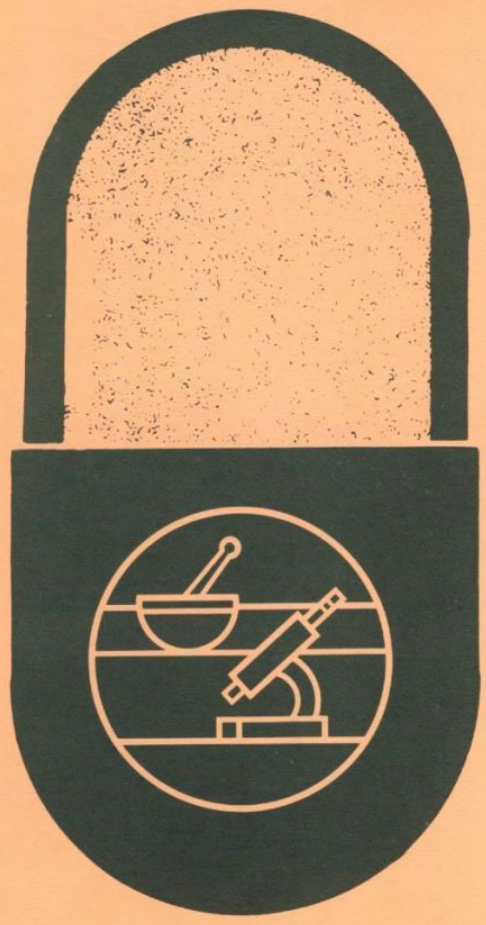
CUMULATIVE
SUPPLEMENT 3
AUG'85-NOV'85



# 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

## NOVEMBER 1985

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CUMULATIVE SUPPLEMENT

NOVEMBER 1985

# 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 |

## 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<br>Pseudoephedrine Sulfate<br>Tablet; Oral | 2mg<br>60mg |
| Pseudoephedrine HCl<br>Triprolidine HCl<br>Tablet or Capsule; Oral | 60mg<br>2.5mg |
| Pseudoephedrine HCl<br>Triprolidine HCl<br>Syrup; Oral | 30mg/5ml<br>1.25mg/5ml |
| Triprolidine HCl<br>Syrup; Oral | 1.25mg/5ml |
| Triprolidine HCl<br>Tablet; Oral | 2.5mg |

## 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) |
| parenteral multivitamin products | SEP 17, 1984 (49 FR 36446) |
| 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 |
|---|---|---|
| DRUG PRODUCTS LISTED | 8048 | 8230 |
| SINGLE SOURCE | 2096 (26.0%) | 2100 (25.5%) |
| MULTISOURCE(1) | 5952 (74.0%) | 6130 (74.5%) |
| THERAPEUTICALLY EQUIVALENT | 4864 (60.5%) | 5034 (61.3%) |
| NOT THERAPEUTICALLY EQUIVALENT | 1054 (13.2%) | 1058 (12.9%) |
| EXCEPTIONS(2) | 25 ( 0.3%) | 29 ( 0.3%) |
| NEW MOLECULAR ENTITIES APPROVED | - | 3 |
| NUMBER OF APPLICANTS | 306 | 313 |

### B. ACTIVITY FOR SUPPLEMENT NUMBER 3

| | NOV '85 | CUMULATIVE |
|---|---|---|
| DRUG PRODUCTS ADDED: | 57 | 57 |
| NEWLY APPROVED | 50 | 50 |
| DESI EFFECTIVE | 5 | 5 |
| REMARKETED | 2 | 2 |
| DRUG PRODUCTS REMOVED: | 0 | 0 |
| WITHDRAWN APPROVAL | 0 | 0 |
| RX TO OTC SWITCH | 0 | 0 |
| NET GAIN IN DRUG PRODUCTS | 55 | 55 |
| SINGLE SOURCE PRODUCTS APPROVED | 6 | 6 |
| MULTISOURCE DRUG PRODUCTS APPROVED | 51 | 51 |
| NEW MOLECULAR ENTITIES APPROVED: | 3 | 3 |
| AS THE ENTITY | 0 | 0 |
| AS A SALT, ESTER OR DERIVATIVE OF THE ENTITY | 3 | 3 |

(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

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

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

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
**ACETAMINOPHEN AND CODEINE PHOSPHATE #2**
AA SUPERPHARM 300MG;15MG¤ N89183 001
OCT 18, 1985
**ACETAMINOPHEN AND CODEINE PHOSPHATE #3**
AA SUPERPHARM 300MG;30MG¤ N89184 001
OCT 18, 1985
**ACETAMINOPHEN AND CODEINE PHOSPHATE #4**
AA SUPERPHARM 300MG;60MG¤ N89185 001
OCT 18, 1985
**ACETAMINOPHEN W/ CODEINE**
/AA/ /VITARINE/ /300MG;30MG/ /N85917.001/
**ACETAMINOPHEN W/ CODEINE #4**
/AA/ /VITARINE/ /300MG;60MG/ /N87423.001/
**ACETAMINOPHEN W/ CODEINE #2**
/AA/ /VITARINE/ /300MG;15MG/ /N87433.001/

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/

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**
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

AMINO ACIDS (PAGE 3-7)

INJECTABLE; INJECTION
AMINOSYN-PF 7%
ABBOTT LABORATORIES 7%¤ N19398 001
SEP 06, 1985

AMINOPHYLLINE (PAGE 3-10)

TABLET; ORAL
**AMINOPHYLLINE**
AB CORD LABORATORIES 100MG N85262 002
/BC/ /CORD.LABORATORIES/ /100MG/ /N85262.002/

AMOXICILLIN (PAGE 3-15)

CAPSULE; ORAL
**AMOXICILLIN**
AB LABORATORIOS ATRAL 250MG¤ N62528 001
AUG 07, 1985
AB 500MG¤ N62528 002
AUG 07, 1985

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

> ADD > INJECTABLE; INJECTION
> ADD > M.V.I.-12 LYOPHILIZED
> ADD > USV PHARMACEUTICAL 100MG/VIAL;0.06MG/VIAL;0.005MG/VIAL
> ADD > 15MG/VIAL;200 IU/VIAL;0.4MG/VIAL;
> ADD > 40MG/VIAL;4MG/VIAL;3.6MG/VIAL;
> ADD > 3MG/VIAL;3,300 IU/VIAL;10 IU/VIAL*
> ADD > N18933 002
> ADD > AUG 08, 1985

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

> ADD > INJECTABLE; INJECTION
> ADD > M.V.C. 9+3
> ADD > AP LYPHOMED 10MG/ML;0.006MG/ML;0.5UGM/ML;
> ADD > 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;
> ADD > 0.4MG/ML;0.36MG/ML;0.3MG/ML;
> ADD > 330 IU/ML;1 IU/ML* N18440 002
> ADD > AUG 08, 1985
> ADD > MVC PLUS
> ADD > AP ASCOT HOSP PHARMS 10MG/ML;0.006MG/ML;0.5UGM/ML;
> ADD > 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;
> ADD > 0.4MG/ML;0.36MG/ML;0.3MG/ML;
> ADD > 330 IU/ML;1 IU/ML* N18439 002
> ADD > AUG 08, 1985
> ADD > M.V.I.-12
> ADD > AP USV PHARMACEUTICAL 10MG/ML;0.006MG/ML;0.5UGM/ML
> ADD > 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML;
> ADD > 0.4MG/ML;0.36MG/ML;0.3MG/ML;
> ADD > 330 IU/ML;1 IU/ML* N08809 004
> ADD > AUG 08, 1985

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

> ADD > INJECTABLE; INJECTION
> ADD > BEROCCA PN
> ADD > HOFFMANN-LA ROCHE 50MG/ML;0.03MG/ML;0.0025MG/ML;
> ADD > 7.5MG/ML;100 IU/ML;0.2MG/ML;20MG/ML;
> ADD > 2MG/ML;1.8MG/ML;1.5MG/ML;1,650 IU/ML;
> ADD > 5 IU/ML* N06071 004
> ADD > OCT 10, 1985

ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-19)

CAPSULE; ORAL
LANORINAL
AB LANNETT 325MG;50MG;40MG* N86996 002
OCT 11, 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

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 001
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)

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

BETAXOLOL HYDROCHLORIDE (PAGE 3-27)

SOLUTION/DROPS; OPHTHALMIC
BETOPTIC
ALCON LABORATORIES EQ 0.5% BASE* N19270 001
AUG 30, 1985

BUPIVACAINE HYDROCHLORIDE; DEXTROSE (PAGE 3-29)

INJECTABLE; INJECTION
MARCAINE SPINAL

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

>ADD> BUTOCONAZOLE NITRATE (PAGE 3-31)

>ADD> CREAM; VAGINAL
>ADD> FEMSTAT

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

>ADD> SUPPOSITORY; VAGINAL
>ADD> FEMSTAT

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

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 |

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 (PAGE3-38)

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 |

CEFTAZIDIME (PAGE 3-39)

INJECTABLE; INJECTION
FORTAZ

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | AP | GLAXO | 500MG/VIAL | N50578 001 | JUL 19, 1985 |
| >ADD> | AP | | 1GM/VIAL | N50578 002 | JUL 19, 1985 |
| >ADD> | AP | | 2GM/VIAL | N50578 003 | JUL 19, 1985 |

>ADD> TAZIDIME

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | AP | ELI LILLY | 500MG/VIAL¤ | N62640 001 | NOV 20, 1985 |
| >ADD> | AP | | 1GM/VIAL¤ | N62640 002 | NOV 20, 1985 |
| >ADD> | AP | | 1GM/VIAL¤ | N62655 001 | NOV 20, 1985 |
| >ADD> | AP | | 2GM/VIAL¤ | N62655 002 | NOV 20, 1985 |
| >ADD> | AP | | 2GM/VIAL¤ | N62640 003 | NOV 20, 1985 |

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 |

CHLORTHALIDONE (PAGE 3-49)

TABLET; ORAL
**CHLORTHALIDONE**

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

> ADD > CILASTATIN SODIUM; IMIPENEM (PAGE 3-50)

> ADD > INJECTABLE; INJECTION
> ADD > **PRIMAXIN**

| | | | |
|---|---|---|---|
| > ADD > | MS&D RES LABS/MERCK | EQ 250MG BASE/VIAL; 250MG/VIAL¤ | N50587 001 NOV 26, 1985 |
| > ADD > | | EQ 500MG BASE/VIAL; 500MG/VIAL¤ | N50587 002 NOV 26, 1985 |

> ADJ >

CIMETIDINE HYDROCHLORIDE; SODIUM CHLORIDE (PAGE 3-50)

INJECTABLE; INJECTION
TAGAMET IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| SK&F LAB | EQ 6MG BASE/ML;9MG/ML¤ | N19434 001 | OCT 31, 1985 |

CLONIDINE HYDROCHLORIDE (PAGE 3-52)

TABLET; ORAL
**CATAPRES**

| | | | | |
|---|---|---|---|---|
| > ADD > AB | BOEHRINGER INGELHEIM | 0.1MG | N17407 001 | |
| > ADD > AB | | 0.2MG | N17407 002 | |
| > ADD > AB | | 0.3MG | N17407 003 | |

**CLONIDINE HCL**

| | | | | |
|---|---|---|---|---|
| > ADD > AB | PAR PHARMACEUTICAL | 0.1MG¤ | N70461 001 | JUL 08, 1986 : NOV 22, 1985 |
| > ADD > AB | | 0.2MG¤ | N70460 001 | JUL 08, 1986 : NOV 22, 1985 |
| > ADD > 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**

| | | | | |
|---|---|---|---|---|
| > ADD > 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**

| | | | | |
|---|---|---|---|---|
| > ADD > AA | HR CENCI LABS | 10MG/5ML;6.25MG/5ML¤ | N88814 001 | NOV 22, 1985 |

DEXTROSE (PAGE 3-64)

INJECTABLE; INJECTION
**DEXTROSE 5% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML¤ | N19479 001 | SEP 17, 1985 |

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 | OCT 04, 1985 |

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

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

**DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER**

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

**DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT LABORATORIES | 5GM/100ML;900MG/100ML¤ | N19483 001 | OCT 04, 1985 |

DIAZEPAM (PAGE 3-72)

TABLET; ORAL
**DIAZEPAM**

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

DIAZEPAM (PAGE 3-72)

TABLET; ORAL

DIAZEPAM

| | | | | |
|---|---|---|---|---|
| AB | MYLAN PHARMS | 2MG¤ | N70323 001 | SEP 04, 1985 |
| AB | | 5MG¤ | N70324 001 | SEP 04, 1985 |
| AB | | 10MG¤ | N70325 001 | SEP 04, 1985 |
| 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 |
| AB | ZENITH LABORATORIES | 2MG¤ | N70360 001 | SEP 04, 1985 |
| AB | | 5MG¤ | N70361 001 | SEP 04, 1985 |
| AB | | 10MG¤ | N70362 001 | SEP 04, 1985 |

VALIUM

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

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 | |

DISOPYRAMIDE PHOSPHATE (PAGE 3-77)

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

| | | | | |
|---|---|---|---|---|
| >ADD> AB | ZENITH LABORATORIES | EQ 100MG BASE¤ | N70186 001 | NOV 18, 1985 |
| >ADD> 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 | 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¤ | N70558 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; ORAL

DORYX

| | | | | |
|---|---|---|---|---|
| AB | PARKE-DAVIS/W-L | EQ 100MG BASE¤ | N62653 001 | OCT 30, 1985 |

TABLET; ORAL

DOXYCYCLINE HYCLATE

| | | | | |
|---|---|---|---|---|
| AB | PARKE-DAVIS/W-L | EQ 100MG BASE¤ | N62593 001 | AUG 28, 1985 |

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 | |

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE (PAGE 3-83)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | LIDOCAINE HCL AND EPINEPHRINE | | | |
| AP | ABBOTT LABORATORIES | 0.005MG/ML;1.5%* | N88571 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 | | | |
| > ADD > | AB | BARR LABORATORIES | 1MG* | N88891 001 | NOV 01, 1985 |
| > ADD > | | | | | |

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 |

ETHINYL ESTRADIOL; NORETHINDRONE (PAGE 3-89)

TABLET; ORAL-21

| | | | | |
|---|---|---|---|---|
| | ORTHO-NOVUM 7/14-21 | | | |
| > ADD > | ◕ ORTHO PHARMACEUTICAL | 0.035MG;0.5MG AND 1MG | N19004 001 | APR 04, 1984 |

TABLET; ORAL-28

| | | | | |
|---|---|---|---|---|
| | ORTHO-NOVUM 7/14-28 | | | |
| > ADD > | ◕ ORTHO PHARMACEUTICAL | 0.35MG;0.5MG AND 1MG | N19004 002 | APR 04, 1984 |

ETHOXZOLAMIDE (PAGE 3-90)

TABLET: ORAL

| | | | | |
|---|---|---|---|---|
| | ETHAMIDE | | | |
| > ADD > | ◕ 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 |

FLUPHENAZINE HYDROCHLORIDE (PAGE 3-94)

CONCENTRATE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | PERMITIL | | | |
| > ADD > | AA | SCHERING | 5MG/ML | N16008 001 | |
| > ADD > | | PROLIXIN | | | |
| > ADD > | AA | ER SQUIBB AND SONS | 5MG/ML* | N70533 001 | NOV 07, 1985 |
| > ADD > | | | | | |

FLURAZEPAM HYDROCHLORIDE (PAGE 3-95)

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | DALMANE | | | |
| > ADD > | AB | ROCHE PRODUCTS | 15MG | N16721 001 | |
| > ADD > | AB | | 30MG | N16721 002 | |
| > ADD > | | FLURAZEPAM HCL | | | |
| > ADD > | AB | MYLAN PHARMS | 15MG* | N70344 001 | NOV 27, 1985 |
| > ADD > | | | | | |
| > ADD > | AB | | 30MG* | N70345 001 | NOV 27, 1985 |
| > ADD > | | | | | |

FOLIC ACID (PAGE 3-95)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | FOLIC ACID | | | |
| 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 |

TABLET; ORAL
FUROSEMIDE

| | | | | |
|---|---|---|---|---|
| AB | BARR LABORATORIES | 20MG* | N70043 001 | SEP 26, 1985 |
| > ADD > AB | WATSON LABORATORIES | 20MG* | N70449 001 | NOV 22, 1985 |
| > ADD > AB | | 40MG* | N70450 001 | NOV 22, 1985 |

GENTAMICIN SULFATE (PAGE 3-97)

INJECTABLE; INJECTION
GENTAFAIR

| | | | | |
|---|---|---|---|---|
| AP | PHARMAFAIR | EQ 40MG BASE/ML* | N62493 001 | AUG 28, 1985 |

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

| | | | | |
|---|---|---|---|---|
| > ADD > AT | CARTER-GLOGAU LABS | EQ 3MG BASE/ML* | N62523 001 | NOV 25, 1985 |

GLYCINE (PAGE 3-100)

SOLUTION; IRRIGATION
AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| /AT/ | /TRAVENOL LABS/ | /1.5GM/100ML/ | N18522 001 | /FEB/19/1982/ |

GLYCINE 1.5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AT | TRAVENOL LABS | 1.5GM/100ML | N18522 001 | FEB 19, 1982 |

GUANABENZ ACETATE (PAGE 3-102)

TABLET; ORAL
WYTENSIN

| | | | | |
|---|---|---|---|---|
| > ADD > | WYETH LABS/AMRO | EQ 16MG BASE* | N18587 003 | SEP 07, 1982 |

HEPARIN SODIUM (PAGE 3-103)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| > DLT > | /HEP-LOCK PF/ | | | |
| > DLT >/AP/ | /ELKINS-SINN/AHROBINS/10 UNITS/ML/ | | | /N17037 010/ /JUN 10, 1983/ |
| > DLT > | | | | |
| > DLT >/AP/ | | /100 UNITS/ML/ | | /N17037 011/ /JUN 10, 1983/ |
| > DLT > | | | | |

> ADD >
HEP-LOCK U/P

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

> ADD >
HEPARIN LOCK FLUSH

| | | | | |
|---|---|---|---|---|
| AP | LUITPOLD PHARMS | 10 UNITS/ML* | N89063 001 | OCT 09, 1985 |
| AP | | 100 UNITS/ML* | N89064 001 | OCT 09, 1985 |

HYDRALAZINE HYDROCHLORIDE (PAGE 3-107)

INJECTABLE; INJECTION
HYDRALAZINE HYDROCHLORIDE

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

HYDROCHLOROTHIZIDE; SPIRONOLACTONE (PAGE 3-111)

TABLET; ORAL
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| > ADD > 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/ | N10768.006/ | |

HYDROCORTISONE (PAGE 3-112)

LOTION; TOPICAL

> ADD > **STIE-CORT**
> ADD > AT STIEFEL LABORATORIES 1%* N89066 001 NOV 25, 1985
> ADD >
> ADD > AT 2.5%* N89074 001 NOV 26, 1985
> ADD >

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

> ADD > **NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE**
> ADD > AT CARTER-GLOGAU LABS 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML* N62488 001 NOV 06, 1985
> ADD >
> ADD >

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

SUSPENSION; OTIC

**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

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/

TABLET; ORAL

**HYDROXYZINE HCL**

AB QUANTUM PHARMICS 10MG* N88540 001 OCT 22, 1985

AB 25MG* N88551 001 OCT 22, 1985

AB 50MG* N88529 001 OCT 22, 1985

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 | ∂ 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 | ∂ UPJOHN | 300MG | N17463 003 | |
| | | 800MG¤ | N17463 005 | MAY 22, 1985 |

INDOMETHACIN (PAGE 3-122)

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | | **INDO-LEMMON** | | | |
| > ADD > | AB | LEMMON | 25MG¤ | N70266 001 | NOV 07, 1985 |
| > ADD > | 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 |
| | AB | WATSON LABORATORIES | 25MG¤ | N70529 001 | OCT 18, 1985 |
| | AB | | 50MG¤ | N70530 001 | OCT 18, 1985 |

SUSPENSION; ORAL

| | | | |
|---|---|---|---|
| **INDOCIN** | | | |
| MS&D RES LABS/MERCK | 25MG/5ML¤ | N18332 001 | OCT 10, 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** | | | | |
| 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 IN PLASTIC CONTAINER | | | |
| AM MCGAW/AM HOSP | 5GM/100ML | N16772 002 | |
| RESECTISOL | | | |
| /AM MCGAW/AM HOSP/ | /5GM/100ML/ | /N16772/002/ | |

MECLIZINE HYDROCHLORIDE (PAGE 3-135)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| **MECLIZINE HCL** | | | | |
| AA | SUPERPHARM | 12.5MG¤ | N89113 001 | AUG 20, 1985 |
| AA | | 25MG¤ | N89114 001 | AUG 20, 1985 |

MEDROXYPROGESTERONE ACETATE (PAGE 3-136)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PROVERA | | | |
| > ADD > | UPJOHN | 5MG | N11839 003 | |

METHOTREXATE SODIUM (PAGE 3-143)

INJECTABLE; INJECTION

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

METHYLDOPA (PAGE 3-144)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **METHYLDOPA** | | | |
| 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 |

METOCLOPRAMIDE HYDROCHLORIDE (PAGE 3-147)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **CLOPRA-"YELLOW"** | | | |
| AB | QUANTUM PHARMICS | EQ 10MG BASE¤ | N70632 001 | OCT 28, 1985 |
| | **METOCLOPRAMIDE HCL** | | | |
| AB | PUREPAC/KALIPHARMA | EQ 10MG BASE¤ | N70581 001 | OCT 17, 1985 |

METRONIDAZOLE (PAGE 3-148)

TABLET; ORAL

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

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 |

MONOOCTANOIN (PAGE 3-150)

LIQUID; PERFUSION, BILIARY

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

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 |
| > ADD > AP | INTL MEDICATION SYS | 0.4MG/ML¤ | N70417 001 | SEP 24, 1986 : NOV 06, 1985 |
| > ADD > 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 |
| | **NARCAN** | | | |
| AP | DUPONT PHARMS/DUPONT | 0.02MG/ML | N16636 001 | |
| AP | | 0.4MG/ML | N16636 002 | |
| /AP/ | | 1MG/ML | N16636 003 | JUN 14, 1982 |

NIFEDIPINE (PAGE 3-154)

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **PROCARDIA** | | | |
| > ADD > AB | PFIZER LABS/PFIZER | 10MG | N18482 001 | |
| | **ADALAT** | | | |
| > ADD > AB | MILES PHARM/MILES | 10MG¤ | N19478 001 | NOV 27, 1985 |

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

NYSTATIN (PAGE 3-156)

POWDER; ORAL
NILSTAT
>ADD> AA LEDERLE LABS/AM CYAN 100% N50576 001 DEC 22, 1983

>ADD>
NYSTATIN
>ADD> AA PADDOCK LABORATORIES 100%¤ N62613 001 NOV 26, 1985
>ADD>

SUSPENSION; ORAL
NYSTATIN
AA NASKA PHARMACAL 100,000 UNITS/ML¤ N62571 001 OCT 29, 1985

TABLET; ORAL
NYSTATIN
>ADD> AA LEMMON 500,000 UNITS N62506 001 JAN 16, 1984
>ADD>
>ADD> AA PHARM BASICS 500,000 UNITS¤ N62524 001 NOV 26, 1985
>ADD>

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

NYSTATIN; TRIAMCINOLONE ACETONIDE (PAGE 3-157)

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

>ADD> MYCO-TRIACET II
>ADD> AT LEMMON 100,000 UNITS/GM;0.1%¤ N62045 002 NOV 26, 1985
>ADD>

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
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

PENICILLIN G POTASSIUM (PAGE 3-161)

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN G POTASSIUM
>ADD> AA ◑ MYLAN PHARMS 200,000 UNITS/5ML N60752 003
>ADD> AA ◑ 250,000 UNITS/5ML N60752 002
>ADD> AA ◑ 400,000 UNITS/5ML N60752 001

PHENTERMINE HYDROCHLORIDE (PAGE 3-167)

CAPSULE; ORAL
PHENTERMINE HCL
>ADD> AA LEMMON 30MG¤ N87777 001 NOV 01, 1985
>ADD>

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-168)

SYRUP; ORAL
PROMETHAZINE VC PLAIN
>ADD> AA HR CENCI LABS 5MG/5ML;6.25MG/5ML¤ N88815 001 NOV 22, 1985
>ADD>

PHENYTOIN SODIUM, EXTENDED (PAGE 3-169)

CAPSULE; ORAL
/EXTENDED PHENYTOIN SODIUM/
/AB/ /BOLAR PHARMACEUTICAL/100MG/ /N88711 001/ /DEC 21, 1984/

SETROL
AB BOLAR PHARMACEUTICAL 100MG N88711 001 DEC 21, 1984

PHENYTOIN SODIUM, PROMPT (PAGE 3-169)

CAPSULE; ORAL

PHENYTOIN SODIUM

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

PROMPT PHENYTOIN SODIUM

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

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

POTASSIUM CITRATE

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

PRALIDOXIME CHLORIDE (PAGE 3-174)

INJECTABLE; INJECTION

PRALIDOXIME CHLORIDE

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

PROCAINAMIDE HYDROCHLORIDE (PAGE 3-178)

INJECTABLE; INJECTION

PROCAINAMIDE HCL

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | AP | PHARMAFAIR | 100MG/ML* | N88824 001 | NOV 20, 1985 |
| >ADD> | | | | | |
| >ADD> | AP | | 500MG/ML* | N88830 001 | NOV 20, 1985 |
| >ADD> | | | | | |

TABLET, CONTROLLED RELEASE; ORAL

PROCAINAMIDE HCL

| | | | | |
|---|---|---|---|---|
| AB | DANBURY PHARMACAL | 250MG* | N89026 001 | OCT 22, 1985 |
| AB | | 500MG* | N89027 001 | OCT 22, 1985 |
| AB | | 750MG* | N89042 001 | OCT 22, 1985 |

PROMETHAZINE HYDROCHLORIDE (PAGE 3-181)

SYRUP; ORAL

PROMETHAZINE

| | | | | |
|---|---|---|---|---|
| AA | LIFE LABORATORIES | 6.25MG/5ML* | N89013 001 | SEP 20, 1985 |

TABLET; ORAL

PROMETHAZINE HCL

| | | | | |
|---|---|---|---|---|
| BP | LEMMON | 25MG* | N89109 001 | SEP 10, 1985 |

PROPRANOLOL HYDROCHLORIDE (PAGE 3-183)

TABLET; ORAL

PROPRANOLOL

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

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 |

QUINIDINE GLUCONATE (PAGE 3-186)

TABLET, CONTROLLED RELEASE; ORAL
QUINIDINE GLUCONATE
> ADD > AB SUPERPHARM 324MG¤ N89164 001
> ADD > NOV 21, 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

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
◎ SERONO LABS 10 IU/VIAL N17726 001
ASELLACRIN 2
◎ SERONO LABS 2 IU/VIAL N17726 002
JUL 21, 1983

CRESCORMON
◎ 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
> ADD > AB PHARM BASICS 400MG;80MG¤ N70203 001
> ADD > JUN 02, 1987 : NOV 08, 1985
> ADD > AB 800MG;160MG¤ N70204 001
> ADD > 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

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

INJECTABLE; INJECTION
/TECHNECOLL/
/AP/ /MALLINCKRODT/ /N/A/ /N17059/001/

SOLUTION; INJECTION, ORAL
TECHNECOLL
MALLINCKRODT N/A N17059 001

TEMAZEPAM (PAGE 3-203)

CAPSULE; ORAL
**RESTORIL**
AB SANDOZ PHARMS/SANDOZ 15MG N18163 001
AB 30MG N18163 002
**SOMAZ**
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

SYRUP; ORAL
> ADD > **ACCURBRON**
> ADD > AA MERRELL DOW/DOW CHEM 150MG/15ML* N88746 001 NOV 22, 1985
> ADD >
**THEOPHYLLINE**
> ADD > AA NATL PHARM MFG/BARRE 150MG/15ML N86545 001

TABLET; ORAL
QUIBRON-T
MEAD JOHNSON/B-M 300MG* N88656 001 AUG 22, 1985

TABLET, CHEWABLE; ORAL
THEOPHYL
MCNEIL PHARM 100MG* N86506 001 SEP 12, 1985

> ADD > TRIENTINE HYDROCHLORIDE (PAGE 3-216)

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

TROPICAMIDE (PAGE 3-219)

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

VERAPAMIL HYDROCHLORIDE (PAGE 3-220)

INJECTABLE; INJECTION
> ADD > **VERAPAMIL HCL**
> ADD > AP LUITPOLD PHARMS 2.5MG/ML* N70225 001 NOV 12, 1985
> ADD >
> ADD > AP 2.5MG/ML* N70617 001 NOV 12, 1985
> ADD >

VINBLASTINE SULFATE (PAGE 3-221)

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

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

DIPHENHYDRAMINE HCL (PAGE 3-225)

SYRUP; ORAL
DIPHEN
BAY LABORATORIES 12.5MG/5ML* N70118 001
OCT 01, 1985

IBUPROFEN (PAGE 3-225)

TABLET; ORAL
IBUPROFEN
PAR PHARMACEUTICAL 200MG* N70481 001
SEP 24, 1986 : OCT 18, 1985

INSULIN ZINC SUSPENSION BIOSYNTHETIC HUMAN (PAGE 3-226)

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

>ADD> POVIDONE-IODINE

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

PSEUDOEPHEDRINE HYDROCHLORIDE (PAGE 3-228)

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

NO SEPTEMBER - NOVEMBER 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 Approved and Denied List

5. Exclusivity Terms

6. Prescription and OTC Drug Product Patent and Exclusivity Data

# APPENDIX I

## 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 I

### 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 |
| Pentamidine Isethionate 300mg/ml | Pentam 300 Injectable; Injection | LyphoMed | 19264 001 Oct 16, 1984 | ODE Oct 16, 1991 |
| Naltrexone Hydrochloride 50mg | Trexan Tablet; Oral | Dupont Pharms | 18932 001 Nov 20, 1984 | ODE Nov 20, 1991 |
| Potassium Citrate 5meq | Urocit-K Tablet; Oral | Univ of Tx Hlth Sci Ctr | 19071 001 Aug 30, 1985 | ODE Aug 30, 1992 |
| Monooctanoin 100% | Moctanin Liquid; Perfusion Biliary | Ascot Hosp Pharms | 19368 001 Oct 29, 1985 | ODE Oct 29, 1992 |

(continued)

APPENDIX I

DRUG PRODUCTS

(continued)

| Active Ingred.(s) Strength(s) | Trade Name Dosage Form; Route | Applicant | Appl. Prod. Approval Date | Exclusivity Exp. Date |
|---|---|---|---|---|
| Somatrem 5mg/vial | Protropin Injectable; Injection | Genentech | 19107 001 Oct 17, 1985 | ODE Oct 17, 1992 |
| Trientine Hydrochloride 250mg | Cuprid Capsule; Oral | Merck Sharp and Dohme Res Labs | 19194 001 Nov 8, 1985 | ODE 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 |

*New Addition

(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 |

*New Addition

# 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>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>Suppository; Rectal | 80mg | 85 P-0403/CP | New Dosage Form (Pediatric) | Approved<br>Oct 16, 1985 |
| Benztropine Mesylate<br>Syrup; Oral | 0.5mg/5ml | 85 P-0423/CP | New Dosage Form | 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 |
|---|---|---|---|---|
| Brompheniramine Maleate;<br>Pseudoephedrine Hydrochloride<br>Sustained Release Capsule; Oral | 12mg<br>120mg | 85 P-0095/CP | New Combination New Dosage Form | Approved Dec 13, 1985 |
| Chlorpheniramine Maleate;<br>Phenylpropanolamine Hydrochloride<br>Controlled-release Capsule; Oral | 10mg<br>75mg | 85 P-0149/CP | New Strength | Approved Dec 13, 1985 |
| Chlorhexidine Gluconate Solution; Topical | 1.5% | 84 P-0417/CP | New Strength | Approved 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 Dec 6, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Dexbrompheniramine Maleate; Phenylpropanolamine Hydrochloride Time Release Capsule; Oral | 6mg<br>75mg | 85 P-0238/ CP0002 | New Combination | Approved Dec 13, 1985 |
| Dexbrompheniramine Maleate; Pseudoephedrine Hydrochloride Sustained Release Capsule; Oral | 6mg<br>120mg | 85 P-0140/CP | New Combination New Dosage Form | Approved Dec 13, 1985 |
| Diazepam Solution; Oral | 5mg/5ml | 85 P-0090/CP | New Dosage Form | Approved Sep 19, 1985 |
| Diphenhydramine Hydrochloride Concentrate; Oral | 50mg/ml | 84 P-0174/CP | New Strength | Approved Sep 11, 1985 |
| Disulfiram Suspension; Oral | 500mg/30ml | 85 P-0215/CP | New Dosage Form | Approved Oct 8, 1985 |
| Fluorouracil Injectable; Injection | 25mg/ml | 85 P-0208/CP | New Strength | Approved Oct 8, 1985 |

(continued)

APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| 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 |
| 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 |
| Indomethacin<br>Suspension; Oral | 25mg/5ml | 85 P-0077/<br>CP0002 | New Dosage Form | Approved<br>Jul 19, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Isoniazid<br>Concentrate; Oral | 50mg/ml | 85 P-0468/CP | New Strength | Approved<br>Dec 13, 1985 |
| Ketoconazole<br>Suspension; Oral | 20mg/ml | 85 P-0147/CP | New Dosage Form | Approved<br>Sep 27, 1985 |
| Meperidine Hydrochloride<br>Concentrate; Oral | 100mg/ml | 84 P-0175/CP | New Strength | Approved<br>Jun 7, 1985 |
| 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 |
| Nitroglycerin<br>Injectable; Injection | 10mg/ml | 85 P-0134/CP | New Strength | Approved<br>Sep 19, 1985 |
| 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 |

(continued)

APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| 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 |
| 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 |
| Scopolamine Transdermal<br>System/24 Hour<br>Film, Controlled Release;<br>Percutaneous | 1mg | 85 P-0168/CP | New Strength (Dosing Interval) | Approved<br>Sep 27, 1985 |

(continued)

# APPENDIX 4

## I. Petitions Approved

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Theophylline<br>Capsule; Oral | 150mg<br>300mg | 85 P-0175/CP | New Strength | Approved<br>Oct 8, 1985 |
| 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 |
| Aspirin;<br>Chlorzoxazone<br>Tablet; Oral | 325mg<br>250mg | 85 P-0071/CP | New Combination | Denied<br>Sep 3, 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>7.5mg | 85 P-0101/CP | New Combination | Denied 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 Sep 11, 1985 |
| 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 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 Sep 11, 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 | 2mg/ml | 85 P-0063/CP | New Strength | Denied<br>May 29, 1985 |
| 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 |
|---|---|---|---|---|
| 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<br>Capsule; Oral | 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 |
| 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 |

(continued)

APPENDIX 4

## II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Tri-Phasic Contraceptive<br>Tablet; Oral(21 and 28 days) | | 84 P-0443/CP | New Strength<br>(Dose Schedule) | Denied<br>Sep 3, 1985 |
| Ethinyl Estradiol<br>Norethindrone | 0.05mg<br>0.5mg | | | |
| Ethinyl Estradiol<br>Norethindrone | 0.05mg<br>0.75mg | | | |
| Ethinyl Estradiol<br>Norethindrone | 0.05mg<br>1.0mg | | | |
| 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 |
| 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 |

(continued)

APPENDIX 4

## II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| Ibuprofen;<br>Oxycodone Hydrochloride<br>Tablet; Oral | 200mg<br>5mg | 85 P-0141/CP | New Combination | Denied<br>Sep 27, 1985 |
| Indomethacin<br>Tablet, Constant Release; Oral | 75mg | 85 P-0026/CP | New Dosage Form | Denied<br>Sep 16, 1985 |
| 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 |

(continued)

APPENDIX 4

## II. Petitions Denied

(continued)

| Drug Name<br>Dosage Form, Route | Strength | Docket Number | Reason for Petition | Status |
|---|---|---|---|---|
| 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 |
| Triamcinolone Acetonide<br>Suspension; Injection | 2.5mg/ml | 85 P-0001/CP | New Strength | Denied<br>Mar 4, 1985 |
| Triamcinolone Acetonide<br>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)

## 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 |
| >ADD> | I-38 | PATIENT PREOPERATIVE SKIN PREPARATION |

# 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 - NOVEMBER ACTIONS

## PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

| | APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|---|
| >_ADD_> | 12142 003 | 4537883 | AUG 27, 2002 | | |
| >_ADD_> | 12142 004 | 4537883 | AUG 27, 2002 | | |
| >_ADD_> | 12142 005 | 4537883 | AUG 27, 2002 | | |
| | 12365 005 | 4534973 | AUG 13, 2002 | | |
| | 12366 002 | 4534974 | AUG 13, 2002 | | |
| | /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 | |
| | 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/ |
| >_DLT_> | 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/ | | |
| | 17760 001 | | | NDF | SEP 04, 1988 |
| >_ADD_> | 17768 001 | 3855140 | DEC 17, 1991 | I-38 | SEP 24, 1986 |
| | | 3960745 | DEC 17, 1991 | | |
| | 17717 001 | /3839573/ | /OCT 01, 1991/ | | |

(continued)

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

(continued)

| | APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|---|
| | 17862 001 | 4536386 | AUG 20, 2002 | | |
| | 17970 001 | 4536516 | AUG 20, 2002 | | |
| | 18052 001 | /3839573/ | /OCT/01;/1991/ | | |
| | 18053 003 | | | I-37 | SEP 25, 1988 |
| | 18147 002 | /RE29668/ | /DEC/10;/1991/ | | |
| | | /4166347/ | /JUL/11;/1995/ | | |
| | | /3927002/ | /DEC/16;/1992/ | | |
| | 18147 003 | /RE29668/ | /DEC/10;/1991/ | | |
| | | /4166347/ | /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/ | | |
| | 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 | | |
| >_DLT_> | 18506 001 | /3419565/ | /DEC/31;/1985/ | | |
| | | /3717647/ | /FEB/20;/1990/ | | |
| | 18509 001 | | | NP | AUG 07, 1988 |
| | 18513 002 | | | ODE | JUL 28, 1990 |
| >_ADD_> | 18587 003 | 3658993 | APR 25, 1989 | NCE | SEP 07, 1992 |
| | 18683 001 | 4393871 | JUL 19, 2000 | | |
| | 18705 001 | | | NDF | OCT 31, 1988 |
| | 18713 001 | /3839573/ | /OCT/01;/1991/ | | |
| | 18738 001 | 4055652 | OCT 25, 1994 | NCE | AUG 30, 1990 |
| | 18813 001 | /3839573/ | /OCT/01;/1991/ | | |
| | 18827 001 | /3839573/ | /OCT/01;/1991/ | | |

| | APPL/PROD | PATENT NUMBER | PATENT EXPIRES | EXCLUSIVITY CODE | EXCLUSIVITY EXPIRES |
|---|---|---|---|---|---|
| | 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 |
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| | 18928 001 | 4221778 | SEP 09, 1997 | | |
| | 18932 001 | | | ODE | NOV 20, 1991 |
| | 18985 001 | 4544554 | JUL 23, 2002 | | |
| | 18985 002 | 4544554 | JUL 23, 2002 | | |
| | 19011 001 | | | NP | SEP 24, 1986 |
| >_ADD_> | 19059 001 | 4138475 | FEB 06, 1996 | | |
| >_ADD_> | 19059 002 | 4138475 | FEB 06, 1996 | | |
| >_ADD_> | 19059 003 | 4138475 | FEB 06, 1996 | | |
| | 19069 001 | /3839573/ | /OCT/01;/1991/ | | |
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| | 19107 001 | | | NCE | OCT 17, 1990 |
| >_ADD_> | 19107 001 | | | ODE | OCT 17, 1992 |
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| | 19259 001 | 3980778 | SEP 14, 1993 | | |
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| | 19270 001 | 4252984 | FEB 24, 1998 | NCE | AUG 30, 1990 |
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| | 19368 001 | 4205086 | MAY 27, 1997 | NCE | OCT 29, 1990 |
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