

# **APPROVED DRUG PRODUCTS**

## **With Therapeutic Equivalence Evaluations**

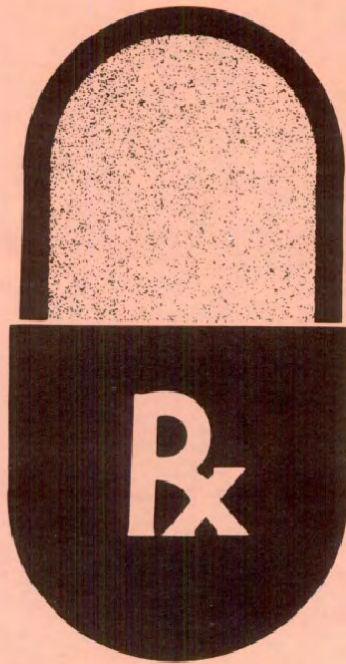


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**CUMULATIVE  
SUPPLEMENT 5  
AUG'84 - JAN'85**



# APPROVED PRESCRIPTION DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

**5<sup>TH</sup> EDITION**

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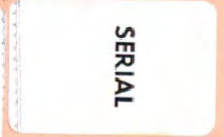
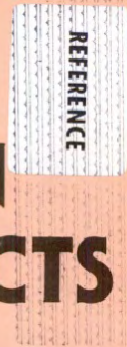
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FOOD AND DRUG ADMINISTRATION  
APPROVED PRESCRIPTION DRUG PRODUCTS  
WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS  
CUMULATIVE SUPPLEMENT

I. PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition (the List), to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature, are identified by the term "List." The cumulative supplements routinely provide updates to two of these lists: The Drug Product List and the DESI Addendum.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (\*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1984. Each subsequent cumulative supplement replaces the previous month's cumulative supplement.

Information in this cumulative supplement follows the format of the Drug Product List. 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.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in the Drug Product List for the revision. (Strength(s) which already exist in the publication will not be repeated for context.) A page number in parentheses referring to the Drug Product List is located to the right of the ingredient(s).

Additions to the Drug Product List 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.

Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol >DEL> (DELETE) to the left of the line containing the overstruck print. The >DEL> 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.

B. ADDENDUM: DESI Pending List

Information in this cumulative supplement follows the format of the Addendum. Additions and deletions are indicated in the same manner as in the cumulative supplement to the Drug Product List. A change in Current Status of a DESI product is also indicated by an addition and a deletion.

II. SPECIAL NOTES

A. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

Categories of counts derived from product information in the Drug Product List and from this cumulative supplement are presented. The report includes counts of new molecular entities approved by the agency during the current month.

B. 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 Drug Product List.

Products

dicyclomine hydrochloride  
isosorbide dinitrate  
nandrolone decanoate

Federal Register Reference

JUN 22, 1984 (49 FR 25681)  
AUG 3, 1984 (49 FR 31151)  
JUL 15, 1983 (48 FR 32395)

(continued)



Products

Federal Register Reference

(continued)

neomycin sulfate with either: MAR 26, 1984 (49 FR 11888)

dexamethasone sodium phosphate,

fluocinolone acetonide,

flurandrenolide,

hydrocortisone, or

methylprednisolone acetate.

[topical anti-infectives for

dermatologic use]

neomycin sulfate, polymyxin B sulfate,

bacitracin zinc, and hydrocortisone

[topical ointment]

nitroglycerin (capsule, controlled release; oral)

nitroglycerin (tablet, controlled release; oral)

parenteral multivitamin products

phenazopyridine hydrochloride and

sulfamethoxazole

sulfanilamide and aminacrine

tranylcypromine sulfate

MAY 4, 1984 (49 FR 19147)

SEP 7, 1984 (49 FR 35428)

SEP 7, 1984 (49 FR 35428)

SEP 17, 1984 (49 FR 36446)

JUL 29, 1983 (48 FR 34516)

AUG 22, 1983 (48 FR 38097)

MAR 22, 1984 (49 FR 10708)

C. 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

OHIO MEDICAL ANESTHETICS

ANALQUEST

ANALQUEST

D. ADDENDUM: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

The addendum of this supplement provides information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984."

The following report provides summary counts derived from product information in the Drug Product List and the current cumulative supplement. The counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the current cumulative supplement. A new column of data will appear in Section A. each three-month period following July '84. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

#### USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved, DESI effective 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, changes from prescription to over-the-counter status and discontinued marketing of products; and, (3) trends in approval of products as either multi-source or single source during each month within the quarter. The report does not reflect category changes from multi-source 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 multi-source and single source products.

#### Drug Product Definition

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

#### New Molecular Entity

The active moiety 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

#### Drug Product Count

This report provides counts in several categories from the List composed of domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Counts of products still pending in the DESI review are not provided. Excluded also are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

# REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

## A. COUNTS CUMULATIVE BY QUARTERS

| CATEGORIES COUNTED              | JULY '84 (BASELINE) | OCT '84      |
|---------------------------------|---------------------|--------------|
| DRUG PRODUCTS LISTED            | 7415                | 7609         |
| SINGLE SOURCE                   | 2005 (27.0%)        | 2045 (26.9%) |
| MULTISOURCE <sup>(1)</sup>      | 5410 (72.9%)        | 5564 (73.1%) |
| THERAPEUTICALLY EQUIVALENT      | 4393 (59.2%)        | 4497 (59.1%) |
| NOT THERAPEUTICALLY EQUIVALENT  | 999 (13.4%)         | 1032 (13.5%) |
| EXCEPTIONS <sup>(2)</sup>       | 18 (0.3%)           | 26 (0.3%)    |
| NEW MOLECULAR ENTITIES APPROVED | -                   | 4            |
| NUMBER OF APPLICANTS            | 295                 | 300          |

## B. ACTIVITY FOR SUPPLEMENT NUMBER 5

|                                    | NOV '84 | DEC '84 | JAN '85 | CUMULATIVE |
|------------------------------------|---------|---------|---------|------------|
| DRUG PRODUCTS ADDED:               | 65      | 68      | 54      | 187        |
| NEWLY APPROVED                     | 65      | 68      | 54      | 187        |
| DESI EFFECTIVE                     | 0       | 0       | 0       | 0          |
| REMARKETED                         | 0       | 0       | 0       | 0          |
| DRUG PRODUCTS REMOVED:             | 1       | 0       | 8       | 9          |
| WITHDRAWN APPROVAL                 | 0       | 0       | 0       | 0          |
| RX TO OTC SWITCH                   | 0       | 0       | 2       | 2          |
| DISCONTINUED MARKETING             | 1       | 0       | 6       | 7          |
| NET GAIN IN DRUG PRODUCTS          | 64      | 68      | 46      | 178        |
| SINGLE SOURCE PRODUCTS APPROVED    | 16      | 26      | 12      | 54         |
| MULTISOURCE DRUG PRODUCTS APPROVED | 49      | 42      | 42      | 133        |
| NEW MOLECULAR ENTITIES APPROVED:   | 2       | 7       | 0       | 9          |
| AS THE ENTITY                      | 0       | 2       | 0       | 2          |
| AS A SALT, ESTER OR DERIVATIVE     |         |         |         |            |
| OF THE ENTITY                      | 2       | 5       | 0       | 7          |

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

(2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE 1-5 OF THE LIST)

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ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)

CAPSULE; ORAL  
 SECTRAL  
 IVE'S LABS/AMMO EQ 200MG BASEM N 18917  
 EQ 400MG BASEM N 18917

ACETAMINOPHEN; BUTALBITAL (PAGE 3-1)

TABLET; ORAL  
 BUTALBITAL AND ACETAMINOPHEN  
 DANBURY PHARMACAL 325MG;50MG N 87550

ACETAMINOPHEN; BUTALBITAL; CAFFEINE (PAGE 3-1)

CAPSULE; ORAL  
 ESSIC  
 GILBERT LABORATORIES 325MG;50MG;40MG N 88825

TABLET; ORAL  
~~ESSIC~~  
 GILBERT LABORATORIES ~~325MG;50MG;40MG~~ N 87629  
~~FORTECET~~  
 SANDOZ PHARMS/SANDOZ ~~325MG;50MG;40MG~~ N 88616  
~~REFAN~~  
 OH GRAHAM LABS ~~325MG;50MG;40MG~~ N 87804

ACETAMINOPHEN; CODEINE PHOSPHATE (PAGE 3-1)

TABLET; ORAL  
~~ACETAMINOPHEN AND CODEINE PHOSPHATE 45/~~  
~~ACETAMINOPHEN AND CODEINE PHOSPHATE~~  
 ZENITH LABORATORIES ~~300MG;60MG~~ N 87083

ACETAMINOPHEN; HYDROCODONE BITARTRATE (PAGE 3-2)

TABLET; ORAL  
~~HYDROCODONE BITARTRATE W/ ACETAMINOPHEN~~  
 BARR LABORATORIES ~~500MG;5MG~~ N 88577

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

CAPSULE; ORAL  
 TYLOX  
 MCNEIL PHARM 500MG;5MG N 88790  
 TYLOX-325  
 MCNEIL PHARM 325MG;5MG N 88246

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE (PAGE 3-2)

TABLET; ORAL  
~~ACETAMINOPHEN~~  
~~OXYCET~~  
 HALSEY DRUG ~~325MG;5MG~~ N 87463

ACETIC ACID, GLACIAL (PAGE 3-3)

SOLUTION/DROPS; OTIC  
~~ACETIC ACID~~  
 THAMES PHARMACAL ~~22M~~ N 88638

ACYCLOVIR (PAGE 3-4)

> ADD > CAPSULE; ORAL  
 > ADD > ZOVIRAX  
 > ADD > BURROUGHS WELLCOME 200MG N 18828

ALLOPURINOL (PAGE 3-5)

TABLET; ORAL  
~~ALLOPURINOL~~  
 BOLAR PHARMACEUTICAL ~~100MG~~ N 18241  
 300MG N 18241  
 CHELSEA LABORATORIES ~~100MG~~ N 18785  
 300MG N 18785  
 DANBURY PHARMACAL ~~100MG~~ N 18832  
 300MG N 18877

AMIDINOCILLIN (PAGE 3-6)

INJECTABLE; INJECTION  
 COACTIN  
 HOFFMANN-LA ROCHE 250MG/VIALM N 50565  
 500MG/VIALM N 50565  
 1GM/VIALM N 50565

AMIKACIN SULFATE (PAGE 3-6)

INJECTABLE; INJECTION  
 AMIKIN  
 BRISTOL LABS/B-M EQ 50MG BASE/MLM N 62562  
 EQ 250MG BASE/MLM N 62562

[illegible]

3



ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE 3-16)

CAPSULE; ORAL  
PROPOXYPHENE COMPOUND 65  
 AA ZENITH LABORATORIES 33.4MG:65MG N 83077  
PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE  
 AA CHELSEA LABORATORIES 33.4MG:32.4MG:65MG N 85732

ASPIRIN; METHOCARBAMOL (PAGE 3-17)

> DLT >  
 > AND >  
 TABLET; ORAL  
METHOCARBAMOL AND ASPIRIN

BENZOYL PEROXIDE; ERYTHROMYCIN (PAGE 3-21)

GEL; TOPICAL  
 BENZAMYLICIN  
 DERMIK/RORER-AMCHEM 5%; 32M N 50557

BENZOTRIAZOLE; RESERPINE (PAGE 3-21)

/TABLET; ORAL/  
 /EVA-R/  
 /AM. ROBINS/ /50MG:0.125MG/ /N 14861/

BETAMETHASONE DIPROPIONATE (PAGE 3-22)

OINTMENT; TOPICAL  
ALPHATREX  
 AB SAVAGE LABS/BYK-GLDN EQ 0.05% BASEM N 19143  
BETAMETHASONE DIPROPIONATE  
 AB E FOUGERA/BYK-GLDN EQ 0.05% BASEM N 19141  
 AB PHARMADERM/BYK-GLDN EQ 0.05% BASEM N 19140  
 DIPROLENE  
 BX SCHERING EQ 0.05% N 18741  
 AB DIPROSONE EQ 0.05% N 17691

BETAMETHASONE VALERATE (PAGE 3-22)

CREAM; TOPICAL  
BETATREX  
 /AB/ /SAVAGE LABS/BYK-GLDN/ EQ 0.1% BASE/ /N 18862/  
 AB SAVAGE LABS/BYK-GLDN EQ 0.1% BASE N 18862  
VALNAC  
 AB NMC LABORATORIES EQ 0.1% BASEM N 70050  
 OINTMENT; TOPICAL  
VALNAC  
 AB NMC LABORATORIES EQ 0.1% BASEM N 70051

BITOLTEROL MESYLATE (PAGE 3-24)

AEROSOL; INHALATION  
 TORNALATE  
 WINTHROP-BRECK/STERL 0.37MG/INH N 18770

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE (PAGE 3-24)

SYRUP; ORAL  
AMRAY  
 AA BAY LABORATORIES 12.5MG/5ML; 10MG/5ML N 88626  
AMBEIVYL  
 AA HARTON LABORATORIES 12.5MG/5ML; 10MG/5ML N 09319  
BREXANYL  
 AA NATL PHARM MFG/BARRE 12.5MG/5ML; 10MG/5ML N 88343

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE (PAGE 3-25)

ELIXIR; ORAL  
 BIPHETAP  
 BAY LABORATORIES 4MG/5ML; 25MG/5ML N 88687  
 /ELIXIR BIPHETAP/  
 /AM. ROBINS/ /4MG/5ML; 25MG/5ML/ /N 13887/  
 /TABLET; CONTROLLED RELEASE; ORAL/  
 BIPHETAP  
 /AM. ROBINS/ /12MG; 75MG/ /N 12436/

BUPRENORPHINE HYDROCHLORIDE (PAGE 3-26)

/INJECTABLE; INJECTION/  
 /BUPRENEX/  
 /MORRICH EATON/PAS/ /EQ 0.3MG BASE/ML/ /N 13601/

BUTABARBITAL SODIUM (PAGE 3-26)

ELIXIR; ORAL  
SODIUM BUTABARBITAL  
BUTABARBITAL SODIUM

CALCITONIN (PAGE 3-27)

INJECTABLE; INJECTION  
 CALCIMAR  
 /ARMOUR PHARM/ /200 MRC UNITS/ML/ /N 17769/  
 /ARMOUR PHARM/ /400 MRC UNITS/VIAL/ /N 17769/  
 ARMOUR PHARM 200 IU/ML N 17769  
 400 IU/VIAL N 17497

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CELLULOSE SODIUM PHOSPHATE (PAGE 3-34)

POWDER; ORAL  
CALCIBIND  
MISSION PHARMACAL 300GM/BOTM N 18757

CHLORDIAZEPOXIDE HYDROCHLORIDE (PAGE 3-37)

CAPSULE; ORAL  
CHLORDIAZEPOXIDE HCL  
> ADD > AB LEMMON 5MG N 88705  
> ADD > AB 10MG N 88706  
> ADD > AB 25MG N 88707

CHLORPROPAMIDE (PAGE 3-42)

TABLET; ORAL  
CHLORPROPAMIDE  
AB BARR LABORATORIES 100MG N 88812  
AB 250MG N 88813  
AB CHELSEA LABORATORIES 100MG N 88865  
AB COLMED LABORATORIES 100MG N 88708  
AB 250MG N 88709  
AB CORD LABORATORIES 100MG N 88725  
AB 250MG N 88726  
AB DANBURY PHARMACAL 100MG N 88952  
AB 250MG N 88926  
AB DURAMED PHARMS 100MG N 88918  
AB 250MG N 88919  
AB LEMMON 100MG N 88768  
AB SUPERPHARM 100MG N 88694  
AB 250MG N 88695  
AB ZENITH LABORATORIES 100MG N 88840  
AB GLUCAMIDE  
AB LEMMON 250MG N 88641

CHYMOPAPAIN (PAGE 3-43)

INJECTABLE; INJECTION  
CHYMOMIACTIN  
SMITH LABORATORIES 4,000 UNITS/VIAL N 18663

CISPLATIN (PAGE 3-44)

INJECTABLE; INJECTION  
/PLATINOL/  
/BRISTOL LABS/B-H/ /10MG/ML/ /N 18057/  
/50MG/VIAL/ /N 18057/  
PLATINOL-AQ  
BRISTOL LABS/B-H 0.5MG/ML N 18057

CLONIDINE (PAGE 3-45)

FILM, CONTROLLED RELEASE; PERCUTANEOUS  
CATAPRES-TTS-1  
BOEHRINGER INGELHEIM 2.5MG N 18891  
CATAPRES-TTS-2  
BOEHRINGER INGELHEIM 5MG N 18891  
CATAPRES-TTS-3  
BOEHRINGER INGELHEIM 7.5MG N 18891

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL  
PHENYLEPHRINE HCL W/ CODEINE  
AA WYETH LABS/AHMO 10MG/5ML; 5MG/5ML; 6.25MG/5ML N 08306  
PROMETH H/ CODEINE  
AA NATL PHARM MFG/BARRE 10MG/5ML; 5MG/5ML; 6.25MG/5ML N 88764  
PROMETHAZINE HCL W/ CODEINE  
> ADD > AA BAY LABORATORIES 10MG/5ML; 5MG/5ML; 6.25MG/5ML N 88896

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL  
PHENYLEPHRINE HCL W/ CODEINE  
AA WYETH LABS/AHMO 10MG/5ML; 6.25MG/5ML N 08306  
PROMETH H/ CODEINE  
AA NATL PHARM MFG/BARRE 10MG/5ML; 6.25MG/5ML N 88763  
PROMETHAZINE HCL W/ CODEINE  
AA BAY LABORATORIES 10MG/5ML; 6.25MG/5ML N 88875

CODEINE PHOSPHATE; PSEUDOPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE (PAGE 3-46)

SYRUP; ORAL  
ACTIVED H/ CODEINE  
AA BURROUGHS WELLCOME 10MG/5ML; 50MG/5ML; 1.25MG/5ML N 12575  
PSEUDOPHEDRINE HCL  
AA BAY LABORATORIES 10MG/5ML; 50MG/5ML; 1.25MG/5ML N 88833

CORTICOTROPIN (PAGE 3-47)

INJECTABLE; INJECTION  
CORTICOTROPIN  
AP CARTER-GLOGAU LABS 60 UNITS/VIAL N 88772

CROMOLYN SODIUM (PAGE 3-48)

SOLUTION/DROPS; OPHTHALMIC  
OPTICROM  
FISONS 4% N 18155



DEXTROSE; THEOPHYLLINE (PAGE 3-62)

| INJECTABLE; INJECTION                                          |                     |                       |         |
|----------------------------------------------------------------|---------------------|-----------------------|---------|
| <u>THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER</u>       |                     |                       |         |
| AP                                                             | TRAVENTOL LABS      | 500/100ML:160MG/100ML | N 18649 |
| AP                                                             |                     | 500/100ML:160MG/100ML | N 18649 |
| AP                                                             |                     | 500/100ML:160MG/100ML | N 18649 |
| AP                                                             |                     | 500/100ML:200MG/100ML | N 18649 |
| AP                                                             |                     | 500/100ML:400MG/100ML | N 18649 |
| <u>THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |                     |                       |         |
| AP                                                             | AM HCGAM/AM HOSP    | 500/100ML:160MG/100ML | N 19083 |
| <u>THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |                     |                       |         |
| AP                                                             | AM HCGAM/AM HOSP    | 500/100ML:160MG/100ML | N 19083 |
| <u>THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |                     |                       |         |
| AP                                                             | AM HCGAM/AM HOSP    | 500/100ML:160MG/100ML | N 19083 |
| <u>THEOPHYLLINE 0.22% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |                     |                       |         |
| AP                                                             | AM HCGAM/AM HOSP    | 500/100ML:200MG/100ML | N 19212 |
| <u>THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>  |                     |                       |         |
| AP                                                             | AM HCGAM/AM HOSP    | 500/100ML:400MG/100ML | N 19212 |
| <u>THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER</u>        |                     |                       |         |
| AP                                                             | ABBOTT LABORATORIES | 500/100ML:160MG/100ML | N 19211 |
| AP                                                             |                     | 500/100ML:160MG/100ML | N 19211 |
| AP                                                             |                     | 500/100ML:160MG/100ML | N 19211 |
| AP                                                             |                     | 500/100ML:200MG/100ML | N 19211 |
| AP                                                             |                     | 500/100ML:400MG/100ML | N 19211 |

DICYCLOMINE HYDROCHLORIDE (PAGE 3-64)

| CAPSULE; ORAL         |                               |  |         |
|-----------------------|-------------------------------|--|---------|
|                       | BENTYL                        |  |         |
|                       | MERRELL DOW/DOW CHEM 10MG     |  | N 07409 |
| INJECTABLE; INJECTION |                               |  |         |
|                       | BENTYL                        |  |         |
|                       | MERRELL DOW/DOW CHEM 10MG/ML  |  | N 08370 |
| SYRUP; ORAL           |                               |  |         |
|                       | BENTYL                        |  |         |
|                       | MERRELL DOW/DOW CHEM 10MG/5ML |  | N 07961 |
| TABLET; ORAL          |                               |  |         |
|                       | BENTYL                        |  |         |
|                       | MERRELL DOW/DOW CHEM 20MG     |  | N 07409 |

DIETHYLPROPION HYDROCHLORIDE (PAGE 3-65)

| TABLET; ORAL |                           |      |         |
|--------------|---------------------------|------|---------|
| AA           | <u>DIETHYLPROPION HCL</u> |      |         |
|              | LEMMON                    | 25MG | N 88642 |

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE (PAGE 3-66)

| INJECTABLE; INJECTION |                      |                                |         |
|-----------------------|----------------------|--------------------------------|---------|
|                       | EMBOLEX              |                                |         |
|                       | SANDOZ PHARMS/SANDOZ | 0.5MG/0.5ML:2,500 UNITS/0.5ML; |         |
|                       |                      | 5.33MG/0.5ML                   | N 18885 |
|                       |                      | 0.5MG/0.7ML:5,000 UNITS/0.7ML; |         |
|                       |                      | 7.46MG/0.7ML                   | N 18885 |

DISULFIRAM (PAGE 3-68)

| TABLET; ORAL |                    |       |         |
|--------------|--------------------|-------|---------|
|              | DISULFIRAM         |       |         |
| BX           | PAR PHARMACEUTICAL | 250MG | N 88792 |
| BX           |                    | 500MG | N 88793 |

DIVALPROEX SODIUM (PAGE 3-69)

| TABLET, ENTERIC COATED; ORAL |                     |               |         |
|------------------------------|---------------------|---------------|---------|
|                              | DEPAKOTE            |               |         |
|                              | ABBOTT LABORATORIES | EQ 125MG BASE | N 18723 |

DOXYCYCLINE HYCLATE (PAGE 3-70)

| CAPSULE; ORAL              |                     |               |         |
|----------------------------|---------------------|---------------|---------|
|                            | <u>DOXY-LEMMON</u>  |               |         |
| AB                         | LEMMON              | EQ 50MG BASE  | N 62497 |
| <u>DOXYCYCLINE HYCLATE</u> |                     |               |         |
| AB                         | PAR PHARMACEUTICAL  | EQ 50MG BASE  | N 62434 |
| AB                         | SUPERPHARM          | EQ 50MG BASE  | N 62469 |
| AB                         |                     | EQ 100MG BASE | N 62469 |
| AB                         | WEST-WARD           | EQ 50MG BASE  | N 62396 |
| AB                         | ZENITH LABORATORIES | EQ 50MG BASE  | N 62500 |
| AB                         |                     | EQ 100MG BASE | N 62500 |

| TABLET; ORAL |                            |               |         |
|--------------|----------------------------|---------------|---------|
|              | <u>DOXYCYCLINE HYCLATE</u> |               |         |
| AB           | ZENITH LABORATORIES        | EQ 100MG BASE | N 62505 |

DOXYLAMINE SUCCINATE (PAGE 3-70)

| TABLET; ORAL                |                      |      |         |
|-----------------------------|----------------------|------|---------|
|                             | <u>DOCAPRYN</u>      |      |         |
| AA                          | MERRELL DOW/DOW CHEM | 25MG | N 06412 |
| <u>DOXYLAMINE SUCCINATE</u> |                      |      |         |
| AA                          | QUANTUM PHARMICS     | 25MG | N 88603 |



GENTAMICIN SULFATE (PAGE 3-86)

ointment; topical

GENTAMICIN SULFATE  
AT E FOUGERA/BYK-GLDN EQ 1MG BASE/GM N 62533  
AT PHARMADERM/BYK-GLDN EQ 1MG BASE/GM N 62534

solution/drops; ophthalmic

GENTAMICIN  
AT ALLERGAN PHARMS EQ 3MG BASE/ML N 62452

GLUTETHIMIDE (PAGE 3-88)

tablet; oral

GLUTETHIMIDE  
/16/ /ZENTH LABORATORIES/ 500MG/ N 13683/

CONADOTROPIN, CHORIONIC (PAGE 3-89)

injectable; injection  
CHORIONIC CONADOTROPIN

>\_ADD> CARTER-GLOGAU LABS 2,000 UNITS/VIAL N 17016

HALCINONIDE (PAGE 3-90)

cream; topical

/N 13683/  
HALC3-E

HEPARIN SODIUM (PAGE 3-91)

injectable; injectable

HEP-FLUM 10  
AP LYPHOMED 10 UNITS/ML N 17651  
HEPARIN LOCK FLUM  
AP LYPHOMED 100 UNITS/ML N 17651  
AP SOLOPAK LABORATORIES 10 UNITS/ML N 88457  
AP 10 UNITS/ML N 88580  
AP 100 UNITS/ML N 88581

HEPARIN SODIUM  
/AP/ ELKINS-SINN/AHROBINS/ 20,000 UNITS/ML/ /N 17037/  
/AP/ 40,000 UNITS/ML/ /N 17037/  
/AP/ 250 UNITS/ML/ /N 17037/

>\_ADD> HEPARIN SODIUM; SODIUM CHLORIDE (PAGE 3-93)

>\_ADD> injectable; injection  
>\_ADD> HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.9%  
>\_ADD> ABBOTT LABORATORIES 10,000 UNITS/100ML;  
>\_ADD> 900MG/100ML N 18911

>\_ADD> HEPARIN SODIUM; SODIUM CHLORIDE (PAGE 3-93)

>\_ADD>

injectable; injection

>\_ADD> HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45%  
>\_ADD> ABBOTT LABORATORIES 10,000 UNITS/100ML;  
>\_ADD> 400MG/100ML N 18911  
>\_ADD> HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.9%  
>\_ADD> ABBOTT LABORATORIES 5,000 UNITS/100ML;  
>\_ADD> 900MG/100ML N 18911  
>\_ADD> HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9%  
>\_ADD> ABBOTT LABORATORIES 5,000 UNITS/100ML;  
>\_ADD> 900MG/100ML N 18911  
>\_ADD> HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.45%  
>\_ADD> ABBOTT LABORATORIES 100 UNITS/ML; 4.5MG/ML N 18911

HEXACHLOROPHENE (PAGE 3-94)

emulsion; topical

AT XTTRIUM LABS 32M N 19055

HYDRALAZINE HYDROCHLORIDE (PAGE 3-95)

tablet; oral

HYDRALAZINE HCL  
AA AMIDE PHARMACEUTICAL 25MG N 88560  
AA 50MG N 88649  
AA ASCOT HOSP PHARMS 25MG N 88310  
AA 50MG N 88311  
AA SUPERPHARM 10MG N 88787  
AA 25MG N 88788  
AA 50MG N 88789

HYDROCHLOROTHIAZIDE ((PAGE 3-96)

tablet; oral

HYDROCHLOROTHIAZIDE  
AB SUPERPHARM 25MG N 88827  
AB 50MG N 88828  
AB 100MG N 88829

HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE (PAGE 3-98)

tablet; oral

LOPRESSOR HCT 50/25  
GEIGY/CIBA-GEIGY 25MG;50MG N 18303  
LOPRESSOR HCT 100/25  
GEIGY/CIBA-GEIGY 25MG;100MG N 18303  
LOPRESSOR HCT 100/50  
GEIGY/CIBA-GEIGY 50MG;100MG N 18303





> ADD > INDOMETHACIN SODIUM TRIHYDRATE (PAGE 3-108)

> ADD > INJECTABLE; INJECTION  
> ADD > INDOCTIN I.V.  
> ADD > MSD/MERCK EQ 1MG BASE/VIAL N 18878

IODOHIPPURATE SODIUM, I-123 (PAGE 3-109)

INJECTABLE; INJECTION  
NEPHROFLOW  
MEDI-PHYSICS 1MCI/ML N 18289

ISOETHARINE MESYLATE (PAGE 3-110)

AEROSOL; INHALATION  
BRONKOMETER  
/BREGN LABS/STERLING//0.61%/  
BN BREGN LABS/STERLING 0.34MG/INH /N 12339  
ISOETHARINE MESYLATE  
BN NATL PHARM MFG/BARRE 0.14MG/INH N 87858

KANAMYCIN SULFATE (PAGE 3-112)

INJECTABLE; INJECTION  
KANTREX  
AP BRISTOL LABS/B-M EQ 75MG BASE/2ML N 62564  
AP EQ 500MG BASE/2ML N 62564  
AP EQ 1GM BASE/5ML N 62564

LABETALOL HYDROCHLORIDE (PAGE 3-113)

INJECTABLE; INJECTION  
NORMODYNE  
SCHERING 5MG/ML N 18687

TABLET; ORAL  
NORMODYNE  
SCHERING 200MG N 18686  
300MG N 18686  
400MG N 18686

TRANDATE  
GLAXO 200MG N 18716  
300MG N 18716  
400MG N 18716

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE (PAGE 3-114)

INJECTABLE; INJECTION  
SCANDONEST L  
AP DEPROCO 0.05MG/ML; 12% N 88388

LIDOCAINE (PAGE 3-114)

> ADD > AEROSOL; ORAL  
> ADD > XYLOCAINE  
> ADD > ASTRA PHARM PRODS 10% N 14394

LINDANE (PAGE 3-116)

LOTION; TOPICAL  
LINDANE  
AT BAY LABORATORIES 1% N 88190

SHAMPOO; TOPICAL  
LINDANE  
AT BAY LABORATORIES 1% N 88191

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE (PAGE 3-119)

SOLUTION; IRRIGATION  
PHYSIOLYTE IN PLASTIC CONTAINER  
ABBOTT LABORATORIES 50MG/100ML; 37MG/100ML; 37MG/100ML; 530MG/100ML; 500MG/100ML N 19024

SYNOVALYTE IN PLASTIC CONTAINER  
TRAVENOL LABS 50MG/100ML; 37MG/100ML; 368MG/100ML; 526MG/100ML; 502MG/100ML N 19326

MEPERIDINE HYDROCHLORIDE (PAGE 3-122)

INJECTABLE; INJECTION  
MEPERIDINE HCL  
AP ABBOTT LABORATORIES 10MG/ML N 88432  
AP INTL MEDICATION SYS 10MG/ML N 86332

SYRUP; ORAL  
DEMEROL  
> ADD > AA KINTHROP LABS/STERL 50MG/5ML N 05010  
> ADD > MEPEXONE HCL  
> ADD > AA ROXANE LABORATORIES 50MG/5ML N 83744

TABLET; ORAL  
MEPERIDINE HCL  
AA BARR LABORATORIES 100MG N 88640

MEPHENTERMINE SULFATE (PAGE 3-123)

INJECTABLE; INJECTION  
MYAMINE SULFATE  
/MYETH LABS/AMMO/ /15MG/ML/ /N 88248/  
/30MG/ML/ /N 88248/  
MYETH LABS/AMMO EQ 15MG BASE/ML N 08248  
EQ 30MG BASE/ML N 08248



NOMIFENSINE MALEATE (PAGE 3-140)

CAPSULE; ORAL

MERITAL

HOECHST-ROUSSEL

25MG#

50MG#

N 18224

N 18224

NOREPINEPHRINE BITARTRATE (PAGE 3-140)

INJECTABLE; INJECTION

LEVOPHED

> DLT > /Hoechst Laboratories/ EQ 1mg Base/ML/  
> ADD > WINTHROP-BREON/STERIL EQ 1MG BASE/ML

/N 07513/  
N 07513

NYSTATIN (PAGE 3-141)

SUSPENSION; ORAL

NYSTATIN

AA BAY LABORATORIES

100,000 UNITS/ML#

N 62512

> ADD > AA

PHARMAFAIR

100,000 UNITS/ML#

N 62541

TABLET; ORAL

NYSTATIN

AA QUANTUM PHARMICS

500,000 UNITS#

N 62525

OXTRIPHYLLINE (PAGE 3-143)

ELIXIR; ORAL

CHILBYL

AA PARKE-DAVIS/W-L

100MG/5ML#

N 09268

OXTRIPHYLLINE

AA BAY LABORATORIES

100MG/5ML

N 88243

OXYPHENBUTAZONE (PAGE 3-143)

TABLET; ORAL

OXYPHENBUTAZONE

AB BOLAR PHARMACEUTICAL

100MG#

N 88399

TANFARIN

AB GEIGY/CIBA-GEIGY

100MG

N 12542

PENTAMIDINE ISETHIONATE (PAGE 3-148)

INJECTABLE; INJECTION

PENTAM 300

LYPHOMED

300MG/VIAL#

N 19264

PENTOXIFYLLINE (PAGE 3-149)

TABLET, CONTROLLED RELEASE; ORAL

TRENTAL

HOECHST-ROUSSEL

400MG#

N 18631

PHENTERMINE HYDROCHLORIDE (PAGE 3-151)

CAPSULE; ORAL

PHENTERMINE HCL

AA

PHARM BASICS

30MG#

N 88797

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE (PAGE 3-153)

SYRUP; ORAL

PHENYLEPHRINE VC

AA

WYETH LABS/AMHO

5MG/5ML; 6.25MG/5ML

N 08604

PROMETH VC PLAIN

AA

NATL PHARM MFG/BARRE

5MG/5ML; 6.25MG/5ML#

N 88761

PROMETHAZINE VC PLAIN

> ADD > AA

BAY LABORATORIES

5MG/5ML; 6.25MG/5ML#

N 88897

PHENYTOIN SODIUM (PAGE 3-153)

INJECTABLE; INJECTION

PHENYTOIN SODIUM

AP

SOLOPAK LABORATORIES

50MG/ML#

N 88519

AP

50MG/5ML#

N 23520

AP

50MG/ML#

N 88521

PHENYTOIN SODIUM, EXTENDED (PAGE 3-153)

CAPSULE; ORAL

DILANTIN

AB

PARKE-DAVIS/W-L

100MG

N 84349

EXTENDED PHENYTOIN SODIUM

AB

BOLAR PHARMACEUTICAL

100MG#

N 88711

PILOCARPINE HYDROCHLORIDE (PAGE 3-154)

GEL; OPHTHALMIC

PILOPINE HS

ALCON LABORATORIES

4%

N 18796

|                                                                                                                   |  |                                 |  |                               |  |                              |  |                                 |  |
|-------------------------------------------------------------------------------------------------------------------|--|---------------------------------|--|-------------------------------|--|------------------------------|--|---------------------------------|--|
| POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM<br>BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE (PAGE 3-155) |  | POTASSIUM CHLORIDE (PAGE 3-156) |  | EDLM PREPARATIONS             |  | COLYTE                       |  | POWDER FOR RECONSTITUTION; ORAL |  |
| 120GM/PACKET;1.49GM/PACKET;                                                                                       |  | 11.36GM/PACKET;2.92GM/PACKET;   |  | 227.1GM/PACKET;1.42GM/PACKET; |  | 9.36GM/PACKET;5.53GM/PACKET; |  | 12.5GM/PACKET;1.5GM/PACKET;     |  |
| 36.0GM/PACKET;4.47GM/PACKET;                                                                                      |  | 10.08GM/PACKET;0.76GM/PACKET;   |  | 34.08GM/PACKET;1.08GM/PACKET; |  |                              |  |                                 |  |
| N 10963                                                                                                           |  | N 10963                         |  | N 10963                       |  | N 10963                      |  | N 10963                         |  |
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PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE  
(PAGE 3-169)

TABLET; ORAL  
 > ADD > ALLERFERD  
 > ADD > AA PRIVATE FORMULATIONS 60MG;2.5MG N 88360  
 > ADD > TRILITRON  
 > ADD > AA NEWTRON PHARMS 60MG;2.5MG N 88515  
 > ADD > AA TRIPROLIDINE HCL AND PSEUDOEPHEDRINE HCL  
 AA ZENITH LABORATORIES 60MG;2.5MG N 85273

QUINIDINE SULFATE (PAGE 3-170)

TABLET; ORAL  
 /AB/ GIN-GUIN  
 ROWELL LABORATORIES /26646/ /N'16255/ > ADD >

RANITIDINE HYDROCHLORIDE (PAGE 3-171)

INJECTABLE; INJECTION  
 ZANTAC  
 GLAXO EQ 25MG BASE/MLM N 19090

RITODRINE HYDROCHLORIDE (PAGE 3-173)

INJECTABLE; INJECTION  
 /AB/ Ritodrine Hcl  
 /AB/ /PUPHAR LABS/ /1614/ML/ /N'16260/ > ADD > AP  
 /AB/ YUTOPAR  
 /AB/ ASTRA PHARM PRODS 10MG/ML N 18560  
 15MG/MLM N 18560

TABLET; ORAL  
 /AB/ Ritodrine Hcl  
 /AB/ /PUPHAR LABS/ /1614/ /N'16260/ > ADD > AP  
 /AB/ YUTOPAR  
 /AB/ ASTRA PHARM PRODUCTS 10MG N 18555

SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)

INJECTABLE; INJECTION  
 LIPOSYN II 10%  
 ABBOTT LABORATORIES 5%;5% N 18997  
 LIPOSYN II 20%  
 ABBOTT LABORATORIES 10%;10% N 18991

SCOPOLAMINE (PAGE 3-174)

FILM, CONTROLLED RELEASE; PERCUTANEOUS  
 /TRANSDERM-9/  
 /ALZA/ /1.5mg/ /N'17874/  
 TRANSDERM-SCOP  
 CIBA/CIBA-GEIGY 1.5MG N 17874

SODIUM CHLORIDE (PAGE 3-176)

INJECTABLE; INJECTION  
 /AB/ SODIUM CHLORIDE IN PLASTIC CONTAINER  
 /AB/ /AM HCGAIN/AM HOSP/ /900/3/100ML/ /N'17464/  
 /AB/ SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 /AB/ AM HCGAIN/AM HOSP 900/3/100ML N 17464  
 /AB/ INVENEX LABS/LIFE 5HS/MLM N 88912

SODIUM LACTATE (PAGE 3-176)

INJECTABLE; INJECTION  
 SODIUM LACTATE IN PLASTIC CONTAINER  
 ABBOTT LABORATORIES 5MEQ/MLM N 18947

SODIUM NITROPRUSSIDE (PAGE 3-178)

INJECTABLE; INJECTION  
 /AB/ SODIUM NITROPRUSSIDE  
 /AB/ LYPHOMED 5MG/VTALM N 70031

SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)

POWDER; ORAL; RECTAL  
 /AB/ KAYEXALATE  
 /AB/ BREON LABS/STERLING 653.6GM/BOT N 11287  
 /AB/ SODIUM POLYSTYRENE SULFONATE  
 /AB/ BAY LABORATORIES 653.6GM/BOTM N 88786

SUSPENSION; ORAL; RECTAL  
 /AB/ SODIUM POLYSTYRENE SULFONATE  
 /AB/ BAY LABORATORIES 15GM/60MLM N 88717

SOYBEAN OIL (PAGE 3-180)

INJECTABLE; INJECTION  
 /AB/ LIPOSYN III 10%  
 /AB/ ABBOTT LABORATORIES 10% N 18969  
 /AB/ LIPOSYN III 20%  
 /AB/ ABBOTT LABORATORIES 20% N 18970

|                                             |    |                                                  |                        |         |  |
|---------------------------------------------|----|--------------------------------------------------|------------------------|---------|--|
| > ADD >                                     | AI | ORTHO PHARMACEUTICAL                             | 100MG;145.3ZEM;172.5MG | N 05796 |  |
| > ADD >                                     | AI | TERCILE SULFA                                    | 100MG;145.3ZEM;172.5MG | N 88453 |  |
| > ADD >                                     | AI | E FOUNGERA/ALTANA                                | 100MG;145.3ZEM;172.5MG | N 88453 |  |
| > ADD >                                     | AI | PHARMADERM/ALTANA                                | 100MG;145.3ZEM;172.5MG | N 88452 |  |
| SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183) |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| SULFACITIMAZOLE & TRIMETHOPRIM              |    |                                                  |                        |         |  |
| AB                                          |    | HEATHEN DRUG                                     | 80MG;160MG             | N 18746 |  |
| AB                                          |    | SULFACITIMAZOLE AND TRIMETHOPRIM                 | 80MG;160MG             | N 18746 |  |
| AB                                          |    | SULFACITIMAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH | 80MG;160MG             | N 70006 |  |
| AB                                          |    | BARR LABORATORIES                                | 80MG;160MG             | N 70007 |  |
| AB                                          |    | TERMIN/SILVA N/S                                 | 80MG;160MG             | N 70000 |  |
| AB                                          |    | CHELSEA LABORATORIES                             | 80MG;160MG             | N 70000 |  |
| AM                                          |    | CHELSEA LABORATORIES                             | 80MG;160MG             | N 70002 |  |
| TERBUHALINE SULFATE (PAGE 3-187)            |    |                                                  |                        |         |  |
| AEROSOL; INHALATION                         |    |                                                  |                        |         |  |
| BRETHAIRE                                   |    |                                                  |                        |         |  |
| GEIGY/CIBA-GEIGY                            |    |                                                  |                        |         |  |
| 0.2MG/TIN                                   |    |                                                  |                        |         |  |
| N 18762                                     |    |                                                  |                        |         |  |
| THEOPHYLLINE (PAGE 3-190)                   |    |                                                  |                        |         |  |
| CAPSULE, CONTROLLED RELEASE; ORAL           |    |                                                  |                        |         |  |
| ELIXOPHYLLIN SR                             |    |                                                  |                        |         |  |
| BC                                          |    | BERLEX/SCHERING                                  | 125MG                  | N 86266 |  |
| BC                                          |    | SLO-BID                                          | 50MG                   | N 86269 |  |
| BC                                          |    | WILLIAM H RORER                                  | 100MG                  | N 87892 |  |
| BC                                          |    |                                                  | 200MG                  | N 87893 |  |
| BC                                          |    | SLO-PHYLLIN                                      | 300MG                  | N 87894 |  |
| > ADD >                                     | BC |                                                  |                        | N 85203 |  |
| THEOPHYLLINE (PAGE 3-191)                   |    |                                                  |                        |         |  |
| THIOPRIDAZINE HYDROCHLORIDE (PAGE 3-192)    |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | THIOPRIDAZINE HCL                                | 100MG                  | N 88737 |  |
| AB                                          |    | BARR LABORATORIES                                | 100MG                  | N 88735 |  |
| AB                                          |    | CORD LABORATORIES                                | 100MG                  | N 88735 |  |
| TOBRAMYCIN (PAGE 3-194)                     |    |                                                  |                        |         |  |
| SOLUTION/DROPS; OPHTHALMIC                  |    |                                                  |                        |         |  |
| TOBREX                                      |    |                                                  |                        |         |  |
| ALCON LABORATORIES 0.3%                     |    |                                                  |                        |         |  |
| N 62535                                     |    |                                                  |                        |         |  |
| LOCAL ANESTHETIC HYDROCHLORIDE (PAGE 3-194) |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | BARR LABORATORIES                                | 100MG                  | N 88737 |  |
| AB                                          |    | CORD LABORATORIES                                | 100MG                  | N 88735 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| TOLAZAMIDE (PAGE 3-194)                     |    |                                                  |                        |         |  |
| TABLET; ORAL                                |    |                                                  |                        |         |  |
| AB                                          |    | ZENITH LABORATORIES                              | 100MG                  | N 18394 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N 15500 |  |
| AB                                          |    | UPJOHN                                           | 100MG                  | N       |  |

TRIAMCINOLONE ACETONIDE (PAGE 3-195)

CREAM; TOPICAL  
ARTISTOCORT A  
 AT LEDERLE LABS/AM CYAN 0.025% N 88818  
 AT 0.1% N 88819  
 AT 0.5% N 88820

OINTMENT; TOPICAL  
ARTISTOCORT A  
 AT LEDERLE LABS/AM CYAN 0.1% N 88780  
 AT 0.5% N 88781

TRIAMCINOLONE ACETONIDE  
 AT PHARMADERM/BYK-GLDN 0.025% N 88692  
 AT 0.1% N 88690

TRIVEX  
 AT SAVAGE LABS/BYK-GLDN 0.025% N 88693  
 AT 0.1% N 88691

VERAPAMIL HYDROCHLORIDE (PAGE 3-202)

TABLET; ORAL  
CALAN  
 AB SEARLE/SEARLE PHARMS 80MG N 18817  
 AB 120MG N 18817

VEROPTIN  
 AB KNOLL PHARMACEUTICAL 80MG N 18593  
 AB 120MG N 18593

TRILOSTANE (PAGE 3-199)

CAPSULE; ORAL  
 MODRASTANE  
 WINTHROP LABS/STERL 30MG N 18719  
 60MG N 18719

TRIPROLOLINE HYDROCHLORIDE (PAGE 3-200)

SYRUP; ORAL  
TRIPROLOLINE HCL  
 > ADD > AA HALSEY DRUG 1.25MG/5ML N 88735

TPISULFAPYRIMIDINES (PAGE 3-200)

SUSPENSION; ORAL  
 /14446/500ml/  
 /64/ /SALE/CHENICAL/ /64443/500ml/ /N'88163/

VECURONIUM BROMIDE (PAGE 3-202)

INJECTABLE; INJECTION  
 /NORCURON (NC-453)/  
 > DLT >  
 > ADD > NORCURON

[illegible][illegible]

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/CAPSULE, CONTROLLED RELEASE, ORAL/  
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

/TABLET, CONTROLLED RELEASE, ORAL/  
(ALL PRODUCTS - SEE SPECIAL NOTE B.)

DESIGN PENDING LIST - OTHER THAN 'EXEMPT' (COURT ORDER) CATEGORY  
CUMULATIVE SUPPLEMENT NUMBER 5 / AUGUST '04 - JANUARY '05

## CURRENT STATUS - INEFFECTIVE

/BENTON, M. J. / PHARMACEUTICALS, INC. /  
/BENTON, M. J. / PHARMACEUTICALS, INC. /

BEROCCA C HOFFMAN-LA ROCHE  
ASCORBIC ACID; BIOTIN; DEHPANTHENOL; NIACINAMIDE; PYRIDOXINE  
HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

BEROCCA C 500 HOFFMAN-LA ROCHE  
ASCORBIC ACID; BIOTIN; DEHPANTHENOL; NIACINAMIDE; PYRIDOXINE  
HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

DINETAPP AH ROBINS  
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;  
PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR DINETAPP AH ROBINS  
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;  
PHENYLPROPANOLAMINE HYDROCHLORIDE

> DLT > /NEOSOLIN G /  
/BENTON, M. J. / PHARMACEUTICALS, INC. /  
/BENTON, M. J. / PHARMACEUTICALS, INC. /

/BENTON, M. J. / PHARMACEUTICALS, INC. /  
/BENTON, M. J. / PHARMACEUTICALS, INC. /

TUSS-ORNADE SKAF LABORATORIES  
CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;  
ISOPROPALAMINE HYDROCHLORIDE

## CURRENT STATUS - EFFECTIVENESS TO BE DETERMINED

M.V.I. PEDIATRIC USV PHARMACEUTICAL  
ASCORBIC ACID; BIOTIN; DEHPANTHENOL; NIACINAMIDE; PYRIDOXINE  
HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

ADDENDUM D: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984. The Act amends section 505 of the Federal Food, Drug and Cosmetic Act, authorizing the Agency to accept abbreviated new drug applications for most previously approved drug products. This new legislation also provides for extending the term of a patent which claims a product, use, or method of manufacture that was subject to a regulatory review period in accordance with the Act.

The statute requires that FDA make publicly available a list of approved drug products containing the following information:

- 1) an alphabetical list of all drugs by official and proprietary name approved for safety and effectiveness, with monthly updates;
- 2) the application number and approval date for each drug product approved from January 1, 1982; and
- 3) whether in vitro and/or in vivo bioequivalence studies are required for ANDA approval.

The Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition, (APDP) and its monthly supplements will be used to satisfy this new requirement.

In addition, the APDP will identify drugs which qualify under the new statute for periods of exclusivity (during which ANDAs and paper NDAs for those drugs may not be submitted or made effective as identified below) and will provide information on the current patent status of the listed drugs. Exclusivity prevents the filing and/or approval of ANDAs or paper NDAs. It does not prevent the filing or approval of a second full NDA. Applications qualifying for periods of exclusivity are:

- (1) A new drug application approved between January 1, 1982, and September 24, 1984, for a drug product all active ingredients (including any ester or salt of the active ingredient) of which had never been approved in any other application. Approval of an ANDA or paper NDA for the same drug may not be made effective for a period of ten years from the date of the approval of the original application.

- (2) A new drug application approved after September 24, 1984, for a drug product all active ingredients (including any ester or salt of the active ingredient) of which had never been approved in any other new drug application. Generally, no subsequent ANDA or paper NDA for the same drug may be submitted for a period of five years from the date of approval of the original application, except that such an application may be submitted after four years if it contains a certification that a patent claiming the drug is invalid or will not be infringed by the product for which approval is sought.
- (3) A new drug application approved after September 24, 1984, for a drug product involving an active ingredient (or any ester or salt of that active ingredient) that has been approved in an earlier new drug application and which includes reports of new clinical investigations (other than bioavailability studies). Such investigations must have been conducted or sponsored by the applicant or for which the applicant had a right of reference, and the investigations must have been essential to approval of the application. If these requirements are met, the approval of a subsequent ANDA or paper NDA may not be made effective for the same drug before the expiration of three years from the date of approval of the original application.
- (4) A supplement to a new drug application approved after September 24, 1984, which contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the applicant or to which the applicant had a right of reference. The approval of a subsequent application for a change approved in the supplement may not be made effective for three years from the date of approval of the original supplement.
- (5) A new drug application (or supplement to a new drug application) approved during the period from January 1, 1982, to September 24, 1984, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application. The approval of a subsequent application for the drug or a significant change made in a supplement may not be made effective for two years from September 24, 1984.

The Act required approved new drug applications to be supplemented with the required patent information by October 24, 1984. Patent information must now be filed with all newly submitted drug applications, and no NDA may be approved after September 24, 1984, without the pertinent patent information. The patent numbers and the expiration dates of any appropriate product or use patent on a marketed drug that is the subject of an approved NDA will be published in the APDP. Patent information on unapproved applications or on patents beyond the scope (i.e., process or manufacturing) of the Act will not be published.

The following explains how the APDP implements this.

#### Antibiotics, Insulin and Biologics

Title I of the Act has been interpreted by the Agency not to include products approved under sections 506 or 507 of the Federal Food, Drug and Cosmetic Act (antibiotic and insulin products). Because of this, (1) antibiotic and insulin products are not considered eligible for exclusivity protection, (2) holders of approved applications for insulin and antibiotic products need not submit the patent information as required of NDA application holders, and (3) Antibiotic Form 6 sponsors are not required to provide the patent certification statement which must be included in NDAs.

However, Title II, the patent term restoration portion of the Act, specifically addresses antibiotic, non-antibiotic, and human biological products (as those terms are used in the Federal Food, Drug and Cosmetic and Public Health Service Acts) in its provisions.

#### Bioavailability/Bioequivalence Requirements

The therapeutic equivalence evaluation codes in Appendix D of the APDP will enable firms to determine whether in vitro and/or in vivo bioavailability/bioequivalence study data must be included with their ANDA submissions.

Currently, drugs approved prior to 1962 fall into three major biopharmaceutic classes: (1) those which pose an actual or potential bioequivalence problem, and for which demonstration of bioequivalence through in vivo testing and acceptable dissolution performance is necessary; (2) those which pose an actual or potential bioequivalence problem but for which an in vivo study may be waived if acceptable dissolution performance is demonstrated (the list of such drugs is provided under TABLE I); and (3) those which pose no actual or potential bioequivalence problem and for which the only biopharmaceutic requirement is demonstration of acceptable dissolution for solid oral dosage forms.

All firms submitting an abbreviated new drug application for a single source drug product or a drug product which was first approved after 1962 will be required to demonstrate in vivo bioequivalence or else submit information sufficient to permit the Agency to waive demonstration of in vivo bioequivalence. Manufacturers of drug products formulated in dosage forms which do not present bioequivalence problems, such as an intravenous solution, may request that the in vivo bioequivalence requirement be waived.

Before the passage of the Drug Price Competition and Patent Term Restoration Act, the Agency approved various drugs with bioavailability/bioequivalence problems and deferred the in vivo testing requirement for a number of reasons. The new law requires information to show that the proposed ANDA drug product is bioequivalent to the listed drug. Therefore, new applications for drugs such as amitriptyline hydrochloride which formerly may have been approved without an in vivo study now require an in vivo study as a condition for approval under the new Act.

#### Topicals

In the absence of contrary data, FDA regarded all pharmaceutically equivalent topical products of pre-1962 (DESI) drugs to be therapeutically equivalent. However, the Agency required that applicants for topical drug products initially approved after 1962, including "paper NDAs," either demonstrate the safety and efficacy of their products through clinical trials or through a bioequivalence study in order to be approved and evaluated as therapeutically equivalent.

The new Act requires applicants to demonstrate the bioequivalence of their topical drug product to the listed drug as one of the requirements for ANDA approval. This is the same policy that is presently being used in the "paper NDA" approval process. The Agency is now reviewing the therapeutic equivalence evaluation policy that has been made on the pre-1962 topical products to determine whether a change in this policy is warranted. In the meantime, an in vivo demonstration of bioequivalence will be required for approval of all topical products unless a waiver or in vitro alternatives can be justified by the applicant.

#### OTC Drug Products Eligible for Abbreviated New Drug Applications

Previous editions of the ADPP excluded OTC drug products, because the main purpose of that publication was to provide information to states regarding FDAs recommendation as to which generic prescription drug products were acceptable candidates for drug product selection. With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, the Agency now has the responsibility to publish an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required. There are some drugs for which there are both approved and unapproved OTC drug products in the market place. This situation occurs as a result of the Agency's current OTC compliance policy which allows the marketing of various unapproved OTC drug products pending the effective date of the applicable final OTC monograph. The OTC products included in ADPP cumulative supplement TABLE II are limited to those for which approved applications are currently required as a condition of marketing. Appropriate patent numbers, exclusivity information, and expiration dates are also included.

NDA's Approved by the Office of Biological Research and Review Not Previously Published in the ADPP

All products accepted and approved under Section 505 of the Act as NDAs by the Office of Biological Research and Review (OBRR) will now be published in the ADPP (see TABLE III). The application holder should have submitted relevant patent and exclusivity information as for other NDA drug products. These products will be listed drugs and ANDA applications may be submitted for marketing of drugs from this group. Appropriate patent numbers, exclusivity information, and expiration dates are also included.

Patent and Exclusivity Information

It was originally planned that TABLE IV of Cumulative Supplement 2 to the ADPP would contain patent and exclusivity information. Because some firms submitted patent information in excess of that covered by the statute, FDA has reviewed all of the patent information to assure that only appropriate patents are listed. The patents that FDA regards as covered by the statutory provisions for submission of patent information are those on the active ingredient or ingredients, or use patents for a particular indication or method of using the product. The Agency will not publish patents relating to chemical intermediates, methods of manufacturing, excipients or formulations. TABLE IV contains patent numbers and expiration dates and, for drug products approved after 1982, the date of approval and application number as required by the Act.

Firms submitting ANDAs after September 24, 1984, that certified that no patent information had been filed should now amend their applications with the appropriate patent certification statement.

TABLES II-IV now identify all drugs which qualify under the new statute for periods of exclusivity. (See pages A-1 & A-2 of the Addendum for an explanation of exclusivity).

FDA has finished reviewing all patent and exclusivity information received initially from interested parties. The Agency believes TABLES II-IV now contain all appropriate patent and exclusivity information that the Agency regards as being covered by the new statute. This table will be updated monthly to include appropriate patent and exclusivity information for new approvals. The exclusivity information column in TABLES II-IV designates the date on which the exclusivity ends and the basis for the exclusivity through the use of codes as explained on pages A-6 and A-7.

FDA invites comments from all interested parties on whether it has excluded any patent or exclusivity information that should have been included, or included patent or exclusivity information that should have been excluded. Any revisions to the list will be published in subsequent supplements.

|     |                                                |
|-----|------------------------------------------------|
| D-1 | ONCE A DAY APPLICATION                         |
| D-2 | ONCE DAILY DOSING                              |
| D-3 | 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   |

## NEW DOSING SCHEDULE

## REFERENCES

|     |                                            |
|-----|--------------------------------------------|
| 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)      |

## ABBREVIATIONS

DO TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMNS OF TABLES I-IV THE FOLLOWING ABBREVIATIONS HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THIS PAGE FOR AN EXPLANATION OF THE EXCLUSIVITY ABBREVIATIONS FOUND IN THE TABLES.



#### INDICATIONS

|      |                                                                    |
|------|--------------------------------------------------------------------|
| 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 | POST-MYOCARDIAL INFARCTION                                         |
| 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 | MI OR STROKE                                                       |
| I-24 | COMBINED USE WITH NICOTINIC ACID TO LOWER CHOLESTEROL LEVEL        |
| I-25 | BLASTOMYCOSES DERMATITIDES                                         |
| I-26 | PEDIATRIC SUBARACHNOID VASCULAR                                    |
| I-27 | PETRIELLIDIUM BOYDII INFECTION                                     |
| I-28 | HEREDITARY ANGIOEDEMA                                              |
| I-29 | INTRACORONARY USE                                                  |
| I-30 | PEDIATRIC USE                                                      |
| I-31 | DIRECT ISOTOPIC CYSTOGRAPHY                                        |

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TABLE 1. LIST OF DRUG PRODUCTS WHICH MUST DEMONSTRATE IN VIVO  
BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

|                                                                                                                |                                                                                                      |                                                                            |
|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| ACETAMINOPHEN; ASPIRIN;<br>BUTALBITAL;<br>CAPSULE OR TABLET; ORAL<br>160-165MG; 160-165MG; 50MG                | ASPIRIN; BUTALBITAL, CAFFEINE<br>CAPSULE OR TABLET; ORAL<br>325MG; 50MG; 40MG;<br>650MG; 50MG; 40MG; | HYDROXYZINE HYDROCHLORIDE<br>TABLET; ORAL<br>10MG<br>25MG<br>50MG<br>100MG |
| ACETAMINOPHEN; ASPIRIN; BUTALBITAL<br>CAPSULE OR TABLET; ORAL<br>325MG; 325MG; 50MG                            | ASPIRIN; CAFFEINE; CARISOPRODOL<br>TABLET; ORAL<br>160MG; 32MG; 200MG                                |                                                                            |
| ACETAMINOPHEN; ASPIRIN;<br>BUTALBITAL; CAFFEINE<br>CAPSULE OR TABLET; ORAL<br>160-165MG; 160-165MG; 50MG; 40MG | ASPIRIN; CAFFEINE; CARISOPRODOL;<br>CODEINE PHOSPHATE<br>TABLET; ORAL<br>160MG; 32MG; 200MG; 16MG    |                                                                            |
| ACETAMINOPHEN; ASPIRIN;<br>BUTALBITAL; CAFFEINE<br>CAPSULE OR TABLET; ORAL<br>325MG; 325MG; 50MG; 40MG         | ASPIRIN; CARISOPRODOL<br>TABLET; ORAL<br>325MG; 200MG                                                |                                                                            |
| ACETAMINOPHEN; BUTALBITAL<br>CAPSULE OR TABLET; ORAL<br>325; 50MG<br>650; 50MG                                 | ASPIRIN; CARISOPRODOL; CODEINE<br>PHOSPHATE<br>325MG; 200MG; 10MG                                    |                                                                            |
| ACETAMINOPHEN; BUTALBITAL;<br>CAFFEINE<br>CAPSULE OR TABLET; ORAL<br>325MG; 50MG; 40MG<br>650MG; 50MG; 40MG    | ASPIRIN; MEPROBAMATE<br>TABLET; ORAL<br>325MG; 200MG                                                 |                                                                            |
| AMINOPHYLLINE<br>TABLET; ORAL<br>100MG<br>200MG                                                                | ASPIRIN; METHOCARBAMOL<br>TABLET; ORAL<br>325MG; 200MG                                               |                                                                            |
| ASPIRIN; BUTALBITAL;<br>CAPSULE OR TABLET; ORAL<br>325; 50MG<br>650; 50MG                                      | CHLOROTHIAZIDE<br>TABLET; ORAL<br>250MG                                                              |                                                                            |
|                                                                                                                | ESTROGENS, CONJUGATED; MEPROBAMATE<br>TABLET; ORAL<br>0.4MG; 200MG<br>0.4MG; 400MG                   |                                                                            |

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TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>           | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>  | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------|---------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| ACETAMINOPHEN<br>120MG                                      | NEOPAP<br>(SUPPOSITORY; RECTAL)                   | WEBCON PHARMS/ALCON   | 16-401<br>11-07-68                   |                                     |                                        |
| ACETAMINOPHEN<br>650MG                                      | TYLENOL<br>(SUPPOSITORY; RECTAL)                  | MCNEIL LABORATORIES   | 17-756<br>05-26-76                   |                                     |                                        |
| ACETAMINOPHEN<br>120MG                                      | TYLENOL<br>(SUPPOSITORY; RECTAL)                  | MCNEIL LABORATORIES   | 17-756<br>05-26-76                   |                                     |                                        |
| ACETAMINOPHEN<br>120MG                                      | ACEPHEN<br>(SUPPOSITORY; RECTAL)                  | G AND W LABORATORIES  | 18-060<br>02-09-78                   |                                     |                                        |
| ACETAMINOPHEN<br>650MG                                      | ACEPHEN<br>(SUPPOSITORY; RECTAL)                  | G AND W LABORATORIES  | 18-060<br>02-09-78                   |                                     |                                        |
| ACETAMINOPHEN<br>650MG                                      | ACETAMINOPHEN<br>(SUPPOSITORY; RECTAL)            | UPSHER-SMITH LABS     | 18-337<br>04-22-80                   |                                     |                                        |
| ACETAMINOPHEN<br>120MG                                      | ACETAMINOPHEN<br>(SUPPOSITORY; RECTAL)            | UPSHER-SMITH LABS     | 18-337<br>09-12-83                   |                                     |                                        |
| ALUMINUM HYDROXIDE; MAGNESIUM<br>TRISILICATE<br>80MG; 20MG  | GAVISCON<br>(TABLET, CHEWABLE; ORAL)              | MARION LABORATORIES   | 18-685<br>12-09-83                   |                                     | NP<br>09-24-86                         |
| ALUMINUM HYDROXIDE; MAGNESIUM<br>TRISILICATE<br>160MG; 40MG | GAVISCON-2<br>(TABLET, CHEWABLE; ORAL)            | MARION LABORATORIES   | 18-685<br>12-09-83                   |                                     | NP<br>09-24-86                         |
| BROMPHENIRAMINE MALEATE<br>8MG                              | DIMETANE<br>(TABLET, CONTROLLED<br>RELEASE; ORAL) | AH ROBINS             | 10-799<br>06-10-83                   |                                     | RTO<br>09-24-86                        |

| ACTIVE INGREDIENT(S)     | STRENGTH(S) | TRADE NAME     | (DOSAGE FORM, ROUTE)                | APPLICANT NAME     | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------|-------------|----------------|-------------------------------------|--------------------|--------|---------------|----------|-----------|-------------|
| BROMPHENIRAMINE MALEATE  | 12MG        | DIMETANE       | (TABLET, CONTROLLED RELEASE; ORAL)  | AH ROBINS          | 10-799 | 06-10-83      |          |           | RTO         |
| CHLORHEXIDINE GLUCONATE  | 0.5%        | HIBITANE       | (TIMCTURE; TOPICAL)                 | ICI AMERICAS       | 18-049 | 12-18-78      |          |           |             |
| CHLORHEXIDINE GLUCONATE  | 0.5%        | HIBISTAT       | (SOLUTION; TOPICAL)                 | ICI AMERICAS       | 18-300 | 05-23-80      |          |           |             |
| CHLORHEXIDINE GLUCONATE  | 4%          | EXIDINE        | (SOLUTION; TOPICAL)                 | XTRITIUM LABS      | 19-125 | 12-24-84      |          |           |             |
| CHLORHEXIDINE GLUCONATE  | 4%          | EXIDINE        | (AEROSOL; TOPICAL)                  | XTRITIUM LABS      | 19-127 | 12-24-84      |          |           |             |
| CHLORHEXIDINE GLUCONATE  | 4%          | HIBICLENS      | (SOLUTION; TOPICAL)                 | ICI AMERICAS       | 17-768 | 09-17-76      |          |           |             |
| CHLORHEXIDINE GLUCONATE  | 4%          | HIBICLENS      | (SPONGE; TOPICAL)                   | ICI AMERICAS       | 18-423 | 08-27-81      |          |           |             |
| CHLORPHENIRAMINE MALEATE | 8MG         | TELDRIN        | (CAPSULE, CONTROLLED RELEASE; ORAL) | MENLEY & JAMES/SKF | 17-369 | 05-11-78      |          |           |             |
| CHLORPHENIRAMINE MALEATE | 12MG        | TELDRIN        | (CAPSULE, CONTROLLED RELEASE; ORAL) | MENLEY & JAMES/SKF | 17-369 | 05-11-78      |          |           |             |
| CHLORPHENIRAMINE MALEATE | 8MG         | CHLOR-TRIMETON | (TABLET, CONTROLLED RELEASE; ORAL)  | SCHERING           | 07-638 | 10-18-78      |          |           |             |

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TABLE 11. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING  
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TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                          | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                                    | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| CHLORPHENIRAMINE MALEATE<br>12MG                                                                           | CHLOR-TRIMETON<br>(TABLET, CONTROLLED<br>RELEASE; ORAL)                                             | SCHERING              | 07-638<br>10-18-78                   |                                     |                                        |
| CHLORPHENIRAMINE MALEATE;<br>PHENYLPROPANOLAMINE<br>HYDROCHLORIDE<br>8MG; 75MG                             | CONTAC<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL)                                                    | MENLEY & JAMES/SKF    | 18-099<br>02-04-80                   |                                     |                                        |
| CHLORPHENIRAMINE MALEATE;<br>PHENYLPROPANOLAMINE<br>HYDROCHLORIDE<br>12MG; 75MG                            | TRIAMINIC-12<br>(TABLET, CONTROLLED<br>RELEASE; ORAL)                                               | DORSEY LABS/SANDOZ    | 18-115<br>07-23-81                   |                                     |                                        |
| CHLORPHENIRAMINE MALEATE;<br>PHENYLPROPANOLAMINE<br>HYDROCHLORIDE<br>4MG; 25MG                             | DEMAZIN<br>(TABLET, CONTROLLED<br>RELEASE; ORAL)                                                    | SCHERING              | 18-556<br>05-14-84                   |                                     | NS<br>09-24-86                         |
| CHLORPHENIRAMINE MALEATE;<br>PHENYLPROPANOLAMINE<br>HYDROCHLORIDE<br>8MG; 75MG                             | PHENYLPROPANOLAMINE HCL<br>W/ CHLORPHENIRAMINE<br>MALEATE<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | CENTRAL PHARMS        | 18-809<br>05-07-84                   |                                     |                                        |
| CHLORPHENIRAMINE MALEATE;<br>PSEUDOEPHEDRINE SULFATE<br>8MG; 120MG                                         | CHLOR-TRIMETON<br>(TABLET, CONTROLLED<br>RELEASE; ORAL)                                             | SCHERING              | 18-397<br>03-31-81                   |                                     |                                        |
| CHLORPHENIRAMINE POLISTIREX;<br>PHENYLPROPANOLAMINE POLISTIREX<br>EQ 4MG MALEATE/5ML;<br>EQ 37.5MG HCL/5ML | CORSYM<br>(SYRUP; ORAL)                                                                             | PENNMALT PHARM        | 18-050<br>01-04-84                   |                                     | NDF<br>09-24-86                        |

TABLE 11  
OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING



TABLE 11. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                         | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                   | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| INSULIN SUSPENSION, ISOPHANE,<br>MIXED BEEF AND PORK<br>40 UNITS/ML                       | NPH ILETIN (BEEF-PORK)<br>(INJECTABLE; INJECTION)                  | LILLY RES LABS DIV    | 17-936<br>02-08-77                   |                                     |                                        |
| INSULIN SUSPENSION, ISOPHANE,<br>MIXED BEEF AND PORK<br>100 UNITS/ML                      | NPH ILETIN (BEEF-PORK)<br>(INJECTABLE; INJECTION)                  | LILLY RES LABS DIV    | 17-936<br>02-08-77                   |                                     |                                        |
| INSULIN SUSPENSION, ISOPHANE,<br>PURIFIED BEEF<br>100 UNITS/ML                            | NPH ILETIN II<br>(INJECTABLE; INJECTION)                           | ELI LILLY             | 18-479<br>06-12-80                   |                                     |                                        |
| INSULIN SUSPENSION, ISOPHANE,<br>PURIFIED PORK<br>100 UNITS/ML                            | INSULIN INSULATARD NPH<br>NORDISK<br>(INJECTABLE; INJECTION)       | NORDISK               | 18-194<br>01-16-80                   |                                     |                                        |
| INSULIN SUSPENSION, ISOPHANE,<br>PURIFIED PORK<br>100 UNITS/ML                            | NPH ILETIN II (PORK)<br>(INJECTABLE; INJECTION)                    | ELI LILLY             | 18-345<br>12-05-79                   |                                     |                                        |
| INSULIN SUSPENSION, ISOPHANE,<br>PURIFIED PORK<br>100 UNITS/ML                            | PROTAPHANE<br>(INJECTABLE; INJECTION)                              | SQUIBB-NOVO           | 18-623<br>07-30-81                   |                                     |                                        |
| INSULIN SUSPENSION, ISOPHANE,<br>PURIFIED PORK; INSULIN,<br>PURIFIED PORK<br>100 UNITS/ML | INSULIN NORDISK MIXTARD<br>(PORK)<br>(INJECTABLE; INJECTION)       | NORDISK               | 18-195<br>01-16-80                   |                                     |                                        |
| INSULIN SUSPENSION, PROTAMINE<br>ZINC, MIXED BEEF AND PORK<br>100 UNITS/ML                | PROTAMINE, ZINC & ILETIN<br>(BEEF-PORK)<br>(INJECTABLE; INJECTION) | ELI LILLY             | 17-932<br>02-08-77                   |                                     |                                        |

| ACTIVE INGREDIENT(S)                                                      | STRENGTH(S)  | TRADE NAME                          | (DOSAGE FORM; ROUTE)    | APPLICANT NAME     | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|---------------------------------------------------------------------------|--------------|-------------------------------------|-------------------------|--------------------|--------|---------------|----------|-----------|-------------|
| INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK; (BEEF-PORK)      | 100 UNITS/ML | PROTAMINE ZINC & Iletin             | (INJECTABLE; INJECTION) | ELI LILLY          | 17-932 | 02-08-77      |          |           |             |
| INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF                         | 40 UNITS/ML  | PROTAMINE ZINC INSULIN              | (INJECTABLE; INJECTION) | ER SQUIBB AND SONS | 17-928 | 02-08-77      |          |           |             |
| INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF                         | 100 UNITS/ML | PROTAMINE ZINC INSULIN              | (INJECTABLE; INJECTION) | ER SQUIBB AND SONS | 17-928 | 02-08-77      |          |           |             |
| INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED BEEF; INSULIN, Iletin II     | 100 UNITS/ML | PROTAMINE ZINC AND Iletin II        | (INJECTABLE; INJECTION) | ELI LILLY          | 18-476 | 06-12-80      |          |           |             |
| INSULIN SUSPENSION, PROTAMINE ZINC, PURIFIED PORK; INSULIN, PURIFIED PORK | 100 UNITS/ML | PROTAMINE ZINC AND Iletin II (PORK) | (INJECTABLE; INJECTION) | ELI LILLY          | 18-346 | 12-05-79      |          |           |             |
| INSULIN ZINC SUSPENSION, BEEF                                             | 40 UNITS/ML  | LENTE INSULIN                       | (INJECTABLE; INJECTION) | SQUIBB-NOVO        | 17-998 | 02-08-77      |          |           |             |
| INSULIN ZINC SUSPENSION, BEEF                                             | 100 UNITS/ML | LENTE INSULIN                       | (INJECTABLE; INJECTION) | SQUIBB-NOVO        | 17-998 | 02-08-77      |          |           |             |
| INSULIN ZINC SUSPENSION, BIOSYNTHETIC HUMAN                               | 100 UNITS/ML | MONOTARD HUMAN                      | (INJECTABLE; INJECTION) | SQUIBB-NOVO        | 18-777 | 06-30-83      |          |           |             |
| INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF                          | 100 UNITS/ML | ULTRAPAD                            | (INJECTABLE; INJECTION) | SQUIBB-NOVO        | 18-385 | 03-17-80      |          |           |             |

TABLE III. DRUGS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

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TABLE 11. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                   | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>  | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------------------------|---------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| INSULIN ZINC SUSPENSION,<br>EXTENDED, PURIFIED BEEF<br>100 UNITS/ML | ULTRALENTE INSULIN<br>(INJECTABLE; INJECTION)     | SQUIBB-NOVO           | 17-997<br>02-08-77                   |                                     |                                        |
| INSULIN ZINC SUSPENSION, PROMPT,<br>BEEF<br>100 UNITS/ML            | SEMILENTE INSULIN<br>(INJECTABLE; INJECTION)      | SQUIBB-NOVO           | 17-996<br>02-08-77                   |                                     |                                        |
| INSULIN ZINC SUSPENSION, PROMPT,<br>PURIFIED PORK<br>100 UNITS/ML   | SEMITARD<br>(INJECTABLE; INJECTION)               | SQUIBB-NOVO           | 18-382<br>03-17-80                   |                                     |                                        |
| INSULIN ZINC SUSPENSION,<br>PURIFIED BEEF<br>100 UNITS/ML           | LENTE ILETIN II<br>(INJECTABLE; INJECTION)        | ELI LILLY             | 18-477<br>06-12-80                   |                                     |                                        |
| INSULIN ZINC SUSPENSION,<br>PURIFIED BEEF AND PORK<br>100 UNITS/ML  | LENTARD<br>(INJECTABLE; INJECTION)                | SQUIBB-NOVO           | 18-384<br>03-17-80                   |                                     |                                        |
| INSULIN ZINC SUSPENSION,<br>PURIFIED PORK<br>100 UNITS/ML           | LENTE ILETIN II (PORK)<br>(INJECTABLE; INJECTION) | ELI LILLY             | 18-347<br>12-05-79                   |                                     |                                        |
| INSULIN ZINC SUSPENSION,<br>PURIFIED PORK<br>100 UNITS/ML           | MONOTARD<br>(INJECTABLE; INJECTION)               | SQUIBB-NOVO           | 18-383<br>03-17-80                   |                                     |                                        |
| INSULIN, BIOSYNTHETIC HUMAN<br>100 UNITS/ML                         | ACTRAPID HUMAN<br>(INJECTABLE; INJECTION)         | SQUIBB-NOVO           | 18-778<br>08-30-83                   |                                     |                                        |

| ACTIVE INGREDIENT(S)                         | STRENGTH(S)  | TRADE NAME                   | (DOSAGE FORM; ROUTE)    | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------------------------------|--------------|------------------------------|-------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| INSULIN, BIOSYNTHETIC HUMAN                  | 100 UNITS/ML | HUMULIN R                    | (INJECTABLE; INJECTION) | ELI LILLY            | 18-780 | 10-28-82      |          |           |             |
| INSULIN, PORK                                | 40 UNITS/ML  | INSULIN                      | (INJECTABLE; INJECTION) | SQUIBB-NOVO          | 17-926 | 02-08-77      |          |           |             |
| INSULIN, PORK                                | 100 UNITS/ML | INSULIN                      | (INJECTABLE; INJECTION) | SQUIBB-NOVO          | 17-926 | 02-08-77      |          |           |             |
| INSULIN, PURIFIED BEEF                       | 100 UNITS/ML | REGULAR Iletin II            | (INJECTABLE; INJECTION) | ELI LILLY            | 18-478 | 06-12-80      |          |           |             |
| INSULIN, PURIFIED PORK                       | 100 UNITS/ML | INSULIN NORDISK QUICK (PORK) | (INJECTABLE; INJECTION) | NORDISK INSULIN LABS | 18-195 | 01-16-80      |          |           |             |
| INSULIN, PURIFIED PORK                       | 100 UNITS/ML | REGULAR Iletin II (PORK)     | (INJECTABLE; INJECTION) | ELI LILLY            | 18-544 | 12-05-79      |          |           |             |
| INSULIN, PURIFIED PORK                       | 100 UNITS/ML | ACTRAPID                     | (INJECTABLE; INJECTION) | SQUIBB-NOVO          | 18-581 | 05-17-80      |          |           |             |
| INSULIN SUSPENSION, ISOPHANE, PURIFIED HUMAN | 100 UNITS/ML | NOVOLIN N                    | (INJECTABLE; INJECTION) | NOVO INDUSTRI A/S    | 19-065 | 01-25-85      |          |           |             |
| NONOXYNOL-9                                  | 100 UNITS/ML | TODAY                        | (SPONGE; VAGINAL)       | VLI CORPORATION      | 18-683 | 04-01-83      |          |           |             |
| POTASSIUM IODIDE                             | 150MG        | THYRO-BLOCK                  | (TABLET; ORAL)          | WALLACE LABS/C-M     | 18-507 | 11-09-79      |          |           |             |
| POTASSIUM IODIDE                             | 100/ML       | POTASSIUM IODIDE             | (SOLUTION; ORAL)        | ROXANE LABORATORIES  | 18-551 | 02-19-82      |          |           |             |

TABLE 11.11.1. DRUGS CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

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| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                    | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>       | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------------------------------------|--------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| POTASSIUM IODIDE<br>130MG                                                            | IOSAT<br>(TABLET; ORAL)                                | ANBEX                 | 18-664<br>10-14-82                   |                                     |                                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE<br>120MG                                               | SUDAFED S.A.<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | BURROUGHS WELLCOME    | 17-941<br>01-15-79                   |                                     |                                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>30MG/5ML; 1.25MG/5ML | ACTIFED<br>(SYRUP; ORAL)                               | BURROUGHS WELLCOME    | 11-935<br>11-26-82                   |                                     | RT0<br>09-24-86                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>60MG; 2.5MG          | ACTIFED<br>(TABLET; ORAL)                              | BURROUGHS WELLCOME    | 11-936<br>11-26-82                   |                                     | RT0<br>09-24-86                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>60MG; 2.5MG          | ACTIFED<br>(CAPSULE; ORAL)                             | BURROUGHS WELLCOME    | 19-208<br>01-15-85                   |                                     | RT0<br>09-24-86                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>30MG/5ML; 1.25MG/5ML | ALLERBAN PLUS<br>(SYRUP; ORAL)                         | BAY LABORATORIES      | 88-116<br>03-04-83                   |                                     | RT0<br>09-24-86                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>60MG; 2.5MG          | TRI-SUDO<br>(TABLET; ORAL)                             | MD PHARMACEUTICAL     | 85-024<br>01-10-84                   |                                     | RT0<br>09-24-86                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>60MG; 2.5MG          | TRIPROLINE<br>(TABLET; ORAL)                           | DANBURY PHARMACAL     | 88-112<br>01-20-83                   |                                     | RT0<br>09-24-86                        |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>30MG/5ML; 1.25MG/5ML | TRIOFED<br>(SYRUP; ORAL)                               | NATL PHARM MFG/BARRE  | 88-115<br>03-04-83                   |                                     | RT0<br>09-24-86                        |

| ACTIVE INGREDIENT(S)                                         | STRENGTH(S)          | TRADE NAME                                                    | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------------------------------------------|----------------------|---------------------------------------------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLOLINE HYDROCHLORIDE | 30MG/5ML; 1.25MG/5ML | TRIPROLOLINE HCL<br>AND PSEUDOEPHEDRINE HCL<br>(TABLET, ORAL) | HALSEY DRUG          | 88-213 | 03-30-84      |          | 09-24-86  | RTO         |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLOLINE HYDROCHLORIDE | 60MG; 2.5MG          | TRIPROLOLINE HCL<br>AND PSEUDOEPHEDRINE HCL<br>(TABLET, ORAL) | CHELSEA LABORATORIES | 88-118 | 01-26-84      |          | 09-24-86  | RTO         |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLOLINE HYDROCHLORIDE | 60MG; 2.5MG          | TRIPROLOLINE HCL<br>AND PSEUDOEPHEDRINE HCL<br>(TABLET, ORAL) | HALSEY DRUG          | 88-192 | 05-01-84      |          | 09-24-86  | RTO         |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLOLINE HYDROCHLORIDE | 60MG; 2.5MG          | TRIPROLOLINE HCL<br>AND PSEUDOEPHEDRINE HCL<br>(TABLET, ORAL) | BOLAR PHARMACEUTICAL | 88-518 | 01-13-84      |          | 09-24-86  | RTO         |
| PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLOLINE HYDROCHLORIDE | 30MG/5ML; 1.25MG/5ML | TRIPROLOLINE HCL<br>AND PSEUDOEPHEDRINE HCL<br>(TABLET, ORAL) | HALSEY DRUG          | 88-213 | 05-01-84      |          | 09-24-86  | RTO         |
| PSEUDOEPHEDRINE SULFATE                                      | 120MG                | AFRINOL<br>(TABLET, CONTROLLED<br>RELEASE, ORAL)              | SCHERING             | 18-191 | 10-30-80      |          |           |             |

TABLE 1. . . OF DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

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TABLE 11. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| TIOCONAZOLE<br>1%                                 | TROSYD<br>(CREAM; TOPICAL)                       | PFIZER CEN RES/PFIZER | 18-682<br>02-18-83                   | 4062966<br>12-13-94                 | NCE<br>02-18-93                        |
| TRIPROLIDINE HYDROCHLORIDE<br>2.5MG               | ACTIDIL<br>(TABLET; ORAL)                        | BURROUGHS WELLCOME    | 11-110<br>04-14-58                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>2.5MG               | TRIPROLIDINE HCL<br>(TABLET; ORAL)               | BOLAR PHARMACEUTICAL  | 84-453<br>02-06-76                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>2.5MG               | TRIPROLIDINE HCL<br>(TABLET; ORAL)               | DANBURY PHARMACAL     | 85-094<br>02-07-77                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>2.5MG               | TRIPROLIDINE HCL<br>(TABLET; ORAL)               | DRUMMER/PHOENIX       | 85-610<br>03-21-78                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>1.25MG/5ML          | ACTIDIL<br>(SYRUP; ORAL)                         | BURROUGHS WELLCOME    | 11-496<br>07-24-58                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>1.25MG/5ML          | BAYIDYL<br>(SYRUP; ORAL)                         | BAY LABORATORIES      | 87-963<br>01-18-83                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>1.25MG/5ML          | TRIPROLIDINE HCL<br>(SYRUP; ORAL)                | NATL PHARM MFG/BARRE  | 85-940<br>07-13-79                   |                                     | RTO<br>09-24-86                        |
| TRIPROLIDINE HYDROCHLORIDE<br>1.25MG/5ML          | TRIPROLIDINE HCL<br>(SYRUP; ORAL)                | PHARMS ASSOC/BEACH    | 87-514<br>02-10-82                   |                                     | RTO<br>09-24-86                        |

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TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                 | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| ANTICOAGULANT CITRATE DEXTROSE<br>SOLUTION USP                    | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 10-102<br>12-14-61                   |                                     |                                        |
| ANTICOAGULANT CITRATE DEXTROSE<br>SOLUTION USP                    | NONE<br>(INJECTABLE; INJECTION)                  | DELMED                | 11-912<br>9-2-59                     |                                     |                                        |
| ANTICOAGULANT CITRATE DEXTROSE<br>SOLUTION USP                    | NONE<br>(INJECTABLE; INJECTION)                  | TRAVENOL LABS         | 10-855<br>06-11-59                   |                                     |                                        |
| ANTICOAGULANT CITRATE DEXTROSE<br>SOLUTION USP                    | NONE<br>(INJECTABLE; INJECTION)                  | TRAVENOL LABS         | 16-918<br>3-17-78                    |                                     |                                        |
| ANTICOAGULANT CITRATE<br>PHOSPHATE DEXTROSE ADENINE-1<br>SOLUTION | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 80-77<br>11-6-80                     |                                     |                                        |
| ANTICOAGULANT CITRATE PHOSPHATE<br>DEXTROSE ADENINE SOLUTION      | NONE<br>(INJECTABLE; INJECTION)                  | DELMED                | 78-519<br>4-23-80                    |                                     |                                        |
| ANTICOAGULANT CITRATE PHOSPHATE<br>DEXTROSE ADENINE SOLUTION      | NONE<br>(INJECTABLE; INJECTION)                  | TERUMO AMERICA        | 82-528<br>11-3-82                    |                                     |                                        |
| ANTICOAGULANT CITRATE PHOSPHATE<br>DEXTROSE ADENINE SOLUTION      | NONE<br>(INJECTABLE; INJECTION)                  | TRAVENOL LABS         | 77-420<br>5-12-78                    |                                     |                                        |
| ANTICOAGULANT CITRATE<br>PHOSPHATE DEXTROSE SOLUTION USP          | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 16-527<br>6-22-70                    |                                     |                                        |
| ANTICOAGULANT CITRATE<br>PHOSPHATE DEXTROSE SOLUTION<br>USP       | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 80-222<br>8-23-82                    |                                     |                                        |

| ACTIVE INGREDIENT(S)                                                                                                                                                                                    | TRADE NAME                                         | APPLICANT NAME    | NDA #         | PATENT #  | EXCLUSIVITY |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------------|---------------|-----------|-------------|
| STRENGTH(S)                                                                                                                                                                                             | (DOSAGE FORM; ROUTE)                               |                   | APPROVAL DATE | EXP. DATE |             |
| ANTI COAGULANT CITRATE PHOSPHATE                                                                                                                                                                        | NONE                                               | DELMED            | 16-907        |           |             |
| DEXTRROSE SOLUTION USP                                                                                                                                                                                  | (INJECTABLE; INJECTION)                            |                   | 5-15-73       |           |             |
| ANTI COAGULANT CITRATE PHOSPHATE                                                                                                                                                                        | NONE                                               | TERUMO AMERICA    | 78-1211       |           |             |
| DEXTRROSE SOLUTION USP                                                                                                                                                                                  | (INJECTABLE; INJECTION)                            |                   | 6-10-81       |           |             |
| ANTI COAGULANT CITRATE PHOSPHATE                                                                                                                                                                        | NONE                                               | TRAVENOL LABS     | 17-401        |           |             |
| DEXTRROSE SOLUTION USP                                                                                                                                                                                  | (INJECTABLE; INJECTION)                            |                   | 12-6-77       |           |             |
| ANTI COAGULANT CITRATE PHOSPHATE                                                                                                                                                                        | NONE                                               | TRAVENOL LABS     | 81-1012       |           |             |
| DEXTRROSE SOLUTION USP                                                                                                                                                                                  | (INJECTABLE; INJECTION)                            |                   | 6-28-83       |           |             |
| ANTI COAGULANT CITRATE PHOSPHATE                                                                                                                                                                        | AD SOL <sup>R</sup> RED CELL PRESERVATION SOLUTION | TRAVENOL LABS     | 81-1104       |           |             |
| DEXTRROSE SOLUTION USP WITH:                                                                                                                                                                            | (INJECTABLE; INJECTION)                            |                   | 5-16-83       |           |             |
| AS-1: DEXTROSE USP 2.2GM/100ML, SODIUM CHLORIDE USP 0.9GM/100ML, MANNITOL USP 0.75GM/100ML, ADENINE 0.27GM/100ML                                                                                        |                                                    |                   |               |           |             |
| ANTI COAGULANT CITRATE PHOSPHATE                                                                                                                                                                        | AS-2 NUTRIGEL ADITIVE SYSTEM                       | CUTTER BIOL/MILES | 82-915        |           |             |
| DOUBLE DEXTROSE SOLUTION WITH:                                                                                                                                                                          | (INJECTABLE; INJECTION)                            |                   | 9-22-83       |           |             |
| AS-2: CITRIC ACID USP 0.42GM/100ML, DIBASIC SODIUM PHOSPHATE USP 0.285GM/100ML, SODIUM CHLORIDE USP 0.718 GM/100ML, ADENINE 0.017GM/100ML, DEXTROSE USP 0.396GM/100ML, SODIUM CITRATE USP 0.588GM/100ML |                                                    |                   |               |           |             |

TABLE 111. FDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

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TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                                                                                                                                                                                                     | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>            | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| ANTICOAGULANT CITRATE PHOSPHATE<br>DOUBLE DEXTROSE SOLUTION WITH:<br>AS-3: CITRIC ACID USP 0.042<br>GM/100ML, MONOBASIC SODIUM<br>PHOSPHATE USP 0.276GM/100ML,<br>SODIUM CHLORIDE USP 0.410<br>GM/100ML, ADENINE 0.30<br>GM/100ML, DEXTROSE USP 1.10<br>GM/100ML, SODIUM CITRATE USP<br>0.588GM/100ML | AS-3 NUTRICEL ADDITIVE<br>SYSTEM<br>(INJECTABLE; INJECTION) | CUTTER BIOL/MILES     | 82-915<br>10-19-84                   |                                     |                                        |
| ANTICOAGULANT HEPARIN SOLUTION<br>USP                                                                                                                                                                                                                                                                 | NONE<br>(INJECTABLE; INJECTION)                             | DELMED                | 77-822<br>5-17-78                    |                                     |                                        |
| ANTICOAGULANT HEPARIN SOLUTION<br>USP                                                                                                                                                                                                                                                                 | NONE<br>(INJECTABLE; INJECTION)                             | TRAVENOL LABS         | 81-1217<br>5-16-83                   |                                     |                                        |
| ANTICOAGULANT SODIUM CITRATE<br>SOLUTION USP                                                                                                                                                                                                                                                          | NONE<br>(INJECTABLE; INJECTION)                             | ALPHA THERAPEUTIC     | 81-416<br>10-12-83                   |                                     |                                        |
| ANTICOAGULANT SODIUM CITRATE<br>SOLUTION USP                                                                                                                                                                                                                                                          | NONE<br>(INJECTABLE; INJECTION)                             | CUTTER BIOL/MILES     | 76-305<br>6-30-78                    |                                     |                                        |
| ANTICOAGULANT SODIUM CITRATE<br>SOLUTION USP                                                                                                                                                                                                                                                          | NONE<br>(INJECTABLE; INJECTION)                             | DELMED                | 16-702<br>12-28-70                   |                                     |                                        |
| ANTICOAGULANT SODIUM CITRATE<br>SOLUTION USP                                                                                                                                                                                                                                                          | NONE<br>(INJECTABLE; INJECTION)                             | TERUMO AMERICA        | 78-1214<br>2-8-80                    |                                     |                                        |
| ANTICOAGULANT SODIUM CITRATE<br>SOLUTION USP                                                                                                                                                                                                                                                          | NONE<br>(INJECTABLE; INJECTION)                             | TRAVENOL LABS         | 77-923<br>1-20-78                    |                                     |                                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE)    | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXCLUSIVITY |
|----------------------|-------------|------------|-------------------------|---------------------|--------|---------------|----------|-------------|
| DEXTRAN 40, 10%      | 10GM/100ML  | NONE       | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 16-375 | 7-25-67       |          |             |
| DEXTROSE 5%          | 5GM/100ML   |            |                         |                     |        |               |          |             |
| DEXTRAN 40, 10%      | 10GM/100ML  | NONE       | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 16-375 | 7-25-67       |          |             |
| DEXTRAN 75, 6%       | 6GM/100ML   | NONE       | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 8-819  | 3-31-53       |          |             |
| DEXTRAN 75, 6%       | 6GM/100ML   | NONE       | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 8-819  | 3-31-53       |          |             |
| DEXTRAN 75, 6%       | 6GM/100ML   | NONE       | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-253 | 2-4-83        |          |             |
| DEXTRAN 40, 10%      | 10GM/100ML  | NONE       | (INJECTABLE; INJECTION) | AMERICAN MCGAW      | 16-767 | 4-6-70        |          |             |
| DEXTRAN 40, 10%      | 10GM/100ML  | NONE       | (INJECTABLE; INJECTION) | AMERICAN MCGAW      | 16-767 | 4-6-70        |          |             |
| DEXTRAN 40, 10%      | 10GM/100ML  | NONE       | (INJECTABLE; INJECTION) | AMERICAN MCGAW      | 16-767 | 4-6-70        |          |             |

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                       | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DEXTRAN 70, 6%<br>6GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML   | NONE<br>(INJECTABLE; INJECTION)                  | AMERICAN MCGAW        | 9-024<br>8-18-69                     |                                     |                                        |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML            | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 16-653<br>9-23-69                    |                                     |                                        |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 16-653<br>9-23-69                    |                                     |                                        |
| DEXTRAN 70, 6%<br>6GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML   | NONE<br>(INJECTABLE; INJECTION)                  | CUTTER BIOL/MILES     | 8-716<br>8-11-69                     |                                     |                                        |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML            | NONE<br>(INJECTABLE; INJECTION)                  | PHARMACHEM            | 16-836<br>11-14-70                   |                                     |                                        |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML | NONE<br>(INJECTABLE; INJECTION)                  | PHARMACHEM            | 16-836<br>11-14-70                   |                                     |                                        |
| DEXTRAN 75, 6%<br>6GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML   | NONE<br>(INJECTABLE; INJECTION)                  | PHARMACHEM            | 8-564<br>9-19-52                     |                                     |                                        |

| ACTIVE INGREDIENT(S)                                                  | STRENGTH(S) | TRADE NAME                | (DOSAGE FORM; ROUTE)    | APPLICANT NAME | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-----------------------------------------------------------------------|-------------|---------------------------|-------------------------|----------------|--------|---------------|----------|-----------|-------------|
| DEXTRAN 75, 6%<br>6GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML |             | NONE                      | (INJECTABLE; INJECTION) | PHARMACHEM     | 16-759 | 8-19-70       |          |           |             |
| DEXTRAN 1<br>150MG/ML IN<br>SODIUM CHLORIDE 0.6%<br>6MG/ML            |             | FRONIT                    | (INJECTABLE; INJECTION) | PHARMACIA LABS | 83-715 | 10-30-84      |          |           |             |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML          |             | RHEOMACRODEX <sup>R</sup> | (INJECTABLE; INJECTION) | PHARMACIA LABS | 14-716 | 1-18-67       |          |           |             |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML          |             | RHEOMACRODEX <sup>R</sup> | (INJECTABLE; INJECTION) | PHARMACIA LABS | 14-716 | 1-18-67       |          |           |             |
| DEXTRAN 70, 6%<br>6GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML            |             | MACRODEX <sup>R</sup>     | (INJECTABLE; INJECTION) | PHARMACIA LABS | 6-826  | 6-8-54        |          |           |             |
| DEXTRAN 70, 6%<br>6GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML            |             | MACRODEX <sup>R</sup>     | (INJECTABLE; INJECTION) | PHARMACIA LABS | 6-826  | 6-8-54        |          |           |             |
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>DEXTROSE 5%<br>5GM/100ML          |             | GENTRAN <sup>R</sup> 40   | (INJECTABLE; INJECTION) | TRAVENOL LABS  | 16-828 | 11-4-68       |          |           |             |

TABLE 1.1. - NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

TABLE III. NDA'S APPROVED BY THE OFFICE OF BIOLOGICAL RESEARCH AND REVIEW NOT PREVIOUSLY PUBLISHED

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                       | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                     | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DEXTRAN 40, 10%<br>10GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML                                 | GENTRAN <sup>R</sup> 40<br>(INJECTABLE; INJECTION)                                   | TRAVENOL LABS         | 16-628<br>11-4-68                    |                                     |                                        |
| DEXTRAN 75, 6%<br>6GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML                                   | GENTRAN <sup>R</sup> 75<br>(INJECTABLE; INJECTION)                                   | TRAVENOL LABS         | 16-607<br>1-26-70                    |                                     |                                        |
| DEXTRAN 75, 6%<br>INVERTED SUGAR 10%<br>6GM/100ML; 10GM/100ML<br>IN SODIUM CHLORIDE 0.9%<br>0.9GM/100ML | 6% GENTRAN <sup>R</sup> 75 AND<br>10% TRAVER <sup>R</sup><br>(INJECTABLE; INJECTION) | TRAVENOL LABS         | 8-788<br>2-9-53                      |                                     |                                        |
| HETASTARCH, 6%<br>6GM/100ML IN<br>SODIUM CHLORIDE 0.9%<br>0.9GM/100ML                                   | HESPAN <sup>R</sup><br>(INJECTABLE; INJECTION)                                       | AM CRITICAL CARE      | 16-889<br>7-17-72                    | 3523938<br>8-11-87                  |                                        |
| PROPIOLACTONE 99%<br>99GM/100ML                                                                         | BETAPRONE<br>(SOLUTION; CHEMICAL<br>STERILIZING AGENT)                               | ONEAL JONES & FELDMAN | 11-657<br>9-11-59                    |                                     |                                        |
| UROKINASE<br>5000 IU/VIAL                                                                               | ABBOKINASE OPEN-CATHETER<br>(INJECTABLE; INJECTION)                                  | ABBOTT LABORATORIES   | 76-1021<br>12-15-83                  |                                     | NS<br>09-24-86                         |
| UROKINASE<br>250,000 IU/VIAL                                                                            | ABBOKINASE<br>(INJECTABLE; INJECTION)                                                | ABBOTT LABORATORIES   | 76-1021<br>7-31-78                   |                                     | 1-29<br>09-24-86                       |
| UROKINASE<br>250,000 IU/VIAL                                                                            | BREOKINASE<br>(INJECTABLE; INJECTION)                                                | STERLING DRUG         | 17-873<br>8-28-79                    |                                     |                                        |

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S)                             | TRADE NAME<br>(DOSAGE FORM; ROUTE)                                | APPLICANT NAME     | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE                      | EXCLUSIVITY<br>EXP. DATE |
|-----------------------------------------------------------------|-------------------------------------------------------------------|--------------------|------------------------|--------------------------------------------|--------------------------|
| ACEBUTOLOL HYDROCHLORIDE<br>EQ 200MG BASE                       | SECTRAL<br>(CAPSULE; ORAL)                                        | IVES LABS/AMHO     | 18-917<br>12-28-84     | 3726919<br>04-10-90<br>3857952<br>12-31-91 | NCE<br>12-28-89          |
| ACEBUTOLOL HYDROCHLORIDE<br>EQ 300MG BASE                       | SECTRAL<br>(CAPSULE; ORAL)                                        | IVES LABS/AMHO     | 18-917<br>12-28-84     | 3726919<br>04-10-90<br>3857952<br>12-31-91 | NCE<br>12-28-89          |
| ACEBUTOLOL HYDROCHLORIDE<br>EQ 400MG BASE                       | SECTRAL<br>(CAPSULE; ORAL)                                        | IVES LABS/AMHO     | 18-917<br>12-28-84     | 3726919<br>04-10-90<br>3857952<br>12-31-91 | NCE<br>12-28-89          |
| ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE<br>625MG; EQ 25MG BASE | TALAGEN<br>(TABLET; ORAL)                                         | STERLING DRUG      | 18-458<br>09-23-82     | 4105659<br>08-08-95                        | NC<br>09-24-86           |
| ACETIC ACID, GLACIAL<br>250MG/100ML                             | ACETIC ACID 0.25%<br>IN PLASTIC CONTAINER<br>(SOLUTION; URETHRAL) | TRAVENOL LABS      | 18-523<br>02-19-82     |                                            |                          |
| ACETOHYDROXAMIC ACID<br>250MG                                   | LITHOSTAT<br>(TABLET; ORAL)                                       | URO-RESEARCH       | 18-749<br>05-31-83     |                                            | NCE<br>05-31-93          |
| ACYCLOVIR<br>5%                                                 | ZOVIRAX<br>(OINTMENT; TOPICAL)                                    | BURROUGHS WELLCOME | 18-604<br>03-29-82     | 4199574<br>04-22-97                        | NCE<br>03-29-92          |
| ACYCLOVIR<br>200MG                                              | ZOVIRAX<br>(CAPSULE; ORAL)                                        | BURROUGHS WELLCOME | 18-828<br>01-25-85     | 4199574<br>04-22-97                        | NCE<br>03-29-92          |

| ACTIVE INGREDIENT(S)                  | TRADE NAME            | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|---------------------------------------|-----------------------|----------------------|--------|---------------|----------|-----------|-------------|
| ACETOPIR SODIUM<br>EQ 500MG BASE/VIAL | ZOVIRAX               | BURROUGHS WELLCOME   | 18-603 | 04-22-97      | 4199574  | 03-29-92  | NCE         |
| ALBUTEROL                             | PROVENTIL             | SCHERING             | 17-559 | 05-01-81      | 3644353  | 1-22      | 09-24-86    |
| 0.09MG/INH                            | (AEROSOL; INHALATION) |                      |        |               | 3705233  |           |             |
| 12-05-89                              |                       |                      |        |               | 3644353  | 02-22-89  |             |
| 05-01-81                              |                       |                      |        |               | 3705233  | 12-05-89  |             |
| ALBUTEROL                             | VENTOLIN              | GLAXO                | 18-473 | 05-01-81      | 3644353  |           |             |
| 0.09MG/INH                            | (AEROSOL; INHALATION) |                      |        |               | 3705233  |           |             |
| 12-05-89                              |                       |                      |        |               | 3644353  | 02-22-89  |             |
| 05-01-81                              |                       |                      |        |               | 3705233  | 12-05-89  |             |
| ALBUTEROL SULFATE                     | PROVENTIL             | SCHERING             | 17-853 | 05-07-82      | 3644353  |           |             |
| EQ 2MG BASE                           | (TABLET; ORAL)        |                      |        |               | 3705233  |           |             |
| 12-05-89                              |                       |                      |        |               | 3644353  | 02-22-89  |             |
| 09-24-86                              |                       |                      |        |               | 3705233  | 12-05-89  |             |
| ALCLOMETASONE DIFPROPIONATE           | VADERM                | SCHERING             | 18-702 | 12-14-82      | 4124707  |           |             |
| 0.05%                                 | (OINTMENT; TOPICAL)   |                      |        |               | 4124707  | 11-07-95  |             |
| 12-14-92                              |                       |                      |        |               | 4124707  | 11-07-95  |             |
| ALCLOMETASONE DIFPROPIONATE           | VADERM                | SCHERING             | 18-707 | 12-14-82      | 4124707  |           |             |
| 0.05%                                 | (CREAM; TOPICAL)      |                      |        |               | 4124707  | 11-07-95  |             |
| 12-14-92                              |                       |                      |        |               | 4124707  | 11-07-95  |             |
| ALLOPURINOL                           | ALLOPURINOL           | BOLAR PHARMACEUTICAL | 18-241 | 11-16-84      |          |           |             |
| 100MG                                 | (TABLET; ORAL)        |                      |        |               |          |           |             |
| ALLOPURINOL                           | ALLOPURINOL           | BOLAR PHARMACEUTICAL | 18-241 | 11-16-84      |          |           |             |
| 300MG                                 | (TABLET; ORAL)        |                      |        |               |          |           |             |

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| ALLOPURINOL<br>100MG                              | ALLOPURINOL<br>(TABLET; ORAL)                    | CHELSEA LABORATORIES  | 18-785<br>09-28-84                   |                                            |                                        |
| ALLOPURINOL<br>300MG                              | ALLOPURINOL<br>(TABLET; ORAL)                    | CHELSEA LABORATORIES  | 18-785<br>09-28-84                   |                                            |                                        |
| ALLOPURINOL<br>100MG                              | ALLOPURINOL<br>(TABLET; ORAL)                    | DANBURY PHARMACAL     | 18-832<br>09-28-84                   |                                            |                                        |
| ALLOPURINOL<br>300MG                              | ALLOPURINOL<br>(TABLET; ORAL)                    | DANBURY PHARMACAL     | 18-877<br>09-28-84                   |                                            |                                        |
| ALLOPURINOL<br>100MG                              | ZYLOPRIM<br>(TABLET; ORAL)                       | BURROUGHS WELLCOME    | 16-084<br>08-19-66                   | 3624205<br>11-30-88                        |                                        |
| ALLOPURINOL<br>300MG                              | ZYLOPRIM<br>(TABLET; ORAL)                       | BURROUGHS WELLCOME    | 16-084<br>01-14-74                   | 3624205<br>11-30-88                        |                                        |
| ALLOPURINOL<br>100MG                              | LOPURIN<br>(TABLET; ORAL)                        | BOOTS PHARMACEUTICAL  | 18-297<br>06-10-80                   | 3624205<br>11-30-88                        |                                        |
| ALLOPURINOL<br>300MG                              | LOPURIN<br>(TABLET; ORAL)                        | BOOTS PHARMACEUTICAL  | 18-297<br>06-10-80                   | 3624205<br>11-30-88                        |                                        |
| ALPRAZOLAM<br>0.25MG                              | XANAX<br>(TABLET; ORAL)                          | UPJOHN                | 18-276<br>10-16-81                   | 3987052<br>10-19-93<br>3980789<br>09-14-93 |                                        |
| ALPRAZOLAM<br>0.5MG                               | XANAX<br>(TABLET; ORAL)                          | UPJOHN                | 18-276<br>10-16-81                   | 3987052<br>10-19-93<br>3980789<br>09-14-93 |                                        |

| ACTIVE INGREDIENT(S)                                             | TRADE NAME                                         | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY    |
|------------------------------------------------------------------|----------------------------------------------------|----------------------|--------|---------------|----------|-----------|----------------|
| ALPRAZOLAM<br>1MG                                                | XANAX<br>(TABLET; ORAL)                            | UPJOHN               | 18-276 | 10-16-81      | 3987052  | 10-19-93  |                |
| AMCINONIDE<br>0.1%                                               | CYCLOOINT<br>(CREAM; TOPICAL)                      | LEDERLE LABS/AM CYAN | 18-116 | 10-18-71      | 4158055  | 06-12-96  |                |
| AMCINONIDE<br>0.1%                                               | CYCLOOINT<br>(OINTMENT; TOPICAL)                   | LEDERLE LABS/AM CYAN | 18-498 | 11-13-81      | 4158055  | 06-12-96  |                |
| AMITRIPTYLINE HYDROCHLORIDE;<br>HYDROCHLOROTHIAZIDE<br>5MG; 50MG | MODURETIC 5/50<br>(TABLET; ORAL)                   | MSD/MERCK            | 18-201 | 10-05-81      | 3781430  | 12-25-90  |                |
| AMINO ACIDS<br>6.9%                                              | FREEMINE HBC 6.9%<br>(INJECTABLE; INJECTION)       | AM MOGAN/AM HOSP     | 16-822 | 05-17-83      |          |           | NS<br>09-24-86 |
| AMINO ACIDS<br>6.5%                                              | RENNIN W/O ELECTROLYTES<br>(INJECTABLE; INJECTION) | TRAVENOL LABS        | 17-493 | 10-13-82      |          |           | NS<br>09-24-86 |
| AMINO ACIDS<br>8.5%                                              | NOVAMINE 8.5%<br>(INJECTABLE; INJECTION)           | CUTTER LABS/MILES    | 17-957 | 08-09-82      |          |           |                |
| AMINO ACIDS<br>11.4%                                             | NOVAMINE 11.4%<br>(INJECTABLE; INJECTION)          | CUTTER LABS/MILES    | 17-957 | 08-09-82      |          |           |                |
| AMINO ACIDS<br>8%                                                | HEPATAMINE 8%<br>(INJECTABLE; INJECTION)           | AM MOGAN/AM HOSP     | 18-676 | 08-03-82      | 3950529  | 04-13-93  | NS<br>09-24-86 |
| AMINO ACIDS<br>4%                                                | BRAINCHAMIN 4%<br>(INJECTABLE; INJECTION)          | TRAVENOL LABS        | 18-678 | 09-28-84      | 4438144  | 03-20-01  | NS<br>09-24-86 |

TABLE 1: NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S) | TRADE NAME<br>(DOSAGE FORM; ROUTE)                                                   | APPLICANT NAME      | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE | EXCLUSIVITY<br>EXP. DATE |
|-------------------------------------|--------------------------------------------------------------------------------------|---------------------|------------------------|-----------------------|--------------------------|
| AMINO ACIDS<br>4%                   | BRANCHAMIN 4%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                     | TRAVENOL LABS       | 18-684<br>09-28-84     | 4438144<br>03-20-01   | NS<br>09-24-86           |
| AMINO ACIDS<br>6.5%                 | NEOPHAM 6.5%<br>(INJECTABLE; INJECTION)                                              | CUTTER-VITRUM       | 18-792<br>01-17-84     |                       | NS<br>09-24-86           |
| AMINO ACIDS<br>3.5%                 | AMINOSYN 3.5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                     | ABBOTT LABORATORIES | 18-804<br>05-15-84     |                       | NS<br>09-24-86           |
| AMINO ACIDS<br>3.5%                 | AMINOSYN 3.5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                     | ABBOTT LABORATORIES | 18-875<br>08-08-84     |                       | NS<br>09-24-86           |
| AMINO ACIDS<br>5.2%                 | AMINESS 5.2% ESSENTIAL<br>AMINO ACIDS W/ HISTADINE<br>(INJECTABLE; INJECTION)        | CUTTER-VITRUM       | 18-901<br>04-06-84     |                       |                          |
| AMINO ACIDS<br>5.5%                 | TRAVASOL 5.5%<br>W/O ELECTROLYTES<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-931<br>08-23-84     |                       | NS<br>09-24-86           |
| AMINO ACIDS<br>8.5%                 | TRAVASOL 8.5%<br>W/O ELECTROLYTES<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-931<br>08-23-84     |                       |                          |
| AMINO ACIDS<br>10%                  | TRAVASOL 10%<br>W/O ELECTROLYTES<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  | TRAVENOL LABS       | 18-931<br>08-23-84     |                       |                          |

ACTIVE INGREDIENT(S)

STRENGTH(S)

AMINO ACIDS

6%

AMINO ACIDS; CALCIUM ACETATE;

GLYCERIN; MAGNESIUM ACETATE;

PHOSPHORIC ACID; POTASSIUM CHLORIDE;

SODIUM ACETATE; SODIUM CHLORIDE

3%; 26MG/100ML; 3GM/100ML;

54MG/100ML; 41MG/100ML;

149MG/100ML; 204MG/100ML;

117MG/100ML

AMINO ACIDS; DEXTROSE

3.5%; 5%

AMINO ACIDS; DEXTROSE

3.5%; 25%

AMINO ACIDS; DEXTROSE

3.5%; 25%

AMINO ACIDS; DEXTROSE

4.25%; 25%

AMINO ACIDS; DEXTROSE

AMINO ACIDS; MAGNESIUM ACETATE;

PHOSPHORIC ACID; POTASSIUM ACETATE;

SODIUM CHLORIDE

3.5%; 21MG/100ML; 40MG/100ML;

128MG/100ML; 234MG/100ML

TRADE NAME

TROPHAMINE 6%

(INJECTABLE; INJECTION)

PERIPHRAMINE

(INJECTABLE; INJECTION)

APPLICANT NAME

AM MCGAM/AM HDSP

AM MCGAM/AM HDSP

NDA #

19-018

07-20-84

18-582

05-08-82

PATENT #

EXP. DATE

EXP. DATE

EXP. DATE

EXCLUSIVITY

NS

NC

09-24-86

09-24-86

09-24-86

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S)                                                                                                                    | TRADE NAME<br>(DOSAGE FORM; ROUTE)                                                           | APPLICANT NAME      | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE                      | EXCLUSIVITY<br>EXP. DATE |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|---------------------|------------------------|--------------------------------------------|--------------------------|
| AMINO ACIDS; MAGNESIUM ACETATE;<br>PHOSPHORIC ACID; POTASSIUM ACETATE;<br>SODIUM CHLORIDE<br>3.5%; 21MG/100ML; 40MG/100ML;<br>128MG/100ML; 234MG/100ML | AMINOSYN 3.5% M<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                           | ABBOTT LABORATORIES | 18-875<br>08-08-84     |                                            | NC<br>09-24-86           |
| AMINOACETIC ACID<br>1.5GM/100ML                                                                                                                        | AMINOACETIC ACID 1.5%<br>IN PLASTIC CONTAINER<br>(SOLUTION; IRRIGATION)                      | TRAVENOL LABS       | 18-522<br>02-19-82     |                                            |                          |
| AMINOCAPROIC ACID<br>250MG/ML                                                                                                                          | AMINOCAPROIC ACID<br>(INJECTABLE; INJECTION)                                                 | ELKINS-SINN/AROBINS | 18-590<br>10-29-82     |                                            |                          |
| AMINOGLUTETHIMIDE<br>250MG                                                                                                                             | CYTADREN<br>(TABLET; ORAL)                                                                   | CIBA/CIBA-GEIGY     | 18-202<br>10-29-80     | 3595960<br>07-27-88<br>3944671<br>03-16-93 |                          |
| AMINOPHYLLINE<br>300MG/5ML                                                                                                                             | SOMOPHYLLIN<br>(ENEMA; RECTAL)                                                               | FISONS              | 18-232<br>04-02-82     |                                            | NR<br>09-24-86           |
| AMINOPHYLLINE; SODIUM CHLORIDE<br>100MG/100ML; 450MG/100ML                                                                                             | AMINOPHYLLINE W/<br>SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-924<br>12-12-84     |                                            |                          |
| AMINOPHYLLINE; SODIUM CHLORIDE<br>200MG/100ML; 450MG/100ML                                                                                             | AMINOPHYLLINE W/<br>SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-924<br>12-12-84     |                                            |                          |

| ACTIVE INGREDIENT(S)                                       | TRADE NAME                                                                                   | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE                       | EXCLUSIVITY |
|------------------------------------------------------------|----------------------------------------------------------------------------------------------|---------------------|--------|---------------|----------|---------------------------------|-------------|
| AMINOPHYLLINE; SODIUM CHLORIDE<br>400MG/100ML; 450MG/100ML | AMINOPHYLLINE W/<br>SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-924 | 12-1-84       |          |                                 |             |
| AMINOPHYLLINE; SODIUM CHLORIDE<br>500MG/100ML; 450MG/100ML | AMINOPHYLLINE W/<br>SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-924 | 12-1-84       |          |                                 |             |
| AMITRIPTYLINE HYDROCHLORIDE<br>10MG                        | ELAVIL<br>(TABLET; ORAL)                                                                     | MS&D/MERCK          | 12-703 | 04-07-61      |          | 05-21-85<br>3428735<br>02-18-86 |             |
| AMITRIPTYLINE HYDROCHLORIDE<br>25MG                        | ELAVIL<br>(TABLET; ORAL)                                                                     | MS&D/MERCK          | 12-703 | 07-05-74      |          | 05-21-85<br>3428735<br>02-18-86 |             |
| AMITRIPTYLINE HYDROCHLORIDE<br>50MG                        | ELAVIL<br>(TABLET; ORAL)                                                                     | MS&D/MERCK          | 12-703 | 04-07-61      |          | 05-21-85<br>3428735<br>02-18-86 |             |
| AMITRIPTYLINE HYDROCHLORIDE<br>75MG                        | ELAVIL<br>(TABLET; ORAL)                                                                     | MS&D/MERCK          | 12-703 | 10-28-76      |          | 05-21-85<br>3428735<br>02-18-86 |             |
| AMITRIPTYLINE HYDROCHLORIDE<br>100MG                       | ELAVIL<br>(TABLET; ORAL)                                                                     | MS&D/MERCK          | 12-703 | 10-28-76      |          | 05-21-85<br>3428735<br>02-18-86 |             |

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>               | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-----------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| AMITRIPTYLINE HYDROCHLORIDE<br>150MG                            | ELAVIL<br>(TABLET; ORAL)                         | MS&D/MERCK            | 12-703<br>09-17-76                   | 3384663<br>05-21-85<br>3428735<br>02-18-86 |                                        |
| AMITRIPTYLINE HYDROCHLORIDE<br>10MG/ML                          | ELAVIL<br>(INJECTABLE; INJECTION)                | MS&D/MERCK            | 12-704<br>04-11-61                   | 3384663<br>05-21-85<br>3428735<br>02-18-86 |                                        |
| AMITRIPTYLINE HYDROCHLORIDE;<br>CHLORDIAZEPOXIDE<br>12.5MG; 5MG | LIMBITROL<br>(TABLET; ORAL)                      | HOFFMANN-LA ROCHE     | 16-949<br>12-23-77                   | 3384663<br>05-21-85<br>4316897<br>02-23-99 |                                        |
| AMITRIPTYLINE HYDROCHLORIDE;<br>CHLORDIAZEPOXIDE<br>25MG; 10MG  | LIMBITROL<br>(TABLET; ORAL)                      | HOFFMANN-LA ROCHE     | 16-949<br>12-23-77                   | 3384663<br>05-21-85<br>4316897<br>02-23-99 |                                        |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>10MG; 4MG       | ETRAFON A<br>(TABLET; ORAL)                      | SCHERING              | 14-713<br>12-30-65                   | 3384663<br>05-21-85                        |                                        |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>25MG; 2MG       | ETRAFON 2-25<br>(TABLET; ORAL)                   | SCHERING              | 14-713<br>12-30-65                   | 3384663<br>05-21-85                        |                                        |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>25MG; 4MG       | ETRAFON-FORTE<br>(TABLET; ORAL)                  | SCHERING              | 14-713<br>12-30-65                   | 3384663<br>05-21-85                        |                                        |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>10MG; 2MG       | ETRAFON 2-10<br>(TABLET; ORAL)                   | SCHERING              | 14-713<br>12-30-65                   | 3384663<br>05-21-85                        |                                        |

| ACTIVE INGREDIENT(S)                                      | TRADE NAME                     | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-----------------------------------------------------------|--------------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>10MG; 4MG | TRIAVIL 4-10<br>(TABLET; ORAL) | MS&D/MERCK           | 14-715 | 12-30-65      | 3584663  | 05-21-85  | 02-18-86    |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>25MG; 2MG | TRIAVIL 2-25<br>(TABLET; ORAL) | MS&D/MERCK           | 14-715 | 08-23-65      | 3584663  | 05-21-85  | 02-18-86    |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>10MG; 2MG | TRIAVIL 2-10<br>(TABLET; ORAL) | MS&D/MERCK           | 14-715 | 04-04-67      | 3584663  | 05-21-85  | 02-18-86    |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>25MG; 4MG | TRIAVIL 4-25<br>(TABLET; ORAL) | MS&D/MERCK           | 14-715 | 08-23-65      | 3584663  | 05-21-85  | 02-18-86    |
| AMITRIPTYLINE HYDROCHLORIDE;<br>PERPHENAZINE<br>50MG; 4MG | TRIAVIL 4-50<br>(TABLET; ORAL) | MS&D/MERCK           | 14-715 | 03-15-78      | 3584663  | 05-21-85  | 02-18-86    |
| AMOXAPINE<br>25MG                                         | ASENDIN<br>(TABLET; ORAL)      | FEDERLE LABS/AM CYAN | 18-021 | 09-22-80      | 3546226  | 12-08-87  | 05-16-89    |
|                                                           |                                |                      |        |               |          | 3681357   | 08-01-89    |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                      | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|------------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| AMOXAPINE<br>50MG                                                      | ASENDIN<br>(TABLET; ORAL)                        | LEDERLE LABS/AM CYAN  | 18-021<br>09-22-80                   | 3546226<br>12-08-87<br>3663696<br>05-16-89<br>3681357<br>08-01-89 |                                        |
| AMOXAPINE<br>100MG                                                     | ASENDIN<br>(TABLET; ORAL)                        | LEDERLE LABS/AM CYAN  | 18-021<br>09-22-80                   | 3546226<br>12-08-87<br>3663696<br>05-16-89<br>3681357<br>08-01-89 |                                        |
| AMOXAPINE<br>150MG                                                     | ASENDIN<br>(TABLET; ORAL)                        | LEDERLE LABS/AM CYAN  | 18-021<br>09-22-80                   | 3546226<br>12-08-87<br>3663696<br>05-16-89<br>3681357<br>08-01-89 |                                        |
| AMRINONE LACTATE<br>EQ 5MG BASE/ML                                     | INOCOR<br>(INJECTABLE; INJECTION)                | WINTHROP LABS/STERL   | 18-700<br>07-31-84                   | 4072746<br>02-07-95                                               | NCE<br>07-31-94                        |
| ASPIRIN; CAFFEINE;<br>DIHYDROCODEINE BITARTRATE<br>356.4MG; 30MG; 16MG | SYNALGOS-DC<br>(CAPSULE; ORAL)                   | IVES LABS/AMHO        | 11-483<br>09-06-83                   |                                                                   |                                        |
| ASPIRIN; CAFFEINE;<br>ORPHENADRINE CITRATE<br>385MG; 30MG; 25MG        | NORGESIC<br>(TABLET; ORAL)                       | RIKER LABS/3M         | 13-416<br>10-27-82                   |                                                                   |                                        |
| ASPIRIN; CAFFEINE;<br>ORPHENADRINE CITRATE<br>770MG; 60MG; 50MG        | NORGESIC FORTE<br>(TABLET; ORAL)                 | RIKER LABS/3M         | 13-416<br>10-27-82                   |                                                                   |                                        |

| ACTIVE INGREDIENT(S)                             | STRENGTH(S)                               | TRADE NAME               | (DOSAGE FORM, ROUTE) | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------------------------------|-------------------------------------------|--------------------------|----------------------|----------------------|--------|---------------|----------|-----------|-------------|
| ASPIRIN; CAFFEINE;<br>PROPOXYPHENE HYDROCHLORIDE | 32.4MG; 32.4MG;<br>32.4MG; 32.4MG; 32.4MG | DARVON COMPOUND          | (CAPSULE; ORAL)      | ELI LILLY INDSTRS/PR | 10-996 | 03-08-83      |          |           |             |
| ASPIRIN; CAFFEINE;<br>PROPOXYPHENE HYDROCHLORIDE | 32.4MG; 32.4MG;<br>32.4MG; 32.4MG; 32.4MG | DARVON COMPOUND-65       | (CAPSULE; ORAL)      | ELI LILLY INDSTRS/PR | 10-996 | 03-08-83      |          |           |             |
| ASPIRIN; CARISOPRODOL                            | 325MG; 200MG                              | SOMA COMPOUND            | (TABLET; ORAL)       | WALLACE PHARMS/C-W   | 12-365 | 07-11-83      |          |           |             |
| ASPIRIN; CARISOPRODOL;<br>CODEINE PHOSPHATE      | 325MG; 200MG; 16MG                        | SOMA COMPOUND W/ CODEINE | (TABLET; ORAL)       | WALLACE PHARMS/C-W   | 12-366 | 07-11-83      |          |           |             |
| EQUAGESIC                                        | 325MG; 200MG                              | (TABLET; ORAL)           |                      | WYETH LABS/MHD       | 11-702 | 12-29-83      |          |           |             |
| ASPIRIN; PENTAZOCINE HYDROCHLORIDE               | 325MG; EQ 12.5MG BASE                     | TALWIN COMPOUND          | (TABLET; ORAL)       | WINTHROP LABS/STERL  | 16-891 | 11-12-75      |          |           |             |
| ATENOLOL                                         | 50MG                                      | TENORMIN                 | (TABLET; ORAL)       | STUART PHARMS/ICI MM | 18-240 | 08-19-81      |          |           |             |
| TENORMIN                                         | 100MG                                     | TENORMIN                 | (TABLET; ORAL)       | STUART PHARMS/ICI MM | 18-240 | 08-19-81      |          |           |             |

TABLE WITH NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>           | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>  | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------|---------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| ATENOLOL; CHLORTHALIDONE<br>100MG; 25MG                     | TENORETIC 100<br>(TABLET; ORAL)                   | STUART PHARMS/ICI AM  | 18-760<br>06-08-84                   | 3663607<br>05-16-89<br>3934032<br>01-20-93<br>3836671<br>09-17-91 | NC<br>09-24-86                         |
| ATENOLOL; CHLORTHALIDONE<br>50MG; 25MG                      | TENORETIC 50<br>(TABLET; ORAL)                    | STUART PHARMS/ICI AM  | 18-760<br>06-08-84                   | 3663607<br>05-16-89<br>3934032<br>01-20-93<br>3836671<br>09-17-91 | NC<br>09-24-86                         |
| ATRACURIUM BESYLATE<br>10MG/ML                              | TRACRIUM<br>(INJECTABLE; INJECTION)               | BURROUGHS WELLCOME    | 18-831<br>11-23-83                   | 4179507<br>12-18-96                                               | NCE<br>11-23-93                        |
| ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE<br>0.025MG; 0.5MG | MOTOFEN HALF-STRENGTH<br>(TABLET; ORAL)           | MCNEIL LABORATORIES   | 17-744<br>07-14-78                   | 3646207<br>02-28-89                                               |                                        |
| ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE<br>0.025MG; 1MG   | MOTOFEN<br>(TABLET; ORAL)                         | MCNEIL LABORATORIES   | 17-744<br>07-14-78                   | 3646207<br>02-28-89                                               |                                        |
| AZATADINE MALEATE<br>1MG                                    | OPTIMINE<br>(TABLET; ORAL)                        | SCHERING              | 17-601<br>03-29-77                   | 3419565<br>12-31-85<br>3717647<br>02-20-90                        |                                        |
| AZATADINE MALEATE;<br>PSEUDOEPHEDRINE SULFATE<br>1MG; 120MG | TRINALIN<br>(TABLET, CONTROLLED<br>RELEASE; ORAL) | SCHERING              | 18-506<br>03-23-82                   | 3419565<br>12-31-85<br>3717647<br>02-20-90                        | NC<br>09-24-86                         |

| ACTIVE INGREDIENT(S)                   | TRADE NAME                   | APPLICANT NAME     | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------------------------|------------------------------|--------------------|--------|---------------|----------|-----------|-------------|
| BACLOFEN 10MG                          | LIORESAL (TABLET; ORAL)      | GEIGY/CIBA-GEIGY   | 17-851 | 11-22-77      | 10-07-86 | 1471548   |             |
| BACLOFEN 20MG                          | LIORESAL DS (TABLET; ORAL)   | GEIGY/CIBA-GEIGY   | 17-851 | 01-20-82      | 10-07-86 | 1471548   | NS          |
| BENDROFLUMETHIAZIDE 2.5MG              | NATURETIN-2.5 (TABLET; ORAL) | ER SQUIBB AND SONS | 12-164 | 12-07-59      | 07-09-85 | 3392168   |             |
| BENDROFLUMETHIAZIDE 5MG                | NATURETIN-5 (TABLET; ORAL)   | ER SQUIBB AND SONS | 12-164 | 12-07-59      | 07-09-85 | 3392168   |             |
| BENDROFLUMETHIAZIDE 10MG               | NATURETIN-10 (TABLET; ORAL)  | ER SQUIBB AND SONS | 12-164 | 03-29-77      | 07-09-85 | 3392168   |             |
| BENDROFLUMETHIAZIDE; NADOLOL 5MG; 40MG | CORZIDE (TABLET; ORAL)       | ER SQUIBB AND SONS | 18-647 | 05-25-83      | 09-21-93 | 3982021   | NC          |
| BENDROFLUMETHIAZIDE; NADOLOL 5MG; 80MG | CORZIDE (TABLET; ORAL)       | ER SQUIBB AND SONS | 18-647 | 05-25-83      | 09-21-93 | 3982021   | NC          |
| BENTRIONIDE 500MG/7.5ML                | CHYMEX (SOLUTION; ORAL)      | ADRIA LABORATORIES | 18-566 | 12-29-83      | 04-02-91 | 3801562   | NC          |
| BETAMETHASONE 0.6MG                    | CELESTONE (TABLET; ORAL)     | SCHERING           | 12-657 | 04-17-61      | 12-23-86 | 3485854   |             |

TABLETS APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                  | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>  | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|------------------------------------------------------------------------------------|---------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| BETAMETHASONE<br>0.6MG/5ML                                                         | CELESTONE<br>(SYRUP; ORAL)                        | SCHERING              | 14-215<br>04-18-64                   | 3485854<br>12-23-86                 |                                        |
| BETAMETHASONE<br>0.2%                                                              | CELESTONE<br>(CREAM; TOPICAL)                     | SCHERING              | 14-762<br>04-10-64                   | 3485854<br>12-23-86                 |                                        |
| BETAMETHASONE ACETATE;<br>BETAMETHASONE SODIUM PHOSPHATE<br>3MG/ML; EQ 3MG BASE/ML | CELESTONE SOLUSPAN<br>(INJECTABLE; INJECTION)     | SCHERING              | 14-602<br>03-03-65                   | 3485854<br>12-23-86                 |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | DIPROLENE<br>(OINTMENT; TOPICAL)                  | SCHERING              | 18-741<br>07-27-83                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | BETAMETHASONE DIPROPIONATE<br>(CREAM; TOPICAL)    | PHARMADERM/BYK-GLDN   | 19-136<br>06-26-84                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | BETAMETHASONE DIPROPIONATE<br>(CREAM; TOPICAL)    | E FOUGERA/BYK-GLDN    | 19-137<br>06-26-84                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | ALPHATREX<br>(CREAM; TOPICAL)                     | SAVAGE LABS/BYK-GLDN  | 19-138<br>06-26-84                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | BETAMETHASONE DIPROPIONATE<br>(OINTMENT; TOPICAL) | PHARMADERM/BYK-GLDN   | 19-140<br>09-04-84                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | BETAMETHASONE DIPROPIONATE<br>(OINTMENT; TOPICAL) | E FOUGERA/BYK-GLDN    | 19-141<br>09-04-84                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | ALPHATREX<br>(OINTMENT; TOPICAL)                  | SAVAGE LABS/BYK-GLDN  | 19-143<br>09-04-84                   |                                     |                                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | DIPROSONE<br>(CREAM; TOPICAL)                     | SCHERING              | 17-536<br>01-29-75                   |                                     | D-1<br>09-24-86                        |
| BETAMETHASONE DIPROPIONATE<br>EQ 0.05% BASE                                        | DIPROSONE<br>(OINTMENT; TOPICAL)                  | SCHERING              | 17-691<br>04-15-76                   |                                     | D-1<br>09-24-86                        |

| ACTIVE INGREDIENT(S)                      | STRENGTH(S)       | TRADE NAME                  | (DOSAGE FORM; ROUTE) | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------------------|-------------------|-----------------------------|----------------------|----------------------|--------|---------------|----------|-----------|-------------|
| BETAMETHASONE VALERATE                    | EQ 0.05% BASE     | BETAMETHASONE DIFPROPIONATE | DIFROSONE            | SCHERING             | 17-781 | 02-01-77      |          | 09-24-86  | D-1         |
| BETAMETHASONE DIFPROPIONATE               | EQ 0.05% BASE     | DIFROSONE                   | (LOTION; TOPICAL)    | SCHERING             | 17-829 | 05-24-77      |          | 09-24-86  | D-1         |
| BETAMETHASONE DIFPROPIONATE               | EQ 0.1% BASE      | DIFROSONE                   | (ABROSOL; TOPICAL)   | SCHERING             | 18-827 | 07-10-84      | 3660577  | 09-02-89  | NC          |
| BETAMETHASONE DIFPROPIONATE; CLOTRIMAZOLE | EQ 0.05% BASE; 1% | LOTRIZONE                   | (CREAM; TOPICAL)     | SCHERING             | 18-842 | 03-24-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETADON                     | (CREAM; TOPICAL)     | LEMON                | 18-839 | 06-30-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETAMETHASONE VALERATE      | (CREAM; TOPICAL)     | PHARMADERM/BYK-GLDN  | 18-860 | 08-31-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETAMETHASONE VALERATE      | (CREAM; TOPICAL)     | E FOUGERA/BYK-GLDN   | 18-861 | 08-31-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETATREX                    | (CREAM; TOPICAL)     | SAVAGE LABS/BYK-GLDN | 18-862 | 08-31-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETATREX                    | (CREAM; TOPICAL)     | SAVAGE LABS/BYK-GLDN | 18-863 | 08-31-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETAMETHASONE VALERATE      | (OINTMENT; TOPICAL)  | SAVAGE LABS/BYK-GLDN | 18-864 | 08-31-83      |          |           |             |
| BETAMETHASONE VALERATE                    | EQ 0.1% BASE      | BETAMETHASONE VALERATE      | (OINTMENT; TOPICAL)  | PHARMADERM/BYK-GLDN  | 18-864 | 08-31-83      |          |           |             |

10-01-91  
3639573  
11-03-98  
4298604  
12-05-89  
3705172

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| BETAMETHASONE VALERATE<br>EQ 0.1% BASE            | BETAMETHASONE VALERATE<br>(OINTMENT; TOPICAL)    | E FOUGERA/BYK-GLDN    | 18-865<br>08-31-83                   |                                            |                                        |
| BETAMETHASONE VALERATE<br>EQ 0.1% BASE            | BETAMETHASONE VALERATE<br>(LOTION; TOPICAL)      | E FOUGERA/BYK-GLDN    | 18-866<br>08-31-83                   |                                            |                                        |
| BETAMETHASONE VALERATE<br>EQ 0.1% BASE            | BETATREX<br>(LOTION; TOPICAL)                    | SAVAGE LABS/BYK-GLDN  | 18-867<br>08-31-83                   |                                            |                                        |
| BETAMETHASONE VALERATE<br>EQ 0.1% BASE            | BETAMETHASONE VALERATE<br>(LOTION; TOPICAL)      | PHARMADERM/BYK-GLDN   | 18-870<br>08-31-83                   |                                            |                                        |
| BETHANIDINE SULFATE<br>10MG                       | TENATHAN<br>(TABLET; ORAL)                       | AH ROBINS             | 17-675<br>05-29-81                   | 3495013<br>02-10-87                        |                                        |
| BETHANIDINE SULFATE<br>25MG                       | TENATHAN<br>(TABLET; ORAL)                       | AH ROBINS             | 17-675<br>05-29-81                   | 3495013<br>02-10-87                        |                                        |
| BIBUTEROL MESYLATE<br>0.8%                        | TORNALATE<br>(AEROSOL; INHALATION)               | WINTHROP-BREON/STERL  | 18-770<br>12-28-84                   | 4138581<br>02-06-96                        | NCE<br>12-28-89                        |
| BRETYLIUM TOSYLATE<br>50MG/ML                     | BRETYLOL<br>(INJECTABLE; INJECTION)              | AM CRITICAL CARE/AHS  | 17-954<br>07-18-78                   | RE29618<br>04-29-86                        |                                        |
| BROMOCRIPTINE MESYLATE<br>EQ 2.5MG BASE           | PARLODEL<br>(TABLET; ORAL)                       | SANDOZ PHARMS/SANDOZ  | 17-962<br>06-28-78                   | 3752888<br>08-14-90<br>3752814<br>08-14-90 | 1-16<br>12-14-87                       |
| BROMOCRIPTINE MESYLATE<br>EQ 5MG BASE             | PARLODEL<br>(CAPSULE; ORAL)                      | SANDOZ PHARMS/SANDOZ  | 17-962<br>03-01-82                   | 3752888<br>08-14-90<br>3752814<br>08-14-90 | 1-16<br>12-14-87                       |

| ACTIVE INGREDIENT(S)                | STRENGTH(S)                   | TRADE NAME  | (DOSAGE FORM; ROUTE)               | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------------|-------------------------------|-------------|------------------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| BROMODIPHENHYDRAMINE HYDROCHLORIDE; | 12.5MG/5ML; 10MG/5ML          | AMBENYL     | (SYRUP; ORAL)                      | MARION LABORATORIES | 09-319 | 01-10-84      |          |           |             |
| CODEINE PHOSPHATE                   |                               |             |                                    |                     |        |               |          |           |             |
| BROMPHENIRAMINE MALEATE;            | 2MG/5ML; 10MG/5ML; 12.5MG/5ML | DIMETANE-DC | (SYRUP; ORAL)                      | AH ROBINS           | 11-694 | 03-29-84      |          |           |             |
| PHENYLPROPANOLAMINE HYDROCHLORIDE   |                               |             |                                    |                     |        |               |          |           |             |
| BROMPHENIRAMINE MALEATE;            | 2MG/5ML; 10MG/5ML; 12.5MG/5ML | DIMETANE-DX | (SYRUP; ORAL)                      | AH ROBINS           | 11-694 | 03-29-84      |          |           |             |
| DEXTROMETHORPHAN HYDROBROMIDE;      |                               |             |                                    |                     |        |               |          |           |             |
| PSEUDOPHEDRINE HYDROCHLORIDE        |                               |             |                                    |                     |        |               |          |           |             |
| BROMPHENIRAMINE MALEATE;            | 2MG/5ML; 10MG/5ML; 30MG/5ML   | DIMETANE-DX | (SYRUP; ORAL)                      | AH ROBINS           | 19-279 | 08-24-84      |          |           |             |
| DEXTROMETHORPHAN HYDROBROMIDE;      |                               |             |                                    |                     |        |               |          |           |             |
| PSEUDOPHEDRINE HYDROCHLORIDE        |                               |             |                                    |                     |        |               |          |           |             |
| BROMPHENIRAMINE MALEATE;            | 2MG/5ML; 10MG/5ML; 30MG/5ML   | DIMETAPP    | (TABLET, CONTROLLED RELEASE; ORAL) | AH ROBINS           | 12-436 | 04-02-84      |          |           |             |
| PHENYLPROPANOLAMINE HYDROCHLORIDE   |                               |             |                                    |                     |        |               |          |           |             |
| 12MG; 75MG                          |                               |             |                                    |                     |        |               |          |           |             |
| BROMPHENIRAMINE MALEATE;            | 4MG/5ML; 25MG/5ML             | BUNEX       | (TABLET; ORAL)                     | HOFFMANN-LA ROCHE   | 18-225 | 02-28-83      |          |           |             |
| PHENYLPROPANOLAMINE HYDROCHLORIDE   |                               |             |                                    |                     |        |               |          |           |             |
| BUNEX                               |                               |             |                                    |                     |        |               |          |           |             |
| BUMETANIDE                          |                               |             |                                    |                     |        |               |          |           |             |
| 0.5MG                               |                               |             |                                    |                     |        |               |          |           |             |
| BUMETANIDE                          |                               |             |                                    |                     |        |               |          |           |             |
| 1MG                                 |                               |             |                                    |                     |        |               |          |           |             |
| BUMETANIDE                          |                               |             |                                    |                     |        |               |          |           |             |
| 0.5MG                               |                               |             |                                    |                     |        |               |          |           |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S)                                        | TRADE NAME<br>(DOSAGE FORM; ROUTE)         | APPLICANT NAME      | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE                      | EXCLUSIVITY<br>EXP. DATE |
|----------------------------------------------------------------------------|--------------------------------------------|---------------------|------------------------|--------------------------------------------|--------------------------|
| BUMETANIDE<br>0.25MG/ML                                                    | BUMEX<br>(INJECTABLE; INJECTION)           | HOFFMANN-LA ROCHE   | 18-226<br>02-28-83     | 3634583<br>01-11-89<br>3806534<br>04-23-91 | NCE<br>02-28-93          |
| BUPIVACAINE HYDROCHLORIDE; DEXTROSE<br>0.75%; 8.25%                        | MARCAINE SPINAL<br>(INJECTABLE; INJECTION) | BREON LABS/STERLING | 18-692<br>05-04-84     |                                            | NC<br>09-24-86           |
| BUPIVACAINE HYDROCHLORIDE;<br>EPINEPHRINE BITARTRATE<br>0.5%; 0.0091MG/ML  | SENSORCAINE<br>(INJECTABLE; INJECTION)     | ASTRA PHARM PRODS   | 18-304<br>09-02-83     |                                            |                          |
| BUPIVACAINE HYDROCHLORIDE;<br>EPINEPHRINE BITARTRATE<br>0.75%; 0.0091MG/ML | SENSORCAINE<br>(INJECTABLE; INJECTION)     | ASTRA PHARM PRODS   | 18-304<br>09-02-83     |                                            |                          |
| BUTORPHANOL TARTRATE<br>1MG/ML                                             | STADOL<br>(INJECTABLE; INJECTION)          | BRISTOL LABS/B-M    | 17-857<br>08-22-78     | 3819635<br>06-25-91                        |                          |
| BUTORPHANOL TARTRATE<br>2MG/ML                                             | STADOL<br>(INJECTABLE; INJECTION)          | BRISTOL LABS/B-M    | 17-857<br>08-22-78     | 3819635<br>06-25-91                        |                          |
| CALCEFEDIOL, ANHYDROUS<br>0.02MG                                           | CALDEROL<br>(CAPSULE; ORAL)                | UPJOHN              | 18-312<br>08-05-80     | 3833622<br>09-03-91<br>3565924<br>03-23-86 |                          |
| CALCEFEDIOL, ANHYDROUS<br>0.05MG                                           | CALDEROL<br>(CAPSULE; ORAL)                | UPJOHN              | 18-312<br>08-05-80     | 3833622<br>09-03-91<br>3565924<br>03-23-86 |                          |
| CALCITONIN<br>200 IU/VIAL                                                  | CALCIMAR<br>(INJECTABLE; INJECTION)        | ARMOUR PHARM        | 17-769<br>12-21-84     |                                            | 1-18<br>12-21-87         |

| ACTIVE INGREDIENT(S)                                                                                                                                                                                                                       | STRENGTH(S)  | TRADE NAME                                                                                    | (DOSAGE FORM; ROUTE)    | APPLICANT NAME    | NDA #  | APPROVAL DATE | PATENT #                                                          | EXP. DATE                                             | EXCLUSIVITY |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------------------------------------------------------------------------------------|-------------------------|-------------------|--------|---------------|-------------------------------------------------------------------|-------------------------------------------------------|-------------|
| CALCIOTININ                                                                                                                                                                                                                                | 400 IU/1VIAL | CALCIUMAR                                                                                     | (INJECTABLE; INJECTION) | ARMOUR PHARM      | 17-497 | 12-21-84      |                                                                   | 1-18                                                  | 12-21-87    |
| CALCIOTRIOL                                                                                                                                                                                                                                | 0.25 UGM     | ROCATRIOL                                                                                     | (CAPSULE; ORAL)         | HOFFMANN-LA ROCHE | 18-044 | 08-17-78      | 4391802<br>07-05-00<br>4341774<br>07-27-99<br>4225596<br>09-30-97 |                                                       |             |
| CALCIOTRIOL                                                                                                                                                                                                                                | 0.5 UGM      | ROCATRIOL                                                                                     | (CAPSULE; ORAL)         | HOFFMANN-LA ROCHE | 18-044 | 08-17-78      | 4391802<br>10-10-89<br>3697559                                    | 4341774<br>07-05-00<br>4391802<br>10-10-89<br>3697559 |             |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;<br>SODIUM ACETATE;<br>SODIUM CHLORIDE; SODIUM CITRATE;<br>SODIUM CHLORIDE; 30MG/100ML;<br>74MG/100ML;<br>500MG/100ML;<br>640MG/100ML;<br>74MG/100ML;<br>9.6GM/100ML |              | ISOLTE E W/ DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                    |                         | AM MCGAW/AM HOSP  | 18-269 | 01-17-85      |                                                                   |                                                       |             |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE;<br>SODIUM ACETATE;<br>SODIUM CHLORIDE;<br>SODIUM CHLORIDE; 30MG/100ML;<br>200MG/100ML;<br>9.6GM/100ML                                                                                   |              | DIALYTE CONCENTRATE<br>W/ DEXTROSE 30%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL) |                         | AM MCGAW/AM HOSP  | 18-807 | 08-26-85      |                                                                   |                                                       |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                                                              | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                              | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE; SODIUM ACETATE;<br>SODIUM CHLORIDE<br>510MG/100ML; 50GM/100ML; 200MG/100ML;<br>9.2GM/100ML; 9.6GM/100ML     | DIALYTE CONCENTRATE<br>W/ DEXTROSE 50%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL) | AM MCGAW/AM HOSP      | 18-807<br>08-26-83                   |                                     |                                        |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE; SODIUM ACETATE;<br>SODIUM CHLORIDE<br>510MG/100ML; 30GM/100ML; 200MG/100ML;<br>9.4GM/100ML; 11GM/100ML      | DIALYTE CONCENTRATE<br>W/ DEXTROSE 30%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL) | AM MCGAW/AM HOSP      | 18-807<br>08-26-83                   |                                     |                                        |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE; SODIUM ACETATE;<br>SODIUM CHLORIDE<br>510MG/100ML; 50GM/100ML; 200MG/100ML;<br>9.4GM/100ML; 11GM/100ML      | DIALYTE CONCENTRATE<br>W/ DEXTROSE 50%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL) | AM MCGAW/AM HOSP      | 18-807<br>08-26-83                   |                                     |                                        |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM LACTATE<br>25.7MG/100ML; 1.5GM/100ML;<br>15.2MG/100ML; 567MG/100ML; 392MG/100ML  | DELFLX<br>W/ DEXTROSE 1.5%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL)             | DELMED                | 18-883<br>11-30-84                   |                                     |                                        |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM LACTATE<br>25.7MG/100ML; 2.5GM/100ML;<br>15.2MG/100ML; 567MG/100ML; 392MG/100ML  | DELFLX<br>W/ DEXTROSE 2.5%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL)             | DELMED                | 18-883<br>11-30-84                   |                                     |                                        |
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM LACTATE<br>25.7MG/100ML; 4.25GM/100ML;<br>15.2MG/100ML; 567MG/100ML; 392MG/100ML | DELFLX<br>W/ DEXTROSE 4.25%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL)            | DELMED                | 18-883<br>11-30-84                   |                                     |                                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) |
|----------------------|-------------|
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TRADE NAME  
(DOSAGE FORM; ROUTE)

APPLICANT NAME

APPROVAL DATE \_\_\_\_\_

PATENT # \_\_\_\_\_  
EXP. DATE \_\_\_\_\_

EXP. DATE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                                                                                              | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                   | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| CALCIUM CHLORIDE; DEXTROSE;<br>MAGNESIUM CHLORIDE; SODIUM CHLORIDE;<br>SODIUM LACTATE<br>26MG/100ML; 2.5GM/100ML; 15MG/100ML;<br>560MG/100ML; 390MG/100ML                                      | DIALYTE<br>W/ DEXTROSE 2.5%<br>IN PLASTIC CONTAINER<br>(SOLUTION; INTRAPERITONEAL) | AM MCGAW/AM HOSP      | 18-460<br>11-02-83                   |                                     |                                        |
| CALCIUM CHLORIDE; DEXTROSE;<br>POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>33MG/100ML; 5GM/100ML;<br>30MG/100ML; 860MG/100ML                                                                        | DEXTROSE 5% AND RINGER'S<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)        | TRAVENOL LABS         | 18-635<br>02-07-83                   |                                     |                                        |
| CALCIUM CHLORIDE; MAGNESIUM CHLORIDE;<br>POTASSIUM CHLORIDE; SODIUM ACETATE;<br>SODIUM CHLORIDE<br>16.5MG/ML; 25.4MG/ML; 74.6MG/ML;<br>121MG/ML; 16.1MG/ML                                     | TPN ELECTROLYTES<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                | ABBOTT LABORATORIES   | 18-895<br>07-20-84                   |                                     | NC<br>09-24-86                         |
| CALCIUM CHLORIDE; MAGNESIUM CHLORIDE;<br>POTASSIUM CHLORIDE; SODIUM ACETATE;<br>SODIUM CHLORIDE; SODIUM CITRATE<br>35MG/100ML; 30MG/100ML; 74MG/100ML;<br>640MG/100ML; 500MG/100ML; 74MG/100ML | ISOLYTE E<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                       | AM MCGAW/AM HOSP      | 18-899<br>10-31-83                   |                                     |                                        |
| CALCIUM CHLORIDE; MAGNESIUM CHLORIDE;<br>POTASSIUM CHLORIDE;<br>SODIUM CHLORIDE<br>17.6MG/100ML; 325.3MG/100ML;<br>119.3MG/100ML; 643MG/100ML                                                  | PLEGISOL<br>IN PLASTIC CONTAINER<br>(SOLUTION;<br>PERFUSION, CARDIAC)              | ABBOTT LABORATORIES   | 18-608<br>02-26-82                   |                                     | NC<br>09-24-86                         |
| CALCIUM CHLORIDE; POTASSIUM CHLORIDE;<br>SODIUM ACETATE; SODIUM CHLORIDE<br>20MG/100ML; 30MG/100ML; 380MG/100ML;<br>600MG/100ML                                                                | ACETATED RINGER'S<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)               | AM MCGAW/AM HOSP      | 18-725<br>11-29-82                   |                                     |                                        |

[illegible]



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| CAPTOPRIL<br>12.5MG                               | CAPOTEN<br>(TABLET; ORAL)                        | ER SQUIBB AND SONS    | 18-343<br>01-17-85                   | 4105776<br>08-08-95                        | 1-20<br>09-24-86<br>D-7<br>10-12-87    |
| CAPTOPRIL<br>25MG                                 | CAPOTEN<br>(TABLET; ORAL)                        | ER SQUIBB AND SONS    | 18-343<br>04-06-81                   | 4105776<br>08-08-95                        | 1-20<br>09-24-86<br>D-7<br>10-12-87    |
| CAPTOPRIL<br>50MG                                 | CAPOTEN<br>(TABLET; ORAL)                        | ER SQUIBB AND SONS    | 18-343<br>04-06-81                   | 4105776<br>08-08-95                        | 1-20<br>09-24-86<br>D-7<br>10-12-87    |
| CAPTOPRIL<br>100MG                                | CAPOTEN<br>(TABLET; ORAL)                        | ER SQUIBB AND SONS    | 18-343<br>04-06-81                   | 4105776<br>08-08-95                        | 1-20<br>09-24-86<br>D-7<br>10-12-87    |
| CAPTOPRIL; HYDROCHLOROTHIAZIDE<br>25MG; 15MG      | CAPOZIDE 25/15<br>(TABLET; ORAL)                 | ER SQUIBB AND SONS    | 18-709<br>10-12-84                   | 4105776<br>08-08-95<br>4217347<br>08-12-97 | NC<br>10-12-87                         |
| CAPTOPRIL; HYDROCHLOROTHIAZIDE<br>50MG; 15MG      | CAPOZIDE 50/15<br>(TABLET; ORAL)                 | ER SQUIBB AND SONS    | 18-709<br>10-12-84                   | 4105776<br>08-08-95<br>4217347<br>08-12-97 | NC<br>10-12-87                         |
| CAPTOPRIL; HYDROCHLOROTHIAZIDE<br>50MG; 25MG      | CAPOZIDE 50/25<br>(TABLET; ORAL)                 | ER SQUIBB AND SONS    | 18-709<br>10-12-84                   | 4105776<br>08-08-95<br>4217347<br>08-12-97 | NC<br>10-12-87                         |

ACTIVE INGREDIENT(S)

STRENGTH(S)

CARBAMAZEPINE

200MG

100MG

CARBIDOPA

25MG

CARBIDOPA; LEVODOPA

10MG; 100MG

CARBIDOPA; LEVODOPA

25MG; 250MG

TRADE NAME

TEGRETOL

TEGRETOL

LODOSYN

SINEMET

SINEMET

(TABLET; ORAL)

(TABLET; CHEWABLE; ORAL)

(TABLET; ORAL)

(TABLET; ORAL)

APPLICANT NAME

GEIGY/CIBA-GEIGY

GEIGY/CIBA-GEIGY

MS&D/MERCK

MS&D/MERCK

MS&D/MERCK

MS&D/MERCK

MS&D/MERCK

NDA #

16-608

03-11-68

18-281

12-14-81

17-830

04-25-77

17-555

05-02-75

05-02-75

PATENT #

4409212

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EXCLUSIVITY

EXP. DATE

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TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>    | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                                                                             | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|-----------------------------------------------------|-----------------------|--------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------|
| CARBIDOPA; LEVODOPA<br>25MG; 100MG                | SINEMET<br>(TABLET; ORAL)                           | MS&D/MERCK            | 17-555<br>05-02-75                   | 3462536<br>08-19-86<br>3769424<br>10-30-90<br>3781415<br>12-25-90<br>3830827<br>08-20-91<br>RE29692<br>10-30-90 |                                        |
| CARBOPROST TROMETHAMINE<br>EQ 0.25MG BASE/ML      | PROSTIN/15M<br>(INJECTABLE; INJECTION)              | UPJOHN                | 17-989<br>01-09-79                   | 3728382<br>04-17-90                                                                                             |                                        |
| CELLULOSE SODIUM PHOSPHATE<br>2.5GM/PACKET        | CALCIBIND<br>(POWDER; ORAL)                         | MISSION PHARMACAL     | 18-757<br>12-28-82                   |                                                                                                                 | NCE<br>12-28-92                        |
| CERULETIDE DIETHYLAMINE<br>0.02MG/ML              | TYMTRAN<br>(INJECTABLE; INJECTION)                  | ADRIA LABORATORIES    | 18-296<br>12-24-81                   | 3472832<br>10-14-86                                                                                             |                                        |
| CHENODIOL<br>250MG                                | CHENIX<br>(TABLET; ORAL)                            | ROWELL LABORATORIES   | 18-513<br>07-28-83                   |                                                                                                                 | NCE<br>07-28-93                        |
| CHLORDIAZEPOXIDE<br>25MG                          | LIBRITABS<br>(TABLET; ORAL)                         | ROCHE PRODUCTS        | 13-071<br>10-31-66                   | 4316897<br>02-23-99                                                                                             |                                        |
| CHLORDIAZEPOXIDE<br>5MG                           | LIBRITABS<br>(TABLET; ORAL)                         | ROCHE PRODUCTS        | 13-071<br>10-31-66                   | 4316897<br>02-23-99                                                                                             |                                        |
| CHLORDIAZEPOXIDE<br>10MG                          | LIBRITABS<br>(TABLET; ORAL)                         | ROCHE PRODUCTS        | 13-071<br>10-31-66                   | 4316897<br>02-23-99                                                                                             |                                        |
| CHLORDIAZEPOXIDE<br>30MG                          | LIBRELEAS<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | HOFFMANN-LA ROCHE     | 17-813<br>09-12-83                   | 4316897<br>02-23-99                                                                                             | NDF<br>09-24-86                        |

| ACTIVE INGREDIENT(S)                    | STRENGTH(S) | TRADE NAME  | (DOSAGE FORM, ROUTE)    | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXCLUSIVITY | EXP. DATE |
|-----------------------------------------|-------------|-------------|-------------------------|----------------------|--------|---------------|----------|-------------|-----------|
| CHLORDIAZEPOXIDE HYDROCHLORIDE          | 5MG         | LIBRIUM     | (CAPSULE; ORAL)         | ROCHE PRODUCTS       | 12-249 | 02-24-60      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE HYDROCHLORIDE          | 10MG        | LIBRIUM     | (CAPSULE; ORAL)         | ROCHE PRODUCTS       | 12-249 | 02-24-60      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE HYDROCHLORIDE          | 25MG        | LIBRIUM     | (CAPSULE; ORAL)         | ROCHE PRODUCTS       | 12-249 | 02-24-60      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE HYDROCHLORIDE          | 100MG/ML    | LIBRIUM     | (INJECTABLE; INJECTION) | HOFFMANN-LA ROCHE    | 12-301 | 07-21-61      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE HYDROCHLORIDE;         |             | LIBRAX      | (CAPSULE; ORAL)         | HOFFMANN-LA ROCHE    | 12-750 | 05-02-61      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE; CLIDINIUM BROMIDE     | 5MG; 2.5MG  |             |                         |                      |        |               |          |             |           |
| CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED | 5MG; 0.2MG  | MENIUM 5-2  | (TABLET; ORAL)          | HOFFMANN-LA ROCHE    | 14-740 | 02-23-99      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED | 5MG; 0.4MG  | MENIUM 5-4  | (TABLET; ORAL)          | HOFFMANN-LA ROCHE    | 14-740 | 02-23-99      | 431 6897 |             |           |
| CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED | 10MG; 0.4MG | MENIUM 10-4 | (TABLET; ORAL)          | HOFFMANN-LA ROCHE    | 14-740 | 02-23-99      | 431 6897 |             |           |
| CHLOROXINE                              | 2%          | CAPITROL    | (SHAMPOO; TOPICAL)      | WESTWOOD PHARMS      | 17-594 | 10-19-76      | 3886277  |             |           |
| CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE | 15MG; 0.1MG | COMBIPRES   | (TABLET; ORAL)          | BOEHRINGER INGELHEIM | 17-503 | 08-22-74      | 3454701  |             |           |
| CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE | 15MG; 0.2MG | COMBIPRES   | (TABLET; ORAL)          | BOEHRINGER INGELHEIM | 17-503 | 08-22-74      | 3454701  |             |           |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>      | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE<br>15MG; 0.3MG | COMBIPRES<br>(TABLET; ORAL)                      | BOEHRINGER INGELHEIM  | 17-503<br>04-10-84                   | 3454701<br>07-08-86                        |                                        |
| CHOLESTYRAMINE<br>EQ 4GM RESIN/PACKET                  | QUESTRAN<br>(POWDER; ORAL)                       | MEAD JOHNSON/B-M      | 16-019<br>12-06-66                   | 3383281<br>05-18-85                        | 1-23<br>09-24-86                       |
| CHOLESTYRAMINE<br>EQ 4GM RESIN/PACKET                  | QUESTRAN<br>(POWDER; ORAL)                       | MEAD JOHNSON/B-M      | 16-640<br>08-03-73                   | 3383281<br>05-18-85                        | 1-23<br>09-24-86                       |
| CHYMOPAPAIN<br>12,500 UNITS/VIAL                       | DISCAGE<br>(INJECTABLE; INJECTION)               | TRAVENOL LABS         | 18-625<br>01-18-84                   |                                            | NCE<br>11-10-92                        |
| CHYMOPAPAIN<br>10,000 UNITS/VIAL                       | CHYMODIACTIN<br>(INJECTABLE; INJECTION)          | SMITH LABORATORIES    | 18-663<br>11-10-82                   | 4439423<br>03-26-01                        | NCE<br>11-10-92                        |
| CHYMOPAPAIN<br>4,000 UNITS/VIAL                        | CHYMODIACTIN<br>(INJECTABLE; INJECTION)          | SMITH LABORATORIES    | 18-663<br>08-21-84                   | 4439423<br>03-26-01                        | NCE<br>11-10-92                        |
| CYCLOPIROX OLAMINE<br>1%                               | LOPROX<br>(CREAM; TOPICAL)                       | HOECHST-ROUSSEL       | 18-748<br>12-30-82                   | 3883545<br>05-13-92                        | NCE<br>12-30-92                        |
| CIMETIDINE<br>200MG                                    | TAGAMET<br>(TABLET; ORAL)                        | SK&F LAB              | 17-920<br>08-16-77                   | 3950333<br>04-13-93<br>4024271<br>05-17-94 |                                        |
| CIMETIDINE<br>300MG                                    | TAGAMET<br>(TABLET; ORAL)                        | SK&F LAB              | 17-920<br>08-16-77                   | 3950333<br>04-13-93<br>4024271<br>05-17-94 |                                        |

| ACTIVE INGREDIENT(S)          | STRENGTH(S)                            | TRADE NAME            | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------|----------------------------------------|-----------------------|---------------------|--------|---------------|----------|-----------|-------------|
| CINMETIDINE                   | 400MG                                  | TAGMET                | SK&F LAB            | 17-920 | 12-14-83      | 3950333  | 04-13-93  | NS          |
| CINMETIDINE                   | 400MG                                  | TAGMET                | SK&F LAB            | 17-920 | 12-14-83      | 3950333  | 04-13-93  | NS          |
| CINMETIDINE HYDROCHLORIDE     | EQ 300MG BASE/5ML                      | TAGMET                | SK&F LAB            | 17-924 | 08-16-77      | 3950333  | 04-13-93  |             |
| CINMETIDINE HYDROCHLORIDE     | EQ 150MG BASE/ML                       | TAGMET                | SK&F LAB            | 17-939 | 08-16-77      | 3950333  | 04-13-93  |             |
| CINOXACIN                     | 250MG                                  | CINOBAC               | ELI LILLY           | 18-067 | 06-13-80      | 3669965  | 06-13-89  |             |
| CINOXACIN                     | 500MG                                  | CINOBAC               | ELI LILLY           | 18-067 | 06-13-80      | 3669965  | 06-13-89  |             |
| CISPLATIN                     | 0.5MG/ML                               | PLATINOL-AQ           | BRISTOL LABS/B-M    | 18-507 | 07-18-84      | 4177263  | 12-04-96  | NDF         |
| CITRIC ACID; MAGNESIUM OXIDE; |                                        | IRRIGATING SOLUTION G | TRAVENOL LABS       | 18-519 | 06-22-82      |          |           | NC          |
| SODIUM CARBONATE              | 3.24GM/100ML; 380MG/100ML; 430MG/100ML | IN PLASTIC CONTAINER  |                     |        |               |          |           |             |
| CITRIC ACID; MAGNESIUM OXIDE; |                                        | UROLOGIC G            | ABBOTT LABORATORIES | 18-904 | 05-27-83      |          |           | NC          |
| SODIUM CARBONATE              | 3.24GM/100ML; 380MG/100ML; 430MG/100ML | IN PLASTIC CONTAINER  |                     |        |               |          |           |             |

TABLE 1: NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                              | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>              | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------------------------------|---------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| CLEMASTINE FUMARATE;<br>PHENYLPROPANOLAMINE HYDROCHLORIDE<br>EQ 1MG BASE; 75MG | TAVIST D<br>(TABLET, CONTROLLED<br>RELEASE; ORAL)             | DORSEY LABS/SANDOZ    | 18-298<br>12-15-82                   | 3933999<br>01-20-93                 | NDF<br>09-24-86                        |
| CLONIPHENE CITRATE<br>50MG                                                     | CLONIPHENE CITRATE<br>(TABLET; ORAL)                          | PLANTEX/IKAPHARM      | 18-361<br>03-22-82                   |                                     |                                        |
| CLONAZEPAM<br>0.5MG                                                            | CLONOPIN<br>(TABLET; ORAL)                                    | HOFFMANN-LA ROCHE     | 17-533<br>06-04-75                   | 4316897<br>02-23-99                 |                                        |
| CLONAZEPAM<br>1MG                                                              | CLONOPIN<br>(TABLET; ORAL)                                    | HOFFMANN-LA ROCHE     | 17-533<br>06-04-75                   | 4316897<br>02-23-99                 |                                        |
| CLONAZEPAM<br>2MG                                                              | CLONOPIN<br>(TABLET; ORAL)                                    | HOFFMANN-LA ROCHE     | 17-533<br>06-04-75                   | 4316897<br>02-23-99                 |                                        |
| CLONIDINE<br>2.5MG                                                             | CATAPRES-TTS-1<br>(FILM, CONTROLLED RELEASE;<br>PERCUTANEOUS) | BOEHRINGER INGELHEIM  | 18-891<br>10-10-84                   | 3454701<br>07-08-86                 | NR<br>10-10-87                         |
| CLONIDINE<br>5MG                                                               | CATAPRES-TTS-2<br>(FILM, CONTROLLED RELEASE;<br>PERCUTANEOUS) | BOEHRINGER INGELHEIM  | 18-891<br>10-10-84                   | 3454701<br>07-08-86                 | NR<br>10-10-87                         |
| CLONIDINE<br>7.5MG                                                             | CATAPRES-TTS-3<br>(FILM, CONTROLLED RELEASE;<br>PERCUTANEOUS) | BOEHRINGER INGELHEIM  | 18-891<br>10-10-84                   | 3454701<br>07-08-86                 | NR<br>10-10-87                         |
| CLONIDINE HYDROCHLORIDE<br>0.1MG                                               | CATAPRES<br>(TABLET; ORAL)                                    | BOEHRINGER INGELHEIM  | 17-407<br>09-03-74                   | 3454701<br>07-08-86                 |                                        |
| CLONIDINE HYDROCHLORIDE<br>0.2MG                                               | CATAPRES<br>(TABLET; ORAL)                                    | BOEHRINGER INGELHEIM  | 17-407<br>09-03-74                   | 3454701<br>07-08-86                 |                                        |

| ACTIVE INGREDIENT(S)    | TRADE NAME          | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------|---------------------|----------------------|--------|---------------|----------|-----------|-------------|
| CLONIDINE HYDROCHLORIDE | CATAPRES            | BOEHRINGER INGELHEIM | 17-407 | 09-20-79      | 3454701  | 07-08-86  |             |
| 0.3MG                   | (TABLET; ORAL)      |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE            | ABBOTT LABORATORIES  | 17-105 | 06-23-72      | RE28315  | 06-23-87  |             |
| 3.75MG                  | (CAPSULE; ORAL)     |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE            | ABBOTT LABORATORIES  | 17-105 | 06-23-72      | RE28315  | 06-23-87  |             |
| 7.5MG                   | (CAPSULE; ORAL)     |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE            | ABBOTT LABORATORIES  | 17-105 | 06-23-72      | RE28315  | 06-23-87  |             |
| 15MG                    | (CAPSULE; ORAL)     |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE SD         | ABBOTT LABORATORIES  | 17-105 | 03-31-75      | RE28315  | 06-23-87  |             |
| 22.5MG                  | (TABLET; ORAL)      |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE SD         | ABBOTT LABORATORIES  | 17-105 | 08-04-76      | RE28315  | 06-23-87  |             |
| 11.25MG                 | (TABLET; ORAL)      |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE            | ABBOTT LABORATORIES  | 17-105 | 03-10-80      | RE28315  | 06-23-87  |             |
| 3.75MG                  | (TABLET; ORAL)      |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE            | ABBOTT LABORATORIES  | 17-105 | 03-10-80      | RE28315  | 06-23-87  |             |
| 7.5MG                   | (TABLET; ORAL)      |                      |        |               |          |           |             |
| CLOFAZEPATE DIPOTASSIUM | TRANXENE            | ABBOTT LABORATORIES  | 17-105 | 03-10-80      | RE28315  | 06-23-87  |             |
| 15MG                    | (TABLET; ORAL)      |                      |        |               |          |           |             |
| CLOTIMAZOLE             | LOTIMIN             | SCHERING             | 17-613 | 02-03-75      | 3660577  | 05-02-89  |             |
| 15                      | (SOLUTION; TOPICAL) |                      |        |               |          |           |             |

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| CLOTRIMAZOLE<br>1%                                | LOTIMIN<br>(CREAM; TOPICAL)                      | SCHERING              | 17-619<br>03-18-75                   | 3660577<br>05-02-89<br>3705172<br>12-05-89<br>3660577<br>10-01-91 |                                        |
| CLOTRIMAZOLE<br>1%                                | GYNE-LOTIMIN<br>(CREAM; VAGINAL)                 | SCHERING              | 18-052<br>11-08-78                   | 3839573<br>10-01-91<br>3705172<br>12-05-89<br>3660577<br>05-02-89 |                                        |
| CLOTRIMAZOLE<br>100MG                             | GYNE-LOTIMIN<br>(TABLET; VAGINAL)                | SCHERING              | 17-717<br>03-24-76                   | 3839573<br>10-01-91<br>3705172<br>12-05-89<br>3660577<br>05-02-89 |                                        |
| CLOTRIMAZOLE<br>1%                                | MYCELEX<br>(SOLUTION; TOPICAL)                   | MILES PHARMS/MILES    | 18-181<br>01-15-79                   | 3839573<br>10-01-91<br>3705172<br>12-05-89<br>3660577<br>05-02-89 |                                        |
| CLOTRIMAZOLE<br>100MG                             | MYCELEX-G<br>(TABLET; VAGINAL)                   | MILES PHARMS/MILES    | 18-182<br>02-27-79                   | 3839573<br>10-01-91<br>3705172<br>12-05-89<br>3660577<br>05-02-89 |                                        |

ACTIVE INGREDIENT(S)

CLOTRIMAZOLE

1%

CLOTRIMAZOLE

1%

CLOTRIMAZOLE

10MG

CLOTRIMAZOLE

1%

CODEINE PHOSPHATE;  
PHENYLEPHRINE HYDROCHLORIDE;  
PROPETHAZINE HYDROCHLORIDE  
10MG/5ML; 2MG/5ML; 6.25MG/5ML

TRADE NAME

MYCELEX

(CREAM; TOPICAL)

MYCELEX-G

(CREAM; VAGINAL)

MYCELEX

(TROCHE/LOZENGE; ORAL)

LOTIRMIN

(LOTION; TOPICAL)

PHENERGAN VC W/ CODEINE  
(SYRUP; ORAL)

APPLICANT NAME

MILES PHARMS/MILES

MILES PHARMS/MILES

MILES PHARMS/MILES

SCHERING

WYETH LABS/AMHO

NDA #

18-183

18-230

18-713

18-813

08-306

PATENT #

3839573

3839573

3839573

3839573

08-306

EXP. DATE

10-01-91

10-01-91

10-01-91

10-01-91

04-02-84

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                    | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>  | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                                                                             | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|----------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|-----------------------|--------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------|
| CODEINE PHOSPHATE;<br>PROMETHAZINE HYDROCHLORIDE<br>10MG/5ML; 6.25MG/5ML                                             | PHENERGAN W/ CODEINE<br>(SYRUP; ORAL)             | WYETH LABS/AMHO       | 08-306<br>04-02-84                   |                                                                                                                 |                                        |
| CODEINE PHOSPHATE;<br>PSEUDOEPHEDRINE HYDROCHLORIDE;<br>TRIPROLIDINE HYDROCHLORIDE<br>10MG/5ML; 30MG/5ML; 1.25MG/5ML | ACTIFED W/ CODEINE<br>(SYRUP; ORAL)               | BURROUGHS WELLCOME    | 12-575<br>04-04-84                   |                                                                                                                 |                                        |
| COLESTIPOL HYDROCHLORIDE<br>50M/PAKET                                                                                | COLESTID<br>(GRANULE; ORAL)                       | UPJOHN                | 17-563<br>04-04-77                   | 3692895<br>09-19-89                                                                                             | 1-24<br>09-24-86                       |
| COLESTIPOL HYDROCHLORIDE<br>500GM/BOT                                                                                | COLESTID<br>(GRANULE; ORAL)                       | UPJOHN                | 17-563<br>04-04-77                   | 3692895<br>09-19-89                                                                                             | 1-24<br>09-24-86                       |
| COPPER<br>85MG                                                                                                       | CU-7<br>(INTRAUTERINE DEVICE;<br>INTRAUTERINE)    | SEARLE PHARMS         | 17-408<br>02-25-74                   | 3563235<br>02-16-88<br>4040417<br>08-09-94<br>3783861<br>01-08-91<br>3803308<br>12-01-87<br>RE28399<br>04-29-92 |                                        |
| COPPER<br>120MG                                                                                                      | TATUM-T<br>(INTRAUTERINE DEVICE;<br>INTRAUTERINE) | SEARLE PHARMS         | 18-205<br>08-16-79                   | 3563235<br>02-16-88<br>4040417<br>08-09-94<br>3783861<br>01-08-91<br>3803308<br>12-01-87<br>RE28399<br>04-29-92 |                                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME       | (DOSAGE FORM; ROUTE)   | APPLICANT NAME | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------------|------------------------|----------------|--------|---------------|----------|-----------|-------------|
| CHROMOLYN SODIUM     | 4%          | CHROMOLYN SODIUM | INHAL                  | FISONS         | 16-990 | 08-22-89      | 3686412  | 09-24-86  | 1-22        |
|                      |             |                  | (CAPSULE; INHALATION)  |                |        | 06-20-75      |          |           |             |
| CHROMOLYN SODIUM     | 4%          | NASALCROM        | (SOLUTION; NASAL)      | FISONS         | 18-506 | 08-22-89      | 3686412  | 09-24-86  | NDF         |
|                      |             |                  |                        |                |        | 03-18-85      |          |           |             |
|                      |             |                  |                        |                |        | 08-22-89      | 3777033  |           |             |
|                      |             |                  |                        |                |        | 08-22-89      | 3419578  |           |             |
|                      |             |                  |                        |                |        | 12-31-85      |          |           |             |
| CHROMOLYN SODIUM     | 4%          | OPTICROM         | (SOLUTION; OPHTHALMIC) | FISONS         | 18-155 | 08-22-89      | 3686412  | 10-03-87  | NDF         |
|                      |             |                  |                        |                |        | 10-03-84      |          |           |             |
|                      |             |                  |                        |                |        | 08-22-89      | 3777033  |           |             |
|                      |             |                  |                        |                |        | 08-22-89      | 3419578  |           |             |
|                      |             |                  |                        |                |        | 12-31-85      |          |           |             |
|                      |             |                  |                        |                |        | 08-22-89      | 3975536  |           |             |
|                      |             |                  |                        |                |        | 08-17-93      | 4053628  |           |             |
|                      |             |                  |                        |                |        | 10-11-94      |          |           |             |

TABLE 1. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S)   | TRADE NAME<br>(DOSAGE FORM; ROUTE) | APPLICANT NAME     | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE                                                                    | EXCLUSIVITY<br>EXP. DATE |
|---------------------------------------|------------------------------------|--------------------|------------------------|------------------------------------------------------------------------------------------|--------------------------|
| CROMOLYN SODIUM<br>10MG/ML            | INTAL<br>(SOLUTION; INHALATION)    | FISONS             | 18-596<br>05-28-82     | 3686412<br>08-22-89<br>3777033<br>08-22-89<br>3419578<br>12-31-85<br>3975536<br>08-17-93 | 1-22<br>01-19-88         |
| CYCLOBENZAPRINE HYDROCHLORIDE<br>5MG  | FLEXERIL<br>(TABLET; ORAL)         | MS&D/MERCK         | 17-821<br>08-26-77     | 3454643<br>07-08-86<br>3882246<br>05-06-92                                               |                          |
| CYCLOBENZAPRINE HYDROCHLORIDE<br>10MG | FLEXERIL<br>(TABLET; ORAL)         | MS&D/MERCK         | 17-821<br>08-26-77     | 3454643<br>07-08-86<br>3882246<br>05-06-92                                               |                          |
| CYCLOPHOSPHAMIDE<br>1GM/VIAL          | CYTOXAN<br>(INJECTABLE; INJECTION) | MEAD JOHNSON/B-M   | 12-142<br>08-30-82     |                                                                                          | NS<br>09-24-86           |
| CYCLOPHOSPHAMIDE<br>1GM/VIAL          | NEOSAR<br>(INJECTABLE; INJECTION)  | ADRIA LABORATORIES | 87-442<br>07-08-83     |                                                                                          | NS<br>09-24-86           |
| CYCLOPHOSPHAMIDE<br>2GM/VIAL          | CYTOXAN<br>(INJECTABLE; INJECTION) | MEAD JOHNSON/B-M   | 12-142<br>08-30-82     |                                                                                          | NS<br>09-24-86           |
| DANTROLENE SODIUM<br>25MG             | DANTRIUM<br>(CAPSULE; ORAL)        | NORWICH EATON/P&G  | 17-443<br>01-15-74     | 3415821<br>12-10-85                                                                      |                          |
| DANTROLENE SODIUM<br>100MG            | DANTRIUM<br>(CAPSULE; ORAL)        | NORWICH EATON/P&G  | 17-443<br>01-15-74     | 3415821<br>12-10-85                                                                      |                          |
| DANTROLENE SODIUM<br>50MG             | DANTRIUM<br>(CAPSULE; ORAL)        | NORWICH EATON/P&G  | 17-443<br>10-10-75     | 3415821<br>12-10-85                                                                      |                          |

| ACTIVE INGREDIENT(S)                | TRADE NAME       | (DOSAGE FORM; ROUTE)    | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------------|------------------|-------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| DANTROLENE SODIUM<br>20MG/VIAL      | DANTRIUM         | (INJECTABLE; INJECTION) | NORWICH EATON/P&G    | 18-264 | 09-18-79      |          | 12-10-85  |             |
| DEFEROXAMINE MESYLATE<br>500MG/VIAL | DEFERAL MESYLATE | (INJECTABLE; INJECTION) | CIBA/CIBA-GEIGY      | 16-267 | 04-01-68      |          | 10-07-86  |             |
| DESIPRAMINE HYDROCHLORIDE<br>25MG   | PERTOFRANE       | (CAPSULE; ORAL)         | USV LABORATORIES     | 13-621 | 12-18-64      |          | 07-08-86  |             |
| DESIPRAMINE HYDROCHLORIDE<br>50MG   | PERTOFRANE       | (CAPSULE; ORAL)         | USV LABORATORIES     | 13-621 | 04-10-68      |          | 07-08-86  |             |
| DESIPRAMINE HYDROCHLORIDE<br>25MG   | NORPRAMIN        | (TABLET; ORAL)          | MERRELL DOW/DOW CHEM | 14-399 | 11-20-64      |          | 07-08-86  |             |
| DESIPRAMINE HYDROCHLORIDE<br>50MG   | NORPRAMIN        | (TABLET; ORAL)          | MERRELL DOW/DOW CHEM | 14-399 | 01-09-67      |          | 07-08-86  |             |
| DESIPRAMINE HYDROCHLORIDE<br>75MG   | NORPRAMIN        | (TABLET; ORAL)          | MERRELL DOW/DOW CHEM | 14-399 | 03-01-77      |          | 07-08-86  |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| DESIPRAMINE HYDROCHLORIDE<br>100MG                | NORPRAMIN<br>(TABLET; ORAL)                      | MERRELL DOW/DOW CHEM  | 14-399<br>03-01-77                   | 3454698<br>07-08-86<br>3454554<br>07-08-86 |                                        |
| DESIPRAMINE HYDROCHLORIDE<br>150MG                | NORPRAMIN<br>(TABLET; ORAL)                      | MERRELL DOW/DOW CHEM  | 14-399<br>03-01-77                   | 3454698<br>07-08-86<br>3454554<br>07-08-86 |                                        |
| DESIPRAMINE HYDROCHLORIDE<br>10MG                 | NORPRAMIN<br>(TABLET; ORAL)                      | MERRELL DOW/DOW CHEM  | 14-399<br>02-11-82                   | 3454698<br>07-08-86<br>3454554<br>07-08-86 | NS<br>09-24-86                         |
| DESMOPRESSIN ACETATE<br>0.01%                     | DDAVP<br>(SOLUTION; NASAL)                       | ARMOUR PHARM          | 17-922<br>02-21-78                   | 3497491<br>02-24-87                        |                                        |
| DESMOPRESSIN ACETATE<br>0.004MG/ML                | DDAVP<br>(INJECTABLE; INJECTION)                 | ARMOUR PHARM          | 18-938<br>03-30-84                   | 3497491<br>02-24-87                        | NDF<br>09-24-86                        |
| DESONIDE<br>0.05%                                 | DESOWEN<br>(CREAM; TOPICAL)                      | OWEN LABS/DERM PRODS  | 19-048<br>12-14-84                   |                                            |                                        |
| DESOXIMETASONE<br>0.05%                           | TOPICORT<br>(GEL; TOPICAL)                       | HOECHST-ROUSSEL       | 18-586<br>03-29-82                   |                                            | NDF<br>09-24-86                        |
| DESOXIMETASONE<br>0.05%                           | TOPICORT<br>(OINTMENT; TOPICAL)                  | HOECHST-ROUSSEL       | 18-594<br>01-17-85                   |                                            | NDF<br>09-24-86                        |
| DESOXIMETASONE<br>0.25%                           | TOPICORT<br>(OINTMENT; TOPICAL)                  | HOECHST-ROUSSEL       | 18-763<br>09-30-83                   |                                            | NDF<br>09-24-86                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM, ROUTE) | APPLICANT NAME | NDA # | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------|----------------------|----------------|-------|---------------|----------|-----------|-------------|
|----------------------|-------------|------------|----------------------|----------------|-------|---------------|----------|-----------|-------------|

DEXAMETHASONE  
0.5MG

DECADRON  
(TABLET, ORAL)

MSD/MERCK

11-664  
10-30-58

3375261  
RE28369  
03-26-85

DEXAMETHASONE  
0.75MG

DECADRON  
(TABLET, ORAL)

MSD/MERCK

11-664  
10-30-58

3375261  
RE28369  
03-26-85

DEXAMETHASONE  
1.5MG

DECADRON  
(TABLET, ORAL)

MSD/MERCK

11-664  
10-30-58

3375261  
RE28369  
03-26-85

DEXAMETHASONE  
0.25MG

DECADRON  
(TABLET, ORAL)

MSD/MERCK

11-664  
07-26-79

3375261  
RE28369  
03-26-85

DEXAMETHASONE  
4MG

DECADRON  
(TABLET, ORAL)

MSD/MERCK

11-664  
07-26-79

3375261  
RE28369  
03-26-85

DEXAMETHASONE  
6MG

DECADRON  
(TABLET, ORAL)

MSD/MERCK

11-664  
07-30-82

3375261  
RE28369  
03-26-85

DEXAMETHASONE  
6MG

DEXAMETHASONE  
(TABLET, ORAL)

PAR PHARMACEUTICAL

88-481  
11-28-83

03-26-85

NS  
09-24-86

TABLE 1. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| DEXAMETHASONE<br>6MG                              | DEXAMETHASONE<br>(TABLET; ORAL)                  | ROXANE LABORATORIES   | 88-316<br>09-15-83                   |                                            | NS<br>09-24-86                         |
| DEXAMETHASONE<br>0.5MG/5ML                        | DECADRON<br>(ELIXIR; ORAL)                       | MS&D/MERCK            | 12-376<br>09-02-60                   | 3375261<br>03-26-85<br>RE28369<br>03-26-85 |                                        |
| DEXAMETHASONE<br>0.5MG/5ML                        | HEXADROL<br>(ELIXIR; ORAL)                       | ORGANON/AKZONA        | 12-674<br>04-23-64                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE<br>0.5MG                            | HEXADROL<br>(TABLET; ORAL)                       | ORGANON/AKZONA        | 12-675<br>07-01-78                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE<br>0.75MG                           | HEXADROL<br>(TABLET; ORAL)                       | ORGANON/AKZONA        | 12-675<br>07-01-78                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE<br>1.5MG                            | HEXADROL<br>(TABLET; ORAL)                       | ORGANON/AKZONA        | 12-675<br>09-24-65                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE<br>4MG                              | HEXADROL<br>(TABLET; ORAL)                       | ORGANON/AKZONA        | 12-675<br>07-01-74                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE<br>10MG/25GM                        | DECASPRAY<br>(AEROSOL; TOPICAL)                  | MS&D/MERCK            | 12-731<br>03-29-61                   | 3375261<br>03-26-85<br>RE28369<br>03-26-85 |                                        |
| DEXAMETHASONE<br>0.04%                            | HEXADROL<br>(CREAM; TOPICAL)                     | ORGANON/AKZONA        | 13-304<br>01-09-67                   | RE28369<br>03-26-85                        |                                        |

| ACTIVE INGREDIENT(S)           | TRADE NAME                   | APPLICANT NAME | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------------|------------------------------|----------------|--------|---------------|----------|-----------|-------------|
| STRENGTH(S)                    | (DOSAGE FORM; ROUTE)         |                |        |               |          |           |             |
| DEXAMETHASONE                  | DECADERM                     | MS&D/MERCK     | 13-538 | 05-03-65      | 3375261  | 03-26-85  |             |
| 0.1%                           | (GEL; TOPICAL)               |                |        |               | RE28369  | 03-26-85  |             |
| DEXAMETHASONE ACETATE          | DECADRON-LA                  | MS&D/MERCK     | 16-675 | 09-06-73      | 3375261  | 03-26-85  |             |
| EQ 8MG BASE/ML                 | (INJECTABLE; INJECTION)      |                |        |               | RE28369  | 03-26-85  |             |
| DEXAMETHASONE SODIUM PHOSPHATE | DECADRON                     | MS&D/MERCK     | 11-977 | 09-02-59      | 3375261  | 03-26-85  |             |
| EQ 0.05% PHOSPHATE             | (OINTMENT; OPHTHALMIC)       |                |        |               | RE28369  | 03-26-85  |             |
| DEXAMETHASONE SODIUM PHOSPHATE | DECADRON                     | MS&D/MERCK     | 11-983 | 08-26-59      | 3375261  | 03-26-85  |             |
| EQ 0.1% PHOSPHATE              | (CREAM; TOPICAL)             |                |        |               | RE28369  | 03-26-85  |             |
| DEXAMETHASONE SODIUM PHOSPHATE | DECADRON                     | MS&D/MERCK     | 11-984 | 09-23-59      | 3375261  | 03-26-85  |             |
| EQ 0.1% PHOSPHATE              | (SOLUTION; OPHTHALMIC, OTIC) |                |        |               | RE28369  | 03-26-85  |             |
| DEXAMETHASONE SODIUM PHOSPHATE | DECADRON                     | MS&D/MERCK     | 12-071 | 05-12-61      | 3375261  | 03-26-85  |             |
| EQ 4MG PHOSPHATE/ML            | (INJECTABLE; INJECTION)      |                |        |               | RE28369  | 03-26-85  |             |
| DEXAMETHASONE SODIUM PHOSPHATE | DECADRON                     | MS&D/MERCK     | 12-071 | 03-01-77      | 3375261  | 03-26-85  |             |
| EQ 24MG PHOSPHATE/ML           | (INJECTABLE; INJECTION)      |                |        |               | RE28369  | 03-26-85  |             |

TABLE IN 10.0 NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                          | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| DEXAMETHASONE SODIUM PHOSPHATE<br>EQ 0.1MG PHOSPHATE/INH                                   | DECADRON<br>(AEROSOL; INHALATION)                               | MS&D/MERCK            | 13-413<br>09-17-62                   | 3375261<br>03-26-85<br>RE28369<br>03-26-85 |                                        |
| DEXAMETHASONE SODIUM PHOSPHATE<br>EQ 0.1MG PHOSPHATE/INH                                   | DECADRON<br>(AEROSOL; NASAL)                                    | MS&D/MERCK            | 14-242<br>12-17-65                   | 3375261<br>03-26-85<br>RE28369<br>03-26-85 |                                        |
| DEXAMETHASONE SODIUM PHOSPHATE<br>EQ 4MG PHOSPHATE/ML                                      | HEXADROL<br>(INJECTABLE; INJECTION)                             | ORGANON/AKZONA        | 14-694<br>03-14-75                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE SODIUM PHOSPHATE<br>EQ 10MG PHOSPHATE/ML                                     | HEXADROL<br>(INJECTABLE; INJECTION)                             | ORGANON/AKZONA        | 14-694<br>03-14-75                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE SODIUM PHOSPHATE<br>EQ 20MG PHOSPHATE/ML                                     | HEXADROL<br>(INJECTABLE; INJECTION)                             | ORGANON/AKZONA        | 14-694<br>04-27-81                   | RE28369<br>03-26-85                        |                                        |
| DEXAMETHASONE SODIUM PHOSPHATE;<br>LIDOCAINE HYDROCHLORIDE<br>EQ 4MG PHOSPHATE/ML; 10MG/ML | DECADRON W/ XYLOCAINE<br>(INJECTABLE; INJECTION)                | MS&D/MERCK            | 13-334<br>07-11-62                   | 3375261<br>03-26-85<br>RE28369<br>03-26-85 |                                        |
| DEXTROMETHORPHAN HYDROBROMIDE;<br>FROMETHAZINE HYDROCHLORIDE<br>15MG/5ML; 6.25MG/5ML       | PHENERGAN W/ DEXTROMETHORPHAN<br>(SYRUP; ORAL)                  | WYETH LABS/AMHO       | 11-265<br>04-02-84                   |                                            |                                        |
| DEXTROSE<br>60GM/100ML                                                                     | DEXTROSE 60% IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION) | TRAVENOL LABS         | 17-521<br>03-26-82                   |                                            |                                        |
| DEXTROSE<br>70GM/100ML                                                                     | DEXTROSE 70% IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION) | TRAVENOL LABS         | 17-521<br>03-26-82                   |                                            |                                        |

ACTIVE INGREDIENT(S)

STRENGTH(S)

TRADE NAME  
(DOSAGE FORM; ROUTE)

APPLICANT NAME

NDA #  
APPROVAL DATE

PATENT #  
EXP. DATE

EXCLUSIVITY  
EXP. DATE

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>          | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                                 | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DEXTROSE<br>50MG/ML                                        | DEXTROSE 5% IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION)                                   | ABBOTT LABORATORIES   | 19-222<br>07-13-84                   |                                     |                                        |
| DEXTROSE; DOPAMINE HYDROCHLORIDE<br>5GM/100ML; 80MG/100ML  | DOPAMINE HCL<br>(INJECTABLE; INJECTION)                                                          | ABBOTT LABORATORIES   | 18-132<br>02-04-82                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; DOPAMINE HYDROCHLORIDE<br>5GM/100ML; 160MG/100ML | DOPAMINE HCL<br>(INJECTABLE; INJECTION)                                                          | ABBOTT LABORATORIES   | 18-132<br>02-04-82                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; DOPAMINE HYDROCHLORIDE<br>5GM/100ML; 80MG/100ML  | DOPAMINE HCL IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION)                                  | ABBOTT LABORATORIES   | 18-826<br>09-30-83                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; DOPAMINE HYDROCHLORIDE<br>5GM/100ML; 160MG/100ML | DOPAMINE HCL IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION)                                  | ABBOTT LABORATORIES   | 18-826<br>09-30-83                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; DOPAMINE HYDROCHLORIDE<br>5GM/100ML; 320MG/100ML | DOPAMINE HCL IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION)                                  | ABBOTT LABORATORIES   | 18-826<br>09-30-83                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; HEPARIN SODIUM<br>5GM/100ML; 200 UNITS/100ML     | HEPARIN SODIUM 1,000 UNITS<br>AND DEXTROSE 5% IN<br>PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 19-130<br>12-31-83                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; HEPARIN SODIUM<br>5GM/100ML; 200 UNITS/100ML     | HEPARIN SODIUM 2,000 UNITS<br>AND DEXTROSE 5% IN<br>PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 19-130<br>12-31-83                   |                                     | NC<br>09-24-86                         |
| DEXTROSE; HEPARIN SODIUM<br>5GM/100ML; 1,000 UNITS/100ML   | HEPARIN SODIUM 5,000 UNITS<br>AND DEXTROSE 5% IN<br>PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 19-130<br>12-31-83                   |                                     | NC<br>09-24-86                         |

| ACTIVE INGREDIENT(S)              | STRENGTH(S)                   | TRADE NAME         | (DOSAGE FORM; ROUTE)                                                                              | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-----------------------------------|-------------------------------|--------------------|---------------------------------------------------------------------------------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| DEXTROSE; HEPARIN SODIUM          | 5GM/100ML; 4,000 UNITS/100ML  | HEPARIN SODIUM     | HEPARIN SODIUM 20,000 UNITS<br>AND DEXTROSE 5% IN<br>PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-814 | 10-31-83      |          |           | NC          |
| DEXTROSE; HEPARIN SODIUM          | 5GM/100ML; 5,000 UNITS/100ML  | HEPARIN SODIUM     | HEPARIN SODIUM<br>12,500 UNITS<br>IN DEXTROSE 5%<br>(INJECTABLE; INJECTION)                       | ABBOTT LABORATORIES | 18-911 | 01-30-85      |          |           |             |
| DEXTROSE; HEPARIN SODIUM          | 5GM/100ML; 10,000 UNITS/100ML | HEPARIN SODIUM     | HEPARIN SODIUM<br>10,000 UNITS<br>IN DEXTROSE 5%<br>(INJECTABLE; INJECTION)                       | ABBOTT LABORATORIES | 18-911 | 01-30-85      |          |           |             |
| DEXTROSE; HEPARIN SODIUM          | 5GM/100ML; 10,000 UNITS/100ML | HEPARIN SODIUM     | HEPARIN SODIUM<br>25,000 UNITS<br>IN DEXTROSE 5%<br>(INJECTABLE; INJECTION)                       | ABBOTT LABORATORIES | 18-911 | 01-30-85      |          |           |             |
| DEXTROSE; LIDOCAINE HYDROCHLORIDE | 5GM/100ML; 800MG/100ML        | LIDOCAINE HCL 0.8% | LIDOCAINE HCL 0.8%<br>IN DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)           | ABBOTT LABORATORIES | 18-588 | 11-05-82      |          |           | NS          |
| DEXTROSE; LIDOCAINE HYDROCHLORIDE | 5GM/100ML; 800MG/100ML        | LIDOCAINE HCL 0.8% | LIDOCAINE HCL 0.8%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)          | TRAVENOL LABS       | 18-461 | 02-22-82      |          |           | NS          |
| DEXTROSE; LIDOCAINE HYDROCHLORIDE | 5GM/100ML; 200MG/100ML        | LIDOCAINE HCL 0.2% | LIDOCAINE HCL 0.2%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)          | AM MCGAW/AM HOSP    | 18-967 | 03-30-84      |          |           | NS          |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                                                                           | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                                | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DEXTROSE; LIDOCAINE HYDROCHLORIDE<br>5GM/100ML; 400MG/100ML                                                                                                                 | LIDOCAINE HCL 0.4%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)        | AM MCGAW/AM HOSP      | 18-967<br>03-30-84                   |                                     | NS<br>09-24-86                         |
| DEXTROSE; LIDOCAINE HYDROCHLORIDE<br>5GM/100ML; 800MG/100ML                                                                                                                 | LIDOCAINE HCL 0.8%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)        | AM MCGAW/AM HOSP      | 18-967<br>03-30-84                   |                                     | NS<br>09-24-86                         |
| DEXTROSE; MAGNESIUM CHLORIDE;<br>POTASSIUM CHLORIDE;<br>POTASSIUM PHOSPHATE DIBASIC;<br>SODIUM ACETATE<br>5GM/100ML; 31MG/100ML;<br>130MG/100ML; 26MG/100ML;<br>320MG/100ML | ISOLYTE P W/<br>DEXTROSE 5% IN<br>PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                  | AM MCGAW/AM HOSP      | 19-025<br>12-27-84                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE<br>5GM/100ML; 75MG/100ML                                                                                                                       | DEXTROSE 5% AND<br>POTASSIUM CHLORIDE 0.075%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 18-744<br>11-09-82                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE<br>5GM/100ML; 150MG/100ML                                                                                                                      | DEXTROSE 5% AND<br>POTASSIUM CHLORIDE 0.15%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  | AM MCGAW/AM HOSP      | 18-744<br>11-09-82                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE<br>5GM/100ML; 220MG/100ML                                                                                                                      | DEXTROSE 5% AND<br>POTASSIUM CHLORIDE 0.22%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  | AM MCGAW/AM HOSP      | 18-744<br>11-09-82                   |                                     |                                        |

| ACTIVE INGREDIENT(S) | TRADE NAME | APPLICANT NAME | NDA # | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|------------|----------------|-------|---------------|----------|-----------|-------------|
|----------------------|------------|----------------|-------|---------------|----------|-----------|-------------|

TABLE 1. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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18-744 11-09-82 AM MCGAW/AM HDSP

DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

DEXTROSE 5% AND ELECTROLYTE NO 75 IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

18-840 06-29-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE 5GM/100ML; 205MG/100ML; 100MG/100ML; 120MG/100ML; 220MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 10MG IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

18-566 02-10-83 TRAVENOL LABS

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 15MG IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

18-566 02-10-83 TRAVENOL LABS

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 20MG IN PLASTIC CONTAINER (INJECTABLE; INJECTION)

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 300MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML

18-566 02-10-83 TRAVENOL LABS

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 450MG/100ML



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                    | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                                             | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 300MG/100ML; 450MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS         | 18-566<br>02-10-83                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 150MG/100ML; 200MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)  | TRAVENOL LABS         | 18-567<br>02-16-83                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 224MG/100ML; 200MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)  | TRAVENOL LABS         | 18-567<br>02-16-83                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 150MG/100ML; 200MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)  | TRAVENOL LABS         | 18-567<br>02-16-83                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 224MG/100ML; 200MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)  | TRAVENOL LABS         | 18-567<br>02-16-83                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 75MG/100ML; 330MG/100ML  | DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)  | TRAVENOL LABS         | 18-629<br>03-23-82                   |                                     |                                        |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>5GM/100ML; 150MG/100ML; 330MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS         | 18-629<br>03-23-82                   |                                     |                                        |

| ACTIVE INGREDIENT(S)                          | STRENGTH(S)                         | TRADE NAME                                                               | (DOSAGE FORM; ROUTE)                                                            | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-----------------------------------------------|-------------------------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | 50M/100ML; 224MG/100ML; 330MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE                                             | 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-629 | 03-23-82      |          |           |             |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | 50M/100ML; 150MG/100ML; 330MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE                                             | 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-629 | 03-23-82      |          |           |             |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | 50M/100ML; 75MG/100ML; 330MG/100ML  | DEXTROSE 5%, SODIUM CHLORIDE                                             | 0.33% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-629 | 03-23-82      |          |           |             |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | 50M/100ML; 300MG/100ML; 330MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE                                             | 0.33% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-629 | 03-23-82      |          |           |             |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | 50M/100ML; 224MG/100ML; 330MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE                                             | 0.33% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-629 | 03-23-82      |          |           |             |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | 50M/100ML; 300MG/100ML; 330MG/100ML | DEXTROSE 5%, SODIUM CHLORIDE                                             | 0.33% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-629 | 03-23-82      |          |           |             |
| DEXTROSE; THEOPHYLLINE                        | 50M/100ML; 40MG/100ML               | THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION) |                                                                                 | ABBOTT LABORATORIES | 19-211 | 12-14-84      |          |           |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                         | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DEXTROSE; THEOPHYLLINE<br>5GM/100ML; 40MG/100ML   | THEOPHYLLINE 0.04%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 19-083<br>11-07-84                   |                                     |                                        |
| DEXTROSE; THEOPHYLLINE<br>5GM/100ML; 80MG/100ML   | THEOPHYLLINE IN<br>DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)        | ABBOTT LABORATORIES   | 19-211<br>12-14-84                   |                                     |                                        |
| DEXTROSE; THEOPHYLLINE<br>5GM/100ML; 80MG/100ML   | THEOPHYLLINE 0.08%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 19-083<br>11-07-84                   |                                     |                                        |
| DEXTROSE; THEOPHYLLINE<br>5GM/100ML; 160MG/100ML  | THEOPHYLLINE IN<br>DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)        | ABBOTT LABORATORIES   | 19-211<br>12-14-84                   |                                     |                                        |
| DEXTROSE; THEOPHYLLINE<br>5GM/100ML; 160MG/100ML  | THEOPHYLLINE 0.16%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 19-083<br>11-07-84                   |                                     |                                        |
| DEXTROSE; THEOPHYLLINE<br>5GM/100ML; 200MG/100ML  | THEOPHYLLINE IN<br>DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)        | ABBOTT LABORATORIES   | 19-211<br>12-14-84                   |                                     |                                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE) | APPLICANT NAME | NDA # | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------|----------------------|----------------|-------|---------------|----------|-----------|-------------|
|----------------------|-------------|------------|----------------------|----------------|-------|---------------|----------|-----------|-------------|

TABLE 1. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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|                        |                        |                                                                                         |                     |        |          |  |  |  |  |
|------------------------|------------------------|-----------------------------------------------------------------------------------------|---------------------|--------|----------|--|--|--|--|
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 400MG/100ML | THEOPHYLLINE AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)         | TRAVENOL LABS       | 18-649 | 07-26-82 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 200MG/100ML | THEOPHYLLINE AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)         | TRAVENOL LABS       | 18-649 | 07-26-82 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 160MG/100ML | THEOPHYLLINE AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)         | TRAVENOL LABS       | 18-649 | 07-26-82 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 80MG/100ML  | THEOPHYLLINE AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)         | TRAVENOL LABS       | 18-649 | 07-26-82 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 400MG/100ML | THEOPHYLLINE AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)         | TRAVENOL LABS       | 18-649 | 07-26-82 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 400MG/100ML | THEOPHYLLINE 0.4%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGRAW/HM HOSP   | 19-212 | 11-07-84 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 400MG/100ML | THEOPHYLLINE IN<br>DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)       | ABBOTT LABORATORIES | 19-211 | 12-14-84 |  |  |  |  |
| DEXTROSE; THEOPHYLLINE | 5GM/100ML; 200MG/100ML | THEOPHYLLINE 0.2%<br>AND DEXTROSE 5%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGRAW/HM HOSP   | 19-212 | 11-07-84 |  |  |  |  |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>        | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>     | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|----------------------------------------------------------|------------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| DIATRIZOATE<br>MEGLUMINE<br>30%                          | RENO-M-DIP<br>(INJECTABLE; INJECTION)                | ER SQUIBB AND SONS    | 10-040<br>01-08-60                   |                                            | 1-7; 1-8<br>09-24-86                   |
| DIATRIZOATE MEGLUMINE;<br>DIATRIZOATE SODIUM<br>52%; 8%  | RENOGRAFIN-60<br>(INJECTABLE; INJECTION)             | ER SQUIBB AND SONS    | 10-040<br>08-29-74                   |                                            | 1-8<br>09-24-86                        |
| DIATRIZOATE MEGLUMINE;<br>DIATRIZOATE SODIUM<br>66%; 10% | RENOGRAFIN-76<br>(INJECTABLE; INJECTION)             | ER SQUIBB AND SONS    | 10-040<br>10-27-72                   |                                            | 1-5<br>09-24-86                        |
| DIAZEPAM<br>2MG                                          | VALIUM<br>(TABLET; ORAL)                             | HOFFMANN-LA ROCHE     | 13-263<br>11-15-63                   | 4316897<br>02-23-99<br>3371085<br>02-27-85 |                                        |
| DIAZEPAM<br>5MG                                          | VALIUM<br>(TABLET; ORAL)                             | HOFFMANN-LA ROCHE     | 13-263<br>11-15-63                   | 4316897<br>02-23-99<br>3371085<br>02-27-85 |                                        |
| DIAZEPAM<br>10MG                                         | VALIUM<br>(TABLET; ORAL)                             | HOFFMANN-LA ROCHE     | 13-263<br>11-15-63                   | 4316897<br>02-23-99<br>3371085<br>02-27-85 |                                        |
| DIAZEPAM<br>5MG/ML                                       | VALIUM<br>(INJECTABLE; INJECTION)                    | HOFFMANN-LA ROCHE     | 16-087<br>08-24-66                   | 4316897<br>02-23-99<br>3371085<br>02-27-85 |                                        |
| DIAZEPAM<br>15MG                                         | VALRELEASE<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | HOFFMANN-LA ROCHE     | 18-179<br>03-12-81                   | 4316897<br>02-23-99<br>3371085<br>02-27-85 |                                        |

| ACTIVE INGREDIENT(S)                  | TRADE NAME   | (DOSAGE FORM; ROUTE)    | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY     |
|---------------------------------------|--------------|-------------------------|----------------------|--------|---------------|----------|-----------|-----------------|
| DIAZOXIDE<br>15MG/ML                  | HYPERSTAT    | (INJECTABLE; INJECTION) | SCHERING             | 16-996 | 01-22-73      |          |           | 1-1<br>09-24-86 |
| DICLOMININE HYDROCHLORIDE<br>10MG     | BENTYL       | (CAPSULE; ORAL)         | MERRELL DOW/DOW CHEM | 07-409 | 10-15-84      |          |           |                 |
| DICLOMININE HYDROCHLORIDE<br>20MG     | BENTYL       | (CAPSULE; ORAL)         | MERRELL DOW/DOW CHEM | 07-409 | 10-15-84      |          |           |                 |
| DICLOMININE HYDROCHLORIDE<br>10MG/ML  | BENTYL       | (INJECTABLE; INJECTION) | MERRELL DOW/DOW CHEM | 08-370 | 10-15-84      |          |           |                 |
| DICLOMININE HYDROCHLORIDE<br>10MG/5ML | BENTYL       | (SYRUP; ORAL)           | MERRELL DOW/DOW CHEM | 07-961 | 10-15-84      |          |           |                 |
| DIFLORASONE DIACETATE<br>0.05%        | FLORONE      | (CREAM; TOPICAL)        | UPJOHN               | 17-741 | 09-14-77      |          |           |                 |
| DIFLORASONE DIACETATE<br>0.05%        | FLORONE      | (OINTMENT; TOPICAL)     | UPJOHN               | 17-994 | 03-01-78      |          |           |                 |
| DIFLUNISAL<br>250MG                   | DOLOBID      | (TABLET; ORAL)          | MSD/MERCK            | 18-445 | 04-19-82      |          |           |                 |
| DIFLUNISAL<br>500MG                   | DOLOBID      | (TABLET; ORAL)          | MSD/MERCK            | 18-445 | 04-19-82      |          |           |                 |
| DIGOXIN<br>0.2MG                      | LANOXIN CAPS | (CAPSULE; ORAL)         | BURROUGHS WELLCOME   | 18-118 | 07-26-82      |          |           | NDP<br>09-24-86 |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                        | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| DIGOXIN<br>0.05MG                                                                                                        | LANOXICAPS<br>(CAPSULE; ORAL)                    | BURROUGHS WELLCOME    | 18-118<br>07-26-82                   |                                            | NDF<br>09-24-86                        |
| DIGOXIN<br>0.1MG                                                                                                         | LANOXICAPS<br>(CAPSULE; ORAL)                    | BURROUGHS WELLCOME    | 18-118<br>07-26-82                   |                                            | NDF<br>09-24-86                        |
| DIHYDROERGOTAMINE MESYLATE;<br>HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE<br>0.5MG/0.5ML; 2500 UNITS/0.5ML;<br>5.33MG/0.5ML | EMBOLEX<br>(INJECTABLE; INJECTION)               | SANDOZ PHARMS/SANDOZ  | 18-885<br>11-30-84                   | 4451458<br>05-29-01                        | NC<br>11-30-87                         |
| DIHYDROERGOTAMINE MESYLATE;<br>HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE<br>0.5MG/0.7ML; 5000 UNITS/0.7ML;<br>7.46MG/0.7ML | EMBOLEX<br>(INJECTABLE; INJECTION)               | SANDOZ PHARMS/SANDOZ  | 18-885<br>11-30-84                   | 4451458<br>05-29-01                        | NC<br>11-30-87                         |
| DILTIAZEM HYDROCHLORIDE<br>30MG                                                                                          | CARDIZEM<br>(TABLET; ORAL)                       | MARION LABORATORIES   | 18-602<br>11-05-82                   | 3562257<br>02-09-88                        | NCE<br>11-05-92                        |
| DILTIAZEM HYDROCHLORIDE<br>60MG                                                                                          | CARDIZEM<br>(TABLET; ORAL)                       | MARION LABORATORIES   | 18-602<br>11-05-82                   | 3562257<br>02-09-88                        | NCE<br>11-05-92                        |
| DINOPROST TROMETHAMINE<br>EQ 5MG BASE/ML                                                                                 | PROSTIN F2 ALPHA<br>(INJECTABLE; INJECTION)      | UPJOHN                | 17-434<br>11-26-73                   | 3706789<br>12-19-89<br>3778506<br>12-11-90 |                                        |
| DINOPROSTONE<br>20MG                                                                                                     | PROSTIN E2<br>(SUPPOSITORY; VAGINAL)             | UPJOHN                | 17-810<br>08-23-77                   | 3899587<br>08-12-92<br>3598858<br>08-10-88 |                                        |

| ACTIVE INGREDIENT(S)     | TRADE NAME         | APPLICANT NAME                      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------|--------------------|-------------------------------------|--------|---------------|----------|-----------|-------------|
| DIPYRIN HYDROCHLORIDE    | 0.1%               | PROLINE                             | 18-239 | 05-02-80      | 3839584  | 10-01-91  |             |
|                          |                    | (SOLUTION; OPHTHALMIC)              |        |               |          | 05-07-91  |             |
| DISOPYRAMIDE PHOSPHATE   | EQ 100MG BASE      | NORPACE CR                          | 18-655 | 07-20-82      |          |           | NDF         |
|                          |                    | (CAPSULE, CONTROLLED RELEASE; ORAL) |        |               |          |           |             |
| DISOPYRAMIDE PHOSPHATE   | EQ 150MG BASE      | NORPACE CR                          | 18-655 | 07-20-82      |          |           | NDF         |
|                          |                    | (CAPSULE, CONTROLLED RELEASE; ORAL) |        |               |          |           |             |
| DIVALproex Sodium        | EQ 250MG BASE      | DEPAKOTE                            | 18-723 | 03-10-83      |          |           | NE          |
|                          |                    | (TABLET, ENTERIC COATED; ORAL)      |        |               |          |           |             |
| DIVALproex Sodium        | EQ 500MG BASE      | DEPAKOTE                            | 18-723 | 03-10-83      |          |           | NE          |
|                          |                    | (TABLET, ENTERIC COATED; ORAL)      |        |               |          |           |             |
| DOBUTAMINE HYDROCHLORIDE | EQ 250MG BASE/VIAL | DOBUTREX                            | 17-820 | 07-18-78      |          |           |             |
|                          |                    | (INJECTABLE; INJECTION)             |        |               |          |           |             |
|                          |                    | ELI LILLY                           |        |               |          | 3987200   |             |
| DOBUTAMINE HYDROCHLORIDE | 80MG/ML            | DOBUTREX                            | 18-132 | 07-09-82      |          |           |             |
|                          |                    | (INJECTABLE; INJECTION)             |        |               |          |           |             |
| DOBUTAMINE HYDROCHLORIDE | 80MG/ML            | DOBUTREX                            | 18-132 | 07-09-82      |          |           |             |
|                          |                    | (INJECTABLE; INJECTION)             |        |               |          |           |             |
| DOBUTAMINE HYDROCHLORIDE | 80MG/ML            | DOBUTREX                            | 18-598 | 03-22-82      |          |           |             |
|                          |                    | (INJECTABLE; INJECTION)             |        |               |          |           |             |
| DOBUTAMINE HYDROCHLORIDE | 40MG/ML            | DOBUTREX                            | 18-549 | 03-11-83      |          |           |             |
|                          |                    | (INJECTABLE; INJECTION)             |        |               |          |           |             |
| DOBUTAMINE HYDROCHLORIDE | 40MG/ML            | DOBUTREX                            | 18-656 | 06-28-83      |          |           |             |
|                          |                    | (INJECTABLE; INJECTION)             |        |               |          |           |             |
|                          |                    | ASTRA PHARM PRODS                   |        |               |          |           |             |

TABLE 1.1. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| DOXEPIN HYDROCHLORIDE<br>EQ 25MG BASE             | SINEQUAN<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 16-798<br>09-23-69                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 50MG BASE             | SINEQUAN<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 16-798<br>09-23-69                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 10MG BASE             | SINEQUAN<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 16-798<br>03-31-75                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 100MG BASE            | SINEQUAN<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 16-798<br>03-31-75                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 75MG BASE             | SINEQUAN<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 16-798<br>06-04-76                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 150MG BASE            | SINEQUAN<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 16-798<br>03-15-78                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 10MG BASE             | ADAPIN<br>(CAPSULE; ORAL)                        | PENNWALT PHARM        | 16-987<br>01-31-72                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 25MG BASE             | ADAPIN<br>(CAPSULE; ORAL)                        | PENNWALT PHARM        | 16-987<br>01-31-72                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 50MG BASE             | ADAPIN<br>(CAPSULE; ORAL)                        | PENNWALT PHARM        | 16-987<br>01-31-72                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 100MG BASE            | ADAPIN<br>(CAPSULE; ORAL)                        | PENNWALT PHARM        | 16-987<br>12-12-77                   | 3420851<br>01-07-86                 |                                        |
| DOXEPIN HYDROCHLORIDE<br>EQ 75MG BASE             | ADAPIN<br>(CAPSULE; ORAL)                        | PENNWALT PHARM        | 16-987<br>04-15-80                   | 3420851<br>01-07-86                 |                                        |

| ACTIVE INGREDIENT(S)                   | STRENGTH(S)      | TRADE NAME   | (DOSAGE FORM; ROUTE)    | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------------------------|------------------|--------------|-------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| DOXEPIN HYDROCHLORIDE                  | EQ 10MG BASE/ML  | SINEQUAN     | (CONCENTRATE; ORAL)     | PFIZER LABS/PFIZER   | 17-516 | 03-11-74      | 3420851  | 01-07-86  |             |
| ECONAZOLE NITRATE                      | 1%               | SPECTAZOLE   | (CREAM; TOPICAL)        | ORTHO PHARMACEUTICAL | 18-751 | 12-23-82      | 3717655  | 02-20-90  | NCE         |
| ENFLURANE                              | 99.9%            | ETHRANE      | (LIQUID; INHALATION)    | ANALQUEST/BOC        | 17-087 | 08-28-72      | 3469011  | 09-23-86  |             |
|                                        |                  |              |                         |                      |        |               | 3527813  | 09-08-87  |             |
| EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE | 0.005MG/ML; 0.5% | DURANEST     | (INJECTABLE; INJECTION) | ASTRA PHARM PRODS    | 17-751 | 08-30-76      | 3862321  | 01-21-92  |             |
|                                        |                  |              |                         |                      |        |               | 3812147  | 05-21-91  |             |
| EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE | 0.005MG/ML; 1%   | DURANEST     | (INJECTABLE; INJECTION) | ASTRA PHARM PRODS    | 17-751 | 08-30-76      | 3862321  | 01-21-92  |             |
|                                        |                  |              |                         |                      |        |               | 3812147  | 05-21-91  |             |
| EPINEPHRINE; ETIDOCALINE HYDROCHLORIDE | 0.005MG/ML; 1.5% | DURANEST     | (INJECTABLE; INJECTION) | ASTRA PHARM PRODS    | 17-751 | 08-30-76      | 3862321  | 01-21-92  |             |
|                                        |                  |              |                         |                      |        |               | 3812147  | 05-21-91  |             |
| ERGOLOID MESYLATES                     | IMG              | HYDERGINE LC | (CAPSULE; ORAL)         | SANDOZ PHARMS/SANDOZ | 18-706 | 01-18-83      |          |           | NDF         |
| ESTROGENS, CONJUGATED                  | 0.9MG            | PREMARIN     | (TABLET; ORAL)          | AYERST LABS/AYERST   | 04-782 | 01-26-84      |          |           | NS          |

TABLE CONTAINS INFORMATION FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                         | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                                                      | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------|
| ETHINYL ESTRADIOL; LEVONORGESTREL<br>0.03MG; 0.15MG                                       | NORDETTE-21<br>(TABLET; ORAL-21)                 | WYETH LABS/AMHO       | 18-668<br>05-10-82                   | 3666858<br>05-30-89<br>3850911<br>11-26-91<br>3959322<br>11-26-91                        | NC<br>09-24-86                         |
| ETHINYL ESTRADIOL; LEVONORGESTREL<br>0.03MG; 0.15MG                                       | NORDETTE-28<br>(TABLET; ORAL-28)                 | WYETH LABS/AMHO       | 18-782<br>07-21-82                   | 3666858<br>05-30-89<br>3850911<br>11-26-91<br>3959322<br>11-26-91                        | NC<br>09-24-86                         |
| ETHINYL ESTRADIOL; LEVONORGESTREL<br>0.03MG; 0.05MG<br>0.04MG; 0.075MG<br>0.03MG; 0.125MG | TRIPHASIL-28<br>(TABLET; ORAL-28)                | WYETH LABS/AMHO       | 19-190<br>11-01-84                   | 3666858<br>05-30-89<br>3850911<br>11-26-91<br>3959322<br>11-26-91<br>3957982<br>05-18-93 | NS<br>11-01-87                         |
| ETHINYL ESTRADIOL; LEVONORGESTREL<br>0.03MG; 0.05MG<br>0.04MG; 0.075MG<br>0.03MG; 0.125MG | TRIPHASIL-21<br>(TABLET; ORAL-21)                | WYETH LABS/AMHO       | 19-192<br>11-01-84                   | 3666858<br>05-30-89<br>3850911<br>11-26-91<br>3959322<br>11-26-91<br>3957982<br>05-18-93 | NS<br>11-01-87                         |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE) | APPLICANT NAME | NDA # | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------|----------------------|----------------|-------|---------------|----------|-----------|-------------|
|----------------------|-------------|------------|----------------------|----------------|-------|---------------|----------|-----------|-------------|

|                                  |                                |                       |                   |                       |        |          |         |          |          |
|----------------------------------|--------------------------------|-----------------------|-------------------|-----------------------|--------|----------|---------|----------|----------|
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG AND 1MG         | ORTHOD-NOVUM 10/11-21 | (TABLET; ORAL-21) | ORTHOD PHARMACEUTICAL | 18-354 | 01-11-82 |         | 09-24-86 | D-5      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG AND 1MG         | ORTHOD-NOVUM 10/11-28 | (TABLET; ORAL-28) | ORTHOD PHARMACEUTICAL | 18-354 | 01-11-82 |         | 09-24-86 | D-5      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG AND 1MG         | TRI-NORINYL 21-DAY    | (TABLET; ORAL-21) | SYNTEX (FP)           | 18-977 | 04-13-84 | 4390531 | 09-24-86 | D-6      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG AND 1MG         | TRI-NORINYL 28-DAY    | (TABLET; ORAL-28) | SYNTEX (FP)           | 18-977 | 04-13-84 | 4390531 | 09-24-86 | D-6      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG, 0.75MG AND 1MG | ORTHOD-NOVUM 7/7-7-21 | (TABLET; ORAL-21) | ORTHOD PHARMACEUTICAL | 18-985 | 04-04-84 |         | 09-24-86 | D-3      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG, 0.75MG AND 1MG | ORTHOD-NOVUM 7/7-7-28 | (TABLET; ORAL-28) | ORTHOD PHARMACEUTICAL | 18-985 | 04-04-84 |         | 09-24-86 | D-3      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG AND 1MG         | ORTHOD-NOVUM 7/14-21  | (TABLET; ORAL-21) | ORTHOD PHARMACEUTICAL | 19-004 | 04-04-84 |         | 09-24-86 | D-4      |
| ETHINYL ESTRADIOL; NORETHINDRONE | 0.035MG; 0.5MG AND 1MG         | ORTHOD-NOVUM 7/14-28  | (TABLET; ORAL-28) | ORTHOD PHARMACEUTICAL | 19-004 | 04-04-84 |         | 09-24-86 | D-4      |
| ETHINYL ESTRADIOL; NORGESTREL    | 0.05MG; 0.5MG                  | OVRAL                 | (TABLET; ORAL-21) | WYETH LABS/MHO        | 16-672 | 04-16-68 | 366858  | 05-30-89 | 11-26-91 |
| ETHINYL ESTRADIOL; NORGESTREL    | 0.05MG; 0.5MG                  | OVRAL-28              | (TABLET; ORAL-28) | WYETH LABS/MHO        | 16-806 | 11-26-68 | 366858  | 05-30-89 | 11-26-91 |

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                                                      | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------|
| ETHINYL ESTRADIOL; NORGESTREL<br>0.03MG; 0.3MG    | LO/OVRAL<br>(TABLET; ORAL-21)                    | WYETH LABS/AMHO       | 17-612<br>03-17-75                   | 3666858<br>05-30-89<br>3850911<br>11-26-91<br>3959322<br>11-26-91                        |                                        |
| ETHINYL ESTRADIOL; NORGESTREL<br>0.03MG; 0.3MG    | LO/OVRAL-28<br>(TABLET; ORAL-28)                 | WYETH LABS/AMHO       | 17-802<br>03-16-76                   | 3666858<br>05-30-89<br>3850911<br>11-26-91<br>3959322<br>11-26-91                        |                                        |
| ETIDOCAINE HYDROCHLORIDE<br>0.5%                  | DURANEST<br>(INJECTABLE; INJECTION)              | ASTRA PHARM PRODS     | 17-751<br>08-30-76                   | 3862321<br>01-21-92<br>3812147<br>05-21-91                                               |                                        |
| ETIDOCAINE HYDROCHLORIDE<br>1%                    | DURANEST<br>(INJECTABLE; INJECTION)              | ASTRA PHARM PRODS     | 17-751<br>08-30-76                   | 3862321<br>01-21-92<br>3812147<br>05-21-91                                               |                                        |
| ETIDRONATE DISODIUM<br>200MG                      | DIDRONEL<br>(TABLET; ORAL)                       | NORWICH EATON/P&G     | 17-831<br>09-01-77                   | 4254114<br>03-03-98<br>4216211<br>08-05-97<br>4137309<br>01-30-96<br>3683080<br>08-08-89 |                                        |

| ACTIVE INGREDIENT(S)       | STRENGTH(S)       | TRADE NAME                         | APPLICANT NAME       | NDA #         | PATENT #  | EXCLUSIVITY |
|----------------------------|-------------------|------------------------------------|----------------------|---------------|-----------|-------------|
|                            |                   | (DOSAGE FORM; ROUTE)               |                      | APPROVAL DATE | EXP. DATE | EXP. DATE   |
| ETIDRONATE DISODIUM        | 400MG             | DIDRONEL                           | NORMICH EATON/P&G    | 17-831        | 4254114   | NS          |
|                            |                   | (TABLET; ORAL)                     |                      | 07-06-84      | 03-03-98  | 09-24-86    |
|                            |                   |                                    |                      |               | 4216211   |             |
|                            |                   |                                    |                      |               | 08-05-97  |             |
|                            |                   |                                    |                      |               | 4137309   |             |
|                            |                   |                                    |                      |               | 01-30-96  |             |
|                            |                   |                                    |                      |               | 3683080   |             |
|                            |                   |                                    |                      |               | 08-08-89  |             |
| ETONIDATE                  | 2MG/ML            | AMIDATE                            | ABBOTT LABORATORIES  | 18-227        |           | NCE         |
|                            |                   | (INJECTABLE; INJECTION)            |                      | 09-07-82      |           | 09-07-92    |
| ETOPOSIDE                  | 20MG/ML           | VEPESID                            | BRISTOL LABS/B-M     | 18-768        | 3524844   | NCE         |
|                            |                   | (INJECTABLE; INJECTION)            |                      | 11-10-83      | 08-18-87  | 11-10-93    |
| FENFLURAMINE HYDROCHLORIDE | 60MG              | PONDIMIN                           | AH ROBINS            | 16-618        |           | NDF         |
|                            |                   | (TABLET; CONTROLLED RELEASE; ORAL) |                      | 07-27-82      |           | 09-24-86    |
| FENOPROFEN CALCIUM         | EQ 300MG BASE     | NALFON                             | DISTA PRODS/LILLY    | 17-604        | 3600437   |             |
|                            |                   | (CAPSULE; ORAL)                    |                      | 03-16-76      | 08-17-88  |             |
| FENOPROFEN CALCIUM         | EQ 200MG BASE     | NALFON 200                         | DISTA PRODS/LILLY    | 17-604        | 3600437   |             |
|                            |                   | (CAPSULE; ORAL)                    |                      | 10-15-80      | 08-17-88  |             |
| FENOPROFEN CALCIUM         | EQ 600MG BASE     | NALFON                             | DISTA PRODS/LILLY    | 17-710        | 3600437   |             |
|                            |                   | (TABLET; ORAL)                     |                      | 03-16-76      | 08-17-88  |             |
| FENTANYL CITRATE           | EQ 0.05MG BASE/ML | FENTANYL CITRATE                   | ABBOTT LABORATORIES  | 19-115        |           |             |
|                            |                   | (INJECTABLE; INJECTION)            |                      | 01-12-85      |           |             |
| FENTANYL CITRATE           | EQ 0.05MG BASE/ML | FENTANYL                           | ELKINS-SINN/ARROBINS | 19-101        |           |             |
|                            |                   | (INJECTABLE; INJECTION)            |                      | 07-11-84      |           |             |
| FLUCYTOSINE                | 250MG             | ANCOBON                            | HOFFMANN-LA ROCHE    | 17-001        | 3368938   |             |
|                            |                   | (CAPSULE; ORAL)                    |                      | 11-26-71      | 02-13-85  |             |

TABLE 14.10. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| FLUCYTOSINE<br>500MG                              | ANCOBON<br>(CAPSULE; ORAL)                       | HOFFMANN-LA ROCHE     | 17-001<br>11-26-71                   | 3368938<br>02-13-85                 |                                        |
| FLUNISOLIDE<br>0.025MG/INH                        | BRONALIDE<br>(AEROSOL; INHALATION)               | SYNTEX LABS/SYNTEX    | 18-340<br>08-17-84                   |                                     | NDF<br>09-24-86                        |
| FLUOCINONIDE<br>0.05%                             | LIDEX<br>(SOLUTION; TOPICAL)                     | SYNTEX LABS/SYNTEX    | 18-849<br>04-06-84                   |                                     | NDF<br>09-24-86                        |
| FLUOCINONIDE<br>0.05%                             | VASODERM<br>(CREAM; TOPICAL)                     | K-LINE PHARMS         | 19-117<br>06-26-84                   |                                     |                                        |
| FLUPHENAZINE DECANOATE<br>25MG/ML                 | PROLIXIN DECANOATE<br>(INJECTABLE; INJECTION)    | ER SQUIBB AND SONS    | 16-727<br>06-20-72                   | 3394131<br>07-23-85                 |                                        |
| FLUPHENAZINE ENANTHATE<br>25MG/ML                 | PROLIXIN ENANTHATE<br>(INJECTABLE; INJECTION)    | ER SQUIBB AND SONS    | 16-110<br>03-15-67                   | 3394131<br>07-23-85                 |                                        |
| FLURANDRENOLIDE<br>0.004MG/SQ CM                  | CORDRAN<br>(TAPE; TOPICAL)                       | DISTA PRODS/LILLY     | 16-455<br>07-29-69                   | 3632740<br>01-04-89                 |                                        |
| FLURAZEPAM HYDROCHLORIDE<br>15MG                  | DALMANE<br>(CAPSULE; ORAL)                       | ROCHE PRODUCTS        | 16-721<br>04-07-70                   | 4316897<br>02-23-99                 |                                        |
| FLURAZEPAM HYDROCHLORIDE<br>30MG                  | DALMANE<br>(CAPSULE; ORAL)                       | ROCHE PRODUCTS        | 16-721<br>04-07-70                   | 4316897<br>02-23-99                 |                                        |
| FUROSEMIDE<br>20MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | CHELSEA LABORATORIES  | 18-369<br>05-14-82                   |                                     |                                        |
| FUROSEMIDE<br>40MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | CHELSEA LABORATORIES  | 18-369<br>05-14-82                   |                                     |                                        |





TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| FUROSEMIDE<br>80MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | CORD LABORATORIES     | 18-569<br>08-14-84                   |                                     |                                        |
| FUROSEMIDE<br>10MG/ML                             | FUROSEMIDE<br>(INJECTABLE; INJECTION)            | NATCON                | 18-579<br>11-30-83                   |                                     |                                        |
| FUROSEMIDE<br>10MG/ML                             | FUROSEMIDE<br>(INJECTABLE; INJECTION)            | ABBOTT LABORATORIES   | 18-667<br>05-28-82                   |                                     |                                        |
| FUROSEMIDE<br>10MG/ML                             | FUROSEMIDE<br>(INJECTABLE; INJECTION)            | WYETH LABS/AMHO       | 18-670<br>07-20-82                   |                                     |                                        |
| FUROSEMIDE<br>40MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | DRUMMER/PHOENIX       | 18-750<br>07-30-84                   |                                     |                                        |
| FUROSEMIDE<br>20MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | INTL MEDICATION SYS   | 18-753<br>02-28-84                   |                                     |                                        |
| FUROSEMIDE<br>40MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | INTL MEDICATION SYS   | 18-753<br>02-28-84                   |                                     |                                        |
| FUROSEMIDE<br>40MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | BARR LABORATORIES     | 18-790<br>11-29-83                   |                                     |                                        |
| FUROSEMIDE<br>20MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | ROXANE LABORATORIES   | 18-823<br>11-10-83                   |                                     |                                        |
| FUROSEMIDE<br>40MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | ROXANE LABORATORIES   | 18-823<br>11-10-83                   |                                     |                                        |
| FUROSEMIDE<br>20MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | KALAPHARM             | 18-868<br>06-28-83                   |                                     |                                        |
| FUROSEMIDE<br>40MG                                | FUROSEMIDE<br>(TABLET; ORAL)                     | KALAPHARM             | 18-868<br>06-28-83                   |                                     |                                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE)    | APPLICANT NAME    | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------|-------------------------|-------------------|--------|---------------|----------|-----------|-------------|
| FUROSEMIDE           | 10MG/ML     | FUROSEMIDE | (INJECTABLE; INJECTION) | INVENEX LABS/LIFE | 18-902 | 05-22-84      |          |           |             |
| FUROSEMIDE           | 10MG/ML     | FUROSEMIDE | (INJECTABLE; INJECTION) | INVENEX LABS/LIFE | 19-036 | 08-13-84      |          |           |             |
| GENFIBROZIL          | 200MG       | LOPID      | (CAPSULE; ORAL)         | PARKER-DAYIS/W-L  | 18-422 | 07-04-89      | 3674836  |           |             |
| GENFIBROZIL          | 300MG       | LOPID      | (CAPSULE; ORAL)         | PARKER-DAYIS/W-L  | 18-422 | 12-21-81      | 3674836  |           |             |
| GLIPIZIDE            | 5MG         | GLUCOTROL  | (TABLET; ORAL)          | ROERIG/PFIZER     | 17-783 | 05-08-84      | 3669966  | 05-08-94  | NCE         |
| GLIPIZIDE            | 10MG        | GLUCOTROL  | (TABLET; ORAL)          | ROERIG/PFIZER     | 17-783 | 05-08-84      | 3669966  | 05-08-94  | NCE         |
| GLYBURIDE            | 1.25MG      | MICRONASE  | (TABLET; ORAL)          | UPJOHN            | 17-498 | 05-01-84      | 3426067  | 05-01-94  | NCE         |
| GLYBURIDE            | 2.5MG       | MICRONASE  | (TABLET; ORAL)          | UPJOHN            | 17-498 | 05-01-84      | 3426067  | 05-01-94  | NCE         |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                                                                             | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------------------------|
| GLYBURIDE<br>5MG                                  | MICRONASE<br>(TABLET; ORAL)                      | UPJOHN                | 17-498<br>05-01-84                   | 3426067<br>04-21-92<br>3454635<br>04-21-92<br>3507954<br>04-21-92<br>3507961<br>04-21-92                        | NCE<br>05-01-94                        |
| GLYBURIDE<br>1.25MG                               | DIABETA<br>(TABLET; ORAL)                        | HOECHST-ROUSSEL       | 17-532<br>05-01-84                   | 3426067<br>04-21-92<br>3454635<br>04-21-92<br>3507961<br>04-21-92<br>3507954<br>04-21-92<br>4060634<br>09-07-93 | NCE<br>05-01-94                        |
| GLYBURIDE<br>2.5MG                                | DIABETA<br>(TABLET; ORAL)                        | HOECHST-ROUSSEL       | 17-532<br>05-01-84                   | 3426067<br>04-21-92<br>3454635<br>04-21-92<br>3507961<br>04-21-92<br>3507954<br>04-21-92<br>4060634<br>09-07-93 | NCE<br>05-01-94                        |

| ACTIVE INGREDIENT(S)                            | TRADE NAME                                        | APPLICANT NAME     | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY     |
|-------------------------------------------------|---------------------------------------------------|--------------------|--------|---------------|----------|-----------|-----------------|
| GLIBURIDE<br>5MG                                | DIABETA<br>(TABLET; ORAL)                         | HOECHST-ROUSSEL    | 17-532 | 05-01-84      | 3426067  | 04-21-92  | 05-01-94<br>NCE |
| GONADORELIN HYDROCHLORIDE<br>EQ 0.1MG BASE/VIAL | FACTREL<br>(INJECTABLE; INJECTION)                | AYERST LABS/AMHO   | 18-123 | 09-30-82      | 3947569  | 03-30-93  | 09-30-92<br>NCE |
|                                                 | FACTREL<br>(INJECTABLE; INJECTION)                | AYERST LABS/AMHO   | 18-123 | 09-30-82      | 3947569  | 03-30-93  | 09-30-92<br>NCE |
| GONADORELIN HYDROCHLORIDE<br>EQ 0.5MG BASE/VIAL | FACTREL<br>(INJECTABLE; INJECTION)                | AYERST LABS/AMHO   | 18-123 | 09-30-82      | 3947569  | 03-30-93  | 09-30-92<br>NCE |
|                                                 | FACTREL<br>(INJECTABLE; INJECTION)                | AYERST LABS/AMHO   | 18-123 | 09-30-82      | 3947569  | 03-30-93  | 09-30-92<br>NCE |
| GONADOTROPIN, CHORIONIC<br>2,000 UNITS/VIAL     | CHORIONIC GONADOTROPIN<br>(INJECTABLE; INJECTION) | CARTER-GLOBAU LABS | 17-016 | 12-27-84      |          |           |                 |
| GUANABENZ ACETATE<br>EQ 4MG BASE                | WYTENSIN<br>(TABLET; ORAL)                        | WYETH LABS/AMHO    | 18-587 | 09-07-82      | 3658993  | 04-25-89  | 09-07-92<br>NCE |
| GUANABENZ ACETATE<br>EQ 8MG BASE                | WYTENSIN<br>(TABLET; ORAL)                        | WYETH LABS/AMHO    | 18-587 | 09-07-82      | 3658993  | 04-25-89  | 09-07-92<br>NCE |
| GUANADREL SULFATE<br>10MG                       | HYLOREL<br>(TABLET; ORAL)                         | UPJOHN             | 18-104 | 12-29-82      | 3547951  | 12-15-87  | 12-29-92<br>NCE |
| GUANADREL SULFATE<br>25MG                       | HYLOREL<br>(TABLET; ORAL)                         | UPJOHN             | 18-104 | 12-29-82      | 3547951  | 12-15-87  | 12-29-92<br>NCE |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| HALAZEPAM<br>20MG                                 | PAXIPAM<br>(TABLET; ORAL)                        | SCHERING              | 17-736<br>09-24-81                   | 3429874<br>02-25-86                 |                                        |
| HALAZEPAM<br>40MG                                 | PAXIPAM<br>(TABLET; ORAL)                        | SCHERING              | 17-736<br>09-24-81                   | 3429874<br>02-25-86                 |                                        |
| HALOPERIDOL<br>0.5MG                              | HALDOL<br>(TABLET; ORAL)                         | MCNEIL PHARM          | 15-921<br>04-12-67                   | 3438991<br>04-15-86                 | NS<br>09-24-86                         |
| HALOPERIDOL<br>1MG                                | HALDOL<br>(TABLET; ORAL)                         | MCNEIL PHARM          | 15-921<br>04-12-67                   | 3438991<br>04-15-86                 |                                        |
| HALOPERIDOL<br>2MG                                | HALDOL<br>(TABLET; ORAL)                         | MCNEIL PHARM          | 15-921<br>04-12-67                   | 3438991<br>04-15-86                 |                                        |
| HALOPERIDOL<br>5MG                                | HALDOL<br>(TABLET; ORAL)                         | MCNEIL PHARM          | 15-921<br>04-16-74                   | 3438991<br>04-15-86                 |                                        |
| HALOPERIDOL<br>10MG                               | HALDOL<br>(TABLET; ORAL)                         | MCNEIL PHARM          | 15-921<br>04-16-74                   | 3438991<br>04-15-86                 |                                        |
| HALOPERIDOL<br>20MG                               | HALDOL<br>(TABLET; ORAL)                         | MCNEIL PHARM          | 15-921<br>02-02-82                   | 3438991<br>04-15-86                 | NS<br>09-24-86                         |
| HALOPERIDOL LACTATE<br>EQ 2MG BASE/ML             | HALDOL<br>(CONCENTRATE; ORAL)                    | MCNEIL LABORATORIES   | 15-922<br>04-12-67                   | 3438991<br>04-15-86                 |                                        |
| HALOPERIDOL LACTATE<br>EQ 5MG BASE/ML             | HALDOL<br>(INJECTABLE; INJECTION)                | MCNEIL LABORATORIES   | 15-923<br>07-18-71                   | 3438991<br>04-15-86                 |                                        |
| HEPARIN SODIUM<br>10 UNITS/ML                     | HEPARIN LOCK FLUSH<br>(INJECTABLE; INJECTION)    | INVENEX LABS/LIFE     | 17-029<br>05-06-82                   |                                     |                                        |

| ACTIVE INGREDIENT(S)                                               | TRADE NAME                                                                                                | (DOSAGE FORM; ROUTE) | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|----------------------|---------------------|--------|---------------|----------|-----------|-------------|
| HEPARIN SODIUM; SODIUM CHLORIDE<br>200 UNITS/100ML; 900MG/100ML    | HEPARIN SODIUM 1000 UNITS<br>AND SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  |                      | TRAVENOL LABS       | 18-609 | 04-28-82      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>200 UNITS/100ML; 900MG/100ML    | HEPARIN SODIUM 2000 UNITS<br>AND SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  |                      | TRAVENOL LABS       | 18-609 | 04-28-82      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>500 UNITS/100ML; 900MG/100ML    | HEPARIN SODIUM 5000 UNITS<br>AND SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  |                      | TRAVENOL LABS       | 18-609 | 04-28-82      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>1,000 UNITS/100ML; 900MG/100ML  | HEPARIN SODIUM 5000 UNITS<br>IN SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)   |                      | ABBOTT LABORATORIES | 18-916 | 01-31-84      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>10,000 UNITS/100ML; 900MG/100ML | HEPARIN SODIUM 10,000 UNITS<br>IN SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) |                      | ABBOTT LABORATORIES | 18-916 | 01-31-84      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>5,000 UNITS/100ML; 900MG/100ML  | HEPARIN SODIUM 12,500 UNITS<br>IN SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) |                      | ABBOTT LABORATORIES | 18-916 | 01-31-84      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>100 UNITS/ML; 4.5MG/ML          | HEPARIN SODIUM 5,000 UNITS<br>IN SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) |                      | ABBOTT LABORATORIES | 18-916 | 01-31-84      |          |           |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                  | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                                           | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| HEPARIN SODIUM; SODIUM CHLORIDE<br>100 UNITS/ML; 4.5MG/ML          | HEPARIN SODIUM 5,000 UNITS<br>IN SODIUM CHLORIDE 0.45%<br>(INJECTABLE; INJECTION)                          | ABBOTT LABORATORIES   | 18-911<br>01-30-85                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>10,000 UNITS/100ML; 450MG/100ML | HEPARIN SODIUM 10,000 UNITS<br>IN SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES   | 18-916<br>01-31-84                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>10,000 UNITS/100ML; 450MG/100ML | HEPARIN SODIUM 10,000 UNITS<br>IN SODIUM CHLORIDE 0.45%<br>(INJECTABLE; INJECTION)                         | ABBOTT LABORATORIES   | 18-911<br>01-30-85                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>10,000 UNITS/100ML; 900MG/100ML | HEPARIN SODIUM 10,000 UNITS<br>IN SODIUM CHLORIDE 0.9%<br>(INJECTABLE; INJECTION)                          | ABBOTT LABORATORIES   | 18-911<br>01-30-85                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>5,000 UNITS/100ML; 450MG/100ML  | HEPARIN SODIUM 12,500 UNITS<br>IN SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES   | 18-916<br>01-31-84                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>5,000 UNITS/100ML; 900MG/100ML  | HEPARIN SODIUM 12,500 UNITS<br>IN SODIUM CHLORIDE 0.9%<br>(INJECTABLE; INJECTION)                          | ABBOTT LABORATORIES   | 18-911<br>01-30-85                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>5,000 UNITS/100ML; 900MG/100ML  | HEPARIN SODIUM 25,000 UNITS<br>IN SODIUM CHLORIDE 0.9%<br>(INJECTABLE; INJECTION)                          | ABBOTT LABORATORIES   | 18-911<br>01-30-85                   |                                     |                                        |
| HEPARIN SODIUM; SODIUM CHLORIDE<br>5,000 UNITS/100ML; 450MG/100ML  | HEPARIN SODIUM 25,000 UNITS<br>IN SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES   | 18-916<br>01-31-84                   |                                     |                                        |

| ACTIVE INGREDIENT(S)                 | STRENGTH(S)                     | TRADE NAME                  | (DOSAGE FORM; ROUTE)    | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------------------|---------------------------------|-----------------------------|-------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| HEPARIN SODIUM; SODIUM CHLORIDE      | 10,000 UNITS/100ML; 450MG/100ML | HEPARIN SODIUM 25,000 UNITS | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-916 | 01-31-84      |          |           |             |
| HEPARIN SODIUM; SODIUM CHLORIDE      | 5,000 UNITS/100ML; 900MG/100ML  | HEPARIN SODIUM 25,000 UNITS | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-916 | 01-31-84      |          |           |             |
| HEXACHLOROPHENE                      | 3%                              | TURGEX                      | (SOLUTION; TOPICAL)     | XTRILUM LABS        | 19-055 | 11-30-84      |          |           |             |
| HYDROCHLOROTHIAZIDE;                 | 25MG; 50MG                      | LOPRESSOR HCT 50/25         | (TABLET; ORAL)          | GEIGY/CIBA-GEIGY    | 18-303 | 12-31-84      |          |           | NC          |
| HYDROCHLOROTHIAZIDE;                 | 25MG; 100MG                     | LOPRESSOR HCT 100/25        | (TABLET; ORAL)          | GEIGY/CIBA-GEIGY    | 18-303 | 12-31-84      |          |           | NC          |
| HYDROCHLOROTHIAZIDE;                 | 25MG; 100MG                     | LOPRESSOR HCT 100/50        | (TABLET; ORAL)          | GEIGY/CIBA-GEIGY    | 18-303 | 12-31-84      |          |           | NC          |
| HYDROCHLOROTHIAZIDE;                 | 50MG; 100MG                     | LOPRESSOR HCT 100/50        | (TABLET; ORAL)          | GEIGY/CIBA-GEIGY    | 18-303 | 12-31-84      |          |           | NC          |
| HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE | 25MG; 10MG                      | TIMOLOL                     | (TABLET; ORAL)          | MSD/MERCK           | 18-061 | 12-11-81      |          |           |             |
| HYDROCHLOROTHIAZIDE; TRIAMTERENE     | 50MG; 75MG                      | MAXIDE                      | (TABLET; ORAL)          | MYLAN PHARMS        | 19-129 | 10-22-84      |          |           | NS          |

TABLETS APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| HYDROCORTISONE ACETATE<br>10%                     | CORTIFOAM<br>(AEROSOL; RECTAL)                   | REED&CARNRICK PHARMS  | 17-351<br>02-10-82                   |                                     | NDF<br>09-24-86                        |
| HYDROCORTISONE BUTYRATE<br>0.1%                   | LOCOID<br>(CREAM; TOPICAL)                       | OWEN LABS/DERM PRODS  | 18-795<br>01-07-83                   |                                     | NP<br>09-24-86                         |
| HYDROCORTISONE BUTYRATE<br>0.1%                   | LOCOID<br>(OINTMENT; TOPICAL)                    | OWEN LABS/DERM PRODS  | 19-106<br>07-03-84                   |                                     | NP<br>09-24-86                         |
| HYDROCORTISONE VALERATE<br>0.2%                   | WESTCORT<br>(OINTMENT; TOPICAL)                  | WESTWOOD PHARMS       | 18-726<br>08-08-83                   |                                     | NDF<br>09-24-86                        |
| HYDROMORPHONE HYDROCHLORIDE<br>10MG/ML            | DILAUDID-HP<br>(INJECTABLE; INJECTION)           | KNOLL PHARMACEUTICAL  | 19-034<br>01-11-84                   |                                     | NCE<br>01-11-94                        |
| HYDROXYUREA<br>500MG                              | HYDREA<br>(CAPSULE; ORAL)                        | ER SQUIBB AND SONS    | 16-295<br>12-07-67                   | 3968249<br>07-06-93                 |                                        |
| IBUPROFEN<br>400MG                                | MOTRIN<br>(TABLET; ORAL)                         | UPJOHN MANUFACTURING  | 17-463<br>09-19-74                   | 3385886<br>05-28-85                 | 1-2<br>09-24-86                        |
| IBUPROFEN<br>300MG                                | MOTRIN<br>(TABLET; ORAL)                         | UPJOHN MANUFACTURING  | 17-463<br>09-19-74                   | 3385886<br>05-28-85                 | 1-2<br>09-24-86                        |
| IBUPROFEN<br>600MG                                | MOTRIN<br>(TABLET; ORAL)                         | UPJOHN MANUFACTURING  | 17-463<br>03-09-79                   | 3385886<br>05-28-85                 | 1-2<br>09-24-86                        |
| IBUPROFEN<br>400MG                                | RUFEN<br>(TABLET; ORAL)                          | BOOTS PHARMACEUTICAL  | 18-197<br>05-19-81                   | 3385886<br>05-28-85                 | 1-2<br>09-24-86                        |
| IBUPROFEN<br>600MG                                | RUFEN<br>(TABLET; ORAL)                          | BOOTS PHARMACEUTICAL  | 18-197<br>03-05-84                   | 3385886<br>05-28-85                 | 1-2<br>09-24-86                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME   | (DOSAGE FORM; ROUTE)                | APPLICANT NAME       | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|--------------|-------------------------------------|----------------------|---------------|----------|-----------|-------------|
| INDOMETHACIN         | 2.5MG       | LOZOL        | (TABLET; ORAL)                      | USV PHARMACEUTICAL   | 18-538        | 3565911  | NCE       | 07-06-93    |
| INDOMETHACIN         | 50MG        | INDOCIN      | (SUPPOSITORY; RECTAL)               | MS&D RES LABS/MERCK  | 17-814        |          | NDF       | 09-24-86    |
| INDOMETHACIN         | 75MG        | INDOCIN SR   | (CAPSULE, CONTROLLED RELEASE; ORAL) | MS&D/MERCK           | 18-185        |          | NDF       | 09-24-86    |
| INDOMETHACIN         | 50MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | CHELSEA LABORATORIES | 18-690        |          |           |             |
| INDOMETHACIN         | 25MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | CHELSEA LABORATORIES | 07-31-84      |          |           |             |
| INDOMETHACIN         | 50MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | ZENITH LABORATORIES  | 18-730        |          |           |             |
| INDOMETHACIN         | 50MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | ZENITH LABORATORIES  | 05-04-84      |          |           |             |
| INDOMETHACIN         | 50MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | PAR PHARMACEUTICAL   | 18-829        |          |           |             |
| INDOMETHACIN         | 25MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | PAR PHARMACEUTICAL   | 08-06-84      |          |           |             |
| INDOMETHACIN         | 25MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | LEDERLE LABS/AM CYAN | 18-851        |          |           |             |
| INDOMETHACIN         | 50MG        | INDOMETHACIN | (CAPSULE; ORAL)                     | LEDERLE LABS/AM CYAN | 05-18-84      |          |           |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>  | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|----------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| INDOMETHACIN<br>25MG                               | INDOMETHACIN<br>(CAPSULE; ORAL)                  | MYLAN PHARMS          | 18-858<br>04-20-84                   |                                     |                                        |
| INDOMETHACIN<br>50MG                               | INDOMETHACIN<br>(CAPSULE; ORAL)                  | MYLAN PHARMS          | 18-858<br>04-20-84                   |                                     |                                        |
| INDOMETHACIN<br>25MG                               | INDOMETHACIN<br>(CAPSULE; ORAL)                  | PARKE-DAVIS/W-L       | 18-806<br>11-23-84                   |                                     |                                        |
| INDOMETHACIN<br>50MG                               | INDOMETHACIN<br>(CAPSULE; ORAL)                  | PARKE-DAVIS/W-L       | 18-806<br>11-23-84                   |                                     |                                        |
| INDOMETHACIN SODIUM TRIHYDRATE<br>EQ 1MG BASE/VIAL | INDOCIN I. V.<br>(INJECTABLE; INJECTION)         | MS&D/MERCK            | 18-878<br>01-30-85                   |                                     |                                        |
| IODAMIDE MEGLUMINE<br>24%                          | RENOVUE-DIP<br>(INJECTABLE; INJECTION)           | ER SQUIBB AND SONS    | 17-903<br>07-10-78                   |                                     | 1-6<br>09-24-86                        |
| IODAMIDE MEGLUMINE<br>65%                          | RENOVUE-65<br>(INJECTABLE; INJECTION)            | ER SQUIBB AND SONS    | 17-902<br>07-24-78                   |                                     | 1-6<br>09-24-86                        |
| IODOHIPPURATE SODIUM,<br>1-123<br>1MC1/ML          | NEPHROFLOW<br>(INJECTABLE; INJECTION)            | MEDI-PHYSICS          | 18-289<br>12-28-84                   |                                     | NCE<br>12-28-89                        |
| IOXOXAMATE MEGLUMINE<br>9.9%                       | CHOLOVUE<br>(INJECTABLE; INJECTION)              | ER SQUIBB AND SONS    | 18-076<br>08-14-81                   | 3654272<br>04-04-89                 |                                        |
| IOXOXAMATE MEGLUMINE<br>40.3%                      | CHOLOVUE<br>(INJECTABLE; INJECTION)              | ER SQUIBB AND SONS    | 18-077<br>08-14-81                   | 3654272<br>04-04-89                 |                                        |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE) | APPLICANT NAME    | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------|----------------------|-------------------|--------|---------------|----------|-----------|-------------|
| ISOFLURANE           | 99.9%       | FORANE     | (GAS; INHALATION)    | ANQUEST/BOC       | 17-624 | 12-18-79      | 3535425  | 01-24-93  |             |
| ISOTRETINOIN         | 10MG        | ACUTANE    | (CAPSULE; ORAL)      | HOFFMANN-LA ROCHE | 18-662 | 05-07-82      | 4200647  | 04-29-97  | NCE         |
| ISOTRETINOIN         | 20MG        | ACUTANE    | (CAPSULE; ORAL)      | HOFFMANN-LA ROCHE | 18-662 | 03-28-83      | 4200647  | 04-29-97  | NCE         |
| ISOTRETINOIN         | 40MG        | ACUTANE    | (CAPSULE; ORAL)      | HOFFMANN-LA ROCHE | 18-662 | 05-07-82      | 4200647  | 04-29-97  | NCE         |
| KETOCONAZOLE         | 200MG       | NIZORAL    | (TABLET; ORAL)       | JANSSEN PHARMA    | 18-533 | 06-12-81      | 4335125  | 06-15-99  | 1-25        |

TABLE IV. INDICATIONS APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| LABETALOL HYDROCHLORIDE<br>200MG                  | NORMODYNE<br>(TABLET; ORAL)                      | SCHERING              | 18-686<br>08-01-84                   | 4012444<br>03-15-94<br>4006755<br>01-03-95                        | NCE<br>08-01-94                        |
| LABETALOL HYDROCHLORIDE<br>300MG                  | NORMODYNE<br>(TABLET; ORAL)                      | SCHERING              | 18-686<br>08-01-84                   | 4012444<br>03-15-94<br>4006755<br>01-03-95                        | NCE<br>08-01-94                        |
| LABETALOL HYDROCHLORIDE<br>400MG                  | NORMODYNE<br>(TABLET; ORAL)                      | SCHERING              | 18-686<br>08-01-84                   | 4012444<br>03-15-94<br>4006755<br>01-03-95                        | NCE<br>08-01-94                        |
| LABETALOL HYDROCHLORIDE<br>5MG/ML                 | NORMODYNE<br>(INJECTABLE; INJECTION)             | SCHERING              | 18-687<br>08-01-84                   | 4012444<br>03-15-94<br>4006755<br>01-03-95<br>4328213<br>05-04-99 | NCE<br>08-01-94                        |
| LABETALOL HYDROCHLORIDE<br>200MG                  | TRANDATE<br>(TABLET; ORAL)                       | GLAXO                 | 18-716<br>08-01-84                   | 4012444<br>03-15-94<br>4006755<br>01-03-95                        | NCE<br>08-01-94                        |
| LABETALOL HYDROCHLORIDE<br>300MG                  | TRANDATE<br>(TABLET; ORAL)                       | GLAXO                 | 18-716<br>08-01-84                   | 4012444<br>03-15-94<br>4006755<br>01-03-95                        | NCE<br>08-01-94                        |

| ACTIVE INGREDIENT(S)     | STRENGTH(S)  | TRADE NAME        | (DOSAGE FORM, ROUTE)               | APPLICANT NAME       | NDA #    | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|--------------------------|--------------|-------------------|------------------------------------|----------------------|----------|---------------|----------|-----------|-------------|
| LABETALOL HYDROCHLORIDE  | 400MG        | TRANDATE          | (TABLET, ORAL)                     | GLAXO                | 18-716   | 08-01-84      | 4012444  | 08-01-94  | NCE         |
| LACTULOSE                | 100M/15ML    | CEPHULAC          | (SYRUP, ORAL)                      | MERRELL DOW/DOW CHEM | 17-657   | 03-25-76      | 3461204  | 08-12-86  |             |
|                          |              |                   |                                    |                      |          |               | 3867524  | 02-18-92  |             |
|                          |              |                   |                                    |                      |          |               | 3860708  | 01-14-92  |             |
|                          |              |                   |                                    |                      |          |               | 3860707  | 01-14-92  |             |
|                          |              |                   |                                    |                      |          |               | 3562388  | 02-09-88  |             |
|                          |              |                   |                                    |                      |          |               | 3558774  | 01-26-88  |             |
| LEUCOVORIN CALCIIUM      | EQ 5MG BASE  | WELLCOVORIN       | (TABLET, ORAL)                     | BURROUGHS WELLCOME   | 18-342   | 07-08-85      |          | 09-24-86  | NDF         |
| LEUCOVORIN CALCIIUM      | EQ 25MG BASE | WELLCOVORIN       | (TABLET, ORAL)                     | BURROUGHS WELLCOME   | 18-152   | 03-29-82      |          | 09-24-86  | NS          |
| LITHIUM CARBONATE        | 450MG        | ESKALITH CR       | (TABLET, CONTROLLED RELEASE, ORAL) | SKKF LABORATORIES    | 18-558   | 01-29-82      |          |           |             |
| LITHIUM CARBONATE        | 300MG        | LITHIUM CARBONATE | (TABLET, ORAL)                     | ROXANE LABORATORIES  | 12-28-76 |               |          |           |             |
| LOPERAMIDE HYDROCHLORIDE | 2MG          | IMODIUM           | (CAPSULE, ORAL)                    | JANSSEN PHARMA       | 17-694   | 01-30-90      | 3714159  | 09-24-86  | 1-30        |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                             | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                  | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| LOPERAMIDE HYDROCHLORIDE<br>1MG/5ML                                                                           | IMODIUM<br>(SOLUTION; ORAL)                                       | JANSSEN PHARMA        | 19-037<br>07-31-84                   | 3714159<br>01-30-90                        | NDF<br>09-24-86                        |
| LOXAPINE HYDROCHLORIDE<br>EQ 50MG BASE/ML                                                                     | LOXITANE<br>(INJECTABLE; INJECTION)                               | LEDERLE LABS/AM CYAN  | 18-039<br>10-26-79                   | 3546226<br>12-08-87                        |                                        |
| LOXAPINE HYDROCHLORIDE<br>EQ 25MG BASE/ML                                                                     | LOXITANE<br>(CONCENTRATE; ORAL)                                   | LEDERLE LABS/AM CYAN  | 17-658<br>05-04-76                   | 3546226<br>12-08-87<br>4049809<br>09-20-94 |                                        |
| LOXAPINE SUCCINATE<br>EQ 5MG BASE                                                                             | LOXITANE<br>(CAPSULE; ORAL)                                       | LEDERLE LABS/AM CYAN  | 17-525<br>10-25-77                   | 3546226<br>12-08-87                        |                                        |
| LOXAPINE SUCCINATE<br>EQ 10MG BASE                                                                            | LOXITANE<br>(CAPSULE; ORAL)                                       | LEDERLE LABS/AM CYAN  | 17-525<br>02-25-75                   | 3546226<br>12-08-87                        |                                        |
| LOXAPINE SUCCINATE<br>EQ 25MG BASE                                                                            | LOXITANE<br>(CAPSULE; ORAL)                                       | LEDERLE LABS/AM CYAN  | 17-525<br>02-25-75                   | 3546226<br>12-08-87                        |                                        |
| LOXAPINE SUCCINATE<br>EQ 50MG BASE                                                                            | LOXITANE<br>(CAPSULE; ORAL)                                       | LEDERLE LABS/AM CYAN  | 17-525<br>02-25-75                   | 3546226<br>12-08-87                        |                                        |
| MAFENIDE ACETATE<br>EQ 85MG BASE/GM                                                                           | SULFAMYLOX<br>(CREAM; TOPICAL)                                    | WINTHROP LABS/STERL   | 16-763<br>01-24-69                   | 3497599<br>01-26-88                        |                                        |
| MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM<br>ACETATE; SODIUM CHLORIDE<br>32MG/100ML; 128MG/100ML; 234MG/100ML | PLASMA-LYTE 56 IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION) | TRAVENOL LABS         | 19-047<br>06-15-84                   |                                            | NC<br>09-24-86                         |

| ACTIVE INGREDIENT(S)                                                                                                                                                                                                                                        | TRADE NAME                                                          | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;<br>POTASSIUM PHOSPHATE, MONOBASIC; SODIUM<br>ACETATE; SODIUM CHLORIDE; SODIUM<br>GLUCONATE; SODIUM CHLORIDE; SODIUM<br>CHLORIDE; 0.82MG/100ML; 500MG/100ML;<br>370MG/100ML; 530MG/100ML; 500MG/100ML;<br>12MG/100ML | ISOLYTE'S PH 7.4 IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGRAW/HM HOSP   | 19-006 | 04-04-84      |          | 09-24-86  | NC          |
| MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM CHLORIDE;<br>SODIUM ACETATE; SODIUM CHLORIDE; SODIUM<br>GLUCONATE                                                                                                                        | PHYSIO SOL IN PLASTIC<br>CONTAINER<br>(SOLUTION; IRRIGATION)        | ABBOTT LABORATORIES | 17-637 | 07-08-82      |          | 09-24-86  | NC          |
| MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM CHLORIDE; SODIUM<br>GLUCONATE                                                                                                                                                            | PHYSIO SOL IN PLASTIC<br>CONTAINER<br>(SOLUTION; IRRIGATION)        | ABBOTT LABORATORIES | 18-406 | 07-08-82      |          | 09-24-86  | NC          |
| MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM CHLORIDE; SODIUM<br>GLUCONATE                                                                                                                                                            | PHYSIO SOL IN PLASTIC<br>CONTAINER<br>(SOLUTION; IRRIGATION)        | AM MCGRAW/HM HOSP   | 19-024 | 06-08-84      |          | 09-24-86  | NC          |
| MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;<br>SODIUM CHLORIDE; SODIUM CHLORIDE; SODIUM<br>GLUCONATE                                                                                                                                                            | SYNOVALYTE<br>IN PLASTIC CONTAINER<br>(SOLUTION; IRRIGATION)        | TRAVENOL LABS       | 19-326 | 01-25-85      |          |           |             |

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S)                                                                                                                                                  | TRADE NAME<br>(DOSAGE FORM; ROUTE)      | APPLICANT NAME       | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE | EXCLUSIVITY<br>EXP. DATE |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------------|------------------------|-----------------------|--------------------------|
| MAGNESIUM SULFATE; POTASSIUM CHLORIDE;<br>POTASSIUM PHOSPHATE, MONOBASIC; SODIUM<br>CHLORIDE; SODIUM PHOSPHATE<br>20MG/100ML; 40MG/100ML; 6.25MG/100ML;<br>800MG/100ML; 8.75MG/100ML | TIS-U-SOL<br>(SOLUTION; IRRIGATION)     | TRAVENOL LABS        | 18-508<br>02-19-82     |                       | NC<br>09-24-86           |
| MALATHION<br>0.5%                                                                                                                                                                    | PRIODERM<br>(LOTION; TOPICAL)           | PURDUE FREDERICK     | 18-613<br>08-02-82     |                       | NCE<br>08-02-92          |
| MAPROTILINE HYDROCHLORIDE<br>25MG                                                                                                                                                    | LUDIOMIL<br>(TABLET; ORAL)              | CIBA/CIBA-GEIGY      | 17-543<br>12-01-80     | 3399201<br>08-27-85   |                          |
| MAPROTILINE HYDROCHLORIDE<br>50MG                                                                                                                                                    | LUDIOMIL<br>(TABLET; ORAL)              | CIBA/CIBA-GEIGY      | 17-543<br>12-01-80     | 3399201<br>08-27-85   |                          |
| MAPROTILINE HYDROCHLORIDE<br>75MG                                                                                                                                                    | LUDIOMIL<br>(TABLET; ORAL)              | CIBA/CIBA-GEIGY      | 17-543<br>09-30-82     | 3399201<br>08-27-85   | NS<br>09-24-86           |
| MAZINDOL<br>1MG                                                                                                                                                                      | SANOREX<br>(TABLET; ORAL)               | SANDOZ PHARMS/SANDOZ | 17-247<br>06-14-73     | 3763178<br>10-02-90   |                          |
| MAZINDOL<br>2MG                                                                                                                                                                      | SANOREX<br>(TABLET; ORAL)               | SANDOZ PHARMS/SANDOZ | 17-247<br>06-14-73     | 3763178<br>10-02-90   |                          |
| MAZINDOL<br>2MG                                                                                                                                                                      | MAZANOR<br>(TABLET; ORAL)               | WYETH LABS/AMHO      | 17-980<br>08-28-80     | 3763178<br>10-02-90   |                          |
| MAZINDOL<br>1MG                                                                                                                                                                      | MAZANOR<br>(TABLET; ORAL)               | WYETH LABS/AMHO      | 17-980<br>02-02-82     | 3763178<br>10-02-90   |                          |
| MEBENDAZOLE<br>100MG                                                                                                                                                                 | VERMOX<br>(TABLET, CHEWABLE; ORAL)      | JANSSEN PHARMA       | 17-481<br>06-28-74     | 3657267<br>04-18-89   |                          |
| MEDROXYPROGESTERONE ACETATE<br>100MG/ML                                                                                                                                              | DEPO-PROVERA<br>(INJECTABLE; INJECTION) | UPJOHN               | 12-541<br>01-16-76     | 3377364<br>04-09-85   |                          |

| ACTIVE INGREDIENT(S)          | STRENGTH(S)            | TRADE NAME   | (DOSAGE FORM; ROUTE)               | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------|------------------------|--------------|------------------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| MEDROXYPROGESTERONE ACETATE   | 400MG/ML               | DEPO-PROVERA | (INJECTABLE; INJECTION)            | UP JOHN              | 12-541 | 04-09-85      | 3577364  |           |             |
| MELUMINEX; METHIZOIC ACID     | 140.1MG/ML; 461.6MG/ML | ISOPAQUE-280 | (INJECTABLE; INJECTION)            | WINTROP LABS/STERIL  | 17-506 | 04-30-74      | 3476802  | 11-04-86  |             |
| METAPROTTERENOL SULFATE       | 20MG                   | ALUPENT      | (TABLET; ORAL)                     | BOEHRINGER INGELHEIM | 15-874 | 05-13-74      | 3422196  | 01-14-86  |             |
| METAPROTTERENOL SULFATE       | 10MG                   | ALUPENT      | (TABLET; ORAL)                     | BOEHRINGER INGELHEIM | 15-874 | 08-08-77      | 3422196  | 01-14-86  |             |
| METAPROTTERENOL SULFATE       | 0.65MG/INH             | ALUPENT      | (AEROSOL; INHALATION)              | BOEHRINGER INGELHEIM | 16-402 | 07-31-73      | 3422196  | 01-14-86  |             |
| METAPROTTERENOL SULFATE       | 10MG/5ML               | ALUPENT      | (SYRUP; ORAL)                      | BOEHRINGER INGELHEIM | 17-571 | 05-23-75      | 3422196  | 01-14-86  |             |
| METAPROTTERENOL SULFATE       | 5%                     | ALUPENT      | (SOLUTION; INHALATION)             | BOEHRINGER INGELHEIM | 17-559 | 09-18-80      | 3422196  | 01-14-86  |             |
| METAPROTTERENOL SULFATE       | 0.6%                   | ALUPENT      | (SOLUTION; INHALATION)             | BOEHRINGER INGELHEIM | 18-761 | 06-30-83      | 3422196  | 01-14-86  |             |
| METHYLDOPA                    | 250MG                  | METHYLDOPA   | (TABLET; ORAL)                     | CORD LABORATORIES    | 18-934 | 06-29-84      |          |           |             |
| METHYLDOPA                    | 500MG                  | METHYLDOPA   | (TABLET; ORAL)                     | CORD LABORATORIES    | 18-934 | 06-29-84      |          |           |             |
| METHYLPHENIDATE HYDROCHLORIDE | 20MG                   | RITALIN-SR   | (TABLET; CONTROLLED RELEASE; ORAL) | CIBA/CIBA-GEIGY      | 18-029 | 03-30-82      |          |           | NDF         |

09-24-86

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| METOCLOPRAMIDE<br>EQ 5MG BASE/5ML                 | REGLAN<br>(SYRUP; ORAL)                          | AH ROBINS             | 18-821<br>3-25-83                    |                                     | NDF<br>09-24-86                        |
| METOCLOPRAMIDE HYDROCHLORIDE<br>EQ 5MG BASE/ML    | REGLAN<br>(INJECTABLE; INJECTION)                | AH ROBINS             | 17-862<br>02-07-79                   |                                     | 1-12; 1-13;<br>1-14<br>12-20-87        |
| METOCLOPRAMIDE HYDROCHLORIDE<br>EQ 10MG BASE      | REGLAN<br>(TABLET; ORAL)                         | AH ROBINS             | 17-854<br>12-30-80                   |                                     | 1-4<br>09-24-86                        |
| METOPROLOL TARTRATE<br>50MG                       | LOPRESSOR<br>(TABLET; ORAL)                      | GEIGY/CIBA-GEIGY      | 17-963<br>08-07-78                   | 3998790<br>12-21-93                 |                                        |
| METOPROLOL TARTRATE<br>100MG                      | LOPRESSOR<br>(TABLET; ORAL)                      | GEIGY/CIBA-GEIGY      | 17-963<br>08-07-78                   | 3998790<br>12-21-93                 |                                        |
| METOPROLOL TARTRATE<br>1MG/ML                     | LOPRESSOR<br>(INJECTABLE; INJECTION)             | GEIGY/CIBA-GEIGY      | 18-704<br>03-30-84                   | 3998790<br>12-21-93                 | NDF<br>09-24-86                        |
| METRIZAMIDE<br>3.75GM/VIAL                        | AMIPAQUE<br>(INJECTABLE; INJECTION)              | WINTHROP LABS/STERL   | 17-982<br>08-23-78                   | 3701771<br>10-31-89                 | 1-26<br>09-24-86                       |
| METRIZAMIDE<br>6.75GM/VIAL                        | AMIPAQUE<br>(INJECTABLE; INJECTION)              | WINTHROP LABS/STERL   | 17-982<br>08-23-78                   | 3701771<br>10-31-89                 | 1-26<br>09-24-86                       |
| METRONIDAZOLE<br>500MG                            | METRONIDAZOLE<br>(TABLET; ORAL)                  | ZENITH LABORATORIES   | 18-517<br>05-05-82                   |                                     |                                        |
| METRONIDAZOLE<br>250MG                            | METRONIDAZOLE<br>(TABLET; ORAL)                  | CHELSEA LABORATORIES  | 18-599<br>09-17-82                   |                                     |                                        |
| METRONIDAZOLE<br>500MG                            | METRONIDAZOLE<br>(TABLET; ORAL)                  | CHELSEA LABORATORIES  | 18-599<br>02-13-84                   |                                     |                                        |

| ACTIVE INGREDIENT(S) | TRADE NAME              | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------------------|----------------------|--------|---------------|----------|-----------|-------------|
| METRONIDAZOLE        | METRYL                  | DRUMMER/PHOENIX      | 18-620 | 03-04-82      |          |           |             |
| 250MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRYL 500              | DRUMMER/PHOENIX      | 18-620 |               |          |           |             |
| 500MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRO 1.5%              | AM MCGAW/AM HOSP     | 18-674 | 08-31-82      |          |           |             |
| 500MG/100ML          | (INJECTABLE; INJECTION) |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | CORD LABORATORIES    | 18-740 | 10-22-82      |          |           |             |
| 250MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | CORD LABORATORIES    | 18-740 | 10-22-82      |          |           |             |
| 500MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | CORD LABORATORIES    | 18-740 | 10-22-82      |          |           |             |
| 500MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | DANBURY PHARMACAL    | 18-764 | 09-17-82      |          |           |             |
| 250MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | DANBURY PHARMACAL    | 18-764 | 12-20-82      |          |           |             |
| 500MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | BARR LABORATORIES    | 18-818 | 02-16-83      |          |           |             |
| 250MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | BARR LABORATORIES    | 18-818 | 02-16-83      |          |           |             |
| 500MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | METRONIDAZOLE           | PAR PHARMACEUTICAL   | 18-845 | 08-18-83      |          |           |             |
| 250MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | PROTOSTAT               | ORTHO PHARMACEUTICAL | 18-871 | 03-02-83      |          |           |             |
| 250MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |
| METRONIDAZOLE        | PROTOSTAT               | ORTHO PHARMACEUTICAL | 18-871 | 03-02-83      |          |           |             |
| 500MG                | (TABLET; ORAL)          |                      |        |               |          |           |             |

TABLE IV-1. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>    | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                   | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|------------------------------------------------------|--------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| METRONIDAZOLE<br>500MG/100ML                         | METRONIDAZOLE<br>(INJECTABLE; INJECTION)                           | ABBOTT LABORATORIES   | 18-889<br>11-18-83                   |                                     |                                        |
| METRONIDAZOLE<br>500MG/100ML                         | METRONIDAZOLE IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION)   | ABBOTT LABORATORIES   | 18-890<br>11-18-83                   |                                     |                                        |
| METRONIDAZOLE<br>500MG/100ML                         | METRO I.V. IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION)      | AM MCGAW/AM HOSP      | 18-900<br>09-29-83                   |                                     |                                        |
| METRONIDAZOLE<br>500MG/100ML                         | METRONIDAZOLE<br>(INJECTABLE; INJECTION)                           | ELKINS-SINN/AHROBINS  | 18-907<br>03-30-84                   |                                     |                                        |
| METRONIDAZOLE<br>500MG/100ML                         | FLAGYL I.V. RTU<br>(INJECTABLE; INJECTION)                         | SEARLE PHARMS         | 18-353<br>05-29-81                   |                                     | 1-11<br>12-20-87                       |
| METRONIDAZOLE<br>500MG/100ML                         | FLAGYL I.V. RTU<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | SEARLE PHARMS         | 18-657<br>12-24-81                   |                                     | 1-11<br>12-20-87                       |
| METRONIDAZOLE<br>500MG                               | METRONIDAZOLE<br>(TABLET; ORAL)                                    | PAR PHARMACEUTICAL    | 18-930<br>08-18-83                   |                                     |                                        |
| METRONIDAZOLE<br>250MG                               | METRONIDAZOLE<br>(TABLET; ORAL)                                    | LNK INTERNATIONAL     | 19-029<br>04-10-84                   |                                     |                                        |
| METRONIDAZOLE<br>HYDROCHLORIDE<br>EQ 500MG BASE/VIAL | FLAGYL I.V.<br>(INJECTABLE; INJECTION)                             | SEARLE PHARMS         | 18-353<br>11-28-80                   |                                     | 1-11<br>12-20-87                       |

ACTIVE INGREDIENT(S)  
STRENGTH(S)

MICONAZOLE  
10MG/ML

MONISTAT  
(INJECTABLE; INJECTION)

JANSSEN PHARMA

18-040

3717655

02-20-90

EXP. DATE  
EXCLUSIVITY

MICONAZOLE NITRATE  
25

MONISTAT 7  
(CREAM; VAGINAL)

ORTHO PHARMACEUTICAL

17-450

3717655

02-20-90

MICONAZOLE NITRATE  
25

MONISTAT-DERM  
(CREAM; TOPICAL)

ORTHO PHARMACEUTICAL

17-494

3717655

02-20-90

MICONAZOLE NITRATE  
25

MONISTAT-DERM  
(LOTION; TOPICAL)

ORTHO PHARMACEUTICAL

17-739

3717655

02-20-90

MICONAZOLE NITRATE  
100MG

MONISTAT 7  
(SUPPOSITORY; VAGINAL)

ORTHO PHARMACEUTICAL

18-520

3717655

02-20-90

MICONAZOLE NITRATE  
200MG

MONISTAT 3  
(SUPPOSITORY; VAGINAL)

ORTHO PHARMACEUTICAL

18-888

3717655

02-20-90

MICONIDIL  
2.5MG

LONITEN  
(TABLET; ORAL)

UPJOHN

18-154

3461461

08-12-86

TABLE 10.10.1. APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| MINOXIDIL<br>10MG                                 | LONITEN<br>(TABLET; ORAL)                        | UPJOHN                | 18-154<br>10-18-79                   | 3461461<br>08-12-86                        |                                        |
| MOLINDONE HYDROCHLORIDE<br>5MG                    | MOBAN<br>(TABLET; ORAL)                          | DUPONT PHARMS/DUPONT  | 17-111<br>07-03-74                   | 3491093<br>01-20-87                        |                                        |
| MOLINDONE HYDROCHLORIDE<br>10MG                   | MOBAN<br>(TABLET; ORAL)                          | DUPONT PHARMS/DUPONT  | 17-111<br>07-03-74                   | 3491093<br>01-20-87                        |                                        |
| MOLINDONE HYDROCHLORIDE<br>25MG                   | MOBAN<br>(TABLET; ORAL)                          | DUPONT PHARMS/DUPONT  | 17-111<br>07-03-74                   | 3491093<br>01-20-87                        |                                        |
| MOLINDONE HYDROCHLORIDE<br>50MG                   | MOBAN<br>(TABLET; ORAL)                          | DUPONT PHARMS/DUPONT  | 17-111<br>01-05-81                   | 3491093<br>01-20-87                        |                                        |
| MOLINDONE HYDROCHLORIDE<br>100MG                  | MOBAN<br>(TABLET; ORAL)                          | DUPONT PHARMS/DUPONT  | 17-111<br>01-05-81                   | 3491093<br>01-20-87                        |                                        |
| MOLINDONE HYDROCHLORIDE<br>20MG/ML                | MOBAN<br>(CONCENTRATE; ORAL)                     | DUPONT PHARMS/DUPONT  | 17-938<br>12-28-79                   | 3491093<br>01-20-87                        |                                        |
| MORPHINE SULFATE<br>0.5MG/ML                      | DURAMORPH PF<br>(INJECTABLE; INJECTION)          | ELKINS-SINN/AHROBINS  | 18-565<br>09-18-84                   |                                            | NR; D-8<br>09-24-86                    |
| MORPHINE SULFATE<br>1MG/ML                        | DURAMORPH PF<br>(INJECTABLE; INJECTION)          | ELKINS-SINN/AHROBINS  | 18-565<br>09-18-84                   |                                            | NR; D-8<br>09-24-86                    |
| NADOLOL<br>40MG                                   | CORGARD<br>(TABLET; ORAL)                        | ER SQUIBB AND SONS    | 18-063<br>12-10-79                   | 3982021<br>09-21-93<br>3935267<br>01-27-93 |                                        |
| NADOLOL<br>80MG                                   | CORGARD<br>(TABLET; ORAL)                        | ER SQUIBB AND SONS    | 18-063<br>12-10-79                   | 3982021<br>09-21-93<br>3935267<br>01-27-93 |                                        |

ACTIVE INGREDIENT(S)

STRENGTH(S)

TRADE NAME  
(DOSAGE FORM, ROUTE)

APPLICANT NAME

NDA #  
APPROVAL DATE

PATENT #  
EXP. DATE

EXCLUSIVITY  
EXP. DATE

NADOLOL  
NADOLOL  
80MG  
NADOLOL  
40MG  
NADOLOL  
160MG  
NADOLOL  
120MG

CORGARD  
CORGARD  
(TABLET, ORAL)  
CORGARD  
(TABLET, ORAL)  
CORGARD  
(TABLET, ORAL)  
CORGARD  
(TABLET, ORAL)  
CORGARD  
(TABLET, ORAL)  
CORGARD  
(TABLET, ORAL)

ER SQUIBB AND SONS  
ER SQUIBB AND SONS  
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18-063  
12-10-79  
18-064  
12-10-79  
18-064  
12-10-79  
18-064  
12-10-79  
18-064  
12-10-79

3982021  
09-21-93  
3935267  
01-27-93  
3982021  
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3935267  
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3982021  
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3982021  
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3935267  
01-27-93  
3982021  
09-21-93  
3935267  
01-27-93

NS  
09-24-86



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                           | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                                                      | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-----------------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|------------------------------------------------------------------------------------------|----------------------------------------|
| NALIDIXIC ACID<br>250MG                                                     | NEGRAM<br>(TABLET; ORAL)                         | WINTHROP LABS/STERL   | 14-214<br>12-27-67                   | 3590036<br>06-29-88                                                                      |                                        |
| NALIDIXIC ACID<br>500MG                                                     | NEGRAM<br>(TABLET; ORAL)                         | WINTHROP LABS/STERL   | 14-214<br>03-06-64                   | 3590036<br>06-29-88                                                                      |                                        |
| NALIDIXIC ACID<br>1GM                                                       | NEGRAM<br>(TABLET; ORAL)                         | WINTHROP LABS/STERL   | 14-214<br>03-06-64                   | 3590036<br>06-29-88                                                                      |                                        |
| NALIDIXIC ACID<br>250MG/5ML                                                 | NEGRAM<br>(SUSPENSION; ORAL)                     | WINTHROP LABS/STERL   | 17-430<br>04-17-73                   | 3590036<br>06-29-88                                                                      |                                        |
| NALOXONE HYDROCHLORIDE<br>1MG/ML                                            | NARCAN<br>(INJECTABLE; INJECTION)                | DUPONT PHARMS/DUPONT  | 16-636<br>06-14-82                   |                                                                                          | NS<br>09-24-86                         |
| NALOXONE HYDROCHLORIDE; PENTAZOCINE<br>HYDROCHLORIDE<br>0.5MG; EQ 50MG BASE | TALWIN NX<br>(TABLET; ORAL)                      | WINTHROP LABS/STERL   | 18-733<br>12-16-82                   | 4105659<br>08-08-95                                                                      | NC<br>09-24-86                         |
| NALTREXONE HYDROCHLORIDE<br>50MG                                            | TREXAN<br>(TABLET; ORAL)                         | DUPONT PHARMS/DUPONT  | 18-932<br>11-20-84                   |                                                                                          | NCE<br>11-20-89                        |
| NAPROXEN<br>125MG                                                           | NAPROSYN<br>(TABLET; ORAL)                       | SYNTEX PR             | 17-581<br>03-11-76                   | 3998966<br>12-21-93<br>4009197<br>09-09-92<br>4001301<br>09-09-92<br>3904682<br>09-09-92 | NS<br>09-24-86                         |

| ACTIVE INGREDIENT(S) | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE) | APPLICANT NAME | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|----------------------|-------------|------------|----------------------|----------------|--------|---------------|----------|-----------|-------------|
| NAPROXEN SODIUM      | 275MG       | NAPROX     | (TABLET; ORAL)       | SYNTEX PR      | 18-164 | 09-04-80      | 3998966  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4009197  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4001301  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 12-21-93 | 09-09-92  |             |
| NAPROXEN             | 500MG       | NAPROSYN   | (TABLET; ORAL)       | SYNTEX PR      | 17-581 | 04-15-82      | 3998966  | 09-09-92  | NS          |
|                      |             |            |                      |                |        |               | 4009197  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4001301  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 12-21-93 | 09-09-92  |             |
| NAPROXEN             | 375MG       | NAPROSYN   | (TABLET; ORAL)       | SYNTEX PR      | 17-581 | 07-18-80      | 3998966  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4009197  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4001301  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 12-21-93 | 09-09-92  |             |
| NAPROXEN             | 250MG       | NAPROSYN   | (TABLET; ORAL)       | SYNTEX PR      | 17-581 | 03-11-76      | 3998966  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4009197  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 4001301  | 09-09-92  |             |
|                      |             |            |                      |                |        |               | 12-21-93 | 09-09-92  |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| NICLOSAMIDE<br>500MG                              | NICLOCIDE<br>(TABLET, CHEWABLE; ORAL)            | MILES PHARMS/MILES    | 18-669<br>05-14-82                   |                                     | NCE<br>05-14-92                        |
| NICOTINE RESIN COMPLEX<br>EQ 2MG BASE             | NICORETTE<br>(GUM, CHEWING; ORAL)                | MERRELL DOW/DOW CHEM  | 18-612<br>01-13-84                   |                                     | NCE<br>01-13-94                        |
| NIFEDIPINE<br>10MG                                | PROCARDIA<br>(CAPSULE; ORAL)                     | PFIZER LABS/PFIZER    | 18-482<br>12-31-81                   | 3644627<br>02-22-89                 |                                        |
| NITROGLYCERIN<br>0.5MG/ML                         | TRIDIL<br>(INJECTABLE; INJECTION)                | AM CRITICAL CARE/AHS  | 18-537<br>06-16-83                   |                                     | NDF<br>09-24-86                        |
| NITROGLYCERIN<br>5MG/ML                           | NITROSTAT<br>(INJECTABLE; INJECTION)             | PARKE-DAVIS/W-L       | 18-588<br>12-23-83                   |                                     | NDF<br>09-24-86                        |
| NITROGLYCERIN<br>5MG/ML                           | NITRO-BID<br>(INJECTABLE; INJECTION)             | MARION LABORATORIES   | 18-621<br>01-05-82                   |                                     | NDF<br>09-24-86                        |
| NITROGLYCERIN<br>1MG/ML                           | NITRONAL<br>(INJECTABLE; INJECTION)              | G POHL-BOSKAMP        | 18-672<br>08-30-83                   |                                     | NDF<br>09-24-86                        |
| NITROGLYCERIN<br>5MG/ML                           | NITRONAL<br>(INJECTABLE; INJECTION)              | G POHL-BOSKAMP        | 18-672<br>08-30-83                   |                                     | NDF<br>09-24-86                        |
| NITROGLYCERIN<br>0.8MG/ML                         | NITROL<br>(INJECTABLE; INJECTION)                | KREMERS-URBAN         | 18-774<br>01-19-83                   |                                     | NDF<br>09-24-86                        |
| NCMIFENSINE MALEATE<br>25MG                       | MERITAL<br>(CAPSULE; ORAL)                       | HOECHST-ROUSSEL       | 18-224<br>12-31-84                   |                                     | NCE<br>12-31-89                        |
| NCMIFENSINE MALEATE<br>50MG                       | MERITAL<br>(CAPSULE; ORAL)                       | HOECHST-ROUSSEL       | 18-224<br>12-31-84                   |                                     | NCE<br>12-31-89                        |

| ACTIVE INGREDIENT(S)         | STRENGTH(S)      | TRADE NAME  | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|------------------------------|------------------|-------------|----------------------|--------|---------------|----------|-----------|-------------|
| NORTHIPITYLINE HYDROCHLORIDE | 5MG              | AYGESTIN    | AYERST LABS/MHMO     | 18-405 | 04-21-82      |          |           |             |
| NORGESTREL                   | 0.075MG          | OVRETTE     | WYETH LABS/MHMO      | 17-031 | 10-23-73      |          | 05-30-89  | 3666858     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 10MG BASE     | AVENTYL HCL | ELI LILLY            | 14-684 | 11-06-64      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 25MG BASE     | AVENTYL HCL | ELI LILLY            | 14-684 | 11-06-64      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 10MG BASE/5ML | AVENTYL HCL | ELI LILLY            | 14-685 | 11-06-64      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 10MG BASE     | PAMELOR     | SANDOZ PHARMS/SANDOZ | 18-012 | 08-01-77      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 10MG BASE     | PAMELOR     | SANDOZ PHARMS/SANDOZ | 18-013 | 08-01-77      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 25MG BASE     | PAMELOR     | SANDOZ PHARMS/SANDOZ | 18-013 | 08-01-77      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 75MG BASE     | PAMELOR     | SANDOZ PHARMS/SANDOZ | 18-013 | 06-14-79      |          | 11-25-92  | 3922305     |
| NORTHIPITYLINE HYDROCHLORIDE | EQ 50MG BASE     | PAMELOR     | SANDOZ PHARMS/SANDOZ | 18-013 | 06-14-79      |          | 11-25-92  | 3922305     |

TABLE IV. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| OXAMINQUINE<br>250MG                              | VANSIL<br>(CAPSULE; ORAL)                        | PFIZER LABS/PFIZER    | 18-069<br>07-23-80                   | 3903283<br>09-02-92<br>3821228<br>06-28-91<br>3925391<br>12-09-92 |                                        |
| OXPRENOLOL HYDROCHLORIDE<br>20MG                  | TRASICOR<br>(CAPSULE; ORAL)                      | CIBA/CIBA-GEIGY       | 18-166<br>12-28-83                   | 3483221<br>12-09-86                                               | NCE<br>12-28-93                        |
| OXPRENOLOL HYDROCHLORIDE<br>40MG                  | TRASICOR<br>(CAPSULE; ORAL)                      | CIBA/CIBA-GEIGY       | 18-166<br>12-28-83                   | 3483221<br>12-09-86                                               | NCE<br>12-28-93                        |
| OXPRENOLOL HYDROCHLORIDE<br>80MG                  | TRASICOR<br>(CAPSULE; ORAL)                      | CIBA/CIBA-GEIGY       | 18-166<br>12-28-83                   | 3483221<br>12-09-86                                               | NCE<br>12-28-93                        |
| OXPRENOLOL HYDROCHLORIDE<br>160MG                 | TRASICOR<br>(CAPSULE; ORAL)                      | CIBA/CIBA-GEIGY       | 18-166<br>12-28-83                   | 3483221<br>12-09-86                                               | NCE<br>12-28-93                        |
| PANCURONIUM BROMIDE<br>2MG/ML                     | PAVULON<br>(INJECTABLE; INJECTION)               | ORGANON/AKZONA        | 17-015<br>10-24-72                   | 3553212<br>01-05-88                                               |                                        |
| PANCURONIUM BROMIDE<br>1MG/ML                     | PAVULON<br>(INJECTABLE; INJECTION)               | ORGANON/AKZONA        | 17-015<br>09-14-73                   | 3553212<br>01-05-88                                               |                                        |
| PARAMETHASONE ACETATE<br>1MG                      | HALDRONE<br>(TABLET; ORAL)                       | ELI LILLY             | 12-772<br>04-17-61                   | 3499016<br>03-03-87                                               |                                        |
| PARAMETHASONE ACETATE<br>2MG                      | HALDRONE<br>(TABLET; ORAL)                       | ELI LILLY             | 12-772<br>04-17-61                   | 3499016<br>03-03-87                                               |                                        |
| PENTAGASTRIN<br>0.25MG/ML                         | PEPTAVLON<br>(INJECTABLE; INJECTION)             | AYERST LABS/AMHO      | 17-048<br>07-26-74                   | 3896103<br>07-22-92                                               |                                        |

| ACTIVE INGREDIENT(S)                                       | STRENGTH(S)         | TRADE NAME             | (DOSAGE FORM; ROUTE)                        | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY     |
|------------------------------------------------------------|---------------------|------------------------|---------------------------------------------|----------------------|--------|---------------|----------|-----------|-----------------|
| PENTAMIDINE ISETHIONATE                                    | 300MG/VIAL          | PENTAM 300             | (INJECTABLE; INJECTION)                     | LYPHOMED             | 19-264 |               |          |           |                 |
| PENTAZOCINE LACTATE                                        | EQ 30MG BASE/ML     | TALWIN                 | (INJECTABLE; INJECTION)                     | WINTROP LABS/STERL   | 16-194 | 07-24-67      | 4105659  | 08-08-95  |                 |
| PENTETATE INDIUM DISODIUM, IN-111                          | IMP/ML              | MP1 INDIUM DTPA IN 111 | (INJECTABLE; INJECTION)                     | MEDI-PHYSICS         | 17-707 | 02-18-82      |          |           | NCE<br>02-18-92 |
| PENTOXIFYLLINE                                             | 400MG               | TRENTAL                | (TABLET, CONTROLLED<br>RELEASE; ORAL)       | HOECHST-ROUSSEL      | 18-631 | 08-30-84      | 3737433  | 06-05-90  | NCE<br>08-30-94 |
| PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE<br>HYDROCHLORIDE | 5MG/5ML; 6.25MG/5ML | PHENERGAN VC           | (SYRUP; ORAL)                               | WYETH LABS/WHO       | 08-604 | 04-02-84      |          |           |                 |
| PILOCARPINE                                                | 5MG                 | OCUSERT Pilo-20        | (INSERT, CONTROLLED<br>RELEASE; OPHTHALMIC) | ALZA                 | 17-431 | 07-29-74      | 391628   | 06-08-93  |                 |
| PILOCARPINE                                                | 11MG                | OCUSERT Pilo-40        | (INSERT, CONTROLLED<br>RELEASE; OPHTHALMIC) | ALZA                 | 17-548 | 07-29-72      | 391628   | 06-08-93  |                 |
| PILOCARPINE HYDROCHLORIDE                                  | 45                  | PILOPINE HS            | (GEL; OPHTHALMIC)                           | ALCON LABORATORIES   | 18-796 | 10-01-84      |          |           | NDF<br>10-01-87 |
| PIMOZIDE                                                   | 2MG                 | ORAP                   | (TABLET; ORAL)                              | MCNEIL PHARM         | 17-473 | 07-31-84      |          |           | NCE<br>07-31-94 |
| PINDOLOL                                                   | 5MG                 | VISKEN                 | (TABLET; ORAL)                              | SANDOZ PHARMS/SANDOZ | 18-285 | 09-03-82      | 3471515  | 10-07-86  | NCE<br>09-03-92 |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| ACTIVE INGREDIENT(S)<br>STRENGTH(S) | TRADE NAME<br>(DOSAGE FORM; ROUTE) | APPLICANT NAME       | NDA #<br>APPROVAL DATE | PATENT #<br>EXP. DATE                                                                                                                  | EXCLUSIVITY<br>EXP. DATE |
|-------------------------------------|------------------------------------|----------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| PINDOLOL<br>10MG                    | VISKEN<br>(TABLET; ORAL)           | SANDOZ PHARMS/SANDOZ | 18-285<br>09-03-82     | 3471515<br>10-07-86                                                                                                                    | NCE<br>09-03-92          |
| PINDOLOL<br>15MG                    | VISKEN<br>(TABLET; ORAL)           | SANDOZ PHARMS/SANDOZ | 18-285<br>09-03-82     | 3471515<br>10-07-86                                                                                                                    | NCE<br>09-03-92          |
| PIROXICAM<br>10MG                   | FELDENE<br>(CAPSULE; ORAL)         | PFIZER LABS/PFIZER   | 18-147<br>04-06-82     | 3591584<br>07-06-88<br>3674876<br>07-04-89<br>3862319<br>01-21-92<br>4100347<br>07-11-95<br>3927002<br>12-16-92<br>RE29668<br>12-10-91 | NCE<br>04-06-92          |
| PIROXICAM<br>20MG                   | FELDENE<br>(CAPSULE; ORAL)         | PFIZER LABS/PFIZER   | 18-147<br>04-06-82     | 3591584<br>07-06-88<br>3674876<br>07-04-89<br>3862319<br>01-21-92<br>4100347<br>07-11-95<br>3927002<br>12-16-92<br>RE29668<br>12-10-91 | NCE<br>04-06-92          |

| ACTIVE INGREDIENT(S)                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE)                 | APPLICANT NAME     | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|------------|--------------------------------------|--------------------|--------|---------------|----------|-----------|-------------|
| POLYETHYLENE GLYCOL 3350;<br>POTASSIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>SODIUM SULFATE;<br>22.74GM/BOT;<br>5.86GM/BOT;<br>6.74GM/BOT;<br>2.97GM/BOT;<br>236GM/BOT;<br>SODIUM SULFATE;<br>SODIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>POLYETHYLENE GLYCOL 3350;<br>POTASSIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>SODIUM SULFATE;<br>1.20GM/PACKET;<br>1.49GM/PACKET;<br>3.36GM/PACKET;<br>2.92GM/PACKET;<br>11.36GM/PACKET |             | GOLYTEL    | (POWDER FOR<br>RECONSTITUTION; ORAL) | BRAINTREE LABS     | 19-011 | 07-13-84      |          |           |             |
| POLYETHYLENE GLYCOL 3350;<br>POTASSIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>SODIUM SULFATE;<br>1.20GM/PACKET;<br>1.49GM/PACKET;<br>3.36GM/PACKET;<br>2.92GM/PACKET;<br>11.36GM/PACKET                                                                                                                                                                                                                                                                                |             | COLYTE     | (POWDER FOR<br>RECONSTITUTION; ORAL) | EDLAW PREPARATIONS | 18-983 | 10-26-84      |          |           |             |
| POLYETHYLENE GLYCOL 3350;<br>POTASSIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>SODIUM SULFATE;<br>22.74GM/BOT;<br>5.86GM/BOT;<br>6.74GM/BOT;<br>2.97GM/BOT;<br>236GM/BOT;<br>SODIUM SULFATE;<br>SODIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>POLYETHYLENE GLYCOL 3350;<br>POTASSIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>SODIUM SULFATE;<br>2.271GM/PACKET;<br>2.82GM/PACKET;<br>6.36GM/PACKET;<br>5.33GM/PACKET;<br>21.5GM/PACKET |             | COLYTE     | (POWDER FOR<br>RECONSTITUTION; ORAL) | EDLAW PREPARATIONS | 18-983 | 10-26-84      |          |           |             |

TABLE 14-1. NDAs APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                                                                                                                                                       | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| POLYETHYLENE GLYCOL 3350;<br>POTASSIUM CHLORIDE;<br>SODIUM BICARBONATE;<br>SODIUM CHLORIDE;<br>SODIUM SULFATE<br>360GM/PACKET;<br>4.47GM/PACKET;<br>10.08GM/PACKET;<br>8.76GM/PACKET;<br>34.08GM/PACKET | COLYTE<br>(POWDER FOR<br>RECONSTITUTION; ORAL)   | EDLAW PREPARATIONS    | 18-983<br>10-26-84                   |                                                                   |                                        |
| POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE<br>0.5MG; 1MG                                                                                                                                                      | MINIZIDE<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 17-986<br>06-13-80                   | 3511836<br>05-12-87<br>3663706<br>05-16-89<br>4130647<br>12-19-95 |                                        |
| POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE<br>0.5MG; 2MG                                                                                                                                                      | MINIZIDE<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 17-986<br>06-13-80                   | 3511836<br>05-12-87<br>3663706<br>05-16-89<br>4130647<br>12-19-95 |                                        |
| POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE<br>0.5MG; 5MG                                                                                                                                                      | MINIZIDE<br>(CAPSULE; ORAL)                      | PFIZER LABS/PFIZER    | 17-986<br>06-13-80                   | 3511836<br>05-12-87<br>3663706<br>05-16-89<br>4130647<br>12-19-95 |                                        |

| ACTIVE INGREDIENT(S)                | STRENGTH(S)              | TRADE NAME                                                             | (DOSAGE FORM; ROUTE)    | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------------------|--------------------------|------------------------------------------------------------------------|-------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| POTASSIUM CHLORIDE                  | 2MEQ/ML                  | POTASSIUM ACETATE IN PLASTIC CONTAINER                                 | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-896 | 07-20-84      |          |           | NDF         |
| POTASSIUM CHLORIDE                  | 10MEQ                    | KLOTRIX<br>(TABLET, CONTROLLED RELEASE; ORAL)                          |                         | MEAD JOHNSON/B-M    | 17-850 | 05-22-80      | 4140756  | 02-20-96  |             |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE | 150MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER | (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-630 | 02-17-83      |          |           |             |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE | 300MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER | (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-630 | 02-17-83      |          |           |             |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE | 150MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER | (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-630 | 02-17-83      |          |           |             |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE | 300MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER | (INJECTABLE; INJECTION) | TRAVENOL LABS       | 18-630 | 02-17-83      |          |           |             |

TABLE 1. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>               | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                                         | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>75MG/100ML; 900MG/100ML  | SODIUM CHLORIDE 0.9% AND<br>POTASSIUM CHLORIDE 0.075%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | AM MCGAW/AM HOSP      | 18-722<br>11-09-82                   |                                     |                                        |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>150MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND<br>POTASSIUM CHLORIDE 0.15%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  | AM MCGAW/AM HOSP      | 18-722<br>11-09-82                   |                                     |                                        |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>220MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND<br>POTASSIUM CHLORIDE 0.22%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)  | AM MCGAW/AM HOSP      | 18-722<br>11-09-82                   |                                     |                                        |
| POTASSIUM CHLORIDE; SODIUM CHLORIDE<br>300MG/100ML; 900MG/100ML | SODIUM CHLORIDE 0.9% AND<br>POTASSIUM CHLORIDE 0.3%<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)   | AM MCGAW/AM HOSP      | 18-722<br>11-09-82                   |                                     |                                        |
| PRALIDOXIME CHLORIDE<br>300MG/ML                                | PROTOPAM<br>(INJECTABLE; INJECTION)                                                                      | AYERST LABS/AMHO      | 18-799<br>12-13-82                   |                                     | NDF<br>09-24-86                        |
| PRALIDOXIME CHLORIDE<br>300MG/ML                                | PRALIDOXIME CHLORIDE<br>(INJECTABLE; INJECTION)                                                          | SURVIVAL TECHNOLOGY   | 18-986<br>12-13-82                   |                                     | NDF<br>09-24-86                        |
| PRAZEPAM<br>20MG                                                | CENTRAX<br>(CAPSULE; ORAL)                                                                               | PARKE-DAVIS/W-L       | 18-144<br>05-10-82                   |                                     | NS<br>09-24-86                         |
| PRAZIQUANTEL<br>600MG                                           | BILTRICIDE<br>(TABLET; ORAL)                                                                             | MILES PHARMS/MILES    | 18-714<br>12-29-82                   | 4001411<br>01-04-94                 | NCE<br>12-29-92                        |

| ACTIVE INGREDIENT(S)   | STRENGTH(S)  | TRADE NAME | (DOSAGE FORM, ROUTE) | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|------------------------|--------------|------------|----------------------|----------------------|--------|---------------|----------|-----------|-------------|
| PRAZOSIN HYDROCHLORIDE | 5MG          | MINIPRESS  | (CAPSULE; ORAL)      | PFIZER LABS/PFIZER   | 17-442 | 06-23-76      | 3511836  | 05-12-87  | 3663706     |
|                        |              |            |                      |                      |        |               | 05-16-89 | 4092315   | 4130647     |
|                        |              |            |                      |                      |        |               | 05-30-95 | 4092315   | 4130647     |
|                        |              |            |                      |                      |        |               | 12-19-95 |           |             |
| PRAZOSIN HYDROCHLORIDE | 1MG          | MINIPRESS  | (CAPSULE; ORAL)      | PFIZER LABS/PFIZER   | 17-442 | 06-23-76      | 3511836  | 05-12-87  | 3663706     |
|                        |              |            |                      |                      |        |               | 05-16-89 | 4092315   | 4130647     |
|                        |              |            |                      |                      |        |               | 05-30-95 | 4092315   | 4130647     |
|                        |              |            |                      |                      |        |               | 12-19-95 |           |             |
| PRAZOSIN HYDROCHLORIDE | 2MG          | MINIPRESS  | (CAPSULE; ORAL)      | PFIZER LABS/PFIZER   | 17-442 | 06-23-76      | 3511836  | 05-12-87  | 3663706     |
|                        |              |            |                      |                      |        |               | 05-16-89 | 4092315   | 4130647     |
|                        |              |            |                      |                      |        |               | 05-30-95 | 4092315   | 4130647     |
|                        |              |            |                      |                      |        |               | 12-19-95 |           |             |
| PRAZOSIN HYDROCHLORIDE | 250MG        | LORELCO    | (TABLET; ORAL)       | MERRELL DOW/DOW CHEM | 17-535 | 02-01-77      | 3576883  | 04-27-88  | 3862332     |
|                        |              |            |                      |                      |        |               | 01-21-92 |           |             |
| PRAZOSIN HYDROCHLORIDE | EQ 50MG BASE | MATULANE   | (CAPSULE; ORAL)      | HOFFMANN-LA ROCHE    | 16-785 | 07-22-69      | 3520926  | 07-21-87  |             |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>     | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| PROPRANOLOL HYDROCHLORIDE<br>10MG                 | INDERAL<br>(TABLET; ORAL)                            | AYERST LABS/AMHO      | 16-418<br>11-13-67                   |                                     | 1-15<br>09-24-86                       |
| PROPRANOLOL HYDROCHLORIDE<br>20MG                 | INDERAL<br>(TABLET; ORAL)                            | AYERST LABS/AMHO      | 16-418<br>10-16-74                   |                                     | 1-15<br>09-24-86                       |
| PROPRANOLOL HYDROCHLORIDE<br>40MG                 | INDERAL<br>(TABLET; ORAL)                            | AYERST LABS/AMHO      | 16-418<br>11-13-67                   |                                     | 1-15<br>09-24-86                       |
| PROPRANOLOL HYDROCHLORIDE<br>60MG                 | INDERAL<br>(TABLET; ORAL)                            | AYERST LABS/AMHO      | 16-418<br>01-18-83                   |                                     | NS<br>09-24-86                         |
| PROPRANOLOL HYDROCHLORIDE<br>80MG                 | INDERAL<br>(TABLET; ORAL)                            | AYERST LABS/AMHO      | 16-418<br>10-16-74                   |                                     | 1-15<br>09-24-86                       |
| PROPRANOLOL HYDROCHLORIDE<br>80MG                 | INDERAL LA<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | AYERST LABS/AMHO      | 18-553<br>04-19-83                   |                                     | NDF<br>09-24-86                        |
| PROPRANOLOL HYDROCHLORIDE<br>90MG                 | INDERAL<br>(TABLET; ORAL)                            | AYERST LABS/AMHO      | 16-418<br>01-18-83                   |                                     | NS<br>09-24-86                         |
| PROPRANOLOL HYDROCHLORIDE<br>120MG                | INDERAL LA<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | AYERST LABS/AMHO      | 18-553<br>04-19-83                   |                                     | NDF<br>09-24-86                        |
| PROPRANOLOL HYDROCHLORIDE<br>160MG                | INDERAL LA<br>(CAPSULE, CONTROLLED<br>RELEASE; ORAL) | AYERST LABS/AMHO      | 18-553<br>04-19-83                   |                                     | NDF<br>09-24-86                        |
| PROTAMINE SULFATE<br>250MG/VIAL                   | PROTAMINE SULFATE<br>(INJECTABLE; INJECTION)         | UPJOHN                | 07-413<br>08-02-84                   |                                     | NS<br>09-24-86                         |
| PROTIRELIN<br>0.5MG/ML                            | THYPINONE<br>(INJECTABLE; INJECTION)                 | ABBOTT LABORATORIES   | 17-638<br>11-05-76                   | 3746697<br>07-17-90                 |                                        |

| ACTIVE INGREDIENT(S)       | STRENGTH(S)       | TRADE NAME     | (DOSAGE FORM, ROUTE)    | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY     |
|----------------------------|-------------------|----------------|-------------------------|---------------------|--------|---------------|----------|-----------|-----------------|
| PROTIRELIN                 | 0.5MG/ML          | RELEFACT TRH   | (INJECTABLE; INJECTION) | HOECHST-ROUSSEL     | 18-087 | 07-18-78      | 3746697  | 07-17-90  |                 |
| PROTIRELIN HYDROCHLORIDE   | 5MG               | VIVACTIL       | (TABLET; ORAL)          | MSD/MERCK           | 16-012 | 09-27-67      | 3372196  | 03-05-85  |                 |
| PROTIRELIN HYDROCHLORIDE   | 10MG              | VIVACTIL       | (TABLET; ORAL)          | MSD/MERCK           | 16-012 | 09-27-67      | 3372196  | 03-05-85  |                 |
| PYRANTHEL PAMOATE          | EQ 250MG BASE/5ML | ANTIMINTH      | (SUSPENSION; ORAL)      | ROERIG/PFIZER       | 16-883 | 12-30-71      | 3644624  | 02-22-89  |                 |
|                            |                   |                |                         |                     |        | 16-883        | 3549624  | 12-22-87  |                 |
| RANITIDINE HYDROCHLORIDE   | EQ 150MG BASE     | ZANTAC         | (TABLET; ORAL)          | GLAXO               | 18-703 | 06-09-83      | 4128658  | 12-05-95  | 06-09-93<br>NCE |
| RANITIDINE HYDROCHLORIDE   | EQ 250MG BASE/ML  | ZANTAC         | (INJECTABLE; INJECTION) | GLAXO               | 19-090 | 10-19-84      | 4128658  | 12-05-95  | 06-09-93<br>NCE |
| RITODRINE HYDROCHLORIDE    | 10MG              | YUTOPAR        | (TABLET; ORAL)          | ASTRA PHARM PRODS   | 18-555 | 12-12-80      | 3410944  | 11-12-85  |                 |
| RITODRINE HYDROCHLORIDE    | 10MG/ML           | YUTOPAR        | (INJECTABLE; INJECTION) | ASTRA PHARM PRODS   | 18-580 | 12-12-80      | 3410944  | 11-12-85  |                 |
| RITODRINE HYDROCHLORIDE    | 15MG/ML           | YUTOPAR        | (INJECTABLE; INJECTION) | ASTRA PHARM PRODS   | 18-580 | 09-27-84      | 3410944  | 11-12-85  |                 |
| SAFFLOWER OIL; SOYBEAN OIL | 10%; 10%          | LIPOSYN II 20% | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-991 | 08-27-84      |          |           | 09-24-86<br>NP  |
| SAFFLOWER OIL; SOYBEAN OIL | 5%; 5%            | LIPOSYN II 10% | (INJECTABLE; INJECTION) | ABBOTT LABORATORIES | 18-997 | 08-27-84      |          |           | 09-24-86<br>NP  |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                                          | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|-------------------------------------------------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| SARALASIN ACETATE<br>EQ 0.6MG BASE/ML             | SARENIN<br>(INJECTABLE; INJECTION)                                                        | NORWICH EATON/P&G     | 18-009<br>05-29-81                   | 3932624<br>01-13-93<br>3886134<br>05-27-92 |                                        |
| SCOPOLAMINE<br>1.5MG                              | TRANSDERM-SCOP<br>(FILM, CONTROLLED<br>RELEASE; PERCUTANEOUS)                             | CIBA/CIBA-GEIGY       | 17-874<br>12-31-79                   | 4031894<br>06-28-94<br>4262003<br>04-14-98 |                                        |
| SELENIUM SULFIDE<br>2.5%                          | SELSUN<br>(SHAMPOO/LOTION; TOPICAL)                                                       | ABBOTT LABS           | 07-936<br>05-17-51                   |                                            | 1-3<br>09-24-86                        |
| SILVER SULFADIAZINE<br>1%                         | SILVADENE<br>(CREAM; TOPICAL)                                                             | MARION LABORATORIES   | 17-381<br>11-26-73                   | 3761590<br>09-24-90                        |                                        |
| SILVER SULFADIAZINE<br>1%                         | SSD<br>(CREAM; TOPICAL)                                                                   | TRAVENOL LABS         | 18-578<br>02-25-82                   |                                            |                                        |
| SINCALIDE<br>0.005MG/VIAL                         | KINEVAC<br>(INJECTABLE; INJECTION)                                                        | ER SQUIBB AND SONS    | 17-697<br>07-21-76                   | 3839315<br>10-01-91                        |                                        |
| SODIUM ACETATE, ANHYDROUS<br>2MEQ/ML              | SODIUM ACETATE IN<br>PLASTIC CONTAINER<br>(INJECTABLE; INJECTION)                         | ABBOTT LABORATORIES   | 18-893<br>05-04-83                   |                                            | PP<br>09-24-86                         |
| SODIUM CHLORIDE<br>450MG/100ML                    | SODIUM CHLORIDE 0.45%<br>IN PLASTIC CONTAINER<br>(SOLUTION; IRRIGATION)                   | TRAVENOL LABS         | 18-497<br>02-19-82                   |                                            |                                        |
| SODIUM CHLORIDE<br>9MG/ML                         | BACTERIOSTATIC SODIUM<br>CHLORIDE 0.9% IN PLASTIC<br>CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES   | 18-800<br>10-29-82                   |                                            |                                        |

ACTIVE INGREDIENT(S)

SODIUM CHLORIDE  
9MG/ML

SODIUM CHLORIDE  
2.5MG/ML

SODIUM CHLORIDE  
3GM/100ML

SODIUM CHLORIDE  
5GM/100ML

SODIUM CHLORIDE  
9MG/ML

SODIUM CHLORIDE  
9MG/ML

SODIUM IODIDE, I-123  
100 UCI

SODIUM IODIDE, I-123  
200 UCI

SODIUM IODIDE, I-123  
400 UCI

SODIUM LACTATE  
5MG/ML

TRADE NAME

(DOSAGE FORM, ROUTE)

SODIUM CHLORIDE 0.9%  
IN PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

SODIUM CHLORIDE IN  
PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

SODIUM CHLORIDE 3% IN  
PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

SODIUM CHLORIDE 5% IN  
PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

SODIUM CHLORIDE 0.9% IN  
PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

SODIUM CHLORIDE 0.9%  
IN PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

SODIUM IODIDE I 123  
(CAPSULE; ORAL)

SODIUM IODIDE I 123  
(CAPSULE; ORAL)

SODIUM LACTATE IN  
PLASTIC CONTAINER  
(INJECTABLE; INJECTION)

APPLICANT NAME

ABBOTT LABORATORIES

ABBOTT LABORATORIES

TRAVENOL LABS

TRAVENOL LABS

ABBOTT LABORATORIES

ABBOTT LABORATORIES

NDA #  
APPROVAL DATE

18-803

10-29-82

18-897

07-20-84

19-022

11-01-85

19-022

11-01-85

19-217

07-13-84

ABBOTT LABORATORIES

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

BENEDICT NUCLER PHARM

PATENT #  
EXP. DATE

18-947

05-27-82

18-671

05-27-82

18-671

05-27-82

18-671

05-27-82

18-671

NS

09-24-86



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>                               | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                     | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| SODIUM NITROPRUSSIDE<br>50MG/VIAL                                               | SODIUM NITROPRUSSIDE<br>(INJECTABLE; INJECTION)                      | ELKINS-SINN/AHROBINS  | 18-581<br>07-28-82                   |                                     |                                        |
| SODIUM PHOSPHATE, DIBASIC; SODIUM<br>PHOSPHATE, MONOBASIC<br>142MG/ML; 276MG/ML | SODIUM PHOSPHATES<br>IN PLASTIC CONTAINER<br>(INJECTABLE; INJECTION) | ABBOTT LABORATORIES   | 18-892<br>05-10-83                   |                                     | NP<br>09-24-86                         |
| SOMATROPIN<br>2 IU/VIAL                                                         | ASELLAGRIN 2<br>(INJECTABLE; INJECTION)                              | SERONO LABS           | 17-726<br>07-21-83                   |                                     | NS<br>09-24-86                         |
| SORBITOL<br>3GM/100ML                                                           | SORBITOL 3% IN PLASTIC<br>CONTAINER<br>(SOLUTION; IRRIGATION)        | TRAVENOL LABS         | 18-512<br>05-27-82                   |                                     |                                        |
| SOYBEAN OIL<br>10%                                                              | SOYACAL 10%<br>(INJECTABLE; INJECTION)                               | ALPHA THERAPEUTIC     | 18-465<br>06-29-83                   |                                     |                                        |
| SOYBEAN OIL<br>10%                                                              | TRAVAMULSION 10%<br>(INJECTABLE; INJECTION)                          | TRAVENOL LABS         | 18-660<br>02-26-82                   |                                     |                                        |
| SOYBEAN OIL<br>20%                                                              | TRAVAMULSION 20%<br>(INJECTABLE; INJECTION)                          | TRAVENOL LABS         | 18-758<br>02-15-83                   |                                     |                                        |
| SOYBEAN OIL<br>20%                                                              | SOYACAL 20%<br>(INJECTABLE; INJECTION)                               | ALPHA THERAPEUTIC     | 18-786<br>06-29-83                   |                                     |                                        |
| SOYBEAN OIL<br>10%                                                              | LIPOSYN III 10%<br>(INJECTABLE; INJECTION)                           | ABBOTT LABORATORIES   | 18-969<br>09-24-84                   |                                     |                                        |
| SOYBEAN OIL<br>20%                                                              | LIPOSYN III 20%<br>(INJECTABLE; INJECTION)                           | ABBOTT LABORATORIES   | 18-970<br>09-25-84                   |                                     |                                        |
| STANOZOLOL<br>2MG                                                               | WINSTROL<br>(TABLET; ORAL)                                           | WINTHROP LABS/STERL   | 12-885<br>11-30-61                   | 3704295<br>11-28-89                 | 1-28<br>09-24-86                       |

| ACTIVE INGREDIENT(S)           | TRADE NAME                                        | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXPIRATION DATE | EXCLUSIVITY |
|--------------------------------|---------------------------------------------------|---------------------|--------|---------------|----------|-----------------|-------------|
| STREPTOCIN                     | ZANOSAR                                           | UP JOHN             | 17-961 | 05-07-82      |          | 05-07-92        | NCE         |
| 1GM/VIAL                       | (INJECTABLE; INJECTION)                           |                     |        |               |          |                 |             |
| SUCRALFATE                     | CARAFATE                                          | MARION LABORATORIES | 18-333 | 10-30-81      |          | 03-11-86        |             |
| 1GM                            | (TABLET; ORAL)                                    |                     |        |               |          |                 |             |
| SUFENTANIL CITRATE             | SUFENTA                                           | JANSSEN PHARMA      | 19-050 | 05-04-84      |          | 12-21-93        | NCE         |
| EQ 0.05MG BASE/ML              | (INJECTABLE; INJECTION)                           |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | BACTRIM                                           | HOFMANN-LA ROCHE    | 17-377 | 07-30-73      |          | 06-02-87        |             |
| 400MG; 80MG                    | (TABLET; ORAL)                                    |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | BACTRIM DS                                        | HOFMANN-LA ROCHE    | 17-377 | 03-01-78      |          | 06-02-87        |             |
| 800MG; 160MG                   | (TABLET; ORAL)                                    |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | BACTRIM                                           | HOFMANN-LA ROCHE    | 17-560 | 04-16-75      |          | 06-02-87        | 1-21        |
| 200MG/5ML; 40MG/5ML            | (SUSPENSION; ORAL)                                |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | BACTRIM PEDIATRIC                                 | HOFMANN-LA ROCHE    | 17-560 | 12-10-79      |          | 06-02-87        | 1-21        |
| 200MG/5ML; 40MG/5ML            | (SUSPENSION; ORAL)                                |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | BACTRIM                                           | HOFMANN-LA ROCHE    | 18-374 | 06-25-81      |          | 06-02-87        | 3551564     |
| 80MG/ML; 16MG/ML               | (INJECTABLE; INJECTION)                           |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | BACTRIM                                           | HOFMANN-LA ROCHE    | 18-374 | 06-25-81      |          | 06-02-87        | RE28636     |
| 800MG; 160MG                   | (TABLET; ORAL)                                    |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH | DRUMMER/PHOENIX     | 18-598 | 05-19-82      |          |                 |             |
| 400MG; 80MG                    | (TABLET; ORAL)                                    |                     |        |               |          |                 |             |
| SULFAMETHOXAZOLE; TRIMETHOPRIM | SULFAMETHOXAZOLE AND TRIMETHOPRIM                 | DRUMMER/PHOENIX     | 18-598 | 05-19-82      |          |                 |             |
| 800MG; 160MG                   | (TABLET; ORAL)                                    |                     |        |               |          |                 |             |

TABLE IN NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u>     | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>                       | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|-------------------------------------------------------|------------------------------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>200MG/5ML; 40MG/5ML | SULFATRIM PEDIATRIC<br>(SUSPENSION; ORAL)                              | NATL PHARM MFG/BARRE  | 18-615<br>01-07-83                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>200MG/5ML; 40MG/5ML | SULFATRIM<br>(SUSPENSION; ORAL)                                        | NATL PHARM MFG/BARRE  | 18-615<br>01-07-83                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>200MG/5ML; 40MG/5ML | SMZ-TMP<br>(SUSPENSION; ORAL)                                          | BIOCRAFT LABS         | 18-812<br>01-28-83                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>200MG/5ML; 40MG/5ML | SMZ-TMP PEDIATRIC<br>(SUSPENSION; ORAL)                                | BIOCRAFT LABS         | 18-812<br>06-10-83                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>400MG; 80MG         | SULFAMETHOXAZOLE AND<br>TRIMETHOPRIM<br>(TABLET; ORAL)                 | DANBURY PHARMACAL     | 18-852<br>05-09-83                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>800MG; 160MG        | SULFAMETHOXAZOLE AND<br>TRIMETHOPRIM DOUBLE STRENGTH<br>(TABLET; ORAL) | DANBURY PHARMACAL     | 18-854<br>05-09-83                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>400MG; 80MG         | SULFAMETHOXAZOLE &<br>TRIMETHOPRIM<br>(TABLET; ORAL)                   | HEATHER DRUG          | 18-946<br>08-10-84                   |                                     |                                        |
| SULFAMETHOXAZOLE; TRIMETHOPRIM<br>800MG; 160MG        | SULFAMETHOXAZOLE &<br>TRIMETHOPRIM<br>(TABLET; ORAL)                   | HEATHER DRUG          | 18-946<br>08-10-84                   |                                     |                                        |
| SULFASALAZINE<br>500MG                                | AZULFIDINE<br>(TABLET, ENTERIC COATED;<br>ORAL)                        | PHARMACIA/PHARMACIA   | 07-073<br>04-06-83                   |                                     | NDF<br>09-24-86                        |
| SULFASALAZINE<br>500MG                                | SULFASALAZINE<br>(TABLET, ENTERIC COATED;<br>ORAL)                     | BOLAR PHARMACEUTICAL  | 88-052<br>05-24-83                   |                                     | NDF<br>09-24-86                        |

| ACTIVE INGREDIENT(S)                              | STRENGTH(S)           | TRADE NAME | (DOSAGE FORM; ROUTE)          | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|---------------------------------------------------|-----------------------|------------|-------------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| SUL INDAC                                         | 150MG                 | CLINORIL   | (TABLET; ORAL)                | MSD/MERCK           | 17-911 | 09-27-78      | 3654349  | 04-04-89  |             |
| SUL INDAC                                         | 200MG                 | CLINORIL   | (TABLET; ORAL)                | MSD/MERCK           | 17-911 | 09-27-78      | 372548   | 04-03-90  |             |
| SUTILANS                                          | 82,000 UNITS/GM       | TRAVASE    | (OINTMENT; TOPICAL)           | TRAVENOL LABS       | 12-828 | 06-12-69      | 3409719  | 11-05-85  |             |
| TECHNETIUM, TC-99M SODIUM PERTECHNETATE GENERATOR | 0.22-2.22Ci/GENERATOR | MINITEC    | (SOLUTION; INTRAVENOUS, ORAL) | ER SQUIBB AND SONS  | 17-339 | 06-03-74      |          |           | 1-31        |
| TECHNETIUM, TC-99M, ALBUMIN COLLOID KIT           | N/A                   | MIROLITE   | (INJECTABLE; INJECTION)       | MED DIAG/NE NUCLEAR | 18-263 | 03-25-83      |          |           |             |
| TECHNETIUM, TC-99M, DISOFENIN KIT                 | N/A                   | HEPATOLITE | (INJECTABLE; INJECTION)       | MED DIAG/NE NUCLEAR | 18-467 | 03-16-82      |          |           | NP          |
| TECHNETIUM, TC 99M, PYROPHOSPHATE KIT             | N/A                   | PHOSPHOTEC | (INJECTABLE; INJECTION)       | ER SQUIBB AND SONS  | 17-680 | 10-20-76      |          |           | 1-9         |
|                                                   |                       |            |                               |                     |        |               |          |           | 09-24-86    |

TABLE 1. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u>   | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|----------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| TECHNETIUM, TC-99M, GLUCAPTATE KIT<br>N/A         | TECHNISCAN GLUCAPTATE<br>(INJECTABLE; INJECTION)   | MS&D/MERCK            | 18-272<br>01-27-82                   |                                            |                                        |
| TECHNETIUM, TC-99M, MEDRONATE<br>N/A              | OSTEOLITE<br>(INJECTABLE; INJECTION)               | MED DIAG/NE NUCLEAR   | 17-972<br>12-16-77                   |                                            |                                        |
| TECHNETIUM, TC-99M, MEDRONATE<br>N/A              | AMERSCAN<br>(INJECTABLE; INJECTION)                | AMERSHAM/RADIOCHEM    | 18-335<br>08-05-82                   |                                            |                                        |
| TECHNETIUM, TC-99M, SUCCIMER KIT<br>N/A           | MP1 DMSA KIDNEY REAGENT<br>(INJECTABLE; INJECTION) | MEDI-PHYSICS          | 17-944<br>05-18-82                   | 4208398<br>06-17-97<br>4233285<br>11-11-97 | NP<br>09-24-86                         |
| TERBUTALINE SULFATE<br>1MG/ML                     | BRIGANYL<br>(INJECTABLE; INJECTION)                | MERRELL DOW/DOW CHEM  | 17-466<br>03-25-74                   | 3937838<br>02-10-93<br>4011258<br>03-08-94 |                                        |
| TERBUTALINE SULFATE<br>2.5MG                      | BRIGANYL<br>(TABLET; ORAL)                         | MERRELL DOW/DOW CHEM  | 17-618<br>04-22-75                   | 3937838<br>02-10-93<br>4011258<br>03-08-94 |                                        |
| TERBUTALINE SULFATE<br>5MG                        | BRIGANYL<br>(TABLET; ORAL)                         | MERRELL DOW/DOW CHEM  | 17-618<br>04-22-75                   | 3937838<br>02-10-93<br>4011258<br>03-08-94 |                                        |
| TERBUTALINE SULFATE<br>2.5MG                      | BRETHINE<br>(TABLET; ORAL)                         | GEIGY/CIBA-GEIGY      | 17-849<br>05-17-76                   | 3937838<br>02-10-93<br>4011258<br>03-08-94 |                                        |

| ACTIVE INGREDIENT(S)      | STRENGTH(S)   | TRADE NAME               | (DOSAGE FORM; ROUTE)    | APPLICANT NAME      | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|---------------------------|---------------|--------------------------|-------------------------|---------------------|---------------|----------|-----------|-------------|
| TERBUTALINE SULFATE       | 5MG           | BRETHINE                 | (TABLET; ORAL)          | GEIGY/CIBA-GEIGY    | 17-849        | 05-17-76 | 02-10-93  | 3937838     |
| TERBUTALINE SULFATE       | 1MG/ML        | BRETHINE                 | (INJECTABLE; INJECTION) | GEIGY/CIBA-GEIGY    | 18-571        | 11-30-81 | 02-10-93  | 3937838     |
| TERBUTALINE SULFATE       | 0.2MG/INH     | BRETHINE                 | (AEROSOL; INHALATION)   | GEIGY/CIBA-GEIGY    | 18-762        | 08-17-84 | 02-10-93  | 3937838     |
| THALLOUS CHLORIDE, TL-201 | 2MG/ML        | THALLOUS CHLORIDE TL 201 | (INJECTABLE; INJECTION) | MED1-PHYSICS        | 18-110        | 02-01-82 |           | NS          |
| THALLOUS CHLORIDE, TL-201 | 1MG/ML        | THALLOUS CHLORIDE TL 201 | (INJECTABLE; INJECTION) | AMERSHAM/RAD IOCHEM | 18-548        | 12-30-82 |           |             |
| TIMOLOL MALEATE           | 5MG           | BLOCADREN                | (TABLET; ORAL)          | MS&D/MERCK          | 18-017        | 11-25-81 | 04-11-89  | 3655663     |
| TIMOLOL MALEATE           | 10MG          | BLOCADREN                | (TABLET; ORAL)          | MS&D/MERCK          | 18-017        | 11-25-81 | 04-11-89  | 3655663     |
| TIMOLOL MALEATE           | 20MG          | BLOCADREN                | (TABLET; ORAL)          | MS&D/MERCK          | 18-017        | 11-25-81 | 04-11-89  | 3655663     |
| TIMOLOL MALEATE           | EQ 0.25% BASE | TIMOPTIC                 | (SOLUTION; OPHTHALMIC)  | MS&D/MERCK          | 18-086        | 08-17-78 | 03-25-97  | 4195085     |

TABLETS APPROVED FROM 1-1-82 TO 1-31-85 AND NDAs WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>        | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|--------------------------------------------|----------------------------------------|
| TIMOLOL MALEATE<br>EQ 0.5% BASE                   | TIMOPTIC<br>(SOLUTION; OPHTHALMIC)               | MS&D/MERCK            | 18-086<br>08-17-78                   | 4195085<br>03-25-97<br>3655663<br>04-11-89 |                                        |
| TOCAINIDE HYDROCHLORIDE<br>400MG                  | TONOCARD<br>(TABLET; ORAL)                       | MS&D/MERCK            | 18-257<br>11-09-84                   | 4218477<br>08-19-97<br>4237068<br>12-02-97 | NCE<br>11-09-89                        |
| TOCAINIDE HYDROCHLORIDE<br>600MG                  | TONOCARD<br>(TABLET; ORAL)                       | MS&D/MERCK            | 18-257<br>11-09-84                   | 4218477<br>08-19-97<br>4237068<br>12-02-97 | NCE<br>11-09-89                        |
| TOLAZAMIDE<br>100MG                               | TOLAZAMIDE<br>(TABLET; ORAL)                     | ZENITH LABORATORIES   | 18-894<br>11-02-84                   |                                            |                                        |
| TOLAZAMIDE<br>250MG                               | TOLAZAMIDE<br>(TABLET; ORAL)                     | ZENITH LABORATORIES   | 18-894<br>11-02-84                   |                                            |                                        |
| TOLAZAMIDE<br>500MG                               | TOLAZAMIDE<br>(TABLET; ORAL)                     | ZENITH LABORATORIES   | 18-894<br>11-02-84                   |                                            |                                        |
| TOLMETIN SODIUM<br>EQ 200MG BASE                  | TOLECTIN<br>(TABLET; ORAL)                       | MONEIL LABORATORIES   | 17-628<br>03-24-76                   | 3752826<br>08-14-90                        |                                        |
| TOLMETIN SODIUM<br>EQ 400MG BASE                  | TOLECTIN DS<br>(CAPSULE; ORAL)                   | MONEIL LABORATORIES   | 18-084<br>10-30-79                   | 3752826<br>08-14-90                        |                                        |
| TRAZODONE HYDROCHLORIDE<br>50MG                   | DESYREL<br>(TABLET; ORAL)                        | MEAD JOHNSON/B-M      | 18-207<br>12-24-81                   | 3381009<br>04-30-85                        |                                        |
| TRAZODONE HYDROCHLORIDE<br>100MG                  | DESYREL<br>(TABLET; ORAL)                        | MEAD JOHNSON/B-M      | 18-207<br>12-24-81                   | 3381009<br>04-30-85                        |                                        |

| ACTIVE INGREDIENT(S)    | STRENGTH(S) | TRADE NAME | (DOSAGE FORM; ROUTE)  | APPLICANT NAME       | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|-------------------------|-------------|------------|-----------------------|----------------------|--------|---------------|----------|-----------|-------------|
| TRITINOLIN              | 0.05%       | RETIN-A    | (SOLUTION; TOPICAL)   | ORTHO PHARMACEUTICAL | 16-921 | 10-20-71      | 04-24-90 | 3729568   |             |
| TRITINOLIN              | 0.1%        | RETIN-A    | (CREAM; TOPICAL)      | ORTHO PHARMACEUTICAL | 17-340 | 01-26-73      | 04-24-90 | 3729568   |             |
| TRITINOLIN              | 0.05%       | RETIN-A    | (CREAM; TOPICAL)      | ORTHO PHARMACEUTICAL | 17-522 | 07-19-74      | 04-24-90 | 3729568   |             |
| TRITINOLIN              | 0.01%       | RETIN-A    | (GEL; TOPICAL)        | ORTHO PHARMACEUTICAL | 17-955 | 10-05-78      | 04-24-90 | 3729568   |             |
| TRITINOLIN              | 0.025%      | RETIN-A    | (GEL; TOPICAL)        | ORTHO PHARMACEUTICAL | 17-579 | 04-18-75      | 04-24-90 | 3729568   |             |
| TRIAMCINOLONE ACETONIDE | 0.25MG/INH  | AZAMCORT   | (AEROSOL; INHALATION) | WILLIAM H ROBER      | 18-117 | 04-23-83      | 08-05-92 | 3897779   | NDF         |
| TRIAZOLAM               | 0.25MG      | HALCION    | (TABLET; ORAL)        | UP JOHN              | 17-892 | 11-15-82      | 09-14-93 | 3980790   | NCE         |
| TRIAZOLAM               | 0.5MG       | HALCION    | (TABLET; ORAL)        | UP JOHN              | 17-892 | 11-15-82      | 09-14-93 | 3980790   | NCE         |
| TRILOSTANE              | 30MG        | MODASTANE  | (CAPSULE; ORAL)       | WINTROP LABS/STERL   | 18-719 | 12-21-84      | 10-19-93 | 3987052   | NCE         |



TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u>                               | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------------------------------------|----------------------------------------|
| TRILOSTANE<br>60MG                                | MODRASTANE<br>(CAPSULE; ORAL)                    | WINTHROP LABS/STERL   | 18-719<br>12-21-84                   |                                                                   | NCE<br>12-21-89                        |
| TRIMETHOPRIM<br>200MG                             | PROLOPRIM<br>(TABLET; ORAL)                      | BURROUGHS WELLCOME    | 17-943<br>07-14-82                   |                                                                   | NS<br>09-24-86                         |
| TRIMETHOPRIM<br>200MG                             | TRIMPEX 200<br>(TABLET; ORAL)                    | HOFFMANN-LA ROCHE     | 17-952<br>11-09-82                   |                                                                   | NS<br>09-24-86                         |
| TRIMETHOPRIM<br>100MG                             | TRIMETHOPRIM<br>(TABLET; ORAL)                   | BIOCRAFT LABS         | 18-679<br>07-30-82                   |                                                                   |                                        |
| TRIMIPRAMINE MALEATE<br>EQ 100MG BASE             | SURMONTIL<br>(CAPSULE; ORAL)                     | IVES LABS/AMHO        | 16-792<br>09-15-82                   |                                                                   | NS<br>09-24-86                         |
| VECURIUM BROMIDE<br>10MG/VIAL                     | NORCURON (NC-45)<br>(INJECTABLE; INJECTION)      | ORGANON/AKZONA        | 18-776<br>04-30-84                   | 3553212<br>01-05-88<br>4237126<br>12-02-97<br>4297351<br>10-27-98 | NCE<br>04-30-94                        |
| VERAPAMIL HYDROCHLORIDE<br>80MG                   | ISOPTIN<br>(TABLET; ORAL)                        | KNOLL PHARMACEUTICAL  | 18-593<br>03-08-82                   |                                                                   | NR<br>09-24-86                         |
| VERAPAMIL HYDROCHLORIDE<br>120MG                  | ISOPTIN<br>(TABLET; ORAL)                        | KNOLL PHARMACEUTICAL  | 18-593<br>03-08-82                   |                                                                   | NR<br>09-24-86                         |
| VERAPAMIL HYDROCHLORIDE<br>80MG                   | CALAN<br>(TABLET; ORAL)                          | SEARLE/SEARLE PHARMS  | 18-817<br>09-10-84                   |                                                                   | NR<br>09-24-86                         |
| VERAPAMIL HYDROCHLORIDE<br>120MG                  | CALAN<br>(TABLET; ORAL)                          | SEARLE/SEARLE PHARMS  | 18-817<br>09-10-84                   |                                                                   | NR<br>09-24-86                         |

| ACTIVE INGREDIENT(S)         | STRENGTH(S) | TRADE NAME   | (DOSAGE FORM; ROUTE)    | APPLICANT NAME      | NDA #  | APPROVAL DATE | PATENT # | EXP. DATE | EXCLUSIVITY |
|------------------------------|-------------|--------------|-------------------------|---------------------|--------|---------------|----------|-----------|-------------|
| VERAPAMIL HYDROCHLORIDE      | 2.5MG/ML    | CALAN        | (INJECTABLE; INJECTION) | SEARLE PHARMS       | 18-925 | 03-30-84      |          |           |             |
| VERAPAMIL HYDROCHLORIDE      | 2.5MG/ML    | CALAN        | (INJECTABLE; INJECTION) | SEARLE PHARMS       | 19-038 | 03-30-84      |          |           |             |
| WATER FOR INJECTION, STERILE | 100%        |              |                         | TRAVENOL LABS       | 18-595 | 01-17-83      |          |           |             |
| WATER FOR INJECTION, STERILE | 100%        |              |                         | TRAVENOL LABS       | 18-632 | 06-30-82      |          |           |             |
| WATER FOR INJECTION, STERILE | 100%        |              |                         | ABBOTT LABORATORIES | 18-801 | 10-27-82      |          |           |             |
| WATER FOR INJECTION, STERILE | 100%        |              |                         | ABBOTT LABORATORIES | 18-802 | 10-27-82      |          |           |             |
| WATER FOR INJECTION, STERILE | 100%        |              |                         | AM MCGAW/AM HOSP    | 19-077 | 03-02-84      |          |           |             |
| XENON, XE-127                | 5MG1/VIAL   | XENON XE 127 | (GAS; INHALATION)       | MALLINCKRODT        | 18-536 | 10-01-82      |          |           | NCE         |

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 1-31-85 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

| <u>ACTIVE INGREDIENT(S)</u><br><u>STRENGTH(S)</u> | <u>TRADE NAME</u><br><u>(DOSAGE FORM; ROUTE)</u> | <u>APPLICANT NAME</u> | <u>NDA #</u><br><u>APPROVAL DATE</u> | <u>PATENT #</u><br><u>EXP. DATE</u> | <u>EXCLUSIVITY</u><br><u>EXP. DATE</u> |
|---------------------------------------------------|--------------------------------------------------|-----------------------|--------------------------------------|-------------------------------------|----------------------------------------|
| XENON, XE-127<br>10MC1/VIAL                       | XENON XE 127<br>(GAS; INHALATION)                | MALLINCKRODT          | 18-536<br>10-01-82                   |                                     | NCE<br>10-01-92                        |
| XENON, XE-133<br>10MC1/VIAL                       | XENON XE 133<br>(GAS; INHALATION)                | MALLINCKRODT          | 18-327<br>03-09-82                   |                                     |                                        |
| XENON, XE-133<br>20MC1/VIAL                       | XENON XE 133<br>(GAS; INHALATION)                | MALLINCKRODT          | 18-327<br>03-09-82                   |                                     |                                        |

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