**CUMULATIVE SUPPLEMENT 2**

**JAN'93-FEB'93**

# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

**13TH EDITION**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

# APPROVED DRUG PRODUCTS
# with
# THERAPEUTIC EQUIVALENCE EVALUATIONS

## 13TH EDITION

## Cumulative Supplement 2

## February 1993

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# with
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## 13TH EDITION

## CUMULATIVE SUPPLEMENT 2

## FEBRUARY 1993

## 1.0 INTRODUCTION

### 1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 13th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**ADD**> to the left of the line on which new information exists. The >**ADD**> symbol is then dropped in subsequent Cumulative Supplements for that item.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**DLT**> (DELETE) to the left of the line containing overstruck print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the " ə " symbol to designate their non-marketed status. All products having a " ə " symbol in the 12th Cumulative Supplement of the 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th Edition.

## 1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

| Products | Federal Register Reference |
|---|---|
| Nitroglycerin (capsule, controlled release;oral) | SEP 7, 1984 (49 FR 35428) |
| Nitroglycerin (tablet, controlled release;oral) | SEP 7, 1984 (49 FR 35428) |
| Nitroglycerin (tablet, controlled release;buccal) | JUL 5, 1985 (50 FR 27688) |
| Tranylcypromine Sulfate | MAR 22, 1984 (49 FR 10708) |

## 1.3 APPLICANT NAME CHANGES

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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT NAME CHANGES

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|
| RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV MCNEILAB (JOHNSON RW) | RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW) |

## 1.4 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

| FORMER USP MONOGRAPH TITLE (FORMER ADP DOSAGE FORM; ROUTE) | NEW USP MONOGRAPH TITLE (NEW ADP DOSAGE FORM; ROUTE) |
|---|---|

**THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF FEBRUARY 1993.**

## 1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1992) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

### DEFINITIONS

#### Drug Product

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

#### New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

## REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

### COUNTS CUMULATIVE BY QUARTER

| CATEGORIES COUNTED | DEC 1992 | MAR 1993 | JUN 1993 | SEP 1993 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 9488 | | | |
| SINGLE SOURCE | 2245 (23.7%) | | | |
| MULTISOURCE | 7243 (76.3%) | | | |
| THERAPEUTICALLY EQUIVALENT | 6516 (68.6%) | | | |
| NOT THERAPEUTICALLY EQUIVALENT | 577 ( 6.1%) | | | |
| EXCEPTIONS[1] | 150 ( 1.6%) | | | |
| NEW MOLECULAR ENTITIES APPROVED | -- | | | |
| NUMBER OF APPLICANTS | 477 | | | |

[1]Amino acid-containing products of varying composition (see Introduction, page xvii of the List).

## ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

**ALLAY**

| | | | | |
|---|---|---|---|---|
| /AA/ | /LUCHEM/ | /500MG;5MG/ | /N89907/001/ | |
| | | | /JAN/13,/1989/ | |
| AA | NORTON HN | 500MG;5MG | N89907 001 | |
| | | | JAN 13, 1989 | |

TABLET; ORAL

**ANEXSIA**

| | | | | |
|---|---|---|---|---|
| AA | BOEHRINGER MANNHEIM | 500MG;5MG | N89160 001 | |
| | | | APR 23, 1987 | |
| /AA/ | /SKCP/ | /500MG;5MG/ | /N89160/001/ | |
| | | | /APR/23,/1987/ | |

**ANEXSIA 7.5/650**

| | | | | |
|---|---|---|---|---|
| AA | BOEHRINGER MANNHEIM | 650MG;7.5MG | N89725 001 | |
| | | | SEP 30, 1987 | |
| /AA/ | /SKCP/ | /650MG;7.5MG/ | /N89725/001/ | |
| | | | /SEP/30,/1987/ | |

**HYDROCODONE BITARTRATE AND ACETAMINOPHEN**

| | | | | |
|---|---|---|---|---|
| /AA/ | /LUCHEM/ | /500MG;5MG/ | /N89696/001/ | |
| | | | /APR/21,/1988/ | |
| AA | NORTON HN | 500MG;5MG | N89696 001 | |
| | | | APR 21, 1988 | |

## AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

**AMANTADINE HCL**

| | | | | |
|---|---|---|---|---|
| >DLT >/AB/ | /BOLAR/ | /100MG/ | /N71382/001/ | |
| >DLT > | | | /JAN/21,/1987/ | |
| >ADD > | a BOLAR | 100MG | N71382 001 | |
| >ADD > | | | JAN 21, 1987 | |

## AMINO ACIDS

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| >ADD > | NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER | | | |
| >ADD > | BAXTER | 15% | N20107 001 | |
| >ADD > | | | FEB 05, 1993 | |
| | /NOVAMINE/8.5%/ | | | |
| | /KABIVITRUM/ | /8.5%/ | /N17957/002/ | |
| | | | /AUG/09,/1982/ | |
| | a KABIVITRUM | 8.5% | N17957 002 | |
| | | | AUG 09, 1982 | |

## AMINO ACIDS

INJECTABLE; INJECTION

TRAVASOL 10% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| BAXTER | 10% | | N18931 003 |
| | | | AUG 23, 1984 |
| | /10%/ | | /N18931/004/ |
| | | | /APR/23,/1988/ |
| /TRAVASOL/10%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/ | | | |
| /BAXTER/ | /10%/ | | /N18931/003/ |
| | | | /AUG/23,/1984/ |

TRAVASOL 5.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| BAXTER | 5.5% | | N18931 001 |
| | | | AUG 23, 1984 |
| /TRAVASOL/5.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/ | | | |
| /BAXTER/ | /5.5%/ | | /N18931/001/ |
| | | | /AUG/23,/1984/ |

TRAVASOL 8.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| BAXTER | 8.5% | | N18931 002 |
| | | | AUG 23, 1984 |
| /TRAVASOL/8.5%/W/O/ELECTROLYTES/IN/PLASTIC/CONTAINER/ | | | |
| /BAXTER/ | /8.5%/ | | /N18931/002/ |
| | | | /AUG/23,/1984/ |

## AMINOCAPROIC ACID

INJECTABLE; INJECTION

**AMINOCAPROIC ACID**

| | | | | |
|---|---|---|---|---|
| >DLT >/AP/ | /LYPHOMED/ | /250MG/ML/ | /N70522/001/ | |
| >DLT > | | | /JUN/17,/1986/ | |
| >ADD > | a LYPHOMED | 250MG/ML | N70522 001 | |
| >ADD > | | | JUN 17, 1986 | |

## AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

**ELAVIL**

| | | | |
|---|---|---|---|
| /AP/ | /MSD/ | /10MG/ML/ | /N12704/001/ |
| AP | ZENECA | 10MG/ML | N12704 001 |

TABLET; ORAL

**ELAVIL**

| | | | |
|---|---|---|---|
| /AB/ | /MSD/ | /10MG/ | /N12703/001/ |
| /AB/ | /+/ | /25MG/ | /N12703/003/ |
| /AB/ | | /50MG/ | /N12703/004/ |
| /AB/ | | /75MG/ | /N12703/005/ |
| /AB/ | | /100MG/ | /N12703/006/ |
| /AB/ | | /150MG/ | /N12703/007/ |

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
ELAVIL

| | | | | |
|---|---|---|---|---|
| AB | ZENECA | 10MG | N12703 | 001 |
| AB | + | 25MG | N12703 | 003 |
| AB | | 50MG | N12703 | 004 |
| AB | | 75MG | N12703 | 005 |
| AB | | 100MG | N12703 | 006 |
| AB | | 150MG | N12703 | 007 |

AMOXICILLIN

CAPSULE; ORAL
/TRIMOX/

| | | | | |
|---|---|---|---|---|
| /AB/ | /SQUIBB/ | /250MG/ | /N62098/ | /001/ |
| /AB/ | | /250MG/ | /N62152/ | /001/ |
| /AB/ | | /500MG/ | /N62098/ | /002/ |
| /AB/ | | /500MG/ | /N62152/ | /002/ |
| | ə APOTHECON | 250MG | N62098 | 001 |
| | ə | 250MG | N62152 | 001 |
| | ə | 500MG | N62098 | 002 |
| | ə | 500MG | N62152 | 002 |

POWDER FOR RECONSTITUTION; ORAL
/TRIMOX/

| | | | | |
|---|---|---|---|---|
| /AB/ | /SQUIBB/ | /125MG/5ML/ | /N62099/ | /001/ |
| /AB/ | | /125MG/5ML/ | /N62154/ | /001/ |
| /AB/ | | /250MG/5ML/ | /N62099/ | /002/ |
| /AB/ | | /250MG/5ML/ | /N62154/ | /002/ |
| | ə APOTHECON | 125MG/5ML | N62099 | 001 |
| | ə | 125MG/5ML | N62154 | 001 |
| | ə | 250MG/5ML | N62099 | 002 |
| | ə | 250MG/5ML | N62154 | 002 |

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

| | | | | |
|---|---|---|---|---|
| >DLT> | /CAPSULE;/ORAL/ | | | |
| >DLT> | /DELCOBESE/ | | | |
| >DLT> | /LEMMON/ | /1.25MG;1.25MG;1.25MG;/ | | |
| >DLT> | | /1.25MG/ | /N83564/ | /001/ |
| >DLT> | | /2.5MG;2.5MG;2.5MG;2.5MG/ | /N83564/ | /002/ |
| >DLT> | | /3.75MG;3.75MG;3.75MG;/ | | |
| >DLT> | | /3.75MG/ | /N83564/ | /003/ |
| >DLT> | | /5MG;5MG;5MG;5MG/ | /N83564/ | /004/ |

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE ADIPATE; DEXTROAMPHETAMINE SULFATE

| | | | | |
|---|---|---|---|---|
| >DLT> | /CAPSULE;/ORAL/ | | | |
| >DLT> | /DELCOBESE/ | | | |
| >ADD> | ə LEMMON | 1.25MG;1.25MG;1.25MG; | | |
| >ADD> | | 1.25MG | N83564 | 001 |
| >ADD> | ə | 2.5MG;2.5MG;2.5MG;2.5MG | N83564 | 002 |
| >ADD> | ə | 3.75MG;3.75MG;3.75MG; | | |
| >ADD> | | 3.75MG | N83564 | 003 |
| >ADD> | ə | 5MG;5MG;5MG;5MG | N83564 | 004 |

| | | | | |
|---|---|---|---|---|
| >DLT> | /TABLET;/ORAL/ | | | |
| >DLT> | /DELCOBESE/ | | | |
| >DLT> | /LEMMON/ | /1.25MG;1.25MG;1.25MG;/ | | |
| >DLT> | | /1.25MG/ | /N83563/ | /004/ |
| >DLT> | | /2.5MG;2.5MG;2.5MG;2.5MG/ | /N83563/ | /003/ |
| >DLT> | | /3.75MG;3.75MG;3.75MG;/ | | |
| >DLT> | | /3.75MG/ | /N83563/ | /002/ |
| >DLT> | | /5MG;5MG;5MG;5MG/ | /N83563/ | /001/ |
| >ADD> | ə LEMMON | 1.25MG;1.25MG;1.25MG; | | |
| >ADD> | | 1.25MG | N83563 | 004 |
| >ADD> | ə | 2.5MG;2.5MG;2.5MG;2.5MG | N83563 | 003 |
| >ADD> | ə | 3.75MG;3.75MG;3.75MG; | | |
| >ADD> | | 3.75MG | N83563 | 002 |
| >ADD> | ə | 5MG;5MG;5MG;5MG | N83563 | 001 |

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM

| | | | |
|---|---|---|---|
| /AP/ | /LILLY/ | /EQ 500MG BASE/VIAL/ | /N62565/001/ /APR/04,/1985/ |
| /AP/ | | /EQ 1GM BASE/VIAL/ | /N62565/002/ /APR/04,/1985/ |
| /AP/ | | /EQ 2GM BASE/VIAL/ | /N62565/003/ /JUN/24,/1986/ |
| | ə LILLY | EQ 500MG BASE/VIAL | N62565 001 APR 04, 1985 |
| | ə | EQ 1GM BASE/VIAL | N62565 002 APR 04, 1985 |
| | ə | EQ 2GM BASE/VIAL | N62565 003 JUN 24, 1986 |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
/PRINCIPEN 'I250'/

| | | | | |
|---|---|---|---|---|
| /AB/ | /SQUIBB/ | /EQ 250MG BASE/ | /N50056/ | /001/ |
| /AB/ | | /EQ 250MG BASE/ | /N62157/ | /002/ |

## AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | PRINCIPEN '250' | | | | |
| | ∂ APOTHECON | EQ 250MG BASE | N50056 001 | | |
| | ∂ | EQ 250MG BASE | N62157 002 | | |
| | PRINCIPEN '500' | | | | |
| AB | SQUIBB | EQ 500MG BASE | N50056 002 | | |
| AB | | EQ 500MG BASE | N62157 001 | | |
| | ∂ APOTHECON | EQ 500MG BASE | N50056 002 | | |
| | ∂ | EQ 500MG BASE | N62157 001 | | |

POWDER FOR RECONSTITUTION; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | PRINCIPEN '125' | | | | |
| AB | SQUIBB | EQ 125MG BASE/5ML | N60127 002 | | |
| AB | | EQ 125MG BASE/5ML | N62151 001 | | |
| | ∂ APOTHECON | EQ 125MG BASE/5ML | N60127 002 | | |
| | ∂ | EQ 125MG BASE/5ML | N62151 001 | | |
| | PRINCIPEN '250' | | | | |
| AB | SQUIBB | EQ 250MG BASE/5ML | N60127 001 | | |
| AB | | EQ 250MG BASE/5ML | N62151 002 | | |
| | ∂ APOTHECON | EQ 250MG BASE/5ML | N60127 001 | | |
| | ∂ | EQ 250MG BASE/5ML | N62151 002 | | |

## AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | PRINCIPEN W // PROBENECID | | | | |
| | +// SQUIBB | EQ 389MG BASE;111MG | N50488 001 | | |
| | | EQ 389MG BASE;111MG | N62150 001 | | |
| | ∂ APOTHECON | EQ 389MG BASE;111MG | N50488 001 | | |
| | ∂ | EQ 389MG BASE;111MG | N62150 001 | | |

## ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | M.V.C. 9+3 | | | | |
| AP | FUJISAWA | 10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.34MG/ML;0.3MG/ML; 330 UNITS/ML;1 IU/ML | N18440 002 | | AUG 08, 1985 |
| AP | LYPHOMED | 10MG/ML;0.006MG/ML;0.5UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.34MG/ML;0.3MG/ML; 330 UNITS/ML;1 IU/ML | N18440 002 | | AUG 08, 1985 |

## ASPIRIN; BUTALBITAL

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | AXOTAL | | | | |
| DLT | +// ADRIA | 650MG;50MG | N88305 001 | | OCT 13, 1983 |
| ADD | + SAVAGE | 650MG;50MG | N88305 001 | | OCT 13, 1983 |

## BENZONATATE

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | BENZONATATE | | | | |
| AA | PHARMACAPS | 100MG | N81297 001 | | JAN 29, 1993 |
| | TESSALON | | | | |
| AA | FOREST LABS | 100MG | N11210 001 | | |

## BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

| | | | | | |
|---|---|---|---|---|---|
| | BETAMETHASONE DIPROPIONATE | | | | |
| DLT | AB PHARMADERM | EQ 0.05% BASE | N19136 001 | | JUN 26, 1984 |
| ADD | ∂ PHARMADERM | EQ 0.05% BASE | N19136 001 | | JUN 26, 1984 |

LOTION; TOPICAL

| | | | | | |
|---|---|---|---|---|---|
| | BETAMETHASONE DIPROPIONATE | | | | |
| DLT | AB PHARMADERM | EQ 0.05% BASE | N70274 001 | | AUG 12, 1985 |
| ADD | ∂ PHARMADERM | EQ 0.05% BASE | N70274 001 | | AUG 12, 1985 |

## BETAMETHASONE VALERATE

CREAM; TOPICAL

| | | | | | |
|---|---|---|---|---|---|
| | BETAMETHASONE VALERATE | | | | |
| DLT | AB PHARMADERM | EQ 0.1% BASE | N18860 002 | | AUG 31, 1983 |
| ADD | ∂ PHARMADERM | EQ 0.1% BASE | N18860 002 | | AUG 31, 1983 |

BETAMETHASONE VALERATE

LOTION; TOPICAL
BETAMETHASONE VALERATE

| | | | | | |
|---|---|---|---|---|---|
| >DLT > | /AB/ | /PHARMADERM/ | /EQ 0.1% BASE/ | /N18870/001/ /AUG/31/1983/ |
| >DLT > | | | | |
| >ADD > | | ∂ PHARMADERM | EQ 0.1% BASE | N18870 001 AUG 31, 1983 |
| >ADD > | | | | |

OINTMENT; TOPICAL
BETAMETHASONE VALERATE

| | | | | | |
|---|---|---|---|---|---|
| >DLT > | /AB/ | /PHARMADERM/ | /EQ 0.1% BASE/ | /N18864/001/ /AUG/31/1983/ |
| >DLT > | | | | |
| >ADD > | | ∂ PHARMADERM | EQ 0.1% BASE | N18864 001 AUG 31, 1983 |
| >ADD > | | | | |

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE

| | | | | |
|---|---|---|---|---|
| /AA/ | /ZENITH/ | /4MG/ | /N84351/001/ | |
| | ∂ ZENITH | 4MG | N84351 001 | |

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION
CALCIUM GLUCEPTATE

| | | | | | |
|---|---|---|---|---|---|
| >DLT > | /AP/ | /LYPHOMED/ | /EQ 90MG CALCIUM/5ML/ | /N89373/001/ /APR/30/1987/ |
| >DLT > | | | | |
| >ADD > | | ∂ LYPHOMED | EQ 90MG CALCIUM/5ML | N89373 001 APR 30, 1987 |
| >ADD > | | | | |

CARISOPRODOL

TABLET; ORAL
/BELA/

| | | | | |
|---|---|---|---|---|
| /AA/ | /SCHERING/ | /350MG/ | /N12155/001/ | |
| | ∂ SCHERING | 350MG | N12155 001 | |

CEFOXITIN SODIUM

INJECTABLE; INJECTION
MEFOXIN IN PLASTIC CONTAINER

| | | |
|---|---|---|
| MERCK | EQ 20MG BASE/ML | N63182 001 JAN 25, 1993 |
| | EQ 40MG BASE/ML | N63182 002 JAN 25, 1993 |

CEFUROXIME SODIUM

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| >ADD > | | CEFUROXIME | | | |
| >ADD > | AP | MARSAM | EQ 750MG BASE/VIAL | N64035 001 FEB 26, 1993 | |
| >ADD > | | | | | |
| >ADD > | AP | | EQ 1.5GM BASE/VIAL | N64035 002 FEB 26, 1993 | |
| >ADD > | | | | | |
| >ADD > | AP | | EQ 7.5GM BASE/VIAL | N64036 001 FEB 26, 1993 | |
| >ADD > | | | | | |
| | | KEFUROX | | | |
| >ADD > | AP | LILLY | EQ 7.5GM BASE/VIAL | N62591 003 DEC 17, 1987 | |
| >ADD > | | | | | |

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

| | | | | | |
|---|---|---|---|---|---|
| >DLT > | /AP/ | /LYPHOMED/ | /25MG/ML/ | /N84911/001/ | |
| >ADD > | | ∂ LYPHOMED | 25MG/ML | N84911 001 | |

>ADD > CLADRIBINE

>ADD > INJECTABLE; INJECTION
>ADD > LEUSTATIN

| | | | | |
|---|---|---|---|---|
| >ADD > | + | JOHNSON RW | 1MG/ML | N20229 001 FEB 26, 1993 |
| >ADD > | | | | |

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

| | | | | |
|---|---|---|---|---|
| /BP/ | /HEATHER/ | /25MG/ | /N85736/001/ | |
| | ∂ HEATHER | 25MG | N85736 001 | |

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN

| | | | | |
|---|---|---|---|---|
| /AP/ | /FUJISAWA/ | /1MG/ML/ | /N83075/001/ | |
| | ∂ FUJISAWA | 1MG/ML | N83075 001 | |

CYCLOBENZAPRINE

TABLET; ORAL
CYCLOBENZAPRINE HCL

| | | | | |
|---|---|---|---|---|
| >ADD > | AB | INVAMED | 10MG | N73683 001 FEB 26, 1993 |
| >ADD > | | | | |

## DEXAMETHASONE

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| /DEXAMETHASONE/ | | | | |
| /ROXANE/ | /0.5MG/5ML/ | /N88248/001/ | | |
| | | /SEP/01,/1983/ | | |
| ə ROXANE | 0.5MG/5ML | N88248 001 | | |
| | | SEP 01, 1983 | | |

## DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| >_DLT_> | /DEXAMPEX/ | | | |
| >_DLT_>/AA/ | /LEMMON/ | /5MG/ | /N83735/001/ | |
| >_DLT_>/AA/ | | /10MG/ | /N83735/002/ | |
| >_ADD_> | ə LEMMON | 5MG | N83735 001 | |
| >_ADD_> | ə | 10MG | N83735 002 | |

## DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

| | | | | |
|---|---|---|---|---|
| AP | MARSAM | 5MG/ML | N72370 001 | |
| | | | JAN 29, 1993 | |
| AP | | 5MG/ML | N72371 001 | |
| | | | JAN 29, 1993 | |
| AP | | 5MG/ML | N72397 001 | |
| | | | JAN 29, 1993 | |

TABLET; ORAL

DIAZEPAM

| | | | | |
|---|---|---|---|---|
| /AB/ | /ZENITH/ | /2MG/ | /N70360/001/ | |
| | | | /SEP/04,/1985/ | |
| /AB/ | | /5MG/ | /N70361/001/ | |
| | | | /SEP/04,/1985/ | |
| | ə ZENITH | 2MG | N70360 001 | |
| | | | SEP 04, 1985 | |
| | ə | 5MG | N70361 001 | |
| | | | SEP 04, 1985 | |

## DIAZOXIDE

CAPSULE; ORAL

PROGLYCEM

| | | | |
|---|---|---|---|
| + BAKER NORTON | 50MG | N17425 001 | |
| /+//MEDCL/MKTG/ | /50MG/ | /N17425/001/ | |

## DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

| | | | | | |
|---|---|---|---|---|---|
| >_DLT_>/AP/ | /LYPHOMED/ | /40MG/ML/ | /N70012/001/ | | |
| >_DLT_> | | | /JUN/12,/1985/ | | |
| >_ADD_> | ə LYPHOMED | 40MG/ML | N70012 001 | | |
| >_ADD_> | | | JUN 12, 1985 | | |

## DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

| | | | | | |
|---|---|---|---|---|---|
| >_DLT_>/AP/ | /SMITH/NEPHEW/SOLOPAK/ | 2.5MG/ML/ | /N71754/001/ | | |
| >_DLT_> | | | /SEP/06,/1988/ | | |
| >_DLT_>/AP/ | | 2.5MG/ML/ | /N71755/001/ | | |
| >_DLT_> | | | /SEP/06,/1988/ | | |
| >_ADD_> AP | SOLOPAK | 2.5MG/ML | N71754 001 | | |
| >_ADD_> | | | SEP 06, 1988 | | |
| >_ADD_> AP | | 2.5MG/ML | N71755 001 | | |
| >_ADD_> | | | SEP 06, 1988 | | |

## EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

| | | | |
|---|---|---|---|
| >_ADD_> AP | STERLING WINTHROP | 0.01MG/ML;2% | N40057 002 |
| >_ADD_> | | | FEB 26, 1993 |
| >_ADD_> AP | | 0.02MG/ML;2% | N40057 001 |
| >_ADD_> | | | FEB 26, 1993 |

## ERGOLOID MESYLATES

TABLET; SUBLINGUAL

HYDROGENATED ERGOT ALKALOIDS

| | | | | |
|---|---|---|---|---|
| /AA/ | /ZENITH/ | /0.5MG/ | /N87186/001/ | |
| | ə ZENITH | 0.5MG | N87186 001 | |

## ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

| | | | | |
|---|---|---|---|---|
| >_ADD_> | ERGOMAR | | | |
| >_ADD_> AA | FISONS | 2MG | N87693 001 | |
| >_ADD_> | | | FEB 24, 1983 | |
| >_DLT_> | /2/ | /2MG/ | /N87693/001/ | |
| >_DLT_> | | | /FEB/24,/1983/ | |

ERYTHROMYCIN

GEL; TOPICAL
ERYGEL
/AT/ /HERBERT/ /1%/ /N50617/001/ /OCT/21,/1987/
AT + HERBERT 2% N50617 001 OCT 21, 1987

ERYTHROMYCIN
AT STIEFEL 2% N63211 001 JAN 29, 1993

GADODIAMIDE

INJECTABLE; INJECTION
OMNISCAN
STERLING WINTHROP 287MG/ML N20123 001 JAN 08, 1993

GEMFIBROZIL

CAPSULE; ORAL
GEMFIBROZIL
AB MYLAN 300MG N73466 001 JAN 25, 1993
AB PUREPAC 300MG N72929 001 JAN 29, 1993

LOPID
AB + PARKE DAVIS 300MG N18422 002

GENTAMICIN SULFATE

CREAM; TOPICAL
GENTAMICIN SULFATE
>DLT >/AT/ /PHARMADERM/ /EQ 1MG BASE/GM/ /N62530/001/ /JUL/05,/1984/
>DLT >
>ADD > ə PHARMADERM EQ 1MG BASE/GM N62530 001 JUL 05, 1984
>ADD >

HALOPERIDOL LACTATE

CONCENTRATE; ORAL
HALOPERIDOL
>ADD > AA PHARM ASSOC EQ 2MG BASE/ML N73037 001 FEB 26, 1993
>ADD >

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL
>ADD > AP MARSAM EQ 5MG BASE/ML N72516 001 FEB 25, 1993
>ADD >
>ADD > AP EQ 5MG BASE/ML N72517 001 FEB 25, 1993
>ADD >
>DLT >/AP/ /SMITH/NEPHEW/SOLOPAK/ /EQ 5MG BASE/ML/ /N70801/001/ /DEC/14,/1987/
>DLT >
>DLT >/AP/ /EQ 5MG BASE/ML/ /N70864/001/ /DEC/14,/1987/
>DLT >
>ADD > AP SOLOPAK EQ 5MG BASE/ML N70801 001 DEC 14, 1987
>ADD >
>ADD > AP EQ 5MG BASE/ML N70864 001 DEC 14, 1987
>ADD >

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
/AT/ /BIOCRAFT/ /0.5%/ /N80400/002/
/AT/ /1%/ /N80400/003/
/AT/ /2.5%/ /N80400/004/
ə BIOCRAFT 0.5% N80400 002
ə 1% N80400 003
ə 2.5% N80400 004
>DLT >/AT/ /PHARMADERM/ /1%/ /N88845/001/ /FEB/27,/1986/
>DLT >
>ADD > ə PHARMADERM 1% N88845 001 FEB 27, 1986
>ADD >

IBUPROFEN

TABLET; ORAL
IBUPROFEN
AB NORTON HN 400MG N71145 001 SEP 23, 1986
AB 600MG N71146 001 SEP 23, 1986
AB 800MG N71769 001 MAY 08, 1987

/TEEN/
/AB/ /LUCHEN/ /400MG/ /N71145/001/ /SEP/23,/1986/
/AB/ /600MG/ /N71146/001/ /SEP/23,/1986/
/AB/ /800MG/ /N71769/001/ /MAY/08,/1987/

## ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALITION

**ISOETHARINE HCL**

| | | | | |
|---|---|---|---|---|
| /AN/ | /ASTRA/ | /0.125%/ | /N87938/001/ /NOV/15,/1982/ | |
| | | /0.062%/ | /N87937/001/ /NOV/15,/1982/ | |
| | ∂ ASTRA | 0.062% | N87937 001 NOV 15, 1982 | |
| | ∂ | 0.125% | N87938 001 NOV 15, 1982 | |

## ISOFLURANE

LIQUID; INHALATION

**FORANE**

| | | | | |
|---|---|---|---|---|
| AN | + ANAQUEST | 99.9% | N17624 001 | |

**ISOFLURANE**

| | | | | |
|---|---|---|---|---|
| AN | ABBOTT | 99.9% | N74097 001 JAN 25, 1993 | |

## ISOSORBIDE DINITRATE

TABLET; ORAL

**SORBITRATE**

| | | | | |
|---|---|---|---|---|
| /AB/ | /ICI/ | /20MG/ | /N86405/002/ /AUG/21,/1990/ | |
| /AB/ | | /30MG/ | /N88124/001/ /AUG/21,/1990/ | |
| /AB/ | | /40MG/ | /N88125/001/ /AUG/21,/1990/ | |
| AB | ZENECA | 20MG | N86405 002 AUG 21, 1990 | |
| AB | | 30MG | N88124 001 AUG 21, 1990 | |
| AB | | 40MG | N88125 001 AUG 21, 1990 | |

## KANAMYCIN SULFATE

INJECTABLE; INJECTION

**KLEOCIL**

| | | | | |
|---|---|---|---|---|
| /AP/ | /SMITHKLINE/BEECHAM/ | /EQ 75MG BASE/2ML/ | /N62170/001/ | |
| /AP/ | | /EQ 500MG BASE/2ML/ | /N62170/002/ | |
| /AP/ | | /EQ 1GM BASE/3ML/ | /N62170/003/ | |
| | ∂ SMITHKLINE BEECHAM | EQ 75MG BASE/2ML | N62170 001 | |
| | ∂ | EQ 500MG BASE/2ML | N62170 002 | |
| | ∂ | EQ 1GM BASE/3ML | N62170 003 | |

## KETOPROFEN

CAPSULE; ORAL

**KETOFROFEN**

| | | | | |
|---|---|---|---|---|
| AB | LEDERLE | 25MG | N74014 001 JAN 29, 1993 | |
| AB | | 50MG | N74014 002 JAN 29, 1993 | |
| AB | | 75MG | N74014 003 JAN 29, 1993 | |

## LEUCOVORIN CALCIUM

TABLET; ORAL

**LEUCOVORIN CALCIUM**

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | AB | LEDERLE | EQ 10MG BASE | N71962 001 NOV 19, 1987 | |
| >ADD> | AB | + | EQ 15MG BASE | N71104 001 MAR 04, 1987 | |
| >ADD> | AB | ROXANE | EQ 5MG BASE | N72733 001 FEB 22, 1993 | |
| >ADD> | AB | | EQ 10MG BASE | N72734 001 FEB 22, 1993 | |
| >ADD> | AB | | EQ 15MG BASE | N72735 001 FEB 22, 1993 | |
| >ADD> | AB | | EQ 25MG BASE | N72736 001 FEB 22, 1993 | |

## LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

**LIDOCAINE HCL**

| | | | | | |
|---|---|---|---|---|---|
| >DLT>/AP/ | /LYPHOMED/ | /1%/ | /N86761/001/ | | |
| >DLT>/AP/ | | /2%/ | /N86761/002/ | | |
| >ADD> | ∂ LYPHOMED | 1% | N86761 001 | | |
| >ADD> | ∂ | 2% | N86761 002 | | |

## LIOTRIX (T4;T3)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | THYROLAR-0.25 | | | |
| >ADD> | FOREST LABS | 0.0125MG;0.0031MG | N16807 001 | |
| >DLT> | /RHONE/POULENC/RORER//0.0125MG;0.0031MG/ | | /N16807/001/ | |
| | THYROLAR-0.5 | | | |
| >ADD> | FOREST LABS | 0.025MG;0.00625MG | N16807 005 | |
| >DLT> | /RHONE/POULENC/RORER//0.025MG;0.00625MG/ | | /N16807/005/ | |
| | THYROLAR-1 | | | |
| >ADD> | FOREST LABS | 0.05MG;0.0125MG | N16807 004 | |
| >DLT> | /RHONE/POULENC/RORER//0.05MG;0.0125MG/ | | /N16807/004/ | |

LIOTRIX (T4;T3)

TABLET; ORAL

THYROLAR-2

| | | | |
|---|---|---|---|
| >ADD > | FOREST LABS | 0.1MG;0.025MG | N16807 002 |
| >DLT > | /RHONE/POULENC/RORER//0.1MG;0.025MG/ | | /N16807/002/ |

THYROLAR-3

| | | | |
|---|---|---|---|
| >ADD > | + FOREST LABS | 0.15MG;0.0375MG | N16807 003 |
| >DLT > | /+//RHONE/POULENC/RORER//0.15MG;0.0375MG/ | | /N16807/003/ |

THYROLAR-5

| | | | |
|---|---|---|---|
| >ADD > | @ FOREST LABS | 0.25MG;0.0625MG | N16807 006 |
| >DLT > | /@/RHONE/POULENC/RORER//0.25MG;0.0625MG/ | | /N16807/006/ |

MANGANESE SULFATE

INJECTABLE; INJECTION

MANGANESE SULFATE

| | | | |
|---|---|---|---|
| | FUJISAWA | EQ 0.1MG MANGANESE/ML | N19228 001 MAY 05, 1987 |
| | /LYPHOMED/ | /EQ/0.1MG/MANGANESE/ML/ | /N19228/001/ /MAY/05,/1987/ |

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

/METHAMPEX/

| | | | |
|---|---|---|---|
| >DLT >/AA/ | /LEMMON/ | /10MG/ | /N83889/001/ |
| >ADD > | @ LEMMON | 10MG | N83889 001 |

METHAMPHETAMINE HCL

| | | | |
|---|---|---|---|
| >DLT >/AA/ | /REXAR/ | /10MG/ | /N84931/002/ |
| >ADD > | REXAR | 10MG | N84931 002 |

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM

| | | | |
|---|---|---|---|
| >DLT >/AP/ | /LYPHOMED/ | /EQ 25MG BASE/ML/ | /N89263/001/ /JUN/13,/1986/ |
| >ADD > | @ LYPHOMED | EQ 25MG BASE/ML | N89263 001 JUN 13, 1986 |

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

METHYLDOPATE HCL

| | | | |
|---|---|---|---|
| >DLT >/AP/ | /LYPHOMED/ | /50MG/ML/ | /N70652/001/ /JUN/03,/1986/ |
| >ADD > | @ LYPHOMED | 50MG/ML | N70652 001 JUN 03, 1986 |

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

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

METRONIDAZOLE

TABLET; ORAL

/SATRIC/

| | | | |
|---|---|---|---|
| /AB/ | /SAVAGE/ | /250MG/ | /N70029/001/ /MAR/19,/1985/ |
| /AB/ | | /500MG/ | /N70731/001/ /JUN/08,/1987/ |
| | @ SAVAGE | 250MG | N70029 001 MAR 19, 1985 |
| | @ | 500MG | N70731 001 JUN 08, 1987 |

NABILONE

| | | | |
|---|---|---|---|
| >DLT > | /CAPSULE;ORAL/ | | |
| >DLT > | /CESAMET/ | | |
| >DLT > | /+//LILLY/ | /1MG/ | /N18677/001/ /DEC/26,/1985/ |

NABILONE

>DLT> /CAPSULE;ORAL/
>DLT> /CESAMET/
>ADD> @ LILLY 1MG N18677 001 DEC 26, 1985
>ADD>

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL
>DLT>/AP/ /LYPHOMED/ /0.02MG/ML/ /N70661/001/ /NOV/17,/1986/
>DLT>
>ADD> @ LYPHOMED 0.02MG/ML N70661 001 NOV 17, 1986
>ADD>

NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE
>DLT>/AO/ /LYPHOMED/ /100MG/ML/ /N88290/001/ /OCT/03,/1983/
>DLT>
>DLT>/AO/ /200MG/ML/ /N88317/001/ /OCT/14,/1983/
>DLT>
>ADD> @ LYPHOMED 100MG/ML N88290 001 OCT 03, 1983
>ADD>
>ADD> @ 200MG/ML N88317 001 OCT 14, 1983
>ADD>

NIACIN

TABLET; ORAL
NIACIN
/AA/ /ZENITH/ /500MG/ /N83180/001/
@ ZENITH 500MG N83180 001

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN
/AB/ /ZENITH/ /50MG/ /N80078/002/
/AB/ /100MG/ /N80078/001/
@ ZENITH 50MG N80078 002
@ 100MG N80078 001

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN
AB ZENITH 50MG N73671 001 JAN 28, 1993
AB 100MG N73652 001 JAN 28, 1993

NYSTATIN

CREAM; TOPICAL
NYSTATIN
AT TARO 100,000 UNITS/GM N64022 001 JAN 29, 1993

SUSPENSION; ORAL
NYSTATIN
>DLT>/AA/ /PHARMADERM/ /100,000 UNITS/ML/ /N62518/001/ /JUL/06,/1984/
>DLT>
>ADD> @ PHARMADERM 100,000 UNITS/ML N62518 001 JUL 06, 1984
>ADD>

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
NYSTATIN-TRIAMCINOLONE ACETONIDE
>DLT>/AT/ /PHARMADERM/ /100,000 UNITS/GM;0.1%/ /N62596/001/ /OCT/08,/1985/
>DLT>
>ADD> @ PHARMADERM 100,000 UNITS/GM;0.1% N62596 001 OCT 08, 1985
>ADD>

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENICILLIN
/AA/ /BIOCRAFT/ /200,000 UNITS/5ML/ /N60307/002/
BIOCRAFT 200,000 UNITS/5ML N60307 002
/PENTIDS,,200,/
/AA/ /SQUIBB/ /200,000 UNITS/5ML/ /N62149/001/
@ APOTHECON 200,000 UNITS/5ML N62149 001
/PENTIDS,,400,/
/AA/ /SQUIBB/ /400,000 UNITS/5ML/ /N62149/002/
@ APOTHECON 400,000 UNITS/5ML N62149 002

TABLET; ORAL
PENICILLIN G POTASSIUM
@ APOTHECON 250,000 UNITS N60392 003

## PENICILLIN G POTASSIUM

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PENICILLIN G POTASSIUM | | | | | | | |
| /AB/ | /SQUIBB/ | /250,000 UNITS/ | /N60392/003/ | | | | | |
| | PENTIDS 200 | | | | | | | |
| /AB/ | /SQUIBB/ | /200,000 UNITS/ | /N62155/001/ | | | | | |
| | ə APOTHECON | 200,000 UNITS | N62155 001 | | | | | |
| | PENTIDS 250 | | | | | | | |
| /AB/ | /SQUIBB/ | /250,000 UNITS/ | /N62155/002/ | | | | | |
| | ə APOTHECON | 250,000 UNITS | N62155 002 | | | | | |
| | PENTIDS 400 | | | | | | | |
| /AB/ | /SQUIBB/ | /400,000 UNITS/ | /N60392/004/ | | | | | |
| /AB/ | | /400,000 UNITS/ | /N62155/003/ | | | | | |
| | ə APOTHECON | 400,000 UNITS | N60392 004 | | | | | |
| | ə | 400,000 UNITS | N62155 003 | | | | | |
| | PENTIDS 800 | | | | | | | |
| /AB/ | /SQUIBB/ | /800,000 UNITS/ | /N60392/005/ | | | | | |
| /AB/ | | /800,000 UNITS/ | /N62155/004/ | | | | | |
| | ə APOTHECON | 800,000 UNITS | N60392 005 | | | | | |
| | ə | 800,000 UNITS | N62155 004 | | | | | |

## PENICILLIN G PROCAINE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | DURACILLIN A.S. | | |
| /AP/ | /LILLY/ | /300,000 UNITS/ML/ | /N60093/001/ |
| | ə LILLY | 300,000 UNITS/ML | N60093 001 |

## PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

| | | | |
|---|---|---|---|
| | VEETIDS 125 | | |
| /AA/ | /SQUIBB/ | /EQ 125MG BASE/5ML/ | /N61206/001/ |
| | ə APOTHECON | EQ 125MG BASE/5ML | N61206 001 |
| | VEETIDS 250 | | |
| /AA/ | /SQUIBB/ | /EQ 250MG BASE/5ML/ | /N61206/002/ |
| | ə APOTHECON | EQ 250MG BASE/5ML | N61206 002 |

TABLET; ORAL

| | | | |
|---|---|---|---|
| | VEETIDS 250 | | |
| /AB/ | /SQUIBB/ | /EQ 250MG BASE/ | /N61164/001/ |
| /AB/ | | /EQ 250MG BASE/ | /N62156/002/ |
| | ə APOTHECON | EQ 250MG BASE | N61164 001 |
| | ə | EQ 250MG BASE | N62156 002 |
| | VEETIDS 500 | | |
| /AB/ | /SQUIBB/ | /EQ 500MG BASE/ | /N61164/002/ |
| /AB/ | | /EQ 500MG BASE/ | /N62156/001/ |
| | ə APOTHECON | EQ 500MG BASE | N61164 002 |
| | ə | EQ 500MG BASE | N62156 001 |

## PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PHENTERMINE HCL | | | | | | | |
| /AA/ | /ZENITH/ | /30MG/ | /N86329/001/ | | | | | |
| | ə ZENITH | 30MG | N86329 001 | | | | | |

## PINDOLOL

TABLET; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PINDOLOL | | | | | | | |
| | ZENITH | 5MG | N73687 001 | > ADD > | AB | ZENITH | 5MG | N73687 001 |
| | | | FEB 26, 1993 | > ADD > | | | | FEB 26, 1993 |
| | | 10MG | N73687 002 | > ADD > | AB | | 10MG | N73687 002 |
| | | | FEB 26, 1993 | > ADD > | | | | FEB 26, 1993 |

## PIROXICAM

CAPSULE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PIROXICAM | | | | | | | |
| | ROXANE | 10MG | N73651 001 | > ADD > | AB | ROXANE | 10MG | N73651 001 |
| | | | FEB 26, 1993 | > ADD > | | | | FEB 26, 1993 |
| | | 20MG | N73651 002 | > ADD > | AB | | 20MG | N73651 002 |
| | | | FEB 26, 1993 | > ADD > | | | | FEB 26, 1993 |

## POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | K-LEASE | | | | | | | |
| | | | | > DLT > | /AB/ | /ADRIA/ | /8MEQ/ | /N73398/001/ |
| | | | | > DLT > | | | | /JAN/28,/1992/ |
| | | | | > DLT > | /AB/ | | /10 MEQ/ | /N72427/001/ |
| | | | | > DLT > | | | | /MAR/28,/1990/ |
| | | | | > ADD > | AB | SAVAGE | 8MEQ | N73398 001 |
| | | | | > ADD > | | | | JAN 28, 1992 |
| | | | | > ADD > | AB | | 10 MEQ | N72427 001 |
| | | | | > ADD > | | | | MAR 28, 1990 |

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | K+8 | | | | | | | |
| | ALRA | 8MEQ | N70998 001 | | AB | ALRA | 8MEQ | N70998 001 |
| | | | JAN 25, 1993 | | | | | JAN 25, 1993 |

## PRAZEPAM

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | > DLT > | /TABLET;ORAL/ | | | |
| | | | | > DLT > | /CENTRAX/ | | | |
| | | | | > DLT > | /+//PARKE/DAVIS/ | | /10MG/ | /N17415/001/ |



## PRAZEPAM

## SODIUM CHLORIDE

PRAZEPAM

> DLT > /TABLET;ORAL/
> DLT > /CENTRAX/
> ADD > @ PARKE DAVIS 10MG N17415 001

PREDNISONE

TABLET; ORAL
DELTASONE
> ADD > AB UPJOHN 2.5MG N09986 005
> DLT > /BX/ /2.5MG/ /N09986/005/
PREDNISONE
/AA/ /HEATHER/ /10MG/ /N84341/001/
/AB/ /20MG/ /N85543/001/
/AB/ /50MG/ /N86946/001/
@ HEATHER 10MG N84341 001
@ 20MG N85543 001
@ 50MG N86946 001

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HCL
> DLT >/AP/ /LYPHOMED/ /100MG/ML/ /N89415/001/ /NOV/17,/1986/
> DLT >
> DLT >/AP/ /500MG/ML/ /N89416/001/ /NOV/17,/1986/
> DLT >
> ADD > @ LYPHOMED 100MG/ML N89415 001 NOV 17, 1986
> ADD >
> ADD > @ 500MG/ML N89416 001 NOV 17, 1986
> ADD >

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL
> DLT > /BP/ /BOLAR/ /25MG/ /N83204/001/
> ADD > @ BOLAR 25MG N83204 001
/BP/ /ZENITH/ /50MG/ /N83613/001/
@ ZENITH 50MG N83613 001

SODIUM CHLORIDE

INJECTABLE; INJECTION
BACTERIOSTATIC SODIUM CHLORIDE 0,9% IN PLASTIC CONTAINER
AP FUJISAWA 9MG/ML N88911 001 FEB 07, 1985

SODIUM CHLORIDE

INJECTABLE; INJECTION
BACTERIOSTATIC SODIUM CHLORIDE 0,9% IN PLASTIC CONTAINER
/AP/ /LYPHOMED/ /9MG/ML/ /N88911/001/ /FEB/07,/1985/

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE
/AB/ /HEATHER/ /500MG/ /N80189/001/
@ HEATHER 500MG N80189 001

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
/TECHNETIUM/TC/99M/MAA/
/BS/ /MEDI/PHYSICS/ /N/A/ /N17773/001/
@ MEDI PHYSICS N/A N17773 001

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL
/AB/ /ZENITH/ /100MG/ /N88273/001/ /OCT/03,/1983/
@ ZENITH 100MG N88273 001 OCT 03, 1983

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE
> DLT >/AT/ /PHARMADERM/ /0.025%/ /N87990/001/ /JUL/07,/1983/
> DLT >
> DLT >/AT/ /0.1%/ /N87991/001/ /JUL/07,/1983/
> DLT >
> DLT >/AT/ /0.5%/ /N87992/001/ /JUL/07,/1983/
> DLT >
> ADD > @ PHARMADERM 0.025% N87990 001 JUL 07, 1983
> ADD >
> ADD > @ 0.1% N87991 001 JUL 07, 1983
> ADD >
> ADD > @ 0.5% N87992 001 JUL 07, 1983
> ADD >

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL
**TRIAMCINOLONE ACETONIDE**

| | | | | |
|---|---|---|---|---|
| >DLT >/AT/ | /PHARMADERM/ | /0.025%/ | /N88692/001/ | |
| >DLT > | | | /AUG/02,/1984/ | |
| >DLT >/AT/ | | /0.1%/ | /N88690/001/ | |
| >DLT > | | | /AUG/02,/1984/ | |
| >ADD > | ə PHARMADERM | 0.025% | N88692 001 | |
| >ADD > | | | AUG 02, 1984 | |
| >ADD > | ə | 0.1% | N88690 001 | |
| >ADD > | | | AUG 02, 1984 | |

TRIFLUPROMAZINE

/SUSPENSION;/ORAL/
/VESPRIN/

| | | | |
|---|---|---|---|
| /SQUIBB/ | /EQ/50MG/HCL/5ML/ | /N11491/004/ | |
| ə APOTHECON | EQ 50MG HCL/5ML | N11491 004 | |

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
**VERAPAMIL HCL**

| | | | |
|---|---|---|---|
| >ADD > AP | MARSAM | 2.5MG/ML | N72233 001 |
| >ADD > | | | FEB 26, 1993 |

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

| | | |
|---|---|---|
| FUJISAWA | 1MG/ML | N89515 001 |
| | | APR 29, 1987 |
| /LYPHOMED/ | /1MG/ML/ | /N89515/001/ |
| | | /APR/29,/1987/ |

VITAMIN A PALMITATE

CAPSULE; ORAL
AFAXIN

| | | |
|---|---|---|
| ə STERLING | EQ 50,000 UNITS BASE | N83187 001 |
| **VITAMIN A** | | |
| >DLT >/AA/ /ZENITH/ | /EQ 50,000 UNITS BASE/ | /N83035/001/ |
| /AA/ | /EQ 50,000 UNITS BASE/ | /N83190/001/ |
| >ADD > ə ZENITH | EQ 50,000 UNITS BASE | N83035 001 |
| ə | EQ 50,000 UNITS BASE | N83190 001 |

XENON, XE-133

GAS; INHALATION
**XENON XE 133**

| | | | |
|---|---|---|---|
| AA | MEDI PHYSICS | 10MCI/VIAL | N17687 002 |
| AA | | 20MCI/VIAL | N17687 003 |

XYLOSE

POWDER; ORAL
**XYLO-PFAN**

| | | | |
|---|---|---|---|
| >DLT >/AA/ | /ADRIA/ | /25GM/BOT/ | /N17605/001/ |
| >ADD > AA | SAVAGE | 25GM/BOT | N17605 001 |



CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

| | | |
|---|---|---|
| ISOCLOR | | |
| CIBA | 8MG;120MG | N18747 001<br>MAR 06, 1986 |
| /FISONS/ | /8MG;120MG/ | /N18747/001/<br>/MAR/06,/1986/ |

IBUPROFEN

TABLET; ORAL

| | | |
|---|---|---|
| IBUPROFEN | | |
| /LUCHEM/ | /200MG/ | /N72901/001/<br>/DEC/19,/1991/ |
| | /200MG/ | /N72903/001/<br>/DEC/19,/1991/ |
| IBUPROFEN | | |
| NORTON HN | 200MG | N71144 001<br>JAN 20, 1987 |
| | 200MG | N72901 001<br>DEC 19, 1991 |
| | 200MG | N72903 001<br>DEC 19, 1991 |
| IBUPROFEN | | |
| /ZENITH/ | /200MG/ | /N71154/001/<br>/OCT/27,/1987/ |
| ∂ ZENITH | 200MG | N71154 001<br>OCT 27, 1987 |
| /NEUVIL/<br>/LUCHEM/ | /200MG/ | /N71144/001/<br>/JAN/20,/1987/ |

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 2 / FEB '93

INDIUM$^{111}$ CHLORIDE

SOLUTION; INJECTION
INDICLOR
AMERSHAM N/A N19862
DEC 29, 1992

## LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
*[January thru February 1993]*

| NAME<br>*Generic/Chemical*<br>*TN=Trade Name* | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>*DD=Date Designated*<br>*MA=Marketing Approval* |
|---|---|---|
| COLFOSCERIL PALMITATE, CETYL ALCOHOL, TYLOXAPOL<br>TN= EXOSURF | TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME. | BURROUGHS WELLCOME COMPANY<br>3030 CORNWALLIS ROAD<br>RESEARCH TRIANGLE PK NC 27709<br>DD 01/11/93 MA / / |
| CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR GENE<br>TN= | TREATMENT OF CYSTIC FIBROSIS. | GENETIC THERAPY, INC.<br>19 FIRSTFIELD ROAD<br>GAITHERSBURG MD 20878<br>DD 01/08/93 MA / / |
| IMMUNE GLOBULIN INTRAVENOUS (HUMAN)<br>TN= GAMIMUNE N | INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS AFFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS. | MILES, INC.<br>4TH & PARKER STREETS<br>BERKELEY CA 94710<br>DD 02/18/93 MA / / |
| INTERFERON BETA, RECOMBINANT HUMAN<br>TN= | TREATMENT OF PRIMARY BRAIN TUMORS. | BIOGEN, INC.<br>14 CAMBRIDGE CENTER<br>CAMBRIDGE MA 02142<br>DD 01/13/93 MA / / |
| MONOCLONAL ANTIBODY FOR IMMUNIZATION AGAINST LUPUS NEPHRITIS<br>TN= | TREATMENT OF LUPUS NEPHRITIS. | MEDCLONE, INC.<br>2435 MILITARY AVENUE<br>LOS ANGELES CA 90064<br>DD 01/07/93 MA / / |
| SOMATROPIN<br>TN= BIOTROPIN | TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS. | BIO-TECHNOLOGY GENERAL CORPORATION<br>1250 BROADWAY, 20th FLOOR<br>NEW YORK NY 10001<br>DD 02/12/93 MA / / |
| THALIDOMIDE<br>TN= | TREATMENT OF THE CLINICAL MANIFESTATIONS OF MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA. | CELGENE CORPORATION<br>7 POWDER HORN DRIVE<br>WARREN NJ 07059<br>DD 01/12/93 MA / / |
| TRETINOIN<br>TN= TRETINOIN LF, IV | TREATMENT OF ACUTE AND CHRONIC LEUKEMIA. | ARGUS PHARMACEUTICALS, INC.<br>3400 RESEARCH FOREST DRIVE<br>THE WOODLANDS TX 77381<br>DD 01/14/93 MA / / |
| TUMOR NECROSIS FACTOR-BINDING PROTEIN 1<br>TN= | TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 COUNTS LESS THAN 200 CELLS PER MM3. | SERONO LABORATORIES, INC.<br>100 LONGWATER CIRCLE<br>NORWELL MA 02061<br>DD 01/06/93 MA / / |
| TUMOR NECROSIS FACTOR-BINDING PROTEIN II<br>TN= | TREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM3. | SERONO LABORATORIES, INC.<br>100 LONGWATER CIRCLE<br>NORWELL MA 02061<br>DD 01/06/93 MA / / |

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

---

NO FEBRUARY 1993 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

| DRUG NAME (DOSAGE FORM) | DATE | REVISED DATE |
|---|---|---|

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| | | |
|---|---|---|
| TRIAZOLAM (TABLET) | DEC 24, 1992 | |

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| CHLORPROMAZINE HYDROCHLORIDE<br>SOLUTION; ORAL | 25MG/5ML | 92 P-0284/<br>CP1 | UDL | NEW STRENGTH | APPROVED<br>JAN 07, 1993 |
| DOBUTAMINE HYDROCHLORIDE<br>INJECTABLE; INJECTION | EQ 12.5MG BASE/ML<br>(40ML/VIAL) | 92 P-0365/<br>CP1 | LYPHOMED | NEW STRENGTH | APPROVED<br>FEB 11, 1993 |
| ETOPOSIDE<br>INJECTABLE; INJECTION | 20MG/ML<br>(12.5MG/VIAL) | 92 P-0355/<br>CP1 | LEDERLE | NEW STRENGTH | APPROVED<br>JAN 07, 1993 |
| ETOPOSIDE<br>INJECTABLE; INJECTION | 20MG/ML<br>(50ML/CONTAINER) | 91 P-0460/<br>CP1 | ABBOTT | NEW STRENGTH | APPROVED<br>FEB 11, 1993 |
| LACTULOSE<br>CRYSTAL; ORAL | 10GM/PACKET | 92 P-0370/<br>CP1 | BENNETT AND COMPANY | NEW DOSAGE<br>FORM | APPROVED<br>JAN 07, 1993 |

## EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

### REFERENCES
*NEW INDICATION*

| | |
|---|---|
| I-87 | RENAL IMAGING AGENT FOR USE IN CHILDREN |
| I-88 | MANAGEMENT OF ENDOMETRIOSIS |

### REFERENCES
*PATENT USE CODE*

| | |
|---|---|
| U-74 | METHOD OF PROVIDING HYPNOTIC EFFECT |
| U-75 | RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS |
| U-76 | USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| | 19604 001 | ALBUTEROL SULFATE; VOLMAX | 4851229 | JUN 14, 2005 | | | |
| | | | 4777049 | OCT 11, 2005 | | | |
| | | | 4751071 | JUN 14, 2005 | | | |
| | 19604 002 | ALBUTEROL SULFATE; VOLMAX | 4851229 | JUN 14, 2005 | | | |
| | | | 4777049 | OCT 11, 2005 | | | |
| | | | 4751071 | JUN 14, 2005 | | NS | DEC 23, 1995 |
| >ADD> | 20045 001 | AVOBENZONE; SHADE UVAGUARD | 4522807 | JUN 11, 2002 | | NC | DEC 07, 1995 |
| | | | 4387089 | JUN 07, 2002 | | | |
| >ADD> | 19807 001 | BETAXOLOL HYDROCHLORIDE; KERLEDEX | 4252984 | AUG 30, 1999 | | | |
| >DLT> | ~~19807 001~~ | ~~BETAXOLOL HYDROCHLORIDE; KERLEDEX~~ | ~~4252984~~ | ~~FEB 24, 1998~~ | | | |
| >ADD> | 19807 002 | BETAXOLOL HYDROCHLORIDE; KERLEDEX | 4252984 | AUG 30, 1999 | | | |
| >DLT> | ~~19807 002~~ | ~~BETAXOLOL HYDROCHLORIDE; KERLEDEX~~ | ~~4252984~~ | ~~FEB 24, 1998~~ | | | |
| >ADD> | 20229 001 | CLADRIBINE; LEUSTATIN | | | | NCE | FEB 26, 1998 |
| | 18651 001 | DRONABINOL; MARINOL | | | | ODE | DEC 22, 1999 |
| | 18651 002 | DRONABINOL; MARINOL | | | | ODE | DEC 22, 1999 |
| | 18651 003 | DRONABINOL; MARINOL | | | | ODE | DEC 22, 1999 |
| >ADD> | 19616 004 | ENOXACIN; PENETREX | 4359578 | NOV 16, 2001 | | NCE | DEC 31, 1996 |
| >DLT> | ~~19616 004~~ | ~~ENOXACIN; PENETREX~~ | ~~4359578~~ | ~~NOV 11, 1999~~ | | ~~NCE~~ | ~~DEC 31, 1996~~ |
| >ADD> | 19616 005 | ENOXACIN; PENETREX | 4359578 | NOV 16, 2001 | | NCE | DEC 31, 1996 |
| >DLT> | ~~19616 005~~ | ~~ENOXACIN; PENETREX~~ | ~~4359578~~ | ~~NOV 11, 1999~~ | | ~~NCE~~ | ~~DEC 31, 1996~~ |
| >ADD> | 20073 001 | FLUMAZENIL; MAZICON | 4316839 | MAR 03, 2003 | | NCE | DEC 20, 1996 |
| >DLT> | ~~20073 001~~ | ~~FLUMAZENIL; MAZICON~~ | ~~4316839~~ | ~~FEB 23, 1999~~ | | ~~NCE~~ | ~~DEC 20, 1996~~ |
| >ADD> | 20068 001 | FOSCARNET SODIUM; FOSCAVIR | 4215113 | JUN 06, 2000 | U-64 | NCE | SEP 27, 1996 |
| >DLT> | ~~20068 001~~ | ~~FOSCARNET SODIUM; FOSCAVIR~~ | ~~4215113~~ | ~~JUL 29, 1997~~ | ~~U-64~~ | ~~NCE~~ | ~~SEP 27, 1996~~ |
| | 20123 001 | GADODIAMIDE; OMNISCAN | 4687659 | AUG 18, 2004 | U-76 | NCE | JAN 08, 1998 |
| >ADD> | 19726 001 | GOSERELIN ACETATE; ZOLADEX | | | | I-88 | FEB 02, 1996 |
| | 19891 001 | HYDROMORPHONE HYDROCHLORIDE; DILAUDID | | | | NCE | JAN 11, 1994 |
| | 19892 001 | HYDROMORPHONE HYDROCHLORIDE; DILAUDID | | | | NCE | JAN 11, 1994 |
| >ADD> | 19084 001 | KETOCONAZOLE; NIZORAL | 4335125 | JUN 15, 1999 | | I-30 | JAN 27, 1996 |
| | 19700 001 | KETOROLAC TROMETHAMINE; ACULAR | 5110493 | MAY 05, 2009 | U-75 | NCE | NOV 30, 1994 |
| | | | 4454151 | JUN 12, 2001 | U-75 | NDF | NOV 09, 1995 |
| | | | 4089969 | MAY 16, 1997 | U-75 | | |
| | 18948 001 | LEVOCARNITINE; CARNITOR | | | | I-86 | DEC 16, 1995 |
| | 18948 002 | LEVOCARNITINE; CARNITOR | | | | I-86 | DEC 16, 1995 |
| >ADD> | 20013 001 | LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN | 4528287 | MAY 05, 2005 | U-36 | NCE | FEB 21, 1997 |
| >DLT> | ~~20013 001~~ | ~~LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN~~ | ~~4528287~~ | ~~JUL 09, 2002~~ | ~~U-36~~ | ~~NCE~~ | ~~FEB 21, 1997~~ |
| | 17659 001 | METAPROTERENOL SULFATE; ALUPENT | | | | I-67 | NOV 14, 1994 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 20098 001 | MIVACURIUM CHLORIDE; MIVACRON | 4761418 | JAN 22, 2006 | | NCE | JAN 22, 1997 |
| >DLT> | ~~20098 001~~ | ~~MIVACURIUM CHLORIDE; MIVACRON~~ | ~~4761418~~ | ~~AUG 02, 2005~~ | | ~~NCE~~ | ~~JAN 22, 1997~~ |
| >ADD> | 20098 002 | MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5% | 4761418 | JAN 22, 2006 | | NCE | JAN 22, 1997 |
| >DLT> | ~~20098 002~~ | ~~MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%~~ | ~~4761418~~ | ~~AUG 02, 2005~~ | | ~~NCE~~ | ~~JAN 22, 1997~~ |
| >ADD> | 19583 001 | NABUMETONE; RELAFEN | 4420639 | DEC 13, 2002 | | NCE | DEC 24, 1996 |
| >DLT> | ~~19583 001~~ | ~~NABUMETONE; RELAFEN~~ | ~~4420639~~ | ~~DEC 13, 2000~~ | | ~~NCE~~ | ~~DEC 24, 1996~~ |
| >ADD> | 19583 002 | NABUMETONE; RELAFEN | 4420639 | DEC 13, 2002 | | NCE | DEC 24, 1996 |
| >DLT> | ~~19583 002~~ | ~~NABUMETONE; RELAFEN~~ | ~~4420639~~ | ~~DEC 13, 2000~~ | | ~~NCE~~ | ~~DEC 24, 1996~~ |
| | 20109 001 | NAFARELIN ACETATE; SYNAREL | 4234571 | NOV 18, 1999 | | NCE | FEB 13, 1995 |
| | 20150 001 | NICOTINE; NICOTROL | 4915950 | APR 10, 2007 | | NP | APR 22, 1995 |
| | 20150 002 | NICOTINE; NICOTROL | 4915950 | APR 10, 2007 | | NP | APR 22, 1995 |
| | 20150 003 | NICOTINE; NICOTROL | 4915950 | APR 10, 2007 | | NP | APR 22, 1995 |
| | 20066 001 | NICOTINE POLACRILEX; NICORETTE DS | | | | NCE | JAN 13, 1994 |
| | 20103 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4695578 | SEP 22, 2004 | | NCE | JAN 04, 1996 |
| | 20103 002 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4695578 | SEP 22, 2004 | | NCE | JAN 04, 1996 |
| >ADD> | 20036 001 | PAMIDRONATE DISODIUM; AREDIA | 3962432 | FEB 01, 1997 | U-53 | | |
| >DLT> | ~~20036 001~~ | ~~PAMIDRONATE DISODIUM; AREDIA~~ | ~~3962432~~ | ~~FEB 16, 1993~~ | ~~U-53~~ | | |
| >ADD> | 19568 001 | PREDNICARBATE; DERMATOP | 4242334 | DEC 30, 1999 | U-50 | NE | SEP 23, 1994 |
| >DLT> | ~~19568 001~~ | ~~PREDNICARBATE; DERMATOP~~ | ~~4242334~~ | ~~DEC 30, 1997~~ | ~~U-50~~ | ~~NE~~ | ~~SEP 23, 1994~~ |
| | 50689 001 | RIFABUTIN; MYCOBUTIN | | | | ODE | DEC 23, 1999 |
| >ADD> | 19839 001 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4536518 | DEC 31, 2005 | | NCE | DEC 30, 1996 |
| >DLT> | ~~19839 001~~ | ~~SERTRALINE HYDROCHLORIDE; ZOLOFT~~ | ~~4536518~~ | ~~AUG 20, 2002~~ | | ~~NCE~~ | ~~DEC 30, 1996~~ |
| >ADD> | 19839 002 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4536518 | DEC 31, 2005 | | NCE | DEC 30, 1996 |
| >DLT> | ~~19839 002~~ | ~~SERTRALINE HYDROCHLORIDE; ZOLOFT~~ | ~~4536518~~ | ~~AUG 20, 2002~~ | | ~~NCE~~ | ~~DEC 30, 1996~~ |
| >ADD> | 19839 003 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4536518 | DEC 31, 2005 | | NCE | DEC 30, 1996 |
| >DLT> | ~~19839 003~~ | ~~SERTRALINE HYDROCHLORIDE; ZOLOFT~~ | ~~4536518~~ | ~~AUG 20, 2002~~ | | ~~NCE~~ | ~~DEC 30, 1996~~ |
| >ADD> | 19839 004 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4536518 | DEC 31, 2005 | | NCE | DEC 30, 1996 |
| >DLT> | ~~19839 004~~ | ~~SERTRALINE HYDROCHLORIDE; ZOLOFT~~ | ~~4536518~~ | ~~AUG 20, 2002~~ | | ~~NCE~~ | ~~DEC 30, 1996~~ |
| >ADD> | 19766 001 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1997 |
| >DLT> | ~~19766 001~~ | ~~SIMVASTATIN; ZOCOR~~ | ~~4444784~~ | ~~APR 24, 2001~~ | ~~U-59~~ | ~~NCE~~ | ~~DEC 23, 1997~~ |
| >ADD> | 19766 002 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1997 |
| >DLT> | ~~19766 002~~ | ~~SIMVASTATIN; ZOCOR~~ | ~~4444784~~ | ~~APR 24, 2001~~ | ~~U-59~~ | ~~NCE~~ | ~~DEC 23, 1997~~ |
| >ADD> | 19766 003 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1997 |
| >DLT> | ~~19766 003~~ | ~~SIMVASTATIN; ZOCOR~~ | ~~4444784~~ | ~~APR 24, 2001~~ | ~~U-59~~ | ~~NCE~~ | ~~DEC 23, 1997~~ |
| >ADD> | 19766 004 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1997 |
| >DLT> | ~~19766 004~~ | ~~SIMVASTATIN; ZOCOR~~ | ~~4444784~~ | ~~APR 24, 2001~~ | ~~U-59~~ | ~~NCE~~ | ~~DEC 23, 1997~~ |
| | 20080 001 | SUMATRIPTAN SUCCINATE; IMITREX | 4816470 | MAR 28, 2006 | U-72 | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 19882 001 | TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3 | | | | I-87 | NOV 27, 1995 |
| >ADD> | 20043 003 | TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX | 4730000 | JAN 30, 2006 | U-36 | NCE | JAN 30, 1997 |
| >DLT> | ~~20043 003~~ | ~~TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX~~ | ~~4730000~~ | ~~MAR 08, 2005~~ | ~~U-36~~ | ~~NCE~~ | ~~JAN 30, 1997~~ |
| >ADD> | 20043 004 | TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX | 4730000 | JAN 30, 2006 | U-36 | NCE | JAN 30, 1997 |
| >DLT> | ~~20043 004~~ | ~~TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX~~ | ~~4730000~~ | ~~MAR 08, 2005~~ | ~~U-36~~ | ~~NCE~~ | ~~JAN 30, 1997~~ |
| >ADD> | 18163 003 | TEMAZEPAM; RESTORIL | 5030632 | JUL 09, 2008 | U-70 | NS | OCT 25, 1994 |
| >DLT> | ~~19979 001~~ | ~~TICLOPIDINE HYDROCHLORIDE; TICLID~~ | ~~4051141~~ | ~~SEP 27, 1994~~ | | ~~NCE~~ | ~~OCT 31, 1996~~ |
| >DLT> | ~~19979 001~~ | ~~TICLOPIDINE HYDROCHLORIDE; TICLID~~ | ~~4591592~~ | ~~MAY 27, 2003~~ | | | |
| >ADD> | 19979 002 | TICLOPIDINE HYDROCHLORIDE; TICLID | 4051141 | SEP 27, 1996 | | NCE | OCT 31, 1996 |
| >DLT> | ~~19979 002~~ | ~~TICLOPIDINE HYDROCHLORIDE; TICLID~~ | ~~4051141~~ | ~~SEP 27, 1994~~ | | ~~NCE~~ | ~~OCT 31, 1996~~ |
| >ADD> | 19979 002 | TICLOPIDINE HYDROCHLORIDE; TICLID | 4591592 | NOV 01, 2005 | | | |
| >DLT> | ~~19979 002~~ | ~~TICLOPIDINE HYDROCHLORIDE; TICLID~~ | ~~4591592~~ | ~~MAY 27, 2003~~ | | | |
| >ADD> | 18776 003 | VECURONIUM BROMIDE; NORCURON | 4297351 | OCT 27, 1998 | | | |
| >ADD> | | | 4237126 | DEC 02, 1997 | | NCE | APR 30, 1994 |
| | 19908 001 | ZOLPIDEM TARTRATE; AMBIEN | 4382938 | MAY 10, 2000 | U-74 | NCE | DEC 16, 1997 |
| | 19908 002 | ZOLPIDEM TARTRATE; AMBIEN | 4382938 | MAY 10, 2000 | U-74 | NCE | DEC 16, 1997 |

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 19862 001 | INDIUM 111 CHLORIDE; INDICLOR | | | | NCE | DEC 29, 1997 |

*U.S. Government Printing Office: 1993 — 342-345/60009