# APPROVED DRUG PRODUCTS
## With Therapeutic Equivalence Evaluations

## The "Orange Book"

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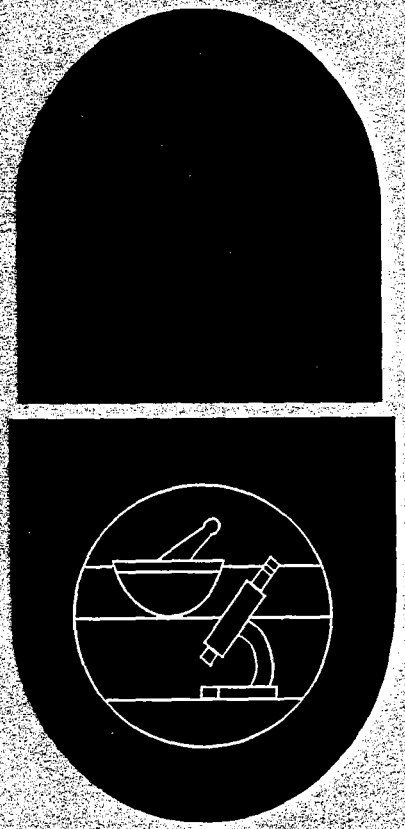
CUMULATIVE SUPPLEMENT 12

JAN'94-DEC'94



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

14TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DRUG INFORMATION RESOURCES

# APPROVED DRUG PRODUCTS
# with
# THERAPEUTIC EQUIVALENCE EVALUATIONS

## 14TH EDITION

## Cumulative Supplement 12

## DECEMBER 1994

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**APPROVED DRUG PRODUCTS**
**with**
**THERAPEUTIC EQUIVALENCE EVALUATIONS**

**14TH EDITION**

**CUMULATIVE SUPPLEMENT 12**

**DECEMBER 1994**

# 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, 14th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 shaded print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the shaded 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 "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 14th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 15th 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 07, 1984 (49 FR 35428) |
| Nitroglycerin (film, extended release; transdermal*) | JUL 15, 1993 (58 FR 38129) |
| Nitroglycerin (tablet, controlled release;oral) | SEP 07, 1984 (49 FR 35428) |
| Nitroglycerin (tablet, controlled release;buccal) | JUL 05, 1985 (50 FR 27688) |

*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

## 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. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

APPLICANT NAME CHANGES

| FORMER APPLICANT NAME<br>(FORMER ABBREVIATED NAME) | NEW APPLICANT NAME<br>(NEW ABBREVIATED NAME) |
|---|---|
| ADRIA LABORATORIES DIV ERBAMONT INC<br>(ADRIA) | PHARMACIA INC<br>(PHARMACIA) |
| BANNER GELATIN PRODUCTS CORP<br>(BANNER GELATIN) | BANNER PHARMACAPS INC<br>(BANNER PHARMACAPS) |
| *BROCADES PHARMA BV DIV YAMANOUCHI GROUP<br>(BROCADES PHARMA) | *YAMANOUCHI EUROPE BV<br>(YAMANOUCHI) |
| CLONMEL CHEMICALS CO LTD<br>(CLONMEL) | CLONMEL HEALTH CARE<br>(CLONMEL HLTH CARE) |
| DUPONT PHARMACEUTICALS<br>(DUPONT) | DUPONT MERCK PHARMACEUTICAL CO<br>(DUPONT MERCK) |
| *G POHL BOSKAMP GMBH AND CO<br>(BOSKAMP) | *G POHL BOSKAMP GMBH AND CO<br>(POHL BOSKAMP) |
| GYNEX INC<br>(GYNEX) | BTG PHARMACEUTICALS CORP SUB<br>BIOTECHNOLOGY GENERAL CORP<br>(BTG PHARMS) |
| KABI PHARMACIA INC<br>(KABI) | PHARMACIA INC<br>(PHARMACIA) |
| *KM LEE LABORATORIES<br>(LEE LABS) | *KM LEE LABORATORIES INC<br>(KM LEE) |

APPLICANT NAME CHANGES

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|
| *LABORATOIRES FOURNIER SA (FOURNIER) | *LABORATOIRES FOURNIER SCA (LABS FOURNIER) |
| *LABORATORIOS ATRAL SARL (ATRAL) | *LABORATORIOS ATRAL SARL (LABS ATRAL) |
| MALLINCKRODT SPECIALTY CHEMICALS CO (MALLINCKRODT) | MALLINCKRODT CHEMICAL INC (MALLINCKRODT) |
| *MM MAST AND CO (MAST) | *MM MAST AND CO (MM MAST) |
| NORTH AMERICAN CHEMICAL CORP (NORTH AM CHEM) | GOLDEN PHARMACEUTICALS INC (GOLDEN PHARMS) |
| PHARMACEUTICAL BASICS INC (PHARM BASICS) | ROSEMONT PHARMACEUTICAL CORP (ROSEMONT) |
| *PRIVATE FORMULATIONS INC (PRIVATE FORM) | *PRIVATE FORMULATIONS INC (PVT FORM) |
| RICHLYN LABORATORIES INC (RICHLYN) | GLOBAL PHARMACEUTICAL CORP (GLOBAL PHARMS) |
| *SCHWARZ PHARMA DIV KREMERS URBAN CO (SCHWARZ PHARMA) | *SCHWARZ PHARMA KREMERS URBAN CO SUB SCHWARZ PHARMA AG (SPKU) |
| SQUIBB DIAGNOSTICS (SQUIBB) | BRACCO DIAGNOSTICS INC (BRACCO DXS) |
| *WHITEWORTH TOWNE PAULSEN INC (WHITE TOWNE PAULSEN) | *WHITEWORTH TOWNE PAULSEN INC (WHITEWORTH TOWNE) |

## 1.4 NEW INDICATIONS FOR PREVIOUSLY APPROVED DRUG PRODUCTS

When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by the same firm, the application is either submitted as a supplement to the original NDA (if the clinical expertise for the review of the new indication resides in the same division that reviewed the original NDA), or as a "Type 6 NDA" and assigned a new NDA number

(if the clinical expertise for the review of the new indication resides in another review division). When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by a different firm, the application is classified as "Type 6" and assigned a new NDA number.For administrative purposes, FDA has been listing all "Type 6 NDA's" in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, (ADP), even when the application was submitted by the original NDA holder. However, FDA has determined that the practice of listing a separate "Type 6 NDA" number in the ADP when the applicant is the original NDA holder may cause confusion to the ADP reader.

Accordingly, to prevent confusion and to eliminate duplicity of data, the approval of an application for a new indication for a previously approved drug product submitted by the original NDA holder will no longer be listed in the ADP. Any exclusivity awarded for that approval will be shown in the Patent and Exclusivity Information Addendum under the original NDA number. However, approval of an application for a new indication submitted by an applicant other than the original NDA holder will be shown in the appropriate drug product list of the ADP. Any exclusivity awarded will be shown under the NDA number of the new applicant.

All approvals of "Type 6" applications submitted by the original NDA holder currently in the ADP are listed in the table below. For reference purposes, the original NDA number is listed next to the corresponding "Type 6 NDA Number". This data ("Type 6 NDA Number") will continue to be listed in the remaining Cumulative Supplements to the 14th Edition of the ADP; but it will not appear in the 15th Edition of the ADP.

| TYPE 6 NDA NUMBER | ORIGINAL NDA NUMBER | ACTIVE INGREDIENT (TRADE NAME) | DOSAGE FORM (ROUTE) |
|---|---|---|---|
| 17-117 | 16-020 | AMANTADINE HCL (SYMMETREL) | CAPSULE (ORAL) |
| 17-118 | 16-023 | AMANTADINE HCL (SYMMETREL) | SYRUP (ORAL) |
| 50-697 | 50-662 | CLARITHROMYCIN (BIAXIN) | TABLET (ORAL) |
| 19-576 | 19-084 | KETOCONAZOLE (NIZORAL) | CREAM (TOPICAL) |
| 19-648 | 19-084 | KETOCONAZOLE (NIZORAL) | CREAM (TOPICAL) |
| 18-064 | 18-063 | NADOLOL (CORGARD) | TABLET (ORAL) |
| 20-109 | 19-886 | NAFARELIN ACETATE (SYNAREL) | SPRAY, METERED (NASAL) |
| 20-223 | 19-057 | TERAZOSIN HCL (HYTRIN) | TABLET (ORAL) |

## 1.5 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 DECEMBER 1994.**

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

### DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. 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 1993) 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 1993 | JUN 1994 | SEP 1994 | DEC 1994 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 9140 | 9079 | 9092 | 9141 |
| SINGLE SOURCE | 2144 (23.5%) | 2150 (23.7%) | 2127 (23.4%) | 2178 (23.8%) |
| MULTISOURCE | 6996 (76.5%) | 6929 (76.3%) | 6965 (76.6%) | 6963 (76.2%) |
| THERAPEUTICALLY EQUIVALENT | 6292 (68.8%) | 6290 (69.3%) | 6329 (69.6%) | 6330 (69.2%) |
| NOT THERAPEUTICALLY EQUIVALENT | 527 ( 5.8%) | 458 ( 5.0%) | 453 ( 5.0%) | 453 ( 5.0%) |
| EXCEPTIONS[1] | 177 ( 1.9%) | 181 ( 2.0%) | 183 ( 2.0%) | 180 ( 2.0%) |
| NEW MOLECULAR ENTITIES APPROVED | -- | 5 | 2 | 10 |
| NUMBER OF APPLICANTS | 526 | 490 | 539 | 534 |

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

ACETAMINOPHEN; BUTALBITAL; CAPSULE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | MEDIGESIC PLUS | | | |
| AB | US CHEM | 325MG;50MG;40MG | N89115 001 | |
| | | | JAN 14, 1986 | |
| | @ | 325MG;50MG;40MG | N89115 001 | |
| | | | JAN 14, 1986 | |

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | COMPAL | | | |
| AA | PURDUE FREDERICK | 356.4MG;30MG;16MG | N88584 001 | |
| | | | MAR 04, 1986 | |
| | DHC PLUS | | | |
| AA | PURDUE FREDERICK | 356.4MG;30MG;16MG | N88584 001 | |
| | | | MAR 04, 1986 | |

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ACETAMINOPHEN AND CODEINE PHOSPHATE | | | |
| > ADD > | AA | ROYCE LABS | 300MG;15MG | N89997 001 | |
| > ADD > | | | | DEC 28, 1994 | |
| > ADD > | AA | | 300MG;30MG | N89998 001 | |
| > ADD > | | | | DEC 28, 1994 | |
| > ADD > | AA | | 300MG;60MG | N89999 001 | |
| > ADD > | | | | DEC 28, 1994 | |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | CO-GESIC | | | |
| AA | CENT PHARMS | 500MG;5MG | N89360 001 | |
| | | | MAR 02, 1988 | |
| | @ | 500MG;5MG | N89360 001 | |
| | | | MAR 02, 1988 | |

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | TALACEN | | | |
| + | SANOFI WINTHROP | 650MG;EQ 25MG BASE | N18458 001 | |
| | | | SEP 23, 1982 | |

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | TALACEN | | | |
| + | STERLING WINTHROP | 650MG;EQ 25MG BASE | N18458 001 | |
| | | | SEP 23, 1982 | |

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN | | | |
| > ADD > | AB | LEMMON | 650MG;100MG | N74119 001 | |
| > ADD > | | | | DEC 19, 1994 | |

ACETAZOLAMIDE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | DIAMOX | | | |
| > DLT > | + | LEDERLE | 500MG | N12945 001 | |
| > ADD > | + | STORZ OPHTHALM | 500MG | N12945 001 | |

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | DIAMOX | | | |
| > DLT > | AB | LEDERLE | 125MG | N08943 001 | |
| > DLT > | AB | + | 250MG | N08943 002 | |
| > ADD > | AB | STORZ OPHTHALM | 125MG | N08943 001 | |
| > ADD > | AB | + | 250MG | N08943 002 | |

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | DIAMOX | | | |
| > DLT > | + LEDERLE | EQ 500MG BASE/VIAL | N09388 001 | |
| > DLT > | | | DEC 05, 1990 | |
| > ADD > | + STORZ OPHTHALM | EQ 500MG BASE/VIAL | N09388 001 | |
| > ADD > | | | DEC 05, 1990 | |

ACETIC ACID, GLACIAL; ALUMINUM ACETATE

SOLUTION/DROPS; OTIC

| | | | | |
|---|---|---|---|---|
| | ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE | | | |
| AT | BAUSCH AND LOMB | 2%;0.79% | N40063 001 | |
| | | | FEB 25, 1994 | |
| | BOROFAIR | | | |
| AT | PHARMAFAIR | 2%;0.79% | N88606 001 | |
| | | | AUG 21, 1985 | |

## ACETIC ACID, GLACIAL; ALUMINUM ACETATE

SOLUTION/DROPS; OTIC

| | | | | |
|---|---|---|---|---|
| | **BOROFAIR** | | | |
| | @ PHARMAFAIR | 2%;0.79% | N88606 001 | AUG 21, 1985 |
| | **DOMEBORO** | | | |
| AT | MILES | 2%;0.79% | N84476 001 | |
| AT | + | 2%;0.79% | N84476 001 | |

## ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

| | | | | |
|---|---|---|---|---|
| | **HYDROCORTISONE AND ACETIC ACID** | | | |
| AT | BAUSCH AND LOMB | 2%;1% | N40097 001 | OCT 31, 1994 |

## ACETYLCHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | MIOCHOL | | | |
| | + CIBA VISION | 20MG/VIAL | N16211 001 | |
| | + IOLAB | 20MG/VIAL | N16211 001 | |
| | MIOCHOL-E | | | |
| | + CIBA VISION | 20MG/VIAL | N20213 001 | SEP 22, 1993 |
| | + IOLAB | 20MG/VIAL | N20213 001 | SEP 22, 1993 |

## ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

| | | | | |
|---|---|---|---|---|
| | **ACETYLCYSTEINE** | | | |
| AN | ABBOTT | 10% | N73664 001 | AUG 30, 1994 |
| AN | | 20% | N74037 001 | AUG 30, 1994 |

## ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | SEMPREX-D | | | |
| | + BURROUGHS WELLCOME | 8MG;60MG | N19806 001 | MAR 25, 1994 |

## ALBUTEROL SULFATE

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | **ALBUTEROL SULFATE** | | | |
| AA | MOVA | EQ 2MG BASE/5ML | N74302 001 | SEP 30, 1994 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **ALBUTEROL SULFATE** | | | |
| AB | WARNER CHILCOTT | EQ 2MG BASE | N72817 001 | JAN 09, 1990 |
| AB | | EQ 4MG BASE | N72818 001 | JAN 09, 1990 |
| | @ | EQ 2MG BASE | N72817 001 | JAN 09, 1990 |
| | @ | EQ 4MG BASE | N72818 001 | JAN 09, 1990 |

## ALPRAZOLAM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **ALPRAZOLAM** | | | |
| AB | MYLAN | 0.25MG | N74215 001 | JAN 27, 1994 |
| AB | | 0.5MG | N74215 002 | JAN 27, 1994 |
| AB | | 1MG | N74215 003 | JAN 27, 1994 |
| AB | | 2MG | N74215 004 | JAN 27, 1994 |
| AB | NOVOPHARM | 0.25MG | N74085 001 | FEB 16, 1994 |
| AB | | 0.5MG | N74085 002 | FEB 16, 1994 |
| AB | | 1MG | N74085 003 | FEB 16, 1994 |
| AB | ZENITH LABS | 0.25MG | N74294 001 | JUL 29, 1994 |
| AB | | 0.5MG | N74294 002 | JUL 29, 1994 |
| AB | | 1MG | N74294 003 | JUL 29, 1994 |
| AB | | 2MG | N74294 004 | JUL 29, 1994 |

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL
AMANTADINE HCL

| | | | | |
|---|---|---|---|---|
| AA | HI TECH PHARMA | 50MG/5ML | N74170 001 OCT 28, 1994 | |

AMBENONIUM CHLORIDE

TABLET; ORAL
MYTELASE

| | | | |
|---|---|---|---|
| | SANOFI WINTHROP | 10MG | N10155 002 |
| | STERLING WINTHROP | 10MG | N10155 002 |

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKACIN

| | | | |
|---|---|---|---|
| AP | ABBOTT | EQ 50MG BASE/ML | N63263 001 NOV 30, 1994 |
| AP | | EQ 250MG BASE/ML | N63264 001 NOV 30, 1994 |
| AP | | EQ 250MG BASE/ML | N63265 001 NOV 30, 1994 |
| AP | | EQ 250MG BASE/ML | N63266 001 OCT 31, 1994 |
| | | EQ 62.5MG BASE/ML | N63283 001 OCT 31, 1994 |
| AP | BEDFORD | EQ 50MG BASE/ML | N63313 001 APR 11, 1994 |
| AP | | EQ 250MG BASE/ML | N63315 001 APR 11, 1994 |
| AP | ELKINS SINN | EQ 50MG BASE/ML | N63274 001 MAY 18, 1992 |
| AP + | | EQ 50MG BASE/ML | N63274 001 MAY 18, 1992 |
| AP | | EQ 250MG BASE/ML | N63275 001 MAY 18, 1992 |
| AP + | | EQ 250MG BASE/ML | N63275 001 MAY 18, 1992 |
| | AMIKIN | | |
| | @ APOTHECON | EQ 50MG BASE/ML | N50495 001 |
| | @ | EQ 250MG BASE/ML | N50495 002 |
| AP + | BRISTOL | EQ 50MG BASE/ML | N50495 001 |
| AP | | EQ 50MG BASE/ML | N62562 001 SEP 20, 1984 |
| AP + | | EQ 250MG BASE/ML | N50495 002 |

AMIKACIN SULFATE

INJECTABLE; INJECTION
AMIKIN

| | | | |
|---|---|---|---|
| AP | BRISTOL | EQ 250MG BASE/ML | N62562 002 SEP 20, 1984 |
| | @ | EQ 50MG BASE/ML | N62562 001 SEP 20, 1984 |
| | @ | EQ 250MG BASE/ML | N62562 002 SEP 20, 1984 |

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION
AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| | ABBOTT | 5%;25GM/100ML | N19565 001 DEC 17, 1986 |
| | @ | 5%;25GM/100ML | N19565 001 DEC 17, 1986 |

AMINOPHYLLINE

INJECTABLE; INJECTION
AMINOPHYLLINE

| | | | |
|---|---|---|---|
| AP | FUJISAWA | 25MG/ML | N87886 001 AUG 30, 1983 |
| | @ | 25MG/ML | N87886 001 AUG 30, 1983 |
| AP | KING PHARMS | 25MG/ML | N86606 001 |
| AP | SMITHKLINE BEECHAM | 25MG/ML | N86606 001 |

TABLET; ORAL
AMINOPHYLLINE

| | | | |
|---|---|---|---|
| AB | GLOBAL PHARMS | 100MG | N84574 001 |
| AB | | 200MG | N84576 001 |
| BD | LANNETT | 100MG | N84588 001 |
| BD | | 200MG | N84588 002 |
| | @ | 100MG | N84588 001 |
| | @ | 200MG | N84588 002 |
| BD | RICHLYN | 100MG | N84574 001 |
| BD | | 200MG | N84576 001 |

AMINOSALICYLIC ACID

GRANULE, DELAYED RELEASE; ORAL

PASER

| | | | | |
|---|---|---|---|---|
| + | JACOBUS | 4GM/PACKET | N74346 001 JUN 30, 1994 | |

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

**AMITRIPTYLINE HCL**

| | | | | |
|---|---|---|---|---|
| AB | LEMMON | 10MG | N86610 001 | |
| AB | | 25MG | N86859 001 | |
| AB | | 50MG | N86857 001 | |
| AB | | 75MG | N86860 001 | |
| AB | | 100MG | N86854 001 | |
| AB | | 150MG | N86853 001 | |
| @ | | 10MG | N86610 001 | |
| @ | | 25MG | N86859 001 | |
| @ | | 50MG | N86857 001 | |
| @ | | 75MG | N86860 001 | |
| @ | | 100MG | N86854 001 | |
| @ | | 150MG | N86853 001 | |

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

**TRIAVIL 2-10**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | | LOTUS | 10MG;2MG | N14715 004 |
| > DLT > | AB | | MSD | 10MG;2MG | N14715 004 |

**TRIAVIL 2-25**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | | LOTUS | 25MG;2MG | N14715 002 |
| > DLT > | AB | | MSD | 25MG;2MG | N14715 002 |

**TRIAVIL 4-10**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | | LOTUS | 10MG;4MG | N14715 003 |
| > DLT > | AB | | MSD | 10MG;4MG | N14715 003 |

**TRIAVIL 4-25**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | + | LOTUS | 25MG;4MG | N14715 005 |
| > DLT > | AB | + | MSD | 25MG;4MG | N14715 005 |

**TRIAVIL 4-50**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | + | LOTUS | 50MG;4MG | N14715 006 |
| > DLT > | AB | + | MSD | 50MG;4MG | N14715 006 |

AMOXICILLIN

CAPSULE; ORAL

**AMOXICILLIN**

| | | | | |
|---|---|---|---|---|
| AB | BIOCHEMIE | 250MG | N64076 001 SEP 30, 1994 | |
| AB | | 500MG | N64076 002 SEP 30, 1994 | |

**POLYMOX**

| | | | | |
|---|---|---|---|---|
| AB | APOTHECON | 250MG | N63099 001 MAR 20, 1992 | |
| AB | | 500MG | N63099 002 MAR 20, 1992 | |
| AB | BRISTOL MYERS | 250MG | N63099 001 MAR 20, 1992 | |
| AB | | 500MG | N63099 002 MAR 20, 1992 | |

POWDER FOR RECONSTITUTION; ORAL

**POLYMOX**

| | | | | |
|---|---|---|---|---|
| @ | APOTHECON | 125MG/5ML | N61851 001 | |
| @ | | 125MG/5ML | N62323 001 | |
| @ | | 250MG/5ML | N61851 002 | |
| @ | | 250MG/5ML | N62323 002 | |
| AB | BRISTOL | 125MG/5ML | N61851 001 | |
| AB | | 125MG/5ML | N62323 001 | |
| AB | | 250MG/5ML | N61851 002 | |
| AB | | 250MG/5ML | N62323 002 | |

AMPHETAMINE SULFATE

TABLET; ORAL

**AMPHETAMINE SULFATE**

| | | | | |
|---|---|---|---|---|
| | LANNETT | 5MG | N83901 001 AUG 31, 1984 | |
| | | 10MG | N83901 002 AUG 31, 1984 | |
| @ | | 5MG | N83901 001 AUG 31, 1984 | |
| @ | | 10MG | N83901 002 AUG 31, 1984 | |

AMPHOTERICIN B

INJECTABLE; INJECTION

**AMPHOTERICIN B**

| | | | | |
|---|---|---|---|---|
| AP | FUJISAWA | 50MG/VIAL | N62728 001 APR 13, 1987 | |

AMPHOTERICIN B

INJECTABLE; INJECTION
**AMPHOTERICIN B**
@ FUJISAWA — 50MG/VIAL — N62728 001 APR 13, 1987

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
**POLYCILLIN**
@ APOTHECON — EQ 125MG BASE/5ML — N62297 001
@ — EQ 250MG BASE/5ML — N62297 002
AB BRISTOL — EQ 125MG BASE/5ML — N62297 001
AB — EQ 250MG BASE/5ML — N62297 002

AMRINONE LACTATE

INJECTABLE; INJECTION
INOCOR
SANOFI WINTHROP — EQ 5MG BASE/ML — N18700 001 JUL 31, 1984
STERLING WINTHROP — EQ 5MG BASE/ML — N18700 001 JUL 31, 1984

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VASOCON-A
+ CIBA VISION — 0.5%;0.05% — N18746 001 APR 30, 1990
+ IOLAB — 0.5%;0.05% — N18746 001 APR 30, 1990

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;0.5 UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 UNITS/ML;1 IU/ML — N18440 002 AUG 08, 1985

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

INJECTABLE; INJECTION
M.V.C. 9+3
@ FUJISAWA — 10MG/ML;0.006MG/ML;0.5 UGM/ML; 1.5MG/ML;20 IU/ML;0.04MG/ML;4MG/ML; 0.4MG/ML;0.36MG/ML;0.3MG/ML; 330 UNITS/ML;1 IU/ML — N18440 002 AUG 08, 1985

ASPIRIN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
TALWIN COMPOUND
+ SANOFI WINTHROP — 325MG;EQ 12.5MG BASE — N16891 001
+ STERLING WINTHROP — 325MG;EQ 12.5MG BASE — N16891 001

ATENOLOL

TABLET; ORAL
**ATENOLOL**
AB GENPHARM — **50MG** — **N74126 001** MAR 23, 1994
AB — **100MG** — **N74126 002** MAR 23, 1994
AB INVAMED — **25MG** — **N74265 001** FEB 28, 1994
AB — **50MG** — **N74265 002** FEB 28, 1994
AB — **100MG** — **N74265 003** FEB 28, 1994

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
LOFENE
AA LANNETT — 0.025MG;2.5MG — N85372 001
@ — 0.025MG;2.5MG — N85372 001

AZITHROMYCIN DIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
ZITHROMAX

| | | | | |
|---|---|---|---|---|
| | + | PFIZER | EQ 1GM BASE/PACKET | N50693 001<br>SEP 28, 1994 |

BACITRACIN

OINTMENT; OPHTHALMIC
**BACITRACIN**

| | | | | |
|---|---|---|---|---|
| **AT** | | PHARMADERM | 500 UNITS/GM | N62158 001 |
| | @ | | 500 UNITS/GM | N62158 001 |
| **AT** | | PHARMAFAIR | 500 UNITS/GM | N62453 001<br>MAR 28, 1984 |
| | @ | | 500 UNITS/GM | N62453 001<br>MAR 28, 1984 |

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
**OCUMYCIN**

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | **AT** | | PHARMAFAIR | 500 UNITS/GM;<br>10,000 UNITS/GM | N62430 001<br>APR 08, 1983 |
| > ADD > | | @ | | 500 UNITS/GM;<br>10,000 UNITS/GM | N62430 001<br>APR 08, 1983 |

**POLYSPORIN**

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | **AT** | + | BURROUGHS WELLCOME | 500 UNITS/GM;<br>10,000 UNITS/GM | N61229 001 |
| > ADD > | | + | | 500 UNITS/GM;<br>10,000 UNITS/GM | N61229 001 |

BACLOFEN

TABLET; ORAL
**BACLOFEN**

| | | | | |
|---|---|---|---|---|
| **AB** | | ROYCE LABS | 10MG | N73092 001<br>JAN 28, 1994 |
| **AB** | | | 20MG | N73093 001<br>JAN 28, 1994 |

BENZYL BENZOATE

EMULSION; TOPICAL
BENZYL BENZOATE

| | | | | |
|---|---|---|---|---|
| | + | LANNETT | 50% | N84535 001 |
| | @ | | 50% | N84535 001 |

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL
DIPROLENE

| | | | | |
|---|---|---|---|---|
| | + | SCHERING | EQ 0.05% BASE | N19408 001<br>JAN 31, 1986 |
| | @ | | EQ 0.05% BASE | N19408 001<br>JAN 31, 1986 |

GEL; TOPICAL
DIPROLENE

| | | | | |
|---|---|---|---|---|
| | + | SCHERING | EQ 0.05% BASE | N19408 002<br>NOV 22, 1991 |

LOTION; TOPICAL
**BETAMETHASONE DIPROPIONATE**

| | | | | |
|---|---|---|---|---|
| **AB** | | TARO PHARMS | **EQ 0.05% BASE** | **N74272 001**<br>SEP 30, 1994 |

OINTMENT; TOPICAL
**BETAMETHASONE DIPROPIONATE**

| | | | | |
|---|---|---|---|---|
| **AB** | | TARO PHARMS | **EQ 0.05% BASE** | **N74271 001**<br>SEP 15, 1994 |

BETAMETHASONE VALERATE

LOTION; TOPICAL
**BETAMETHASONE VALERATE**

| | | | | |
|---|---|---|---|---|
| **AB** | | PHARMAFAIR | EQ 0.1% BASE | N70484 001<br>MAY 29, 1987 |
| | @ | | EQ 0.1% BASE | N70484 001<br>MAY 29, 1987 |

OINTMENT; TOPICAL
BETAMETHASONE VALERATE

| | | | | |
|---|---|---|---|---|
| B* | | CLAY PARK | EQ 0.1% BASE | N71478 001<br>DEC 23, 1987 |
| | @ | | EQ 0.1% BASE | N71478 001<br>DEC 23, 1987 |

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE

| | | | |
|---|---|---|---|
| AA | LANNETT | 5MG | N84702 001 |
| AA | | 10MG | N84712 001 |
| AA | | 25MG | N84074 001 |
| | @ | 5MG | N84702 001 |
| | @ | 10MG | N84712 001 |
| | @ | 25MG | N84074 001 |

BITOLTEROL MESYLATE

AEROSOL, METERED; INHALATION
TORNALATE

| | | | |
|---|---|---|---|
| | + SANOFI WINTHROP | 0.37MG/INH | N18770 001 DEC 28, 1984 |
| | + STERLING WINTHROP | 0.37MG/INH | N18770 001 DEC 28, 1984 |

SOLUTION; INHALATION
TORNALATE

| | | | |
|---|---|---|---|
| | SANOFI WINTHROP | 0.2% | N19548 001 FEB 19, 1992 |
| | STERLING WINTHROP | 0.2% | N19548 001 FEB 19, 1992 |

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL
DIMETANE-DX

| | | | |
|---|---|---|---|
| AA | ROBINS AH | 2MG/5ML;10MG/5ML;30MG/5ML | N11694 007 MAR 29, 1984 |

BUDESONIDE

AEROSOL, METERED; NASAL
RHINOCORT

| | | | |
|---|---|---|---|
| | + ASTRA | 0.05MG/INH | N20233 001 FEB 14, 1994 |

BUMETANIDE

INJECTABLE; INJECTION
BUMETANIDE

| | | | |
|---|---|---|---|
| AP | SANOFI WINTHROP | 0.25MG/ML | N74332 001 OCT 31, 1994 |

BUMEX

| | | | |
|---|---|---|---|
| AP | + ROCHE | 0.25MG/ML | N18226 001 FEB 28, 1983 |

BUTABARBITAL SODIUM

ELIXIR; ORAL
BUTALAN

| | | | |
|---|---|---|---|
| | LANNETT | 33.3MG/5ML | N85880 001 |
| | @ | 33.3MG/5ML | N85880 001 |

TABLET; ORAL
BUTISOL SODIUM

| | | | |
|---|---|---|---|
| AA | WALLACE | 100MG | N00793 005 |
| | + | 100MG | N00793 005 |

SODIUM BUTABARBITAL

| | | | |
|---|---|---|---|
| AA | LANNETT | 100MG | N85881 001 |
| | @ | 100MG | N85881 001 |
| AA | ZENITH | 30MG | N84040 001 |
| | @ ZENITH LABS | 30MG | N84040 001 |

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL
MIGERGOT

| | | | |
|---|---|---|---|
| BR | G AND W LABS | 100MG;2MG | N86557 001 OCT 04, 1983 |

WIGRAINE

| | | | |
|---|---|---|---|
| BR | ORGANON | 100MG;2MG | N86557 001 OCT 04, 1983 |

CALCIFEDIOL

CAPSULE; ORAL
CALDEROL

| | | | |
|---|---|---|---|
| | ORGANON | 0.02MG | N18312 001 |
| | + | 0.05MG | N18312 002 |

CALCIFEDIOL, ANHYDROUS

CAPSULE; ORAL
CALDEROL
ORGANON 0.02MG N18312 001
* 0.05MG N18312 002

CALCIUM; MEGLUMINE; METRIZOIC ACID

INJECTABLE; INJECTION
ISOPAQUE 280
@ NYCOMED 0.35MG/ML;140.1MG/ML; 461.8MG/ML N17506 001
@ STERLING WINTHROP 0.35MG/ML;140.1MG/ML; 461.8MG/ML N17506 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL
DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
AT FRESENIUS 18.4MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20171 001 AUG 19, 1992

DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
AT FRESENIUS 18.4MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20171 002 AUG 19, 1992

DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER
AT FRESENIUS 18.4MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20171 003 AUG 19, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT BAXTER 18.3MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20183 001 DEC 04, 1992

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL
DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT BAXTER 18.3MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20183 002 DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
AT BAXTER 18.3MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20183 003 DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER
AT BAXTER 18.3MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N20183 004 DEC 04, 1992

DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT BAXTER 18.3MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML N17512 004

INPERSOL W/ DEXTROSE 1.5% IN PLASTIC CONTAINER
AT ABBOTT 25.7MG/100ML;1.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 002
AT FRESENIUS 25.7MG/100ML;1.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 002

INPERSOL W/ DEXTROSE 2.5% IN PLASTIC CONTAINER
AT ABBOTT 25.7MG/100ML;2.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 003
AT FRESENIUS 25.7MG/100ML;2.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 003

INPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER
AT ABBOTT 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 007 JUN 24, 1988
AT FRESENIUS 25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML N18379 007 JUN 24, 1988

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

INPERSOL W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | AT | ABBOTT | 25.7MG/100ML;4.25GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML | N18379 001 |
| | AT | FRESENIUS | 25.7MG/100ML;4.25GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100ML | N18379 001 |

INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | AT | ABBOTT | 18.4MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 001 JUN 13, 1994 |
| > ADD > | AT | FRESENIUS | 18.4MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 001 JUN 13, 1994 |

INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | AT | ABBOTT | 18.4MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 002 JUN 13, 1994 |
| > ADD > | AT | FRESENIUS | 18.4MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 002 JUN 13, 1994 |

INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | AT | ABBOTT | 18.4MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 003 JUN 13, 1994 |
| > ADD > | AT | FRESENIUS | 18.4MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 003 JUN 13, 1994 |

INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| > DLT > | AT | ABBOTT | 18.4MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 004 JUN 13, 1994 |
| > ADD > | AT | FRESENIUS | 18.4MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N20374 004 JUN 13, 1994 |

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

INPERSOL-LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT | 25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 004 JUL 07, 1982 |
| AT | FRESENIUS | 25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 004 JUL 07, 1982 |

INPERSOL-LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT | 25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 005 JUL 07, 1982 |
| AT | FRESENIUS | 25.7MG/100ML;2.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 005 JUL 07, 1982 |

INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT | 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 008 JUN 24, 1988 |
| AT | FRESENIUS | 25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 008 JUN 24, 1988 |

INPERSOL-LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT | 25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 006 JUL 07, 1982 |
| AT | FRESENIUS | 25.7MG/100ML;4.25GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML | N18379 006 JUL 07, 1982 |

CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

INPERSOL-ZM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| @ | ABBOTT | 25.7MG/100ML;1.5GM/100ML; 538MG/100ML;448MG/100ML | N19395 001 MAR 26, 1986 |

CALCIUM CHLORIDE; DEXTROSE; SODIUM CHLORIDE; SODIUM LACTATE

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

CALCIUM METRIZOATE; MEGLUMINE METRIZOATE; METRIZOATE MAGNESIUM; METRIZOATE SODIUM

INJECTABLE; INJECTION
ISOPAQUE 440
@ NYCOMED — 0.78MG/ML;75.9MG/ML;0.15MG/ML; 16.6MG/ML — N16847 001
@ STERLING WINTHROP — 0.78MG/ML;75.9MG/ML;0.15MG/ML; 16.6MG/ML — N16847 001

CARBACHOL

INJECTABLE; INJECTION
CARBACHOL
@ PHARMAFAIR — 0.01% — N70292 001 MAY 21, 1986
MIOSTAT
\+ ALCON — 0.01% — N16968 001

SOLUTION; INTRAOCULAR
CARBACHOL
@ PHARMAFAIR — 0.01% — N70292 001 MAY 21, 1986
MIOSTAT
\+ ALCON — 0.01% — N16968 001

CARBAMAZEPINE

SUSPENSION; ORAL
TEGRETOL
\+ BASEL PHARMS — 100MG/5ML — N18927 001 DEC 18, 1987
* GEIGY — 100MG/5ML — N18927 001 DEC 18, 1987

TABLET; ORAL
**TEGRETOL**
AB + BASEL PHARMS — **200MG** — **N16608 001**
AB * GEIGY — **200MG** — **N16608 001**

TABLET, CHEWABLE; ORAL
**TEGRETOL**
AB + BASEL PHARMS — **100MG** — **N18281 001**
AB * GEIGY — **100MG** — **N18281 001**

CARBIDOPA; LEVODOPA

TABLET; ORAL
**CARBIDOPA AND LEVODOPA**
AB SCS — **10MG;100MG** — **N74080 001** MAR 25, 1994
AB — **25MG;100MG** — **N74080 002** MAR 25, 1994
AB — **25MG;250MG** — **N74080 003** MAR 25, 1994

TABLET, EXTENDED RELEASE; ORAL
SINEMET CR
MERCK SHARP DOHME — 25MG;100MG — N19856 002 DEC 24, 1992

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL
**CEFADROXIL**
AB APOTHECON — **EQ 500MG BASE** — **N62291 001**
AB ZENITH LABS — **EQ 500MG BASE** — **N62766 001** MAR 03, 1987
@ — EQ 500MG BASE — N62766 001 MAR 03, 1987
ULTRACEF
AB BRISTOL — EQ 500MG BASE — N62291 001

CEFADROXIL/CEFADROXIL HEMIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | CEFADROXIL | | | |
| AB | APOTHECON | EQ 125MG BASE/5ML | N62334 001 | |
| AB | | EQ 250MG BASE/5ML | N62334 002 | |
| AB | | EQ 500MG BASE/5ML | N62334 003 | |
| | ULTRACEF | | | |
| AB | BRISTOL | EQ 125MG BASE/5ML | N62334 001 | |
| AB | | EQ 250MG BASE/5ML | N62334 002 | |
| AB | | EQ 500MG BASE/5ML | N62334 003 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | CEFADROXIL | | | |
| AB | ZENITH LABS | EQ 1GM BASE | N62774 001 | APR 08, 1987 |
| | @ | EQ 1GM BASE | N62774 001 | APR 08, 1987 |
| | ULTRACEF | | | |
| AB | APOTHECON | EQ 1GM BASE | N62390 001 | JUN 10, 1982 |
| AB | BRISTOL | EQ 1GM BASE | N62390 001 | JUN 10, 1982 |

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | CEFAZOLIN SODIUM | | | |
| AP | FUJISAWA | EQ 500MG BASE/VIAL | N62688 002 | NOV 17, 1986 |
| AP | | EQ 1GM BASE/VIAL | N62688 003 | NOV 17, 1986 |
| AP | | EQ 10GM BASE/VIAL | N62688 004 | NOV 17, 1986 |
| AP | | EQ 20GM BASE/VIAL | N62688 005 | AUG 03, 1987 |
| | @ | EQ 500MG BASE/VIAL | N62688 002 | NOV 17, 1986 |
| | @ | EQ 1GM BASE/VIAL | N62688 003 | NOV 17, 1986 |
| | @ | EQ 10GM BASE/VIAL | N62688 004 | NOV 17, 1986 |
| | @ | EQ 20GM BASE/VIAL | N62688 005 | AUG 03, 1987 |

> ADD >
> ADD >
> ADD >
> ADD >

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | CEFIZOX | | | |
| | FUJISAWA | EQ 1GM BASE/VIAL | N63294 002 | MAR 31, 1994 |
| | | EQ 2GM BASE/VIAL | N63294 003 | MAR 31, 1994 |

CEFUROXIME AXETIL

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | CEFTIN | | | |
| + | GLAXO | EQ 125MG BASE/5ML | N50672 001 | JUN 30, 1994 |

CEPHALEXIN

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | CEPHALEXIN | | | |
| AB | APOTHECON | EQ 250MG BASE | N63186 001 | DEC 30, 1994 |
| AB | | EQ 500MG BASE | N63186 002 | DEC 30, 1994 |

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | CEPHALOTHIN SODIUM | | | |
| AP | FUJISAWA | EQ 1GM BASE/VIAL | N62666 002 | JUN 10, 1987 |
| AP | | EQ 2GM BASE/VIAL | N62666 001 | JUN 10, 1987 |
| | @ | EQ 1GM BASE/VIAL | N62666 002 | JUN 10, 1987 |
| | @ | EQ 2GM BASE/VIAL | N62666 001 | JUN 10, 1987 |
| | SEFFIN | | | |
| AP | GLAXO | EQ 1GM BASE/VIAL | N62435 001 | NOV 15, 1983 |
| AP | | EQ 2GM BASE/VIAL | N62435 002 | NOV 15, 1983 |
| + | | EQ 10GM BASE/VIAL | N62435 003 | NOV 15, 1983 |
| | @ | EQ 1GM BASE/VIAL | N62435 001 | NOV 15, 1983 |

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
SEFFIN
@ GLAXO — EQ 2GM BASE/VIAL — N62435 002 NOV 15, 1983
@ — EQ 10GM BASE/VIAL — N62435 003 NOV 15, 1983

CHENODIOL

TABLET; ORAL
CHENIX
* SOLVAY — 250MG — N18513 002 JUL 28, 1983
@ — 250MG — N18513 002 JUL 28, 1983

CHLORAMPHENICOL

CREAM; TOPICAL
CHLOROMYCETIN
PARKE DAVIS — 1% — N50183 001
@ — 1% — N50183 001

OINTMENT; OPHTHALMIC
CHLOROFAIR
AT PHARMAFAIR — 1% — N62439 001 APR 21, 1983
@ — 1% — N62439 001 APR 21, 1983

SOLUTION/DROPS; OPHTHALMIC
CHLOROFAIR
AT PHARMAFAIR — 0.5% — N62437 001 APR 14, 1983
@ — 0.5% — N62437 001 APR 14, 1983

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIDEX
AT + PROCTER AND GAMBLE — 0.12% — N19028 001 AUG 13, 1986

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIOGARD
AT COLGATE PALMOLIVE — 0.12% — N73695 001 JAN 14, 1994

CHLORMERODRIN, HG-197

INJECTABLE; INJECTION
CHLORMERODRIN HG 197
@ BRACCO DXS — 0.6-1.4mCi/ML — N17269 001
@ SQUIBB — 0.6-1.4mCi/ML — N17269 001

CHLORMEZANONE

TABLET; ORAL
TRANCOPAL
SANOFI WINTHROP — 100MG — N11467 003
200MG — N11467 005
STERLING WINTHROP — 100MG — N11467 003
200MG — N11467 005

CHLOROQUINE HYDROCHLORIDE

INJECTABLE; INJECTION
ARALEN HCL
+ SANOFI WINTHROP — EQ 40MG BASE/ML — N06002 002
* STERLING WINTHROP — EQ 40MG BASE/ML — N06002 002

CHLOROQUINE PHOSPHATE

TABLET; ORAL
ARALEN
AA + SANOFI WINTHROP — EQ 300MG BASE — N06002 001
AA STERLING WINTHROP — EQ 300MG BASE — N06002 001

CHLOROQUINE PHOSPHATE; PRIMAQUINE PHOSPHATE

TABLET; ORAL
ARALEN PHOSPHATE W/ PRIMAQUINE PHOSPHATE
@ SANOFI WINTHROP — EQ 300MG BASE; EQ 45MG BASE — N14860 002

CHLOROQUINE PHOSPHATE; PRIMAQUINE PHOSPHATE

TABLET; ORAL
ARALEN PHOSPHATE W/ PRIMAQUINE PHOSPHATE
@ STERLING WINTHROP | EQ 300MG BASE; EQ 45MG BASE | N14860 002

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
AA ZENITH | 4MG | N80779 001
@ ZENITH LABS | 4MG | N80779 001

CHLORTHALIDONE

TABLET; ORAL
THALITONE
HORUS THERAP | 15MG | N19574 001 | DEC 20, 1988
+ | 15MG | N19574 001 | DEC 20, 1988

CHOLESTYRAMINE

TABLET; ORAL
QUESTRAN
+ BRISTOL MYERS SQUIBB | EQ 1GM RESIN | N73403 001 | APR 28, 1994 | >ADD> >ADD> >ADD> >ADD> >ADD>

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC
CATARASE
@ CIBA VISION | 150 UNITS/VIAL | N18121 001
+ | 300 UNITS/VIAL | N16938 001
@ IGLAB | 150 UNITS/VIAL | N18121 001
* | 300 UNITS/VIAL | N16938 001

CIMETIDINE

TABLET; ORAL
CIMETIDINE
AB ENDO LABS | 200MG | N74281 001 | MAY 17, 1994 | >ADD>

CIMETIDINE

TABLET; ORAL
CIMETIDINE

| | | | | |
|---|---|---|---|---|
| AB | ENDO LABS | 300MG | N74281 002 | MAY 17, 1994 |
| AB | | 400MG | N74281 003 | MAY 17, 1994 |
| AB | | 800MG | N74329 001 | MAY 17, 1994 |
| AB | MYLAN | 200MG | N74246 001 | MAY 17, 1994 |
| AB | | 300MG | N74246 002 | MAY 17, 1994 |
| AB | | 400MG | N74246 003 | MAY 17, 1994 |
| AB | | 800MG | N74246 004 | MAY 17, 1994 |
| AB | NOVOPHARM | 200MG | N74151 001 | MAY 17, 1994 |
| AB | | 300MG | N74151 002 | MAY 17, 1994 |
| AB | | 400MG | N74151 003 | MAY 17, 1994 |
| AB | | 800MG | N74463 001 | MAY 17, 1994 |
| AB | ROXANE | 300MG | N74361 001 | DEC 23, 1994 |
| AB | | 400MG | N74361 002 | DEC 23, 1994 |
| AB | | 800MG | N74371 001 | DEC 23, 1994 |

TAGAMET

| | | | | |
|---|---|---|---|---|
| AB | SMITHKLINE BEECHAM | 200MG | N17920 002 | |
| AB | | 300MG | N17920 003 | |
| AB | | 400MG | N17920 004 | DEC 14, 1983 |
| AB + | | 800MG | N17920 005 | APR 30, 1986 |

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

| | | | | |
|---|---|---|---|---|
| AP | ENDO LABS | EQ 300MG BASE/2ML | N74005 001 | AUG 31, 1994 |
| AP | LUITPOLD | EQ 300MG BASE/2ML | N74353 001 | DEC 20, 1994 |

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | | **CIMETIDINE HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER** | | | |
| > ADD > | **AP** | ABBOTT | **EQ 6MG BASE/ML** | **N74269 001** | |
| > ADD | | | | DEC 27, 1994 | |
| > ADD > | + | | EQ 90MG BASE/100ML | N74468 005 | |
| > ADD > | | | | DEC 29, 1994 | |
| > ADD > | + | | EQ 120MG BASE/100ML | N74468 006 | |
| > ADD > | | | | DEC 29, 1994 | |
| > ADD > | + | | EQ 180MG BASE/100ML | N74468 003 | |
| > ADD > | | | | DEC 29, 1994 | |
| > ADD > | + | | EQ 240MG BASE/100ML | N74468 004 | |
| > ADD > | | | | DEC 29, 1994 | |
| > ADD > | + | | EQ 360MG BASE/100ML | N74468 001 | |
| > ADD > | | | | DEC 29, 1994 | |
| > ADD > | + | | EQ 480MG BASE/100ML | N74468 002 | |
| > ADD > | | | | DEC 29, 1994 | |
| | | **TAGAMET** | | | |
| | **AP** | + SMITHKLINE BEECHAM | **EQ 300MG BASE/2ML** | **N17939 002** | |
| | | **TAGAMET HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER** | | | |
| > ADD > | **AP** | + SMITHKLINE BEECHAM | **EQ 6MG BASE/ML** | **N19434 001** | |
| > ADD > | | | | OCT 31, 1985 | |

SOLUTION; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | **CIMETIDINE HCL** | | | |
| | **AA** | BARRE | **EQ 300MG BASE/5ML** | **N74176 001** | |
| | | | | JUN 01, 1994 | |
| > ADD > | **AA** | ENDO LABS | **EQ 300MG BASE/5ML** | **N74251 001** | |
| > ADD > | | | | DEC 22, 1994 | |
| | | **TAGAMET** | | | |
| | **AA** | SMITHKLINE BEECHAM | **EQ 300MG BASE/5ML** | **N17924 001** | |

CLEMASTINE FUMARATE

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | **CLEMASTINE FUMARATE** | | | |
| **AA** | LEMMON | **EQ 0.5MG BASE/5ML** | **N73399 001** | |
| | | | JUN 30, 1994 | |

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **CLINDAMYCIN PHOSPHATE** | | | |
| **AP** | BEDFORD | **EQ 150MG BASE/ML** | **N63163 001** | |
| | | | JUN 30, 1994 | |

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **CLINDAMYCIN PHOSPHATE** | | | |
| **AP** | DUPONT | **EQ 150MG BASE/ML** | **N62908 001** | |
| | | | FEB 01, 1989 | |
| | @ DUPONT MERCK | EQ 150MG BASE/ML | N62908 001 | |
| | | | FEB 01, 1989 | |
| **AP** | FUJISAWA | **EQ 150MG BASE/ML** | **N62747 001** | |
| | | | JUN 03, 1988 | |
| | @ | EQ 150MG BASE/ML | N62747 001 | |
| | | | JUN 03, 1988 | |

SOLUTION; TOPICAL

| | | | |
|---|---|---|---|
| | CLEOCIN | | |
| | UPJOHN | EQ 1% BASE | N50537 002 |
| | | | FEB 22, 1994 |

CLOBETASOL PROPIONATE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **CLOBETASOL PROPIONATE** | | | |
| **AB** | COPLEY PHARM | **0.05%** | **N74087 001** | |
| | | | FEB 16, 1994 | |
| **AB** | NMC | **0.05%** | **N74139 001** | |
| | | | AUG 03, 1994 | |
| | **TEMOVATE** | | | |
| **AB** | + GLAXO | **0.05%** | **N19322 001** | |
| | | | DEC 27, 1985 | |
| **AB** | + | **0.05%** | **N20340 001** | |
| | | | JUN 17, 1994 | |
| | TEMOVATE EMOLLIENT | | | |
| BX | + GLAXO | 0.05% | N20340 001 | |
| | | | JUN 17, 1994 | |

GEL; TOPICAL

| | | | |
|---|---|---|---|
| | TEMOVATE | | |
| | + GLAXO | 0.05% | N20337 001 |
| | | | APR 29, 1994 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **CLOBETASOL PROPIONATE** | | | |
| **AB** | COPLEY PHARM | **0.05%** | **N74089 001** | |
| | | | FEB 16, 1994 | |
| **AB** | NMC | **0.05%** | **N74128 001** | |
| | | | AUG 03, 1994 | |
| | **TEMOVATE** | | | |
| **AB** | + GLAXO | **0.05%** | **N19323 001** | |
| | | | DEC 27, 1985 | |

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL
ANAFRANIL
BASEL PHARMS 25MG N19906 001 DEC 29, 1989
50MG N19906 002 DEC 29, 1989
+ 75MG N19906 003 DEC 29, 1989
CIBA 25MG N19906 001 DEC 29, 1989
50MG N19906 002 DEC 29, 1989
# 75MG N19906 003 DEC 29, 1989

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
**PROMETHAZINE VC W/ CODEINE**
**AA** PENNEX **10MG/5ML;5MG/5ML; 6.25MG/5ML** **N88896 001** JAN 04, 1985
@ PENNEX PHARMS 10MG/5ML;5MG/5ML; 6.25MG/5ML N88896 001 JAN 04, 1985

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
**PROMETHAZINE W/ CODEINE**
**AA** PENNEX **10MG/5ML;6.25MG/5ML** **N88875 001** DEC 17, 1984
@ PENNEX PHARMS 10MG/5ML;6.25MG/5ML N88875 001 DEC 17, 1984

COLESTIPOL HYDROCHLORIDE

TABLET; ORAL
COLESTID
UPJOHN 1GM N20222 001 JUL 19, 1994

CORTISONE ACETATE

INJECTABLE; INJECTION
CORTISONE ACETATE
BP STERIS 25MG/ML N81147 003
BP 25MG/ML N85677 001
BP 50MG/ML N83147 004
BP 50MG/ML N85677 002
@ 25MG/ML N83147 003
@ 25MG/ML N85677 001
@ 50MG/ML N83147 004
@ 50MG/ML N85677 002
BP UPJOHN 25MG/ML N08126 002
@ 25MG/ML N08126 002
CORTONE
MERCK SHARP DOHME 25MG/ML N07110 002
+ 50MG/ML N07110 003
BP MSD 25MG/ML N07110 002
BP + 50MG/ML N07110 003

TABLET; ORAL
CORTISONE ACETATE
BP INWOOD 25MG N80731 001
@ INWOOD LABS 25MG N80731 001

CROMOLYN SODIUM

SOLUTION; INHALATION
**CROMOLYN SODIUM**
**AN** DEY **10MG/ML** **N74209 001** APR 26, 1994

**INTAL**
**AN** + FISONS **10MG/ML** **N18596 001** MAY 28, 1982

CYANOCOBALAMIN

INJECTABLE; INJECTION
>DLT> >DLT> >ADD> BERUBIGEN
**AP** UPJOHN 1MG/ML N06798 001
@ 1MG/ML N06798 001

CYANOCOBALAMIN, CO-57

CAPSULE; ORAL
RUBRATOPE-57
BRACCO DXS 0.5-1 uCi N16089 002

CYANOCOBALAMIN, CO-57

CAPSULE; ORAL
RUBRATOPE-57
SQUIBB 0.5-1 uCi N16089 002

CYANOCOBALAMIN, CO-60

CAPSULE; ORAL
RUBRATOPE-60
@ BRACCO DXS 0.5-1 uCi N16090 002
@ SQUIBB 0.5-1 uCi N16090 002

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
**CYCLOBENZAPRINE HCL**
**AB** ROYCE LABS **10MG** **N74436 001**
NOV 30, 1994

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
**CYCLOGYL**
**AT** + ALCON **0.5%** **N84109 001**
\+ 0.5% N84109 001
**PENTOLAIR**
**AT** BAUSCH AND LOMB **1%** **N40075 001**
APR 29, 1994
**AT** PHARMAFAIR **0.5%** **N88643 001**
FEB 09, 1987
**AT** **1%** **N88150 001**
FEB 25, 1983
@ 0.5% N88643 001
FEB 09, 1987
@ 1% N88150 001
FEB 25, 1983

CYCLOSPORINE

CAPSULE; ORAL
SANDIMMUNE
> ADD > SANDOZ 50MG N50625 003
> ADD > NOV 23, 1992

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
**CYPROHEPTADINE HCL**
**AA** CHELSEA **4MG** **N86165 001**
@ CHELSEA LABS 4MG N86165 001

CYSTEAMINE BITARTRATE

CAPSULE; ORAL
CYSTAGON
MYLAN EQ 50MG BASE N20392 001
AUG 15, 1994
\+ EQ 150MG BASE N20392 002
AUG 15, 1994

CYTARABINE

INJECTABLE; INJECTION
**CYTARABINE**
\+ BULL D 20MG/ML N72945 001
FEB 28, 1994
**AP** CETUS BEN VENUE **1GM/VIAL** **N74245 001**
AUG 31, 1994
**AP** **2GM/VIAL** **N74245 002**
AUG 31, 1994
**CYTOSAR-U**
**AP** + UPJOHN **1GM/VIAL** **N16793 003**
DEC 21, 1987
**AP** + **2GM/VIAL** **N16793 004**
DEC 21, 1987

DACTINOMYCIN

INJECTABLE; INJECTION
COSMEGEN
\+ MERCK SHARP DOHME 0.5MG/VIAL N50682 001
\+ MSD 0.5MG/VIAL N60467 001

> ADD > DALTEPARIN SODIUM

> ADD > INJECTABLE; INJECTION
> ADD > FRAGMIN
> ADD > \+ PHARMACIA 2,500 IU/0.2ML N20287 001
> ADD > DEC 22, 1994

DANAZOL

CAPSULE; ORAL
DANOCRINE

| | | | | |
|---|---|---|---|---|
| | SANOFI WINTHROP | 50MG | | N17557 003 |
| | | 100MG | | N17557 004 |
| + | | 200MG | | N17557 002 |
| | STERLING WINTHROP | 50MG | | N17557 003 |
| | | 100MG | | N17557 004 |
| + | | 200MG | | N17557 002 |

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
DESMOPRESSIN ACETATE

| | | | | |
|---|---|---|---|---|
| + | RHONE POULENC RORER | 0.15MG/INH | | N20355 001 |
| | | | | MAR 07, 1994 |

DESONIDE

OINTMENT; TOPICAL
**DESONIDE**

| | | | | |
|---|---|---|---|---|
| **AB** | TARO | **0.05%** | | **N74254 001** |
| | | | | AUG 03, 1994 |

DEXAMETHASONE

TABLET; ORAL
DECADRON

| | | | | |
|---|---|---|---|---|
| BP | MERCK SHARP DOHME | 0.25MG | | N11664 004 |
| | MSD | 0.25MG | | N11664 004 |

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
**DEXASPORIN**

| | | | | |
|---|---|---|---|---|
| **AT** | BAUSCH AND LOMB | **0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM** | | **N64063 001** |
| | | | | JUL 25, 1994 |

DEXAMETHASONE SODIUM PHOSPHATE

AEROSOL; NASAL
DEXACORT

| | | | | |
|---|---|---|---|---|
| + | ADAMS LABS | EQ 0.1MG PHOSPHATE/INH | | N14242 001 |

DEXAMETHASONE SODIUM PHOSPHATE

AEROSOL; NASAL
DEXACORT

| | | | | |
|---|---|---|---|---|
| + | MEDEVA | EQ 0.1MG PHOSPHATE/INH | | N14242 001 |

AEROSOL, METERED; INHALATION
DECADRON

| | | | | |
|---|---|---|---|---|
| + | MSD | EQ 0.1MG PHOSPHATE/INH | | N13413 001 |

DEXACORT

| | | | | |
|---|---|---|---|---|
| + | MEDEVA | EQ 0.1MG PHOSPHATE/INH | | N13413 001 |

OINTMENT; OPHTHALMIC
DEXAIR

| | | | | |
|---|---|---|---|---|
| AT | PHARMAFAIR | EQ 0.05% PHOSPHATE | | N88071 001 |
| | | | | DEC 28, 1982 |
| | @ | EQ 0.05% PHOSPHATE | | N88071 001 |
| | | | | DEC 28, 1982 |

SOLUTION/DROPS; OPHTHALMIC
DEXAIR

| | | | | |
|---|---|---|---|---|
| | PHARMAFAIR | EQ 0.1% PHOSPHATE | | N88433 001 |
| | | | | DEC 15, 1983 |
| | @ | EQ 0.1% PHOSPHATE | | N88433 001 |
| | | | | DEC 15, 1983 |

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
**NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE**

| | | | | |
|---|---|---|---|---|
| **AT** | PHARMAFAIR | **EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML** | | **N62539 001** |
| | | | | JAN 10, 1985 |
| | @ | EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML | | N62539 001 |
| | | | | JAN 10, 1985 |

DEXTROAMPHETAMINE SULFATE

ELIXIR; ORAL
DEXEDRINE

| | | | | |
|---|---|---|---|---|
| | SMITHKLINE BEECHAM | 5MG/5ML | | N83902 001 |
| | @ | 5MG/5ML | | N83902 001 |

TABLET; ORAL
**DEXTROAMPHETAMINE SULFATE**

| | | | | |
|---|---|---|---|---|
| **AA** | LANNETT | **5MG** | | **N83903 001** |

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **DEXTROAMPHETAMINE SULFATE** | | | |
| AA | LANNETT | 10MG | N83903 003 | |
| | | 15MG | N85652 001 | |
| | @ | 5MG | N83903 001 | |
| | @ | 10MG | N83903 003 | |
| | @ | 15MG | N85652 001 | |

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | **PROMETHAZINE W/ DEXTROMETHORPHAN** | | | |
| AA | PENNEX | 15MG/5ML;6.25MG/5ML | N88864 001 | JAN 04, 1985 |
| | @ PENNEX PHARMS | 15MG/5ML;6.25MG/5ML | N88864 001 | JAN 04, 1985 |

DEXTROSE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **DEXTROSE 5% IN PLASTIC CONTAINER** | | | |
| AP | MCGAW | 50MG/ML | N16730 002 | |

DEXTROTHYROXINE SODIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | CHOLOXIN | | | |
| | BOOTS | 4MG | N12302 004 | |
| | * | 6MG | N12302 006 | |
| | + | 4MG | N12302 004 | |
| | @ | 6MG | N12302 006 | |

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | CARDIOGRAFIN | | | |
| | @ BRACCO DXS | 85% | N11620 002 | |
| | @ SQUIBB | 85% | N11620 002 | |
| | **HYPAQUE** | | | |
| AP | NYCOMED | 30% | N16403 002 | |
| AP | | 60% | N16403 001 | |
| AP | STERLING WINTHROP | 30% | N16403 002 | |
| AP | | 60% | N16403 001 | |

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **RENO-60** | | | |
| AP | BRACCO DXS | 60% | N10040 016 | |
| | **RENO-DIP** | | | |
| AP | BRACCO DXS | 30% | N10040 012 | |
| | **RENO-M-60** | | | |
| AP | SQUIBB | 60% | N10040 016 | |
| | **RENO-M-DIP** | | | |
| AP | SQUIBB | 30% | N10040 012 | |

SOLUTION; URETERAL

| | | | | |
|---|---|---|---|---|
| | **RENO-30** | | | |
| AT | BRACCO DXS | 30% | N10040 021 | |
| | **RENO-M-30** | | | |
| AT | SQUIBB | 30% | N10040 021 | |

SOLUTION; URETHRAL

| | | | | |
|---|---|---|---|---|
| | **HYPAQUE-CYSTO** | | | |
| AT | NYCOMED | 30% | N16403 003 | |
| AT | STERLING WINTHROP | 30% | N16403 003 | |

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **HYPAQUE-76** | | | |
| AP | NYCOMED | 66%;10% | N86505 001 | |
| AP | STERLING WINTHROP | 66%;10% | N86505 001 | |
| | HYPAQUE-M,75% | | | |
| | @ NYCOMED | 50%;25% | N10220 003 | |
| | @ STERLING WINTHROP | 50%;25% | N10220 003 | |
| | HYPAQUE-M,90% | | | |
| | @ NYCOMED | 60%;30% | N10220 002 | |
| | @ STERLING WINTHROP | 60%;30% | N10220 002 | |
| | **MD-60** | | | |
| AP | MALLINCKRODT | 52%;8% | N87074 001 | |
| | @ | 52%;8% | N87074 001 | |

DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINE

SOLUTION; INTRAUTERINE

| | | | | |
|---|---|---|---|---|
| | SINOGRAFIN | | | |
| | BRACCO DXS | 52.7%;26.8% | N11324 002 | |
| | SQUIBB | 52.7%;26.8% | N11324 002 | |

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | HYPAQUE | | | | |
| AP | NYCOMED | 50% | N09561 001 | | |
| | | 25% | N09561 003 | | |
| AP | STERLING WINTHROP | 50% | N09561 001 | | |
| | | 25% | N09561 003 | | |

POWDER FOR RECONSTITUTION; ORAL, RECTAL

| | | | | | |
|---|---|---|---|---|---|
| | HYPAQUE | | | | |
| | NYCOMED | 100% | N11386 001 | | |
| | STERLING WINTHROP | 100% | N11386 001 | | |

SOLUTION; ORAL, RECTAL

| | | | | | |
|---|---|---|---|---|---|
| | HYPAQUE | | | | |
| | NYCOMED | 40% | N11386 003 | | |
| | STERLING WINTHROP | 40% | N11386 003 | | |

SOLUTION; URETERAL

| | | | | | |
|---|---|---|---|---|---|
| | HYPAQUE SODIUM 20% | | | | |
| | NYCOMED | 20% | N09561 002 | | |
| @ | STERLING WINTHROP | 20% | N09561 002 | >_DLT_> | |

DICLOXACILLIN SODIUM

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | DYNAPEN | | | | |
| AB | APOTHECON | EQ 500MG BASE | N61454 003 | | |

DICUMAROL

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | DICUMAROL | | | | |
| | ABBOTT | 25MG | N05545 003 | | |
| + | | 25MG | N05545 003 | | |

DIENESTROL

CREAM; VAGINAL

| | | | | | |
|---|---|---|---|---|---|
| | ESTRAGUARD | | | | |
| AT | SOLVAY | 0.01% | N84436 001 | | |
| @ | | 0.01% | N84436 001 | >_DLT_> | |

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | TEPANIL | | | | |
| AA | 3M | 25MG | N11673 001 | | |
| @ | | 25MG | N11673 001 | | |

DIETHYLSTILBESTROL

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | DIETHYLSTILBESTROL | | | | |
| BP | LILLY | 1MG | N04041 004 | | |
| BP | + | 5MG | N04041 005 | | |
| | | 1MG | N04041 004 | | |
| | + | 5MG | N04041 005 | | |
| | STILBESTROL | | | | |
| BP | TABLICAPS | 1MG | N83002 001 | | |
| BP | | 5MG | N83006 001 | | |
| @ | | 1MG | N83002 001 | | |
| @ | | 5MG | N83006 001 | | |

TABLET, DELAYED RELEASE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | DIETHYLSTILBESTROL | | | | |
| BE | + LILLY | 1MG | N04039 004 | >_DLT_> | |
| BE | + | 5MG | N04039 006 | >_DLT_> | |
| @ | | 1MG | N04039 004 | >_ADD_> | |
| @ | | 5MG | N04039 006 | >_ADD_> | |
| | STILBESTROL | | | | |
| BE | TABLICAPS | 0.5MG | N83003 001 | | |
| BE | | 1MG | N83005 001 | | |
| BE | | 5MG | N83007 001 | | |
| @ | | 0.5MG | N83003 001 | | |
| @ | | 1MG | N83005 001 | | |
| @ | | 5MG | N83007 001 | | |
| | STILBETIN | | | | |
| BE | SQUIBB | 0.5MG | N04056 012 | | |
| BE | | 1MG | N04056 013 | | |
| BE | | 5MG | N04056 014 | | |
| @ | | 0.5MG | N04056 012 | | |
| @ | | 1MG | N04056 013 | | |
| @ | | 5MG | N04056 014 | | |

DIETHYLSTILBESTROL; METHYLTESTOSTERONE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | TYLOSTERONE | | | | |
| | + LILLY | 0.25MG;5MG | N07651 001 | >_DLT_> | |

DIETHYLSTILBESTROL; METHYLTESTOSTERONE

TABLET; ORAL
TYLOSTERONE

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | @ LILLY | 0.25MG;5MG | N07661 001 | | |
| > ADD > | | | | | |

DILTIAZEM HYDROCHLORIDE

TABLET; ORAL
DILTIAZEM HCL

| | | | | | |
|---|---|---|---|---|---|
| AB | NOVOPHARM | 30MG | N74084 001 | > ADD > | |
| | | | FEB 25, 1994 | > ADD > | |
| AB | | 60MG | N74084 002 | > ADD > | |
| | | | FEB 25, 1994 | | |

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

| | | | | | |
|---|---|---|---|---|---|
| AA | LANNETT | 25MG | N80868 001 | > DLT > | |
| AA | | 50MG | N80868 002 | > DLT > | |
| | @ | 25MG | N80868 001 | > DLT > | |
| | @ | 50MG | N80868 002 | > DLT > | |
| AA | ROXANE | 50MG | N80635 001 | > DLT > | |
| | @ | 50MG | N80635 001 | > DLT > | |
| | | | | > ADD > | |
| | | | | > ADD > | |
| | | | | > ADD > | |
| | | | | > ADD > | |
| | | | | > ADD > | |
| | | | | > ADD > | |
| | | | | > ADD > | |

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
DIPIVEFRIN HCL

| | | | | |
|---|---|---|---|---|
| AT | ALCON | 0.1% | N73636 001 | > ADD > |
| | | | JUN 30, 1994 | |
| | PROPINE | | | |
| AT | + ALLERGAN | 0.1% | N18239 001 | |

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTAMINE HCL

| | | | |
|---|---|---|---|
| AP | BEDFORD | EQ 12.5MG BASE/ML | N74277 001 |
| | | | OCT 31, 1994 |

DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | ABBOTT | EQ 400MG BASE/100ML | N20201 006 |
| | | | JUL 07, 1994 |

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AP | + BAXTER | EQ 400MG BASE/100ML | N20255 005 |
| | | | OCT 19, 1993 |

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
TRUSOPT

| | | | |
|---|---|---|---|
| | + MERCK | EQ 2% BASE | N20408 001 |
| | | | DEC 09, 1994 |

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

| | | | |
|---|---|---|---|
| | @ PISONS | EQ 10MG BASE | N16987 001 |
| | @ | EQ 25MG BASE | N16987 002 |
| | @ | EQ 50MG BASE | N16987 003 |
| | @ | EQ 75MG BASE | N16987 006 |
| | @ | EQ 100MG BASE | N16987 004 |
| | @ | EQ 150MG BASE | N16987 007 |
| | | | APR 13, 1987 |
| | @ LOTUS BIOCHEM | EQ 10MG BASE | N16987 001 |
| | @ | EQ 25MG BASE | N16987 002 |
| | @ | EQ 50MG BASE | N16987 003 |
| | @ | EQ 75MG BASE | N16987 006 |
| | @ | EQ 100MG BASE | N16987 004 |
| | @ | EQ 150MG BASE | N16987 007 |
| | | | APR 13, 1987 |

CREAM; TOPICAL
ZONALON

| | | | |
|---|---|---|---|
| | + GENDERM | 5% | N20126 001 |
| | | | APR 01, 1994 |

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS

| | | | |
|---|---|---|---|
| AP | + PHARMACIA | 200MG/100ML | N50629 002 |
| | | | MAY 03, 1988 |
| AP | | 200MG/100ML | N63165 002 |
| | | | JAN 30, 1991 |

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

| | | | | |
|---|---|---|---|---|
| * | PHARMACIA | 200MG/100ML | N50629 002 | MAY 03, 1988 |
| | | 200MG/100ML | N63165 002 | JAN 30, 1991 |

DOXORUBICIN HCL

| | | | | |
|---|---|---|---|---|
| AP | CETUS BEN VENUE | 200MG/100ML | N64097 001 | SEP 13, 1994 |

ENFLURANE

LIQUID; INHALATION

ENFLURANE

| | | | | |
|---|---|---|---|---|
| AN | INHALON | 99.9% | N74396 001 | JUL 29, 1994 |

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

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

ERGOCALCIFEROL

CAPSULE; ORAL

DELTALIN

| | | | | |
|---|---|---|---|---|
| AA | LILLY | 50,000 IU | N80884 001 | |
| | @ | 50,000 IU | N80884 001 | |

DRISDOL

| | | | | |
|---|---|---|---|---|
| AA | + SANOFI WINTHROP | 50,000 IU | N03444 001 | |
| AA | STERLING WINTHROP | 50,000 IU | N03444 001 | |

VITAMIN D

| | | | | |
|---|---|---|---|---|
| AA | LANNETT | 50,000 IU | N80825 001 | |
| | @ | 50,000 IU | N80825 001 | |
| AA | WEST WARD | 50,000 IU | N83102 001 | |
| | @ WEST WARD PHARM | 50,000 IU | N83102 001 | |

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYC

| | | | | |
|---|---|---|---|---|
| AB | PARKE DAVIS | 250MG | N62546 001 | JUL 25, 1985 |
| | @ | 250MG | N62546 001 | JUL 25, 1985 |

OINTMENT; OPHTHALMIC

ERYTHROMYCIN

| | | | | |
|---|---|---|---|---|
| AT | BAUSCH AND LOMB | 0.5% | N64067 001 | JUL 29, 1994 |
| AT | FOUGERA | 0.5% | N62447 001 | SEP 26, 1983 |
| AT | | 5MG/GM | N62447 001 | SEP 26, 1983 |

ILOTYCIN

| | | | | |
|---|---|---|---|---|
| AT | + DISTA | 0.5% | N50368 001 | |
| AT | * | 5MG/GM | N50368 001 | |

SOLUTION; TOPICAL

ERYTHROMYCIN

| | | | | |
|---|---|---|---|---|
| AT | BARRE | 2% | N62957 001 | JUL 21, 1988 |
| | @ | 2% | N62957 001 | JUL 21, 1988 |
| AT | BAUSCH AND LOMB | 2% | N64039 001 | JAN 27, 1994 |
| AT | PHARMAFAIR | 2% | N62616 001 | JUL 25, 1985 |
| | @ | 2% | N62616 001 | JUL 25, 1985 |

TABLET, COATED PARTICLES; ORAL

PCE

| | | | | |
|---|---|---|---|---|
| | ABBOTT | 333MG | N50611 001 | SEP 09, 1986 |
| | + | 333MG | N50611 001 | SEP 09, 1986 |

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

E.E.S.

| | | | | |
|---|---|---|---|---|
| AB | + ABBOTT | EQ 200MG BASE/5ML | N50207 001 | |
| AB | | EQ 200MG BASE/5ML | N50207 001 | |

ERYPED

| | | | | |
|---|---|---|---|---|
| | ABBOTT | EQ 400MG BASE/5ML | N50207 002 | |

## ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

ERYPED

| | | | | | |
|---|---|---|---|---|---|
| AB | + ABBOTT | EQ 200MG BASE/5ML | N50207 003 | | |
| | | | MAR 30, 1987 | | |
| | + | EQ 400MG BASE/5ML | N50207 002 | | |

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

| | | | | | |
|---|---|---|---|---|---|
| AB | DISTA | EQ 200MG BASE/5ML | N62177 001 | | |
| AB | | EQ 400MG BASE/5ML | N62177 002 | | |
| | @ | EQ 200MG BASE/5ML | N62177 001 | | |
| | @ | EQ 400MG BASE/5ML | N62177 002 | | |
| AB | PHARMAFAIR | EQ 200MG BASE/5ML | N62559 001 | | |
| | | | MAR 15, 1985 | | |
| AB | | EQ 400MG BASE/5ML | N62558 001 | | |
| | | | MAR 15, 1985 | | |
| | @ | EQ 200MG BASE/5ML | N62559 001 | | |
| | | | MAR 15, 1985 | | |
| | @ | EQ 400MG BASE/5ML | N62558 001 | | |
| | | | MAR 15, 1985 | | |

TABLET; ORAL

E.E.S. 400

| | | | | | |
|---|---|---|---|---|---|
| AB | * ABBOTT | EQ 400MG BASE | N61905 001 | | |
| AB | | EQ 400MG BASE | N61905 002 | | |
| | | | AUG 12, 1982 | | |
| AB | + | EQ 400MG BASE | N61905 002 | | |
| | | | AUG 12, 1982 | | |
| | @ | EQ 400MG BASE | N61905 001 | | |

## ERYTHROMYCIN STEARATE

TABLET; ORAL

ERYPAR

| | | | | | |
|---|---|---|---|---|---|
| AB | PARKE DAVIS | EQ 250MG BASE | N62322 001 | | |
| | @ WARNER CHILCOTT | EQ 250MG BASE | N62322 001 | | |

ERYTHROMYCIN STEARATE

| | | | | | |
|---|---|---|---|---|---|
| AB | PUREPAC | EQ 250MG BASE | N61743 001 | | |
| | @ PUREPAC PHARM | EQ 250MG BASE | N61743 001 | | |

## ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | | | | | |
| >ADD> | BX 3M | 0.05MG/24HR | N20375 001 | | |
| >ADD> | | | DEC 22, 1994 | | |

## ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | | | | | |
| >ADD> | BX 3M | 0.1MG/24HR | N20375 002 | | |
| >ADD> | | | DEC 22, 1994 | | |

ESTRADERM

| | | | | | |
|---|---|---|---|---|---|
| BX | + CIBA | 0.05MG/24HR | N19081 002 | | |
| | | | SEP 10, 1986 | | |
| BX | + | 0.1MG/24HR | N19081 003 | | |
| | | | SEP 10, 1986 | | |

VIVELLE

| | | | | | |
|---|---|---|---|---|---|
| BX | NOVEN | 0.05MG/24HR | N20323 002 | | |
| | | | OCT 28, 1994 | | |
| BX | | 0.1MG/24HR | N20323 004 | | |
| | | | OCT 28, 1994 | | |
| | | 0.0375MG/24HR | N20323 001 | | |
| | | | OCT 28, 1994 | | |
| | | 0.075MG/24HR | N20323 003 | | |
| | | | OCT 28, 1994 | | |

## ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

DELADUMONE

| | | | | | |
|---|---|---|---|---|---|
| AO | * SQUIBB | 4MG/ML;90MG/ML | N09545 001 | | |
| | @ | 4MG/ML;90MG/ML | N09545 001 | | |

TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE

| | | | | | |
|---|---|---|---|---|---|
| AO | STERIS | 4MG/ML;90MG/ML | N85865 001 | | |
| | + | 4MG/ML;90MG/ML | N85865 001 | | |

## ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

PREMPHASE (PREMARIN;CYCRIN 14/14)

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | | | | | |
| >ADD> | + WYETH AYERST | 0.625MG,0.625MG;N/A,5MG | N20303 002 | | |
| >ADD> | | | DEC 30, 1994 | | |

PREMPRO (PREMARIN;CYCRIN 14/14)

| | | | | | |
|---|---|---|---|---|---|
| >ADD> | | | | | |
| >ADD> | WYETH AYERST | 0.625MG,0.625MG;2.5MG, | | | |
| >ADD> | | 2.5MG | N20303 001 | | |
| >ADD> | | | DEC 30, 1994 | | |

## ESTROGENS, ESTERIFIED

TABLET; ORAL

ESTRATAB

| | | | | | |
|---|---|---|---|---|---|
| BS | SOLVAY | 0.625MG | N83209 001 | | |

ESTROGENS, ESTERIFIED

TABLET; ORAL
ESTRATAB

| | | | | |
|---|---|---|---|---|
| BS | + | SOLVAY | 0.625MG | N83209 001 |
| BS | | | 2.5MG | N83857 001 |
| BS | + | | 2.5MG | N83857 001 |

MENEST

| | | | | |
|---|---|---|---|---|
| BS | + | SMITHKLINE BEECHAM | 0.625MG | N84948 001 |
| BS | | | 0.625MG | N84948 001 |
| BS | + | | 2.5MG | N84949 001 |
| BS | | | 2.5MG | N84949 001 |

ESTRONE

INJECTABLE; INJECTION
ESTRONE

| | | | | |
|---|---|---|---|---|
| BP | | STERIS | 2MG/ML | N83397 001 |
| | @ | | 2MG/ML | N83397 001 |

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL
MYAMBUTOL

| | | | | |
|---|---|---|---|---|
| | | LEDERLE | 200MG | N16320 002 |
| | | | 400MG | N16320 003 |
| | + | | 500MG | N16320 004 |
| | @ | | 200MG | N16320 002 |
| | + | | 400MG | N16320 003 |
| | @ | | 500MG | N16320 004 |

ETHINAMATE

CAPSULE; ORAL
VALMID

| | | | | |
|---|---|---|---|---|
| | | DISTA | 500MG | N09750 001 |
| | @ | | 500MG | N09750 001 |

ETHINYL ESTRADIOL; FERROUS FUMARATE; NORETHINDRONE

TABLET; ORAL-28
NORQUEST FE

| | | | | |
|---|---|---|---|---|
| | + | SYNTEX | 0.035MG;75MG;1MG | N18926 001 JUL 18, 1986 |

ETHINYL ESTRADIOL; FERROUS FUMARATE; NORETHINDRONE

TABLET; ORAL-28
NORQUEST FE

| | | | | |
|---|---|---|---|---|
| | @ | SYNTEX | 0.035MG;75MG;1MG | N18926 001 JUL 18, 1986 |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

| | | | | |
|---|---|---|---|---|
| | | WATSON | 0.035MG,0.035MG;0.5MG,1MG | N71041 001 SEP 24, 1991 |
| AB | | WATSON LABS | 0.035MG,0.035MG;0.5MG,1MG | N71041 001 SEP 24, 1991 |

ORTHO-NOVUM 7/14-21

| | | | | |
|---|---|---|---|---|
| AB | + | JOHNSON RW | 0.035MG,0.035MG;0.5MG,1MG | N19004 001 APR 04, 1984 |
| | @ | | 0.035MG,0.035MG;0.5MG,1MG | N19004 001 APR 04, 1984 |

TABLET; ORAL-28
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

| | | | | |
|---|---|---|---|---|
| | | WATSON | 0.035MG,0.035MG;0.5MG,1MG | N71042 001 SEP 24, 1991 |
| AB | | WATSON LABS | 0.035MG,0.035MG;0.5MG,1MG | N71042 001 SEP 24, 1991 |

ORTHO-NOVUM 7/14-28

| | | | | |
|---|---|---|---|---|
| AB | + | JOHNSON RW | 0.035MG,0.035MG;0.5MG,1MG | N19004 002 APR 04, 1984 |
| | @ | | 0.035MG,0.035MG;0.5MG,1MG | N19004 002 APR 04, 1984 |

ETODOLAC

TABLET; ORAL
LODINE

| | | | | |
|---|---|---|---|---|
| | + | WYETH AYERST | 400MG | N18922 004 JUL 29, 1993 |

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE

| | | | | |
|---|---|---|---|---|
| AP | | GENSIA | 20MG/ML | N74284 001 FEB 10, 1994 |

ETOPOSIDE

INJECTABLE; INJECTION
VEPESID
AP + BRISTOL 20MG/ML N18768 001 NOV 10, 1983

FAMCICLOVIR

TABLET; ORAL
FAMVIR
+ SMITHKLINE BEECHAM 500MG N20363 002 JUN 29, 1994

FAMOTIDINE

INJECTABLE; INJECTION
PEPCID IN PLASTIC CONTAINER
+ MERCK 0.4MG/ML N20249 001 FEB 18, 1994

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL
PLENDIL
+ ASTRA MERCK 2.5MG N19834 004 SEP 22, 1994
+ 5MG N19834 001 JUL 25, 1991
+ 10MG N19834 002 JUL 25, 1991
MERCK 5MG N19834 001 JUL 25, 1991
10MG N19834 002 JUL 25, 1991

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
+ PFIZER 50MG N19949 001 JAN 29, 1990
+ 100MG N19949 002 JAN 29, 1990

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
PFIZER 50MG N19949 001 JAN 29, 1990
100MG N19949 002 JAN 29, 1990
150MG N20322 001 JUN 30, 1994

FLUDEOXYGLUCOSE, F-18

INJECTABLE; INJECTION
FLUDEOXYGLUCOSE F 18
+ DOWNSTATE CLINCL 6.8-35.7mCi/ML N20306 001 AUG 19, 1994

FLUMAZENIL

INJECTABLE; INJECTION
MAZICON
+ ROCHE 0.1MG/ML N20073 001 DEC 20, 1991
ROMAZICON
+ ROCHE 0.1MG/ML N20073 001 DEC 20, 1991

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE
AT TARO PHARMS 0.025% N40042 001 OCT 31, 1994
AT 0.1% N40035 001 OCT 31, 1994

OINTMENT; TOPICAL
FLUOCINOLONE ACETONIDE
AT TARO PHARMS 0.025% N40041 001 SEP 15, 1994

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE
AT PHARMAFAIR 0.01% N88449 001 FEB 08, 1984

FLUOCINOLONE ACETONIDE

SOLUTION; TOPICAL
FLUOCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| | @ PHARMAFAIR | 0.01% | N88449 001 FEB 08, 1984 | |

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

| | | | | |
|---|---|---|---|---|
| B* | CLAY PARK | 0.05% | N71790 001 JUL 13, 1988 | |
| | @ | 0.05% | N71790 001 JUL 13, 1988 | |
| AB | FOUGERA | 0.05% | N73030 001 OCT 17, 1994 | |

GEL; TOPICAL
FLUOCINONIDE

| | | | | |
|---|---|---|---|---|
| >ADD> | AB | FOUGERA | 0.05% | N72933 001 DEC 30, 1994 |

FLUORESCEIN SODIUM

INJECTABLE; INJECTION
FUNDUSCEIN-25

| | | | | |
|---|---|---|---|---|
| | + | CIBA VISION | 25% | N17869 001 |
| | + | IOLAB | 25% | N17869 001 |

FLUOROMETHOLONE

SUSPENSION/DROPS; OPHTHALMIC
FLUOR-OP

| | | | | |
|---|---|---|---|---|
| AB | | CIBA VISION | 0.1% | N70185 001 FEB 27, 1986 |
| AB | | IOLAB | 0.1% | N70185 001 FEB 27, 1986 |

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL

| | | | | |
|---|---|---|---|---|
| AP | + | ADRIA | 50MG/ML | N17959 001 |

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL

| | | | | |
|---|---|---|---|---|
| AP | | ADRIA | 50MG/ML | N40023 001 OCT 18, 1991 |
| AP | + | PHARMACIA | 50MG/ML | N40023 001 OCT 18, 1991 |
| | @ | | 50MG/ML | N17959 001 |

FLURANDRENOLIDE

CREAM; TOPICAL
CORDRAN SP

| | | | | |
|---|---|---|---|---|
| | + | DISTA | 0.025% | N12806 003 |
| | + | | 0.05% | N12806 002 |
| | + | LILLY | 0.025% | N12806 003 |
| | + | | 0.05% | N12806 002 |

LOTION; TOPICAL
CORDRAN

| | | | | |
|---|---|---|---|---|
| AT | + | DISTA | 0.05% | N13790 001 |
| AT | + | LILLY | 0.05% | N13790 001 |

OINTMENT; TOPICAL
CORDRAN

| | | | | |
|---|---|---|---|---|
| | + | DISTA | 0.025% | N12806 004 |
| | + | | 0.05% | N12806 001 |
| | + | LILLY | 0.025% | N12806 004 |
| | + | | 0.05% | N12806 001 |

TAPE; TOPICAL
CORDRAN

| | | | | |
|---|---|---|---|---|
| | + | DISTA | 0.004MG/SQ CM | N16455 001 |
| | + | LILLY | 0.004MG/SQ CM | N16455 001 |

FLURBIPROFEN

TABLET; ORAL
ANSAID

| | | | | |
|---|---|---|---|---|
| AB | | UPJOHN | 50MG | N18766 002 OCT 31, 1988 |
| AB | + | | 100MG | N18766 003 OCT 31, 1988 |

FLURBIPROFEN

| | | | | |
|---|---|---|---|---|
| AB | | MYLAN | 50MG | N74358 001 JUN 20, 1994 |

FLURBIPROFEN

TABLET; ORAL
FLURBIPROFEN

| | | | |
|---|---|---|---|
| AB | MYLAN | 100MG | N74358 002<br>JUN 20, 1994 |

FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL
FLONASE

| | | | |
|---|---|---|---|
| + | GLAXO | 0.05MG/INH | N20121 001<br>OCT 19, 1994 |

> ADD > FLUVOXAMINE MALEATE

> ADD > TABLET; ORAL
> ADD > LUVOX

| | | | |
|---|---|---|---|
| > ADD > | @ SOLVAY | 25MG | N20243 001<br>DEC 05, 1994 |
| > ADD > | | 50MG | N20243 002<br>DEC 05, 1994 |
| > ADD > | + | 100MG | N20243 003<br>DEC 05, 1994 |
| > ADD > | @ | 150MG | N20243 004<br>DEC 05, 1994 |

FOLIC ACID

TABLET; ORAL
FOLIC ACID

| | | | |
|---|---|---|---|
| AA | LANNETT | 1MG | N80816 001 |
| | @ | 1MG | N80816 001 |
| AA | PUREPAC | 1MG | N80784 001 |
| | @ PUREPAC PHARM | 1MG | N80784 001 |

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET; ORAL
MONOPRIL-HCT

| | | | |
|---|---|---|---|
| | BRISTOL MYERS SQUIBB | 10MG;12.5MG | N20286 002<br>NOV 30, 1994 |
| + | | 20MG;12.5MG | N20286 001<br>NOV 30, 1994 |

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE

| | | | |
|---|---|---|---|
| AP | MARSAM | 10MG/ML | N74017 001<br>JUN 30, 1994 |
| AP | ORGANON | 10MG/ML | N70017 001<br>DEC 15, 1986 |
| @ | | 10MG/ML | N70017 001<br>DEC 15, 1986 |
| AP | SANOFI WINTHROP | 10MG/ML | N74337 001<br>OCT 31, 1994 |
| AP | WARNER CHILCOTT | 10MG/ML | N18420 001<br>FEB 26, 1982 |
| @ | | 10MG/ML | N18420 001<br>FEB 26, 1982 |

GADODIAMIDE

INJECTABLE; INJECTION
OMNISCAN

| | | |
|---|---|---|
| NYCOMED | 287MG/ML | N20123 001<br>JAN 08, 1993 |
| STERLING WINTHROP | 287MG/ML | N20123 001<br>JAN 08, 1993 |

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION
GALLIUM CITRATE GA 67

| | | | |
|---|---|---|---|
| BS | DUPONT | 2mCi/ML | N17478 001 |
| BS | DUPONT MERCK | 2mCi/ML | N17478 001 |

> ADD > GANCICLOVIR

> ADD > CAPSULE; ORAL
> ADD > CYTOVENE

| | | | |
|---|---|---|---|
| > ADD > | + SYNTEX | 250MG | N20460 001<br>DEC 22, 1994 |

GEMFIBROZIL

TABLET; ORAL
GEMFIBROZIL

| | | | |
|---|---|---|---|
| AB | PUREPAC PHARM | 600MG | N74360 001<br>AUG 31, 1994 |

GEMFIBROZIL

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | GEMFIBROZIL | | | |
| AB | WATSON LABS | 600MG | N74156 001 | OCT 24, 1994 |

GENTAMICIN SULFATE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | GARAMYCIN | | | |
| AT | + SCHERING | EQ 0.1% BASE | N60462 001 | |
| AT | * | EQ 1MG BASE/GM | N60462 001 | |
| | GENTAFAIR | | | |
| AT | PHARMAFAIR | EQ 1MG BASE/GM | N62458 001 | SEP 01, 1983 |
| | @ | EQ 0.1% BASE | N62458 001 | SEP 01, 1983 |
| | GENTAMICIN | | | |
| AT | CLAY PARK | EQ 0.1% BASE | N62307 001 | |
| AT | | EQ 1MG BASE/GM | N62307 001 | |
| | GENTAMICIN SULFATE | | | |
| AT | BAUSCH AND LOMB | EQ 0.1% BASE | N64056 001 | APR 29, 1994 |
| AT | FOUGERA | EQ 0.1% BASE | N62531 001 | JUL 05, 1984 |
| AT | | EQ 1MG BASE/GM | N62531 001 | JUL 05, 1984 |
| AT | NMC | EQ 0.1% BASE | N62471 001 | SEP 27, 1983 |
| AT | | EQ 1MG BASE/GM | N62471 001 | SEP 27, 1983 |
| AT | THAMES | EQ 0.1% BASE | N62427 001 | MAY 26, 1983 |
| AT | | EQ 1MG BASE/GM | N62427 001 | MAY 26, 1983 |

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | APOGEN | | | |
| AP | KING PHARMS | EQ 10MG BASE/ML | N62289 001 | |
| AP | | EQ 40MG BASE/ML | N62289 002 | |
| AP | SMITHKLINE BEECHAM | EQ 10MG BASE/ML | N62289 001 | |
| AP | | EQ 40MG BASE/ML | N62289 002 | |
| | GARAMYCIN | | | |
| AP | * SCHERING | EQ 2MG BASE/ML | N50505 001 | |

INJECTABLE; INTRATHECAL

| | | | |
|---|---|---|---|
| | GARAMYCIN | | |
| + | SCHERING | EQ 2MG BASE/ML | N50505 001 |

GENTAMICIN SULFATE

OINTMENT; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | GARAMYCIN | | | |
| AT | + SCHERING | EQ 0.3% BASE | N50425 001 | |
| AT | * | EQ 3MG BASE/GM | N50425 001 | |
| | GENTACIDIN | | | |
| AT | IOLAB | EQ 0.3% BASE | N62501 001 | JUL 26, 1984 |
| AT | | EQ 3MG BASE/GM | N62501 001 | JUL 26, 1984 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | GARAMYCIN | | | |
| AT | + SCHERING | EQ 0.1% BASE | N60463 001 | |
| AT | * | EQ 1MG BASE/GM | N60463 001 | |
| | GENTAFAIR | | | |
| AT | PHARMAFAIR | EQ 0.1% BASE | N62444 001 | MAY 26, 1983 |
| | @ | EQ 0.1% BASE | N62444 001 | MAY 26, 1983 |
| | GENTAMICIN | | | |
| AT | CLAY PARK | EQ 0.1% BASE | N62351 001 | FEB 18, 1982 |
| AT | | EQ 1MG BASE/GM | N62351 001 | FEB 18, 1982 |
| | GENTAMICIN SULFATE | | | |
| AT | BAUSCH AND LOMB | EQ 0.1% BASE | N64054 001 | APR 29, 1994 |
| AT | FOUGERA | EQ 0.1% BASE | N62533 001 | OCT 05, 1984 |
| AT | | EQ 1MG BASE/GM | N62533 001 | OCT 05, 1984 |
| AT | NMC | EQ 0.1% BASE | N62496 001 | MAR 14, 1984 |
| AT | | EQ 1MG BASE/GM | N62496 001 | MAR 14, 1984 |
| AT | PHARMADERM | EQ 0.1% BASE | N62534 001 | OCT 10, 1984 |
| AT | | EQ 1MG BASE/GM | N62534 001 | OCT 10, 1984 |
| AT | THAMES | EQ 0.1% BASE | N62477 001 | DEC 23, 1983 |
| AT | | EQ 1MG BASE/GM | N62477 001 | DEC 23, 1983 |

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | GARAMYCIN | | | |
| AT | + SCHERING | EQ 0.3% BASE | N50039 002 | |

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | GARAMYCIN | | | |
| AT | * SCHERING | EQ 3MG BASE/ML | N50039 002 | |
| | GENOPTIC | | | |
| AT | ALLERGAN | EQ 0.3% BASE | N62452 001 OCT 10, 1984 | |
| AT | | EQ 3MG BASE/ML | N62452 001 OCT 10, 1984 | |
| | GENTACIDIN | | | |
| AT | IOLAB | EQ 0.3% BASE | N62480 001 MAR 30, 1984 | |
| AT | | EQ 3MG BASE/ML | N62480 001 MAR 30, 1984 | |
| | GENTAFAIR | | | |
| | @ PHARMAFAIR | EQ 0.3% BASE | N62440 001 MAY 03, 1983 | |
| | GENTAMICIN SULFATE | | | |
| AT | AKORN | EQ 0.3% BASE | N62635 001 JAN 08, 1987 | |
| AT | | EQ 3MG BASE/ML | N62635 001 JAN 08, 1987 | |
| AT | BAUSCH AND LOMB | EQ 0.3% BASE | N64048 001 MAY 11, 1994 | |
| AT | STERIS | EQ 0.3% BASE | N62523 001 NOV 25, 1985 | |
| AT | | EQ 3MG BASE/ML | N62523 001 NOV 25, 1985 | |

GLIPIZIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | GLIPIZIDE | | | > DLT > | |
| AB | CIRCA | 5MG | N74370 001 NOV 22, 1994 | > DLT > > ADD > > ADD > | |
| AB | | 10MG | N74370 002 NOV 22, 1994 | | |
| AB | ENDO LABS | 5MG | N74378 001 NOV 28, 1994 | | |
| AB | | 10MG | N74378 002 NOV 28, 1994 | | |
| AB | MYLAN | 5MG | N74226 001 MAY 10, 1994 | | |
| AB | | 10MG | N74226 002 MAY 10, 1994 | | |
| | GLUCOTROL | | | | |
| AB | PFIZER | 5MG | N17783 001 MAY 08, 1984 | | |

GLIPIZIDE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | GLUCOTROL | | |
| AB | + PFIZER | 10MG | N17783 002 MAY 08, 1984 |

TABLET, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | GLUCOTROL XL | | |
| | + PFIZER | 5MG | N20329 001 APR 26, 1994 |
| | + | 10MG | N20329 002 APR 26, 1994 |

GLUTETHIMIDE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | GLUTETHIMIDE | | |
| AA | HALSEY | 250MG | N89458 001 OCT 10, 1986 |
| | | 250MG | N89458 001 OCT 10, 1986 |
| AA | LANNETT | 250MG | N83475 001 |
| AA | | 500MG | N85571 001 |
| | @ | 250MG | N83475 001 |
| | @ | 500MG | N85571 001 |

GLYBURIDE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | GLYNASE | | |
| | UPJOHN | 4.5MG | N20051 003 SEP 24, 1993 |
| | @ | 4.5MG | N20051 003 SEP 24, 1993 |

GLYCOPYRROLATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | GLYCOPYRROLATE | | |
| AP | FUJISAWA | 0.2MG/ML | N88475 001 JUN 12, 1984 |
| | @ | 0.2MG/ML | N88475 001 JUN 12, 1984 |

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | A.P.L. | | |
| AP | * | WYETH AYERST | 20,000 UNITS/VIAL | N17055 003 |
| | + | | 20,000 UNITS/VIAL | N17055 003 |
| | | CHORIONIC GONADOTROPIN | | |
| AP | | FUJISAWA | 5,000 UNITS/VIAL | N17067 001 |
| AP | | | 20,000 UNITS/VIAL | N17067 003 |
| | @ | | 5,000 UNITS/VIAL | N17067 001 |
| | @ | | 20,000 UNITS/VIAL | N17067 003 |
| AP | | STERIS | 20,000 UNITS/VIAL | N17016 004 |
| | * | | 15,000 UNITS/VIAL | N17016 010 |
| | | | | FEB 15, 1985 |
| | @ | | 15,000 UNITS/VIAL | N17016 010 |
| | | | | FEB 15, 1985 |
| | @ | | 20,000 UNITS/VIAL | N17016 004 |

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | | NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN | | |
| AT | | PHARMAFAIR | 0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML | N62383 001 |
| | | | | AUG 31, 1982 |
| | @ | | 0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML | N62383 001 |
| | | | | AUG 31, 1982 |

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | KYTRIL | | |
| | * | SMITHKLINE BEECHAM | EQ 3MG BASE/ML | N20239 001 |
| | | | | DEC 29, 1993 |
| | + | | EQ 1MG BASE/ML | N20239 002 |
| | | | | MAR 11, 1994 |
| | @ | | EQ 3MG BASE/ML | N20239 001 |
| | | | | DEC 29, 1993 |

GUANABENZ ACETATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | GUANABENZ ACETATE | | |
| AB | | COPLEY PHARM | EQ 4MG BASE | N74267 001 |
| | | | | JUN 01, 1994 |

GUANABENZ ACETATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | GUANABENZ ACETATE | | |
| AB | | COPLEY PHARM | EQ 8MG BASE | N74267 002 |
| | | | | JUN 01, 1994 |
| AB | | WATSON LABS | EQ 4MG BASE | N74025 001 |
| | | | | FEB 28, 1994 |
| AB | | | EQ 8MG BASE | N74025 002 |
| | | | | FEB 28, 1994 |
| | | WYTENSIN | | |
| AB | | WYETH AYERST | EQ 4MG BASE | N18587 001 |
| | | | | SEP 07, 1982 |
| AB | + | | EQ 8MG BASE | N18587 002 |
| | | | | SEP 07, 1982 |

HEPARIN CALCIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | CALCIPARINE | | |
| | + | CHOAY | 25,000 UNITS/ML | N18237 001 |
| | * | DUPONT | 25,000 UNITS/ML | N18237 001 |

HEPARIN SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | HEPARIN SODIUM | | |
| AP | | AKORN | 1,000 UNITS/ML | N17486 001 |
| AP | | | 5,000 UNITS/ML | N17486 002 |
| AP | | | 10,000 UNITS/ML | N17486 003 |
| AP | | | 20,000 UNITS/ML | N17486 004 |
| AP | | | 40,000 UNITS/ML | N17486 005 |
| | @ | | 1,000 UNITS/ML | N17486 001 |
| | @ | | 5,000 UNITS/ML | N17486 002 |
| | @ | | 10,000 UNITS/ML | N17486 003 |
| | @ | | 20,000 UNITS/ML | N17486 004 |
| | @ | | 40,000 UNITS/ML | N17486 005 |

HEXACHLOROPHENE

EMULSION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | PHISOHEX | | |
| | + | SANOFI WINTHROP | 3% | N06882 001 |
| | @ | | 3% | N08402 001 |
| | * | STERLING WINTHROP | 3% | N06882 001 |
| | @ | | 3% | N08402 001 |

HEXACHLOROPHENE

SPONGE; TOPICAL
PHISO-SCRUB

| | | | | |
|---|---|---|---|---|
| | @ | SANOFI WINTHROP | 3% | N17446 001 |
| | @ | STERLING WINTHROP | 3% | N17446 001 |

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

| | | | | |
|---|---|---|---|---|
| AA | | AMIDE PHARM | 25MG | N88560 001<br>OCT 04, 1984 |
| AA | | | 50MG | N88649 001<br>OCT 18, 1984 |
| | @ | | 25MG | N88560 001<br>OCT 04, 1984 |
| | @ | | 50MG | N88649 001<br>OCT 18, 1984 |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| BP | | DANBURY PHARMA | 25MG;15MG;0.1MG | N87556 001 |
| | @ | | 25MG;15MG;0.1MG | N87556 001 |

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| AB | | WEST WARD | 25MG | N84899 001 |
| | @ | WEST WARD PHARM | 25MG | N84899 001 |
| AB | | ZENITH | 50MG | N84658 001 |
| | @ | ZENITH LABS | 50MG | N84658 001 |

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL
NORMOZIDE

| | | | | |
|---|---|---|---|---|
| | | SCHERING | 25MG;100MG | N19046 001<br>APR 06, 1987 |
| | | | 25MG;200MG | N19046 002<br>APR 06, 1987 |

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL
NORMOZIDE

| | | | | |
|---|---|---|---|---|
| | + | SCHERING | 25MG;300MG | N19046 003<br>APR 06, 1987 |
| | @ | | 25MG;100MG | N19046 001<br>APR 06, 1987 |
| | @ | | 25MG;200MG | N19046 002<br>APR 06, 1987 |
| | @ | | 25MG;300MG | N19046 003<br>APR 06, 1987 |

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
HYDROCHLOROTHIAZIDE W/ RESERPINE

| | | | | |
|---|---|---|---|---|
| BP | | ROXANE | 50MG;0.125MG | N84603 001 |
| | @ | | 50MG;0.125MG | N84603 001 |

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE

| | | | | |
|---|---|---|---|---|
| AB | + | SMITHKLINE BEECHAM | 25MG;50MG | N16042 002 |
| | | | 25MG;37.5MG | N16042 003<br>MAR 03, 1994 |
| | @ | | 25MG;50MG | N16042 002 |

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

| | | | | |
|---|---|---|---|---|
| AB | | GENEVA PHARMS | 25MG;50MG | N73191 001<br>JUL 31, 1991 |
| | + | | 25MG;50MG | N73191 001<br>JUL 31, 1991 |

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| AT | | LEMMON | 1% | N85191 001 |
| | @ | | 1% | N85191 001 |
| AT | | PHARMAFAIR | 1% | N87838 001<br>JUL 28, 1982 |
| | @ | | 1% | N87838 001<br>JUL 28, 1982 |

ENEMA; RECTAL
CORTENEMA

| | | | | |
|---|---|---|---|---|
| | + | SOLVAY | 100MG/60ML | N16199 001 |

## HYDROCORTISONE

ENEMA; RECTAL

| | | | | |
|---|---|---|---|---|
| | HYDROCORTISONE | | | |
| AT | COPLEY PHARM | 100MG/60ML | N74171 001 | MAY 27, 1994 |

GEL; TOPICAL

| | | | | |
|---|---|---|---|---|
| | NUTRACORT | | | |
| AT | + GALDERMA | 1% | N84698 001 | |
| | @ | 1% | N84698 001 | |
| | PENECORT | | | |
| AT | ALLERGAN HERBERT | 1% | N88215 001 | JUN 06, 1984 |
| | + | 1% | N88215 001 | JUN 06, 1984 |

LOTION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | HYDROCORTISONE | | | |
| AT | CLAY PARK | 1% | N85663 001 | |
| | @ | 1% | N85663 001 | |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | HYDROCORTISONE | | | |
| AT | CLAY PARK | 1% | N85028 001 | |
| | @ | 1% | N85028 001 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | HYDROCORTISONE | | | |
| BP | DANBURY PHARMA | 20MG | N80355 001 | |
| | @ | 20MG | N80355 001 | |
| BP | INWOOD | 20MG | N80732 001 | |
| | @ INWOOD LABS | 20MG | N80732 001 | |

## HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

| | | | | |
|---|---|---|---|---|
| | NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE | | | |
| AT | PHARMAFAIR | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62394 001 | SEP 29, 1982 |
| | @ | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62394 001 | SEP 29, 1982 |

SUSPENSION; OTIC

| | | | | |
|---|---|---|---|---|
| | OTICAIR | | | |
| AT | PHARMAFAIR | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62399 001 | NOV 18, 1982 |

## HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC

| | | | | |
|---|---|---|---|---|
| | OTICAIR | | | |
| | @ PHARMAFAIR | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N62399 001 | NOV 18, 1982 |

## HYDROCORTISONE ACETATE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | HYDROCORTISONE ACETATE | | | |
| AT | PARKE DAVIS | 1% | N89914 001 | JAN 03, 1989 |
| | @ | 1% | N89914 001 | JAN 03, 1989 |

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | HYDROCORTISONE ACETATE | | | |
| BP | STERIS | 50MG/ML | N85214 001 | |
| | @ | 50MG/ML | N85214 001 | |

## HYDROCORTISONE ACETATE; UREA

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | CARMOL HC | | | |
| AT | + KENWOOD LABS | 1%;10% | N80505 001 | |
| AT | + SYNTEX | 1%;10% | N80505 001 | |

## HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | LOCOID | | | |
| | + BROCADES PHARMA | 0.1% | N18514 001 | MAR 31, 1982 |
| | + YAMANOUCHI | 0.1% | N18514 001 | MAR 31, 1982 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | LOCOID | | | |
| | @ BROCADES PHARMA | 0.1% | N18652 001 | OCT 29, 1982 |
| | @ YAMANOUCHI | 0.1% | N18652 001 | OCT 29, 1982 |

HYDROCORTISONE BUTYRATE

SOLUTION; TOPICAL
LOCOID

| | | | | |
|---|---|---|---|---|
| | * | BROCADES PHARMA | 0.1% | N19116 001 FEB 25, 1987 |
| | + | YAMANOUCHI | 0.1% | N19116 001 FEB 25, 1987 |

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

| | | | | |
|---|---|---|---|---|
| AP | | ABBOTT | EQ 250MG BASE/VIAL | N89578 001 APR 11, 1989 |
| AP | | | EQ 500MG BASE/VIAL | N89579 001 APR 11, 1989 |
| AP | | | EQ 1GM BASE/VIAL | N89580 001 APR 11, 1989 |
| | @ | | EQ 250MG BASE/VIAL | N89578 001 APR 11, 1989 |
| | @ | | EQ 500MG BASE/VIAL | N89579 001 APR 11, 1989 |
| | @ | | EQ 1GM BASE/VIAL | N89580 001 APR 11, 1989 |

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION
DILAUDID-HP

| | | | | |
|---|---|---|---|---|
| | + | KNOLL PHARM | 250MG/VIAL | N19034 002 AUG 04, 1994 |

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL
HYDROXYCHLOROQUINE SULFATE

| | | | | |
|---|---|---|---|---|
| AB | | COPLEY PHARM | 200MG | N40081 001 SEP 30, 1994 |

PLAQUENIL

| | | | | |
|---|---|---|---|---|
| AB | + | SANOFI WINTHROP | 200MG | N09768 001 |
| AB | * | STERLING WINTHROP | 200MG | N09768 001 |

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
DELALUTIN

| | | | | |
|---|---|---|---|---|
| AO | * | SQUIBB | 125MG/ML | N10347 004 |
| AO | | | 125MG/ML | N16911 001 |
| AO | * | | 250MG/ML | N10347 002 |
| AO | | | 250MG/ML | N16911 002 |
| | @ | | 125MG/ML | N10347 004 |
| | @ | | 125MG/ML | N16911 001 |
| | @ | | 250MG/ML | N10347 002 |
| | @ | | 250MG/ML | N16911 002 |

HYDROXYPROGESTERONE CAPROATE

| | | | | |
|---|---|---|---|---|
| AO | | AKORN | 125MG/ML | N18004 001 |
| | + | | 125MG/ML | N18004 001 |
| AO | * | STERIS | 125MG/ML | N17439 001 |
| AO | | | 250MG/ML | N17439 002 |
| | @ | | 125MG/ML | N17439 001 |
| | + | | 250MG/ML | N17439 002 |

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| AP | | SMITH NEPHEW SOLOPAK | 25MG/ML | N87591 001 |
| AP | | | 50MG/ML | N87593 001 |
| AP | | | 50MG/ML | N87595 001 |
| AP | | SOLOPAK | 25MG/ML | N87591 001 |
| AP | | | 50MG/ML | N87593 001 |
| AP | | | 50MG/ML | N87595 001 |

ORGATRAX

| | | | | |
|---|---|---|---|---|
| AP | | ORGANON | 25MG/ML | N87014 001 |
| AP | | | 50MG/ML | N87014 002 |
| | @ | | 25MG/ML | N87014 001 |
| | @ | | 50MG/ML | N87014 002 |

SYRUP; ORAL
HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| AA | | HI TECH PHARMA | 10MG/5ML | N40010 001 OCT 28, 1994 |

TABLET; ORAL
HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| AB | | AMIDE PHARM | 10MG | N89071 001 JUL 22, 1986 |
| AB | | | 25MG | N89072 001 JUL 22, 1986 |

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

| | HYDROXYZINE HCL | | |
|---|---|---|---|
| AB | AMIDE PHARM | 50MG | N89073 001 JUL 22, 1986 |
| @ | | 10MG | N89071 001 JUL 22, 1986 |
| @ | | 25MG | N89072 001 JUL 22, 1986 |
| @ | | 50MG | N89073 001 JUL 22, 1986 |
| AB | ROYCE LABS | 10MG | N81149 001 MAR 18, 1994 |
| AB | | 25MG | N81150 001 MAR 18, 1994 |
| AB | | 50MG | N81151 001 MAR 18, 1994 |

IBUPROFEN

TABLET; ORAL

| | MOTRIN | | |
|---|---|---|---|
| | MCNEIL CONS PRODS | 100MG | N20418 001 NOV 16, 1994 |

TABLET, CHEWABLE; ORAL

| | MOTRIN | | |
|---|---|---|---|
| | MCNEIL CONS PRODS | 50MG | N20135 001 NOV 16, 1994 |
| + | | 100MG | N20135 002 NOV 16, 1994 |

IMIGLUCERASE

INJECTABLE; INJECTION

| | CEREZYME | | |
|---|---|---|---|
| + | GENZYME | 200 UNITS/VIAL | N20367 001 MAY 23, 1994 |

INDIUM IN-111 PENTETREOTIDE KIT

INJECTABLE; INJECTION

| | OCTREOSCAN | | |
|---|---|---|---|
| | MALLINCKRODT | 3mCi/ML | N20314 001 JUN 02, 1994 |

INDOMETHACIN

CAPSULE; ORAL

| | INDOMETHACIN | | |
|---|---|---|---|
| AB | CHELSEA | 25MG | N18690 001 JUL 31, 1984 |
| AB | | 50MG | N18690 002 JUL 31, 1984 |
| @ | CHELSEA LABS | 25MG | N18690 001 JUL 31, 1984 |
| @ | | 50MG | N18690 002 JUL 31, 1984 |

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION

| | HUMULIN R | | |
|---|---|---|---|
| + | LILLY | 500 UNITS/ML | N18780 004 MAR 31, 1994 |

INVERT SUGAR

INJECTABLE; INJECTION

| | TRAVERT 10% IN PLASTIC CONTAINER | | |
|---|---|---|---|
| | BAXTER | 10GM/100ML | N16717 001 |
| @ | | 10GM/100ML | N16717 001 |

IOBENGUANE SULFATE I 131

INJECTABLE; INJECTION

| | IOBENGUANE SULFATE I 131 | | |
|---|---|---|---|
| | CIS | 2.3mCi/ML | N20084 001 MAR 25, 1994 |

IODAMIDE MEGLUMINE

INJECTABLE; INJECTION

| | RENOVUE-65 | | |
|---|---|---|---|
| + | BRACCO DXS | 65% | N17902 001 |
| + | SQUIBB | 65% | N17902 001 |

IODIPAMIDE MEGLUMINE

| | | | |
|---|---|---|---|
| INJECTABLE; INJECTION | | | |
| CHOLOGRAFIN MEGLUMINE | | | |
| + BRACCO DXS | 10.3% | | N09321 007 |
| + | 52% | | N09321 003 |
| + SQUIBB | 10.3% | | N09321 007 |
| + | 52% | | N09321 003 |

IODIPAMIDE SODIUM

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| CHOLOGRAFIN SODIUM | | |
| @ BRACCO DXS | 20% | N09321 001 |
| @ SQUIBB | 20% | N09321 001 |

IODOHIPPURATE SODIUM, I-123

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| NEPHROPLON | | |
| MEDI PHYSICS | 1mCi/ML | N18289 001 |
| | | DEC 28, 1984 |
| @ | 1mCi/ML | N18289 001 |
| | | DEC 28, 1984 |

IODOXAMATE MEGLUMINE

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| CHOLOVUE | | |
| @ BRACCO DXS | 9.9% | N18077 001 |
| @ | 40.3% | N18076 001 |
| @ SQUIBB | 9.9% | N18077 001 |
| @ | 40.3% | N18076 001 |

IOHEXOL

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| OMNIPAQUE 140 | | |
| + NYCOMED | 30.2% | N18956 005 |
| | | NOV 30, 1988 |
| + STERLING WINTHROP | 30.2% | N18956 005 |
| | | NOV 30, 1988 |
| OMNIPAQUE 210 | | |
| + NYCOMED | 45.3% | N18956 006 |
| | | JUN 30, 1989 |

IOHEXOL

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| OMNIPAQUE 210 | | |
| + STERLING WINTHROP | 45.3% | N18956 006 |
| | | JUN 30, 1989 |
| SOLUTION; INJECTION, ORAL | | |
| OMNIPAQUE 350 | | |
| + NYCOMED | 75.5% | N18956 004 |
| | | DEC 26, 1985 |
| + STERLING WINTHROP | 75.5% | N18956 004 |
| | | DEC 26, 1985 |
| SOLUTION; INJECTION, ORAL, RECTAL | | |
| OMNIPAQUE 180 | | |
| + NYCOMED | 38.8% | N18956 001 |
| | | DEC 26, 1985 |
| + STERLING WINTHROP | 38.8% | N18956 001 |
| | | DEC 26, 1985 |
| OMNIPAQUE 240 | | |
| + NYCOMED | 51.8% | N18956 002 |
| | | DEC 26, 1985 |
| + STERLING WINTHROP | 51.8% | N18956 002 |
| | | DEC 26, 1985 |
| OMNIPAQUE 300 | | |
| + NYCOMED | 64.7% | N18956 003 |
| | | DEC 26, 1985 |
| + STERLING WINTHROP | 64.7% | N18956 003 |
| | | DEC 26, 1985 |
| SOLUTION; URETHRAL | | |
| OMNIPAQUE 70 | | |
| + NYCOMED | 15.1% | N18956 007 |
| | | JUN 01, 1994 |
| + STERLING WINTHROP | 15.1% | N18956 007 |
| | | JUN 01, 1994 |

IOPAMIDOL

| | | |
|---|---|---|
| INJECTABLE; INTRAVASCULAR | | |
| ISOVUE-200 | | |
| BRACCO DXS | 41% | N20327 001 |
| | | OCT 12, 1994 |
| ISOVUE-250 | | |
| BRACCO DXS | 51% | N20327 002 |
| | | OCT 12, 1994 |

IOPAMIDOL

INJECTABLE; INTRAVASCULAR
ISOVUE-300
BRACCO DXS 61% N20327 003
OCT 12, 1994

ISOVUE-370
BRACCO DXS 76% N20327 004
OCT 12, 1994

IOPANOIC ACID

TABLET; ORAL
TELEPAQUE
NYCOMED 500MG N08032 001
+ STERLING WINTHROP 500MG N08032 001

IPODATE CALCIUM

GRANULE; ORAL
ORAGRAFIN CALCIUM
BRACCO DXS 3GM/PACKET N12968 001
+ SQUIBB 3GM/PACKET N12968 001

IPODATE SODIUM

CAPSULE; ORAL
**ORAGRAFIN SODIUM**
**AA** BRACCO DXS **500MG** **N12967 001**
**AA** + SQUIBB **500MG** **N12967 001**

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
**BRONKOSOL**
**AN** + SANOFI WINTHROP **1%** **N12339 008**
@ 0.25% N12339 009
**AN** + STERLING WINTHROP **1%** **N12339 008**
@ 0.25% N12339 009

ISOETHARINE MESYLATE

AEROSOL, METERED; INHALATION
BRONKOMETER
+ SANOFI WINTHROP 0.34MG/INH N12339 007

ISOETHARINE MESYLATE

AEROSOL, METERED; INHALATION
BRONKOMETER
+ STERLING WINTHROP 0.34MG/INH N12339 007

ISOFLURANE

LIQUID; INHALATION
**ISOFLURANE**
**AN** INHALON **99.9%** **N74416 001**
SEP 30, 1994

ISONIAZID; PYRAZINAMIDE; RIFAMPIN

TABLET; ORAL
RIFATER
+ MARION MERRELL DOW 50MG;300MG;120MG N50705 001
MAY 31, 1994

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION
ISUPREL
+ SANOFI WINTHROP 0.131MG/INH N11178 001
+ STERLING WINTHROP 0.131MG/INH N11178 001

INJECTABLE; INJECTION
**ISUPREL**
**AP** + SANOFI WINTHROP **0.2MG/ML** **N10515 001**
**AP** + STERLING WINTHROP **0.2MG/ML** **N10515 001**

SOLUTION; INHALATION
> DLT > AEROLONE
> DLT > + LILLY 0.25% N07245 001
> ADD > @ 0.25% N07245 001
ISUPREL
+ SANOFI WINTHROP 0.5% N06327 002
+ 1% N06327 003
+ STERLING WINTHROP 0.5% N06327 002
+ 1% N06327 003

TABLET, RECTAL, SUBLINGUAL
ISUPREL
@ SANOFI WINTHROP 10MG N06328 001
@ 15MG N06328 002

ISOPROTERENOL HYDROCHLORIDE

TABLET; RECTAL, SUBLINGUAL
ISUPREL
STERLING WINTHROP 10MG N06328 001
@ 15MG N06328 002

ISOSORBIDE MONONITRATE

TABLET; ORAL
ISMO
AB + WYETH 20MG N19091 001
DEC 30, 1991
EX * 20MG N19091 001
DEC 30, 1991

MONOKET
AB SCHWARZ 20MG N20215 001
JUN 30, 1993
EX SCHWARZ PHARMA 20MG N20215 001
JUN 30, 1993

ISRADIPINE

CAPSULE; ORAL
DYNACIRC
SANDOZ 5MG N19546 002
DEC 20, 1990
+ 5MG N19546 002
DEC 20, 1990

TABLET, EXTENDED RELEASE; ORAL
DYNACIRC CR
+ SANDOZ 5MG N20336 001
JUN 01, 1994
+ 10MG N20336 002
JUN 01, 1994

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX
* APOTHECON EQ 500MG BASE N61911 001 >ADD>
EQ 500MG BASE N62726 001 >ADD>
MAR 06, 1987 >ADD>
@ EQ 500MG BASE N60516 001 >ADD>
@ EQ 500MG BASE N61911 001 >ADD>

KANAMYCIN SULFATE

CAPSULE; ORAL
KANTREX
+ APOTHECON EQ 500MG BASE N62726 001
MAR 06, 1987
AB * BRISTOL EQ 500MG BASE N60516 001

INJECTABLE; INJECTION
KANTREX
AP * APOTHECON EQ 75MG BASE/2ML N61655 003
AP EQ 75MG BASE/2ML N61901 003
AP + EQ 75MG BASE/2ML N61901 003
AP * EQ 500MG BASE/2ML N61655 001
AP EQ 500MG BASE/2ML N61901 001
AP + EQ 500MG BASE/2ML N61901 001
AP * EQ 1GM BASE/3ML N61655 002
AP EQ 1GM BASE/3ML N61901 002
AP + EQ 1GM BASE/3ML N61901 002
@ EQ 75MG BASE/2ML N61655 003
@ EQ 75MG BASE/2ML N62564 001
SEP 21, 1984
@ EQ 500MG BASE/2ML N61655 001
@ EQ 500MG BASE/2ML N62564 002
SEP 21, 1984
@ EQ 1GM BASE/3ML N61655 002
@ EQ 1GM BASE/3ML N62564 003
SEP 21, 1984
AP BRISTOL EQ 75MG BASE/2ML N62564 001
SEP 21, 1984
AP EQ 500MG BASE/2ML N62564 002
SEP 21, 1984
AP EQ 1GM BASE/3ML N62564 003
SEP 21, 1984

KLEBCIL
@ KING PHARMS EQ 75MG BASE/2ML N62170 001
@ EQ 500MG BASE/2ML N62170 002
@ 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

LAMOTRIGINE

TABLET; ORAL
LAMICTAL
BURROUGHS WELLCOME 25MG N20241 005
DEC 27, 1994

> ADD > LAMOTRIGINE

> ADD > TABLET; ORAL
> ADD > LAMICTAL
> ADD > @ BURROUGHS WELLCOME 50MG N20241 006
> ADD > DEC 27, 1994
> ADD > 100MG N20241 001
> ADD > DEC 27, 1994
> ADD > 150MG N20241 002
> ADD > DEC 27, 1994
> ADD > + 200MG N20241 003
> ADD > DEC 27, 1994
> ADD > @ 250MG N20241 004
> ADD > DEC 27, 1994

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
**LEUCOVORIN CALCIUM**
**AP** ELKINS SINN **EQ 100MG BASE/VIAL** **N81224 001**
JUN 03, 1994
+ IMMUNEX EQ 3MG BASE/ML N08107 001
@ EQ 3MG BASE/ML N08107 001

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT-PED
> DLT > + TAP 3.75MG/VIAL,7.5MG/VIAL N20263 003
> DLT > APR 16, 1993
> DLT > + 7.5MG/VIAL,7.5MG/VIAL N20263 004
> DLT > APR 16, 1993
> ADD > @ TAP PHARMS 3.75MG/VIAL,7.5MG/VIAL N20263 003
> ADD > APR 16, 1993
> ADD > @ 7.5MG/VIAL,7.5MG/VIAL N20263 004
> ADD > APR 16, 1993
> ADD > + 11.25MG/VIAL N20263 005
> ADD > JAN 21, 1994
> ADD > + 15MG/VIAL N20263 006
> ADD > JAN 21, 1994

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
**BETAGAN**
**AT** + ALLERGAN **0.5%** **N19814 001**
JUN 28, 1989

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
**BETAGAN**
**AT** + ALLERGAN **0.5%** **N19219 002**
DEC 19, 1985

**LEVOBUNOLOL HCL**
**AT** BAUSCH AND LOMB **0.25%** **N74307 001**
MAR 04, 1994
**AT** **0.5%** **N74326 001**
MAR 04, 1994

LEVOCABASTINE HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
LIVOSTIN
+ CIBA VISION EQ 0.05% BASE N20219 001
NOV 10, 1993
+ IOLAB EQ 0.05% BASE N20219 001
NOV 10, 1993

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
**ARESTOCAINE HCL W/ LEVONORDEFRIN**
**AP** CARLISLE **0.05MG/ML;2%** **N85010 001**
@ SOLVAY 0.05MG/ML;2% N85010 001
**CARBOCAINE W/ NEO-COBEFRIN**
**AP** + COOK WAITE **0.05MG/ML;2%** **N12125 002**
**AP** + EASTMAN KODAK **0.05MG/ML;2%** **N12125 002**

LEVONORDEFRIN; PROCAINE HYDROCHLORIDE; PROPOXYCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
RAVOCAINE AND NOVOCAIN W/ NEO-COBEFRIN
@ EASTMAN KODAK 0.05MG/ML;2%;0.4% N08592 007
@ STERLING WINTHROP 0.05MG/ML;2%;0.4% N08592 007

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL
MYLOCAINE
**AT** PENNEX **4%** **N87881 001**
NOV 18, 1982

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | MYLOCAINE | | | |
| | @ PENNEX PHARMS | 4% | | N87881 001 |
| | | | | NOV 18, 1982 |
| | PEDIATRIC LTA KIT | | | |
| AT | ABBOTT | 2% | | N88572 001 |
| | | | | JUL 31, 1984 |
| | @ | 2% | | N88572 001 |
| | | | | JUL 31, 1984 |

LIOTRIX (T4;T3)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | EUTHROID-0.5 | | | |
| | PARKE DAVIS | 0.03MG;0.0075MG | | N16680 001 |
| | @ | 0.03MG;0.0075MG | | N16680 001 |
| | EUTHROID-1 | | | |
| | PARKE DAVIS | 0.06MG;0.015MG | | N16680 002 |
| | @ | 0.06MG;0.015MG | | N16680 002 |
| | EUTHROID-2 | | | |
| | PARKE DAVIS | 0.12MG;0.03MG | | N16680 003 |
| | @ | 0.12MG;0.03MG | | N16680 003 |
| | EUTHROID-3 | | | |
| | + PARKE DAVIS | 0.18MG;0.045MG | | N16680 004 |
| | @ | 0.18MG;0.045MG | | N16680 004 |

LISINOPRIL

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PRINIVIL | | | |
| AB | MERCK | 2.5MG | | N19558 006 |
| | | | | JAN 28, 1994 |
| | ZESTRIL | | | |
| AB | ZENECA | 2.5MG | | N19777 005 |
| | | | | APR 29, 1993 |

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | LITHOBID | | | |
| | @ CIBA | 300MG | | N18027 001 |
| | @ SOLVAY | 300MG | | N18027 001 |

LITHIUM CITRATE

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | CIBALITH-S | | | |
| AA | CIBA | EQ 300MG CARBONATE/5ML | | N17672 001 |
| AA | SOLVAY | EQ 300MG CARBONATE/5ML | | N17672 001 |

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | CLARITIN-D | | | |
| | + SCHERING | 5MG;120MG | | N19670 001 |
| | | | | NOV 14, 1994 |

LORAZEPAM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | ATIVAN | | | |
| AP | + WYETH AYERST | 2MG/ML | | N18140 001 |
| AP | + | 4MG/ML | | N18140 002 |
| | LORAZEPAM | | | |
| AP | ABBOTT | 2MG/ML | | N74280 001 |
| | | | | MAY 27, 1994 |
| AP | | 2MG/ML | | N74282 001 |
| | | | | MAY 27, 1994 |
| AP | | 4MG/ML | | N74280 002 |
| | | | | MAY 27, 1994 |
| AP | | 4MG/ML | | N74282 002 |
| | | | | MAY 27, 1994 |
| AP | STERIS | 2MG/ML | | N74276 001 |
| | | | | APR 15, 1994 |
| AP | | 4MG/ML | | N74276 002 |
| | | | | APR 15, 1994 |
| AP | STERLING WINTHROP | 2MG/ML | | N74243 001 |
| | | | | APR 12, 1994 |
| AP | | 2MG/ML | | N74300 001 |
| | | | | APR 12, 1994 |
| AP | | 4MG/ML | | N74243 002 |
| | | | | APR 12, 1994 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | LORAZEPAM | | | |
| AB | WARNER CHILCOTT | 1MG | | N71038 001 |
| | | | | JAN 12, 1988 |
| AB | | 2MG | | N71039 001 |
| | | | | JAN 12, 1988 |

LORAZEPAM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | LORAZEPAM | | | |
| | @ WARNER CHILCOTT | 1MG | | N71038 001 JAN 12, 1988 |
| | @ | 2MG | | N71039 001 JAN 12, 1988 |

MAGNESIUM SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | MAGNESIUM SULFATE IN PLASTIC CONTAINER | | | |
| | ABBOTT | 4GM/100ML | | N20309 001 JUN 24, 1994 |
| | | 80MG/ML | | N20309 002 JUN 24, 1994 |

MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | DEPO-PROVERA | | | |
| | UPJOHN | 150MG/ML | | N20246 001 OCT 29, 1992 |
| + | | 150MG/ML | | N20246 001 OCT 29, 1992 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | CYCRIN | | | |
| AB | ESI | 2.5MG | | N81239 001 OCT 30, 1992 |
| AB | | 5MG | | N81240 001 OCT 30, 1992 |
| AB | | 10MG | | N89386 001 SEP 09, 1987 |
| AB | WYETH AYERST | 2.5MG | | N81239 001 OCT 30, 1992 |
| AB | | 5MG | | N81240 001 OCT 30, 1992 |
| AB | | 10MG | | N89386 001 SEP 09, 1987 |

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | HUMEGON | | | |
| AB | ORGANON | 75 IU/VIAL;75 IU/VIAL | | N20328 001 SEP 01, 1994 |
| AB | | 150 IU/VIAL;150 IU/VIAL | | N20328 002 SEP 01, 1994 |
| | | 75 IU/VIAL;75 IU/VIAL | | N20328 001 SEP 01, 1994 |
| | | 150 IU/VIAL;150 IU/VIAL | | N20328 002 SEP 01, 1994 |
| | PERGONAL | | | |
| AB + | SERONO | 75 IU/AMP;75 IU/AMP | | N17646 001 |
| AB + | | 150 IU/AMP;150 IU/AMP | | N17646 002 MAY 20, 1985 |
| + | SERONO LABS | 75 IU/AMP;75 IU/AMP | | N17646 001 |
| + | | 150 IU/AMP;150 IU/AMP | | N17646 002 MAY 20, 1985 |

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | ARESTOCAINE HCL | | | |
| AP | CARLISLE | 3% | | N84777 002 APR 18, 1982 |
| | @ SOLVAY | 3% | | N84777 002 APR 18, 1982 |
| | CARBOCAINE | | | |
| AP + | COOK WAITE | 3% | | N12125 003 |
| AP + | EASTMAN KODAK | 3% | | N12125 003 |

MEPROBAMATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | MEPRIAM | | | |
| AA | LEMMON | 400MG | | N16069 001 |
| | @ | 400MG | | N16069 001 |

METAPROTERENOL SULFATE

SOLUTION; INHALATION

| | | | | |
|---|---|---|---|---|
| | METAPROTERENOL SULFATE | | | |
| > DLT > AN | DEY | 5% | | N70805 001 AUG 17, 1987 |
| > DLT > | | | | |

METAPROTERENOL SULFATE

SOLUTION; INHALATION
METAPROTERENOL SULFATE

| | | | | |
|---|---|---|---|---|
| > ADD > | | @ DEY | 5% | N70805 001 |
| > ADD > | | | | AUG 17, 1987 |

METARAMINOL BITARTRATE

INJECTABLE; INJECTION
METARAMINOL BITARTRATE

| | | | | |
|---|---|---|---|---|
| | AP | FUJISAWA | EQ 10MG BASE/ML | N80431 001 |
| | | @ | EQ 10MG BASE/ML | N80431 001 |

> ADD > METFORMIN HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > GLUCOPHAGE

| | | | | |
|---|---|---|---|---|
| > ADD > | | LIPHA | 500MG | N20357 001 |
| > ADD > | | | | DEC 29, 1994 |
| > ADD > | | + | 850MG | N20357 002 |
| > ADD > | | | | DEC 29, 1994 |

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL
METHADONE HCL

| | | | | |
|---|---|---|---|---|
| | AA | UDL | 10MG/ML | N40088 001 |
| | | | | NOV 30, 1994 |

METHAZOLAMIDE

TABLET; ORAL
METHAZOLAMIDE

| | | | | |
|---|---|---|---|---|
| | AB | MIKART | 25MG | N40062 001 |
| | | | | JAN 27, 1994 |
| | AB | | 50MG | N40062 002 |
| | | | | JAN 27, 1994 |

NEPTAZANE

| | | | | |
|---|---|---|---|---|
| > DLT > | AB | LEDERLE | 25MG | N11721 002 |
| > DLT > | | | | NOV 25, 1991 |
| > DLT > | AB | * | 50MG | N11721 001 |
| > ADD > | AB | STORZ OPHTHALM | 25MG | N11721 002 |
| > ADD > | | | | NOV 25, 1991 |
| > ADD > | AB | + | 50MG | N11721 001 |

METHDILAZINE

TABLET, CHEWABLE; ORAL
TACARYL

| | | | | |
|---|---|---|---|---|
| | | WESTWOOD SQUIBB | 3.6MG | N11950 009 |
| | | @ | 3.6MG | N11950 009 |

METHDILAZINE HYDROCHLORIDE

SYRUP; ORAL
TACARYL

| | | | | |
|---|---|---|---|---|
| | | WESTWOOD SQUIBB | 4MG/5ML | N11950 007 |
| | | @ | 4MG/5ML | N11950 007 |

TABLET; ORAL
TACARYL

| | | | | |
|---|---|---|---|---|
| | | WESTWOOD SQUIBB | 8MG | N11950 006 |
| | | @ | 8MG | N11950 006 |

METHOTREXATE SODIUM

INJECTABLE; INJECTION
FOLEX PFS

| | | | | |
|---|---|---|---|---|
| | AP | ADRIA | EQ 25MG BASE/ML | N89180 001 |
| | | | | JAN 03, 1986 |
| | | @ PHARMACIA | EQ 25MG BASE/ML | N89180 001 |
| | | | | JAN 03, 1986 |

TABLET; ORAL
METHOTREXATE SODIUM

| | | | | |
|---|---|---|---|---|
| | AB | ROXANE | EQ 2.5MG BASE | N40054 001 |
| | | | | AUG 01, 1994 |

METHSCOPOLAMINE BROMIDE

TABLET; ORAL
PAMINE

| | | | | |
|---|---|---|---|---|
| | AA | BRADLEY | 2.5MG | N08848 001 |
| | AA | + KENWOOD LABS | 2.5MG | N08848 001 |

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-METHAPRED

| | | | | |
|---|---|---|---|---|
| | AP | ABBOTT | EQ 40MG BASE/VIAL | N89573 001 |
| | | | | FEB 22, 1991 |

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | A-METHAPRED | | | |
| AP | ABBOTT | EQ 125MG BASE/VIAL | N89574 001 | FEB 22, 1991 |
| AP | | EQ 500MG BASE/VIAL | N89575 001 | FEB 22, 1991 |
| | @ | EQ 40MG BASE/VIAL | N89573 001 | FEB 22, 1991 |
| | @ | EQ 125MG BASE/VIAL | N89574 001 | FEB 22, 1991 |
| | @ | EQ 500MG BASE/VIAL | N89575 001 | FEB 22, 1991 |
| | METHYLPREDNISOLONE | | | |
| AP | ORGANON | EQ 500MG BASE/VIAL | N87535 001 | JUN 25, 1982 |
| AP | | EQ 1GM BASE/VIAL | N87535 002 | JUN 25, 1982 |
| | @ | EQ 500MG BASE/VIAL | N87535 001 | JUN 25, 1982 |
| | @ | EQ 1GM BASE/VIAL | N87535 002 | JUN 25, 1982 |

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

| | | | | |
|---|---|---|---|---|
| | METHYLTESTOSTERONE | | | |
| | PRIVATE FORM | 5MG | N83836 001 | |
| | @ PVT FORM | 5MG | N83836 001 | |
| BP | TABLICAPS | 10MG | N85125 001 | |
| | @ | 10MG | N85125 001 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ANDROID 25 | | | |
| AB | ICN | 25MG | N87147 001 | |
| AB | + | 25MG | N87147 001 | |
| | METHYLTESTOSTERONE | | | |
| BP | DANBURY PHARMA | 10MG | N80933 001 | |
| BP | | 25MG | N80931 001 | |
| | @ | 10MG | N80933 001 | |
| | @ | 25MG | N80931 001 | |
| BP | PUREPAC | 10MG | N80475 002 | |
| BP | | 25MG | N80475 003 | |
| | @ PUREPAC PHARM | 10MG | N80475 002 | |
| | @ | 25MG | N80475 003 | |
| BP | TABLICAPS | 10MG | N80313 001 | |
| BP | | 25MG | N85270 001 | |

METHYLTESTOSTERONE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | METHYLTESTOSTERONE | | | |
| | @ TABLICAPS | 10MG | N80313 001 | |
| | @ | 25MG | N85270 001 | |
| BP | WEST WARD | 10MG | N84331 001 | |
| BP | | 25MG | N84331 002 | |
| | @ WEST WARD PHARM | 10MG | N84331 001 | |
| | @ | 25MG | N84331 002 | |
| | ORETON METHYL | | | |
| BP | + SCHERING | 25MG | N03158 002 | |
| | @ | 25MG | N03158 002 | |

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | MAXOLON | | | |
| AB | KING PHARMS | EQ 10MG BASE | N70106 001 | MAR 04, 1986 |
| | @ | EQ 10MG BASE | N70106 001 | MAR 04, 1986 |

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | TOPROL XL | | | |
| | + HASSLE AB | EQ 50MG TARTRATE | N19962 001 | JAN 10, 1992 |
| | + | EQ 100MG TARTRATE | N19962 002 | JAN 10, 1992 |
| | + | EQ 200MG TARTRATE | N19962 003 | JAN 10, 1992 |
| | TOPROL-XL | | | |
| | + ASTRA | EQ 50MG TARTRATE | N19962 001 | JAN 10, 1992 |
| | + | EQ 100MG TARTRATE | N19962 002 | JAN 10, 1992 |
| | + | EQ 200MG TARTRATE | N19962 003 | JAN 10, 1992 |

METOPROLOL TARTRATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | METOPROLOL TARTRATE | | | |
| AB | APOTHECON | 50MG | N74258 001 | JAN 27, 1994 |

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

| | | | | |
|---|---|---|---|---|
| AB | APOTHECON | 100MG | N74258 002 | JAN 27, 1994 |
| AB | COPLEY PHARM | 50MG | N74333 001 | JAN 27, 1994 |
| AB | | 100MG | N74333 002 | JAN 27, 1994 |
| AB | GENEVA PHARMS | 50MG | N73288 001 | MAR 25, 1994 |
| AB | | 100MG | N73289 001 | MAR 25, 1994 |
| AB | NOVOPHARM | 50MG | N74143 001 | SEP 30, 1994 |
| AB | | 100MG | N74143 002 | SEP 30, 1994 |
| AB | PUREPAC PHARM | 50MG | N74380 001 | JUL 29, 1994 |
| AB | | 100MG | N74380 002 | JUL 29, 1994 |
| AB | WATSON LABS | 50MG | N74217 001 | MAY 27, 1994 |
| AB | | 100MG | N74217 002 | MAY 27, 1994 |

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE

| | | | | |
|---|---|---|---|---|
| | @ NYCOMED | 2.5GM/VIAL | N17982 003 | SEP 12, 1983 |
| | + | 3.75GM/VIAL | N17982 001 | |
| | + | 6.75GM/VIAL | N17982 002 | |
| | @ | 13.5GM/VIAL | N17982 004 | SEP 12, 1983 |
| | @ STERLING WINTHROP | 2.5GM/VIAL | N17982 003 | SEP 12, 1983 |
| | + | 3.75GM/VIAL | N17982 001 | |
| | + | 6.75GM/VIAL | N17982 002 | |
| | @ | 13.5GM/VIAL | N17982 004 | SEP 12, 1983 |

MILRINONE LACTATE

INJECTABLE; INJECTION
PRIMACOR

| | | | | |
|---|---|---|---|---|
| | + SANOFI WINTHROP | EQ 1MG BASE/ML | N19436 001 | DEC 31, 1987 |
| | + STERLING WINTHROP | EQ 1MG BASE/ML | N19436 001 | DEC 31, 1987 |

PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | @ SANOFI WINTHROP | EQ 10MG BASE/100ML | N20343 001 | AUG 09, 1994 |
| | @ | EQ 15MG BASE/100ML | N20343 002 | AUG 09, 1994 |
| | + | EQ 20MG BASE/100ML | N20343 003 | AUG 09, 1994 |
| | @ STERLING WINTHROP | EQ 10MG BASE/100ML | N20343 001 | AUG 09, 1994 |
| | @ | EQ 15MG BASE/100ML | N20343 002 | AUG 09, 1994 |
| | + | EQ 20MG BASE/100ML | N20343 003 | AUG 09, 1994 |

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL
MINOCIN

| | | | | |
|---|---|---|---|---|
| | @ LEDERLE | EQ 50MG BASE | N50451 003 | AUG 10, 1982 |
| | @ | EQ 100MG BASE | N50451 002 | AUG 10, 1982 |

MINOCYCLINE HCL

| | | | | |
|---|---|---|---|---|
| | LEDERLE | EQ 50MG BASE | N50451 003 | AUG 10, 1982 |
| | | EQ 100MG BASE | N50451 002 | AUG 10, 1982 |

MITOMYCIN

INJECTABLE; INJECTION
MUTAMYCIN

| | | | | |
|---|---|---|---|---|
| AP | + BRISTOL | 5MG/VIAL | N50450 001 | |
| AP | + | 20MG/VIAL | N50450 002 | |
| | @ | 5MG/VIAL | N50450 001 | |
| | @ | 20MG/VIAL | N50450 002 | |
| AP | BRISTOL MYERS | 5MG/VIAL | N62336 001 | |
| AP | + | 5MG/VIAL | N62336 001 | |
| AP | | 20MG/VIAL | N62336 002 | |

MITOMYCIN

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | MUTAMYCIN | | | |
| AP | + | BRISTOL MYERS | 20MG/VIAL | N62336 002 | |
| | | | 40MG/VIAL | N62336 003 | |
| | | | | MAR 10, 1988 | |
| | + | | 40MG/VIAL | N62336 003 | |
| | | | | MAR 10, 1988 | |

NADOLOL

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | CORGARD | | | |
| AB | | SQUIBB | 120MG | N18063 003 | |
| AB | | | 120MG | N18064 003 | |
| AB | + | | 160MG | N18063 004 | |
| AB | | | 160MG | N18064 004 | |
| | | NADOLOL | | | |
| AB | | COPLEY PHARM | 80MG | N74368 001 | |
| | | | | AUG 31, 1994 | |
| AB | | | 120MG | N74368 002 | |
| | | | | AUG 31, 1994 | |
| AB | | | 160MG | N74368 003 | |
| | | | | AUG 31, 1994 | |

NAFCILLIN SODIUM

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | NAFCIL | | | > ADD > |
| AP | | APOTHECON | EQ 500MG BASE/VIAL | N61984 001 | > ADD > |
| AP | | | EQ 1GM BASE/VIAL | N61984 002 | > ADD > |
| AP | | | EQ 2GM BASE/VIAL | N61984 003 | > DLT > |
| AP | | | EQ 4GM BASE/VIAL | N61984 005 | > DLT > |
| AP | | BRISTOL | EQ 500MG BASE/VIAL | N61984 001 | > DLT > |
| AP | | | EQ 1GM BASE/VIAL | N61984 002 | |
| AP | | | EQ 2GM BASE/VIAL | N61984 003 | |
| AP | | | EQ 4GM BASE/VIAL | N61984 005 | |
| | | UNIPEN | | | |
| AP | | WYETH AYERST | EQ 10GM BASE/VIAL | N50320 005 | |
| | @ | | EQ 20GM BASE/VIAL | N50320 006 | |

NALIDIXIC ACID

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | | NEGGRAM | | |
| | + | SANOFI WINTHROP | 250MG/5ML | N17430 001 |

NALIDIXIC ACID

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | | NEGGRAM | | |
| | + | STERLING WINTHROP | 250MG/5ML | N17430 001 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | NEGGRAM | | |
| AB | | SANOFI WINTHROP | 250MG | N14214 002 |
| AB | | | 500MG | N14214 004 |
| AB | + | | 1GM | N14214 005 |
| AB | | STERLING WINTHROP | 250MG | N14214 002 |
| AB | | | 500MG | N14214 004 |
| AB | + | | 1GM | N14214 005 |

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | TALWIN NX | | |
| | + | SANOFI WINTHROP | EQ 0.5MG BASE; EQ 50MG BASE | N18733 001 |
| | | | | DEC 16, 1982 |
| | + | STERLING WINTHROP | EQ 0.5MG BASE; EQ 50MG BASE | N18733 001 |
| | | | | DEC 16, 1982 |

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | REVIA | | |
| | + | DUPONT MERCK | 50MG | N18932 001 |
| | | | | NOV 20, 1984 |
| | | TREXAN | | |
| | + | DUPONT | 50MG | N18932 001 |
| | | | | NOV 20, 1984 |

NANDROLONE PHENPROPIONATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | DURABOLIN | | |
| AO | + | ORGANON | 50MG/ML | N11891 002 |
| | | DURABOLIN-50 | | |
| AO | + | ORGANON | 50MG/ML | N11891 002 |

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | NAFAZAIR | | | |
| AT | BAUSCH AND LOMB | 0.1% | N40073 001 | |
| | | | MAY 25, 1994 | |
| AT | PHARMAFAIR | 0.1% | N88101 001 | |
| | | | APR 15, 1983 | |
| | @ | 0.1% | N88101 001 | > ADD > |
| | | | APR 15, 1983 | > ADD > |
| | VASOCON | | | > ADD > |
| AT | CIBA VISION | 0.1% | N80235 002 | > ADD > |
| | | | MAR 24, 1983 | |
| AT | IOLAB | 0.1% | N80235 002 | |
| | | | MAR 24, 1983 | |

NAPROXEN

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | NAPROSYN | | | |
| AB | + SYNTEX | 25MG/ML | N18965 001 | > ADD > |
| | | | MAR 23, 1987 | > ADD > |
| | NAPROXEN | | | > ADD > |
| AB | ROXANE | 25MG/ML | N74190 001 | > ADD > |
| | | | MAR 30, 1994 | > ADD > |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | NAPROSYN | | | > ADD > |
| AB | SYNTEX | 500MG | N17581 004 | > ADD > |
| | | | APR 15, 1982 | > ADD > |
| AB | + | 500MG | N17581 004 | > ADD > |
| | | | APR 15, 1982 | > ADD > |
| | NAPROXEN | | | > ADD > |
| AB | ROXANE | 250MG | N74211 001 | |
| | | | FEB 28, 1994 | |
| AB | | 375MG | N74211 002 | |
| | | | FEB 28, 1994 | |
| AB | | 500MG | N74211 003 | |
| | | | FEB 28, 1994 | |

TABLET, DELAYED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | EC-NAPROSYN | | |
| | + SYNTEX | 375MG | N20067 002 |
| | | | OCT 14, 1994 |
| | + | 500MG | N20067 003 |
| | | | OCT 14, 1994 |

NAPROXEN SODIUM

TABLET; ORAL

| | | | |
|---|---|---|---|
| | NAPROXEN SODIUM | | |
| AB | COPLEY PHARM | EQ 250MG BASE | N74289 001 |
| | | | JAN 27, 1994 |
| AB | | EQ 500MG BASE | N74289 002 |
| | | | JAN 27, 1994 |
| AB | INVAMED | EQ 250MG BASE | N74495 001 |
| | | | DEC 05, 1994 |
| AB | | EQ 500MG BASE | N74495 002 |
| | | | DEC 05, 1994 |
| AB | MYLAN | EQ 250MG BASE | N74367 001 |
| | | | AUG 31, 1994 |
| AB | | EQ 500MG BASE | N74367 002 |
| | | | AUG 31, 1994 |

NEFAZODONE HYDROCHLORIDE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | SERZONE | | |
| | @ BRISTOL MYERS SQUIBB | 50MG | N20152 001 |
| | | | DEC 22, 1994 |
| | | 100MG | N20152 002 |
| | | | DEC 22, 1994 |
| | | 150MG | N20152 003 |
| | | | DEC 22, 1994 |
| | | 200MG | N20152 004 |
| | | | DEC 22, 1994 |
| | + | 250MG | N20152 005 |
| | | | DEC 22, 1994 |
| | @ | 300MG | N20152 006 |
| | | | DEC 22, 1994 |

NEOMYCIN SULFATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | NEOMYCIN SULFATE | | |
| AA | LANNETT | EQ 350MG BASE | N60607 001 |
| | @ | EQ 350MG BASE | N60607 001 |

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

| | | | |
|---|---|---|---|
| | HABITROL | | |
| BC | BASEL PHARMS | 7MG/24HR | N20076 001 |
| | | | NOV 27, 1991 |

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

| | | | | |
|---|---|---|---|---|
| | | HABITROL | | |
| BC | + | BASEL PHARMS | 7MG/24HR | N20076 001 NOV 27, 1991 |
| BC | | | 14MG/24HR | N20076 002 NOV 27, 1991 |
| BC | + | | 14MG/24HR | N20076 002 NOV 27, 1991 |
| BC | | | 21MG/24HR | N20076 003 NOV 27, 1991 |
| BC | + | | 21MG/24HR | N20076 003 NOV 27, 1991 |

NITROFURANTOIN

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | FURALAN | | |
| AB | | LANNETT | 50MG | N80017 001 |
| AB | | | 100MG | N80017 002 |
| | @ | | 50MG | N80017 001 |
| | @ | | 100MG | N80017 002 |

NITROFURAZONE

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | | NITROFURAZONE | | |
| AT | | LANNETT | 0.2% | N84393 001 |
| | @ | | 0.2% | N84393 001 |

NITROGLYCERIN

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | NITROGLYCERIN | | |
| AP | | INTL MEDICATION | 5MG/ML | N70026 001 SEP 10, 1985 |
| | @ | | 5MG/ML | N70026 001 SEP 10, 1985 |
| | | NITROGLYCERIN IN DEXTROSE 5% | | |
| AP | | ABBOTT | 0.1MG/ML | N74083 001 OCT 26, 1994 |
| | | NITRONAL | | |
| | # | BOSKAMP | 1MG/ML | N18672 001 AUG 30, 1983 |

NITROGLYCERIN

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | NITRONAL | | |
| | @ | POHL BOSKAMP | 1MG/ML | N18672 001 AUG 30, 1983 |
| | | NITROSTAT | | |
| AP | | PARKE DAVIS | 5MG/ML | N70863 001 JAN 08, 1987 |
| | | | 10MG/ML | N70871 001 JAN 08, 1987 |
| | | | 10MG/ML | N70872 001 JAN 08, 1987 |
| | @ | | 5MG/ML | N70863 001 JAN 08, 1987 |
| | @ | | 10MG/ML | N70871 001 JAN 08, 1987 |
| | @ | | 10MG/ML | N70872 001 JAN 08, 1987 |

NOREPINEPHRINE BITARTRATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | LEVOPHED | | |
| | + | SANOFI WINTHROP | EQ 1MG BASE/ML | N07513 001 |
| | # | STERLING WINTHROP | EQ 1MG BASE/ML | N07513 001 |

NOREPINEPHRINE BITARTRATE; PROCAINE HYDROCHLORIDE; PROPOXYCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | RAVOCAINE AND NOVOCAIN W/ LEVOPHED | | |
| | | EASTMAN KODAK | EQ 0.033MG BASE/ML;2%; 0.4% | N08592 003 |
| | | STERLING WINTHROP | EQ 0.033MG BASE/ML;2%; 0.4% | N08592 003 |

NORETHINDRONE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | NORLUTIN | | |
| | # | PARKE DAVIS | 5MG | N10895 002 |
| | @ | | 5MG | N10895 002 |

NYSTATIN

SUSPENSION; ORAL

NYSTATIN

| | | | | |
|---|---|---|---|---|
| AA | | BAUSCH AND LOMB | 100,000 UNITS/ML | N64042 001<br>FEB 28, 1994 |
| AA | | PHARMAFAIR | 100,000 UNITS/ML | N62541 001<br>JAN 16, 1985 |
| | @ | | 100,000 UNITS/ML | N62541 001<br>JAN 16, 1985 |

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYCOLOG-II

| | | | | |
|---|---|---|---|---|
| AT | + | APOTHECON | 100,000 UNITS/GM;0.1% | N60576 002<br>MAY 01, 1985 |
| AT | | | 100,000 UNITS/GM;0.1% | N62606 001<br>MAY 15, 1985 |
| AT | * | SQUIBB | 100,000 UNITS/GM;0.1% | N60576 002<br>MAY 01, 1985 |
| AT | | | 100,000 UNITS/GM;0.1% | N62606 001<br>MAY 15, 1985 |

NYSTATIN AND TRIAMCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| AT | | BARRE | 100,000 UNITS/GM;0.1% | N63010 001<br>DEC 20, 1988 |
| | @ | | 100,000 UNITS/GM;0.1% | N63010 001<br>DEC 20, 1988 |
| B* | | CLAY PARK | 100,000 UNITS/GM;0.1% | N62186 002<br>JUN 06, 1985 |
| | @ | | 100,000 UNITS/GM;0.1% | N62186 002<br>JUN 06, 1985 |
| AT | | PHARMAFAIR | 100,000 UNITS/GM;0.1% | N62657 001<br>JUL 10, 1986 |
| | @ | | 100,000 UNITS/GM;0.1% | N62657 001<br>JUL 30, 1986 |

OINTMENT; TOPICAL

MYCOLOG-II

| | | | | |
|---|---|---|---|---|
| AT | + | APOTHECON | 100,000 UNITS/GM;0.1% | N60572 001<br>JUN 28, 1985 |
| AT | * | WESTWOOD SQUIBB | 100,000 UNITS/GM;0.1% | N60572 001<br>JUN 28, 1985 |

NYSTATIN-TRIAMCINOLONE ACETONIDE

| | | | | |
|---|---|---|---|---|
| AT | | PHARMADERM | 100,000 UNITS/GM;0.1% | N62603 001<br>OCT 09, 1985 |
| | @ | | 100,000 UNITS/GM;0.1% | N62603 001<br>OCT 09, 1985 |

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRILOSEC

| | | | | |
|---|---|---|---|---|
| | + | ASTRA MERCK | 20MG | N19810 001<br>SEP 14, 1989 |
| | * | MERCK | 20MG | N19810 001<br>SEP 14, 1989 |

ORPHENADRINE HYDROCHLORIDE

TABLET; ORAL

DISIPAL

| | | | | |
|---|---|---|---|---|
| | | 3M | 50MG | N10653 001 |
| | @ | | 50MG | N10653 001 |

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAXIL

| | | | | |
|---|---|---|---|---|
| | | SMITHKLINE BEECHAM | EQ 30MG BASE | N20031 003<br>DEC 29, 1992 |
| | + | | EQ 30MG BASE | N20031 003<br>DEC 29, 1992 |

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

| | | | | |
|---|---|---|---|---|
| | @ | APOTHECON | 1,000,000 UNITS/VIAL | N60362 001 |
| | @ | | 5,000,000 UNITS/VIAL | N60362 003 |
| | @ | | 10,000,000 UNITS/VIAL | N60362 004 |
| | @ | | 20,000,000 UNITS/VIAL | N60362 002 |
| AP | | SQUIBB | 1,000,000 UNITS/VIAL | N60362 001 |
| AP | | | 5,000,000 UNITS/VIAL | N60362 003 |
| AP | | | 10,000,000 UNITS/VIAL | N60362 004 |
| AP | | | 20,000,000 UNITS/VIAL | N60362 002 |

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

BETAPEN-VK

| | | | | |
|---|---|---|---|---|
| | @ | APOTHECON | EQ 125MG BASE/5ML | N61149 001 |
| | @ | | EQ 250MG BASE/5ML | N61149 002 |
| AA | | BRISTOL | EQ 125MG BASE/5ML | N61149 001 |

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

| | | | |
|---|---|---|---|
| | **BETAPEN-VK** | | |
| AA | BRISTOL | EQ 250MG BASE/5ML | N61149 002 |
| | **VEETIDS** | | |
| AA | APOTHECON | EQ 125MG BASE/5ML | N61410 001 |
| AA | | EQ 250MG BASE/5ML | N61410 002 |

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **UTICILLIN VK** | | |
| AB | UPJOHN | EQ 500MG BASE | N61651 002 |
| | @ | EQ 500MG BASE | N61651 002 |

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **PENTACARINAT** | | |
| AP | RHONE POULENC RORER | 300MG/VIAL | N73447 001<br>APR 28, 1994 |

PENTAZOCINE LACTATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | TALWIN | | |
| | + SANOFI WINTHROP | EQ 30MG BASE/ML | N16194 001 |
| | + STERLING WINTHROP | EQ 30MG BASE/ML | N16194 001 |

PENTOBARBITAL SODIUM

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | PENTOBARBITAL SODIUM | | |
| AA | LANNETT | 50MG | N85937 001 |
| AA | | 100MG | N85915 001 |
| | @ | 50MG | N85937 001 |
| | @ | 100MG | N85915 001 |

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **PHENDIMETRAZINE TARTRATE** | | |
| AA | ZENITH | 35MG | N85611 001 |
| | @ ZENITH LABS | 35MG | N85611 001 |

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | **PHENTERMINE HCL** | | |
| AA | LANNETT | 30MG | N87022 001<br>FEB 03, 1983 |
| | @ | 30MG | N87022 001<br>FEB 03, 1983 |
| AA | LEMMON | 30MG | N88612 001<br>APR 04, 1984 |
| AA | | 30MG | N88613 001<br>APR 09, 1984 |
| AA | | 30MG | N88614 001<br>APR 09, 1984 |
| | @ | 30MG | N88612 001<br>APR 04, 1984 |
| | @ | 30MG | N88613 001<br>APR 09, 1984 |
| | @ | 30MG | N88614 001<br>APR 09, 1984 |

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

| | | | |
|---|---|---|---|
| | **PROMETHAZINE VC PLAIN** | | |
| AA | PENNEX | 5MG/5ML;6.25MG/5ML | N88897 001<br>JAN 04, 1985 |
| | @ PENNEX PHARMS | 5MG/5ML;6.25MG/5ML | N88897 001<br>JAN 04, 1985 |

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | DIPHENYLAN SODIUM | | |
| BX | LANNETT | 100MG | N80857 002 |
| | | 30MG | N80857 001 |
| | @ | 30MG | N80857 001 |
| | @ | 100MG | N80857 002 |

PHYTONADIONE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | PHYTONADIONE | | |
| BP | SMITHKLINE BEECHAM | 1MG/0.5ML | N84060 001 |
| BP | | 10MG/ML | N84060 002 |
| | @ | 1MG/0.5ML | N84060 001 |

PHYTONADIONE

INJECTABLE; INJECTION
PHYTONADIONE
@ SMITHKLINE BEECHAM 10MG/ML N84060 002

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL
SALAGEN
+ MGI 5MG N20237 001
MAR 22, 1994

PINDOLOL

TABLET; ORAL
PINDOLOL
AB MUTUAL PHARM 5MG N74063 001
JAN 27, 1994
AB 10MG N74063 002
JAN 27, 1994

PIPERAZINE CITRATE

SYRUP; ORAL
BRYREL
@ SANOFI WINTHROP EQ 500MG BASE/5ML N17796 001
@ STERLING WINTHROP EQ 500MG BASE/5ML N17796 001
VERMIDOL
AA SOLVAY EQ 500MG BASE/5ML N80992 001
@ EQ 500MG BASE/5ML N80992 001

PIROXICAM

CAPSULE; ORAL
PIROXICAM
AB NOVOPHARM 10MG N73637 001
JAN 28, 1994
AB 20MG N73638 001
JAN 28, 1994

PLICAMYCIN

INJECTABLE; INJECTION
MITHRACIN
* MILES 2.5MG/VIAL N50109 001
+ PFIZER 2.5MG/VIAL N50109 001

POLYMYXIN B SULFATE

INJECTABLE; INJECTION
AEROSPORIN
AP * BURROUGHS WELLCOME 500,000 UNITS/VIAL N62036 001
AP + EQ 500,000 U BASE/VIAL N62036 001
POLYMIXIN B SULFATE
AP PFIZER 500,000 UNITS/VIAL N60716 001
AP EQ 500,000 U BASE/VIAL N60716 001
POLYMYXIN B SULFATE
AP PHARMA TEK EQ 500,000 U BASE/VIAL N63000 001
SEP 30, 1994

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE
AP FUJISAWA 2MEQ/ML N87885 001
FEB 03, 1983
@ 2MEQ/ML N87885 001
FEB 03, 1983

TABLET, EXTENDED RELEASE; ORAL
K-DUR 20
SCHERING 20MEQ N19439 001
JUN 13, 1986
+ 20MEQ N19439 001
JUN 13, 1986

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE
BX BUNDY 5MG N83675 001
@ 5MG N83675 001
BX ICN 5MG N80236 001
@ 5MG N80236 001
BX INWOOD 5MG N80748 001
@ INWOOD LABS 5MG N80748 001

Bob Rochon

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

| | | | | |
|---|---|---|---|---|
| BX | | TABLICAPS | 5MG | N85170 001 |
| | @ | | 5MG | N85170 001 |

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC
ECONOPRED PLUS

| | | | | |
|---|---|---|---|---|
| > DLT > | AT | ALCON | 1% | N17469 001 |
| > ADD > | BX | | 1% | N17469 001 |

PRED FORTE

| | | | | |
|---|---|---|---|---|
| > DLT > | AT | + ALLERGAN | 1% | N17011 001 |
| > ADD > | BX | + | 1% | N17011 001 |

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

OINTMENT; OPHTHALMIC
CETAPRED

| | | | | |
|---|---|---|---|---|
| | | ALCON | 0.25%;10% | N87771 001 AUG 06, 1993 |
| | + | | 0.25%;10% | N87771 001 AUG 06, 1993 |

METIMYD

| | | | | |
|---|---|---|---|---|
| AT | + | SCHERING | 0.5%;10% | N10210 002 |

VASOCIDIN

| | | | | |
|---|---|---|---|---|
| | | CIBA VISION | 0.5%;10% | N88791 001 OCT 05, 1984 |
| | | IOLAB | 0.5%;10% | N88791 001 OCT 05, 1984 |

SUSPENSION/DROPS; OPHTHALMIC
BLEPHAMIDE

| | | | | |
|---|---|---|---|---|
| | | ALLERGAN | 0.2%;10% | N12813 002 |
| | + | | 0.2%;10% | N12813 002 |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
INFLAMASE FORTE

| | | | | |
|---|---|---|---|---|
| AT | + | CIBA VISION | EQ 0.9% PHOSPHATE | N80751 002 |
| AT | + | IOLAB | EQ 0.9% PHOSPHATE | N80751 002 |

INFLAMASE MILD

| | | | | |
|---|---|---|---|---|
| AT | + | CIBA VISION | EQ 0.11% PHOSPHATE | N80751 001 |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
INFLAMASE MILD

| | | | | |
|---|---|---|---|---|
| AT | + | IOLAB | EQ 0.11% PHOSPHATE | N80751 001 |

PREDAIR FORTE

| | | | | |
|---|---|---|---|---|
| AT | | PHARMAFAIR | EQ 0.9% PHOSPHATE | N88165 001 MAR 28, 1983 |
| | @ | | EQ 0.9% PHOSPHATE | N88165 001 MAR 28, 1983 |

PREDNISOLONE SODIUM PHOSPHATE

| | | | | |
|---|---|---|---|---|
| AT | | BAUSCH AND LOMB | EQ 0.11% PHOSPHATE | N40065 001 JUL 29, 1994 |
| AT | | | EQ 0.9% PHOSPHATE | N40070 001 JUL 29, 1994 |

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
VASOCIDIN

| | | | | |
|---|---|---|---|---|
| AT | + | CIBA VISION | EQ 0.23% PHOSPHATE;10% | N18988 001 AUG 26, 1988 |
| AT | + | IOLAB | EQ 0.23% PHOSPHATE;10% | N18988 001 AUG 26, 1988 |

PREDNISONE

TABLET; ORAL
PREDNISONE

| | | | |
|---|---|---|---|
| | @ 1ST TX | 5MG | N80371 001 |
| BX | BUNDY | 5MG | N83676 001 |
| | @ | 5MG | N83676 001 |
| BX | DANBURY PHARMA | 50MG | N86867 001 |
| | @ | 50MG | N86867 001 |
| | @ FERRANTE | 2.5MG | N80563 001 |
| | @ | 5MG | N80563 002 |
| BX | FIRST TX | 5MG | N80371 001 |
| BX | ICN | 5MG | N80237 001 |
| | @ | 5MG | N80237 001 |
| BX | INWOOD | 1MG | N80328 001 |
| BX | | 2.5MG | N80306 001 |
| | @ INWOOD LABS | 1MG | N80328 001 |
| | @ | 2.5MG | N80306 001 |
| BX | MK | 2.5MG | N80563 001 |
| BX | | 5MG | N80563 002 |
| BX | NYLOS | 5MG | N85115 001 |
| | @ | 5MG | N85115 001 |

PREDNISONE

TABLET; ORAL
PREDNISONE

| | | | | |
|---|---|---|---|---|
| BX | REXALL | 5MG | N80232 001 | |
| @ | | 5MG | N80232 001 | |
| BX | SPERTI | 1MG | N80359 001 | |
| BX | | 2.5MG | N80359 002 | |
| BX | | 5MG | N80359 003 | |
| @ | | 1MG | N80359 001 | |
| @ | | 2.5MG | N80359 002 | |
| @ | | 5MG | N80359 003 | |
| BX | WHITE TOWNE PAULSEN | 20MG | N84913 002 | |
| @ | WHITEWORTH TOWNE | 20MG | N84913 002 | |

PRIMAQUINE PHOSPHATE

TABLET; ORAL
PRIMAQUINE

| | | | | |
|---|---|---|---|---|
| | SANOFI WINTHROP | EQ 15MG BASE | N08316 001 | |
| | STERLING WINTHROP | EQ 15MG BASE | N08316 001 | > DLT > |
| | | | | > DLT > |
| | | | | > DLT > |
| | | | | > ADD > |

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
**PROMETHAZINE PLAIN**

| | | | |
|---|---|---|---|
| **AA** | PENNEX | **6.25MG/5ML** | **N87953 001**<br>**NOV 15, 1982** |
| @ | PENNEX PHARMS | 6.25MG/5ML | N87953 001<br>NOV 15, 1982 |

TABLET; ORAL
PROMETHAZINE HCL

| | | | |
|---|---|---|---|
| BP | TABLICAPS | 12.5MG | N84080 001 |
| BP | | 25MG | N84027 001 |
| @ | | 12.5MG | N84080 001 |
| @ | | 25MG | N84027 001 |
| | REMSED | | |
| BP | DUPONT | 25MG | N83176 002 |
| @ | DUPONT MERCK | 25MG | N83176 002 |

PROPANTHELINE BROMIDE

TABLET; ORAL
**PRO-BANTHINE**

| | | | |
|---|---|---|---|
| **AA** | + ROBERTS LABS | **7.5MG** | **N08732 003** |

PROPANTHELINE BROMIDE

TABLET; ORAL
**PRO-BANTHINE**

| | | | |
|---|---|---|---|
| **AA** | + ROBERTS LABS | **15MG** | **N08732 002** |
| **AA** | SCS PHARMS | **7.5MG** | **N08732 003** |
| **AA** | | **15MG** | **N08732 002** |

PROPARACAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
KAINAIR

| | | | |
|---|---|---|---|
| AT | PHARMAFAIR | 0.5% | N88087 001<br>JUN 07, 1983 |
| @ | | 0.5% | N88087 001<br>JUN 07, 1983 |

PROPIOLACTONE

SOLUTION; IRRIGATION
BETAPRONE

| | | | |
|---|---|---|---|
| | FOREST LABS | N/A | N11657 001 |
| @ | | N/A | N11657 001 |

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

| | | | |
|---|---|---|---|
| BD | DANBURY PHARMA | 50MG | N80932 001 |
| @ | | 50MG | N80932 001 |
| BD | LANNETT | 50MG | N80016 001 |
| @ | | 50MG | N80016 001 |
| BD | TABLICAPS | 50MG | N80840 001 |
| @ | | 50MG | N80840 001 |

PROTIRELIN

INJECTABLE; INJECTION
RELEFACT TRH

| | | | |
|---|---|---|---|
| AP | FERRING LABS | 0.5MG/ML | N18087 001 |

THYREL TRH

| | | | |
|---|---|---|---|
| AP | FERRING LABS | 0.5MG/ML | N18087 001 |

PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
NOVAFED
DOW PHARMS 120MG N17603 001
\+ 120MG N17603 001

PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE

TABLET, EXTENDED RELEASE; ORAL
SELDANE-D
\+ MARION MERRELL DOW 120MG;60MG N19664 001 AUG 19, 1991
MERRELL DOW 120MG;60MG N19664 001 AUG 19, 1991

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
ALLERFED
AA PRIVATE FORM 60MG;2.5MG N88860 001 JAN 31, 1985
@ PVT FORM 60MG;2.5MG N88860 001 JAN 31, 1985
TRIPHED
AA LEMMON 60MG;2.5MG N88630 001 MAY 17, 1984
@ 60MG;2.5MG N88630 001 MAY 17, 1984

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL
PYRIDOSTIGMINE BROMIDE
KALI DUPHAR 30MG N89572 001 NOV 27, 1990
@ SOLVAY 30MG N89572 001 NOV 27, 1990

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDEX
AB \+ ROBINS AH 300MG N12796 002

QUINIDINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
QUINIDINE SULFATE
AB COPLEY PHARM 300MG N40045 001 JUN 30, 1994

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL
ZANTAC 150
GLAXO EQ 150MG BASE N20095 001 MAR 08, 1994
ZANTAC 300
\+ GLAXO EQ 300MG BASE N20095 002 MAR 08, 1994

GRANULE, EFFERVESCENT; ORAL
ZANTAC 150
\+ GLAXO EQ 150MG BASE/PACKET N20251 002 MAR 31, 1994

TABLET, EFFERVESCENT; ORAL
ZANTAC 150
\+ GLAXO EQ 150MG BASE N20251 001 MAR 31, 1994

RAUWOLFIA SERPENTINA

TABLET; ORAL
>_DLT_>
>_DLT_>
>_ADD_>
HIWOLFIA
BP BOWMAN 50MG N09276 005
@ BOWMAN PHARMS 50MG N09276 005

RESERPINE

ELIXIR, ORAL
SERPASIL
CIBA 0.2MG/4ML N09115 005
@ 0.2MG/4ML N09115 005

TABLET; ORAL
RESERPINE
BP EON LABS 0.25MG N09838 002
BP \+ 0.25MG N09838 002
SERPASIL
BP CIBA 0.1MG N09115 001

RESERPINE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | SERPASIL | | | |
| | BP + | CIBA | 0.25MG | N09115 003 | |
| | @ | | 0.1MG | N09115 001 | |
| | @ | | 0.25MG | N09115 003 | |
| >DLT> | | SERPIVITE | | | |
| >DLT> | BP | VITARINE | 0.25MG | N09645 002 | |
| >ADD> | @ | | 0.25MG | N09645 002 | |

>ADD> RIMEXOLONE

>ADD> SUSPENSION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| >ADD> | | VEXOL | | |
| >ADD> | + | ALCON | 1% | N20474 001 |
| >ADD> | | | | DEC 30, 1994 |

ROCURONIUM BROMIDE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| ZEMURON | | | |
| + | ORGANON | 10MG/ML | N20214 002 |
| | | | MAR 17, 1994 |
| ZEMURON (P/F) | | | |
| + | ORGANON | 10MG/ML | N20214 001 |
| | | | MAR 17, 1994 |

ROSE BENGAL SODIUM, I-131

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| ROBENGATOPE | | | | |
| @ | BRACCO DXS | 0.5mCi/VIAL | N16224 001 | |
| @ | | 1mCi/VIAL | N16224 002 | |
| @ | | 2mCi/VIAL | N16224 003 | >DLT> |
| @ | SQUIBB | 0.5mCi/VIAL | N16224 001 | >DLT> |
| @ | | 1mCi/VIAL | N16224 002 | >ADD> |
| @ | | 2mCi/VIAL | N16224 003 | >ADD> |

SALMETEROL XINAFOATE

AEROSOL, METERED; INHALATION

| | | | |
|---|---|---|---|
| SEREVENT | | | |
| + | GLAXO | EQ 0.021MG BASE/INH | N20236 001 |
| | | | FEB 04, 1994 |

SECOBARBITAL SODIUM

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| SECOBARBITAL SODIUM | | | | |
| AA | | LANNETT | 50MG | N85909 001 |
| AA | | | 100MG | N85903 001 |
| @ | | | 50MG | N85909 001 |
| @ | | | 100MG | N85903 001 |
| SECONAL SODIUM | | | | |
| AA | | LILLY | 50MG | N86101 001 |
| | | | | OCT 03, 1983 |
| | + | | 50MG | N86101 001 |
| | | | | OCT 03, 1983 |

SELENOMETHIONINE, SE-75

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| SETHOTOPE | | | |
| @ | BRACCO DXS | 85-550 uCi/ML | N17047 001 |
| @ | SQUIBB | 85-550 uCi/ML | N17047 001 |

SILVER SULFADIAZINE

DRESSING; TOPICAL

| | | | |
|---|---|---|---|
| SILDIMAC | | | |
| @ | BIOPLASTY | 1% | N19608 001 |
| | | | NOV 30, 1989 |
| @ | ENQUAY | 1% | N19608 001 |
| | | | NOV 30, 1989 |

SODIUM CHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER | | | | |
| AP | | ABBOTT | 9MG/ML | N18800 001 |
| | | | | OCT 29, 1982 |
| AP | + | | 9MG/ML | N18800 001 |
| | | | | OCT 29, 1982 |
| SODIUM CHLORIDE | | | | |
| | | MCGAW | 20GM/100ML | N17038 001 |
| @ | | | 20GM/100ML | N17038 001 |

SODIUM CHROMATE, CR-51

INJECTABLE; INJECTION
CHROMITOPE SODIUM

| | | | |
|---|---|---|---|
| | BRACCO DXS | 250 uCi/VIAL | N13993 001 |
| | | 1mCi/VIAL | N13993 003 |
| | | 2mCi/VIAL | N13993 002 |
| @ | | | |
| | SQUIBB | 250 uCi/VIAL | N13993 001 |
| | | 1mCi/VIAL | N13993 003 |
| @ | | 2mCi/VIAL | N13993 002 |

SODIUM IODIDE, I-123

CAPSULE; ORAL
SODIUM IODIDE I 123

| | | | |
|---|---|---|---|
| AA | GOLDEN PHARMS | 100 uCi | N18671 001 MAY 27, 1982 |
| AA | | 200 uCi | N18671 002 MAY 27, 1982 |
| AA | NORTH AM CHEM | 100 uCi | N18671 001 MAY 27, 1982 |
| AA | | 200 uCi | N18671 002 MAY 27, 1982 |

SODIUM IODIDE, I-131

CAPSULE; ORAL
IODOTOPE

| | | | |
|---|---|---|---|
| | BRACCO DXS | 8-100 uCi | N10929 001 |
| | | 1-50mCi | N10929 003 |
| | SQUIBB | 8-100 uCi | N10929 001 |
| | | 1-50mCi | N10929 003 |

SOLUTION; ORAL
IODOTOPE

| | | | |
|---|---|---|---|
| | BRACCO DXS | 7-106mCi/BOT | N10929 002 |
| | SQUIBB | 7-106mCi/BOT | N10929 002 |

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS

| | | | |
|---|---|---|---|
| AP | ABBOTT | 50MG/VIAL | N18450 001 |
| | @ | 50MG/VIAL | N18450 001 |

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL
PHOSPHOTOPE

| | | | |
|---|---|---|---|
| | @ BRACCO DXS | 1-8mCi/VIAL | N10927 001 |
| | @ SQUIBB | 1-8mCi/VIAL | N10927 001 |

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
KAYEXALATE

| | | | |
|---|---|---|---|
| AA | SANOFI WINTHROP | 453.6GM/BOT | N11287 001 |
| AA | STERLING WINTHROP | 453.6GM/BOT | N11287 001 |

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE

| | | | |
|---|---|---|---|
| | BERLEX | 120MG | N19865 005 APR 20, 1994 |

> ADD >

SPIRAPRIL HYDROCHLORIDE

> ADD >

TABLET; ORAL
RENORMAX

| | | | |
|---|---|---|---|
| | SANDOZ | 3MG | N20240 001 DEC 29, 1994 |
| | | 6MG | N20240 002 DEC 29, 1994 |
| | | 12MG | N20240 003 DEC 29, 1994 |
| | + | 24MG | N20240 004 DEC 29, 1994 |

STANOZOLOL

TABLET; ORAL
WINSTROL

| | | | |
|---|---|---|---|
| | + SANOFI WINTHROP | 2MG | N12885 001 MAY 14, 1984 |
| | + STERLING WINTHROP | 2MG | N12885 001 MAY 14, 1984 |

STAVUDINE

CAPSULE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | ZERIT | | | |
| | @ | BRISTOL MYERS SQUIBB | 5MG | | N20412 001 JUN 24, 1994 |
| | | | 15MG | | N20412 002 JUN 24, 1994 |
| | | | 20MG | | N20412 003 JUN 24, 1994 |
| | | | 30MG | | N20412 004 JUN 24, 1994 |
| | + | | 40MG | | N20412 005 JUN 24, 1994 |

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | STREPTOMYCIN SULFATE | | |
| AP | | PFIZER | EQ 1GM BASE/2ML | N60111 001 |
| | | | EQ 1GM BASE/2.5ML | N60111 001 |

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

| | | | | | |
|---|---|---|---|---|---|
| | | | QUELICIN | | |
| > DLT > | AP | + | ABBOTT | 100MG/ML | N08845 004 |
| > ADD > | | + | | 100MG/ML | N08845 004 |
| | | | SUCOSTRIN | | |
| > DLT > | AP | | SQUIBB | 100MG/ML | N08847 003 |
| > ADD > | | @ | | 100MG/ML | N08847 003 |

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

| | | | | | |
|---|---|---|---|---|---|
| | | | SULF-10 | | |
| AT | | | CIBA VISION | 10% | N80025 001 |
| AT | | | IOLAB | 10% | N80025 001 |
| | | | SULFACETAMIDE SODIUM | | |
| > ADD > | AT | | BAUSCH AND LOMB | 10% | N40066 001 DEC 28, 1994 |
| > ADD > | AT | | PHARMAFAIR | 10% | N88947 001 MAY 17, 1985 |
| | | @ | | 10% | N88947 001 MAY 17, 1985 |

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

| | | | | | |
|---|---|---|---|---|---|
| | | | SULFAIR 10 | | |
| AT | | | PHARMAFAIR | 10% | N87949 001 DEC 13, 1982 |
| | | @ | | 10% | N87949 001 DEC 13, 1982 |
| | | | SULFAIR FORTE | | |
| AT | | | PHARMAFAIR | 30% | N88385 001 OCT 13, 1983 |
| | | @ | | 30% | N88385 001 OCT 13, 1983 |
| | | | SULFAIR-15 | | |
| AT | | | PHARMAFAIR | 15% | N88186 001 MAY 25, 1983 |
| | | @ | | 15% | N88186 001 MAY 25, 1983 |

SULFADIAZINE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | | SULFADIAZINE | | |
| AB | | + | EON LABS | 500MG | N40091 001 JUL 29, 1994 |
| AB | | | EON MANUFACTURE LABS | 500MG | N40091 001 JUL 29, 1994 |
| AB | | + | LILLY | 500MG | N04122 002 |
| | | @ | | 500MG | N04122 002 |

SULFADIAZINE; SULFAMERAZINE

SUSPENSION; ORAL

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | | | SULFONAMIDES DUPLEX | | |
| > DLT > | | | LILLY | 250MG/5ML;250MG/5ML | N06317 007 |
| > ADD > | | @ | | 250MG/5ML;250MG/5ML | N06317 007 |

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | SULFAMETHOXAZOLE AND TRIMETHOPRIM | | |
| AP | | FUJISAWA | 80MG/ML;16MG/ML | N70223 001 DEC 29, 1987 |
| | @ | | 80MG/ML;16MG/ML | N70223 001 DEC 29, 1987 |

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | BACTRIM | | | |
| AB | + ROCHE | 200MG/5ML;40MG/5ML | N17560 001 | |
| | @ | 200MG/5ML;40MG/5ML | N17560 001 | |
| | BACTRIM PEDIATRIC | | | |
| AB | ROCHE | 200MG/5ML;40MG/5ML | N17560 002 | |
| AB | + | 200MG/5ML;40MG/5ML | N17560 002 | |
| | TRIMETH/SULFA | | | |
| AB | BARRE | 200MG/5ML;40MG/5ML | N72398 001 | MAY 23, 1988 |
| | @ | 200MG/5ML;40MG/5ML | N72398 001 | MAY 23, 1988 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | SULFAMETHOXAZOLE AND TRIMETHOPRIM | | | |
| AB | EON LABS | 400MG;80MG | N18598 003 | MAY 19, 1982 |
| | @ | 400MG;80MG | N18598 003 | MAY 19, 1982 |
| | UROPLUS DS | | | |
| AB | SHIONOGI | 800MG;160MG | N71816 001 | SEP 28, 1987 |
| | @ | 800MG;160MG | N71816 001 | SEP 28, 1987 |
| | UROPLUS SS | | | |
| AB | SHIONOGI | 400MG;80MG | N71815 001 | SEP 28, 1987 |
| | @ | 400MG;80MG | N71815 001 | SEP 28, 1987 |

SULFASALAZINE

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | AZULFIDINE | | | |
| | + KABI | 250MG/5ML | N18605 001 | |
| | | 250MG/5ML | N86983 001 | |
| | @ PHARMACIA | 250MG/5ML | N18605 001 | |
| | + | 250MG/5ML | N86983 001 | |

SULFISOXAZOLE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | SULFISOXAZOLE | | | |
| AB | LANNETT | 500MG | N80085 001 | |
| | @ | 500MG | N80085 001 | |

TACROLIMUS

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | PROGRAF | | | |
| | + FUJISAWA | EQ 1MG BASE | N50708 001 | APR 08, 1994 |
| | + | EQ 5MG BASE | N50708 002 | APR 08, 1994 |

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | PROGRAF | | | |
| | + FUJISAWA | EQ 5MG BASE/ML | N50709 001 | APR 08, 1994 |

TALBUTAL

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | LOTUSATE | | | |
| | @ SANOFI WINTHROP | 120MG | N09410 005 | |
| | @ STERLING WINTHROP | 120MG | N09410 005 | |

TAMOXIFEN CITRATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | NOLVADEX | | | |
| | + ZENECA | EQ 20MG BASE | N17970 002 | MAR 21, 1994 |
| | @ | EQ 20MG BASE | N17970 002 | MAR 21, 1994 |

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | MACROTEC | | | |
| BS | BRACCO DXS | N/A | N17833 001 | |
| BS | SQUIBB | N/A | N17833 001 | |

TECHNETIUM TC-99M BICISATE KIT

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | NEUROLITE | | | |
| | DUPONT MERCK | N/A | N20256 001 | NOV 23, 1994 |

TECHNETIUM TC-99M FERPENTETATE KIT

INJECTABLE; INJECTION
RENOTEC
@ BRACCO DXS N/A N17045 001
@ SQUIBB N/A N17045 001

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
MDP-SQUIBB
AP BRACCO DXS N/A N18107 001
AP SQUIBB N/A N18107 001

TECHNETIUM TC-99M OXIDRONATE KIT

INJECTABLE; INJECTION
OSTEOSCAN HDP
MALLINCKRODT N/A N18321 001
TECHNESCAN HDP
MALLINCKRODT N/A N18321 001

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
DTPA
AP MERCK N/A N18511 001
DEC 29, 1989

TECHNESCAN DTPA KIT
AP MERCK N/A N18511 001
DEC 29, 1989

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION
CARDIOLITE
DUPONT N/A N19785 001
DEC 21, 1990

DUPONT MERCK N/A N19785 001
DEC 21, 1990

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL
TESULOID
AP SQUIBB N/A N16923 001

SOLUTION; INTRAVENOUS, ORAL
TESULOID
AP BRACCO DXS N/A N16923 001

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
HYTRIN
ABBOTT EQ 1MG BASE N20347 001
DEC 14, 1994
+ EQ 2MG BASE N20347 002
DEC 14, 1994
EQ 5MG BASE N20347 003
DEC 14, 1994
EQ 10MG BASE N20347 004
DEC 14, 1994

TETRACYCLINE

SYRUP; ORAL
ACHROMYCIN V
AB + LEDERLE EQ 125MG HCL/5ML N50263 002
SUMYCIN
AB SQUIBB EQ 125MG HCL/5ML N60400 001
TETRACYCLINE
AB BARRE EQ 125MG HCL/5ML N60633 001
AB MK EQ 125MG HCL/5ML N60174 001
TETRACYCLINE HCL
AB PUREPAC EQ 125MG HCL/5ML N60291 001
TETRACYN
AB PFIPHARMECS EQ 125MG HCL/5ML N60095 001
TETRAMED
AB ZENITH EQ 125MG HCL/5ML N61468 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
AB ICN 500MG N60471 002
@ 500MG N60471 002

## TETRACYCLINE HYDROCHLORIDE

| | | | | |
|---|---|---|---|---|
| | FIBER, EXTENDED RELEASE; PERIODONTAL | | | |
| | ACTISITE | | | |
| | + ON SITE | 12.7MG/FIBER | N50653 001 MAR 25, 1994 | |
| | SYRUP; ORAL | | | |
| | ACHROMYCIN V | | | |
| AB | + LEDERLE | 125MG/5ML | N50263 002 | |
| | SUMYCIN | | | |
| AB | SQUIBB | 125MG/5ML | N60400 001 | |
| | TETRACYCLINE HCL | | | |
| AB | BARRE | 125MG/5ML | N60633 001 | |
| AB | MK LABS | 125MG/5ML | N60174 001 | |
| AB | PUREPAC PHARM | 125MG/5ML | N60291 001 | |
| | TETRACYN | | | |
| AB | PFIPHARMECS | 125MG/5ML | N60095 001 | |
| | TETRAMED | | | |
| AB | ZENITH LABS | 125MG/5ML | N61468 001 | |
| | TABLET; ORAL | | | |
| | PANMYCIN | | | |
| AB | UPJOHN | 500MG | N61705 002 | |
| | @ | 250MG | N61705 001 | |
| | @ | 500MG | N61705 002 | |
| | SUMYCIN | | | |
| AB | + APOTHECON | 500MG | N61147 004 | |
| | + | 500MG | N61147 004 | |

## TETRAHYDROZOLINE HYDROCHLORIDE

| | | | |
|---|---|---|---|
| | SOLUTION; NASAL | | |
| | TYZINE | | |
| | + KENWOOD LABS | 0.05% | N86576 002 |
| | | 0.1% | N86576 001 |
| | + KEY PHARMS | 0.05% | N86576 002 |
| | | 0.1% | N86576 001 |
| | SPRAY; NASAL | | |
| | TYZINE | | |
| | + KENWOOD LABS | 0.1% | N86576 003 |
| | + KEY PHARMS | 0.1% | N86576 003 |

## THEOPHYLLINE

| | | | |
|---|---|---|---|
| | CAPSULE, EXTENDED RELEASE; ORAL | | |
| | SLO-BID | | |
| AB | RHONE POULENC RORER | 100MG | N87892 001 JAN 31, 1985 |
| AB | | 125MG | N89540 001 MAY 10, 1989 |
| AB | | 200MG | N87893 001 JAN 31, 1985 |
| AB | + | 300MG | N87894 001 JAN 31, 1985 |
| | THEOPHYLLINE | | |
| AB | INWOOD LABS | 100MG | N40052 001 FEB 14, 1994 |
| AB | | 125MG | N40052 002 FEB 14, 1994 |
| AB | | 200MG | N40052 003 FEB 14, 1994 |
| AB | | 300MG | N40052 004 FEB 14, 1994 |
| | ELIXIR; ORAL | | |
| | LANOPHYLLIN | | |
| AA | LANNETT | 80MG/15ML | N84578 001 |
| | @ | 80MG/15ML | N84578 001 |
| | THEOPHYLLINE | | |
| AA | BARRE | 80MG/15ML | N89223 001 MAY 27, 1988 |
| | @ | 80MG/15ML | N89223 001 MAY 27, 1988 |
| | @ CENCI | 80MG/15ML | N87679 001 APR 15, 1982 |
| AA | LIPE LABS | 80MG/15ML | N87679 001 APR 15, 1982 |
| | INJECTABLE; INJECTION | | |
| | THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER | | |
| AP | MCGAW | 200MG/100ML | N19212 001 NOV 07, 1984 |
| | @ | 200MG/100ML | N19212 001 NOV 07, 1984 |
| | THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER | | |
| AP | MCGAW | 400MG/100ML | N19212 002 NOV 07, 1984 |
| AP | | 4MG/ML | N19212 003 NOV 07, 1984 |
| | @ | 400MG/100ML | N19212 002 NOV 07, 1984 |

THEOPHYLLINE

INJECTABLE; INJECTION

THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | @ MCGAW | 4MG/ML | N19212 003 | |
| | | | NOV 07, 1984 | |

THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | BAXTER | 4MG/ML | N18649 007 | |
| | | | JUL 26, 1982 | |

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | ABBOTT | 4MG/ML | N19211 007 | |
| | | | DEC 14, 1984 | |

SYRUP; ORAL

ACCURBRON

| | | | | |
|---|---|---|---|---|
| | MERRELL DOW | 150MG/15ML | N88746 001 | |
| | | | NOV 22, 1985 | |
| | @ | 150MG/15ML | N88746 001 | |
| | | | NOV 22, 1985 | |

THEOPHYLLINE

| | | | | |
|---|---|---|---|---|
| AA | BARRE | 80MG/15ML | N86001 001 | |
| | @ | 80MG/15ML | N86001 001 | |

THIOTEPA

INJECTABLE; INJECTION

THIOPLEX

| | | | | |
|---|---|---|---|---|
| > ADD > | | | | |
| > ADD > | AP LEDERLE | 15MG/VIAL | N20058 001 | |
| > ADD > | | | DEC 22, 1994 | |

THIOTEPA

| | | | | |
|---|---|---|---|---|
| > ADD > | AP + IMMUNEX | 15MG/VIAL | N11683 001 | |

THYROGLOBULIN

TABLET; ORAL

PROLOID

| | | | | |
|---|---|---|---|---|
| BP | * PARKE DAVIS | 65MG | N02245 002 | |
| | | 32MG | N02245 005 | |
| | | 100MG | N02245 008 | |
| | | 130MG | N02245 010 | |
| | | 200MG | N02245 007 | |
| | @ | 32MG | N02245 005 | > DLT > |
| | @ | 65MG | N02245 002 | > ADD > |
| | @ | 100MG | N02245 008 | |
| | @ | 130MG | N02245 010 | |
| | @ | 200MG | N02245 007 | |

THYROGLOBULIN

| | | | | |
|---|---|---|---|---|
| | + GLOBAL PHARMS | 64.8MG | N80151 001 | |

THYROGLOBULIN

TABLET; ORAL

THYROGLOBULIN

| | | | | |
|---|---|---|---|---|
| BP | RICHLYN | 64.8MG | N80151 001 | |

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN

| | | | | |
|---|---|---|---|---|
| AT | STERIS | 0.3% | N63176 001 | |
| | | | MAY 25, 1994 | |

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

| | | | | |
|---|---|---|---|---|
| AP | APOTHECON | EQ 10MG BASE/ML | N64021 001 | |
| | | | MAY 31, 1994 | |
| AP | | EQ 40MG BASE/ML | N64021 002 | |
| | | | MAY 31, 1994 | |
| AP | | EQ 40MG BASE/ML | N64026 001 | |
| | | | MAY 31, 1994 | |
| AP | ASTRA | EQ 10MG BASE/ML | N63119 001 | |
| | | | OCT 31, 1994 | |
| AP | | EQ 40MG BASE/ML | N63120 001 | |
| | | | OCT 31, 1994 | |
| AP | | EQ 40MG BASE/ML | N63121 001 | |
| | | | OCT 31, 1994 | |
| AP | | EQ 40MG BASE/ML | N63122 001 | |
| | | | OCT 31, 1994 | |

TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | + ABBOTT | EQ 1.6MG BASE/ML | N63081 006 | |
| | | | JUN 02, 1993 | |

TOLBUTAMIDE

TABLET; ORAL

ORINASE

| | | | | |
|---|---|---|---|---|
| | UPJOHN | 250MG | N10670 002 | |
| | @ | 250MG | N10670 002 | |

TOLMETIN SODIUM

TABLET; ORAL
TOLMETIN SODIUM

| | | | | |
|---|---|---|---|---|
| AB | MYLAN | EQ 600MG BASE | N74473 001 | AUG 30, 1994 |

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE

| | | | |
|---|---|---|---|
| BP | MYLAN | 2MG | N84406 001 |
| | @ | 2MG | N84406 001 |

TRIAMCINOLONE ACETONIDE

AEROSOL; TOPICAL
KENALOG

| | | | | |
|---|---|---|---|---|
| | + | APOTHECON | 0.147MG/GM | N12104 001 |
| | + | WESTWOOD SQUIBB | 0.147MG/GM | N12104 001 |

CREAM; TOPICAL
KENALOG

| | | | | |
|---|---|---|---|---|
| AT | + | APOTHECON | 0.025% | N11601 003 |
| AT | + | | 0.1% | N11601 006 |
| AT | + | | 0.5% | N83943 001 |
| AT | + | WESTWOOD SQUIBB | 0.025% | N11601 003 |
| AT | + | | 0.1% | N11601 006 |
| AT | + | | 0.5% | N83943 001 |

TRIAMCINOLONE ACETONIDE

| | | | |
|---|---|---|---|
| AT | TARO PHARMS | 0.025% | N40038 001 OCT 26, 1994 |

OINTMENT; TOPICAL
KENALOG

| | | | | |
|---|---|---|---|---|
| AT | + | APOTHECON | 0.025% | N11600 003 |
| AT | + | | 0.1% | N11600 001 |
| AT | + | | 0.5% | N83944 001 |
| AT | + | WESTWOOD SQUIBB | 0.025% | N11600 003 |
| AT | + | | 0.1% | N11600 001 |
| AT | + | | 0.5% | N83944 001 |

TRIAMCINOLONE ACETONIDE

| | | | |
|---|---|---|---|
| AT | TARO PHARMS | 0.025% | N40040 001 SEP 30, 1994 |
| AT | | 0.1% | N40037 001 SEP 30, 1994 |

TRIAZOLAM

TABLET; ORAL
HALCION

| | | | |
|---|---|---|---|
| AB | UPJOHN | 0.125MG | N17892 003 APR 26, 1985 |
| AB | | 0.25MG | N17892 001 NOV 15, 1982 |

TRIAZOLAM

| | | | |
|---|---|---|---|
| AB | ALPHAPHARM | 0.125MG | N74031 001 MAR 25, 1994 |
| AB | | 0.25MG | N74031 002 MAR 25, 1994 |
| AB | ROXANE | 0.125MG | N74224 001 JUN 01, 1994 |
| AB | | 0.25MG | N74224 002 JUN 01, 1994 |

TRIHEXYPHENIDYL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
ARTANE

| | | | |
|---|---|---|---|
| * | LEDERLE | 5MG | N06773 010 |
| | | 5MG | N12947 001 |
| | @ | 5MG | N06773 010 |
| | + | 5MG | N12947 001 |

TRILOSTANE

CAPSULE; ORAL
MODRASTANE

| | | | |
|---|---|---|---|
| | SANOFI WINTHROP | 30MG | N18719 002 DEC 31, 1984 |
| | + | 60MG | N18719 001 DEC 31, 1984 |
| | STERLING WINTHROP | 30MG | N18719 002 DEC 31, 1984 |
| | + | 60MG | N18719 001 DEC 31, 1984 |

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

SUSPENSION; ORAL
LANTRISUL

| | | | |
|---|---|---|---|
| AB | LANNETT | 167MG/5ML;167MG/5ML; 167MG/5ML | N80123 002 |

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

SUSPENSION; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | | LANTRISUL | | | |
| | | @ LANNETT | | 167MG/5ML;167MG/5ML; 167MG/5ML | N80123 002 |
| > DLT > | | NEOTRIZINE | | | |
| > DLT > | AB | + LILLY | | 167MG/5ML;167MG/5ML; 167MG/5ML | N06317 012 |
| > ADD > | | @ | | 167MG/5ML;167MG/5ML; 167MG/5ML | N06317 012 |
| | | TERFONYL | | | |
| > DLT > | AB | SQUIBB | | 167MG/5ML;167MG/5ML; 167MG/5ML | N06904 002 |
| > ADD > | | + | | 167MG/5ML;167MG/5ML; 167MG/5ML | N06904 002 |

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | | NEOTRIZINE | | | |
| > DLT > | AB | + LILLY | | 167MG;167MG;167MG | N06317 011 |
| > ADD > | | @ | | 167MG;167MG;167MG | N06317 011 |
| | | TERFONYL | | | |
| > DLT > | AB | SQUIBB | | 167MG;167MG;167MG | N06904 001 |
| > ADD > | AB | + | | 167MG;167MG;167MG | N06904 001 |

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | MYDRIAFAIR | | | |
| AT | PHARMAFAIR | 0.5% | | N88274 001 SEP 16, 1983 |
| AT | | 1% | | N88230 001 SEP 16, 1983 |
| | @ | 0.5% | | N88274 001 SEP 16, 1983 |
| | @ | 1% | | N88230 001 SEP 16, 1983 |
| | TROPICAMIDE | | | |
| AT | BAUSCH AND LOMB | 0.5% | | N40067 001 JUL 27, 1994 |
| AT | | 1% | | N40064 001 JUL 27, 1994 |

TYROPANOATE SODIUM

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | BILOPAQUE | | |
| | NYCOMED | 750MG | N13731 001 |

TYROPANOATE SODIUM

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | BILOPAQUE | | | |
| | STERLING WINTHROP | 750MG | | N13731 001 |

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | ISOPTIN SR | | | |
| AB | + KNOLL PHARM | 180MG | | N19152 002 DEC 15, 1989 |
| | VERAPAMIL HCL | | | |
| AB | BAKER NORTON | 180MG | | N74330 001 JAN 31, 1994 |

VINBLASTINE SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | VINBLASTINE SULFATE | | | |
| AP | BULL | 10MG/VIAL | | N89565 001 AUG 18, 1987 |
| AP | FAULDING | 10MG/VIAL | | N89565 001 AUG 18, 1987 |

VINCRISTINE SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | VINCRISTINE SULFATE | | | |
| AP | FUJISAWA | 1MG/ML | | N70411 001 SEP 10, 1986 |
| | @ | 1MG/ML | | N70411 001 SEP 10, 1986 |
| | VINCRISTINE SULFATE PFS | | | |
| AP | BULL | 1MG/ML | | N71484 001 APR 19, 1988 |
| AP | FAULDING | 1MG/ML | | N71484 001 APR 19, 1988 |

> ADD > VINORELBINE TARTRATE

> ADD > INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| > ADD > | NAVELBINE | | | |
| > ADD > | + BURROUGHS WELLCOME | EQ 10MG BASE/ML | | N20388 001 DEC 23, 1994 |

ACETAMINOPHEN

SUPPOSITORY; RECTAL
INFANTS' FEVERALL
UPSHER SMITH 80MG N18337 004
AUG 26, 1992

TABLET, EXTENDED RELEASE; ORAL
TYLENOL
+ MCNEIL CONS PRODS 650MG N19872 001
JUN 08, 1994

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER
+ STERLING 650MG N16030 001
+ STERLING WINTHROP 650MG N16030 001
MEASURIN
+ STERLING 650MG N16030 002
+ STERLING WINTHROP 650MG N16030 002

BACITRACIN

OINTMENT; TOPICAL
BACITRACIN
COMBE 500 UNITS/GM N62799 001
MAY 14, 1987
@ 500 UNITS/GM N62799 001
MAY 14, 1987

CHLORPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC 24 CHLORPHENIRAMINE
ALZA 16MG N19746 002
NOV 18, 1994

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MYCELEX-7 COMBINATION PACK
MILES 1%,100MG N20389 002
JUN 23, 1994

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
BARRE 12.5MG/5ML N70497 001
APR 25, 1989
@ 12.5MG/5ML N70497 001
APR 25, 1989

EPINEPHRINE

AEROSOL, METERED; INHALATION
BRONKAID MIST
+ STERLING 0.25MG/INH N16803 001
+ STERLING WINTHROP 0.25MG/INH N16803 001

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MCNEIL CONS PRODS 200MG N73019 001
MAR 30, 1994
PVT FORM 200MG N73691 001
FEB 25, 1994

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN BR
+ LILLY 100 UNITS/ML N19529 001
APR 28, 1986
@ 100 UNITS/ML N19529 001
APR 28, 1986

INSULIN SUSP ISOPHANE BEEF

INJECTABLE; INJECTION
NPH INSULIN
+ NOVO NORDISK 40 UNITS/ML N17929 001
@ 40 UNITS/ML N17929 001

INSULIN SUSP ISOPHANE BEEF/PORK

INJECTABLE; INJECTION
NPH ILETIN I (BEEF-PORK)

| | | | |
|---|---|---|---|
| * | LILLY | 40 UNITS/ML | N17936 001 |
| @ | | 40 UNITS/ML | N17936 001 |

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

| | | | |
|---|---|---|---|
| | NAPHCON-A | | |
| + | ALCON | 0.025%;0.3% | N20226 001<br>JUN 08, 1994 |
| | OPCON-A | | |
| + | BAUSCH AND LOMB | 0.027%;0.315% | N20065 001<br>JUN 08, 1994 |

NAPROXEN SODIUM

TABLET; ORAL

| | | | |
|---|---|---|---|
| | ALEVE | | |
| | HAMILTON PHARMS | EQ 200MG BASE | N20204 002<br>JAN 11, 1994 |

PERMETHRIN

LOTION; TOPICAL

| | | | |
|---|---|---|---|
| | NIX | | |
| * | BURROUGHS WELLCOME | 1% | N19918 001<br>MAY 02, 1990 |
| + | WARNER WELLCOME | 1% | N19918 001<br>MAY 02, 1990 |

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | EFIDAC/24 | | |
| + | CIBA CONS | 240MG | N20021 002<br>DEC 15, 1992 |
| | PSEUDOEPHEDRINE HCL | | |
| | ALZA | 240MG | N20021 002<br>DEC 15, 1992 |
| | SUDAFED 12 HOUR | | |
| * | BURROUGHS WELLCOME | 120MG | N73585 001<br>OCT 31, 1991 |

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR

| | | | |
|---|---|---|---|
| + | WARNER WELLCOME | 120MG | N73585 001<br>OCT 31, 1991 |

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP

INJECTABLE; INJECTION
BLOOD PACK UNIT CPDA-1 IN PLASTIC CONTAINER
BAXTER HLTHCARE — N940404
JUL 28, 1994

INDIUM $IN^{111}$ CHLORIDE STERILE SOLUTION

INJECTABLE; INJECTION
ULTRAPURE
MALLINCKRODT N/A — N19841
SEP 27, 1994

## *LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS*
*[January-December, 1994]*

| ***NAME*** *Generic/Chemical* *TN=Trade Name* | ***INDICATION DESIGNATED*** | ***SPONSOR & ADDRESS*** *DD=Date Designated* *MA=Marketing Approval* |
|---|---|---|
| 8-METHOXSALEN<br>TN= UVADEX | FOR THE PREVENTION OF ACUTE REJECTION OF CARDIAC ALLOGRAFTS. | THERAKOS, INCORPORATED<br>201 BRANDYWINE PARKWAY<br>WEST CHESTER PA 19380<br>DD 05/12/94 MA / / |
| AMINOSALICYLIC ACID<br>TN= PASER GRANULES | TREATMENT OF TUBERCULOSIS INFECTIONS. | JACOBUS PHARMACEUTICAL COMPANY<br>37 CLEVELAND LANE<br>PRINCETON NJ 08540<br>DD 02/19/92 MA 06/30/94 |
| AMINOSIDINE<br>TN= PAROMOMYCIN | TREATMENT OF VISCERAL LEISHMANIASIS (KALA-AZAR). | KANYOK, THOMAS P. PHARM.D.<br>UNIV. OF ILLINOIS AT CHICAGO<br>CHICAGO IL 60612<br>DD 09/09/94 MA / / |
| AMIODARONE HCL<br>TN= CORDARONE | FOR THE ACUTE TREATMENT AND PROPHYLAXIS OF LIFE-THREATENING VENTRICULAR TACHYCARDIA OR VENTRICULAR FIBRILLATION. | WYETH-AYERST LABORATORIES<br>P.O. BOX 8299<br>PHILADELPHIA PA 19101-1245<br>DD 03/16/94 MA / / |
| AMMONIUM TETRATHIOMOLYBDATE<br>TN= | TREATMENT OF WILSON'S DISEASE. | BREWER, GEORGE J. M.D.<br>UNIVERSITY OF MICHIGAN MEDICAL SCHOOL<br>ANN ARBOR MI 48109-0618<br>DD 01/31/94 MA / / |
| ANTIVENIN, POLYVALENT CROTALID (OVINE) FAB<br>TN= CROTAB | TREATMENT OF ENVENOMATIONS INFLICTED BY NORTH AMERICAN CROTALID SNAKES. | THERAPEUTIC ANTIBODIES INC.<br>1500 21ST AVENUE SOUTH, SUITE 310<br>NASHVILLE TN 37212<br>DD 01/12/94 MA / / |
| ARGININE BUTYRATE<br>TN= | TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA. | VERTEX PHARMACEUTICALS INC.<br>40 ALLSTON STREET<br>CAMBRIDGE MA 02139-4211<br>DD 05/25/94 MA / / |
| AUTOLYMPHOCYTE THERAPY<br>TN= | TREATMENT OF RENAL CELL CARCINOMA. | CELLCOR INCORPORATED<br>200 WELLS AVENUE<br>NEWTON MA 02159<br>DD 07/12/94 MA / / |
| BACLOFEN<br>TN= LIORESAL INTRATHECAL | TREATMENT OF SPASTICITY ASSOCIATED WITH CEREBRAL PALSY. | MEDTRONIC, INCORPORATED<br>800 53RD AVENUE N.E.<br>MINNEAPOLIS MN 55432<br>DD 09/26/94 MA / / |
| BETAINE<br>TN= | TREATMENT OF HOMOCYSTINURIA. | ORPHAN MEDICAL<br>13911 RIDGEDALE DRIVE<br>MINNETONKA MN 55305<br>DD 05/16/94 MA / / |
| BOVINE IMMUNOGLOBULIN CONCENTRATE, CRYPTOSPORIDIUM PARVUM<br>TN= SPORIDIN-G | TREATMENT AND SYMPTOMATIC RELIEF OF CRYPTOSPORIDIUM PARVUM INFECTION OF THE GASTROINTESTINAL TRACT IN IMMUNOCOMPROMISED PATIENTS. | GALAGEN, INCORPORATED<br>4001 LEXINGTON AVENUE NORTH<br>ARDEN HILLS MN 55126-2998<br>DD 03/01/94 MA / / |
| BUPRENORPHINE HYDROCHLORIDE<br>TN= | TREATMENT OF OPIATE ADDICTION IN OPIATE USERS. | RECKITT & COLMAN PHARMACEUTICALS, INC.<br>1901 HUGUENOT ROAD<br>RICHMOND VA 23235<br>DD 06/15/94 MA / / |

## CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| BUPRENORPHINE IN COMBINATION WITH NALOXONE<br>TN= | TREATMENT OF OPIATE ADDICTION IN OPIATE USERS. | RECKITT & COLMAN PHARMACEUTICALS INC.<br>1901 HUGUENOT ROAD<br>RICHMOND VA 23235<br>DD 10/27/94 MA / / |
| BUSULFAN<br>TN= | FOR USE AS PREPARATIVE THERAPY FOR MALIGNANCIES TREATED WITH BONE MARROW TRANSPLANTATION. | SPARTA PHARMACEUTICALS, INC.<br>P.O. BOX 13288<br>RESEARCH TRIANGLE PK NC 27709<br>DD 04/21/94 MA / / |
| BUSULFAN<br>TN= | AS PREPARATIVE THERAPY IN THE TREATMENT OF MALIGNANCIES WITH BONE MARROW TRANSPLANTATION. | ORPHAN MEDICAL<br>13911 RIDGEDALE DRIVE<br>MINNETONKA MN 55305<br>DD 07/28/94 MA / / |
| CCD 1042<br>TN= | TREATMENT OF INFANTILE SPASMS. | COCENSYS, INC.<br>213 TECHNOLOGY DRIVE<br>IRVINE CA 92718<br>DD 05/25/94 MA / / |
| CHIMERIC (MURINE VARIABLE, HUMAN CONSTANT) MAB TO CD20<br>TN= | TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA. | IDEC PHARMACEUTICALS CORPORATION<br>11011 TORREYANA ROAD<br>SAN DIEGO CA 92121<br>DD 06/13/94 MA / / |
| CHOLINE CHLORIDE<br>TN= | TREATMENT OF CHOLINE DEFICIENCY,SPECIFICALLY THE CHOLINE DEFICIENCY, HEPATIC STEATOSIS, AND CHOLESTASIS, ASSOCIATED WITH LONG-TERM PARENTERAL NUTRITION. | BUCHMAN, ALAN M.D.<br>6550 FANNIN, SUITE 1122<br>HOUSTON TX 77030<br>DD 02/10/94 MA / / |
| CLADRIBINE<br>TN= LEUSTATIN | TREATMENT OF THE CHRONIC PROGRESSIVE FORM OF MULTIPLE SCLEROSIS. | R.W. JOHNSON RESEARCH INSTITUTE<br>700 ROUTE 200 SOUTH, P.O. BOX 670<br>RARITAN NJ 08869-0670<br>DD 04/19/94 MA / / |
| CLONAZEPAM<br>TN= KLONOPIN | TREATMENT OF HYPEREKPLEXIA (STARTLE DISEASE). | HOFFMAN-LA ROCHE, INCORPORATED<br>340 KINGSLAND STREET<br>NUTLEY NJ 07110-1199<br>DD 08/04/94 MA / / |
| COAGULATION FACTOR IX (RECOMBINANT)<br>TN= | TREATMENT OF HEMOPHILIA B. | GENETICS INSTITUTE, INCORPORATED<br>87 CAMBRIDGE PARK DRIVE<br>CAMBRIDGE MA 02140<br>DD 10/03/94 MA / / |
| COUMARIN<br>TN= ONCOSTATE | TREATMENT OF RENAL CELL CARCINOMA. | SCHAPER AND BRUMMER GmbH & CO., KG<br>1425 BROAD STREET<br>CLIFTON NJ 07013<br>DD 12/22/94 MA / / |
| CY-1899<br>TN= | TREATMENT OF CHRONIC ACTIVE HEPATITIS B INFECTION IN HLA-A2 POSITIVE PATIENTS. | CYTEL CORPORATION<br>3525 JOHN HOPKINS COURT<br>SAN DIEGO CA 92121<br>DD 03/16/94 MA / / |
| CYSTEAMINE<br>TN= CYSTAGON | TREATMENT OF NEPHROPATHIC CYSTINOSIS. | MYLAN LABORATORIES, INC<br>781 CHESTNUT RIDGE ROAD, PO BOX 4310<br>MORGANTOWN WV 26504-4310<br>DD 01/25/91 MA 08/15/94 |

## CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| DAPSONE<br>TN= | PROPHYLAXIS OF TOXOPLASMOSIS IN SEVERELY IMMUNOCOMPROMISED PATIENTS WITH CD4 COUNTS BELOW 100. | JACOBUS PHARMACEUTICAL COMPANY<br>37 CLEVELAND LANE, PO BOX 5290<br>PRINCETON NJ 08540<br>DD 11/07/94 MA / / |
| DEHYDROEPIANDROSTERONE<br>TN= | TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND THE REDUCTION IN THE USE OF STEROIDS IN STEROID-DEPENDENT SLE PATIENTS. | GENELABS TECHNOLOGIES, INC.<br>505 PENOBSCOT DRIVE<br>REDWOOD CITY CA 94063<br>DD 07/13/94 MA / / |
| DESMOPRESSIN ACETATE<br>TN= | TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE. | RHONE-POULENC RORER PHARM.<br>500 ARCOLA ROAD<br>COLLEGEVILLE PA 19426<br>DD 01/22/91 MA 03/07/94 |
| DIMETHYL SULFOXIDE<br>TN= | TREATMENT OF INCREASED INTRACRANIAL PRESSURE IN PATIENTS WITH SEVERE, CLOSED-HEAD INJURY, ALSO KNOWN AS TRAUMATIC BRAIN COMA, FOR WHOM NO OTHER EFFECTIVE TREATMENT IS AVAILABLE. | PHARMA 21<br>4850 S.W. SCHOLLS FERRY ROAD, SUITE 301<br>PORTLAND OR 97225-1686<br>DD 11/22/94 MA / / |
| ELLIOTT'S B SOLUTION<br>TN= | TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIAS AND ACUTE LYMPHOBLASTIC LYMPHOMAS. | ORPHAN MEDICAL<br>13911 RIDGEDALE DRIVE<br>MINNETONKA MN 55305<br>DD 08/24/94 MA / / |
| FGN-1<br>TN= | FOR THE SUPPRESSION AND CONTROL OF COLONIC ADENOMATOUS POLYPS IN THE INHERITED DISEASE ADENOMATOUS POLYPOSIS COLI. | CELL PATHWAYS, INC.<br>1700 BROADWAY, SUITE 2000<br>DENVER CO 80290<br>DD 02/14/94 MA / / |
| FILGRASTIM<br>TN= NEUPOGEN | TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS. | AMGEN, INC.<br>1840 DEHAVILLAND DRIVE<br>THOUSAND OAKS CA 91320-1789<br>DD 10/01/90 MA 06/15/94 |
| GAMMA-HYDROXYBUTYRATE<br>TN= | TREATMENT OF NARCOLEPSY. | ORPHAN MEDICAL<br>13911 RIDGEDALE DRIVE<br>MINNETONKA MN 55305<br>DD 11/07/94 MA / / |
| GAMMALINOLENIC ACID<br>TN= | TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS. | ZURIER, ROBERT B. M.D.<br>55 LAKE AVE. UNIV. OF MASS. MED. CTR.<br>WORCESTER MA 01655<br>DD 07/27/94 MA / / |
| HEME ARGINATE<br>TN= NORMOSANG | TREATMENT OF MYELODYSPLASTIC SYNDROMES. | LEIRAS, INCORPORATED<br>1850 CENTENNIAL PARK DRIVE, SUITE 450<br>RESTON VA 22091<br>DD 03/01/94 MA / / |
| I-131 RADIOLABELED B1 MONOCLONAL ANTIBODY<br>TN= | TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA. | COULTER CORPORATION<br>11800 S.W. 147 AVENUE, P.O. BOX 169015<br>MIAMI FL 33116-9015<br>DD 05/16/94 MA / / |
| IMIGLUCERASE<br>TN= CEREZYME | FOR REPLACEMENT THERAPY IN PATIENTS WITH TYPES I, II, AND III GAUCHER'S DISEASE. | GENZYME CORPORATION<br>ONE KENDALL SQUARE<br>CAMBRIDGE MA 02139<br>DD 11/05/91 MA 05/23/94 |

## CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| IN-111 MURINE MAB(2B8-MX-DTPA) & Y-90 MURINE MAB(2B8-MXDTPA)<br>TN= MELIMMUNE | TREATMENT OF B-CELL NON-HODGKIN'S LYMPHOMA. | IDEC PHARMACEUTICALS CORPORATION<br>11011 TORREYANA ROAD<br>SAN DIEGO CA 92121<br>DD 09/06/94 MA / / |
| ISOBUTYRAMIDE<br>TN= | TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA. | VERTEX PHARMACEUTICALS INC.<br>40 ALLSTON STREET<br>CAMBRIDGE MA 02139-4211<br>DD 05/25/94 MA / / |
| L-2-OXOTHIAZOLIDINE-4-CARBOXYLIC ACID<br>TN= PROCYSTEINE | TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME. | FREE RADICAL SCIENCES, INC.<br>245 FIRST STREET<br>CAMBRIDGE MA 02142<br>DD 06/14/94 MA / / |
| L-CYSTEINE<br>TN= | FOR THE PREVENTION AND LESSENING OF PHOTOSENSITIVITY IN ERYTHROPOIETIC PROTOPORPHYRIA. | TYSON AND ASSOCIATES<br>12832 SOUTH CHADRON AVENUE<br>HAWTHORNE CA 90250<br>DD 05/16/94 MA / / |
| LIPOSOME ENCAPSULATED RECOMBINANT INTERLEUKIN-2<br>TN= | TREATMENT OF CANCERS OF THE KIDNEY AND RENAL PELVIS. | ONCOTHERAPEUTICS, INC.<br>1002 EASTPARK BOULEVARD<br>CRANBURY NJ 08512<br>DD 06/20/94 MA / / |
| MELANOMA CELL VACCINE<br>TN= | TREATMENT OF INVASIVE MELANOMA. | MORTON, DONALD L. M.D.<br>JOHN WAYNE CANCER INSTITUTE<br>SANTA MONICA CA 90404<br>DD 10/13/94 MA / / |
| MITOGUAZONE<br>TN= | TREATMENT OF DIFFUSE NON-HODGKIN'S LYMPHOMA, INCLUDING AIDS-RELATED DIFFUSE NON-HODGKIN'S LYMPHOMA. | CTRC RESEARCH FOUNDATION<br>11812 BECKET STREET<br>POTOMAC MD 20854<br>DD 03/18/94 MA / / |
| MONOCLONAL AB(MURINE) ANTI-IDIOTYPE MELANOMA ASS'TED ANTIGEN<br>TN= MELIMMUNE | TREATMENT OF INVASIVE CUTANEOUS MELANOMA. | IDEC PHARMACEUTICALS CORPORATION<br>11011 TORREYANA ROAD<br>SAN DIEGO CA 92121<br>DD 09/19/94 MA / / |
| N-TRIFLUOROACETYLADRIAMYCIN-14-VALERATE<br>TN= | TREATMENT OF CARCINOMA IN SITU OF THE URINARY BLADDER. | ANTHRA PHARMACEUTICALS, INC.<br>19 CARSON ROAD<br>PRINCETON NJ 08540<br>DD 05/23/94 MA / / |
| NEUROTROPHIN-1<br>TN= | TREATMENT OF MOTOR NEURON DISEASE/AMYOTROPHIC LATERAL SCLEROSIS. | ERICSSON, ARTHUR DALE, M.D.<br>6560 FANNIN, SCURLOCK TOWER, SUITE 720<br>HOUSTON TX 77303<br>DD 09/13/94 MA / / |
| ORGOTEIN FOR INJECTION<br>TN= | TREATMENT OF FAMILIAL AMYOTROPHIC LATERAL SCLEROSIS ASSOCIATED WITH A MUTATION OF THE GENE (ON CHROMOSOME 21q) FOR COPPER, ZINC SUPEROXIDE DISMUTASE. | OXIS INTERNATIONAL, INC.<br>6040 N. CUTTER CIRCLE, SUITE 317<br>PORTLAND OR 97217<br>DD 12/22/94 MA / / |
| OXANDROLONE<br>TN= HEPANDRIN | TREATMENT OF MODERATE/SEVERE ACUTE ALCOHOLIC HEPATITIS IN THE PRESENCE OF MODERATE PROTEIN CALORIE MALNUTRITION. | BIO-TECHNOLOGY GENERAL CORP.<br>70 WOOD AVENUE SOUTH<br>ISELIN NJ 08830<br>DD 03/18/94 MA / / |

## CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

| NAME<br>Generic/Chemical<br>TN= Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD= Date Designated<br>MA= Marketing Approval |
|---|---|---|
| PEGASPARGASE<br>TN= ONCASPAR | TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL). | ENZON, INC.<br>40 KINGSBRIDGE ROAD<br>PISCATAWAY NJ 08854-3998<br>DD 10/20/89 MA 02/01/94 |
| PILOCARPINE<br>TN= SALAGEN | TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER. | MGI PHARMA, INC.<br>SUITE 300 E, 9900 BREN ROAD EAST<br>MINNEAPOLIS MN 55343-9667<br>DD 09/24/90 MA 03/22/94 |
| PROGESTERONE<br>TN= | ESTABLISHMENT AND MAINTENANCE OF PREGNANCY IN WOMEN UNDERGOING IN VITRO FERTILIZATION OR EMBRYO TRANSFER PROCEDURES. | GYNOPHARMA, INC.<br>50 DIVISION STREET<br>SOMERVILLE NJ 08876<br>DD 12/22/94 MA / / |
| RECOMBINANT HUMAN GELSOLIN<br>TN= | TREATMENT OF THE RESPIRATORY SYMPTOMS OF CYSTIC FIBROSIS. | BIOGEN, INC.<br>14 CAMBRIDGE CENTER<br>CAMBRIDGE MA 02124<br>DD 01/12/94 MA / / |
| RECOMBINANT HUMAN LUTEINIZING HORMONE<br>TN= | FOR USE IN ASSOCIATION WITH RECOMBINANT HUMAN FOLLICLE STIMULATING HORMONE FOR THE TREATMENT OF WOMEN WITH CHRONIC ANOVULATION DUE TO HYPOGONADOTROPIC HYPOGONADISM. | SERONO LABORATORIES, INCORPORATED<br>100 LONGWATER CIRCLE<br>NORWELL MA 02061<br>DD 10/07/94 MA / / |
| RECOMBINANT METHIONYL BRAIN-DERIVED NEUROTROPHIC FACTOR<br>TN= | TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS. | AMGEN, INCORPORATED<br>1840 DEHAVILLAND DRIVE<br>THOUSAND OAKS CA 91320-1789<br>DD 11/28/94 MA / / |
| RECOMBINANT VACCINIA (HUMAN PAPILLOMAVIRUS)<br>TN= TA-HPV | TREATMENT OF CERVICAL CANCER. | CANTAB PHARMACEUTICALS RESEARCH, LTD.<br>184 CAMBRIDGE SCIENCE PARK<br>CAMBRIDGE CB4 4GN UK<br>DD 08/24/94 MA / / |
| REDUCED L-GLUTATHIONE<br>TN= CACHEXON | TREATMENT OF AIDS-ASSOCIATED CACHEXIA. | TELLURIDE PHARMACEUTICAL CORPORATION<br>146 FLANDERS DRIVE<br>HILLSBOROUGH NJ 08876-4656<br>DD 02/14/94 MA / / |
| RICIN (BLOCKED) CONJUGATED MURINE MOAB (CD6)<br>TN= | TREATMENT OF CUTANEOUS T-CELL LYMPHOMAS, ACUTE T-CELL LEUKEMIA-LYMPHOMA, AND RELATED MATURE T-CELL MALIGNANCIES. | IMMUNOGEN, INC.<br>148 SIDNEY STREET<br>CAMBRIDGE MA 02139-4239<br>DD 09/06/94 MA / / |
| RIFAMPIN, ISONIAZID, PYRAZINAMIDE<br>TN= RIFATER | SHORT-COURSE TREATMENT OF TUBERCULOSIS. | MARION MERRELL DOW, INC.<br>P.O. BOX 9627<br>KANSAS CITY MO 64134-0627<br>DD 09/12/85 MA 05/31/94 |
| SODIUM DICHLOROACETATE<br>TN= | TREATMENT OF LACTIC ACIDOSIS IN PATIENTS WITH SEVERE MALARIA. | STACPOOLE, PETER W., PH.D., M.D.<br>UNIVERSITY OF FLORIDA<br>GAINESVILLE FL 32610-0277<br>DD 11/10/94 MA / / |
| SOLUBLE RECOMBINANT HUMAN COMPLEMENT RECEPTOR TYPE 1<br>TN= | PREVENTION OR REDUCTION OF ADULT RESPIRATORY DISTRESS SYNDROME. | T CELL SCIENCES, INC.<br>38 SIDNEY STREET<br>CAMBRIDGE MA 02139-4135<br>DD 11/21/94 MA / / |

## CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| SOMATOSTATIN<br>TN= | TREATMENT OF BLEEDING ESOPHAGEAL VARICES. | UCB PHARMACEUTICALS, INC.<br>PO BOX 4410<br>HAMPTON VA 23664-0410<br>DD 12/22/94 MA / / |
| SOMATROPIN<br>TN= NUTROPIN<br>(EXCLUSIVITY NOT APPLICABLE) | FOR USE IN THE LONG-TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION. | GENENTECH, INC.<br>460 POINT SAN BRUNO BOULEVARD<br>SOUTH SAN FRANCISCO CA 94080<br>DD 03/06/87 MA 03/09/94 |
| SOMATROPIN<br>TN= GENOTROPIN/GENOTONORM | TREATMENT OF ADULTS WITH GROWTH HORMONE DEFICIENCY. | PHARMACIA, INC.<br>P.O. BOX 16529<br>COLUMBUS OH 43216-6529<br>DD 09/06/94 MA / / |
| SULFADIAZINE<br>TN= | FOR USE IN COMBINATION WITH PYRIMETHAMINE FOR THE TREATMENT OF TOXOPLASMA GONDII ENCEPHALITIS IN PATIENTS WITH AND WITHOUT ACQUIRED IMMUNODEFICIENCY SYNDROME. | EON LABS MANUFACTURING, INC.<br>227-15 NORTH CONDUIT AVENUE<br>LAURELTON NY 11413<br>DD 03/14/94 MA 07/29/94 |
| TIZANIDINE HCL<br>TN= ZANAFLEX | TREATMENT OF SPASTICITY ASSOCIATED WITH MULTIPLE SCLEROSIS AND SPINAL CORD INJURY. | ATHENA NEUROSCIENCES, INC.<br>800F GATEWAY BOULEVARD<br>SOUTH SAN FRANCISCO CA 94080<br>DD 01/31/94 MA / / |
| TOBRAMYCIN FOR INHALATION<br>TN= | TREATMENT OF BRONCHOPULMONARY INFECTIONS OF PSEUDOMONAS AERUGINOSA IN CYSTIC FIBROSIS PATIENTS. | PATHOGENESIS CORPORATION<br>201 ELLIOTT AVENUE WEST, SUITE 150<br>SEATTLE WA 98119<br>DD 10/13/94 MA / / |
| TREOSULFAN<br>TN= OVASTAT | TREATMENT OF OVARIAN CANCER. | MEDAC GmbH c/o PRINCETON REG. ASSOC.<br>65 SOUTH MAIN STREET<br>PENNINGTION NJ 08534<br>DD 05/16/94 MA / / |

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

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NO DECEMBER 1994 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, 14TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| | | |
|---|---|---|
| ALBUTEROL (METERED DOSE INHALER - *IN VIVO*) | JAN 27, 1994 | |
| DICLOFENAC SODIUM (TABLET) | DEC 24, 1992 | OCT 06, 1994 |
| FLURBIPROFEN (TABLET) | DEC 24, 1992 | FEB 04, 1994 |
| PHENYTOIN (SUSPENSION AND CHEWABLE TABLET) | MAR 04, 1994 | |
| PHENYTOIN SODIUM (CAPSULE, EXTENDED AND PROMPT) | MAR 04, 1994 | |
| TOLMETIN SODIUM (CAPSULE AND TABLET) | APR 20, 1989 | OCT 06, 1994 |

# ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|

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.

| | | | | | |
|---|---|---|---|---|---|
| ACETAMINOPHEN;<br>BUTALBITAL;<br>CAFFEINE;<br>HYDROCODONE BITARTRATE<br>CAPSULE; ORAL | 325MG<br>50MG<br>40MG<br>5MG | 93 P-0346/<br>CP1 | MIKART | NEW<br>COMBINATION | APPROVED<br>NOV 15, 1994 |
| ACETAMINOPHEN;<br>BUTALBITAL;<br>CAFFEINE;<br>HYDROCODONE BITARTRATE<br>TABLET; ORAL | 325MG<br>50MG<br>40MG<br>5MG | 93 P-0346/<br>CP1 | MIKART | NEW<br>COMBINATION<br>NEW DOSAGE<br>FORM | APPROVED<br>NOV 15, 1994 |
| ACETAMINOPHEN;<br>BUTALBITAL;<br>CAFFEINE;<br>HYDROCODONE BITARTRATE<br>TABLET; ORAL | 500MG<br>50MG<br>40MG<br>5MG | 93 P-0298/<br>CP1 | ARNOLD & PORTER | NEW<br>COMBINATION<br>NEW DOSAGE<br>FORM<br>NEW STRENGTH | APPROVED<br>NOV 15, 1994 |
| ACYCLOVIR<br>TABLET; ORAL | 200MG | 93 P-0339/<br>CP1 | NOVOPHARM | NEW DOSAGE<br>FORM | APPROVED<br>FEB 08, 1994 |
| ACYCLOVIR SODIUM<br>INJECTABLE; INJECTION | 25MG/ML<br>(20ML/VIAL)<br>(40ML/VIAL) | 93 P-0469/<br>CP1 | FAULDING | NEW DOSAGE<br>FORM | APPROVED<br>JUN 09, 1994 |
| ESTRADIOL<br>TABLET; ORAL | 1.5MG | 93 P-0344/<br>CP1 | BRISTOL MYERS SQIBB | NEW STRENGTH | APPROVED<br>JUN 08, 1994 |
| LOPERAMIDE HYDROCHLORIDE<br>TABLET, EFFERVESCENT; ORAL | 1MG | 93 P-0332/<br>CP1 | ELLIS PHARM<br>CONSULTING | NEW DOSAGE<br>FORM | APPROVED<br>FEB 08, 1994 |
| METHYLTESTOSTERONE<br>CAPSULE; ORAL | 25MG | 93 P-0459/<br>CP1 | ICN | NEW DOSAGE<br>FORM | APPROVED<br>JUN 08, 1994 |
| MORPHINE SULFATE<br>CAPSULE, EXTENDED<br>RELEASE; ORAL | 15MG<br>60MG<br>100MG | 93 P-0446/<br>CP1 | PHARMA CONSULT | NEW DOSAGE<br>FORM | APPROVED<br>JUN 08, 1994 |
| MORPHINE SULFATE<br>CAPSULE, EXTENDED<br>RELEASE; ORAL | 90MG | 93 P-0446/<br>CP1 | PHARMA CONSULT | NEW DOSAGE<br>FORM<br>NEW STRENGTH | APPROVED<br>JUN 08, 1994 |
| PREDNISONE<br>TABLET, CHEWABLE; ORAL | 1MG<br>2.5MG<br>20MG<br>50MG | 93 P-0333/<br>CP1 | DURA | NEW DOSAGE<br>FORM | APPROVED<br>JUN 08, 1994 |
| PSEUDOEPHEDRINE<br>HYDROCHLORIDE;<br>TERFENADINE<br>CAPSULE, EXTENDED<br>RELEASE; ORAL | 120MG<br><br>60MG | 93 P-0367/<br>CP1 | EURAND AMERICA | NEW DOSAGE<br>FORM | APPROVED<br>FEB 08, 1994 |

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| VALPROIC ACID<br>CAPSULE; ORAL | 500MG | 93 P-0452/<br>CP1 | KROSS | NEW STRENGTH | APPROVED<br>DEC 19, 1994 |
| ***ERRATA*** | | | | | |
| CIMETIDINE<br>TABLET, EFFERVESCENT; ORAL | 200MG<br>300MG<br>400MG<br>800MG | 93 P-0048/<br>CP1* | FLEMINGTON PHARM | NEW DOSAGE<br>FORM | APPROVED<br>SEP 18, 1993 |

*Not previously published

## 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, 14TH 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 DOSING SCHEDULE*

D-21 ALTERNATIVE DOSAGE OF 300MG ONCE DAILY AFTER THE EVENING MEAL
D-22 REDUCTION IN INFUSION TIME FROM 24 TO 4 HOURS FOR THE 60MG DOSE
D-23 INCREASE MAXIMUM DOSE AND VARIATIONS IN THE DOSING REGIMEN
D-24 FOR OVARIAN CANCER THE RECOMMENDED REGIMEN IS 135MG/$M^2$ OR 175MG/$M^2$ INTRAVENOUSLY OVER THREE HOURS EVERY THREE WEEKS
D-25 ADDITIONAL DOSAGE REGIMEN EQUAL TO HALF OF THE ORIGINAL DOSING REGIMEN

### REFERENCES
*NEW INDICATION*

I-99 PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER
I-100 TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY
I-101 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY
I-102 TREATMENT OF OBSESSIVE-COMPULSIVE DISORDER
I-103 PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOCOMPROMISED AND CONSIDERED TO BE AT RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA
I-104 TREATMENT OF PULMONARY AND EXTRAPULMONARY ASPERGILLOSIS IN PATIENTS WHO ARE INTOLERANT OF OR WHO ARE REFRACTORY TO AMPHOTERICIN B THERAPY
I-105 TREATMENT OF METASTATIC CARCINOMA OF THE BREAST AFTER FAILURE OF FIRST-LINE OR SUBSEQUENT CHEMOTHERAPY
I-106 TREATMENT OF ACROMEGALY
I-107 VAGINAL CANDIDIASIS
I-108 EXPANDED USE-FOR ICU PATIENTS UNDERGOING LONG-TERM INFUSION DURING MECHANICAL VENTILATION
I-109 TYPHOID FEVER
I-110 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH RADIOTHERAPY
I-111 TREATMENT OF PAGET'S DISEASE OF BONE
I-112 MANAGEMENT OF MODERATE TO SEVERE PAIN
I-113 TREATMENT OF PROSTATITIS
I-114 USE IN CHILDREN TO VISUALIZE LESIONS WITH ABNORMAL VASCULARITY IN THE BRAIN (INTRACRANIAL LESIONS), SPINE AND ASSOCIATED TISSUE
I-115 USE IN MRI IN ADULTS TO VISUALIZE LESIONS IN THE HEAD AND NECK
I-116 MAINTENANCE OF HEALING OF EROSIVE ESOPHAGITIS

### REFERENCES
*PATENT USE CODE*

U-91 ALTERNATIVE THERAPY TO TRIMETHOPRIM-SULFAMETHOXAZOLE FOR TREATMENT OF MODERATE-TO-SEVERE PNEUMOCYSTIS CARINII PNEUMONIA IN IMMUNOCOMPROMISED AND AIDS PATIENTS
U-92 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN DEPENDENT DIABETES MELLITUS AND RETINOPATHY
U-93 USE AS AN ANTIHISTAMINE/DECONGESTANT
U-94 TREATMENT OF ADULTS WITH ADVANCED HIV INFECTION WHO ARE INTOLERANT OF APPROVED THERAPIES WITH PROVEN CLINICAL BENEFIT OR WHO HAVE EXPERIENCED SIGNIFICANT CLINICAL OR IMMUNOLOGIC DETERIORATION WHILE RECEIVING THESE THERAPIES OR FOR WHOM SUCH THERAPIES ARE CONTRAINDICATED
U-95 SHORT TERM MANAGEMENT OF MODERATE PRURITIS IN ADULTS WITH ATOPIC DERMATITIS AND LICHEN SIMPLEX CHRONICUS

## EXCLUSIVITY TERMS

## REFERENCES

*PATENT USE CODE*

| | |
|---|---|
| U-96 | METHOD OF TREATING VARICELLA ZOSTER (SHINGLES) INFECTIONS |
| U-97 | A METHOD OF TREATING A PATIENT IN NEED OF MEMORY ENHANCEMENT |
| U-98 | A METHOD OF INDUCING REGRESSION OF LEUKEMIA CELL GROWTH IN A MAMMAL |
| U-99 | METHOD OF PROVIDING POTASSIUM TO A SUBJECT IN NEED OF POTASSIUM |
| U-100 | METHOD OF TREATING OCULAR INFLAMMATION |
| U-101 | ADJUNCT TO CONVENTIONAL CT OR MRI IMAGING IN THE LOCALIZATION OF STROKE IN PATIENTS IN WHOM STROKE HAS ALREADY BEEN DIAGNOSED |

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 |
|---|---|---|---|---|---|---|---|
| | 19872 001 | ACETAMINOPHEN; TYLENOL | | | | NDF | JUN 08, 1997 |
| | 19806 001 | ACRIVASTINE; SEMPREX-D | 4650807 | MAR 17, 2004 | U-93 | | |
| | | | 4501893 | FEB 26, 2002 | | NC | MAR 25, 1997 |
| | 74346 001 | AMINOSALICYLIC ACID; PASER | | | | ODE | JUN 30, 2001 |
| | 18700 001 | AMRINONE LACTATE; INOCOR | 4072746 | JUL 31, 1998 | U-7 | NCE | JUL 31, 1994 |
| | 20304 001 | APROTININ BOVINE; TRASYLOL | | | | ODE | DEC 29, 2000 |
| | | | | | | D-25 | OCT 12, 1997 |
| | 18831 001 | ATRACURIUM BESYLATE; TRACRIUM | 4179507 | DEC 18, 1996 | | I-108 | JUN 06, 1997 |
| | 20233 001 | BUDESONIDE; RHINOCORT | | | | NCE | FEB 14, 1999 |
| | 18731 001 | BUSPIRONE HYDROCHLORIDE; BUSPAR | 5015646 | MAY 14, 2008 | U-13 | | |
| | 18731 002 | BUSPIRONE HYDROCHLORIDE; BUSPAR | 5015646 | MAY 14, 2008 | U-13 | | |
| | 18343 001 | CAPTOPRIL; CAPOTEN | 5238924 | AUG 24, 2010 | U-92 | I-101 | JAN 28, 1997 |
| | 18343 002 | CAPTOPRIL; CAPOTEN | 5238924 | AUG 24, 2010 | U-92 | I-101 | JAN 28, 1997 |
| | 18343 003 | CAPTOPRIL; CAPOTEN | 5238924 | AUG 24, 2010 | U-92 | I-101 | JAN 28, 1997 |
| | 18343 005 | CAPTOPRIL; CAPOTEN | 5238924 | AUG 24, 2010 | U-92 | I-101 | JAN 28, 1997 |
| | 18343 006 | CAPTOPRIL; CAPOTEN | 5238924 | AUG 24, 2010 | U-92 | I-95 | SEP 23, 1996 |
| | | | 4105776 | AUG 08, 1995 | | I-101 | JAN 28, 1997 |
| >ADD> | 19746 002 | CHLORPHENIRAMINE MALEATE; EFIDAC 24 CHLORPHENIRAMINE | 4857330 | AUG 15, 2006 | | | |
| >ADD> | | | 4673405 | MAR 18, 2003 | | | |
| >ADD> | | | 4576604 | MAR 18, 2003 | | | |
| >ADD> | 19574 001 | CHLORTHALIDONE; THALITONE | 4933360 | JUN 12, 2007 | | | |
| | 19537 002 | CIPROFLOXACIN HYDROCHLORIDE; CIPRO | 4670444 | OCT 01, 2002 | U-36 | I-66 | JUL 21, 1997 |
| | | | | | | I-109 | JUL 21, 1997 |
| | 19537 003 | CIPROFLOXACIN HYDROCHLORIDE; CIPRO | 4670444 | OCT 01, 2002 | U-36 | I-66 | JUL 21, 1997 |
| | | | | | | I-109 | JUL 21, 1997 |
| | 19537 004 | CIPROFLOXACIN HYDROCHLORIDE; CIPRO | 4670444 | OCT 01, 2002 | U-36 | I-66 | JUL 21, 1997 |
| | | | | | | I-109 | JUL 21, 1997 |
| | 20392 001 | CYSTEAMINE BITARTRATE; CYSTAGON | | | | NCE | AUG 15, 1999 |
| | | | | | | ODE | AUG 15, 2001 |
| | 20392 002 | CYSTEAMINE BITARTRATE; CYSTAGON | | | | NCE | AUG 15, 1999 |
| | | | | | | ODE | AUG 15, 2001 |
| >ADD> | 20287 001 | DALTEPARIN SODIUM; FRAGMIN | | | | NCE | DEC 22, 1999 |
| | 20355 001 | DESMOPRESSIN ACETATE; DESMOPRESSIN ACETATE | | | | NP | MAR 07, 1997 |
| | | | | | | ODE | MAR 07, 2001 |

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 |
|---|---|---|---|---|---|---|---|
| | 20062 001 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5364620 | NOV 14, 2011 | U-3 | | |
| | | | 5286497 | FEB 14, 2011 | | | |
| | 20062 002 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5364620 | NOV 14, 2011 | U-3 | | |
| | | | 5286497 | FEB 14, 2011 | | | |
| | 20062 003 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5364620 | NOV 14, 2011 | U-3 | | |
| | | | 5286497 | FEB 14, 2011 | | | |
| | 20062 004 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5364620 | NOV 14, 2011 | U-3 | | |
| | | | 5286497 | FEB 14, 2011 | | | |
| >ADD> | 20408 001 | DORZOLAMIDE HYDROCHLORIDE; TRUSOPT | | | | NCE | DEC 09, 1999 |
| | 20126 001 | DOXEPIN HYDROCHLORIDE; ZONALON | 4395420 | JUL 26, 2000 | U-95 | NDF | APR 01, 1997 |
| | 20323 001 | ESTRADIOL; VIVELLE | | | | NS | OCT 28, 1997 |
| | 20323 003 | ESTRADIOL; VIVELLE | | | | NS | OCT 28, 1997 |
| | 81295 001 | ESTRADIOL; ESTRACE | | | | I-76 | SEP 08, 1995 |
| >ADD> | 20303 001 | ESTROGENS, CONJUGATED; PREMPRO (PREMARIN/CYCRIN) | | | | NP | DEC 30, 1997 |
| >ADD> | 20303 002 | ESTROGENS, CONJUGATED; PREMPHASE (PREMARIN/CYCRIN) | | | | NP | DEC 30, 1997 |
| | 18922 004 | ETODOLAC; LODINE | 4076831 | FEB 28, 1997 | U-45 | NCE | JAN 31, 1996 |
| | 20363 002 | FAMCICLOVIR; FAMVIR | 5246937 | SEP 21, 2010 | U-96 | NCE | JUN 29, 1999 |
| | 20249 001 | FAMOTIDINE; PEPCID | 4283408 | AUG 11, 2000 | | I-69 | DEC 10, 1994 |
| | 19834 004 | FELODIPINE; PLENDIL | 4264611 | APR 28, 1998 | | NCE | JUL 25, 1996 |
| | 19304 001 | FENOFIBRATE; LIPIDIL | 4058552 | NOV 15, 1994 | | NCE | DEC 31, 1998 |
| | 19960 001 | FLOSEQUINAN; MANOPLAX | 4552884 | DEC 31, 2006 | U-71 | | |
| | 19960 002 | FLOSEQUINAN; MANOPLAX | 4552884 | DEC 31, 2006 | U-71 | | |
| | 19960 003 | FLOSEQUINAN; MANOPLAX | 4552884 | DEC 31, 2006 | U-71 | | |
| | 19960 004 | FLOSEQUINAN; MANOPLAX | 4552884 | DEC 31, 2006 | U-71 | | |
| | 19949 001 | FLUCONAZOLE; DIFLUCAN | 4416682 | NOV 22, 2000 | | I-100 | DEC 30, 1996 |
| | 19949 002 | FLUCONAZOLE; DIFLUCAN | 4416682 | NOV 22, 2000 | | I-100 | DEC 30, 1996 |
| | 19949 003 | FLUCONAZOLE; DIFLUCAN | 4416682 | NOV 22, 2000 | | I-100 | DEC 30, 1996 |
| | 19950 001 | FLUCONAZOLE; DIFLUCAN | 4416682 | NOV 22, 2000 | | I-100 | DEC 30, 1996 |
| | 20322 001 | FLUCONAZOLE; DIFLUCAN | 4416682 | NOV 22, 2000 | | NCE | JAN 29, 1995 |
| | | | 4404216 | OCT 16, 2003 | | I-100 | DEC 30, 1996 |
| | | | | | | NS | JUN 30, 1997 |
| | | | | | | I-107 | JUN 30, 1997 |
| | 18936 001 | FLUOXETINE HYDROCHLORIDE; PROZAC | 4018895 | APR 19, 1994 | U-12 | I-102 | FEB 28, 1997 |
| | 18936 006 | FLUOXETINE HYDROCHLORIDE; PROZAC | 4314081 | FEB 02, 2001 | | I-102 | FEB 28, 1997 |
| | 20101 001 | FLUOXETINE HYDROCHLORIDE; PROZAC | 4314081 | FEB 02, 2001 | | I-102 | FEB 28, 1997 |
| >ADD> | 20243 001 | FLUVOXAMINE MALEATE; LUVOX | 4085225 | APR 18, 1995 | | NCE | DEC 05, 1999 |
| >ADD> | 20243 002 | FLUVOXAMINE MALEATE; LUVOX | 4085225 | APR 18, 1995 | | NCE | DEC 05, 1999 |

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> | 20243 003 | FLUVOXAMINE MALEATE; LUVOX | 4085225 | APR 18, 1995 | | NCE | DEC 05, 1999 |
| >ADD> | 20243 004 | FLUVOXAMINE MALEATE; LUVOX | 4085225 | APR 18, 1995 | | NCE | DEC 05, 1999 |
| >ADD> | 19915 002 | FOSINOPRIL SODIUM; MONOPRIL | 5006344 | APR 09, 2008 | | | |
| >ADD> | 19915 003 | FOSINOPRIL SODIUM; MONOPRIL | 5006344 | APR 09, 2008 | | | |
| | 20286 001 | FOSINOPRIL SODIUM; MONOPRIL-HCT | 5006344 | APR 09, 2008 | | | |
| | | | 4384123 | MAY 17, 2000 | | | |
| | | | 4337201 | JUN 29, 2001 | | NC | NOV 30, 1997 |
| | 20286 002 | FOSINOPRIL SODIUM; MONOPRIL-HCT | 5006344 | APR 09, 2008 | | | |
| | | | 4384123 | MAY 17, 2000 | | | |
| | | | 4337201 | JUN 29, 2001 | | NC | NOV 30, 1997 |
| | 20235 001 | GABAPENTIN; NEURONTIN | 4894476 | JAN 16, 2007 | | | |
| | 20235 002 | GABAPENTIN; NEURONTIN | 4894476 | JAN 16, 2007 | | | |
| | 20235 003 | GABAPENTIN; NEURONTIN | 4894476 | JAN 16, 2007 | | | |
| | 20123 001 | GADODIAMIDE; OMNISCAN | 4687659 | JAN 08, 2007 | U-76 | NCE | JAN 08, 1998 |
| | 20131 001 | GADOTERIDOL; PROHANCE | | | | I-115 | NOV 21, 1997 |
| | | | | | | I-114 | NOV 21, 1997 |
| >ADD> | 20460 001 | GANCICLOVIR; CYTOVENE | 4642346 | FEB 10, 2004 | | | |
| >ADD> | | | 4507305 | OCT 19, 1999 | U-64 | | |
| >ADD> | | | 4423050 | OCT 19, 1999 | U-64 | | |
| >ADD> | | | 4355032 | MAR 16, 2003 | | | |
| | 20329 001 | GLIPIZIDE; GLUCOTROL XL | | | | NDF | APR 26, 1997 |
| | 20329 002 | GLIPIZIDE; GLUCOTROL XL | | | | NDF | APR 26, 1997 |
| | 19778 003 | HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5 | 4472380 | SEP 18, 2001 | | | |
| | | | 4374829 | DEC 30, 2001 | U-3 | NS | NOV 18, 1996 |
| | 19888 001 | HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5 | 4472380 | SEP 18, 2001 | | | |
| | | | 4374829 | DEC 30, 2001 | U-3 | | |
| | 19888 002 | HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25 | 4374829 | DEC 30, 2001 | U-3 | | |
| | 19888 003 | HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5 | 4472380 | SEP 18, 2001 | | NS | NOV 18, 1996 |
| | | | 4374829 | DEC 30, 2001 | U-3 | | |
| | 19771 001 | IBUPROFEN; ADVIL COLD AND SINUS | 4552899 | NOV 12, 2002 | | | |
| | 20135 001 | IBUPROFEN; MOTRIN | | | | NDF | NOV 16, 1997 |
| | 20135 002 | IBUPROFEN; MOTRIN | | | | NDF | NOV 16, 1997 |
| | 20367 001 | IMIGLUCERASE; CEREZYME | | | | NCE | MAY 23, 1999 |
| | | | | | | ODE | MAY 23, 2001 |
| | 20314 001 | INDIUM IN-111 PENTETREOTIDE KIT; OCTREOSCAN | | | | NCE | JUN 02, 1999 |
| | 20084 001 | IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131 | 4584187 | APR 22, 2003 | | NCE | MAR 25, 1999 |

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 |
|---|---|---|---|---|---|---|---|
| | 20327 001 | IOPAMIDOL; ISOVUE-200 | 4001323 | JAN 04, 1996 | | | |
| | 20327 002 | IOPAMIDOL; ISOVUE-250 | 4001323 | JAN 04, 1996 | | | |
| | 20327 003 | IOPAMIDOL; ISOVUE-300 | 4001323 | JAN 04, 1996 | | | |
| | 20327 004 | IOPAMIDOL; ISOVUE-370 | 4001323 | JAN 04, 1996 | | | |
| | 50705 001 | ISONIAZID; RIFATER | | | | ODE | MAY 31, 2001 |
| | 20336 001 | ISRADIPINE; DYNACIRC CR | 5030456 | JUL 09, 2008 | | | |
| | | | 4950486 | AUG 21, 2007 | | NDF | JUN 01, 1997 |
| | | | 4946687 | AUG 07, 2007 | | NCE | DEC 20, 1995 |
| | | | 4816263 | MAR 28, 2006 | U-3 | | |
| | | | 4783337 | SEP 16, 2003 | U-3 | | |
| | | | 4466972 | AUG 21, 2003 | U-3 | | |
| | 20336 002 | ISRADIPINE; DYNACIRC CR | 5030456 | JUL 09, 2008 | | | |
| | | | 4950486 | AUG 21, 2007 | | NDF | JUN 01, 1997 |
| | | | 4946687 | AUG 07, 2007 | | NCE | DEC 20, 1995 |
| | | | 4816263 | MAR 28, 2006 | U-3 | | |
| | | | 4783337 | SEP 16, 2003 | U-3 | | |
| | | | 4466972 | AUG 21, 2003 | U-3 | | |
| | 20083 001 | ITRACONAZOLE; SPORANOX | | | | I-104 | MAR 29, 1997 |
| | 18754 001 | KETOPROFEN; ORUDIS | | | | I-112 | JAN 06, 1997 |
| | 18754 002 | KETOPROFEN; ORUDIS | | | | I-112 | JAN 06, 1997 |
| | 18754 003 | KETOPROFEN; ORUDIS | | | | I-112 | JAN 06, 1997 |
| | 19816 001 | KETOPROFEN; ORUVAIL | | | | NDF | SEP 24, 1996 |
| >ADD> | 20241 001 | LAMOTRIGINE; LAMICTAL | | | | NCE | DEC 27, 1999 |
| >ADD> | 20241 002 | LAMOTRIGINE; LAMICTAL | | | | NCE | DEC 27, 1999 |
| >ADD> | 20241 003 | LAMOTRIGINE; LAMICTAL | | | | NCE | DEC 27, 1999 |
| >ADD> | 20241 004 | LAMOTRIGINE; LAMICTAL | | | | NCE | DEC 27, 1999 |
| >ADD> | 20241 005 | LAMOTRIGINE; LAMICTAL | | | | NCE | DEC 27, 1999 |
| >ADD> | 20241 006 | LAMOTRIGINE; LAMICTAL | | | | NCE | DEC 27, 1999 |
| | 20219 001 | LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN | 4369184 | JAN 18, 2000 | | NCE | NOV 10, 1998 |
| | 19558 006 | LISINOPRIL; PRINIVIL | 4374829 | DEC 30, 2001 | | I-92 | JUN 09, 1996 |
| | 19658 001 | LORATADINE; CLARITIN | 4282233 | AUG 04, 2000 | U-77 | NCE | APR 12, 1998 |
| >ADD> | 19670 001 | LORATADINE; CLARITIN-D | | | | NC | NOV 14, 1997 |
| | 20264 001 | MEGESTROL ACETATE; MEGACE | | | | NDF | SEP 10, 1997 |
| >ADD> | 20357 001 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | NCE | DEC 29, 1999 |
| >ADD> | 20357 002 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | | | | NCE | DEC 29, 1999 |
| >ADD> | 19737 001 | METRONIDAZOLE; METROGEL | 4837378 | JUN 06, 2006 | | ODE | NOV 22, 1995 |
| >ADD> | 20208 001 | METRONIDAZOLE; METROGEL | 4837378 | JUN 06, 2006 | | NDF | AUG 17, 1995 |

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 |
|---|---|---|---|---|---|---|---|
| | 20343 001 | MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5% | 4313951 | FEB 02, 2001 | | | |
| | 20343 002 | MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5% | 4313951 | FEB 02, 2001 | | | |
| | 20343 003 | MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5% | 4313951 | FEB 02, 2001 | | | |
| | 19297 001 | MITOXANTRONE HYDROCHLORIDE; NOVANTRONE | 4820738 | APR 11, 2006 | U-98 | | |
| | 20065 001 | NAPHAZOLINE HYDROCHLORIDE; OPCON-A | | | | NC | JUN 08, 1997 |
| | 20226 001 | NAPHAZOLINE HYDROCHLORIDE; NAPHCON-A | | | | NC | JUN 08, 1997 |
| | 20067 002 | NAPROXEN; EC-NAPROSYN | | | | NDF | OCT 14, 1997 |
| | 20067 003 | NAPROXEN; EC-NAPROSYN | | | | NDF | OCT 14, 1997 |
| | 20204 002 | NAPROXEN SODIUM; ALEVE | | | | NS | JAN 11, 1997 |
| | 19660 001 | NEDOCROMIL SODIUM; TILADE | 4474787 | OCT 02, 2006 | | NCE | DEC 30, 1997 |
| >ADD> | 20152 001 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | JUL 06, 1999 | U-12 | NCE | DEC 22, 1999 |
| >ADD> | 20152 002 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | JUL 06, 1999 | U-12 | NCE | DEC 22, 1999 |
| >ADD> | 20152 003 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | JUL 06, 1999 | U-12 | NCE | DEC 22, 1999 |
| >ADD> | 20152 004 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | JUL 06, 1999 | U-12 | NCE | DEC 22, 1999 |
| >ADD> | 20152 005 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | JUL 06, 1999 | U-12 | NCE | DEC 22, 1999 |
| >ADD> | 20152 006 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | JUL 06, 1999 | U-12 | NCE | DEC 22, 1999 |
| | 20165 001 | NICOTINE; NICODERM | 5364630 | APR 02, 2010 | | | |
| | | | 5344656 | APR 02, 2008 | | | |
| | | | 5342623 | APR 02, 2008 | | | |
| | 20165 002 | NICOTINE; NICODERM | 5364630 | APR 02, 2010 | | | |
| | | | 5344656 | APR 02, 2008 | | | |
| | | | 5342623 | APR 02, 2008 | | | |
| | 20165 003 | NICOTINE; NICODERM | 5364630 | APR 02, 2010 | | | |
| | | | 5344656 | APR 02, 2008 | | | |
| | | | 5342623 | APR 02, 2008 | | | |
| | 19684 001 | NIFEDIPINE; PROCARDIA XL | 5264446 | NOV 23, 2010 | | | |
| | 19684 002 | NIFEDIPINE; PROCARDIA XL | 5264446 | NOV 23, 2010 | | | |
| | 19684 003 | NIFEDIPINE; PROCARDIA XL | 5264446 | NOV 23, 2010 | | | |
| | 19384 002 | NORFLOXACIN; NOROXIN | | | | I-113 | OCT 24, 1997 |
| | 19667 001 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | JUL 26, 2002 | | I-106 | MAY 03, 1997 |
| | 19667 002 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | JUL 26, 2002 | | I-106 | MAY 03, 1997 |
| | 19667 003 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | JUL 26, 2002 | | I-106 | MAY 03, 1997 |
| | 19667 004 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | JUL 26, 2002 | | I-106 | MAY 03, 1997 |
| | 19667 005 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | JUL 26, 2002 | | I-106 | MAY 03, 1997 |
| | 20103 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | | | | I-110 | SEP 26, 1997 |
| | 20103 002 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | | | | I-110 | SEP 26, 1997 |

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PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|
| 20262 001 | PACLITAXEL; TAXOL | | | | I-105 | APR 13, 1997 |
| | | | | | D-24 | JUN 22, 1997 |
| 20036 001 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | DEC 08, 2004 | | D-22 | APR 15, 1997 |
| | | | | | I-111 | SEP 21, 1997 |
| 20036 003 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | DEC 08, 2004 | | D-22 | APR 15, 1997 |
| | | | | | I-111 | SEP 21, 1997 |
| 20036 004 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | DEC 08, 2004 | | D-22 | APR 15, 1997 |
| | | | | | I-111 | SEP 21, 1997 |
| 20031 001 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | DEC 29, 2006 | U-12 | NCE | DEC 29, 1997 |
| 20031 002 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | DEC 29, 2006 | U-12 | NCE | DEC 29, 1997 |
| 20031 003 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | DEC 29, 2006 | U-12 | NCE | DEC 29, 1997 |
| 20031 004 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | DEC 29, 2006 | U-12 | NCE | DEC 29, 1997 |
| 20031 005 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | DEC 29, 2006 | U-12 | NCE | DEC 29, 1997 |
| 20184 001 | PERINDOPRIL ERBUMINE; ACEON | 4508729 | APR 02, 2002 | | NCE | DEC 30, 1998 |
| 20184 002 | PERINDOPRIL ERBUMINE; ACEON | 4508729 | APR 02, 2002 | | NCE | DEC 30, 1998 |
| 20184 003 | PERINDOPRIL ERBUMINE; ACEON | 4508729 | APR 02, 2002 | | NCE | DEC 30, 1998 |
| 20237 001 | PILOCARPINE HYDROCHLORIDE; SALAGEN | | | | ODE | MAR 22, 2001 |
| | | | | | NDF | MAR 22, 1997 |
| 19439 001 | POTASSIUM CHLORIDE; K-DUR 20 | 4863743 | SEP 05, 2006 | U-99 | | |
| 19439 002 | POTASSIUM CHLORIDE; K-DUR 10 | 4863743 | SEP 05, 2006 | U-99 | | |
| 19898 002 | PRAVASTATIN SODIUM; PRAVACHOL | 4346227 | JAN 09, 2004 | | NCE | OCT 31, 1996 |
| 19898 003 | PRAVASTATIN SODIUM; PRAVACHOL | 4346227 | JAN 09, 2004 | | NCE | OCT 31, 1996 |
| 19898 004 | PRAVASTATIN SODIUM; PRAVACHOL | 4346227 | JAN 09, 2004 | | NCE | OCT 31, 1996 |
| 20279 001 | PREDNICARBATE; DERMATOP | | | | NDF | OCT 29, 1996 |
| 19627 001 | PROPOFOL; DIPRIVAN | | | | I-99 | OCT 26, 1996 |
| 20021 002 | PSEUDOEPHEDRINE HYDROCHLORIDE; EFIDAC/24 | 4801461 | MAY 05, 2004 | | | |
| | | 4576604 | MAR 18, 2003 | | | |
| 18703 001 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 4128658 | DEC 05, 1995 | | D-21 | FEB 28, 1997 |
| >ADD> | | | | | I-116 | NOV 03, 1997 |
| 18703 002 | RANITIDINE HYDROCHLORIDE; ZANTAC 300 | 4128658 | DEC 05, 1995 | | D-21 | FEB 28, 1997 |
| >ADD> | | | | | I-116 | NOV 03, 1997 |
| 19675 001 | RANITIDINE HYDROCHLORIDE; ZANTAC | 4521431 | JUN 04, 2002 | | D-21 | FEB 28, 1997 |
| 20095 001 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 5028432 | JUL 02, 2008 | | | |
| | | 4521431 | JUN 04, 2002 | | I-75 | MAY 19, 1995 |
| | | 4128658 | DEC 05, 1995 | | D-21 | FEB 28, 1997 |

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 |
|---|---|---|---|---|---|---|---|
| | 20095 002 | RANITIDINE HYDROCHLORIDE; ZANTAC 300 | 5028432 | JUL 02, 2008 | | | |
| | | | 4521431 | JUN 04, 2002 | | I-75 | MAY 19, 1995 |
| | | | 4128658 | DEC 05, 1995 | | D-21 | FEB 28, 1997 |
| | 20251 001 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 5102665 | APR 07, 2009 | | | |
| | | | 4521431 | JUN 04, 2002 | | I-75 | MAY 19, 1995 |
| | | | 4128658 | DEC 05, 1995 | | D-21 | FEB 28, 1997 |
| | 20251 002 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 5102665 | APR 07, 2009 | | | |
| | | | 4521431 | JUN 04, 2002 | | I-75 | MAY 19, 1995 |
| | | | 4128658 | DEC 05, 1995 | | D-21 | FEB 28, 1997 |
| >ADD> | 20474 001 | RIMEXOLONE; VEXOL | 4686214 | AUG 11, 2004 | U-100 | NCE | DEC 30, 1999 |
| | 20214 001 | ROCURONIUM BROMIDE; ZEMURON (P/F) | 4894369 | JAN 16, 2007 | | NCE | MAR 17, 1999 |
| | 20214 002 | ROCURONIUM BROMIDE; ZEMURON | 4894369 | JAN 16, 2007 | | NCE | MAR 17, 1999 |
| | 20236 001 | SALMETEROL XINAFOATE; SEREVENT | 4992474 | FEB 12, 2008 | | NCE | FEB 04, 1999 |
| >ADD> | 19839 001 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4962128 | OCT 09, 2007 | U-12 | | |
| >ADD> | 19839 002 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4962128 | OCT 09, 2007 | U-12 | | |
| >ADD> | 19839 003 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4962128 | OCT 09, 2007 | U-12 | | |
| >ADD> | 19839 004 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4962128 | OCT 09, 2007 | U-12 | | |
| | 19766 001 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1996 |
| | 19766 002 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1996 |
| | 19766 003 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1996 |
| | 19766 004 | SIMVASTATIN; ZOCOR | 4444784 | DEC 24, 2005 | U-59 | NCE | DEC 23, 1996 |
| | 19640 001 | SOMATROPIN, BIOSYNTHETIC; HUMATROPE | | | | D-23 | APR 15, 1997 |
| | 19640 004 | SOMATROPIN, BIOSYNTHETIC; HUMATROPE | | | | D-23 | APR 15, 1997 |
| | 19865 005 | SOTALOL HYDROCHLORIDE; BETAPACE | | | | NCE | OCT 30, 1997 |
| | | | | | | ODE | OCT 30, 1999 |
| >ADD> | 20240 001 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | | | | NCE | DEC 29, 1999 |
| >ADD> | 20240 002 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | | | | NCE | DEC 29, 1999 |
| >ADD> | 20240 003 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | | | | NCE | DEC 29, 1999 |
| >ADD> | 20240 004 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | | | | NCE | DEC 29, 1999 |
| | 20412 001 | STAVUDINE; ZERIT | 4978655 | DEC 18, 2007 | U-94 | NCE | JUN 24, 1999 |
| | 20412 002 | STAVUDINE; ZERIT | 4978655 | DEC 18, 2007 | U-94 | NCE | JUN 24, 1999 |
| | 20412 003 | STAVUDINE; ZERIT | 4978655 | DEC 18, 2007 | U-94 | NCE | JUN 24, 1999 |
| | 20412 004 | STAVUDINE; ZERIT | 4978655 | DEC 18, 2007 | U-94 | NCE | JUN 24, 1999 |
| | 20412 005 | STAVUDINE; ZERIT | 4978655 | DEC 18, 2007 | U-94 | NCE | JUN 24, 1999 |
| | 40091 001 | SULFADIAZINE; SULFADIAZINE | | | | ODE | JUL 29, 2001 |
| | 17376 001 | SULFAMETHOXAZOLE; SEPTRA | 4209513 | JUN 24, 1997 | | I-103 | JAN 07, 1997 |
| | 17376 002 | SULFAMETHOXAZOLE; SEPTRA DS | 4209513 | JUN 24, 1997 | | I-103 | JAN 07, 1997 |

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 |
|---|---|---|---|---|---|---|---|
| | 17377 001 | SULFAMETHOXAZOLE; BACTRIM | | | | I-103 | JAN 07, 1997 |
| | 17377 002 | SULFAMETHOXAZOLE; BACTRIM DS | | | | I-103 | JAN 07, 1997 |
| | 17560 002 | SULFAMETHOXAZOLE; BACTRIM PEDIATRIC | | | | I-103 | JAN 07, 1997 |
| | 17598 001 | SULFAMETHOXAZOLE; SEPTRA | | | | I-103 | JAN 07, 1997 |
| | 17598 002 | SULFAMETHOXAZOLE; SEPTRA GRAPE | | | | I-103 | JAN 07, 1997 |
| | 20080 001 | SUMATRIPTAN SUCCINATE; IMITREX | 4816470 | DEC 29, 2006 | U-72 | | |
| | 20070 001 | TACRINE HYDROCHLORIDE; COGNEX | 4631286 | DEC 23, 2003 | U-97 | | |
| | 20070 002 | TACRINE HYDROCHLORIDE; COGNEX | 4631286 | DEC 23, 2003 | U-97 | | |
| | 20070 003 | TACRINE HYDROCHLORIDE; COGNEX | 4631286 | DEC 23, 2003 | U-97 | | |
| | 20070 004 | TACRINE HYDROCHLORIDE; COGNEX | 4631286 | DEC 23, 2003 | U-97 | | |
| | 17970 002 | TAMOXIFEN CITRATE; NOLVADEX | 4536516 | AUG 20, 2002 | | | |
| >ADD> | 20256 001 | TECHNETIUM TC-99M BICISATE KIT; NEUROLITE | 5279811 | MAR 18, 2008 | U-101 | NCE | NOV 23, 1999 |
| | 18163 003 | TEMAZEPAM; RESTORIL | 5326758 | JUL 09, 2008 | U-70 | | |
| >ADD> | 20347 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5294615 | MAR 15, 2011 | | | |
| >ADD> | | | 5212176 | MAY 18, 2010 | | | |
| >ADD> | | | 4251532 | FEB 17, 2000 | | | |
| >ADD> | | | 4112097 | SEP 05, 1995 | | | |
| >ADD> | 20347 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5294615 | MAR 15, 2011 | | | |
| >ADD> | | | 5212176 | MAY 18, 2010 | | | |
| >ADD> | | | 4251532 | FEB 17, 2000 | | | |
| >ADD> | | | 4112097 | SEP 05, 1995 | | | |
| >ADD> | 20347 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5294615 | MAR 15, 2011 | | | |
| >ADD> | | | 5212176 | MAY 18, 2010 | | | |
| >ADD> | | | 4251532 | FEB 17, 2000 | | | |
| >ADD> | | | 4112097 | SEP 05, 1995 | | | |
| >ADD> | 20347 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5294615 | MAR 15, 2011 | | | |
| >ADD> | | | 5212176 | MAY 18, 2010 | | | |
| >ADD> | | | 4251532 | FEB 17, 2000 | | | |
| >ADD> | | | 4112097 | SEP 05, 1995 | | | |
| | 20192 001 | TERBINAFINE HYDROCHLORIDE; LAMISIL | 4755534 | JUL 05, 2005 | U-73 | NCE | DEC 30, 1999 |
| | 19762 001 | TESTOSTERONE; TESTODERM | 4867982 | FEB 16, 2005 | | | |
| | | | 4725439 | FEB 16, 2005 | | | |
| | | | 4704282 | NOV 03, 2004 | | NDF | OCT 12, 1996 |
| | 19762 002 | TESTOSTERONE; TESTODERM | 4867982 | FEB 16, 2005 | | | |
| | | | 4725439 | FEB 16, 2005 | | | |
| | | | 4704282 | NOV 03, 2004 | | NDF | OCT 12, 1996 |

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 |
|---|---|---|---|---|---|---|---|
| | 20330 001 | TIMOLOL MALEATE; TIMOPTIC-XE | 4861760 | AUG 29, 2006 | | | |
| | | | 4195085 | MAR 25, 1997 | | NP | NOV 04, 1996 |
| | 20330 002 | TIMOLOL MALEATE; TIMOPTIC-XE | 4861760 | AUG 29, 2006 | | | |
| | | | 4195085 | MAR 25, 1997 | | NP | NOV 04, 1996 |
| | 20326 001 | TRIMETREXATE GLUCURONATE; NEUTREXIN | 4694007 | SEP 15, 2004 | U-91 | ODE | DEC 17, 2000 |
| >ADD> | 20388 001 | VINORELBINE TARTRATE; NAVELBINE | | | | NCE | DEC 23, 1999 |
| | 19908 001 | ZOLPIDEM TARTRATE; AMBIEN | 4382938 | MAY 10, 2005 | U-74 | NCE | DEC 16, 1997 |
| | 19908 002 | ZOLPIDEM TARTRATE; AMBIEN | 4382938 | MAY 10, 2005 | U-74 | NCE | DEC 16, 1997 |