5ML;5MG/5ML; 6.25MG/5ML¤ — N88816 001 NOV 22, 1985

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-53)

SYRUP; ORAL
PROMETHAZINE W/ CODEINE
AA HR CENCI LABS — 10MG/5ML;6.25MG/5ML¤ — N88814 001 NOV 22, 1985

COPPER (PAGE 3-54)

INTRAUTERINE DEVICE; INTRAUTERINE
CU-7
> ADD > ⓐ SEARLE PHARMS — 89MG — N17408 001
TATUM-T
> ADD > ⓐ SEARLE PHARMS — 120MG — N18205 001

CROMOLYN SODIUM (PAGE 3-55)

AEROSOL; INHALATION
INTAL
FISONS — 0.8MG/INH¤ — N18887 001 DEC 05, 1985

DEXCHLORPHENIRAMINE MALEATE (PAGE 3-63)

TABLET; ORAL
DEXCHLORPHENIRAMINE MALEATE
AB SIDMAK LABORATORIES — 2MG¤ — N88682 001 JAN 17, 1986
FOLARAMINE
AB SCHERING — 2MG — N86835 001

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION
DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML¤ | N19479 001<br>SEP 17, 1985 |
| AP | TRAVENOL LABS | 50MG/ML¤ | N16673 003<br>OCT 30, 1985 |

DEXTROSE; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

INJECTABLE; INJECTION
LIDOCAINE HCL 0.2% IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML;200MG/100ML¤ | N18954 001<br>JUL 09, 1985 |

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;<br>300MG/100ML¤ | N18876 001<br>JAN 17, 1986 |

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

| | | | |
|---|---|---|---|
| | ABBOTT LABORATORIES | 5GM/100ML;149MG/100ML;<br>300MG/100ML¤ | N18876 002<br>JAN 17, 1986 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% W/ POTASSIUM CHLORIDE 0.224% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | ABBOTT LABORATORIES | 5GM/100ML;224MG/100ML;<br>300MG/100ML¤ | N18876 003<br>JAN 17, 1986 |

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW LABS | 5GM/100ML;75MG/100ML;<br>330MG/100ML¤ | N18268 011<br>JAN 18, 1986 |

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW LABS | 5GM/100ML;150MG/100ML;<br>330MG/100ML¤ | N18268 012<br>JAN 18, 1986 |

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

| | | | |
|---|---|---|---|
| | KENDALL MCGAW LABS | 5GM/100ML;220MG/100ML;<br>330MG/100ML¤ | N18268 013<br>JAN 18, 1986 |

DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 0.30% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | KENDALL MCGAW LABS | 5GM/100ML;300MG/100ML;<br>330MG/100ML¤ | N18268 014<br>JAN 18, 1986 |

DEXTROSE; SODIUM CHLORIDE (PAGE 3-70)

INJECTABLE; INJECTION
DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML;225MG/100ML | N17606 001 |
| AP | | 5GM/100ML;225MG/100ML¤ | N19482 001<br>OCT 04, 1985 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML;300MG/100ML¤ | N19486 001<br>OCT 04, 1985 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML;450MG/100ML¤ | N19484 001<br>OCT 04, 1985 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML;900MG/100ML¤ | N19483 001<br>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<br>NOV 13, 1985 |

DIAZEPAM (PAGE 3-72)

INJECTABLE; INJECTION
DIAZEPAM

| | | | |
|---|---|---|---|
| AP | CARTER-GLOGAU LABS | 5MG/ML¤ | N70296 001<br>FEB 12, 1986 |
| AP | ELKINS-SINN/AHROBINS | 5MG/ML¤ | N70311 001<br>DEC 16, 1985 |
| AP | | 5MG/ML¤ | N70312 001<br>DEC 16, 1985 |
| AP | | 5MG/ML¤ | N70313 001<br>DEC 16, 1985 |

VALIUM

| | | | |
|---|---|---|---|
| AP | HOFFMANN-LA ROCHE | 5MG/ML | N16087 001 |

TABLET; ORAL
DIAZEPAM

| | | | |
|---|---|---|---|
| AB | BARR LABORATORIES | 2MG¤ | N70152 001<br>NOV 01, 1985 |
| AB | | 5MG¤ | N70153 001<br>NOV 01, 1985 |
| AB | | 10MG¤ | N70154 001<br>NOV 01, 1985 |
| AB | CHELSEA LABORATORIES | 2MG¤ | N70456 001<br>NOV 01, 1985 |
| AB | | 5MG¤ | N70457 001<br>NOV 01, 1985 |
| AB | | 10MG¤ | N70458 001<br>NOV 01, 1985 |

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
DIAZEPAM

| | | | | |
|---|---|---|---|---|
| AB | CORD LABORATORIES | 2MG¤ | N70302 001 | DEC 20, 1985 |
| AB | | 5MG¤ | N70303 001 | DEC 20, 1985 |
| AB | | 10MG¤ | N70304 001 | DEC 20, 1985 |
| AB | LEDERLE LABS/AM CYAN | 2MG¤ | N70226 001 | SEP 26, 1985 |
| AB | | 5MG¤ | N70227 001 | SEP 26, 1985 |
| AB | | 10MG¤ | N70228 001 | SEP 26, 1985 |
| AB | MYLAN PHARMS | 2MG¤ | N70323 001 | SEP 04, 1985 |
| AB | | 5MG¤ | N70324 001 | SEP 04, 1985 |
| AB | | 10MG¤ | N70325 001 | SEP 04, 1985 |
| AB | PAR PHARMACEUTICAL | 2MG¤ | N70462 001 | FEB 25, 1986 |
| AB | | 5MG¤ | N70463 001 | FEB 25, 1986 |
| AB | | 10MG¤ | N70464 001 | FEB 25, 1986 |
| AB | PARKE-DAVIS/W-L | 2MG¤ | N70209 001 | SEP 04, 1985 |
| AB | | 5MG¤ | N70210 001 | SEP 04, 1985 |
| AB | | 10MG¤ | N70222 001 | SEP 04, 1985 |
| > ADD > AB | PUREPAC/KALIPHARMA | 2MG¤ | N70781 001 | MAR 19, 1986 |
| > ADD > AB | | 5MG¤ | N70706 001 | MAR 19, 1986 |
| > ADD > AB | | 10MG¤ | N70707 001 | MAR 19, 1986 |
| AB | SUPERPHARM | 2MG¤ | N70642 001 | DEC 11, 1985 |
| AB | | 5MG¤ | N70643 001 | DEC 11, 1985 |
| AB | | 10MG¤ | N70644 001 | DEC 11, 1985 |
| AB | ZENITH LABORATORIES | 2MG¤ | N70360 001 | SEP 04, 1985 |
| AB | | 5MG¤ | N70361 001 | SEP 04, 1985 |
| AB | | 10MG¤ | N70362 001 | SEP 04, 1985 |

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
Q-PAM

| | | | | |
|---|---|---|---|---|
| AB | QUANTUM PHARMICS | 2MG¤ | N70423 001 | DEC 12, 1985 |
| AB | | 5MG¤ | N70424 001 | DEC 12, 1985 |
| AB | | 10MG¤ | N70425 001 | DEC 12, 1985 |

VALIUM

| | | | | |
|---|---|---|---|---|
| AB | HOFFMANN-LA ROCHE | 2MG | N13263 002 | |
| AB | | 5MG | N13263 004 | |
| AB | | 10MG | N13263 006 | |

DICYCLOMINE HYDROCHLORIDE (PAGE 3-73)

TABLET; ORAL
BENTYL

| | | | | |
|---|---|---|---|---|
| AB | MERRELL DOW/DOW CHEM | 20MG | N07409 001 | OCT 15, 1984 |

DICYCLOMINE HCL

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 20MG | N84600 001 | JUL 29, 1985 |

DIFLORASONE DIACETATE (PAGE 3-74)

CREAM; TOPICAL
DIFLORASONE DIACETATE

| | | | | |
|---|---|---|---|---|
| BX | UPJOHN | 0.05%¤ | N19259 001 | AUG 28, 1985 |

FLORONE

| | | | | |
|---|---|---|---|---|
| BX | UPJOHN | 0.05% | N17741 001 | |

OINTMENT; TOPICAL
DIFLORASONE DIACETATE

| | | | | |
|---|---|---|---|---|
| BX | UPJOHN | 0.05%¤ | N19260 001 | AUG 28, 1985 |

FLORONE

| | | | | |
|---|---|---|---|---|
| BX | UPJOHN | 0.05% | N17994 001 | |

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-76)

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

| | | | | |
|---|---|---|---|---|
| AA | PIONEER PHARMS | 25MG¤ | N89101 001 | DEC 20, 1985 |
| AA | | 50MG¤ | N88880 001 | DEC 20, 1985 |

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

| | | | |
|---|---|---|---|
| AB | BARR LABORATORIES | EQ 100MG BASE* | N70351 001 DEC 17, 1985 |
| AB | | EQ 150MG BASE* | N70352 001 DEC 17, 1985 |
| AB | BOLAR PHARMACEUTICAL | EQ 100MG BASE* | N70240 001 FEB 02, 1986 |
| AB | | EQ 150MG BASE* | N70241 001 FEB 02, 1986 |
| AB | CORD LABORATORIES | EQ 100MG BASE* | N70470 001 DEC 10, 1985 |
| AB | | EQ 150MG BASE* | N70471 001 DEC 10, 1985 |
| AB | ZENITH LABORATORIES | EQ 100MG BASE* | N70186 001 NOV 18, 1985 |
| AB | | EQ 150MG BASE* | N70187 001 NOV 18, 1985 |

DOPAMINE HYDROCHLORIDE (PAGE 3-78)

INJECTABLE; INJECTION

DOPAMINE HCL

| | | | |
|---|---|---|---|
| AP | ASTRA PHARM PRODS | 40MG/ML* | N70087 001 OCT 23, 1985 |
| AP | | 80MG/ML* | N70089 001 OCT 23, 1985 |
| AP | | 80MG/ML* | N70090 001 OCT 23, 1985 |
| AP | | 80MG/ML* | N70091 001 OCT 23, 1985 |
| AP | | 160MG/ML* | N70092 001 OCT 23, 1985 |
| AP | | 160MG/ML* | N70093 001 OCT 23, 1985 |
| AP | | 160MG/ML* | N70094 001 OCT 23, 1985 |
| AP | LYPHOMED | 160MG/ML* | N70364 001 DEC 04, 1985 |
| AP | SOLOPAK LABORATORIES | 40MG/ML* | N70011 001 AUG 29, 1985 |
| AP | | 40MG/ML* | N70046 001 AUG 29, 1985 |
| AP | | 80MG/ML* | N70047 001 AUG 29, 1985 |

DOPASTAT

| | | | |
|---|---|---|---|
| AP | PARKE-DAVIS/W-L | 40MG/ML* | N70358 001 SEP 20, 1985 |
| AP | | 80MG/ML* | N70559 001 SEP 20, 1985 |

INTROPIN

| | | | |
|---|---|---|---|
| AP | AM CRITICAL CARE/AHS | 160MG/ML | N17395 003 |

DOXYCYCLINE HYCLATE (PAGE 3-79)

CAPSULE, COATED PELLETS; ORAL

DORYX

| | | | |
|---|---|---|---|
| AB | FAULDING | EQ 100MG BASE | N50582 001 JUL 22, 1985 |
| AB | PARKE-DAVIS/W-L | EQ 100MG BASE* | N62653 001 OCT 30, 1985 |

CAPSULE; ORAL

/DORYX/

| | | | |
|---|---|---|---|
| /AB/ | /FAULDING/ | /EQ 100MG BASE/ | /N50582 001/ /JUL 22, 1985/ |
| /AB/ | /PARKE-DAVIS/W-L/ | /EQ 100MG BASE*/ | /N62653 001/ /OCT 30, 1985/ |
| >ADD > | AB PARKE-DAVIS/W-L | EQ 50MG BASE* | N62594 001 DEC 05, 1985 |
| >ADD > | AB | EQ 100MG BASE* | N62594 002 DEC 05, 1985 |
| >ADD > | | | |

INJECTABLE; INJECTION

DOXYCYCLINE HYCLATE

| | | | |
|---|---|---|---|
| AP | QUAD PHARMS | EQ 100MG BASE/VIAL* | N62643 001 FEB 13, 1986 |
| AP | | EQ 200MG BASE/VIAL* | N62643 002 FEB 13, 1986 |

TABLET; ORAL

DOXYCYCLINE HYCLATE

| | | | |
|---|---|---|---|
| AB | PARKE-DAVIS/W-L | EQ 100MG BASE* | N62593 001 AUG 28, 1985 |
| >DLT >/AB/ | | /EQ 50MG BASE*/ | /N62594 001/ /DEC 05, 1985/ |
| >DLT >/AB/ | | /EQ 100MG BASE*/ | /N62594 002/ /DEC 05, 1985/ |
| >DLT > | | | |

DOXYLAMINE SUCCINATE (PAGE 3-80)

TABLET; ORAL

DOXYLAMINE SUCCINATE

| | | | |
|---|---|---|---|
| AA | COPLEY PHARM | 25MG* | N88900 001 OCT 08, 1985 |

EDROPHONIUM CHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION

ENLON

| | | | |
|---|---|---|---|
| AP | ANAQUEST/BOC | 10MG/ML* | N88873 001 AUG 06, 1985 |

TENSILON

| | | | |
|---|---|---|---|
| AP | HOFFMANN-LA ROCHE | 10MG/ML | N07959 001 |

ENALAPRIL MALEATE (PAGE 3-81)

TABLET; ORAL
VASOTEC
MS&D RES LABS/MERCK 5MG* N18998 001
DEC 24, 1985
10MG* N18998 002
DEC 24, 1985
20MG* N18998 003
DEC 24, 1985

EPINEPHRINE (PAGE 3-81)

INJECTABLE; INJECTION
SUS-PHRINE
> DLT > /BERLEX/SCHERING/ /5MG/ML/ /N07942.001/
> ADD > FOREST LABORATORIES 5MG/ML N07942 001

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-81)

INJECTABLE; INJECTION
LIDOCAINE HCL AND EPINEPHRINE
AP ABBOTT LABORATORIES 0.005MG/ML;1.5%* N38571 001
SEP 13, 1985
XYLOCAINE W/ EPINEPHRINE
AP ASTRA PHARM PRODS 0.005MG/ML;1.5% N10418 010

ERGOLOID MESYLATES (PAGE 3-82)

TABLET; ORAL
ERGOLOID MESYLATES
AB BARR LABORATORIES 1MG* N88391 001
NOV 01, 1985

ERYTHROMYCIN (PAGE 3-83)

CAPSULE, ENTERIC-COATED PELLETS; ORAL
ERYC
PARKE-DAVIS/W-L 250MG* N62618 001
SEP 25, 1985
ERYC 125
PARKE-DAVIS/W-L 125MG* N62648 001
OCT 24, 1985

ESTRADIOL CYPIONATE; TESTOSTERONE CYPIONATE (PAGE 3-86)

INJECTABLE; INJECTION
DEPO-TESTADIOL
> ADD > AO UPJOHN 2MG/ML;50MG/ML N17968 001
> ADD >
TESTOSTERONE CYPIONATE-ESTRADIOL CYPIONATE
> ADD > AO CARTER-GLOGAU LABS 2MG/ML;50MG/ML* N85603 001
> ADD > MAR 13, 1986

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

TABLET; ORAL-21
ORTHO-NOVUM 7/14-21
@ ORTHO PHARMACEUTICAL 0.035MG;0.5MG AND 1MG N19004 001
APR 04, 1984

TABLET; ORAL-28
ORTHO-NOVUM 7/14-28
@ ORTHO PHARMACEUTICAL 0.35MG;0.5MG AND 1MG N19004 002
APR 04, 1984

ETHOXZOLAMIDE (PAGE 3-90)

TABLET; ORAL
ETHAMIDE
@ ALLERGAN PHARMS 125MG N16144 001

FLECAINIDE ACETATE (PAGE 3-92)

TABLET; ORAL
TAMBOCOR
RIKER LABS/3M 100MG* N18830 001
OCT 31, 1985
200MG* N18830 002
OCT 31, 1985

FLUOCINOLONE ACETONIDE (PAGE 3-92)

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

FLUOROMETHOLONE (PAGE 3-93)

OINTMENT; OPHTHALMIC
FML
ALLERGAN PHARMS 0.1%* N17760 001
SEP 04, 1985

SUSPENSION/DROPS; OPHTHALMIC
FLUOR-CP
AB COOPERVISION PHARMS 0.1%* N70185 001
FEB 27, 1986
FML
AB ALLERGAN PHARMS 0.1% N16851 002
JUL 28, 1982

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

| | | | | |
|---|---|---|---|---|
| > ADD > AP | INTL PHARM PROD | 50MG/ML¤ | N88929 001 | MAR 04, 1986 |
| > ADD > AP | LYPHOMED | 50MG/ML¤ | N89152 001 | MAR 21, 1986 |

FLUPHENAZINE DECANOATE (PAGE 3-94)

INJECTABLE; INJECTION
FLUPHENAZINE

| | | | | |
|---|---|---|---|---|
| AO | QUAD PHARMS | 25MG/ML¤ | N70762 001 | FEB 20, 1986 |

PROLIXIN DECANOATE

| | | | | |
|---|---|---|---|---|
| AO | ER SQUIBB AND SONS | 25MG/ML | N16727 001 | |

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-94)

CONCENTRATE; ORAL
PERMITIL

| | | | | |
|---|---|---|---|---|
| AA | SCHERING | 5MG/ML | N16008 001 | |

PROLIXIN

| | | | | |
|---|---|---|---|---|
| AA | ER SQUIBB AND SONS | 5MG/ML¤ | N70533 001 | NOV 07, 1985 |

FLURAZEPAM HYDROCHLORIDE (PAGE 3-95)

CAPSULE; ORAL
DALMANE

| | | | | |
|---|---|---|---|---|
| AB | ROCHE PRODUCTS | 15MG | N16721 001 | |
| AB | | 30MG | N16721 002 | |

FLURAZEPAM HCL

| | | | | |
|---|---|---|---|---|
| AB | MYLAN PHARMS | 15MG¤ | N70344 001 | NOV 27, 1985 |
| AB | | 30MG¤ | N70345 001 | NOV 27, 1985 |
| > ADD > AB | PAR PHARMACEUTICAL | 15MG¤ | N70444 001 | MAR 20, 1986 |
| > ADD > AB | | 30MG¤ | N70445 001 | MAR 20, 1986 |

/FOLATE SODIUM/(PAGE 3-95)

/INJECTABLE; INJECTION/
/FOLVITE/

| | | | | |
|---|---|---|---|---|
| | /LEDERLE LABS/AM CYAN/5MG BASE/ML/ | | /N05897 008/ | |

FOLIC ACID (PAGE 3-95)

INJECTABLE; INJECTION
FOLIC ACID

| | | | | |
|---|---|---|---|---|
| AP | LYPHOMED | 5MG/ML¤ | N89202 001 | FEB 18, 1986 |

FOLVITE

| | | | | |
|---|---|---|---|---|
| AP | LEDERLE LABS/AM CYAN | 5MG/ML | N05897 008 | |

TABLET; ORAL
FOLIC ACID

| | | | | |
|---|---|---|---|---|
| AA | BARR LABORATORIES | 1MG¤ | N89177 001 | JAN 08, 1986 |
| AA | PIONEER PHARMS | 1MG¤ | N88949 001 | SEP 13, 1985 |

FUROSEMIDE (PAGE 3-96)

INJECTABLE; INJECTION
FUROSEMIDE

| | | | | |
|---|---|---|---|---|
| AP | ASTRA PHARM PRODS | 10MG/ML¤ | N70014 001 | SEP 09, 1985 |
| AP | | 10MG/ML¤ | N70095 001 | SEP 09, 1985 |
| AP | | 10MG/ML¤ | N70096 001 | SEP 09, 1985 |
| AP | SOLOPAK LABORATORIES | 10MG/ML¤ | N70023 001 | FEB 05, 1986 |
| AP | | 10MG/ML¤ | N70078 001 | FEB 05, 1986 |

TABLET; ORAL
FUROSEMIDE

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 20MG¤ | N70043 001 | SEP 26, 1985 |
| AB | DANBURY PHARMACAL | 20MG¤ | N70412 001 | FEB 26, 1986 |
| AB | | 40MG¤ | N70413 001 | FEB 26, 1986 |
| AB | ROXANE LABORATORIES | 80MG¤ | N70086 001 | JAN 24, 1986 |
| AB | WATSON LABORATORIES | 20MG¤ | N70449 001 | NOV 22, 1985 |
| AB | | 40MG¤ | N70450 001 | NOV 22, 1985 |
| AB | | 80MG¤ | N70528 001 | JAN 07, 1986 |

GENTAMICIN SULFATE (PAGE 3-97)

INJECTABLE; INJECTION

GENTAFAIR

| | | | |
|---|---|---|---|
| AP | PHARMAFAIR | EQ 40MG BASE/ML¤ | N62493 001<br>AUG 28, 1985 |

GENTAMICIN SULFATE

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | EQ 10MG BASE/ML¤ | N62612 004<br>FEB 20, 1986 |

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

| | | | |
|---|---|---|---|
| AT | CARTER-GLOGAU LABS | EQ 3MG BASE/ML¤ | N62523 001<br>NOV 25, 1985 |

GENTAMICIN SULFATE; SODIUM CHLORIDE (PAGE 3-98)

INJECTABLE; INJECTION

GENTAMICIN SULFATE IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | EQ 60MG BASE/100ML<br>900MG/100ML¤ | N62588 006<br>JAN 06, 1986 |
| AP | | EQ 70MG BASE/100ML<br>900MG/100ML¤ | N62588 007<br>JAN 06, 1986 |
| AP | | EQ 80MG BASE/100ML<br>900MG/100ML¤ | N62588 008<br>JAN 06, 1986 |
| AP | | EQ 90MG BASE/100ML<br>900MG/100ML¤ | N62588 009<br>JAN 06, 1986 |
| AP | | EQ 100MG BASE/100ML<br>900MG/100ML¤ | N62588 010<br>JAN 06, 1986 |
| AP | | EQ 1.2MG BASE/ML;9MG/ML¤ | N62588 001<br>JAN 06, 1986 |
| AP | | EQ 1.4MG BASE/ML;9MG/ML¤ | N62588 002<br>JAN 06, 1986 |
| AP | | EQ 1.6MG BASE/ML;9MG/ML¤ | N62588 003<br>JAN 06, 1986 |
| AP | | EQ 1.8MG BASE/ML;9MG/ML¤ | N62588 004<br>JAN 06, 1986 |
| AP | | EQ 2MG BASE/ML;9MG/ML¤ | N62588 005<br>JAN 06, 1986 |

GLYCINE (PAGE 3-100)

SOLUTION; IRRIGATION

AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| /AT/ | /TRAVENOL LABS/ | /1.5GM/100ML/ | /N18522 001/ |

GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL

WYTENSIN

| | | | |
|---|---|---|---|
| | WYETH LABS/AMHO | EQ 16MG BASE¤ | N18587 003<br>SEP 07, 1982 |

HALOPERIDOL DECANOATE (PAGE 3-102)

INJECTABLE; INJECTION

HALDOL DECANOATE

| | | | |
|---|---|---|---|
| | MCNEIL PHARM | EQ 50MG BASE/ML¤ | N18701 001<br>JAN 14, 1986 |

HALOPERIDOL LACTATE (PAGE 3-102)

CONCENTRATE; ORAL

HALDOL

| | | | |
|---|---|---|---|
| > ADD > AA | MCNEIL LABORATORIES | EQ 2MG BASE/ML | N15922 001 |

HALOPERIDOL

| | | | |
|---|---|---|---|
| > ADD > AA | BAY LABORATORIES | EQ 2MG BASE/ML¤ | N70710 001<br>APR 15, 1986 : MAR 07, 1986 |

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

/HEP-LOCK/PF/

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

HEP-LOCK U/P

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

HEPARIN LOCK FLUSH

| | | | |
|---|---|---|---|
| AP | CARTER-GLOGAU LABS | 100 UNITS/ML | N17064 001 |
| AP | LUITPOLD PHARMS | 10 UNITS/ML¤ | N89063 001<br>OCT 09, 1985 |
| AP | | 100 UNITS/ML¤ | N89064 001<br>OCT 09, 1985 |

HEPARIN SODIUM

| | | | |
|---|---|---|---|
| /AP/ | CARTER-GLOGAU LABS | /100 UNIT/ML/ | /N17064 001/ |
| AP | | 2,500 UNITS/ML | N17064 015 |
| AP | | 7,500 UNITS/ML | N17064 019 |
| | | 3,000 UNITS/ML | N17064 016 |
| | | 4,000 UNITS/ML | N17064 017 |
| | | 6,000 UNTIS/ML | N17064 018 |

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION
SODIUM HEPARIN

| | | | | |
|---|---|---|---|---|
| /AP/ | /CARTER-GLOBAL LABS/ | /2,500 UNITS/ML/ | /N17064 015/ | |
| /AP/ | | /2,500 UNITS/ML/ | /N17064 019/ | |
| | | /3,000 UNITS/ML/ | /N17064 016/ | |
| | | /4,000 UNITS/ML/ | /N17064 017/ | |
| | | /6,000 UNITS/ML/ | /N17064 018/ | |

SPONGE; TOPICAL
/E-Z SCRUB SURGICAL/

| | | | | |
|---|---|---|---|---|
| | /PARKE-DAVIS/W-L/ | /450MG/ | /N17452 001/ | > ADD > |
| | E-Z SCRUB | | | > ADD > |
| | DESERET/P-D | 450MG | N17452 001 | > ADD > |

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION
HYDRALAZINE HCL

| | | | |
|---|---|---|---|
| AP | SOLOPAK LABORATORIES | 20MG/ML¤ | N88517 001 AUG 22, 1985 |

TABLET; ORAL
HYDRALAZINE HCL

| | | | |
|---|---|---|---|
| AA | HALSEY DRUG | 10MG¤ | N89218 001 JAN 22, 1986 |
| AA | | 25MG¤ | N89130 001 JAN 15, 1986 |
| AA | | 50MG¤ | N89222 001 JAN 22, 1986 |
| AA | | 100MG¤ | N89178 001 JAN 15, 1986 |
| AA | SIDMAK LABORATORIES | 10MG¤ | N89097 001 DEC 18, 1985 |
| AA | | 100MG¤ | N89098 001 DEC 18, 1985 |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE (PAGE 3-108)

CAPSULE; ORAL
HYDRA-ZIDE

| | | | |
|---|---|---|---|
| AB | PAR PHARMACEUTICAL | 25MG;25MG¤ | N88957 001 OCT 21, 1985 |
| AB | | 50MG;50MG¤ | N88946 001 OCT 21, 1985 |
| AB | | 100MG;50MG¤ | N88961 001 OCT 21, 1985 |

HYDROCHLOROTHIAZIDE; METHYLDOPA (PAGE 3-110)

TABLET; ORAL
ALDORIL D30

| | | | |
|---|---|---|---|
| AB | MS&D/MERCK | 30MG;500MG | N13402 003 |

ALDORIL D50

| | | | |
|---|---|---|---|
| AB | MS&D/MERCK | 50MG;500MG | N13402 004 |

ALDORIL 15

| | | | |
|---|---|---|---|
| AB | MS&D/MERCK | 15MG;250MG | N13402 001 |

ALDORIL 25

| | | | |
|---|---|---|---|
| AB | MS&D/MERCK | 25MG;250MG | N13402 002 |

METHYLDOPA AND HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| AB | BOLAR PHARMACEUTICAL | 15MG;250MG¤ | N70365 001 MAR 19, 1986 |
| AB | | 30MG;500MG¤ | N70367 001 MAR 19, 1986 |
| AB | CORD LABORATORIES | 15MG;250MG¤ | N70182 001 JAN 15, 1986 |
| AB | | 25MG;250MG¤ | N70183 001 JAN 15, 1986 |
| AB | | 30MG;500MG¤ | N70543 001 JAN 15, 1986 |
| AB | | 50MG;500MG¤ | N70544 001 JAN 15, 1986 |
| AB | MYLAN PHARMS | 15MG;250MG¤ | N70264 001 JAN 23, 1986 |
| AB | | 25MG;250MG¤ | N70265 001 JAN 23, 1986 |

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

| | | | |
|---|---|---|---|
| AB | PUREPAC/KALIPHARMA | 25MG;25MG¤ | N87999 001 NOV 06, 1985 |
| AB | SUPERPHARM | 25MG;25MG¤ | N89137 001 AUG 26, 1985 |

/HYDROCODONE; PHENYLTOLOXAMINE (PAGE 3-112)/

/SUSPENSION; ORAL/

| | | | |
|---|---|---|---|
| | /TUSSIONEX/ | | |
| | /PENNWALT PHARM/ | /EQ 5MG BASE/5ML;/ /EQ 10MG BASE/5ML/ | /N16768 006/ |

HYDROCORTISONE (PAGE 3-112)

CREAM; TOPICAL
HYDROCORTISONE

| | | | |
|---|---|---|---|
| AT | PHARMADERM/ALTANA | 1%¤ | N88845 001 FEB 27, 1986 |

LOTION; TOPICAL
HYDROCORTISONE

| | | | |
|---|---|---|---|
| AT | THAMES PHARMACAL | 1%¤ | N89024 001 FEB 12, 1986 |

HYDROCORTISONE (PAGE 3-112)

LOTION; TOPICAL
**STIE-CORT**

| | | | | |
|---|---|---|---|---|
| AT | STIEFEL LABORATORIES | 1%¤ | N89066 001 | NOV 25, 1985 |
| AT | | 2.5%¤ | N89074 001 | NOV 26, 1985 |

OINTMENT; TOPICAL
**HYDROCORTISONE IN ABSORBASE**

| | | | | |
|---|---|---|---|---|
| AT | CAROLINA MED PRODS | 1%¤ | N88138 001 | SEP 06, 1985 |

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

SUSPENSION; OTIC
**NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE**

| | | | | |
|---|---|---|---|---|
| AT | CARTER-GLOGAU LABS | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML¤ | N62488 001 | NOV 06, 1985 |

**NEOMYCIN SULFATE, POLYMYXIN B SULFATE & HYDROCORTISONE**

| | | | | |
|---|---|---|---|---|
| AT | 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 | |

**NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE**

| | | | | |
|---|---|---|---|---|
| AT | 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 | OWEN LABS/DERM PRODS | 0.1% | N18795 001 | JAN 07, 1983 |

HYDROCORTISONE BUTYRATE (PAGE 3-116)

OINTMENT; TOPICAL
HYDROCORTISONE BUTYRATE

| | | | | |
|---|---|---|---|---|
| BX | ◑ GIST-BROCADES | 0.1% | N18652 001 | OCT 29, 1982 |

LOCOID

| | | | | |
|---|---|---|---|---|
| BX | OWEN LABS/DERM PRODS | 0.1% | N19106 001 | JUL 03, 1984 |

HYDROFLUMETHIAZIDE; RESERPINE (PAGE 3-117)

TABLET; ORAL
HYDROFLUMETHIAZIDE AND RESERPINE

| | | | | |
|---|---|---|---|---|
| BP | PAR PHARMACEUTICAL | 50MG;0.125MG¤ | N88907 001 | SEP 20, 1985 |

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

INJECTABLE; INJECTION
**HYDROXYZINE**

| | | | | |
|---|---|---|---|---|
| AP | ELKINS-SINN/AHROBINS | 50MG/ML | N85551 002 | |

**HYDROXYZINE HCL**

| | | | | |
|---|---|---|---|---|
| /AP/ | /ELKINS-SINN/AHROBINS/ | 50MG/ML/ | /N85551 002/ | |
| AP | PHARMAFAIR | 25MG/ML¤ | N88862 001 | FEB 14, 1986 |
| AP | | 25MG/ML¤ | N89106 001 | FEB 14, 1986 |
| AP | | 50MG/ML¤ | N89107 001 | FEB 14, 1986 |
| AP | | 50MG/ML¤ | N88881 001 | FEB 14, 1986 |

TABLET; ORAL
**HYDROXYZINE HCL**

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | AB | COLMED LABORATORIES | 10MG¤ | N89121 001 | MAR 20, 1986 |
| >ADD> | AB | | 25MG¤ | N89122 001 | MAR 20, 1986 |
| >ADD> | AB | | 50MG¤ | N89123 001 | MAR 20, 1986 |
| >ADD> | AB | QUANTUM PHARMICS | 10MG¤ | N88540 001 | OCT 22, 1985 |
| | AB | | 25MG¤ | N88551 001 | OCT 22, 1985 |
| | AB | | 50MG¤ | N88529 001 | OCT 22, 1985 |

HYDROXYZINE HYDROCHLORIDE (PAGE 3-118)

TABLET; ORAL
**HYDROXYZINE HCL**

| | | | | |
|---|---|---|---|---|
| AB | SIDMAK LABORATORIES | 10MG¤ | N88617 001 | JAN 10, 1986 |
| AB | | 25MG¤ | N88618 001 | JAN 10, 1986 |
| AB | | 50MG¤ | N88619 001 | JAN 10, 1986 |

HYDROXYZINE PAMOATE (PAGE 3-120)

CAPSULE; ORAL
**HYDROXYZINE PAMOATE**

| | | | | |
|---|---|---|---|---|
| > ADD > AB | PAR PHARMACEUTICAL | EQ 25MG HCL¤ | N89145 001 | MAR 17, 1986 |
| > ADD > AB | | EQ 50MG HCL¤ | N89146 001 | MAR 17, 1986 |

IBUPROFEN (PAGE 3-120)

TABLET; ORAL
**IBUPROFEN**

| | | | | |
|---|---|---|---|---|
| AB | CHELSEA LABORATORIES | 400MG¤ | N70038 001 | SEP 06, 1985 |
| AB | | 600MG¤ | N70041 001 | SEP 06, 1985 |
| AB | DANBURY PHARMACAL | 400MG¤ | N70436 001 | AUG 21, 1985 |
| AB | | 600MG¤ | N70437 001 | AUG 21, 1985 |
| AB | MYLAN PHARMS | 400MG¤ | N70045 001 | SEP 24, 1985 |
| AB | | 600MG¤ | N70057 001 | SEP 24, 1985 |
| AB | OHM LABORATORIES | 400MG¤ | N70818 001 | DEC 26, 1985 |
| AB | ə PAR PHARMACEUTICALS | 300MG¤ | N70328 001 | AUG 06, 1985 |
| AB | | 400MG¤ | N70329 001 | AUG 06, 1985 |
| AB | | 600MG¤ | N70330 001 | AUG 06, 1985 |

**IBUPROHM**

| | | | | |
|---|---|---|---|---|
| AB | OHM LABORATORIES | 400MG¤ | N70469 001 | AUG 29, 1985 |

**MOTRIN**

| | | | | |
|---|---|---|---|---|
| AB | ə UPJOHN | 300MG | N17463 003 | MAY 22, 1985 |
| | | 800MG¤ | N17463 005 | |

INDIUM IN-111 OXYQUINOLINE (PAGE 3-121)

INJECTABLE; INJECTION
INDIUM IN-111 OXYQUINOLINE

| | | | |
|---|---|---|---|
| AMERSHAM/RADIOCHEM | N/A | N19044 001 | DEC 23, 1985 |

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL
**INDO-LEMMON**

| | | | | |
|---|---|---|---|---|
| AB | LEMMON | 25MG¤ | N70266 001 | NOV 07, 1985 |
| AB | | 50MG¤ | N70267 001 | NOV 07, 1985 |

**INDOMETHACIN**

| | | | | |
|---|---|---|---|---|
| AB | DURAMED PHARMS | 25MG¤ | N70326 001 | OCT 18, 1985 |
| AB | | 50MG¤ | N70327 001 | OCT 18, 1985 |
| AB | MYLAN PHARMS | 50MG¤ | N70624 001 | SEP 04, 1985 |
| > ADD > AB | PAR PHARMACEUTICAL | 50MG¤ | N70651 001 | MAR 05, 1986 |
| > ADD > AB | WATSON LABORATORIES | 25MG¤ | N70529 001 | OCT 18, 1985 |
| AB | | 50MG¤ | N70530 001 | OCT 18, 1985 |
| AB | ZENITH LABORATORIES | 25MG¤ | N70719 001 | FEB 12, 1986 |
| AB | | 50MG¤ | N70756 001 | FEB 12, 1986 |

SUSPENSION; ORAL
INDOCIN

| | | | |
|---|---|---|---|
| MS&D RES LABS/MERCK | 25MG/5ML¤ | N18332 001 | OCT 10, 1985 |

IOHEXOL (PAGE 3-123)

INJECTABLE; INJECTION
OMNIPAQUE 180

| | | | |
|---|---|---|---|
| WINTHROP-BREON/STERL | 38.8%¤ | N18956 001 | DEC 26, 1985 |

OMNIPAQUE 240

| | | | |
|---|---|---|---|
| WINTHROP-BREON/STERL | 51.8%¤ | N18956 002 | DEC 26, 1985 |

OMNIPAQUE 300

| | | | |
|---|---|---|---|
| WINTHROP-BREON/STERL | 64.7%¤ | N18956 003 | DEC 26, 1985 |

OMNIPAQUE 350

| | | | |
|---|---|---|---|
| WINTHROP-BREON/STERL | 75.5%¤ | N18956 004 | DEC 26, 1985 |

IOPAMIDOL (PAGE 3-123)

INJECTABLE; INJECTION
ISOVUE-300
ER SQUIBB AND SONS 61%¤ N18735 002
DEC 31, 1985

ISOVUE-370
ER SQUIBB AND SONS 76%¤ N18735 003
DEC 31, 1985

ISOVUE-M 200
ER SQUIBB AND SONS 41%¤ N18735 001
DEC 31, 1985

ISOVUE-M 300
ER SQUIBB AND SONS 61%¤ N18735 004
DEC 31, 1985

ISONIAZID (PAGE 3-125)

SYRUP; ORAL
LANIAZID
AA LANNETT 50MG/5ML¤ N89243 001
FEB 03, 1986

KANAMYCIN SULFATE (PAGE 3-126)

INJECTABLE; INJECTION
KANAMYCIN SULFATE
AP QUAD PHARMS EQ 75MG BASE/2ML¤ N62642 001
FEB 03, 1986
AP EQ 500MG BASE/2ML¤ N62642 002
FEB 03, 1986
AP EQ 1GM BASE/3ML¤ N62642 003
FEB 03, 1986
AP SOLOPAK LABORATORIES EQ 75MG BASE/2ML¤ N62605 003
FEB 26, 1986
AP EQ 500MG BASE/2ML¤ N62605 001
FEB 26, 1986
AP EQ 1GM BASE/3ML¤ N62605 002
FEB 26, 1986

KETOCONAZOLE (PAGE 3-127)

CREAM; TOPICAL
NIZORAL
JANSSEN PHARMA 2%¤ N19084 001
DEC 31, 1985

KETOPROFEN (PAGE 3-127)

CAPSULE; ORAL
ORUDIS
WYETH LABS/AMHO 50MG¤ N18754 002
JAN 09, 1986
75MG¤ N18754 003
JAN 09, 1986

LABETALOL HYDROCHLORIDE (PAGE 3-127)

INJECTABLE; INJECTION
NORMODYNE
AP SCHERING 5MG/ML N18686 001
AUG 01, 1984

TRANDATE
AP GLAXO 5MG/ML¤ N19425 001
DEC 31, 1985

LEUCOVORIN CALCIUM (PAGE 3-127)

TABLET; ORAL
LEUCOVORIN CALCIUM
BX LEDERLE LABS/AM CYAN EQ 5MG BASE¤ N18459 001
JAN 30, 1986

WELLCOVORIN
BX BURROUGHS WELLCOME EQ 5MG BASE N18342 001
JUL 08, 1983

LEVOBUNOLOL HYDROCHLORIDE (PAGE 3-128)

SOLUTION/DROPS; OPHTHALMIC
BETAGAN
ALLERGAN PHARMS 0.5%¤ N19219 002
DEC 19, 1985

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
ATIVAN
AB WYETH LABS/AMHO 0.5MG N17794 001
AB 1MG N17794 002
AB 2MG N17794 003

LORAZEPAM (PAGE 3-132)

TABLET; ORAL
LORAZEPAM

| | | | | |
|---|---|---|---|---|
| > ADD > | AB | AM THERAPEUTIC | 0.5MG¤ | N70727 001 MAR 07, 1986 |
| > ADD > | | | | |
| > ADD > | AB | | 1MG¤ | N70728 001 MAR 07, 1986 |
| > ADD > | | | | |
| > ADD > | AB | | 2MG¤ | N70729 001 MAR 07, 1986 |
| > ADD > | | | | |
| | AB | BARR LABORATORIES | 0.5MG¤ | N70472 001 DEC 10, 1985 |
| | AB | | 1MG¤ | N70473 001 DEC 10, 1985 |
| | AB | | 2MG¤ | N70474 001 DEC 10, 1985 |
| | AB | QUANTUM PHARMICS | 0.5MG¤ | N70200 001 AUG 09, 1985 |
| | AB | | 1MG¤ | N70201 001 AUG 09, 1985 |
| | AB | | 2MG¤ | N70202 001 AUG 09, 1985 |

LOXAPINE SUCCINATE (PAGE 3-132)

TABLET; ORAL
LOXITANE

| | | | |
|---|---|---|---|
| ⓐ | LEDERLE LABS/AM CYAN | EQ 10MG BASE | N17525 006 |
| ⓐ | | EQ 25MG BASE | N17525 007 |
| ⓐ | | EQ 50MG BASE | N17525 008 |

MANNITOL (PAGE 3-134)

SOLUTION; IRRIGATION
RESECTISOL

| | | |
|---|---|---|
| /AM MCGAW/AM HOSP/ | /5GM/100ML/ | /N16772/002/ |

RESECTISOL IN PLASTIC CONTAINER

| | | |
|---|---|---|
| AM MCGAW/AM HOSP | 5GM/100ML | N16772 002 |

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL
MECLIZINE HCL

| | | | | |
|---|---|---|---|---|
| AA | | SIDMAK LABORATORIES | 12.5MG¤ | N88732 001 DEC 11, 1985 |
| AA | | | 25MG¤ | N88734 001 DEC 11, 1985 |
| AA | | SUPERPHARM | 12.5MG¤ | N89113 001 AUG 20, 1985 |
| AA | | | 25MG¤ | N89114 001 AUG 20, 1985 |

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL
MECLIZINE HCL
TABLET, CHEWABLE; ORAL
MECLIZINE HCL

| | | | |
|---|---|---|---|
| AA | SIDMAK LABORATORIES | 25MG¤ | N88733 001 DEC 11, 1985 |

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL
PROVERA

| | | |
|---|---|---|
| UPJOHN | 5MG | N11839 003 |

METHOCARBAMOL (PAGE 3-142)

TABLET; ORAL
METHOCARBAMOL

| | | | |
|---|---|---|---|
| AA | PIONEER PHARMS | 500MG¤ | N88731 001 DEC 13, 1985 |
| AA | | 750MG¤ | N89082 001 DEC 13, 1985 |

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION
FOLEX

| | | | |
|---|---|---|---|
| AP | ADRIA LABS/ERBAMONT | EQ 250MG BASE/VIAL¤ | N88954 001 OCT 24, 1985 |

FOLEX PFS

| | | | |
|---|---|---|---|
| AP | ADRIA LABS/ERBAMONT | EQ 25MG BASE/ML¤ | N89180 001 JAN 03, 1986 |
| AP | | EQ 25MG BASE/ML¤ | N89181 001 JAN 03, 1986 |
| AP | | EQ 25MG BASE/ML¤ | N89182 001 JAN 03, 1986 |

METHOTREXATE LPF

| | | | |
|---|---|---|---|
| AP | LEDERLE LABS/AM CYAN | EQ 25MG BASE/ML | N11719 007 MAR 31, 1982 |

METHOTREXATE SODIUM

| | | | |
|---|---|---|---|
| AP | LYPHOMED | EQ 20MG BASE/VIAL¤ | N88935 001 OCT 11, 1985 |
| AP | | EQ 50MG BASE/VIAL¤ | N88936 001 OCT 11, 1985 |
| AP | | EQ 100MG BASE/VIAL¤ | N89937 001 OCT 11, 1985 |

MEXATE

| | | | |
|---|---|---|---|
| AP | BRISTOL LABS/B-M | EQ 250MG BASE/VIAL | N86358 004 |

METHYCLOTHIAZIDE (PAGE 3-143)

TABLET; ORAL
METHYCLOTHIAZIDE

| | | | | |
|---|---|---|---|---|
| AB | PAR PHARMACEUTICAL | 2.5MG* | N89135 001 | |
| | | | FEB 12, 1986 | |
| AB | | 5MG* | N89136 001 | |
| | | | FEB 12, 1986 | |

METHYLDOPA (PAGE 3-144)

TABLET; ORAL
METHYLDOPA

| | | | | |
|---|---|---|---|---|
| AB | BOLAR PHARMACEUTICAL | 125MG* | N70245 001 | |
| | | | FEB 25, 1986 | |
| AB | | 250MG* | N70246 001 | |
| | | | FEB 25, 1986 | |
| AB | | 500MG* | N70247 001 | |
| | | | FEB 25, 1986 | |
| AB | LEDERLE LABS/AM CYAN | 125MG* | N70070 003 | |
| | | | OCT 15, 1985 | |
| AB | | 250MG* | N70084 001 | |
| | | | OCT 15, 1985 | |
| AB | | 500MG* | N70085 001 | |
| | | | OCT 15, 1985 | |
| AB | PUREPAC/KALIPHARMA | 125MG* | N70749 001 | |
| | | | FEB 07, 1986 | |
| AB | | 250MG* | N70750 001 | |
| | | | FEB 07, 1986 | |
| AB | | 500MG* | N70452 001 | |
| | | | FEB 07, 1986 | |
| AB | ZENITH LABORATORIES | 250MG* | N70098 001 | |
| | | | FEB 20, 1986 | |
| AB | | 500MG* | N70343 001 | |
| | | | FEB 20, 1986 | |

METHYLPREDNISOLONE SODIUM SUCCINATE (PAGE 3-145)

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

| | | | | |
|---|---|---|---|---|
| AP | QUAD PHARMS | EQ 40MG BASE/VIAL* | N89264 001 | |
| | | | JAN 22, 1986 | |
| AP | | EQ 125MG BASE/VIAL* | N89265 001 | |
| | | | JAN 22, 1986 | |
| AP | | EQ 500MG BASE/VIAL* | N89266 001 | |
| | | | JAN 22, 1986 | |
| AP | | EQ 1GM BASE/VIAL* | N89267 001 | |
| | | | JAN 22, 1986 | |

| | | | | |
|---|---|---|---|---|
| > ADD > | AP | LYPHOMED | EQ 40MG BASE/VIAL* | N89143 001 |
| > ADD > | | | | MAR 28, 1986 |
| > ADD > | AP | | EQ 125MG BASE/VIAL* | N89144 001 |
| > ADD > | | | | MAR 28, 1986 |
| > ADD > | AP | | EQ 500MG BASE/VIAL* | N89186 001 |
| > ADD > | | | | MAR 28, 1986 |
| > ADD > | AP | | EQ 500MG BASE/VIAL* | N89187 001 |
| > ADD > | | | | MAR 28, 1986 |
| > ADD > | AP | | EQ 1GM BASE/VIAL* | N89188 001 |
| > ADD > | | | | MAR 28, 1986 |
| > ADD > | AP | | EQ 1GM BASE/VIAL* | N89189 001 |
| > ADD > | | | | MAR 28, 1986 |

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

| | | | | |
|---|---|---|---|---|
| AP | LYPHOMED | EQ 5MG BASE/ML* | N70293 001 | |
| | | | JAN 24, 1986 | |

REGLAN

| | | | | |
|---|---|---|---|---|
| AP | AH ROBINS | EQ 5MG BASE/ML | N17862 001 | |

TABLET; ORAL
CLOPRA-"YELLOW"

| | | | | |
|---|---|---|---|---|
| AB | QUANTUM PHARMICS | EQ 10MG BASE* | N70632 001 | |
| | | | OCT 28, 1985 | |

MAXOLON

| | | | | |
|---|---|---|---|---|
| > ADD > | | | | |
| > ADD > | AB | BEECHAM LABS/BEECHAM | EQ 10MG BASE* | N70106 001 |
| > ADD > | | | | MAR 04, 1986 |

METOCLOPRAMIDE HCL

| | | | | |
|---|---|---|---|---|
| AB | DANBURY PHARMACAL | EQ 10MG BASE* | N70511 001 | |
| | | | JAN 22, 1986 | |
| > ADD > | AB | PAR PHARMACEUTICAL | EQ 10MG BASE* | N70342 001 |
| > ADD > | | | | MAR 25, 1986 |
| AB | PUREPAC/KALIPHARMA | EQ 10MG BASE* | N70581 001 | |
| | | | OCT 17, 1985 | |

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL
METRONIDAZOLE

| | | | | |
|---|---|---|---|---|
| AB | HALSEY DRUG | 500MG* | N70593 001 | |
| | | | FEB 27, 1986 | |
| AB | VITARINE | 250MG | N18620 001 | |
| | | | MAR 04, 1982 | |
| AB | | 500MG | N18620 002 | |
| | | | JUN 02, 1983 | |

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | METRYL | | | | | | | |
| /AB/ | /VITARINE/ | /250MG/ | /N18620 001/ /MAR 04, 1982/ | > ADD > | | | | |
| | METRYL 500 | | | | | | | |
| /AB/ | /VITARINE/ | /500MG/ | /N18620 002/ /JUN 02, 1983/ | > ADD > | | | | |

METRONIDAZOLE HYDROCHLORIDE (PAGE 3-148)

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | FLAGYL I.V. | | | | | | | |
| AP | SEARLE PHARMS | EQ 500MG BASE/VIAL | N18353 001 | | | | | |
| | METRONIDAZOLE HCL | | | | | | | |
| AP | LYPHOMED | EQ 500MG BASE/VIAL¤ | N70295 001 OCT 15, 1985 | > ADD > | AB | BARR LABORATORIES | 250MG¤ | N70270 001 |
| | | | | > ADD > | | | JUN 29, 1988 : | MAR 28, 1986 |
| | | | | > ADD > | AB | | 500MG¤ | N70271 001 |
| | | | | > ADD > | | | JUN 29, 1988 : | MAR 28, 1986 |
| | | | | > ADD > | AB | | 1GM¤ | N70272 001 |
| | | | | > ADD > | | | JUN 29, 1986 : | MAR 28, 1986 |
| | | | | > ADD > | | MEGGDAM | | |
| | | | | > ADD > | AB | WINTHROP-BREON/STERL | 250MG | N14214 002 |
| | | | | > ADD > | AB | | 500MG | N14214 004 |
| | | | | > ADD > | AB | | 1GM | N14214 005 |

MEXILETINE HYDROCHLORIDE (PAGE 3-149)

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| MEXITIL | | | |
| BOEHRINGER INGELHEIM | 150MG¤ | N18873 002 DEC 30, 1985 | |
| | 200MG¤ | N18873 003 DEC 30, 1985 | |
| | 250MG¤ | N18873 004 DEC 30, 1985 | |

MIDAZOLAM HYDROCHLORIDE (PAGE 3-149)

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| VERSED | | | |
| HOFFMANN-LA ROCHE | EQ 5MG BASE/ML¤ | N18654 001 DEC 20, 1985 | |

MONOOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY

| | | | |
|---|---|---|---|
| MOCTANIN | | | |
| ASCOT HOSP PHARMS | 100%¤ | N19368 001 OCT 29, 1985 | |

NABILONE (PAGE 3-150)

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| CESAMET | | | |
| ELI LILLY | 1MG¤ | N18677 001 DEC 26, 1985 | |

NALBUPHINE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | NALBUPHINE | | | | | |
| > ADD > | AP | | QUAD PHARMS | | 10MG/ML¤ | | | N70692 001 MAR 25, 1986 |
| > ADD > | AP | | | | 20MG/ML¤ | | | N70693 001 |
| > ADD > | | | | | | SEP 24, 1986 : | | MAR 25, 1986 |
| | | | NUBAIN | | | | | |
| > ADD > | AP | | DUPONT PHARMS/DUPONT | | 10MG/ML | | | N18024 001 |
| > ADD > | AP | | | | 20MG/ML | | | N18024 002 MAY 27, 1982 |

NALIDIXIC ACID (PAGE 3-151)

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | NALIDIXIC ACID | | | | | |
| > ADD > | AB | | BARR LABORATORIES | | 250MG¤ | | | N70270 001 |
| > ADD > | | | | | | JUN 29, 1988 : | | MAR 28, 1986 |
| > ADD > | AB | | | | 500MG¤ | | | N70271 001 |
| > ADD > | | | | | | JUN 29, 1988 : | | MAR 28, 1986 |
| > ADD > | AB | | | | 1GM¤ | | | N70272 001 |
| > ADD > | | | | | | JUN 29, 1986 : | | MAR 28, 1986 |
| | | | MEGGDAM | | | | | |
| > ADD > | AB | | WINTHROP-BREON/STERL | | 250MG | | | N14214 002 |
| > ADD > | AB | | | | 500MG | | | N14214 004 |
| > ADD > | AB | | | | 1GM | | | N14214 005 |

NALOXONE HYDROCHLORIDE (PAGE 3-151)

INJECTABLE; INJECTION

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | NALOXONE | | | | | |
| AP | | | ELKINS-SINN/AHROBINS | | 0.4MG/ML¤ | | | N70298 001 |
| | | | | | | SEP 24, 1986 : | | OCT 22, 1985 |
| AP | | | | | 0.4MG/ML¤ | | | N70299 001 |
| | | | | | | SEP 24, 1986 : | | OCT 22, 1985 |
| AP | | | | | 0.4MG/ML¤ | | | N70496 001 |
| | | | | | | SEP 24, 1986 : | | OCT 22, 1985 |
| AP | | | INTL MEDICATION SYS | | 0.4MG/ML¤ | | | N70417 001 |
| | | | | | | SEP 24, 1986 : | | NOV 06, 1985 |
| AP | | | | | 0.4MG/ML¤ | | | N70639 001 |
| | | | | | | SEP 24, 1986 : | | JAN 17, 1986 |
| AP | | | WYETH LABS/AMHO | | 0.02MG/ML¤ | | | N70188 001 |
| | | | | | | SEP 24, 1986 : | | OCT 02, 1985 |
| AP | | | | | 0.02MG/ML¤ | | | N70189 001 |
| | | | | | | SEP 24, 1986 : | | OCT 02, 1985 |
| AP | | | | | 0.4MG/ML¤ | | | N70190 001 |
| | | | | | | SEP 24, 1986 : | | OCT 02, 1985 |
| AP | | | | | 0.4MG/ML¤ | | | N70191 001 |
| | | | | | | SEP 24, 1986 : | | OCT 02, 1985 |
| | | | HADGAN | | | | | |
| AP | | | DUPONT PHARMS/DUPONT | | 0.02MG/ML | | | N16636 001 |
| AP | | | | | 0.4MG/ML | | | N16636 002 |
| | | | | /3/ | 1MG/ML | | | N16636 003 JUN 14, 1982 |

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE (PAGE 3-151)

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

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

NANDROLONE DECANOATE (PAGE 3-151)

INJECTABLE; INJECTION
NANDROLONE DECANOATE

| | | | |
|---|---|---|---|
| AO | LEMMON | 50MG/ML¤ | N88554 001 FEB 10, 1986 |
| AO | | 50MG/ML | N87598 001 OCT 06, 1983 |

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL
ADALAT

| | | | |
|---|---|---|---|
| AB | MILES PHARM/MILES | 10MG¤ | N19478 001 NOV 27, 1985 |

PROCARDIA

| | | | |
|---|---|---|---|
| AB | PFIZER LABS/PFIZER | 10MG | N18482 001 |

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¤ | N70026 001 SEP 10, 1985 |
| AP | LYPHOMED | 5MG/ML¤ | N70077 001 DEC 13, 1985 |

> DLT > /NONIFENSINE MALEATE (PAGE 3-155)/

> DLT > /NERITAL/
> DLT > /S/HOECHST-ROUSSEL/ /25MG/ /N18224 001/ /DEC 31, 1984/
> DLT >
> DLT > /S/ /50MG/ /N18224 002/ /DEC 31, 1984/
> DLT >

NYSTATIN (PAGE 3-156)

POWDER; ORAL
NILSTAT

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

NYSTATIN

| | | | |
|---|---|---|---|
| AA | PADDOCK LABORATORIES | 100%¤ | N62613 001 NOV 26, 1985 |

SUSPENSION; ORAL
NYSTATIN

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

TABLET; ORAL
NYSTATIN

| | | | |
|---|---|---|---|
| AA | LEMMON | 500,000 UNITS | N62506 001 JAN 16, 1984 |
| AA | PHARM BASICS | 500,000 UNITS¤ | N62524 001 NOV 26, 1985 |

TABLET; VAGINAL
NYSTATIN

| | | | |
|---|---|---|---|
| AT | SIDMAK LABORATORIES | 100,000 UNITS¤ | N62615 001 OCT 17, 1985 |

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

CREAM; TOPICAL
MYCO-TRIACET II

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

MYTREX F

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

NYSTATIN-TRIAMCINOLONE ACETONIDE

| | | | |
|---|---|---|---|
| AT | E FOUGERA/ALTANA | 100,000 UNITS/GM;0.1%¤ | N62599 001 OCT 08, 1985 |
| AT | PHARMADERM/ALTANA | 100,000 UNITS/GM;0.1%¤ | N62596 001 OCT 08, 1985 |

OINTMENT; TOPICAL
MYCO-TRIACET II

| | | | |
|---|---|---|---|
| AT | LEMMON | 100,000 UNITS/GM;0.1%¤ | N62045 002 NOV 26, 1985 |

MYCOLOG-II

| | | | |
|---|---|---|---|
| AT | ER SQUIBB AND SONS | 100,000 UNITS/GM;0.1% | N60572 001 JUN 28, 1985 |

MYTREX F

| | | | |
|---|---|---|---|
| AT | SAVAGE LABS/ALTANA | 100,000 UNITS/GM;0.1%¤ | N62601 001 OCT 09, 1985 |

NYSTATIN AND TRIAMCINOLONE ACETONIDE

| | | | |
|---|---|---|---|
| AT | CLAY-PARK LABS | 100,000 UNITS/GM;0.1%¤ | N62280 002 OCT 10, 1985 |

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

OINTMENT; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| AT | E FOUGERA/ALTANA | 100,000 UNITS/GM;0.1%¤ | N62602 001 | OCT 09, 1985 |
| AT | PHARMADERM/ALTANA | 100,000 UNITS/GM;0.1%¤ | N62603 001 | OCT 09, 1985 |

OXYPHENBUTAZONE (PAGE 3-159)

TABLET; ORAL
OXYPHENBUTAZONE

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | ∂ BOLAR PHARMACEUTICAL | 100MG | N88399 001 | SEP 17, 1984 |

PENICILLIN G POTASSIUM (PAGE 3-161)

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN 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 | |

> ADD > PERMETHRIN (PAGE 3-164)

> ADD > LOTION; TOPICAL
> ADD > NIX

| | | | | |
|---|---|---|---|---|
| > ADD > | BURROUGHS WELLCOME | 1%¤ | N19435 001 | MAR 31, 1986 |

PHENTERMINE HYDROCHLORIDEPSULE; ORAL

CAPSULE; ORAL
/ADIPEX/

| | | | | |
|---|---|---|---|---|
| /AA/ | /LEMMON/ | /30MG/ | N87126 001 | |

PHENTERMINE HCL

| | | | | |
|---|---|---|---|---|
| AA | LEMMON | 30MG¤ | N87777 001 | NOV 01, 1985 |
| AA | | 30MG | N87126 001 | |

PHENYLBUTAZONE (PAGE 3-168)

CAPSULE; ORAL
PHENYLBUTAZONE

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 100MG¤ | N88994 001 | DEC 04, 1985 |

TABLET; ORAL
PHENYLBUTAZONE

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 100MG¤ | N88863 001 | DEC 04, 1985 |

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-168)

SYRUP; ORAL
PROMETHAZINE VC PLAIN

| | | | | |
|---|---|---|---|---|
| AA | HR CENCI LABS | 5MG/5ML;6.25MG/5ML¤ | N88815 001 | NOV 22, 1985 |

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL
/EXTENDED PHENYTOIN SODIUM/

| | | | | |
|---|---|---|---|---|
| /AB/ | /BOLAR PHARMACEUTICAL/ | 100MG/ | /N88711 001/ | /DEC 21, 1984/ |

/SETROL/
PHENYTEX

| | | | | |
|---|---|---|---|---|
| AB | BOLAR PHARMACEUTICAL | 100MG | N88711 001 | DEC 21, 1984 |

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

CAPSULE; ORAL
PHENYTOIN SODIUM

| | | | | |
|---|---|---|---|---|
| /BX/ | /DANBURY PHARMACAL/ | /100MG/ | /N80905 001/ | |
| /BX/ | /ZENITH LABORATORIES/ | /100MG/ | /N80259 001/ | |

PROMPT PHENYTOIN SODIUM

| | | | | |
|---|---|---|---|---|
| BX | DANBURY PHARMACAL | 100MG | N80905 001 | |
| BX | ZENITH LABORATORIES | 100MG | N80259 001 | |

PIPERAZINE CITRATE (PAGE 3-170)

TABLET; ORAL
ANTEPAR

| | | | |
|---|---|---|---|
| ∂ BURROUGHS WELLCOME | EQ 500MG BASE | N09102 003 | |

POTASSIUM CHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

| | | | | |
|---|---|---|---|---|
| AP | MAURRY BIOLOGICAL | 2MEQ/ML¤ | N88286 001 | SEP 05, 1985 |

POTASSIUM CITRATE (PAGE 3-173)

TABLET; ORAL
> DLT > /POTASSIUM CITRATE/
> ADD > UROCIT-K

| | | | |
|---|---|---|---|
| UNIV TX HLTH SCI CTR | 5MEQ¤ | N19071 001 | AUG 30, 1985 |

PRALIDOXIME CHLORIDE (PAGE 3-174)

INJECTABLE; INJECTION
**PRALIDOXIME CHLORIDE**

| | | | |
|---|---|---|---|
| AP | SURVIVAL TECHNOLOGY | 300MG/ML | N18986 001<br>APR 26, 1983 |
| /AP/ | /PROTOPAM/<br>/SURVIVAL TECHNOLOGY/ | /300MG/ML/ | /N18986 001/<br>/APR 26, 1983/ |

PREDNISOLONE (PAGE 3-174)

SYRUP; ORAL
PRELONE

| | | | |
|---|---|---|---|
| | MURO PHARMACEUTICAL | 15MG/5ML¤ | N89081 001<br>FEB 04, 1986 |

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM (PAGE 3-175)

SUSPENSION/DROPS; OPHTHALMIC
**BLEPHAMIDE**

| | | | |
|---|---|---|---|
| AT | ALLERGAN PHARMS | 0.2%;10% | N12813 002 |

**PREDSULFAIR II**

| | | | |
|---|---|---|---|
| AT | PHARMAFAIR | 0.2%;10%¤ | N88837 001<br>DEC 24, 1985 |

PREDNISONE (PAGE 3-176)

TABLET; ORAL
**DELTASONE**

| | | | |
|---|---|---|---|
| AB | UPJOHN | 5MG | N09986 002 |
| AB | | 10MG | N09986 006 |
| AB | | 20MG | N09986 007 |

**PREDNISONE**

| | | | |
|---|---|---|---|
| AB | MUTUAL PHARM | 5MG¤ | N89245 001<br>DEC 04, 1985 |
| AB | | 10MG¤ | N89246 001<br>DEC 04, 1985 |
| AB | | 20MG¤ | N89247 001<br>DEC 04, 1985 |
| > DLT > /BX/ | /DURAMED PHARMS/ | /20MG/ | /N88396 001/ |
| > ADD > AB | DURAMED PHARMS | 20MG | N88396 001<br>OCT 04, 1983 |
| > DLT > /BX/ | /WEST-WARD/ | /50MG/ | /N88465 001/ |
| > ADD > AB | WEST-WARD | 50MG | N88465 001<br>JUN 01, 1984 |
| AB | WEST-WARD | 10MG¤ | N88832 001<br>DEC 04, 1985 |

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

INJECTABLE; INJECTION
**PROCAINAMIDE HCL**

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 100MG/ML¤ | N89069 001<br>FEB 12, 1986 |
| AP | | 500MG/ML¤ | N89070 001<br>FEB 12, 1986 |
| AP | PHARMAFAIR | 100MG/ML¤ | N88824 001<br>NOV 20, 1985 |
| AP | | 500MG/ML¤ | N88830 001<br>NOV 20, 1985 |

TABLET, CONTROLLED RELEASE; ORAL
**PROCAINAMIDE HCL**

| | | | |
|---|---|---|---|
| AB | DANBURY PHARMACAL | 250MG¤ | N89026 001<br>OCT 22, 1985 |
| AB | | 500MG¤ | N89027 001<br>OCT 22, 1985 |
| AB | | 750MG¤ | N89042 001<br>OCT 22, 1985 |

**RHYTHMIN**

| | | | |
|---|---|---|---|
| AB | SIDMAK LABORATORIES | 250MG¤ | N88958 001<br>DEC 02, 1985 |
| AB | | 500MG¤ | N88959 001<br>DEC 02, 1985 |

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL
**PROMETHAZINE**

| | | | |
|---|---|---|---|
| AA | LIFE LABORATORIES | 6.25MG/5ML¤ | N89013 001<br>SEP 20, 1985 |

TABLET; ORAL
PROMETHAZINE HCL

| | | | |
|---|---|---|---|
| BP | LEMMON | 25MG¤ | N89109 001<br>SEP 10, 1985 |

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL
**PROPRANOLOL**

| | | | |
|---|---|---|---|
| AB | MYLAN PHARMS | 10MG¤ | N70211 001<br>NOV 19, 1985 |
| AB | | 20MG¤ | N70212 001<br>NOV 19, 1985 |
| AB | | 40MG¤ | N70213 001<br>NOV 19, 1985 |
| AB | | 80MG¤ | N70214 001<br>NOV 19, 1985 |

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL
PROPRANOLOL HCL

| | | | |
|---|---|---|---|
| AB | BARR LABORATORIES | 10MG¤ | N70319 001 OCT 22, 1985 |
| AB | | 20MG¤ | N70320 001 OCT 22, 1985 |
| AB | | 40MG¤ | N70103 001 OCT 22, 1985 |
| AB | DURAMED PHARMS | 10MG¤ | N70306 001 SEP 09, 1985 |
| AB | | 20MG¤ | N70307 001 SEP 09, 1985 |
| AB | | 40MG¤ | N70308 001 SEP 09, 1985 |
| AB | | 80MG¤ | N70310 001 SEP 09, 1985 |
| AB | MARTEC PHARMS | 10MG¤ | N70120 001 AUG 06, 1985 |
| AB | | 20MG¤ | N70121 001 AUG 06, 1985 |
| AB | | 40MG¤ | N70122 001 AUG 06, 1985 |
| AB | | 80MG¤ | N70124 001 AUG 06, 1985 |

QUAZEPAM (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 |

RANITIDINE HYDROCHLORIDE (PAGE 3-187)

TABLET; ORAL
/ZANTAC/
/GLAXO/ /EQ 150MG BASE/ /N18703 001/ /JUN 09, 1983/

ZANTAC 150

| | | | |
|---|---|---|---|
| | GLAXO | EQ 150MG BASE | N18703 001 JUN 09, 1983 |

ZANTAC 300

| | | | |
|---|---|---|---|
| | GLAXO | EQ 300MG BASE¤ | N18703 002 DEC 09, 1985 |

RIBAVIRIN (PAGE 3-189)

POWDER FOR RECONSTITUTION; INHALATION
VIRAZOLE

| | | | |
|---|---|---|---|
| | VIRATEK | 6GM/VIAL¤ | N18859 001 DEC 31, 1985 |

SILVER SULFADIAZINE (PAGE 3-191)

CREAM; TOPICAL
SILVADENE

| | | | |
|---|---|---|---|
| /AT/ | /MARION LABORATORIES/ | /1%/ | /N17381 001/ |
| AB | MARION LABORATORIES | 1% | N17381 001 |

SSD

| | | | |
|---|---|---|---|
| /AT/ | /TRAVENOL LABS/ | /1%/ | /N18578 001/ /FEB 25, 1982/ |
| AB | TRAVENOL LABS | 1% | N18578 001 FEB 25, 1982 |

ULTRA DERM

| | | | |
|---|---|---|---|
| AB | CHESEBROUGH-PONDS | 1%¤ | N18810 001 DEC 23, 1985 |

SODIUM BICARBONATE; TARTARIC ACID (PAGE 3-191)

GRANULE, EFFERVESCENT; ORAL
BAROS

| | | | |
|---|---|---|---|
| | MALLINCKRODT | 460MG/GM;420MG/GM¤ | N18509 001 AUG 07, 1985 |

SODIUM CHLORIDE (PAGE 3-191)

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT LABORATORIES | 900MG/100ML¤ | N19480 001 SEP 17, 1985 |
| AP | TRAVENOL LABS | 9MG/ML¤ | 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 |

SOMATREM (PAGE 3-195)

INJECTABLE; INJECTION
PROTROPIN

| | | | |
|---|---|---|---|
| | GENENTECH | 5MG/VIAL¤ | N19107 001 OCT 17, 1985 |

SOMATROPIN (PAGE 3-195)

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| ASELLACRIN 10 | | | |
| ə SERONO LABS | 10 IU/VIAL | N17726 001 | |
| ASELLACRIN 2 | | | |
| ə SERONO LABS | 2 IU/VIAL | N17726 002 | |
| | | JUL 21, 1983 | |
| CRESCORMON | | | |
| ə KABIVITRUM | 4 IU/VIAL | N17992 001 | |

SULCONAZOLE NITRATE (PAGE 3-197)

SOLUTION; TOPICAL

| | | | |
|---|---|---|---|
| SULCOSYN | | | |
| SYNTEX LABS/SYNTEX | 1%* | N18738 001 | |
| | | AUG 30, 1985 | |

SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-198)

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | SULFAMETHOXAZOLE AND TRIMETHOPRIM | | | |
| AB | PLANTEX/IKAPHARM | 200MG/5ML;40MG/5ML* | N70028 001 | |
| | | JUN 02, 1987 : OCT 29, 1985 | | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | SULFAMETHOXAZOLE AND TRIMETHOPRIM | | | |
| AB | PHARM BASICS | 400MG;80MG* | N70203 001 | |
| | | JUN 02, 1987 : NOV 08, 1985 | | |
| AB | | 800MG;160MG* | N70204 001 | |
| | | JUN 02, 1987 : NOV 08, 1985 | | |
| AB | SIDMAK LABORATORIES | 400MG;80MG* | N70215 001 | |
| | | /JUN 02, 1987 :/SEP 10, 1985 | | |
| AB | | 800MG;160MG | N70216 001 | |
| | | /JUN 02, 1987 :/SEP 10, 1985 | | |
| | SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH | | | |
| AB | PLANTEX/IKAPHARM | 800MG;160MG* | N70037 001 | |
| | | JUN 02, 1987 : SEP 19, 1985 | | |
| | SULFAMETHOXAZOLE AND TRIMETHOPRIM SINGLE STRENGTH | | | |
| AB | PLANTEX/IKAPHARM | 400MG;80MG* | N70030 001 | |
| | | JUN 02, 1987 : SEP 19, 1985 | | |

SULFANILAMIDE (PAGE 3-199)

CREAM; VAGINAL

| | | | |
|---|---|---|---|
| VAGITROL | | | |
| LEMMON | 15%* | N88718 001 | |
| | | SEP 19, 1985 | |

SULFINPYRAZONE (PAGE 3-200)

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | SULFINPYRAZONE | | | |
| AB | PAR PHARMACEUTICAL | 200MG* | N88934 001 | |
| | | | SEP 06, 1985 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | SULFINPYRAZONE | | | |
| AB | PAR PHARMACEUTICAL | 100MG* | N88933 001 | |
| | | | SEP 06, 1985 | |

SULFISOXAZOLE DIOLAMINE (PAGE 3-200)

OPHTHALMIC; SOLUTION

| | | | | |
|---|---|---|---|---|
| > ADD > | SULFISOXAZOLE DIOLAMINE | | | |
| > ADD > AT | ə BARNES-HIND PHARMS | EQ 4% BASE | N84148 001 | |
| | GANTRISIN | | | |
| > ADD > AT | HOFFMAN-LAROCHE | EQ 4% BASE | N07757 002 | |

SUPROFEN (PAGE 3-201)

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| SUPROL | | | |
| ORTHO PHARMACEUTICAL | 200MG* | N18217 001 | |
| | | DEC 24, 1985 | |

TECHNETIUM, TC-99M, SULFUR COLLOID (PAGE 3-203)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | /TECHNETIUM TC 99M SULFUR COLLOID/ | | | |
| > DLT > | /GAMMA DIAG LABS/ | /3MCI/ML/ | /N17724 001/ | |

SOLUTION; INJECTION, ORAL

| | | | |
|---|---|---|---|
| > ADD > | TECHNETIUM TC 99M SULFUR COLLOID | | |
| > ADD > | GAMMA DIAG LABS | 3MCI/ML | N17724 001 |

TECHNETIUM, TC-99M, SULFUR COLLOID KIT (PAGE 3-203)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | /TECHNECOLL/ | | | |
| /AP/ | /MALLINCKRODT/ | /N/A/ | /N17059 001/ | |
| | /TESULOID/ | | | |
| /AP/ | /ER SQUIBB AND SONS/ | /N/A/ | /N16923 001/ | |

SOLUTION; INJECTION, ORAL

| | | | |
|---|---|---|---|
| | TECHNECOLL | | |
| AP | MALLINCKRODT | N/A | N17059 001 |
| | TESULOID | | |
| AP | ER SQUIBB AND SONS | N/A | N16923 001 |

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL

**RESTORIL**

| | | | | |
|---|---|---|---|---|
| AB | SANDOZ PHARMS/SANDOZ | 15MG | N18163 001 | |
| AB | | 30MG | N18163 002 | |
| >DLT> | /SOMAZ/ | | | |
| >ADD> | **TEMAZ** | | | |
| AB | QUANTUM PHARMICS | 15MG¤ | N70564 001 OCT 15, 1985 | |
| AB | | 30MG¤ | N70547 001 OCT 15, 1985 | |

THEOPHYLLINE (PAGE 3-206)

CAPSULE, CONTROLLED RELEASE; ORAL

THEO-DUR SPRINKLE

| | | | | |
|---|---|---|---|---|
| BC | KEY PHARMACEUTICALS | 50MG¤ | N88022 001 SEP 10, 1985 | |
| BC | | 125MG¤ | N88016 001 SEP 10, 1985 | |
| BC | | 200MG¤ | N87995 001 SEP 10, 1985 | |
| | | 75MG¤ | N88015 001 SEP 10, 1985 | |

ELIXIR; ORAL

THEOPHYL 225

| | | | | |
|---|---|---|---|---|
| | /KNOLL PHARMACEUTICAL/ | 112.5MG/15ML | /N86485 001/ | |
| | MCNEIL PHARM | 112.5MG/15ML | N86485 001 | |

SYRUP; ORAL

**ACCURBRON**

| | | | | |
|---|---|---|---|---|
| AA | MERRELL DOW/DOW CHEM | 150MG/15ML¤ | N88746 001 NOV 22, 1985 | |

**THEOPHYLLINE**

| | | | | |
|---|---|---|---|---|
| AA | NATL PHARM MFG/BARRE | 150MG/15ML | N86545 001 | |

TABLET; ORAL

QUIBRON-T

| | | | | |
|---|---|---|---|---|
| | MEAD JOHNSON/B-M | 300MG¤ | N88656 001 AUG 22, 1985 | |

SLO-PHYLLIN

| | | | | |
|---|---|---|---|---|
| /BD/ | /WILLIAM H. RORER/ | /100MG/ | /N85202 001/ | >ADD> |
| /BD/ | | /200MG/ | /N85204 001/ | >ADD> |
| AB | WILLIAM H RORER | 100MG | N85202 001 | |
| AB | | 200MG | N85204 001 | |

THEOPHYL-225

| | | | | |
|---|---|---|---|---|
| | /KNOLL PHARMACEUTICAL/ | 225MG/ | /N84726 001/ | |
| | MCNEIL PHARM | 225MG | N84726 001 | |

TABLET, CHEWABLE; ORAL

THEOPHYL

| | | | | |
|---|---|---|---|---|
| | MCNEIL PHARM | 100MG¤ | N86506 001 SEP 12, 1985 | |

THIORIDAZINE HYDROCHLORIDE (PAGE 3-209)

CONCENTRATE; ORAL

**THIORIDAZINE HCL INTENSOL**

| | | | | |
|---|---|---|---|---|
| AA | ROXANE LABORATORIES | 30MG/ML¤ | N88941 001 DEC 16, 1985 | |
| AA | | 100MG/ML¤ | N88942 001 DEC 16, 1985 | |

TOLAZAMIDE (PAGE 3-212)

TABLET; ORAL

**TOLAZAMIDE**

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 100MG¤ | N70162 001 JAN 14, 1986 | |
| AB | | 250MG¤ | N70163 001 JAN 14, 1986 | |
| AB | | 500MG¤ | N70164 001 JAN 14, 1986 | |
| AB | CHELSEA LABORATORIES | 100MG¤ | N70285 001 JAN 09, 1986 | |
| AB | | 250MG¤ | N70286 001 JAN 09, 1986 | |
| AB | | 500MG¤ | N70287 001 JAN 09, 1986 | |
| >ADD> AB | CORD LABORATORIES | 250MG¤ | N70289 001 MAR 13, 1986 | >ADD> |
| >ADD> AB | | 500MG¤ | N70290 001 MAR 13, 1986 | >ADD> |
| AB | DANBURY PHARMACAL | 100MG¤ | N70513 001 JAN 09, 1986 | |
| AB | | 250MG¤ | N70514 001 JAN 09, 1986 | |
| AB | | 500MG¤ | N70515 001 JAN 09, 1986 | |
| AB | DURAMED PHARMS | 100MG¤ | N70165 001 JAN 10, 1986 | |
| AB | | 250MG¤ | N70166 001 JAN 10, 1986 | |
| AB | | 500MG¤ | N70167 001 JAN 10, 1986 | |
| AB | MYLAN PHARMS | 250MG¤ | N70259 001 JAN 02, 1986 | |
| >ADD> AB | | 500MG¤ | N70913 001 MAR 17, 1986 | >ADD> |
| AB | PAR PHARMACEUTICAL | 100MG¤ | N70159 001 JAN 06, 1986 | |
| AB | | 250MG¤ | N70160 001 JAN 06, 1986 | |
| AB | | 500MG¤ | N70161 001 JAN 06, 1986 | |

TRIENTINE HYDROCHLORIDE (PAGE 3-216)

CAPSULE; ORAL
CUPRID
MS&D RES LABS/MERCK 250MG* N19194 001
NOV 08, 1985

TRIMETHOPRIM (PAGE 3-218)

TABLET; ORAL
TRIMETHOPRIM
AB BARR LABORATORIES 100MG* N70494 001
JAN 22, 1986
> ADD > AB 200MG* N70495 001
> ADD > SEP 24, 1986 : MAR 14, 1986

TROPICAMIDE (PAGE 3-219)

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE
AT MAURRY BIOLOGICAL 1%* N88447 001
AUG 28, 1985

VALPROIC ACID (PAGE 3-220)

CAPSULE; ORAL
DEPAKENE
AB ABBOTT LABORATORIES 250MG N18081 001
VALPROIC ACID
AB PAR PHARMACEUTICAL 250MG* N70431 001
FEB 28, 1986

VANCOMYCIN HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
VANCOCIN HCL
> ADD > ELI LILLY EQ 1GM BASE/VIAL* N62476 002
> ADD > MAR 21, 1986
> ADD > EQ 1GM BASE/VIAL* N60180 002
> ADD > MAR 21, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
VERAPAMIL
> ADD > AP QUAD PHARMS 2.5MG/ML N70672 001
> ADD > MAR 07, 1986

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
VERAPAMIL HCL
AP INTL MEDICATION SYS 2.5MG/ML* N70451 001
DEC 16, 1985
AP LUITPOLD PHARMS 2.5MG/ML* N70225 001
NOV 12, 1985
AP 2.5MG/ML* N70617 001
NOV 12, 1985

VINBLASTINE SULFATE (PAGE 3-221)

INJECTABLE; INJECTION
VELBAN
/ELI LILLY/ /10MG/AMP/ /N12665 001/
AP ELI LILLY 10MG/VIAL N12665 001
VINBLASTINE SULFATE
AP LYPHOMED 10MG/VIAL* N89011 001
NOV 18, 1985

WARFARIN SODIUM (PAGE 3-221)

TABLET; ORAL
COUMADIN
/BX/ /DUPONT PHARMS/DUPONT/2.5MG/ /N09218 018/
AB DUPONT PHARMS/DUPONT 2.5MG N09218 018
WARFARIN SODIUM
AB COLMED LABORATORIES 2.5MG* N88720 001
AUG 06, 1985

CHLORHEXIDINE GLUCONATE (PAGE 3-224)

SOLUTION; TOPICAL
EXIDINE
XTTRIUM LABS 2% N19422 001 DEC 17, 1985
2.5% N19421 001 DEC 17, 1985

CHLORPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-225)

CAPSULE, CONTROLLED RELEASE; ORAL
>ADD< ISOCLOR
>ADD< AM CRITICAL CARE/AHS 8MG;120MG N18747 001 MAR 06, 1986
>ADD<

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

DIPHENHYDRAMINE HYDROCHLORIDE (PAGE 3-225)

SYRUP; ORAL
DIPHEN
BAY LABORATORIES 12.5MG/5ML N70118 001 OCT 01, 1985
HYDRAMINE
NATL PHARM MFG/BARRE 12.5MG/5ML N70205 001 JAN 28, 1986

DOXYLAMINE SUCCINATE (PAGE 3-225)

CAPSULE; ORAL
UNISOM
PFIZER LABS/PFIZER 25G N19440 001 FEB 05, 1986

IBUPROFEN (PAGE 3-225)

TABLET; ORAL
IBUPROFEN
BARR LABORATORIES 200MG N70493 001 SEP 24, 1986 : DEC 24, 1985
>ADD< DANBURY PHARMACAL 200MG N70435 001 >ADD< SEP 24, 1986 : MAR 05, 1986
PAR PHARMACEUTICAL 200MG N70481 001 SEP 24, 1986 : OCT 18, 1985
MEDIPREN
MCNEIL CONSUMER PROD 200MG N70475 001 SEP 24, 1986 : FEB 06, 1986

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

INJECTABLE; INJECTION
HUMULIN L
ELI LILLY 100 UNITS/ML N19377 002 SEP 30, 1985

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

INJECTABLE; INJECTION
HUMULIN N
ELI LILLY 100 UNITS/ML N18781 001 OCT 28, 1986

POVIDONE-IODINE (PAGE 3-228)

SPONGE; TOPICAL
POVIDONE-IODINE
PARKE-DAVIS/DESERET 20% N19240 001 NOV 29, 1985

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-228)

CAPSULE; CONTROLLED RELEASE; ORAL
/SUDAFED S.A./
SUDAFED 12 HOUR



>ADD< PYRITHIONE ZINC (PAGE 3-228)

>_ADD_> PYRITHIONE ZINC (PAGE 3-228)

>_ADD_>  LOTION; TOPICAL
>_ADD_>  HEAD & SHOULDERS CONDITIONER
>_ADD_>  PROCTER AND GAMBLE  0.3%  N19412 001
>_ADD_>  MAR 10, 1986
>_ADD_>  0.3%  N19412 002
>_ADD_>  MAR 10, 1986
>_ADD_>  0.3%  N19412 003
>_ADD_>  MAR 10, 1986
>_ADD_>  0.3%  N19412 004
>_ADD_>  MAR 10, 1986

NO SEPTEMBER - MARCH 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

## APPENDIX 1

## ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

The Orphan Drug Act amendments, which provide incentives to encourage the development of orphan drugs and biological products, became effective on January 4, 1983.

Section 526 of the 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 NDA or license approval for a designated orphan drug. The period of exclusivity may be revoked during the seven year period by written consent of the sponsor or by FDA action after finding that the sponsor holding exclusivity cannot assure the availability of sufficient quantities of the drug to meet the needs of patients with the designated orphan indication.

Orphan Drug exclusive approval status (coded ODE) applies only to the 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 exclusivity for the approved indication beginning on the date of NDA or biological license approval for the drug. No subsequent sponsor may receive approval of an NDA, Biological License, paper NDA, or ANDA during the seven year period.

Biologicals, Antibiotics or Drugs that have been approved under Section 505 of the 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.

### BIOLOGICAL PRODUCTS

| Active Ingred.(s)<br>Strength | Trade Name<br>Dosage Form; Route | Applicant | License Number<br>Approval Date | Exclusivity<br>Exp.Date |
|---|---|---|---|---|
| Hemin<br>313mg/amp | Panhematin<br>Injectable; Injection | Abbott<br>Laboratories | 43<br>Jul 20, 1983 | ODE<br>Jul 20, 1990 |

APPENDIX 1

DRUG PRODUCTS

| Active Ingred.(s) Strength(s) | Trade Name Dosage Form; Route | Applicant | Appl. Prod. Approval Date | Exclusivity Exp. Date |
|---|---|---|---|---|
| Chenodiol 250mg | Chenix Tablet; Oral | Rowell Laboratories | 18513 002 Jul 28, 1983 | ODE Jul 28, 1990 |
| L-Carnitine 330mg | L-Carnitine Tablet; Oral | Sigma-Tau | 18948 001 Dec 27, 1985 | ODE Dec 27, 1992 |
| Naltrexone Hydrochloride 50mg | Trexan Tablet; Oral | Dupont Pharms | 18932 001 Nov 20, 1984 | ODE Nov 20, 1991 |
| Monooctanoin 100% | Moctanin Liquid; Perfusion Biliary | Ascot Hosp Pharms | 19368 001 Oct 29, 1985 | ODE Oct 29, 1992 |
| Pentamidine Isethionate 300mg/ml | Pentam 300 Injectable; Injection | LyphoMed | 19264 001 Oct 16, 1984 | ODE Oct 16, 1991 |
| Potassium Citrate 5meq | Urocit-K Tablet; Oral | Univ of Tx Hlth Sci Ctr | 19071 001 Aug 30, 1985 | ODE Aug 30, 1992 |

(continued)

APPENDIX 1

DRUG PRODUCTS

(continued)

| Active Ingred.(s)<br>Strength(s) | Trade Name<br>Dosage Form; Route | Applicant | Appl. Prod.<br>Approval Date | Exclusivity<br>Exp. Date |
|---|---|---|---|---|
| Somatrem<br>5mg/vial | Protropin<br>Injectable;<br>Injection | Genentech | 19107 001<br>Oct 17, 1985 | ODE<br>Oct 17, 1992 |
| 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 |

# APPENDIX 2

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

Acetaminophen; Aspirin;
Butalbital
Capsule or Tablet; Oral
160-165mg; 160-165mg; 50mg

Acetaminophen; Aspirin;
Butalbital
Capsule or Tablet; Oral
325mg; 325mg; 50mg

Acetaminophen; Aspirin;
Butalbital; Caffeine
Capsule or Tablet; Oral
160-165mg; 160-165mg; 50mg; 40mg

Acetaminophen; Aspirin;
Butalbital; Caffeine
Capsule or Tablet; Oral
325mg; 325mg; 50mg; 40mg

Acetaminophen; Butalbital
Capsule or Tablet; Oral
325mg; 50mg
650mg; 50mg

Acetaminophen; Butalbital;
Caffeine
Capsule or Tablet; Oral
325mg; 50mg; 40mg
650mg; 50mg; 40mg

Aminophylline
Tablet; Oral
100mg
200mg

Aspirin; Butalbital;
Capsule or Tablet; Oral
325mg; 50mg
650mg; 50mg

Aspirin; Butalbital; Caffeine
Capsule or Tablet; Oral
325mg; 50mg; 40mg;
650mg; 50mg; 40mg;

Aspirin; Caffeine;
Carisoprodol
Tablet; Oral
160mg; 32mg; 200mg

Aspirin; Caffeine;
Carisoprodol; Codeine Phosphate
Tablet; Oral
160mg; 32mg; 200mg; 16mg

Aspirin; Carisoprodol
Tablet; Oral
325mg; 200mg

Aspirin; Carisoprodol;
Codeine Phosphate
325mg; 200mg; 10mg

Aspirin; Meprobamate
Tablet; Oral
325mg; 200mg

Aspirin; Methocarbamol
Tablet; Oral
325mg; 200mg

Chlorothiazide
Tablet; Oral
250mg

Estrogens, Conjugated; Meprobamate
Tablet; Oral
0.4mg; 200mg
0.4mg; 400mg

Hydroxyzine Hydrochloride
Tablet; Oral
10mg
25mg
50mg
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 18B-31, 5600 Fishers Lane, Rockville, MD 20857.

| Name of Drug | Date |
|---|---|
| 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 |
| Carbamazepine | Dec 05, 1984 |
| Chlordiazepoxide Hydrochloride | Jul 05, 1983 |
| Chlorpropamide | Jul 05, 1983 |
| Chlorthalidone | Jul 05, 1983 |
| Clonidine Hydrochloride | Dec 05, 1984 |
| Diazepam (revised) | Jul 08, 1985 |
| Dicyclomine Hydrochloride | Aug 10, 1984 |
| Dipyridamole | Jul 05, 1983 |
| Disopyramide Phosphate | Jul 09, 1985 |
| Dissolution Testing (General) | Apr 19, 1983 |
| Doxepin Hydrochloride | Apr 02, 1985 |
| Erythromycin | Apr 05, 1977 |
| Flurazepam | Oct 15, 1985 |
| Hydrochlorothiazide | Jul 25, 1983 |

(continued)

APPENDIX 3

(continued)

| Name of Drug | Date |
|---|---|
| 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 |
| Methyltestosterone | Nov 16, 1979 |
| Metoclopramide | Dec 27, 1984 |
| Nitrofurantoin (Macrocrystalline) | Oct 29, 1985 |
| Phentermine Hydrochloride (Dissolution) | Nov 21, 1980 |
| Phentermine Hydrochloride (Slow Dissolving; 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 |
| Quinidine Gluconate (Controlled Release) | Jun 15, 1981 |
| Spironolactone | 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 |
| 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

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Acetaminophen;<br>Codeine Phosphate<br>Soft Gelatin<br>Capsule; Oral | 300mg<br>30mg | 85 P-0543/CP | New Dosage Form | Approved<br>Mar 18, 1986 |
| Acetaminophen;<br>Codeine Phosphate<br>Soft Gelatin<br>Capsule; Oral | 500mg<br>7.5mg | 85 P-0543/<br>CP0002 | New Dosage 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 | New Dosage Form<br>New Strength | Approved<br>Mar 19, 1986 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Acetaminophen;<br>Hydrocodone Bitartrate<br>Solution; Oral | 500mg/15ml<br>5mg/15ml | 84 P-0391/CP | New Dosage Form | Approved<br>Jul 2, 1985 |
| Acetaminophen;<br>Oxycodone Hydrochloride<br>Solution; Oral | 325mg/5ml<br>5mg/5ml | 85 P-0085/CP | New Dosage Form | Approved<br>Aug 23, 1985 |
| Acetaminophen;<br>Oxycodone Hydrochloride<br>Soft Gelatin<br>Capsule; Oral | 500mg<br>5mg | 85 P-0543/<br>CP0003 | New Dosage Form | Approved<br>Mar 18, 1986 |
| Acetaminophen;<br>Propoxyphene Hydrochloride<br>Soft Gelatin<br>Capsule; Oral | 500mg<br>32mg | 85 P-0581/CP | New Dosage Form<br>New Strength | Approved<br>Mar 18, 1986 |
| Acetaminophen<br>Suppository; Rectal | 80mg | 85 P-0403/CP | New Dosage Form<br>(Pediatric) | Approved<br>Oct 16, 1985 |

(continued)

## APPENDIX 4

### I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Aminocaproic Acid<br>Injectable; Injection | 500mg/ml<br>10ml/vial | 85 P-0308/CP | New Strength | Approved<br>Feb 12, 1986 |
| Aminophylline<br>Injectable; Injection | 10mg/ml<br>10ml/vial | 85 P-0459/CP | New Strength | Approved<br>Feb 12, 1986 |
| Aminophylline<br>Injectable; Injection | 50mg/ml<br>20ml/vial | 85 P-0459/CP | New Strength | Approved<br>Feb 12, 1986 |
| Azatadine Maleate;<br>Phenylpropanolamine<br>Hydrochloride<br>Sustained Release<br>Capsule; Oral | 1mg<br>75mg | 85 P-0492/CP | New Combination New Dosage Form | Approved<br>Jan 28, 1986 |
| Benztropine Mesylate<br>Syrup; Oral | 0.5mg/5ml | 85 P-0423/CP | New Dosage Form | Approved<br>Oct 16, 1985 |
| Brompheniramine Maleate;<br>Pseudoephedrine<br>Hydrochloride<br>Sustained Release<br>Capsule; Oral | 12mg<br>120mg | 85 P-0095/CP | New Combination New Dosage Form | Approved<br>Dec 13, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Chlorpheniramine Maleate;<br>Phenylpropanolamine Hydrochloride<br>Controlled-release Capsule; Oral | 10mg<br>75mg | 85 P-0149/CP | New Strength | Approved<br>Dec 13, 1985 |
| Chlorhexidine Gluconate<br>Solution; Topical | 1.5% | 84 P-0417/CP | New Strength | Approved<br>Sep 18, 1985 |
| Codeine Phosphate;<br>Dexbrompheniramine Maleate;<br>Phenylpropanolamine Hydrochloride<br>Syrup; Oral | 10mg/5ml<br>1mg/5ml<br>12.5mg/5ml | 85 P-0269/CP | New Combination | Approved<br>Dec 6, 1985 |
| Dexbrompheniramine Maleate;<br>Phenylpropanolamine Hydrochloride<br>Time Release Capsule; Oral | 6mg<br>75mg | 85 P-0238/<br>CP0002 | New Combination | Approved<br>Dec 13, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Dexbrompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral | 6mg<br>120mg | 85 P-0140/CP | New Combination New Dosage Form | Approved Dec 13, 1985 |
| Dexbrompheniramine Maleate; Pseudoephedrine Sulfate Sustained Release Capsule; Oral | 6mg<br>120mg | 85 P-0140/ CP0002 | New Dosage Form | Approved Jan 22, 1986 |
| Diazepam Solution; Oral | 5mg/5ml | 85 P-0090/CP | New Dosage Form | Approved Sep 19, 1985 |
| Diazepam Syrup; Oral | 2mg/5ml | 85 P-0499/CP | New Dosage Form | Approved Feb 28, 1986 |
| Diazepam Intensol Solution (Concentrate); Oral | 5mg/ml | 85 P-0566/CP | New Dosage Form | Approved Mar 18, 1986 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Diphenhydramine Hydrochloride<br>Concentrate; Oral | 50mg/ml | 84 P-0174/CP | New Strength | Approved<br>Sep 11, 1985 |
| Disulfiram<br>Suspension; Oral | 500mg/30ml | 85 P-0215/CP | New Dosage Form | Approved<br>Oct 8, 1985 |
| Estradiol<br>Tablet; Oral | 0.5mg | 84 P-0308/CP | New Strength | Approved<br>Mar 24, 1986 |
| Fluorouracil<br>Injectable; Injection | 25mg/ml | 85 P-0208/CP | New Strength | Approved<br>Oct 8, 1985 |
| Flurazepam<br>Concentrate; Oral | 30mg/ml | 85 P-0081/CP | New Dosage Form | Approved<br>Jul 10, 1985 |
| Flurazepam Hydrochloride<br>Solution; Oral | 15mg/5ml | 85 P-0091/CP | New Dosage Form | Approved<br>Oct 25, 1985 |
| Furosemide<br>Solution; Oral | 40mg/5ml | 85 P-0106/<br>CP0002 | New Strength | Approved<br>Sep 19, 1985 |
| Furosemide<br>Concentrate; Oral | 80mg/ml | 85 P-0106/CP | New Strength | Approved<br>Sep 19, 1985 |

(continued)

## APPENDIX 4

### I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Haloperidol<br>Solution; Oral | 2mg/5ml | 85 P-0076/<br>CP0002 | New Strength | Approved<br>Mar 26, 1986 |
| Haloperidol<br>Solution; Oral | 5mg/5ml | 85 P-0080/CP | New Strength | Approved<br>Sep 19, 1985 |
| Hydralazine Hydrochloride<br>Solution; Oral | 25mg/5ml | 85 P-0074/CP | New Dosage Form | Approved<br>Jul 3, 1985 |
| Ibuprofen<br>Capsule; Oral | 200mg | 84 P-0383/CP | New Dosage Form | Approved<br>Jun 25, 1985 |
| Ibuprofen<br>Soft Gelatin<br>Capsule; Oral | 300mg<br>400mg<br>600mg | 85 P-0563/CP | New Dosage Form | Approved<br>Mar 19, 1986 |
| Indomethacin<br>Suspension; Oral | 25mg/5ml | 85 P-0077/<br>CP0002 | New Dosage Form | Approved<br>Jul 19, 1985 |
| Isoniazid<br>Concentrate; Oral | 50mg/ml | 85 P-0468/CP | New Strength | Approved<br>Dec 13, 1985 |

(continued)

## APPENDIX 4

### I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Ketoconazole<br>Suspension; Oral | 20mg/ml | 85 P-0147/CP | New Dosage Form | Approved<br>Sep 27, 1985 |
| Leucovorin Calcium<br>Tablet; Oral | 15mg | 85 P-0487/CP | New Strength | Approved<br>Jan 28, 1986 |
| Meperidine Hydrochloride<br>Concentrate; Oral | 100mg/ml | 84 P-0175/CP | New Strength | Approved<br>Jun 7, 1985 |
| Metaproterenol Sulfate<br>Solution; Inhalation | 10mg/2.5ml | 85 P-0509/CP | New Strength | Approved<br>Feb 28, 1986 |
| Metaproterenol Sulfate<br>Solution; Inhalation | 10mg/3ml | 85 P-0429/<br>CP0002 | New Strength | Approved<br>Feb 28, 1986 |
| Metaproterenol Sulfate<br>Solution; Inhalation | 15mg/3ml | 85 P-0429/CP | New Strength | Approved<br>Feb 28, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>20ml/vial | 86 P-0036/CP | New Strength | Approved<br>Mar 18, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>50ml/vial | 85 P-0545/CP | New Strength | Approved<br>Feb 28, 1986 |

(continued)

(continued)



## APPENDIX 4

### I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>50ml/vial | 85 P-0540/CP | New Strength | Approved<br>Feb 28, 1986 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 5mg/ml<br>100ml/vial | 85 P-0540/CP | New Strength | Approved<br>Feb 28, 1986 |
| Methyldopate Hydrochloride<br>Injectable; Injection | 50mg/ml<br>10ml/vial | 85 P-0404/CP | New Strength | Approved<br>Oct 25, 1985 |
| Methyltestosterone<br>Capsule; Oral | 25mg | 85 P-0067/CP | New Dosage Form | Approved<br>Aug 23, 1985 |
| Miconazole Nitrate<br>Cream; Vaginal | 4% | 84 P-0398/CP | New Strength | Approved<br>Mar 31, 1986 |
| Nitroglycerin<br>Injectable; Injection | 10mg/ml | 85 P-0134/CP | New Strength | Approved<br>Sep 19, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Probucol<br>Tablet; Oral | 500mg | 85 P-0337/CP | New Strength | Approved<br>Oct 25, 1985 |
| Procainamide Hydrochloride<br>Tablet; Oral | 375mg | 85 P-0125/CP | 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 | New Dosage Form | Approved<br>Mar 19, 1986 |
| Propranolol Hydrochloride<br>Solution; Oral | 40mg/5ml | 85 P-0073/CP | New Dosage Form | Approved<br>Jul 8, 1985 |
| Propranolol Hydrochloride<br>Concentrate; Oral | 80mg/ml | 85 P-0073/<br>CP0002 | New Dosage Form | Approved<br>Jul 19, 1985 |
| Propranolol Hydrochloride<br>Solution; Oral | 20mg/5ml | 85 P-0073/<br>CP0003 | New Dosage Form | Approved<br>Sep 24, 1985 |
| Propranolol Hydrochloride<br>Tablet; Constant-Release;<br>Oral | 160mg | 85 P-0129/CP | New Dosage Form | Approved<br>Sep 25, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Propranolol Hydrochloride<br>Tablet, Controlled Release;<br>Oral | 80mg<br>120mg<br>160mg | 85 P-0197/CP | New Dosage Form | Approved<br>Sep 27, 1985 |
| Pyridostigmine Bromide<br>Tablet; Oral | 30mg | 85 P-0412/CP | New Strength | Approved<br>Jan 22, 1986 |
| Scopolamine Transdermal System/24 Hour<br>Film, Controlled Release;<br>Percutaneous | 1mg | 85 P-0168/CP | New Strength (Dosing Interval) | Approved<br>Sep 27, 1985 |
| Spironolactone<br>Syrup; Oral | 25mg/5ml | 85 P-0510/CP | New Dosage Form | Approved<br>Jan 22, 1986 |
| Spironolactone<br>Oral; Injection | 25mg/5ml | 86 P-0055/CP<br>Form | New Dosage<br>Mar 28, 1986 | Approved |
| Theophylline<br>Capsule; Oral | 150mg<br>300mg | 85 P-0175/CP | New Strength | Approved<br>Oct 8, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Vinblastine Sulfate<br>Injectable; Injection | 1mg/ml | 86 P-0056/CP | New Dosage Form | Approved<br>Mar 28, 1986 |
| Vincristine Sulfate<br>Injectable; Injection | 2mg/vial | 85 P-0016/CP | New Dosage Form | Approved<br>Nov 8, 1985 |

# APPENDIX 4

## II. Petitions Denied

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Acetaminophen;<br>Hydrocodone<br>Bitartrate<br>Tablet; Oral | 650mg<br>10mg | 85 P-0015/CP | New Strength | Denied<br>Nov 7, 1985 |
| Acetaminophen;<br>Hydrocodone<br>Bitartrate<br>Tablet; Oral | 750mg<br>7.5mg | 85 P-0169/CP | New Strength | Denied<br>Nov 7, 1985 |
| Aminocaproic Acid<br>Injectable; Injection | 500mg/ml | 85 P-0064/CP | New Strength | Denied<br>May 29, 1985 |
| Aminophylline<br>Injectable; Injection | 10mg/ml | 85 P-0066/CP | New Strength | Denied<br>May 3, 1985 |
| Aminophylline<br>Injectable; Injection | 50mg/ml | 85 P-0066/CP | New Strength | Denied<br>May 3, 1985 |

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Aspirin;<br>Chlorzoxazone<br>Tablet; Oral | 325mg<br>250mg | 85 P-0071/CP | New 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 | New 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 | New Combination | Denied<br>Sep 11, 1985 |

(continued)

# APPENDIX 4

## II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Aspirin;<br>Butalbital;<br>Caffeine;<br>Codeine Phosphate<br>Capsule; Oral | 325mg<br>50mg<br>40mg<br>30mg | 85 P-0101/CP | New 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 | New Combination | Denied<br>Sep 11, 1985 |
| Benzoyl Metronidazole<br>Suspension; Injection | 200mg/5ml | 85 P-0258/CP | New Ester<br>New Ingredient | Denied<br>Mar 19, 1986 |
| Bretylium Tosylate<br>Injectable; Injection | 2mg/ml | 85 P-0063/CP | New Strength | Denied<br>May 29, 1985 |

(continued)

## APPENDIX 4

### II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Bretylium Tosylate<br>Injectable; Injection | 4mg/ml | 85 P-0063/<br>CP0002 | New Strength | Denied<br>May 29, 1985 |
| Bretylium Tosylate<br>Injectable; Injection | 8mg/ml | 85 P-0063/<br>CP0003 | New Strength | Denied<br>May 29, 1985 |
| Bretylium Tosylate<br>Injectable; Injection | 10mg/ml | 85 P-0063/<br>CP0004 | 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 | 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 | New<br>Combination | Denied<br>Nov 8, 1985 |

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Cholecalciferol<br>Capsule; Oral<br>Capsule; Oral | 1.25mg | 84 P-0161/CP | New Active Ingredient | Denied<br>Feb 13, 1986 |
| Codeine Phosphate;<br>Ibuprofen<br>Capsule; Oral | 30mg<br>200mg | 84 P-0388/CP | New Combination | Denied<br>Sep 16, 1985 |
| Codeine Phosphate;<br>Ibuprofen | 60mg<br>200mg | 84 P-0388/CP | New Combination | Denied<br>Sep 16, 1985 |
| Codeine Phosphate;<br>Ibuprofen<br>Tablet; Oral | 30mg<br>200mg | 84 P-0388/CP | New Combination | Denied<br>Sep 16, 1985 |
| Codeine Phosphate;<br>Ibuprofen<br>Tablet; Oral | 60mg<br>200mg | 84 P-0388/CP | New Combination | Denied<br>Sep 16, 1985 |

(continued)

APPENDIX 4

## II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Diatrizoate Meglumine;<br>Lidocaine Hydrochloride<br>Injectable; Injection | 60%<br>1.5mg/ml | 84 P-0325/CP | New Combination | Denied<br>Sep 3, 1985 |
| Diazepam Intensol<br>Concentrate; Oral | 10mg/ml | 85 P-0075/CP | New Dosage Form | Denied<br>Sep 24, 1985 |
| Tri-Phasic Contraceptive<br>Tablet; Oral(21 and 28 days)<br>Ethinyl Estradiol<br>Norethindrone<br><br>Ethinyl Estradiol<br>Norethindrone<br><br>Ethinyl Estradiol<br>Norethindrone | <br><br>0.05mg<br>0.5mg<br><br>0.05mg<br>0.75mg<br><br>0.05mg<br>1.0mg | 84 P-0443/CP | New Strength (Dose Schedule) | Denied<br>Sep 3, 1985 |
| Fluphenazine Hydrochloride<br>Injectable; Injection | 5mg/ml | 85 P-0019/CP | New Strength | Denied<br>Oct 25, 1985 |
| Heparin Sodium<br>Injectable; Injection | 2000 Units/ml | 85 P-0065/CP | New Strength | Denied<br>May 29, 1985 |

(continued)

APPENDIX 4

## II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Heparin Sodium<br>Injectable; Injection | 4000 Units/ml | 85 P-0065/CP | New Strength | Denied<br>May 29, 1985 |
| Ibuprofen;<br>Oxycodone Hydrochloride<br>Capsule; Oral | 200mg<br>5mg | 85 P-0141/CP | New<br>Combination | Denied<br>Sep 27, 1985 |
| Ibuprofen;<br>Oxycodone Hydrochloride<br>Tablet; Oral | 200mg<br>5mg | 85 P-0141/CP | New<br>Combination | Denied<br>Sep 27, 1985 |
| Indomethacin<br>Tablet; Oral | 25mg | 85 P-0025/CP | New Dosage<br>Form | Denied<br>Mar 31, 1986 |
| Indomethacin<br>Tablet; Oral | 50mg | 85 P-0025/CP | New Dosage<br>Form | Denied<br>Mar 31, 1986 |
| Indomethacin<br>Tablet, Constant<br>Release; Oral | 75mg | 85 P-0026/CP | New Dosage<br>Form | Denied<br>Sep 16, 1985 |

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Metoclopramide Hydrochloride<br>Injectable; Injection | 10mg/ml | 85 P-0062/CP | New Strength | Denied<br>May 29, 1985 |
| Metoclopramide Hydrochloride<br>Injectable; Injection | 20mg/ml | 85 P-0062/<br>CP0002 | New Strength | Denied<br>May 29, 1985 |
| Metronidazole<br>Sponge; Vaginal | 50-125mg/<br>Sponge | 85 P-0117/CP | New Dosage Form | Denied<br>Oct 8, 1985 |
| Nitroglycerin<br>Transdermal System | None<br>Given | 84 P-0302/CP | New Dosage Form<br>(New Matrix) | Denied<br>Jul 29, 1985 |
| Phenylephrine Hydrochloride;<br>Sulfathiazole<br>Nasal Suspension;<br>Topical | 0.5%<br>5% | 85 P-0205/CP | New Dosage Form<br>New Combination | Denied<br>Nov 14, 1985 |

(continued)

APPENDIX 4

II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form; Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Pseudoephedrine Polisterex Controlled Release Capsule; Oral | 60mg | 85 P-0334/CP | New Salt<br>New Ingredient | Denied<br>Mar 19, 1986 |
| Triamcinolone Acetonide Suspension; Injection | 2.5mg/ml | 85 P-0001/CP | New Strength | Denied<br>Mar 4, 1985 |
| Triamcinolone Acetonide Suspension; Injection | 3mg/ml | 84 P-0240/CP | 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 |
| RTO | 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 |

### REFERENCES

NEW 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 |
| 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 |

(continued)

(continued)



## APPENDIX 5

(continued)

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 |
| 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 OTITIS MEDIA |
| 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 |

(continued)

## APPENDIX 5

(continued)

NEW INDICATION

| | |
|---|---|
| I-29 | INTRACORONARY USE |
| I-30 | PEDIATRIC USE |
| I-31 | DIRECT ISOTOPIC CYSTOGRAPHY |
| I-32 | POSTPARTUM HEMORRHAGE |
| I-33 | USE IN METHODONE 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 WITH CHEMOTHERAPY FOR TREATMENT OF BREAST CANCER FOLLOWING MASTECTOMY |
| I-40 | ANTIDOTE FOR ACETAMINOPHEN OVERDOSE |
| I-41 | MANAGEMENT OF HYPOCALCEMIA AND RESULTANT METABOLIC BONE DISEASE IN RENAL DIALYSIS PATIENTS |

## APPENDIX 6



PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPENDIX 6



PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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

| APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|

NO SEPTEMBER - MARCH ACTIONS

**PRESCRIPTION AND OTC DRUG PRODUCT**
**PATENT AND EXCLUSIVITY DATA**

| | APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|---|
| | 12142 001 | 4537883 | AUG 27, 2002 | | |
| | 12142 002 | 4537883 | AUG 27, 2002 | | |
| | 12142 003 | 4537883 | AUG 27, 2002 | | |
| | 12142 004 | 4537883 | AUG 27, 2002 | | |
| | 12142 005 | 4537883 | AUG 27, 2002 | | |
| | 12365 005 | 4534973 | AUG 13, 2002 | | |
| | 12366 002 | 4534974 | AUG 13, 2002 | | |
| | 13601 001 | | | I-40 | JAN 31, 1988 |
| | 13601 002 | | | I-40 | JAN 31, 1988 |
| >_DLT_> | /14715/001/ | /3428735/ | /FEB/18,/1986/ | | |
| >_ADD_> | 14715 004 | 3428735 | FEB 18, 1986 | | |
| | /16273/001/ | /4324779/ | /APR/13,/1999/ | | |
| | /16273/002/ | /4324779/ | /APR/13,/1999/ | | |
| | /16273/003/ | /4324779/ | /APR/13,/1999/ | | |
| | /16363/001/ | /4324779/ | /APR/13,/1999/ | | |
| | 16636 002 | | | D-9 | SEP 24, 1986 |
| | | | | D-10 | |
| | | | | D-11 | |
| | | | | I-33 | |

| | APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|---|
| | 16983 001 | | | I-36 | SEP 09, 1988 |
| | 16990 001 | 3634582 | JAN 11, 1989 | | |
| | | 3860618 | JAN 14, 1992 | | |
| | 17560 001 | RE28636 | JUN 02, 1987 | /I-21/ | /SEP/24,/1986/ |
| | 17560 002 | RE28636 | JUN 02, 1987 | /I-21/ | /SEP/24,/1986/ |
| | 17581 001 | 3998966 | DEC 21, 1993 | /NS/ | /SEP/24,/1986/ |
| | 17601 001 | /3419565/ | /DEC/31,/1985/ | | |
| | | /3717647/ | /FEB/20,/1990/ | | |
| | 17613 001 | /3839573/ | /OCT/01,/1991/ | | |
| | 17619 001 | /3839573/ | /OCT/01,/1991/ | | |
| | /17688/001/ | /4324779/ | /APR/13,/1999/ | | |
| | 17717 001 | /3839573/ | /OCT/01,/1991/ | | |
| | 17760 001 | | | NDF | SEP 04, 1988 |
| | 17768 001 | 3855140 | DEC 17, 1991 | I-38 | SEP 24, 1986 |
| | | 3960745 | DEC 17, 1991 | | |
| >_ADD_> | 17785 001 | | | NDF | MAR 07, 1989 |
| | 17862 001 | 4536386 | AUG 20, 2002 | | |
| | 17970 001 | 4536516 | AUG 20, 2002 | I-39 | DEC 10, 1988 |
| | 18044 001 | | | I-41 | JAN 22, 1989 |
| | 18044 002 | | | I-41 | JAN 22, 1989 |

(continued)

## APPENDIX 6

### PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

(continued)

| APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|
| 18052 001 | /3839573/ | /OCT/01,/1991/ | | |
| 18053 003 | | | I-37 | SEP 25, 1988 |
| 18147 002 | /RE29668/ | /DEC/10,/1991/ | | |
| | /4100347/ | /JUL/11,/1995/ | | |
| | /3927002/ | /DEC/16,/1992/ | | |
| 18147 003 | /RE29668/ | /DEC/10,/1991/ | | |
| | /4100347/ | /JUL/11,/1995/ | | |
| | /3927002/ | /DEC/16,/1992/ | | |
| /18154/001/ | /3461461/ | /AUG/12,/1986/ | | |
| 18154 001 | 3461461 | MAY 07, 1985 | | |
| /18154/003/ | /3461461/ | /AUG/12,/1986/ | | |
| 18154 003 | 3461461 | MAY 07, 1985 | | |
| 18181 001 | /3839573/ | /OCT/01,/1991/ | | |
| 18182 001 | /3839573/ | /OCT/01,/1991/ | | |
| 18183 001 | /3839573/ | /OCT/01,/1991/ | | |
| 18217 001 | 4035376 | JUL 12, 1994 | NCE | DEC 24, 1990 |
| 18230 001 | /3839573/ | /OCT/01,/1991/ | | |
| 18240 001 | | | I-35 | SEP 04, 1988 |
| 18240 002 | | | I-35 | SEP 04, 1988 |
| 18401 001 | 3433791 | MAR 18, 1986 | | |
| 18423 001 | 3855140 | DEC 17, 1991 | | |
| | 3960745 | DEC 17, 1991 | | |
| 18482 001 | 3784684 | JAN 08, 1991 | | |
| 18506 001 | /3419565/ | /DEC/31,/1985/ | | |
| | /3717647/ | /FEB/20,/1990/ | | |
| 18509 001 | | | NP | AUG 07, 1988 |
| 18513 002 | | | ODE | JUL 28, 1990 |
| 18587 003 | 3658993 | APR 25, 1989 | NCE | SEP 07, 1992 |
| 18644 001 | 3819706 | JUN 25, 1991 | NCE | DEC 30, 1990 |
| | 3885046 | MAY 20, 1992 | | |
| | 4057323 | MAR 26, 2002 | | |
| | 4347257 | AUG 31, 1999 | | |
| | 4393078 | JUL 12, 2000 | | |
| | 4425363 | JAN 10, 2001 | | |
| | 4435449 | MAR 06, 2001 | | |
| | 4438138 | MAR 20, 2001 | | |
| 18644 002 | 3819706 | JUN 25, 1991 | NCE | DEC 30, 1990 |
| | 3885046 | MAY 20, 1992 | | |
| | 4057323 | MAR 26, 2002 | | |
| | 4347257 | AUG 31, 1999 | | |
| | 4393078 | JUL 12, 2000 | | |
| | 4425363 | JAN 10, 2001 | | |
| | 4435449 | MAR 06, 2001 | | |
| | 4438138 | MAR 20, 2001 | | |
| 18644 003 | 3819706 | JUN 25, 1991 | NCE | DEC 30, 1990 |
| | 3885046 | MAY 20, 1992 | | |
| | 4057323 | MAR 26, 2002 | | |
| | 4347257 | AUG 31, 1999 | | |
| | 4393078 | JUL 12, 2000 | | |
| | 4425363 | JAN 10, 2001 | | |
| | 4435449 | MAR 06, 2001 | | |
| | 4438138 | MAR 20, 2001 | | |
| 18654 001 | 4280957 | JUL 28, 1998 | NCE | DEC 20, 1990 |
| 18677 001 | 4087545 | MAY 02, 1995 | NCE | DEC 26, 1990 |
| | 4087547 | MAY 02, 1995 | | |
| 18683 001 | 4393871 | JUL 19, 2000 | | |

(continued)

(continued)

## APPENDIX 6



### PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

(continued)

| APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|
| 18701 001 | 3438991 | APR 15, 1986 | NE | JAN 14, 1989 |
| 18703 002 | 4128658 | DEC 05, 1995 | NCE | JUN 09, 1993 |
| | 4521431 | JUN 04, 2002 | I-15 | JUN 28, 1988 |
| 18705 001 | | | NDF | OCT 31, 1988 |
| 18708 001 | 3845039 | OCT 29, 1991 | NCE | DEC 27, 1990 |
| | 3920818 | NOV 18, 1992 | | |
| 18713 001 | /3839573/ | /OCT/01;/1991/ | | |
| 18735 001 | 4001323 | JAN 04, 1994 | NCE | DEC 31, 1990 |
| 18735 002 | 4001323 | JAN 04, 1994 | NCE | DEC 31, 1990 |
| 18735 003 | 4001323 | JAN 04, 1994 | NCE | DEC 31, 1990 |
| 18735 004 | 4001323 | JAN 04, 1994 | NCE | DEC 31, 1990 |
| 18738 001 | 4055652 | OCT 25, 1994 | NCE | AUG 30, 1990 |
| 18754 002 | 3641127 | FEB 08, 1989 | NCE | JAN 09, 1991 |
| 18754 003 | 3641127 | FEB 08, 1989 | NCE | JAN 09, 1991 |
| 18813 001 | /3839573/ | /OCT/01;/1991/ | | |
| 18827 001 | /3839573/ | /OCT/01;/1991/ | | |
| 18830 001 | 3900481 | AUG 19, 1992 | NCE | OCT 31, 1990 |
| 18830 001 | 4005209 | JAN 25, 1994 | NCE | OCT 31, 1990 |
| 18830 002 | 3900481 | AUG 19, 1992 | NCE | OCT 31, 1990 |
| 18830 002 | 4005209 | JAN 25, 1994 | NCE | OCT 31, 1990 |
| 18859 001 | 4211771 | JUL 08, 1997 | NCE | DEC 31, 1990 |
| | RE29835 | MAR 19, 1991 | | |
| 18873 002 | 3954872 | MAY 04, 1993 | NCE | DEC 30, 1990 |
| | 4031244 | JUN 21, 1994 | | |
| 18873 003 | 3954872 | MAY 04, 1993 | NCE | DEC 30, 1990 |
| | 4031244 | JUN 21, 1994 | | |
| 18873 004 | 3954872 | MAY 04, 1993 | NCE | DEC 30, 1990 |
| | 4031244 | JUN 21, 1994 | | |
| 18887 001 | 3686412 | AUG 22, 1989 | NDF | DEC 05, 1988 |
| | 3777033 | AUG 22, 1989 | | |
| 18891 001 | 4559222 | DEC 17, 2002 | | |
| 18891 002 | 4559222 | DEC 17, 2002 | | |
| 18891 003 | 4559222 | DEC 17, 2002 | | |
| 18928 001 | 4221778 | SEP 09, 1997 | | |
| 18932 001 | | | ODE | NOV 20, 1991 |
| 18948 001 | | | NCE | DEC 27, 1990 |
| | | | ODE | DEC 27, 1992 |
| 18949 001 | /3866526/ | /APR/23;/1991/ | | |
| | /3965257/ | /JUN/22;/1993/ | | |
| | /3966949/ | /JUN/29;/1993/ | | |
| | /4254129/ | /MAR/03;/1998/ | | |
| | /4285957/ | /AUG/25;/1998/ | | |
| 18956 001 | 4021481 | MAY 03, 1994 | NCE | DEC 26, 1990 |
| | 4250113 | FEB 10, 1998 | | |
| 18956 002 | 4021481 | MAY 03, 1994 | NCE | DEC 26, 1990 |
| | 4250113 | FEB 10, 1998 | | |
| 18956 003 | 4021481 | MAY 03, 1994 | NCE | DEC 26, 1990 |
| | 4250113 | FEB 10, 1998 | | |
| 18956 004 | 4021481 | MAY 03, 1994 | NCE | DEC 26, 1990 |
| | 4250113 | FEB 10, 1998 | | |
| 18972 001 | | | NCE | DEC 24, 1990 |
| 18985 001 | 4544554 | JUL 23, 2002 | | |
| 18985 002 | 4544554 | JUL 23, 2002 | | |
| 18998 001 | 4374829 | FEB 22, 2000 | NCE | DEC 24, 1990 |
| 18998 002 | 4374829 | FEB 22, 2000 | NCE | DEC 24, 1990 |
| 18998 003 | 4374829 | FEB 22, 2000 | NCE | DEC 24, 1990 |
| 19011 001 | | | NP | SEP 24, 1986 |
| /19644/001/ | /4335059/ | /JUN/15;/1999/ | /NCE/ | /DEC/23;/1990/ |
| 19044 001 | 4335095 | JUN 15, 1999 | NCE | DEC 23, 1990 |
| 19059 001 | 4138475 | FEB 06, 1996 | PETITION FOR EXCLUSIVITY PENDING | |
| 19059 002 | 4138475 | FEB 06, 1996 | PETITION FOR EXCLUSIVITY PENDING | |
| 19059 003 | 4138475 | FEB 06, 1996 | PETITION FOR EXCLUSIVITY PENDING | |
| 19069 001 | /3839573/ | /OCT/01;/1991/ | | |
| 19071 001 | | | ODE | AUG 30, 1992 |
| | | | NP | AUG 30, 1988 |
| 19079 001 | | | NE | FEB 11, 1989 |
| 19084 001 | 4335125 | JUN 15, 1999 | NDF | DEC 31, 1988 |
| 19107 001 | | | NCE | OCT 17, 1990 |
| 19107 001 | | | ODE | OCT 17, 1992 |
| 19194 001 | | | NCE | NOV 11, 1990 |
| | | | ODE | NOV 11, 1992 |
| 19215 001 | 4078071 | MAR 07, 1995 | NCE | NOV 25, 1990 |
| 19219 002 | 3641152 | FEB 08, 1989 | NCE | DEC 19, 1990 |
| 19259 001 | 3980778 | SEP 14, 1993 | | |
| 19260 001 | 3980778 | SEP 14, 1993 | | |
| 19264 001 | | | ODE | OCT 16, 1991 |
| 19270 001 | 4252984 | FEB 24, 1998 | NCE | AUG 30, 1990 |
| | 4311708 | JAN 19, 1999 | | |
| | 4342783 | AUG 03, 1999 | | |
| 19322 001 | 3721687 | MAR 20, 1990 | NCE | DEC 27, 1990 |
| 19323 001 | 3721687 | MAR 20, 1990 | NCE | DEC 27, 1990 |

(continued)

## APPENDIX 6

### PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

(continued)

| | APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|---|
| | 19359 001 | 4078071 | MAR 07, 1995 | NCE | NOV 25, 1990 |
| | 19368 001 | 4205086 | MAY 27, 1997 | NCE | OCT 29, 1990 |
| | | | | ODE | OCT 29, 1992 |
| > ADD > | 19412 001 | | | NS | MAR 10, 1989 |
| > ADD > | 19412 002 | | | NS | MAR 10, 1989 |
| > ADD > | 19412 003 | | | NS | MAR 10, 1989 |
| > ADD > | 19412 004 | | | NS | MAR 10, 1989 |
| | 19425 001 | 4012444 | MAR 15, 1994 | NCE | AUG 01, 1994 |
| | | 4066755 | JAN 03, 1995 | | |
| | 19434 001 | 3950333 | APR 13, 1993 | | |
| | | 4024271 | MAY 17, 1994 | | |
| > ADD > | 19435 001 | 4024163 | MAY 17, 1994 | NCE | MAR 31, 1991 |
| | 19478 001 | 3644627 | FEB 22, 1989 | | |
| | | 3784684 | JAN 08, 1991 | | |

(continued)

## SUBSCRIPTION FORM

# APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 6TH EDITION (1985)

*MAIL TO:*

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*(If different than Purchaser)*

*CONTACT:*

*TELEPHONE (Include Area Code):*

*METHOD OF PAYMENT:*

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[ ] Purchase Order No. _____
[ ] Check/money order enclosed for $_____
(Make check or money order payable to Superintendent of Documents)

*AUTHORIZING SIGNATURE:*

*DATE:*

| *DESCRIPTION* | *QUANTITY* | *UNIT PRICE* | *TOTAL PRICE* |
|---|---|---|---|
| The 6th Edition is published in October 1985. Subscription includes the Approved Drug Products publication and monthly Cumulative Supplements.<br><br>DOMESTIC [Order No. 917-001-00000-6] | | @ $103.00 | $ |
| FOREIGN [Order No. 917-001-00000-6] | | @ $128.75 | $ |
| ENTER TOTAL | | | $ |