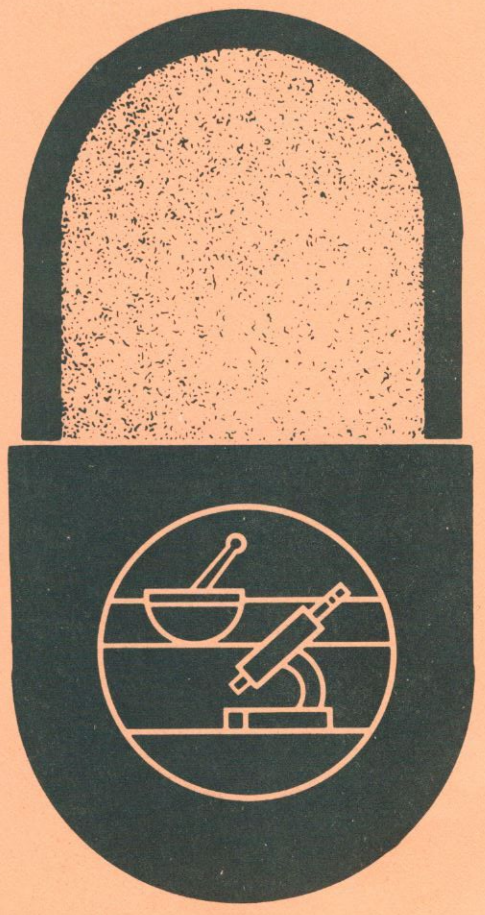
# CUMULATIVE SUPPLEMENT 2

## JAN'91-FEB'91



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

## 11TH EDITION

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

# APPROVED DRUG PRODUCTS

# with

# THERAPEUTIC EQUIVALENCE EVALUATIONS

# 11TH EDITION

## CUMULATIVE SUPPLEMENT 2

## FEBRUARY 1991

## CONTENTS

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# FEBRUARY 1991

## 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, 11th 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 Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 Division of Blood and Blood Products 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, along with the application number and product number (FDA's internal file number). 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. A newly approved product is also identified by a lozenge ( ⌘ ) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

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 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th 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

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 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) | NEW APPLICANT (NAME) | ABBREVIATED NAME |
|---|---|---|
| CORD LABORATORIES INC | GENEVA PHARMACEUTICALS INC | GENEVA |
| PHARMACIA LABORATORIES DIV PHARMACIA INC | KABI PHARMACIA | KABI |

## 1.4 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 1990) 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 1990 | MAR 1991 | JUN 1991 | SEP 1991 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 10003 | | | |
| SINGLE SOURCE | 2090 (20.9%) | | | |
| MULTISOURCE | 7913 (79.1%) | | | |
| THERAPEUTICALLY EQUIVALENT | 7093 (70.9%) | | | |
| NOT THERAPEUTICALLY EQUIVALENT | 685 ( 6.9%) | | | |
| EXCEPTIONS[1] | 135 ( 1.3%) | | | |
| NEW MOLECULAR ENTITIES APPROVED | -- | | | |
| NUMBER OF APPLICANTS | 424 | | | |

[1]Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

## ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE

| | | | |
|---|---|---|---|
| AB | DANBURY | EQ 2MG BASE | N72629 001<br>JAN 31, 1991 |
| AB | | EQ 4MG BASE | N72630 001<br>JAN 31, 1991 |
| AB | MYLAN | EQ 2MG BASE | N72893 001<br>JAN 17, 1991 |
| AB | | EQ 4MG BASE | N72894 001<br>JAN 17, 1991 |

## ALLOPURINOL

TABLET; ORAL
ALLOPURINOL

| | | | |
|---|---|---|---|
| /AB/ | /PUREPAC/ | /100MG/ | /N70579/001/<br>/APR/14,/1986/ |
| /AB/ | | /300MG/ | /N70580/001/<br>/APR/14,/1986/ |
| | ə PUREPAC | 100MG | N70579 001<br>APR 14, 1986 |
| | ə | 300MG | N70580 001<br>APR 14, 1986 |

## ALPRAZOLAM

TABLET; ORAL
XANAX

| | | | |
|---|---|---|---|
| /3/ | /UPJOHN/ | /2MG/ | /N18276/004/<br>/NOV/27,/1985/ |
| | UPJOHN | 2MG | N18276 004<br>NOV 27, 1985 |

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

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

| | | | |
|---|---|---|---|
| /AP/ | /ARMOUR/ | /100MG/VIAL;0.06MG/VIAL;/<br>/0.005MG/VIAL;15MG/VIAL;5UGM/VIAL;/<br>/0.4MG/VIAL;40MG/VIAL;4MG/VIAL;/<br>/3.6MG/VIAL;3MG/VIAL;1MG/VIAL;/<br>/10MG/VIAL/ | /N18933/002/<br>/AUG/08,/1985/ |

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

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

| | | | |
|---|---|---|---|
| AP | ASTRA | 100MG/VIAL;0.06MG/VIAL;<br>0.005MG/VIAL;15MG/VIAL;5UGM/VIAL;<br>0.4MG/VIAL;40MG/VIAL;4MG/VIAL;<br>3.6MG/VIAL;3MG/VIAL;1MG/VIAL;<br>10MG/VIAL | N18933 002<br>AUG 08, 1985 |

## BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

| | | | | | |
|---|---|---|---|---|---|
| >DLT> | /AB/ | /CORD/ | /15MG/ | | /N84292/003/<br>/FEB/09,/1982/ |
| >DLT> | | | | | |
| >DLT> | /AB/ | | /30MG/ | | /N84272/002/ |
| >ADD> | | ə CORD | 15MG | | N84292 003<br>FEB 09, 1982 |
| >ADD> | | ə | 30MG | | N84272 002 |
| >DLT> | /AB/ | /WHITE/TOWNE/PAULSEN/ | /15MG/ | | /N83325/002/ |
| >ADD> | | ə WHITE TOWNE PAULSEN | 15MG | | N83325 002 |

## CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

| | | | | |
|---|---|---|---|---|
| >DLT> | /INJECTABLE;/INJECTION/ | | | |
| >DLT> | /ACETATED/RINGER'S/IN/PLASTIC/CONTAINER/ | | | |
| >DLT> | /MCGAW/ | /20MG/100ML;30MG/100ML;380MG/100ML;/ | | |
| >DLT> | | /600MG/100ML/ | | /N18725/001/ |
| >DLT> | | | | /NOV/29,/1982/ |
| >ADD> | ə MCGAW | 20MG/100ML;30MG/100ML;380MG/100ML; | | |
| >ADD> | | 600MG/100ML | | N18725 001 |
| >ADD> | | | | NOV 29, 1982 |

## CALCIUM GLUCEPTATE

INJECTABLE; INJECTION
CALCIUM GLUCEPTATE

| | | | |
|---|---|---|---|
| /AP/ | /ABBOTT/ | /EQ 90MG CALCIUM/5ML/ | /N83159/001/ |
| | ə ABBOTT | EQ 90MG CALCIUM/5ML | N83159 001 |

## CEPHRADINE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| > DLT > | /VELOSEF '250'/ | | /N50548/001/ | |
| > DLT >/AB/ | /ERSANA/ | /250MG/ | N50548 001 | |
| > ADD > | ə ERSANA | 250MG | | |
| > DLT > | /VELOSEF '500'/ | | /N50548/002/ | |
| > DLT >/AB/ | /ERSANA/ | /500MG/ | N50548 002 | |
| > ADD > | ə ERSANA | 500MG | | |

## CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLORPHENIRAMINE MALEATE

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /10MG/ML/ | /N83593/001/ | |
| > ADD > AP | STERIS | 10MG/ML | N83593 001 | |

## CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /25MG/ML/ | /N85591/001/ | |
| > ADD > AP | STERIS | 25MG/ML | N85591 001 | |

## CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

| | | | | |
|---|---|---|---|---|
| /AB/ | /SUPERPHARM/ | /25MG/ | /N87473/001/ /FEB/09,/1983/ | |
| | ə SUPERPHARM | 25MG | N87473 001 FEB 09, 1983 | |

## CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /EQ 150MG BASE/ML/ | /N62900/001/ /JUN/08,/1988/ | |
| > DLT > | | | | |
| > DLT >/AP/ | | /EQ 150MG BASE/ML/ | /N63079/001/ /MAR/05,/1990/ | |
| > DLT > | | | | |
| > ADD > AP | STERIS | EQ 150MG BASE/ML | N62900 001 JUN 08, 1988 | |
| > ADD > | | | | |
| > ADD > AP | | EQ 150MG BASE/ML | N63079 001 MAR 05, 1990 | |
| > ADD > | | | | |

## CORTISONE ACETATE

INJECTABLE; INJECTION
CORTISONE ACETATE

| | | | | |
|---|---|---|---|---|
| > DLT > /BP/ | /LEMMON/ | /25MG/ML/ | /N85677/001/ | |
| > DLT > /BP/ | | /50MG/ML/ | /N85677/002/ | |
| > ADD > BP | STERIS | 25MG/ML | N85677 001 | |
| > ADD > BP | | 50MG/ML | N85677 002 | |

## CYANOCOBALAMIN

INJECTABLE; INJECTION
COBAVITE

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /0.1MG/ML/ | /N83013/001/ | |
| > DLT >/AP/ | | /1MG/ML/ | /N83064/001/ | |
| > ADD > AP | STERIS | 0.1MG/ML | N83013 001 | |
| > ADD > AP | | 1MG/ML | N83064 001 | |

CYANOCOBALAMIN

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /0.1MG/ML/ | /N83120/001/ | |
| > DLT >/AP/ | | /1MG/ML/ | /N83120/002/ | |
| > ADD > AP | STERIS | 0.1MG/ML | N83120 001 | |
| > ADD > AP | | 1MG/ML | N83120 002 | |

## CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL

| | | | | |
|---|---|---|---|---|
| AT | STERIS | 1% | | N89162 001 JAN 24, 1991 |

## DESMOPRESSIN ACETATE

SOLUTION; NASAL
CONCENTRAID

| | | | | |
|---|---|---|---|---|
| BX | FERRING | 0.01% | | N19776 001 DEC 26, 1990 |
| | | /0.01%/ | | /N19776/001/ /DEC/26,/1990/ |

DDAVP

| | | | | |
|---|---|---|---|---|
| BX | RHONE POULENC RORER | 0.01% | | N17922 001 |
| | | /0.01%/ | | /N17922/001/ |

## DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
/DEXACEN-4/

| | | | | |
|---|---|---|---|---|
| > DLT > | | | | |
| > DLT >/AP/ | /CENTRAL/PHARMS/ | /EQ 4MG PHOSPHATE/ML/ | /N84342/001/ | |
| > ADD > | ə CENTRAL PHARMS | EQ 4MG PHOSPHATE/ML | N84342 001 | |

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /EQ 4MG PHOSPHATE/ML/ | /N84355/001/ |
| > ADD > | AP | STERIS | EQ 4MG PHOSPHATE/ML | N84355 001 |

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /CUTTER/ | /10GM/100ML/ | /N18504/001/ |
| > ADD > | | @ CUTTER | 10GM/100ML | N18504 001 |

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /MCGAW/ | /5GM/100ML;220MG/100ML; | |
| > DLT > | | | /450MG/100ML/ | /N18268/002/ |
| > ADD > | | MCGAW | 5GM/100ML;220MG/100ML; | |
| > ADD > | | | 450MG/100ML | N18268 002 |

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /CUTTER/ | /5GM/100ML;200MG/100ML/ | /N18399/001/ |
| > ADD > | | @ CUTTER | 5GM/100ML;200MG/100ML | N18399 001 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /ABBOTT/ | /5GM/100ML;300MG/100ML/ | /N17799/001/ |
| > ADD > | | ABBOTT | 5GM/100ML;300MG/100ML | N17799 001 |
| > DLT > | /AP/ | /CUTTER/ | /5GM/100ML;300MG/100ML/ | /N18501/001/ |
| > ADD > | | @ CUTTER | 5GM/100ML;300MG/100ML | N18501 001 |

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /CUTTER/ | /5GM/100ML;450MG/100ML/ | /N18400/001/ |
| > ADD > | | @ CUTTER | 5GM/100ML;450MG/100ML | N18400 001 |

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /5MG/ML/ | /N70911/001/ |
| > DLT > | | | | /AUG/28,/1986/ |
| > DLT > | /AP/ | | /5MG/ML/ | /N70912/001/ |
| > DLT > | | | | /AUG/28,/1986/ |
| > DLT > | /AP/ | | /5MG/ML/ | /N70930/001/ |
| > DLT > | | | | /DEC/01,/1986/ |

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

| | | | | |
|---|---|---|---|---|
| > ADD > | AP | STERIS | 5MG/ML | N70911 001 |
| > ADD > | | | | AUG 28, 1986 |
| > ADD > | AP | | 5MG/ML | N70912 001 |
| > ADD > | | | | AUG 28, 1986 |
| > ADD > | AP | | 5MG/ML | N70930 001 |
| > ADD > | | | | DEC 01, 1986 |

DIMENHYDRINATE

INJECTABLE; INJECTION

DIMENHYDRINATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /50MG/ML/ | /N83531/001/ |
| > ADD > | AP | STERIS | 50MG/ML | N83531 001 |

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DIPHENHYDRAMINE HCL

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /10MG/ML/ | /N83533/001/ |
| > ADD > | AP | STERIS | 10MG/ML | N83533 001 |

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

| | | | | |
|---|---|---|---|---|
| > ADD > | AB | LEDERLE | 25MG | N88999 001 |
| > ADD > | | | | FEB 05, 1991 |
| > ADD > | AB | | 50MG | N89000 001 |
| > ADD > | | | | FEB 05, 1991 |
| > ADD > | AB | | 75MG | N89001 001 |
| > ADD > | | | | FEB 05, 1991 |

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTREX

| | | | |
|---|---|---|---|
| > ADD > | LILLY | EQ 12.5MG BASE/ML | N17820 002 |
| > DLT > | | /EQ/250MG/BASE/VIAL/ | /N17820/002/ |

## DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

**ADRIAMYCIN PFS**

| | | | |
|---|---|---|---|
| AP | ADRIA | 2MG/ML | N50629 001 DEC 23, 1987 |
| AP | | 200MG/100ML | N50629 002 MAY 03, 1988 |
| AP | | 2MG/ML¤ | N63165 001 JAN 30, 1991 |
| AP | | 200MG/100ML¤ | N63165 002 JAN 30, 1991 |
| | /2MG/ML/ | | /N50629/002/ /MAY/03,/1988/ |

**DOXORUBICIN HCL**

| | | | |
|---|---|---|---|
| AP | CETUS BEN VENUE | 2MG/ML | N62975 001 MAR 17, 1989 |

## DROPERIDOL

INJECTABLE; INJECTION

**DROPERIDOL**

| | | | |
|---|---|---|---|
| /AP/ | /ASTRA/ | /2.5MG/ML/ | /N72020/001/ /OCT/19,/1988/ |
| | ə ASTRA | 2.5MG/ML | N72020 001 OCT 19, 1988 |

## EDETATE DISODIUM

INJECTABLE; INJECTION

**DISODIUM EDETATE**

| | | | | |
|---|---|---|---|---|
| >DLT> | /AP/ | /LEMMON/ | /150MG/ML/ | /N84356/001/ |
| >ADD> | AP | STERIS | 150MG/ML | N84356 001 |

## EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL W/ EPINEPHRINE

| | | | | |
|---|---|---|---|---|
| >DLT> | /3/ | /LEMMON/ | /0.01MG/ML;1%/ | /N85463/001/ |
| >ADD> | | ə STERIS | 0.01MG/ML;1% | N85463 001 |

## ERGOLOID MESYLATES

TABLET; SUBLINGUAL

~~/DEAPRIL-ST/~~

| | | | | |
|---|---|---|---|---|
| /AA/ | | /BRISTOL/MYERS/SQUIBB/1MG/ | | /N85020/002/ |
| | ə BRISTOL MYERS SQUIBB 1MG | | | N85020 002 |

## ERYTHROMYCIN

SOLUTION; TOPICAL

**ERYTHROMYCIN**

| | | | | |
|---|---|---|---|---|
| AT | CLAY PARK | 2%¤ | | N63038 001 JAN 11, 1991 |

## ESTROGENS, CONJUGATED

TABLET; ORAL

CONJUGATED ESTROGENS

| | | | | |
|---|---|---|---|---|
| >DLT> | /BP/ | /DURAMED/ | /0.3MG/ | /N86492/001/ |
| >ADD> | BP | ə DURAMED | 0.3MG | N86492 001 |
| >DLT> | /BP/ | | /0.625MG/ | /N83272/001/ |
| >ADD> | BP | ə | 0.625MG | N83272 001 |
| >DLT> | /BP/ | | /1.25MG/ | /N83294/001/ |
| >ADD> | BP | ə | 1.25MG | N83294 001 |
| >DLT> | /BP/ | | /2.5MG/ | /N83295/001/ |
| >ADD> | BP | ə | 2.5MG | N83295 001 |

## ESTROPIPATE

TABLET; ORAL

**OGEN**

| | | | | |
|---|---|---|---|---|
| >ADD> | AB | ABBOTT | 0.75MG | N83220 001 |

**ORTHO-EST**

| | | | | |
|---|---|---|---|---|
| >ADD> | AB | JOHNSON RW | 0.75MG¤ | N89567 001 FEB 27, 1991 |

## ETODOLAC

CAPSULE; ORAL

LODINE

| | | | |
|---|---|---|---|
| WYETH AYERST | 200MG¤ | | N18922 002 JAN 31, 1991 |
| | 300MG¤ | | N18922 003 JAN 31, 1991 |

## GALLIUM NITRATE

INJECTABLE; INJECTION

GANITE

| | | | |
|---|---|---|---|
| FUJISAWA PHARM | 25MG/ML¤ | | N19961 002 JAN 17, 1991 |

## HALOBETASOL PROPIONATE

CREAM; TOPICAL
ULTRAVATE
/BRISTOL/MYERS/SQUIBB/0.05%/ /N19967/001/ /DEC/27,/1990/

| | | |
|---|---|---|
| WESTWOOD SQUIBB | 0.05% | N19967 001 DEC 27, 1990 |

OINTMENT; TOPICAL
ULTRAVATE
/BRISTOL/MYERS/SQUIBB/0.05%/ /N19968/001/ /DEC/17,/1990/

| | | |
|---|---|---|
| WESTWOOD SQUIBB | 0.05% | N19968 001 DEC 17, 1990 |

## HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /EQ 5MG BASE/ML/ | /N70713/001/ /MAY/17,/1988/ | |
| > DLT > | | | | |
| > DLT >/AP/ | | /EQ 5MG BASE/ML/ | /N70714/001/ /MAY/17,/1988/ | |
| > DLT > | | | | |
| > DLT >/AP/ | | /EQ 5MG BASE/ML/ | /N70744/001/ /MAY/17,/1988/ | |
| > DLT > | | | | |
| > ADD > AP | STERIS | EQ 5MG BASE/ML | N70713 001 MAY 17, 1988 | |
| > ADD > | | | | |
| > ADD > AP | | EQ 5MG BASE/ML | N70714 001 MAY 17, 1988 | |
| > ADD > | | | | |
| > ADD > AP | | EQ 5MG BASE/ML | N70744 001 MAY 17, 1988 | |
| > ADD > | | | | |

## HEPARIN SODIUM

INJECTABLE; INJECTION
> DLT > /HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%/
> DLT >/AP/ /ABBOTT/ /10,000 UNITS/100ML/ /N18911/006/ /JAN/30,/1985/
> DLT >
> ADD > @ ABBOTT 10,000 UNITS/100ML N18911 006 JAN 30, 1985
> ADD >

## HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL

| | | | | |
|---|---|---|---|---|
| > DLT >/AP/ | /SOLOPAK/ | /20MG/ML/ | /N88517/001/ /AUG/22,/1985/ | |
| > DLT > | | | | |
| > ADD > | @ SOLOPAK | 20MG/ML | N88517 001 AUG 22, 1985 | |
| > ADD > | | | | |

## HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| /BP/ | /CORD/ | /50MG;0.125MG/ | /N88200/001/ /JAN/31,/1984/ | |
| | @ CORD | 50MG;0.125MG | N88200 001 JAN 31, 1984 | |

## HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| > DLT >/AT/ | /WHITE/TOWNE/PAULSEN//1%/ | | /N80496/002/ | |
| > ADD > | @ WHITE TOWNE PAULSEN | 1% | N80496 002 | |

## HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC
OTOCORT

| | | | | |
|---|---|---|---|---|
| > DLT >/AT/ | /LEMMON/ | /1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/ | /N60730/002/ | |
| > DLT > | | | | |
| > ADD > AT | STERIS | 1%;EQ 3.5MG BASE/ML; | | |
| > ADD > | | 10,000 UNITS/ML | N60730 002 | |

SUSPENSION; OTIC
OTOCORT

| | | | | |
|---|---|---|---|---|
| > DLT >/AT/ | /LEMMON/ | /1%;EQ 3.5MG BASE/ML;/ /10,000 UNITS/ML/ | /N62521/001/ /JUL/11,/1985/ | |
| > DLT > | | | | |
| > ADD > AT | STERIS | 1%;EQ 3.5MG BASE/ML; | | |
| > ADD > | | 10,000 UNITS/ML | N62521 001 JUL 11, 1985 | |
| > ADD > | | | | |

## HYDROCORTISONE ACETATE

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE

| | | | |
|---|---|---|---|
| > DLT > /BP/ | /LEMMON/ | /25MG/ML/ | /N83759/001/ |
| > DLT > /BP/ | | /50MG/ML/ | /N83759/002/ |
| > ADD > BP | STERIS | 25MG/ML | N83759 001 |
| > ADD > BP | | 50MG/ML | N83759 002 |

## HYDROCORTISONE BUTYRATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /CREAM;/TOPICAL/ | | | |
| > DLT > | /LOCOID/ | | | |
| > DLT > | /OWEN/GALDERMA/ | /0.1%/ | /N18795/001/ /JAN/07,/1983/ | |
| > DLT > | | | | |

## HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| DLT | LOCOID | | | |
| ADD | ∂ OWEN GALDERMA | 0.1% | N18795 001 | JAN 07, 1983 |

## HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

HYDROCORTISONE SODIUM SUCCINATE

| | | | | |
|---|---|---|---|---|
| DLT | AP LYPHOMED | EQ 100MG BASE/VIAL | N88712 001 | JUN 08, 1984 |
| DLT | | EQ 500MG BASE/VIAL | N88669 001 | JUN 08, 1984 |
| ADD | ∂ LYPHOMED | EQ 100MG BASE/VIAL | N88712 001 | JUN 08, 1984 |
| ADD | ∂ | EQ 500MG BASE/VIAL | N88669 001 | JUN 08, 1984 |

## HYDROXOCOBALAMIN

INJECTABLE; INJECTION

HYDROCOBALAMIN

| | | | | |
|---|---|---|---|---|
| DLT | AP LEMMON | 1MG/ML | N85528 001 | |
| ADD | AP STERIS | 1MG/ML | | |

## HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| DLT | AP LEMMON | 25MG/ML | N87274 001 | |
| DLT | AP LEMMON | 50MG/ML | N87274 002 | |
| ADD | AP STERIS | 25MG/ML | N87274 001 | |
| ADD | AP STERIS | 50MG/ML | N87274 002 | |

TABLET; ORAL

HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| AB | BARR | 10MG | N88409 001 | NOV 15, 1983 |
| | ∂ BARR | 10MG | N88409 001 | NOV 15, 1983 |

## INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

| | | | | |
|---|---|---|---|---|
| DLT | AB ROXANE | 25MG | N70353 001 | JUN 18, 1985 |
| DLT | | | | |
| ADD | ∂ ROXANE | 25MG | N70353 001 | JUN 18, 1985 |

## IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-M 200

| | | | | |
|---|---|---|---|---|
| ADD | SQUIBB | 41% | N18735 001 | DEC 31, 1985 |

ISOVUE-200

| | | | | |
|---|---|---|---|---|
| DLT | SQUIBB | 41% | N18735 001 | DEC 31, 1985 |
| DLT | | | | |
| ADD | SQUIBB | 41% | N18735 006 | JUL 07, 1987 |

## LEVONORGESTREL

IMPLANT; IMPLANTATION

LEVONORGESTREL SYSTEM

WYETH AYERST

| | | | | |
|---|---|---|---|---|
| | | 36MG/IMPLANT | N20088 001 | DEC 10, 1990 |

## LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

| | | | | |
|---|---|---|---|---|
| DLT | S LEMMON | 1% | N83627 001 | |
| DLT | S | 2% | N83627 002 | |
| ADD | ∂ STERIS | 1% | N83627 001 | |
| ADD | ∂ | 2% | N83627 002 | |

## LORAZEPAM

TABLET; ORAL
LORAZEPAM

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /BX/ | /AM/THERAP/ | /0.5MG/ | /N70727/001/ | |
| > DLT > | | | | /MAR/07,/1986/ | |
| > DLT > | /BX/ | | /1MG/ | /N70728/001/ | |
| > DLT > | | | | /MAR/07,/1986/ | |
| > DLT > | /BX/ | | /2MG/ | /N70729/001/ | |
| > DLT > | | | | /MAR/07,/1986/ | |
| > ADD > | | ∂ AM THERAP | 0.5MG | N70727 001 | |
| > ADD > | | | | MAR 07, 1986 | |
| > ADD > | | ∂ | 1MG | N70728 001 | |
| > ADD > | | | | MAR 07, 1986 | |
| > ADD > | | ∂ | 2MG | N70729 001 | |
| > ADD > | | | | MAR 07, 1986 | |

## MANNITOL

INJECTABLE; INJECTION
MANNITOL 10%

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AP/ | /CUTTER/ | /10GM/100ML/ | /N16472/002/ | |
| > ADD > | | ∂ CUTTER | 10GM/100ML | N16472 002 | |

MANNITOL 15%

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AP/ | /CUTTER/ | /15GM/100ML/ | /N16472/005/ | |
| > ADD > | | ∂ CUTTER | 15GM/100ML | N16472 005 | |

MANNITOL 20%

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AP/ | /CUTTER/ | /20GM/100ML/ | /N16472/004/ | |
| > ADD > | | ∂ CUTTER | 20GM/100ML | N16472 004 | |

## METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE

| | | | | | |
|---|---|---|---|---|---|
| | /AB/ | /AM/THERAP/ | /20MG/ | /N72055/001/ | |
| | | | | /JUN/23,/1988/ | |
| | | ∂ AM THERAP | 20MG | N72055 001 | |
| | | | | JUN 23, 1988 | |
| | AB | DANBURY | 10MG¤ | N73013 001 | |
| | | | | JAN 31, 1991 | |
| | AB | | 20MG¤ | N72795 001 | |
| | | | | JAN 31, 1991 | |

## METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /3/ | /LEMMON/ | /20MG/ML/ | /N87248/001/ | |
| > DLT > | /3/ | | /40MG/ML/ | /N85374/001/ | |
| > DLT > | /3/ | | /80MG/ML/ | /N86507/001/ | |

## METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

| | | | | |
|---|---|---|---|---|
| > ADD > | | ∂ STERIS | 20MG/ML | N87248 001 |
| > ADD > | | ∂ | 40MG/ML | N85374 001 |
| > ADD > | | ∂ | 80MG/ML | N86507 001 |

## METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-METHAPRED

| | | | | |
|---|---|---|---|---|
| > ADD > | AP | ABBOTT | EQ 40MG BASE/VIAL¤ | N89573 001 |
| > ADD > | | | | FEB 22, 1991 |
| > ADD > | AP | | EQ 125MG BASE/VIAL¤ | N89574 001 |
| > ADD > | | | | FEB 22, 1991 |
| > ADD > | AP | | EQ 500MG BASE/VIAL¤ | N89575 001 |
| > ADD > | | | | FEB 22, 1991 |
| > ADD > | AP | | EQ 1GM BASE/VIAL¤ | N89576 001 |
| > ADD > | | | | FEB 22, 1991 |

METHYLPREDNISOLONE SODIUM SUCCINATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LYPHOMED/ | /EQ 40MG BASE/VIAL/ | /N88676/001/ |
| > DLT > | | | | /JUN/08,/1984/ |
| > DLT > | /AP/ | | /EQ 125MG BASE/VIAL/ | /N88677/001/ |
| > DLT > | | | | /JUN/08,/1984/ |
| > DLT > | /AP/ | | /EQ 500MG BASE/VIAL/ | /N88678/001/ |
| > DLT > | | | | /JUN/08,/1984/ |
| > DLT > | /AP/ | | /EQ 500MG BASE/VIAL/ | /N89186/001/ |
| > DLT > | | | | /MAR/28,/1986/ |
| > DLT > | /AP/ | | /EQ 1GM BASE/VIAL/ | /N88679/001/ |
| > DLT > | | | | /JUN/08,/1984/ |
| > ADD > | | ∂ LYPHOMED | EQ 40MG BASE/VIAL | N88676 001 |
| > ADD > | | | | JUN 08, 1984 |
| > ADD > | | ∂ | EQ 125MG BASE/VIAL | N88677 001 |
| > ADD > | | | | JUN 08, 1984 |
| > ADD > | | ∂ | EQ 500MG BASE/VIAL | N88678 001 |
| > ADD > | | | | JUN 08, 1984 |
| > ADD > | | ∂ | EQ 500MG BASE/VIAL | N89186 001 |
| > ADD > | | | | MAR 28, 1986 |
| > ADD > | | ∂ | EQ 1GM BASE/VIAL | N88679 001 |
| > ADD > | | | | JUN 08, 1984 |

## METHYPRYLON

TABLET; ORAL
NOLUDAR

| | | | |
|---|---|---|---|
| > DLT > | /ROCHE/ | /50MG/ | /N09660/002/ |
| > ADD > | ∂ ROCHE | 50MG | N09660 002 |

## METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

| | | | |
|---|---|---|---|
| AP | ABBOTT | EQ 10MG BASE/2ML* | N73117 001 JAN 17, 1991 |
| AP | | EQ 10MG BASE/2ML* | N73118 001 JAN 17, 1991 |

## METRONIDAZOLE

INJECTABLE; INJECTION
METRYL IV

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /500MG/100ML/ | /N70042/001/ /DEC/20,/1984/ |
| > DLT > | | | | N70042 001 |
| > ADD > | AP | STERIS | 500MG/100ML | DEC 20, 1984 |
| > ADD > | | | | |

## MICONAZOLE NITRATE

| | | | | |
|---|---|---|---|---|
| > DLT > | | /CREAM;/VAGINAL/ | | |
| > DLT > | | /MONISTAT 7/ | | |
| > DLT > | /AT/ | /JOHNSON/RW/ | /2%/ | /N17456/001/ |
| > DLT > | | /SUPPOSITORY;/VAGINAL/ | | |
| > DLT > | | /MONISTAT 7/ | | |
| > DLT > | /AT/ | /JOHNSON/RW/ | /100MG/ | /N18520/001/ /MAR/15,/1982/ |
| > DLT > | | | | |

## NANDROLONE DECANOATE

INJECTABLE; INJECTION
NANDROLONE DECANOATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /AO/ | /LEMMON/ | /50MG/ML/ | /N87598/001/ /OCT/06,/1983/ |
| > DLT > | | | | N87598 001 |
| > DLT > | /AO/ | | /50MG/ML/ | /N88554/001/ /FEB/10,/1986/ |
| > DLT > | | | | N88554 001 |
| > DLT > | /AO/ | | /100MG/ML/ | /N87599/001/ /OCT/06,/1983/ |
| > DLT > | | | | N87599 001 |
| > ADD > | AO | STERIS | 50MG/ML | OCT 06, 1983 |
| > ADD > | | | | N88554 001 |
| > ADD > | AO | | 50MG/ML | FEB 10, 1986 |
| > ADD > | | | | N87599 001 |
| > ADD > | AO | | 100MG/ML | OCT 06, 1983 |
| > ADD > | | | | |

## ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFRAN

| | | | |
|---|---|---|---|
| | GLAXO | EQ 2MG BASE/ML* | N20007 001 JAN 04, 1991 |

## PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE

| | | | | |
|---|---|---|---|---|
| /BC/ | /VITARINE/ | /105MG/ | /N18074/001/ | |
| | ∂ VITARINE | 105MG | N18074 001 | |

## PIPERAZINE CITRATE

SYRUP; ORAL
PIPERAZINE CITRATE

| | | | | |
|---|---|---|---|---|
| /AA/ | /BARRE/ | /EQ 500MG BASE/5ML/ | /N80774/001/ | |
| | ∂ BARRE | EQ 500MG BASE/5ML | N80774 001 | |

## POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

| | | | | |
|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /2MEQ/ML/ | /N86208/001/ |
| > DLT > | /AP/ | | /3MEQ/ML/ | /N86210/001/ |
| > ADD > | AP | STERIS | 2MEQ/ML | N86208 001 |
| > ADD > | AP | | 3MEQ/ML | N86210 001 |

## PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /BP/ | /CENTRAL/PHARMS/ | /25MG/ML/ | /N84717/001/ |
| > ADD > | | ∂ CENTRAL PHARMS | 25MG/ML | N84717 001 |
| > DLT > | /BP/ | /LEMMON/ | /25MG/ML/ | /N83654/001/ |
| > DLT > | /BP/ | | /50MG/ML/ | /N85781/001/ |
| > ADD > | BP | STERIS | 25MG/ML | N83654 001 |
| > ADD > | BP | | 50MG/ML | N85781 001 |

## PREDNISONE

TABLET; ORAL
PREDNISONE

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /BX/ | /AM THERAP/ | /5MG/ | /N89387/001/ | |
| > DLT > | | | | /NOV/06,/1986/ | |
| > DLT > | /BX/ | | /10MG/ | /N89388/001/ | |
| > DLT > | | | | /NOV/06,/1986/ | |
| > DLT > | /BX/ | | /20MG/ | /N89389/001/ | |
| > DLT > | | | | /NOV/06,/1986/ | |
| > ADD > | | ə AM THERAP | 5MG | N89387 001 | |
| > ADD > | | | | NOV 06, 1986 | |
| > ADD > | | ə | 10MG | N89388 001 | |
| > ADD > | | | | NOV 06, 1986 | |
| > ADD > | | ə | 20MG | N89389 001 | |
| > ADD > | | | | NOV 06, 1986 | |
| > DLT > | /AB/ | /ROXANE/ | /1MG/ | /N87800/001/ | |
| > DLT > | | | | /APR/22,/1982/ | |
| > ADD > | | ə ROXANE | 1MG | N87800 001 | |
| > ADD > | | | | APR 22, 1982 | |

## PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINE HCL

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /1%/ | /N83535/001/ | |
| > DLT > | /AP/ | | /2%/ | /N83535/002/ | |
| > ADD > | AP | STERIS | 1% | N83535 001 | |
| > ADD > | AP | | 2% | N83535 002 | |

## PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /25MG/ML/ | /N83532/001/ | |
| > DLT > | /AP/ | | /50MG/ML/ | /N83532/002/ | |
| > ADD > | AP | STERIS | 25MG/ML | N83532 001 | |
| > ADD > | AP | | 50MG/ML | N83532 002 | |

## PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /AP/ | /LEMMON/ | /100MG/ML/ | /N83760/001/ | |
| > ADD > | AP | STERIS | 100MG/ML | N83760 001 | |

## RAMIPRIL

CAPSULE; ORAL
ALTACE

| | | | | |
|---|---|---|---|---|
| | | HOECHST ROUSSEL | 1.25MG¤ | N19901 001 |
| | | | | JAN 28, 1991 |
| | | | 2.5MG¤ | N19901 002 |
| | | | | JAN 28, 1991 |
| | | | 5MG¤ | N19901 003 |
| | | | | JAN 28, 1991 |
| | | | 10MG¤ | N19901 004 |
| | | | | JAN 28, 1991 |

## RESERPINE

TABLET; ORAL
RESERPINE

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | /BP/ | /WHITE/TOWNE/PAULSEN/ | /0.1MG/ | /N80723/001/ | |
| > DLT > | /BP/ | | /0.25MG/ | /N80723/002/ | |
| > ADD > | | ə WHITE TOWNE PAULSEN | 0.1MG | N80723 001 | |
| > ADD > | | ə | 0.25MG | N80723 002 | |
| > DLT > | | | /1MG/ | /N80723/003/ | |
| > ADD > | | ə | 1MG | N80723 003 | |

## RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL

| | | | | |
|---|---|---|---|---|
| > ADD > | AP | ABBOTT | 10MG/ML¤ | N71618 001 |
| > ADD > | | | | FEB 28, 1991 |
| > ADD > | AP | | 15MG/ML¤ | N71619 001 |
| > ADD > | | | | FEB 28, 1991 |
| | | RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER | | |
| | | ABBOTT | 30MG/100ML¤ | N71438 001 |
| | | | | JAN 22, 1991 |

## SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

| | | | | |
|---|---|---|---|---|
| AT | | CLAY PARK | 2.5%¤ | N89996 001 |
| | | | | JAN 10, 1991 |

## SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
SODIUM NITROPRUSSIDE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| /AP/ | /LYPHOMED/ | /50MG/VIAL/ | /N70031/001/ | > ADD > | AO | STERIS | 100MG/ML | N83667 001 |
| | | | /JAN/17,/1985/ | > ADD > | AO | | 200MG/ML | N83667 002 |
| | ə LYPHOMED | 50MG/VIAL | N70031 001 | | | | | |
| | | | JAN 17, 1985 | | | | | |

## SUCCIMER

CAPSULE; ORAL
CHEMET
MCNEIL 100MG N19998 002
JAN 30, 1991

## SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
COTRIM

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /80MG/ML;16MG/ML/ | /N71556/001/ | | | | |
| > DLT > | | | /DEC/17,/1987/ | | | | |
| > ADD > AP | STERIS | 80MG/ML;16MG/ML | N71556 001 | | | | |
| > ADD > | | | DEC 17, 1987 | | | | |

## TERCONAZOLE

CREAM; VAGINAL
TERAZOL 3
JOHNSON RW 0.8% N19964 001
FEB 21, 1991

## TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT >/AO/ | /LEMMON/ | /100MG/ML/ | /N84401/001/ | | | | |
| > DLT >/AO/ | | /200MG/ML/ | /N84401/002/ | | | | |
| > ADD > AO | STERIS | 100MG/ML | N84401 001 | | | | |
| > ADD > AO | | 200MG/ML | N84401 002 | | | | |

## TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT >/AO/ | /LEMMON/ | /100MG/ML/ | /N83667/001/ | | | | |
| > DLT >/AO/ | | /200MG/ML/ | /N83667/002/ | | | | |

## TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > ADD > AO | STERIS | 100MG/ML | N83667 001 | | | | |
| > ADD > AO | | 200MG/ML | N83667 002 | | | | |

## TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION
TESTOSTERONE PROPIONATE

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT >/AO/ | /LEMMON/ | /25MG/ML/ | /N85490/001/ | | | | |
| > DLT >/AO/ | | /50MG/ML/ | /N85490/002/ | | | | |
| > DLT >/AO/ | | /100MG/ML/ | /N83595/003/ | | | | |
| > ADD > AO | STERIS | 25MG/ML | N85490 001 | | | | |
| > ADD > AO | | 50MG/ML | N85490 002 | | | | |
| > ADD > AO | | 100MG/ML | N83595 003 | | | | |

## THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
> DLT > /THEOPHYLLINE/

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT > /BC/ | /CENTRAL/PHARMS/ | /125MG/ | /N88654/001/ | | | | |
| > DLT > | | | /FEB/12,/1985/ | | | | |
| > DLT > /BC/ | | /250MG/ | /N88689/001/ | | | | |
| > DLT > | | | /FEB/12,/1985/ | | | | |
| > ADD > | ə CENTRAL PHARMS | 125MG | N88654 001 | | | | |
| > ADD > | | | FEB 12, 1985 | | | | |
| > ADD > | ə | 250MG | N88689 001 | | | | |
| > ADD > | | | FEB 12, 1985 | | | | |

TABLET; ORAL
> DLT > /THEOCLEAR-100/

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT > /BD/ | /CENTRAL/PHARMS/ | /100MG/ | /N85353/002/ | | | | |
| > ADD > | ə CENTRAL PHARMS | 100MG | N85353 002 | | | | |
| > DLT > | /THEOCLEAR-200/ | | | | | | |
| > DLT > /BD/ | /CENTRAL/PHARMS/ | /200MG/ | /N85353/001/ | | | | |
| > ADD > | ə CENTRAL PHARMS | 200MG | N85353 001 | | | | |

## THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
THIAMINE HCL

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| > DLT >/AP/ | /LEMMON/ | /100MG/ML/ | /N83534/001/ | | | | |
| > DLT >/AP/ | | /200MG/ML/ | /N83534/002/ | | | | |
| > DLT >/AP/ | /LYPHOMED/ | /100MG/ML/ | /N80509/001/ | | | | |
| > ADD > | ə LYPHOMED | 100MG/ML | N80509 001 | | | | |
| > ADD > AP | STERIS | 100MG/ML | N83534 001 | | | | |
| > ADD > AP | | 200MG/ML | N83534 002 | | | | |

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL
THIORIDAZINE HCL

| | | | | |
|---|---|---|---|---|
| > DLT > | /AB/ | /ROXANE/ | /10MG/ | /N88663/001/ |
| > DLT > | | | | /MAR/15,/1984/ |
| > DLT > | /AB/ | | /25MG/ | /N88664/001/ |
| > DLT > | | | | /MAR/15,/1984/ |
| > DLT > | /AB/ | | /50MG/ | /N88665/001/ |
| > DLT > | | | | /MAR/15,/1984/ |
| > DLT > | /AB/ | | /100MG/ | /N89048/001/ |
| > DLT > | | | | /FEB/26,/1985/ |
| > ADD > | | @ ROXANE | 10MG | N88663 001 |
| > ADD > | | | | MAR 15, 1984 |
| > ADD > | | @ | 25MG | N88664 001 |
| > ADD > | | | | MAR 15, 1984 |
| > ADD > | | @ | 50MG | N88665 001 |
| > ADD > | | | | MAR 15, 1984 |
| > ADD > | | @ | 100MG | N89048 001 |
| > ADD > | | | | FEB 26, 1985 |

THIOTHIXENE

CAPSULE; ORAL
THIOTHIXENE

| | | | | |
|---|---|---|---|---|
| | /AB/ | /AM/THERAP/ | /2MG/ | /N71885/001/ |
| | | | | /AUG/12,/1987/ |
| | | @ AM THERAP | 2MG | N71885 001 |
| | | | | AUG 12, 1987 |

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

| | | | | |
|---|---|---|---|---|
| > ADD > | AB | MYLAN | 50MG¤ | N71405 001 |
| > ADD > | | | | FEB 27, 1991 |
| > ADD > | AB | | 100MG¤ | N71406 001 |
| > ADD > | | | | FEB 27, 1991 |

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
TRIAMCINOLONE DIACETATE

| | | | | |
|---|---|---|---|---|
| > DLT > | /BP/ | /LEMMON/ | /40MG/ML/ | /N85529/001/ |
| > ADD > | BP | STERIS | 40MG/ML | N85529 001 |

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL

> ADD > MICRODERM
> ADD > JOHNSON AND JOHNSON 4%¤ N72295 001
> ADD > FEB 28, 1991

> ADD > MICONAZOLE NITRATE

> ADD > CREAM; VAGINAL
> ADD > MONISTAT 7
> ADD > JOHNSON RW 2%¤ N17450 002
> ADD > FEB 15, 1991

> ADD > SUPPOSITORY; VAGINAL
> ADD > MONISTAT 7
> ADD > JOHNSON RW 100MG¤ N18520 002
> ADD > FEB 15, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 2 / JAN '91 - FEB '91

NO FEBRUARY 1991 APPROVALS

## ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

## ORPHAN DRUG PRODUCT DESIGNATIONS

### BIOLOGICAL DESIGNATIONS

| NAME OF BIOLOGICAL | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE] | SPONSOR NAME |
|---|---|---|
| GENERIC: ANTIVENOM (CROTALIDAE) PURIFIED (AVIAN)<br>TRADE: NOT ESTABLISHED | TREATMENT OF ENVENOMATION BY POISONOUS SNAKES BELONGING TO THE CROTALIDAE FAMILY. | OPHIDIAN PHARMA |
| GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN)<br>TRADE: NOT ESTABLISHED | USE IN CONJUNCTION WITH GANCICLOVIR SODIUM FOR THE TREATMENT OF CYTOMEGALOVIRUS PNEUMONIA IN BONE MARROW TRANSPLANT PATIENTS. | MILES, INC |
| GENERIC: INTERFERON (RECOMBINANT, BETA)<br>TRADE: R-IFN-BETA | SYSTEMIC TREATMENT OF METASTATIC RENAL CELL CARCINOMA. | BIOGEN |

## ORPHAN DRUG PRODUCT DESIGNATIONS

### BIOLOGICAL DESIGNATIONS

| NAME OF BIOLOGICAL | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE] | SPONSOR NAME |
|---|---|---|
| GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN<br>TRADE: MEPIG | TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS. | UNIVAX BIOLOGICS, INC |
| GENERIC: RECOMBINANT HUMAN DEOXYRIBONUCLEASE (RHDNASE)<br>TRADE: NOT ESTABLISHED | TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS. | GENENTECH, INC |
| GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19)<br>TRADE: NOT ESTABLISHED | FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCYTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION. | IMMUNOGEN, INC |
| GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS<br>TRADE: NOT ESTABLISHED | TREATMENT OF SMALL CELL LUNG CANCER. | IMMUNOGEN, INC |

## ORPHAN DRUG PRODUCT DESIGNATIONS

### DRUG DESIGNATIONS

| NAME OF DRUG | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE] | SPONSOR NAME |
|---|---|---|
| GENERIC: CYSTEAMINE HCL<br>TRADE: NOT ESTABLISHED | TREATMENT OF NEPHROPATHIC CYSTINOSIS. | WARNER-LAMBERT COMPANY |
| GENERIC: DESMOPRESSIN ACETATE<br>TRADE: DDAVP HIGH CONCENTRATION | TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE. | RORER PHARMACEUTICAL CORP |
| GENERIC: DRONABINOL<br>TRADE: MARINOL | STIMULATION OF APPETITE AND PREVENTION OF WEIGHT LOSS IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS). | UNIMED, INC |
| GENERIC: GALLIUM NITRATE<br>TRADE: GANITE*/** | TREATMENT OF HYPERCALCEMIA OF MALIGNANCY. [JAN 17, 1998] | FUJISAWA PHARM |
| GENERIC: GENTAMICIN IMPREGNATED PMMA BEADS ON SURGICAL WIRE<br>TRADE: SEPTOPAL | TREATMENT OF CHRONIC OSTEOMYELITIS OF POST-TRAUMATIC, POSTOPERATIVE OR HEMATOGENOUS ORIGIN. | E. MERCK, DARMSTADT |
| GENERIC: IDARUBICIN HCL<br>TRADE: IDAMYCIN | TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PEDIATRIC PATIENTS. | ADRIA |
| GENERIC: PENTOSTATIN<br>TRADE: NOT ESTABLISHED | TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA. | WARNER LAMBERT COMPANY |
| GENERIC: SUCCIMER<br>TRADE: CHEMET*/** | TREATMENT OF LEAD POISONING IN CHILDREN. [JAN 30, 1998] | MCNEIL |

## ORPHAN DRUG PRODUCT DESIGNATIONS

### DRUG DESIGNATIONS

| NAME OF DRUG | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE] | SPONSOR NAME |
|---|---|---|
| GENERIC: URSODEOXYCHOLIC ACID<br>TRADE: ACTIGALL | MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOSIS. | CIBA GEIGY |
| GENERIC: TESTOSTERONE SUBLINGUAL<br>TRADE: NOT ESTABLISHED | TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS. | GYNEX, INC |

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

NO FEBRUARY 1991 ADDITIONS

## BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFD-650, MPN-2 ROOM 278, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO FEBRUARY 1991 ADDITIONS

## ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (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, 11TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

NO FEBRUARY 1991 PETITIONS APPROVED OR DENIED

## EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 11TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEUDLE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

**REFERENCES**
NEW INDICATION

| | |
|---|---|
| I-55 | HYPERTENSION |

**REFERENCES**
PATENT USE CODE

| | |
|---|---|
| U-44 | RELIEF OF NAUSEA AND VOMITING |
| U-45 | TREATMENT OF INFLAMMATION AND ANALGESIA |
| U-46 | TREATMENT OF PANIC DISORDER |

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> | 18276 001 | ALPRAZOLAM; XANAX | 4508726 | APR 02, 2002 | U-46 | | |
| >ADD> | 18276 002 | ALPRAZOLAM; XANAX | 4508726 | APR 02, 2002 | U-46 | | |
| >ADD> | 18276 003 | ALPRAZOLAM; XANAX | 4508726 | APR 02, 2002 | U-46 | | |
| >ADD> | 18276 004 | ALPRAZOLAM; XANAX | 4508726 | APR 02, 2002 | U-46 | | |
| >ADD> | | | 3980789 | SEP 14, 1993 | | ODE | DEC 26, 1997 |
| | 19926 001 | ALTRETAMINE; HEXALEN | 4988731 | JAN 29, 2008 | | | |
| | 18723 001 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | | |
| | 18723 002 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | | |
| | 18723 003 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | | |
| | 19680 001 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | | |
| | 19794 001 | DIVALPROEX SODIUM; DEPAKOTE CP | 4988731 | JAN 29, 2008 | | | |
| | 19794 002 | DIVALPROEX SODIUM; DEPAKOTE CP | 4188390 | FEB 12, 1997 | | NCE | NOV 02, 1995 |
| | 19668 001 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | FEB 12, 1997 | | NCE | NOV 02, 1995 |
| | 19668 002 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | FEB 12, 1997 | | NCE | NOV 02, 1995 |
| | 19668 003 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | FEB 12, 1997 | | NCE | NOV 02, 1995 |
| | 19668 004 | DOXAZOSIN MESYLATE; CARDURA | 4027019 | MAY 31, 1998 | | NC | DEC 29, 1992 |
| >ADD> | 19653 001 | ETHINYL ESTRADIOL; ORTHO CYCLEN-21 | 4027019 | MAY 31, 1998 | | MC | DEC 29, 1992 |
| >DLT> | 19653 001 | ETHINYL ESTRADIOL; ORTHO CYCLEN-21 | 4027019 | MAY 31, 1998 | | NC | DEC 29, 1992 |
| >ADD> | 19653 002 | ETHINYL ESTRADIOL; ORTHO CYCLEN-28 | 4027019 | MAY 31, 1998 | | MC | DEC 29, 1992 |
| >DLT> | 19653 002 | ETHINYL ESTRADIOL; ORTHO CYCLEN-28 | 4076831 | FEB 28, 1995 | U-45 | | |
| | 18922 001 | ETODOLAC; LODINE | 3939178 | FEB 17, 1993 | | NCE | JAN 31, 1996 |
| | 18922 002 | ETODOLAC; LODINE | 4076831 | FEB 28, 1995 | U-45 | | |
| | | | 3939178 | FEB 17, 1993 | | NCE | JAN 31, 1996 |
| | 18922 003 | ETODOLAC; LODINE | 4076831 | FEB 28, 1995 | U-45 | | |
| | | | 3939178 | FEB 17, 1993 | | NCE | JAN 31, 1996 |
| >ADD> | 19949 001 | FLUCONAZOLE; DIFLUCAN | 4404216 | OCT 16, 2003 | | NCE | JAN 29, 1995 |
| >DLT> | 19949 001 | FLUCONAZOLE; DIFLUCAN | 4404216 | SEP 13, 2000 | | MCE | JAN 29, 1998 |
| >ADD> | 19949 002 | FLUCONAZOLE; DIFLUCAN | 4404216 | OCT 16, 2003 | | NCE | JAN 29, 1995 |
| >DLT> | 19949 002 | FLUCONAZOLE; DIFLUCAN | 4404216 | SEP 13, 2000 | | MCE | JAN 29, 1998 |
| >ADD> | 19949 003 | FLUCONAZOLE; DIFLUCAN | 4404216 | OCT 16, 2003 | | NCE | JAN 29, 1995 |
| >DLT> | 19949 003 | FLUCONAZOLE; DIFLUCAN | 4404216 | SEP 13, 2000 | | MCE | JAN 29, 1998 |
| >ADD> | 19950 001 | FLUCONAZOLE; DIFLUCAN | | | | NCE | JAN 17, 1996 |
| >DLT> | 19950 001 | FLUCONAZOLE; DIFLUCAN | | | | | |
| | 19961 002 | GALLIUM NITRATE; GANITE | | | | | |

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> | 18686 001 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| >DLT> | 18686 001 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4012444 | MAR 15, 1994 | | NCE | AUG 01, 1994 |
| | 18687 001 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18687 002 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18687 003 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18687 004 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18716 001 | LABETALOL HYDROCHLORIDE; TRANDATE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18716 002 | LABETALOL HYDROCHLORIDE; TRANDATE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18716 003 | LABETALOL HYDROCHLORIDE; TRANDATE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 18716 004 | LABETALOL HYDROCHLORIDE; TRANDATE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| | 19425 001 | LABETALOL HYDROCHLORIDE; TRANDATE | 4012444 | AUG 02, 1998 | | NCE | AUG 01, 1994 |
| >ADD> | 19886 001 | NAFARELIN ACETATE; SYNAREL | 4234571 | NOV 18, 2001 | | NCE | FEB 13, 1995 |
| >DLT> | 19886 001 | NAFARELIN ACETATE; SYNAREL | 4234571 | NOV 18, 1999 | | NCE | FEB 13, 1995 |
| >ADD> | 19684 001 | NIFEDIPINE; PROCARDIA XL | 4783337 | SEP 16, 2003 | | I-55 | SEP 06, 1992 |
| >ADD> | | | 4765989 | SEP 16, 2003 | | D-2 | SEP 06, 1992 |
| >ADD> | 19684 002 | NIFEDIPINE; PROCARDIA XL | 4783337 | SEP 16, 2003 | | I-55 | SEP 06, 1992 |
| >ADD> | | | 4765989 | SEP 16, 2003 | | D-2 | SEP 06, 1992 |
| >ADD> | 19684 003 | NIFEDIPINE; PROCARDIA XL | 4783337 | SEP 16, 2003 | | I-55 | SEP 06, 1992 |
| >ADD> | | | 4765989 | SEP 16, 2003 | | D-2 | SEP 06, 1992 |
| | 20007 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789 | JUN 28, 2005 | U-44 | NCE | JAN 04, 1996 |
| | 20007 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4695578 | SEP 22, 2004 | | | |
| >ADD> | 18631 001 | PENTOXIFYLLINE; TRENTAL | 3737433 | APR 03, 1997 | | NCE | AUG 30, 1994 |
| >DLT> | 18631 001 | PENTOXIFYLLINE; TRENTAL | 3737433 | JUN 05, 1990 | | NCE | AUG 30, 1994 |
| >ADD> | 19456 001 | PINACIDIL; PINDAC | RE31244 | NOV 08, 1996 | U-3 | NCE | DEC 28, 1994 |
| >DLT> | 19456 001 | PINACIDIL; PINDAC | RE31244 | NOV 08, 1994 | U-3 | NCE | DEC 28, 1994 |
| >ADD> | 19456 002 | PINACIDIL; PINDAC | RE31244 | NOV 08, 1996 | U-3 | NCE | DEC 28, 1994 |
| >DLT> | 19456 002 | PINACIDIL; PINDAC | RE31244 | NOV 08, 1994 | U-3 | NCE | DEC 28, 1994 |
| | 19901 001 | RAMIPRIL; ALTACE | 4587258 | MAY 06, 2003 | | NCE | JAN 28, 1996 |
| | 19901 002 | RAMIPRIL; ALTACE | 4587258 | MAY 06, 2003 | | NCE | JAN 28, 1996 |
| | 19901 003 | RAMIPRIL; ALTACE | 4587258 | MAY 06, 2003 | | NCE | JAN 28, 1996 |
| | 19901 004 | RAMIPRIL; ALTACE | 4587258 | MAY 06, 2003 | | NCE | JAN 28, 1996 |
| >ADD> | 19998 002 | SUCCIMER; CHEMET | | | | ODE | JAN 30, 1998 |
| | 19998 002 | SUCCIMER; CHEMET | | | | NCE | JAN 30, 1996 |