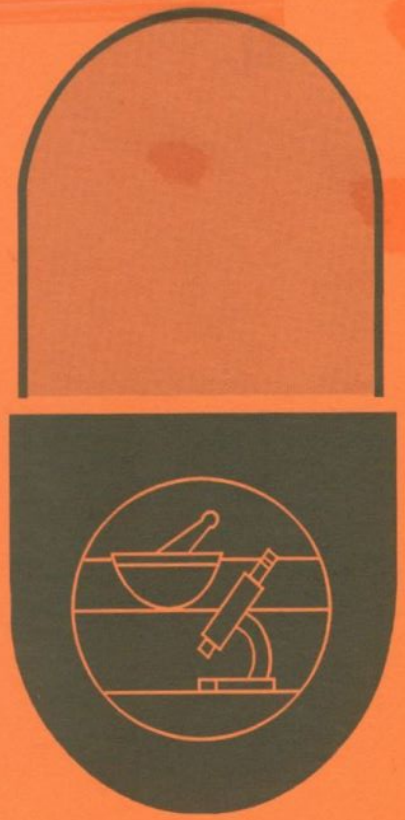
CUMULATIVE
SUPPLEMENT 10
JAN'95-OCT'95



# APPROVED DRUG PRODUCTS

## WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

15TH 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

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

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## APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

16TH EDITION
1996

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# APPROVED DRUG PRODUCTS
# with
# THERAPEUTIC EQUIVALENCE EVALUATIONS

## 15TH EDITION

## Cumulative Supplement 10

## OCTOBER 1995

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

**15TH EDITION**

**CUMULATIVE SUPPLEMENT 10**
**OCTOBER 1995**

## 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, 15th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 15th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 16th Edition.

## 1.2 COURT ORDER AFFECTING URUGUAY ROUND AGREEMENTS ACT-EXTENDED PATENTS

The Uruguay Round Agreements Act (URAA), Public Law 103-465, extended the term of patents issued on or after June 8, 1995, from 17 years from date of issue to 20 years from date of filing. Patents in effect on, or based upon applications filed by, June 8, 1995, are entitled to 17 years from date of issue or 20 years from date of filing, whichever is greater. On June 7, 1995, the Patent and Trademark Office (PTO) published a notice in the *Federal Register* (60 FR 30069) that established the method for calculating the patent term expiration date for any patent subject to both the terms of the URAA and the patent term extension provisions at title 35, U.S.C. § 156. FDA published a notice in the *Federal Register* on July 21, 1995, (60 FR 37652) announcing that it would not publish

in this publication patent expiration dates that the NDA applicant submitting the information stated were not calculated in accordance with the PTO method for determining the correct patent expiration date.

Both PTO's determination of the correct relationship between the extension of patents under the URAA and patent term extensions under title 35, U.S.C. § 156, and FDA's refusal to publish patent expiration dates that are not consistent with the PTO determination have been challenged. On October 16, 1995, the U.S. District Court for the Eastern District of Virginia issued an Opinion and Order finding that PTO had misinterpreted the Patent Code, and that PTO's determination of June 7, 1995, is invalid and unenforceable. The court ordered FDA to publish the patent dates it had, by its July 21, 1995, notice, refused to publish. Therefore, because of the court's order, and pending final resolution of appeals from the October 16, 1995, decision, FDA is publishing the patent term expiration dates that NDA applicants have told FDA are not consistent with PTO's June 7, 1995, determination. Because the district court decision may be reversed upon appeal, users of this publication should consult the most recent supplement and are encouraged to confirm that patent information upon which they intend to rely is current.

## 1.3 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.

## 1.4 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) |
|---|---|
| BOOTS PHARMACEUTICALS INC<br>(BOOTS) | KNOLL PHARMACEUTICAL COMPANY<br>SUB BASF CORPORATION<br>(KNOLL PHARM) |
| BRIAN PHARMACEUTICALS INC<br>(BRIAN) | HYGENICS PHARMACEUTICALS INC<br>(HYGENICS) |

APPLICANT NAME CHANGES

| FORMER APPLICANT NAME (FORMER ABBREVIATED NAME) | NEW APPLICANT NAME (NEW ABBREVIATED NAME) |
|---|---|
| BURROUGHS WELLCOME CO (BURROUGHS WELLCOME) | GLAXO WELLCOME INC (GLAXO WELLCOME) |
| DORSEY LABORATORIES DIV SANDOZ WANDER INC (DORSEY) | SANDOZ CONSUMER HEALTH CARE GROUP DIV SANDOZ PHARMACEUTICALS CORP (SANDOZ) |
| GLAXO INC (GLAXO) | GLAXO WELLCOME INC (GLAXO WELLCOME) |
| MARION MERRELL DOW INC (MARION MERRELL DOW) | HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL) |
| MERRELL DOW PHARMACEUTICALS INC SUB DOW CHEMICAL CO (MERRELL DOW) | HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL) |
| MILES PHARMACEUTICAL DIV MILES INC (MILES) | BAYER CORPORATION (BAYER) |
| PENNEX PHARMACEUTICALS INC (PENNEX) | MORTON GROVE PHARMACEUTICALS INC (MORTON GROVE) |
| TAP PHARMACEUTICALS INC (TAP PHARMS) | TAP HOLDINGS INC (TAP HOLDINGS) |

## 1.5 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The *Approved Drug Products with Therapeutic Equivalence Evaluations* (Prescription Drug Products, OTC Drug Products and the Discontinued Drug Product Lists) is now available on diskette, on a quarterly basis, from the National Technical Information Service. The telephone number for the Subscription Department is (703) 487-6430. Written inquiries regarding this subscription may be forwarded to 5285 Port Royal Road Springfield, VA 22161.

## 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 1994) 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 1994 | MAR 1995 | JUN 1995 | SEP 1995 |
|---|---|---|---|---|
| DRUG PRODUCTS LISTED | 9141 | 9195 | 9221 | 9221 |
| SINGLE SOURCE | 2178 (23.8%) | 2186 (23.8%) | 2186 (23.7%) | 2168 (23.5%) |
| MULTISOURCE | 6963 (76.2%) | 7009 (76.2%) | 7035 (76.3%) | 7053 (76.5%) |
| THERAPEUTICALLY EQUIVALENT | 6330 (69.2%) | 6380 (69.4%) | 6399 (69.4%) | 6427 (69.7%) |
| NOT THERAPEUTICALLY EQUIVALENT | 453 ( 5.0%) | 453 ( 4.9%) | 452 ( 4.9%) | 444 ( 4.8%) |
| EXCEPTIONS[1] | 180 ( 2.0%) | 176 ( 1.9%) | 184 ( 2.0%) | 182 ( 2.0%) |
| NEW MOLECULAR ENTITIES APPROVED | -- | 2 | 10 | 6 |
| NUMBER OF APPLICANTS | 534 | 541 | 559 | 553 |

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

ACARBOSE

TABLET; ORAL
PRECOSE
BAYER 50MG N20482 001
SEP 06, 1995
+ 100MG N20482 002
SEP 06, 1995

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL
ACEBUTOLOL HCL
AB MYLAN EQ 200MG BASE N74288 001
APR 24, 1995
AB EQ 400MG BASE N74288 002
APR 24, 1995
> ADD > AB WATSON LABS EQ 200MG BASE N74007 001
> ADD > OCT 18, 1995
> ADD > AB EQ 400MG BASE N74007 002
> ADD > OCT 18, 1995
SECTRAL
AB WYETH AYERST EQ 200MG BASE N18917 001
DEC 28, 1984
AB + EQ 400MG BASE N18917 003
DEC 28, 1984

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
AB WEST WARD PHARM 325MG;50MG;40MG N89718 001
JUN 12, 1995

ACETAMINOPHEN; CODEINE PHOSPHATE

SOLUTION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
AA BARRE 120MG/5ML;12MG/5ML N85861 001
APAP W/ CODEINE
AA BARRE 120MG/5ML;12MG/5ML N85861 001

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
AA KV PHARM 300MG;30MG N85288 001
AA 300MG;60MG N85365 001

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
KV PHARM 325MG;15MG N85364 001
325MG;45MG N85363 001
@ 300MG;30MG N85288 001
@ 300MG;60MG N85365 001
@ 325MG;15MG N85364 001
@ 325MG;45MG N85363 001
AA MIKART 650MG;30MG N89231 001
MAR 03, 1986
+ 650MG;30MG N89231 001
MAR 03, 1986
+ ROXANE 500MG;15MG N89511 001
APR 25, 1989
+ 500MG;30MG N89512 001
APR 25, 1989
+ 500MG;60MG N89513 001
APR 25, 1989
@ 500MG;15MG N89511 001
APR 25, 1989
@ 500MG;30MG N89512 001
APR 25, 1989
@ 500MG;60MG N89513 001
APR 25, 1989
PHENAPHEN-650 W/ CODEINE
AA + ROBINS AH 650MG;30MG N85856 001
@ 650MG;30MG N85856 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
ANEXSIA
AA BOEHRINGER MANNHEIM 500MG;5MG N89160 001
APR 23, 1987
AA KING PHARMS 500MG;5MG N89160 001
APR 23, 1987
ANEXSIA 7.5/650
AA BOEHRINGER MANNHEIM 650MG;7.5MG N89725 001
SEP 30, 1987
AA KING PHARMS 650MG;7.5MG N89725 001
SEP 30, 1987
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA HALSEY 500MG;5MG N89554 001
JUN 12, 1987
@ 500MG;5MG N89554 001
JUN 12, 1987

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **HYDROCODONE BITARTRATE AND ACETAMINOPHEN** | | |
| AA | | KING PHARMS | 500MG;5MG | N40084 002 JUN 01, 1995 |
| AA | | | 750MG;7.5MG | N40084 001 JUN 01, 1995 |
| AA | + | MIKART | 650MG;10MG | N81223 001 MAY 29, 1992 |
| AA | | WATSON LABS | 650MG;7.5MG | N40094 001 SEP 29, 1995 |
| AA | | | 650MG;10MG | N40094 002 SEP 29, 1995 |

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **ROXILOX** | | |
| AA | | ROXANE | 500MG;5MG | N40061 001 JUL 03, 1995 |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **OXYCET** | | |
| AA | | HALSEY | 325MG;5MG | N87463 001 DEC 07, 1983 |
| AA | | MALLINCKRODT | 325MG;5MG | N87463 001 DEC 07, 1983 |

ACETAZOLAMIDE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | | DIAMOX | | |
| | + | STORZ OPHTHALM | 500MG | N12945 001 |
| | @ | | 500MG | N12945 001 |
| | + | | 500MG | N12945 003 APR 25, 1995 |

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **ACETAZOLAMIDE SODIUM** | | |
| AP | | BEDFORD | EQ 500MG BASE/VIAL | N40089 001 FEB 28, 1995 |
| > ADD > AP | | SANOFI WINTHROP | EQ 500MG BASE/VIAL | N40108 001 OCT 30, 1995 |

> ADD >

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **DIAMOX** | | |
| AP | + | STORZ OPHTHALM | EQ 500MG BASE/VIAL | N09388 001 DEC 05, 1990 |

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

| | | | | |
|---|---|---|---|---|
| | | **ACETYLCYSTEINE** | | |
| AN | | DUPONT MERCK | 10% | N71364 001 MAY 01, 1989 |
| AN | | | 20% | N71365 001 MAY 01, 1989 |
| AN | | FAULDING | 10% | N71364 001 MAY 01, 1989 |
| AN | | | 20% | N71365 001 MAY 01, 1989 |
| AN | | LUITPOLD | 10% | N72489 001 JUL 28, 1995 |
| AN | | | 20% | N72547 001 JUL 28, 1995 |

ADENOSINE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | ADENOSCAN | | |
| | + | MEDCO RES | 3MG/ML | N20059 001 MAY 18, 1995 |

ALBUTEROL SULFATE

SOLUTION; INHALATION

| | | | | |
|---|---|---|---|---|
| | | **ALBUTEROL SULFATE** | | |
| AN | | PACO | EQ 0.083% BASE | N73533 001 SEP 26, 1995 |

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | | **ALBUTEROL SULFATE** | | |
| AA | | BARRE | EQ 2MG BASE/5ML | N74454 001 SEP 25, 1995 |

ALENDRONATE SODIUM

TABLET; ORAL
FOSAMAX
MERCK — EQ 10MG BASE — N20560 001 SEP 29, 1995
\+ — EQ 40MG BASE — N20560 002 SEP 29, 1995

ALPRAZOLAM

TABLET; ORAL
**ALPRAZOLAM**
AB CHELSEA LABS — 0.25MG — N74456 001 AUG 31, 1995
AB — 0.5MG — N74456 002 AUG 31, 1995
AB — 1MG — N74456 003 AUG 31, 1995

ALPROSTADIL

INJECTABLE; INJECTION
CAVERJECT
UPJOHN — 0.01MG/VIAL — N20379 001 JUL 06, 1995
\+ — 0.02MG/VIAL — N20379 002 JUL 06, 1995

ALSEROXYLON

TABLET; ORAL
RAUWILOID
\+ 3M — 2MG — N08867 001
@ — 2MG — N08867 001

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL
**AMANTADINE HCL**
AA PHARM ASSOC — 50MG/5ML — N74509 001 JUL 17, 1995

AMIKACIN SULFATE

INJECTABLE; INJECTION
**AMIKACIN**
AP DUPONT MERCK — EQ 50MG BASE/ML — N63350 001 JUL 30, 1993
AP — EQ 250MG BASE/ML — N63350 002 JUL 30, 1993
AP \+ ELKINS SINN — EQ 50MG BASE/ML — N63274 001 MAY 18, 1992
AP \+ — EQ 250MG BASE/ML — N63275 001 MAY 18, 1992

**AMIKACIN SULFATE**
AP ELKINS SINN — EQ 50MG BASE/ML — N63274 001 MAY 18, 1992
AP — EQ 250MG BASE/ML — N63275 001 MAY 18, 1992
AP FAULDING — EQ 50MG BASE/ML — N63350 001 JUL 30, 1993
AP — EQ 250MG BASE/ML — N63350 002 JUL 30, 1993
AP SANOFI WINTHROP — EQ 250MG BASE/ML — N64098 001 JUN 26, 1995
AP — EQ 250MG BASE/ML — N64099 001 JUN 20, 1995

**AMIKIN**
AP APOTHECON — EQ 50MG BASE/ML — N62311 001
AP \+ — EQ 50MG BASE/ML — N62311 001
AP — EQ 250MG BASE/ML — N62311 002
AP \+ — EQ 250MG BASE/ML — N62311 002
@ — EQ 50MG BASE/ML — N62562 001 SEP 20, 1984
@ — EQ 250MG BASE/ML — N62562 002 SEP 20, 1984
@ BRISTOL — EQ 50MG BASE/ML — N62562 001 SEP 20, 1984
@ — EQ 250MG BASE/ML — N62562 002 SEP 20, 1984

AMIKIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
@ APOTHECON — EQ 5MG BASE/ML — N50618 002 NOV 30, 1987
@ — EQ 10MG BASE/ML — N50618 001 NOV 30, 1987
@ BRISTOL — EQ 5MG BASE/ML — N50618 002 NOV 30, 1987
@ — EQ 10MG BASE/ML — N50618 001 NOV 30, 1987

>ADD< AMINO ACIDS; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE,
>ADD< DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE

>ADD< INJECTABLE; INJECTION
>ADD< TRAVASOL 2.75% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 10%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 2.75%;10GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;216MG/100ML;
>ADD< 112MG/100ML N20147 002
>ADD< OCT 23, 1995
>ADD< TRAVASOL 2.75% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 15%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 2.75%;15GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;216MG/100ML;
>ADD< 112MG/100ML N20147 003
>ADD< OCT 23, 1995
>ADD< TRAVASOL 2.75% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 20%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 2.75%;20GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;216MG/100ML;
>ADD< 112MG/100ML N20147 004
>ADD< OCT 23, 1995
>ADD< TRAVASOL 2.75% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 25%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 2.75%;25GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;216MG/100ML;
>ADD< 112MG/100ML N20147 005
>ADD< OCT 23, 1995
>ADD< TRAVASOL 2.75% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 5%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 2.75%;5GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;216MG/100ML;
>ADD< 112MG/100ML N20147 001
>ADD< OCT 23, 1995
>ADD< TRAVASOL 4.25% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 10%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 4.25%;10GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;297MG/100ML;
>ADD< 77MG/100ML N20147 007
>ADD< OCT 23, 1995
>ADD< TRAVASOL 4.25% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 15%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 4.25%;15GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;297MG/100ML;
>ADD< 77MG/100ML N20147 008
>ADD< OCT 23, 1995

>ADD< AMINO ACIDS; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE,
>ADD< DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE

>ADD< INJECTABLE; INJECTION
>ADD< TRAVASOL 4.25% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 20%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 4.25%;20GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;297MG/100ML;
>ADD< 77MG/100ML N20147 009
>ADD< OCT 23, 1995
>ADD< TRAVASOL 4.25% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 25%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 4.25%;25GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;297MG/100ML;
>ADD< 77MG/100ML N20147 010
>ADD< OCT 23, 1995
>ADD< TRAVASOL 4.25% SULFITE FREE W/ ELECTROLYTES IN DEXTROSE 5%
>ADD< IN PLASTIC CONTAINER
>ADD< BAXTER 4.25%;5GM/100ML;51MG/100ML;
>ADD< 261MG/100ML;297MG/100ML;
>ADD< 77MG/100ML N20147 006
>ADD< OCT 23, 1995

>ADD< AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC;
>ADD< SODIUM ACETATE; SODIUM CHLORIDE

>ADD< INJECTABLE; INJECTION
>ADD< TRAVASOL 3.5% SULFITE FREE W/ ELECTROLYTES IN PLASTIC
>ADD< CONTAINER
>ADD< BAXTER 3.5%;51MG/100ML;131MG/100ML;
>ADD< 218MG/100ML;35MG/100ML N20177 001
>ADD< OCT 23, 1995
>ADD< TRAVASOL 5.5% SULFITE FREE W/ ELECTROLYTES IN PLASTIC
>ADD< CONTAINER
>ADD< BAXTER 5.5%;102MG/100ML;522MG/100ML;
>ADD< 431MG/100ML;224MG/100ML N20173 001
>ADD< OCT 27, 1995
>ADD< TRAVASOL 8.5% SULFITE FREE W/ ELECTROLYTES IN PLASTIC
>ADD< CONTAINER
>ADD< BAXTER 8.5%;102MG/100ML;522MG/100ML;
>ADD< 594MG/100ML;154MG/100ML N20173 002
>ADD< OCT 27, 1995

AMINOPHYLLINE

INJECTABLE; INJECTION
**AMINOPHYLLINE**
AP FUJISAWA 25MG/ML N87200 001

AMINOPHYLLINE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **AMINOPHYLLINE** | | |
| AP | FUJISAWA | **25MG/ML** | **N88407 001** |
| | | | JAN 25, 1984 |
| | @ | 25MG/ML | N87200 001 |
| | @ | 25MG/ML | N88407 001 |
| | | | JAN 25, 1984 |
| AP | KING PHARMS | **25MG/ML** | **N86606 001** |
| | @ | 25MG/ML | N86606 001 |
| | AMINOPHYLLINE IN SODIUM CHLORIDE 0.45% | | |
| | ABBOTT | 100MG/100ML | N88147 002 |
| | | | MAY 03, 1983 |
| | | 200MG/100ML | N88147 003 |
| | | | MAY 03, 1982 |
| | + | 100MG/100ML | N88147 002 |
| | | | MAY 03, 1983 |
| | + | 200MG/100ML | N88147 003 |
| | | | MAY 03, 1983 |

TABLET; ORAL

| | | | |
|---|---|---|---|
| | AMINOPHYLLINE | | |
| BD | PHOENIX LABS NY | 100MG | N85409 001 |
| BD | | 200MG | N85410 001 |
| | @ | 100MG | N85409 001 |
| | @ | 200MG | N85410 001 |

AMINOSALICYLATE SODIUM

POWDER; ORAL

| | | | |
|---|---|---|---|
| | **P.A.S. SODIUM** | | |
| AA | CENTURY PHARMS | **4GM/PACKET** | **N80947 001** |
| | @ | 4GM/PACKET | N80947 001 |
| | **SODIUM AMINOSALICYLATE** | | |
| AA | HEXCEL | **100%** | **N80097 001** |
| | @ | 100% | N80097 001 |

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | CORDARONE | | |
| | + WYETH AYERST | 50MG/ML | N20377 001 |
| | | | AUG 03, 1995 |

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **AMITRIPTYLINE HCL** | | |
| AB | ROXANE | **150MG** | **N86090 001** |
| | @ | 150MG | N86090 001 |

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | LOTREL | | |
| | CIBA GEIGY | EQ 2.5MG BASE;10MG | N20364 002 |
| | | | MAR 03, 1995 |
| | | EQ 5MG BASE;10MG | N20364 003 |
| | | | MAR 03, 1995 |
| | + | EQ 5MG BASE;20MG | N20364 004 |
| | | | MAR 03, 1995 |

AMOXICILLIN

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | **AMOXICILLIN** | | |
| AB | CONSOLIDATED PHARM | **250MG** | **N62058 001** |
| AB | | **500MG** | **N62058 002** |
| | **COMOX** | | |
| AB | COPANOS | **250MG** | **N62058 001** |
| AB | | **500MG** | **N62058 002** |
| | **POLYMOX** | | |
| AB | APOTHECON | **250MG** | **N63099 001** |
| | | | MAR 20, 1992 |
| AB | | **500MG** | **N63099 002** |
| | | | MAR 20, 1992 |
| | **TRIMOX** | | |
| AB | APOTHECON | **250MG** | **N63099 001** |
| | | | MAR 20, 1992 |
| AB | | **500MG** | **N63099 002** |
| | | | MAR 20, 1992 |

POWDER FOR RECONSTITUTION; ORAL

| | | | |
|---|---|---|---|
| | **AMOXICILLIN** | | |
| AB | CONSOLIDATED PHARM | **125MG/5ML** | **N62059 001** |
| AB | | **250MG/5ML** | **N62059 002** |
| | **AMOXICILLIN TRIHYDRATE** | | |
| AB | COPANOS | **125MG/5ML** | **N62059 001** |
| AB | | **250MG/5ML** | **N62059 002** |

AMPHOTERICIN B

INJECTABLE; INJECTION
**AMPHOTERICIN B**

| | | | | |
|---|---|---|---|---|
| AP | | GENSIA | 50MG/VIAL | N64062 001<br>MAR 31, 1995 |

AMPICILLIN SODIUM

INJECTABLE; INJECTION
**AMPICILLIN SODIUM**

| | | | | |
|---|---|---|---|---|
| AP | | APOTHECON | EQ 125MG BASE/VIAL | N61395 001 |
| AP | | | EQ 125MG BASE/VIAL | N62860 001<br>FEB 05, 1988 |
| AP | | | EQ 250MG BASE/VIAL | N61395 002 |
| AP | | | EQ 250MG BASE/VIAL | N62860 002<br>FEB 05, 1988 |
| AP | | | EQ 500MG BASE/VIAL | N61395 003 |
| AP | | | EQ 500MG BASE/VIAL | N62860 003<br>FEB 05, 1988 |
| AP | | | EQ 1GM BASE/VIAL | N61395 004 |
| AP | | | EQ 1GM BASE/VIAL | N62738 001<br>FEB 19, 1987 |
| AP | | | EQ 1GM BASE/VIAL | N62860 004<br>FEB 05, 1988 |
| AP | | | EQ 2GM BASE/VIAL | N61395 005 |
| AP | | | EQ 2GM BASE/VIAL | N62738 002<br>FEB 19, 1987 |
| AP | | | EQ 2GM BASE/VIAL | N62860 005<br>FEB 05, 1988 |
| AP | + | | EQ 10GM BASE/VIAL | N61395 006 |
| | @ | CONSOLIDATED PHARM | EQ 125MG BASE/VIAL | N61936 005 |
| | @ | | EQ 250MG BASE/VIAL | N61936 001 |
| | @ | | EQ 500MG BASE/VIAL | N61936 002 |
| | @ | | EQ 1GM BASE/VIAL | N61936 003 |
| | @ | | EQ 2GM BASE/VIAL | N61936 004 |
| | @ | COPANOS | EQ 125MG BASE/VIAL | N61936 005 |
| | @ | | EQ 250MG BASE/VIAL | N61936 001 |
| | @ | | EQ 500MG BASE/VIAL | N61936 002 |
| | @ | | EQ 1GM BASE/VIAL | N61936 003 |
| | @ | | EQ 2GM BASE/VIAL | N61936 004 |
| | | **PRINCIPEN** | | |
| AP | | APOTHECON | EQ 125MG BASE/VIAL | N61395 001 |
| AP | | | EQ 125MG BASE/VIAL | N62860 001<br>FEB 05, 1988 |
| AP | | | EQ 250MG BASE/VIAL | N61395 002 |
| AP | | | EQ 250MG BASE/VIAL | N62860 002<br>FEB 05, 1988 |

AMPICILLIN SODIUM

INJECTABLE; INJECTION
**PRINCIPEN**

| | | | | |
|---|---|---|---|---|
| AP | | APOTHECON | EQ 500MG BASE/VIAL | N61395 003 |
| AP | | | EQ 500MG BASE/VIAL | N62860 003<br>FEB 05, 1988 |
| AP | | | EQ 1GM BASE/VIAL | N61395 004 |
| AP | | | EQ 1GM BASE/VIAL | N62738 001<br>FEB 19, 1987 |
| AP | | | EQ 1GM BASE/VIAL | N62860 004<br>FEB 05, 1988 |
| AP | | | EQ 2GM BASE/VIAL | N61395 005 |
| AP | | | EQ 2GM BASE/VIAL | N62738 002<br>FEB 19, 1987 |
| AP | | | EQ 2GM BASE/VIAL | N62860 005<br>FEB 05, 1988 |
| AP | + | | EQ 10GM BASE/VIAL | N61395 006 |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
**AMPICILLIN TRIHYDRATE**

| | | | | |
|---|---|---|---|---|
| AB | | BIOCHEMIE | EQ 250MG BASE | N64082 001<br>AUG 29, 1995 |
| AB | | | EQ 500MG BASE | N64082 002<br>AUG 29, 1995 |
| AB | | CONSOLIDATED PHARM | EQ 250MG BASE | N61602 001 |
| AB | | | EQ 500MG BASE | N61602 002 |
| AB | | COPANOS | EQ 250MG BASE | N61602 001 |
| AB | | | EQ 500MG BASE | N61602 002 |

POWDER FOR RECONSTITUTION; ORAL
**AMPICILLIN TRIHYDRATE**

| | | | | |
|---|---|---|---|---|
| AB | | CONSOLIDATED PHARM | EQ 125MG BASE/5ML | N61601 001 |
| AB | | | EQ 250MG BASE/5ML | N61601 002 |
| AB | | COPANOS | EQ 125MG BASE/5ML | N61601 001 |
| AB | | | EQ 250MG BASE/5ML | N61601 002 |
| | | **POLYCILLIN** | | |
| AB | + | BRISTOL | EQ 125MG BASE/5ML | N50308 001 |
| AB | + | | EQ 250MG BASE/5ML | N50308 002 |
| | + | | EQ 500MG BASE/5ML | N50308 003 |
| | @ | | EQ 125MG BASE/5ML | N50308 001 |
| | @ | | EQ 250MG BASE/5ML | N50308 002 |
| | @ | | EQ 500MG BASE/5ML | N50308 003 |

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | VASOCON-A | | | |
| | + CIBA VISION | 0.5%;0.05% | N18746 001 | APR 30, 1990 |

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE** | | | |
| AB | WATSON LABS | 325MG;50MG;40MG;30MG | N74359 001 | AUG 31, 1995 |
| | **FIORINAL W/CODEINE NO 3** | | | |
| AB | + SANDOZ | 325MG;50MG;40MG;30MG | N19429 003 | OCT 26, 1990 |

ASPIRIN; METHOCARBAMOL

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **METHOCARBAMOL AND ASPIRIN** | | | |
| AB | STEVENS J | 325MG;400MG | **N81145 001** | JAN 31, 1995 |

ATENOLOL

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **ATENOLOL** | | | |
| AB | COPLEY PHARM | 50MG | **N74120 001** | FEB 24, 1995 |
| AB | | 100MG | **N74120 002** | FEB 24, 1995 |
| AB | LEMMON | 50MG | **N74056 001** | JAN 18, 1995 |
| AB | | 100MG | **N74056 002** | JAN 18, 1995 |
| AB | MARTEC | 50MG | **N74127 001** | FEB 21, 1995 |
| AB | | 100MG | **N74127 002** | FEB 21, 1995 |

ATOVAQUONE

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | MEPRON | | | |
| | + GLAXO WELLCOME | 750MG/5ML | N20500 001 | FEB 08, 1995 |

ATROPINE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **ATROPEN** | | | |
| AP | + SURVIVAL TECH | **EQ 2MG SULFATE/0.7ML** | **N17106 001** | |
| | + | EQ 2MG SULFATE/0.7ML | N17106 001 | |
| | **ATROPINE** | | | |
| AP | KALI DUPHAR | **EQ 2MG SULFATE/0.7ML** | **N71295 001** | JAN 30, 1987 |
| | ® SOLVAY | EQ 2MG SULFATE/0.7ML | N71295 001 | JAN 30, 1987 |

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **AZATHIOPRINE SODIUM** | | | |
| AP | BEDFORD | **EQ 100MG BASE/VIAL** | **N74419 001** | MAR 31, 1995 |
| | **IMURAN** | | | |
| AP | + GLAXO WELLCOME | **EQ 100MG BASE/VIAL** | **N17391 001** | |

AZELAIC ACID

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | AZELEX | | | |
| | + ALLERGAN | 20% | N20428 001 | SEP 13, 1995 |

AZITHROMYCIN DIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | ZITHROMAX | | | |
| >ADD> | + PFIZER | EQ 100MG BASE/5ML | N50710 001 | OCT 19, 1995 |
| >ADD> | + | EQ 200MG BASE/5ML | N50710 002 | OCT 19, 1995 |

BACITRACIN

INJECTABLE; INJECTION
**BACITRACIN**

| | | | | |
|---|---|---|---|---|
| **AP** | + | PFIZER | **50,000 UNITS/VIAL** | **N60282 001** |
| | @ | | 50,000 UNITS/VIAL | N60282 001 |
| **AP** | | UPJOHN | **50,000 UNITS/VIAL** | **N60733 002** |
| | + | | 50,000 UNITS/VIAL | N60733 002 |

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
**CORTISPORIN**

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | **AT** | + | GLAXO WELLCOME | **400 UNITS/GM;1%;EQ 3.5MG BASE/GM;** | |
| > ADD > | | | | **10,000 UNITS/GM** | **N50416 002** |
| > ADD > | | | **NEOMYCIN AND POLYMYXIN B SULFATES, BACITRACIN ZINC AND HYDROCORTISONE** | | |
| > ADD > | **AT** | | BAUSCH AND LOMB | **400 UNITS/GM;1%;EQ 3.5MG BASE/GM;** | |
| > ADD > | | | | **10,000 UNITS/GM** | **N64068 001** |
| > ADD > | | | | | OCT 30, 1995 |

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | | | **NEOMYCIN AND POLYMYXIN B SULFATES AND BACITRACIN ZINC** | | |
| > ADD > | **AT** | | BAUSCH AND LOMB | **400 UNITS/GM;EQ 3.5MG BASE/GM;** | |
| > ADD > | | | | **10,000 UNITS/GM** | **N64064 001** |
| > ADD > | | | | | OCT 30, 1995 |

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
**BACITRACIN ZINC AND POLYMYXIN B SULFATE**

| | | | | |
|---|---|---|---|---|
| **AT** | | ADV REMEDIES | **500 UNITS/GM;** | |
| | | | **10,000 UNITS/GM** | **N64028 001** |
| | | | | JAN 30, 1995 |
| **AT** | | BAUSCH AND LOMB | **500 UNITS/GM;** | |
| | | | **10,000 UNITS/GM** | **N64046 001** |
| | | | | JAN 26, 1995 |
| | | **POLYSPORIN** | | |
| **AT** | + | GLAXO WELLCOME | **500 UNITS/GM;** | |
| | | | **10,000 UNITS/GM** | **N61229 001** |

BENDROFLUMETHIAZIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | NATURETIN-10 | | |
| | + | APOTHECON | 10MG | N12164 003 |
| | + | SQUIBB | 10MG | N12164 003 |
| | | NATURETIN-2.5 | | |
| | @ | APOTHECON | 2.5MG | N12164 001 |
| | @ | SQUIBB | 2.5MG | N12164 001 |
| | | NATURETIN-5 | | |
| | | APOTHECON | 5MG | N12164 002 |
| | | SQUIBB | 5MG | N12164 002 |

BENTONITE; SULFUR

POWDER; TOPICAL
BENSULFOID

| | | | |
|---|---|---|---|
| @ | POYTHRESS | 66.64%;33.32% | N02918 001 |

BETAMETHASONE BENZOATE

GEL; TOPICAL
UTICORT

| | | | |
|---|---|---|---|
| + | PARKE DAVIS | 0.025% | N17244 001 |
| @ | | 0.025% | N17244 001 |

LOTION; TOPICAL
UTICORT

| | | | |
|---|---|---|---|
| + | PARKE DAVIS | 0.025% | N17528 001 |
| @ | | 0.025% | N17528 001 |

BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL
**BETAMETHASONE DIPROPIONATE**

| | | | | |
|---|---|---|---|---|
| **AB** | | NMC | **EQ 0.05% BASE** | **N74304 001** |
| | | | | AUG 31, 1995 |
| | | **DIPROLENE** | | |
| **AB** | + | SCHERING | **EQ 0.05% BASE** | **N18741 001** |
| | | | | JUL 27, 1983 |

> ADD > BICALUTAMIDE

> ADD > TABLET; ORAL
> ADD > CASODEX
> ADD > + ZENECA 50MG N20498 001
> ADD > OCT 04, 1995

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLOL
AP DUPONT MERCK 50MG/ML N17954 001
AP FAULDING 50MG/ML N17954 001

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL
DIMETANE-DC
AA ROBINS AH 2MG/5ML;10MG/5ML; 12.5MG/5ML N11694 006
MAR 29, 1984
AA + 2MG/5ML;10MG/5ML; 12.5MG/5ML N11694 006
MAR 29, 1984

BUMETANIDE

INJECTABLE; INJECTION
BUMETANIDE
AP BEDFORD 0.25MG/ML N74441 001
JAN 27, 1995

TABLET; ORAL
BUMETANIDE
AB ZENITH LABS 0.5MG N74225 001
APR 24, 1995
AB 1MG N74225 002
APR 24, 1995
AB 2MG N74225 003
APR 24, 1995

BUMEX
AB ROCHE 0.5MG N18225 002
FEB 28, 1983
AB 1MG N18225 001
FEB 28, 1983

BUMETANIDE

TABLET; ORAL
BUMEX
AB + ROCHE 2MG N18225 003
JUN 14, 1985

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
MARCAINE HCL
AP + SANOFI WINTHROP 0.25% N16964 001
AP + 0.5% N16964 006
AP + 0.75% N16964 009
AP + STERLING WINTHROP 0.25% N16964 001
AP + 0.5% N16964 006
AP + 0.75% N16964 009
MARCAINE HCL PRESERVATIVE FREE
AP + SANOFI WINTHROP 0.5% N16964 005

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE

INJECTABLE; INJECTION
MARCAINE HCL W/ EPINEPHRINE
AP + SANOFI WINTHROP 0.25%;0.0091MG/ML N16964 004
AP + 0.5%;0.0091MG/ML N16964 008
AP + 0.75%;0.0091MG/ML N16964 010
AP + STERLING WINTHROP 0.25%;0.0091MG/ML N16964 004
AP + 0.5%;0.0091MG/ML N16964 008
AP + 0.75%;0.0091MG/ML N16964 010

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL
CAFERGOT
AA + SANDOZ 100MG;1MG N06620 001
@ 100MG;1MG N06620 001
ERCATAB
AA GENEVA PHARMS 100MG;1MG N84294 001
AA + 100MG;1MG N84294 001

CALCITONIN, SALMON

INJECTABLE; INJECTION
**CALCITONIN-SALMON**

| | | | |
|---|---|---|---|
| AP | ASTRA | 200 IU/ML | N73690 001<br>APR 14, 1995 |

SPRAY, METERED; NASAL
MIACALCIN

| | | | |
|---|---|---|---|
| + | SANDOZ | 200 IU/INH | N20313 002<br>AUG 17, 1995 |

CAPTOPRIL

TABLET; ORAL
**CAPOTEN**

| | | | |
|---|---|---|---|
| AB | BRISTOL MYERS SQUIBB | 12.5MG | N18343 005<br>JAN 17, 1985 |
| AB | | 25MG | N18343 002 |
| AB | | 50MG | N18343 001 |
| AB | + | 100MG | N18343 003 |

**CAPTOPRIL**

| | | | |
|---|---|---|---|
| AB | APOTHECON | 12.5MG | N74472 001<br>MAR 31, 1995 |
| AB | | 25MG | N74472 002<br>MAR 31, 1995 |
| AB | | 50MG | N74472 003<br>MAR 31, 1995 |
| AB | | 100MG | N74472 004<br>MAR 31, 1995 |

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL
CAPOZIDE 25/25

| | | | |
|---|---|---|---|
| | SQUIBB | 25MG;25MG | N18709 002<br>OCT 12, 1984 |
| + | | 25MG;25MG | N18709 002<br>OCT 12, 1984 |

CAPOZIDE 50/15

| | | | |
|---|---|---|---|
| | SQUIBB | 50MG;15MG | N18709 004<br>OCT 12, 1984 |
| + | | 50MG;15MG | N18709 004<br>OCT 12, 1984 |

CAPOZIDE 50/25

| | | | |
|---|---|---|---|
| + | SQUIBB | 50MG;25MG | N18709 003<br>OCT 12, 1984 |

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL
CAPOZIDE 50/25

| | | | |
|---|---|---|---|
| | SQUIBB | 50MG;25MG | N18709 003<br>OCT 12, 1984 |

CARBACHOL

SOLUTION; INTRAOCULAR
**CARBASTAT**

| | | | |
|---|---|---|---|
| AT | CIBA | 0.01% | N73677 001<br>APR 28, 1995 |

**MIOSTAT**

| | | | |
|---|---|---|---|
| AT | + ALCON | 0.01% | N16968 001 |

CARBIDOPA; LEVODOPA

TABLET; ORAL
**CARBIDOPA AND LEVODOPA**

| | | | |
|---|---|---|---|
| AB | GENEVA PHARMS | 10MG;100MG | N73586 001<br>JUN 29, 1995 |
| AB | | 25MG;100MG | N73587 001<br>JUN 29, 1995 |
| AB | | 25MG;250MG | N73620 001<br>JUN 29, 1995 |

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OCUPRESS

| | | | |
|---|---|---|---|
| > ADD > | + OTSUKA | 1% | N19972 001<br>MAY 23, 1990 |

**OPTIPRESS**

| | | | |
|---|---|---|---|
| > DLT > | + OTSUKA | 1% | N19972 001<br>MAY 23, 1990 |

CARVEDILOL

TABLET; ORAL
COREG

| | | | |
|---|---|---|---|
| | SMITHKLINE BEECHAM | 6.25MG | N20297 003<br>SEP 14, 1995 |
| | | 12.5MG | N20297 002<br>SEP 14, 1995 |

CARVEDILOL

TABLET; ORAL
COREG

| | | | | |
|---|---|---|---|---|
| + | SMITHKLINE BEECHAM | 25MG | | N20297 001 SEP 14, 1995 |

CEFACLOR

CAPSULE; ORAL
CECLOR

| | | | | |
|---|---|---|---|---|
| AB | + | LILLY | EQ 250MG BASE | N50521 001 |
| AB | | | EQ 250MG BASE | N62205 001 |
| AB | + | | EQ 500MG BASE | N50521 002 |
| AB | | | EQ 500MG BASE | N62205 002 |

CEFACLOR

| | | | | |
|---|---|---|---|---|
| AB | | LEDERLE | EQ 250MG BASE | N64107 001 APR 27, 1995 |
| AB | | | EQ 500MG BASE | N64107 002 APR 27, 1995 |
| AB | | ZENITH LABS | EQ 250MG BASE | N64061 001 APR 27, 1995 |
| AB | | | EQ 500MG BASE | N64061 002 APR 27, 1995 |

POWDER FOR RECONSTITUTION; ORAL
CECLOR

| | | | | |
|---|---|---|---|---|
| AB | + | LILLY | EQ 125MG BASE/5ML | N50522 001 |
| AB | | | EQ 125MG BASE/5ML | N62206 001 |
| AB | + | | EQ 187MG BASE/5ML | N62206 003 APR 20, 1988 |
| AB | + | | EQ 250MG BASE/5ML | N50522 002 |
| AB | | | EQ 250MG BASE/5ML | N62206 002 |
| AB | + | | EQ 375MG BASE/5ML | N62206 004 APR 20, 1988 |

CEFACLOR

| | | | | |
|---|---|---|---|---|
| AB | | LEDERLE | EQ 125MG BASE/5ML | N64114 001 APR 28, 1995 |
| AB | | | EQ 187MG BASE/5ML | N64115 001 APR 28, 1995 |
| AB | | | EQ 250MG BASE/5ML | N64116 001 APR 28, 1995 |
| AB | | | EQ 375MG BASE/5ML | N64110 001 APR 28, 1995 |
| AB | | ZENITH LABS | EQ 125MG BASE/5ML | N64087 001 APR 28, 1995 |
| AB | | | EQ 187MG BASE/5ML | N64086 001 APR 28, 1995 |

CEFACLOR

POWDER FOR RECONSTITUTION; ORAL
CEFACLOR

| | | | | |
|---|---|---|---|---|
| AB | | ZENITH LABS | EQ 250MG BASE/5ML | N64085 001 APR 28, 1995 |
| AB | | | EQ 375MG BASE/5ML | N64070 001 APR 28, 1995 |

CEFAMANDOLE NAFATE

INJECTABLE; INJECTION
MANDOL

| | | | | |
|---|---|---|---|---|
| | + | LILLY | EQ 500MG BASE/VIAL | N50504 001 |
| | @ | | EQ 500MG BASE/VIAL | N50504 001 |

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

| | | | | |
|---|---|---|---|---|
| AP | | APOTHECON | EQ 500MG BASE/VIAL | N62831 001 DEC 09, 1988 |
| AP | | | EQ 1GM BASE/VIAL | N62831 002 DEC 09, 1988 |
| AP | | | EQ 10GM BASE/VIAL | N62831 003 SEP 25, 1992 |
| AP | | ELKINS SINN | EQ 250MG BASE/VIAL | N62807 001 JAN 12, 1988 |
| AP | | | EQ 500MG BASE/VIAL | N62807 002 JAN 12, 1988 |
| AP | | | EQ 1GM BASE/VIAL | N62807 003 JAN 12, 1988 |
| AP | | | EQ 5GM BASE/VIAL | N62807 004 JAN 12, 1988 |
| AP | | | EQ 10GM BASE/VIAL | N62807 005 JAN 12, 1988 |
| AP | | | EQ 20GM BASE/VIAL | N62807 006 JAN 12, 1988 |
| | @ | | EQ 250MG BASE/VIAL | N62807 001 JAN 12, 1988 |
| | @ | | EQ 500MG BASE/VIAL | N62807 002 JAN 12, 1988 |
| | @ | | EQ 1GM BASE/VIAL | N62807 003 JAN 12, 1988 |
| | @ | | EQ 5GM BASE/VIAL | N62807 004 JAN 12, 1988 |

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | CEFAZOLIN SODIUM | | |
| | @ ELKINS SINN | EQ 10GM BASE/VIAL | N62807 005 JAN 12, 1988 |
| | @ | EQ 20GM BASE/VIAL | N62807 006 JAN 12, 1988 |
| | ZOLICEF | | |
| AP | APOTHECON | EQ 500MG BASE/VIAL | N62831 001 DEC 09, 1988 |
| AP | | EQ 1GM BASE/VIAL | N62831 002 DEC 09, 1988 |
| AP | | EQ 10GM BASE/VIAL | N62831 003 SEP 25, 1992 |

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

| | | |
|---|---|---|
| CEFOBID | | |
| PFIZER | EQ 1GM BASE/VIAL | N63333 001 MAR 31, 1995 |
| | EQ 2GM BASE/VIAL | N63333 002 MAR 31, 1995 |

CEFORANIDE

INJECTABLE; INJECTION

| | | |
|---|---|---|
| PRECEF | | |
| APOTHECON | 500MG/VIAL | N62579 001 NOV 26, 1984 |
| | 1GM/VIAL | N62579 002 NOV 26, 1984 |
| | 2GM/VIAL | N62579 003 NOV 26, 1984 |
| | 10GM/VIAL | N62579 004 NOV 26, 1984 |
| | 20GM/VIAL | N62579 005 NOV 26, 1984 |
| BRISTOL | 500MG/VIAL | N62579 001 NOV 26, 1984 |
| | 1GM/VIAL | N62579 002 NOV 26, 1984 |
| | 2GM/VIAL | N62579 003 NOV 26, 1984 |
| | 10GM/VIAL | N62579 004 NOV 26, 1984 |

CEFORANIDE

INJECTABLE; INJECTION

| | | |
|---|---|---|
| PRECEF | | |
| BRISTOL | 20GM/VIAL | N62579 005 NOV 26, 1984 |

CEFOXITIN SODIUM

INJECTABLE; INJECTION

| | | |
|---|---|---|
| MEFOXIN IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER | | |
| + MERCK SHARP DOHME | EQ 20MG BASE/ML | N50581 002 SEP 20, 1984 |
| + | EQ 40MG BASE/ML | N50581 001 SEP 20, 1984 |
| @ | EQ 20MG BASE/ML | N50581 002 SEP 20, 1984 |
| @ | EQ 40MG BASE/ML | N50581 001 SEP 20, 1984 |

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | ROCEPHIN | | |
| AP | + ROCHE | EQ 250MG BASE/VIAL | N50585 001 DEC 21, 1984 |
| AP | + | EQ 500MG BASE/VIAL | N50585 002 DEC 21, 1984 |
| AP | + | EQ 1GM BASE/VIAL | N50585 003 DEC 21, 1984 |
| | + | EQ 250MG BASE/VIAL | N50585 001 DEC 21, 1984 |
| | + | EQ 500MG BASE/VIAL | N50585 002 DEC 21, 1984 |
| | + | EQ 1GM BASE/VIAL | N50585 003 DEC 21, 1984 |

CEFUROXIME SODIUM

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | KEFUROX | | |
| AP | + LILLY | EQ 7.5GM BASE/VIAL | N62591 003 DEC 17, 1987 |
| AP | | EQ 7.5GM BASE/VIAL | N62591 003 DEC 17, 1987 |

CEFUROXIME SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | ZINACEF | | |
| AP | | GLAXO | EQ 7.5GM BASE/VIAL | N50558 004<br>OCT 23, 1986 |
| AP | + | GLAXO WELLCOME | EQ 7.5GM BASE/VIAL | N50558 004<br>OCT 23, 1986 |

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | CEPHALEXIN | | |
| AB | | APOTHECON | EQ 125MG BASE/5ML | N62986 001<br>APR 18, 1991 |
| AB | | | EQ 250MG BASE/5ML | N62987 001<br>JUL 25, 1989 |
| AB | | SQUIBB MARK | EQ 125MG BASE/5ML | N62986 001<br>APR 18, 1991 |
| AB | | | EQ 250MG BASE/5ML | N62987 001<br>JUL 25, 1989 |

CEPHRADINE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | VELOSEF | | |
| AB | + | APOTHECON | 250MG | N61764 001 |
| AB | + | | 500MG | N61764 002 |
| AB | + | ERSANA | 250MG | N61764 001 |
| AB | + | | 500MG | N61764 002 |

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | VELOSEF | | |
| | + | APOTHECON | 250MG/VIAL | N61976 001 |
| | + | | 500MG/VIAL | N61976 002 |
| | + | | 1GM/VIAL | N61976 004 |
| | + | | 2GM/VIAL | N61976 003 |
| | + | | 4GM/VIAL | N61976 005 |
| | + | SQUIBB | 250MG/VIAL | N61976 001 |
| | + | | 500MG/VIAL | N61976 002 |
| | + | | 1GM/VIAL | N61976 004 |
| | + | | 2GM/VIAL | N61976 003 |
| | + | | 4GM/VIAL | N61976 005 |

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | VELOSEF '125' | | |
| AB | + | APOTHECON | 125MG/5ML | N61763 001 |

CEPHRADINE

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | VELOSEF '125' | | |
| AB | + | ERSANA | 125MG/5ML | N61763 001 |
| | | VELOSEF '250' | | |
| AB | + | APOTHECON | 250MG/5ML | N61763 002 |
| AB | + | ERSANA | 250MG/5ML | N61763 002 |

CHLORAMPHENICOL

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | MYCHEL | | |
| AB | | ARMENPHARM | 250MG | N60851 001 |
| AB | | RACHELLE | 250MG | N60851 001 |

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | | OPTOMYCIN | | |
| AT | | OPTOPICS | 0.5% | N62171 001<br>MAR 31, 1982 |
| | @ | | 0.5% | N62171 001<br>MAR 31, 1982 |

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | CHLORAMPHENICOL | | |
| AP | | ELKINS SINN | EQ 1GM BASE/VIAL | N62406 001<br>NOV 09, 1982 |
| | @ | | EQ 1GM BASE/VIAL | N62406 001<br>NOV 09, 1982 |

CHLORDIAZEPOXIDE; ESTROGENS, ESTERIFIED

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | MENRIUM 10-4 | | |
| | | ROCHE | 10MG;0.4MG | N14740 006 |
| | @ | | 10MG;0.4MG | N14740 006 |
| | | MENRIUM 5-2 | | |
| | | ROCHE | 5MG;0.2MG | N14740 002 |
| | @ | | 5MG;0.2MG | N14740 002 |
| | | MENRIUM 5-4 | | |
| | + | ROCHE | 5MG;0.4MG | N14740 004 |
| | @ | | 5MG;0.4MG | N14740 004 |

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
CHLORPHENIRAMINE MALEATE

| | | | |
|---|---|---|---|
| AP | STERIS | 10MG/ML | N83593 001 |
| | | 100MG/ML | N86095 001 |
| | @ | 10MG/ML | N83593 001 |
| | @ | 100MG/ML | N86095 001 |

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHLORPROMAZINE HCL

| | | | |
|---|---|---|---|
| AP | STERIS | 25MG/ML | N85591 001 |
| | @ | 25MG/ML | N85591 001 |

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

| | | | |
|---|---|---|---|
| AB | LEMMON | 100MG | N88768 001<br>OCT 11, 1984 |
| | @ | 100MG | N88768 001<br>OCT 11, 1984 |

GLUCAMIDE

| | | | |
|---|---|---|---|
| AB | LEMMON | 250MG | N88641 001<br>OCT 11, 1984 |
| | @ | 250MG | N88641 001<br>OCT 11, 1984 |

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

| | | | |
|---|---|---|---|
| AB | MUTUAL PHARM | 25MG | N89738 001<br>SEP 19, 1988 |
| AB | | 50MG | N89739 001<br>SEP 19, 1988 |
| | @ | 25MG | N89738 001<br>SEP 19, 1988 |
| | @ | 50MG | N89739 001<br>SEP 19, 1988 |

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

| | | | |
|---|---|---|---|
| AA | AMIDE PHARM | 500MG | N40113 001<br>SEP 29, 1995 |

CHOLESTYRAMINE

BAR, CHEWABLE; ORAL
CHOLYBAR

| | | | |
|---|---|---|---|
| + | PARKE DAVIS | EQ 4GM RESIN/BAR | N71621 001<br>MAY 26, 1988 |
| | | EQ 4GM RESIN/BAR | N71739 001<br>MAY 26, 1988 |
| | @ | EQ 4GM RESIN/BAR | N71621 001<br>MAY 26, 1988 |
| | @ | EQ 4GM RESIN/BAR | N71739 001<br>MAY 26, 1988 |

TABLET; ORAL
QUESTRAN

| | | | |
|---|---|---|---|
| + | BRISTOL MYERS SQUIBB | EQ 1GM RESIN | N73403 001<br>APR 28, 1994 |
| | @ | EQ 1GM RESIN | N73403 001<br>APR 28, 1994 |

CIMETIDINE

TABLET; ORAL
CIMETIDINE

| | | | |
|---|---|---|---|
| AB | BAKER NORTON | 200MG | N74424 001<br>JUL 28, 1995 |
| AB | | 300MG | N74424 002<br>JUL 28, 1995 |
| AB | | 400MG | N74424 003<br>JUL 28, 1995 |
| AB | | 800MG | N74424 004<br>JUL 28, 1995 |
| AB | GENEVA PHARMS | 200MG | N74100 001<br>JAN 31, 1995 |
| AB | | 300MG | N74100 002<br>JAN 31, 1995 |
| AB | | 400MG | N74100 003<br>JAN 31, 1995 |
| AB | | 800MG | N74100 004<br>JAN 31, 1995 |

CIMETIDINE

TABLET; ORAL
CIMETIDINE

| | | | |
|---|---|---|---|
| AB | LEK LJUBLJANA | 200MG | N74250 001 JUN 29, 1995 |
| AB | | 300MG | N74250 002 JUN 29, 1995 |
| AB | | 400MG | N74250 003 JUN 29, 1995 |
| AB | | 800MG | N74250 004 JUN 29, 1995 |
| AB | LEMMON | 200MG | N74365 001 FEB 28, 1995 |
| AB | | 300MG | N74365 002 FEB 28, 1995 |
| AB | | 400MG | N74365 003 FEB 28, 1995 |
| AB | | 800MG | N74365 004 FEB 28, 1995 |
| AB | MOVA | 300MG | N74340 001 JUN 23, 1995 |
| AB | | 400MG | N74340 002 JUN 23, 1995 |
| AB | | 800MG | N74339 001 JUN 23, 1995 |
| AB | ZENITH LABS | 200MG | N74401 001 MAY 30, 1995 |
| AB | | 300MG | N74401 002 MAY 30, 1995 |
| AB | | 400MG | N74401 003 MAY 30, 1995 |
| AB | | 800MG | N74402 001 MAY 30, 1995 |

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
CIMETIDINE HCL

| | | | |
|---|---|---|---|
| AP | ABBOTT | EQ 300MG BASE/2ML | N74344 001 JAN 31, 1995 |
| AP | | EQ 300MG BASE/2ML | N74345 001 JAN 31, 1995 |
| AP | | EQ 300MG BASE/2ML | N74422 001 JAN 31, 1995 |

CISAPRIDE MONOHYDRATE

SUSPENSION; ORAL
PROPULSID

| | | | |
|---|---|---|---|
| + | JANSSEN | EQ 1MG BASE/ML | N20398 001 SEP 15, 1995 |

CLINDAMYCIN PHOSPHATE

SOLUTION; TOPICAL
CLEOCIN

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

SWAB; TOPICAL
CLEOCIN

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

CLOBETASOL PROPIONATE

CREAM; TOPICAL
TEMOVATE E

| | | | |
|---|---|---|---|
| BX | + GLAXO WELLCOME | 0.05% | N20340 001 JUN 17, 1994 |

TEMOVATE EMOLLIENT

| | | | |
|---|---|---|---|
| BX | + GLAXO | 0.05% | N20340 001 JUN 17, 1994 |

OINTMENT; TOPICAL
EMBELINE

| | | | |
|---|---|---|---|
| AB | DPT | 0.05% | N74221 001 MAR 31, 1995 |

CLOFIBRATE

CAPSULE; ORAL
CLOFIBRATE

| | | | |
|---|---|---|---|
| AB | GENEVA PHARMS | 500MG | N72191 001 MAY 02, 1988 |
| | @ | 500MG | N72191 001 MAY 02, 1988 |

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL
ANAFRANIL
BASEL PHARMS — 50MG — N19906 002 DEC 29, 1989
\+ — 75MG — N19906 003 DEC 29, 1989
\+ — 50MG — N19906 002 DEC 29, 1989
75MG — N19906 003 DEC 29, 1989

CLOTRIMAZOLE

SOLUTION; TOPICAL
**CLOTRIMAZOLE**
**AT** LEMMON — **1%** — **N73306 001 FEB 28, 1995**

CLOXACILLIN SODIUM

CAPSULE; ORAL
**CLOXACILLIN SODIUM**
**AB** \+ APOTHECON — **EQ 250MG BASE** — **N61452 001**
**AB** \+ — **EQ 500MG BASE** — **N61452 002**
**TEGOPEN**
**AB** \+ APOTHECON — **EQ 250MG BASE** — **N61452 001**
**AB** \+ — **EQ 500MG BASE** — **N61452 002**

POWDER FOR RECONSTITUTION; ORAL
**TEGOPEN**
@ APOTHECON — EQ 125MG BASE/5ML — N50192 001
**AA** BRISTOL — **EQ 125MG BASE/5ML** — **N50192 001**

CLOZAPINE

TABLET; ORAL
CLOZARIL
SANDOZ — 25MG — N19758 001 SEP 26, 1989
\+ — 100MG — N19758 002 SEP 26, 1989
\+ — 25MG — N19758 001 SEP 26, 1989

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

CLOZAPINE

TABLET; ORAL
CLOZARIL
SANDOZ — 100MG — N19758 002 SEP 26, 1989

COLESTIPOL HYDROCHLORIDE

GRANULE; ORAL
COLESTID
UPJOHN — 5GM/SCOOPFUL — N17563 003 SEP 22, 1995
\+ — 5GM/PACKET — N17563 004 SEP 22, 1995

COLISTIN SULFATE

SUSPENSION; ORAL
COLY-MYCIN S
PARKE DAVIS — EQ 25MG BASE/5ML — N50355 001
@ — EQ 25MG BASE/5ML — N50355 001

CORTICOTROPIN

INJECTABLE; INJECTION
**ACTH**
**AP** PARKE DAVIS — **40 UNITS/VIAL** — **N08317 004**
@ — 40 UNITS/VIAL — N08317 004

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
**CROLOM**
**AT** BAUSCH AND LOMB — **4%** — **N74443 001 JAN 30, 1995**
**OPTICROM**
**AT** \+ FISONS — **4%** — **N18155 001 OCT 03, 1984**

CUPRIC SULFATE

INJECTABLE; INJECTION
CUPRIC SULFATE

| | | | | |
|---|---|---|---|---|
| | + | FUJISAWA | EQ 0.4MG COPPER/ML | N19350 001<br>MAY 05, 1987 |
| | @ | | EQ 0.4MG COPPER/ML | N19350 001<br>MAY 05, 1987 |

CYANOCOBALAMIN

INJECTABLE; INJECTION
**CYANOCOBALAMIN**

| | | | | |
|---|---|---|---|---|
| **AP** | | **AKORN** | **1MG/ML** | **N87969 001**<br>**NOV 10, 1983** |
| | @ | | 1MG/ML | N87969 001<br>NOV 10, 1983 |
| | @ | WARNER CHILCOTT | 1MG/ML | N07085 002 |

**RUBRAMIN PC**

| | | | | |
|---|---|---|---|---|
| **AP** | + | **SQUIBB** | **0.1MG/ML** | **N06799 002** |
| | @ | | 0.1MG/ML | N06799 002 |

**SYTOBEX**

| | | | | |
|---|---|---|---|---|
| **AP** | | **PARKE DAVIS** | **1MG/ML** | **N07085 002** |

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
**CYCLOBENZAPRINE HCL**

| | | | | |
|---|---|---|---|---|
| **AB** | | **BARR** | **10MG** | **N73541 001**<br>MAY 23, 1995 |
| **AB** | | SIDMAK LABS NJ | **10MG** | **N74421 001**<br>SEP 29, 1995 |

CYCLOSPORINE

CAPSULE; ORAL
NEORAL

| | | | | |
|---|---|---|---|---|
| BP | | SANDOZ | 25MG | N50715 001<br>JUL 14, 1995 |
| BP | | | 50MG | N50715 003<br>JUL 14, 1995 |
| BP | + | | 100MG | N50715 002<br>JUL 14, 1995 |
| | | | 25MG | N50715 001<br>JUL 14, 1995 |
| | | | 50MG | N50715 003<br>JUL 14, 1995 |
| | + | | 100MG | N50715 002<br>JUL 14, 1995 |

SANDIMMUNE

| | | | | |
|---|---|---|---|---|
| BP | | SANDOZ | 25MG | N50625 001<br>MAR 02, 1990 |
| BP | | | 50MG | N50625 003<br>NOV 23, 1992 |
| BP | + | | 100MG | N50625 002<br>MAR 02, 1990 |
| | | | 25MG | N50625 001<br>MAR 02, 1990 |
| | | | 50MG | N50625 003<br>NOV 23, 1992 |
| | + | | 100MG | N50625 002<br>MAR 02, 1990 |

SOLUTION; ORAL
NEORAL

| | | | | |
|---|---|---|---|---|
| BP | + | SANDOZ | 100MG/ML | N50716 001<br>JUL 14, 1995 |
| | + | | 100MG/ML | N50716 001<br>JUL 14, 1995 |

SANDIMMUNE

| | | | | |
|---|---|---|---|---|
| BP | + | SANDOZ | 100MG/ML | N50574 001<br>NOV 14, 1983 |
| | + | | 100MG/ML | N50574 001<br>NOV 14, 1983 |

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL
**CYPROHEPTADINE HCL**

| | | | | |
|---|---|---|---|---|
| **AA** | | **ASCOT** | **4MG** | **N87685 001**<br>OCT 25, 1982 |
| | @ | | 4MG | N87685 001<br>OCT 25, 1982 |

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL
AP CETUS BEN VENUE EQ 20MG BASE/VIAL N64103 001
FEB 03, 1995

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DDAVP
+ RHONE POULENC 0.015MG/ML N18938 002
APR 25, 1995

SPRAY, METERED; NASAL
DESMOPRESSIN ACETATE
+ RHONE POULENC RORER 0.15MG/INH N20355 001
MAR 07, 1994

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

TABLET; ORAL
DDAVP
RHONE POULENC RORER 0.1MG N19955 001
SEP 06, 1995
+ 0.2MG N19955 002
SEP 06, 1995

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-21
DESOGEN
AB + ORGANON 0.15MG;0.03MG N20071 001
DEC 10, 1992
@ 0.15MG;0.03MG N20071 001
DEC 10, 1992

ORTHO-CEPT
AB JOHNSON RW 0.15MG;0.03MG N20301 001
DEC 14, 1992
0.15MG;0.03MG N20301 001 >ADD>
DEC 14, 1992 >ADD>
>ADD>
>ADD>

DEXAMETHASONE

AEROSOL; TOPICAL
DECASPRAY
+ MERCK SHARP DOHME 0.4% N12731 002
+ 0.04% N12731 002

TABLET; ORAL
HEXADROL
BP ORGANON 0.5MG N12675 004
BP 0.75MG N12675 007
BP 1.5MG N12675 009
@ 0.5MG N12675 004
@ 0.75MG N12675 007
@ 1.5MG N12675 009

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
DEXASPORIN
AT BAUSCH AND LOMB 0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML N64135 001
SEP 13, 1995

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
DEXAMETHASONE
AP FUJISAWA EQ 4MG PHOSPHATE/ML N88448 001
JAN 25, 1984
@ EQ 4MG PHOSPHATE/ML N88448 001
JAN 25, 1984

DEXAMETHASONE SODIUM PHOSPHATE
AP AKORN EQ 4MG PHOSPHATE/ML N84493 001
@ EQ 4MG PHOSPHATE/ML N84493 001

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE
AT BAUSCH AND LOMB EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML N64055 001
OCT 30, 1995

DEXRAZOXANE HYDROCHLORIDE

INJECTABLE; INJECTION
ZINECARD

| | | | | |
|---|---|---|---|---|
| + | PHARMACIA | EQ 250MG BASE/VIAL | N20212 001 | MAY 26, 1995 |
| + | | EQ 500MG BASE/VIAL | N20212 002 | MAY 26, 1995 |

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 2.5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | MCGAW | 2.5GM/100ML | N19626 001 | FEB 02, 1988 |
| @ | | 2.5GM/100ML | N19626 001 | FEB 02, 1988 |

DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| AP | DHL | 5GM/100ML | N19971 001 | SEP 28, 1995 |

DEXTROSE 7.7% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | MCGAW | 7.7GM/100ML | N19626 003 | FEB 02, 1988 |
| @ | | 7.7GM/100ML | N19626 003 | FEB 02, 1988 |

DIAZEPAM

INJECTABLE; INJECTION
DIAZEPAM

| | | | | |
|---|---|---|---|---|
| AP | FUJISAWA | 5MG/ML | N70662 001 | JUN 25, 1986 |
| @ | | 5MG/ML | N70662 001 | JUN 25, 1986 |

DICLOFENAC POTASSIUM

TABLET; ORAL
CATAFLAM

| | | | | |
|---|---|---|---|---|
| | GEIGY | 25MG | N20142 001 | NOV 24, 1993 |
| @ | | 25MG | N20142 001 | NOV 24, 1993 |

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM

| | | | | |
|---|---|---|---|---|
| AB | GENEVA PHARMS | 25MG | N74376 001 | SEP 28, 1995 |
| AB | | 50MG | N74376 002 | SEP 28, 1995 |
| AB | ROXANE | 25MG | N74391 001 | JUN 29, 1995 |
| AB | | 50MG | N74391 002 | JUN 29, 1995 |
| AB | | 75MG | N74391 003 | JUN 29, 1995 |

VOLTAREN

| | | | | |
|---|---|---|---|---|
| AB | + GEIGY | 25MG | N19201 001 | JUL 28, 1988 |
| AB | + | 50MG | N19201 002 | JUL 28, 1988 |
| AB | + | 75MG | N19201 003 | JUL 28, 1988 |

DICLOXACILLIN SODIUM

CAPSULE; ORAL
DICLOXACILLIN SODIUM

| | | | |
|---|---|---|---|
| AB | APOTHECON | EQ 250MG BASE | N61454 001 |
| AB | | EQ 500MG BASE | N61454 003 |
| | | EQ 125MG BASE | N61454 002 |

DYNAPEN

| | | | |
|---|---|---|---|
| AB | APOTHECON | EQ 250MG BASE | N61454 001 |
| AB | | EQ 500MG BASE | N61454 003 |
| | | EQ 125MG BASE | N61454 002 |

POWDER FOR RECONSTITUTION; ORAL
DICLOXACILLIN SODIUM

| | | | |
|---|---|---|---|
| AB | APOTHECON | EQ 62.5MG BASE/5ML | N61455 001 |

DYNAPEN

| | | | |
|---|---|---|---|
| AB | APOTHECON | EQ 62.5MG BASE/5ML | N61455 001 |
| @ | | EQ 62.5MG BASE/5ML | N50337 002 |
| @ | BRISTOL | EQ 62.5MG BASE/5ML | N50337 002 |

DIDANOSINE

POWDER FOR RECONSTITUTION; ORAL
VIDEX

| | | | |
|---|---|---|---|
| | BRISTOL MYERS SQUIBB | 250MG/PACKET | N20155 005 OCT 09, 1991 |

DIDANOSINE

POWDER FOR RECONSTITUTION; ORAL
VIDEX

| | | | | | |
|---|---|---|---|---|---|
| + | BRISTOL MYERS SQUIBB | 375MG/PACKET | N20155 006 OCT 09, 1991 | > ADD > | |
| + | | 250MG/PACKET | N20155 005 OCT 09, 1991 | > ADD > | |
| @ | | 375MG/PACKET | N20155 006 OCT 09, 1991 | > DLT > | |

DIENESTROL

CREAM; VAGINAL
**DIENESTROL**

| | | | | |
|---|---|---|---|---|
| **AT** | + JOHNSON RW | **0.01%** | **N06110 005** | |
| | + | 0.01% | N06110 005 | |
| **DV** | | | | |
| | @ HOECHST MARION RSSL | 0.01% | N83518 001 | |
| **AT** | MERRELL DOW | **0.01%** | **N83518 001** | |

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE DIACETATE

| | | | |
|---|---|---|---|
| @ UPJOHN | 0.05% | N19259 001 AUG 28, 1985 | |

FLORONE E

| | | | |
|---|---|---|---|
| BX + UPJOHN | 0.05% | N19259 001 AUG 28, 1985 | |

PSORCON

| | | | |
|---|---|---|---|
| BX DERMIK | 0.05% | N20205 001 NOV 20, 1992 | |
| BX + | 0.05% | N20205 001 NOV 20, 1992 | |

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILACOR XR

| | | | | | |
|---|---|---|---|---|---|
| > DLT > | BC | RHONE POULENC RORER | 120MG | N20092 001 MAY 29, 1992 | |
| > DLT > | | | | | |
| > ADD > | BC + | | 120MG | N20092 001 MAY 29, 1992 | |
| > ADD > | | | | | |
| > DLT > | BC | | 180MG | N20092 002 MAY 29, 1992 | |
| > DLT > | | | | | |

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILACOR XR

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | BC + | RHONE POULENC RORER | 180MG | N20092 002 MAY 29, 1992 | |
| > ADD > | | | | | |
| > DLT > | BC | | 240MG | N20092 003 MAY 29, 1992 | |
| > DLT > | | | | | |
| > ADD > | BC + | | 240MG | N20092 003 MAY 29, 1992 | |
| > ADD > | | | | | |

INJECTABLE; INJECTION
CARDIZEM

| | | | |
|---|---|---|---|
| + HOECHST MARION RSSL | 25MG/VIAL | N20027 003 AUG 18, 1995 | |

TABLET; ORAL
**DILTIAZEM HCL**

| | | | | |
|---|---|---|---|---|
| **AB** | LEMMON | **30MG** | **N74185 001** | MAY 31, 1995 |
| **AB** | | **60MG** | **N74185 002** | MAY 31, 1995 |
| **AB** | | **90MG** | **N74185 003** | MAY 31, 1995 |
| **AB** | | **120MG** | **N74185 004** | MAY 31, 1995 |
| **AB** | ZENITH LABS | **30MG** | **N74168 001** | MAR 03, 1995 |
| **AB** | | **60MG** | **N74168 002** | MAR 03, 1995 |
| **AB** | | **90MG** | **N74168 003** | MAR 03, 1995 |
| **AB** | | **120MG** | **N74168 004** | MAR 03, 1995 |

DIMENHYDRINATE

INJECTABLE; INJECTION
**DIMENHYDRINATE**

| | | | | |
|---|---|---|---|---|
| **AP** | STERIS | **50MG/ML** | **N83531 001** | |
| | @ | 50MG/ML | N83531 001 | |

DINOPROSTONE

INSERT, EXTENDED RELEASE; VAGINAL
CERVIDIL

| | | | |
|---|---|---|---|
| + CONTROLLED THERAP | 10MG | N20411 001 MAR 30, 1995 | |

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **DIPHENHYDRAMINE HCL** | | | |
| **AA** | WEST WARD PHARM | **50MG** | **N83567 001** | |
| @ | | 50MG | N83567 001 | |

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | **AKPRO** | | | |
| **AT** | AKORN | **0.1%** | **N74382 001** | SEP 29, 1995 |
| | **DIPIVEFRIN HCL** | | | |
| **AT** | BAUSCH AND LOMB | **0.1%** | **N74188 001** | MAY 19, 1995 |

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | DYNABAC | | | |
| + | LILLY | 250MG | N50678 001 | JUN 19, 1995 |

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL

| | | | | |
|---|---|---|---|---|
| | DEPAKOTE | | | |
| + | ABBOTT | EQ 125MG BASE | N19680 001 | SEP 12, 1989 |
| + | | EQ 125MG VALPROIC ACID | N19680 001 | SEP 12, 1989 |

TABLET, DELAYED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | DEPAKOTE | | | |
| | ABBOTT | EQ 125MG BASE | N18723 003 | OCT 26, 1984 |
| | | EQ 250MG BASE | N18723 001 | MAR 10, 1983 |
| + | | EQ 500MG BASE | N18723 002 | MAR 10, 1983 |
| | | EQ 125MG VALPROIC ACID | N18723 003 | OCT 26, 1984 |
| | | EQ 250MG VALPROIC ACID | N18723 001 | MAR 10, 1983 |

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | DEPAKOTE | | | |
| + | ABBOTT | EQ 500MG VALPROIC ACID | N18723 002 | MAR 10, 1983 |

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **DOBUTAMINE HCL** | | | |
| **AP** | ASTRA | **EQ 12.5MG BASE/ML** | **N74098 001** | FEB 21, 1995 |
| **AP** | SANOFI WINTHROP | **EQ 12.5MG BASE/ML** | **N74292 001** | FEB 16, 1995 |

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **DOPAMINE HCL IN DEXTROSE 5%** | | | |
| **AP** | + ABBOTT | **1.6MG/ML** | **N20542 001** | AUG 30, 1995 |
| | **INTROPIN** | | | |
| **AP** | + DUPONT MERCK | **40MG/ML** | **N17395 001** | |
| **AP** | + | **80MG/ML** | **N17395 002** | |
| **AP** | + | **160MG/ML** | **N17395 003** | |
| **AP** | + FAULDING | 40MG/ML | N17395 001 | |
| **AP** | + | 80MG/ML | N17395 002 | |
| **AP** | + | 160MG/ML | N17395 003 | |

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **DOXORUBICIN HCL** | | | |
| **AP** | FUJISAWA | **2MG/ML** | **N63277 001** | OCT 26, 1995 |
| **AP** | GENSIA | **2MG/ML** | **N64140 001** | JUL 28, 1995 |
| **AP** | | **200MG/100ML** | **N64140 002** | JUL 28, 1995 |
| **AP** | PHARMACHEMIE (NL) | **2MG/ML** | **N63336 001** | FEB 28, 1995 |
| **AP** | | **200MG/100ML** | **N63336 004** | FEB 28, 1995 |

> ADD >
> ADD >

DOXYCYCLINE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | DOXYCYCLINE MONOHYDRATE | | | |
| + | VINTAGE PHARMS | EQ 100MG BASE | | N50641 001 DEC 29, 1989 |
| | MONODOX | | | |
| > ADD > | OCLASSEN | EQ 50MG BASE | | N50641 002 FEB 10, 1992 |
| > ADD > | + | EQ 100MG BASE | | N50641 001 DEC 29, 1989 |

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **DOXYCYCLINE HYCLATE** | | | |
| **AB** | HALSEY | **EQ 50MG BASE** | | **N62119 002** MAY 24, 1985 |
| **AB** | | **EQ 100MG BASE** | | **N62119 001** MAY 24, 1985 |
| @ | | EQ 50MG BASE | | N62119 002 MAY 24, 1985 |
| @ | | EQ 100MG BASE | | N62119 001 MAY 24, 1985 |
| **AB** | PVT FORM | **EQ 50MG BASE** | | **N62631 001** JUL 24, 1986 |
| **AB** | | **EQ 100MG BASE** | | **N62631 002** JUL 24, 1986 |
| @ | | EQ 50MG BASE | | N62631 001 JUL 24, 1986 |
| @ | | EQ 100MG BASE | | N62631 002 JUL 24, 1986 |

DROPERIDOL

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **DROPERIDOL** | | | |
| **AP** | DUPONT MERCK | **2.5MG/ML** | | **N71645 001** APR 07, 1988 |
| **AP** | FAULDING | **2.5MG/ML** | | **N71645 001** APR 07, 1988 |
| **AP** | SANOFI WINTHROP | **2.5MG/ML** | | **N72272 001** AUG 31, 1995 |

EDETATE DISODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | SODIUM VERSENATE | | | |
| + | 3M | 200MG/ML | | N10573 001 |
| @ | | 200MG/ML | | N10573 001 |

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | VASERETIC | | | |
| | MERCK | 5MG;12.5MG | | N19221 003 JUL 12, 1995 |

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | FLOLAN | | | |
| + | GLAXO WELLCOME | EQ 0.5MG BASE/VIAL | | N20444 001 SEP 20, 1995 |
| + | | EQ 1.5MG BASE/VIAL | | N20444 002 SEP 20, 1995 |

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

| | | | | |
|---|---|---|---|---|
| | **ERYC** | | | |
| **AB** | FAULDING | **250MG** | | **N50536 001** |
| **AB** | + | **250MG** | | **N50536 001** |
| **AB** | + PARKE DAVIS | **250MG** | | **N62338 001** |
| **AB** | + | **250MG** | | **N62618 001** SEP 25, 1985 |
| @ | | 250MG | | N62338 001 |
| @ | | 250MG | | N62618 001 SEP 25, 1985 |

TABLET, DELAYED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | **ROBIMYCIN** | | | |
| **AB** | ROBINS AH | **250MG** | | **N61633 001** |
| @ | | 250MG | | N61633 001 |

ERYTHROMYCIN ESTOLATE

DROPS; ORAL

| | | | | |
|---|---|---|---|---|
| | ILOSONE | | | |
| + | DISTA | EQ 100MG BASE/ML | | N61894 003 |

ERYTHROMYCIN ESTOLATE

| | | | | |
|---|---|---|---|---|
| | SUSPENSION/DROPS; ORAL | | | |
| | ILOSONE | | | |
| | + DISTA | EQ 100MG BASE/ML | N61894 003 | |

ERYTHROMYCIN ETHYLSUCCINATE

| | | | | |
|---|---|---|---|---|
| | DROPS; ORAL | | | |
| | PEDIAMYCIN | | | |
| | + ROSS LABS | EQ 100MG BASE/2.5ML | N62305 002 | |
| | SUSPENSION; ORAL | | | |
| | **WYAMYCIN E** | | | |
| **AB** | WYETH AYERST | **EQ 200MG BASE/5ML** | **N62123 002** | |
| **AB** | | **EQ 400MG BASE/5ML** | **N62123 001** | |
| | @ | EQ 200MG BASE/5ML | N62123 002 | |
| | @ | EQ 400MG BASE/5ML | N62123 001 | |
| | SUSPENSION/DROPS; ORAL | | | |
| | PEDIAMYCIN | | | |
| | + ROSS LABS | EQ 100MG BASE/2.5ML | N62305 002 | |

ERYTHROMYCIN STEARATE

| | | | | |
|---|---|---|---|---|
| | TABLET; ORAL | | | |
| | **ETHRIL 250** | | | |
| **AB** | SQUIBB | **EQ 250MG BASE** | **N61605 001** | |
| | @ | EQ 250MG BASE | N61605 001 | |
| | **ETHRIL 500** | | | |
| **AB** | SQUIBB | **EQ 500MG BASE** | **N61605 002** | |
| | @ | EQ 500MG BASE | N61605 002 | |

ESTRADIOL

| | | | | |
|---|---|---|---|---|
| | FILM, EXTENDED RELEASE; TRANSDERMAL | | | |
| | CLIMARA | | | |
| BX | 3M | 0.05MG/24HR | N20375 001 DEC 22, 1994 | |
| BX | + | 0.05MG/24HR | N20375 001 DEC 22, 1994 | |
| BX | | 0.1MG/24HR | N20375 002 DEC 22, 1994 | |
| BX | + | 0.1MG/24HR | N20375 002 DEC 22, 1994 | |

ESTRADIOL

| | | | | |
|---|---|---|---|---|
| | FILM, EXTENDED RELEASE; TRANSDERMAL | | | |
| | VIVELLE | | | |
| BX | | 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 | |
| BX | + CIBA GEIGY | 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

| | | | | |
|---|---|---|---|---|
| | INJECTABLE; INJECTION | | | |
| | **DELESTROGEN** | | | |
| **AO** | + SQUIBB | **10MG/ML** | **N09402 002** | |
| | + | 10MG/ML | N09402 002 | |
| | **ESTRADIOL VALERATE** | | | |
| **AO** | STERIS | **10MG/ML** | **N83546 001** | |
| | @ | 10MG/ML | N83546 001 | |

ESTRONE

| | | | | |
|---|---|---|---|---|
| | INJECTABLE; INJECTION | | | |
| | ESTROGENIC SUBSTANCE | | | |
| BP | WYETH AYERST | 2MG/ML | N83488 001 | |
| BP | + | 2MG/ML | N83488 001 | |
| | THEELIN | | | |
| BP | + PARKE DAVIS | 2MG/ML | N03977 002 | |
| | @ | 2MG/ML | N03977 002 | |

ETHANOLAMINE OLEATE

| | | | | |
|---|---|---|---|---|
| | INJECTABLE; INJECTION | | | |
| | ETHAMOLIN | | | |
| | + REED AND CARNRICK | 50MG/ML | N19357 001 DEC 22, 1988 | |

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
+ SPKU 50MG/ML N19357 001 DEC 22, 1988

ETHINYL ESTRADIOL; FERROUS FUMARATE; NORETHINDRONE

TABLET; ORAL-28
NORQUEST FE
> ADD > @ SEARLE 0.035MG;75MG;1MG N18926 001 JUL 18, 1986
> DLT > @ SYNTEX 0.035MG;75MG;1MG N18926 001 JUL 18, 1986

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
**BREVICON 21-DAY**
> ADD > **AB** SEARLE **0.035MG;0.5MG** **N17566 001**
> DLT > **AB** SYNTEX **0.035MG;0.5MG** **N17566 001**
**NORINYL 1+35 21-DAY**
> ADD > **AB** SEARLE **0.035MG;1MG** **N17565 001**
> DLT > **AB** SYNTEX **0.035MG;1MG** **N17565 001**
OVCON-35
+ BRISTOL MYERS SQUIBB 0.035MG;0.4MG N18127 001
+ MEAD JOHNSON 0.035MG;0.4MG N18127 001
OVCON-50
@ BRISTOL MYERS SQUIBB 0.05MG;1MG N18128 001
+ MEAD JOHNSON 0.05MG;1MG N18128 001
TRI-NORINYL 21-DAY
> ADD > + SEARLE 0.035MG,0.035MG;0.5MG,1MG N18977 001 APR 13, 1984
> DLT > + SYNTEX 0.035MG,0.035MG;0.5MG,1MG N18977 001 APR 13, 1984

TABLET; ORAL-28
**BREVICON 28-DAY**
> ADD > **AB** SEARLE **0.035MG;0.5MG** **N17743 001**
> DLT > **AB** SYNTEX **0.035MG;0.5MG** **N17743 001**
**NORINYL 1+35 28-DAY**
> ADD > **AB** SEARLE **0.035MG;1MG** **N17565 002**
> DLT > **AB** SYNTEX **0.035MG;1MG** **N17565 002**
OVCON-35
BRISTOL MYERS SQUIBB 0.035MG;0.4MG N17716 001
MEAD JOHNSON 0.035MG;0.4MG N17716 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28
OVCON-50
BRISTOL MYERS SQUIBB 0.05MG;1MG N17576 001
MEAD JOHNSON 0.05MG;1MG N17576 001
TRI-NORINYL 28-DAY
> ADD > SEARLE 0.035MG,0.035MG;0.5MG,1MG N18977 002 APR 13, 1984
> DLT > SYNTEX 0.035MG,0.035MG;0.5MG,1MG N18977 002 APR 13, 1984

ETHOPROPAZINE HYDROCHLORIDE

TABLET; ORAL
PARSIDOL
PARKE DAVIS 10MG N09078 003
50MG N09078 006
+ 100MG N09078 008
@ 10MG N09078 003
@ 50MG N09078 006
@ 100MG N09078 008

ETOPOSIDE

INJECTABLE; INJECTION
**ETOPOSIDE**
**AP** ABBOTT **20MG/ML** **N74320 001** AUG 30, 1995
**AP** **20MG/ML** **N74351 001** AUG 30, 1995
**AP** BEN VENUE **20MG/ML** **N74290 001** JUL 17, 1995
**AP** GENSIA **20MG/ML** **N74510 001** JUN 29, 1995
**TOPOSAR**
**AP** PHARMACIA **20MG/ML** **N74166 001** FEB 27, 1995

FENOFIBRATE

CAPSULE; ORAL
LIPIDIL
+ LABS FOURNIER 100MG N19304 001 DEC 31, 1993

FENOFIBRATE

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | LIPIDIL | | | |
| | @ LABS FOURNIER | 100MG | N19304 001 | DEC 31, 1993 |

FLUDROCORTISONE ACETATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | FLORINEF | | | |
| + | APOTHECON | 0.1MG | N10060 001 | |
| + | SQUIBB | 0.1MG | N10060 001 | |

FLUNISOLIDE

SPRAY, METERED; NASAL

| | | | | |
|---|---|---|---|---|
| | NASALIDE | | | |
| BX + | SYNTEX | 0.025MG/INH | N18148 001 | |
| | NASAREL | | | |
| BX + | SYNTEX | 0.025MG/INH | N20409 001 | MAR 08, 1995 |

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINOLONE ACETONIDE** | | | |
| AT + | HAMILTON PHARMA CA | 0.01% | N12787 004 | |
| AT + | | 0.025% | N12787 002 | |
| AT + | | 0.025% | N12787 005 | |
| + | | 0.2% | N16161 002 | |
| | **SYNALAR** | | | |
| AT + | SYNTEX | 0.01% | N12787 004 | |
| AT + | | 0.025% | N12787 002 | |
| | SYNALAR-HP | | | |
| + | SYNTEX | 0.2% | N16161 002 | |
| | **SYNEMOL** | | | |
| AT + | SYNTEX | 0.025% | N12787 005 | |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINOLONE ACETONIDE** | | | |
| AT + | HAMILTON PHARMA CA | 0.025% | N13960 001 | |
| | **SYNALAR** | | | |
| AT + | SYNTEX | 0.025% | N13960 001 | |

SOLUTION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINOLONE ACETONIDE** | | | |
| AT + | HAMILTON PHARMA CA | 0.01% | N15296 001 | |

FLUOCINOLONE ACETONIDE

SOLUTION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINOLONE ACETONIDE** | | | |
| AT | PHARMADERM | 0.01% | N88048 001 | DEC 16, 1982 |
| | @ | 0.01% | N88048 001 | DEC 16, 1982 |
| | **SYNALAR** | | | |
| AT + | SYNTEX | 0.01% | N15296 001 | |

FLUOCINONIDE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINONIDE** | | | |
| AB + | HAMILTON PHARMA CA | 0.05% | N16908 002 | |
| | **FLUOCINONIDE EMOLLIENT BASE** | | | |
| AB | HAMILTON PHARMA CA | 0.05% | N16908 003 | |
| | **FLUOCINONIDE EMULSIFIED BASE** | | | |
| AB | NMC | 0.05% | N74204 001 | JUN 13, 1995 |
| | **LIDEX** | | | |
| AB + | SYNTEX | 0.05% | N16908 002 | |
| | **LIDEX-E** | | | |
| AB | SYNTEX | 0.05% | N16908 003 | |

GEL; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINONIDE** | | | |
| AB + | HAMILTON PHARMA CA | 0.05% | N17373 001 | |
| | **LIDEX** | | | |
| AB + | SYNTEX | 0.05% | N17373 001 | |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINONIDE** | | | |
| AB + | HAMILTON PHARMA CA | 0.05% | N16909 002 | |
| | **LIDEX** | | | |
| AB + | SYNTEX | 0.05% | N16909 002 | |

SOLUTION; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **FLUOCINONIDE** | | | |
| AT | FOUGERA | 0.05% | N72934 001 | FEB 27, 1995 |
| AT + | HAMILTON PHARMA CA | 0.05% | N18849 001 | APR 06, 1984 |
| | **LIDEX** | | | |
| AT + | SYNTEX | 0.05% | N18849 001 | APR 06, 1984 |

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | **PERMITIL** | | | | |
| AA | SCHERING | 5MG/ML | N16008 001 | > DLT > | |
| AA | + | 5MG/ML | N16008 001 | > DLT > | |
| | | | | > ADD > | |
| | | | | > ADD > | |

FLURBIPROFEN

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **FLURBIPROFEN** | | | |
| AB | GENEVA PHARMS | 50MG | N74448 001 | JUL 28, 1995 |
| AB | | 100MG | N74448 002 | JUL 28, 1995 |
| AB | LEMMON | 100MG | N74431 001 | MAY 31, 1995 |
| AB | NOVOPHARM | 50MG | N74405 002 | MAY 24, 1995 |
| AB | | 100MG | N74405 001 | MAY 24, 1995 |
| AB | ZENITH LABS | 50MG | N74411 001 | MAY 31, 1995 |
| AB | | 100MG | N74411 002 | MAY 31, 1995 |

FLURBIPROFEN SODIUM

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | **FLURBIPROFEN SODIUM** | | | |
| AT | BAUSCH AND LOMB | 0.03% | N74447 001 | JAN 04, 1995 |
| | **OCUFEN** | | | |
| AT | + ALLERGAN | 0.03% | N19404 001 | DEC 31, 1986 |

FOSINOPRIL SODIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | MONOPRIL | | | |
| | + BRISTOL MYERS SQUIBB | 20MG | N19915 003 | MAY 16, 1991 |
| | | 20MG | N19915 003 | MAY 16, 1991 |
| | + | 40MG | N19915 004 | MAR 28, 1995 |

GALLIUM NITRATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | GANITE | | | |
| | + FUJISAWA | 25MG/ML | N19961 002 | JAN 17, 1991 |
| | + SOLOPAK | 25MG/ML | N19961 002 | JAN 17, 1991 |

GEMFIBROZIL

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | **GEMFIBROZIL** | | | |
| AB | + MYLAN | 300MG | N73466 001 | JAN 25, 1993 |
| | @ | 300MG | N73466 001 | JAN 25, 1993 |
| AB | PUREPAC PHARM | 300MG | N72929 001 | JAN 29, 1993 |
| | @ | 300MG | N72929 001 | JAN 29, 1993 |
| | **LOPID** | | | |
| AB | + PARKE DAVIS | 300MG | N18422 002 | |
| | @ | 300MG | N18422 002 | |

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **GEMFIBROZIL** | | | |
| AB | CHELSEA LABS | 600MG | N74442 001 | APR 28, 1995 |
| AB | INVAMED | 600MG | N74615 001 | SEP 29, 1995 |
| AB | MYLAN | 600MG | N74452 001 | FEB 16, 1995 |

GENTAMICIN SULFATE

OINTMENT; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | **GENTAMICIN SULFATE** | | | |
| AT | ADV REMEDIES | EQ 0.3% BASE | N64093 001 | AUG 31, 1995 |

OINTMENT; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **GENTAMICIN SULFATE** | | | |
| AT | PHARMADERM | EQ 0.1% BASE | N62534 001 | OCT 10, 1984 |
| | @ | EQ 0.1% BASE | N62534 001 | OCT 10, 1984 |

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

| | | | |
|---|---|---|---|
| AT | ALCON | EQ 0.3% BASE | N62196 001 |

GLIPIZIDE

TABLET; ORAL
GLIPIZIDE

| | | | |
|---|---|---|---|
| AB | ALPHAPHARM | 5MG | N74438 001 JUN 20, 1995 |
| AB | | 10MG | N74438 002 JUN 20, 1995 |
| AB | BAKER NORTON | 5MG | N74497 001 AUG 31, 1995 |
| AB | | 10MG | N74497 002 AUG 31, 1995 |
| AB | GENEVA PHARMS | 5MG | N74305 001 APR 07, 1995 |
| AB | | 10MG | N74305 002 APR 07, 1995 |
| AB | INVAMED | 5MG | N74542 001 JUN 20, 1995 |
| AB | | 10MG | N74542 002 JUN 20, 1995 |
| AB | WATSON LABS | 5MG | N74223 001 FEB 27, 1995 |
| AB | | 10MG | N74223 002 FEB 27, 1995 |

GLYBURIDE

TABLET; ORAL
GLUBATE

| | | | |
|---|---|---|---|
| @ | HOECHST ROUSSEL | 1.5MG | N20055 001 APR 17, 1992 |
| @ | | 3MG | N20055 002 APR 17, 1992 |

GLYBURIDE

| | | | |
|---|---|---|---|
| AB | NOVOPHARM | 1.25MG | N74388 001 AUG 29, 1995 |
| AB | | 2.5MG | N74388 002 AUG 29, 1995 |
| AB | | 5MG | N74388 003 AUG 29, 1995 |

GLYBURIDE

TABLET; ORAL
GLYBURIDE (MICRONIZED)

| | | | |
|---|---|---|---|
| AB | HOECHST ROUSSEL | 1.5MG | N20055 001 APR 17, 1992 |
| AB | | 3MG | N20055 002 APR 17, 1992 |

GLYNASE

| | | | |
|---|---|---|---|
| AB | UPJOHN | 1.5MG | N20051 001 MAR 04, 1992 |
| AB | | 3MG | N20051 002 MAR 04, 1992 |

MICRONASE

| | | | |
|---|---|---|---|
| AB | UPJOHN | 1.25MG | N17498 001 MAY 01, 1984 |
| AB | | 2.5MG | N17498 002 MAY 01, 1984 |
| AB + | | 5MG | N17498 003 MAY 01, 1984 |

GLYCINE

SOLUTION; IRRIGATION
GLYCINE 1.5% IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | BAXTER | 1.5GM/100ML | N18522 001 FEB 19, 1982 |
| @ | | 1.5GM/100ML | N18522 001 FEB 19, 1982 |

GRANISETRON HYDROCHLORIDE

TABLET; ORAL
KYTRIL

| | | | |
|---|---|---|---|
| + | SMITHKLINE BEECHAM | EQ 1MG BASE | N20305 001 MAR 16, 1995 |

GUANABENZ ACETATE

TABLET; ORAL
GUANABENZ ACETATE

| | | | |
|---|---|---|---|
| AB | ZENITH LABS | EQ 4MG BASE | N74149 001 APR 07, 1995 |
| AB | | EQ 8MG BASE | N74149 002 APR 07, 1995 |

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

| | | | | | | |
|---|---|---|---|---|---|---|
| > ADD > | | **GUANFACINE HCL** | | | | |
| > ADD > | **AB** | WATSON LABS | **EQ 1MG BASE** | **N74145 001** OCT 17, 1995 | | |
| > ADD > | | | | | | |
| > ADD > | **AB** | | **EQ 2MG BASE** | **N74145 002** OCT 17, 1995 | | |
| > ADD > | | | | | | |
| | | **TENEX** | | | | |
| > ADD > | **AB** | ROBINS AH | **EQ 1MG BASE** | **N19032 001** OCT 27, 1986 | | |
| > ADD > | | | | | | |
| > ADD > | **AB** | + | **EQ 2MG BASE** | **N19032 002** NOV 07, 1988 | | |
| > ADD > | | | | | | |
| > DLT > | | | EQ 1MG BASE | N19032 001 OCT 27, 1986 | | |
| > DLT > | | | | | | |
| > DLT > | | + | EQ 2MG BASE | N19032 002 NOV 07, 1988 | > ADD > | |
| > DLT > | | | | | > ADD > | |
| | | @ | 3MG | N19032 003 NOV 07, 1988 | | |
| | | @ | EQ 3MG BASE | N19032 003 NOV 07, 1988 | | |

HALCINONIDE

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | **HALOG** | | | |
| **AT** | + WESTWOOD SQUIBB | **0.1%** | **N17556 001** | |
| | + | 0.1% | N17556 001 | |
| | **HALOG-E** | | | |
| **AT** | WESTWOOD SQUIBB | **0.1%** | **N18234 001** | |
| | | 0.1% | N18234 001 | |

HEPARIN CALCIUM

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | CALCIPARINE | | |
| | + CHOAY | 25,000 UNITS/ML | N18237 001 |
| | @ SANOFI WINTHROP | 25,000 UNITS/ML | N18237 001 |

HEPARIN SODIUM

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **HEPARIN LOCK FLUSH** | | |
| **AP** | SANOFI WINTHROP | **10 UNITS/ML** | **N40082 001** FEB 28, 1995 |

HEPARIN SODIUM

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **HEPARIN LOCK FLUSH** | | |
| **AP** | SANOFI WINTHROP | **100 UNITS/ML** | **N40082 002** FEB 28, 1995 |
| | **HEPARIN SODIUM** | | |
| **AP** | + ABBOTT | **2,500 UNITS/ML** | **N05264 014** APR 07, 1986 |
| | + | 2,000 UNITS/ML | N05264 013 APR 07, 1986 |
| **AP** | ELKINS SINN | **10,000 UNITS/ML** | **N17037 013** APR 07, 1986 |
| **AP** | | **5,000 UNITS/0.5ML** | **N17037 013** APR 07, 1986 |
| **AP** | MARSAM | **1,000 UNITS/ML** | **N40008 001** OCT 10, 1995 |
| **AP** | PHARMA SERVE NY | **1,000 UNITS/ML** | **N86129 001** |
| **AP** | WYETH AYERST | **2,500 UNITS/ML** | **N17007 007** |
| **AP** | + | **2,500 UNITS/ML** | **N17007 007** |
| | **HEPARIN SODIUM 1000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER** | | |
| **AP** | MCGAW | **200 UNITS/100ML** | **N19130 001** DEC 31, 1984 |
| | @ | 200 UNITS/100ML | N19130 001 DEC 31, 1984 |
| | **HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER** | | |
| **AP** | MCGAW | **200 UNITS/100ML** | **N19042 001** MAR 29, 1985 |
| | @ | 200 UNITS/100ML | N19042 001 MAR 29, 1985 |
| | **HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER** | | |
| **AP** | ABBOTT | **5,000 UNITS/100ML** | **N18916 006** JAN 31, 1984 |
| | | 5,000 UNITS/100ML | N18916 006 JAN 31, 1984 |
| | **HEPARIN SODIUM 12500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER** | | |
| **AP** | MCGAW | **5,000 UNITS/100ML** | **N19802 001** JUL 20, 1992 |
| | @ | 5,000 UNITS/100ML | N19802 001 JUL 20, 1992 |
| | **HEPARIN SODIUM 2000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER** | | |
| **AP** | MCGAW | **200 UNITS/100ML** | **N19130 003** DEC 31, 1984 |

HEPARIN SODIUM

INJECTABLE; INJECTION

**HEPARIN SODIUM 2000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| @ | MCGAW | 200 UNITS/100ML | N19130 003 | DEC 31, 1984 |

**HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| **AP** | MCGAW | **200 UNITS/100ML** | **N19042 002** | MAR 29, 1985 |
| @ | | 200 UNITS/100ML | N19042 002 | MAR 29, 1985 |

**HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| **AP** | ABBOTT | **5,000 UNITS/100ML** | **N18916 007** | JAN 31, 1984 |
| **AP** | | **10,000 UNITS/100ML** | **N18916 008** | JAN 31, 1984 |
| | | 5,000 UNITS/100ML | N18916 007 | JAN 31, 1984 |
| | | 10,000 UNITS/100ML | N18916 008 | JAN 31, 1984 |

**HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| **AP** | MCGAW | **5,000 UNITS/100ML** | **N19802 005** | JUL 20, 1992 |
| **AP** | | **10,000 UNITS/100ML** | **N19802 002** | JUL 20, 1992 |
| @ | | 5,000 UNITS/100ML | N19802 005 | JUL 20, 1992 |
| @ | | 10,000 UNITS/100ML | N19802 002 | JUL 20, 1992 |

**HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| | MCGAW | 5,000 UNITS/100ML | N19802 003 | JUL 20, 1992 |
| @ | | 5,000 UNITS/100ML | N19802 003 | JUL 20, 1992 |

**HEPARIN SODIUM 5000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER**

| | | | | |
|---|---|---|---|---|
| **AP** | MCGAW | **1,000 UNITS/100ML** | **N19130 002** | DEC 31, 1984 |
| @ | | 1,000 UNITS/100ML | N19130 002 | DEC 31, 1984 |

**HEPARIN SODIUM PRESERVATIVE FREE**

| | | | | |
|---|---|---|---|---|
| **AP** | + ABBOTT | **2,500 UNITS/ML** | **N05264 014** | APR 07, 1986 |

HEPARIN SODIUM

INJECTABLE; INJECTION

**HEPARIN SODIUM PRESERVATIVE FREE**

| | | | | |
|---|---|---|---|---|
| | + ABBOTT | 2,000 UNITS/ML | N05264 013 | APR 07, 1986 |
| **AP** | FUJISAWA | **1,000 UNITS/ML** | **N17029 010** | APR 28, 1986 |
| **AP** | + | **1,000 UNITS/ML** | **N17029 010** | APR 28, 1986 |
| **AP** | PHARMA SERVE NY | **1,000 UNITS/ML** | **N86129 001** | |
| **AP** | STERLING WINTHROP | **10,000 UNITS/ML** | **N89522 001** | MAY 04, 1987 |
| **AP** | + | **10,000 UNITS/ML** | **N89522 001** | MAY 04, 1987 |

**LIQUAEMIN LOCK FLUSH**

| | | | | |
|---|---|---|---|---|
| **AP** | ORGANON | **100 UNITS/ML** | **N00552 007** | |
| @ | | 100 UNITS/ML | N00552 007 | |

**LIQUAEMIN SODIUM**

| | | | | |
|---|---|---|---|---|
| **AP** | ORGANON | **1,000 UNITS/ML** | **N00552 004** | |
| **AP** | | **5,000 UNITS/ML** | **N00552 003** | |
| **AP** | | **10,000 UNITS/ML** | **N00552 005** | |
| @ | | 1,000 UNITS/ML | N00552 004 | |
| @ | | 5,000 UNITS/ML | N00552 003 | |
| @ | | 10,000 UNITS/ML | N00552 005 | |

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

**DRALZINE**

| | | | | |
|---|---|---|---|---|
| **AA** | LEMMON | **25MG** | **N84301 001** | |
| @ | | 25MG | N84301 001 | |

**HYDRALAZINE HCL**

| | | | | |
|---|---|---|---|---|
| **AA** | HALSEY | **50MG** | **N89222 001** | JAN 22, 1986 |
| @ | | 50MG | N89222 001 | JAN 22, 1986 |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

APRESOLINE-ESIDRIX

| | | | | |
|---|---|---|---|---|
| | + CIBA | 25MG;15MG | N12026 002 | |
| @ | | 25MG;15MG | N12026 002 | |

## HYDROCHLOROTHIAZIDE

TABLET; ORAL

| | | | | | |
|---|---|---|---|---|---|
| | **HYDROCHLOROTHIAZIDE** | | | | |
| **AB** | ASCOT | **50MG** | **N87540 001** | > DLT > | |
| | | | **FEB 03, 1982** | > DLT > | |
| | @ | 50MG | N87540 001 | > ADD > | |
| | | | FEB 03, 1982 | > ADD > | |
| **AB** | INWOOD LABS | **25MG** | **N85067 001** | | |
| | @ | 25MG | N85067 001 | | |

## HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

| | | | |
|---|---|---|---|
| | HYZAAR | | |
| + | MERCK | 12.5MG;50MG | N20387 001<br>APR 28, 1995 |

## HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | LOPRESSOR HCT | | |
| | CIBA | 25MG;50MG | N18303 001<br>DEC 31, 1984 |
| | | 25MG;100MG | N18303 002<br>DEC 31, 1984 |
| + | | 50MG;100MG | N18303 003<br>DEC 31, 1984 |
| | **LOPRESSOR HCT 100/25** | | |
| | **CIBA** | **25MG;100MG** | **N18303 002**<br>**DEC 31, 1984** |
| | **LOPRESSOR HCT 100/50** | | |
| + | **CIBA** | **50MG;100MG** | **N18303 003**<br>**DEC 31, 1984** |
| | **LOPRESSOR HCT 50/25** | | |
| | **CIBA** | **25MG;50MG** | **N18303 001**<br>**DEC 31, 1984** |

## HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE** | | |
| **AB** | **WARNER CHILCOTT** | **25MG;80MG** | **N71772 001**<br>**JAN 26, 1988** |
| | @ | 25MG;80MG | N71772 001<br>JAN 26, 1988 |

## HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | DYAZIDE | | |
| | SMITHKLINE BEECHAM | 25MG;37.5MG | N16042 003<br>MAR 03, 1994 |
| + | | 25MG;37.5MG | N16042 003<br>MAR 03, 1994 |
| | **TRIAMTERENE AND HYDROCHLOROTHIAZIDE** | | |
| **AB** | ZENITH LABS | **25MG;50MG** | **N74259 001**<br>MAR 30, 1995 |

## HYDROCORTISONE

CREAM; TOPICAL

| | | | |
|---|---|---|---|
| | **FLEXICORT** | | |
| **AT** | **WESTWOOD SQUIBB** | **0.5%** | **N87136 003**<br>**APR 08, 1982** |
| **AT** | | **1%** | **N87136 002**<br>**APR 08, 1982** |
| **AT** | | **2.5%** | **N87136 001**<br>**APR 08, 1982** |
| | @ | 0.5% | N87136 003<br>APR 08, 1982 |
| | @ | 1% | N87136 002<br>APR 08, 1982 |
| | @ | 2.5% | N87136 001<br>APR 08, 1982 |
| | **HYDROCORTISONE** | | |
| **AT** | **CLAY PARK** | **0.5%** | **N84970 002** |
| **AT** | | **1%** | **N85026 001** |
| | @ | 0.5% | N84970 002 |
| | @ | 1% | N85026 001 |

ENEMA; RECTAL

| | | | |
|---|---|---|---|
| | CORTENEMA | | |
| | | **100MG/60ML** | **N16199 001** |
| BR + | SOLVAY | 100MG/60ML | N16199 001 |
| | HYDROCORTISONE | | |
| BR | COPLEY PHARM | 100MG/60ML | N74171 001<br>MAY 27, 1994 |
| | @ | 100MG/60ML | N74171 001<br>MAY 27, 1994 |

LOTION; TOPICAL

| | | | |
|---|---|---|---|
| | **HYDROCORTISONE** | | |
| **AT** | **CLAY PARK** | **0.5%** | **N85662 001** |
| | @ | 0.5% | N85662 001 |

HYDROCORTISONE

OINTMENT; TOPICAL
HYDROCORTISONE

| | | | | |
|---|---|---|---|---|
| | | CLAY PARK | 0.5% | N84969 003 |
| | @ | | 0.5% | N84969 003 |

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC
CORTISPORIN

| | | | | |
|---|---|---|---|---|
| AT | + | BURROUGHS WELLCOME | 10.1MG/ML;EQ 3.5MG BASE/ML; 12,000 UNITS/ML | N50479 001 |
| AT | + | GLAXO WELLCOME | 1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML | N50479 001 |

HYDROCORTISONE; UREA

CREAM; TOPICAL
ALPHADERM

| | | | | |
|---|---|---|---|---|
| AT | | VIVAN | 1%;10% | N86008 001 |
| | @ | | 1%;10% | N86008 001 |

CALMURID HC

| | | | | |
|---|---|---|---|---|
| AT | + | PHARMACIA | 1%;10% | N83947 001 |
| | @ | | 1%;10% | N83947 001 |

HYDROCORTISONE ACETATE

AEROSOL; RECTAL
CORTIFOAM

| | | | | |
|---|---|---|---|---|
| | + | REED AND CARNRICK | 10% | N17351 001 FEB 10, 1982 |
| | + | SPKU | 10% | N17351 001 FEB 10, 1982 |

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL
EPIFOAM

| | | | | |
|---|---|---|---|---|
| > DLT > | BX | REED AND CARNRICK | 1%;1% | N86457 001 |
| > ADD > | BX | SPKU | 1%;1% | N86457 001 |

PROCTOFOAM HC

| | | | |
|---|---|---|---|
| BX | REED AND CARNRICK | 1%;1% | N86195 001 |
| BX | SPKU | 1%;1% | N86195 001 |

HYDROCORTISONE BUTYRATE

OINTMENT; TOPICAL
LOCOID

| | | | |
|---|---|---|---|
| @ | YAMANOUCHI | 0.1% | N18652 001 OCT 29, 1982 |
| + | | 0.1% | N18652 001 OCT 29, 1982 |

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION
DILAUDID-HP

| | | | | |
|---|---|---|---|---|
| AP | + | KNOLL PHARM | 10MG/ML | N19034 001 JAN 11, 1984 |

HYDROMORPHONE HCL

| | | | | |
|---|---|---|---|---|
| AP | | STERIS | 10MG/ML | N74317 001 AUG 23, 1995 |

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
HYDROXYPROGESTERONE CAPROATE

| | | | | |
|---|---|---|---|---|
| | + | AKORN | 125MG/ML | N18004 001 |
| | @ | | 125MG/ML | N18004 001 |

HYDROXYUREA

CAPSULE; ORAL
HYDREA

| | | | | |
|---|---|---|---|---|
| AB | + | SQUIBB | 500MG | N16295 001 |

HYDROXYUREA

| | | | | |
|---|---|---|---|---|
| AB | | ROXANE | 500MG | N74476 001 AUG 18, 1995 |

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

| | | | | |
|---|---|---|---|---|
| AP | | PHARMAFAIR | 50MG/ML | N88881 001 FEB 14, 1986 |
| | @ | | 50MG/ML | N88881 001 FEB 14, 1986 |
| AP | | STERIS | 25MG/ML | N87274 001 |
| AP | | | 50MG/ML | N87274 002 |

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
@ STERIS 25MG/ML N87274 001
@ 50MG/ML N87274 002

SYRUP; ORAL
HYDROXYZINE HCL
AA BARRE 10MG/5ML N88785 001 FEB 03, 1988
@ 10MG/5ML N88785 001 FEB 03, 1988

TABLET; ORAL
HYDROXYZINE HCL
AB HALSEY 50MG N89396 001 MAY 02, 1988
@ 50MG N89396 001 MAY 02, 1988
AB SIDMAK LABS NJ 100MG N81054 001 SEP 25, 1995

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S MOTRIN
BX + MCNEIL CONS PRODS 100MG/5ML N19842 001 SEP 19, 1989
PEDIA PROFEN
BX + MCNEIL CONS PRODS 100MG/5ML N19842 001 SEP 19, 1989

SUSPENSION/DROPS; ORAL
MOTRIN
+ MCNEIL CONS PRODS 40MG/ML N20476 001 MAY 25, 1995

INDAPAMIDE

TABLET; ORAL
INDAPAMIDE
AB ZENITH LABS 2.5MG N74299 001 JUL 27, 1995
LOZOL
AB + RHONE POULENC RORER 2.5MG N18538 001 JUL 06, 1983

INDECAINIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
DECABID
LILLY EQ 50MG BASE N19693 001 DEC 29, 1989
EQ 75MG BASE N19693 002 DEC 29, 1989
+ EQ 100MG BASE N19693 003 DEC 29, 1989
@ EQ 50MG BASE N19693 001 DEC 29, 1989
@ EQ 75MG BASE N19693 002 DEC 29, 1989
@ EQ 100MG BASE N19693 003 DEC 29, 1989

INULIN

INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE
+ CYPROS 100MG/ML N02282 001
+ ISO TEX 100MG/ML N02282 001

IOCETAMIC ACID

TABLET; ORAL
CHOLEBRINE
+ MALLINCKRODT 750MG N17129 001
@ 750MG N17129 001

IOHEXOL

SOLUTION; INJECTION, ORAL
OMNIPAQUE 350
NYCOMED 75.5% N20608 003 OCT 24, 1995

SOLUTION; INJECTION, ORAL, RECTAL
OMNIPAQUE 240
NYCOMED 51.8% N20608 001 OCT 24, 1995
OMNIPAQUE 300
NYCOMED 64.7% N20608 002 OCT 24, 1995

IOPAMIDOL

INJECTABLE; INTRAVASCULAR
ISOVUE-200
@ BRACCO 41% N20327 001 OCT 12, 1994

BRACCO DXS 41% N20327 001 OCT 12, 1994

IOPROMIDE

INJECTABLE; INJECTION
ULTRAVIST
+ BERLEX EQ 150MG IODINE/ML N20220 004 MAY 10, 1995 >ADD>
+ EQ 240MG IODINE/ML N20220 003 MAY 10, 1995 >ADD>
+ EQ 300MG IODINE/ML N20220 002 MAY 10, 1995 >ADD>
+ EQ 370MG IODINE/ML N20220 001 MAY 10, 1995 >ADD>

IOTHALAMATE SODIUM

INJECTABLE; INJECTION
ANGIO-CONRAY
+ MALLINCKRODT 80% N13319 001
@ 80% N13319 001

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
GLOFIL-125
CYPROS 250-300 uCi/ML N17279 001
ISO TEX 250-300 uCi/ML N17279 001

IOTROLAN

INJECTABLE; INTRATHECAL
OSMOVIST
@ BERLEX EQ 190MG IODINE/ML N19580 001 DEC 07, 1989

@ EQ 240MG IODINE/ML N19580 002 DEC 07, 1989

IOTROLAN

INJECTABLE; INTRATHECAL
OSMOVIST
BERLEX EQ 190MG IODINE/ML N19580 001 DEC 07, 1989

EQ 240MG IODINE/ML N19580 002 DEC 07, 1989

IPRATROPIUM BROMIDE

>ADD> SPRAY, METERED; NASAL
>ADD> ATROVENT
>ADD> + BOEHRINGER INGELHEIM 0.021MG/INH N20393 001 OCT 20, 1995
>ADD> + 0.042MG/INH N20394 001 OCT 20, 1995

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL S/F
**AN** + DEY **1%** **N89252 001** SEP 15, 1986

@ 1% N89252 001 SEP 15, 1986

ISOFLURANE

LIQUID; INHALATION
ISOFLURANE
**AN** MARSAM **99.9%** **N74393 001** MAY 12, 1995

**AN** RHONE POULENC **99.9%** **N74502 001** JUN 27, 1995

ISOSORBIDE DINITRATE

CAPSULE, EXTENDED RELEASE; ORAL
DILATRATE-SR
BC REED AND CARNRICK 40MG N19790 001 SEP 02, 1988

BC SPKU 40MG N19790 001 SEP 02, 1988

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | IMDUR | | | |
| | @ SCHERING | 30MG | N20225 001 | AUG 12, 1993 |
| | + | 60MG | N20225 002 | AUG 12, 1993 |
| | + | 120MG | N20225 003 | MAR 30, 1995 |
| | @ SCHERING PLOUGH | 30MG | N20225 001 | AUG 12, 1993 |
| | + | 60MG | N20225 002 | AUG 12, 1993 |

KANAMYCIN SULFATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **KANAMYCIN** | | | |
| **AP** | ELKINS SINN | **EQ 75MG BASE/2ML** | **N62324 001** | |
| **AP** | | **EQ 500MG BASE/2ML** | **N62324 002** | |
| **AP** | | **EQ 1GM BASE/3ML** | **N62324 003** | |
| | @ | EQ 75MG BASE/2ML | N62324 001 | |
| | @ | EQ 500MG BASE/2ML | N62324 002 | |
| | @ | EQ 1GM BASE/3ML | N62324 003 | |

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | ORUVAIL | | | |
| | + WYETH AYERST | 100MG | N19816 003 | FEB 08, 1995 |
| | + | 150MG | N19816 002 | FEB 08, 1995 |

LACTULOSE

SOLUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | **LACTULOSE** | | | |
| **AA** | HI TECH PHARMA | **10GM/15ML** | **N74076 001** | JUL 03, 1995 |

SOLUTION; ORAL, RECTAL

| | | | | |
|---|---|---|---|---|
| | **LACTULOSE** | | | |
| **AA** | HI TECH PHARMA | **10GM/15ML** | **N74077 001** | JUL 03, 1995 |

LANSOPRAZOLE

CAPSULE, DELAYED REL GRANULES; ORAL

| | | | | |
|---|---|---|---|---|
| | PREVACID | | | |
| | TAP HOLDINGS | 15MG | N20406 001 | MAY 10, 1995 |
| | + | 30MG | N20406 002 | MAY 10, 1995 |

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | LEUCOVORIN CALCIUM | | | |
| | + CETUS BEN VENUE | EQ 200MG BASE/VIAL | N40056 001 | MAY 23, 1995 |
| | **WELLCOVORIN** | | | |
| **AP** | BURROUGHS WELLCOME | **EQ 50MG BASE/VIAL** | **N89465 001** | JAN 23, 1989 |
| | + | EQ 25MG BASE/VIAL | N89833 001 | JAN 23, 1989 |
| | @ GLAXO WELLCOME | EQ 25MG BASE/VIAL | N89833 001 | JAN 23, 1989 |
| | @ | EQ 50MG BASE/VIAL | N89465 001 | JAN 23, 1989 |

LEUPROLIDE ACETATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | LUPRON | | | |
| | TAP HOLDINGS | 5MG/ML | N20263 001 | APR 16, 1993 |
| | + | 1MG/0.2ML | N19010 001 | APR 09, 1985 |
| | + TAP PHARMS | 5MG/ML | N19010 001 | APR 09, 1985 |

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **LIDOCAINE HCL** | | | |
| **AP** | AKORN | **1%** | **N85037 001** | |
| **AP** | | **2%** | **N85037 002** | |
| | @ | 1% | N85037 001 | |
| | @ | 2% | N85037 002 | |
| **AP** | FUJISAWA | **2%** | **N80420 004** | |
| | @ | 2% | N80420 004 | |

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL

| | | | |
|---|---|---|---|
| AP | SANOFI WINTHROP | 1% | N40013 001<br>JUN 23, 1995 |
| AP | | 2% | N40078 001<br>JUN 23, 1995 |

SOLUTION; ORAL
LIDOCAINE HCL

| | | | |
|---|---|---|---|
| AT | HI TECH PHARMA | 2% | N40014 001<br>JUL 10, 1995 |

LINDANE

LOTION; TOPICAL
SCABENE

| | | | |
|---|---|---|---|
| AT | STIEFEL | 1% | N86769 001 |
| | @ | 1% | N86769 001 |

SHAMPOO; TOPICAL
SCABENE

| | | | |
|---|---|---|---|
| AT | STIEFEL | 1% | N87940 001<br>APR 08, 1983 |
| | @ | 1% | N87940 001<br>APR 08, 1983 |

LISINOPRIL

TABLET; ORAL
PRINIVIL

| | | | |
|---|---|---|---|
| AB | MERCK | 2.5MG | N19558 006<br>JAN 28, 1994 |
| | | 2.5MG | N19558 006<br>JAN 28, 1994 |

ZESTRIL

| | | | |
|---|---|---|---|
| AB | ZENECA | 2.5MG | N19777 005<br>APR 29, 1993 |
| | @ | 2.5MG | N19777 005<br>APR 29, 1993 |

LITHIUM CARBONATE

TABLET; ORAL
LITHOTABS

| | | | |
|---|---|---|---|
| AB | SOLVAY | 300MG | N16980 001 |

LITHIUM CARBONATE

TABLET; ORAL
LITHOTABS

| | | | |
|---|---|---|---|
| AB | + SOLVAY | 300MG | N16980 001 |

TABLET, EXTENDED RELEASE; ORAL
LITHOBID

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

LOSARTAN POTASSIUM

TABLET; ORAL
COZAAR

| | | | |
|---|---|---|---|
| | MERCK | 25MG | N20386 001<br>APR 14, 1995 |
| | + | 50MG | N20386 002<br>APR 14, 1995 |

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

SOLUTION; IRRIGATION
PHYSIOLYTE IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | MCGAW | 30MG/100ML;37MG/100ML;370MG/100ML;<br>530MG/100ML;500MG/100ML | N19024 001<br>JUN 08, 1984 |
| | | 30MG/100ML;37MG/100ML;370MG/100ML;<br>530MG/100ML;500MG/100ML | N19024 001<br>JUN 08, 1984 |

PHYSIOSOL IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | ABBOTT | 30MG/100ML;37MG/100ML;222MG/100ML;<br>526MG/100ML;502MG/100ML | N17637 002<br>JUL 08, 1982 |
| | | 30MG/100ML;37MG/100ML;222MG/100ML;<br>526MG/100ML;502MG/100ML | N17637 002<br>JUL 08, 1982 |

SYNOVALYTE IN PLASTIC CONTAINER

| | | | |
|---|---|---|---|
| AT | BAXTER | 30MG/100ML;37MG/100ML;368MG/100ML;<br>526MG/100ML;502MG/100ML | N19326 001<br>JAN 25, 1985 |
| | @ | 30MG/100ML;37MG/100ML;368MG/100ML;<br>526MG/100ML;502MG/100ML | N19326 001<br>JAN 25, 1985 |

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER

| | | | | |
|---|---|---|---|---|
| | ABBOTT | 1GM/100ML | N20488 001 | |
| | | | JUL 11, 1995 | |
| + | | 2GM/100ML | N20488 002 | |
| | | | JUL 11, 1995 | |

MANNITOL

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **MANNITOL 10%** | | | |
| AP | ABBOTT | 10GM/100ML | N16269 002 | |
| @ | | 10GM/100ML | N16269 002 | |
| | **MANNITOL 15%** | | | |
| AP | ABBOTT | 15GM/100ML | N16269 003 | |
| @ | | 15GM/100ML | N16269 003 | |
| | **MANNITOL 20%** | | | |
| AP | ABBOTT | 20GM/100ML | N16269 004 | |
| @ | | 20GM/100ML | N16269 004 | |
| | **MANNITOL 25%** | | | |
| AP | ABBOTT | 12.5GM/50ML | N16269 005 | |
| AP | | 12.5GM/50ML | N16269 006 | |
| | | | AUG 25, 1994 | |
| @ | | 12.5GM/50ML | N16269 005 | |
| | **MANNITOL 5%** | | | >ADD> |
| AP | ABBOTT | 5GM/100ML | N16269 001 | >DLT> |
| @ | | 5GM/100ML | N16269 001 | |

MASOPROCOL

CREAM; TOPICAL

| | | | | |
|---|---|---|---|---|
| | ACTINEX | | | |
| + | BLOCK DRUG | 10% | N19940 001 | |
| | | | SEP 04, 1992 | |
| + | SPKU | 10% | N19940 001 | |
| | | | SEP 04, 1992 | |

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

| | | | | |
|---|---|---|---|---|
| | **MEBENDAZOLE** | | | |
| AB | COPLEY PHARM | 100MG | N73580 001 | |
| | | | JAN 04, 1995 | |
| | **VERMOX** | | | |
| AB + | JANSSEN | 100MG | N17481 001 | |

MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION
DEPO-PROVERA

| | | | |
|---|---|---|---|
| + | UPJOHN | 100MG/ML | N12541 002 |
| @ | | 100MG/ML | N12541 002 |

MEGESTROL ACETATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **MEGACE** | | |
| AB | BRISTOL MYERS SQUIBB | 20MG | N16979 001 |
| AB + | | 40MG | N16979 002 |
| AB | MEAD JOHNSON | 20MG | N16979 001 |
| AB + | | 40MG | N16979 002 |
| | **MEGESTROL ACETATE** | | |
| AB | ROXANE | 20MG | N74458 001 |
| | | | SEP 29, 1995 |
| AB | | 40MG | N74458 002 |
| | | | SEP 29, 1995 |

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21
NORINYL 1+80 21-DAY

| | | | |
|---|---|---|---|
| @ | SEARLE | 0.08MG;1MG | N16724 001 |
| @ | SYNTEX | 0.08MG;1MG | N16724 001 |

TABLET; ORAL-28
NORINYL 1+80 28-DAY

| | | | |
|---|---|---|---|
| @ | SEARLE | 0.08MG;1MG | N16725 001 |
| @ | SYNTEX | 0.08MG;1MG | N16725 001 |

METAPROTERENOL SULFATE

SOLUTION; INHALATION

| | | | |
|---|---|---|---|
| | **METAPROTERENOL SULFATE** | | |
| AN | BARRE | 0.4% | N71855 001 |
| | | | JUL 14, 1988 |
| AN | | 0.6% | N71726 001 |
| | | | JUL 14, 1988 |
| AN | PACO | 0.4% | N71855 001 |
| | | | JUL 14, 1988 |
| AN | | 0.6% | N71726 001 |
| | | | JUL 14, 1988 |

METAPROTERENOL SULFATE

SYRUP; ORAL
ALUPENT

| | | | | |
|---|---|---|---|---|
| AA | | BOEHRINGER INGELHEIM | 10MG/5ML | N17571 001 |
| AA | + | | 10MG/5ML | N17571 001 |

METFORMIN HYDROCHLORIDE

TABLET; ORAL
GLUCOPHAGE

| | | | | |
|---|---|---|---|---|
| | | BRISTOL MYERS SQUIBB | 500MG | N20357 001<br>DEC 29, 1994 |
| | + | | 850MG | N20357 002<br>DEC 29, 1994 |
| | | LIPHA | 500MG | N20357 001<br>DEC 29, 1994 |
| | + | | 850MG | N20357 002<br>DEC 29, 1994 |

METHADONE HYDROCHLORIDE

POWDER; FOR RX COMPOUNDING
METHADONE HCL

| | | | |
|---|---|---|---|
| MALLINCKRODT | 50GM/BOT | N06383 002 |
| | 100GM/BOT | N06383 003 |
| | 500GM/BOT | N06383 004 |

TABLET, DISPERSIBLE; ORAL
METHADONE HCL

| | | | |
|---|---|---|---|
| AA | ROXANE | 40MG | N74081 001<br>APR 28, 1995 |

METHICILLIN SODIUM

INJECTABLE; INJECTION
STAPHCILLIN

| | | | |
|---|---|---|---|
| @ | APOTHECON | EQ 900MG BASE/VIAL | N50117 001 |
| @ | | EQ 3.6GM BASE/VIAL | N50117 002 |
| @ | | EQ 5.4GM BASE/VIAL | N50117 003 |
| @ | BRISTOL | EQ 900MG BASE/VIAL | N50117 001 |
| @ | | EQ 3.6GM BASE/VIAL | N50117 002 |
| @ | | EQ 5.4GM BASE/VIAL | N50117 003 |

METHOTRIMEPRAZINE

INJECTABLE; INJECTION
LEVOPROME

| | | | |
|---|---|---|---|
| + | IMMUNEX | 20MG/ML | N15865 001 |
| + | LEDERLE | 20MG/ML | N15865 001 |

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION
METHYLDOPATE HCL

| | | | |
|---|---|---|---|
| AP | DUPONT MERCK | 50MG/ML | N70691 001<br>JUN 19, 1987 |
| AP | | 50MG/ML | N70849 001<br>JUN 19, 1987 |
| AP | FAULDING | 50MG/ML | N70691 001<br>JUN 19, 1987 |
| AP | | 50MG/ML | N70849 001<br>JUN 19, 1987 |

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE ACETATE

| | | | |
|---|---|---|---|
| BP | AKORN | 40MG/ML | N86903 001<br>OCT 20, 1982 |
| BP | | 80MG/ML | N86903 002<br>OCT 20, 1982 |
| | @ | 40MG/ML | N86903 001<br>OCT 20, 1982 |
| | @ | 80MG/ML | N86903 002<br>OCT 20, 1982 |

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL

| | | | |
|---|---|---|---|
| AP | DUPONT MERCK | EQ 10MG BASE/2ML | N70847 001<br>NOV 07, 1988 |
| AP | | EQ 10MG BASE/2ML | N71291 001<br>MAR 03, 1989 |
| AP | FAULDING | EQ 10MG BASE/2ML | N70847 001<br>NOV 07, 1988 |
| AP | | EQ 10MG BASE/2ML | N71291 001<br>MAR 03, 1989 |

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

| | | | | | |
|---|---|---|---|---|---|
| > ADD > | AB | INVAMED | EQ 5MG BASE | | N74478 001 |
| > ADD | | | | | OCT 05, 1995 |
| > ADD > | AB | | EQ 10MG BASE | | N74478 002 |
| > ADD > | | | | | OCT 05, 1995 |

METOPROLOL FUMARATE

TABLET, EXTENDED RELEASE; ORAL
LOPRESSOR

| | | | | |
|---|---|---|---|---|
| | | GEIGY | EQ 100MG TARTRATE | N19786 001 |
| | | | | DEC 27, 1989 |
| | | | EQ 200MG TARTRATE | N19786 002 |
| | | | | DEC 27, 1989 |
| | | | EQ 300MG TARTRATE | N19786 003 |
| | | | | DEC 27, 1989 |
| | + | | EQ 400MG TARTRATE | N19786 004 |
| | | | | DEC 27, 1989 |
| | @ | | EQ 100MG TARTRATE | N19786 001 |
| | | | | DEC 27, 1989 |
| | @ | | EQ 200MG TARTRATE | N19786 002 |
| | | | | DEC 27, 1989 |
| | @ | | EQ 300MG TARTRATE | N19786 003 |
| | | | | DEC 27, 1989 |
| | @ | | EQ 400MG TARTRATE | N19786 004 |
| | | | | DEC 27, 1989 |

METOPROLOL TARTRATE

TABLET; ORAL
METOPROLOL TARTRATE

| | | | | |
|---|---|---|---|---|
| AB | | LEMMON | 50MG | N74141 001 |
| | | | | JAN 31, 1995 |
| AB | | | 100MG | N74141 002 |
| | | | | JAN 31, 1995 |
| AB | | PAR PHARM | 50MG | N74453 001 |
| | | | | APR 27, 1995 |
| AB | | | 100MG | N74453 002 |
| | | | | APR 27, 1995 |

METRONIDAZOLE

CAPSULE; ORAL
FLAGYL

| | | | | |
|---|---|---|---|---|
| | + | SEARLE | 375MG | N20334 001 |
| | | | | MAY 03, 1995 |

CREAM; TOPICAL
METROCREAM

| | | | | |
|---|---|---|---|---|
| | + | GALDERMA | 0.75% | N20531 001 |
| | | | | SEP 20, 1995 |

METYRAPONE

TABLET; ORAL
METOPIRONE

| | | | | |
|---|---|---|---|---|
| | + | CIBA | 250MG | N12911 001 |
| | @ | | 250MG | N12911 001 |

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL
MEXILETINE HCL

| | | | | |
|---|---|---|---|---|
| AB | | NOVOPHARM | 150MG | N74377 001 |
| | | | | MAY 16, 1995 |
| AB | | | 200MG | N74377 002 |
| | | | | MAY 16, 1995 |
| AB | | | 250MG | N74377 003 |
| | | | | MAY 16, 1995 |

MEXITIL

| | | | | |
|---|---|---|---|---|
| AB | | BOEHRINGER INGELHEIM | 150MG | N18873 002 |
| | | | | DEC 30, 1985 |
| AB | | | 200MG | N18873 003 |
| | | | | DEC 30, 1985 |
| AB | + | | 250MG | N18873 004 |
| | | | | DEC 30, 1985 |

MICONAZOLE NITRATE

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE

| | | | | |
|---|---|---|---|---|
| AB | | ABLE | 200MG | N73508 001 |
| | | | | NOV 19, 1993 |
| AB | | NMC | 200MG | N73508 001 |
| | | | | NOV 19, 1993 |

MITOMYCIN

INJECTABLE; INJECTION
MITOMYCIN

| | | | | | |
|---|---|---|---|---|---|
| AP | CETUS BEN VENUE | 5MG/VIAL | N64117 001 APR 19, 1995 | > ADD > | |
| | | 20MG/VIAL | N64117 002 APR 19, 1995 | > DLT > | |

MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL
UNIVASC

| | | | | |
|---|---|---|---|---|
| | SPKU | 7.5MG | N20312 001 APR 19, 1995 | |
| + | | 15MG | N20312 002 APR 19, 1995 | |

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MS CONTIN

| | | | | |
|---|---|---|---|---|
| BC | + PURDUE FREDERICK | 15MG | N19516 003 SEP 12, 1989 | |

ORAMORPH SR

| | | | | |
|---|---|---|---|---|
| BC | ROXANE | 15MG | N19977 004 NOV 23, 1994 | |

MUPIROCIN CALCIUM

OINTMENT; NASAL
BACTROBAN

| | | | | |
|---|---|---|---|---|
| + | SMITHKLINE BEECHAM | EQ 2% ACID | N50703 001 SEP 18, 1995 | |

MYCOPHENOLATE MOFETIL

CAPSULE; ORAL
CELLCEPT

| | | | | |
|---|---|---|---|---|
| + | SYNTEX | 250MG | N50722 001 MAY 03, 1995 | |

NAFARELIN ACETATE

SPRAY, METERED; NASAL
SYNAREL

| | | | | |
|---|---|---|---|---|
| + | SEARLE | EQ 0.2MG BASE/INH | N19886 001 FEB 13, 1990 | |
| + | SYNTEX | EQ 0.2MG BASE/INH | N19886 001 FEB 13, 1990 | |

NAFCILLIN SODIUM

INJECTABLE; INJECTION
NAFCIL

| | | | | |
|---|---|---|---|---|
| AP | APOTHECON | EQ 500MG BASE/VIAL | N61984 001 | |
| AP | | EQ 500MG BASE/VIAL | N62527 001 AUG 02, 1984 | |
| AP | | EQ 1GM BASE/VIAL | N61984 002 | |
| AP | | EQ 1GM BASE/VIAL | N62527 002 AUG 02, 1984 | |
| AP | | EQ 1GM BASE/VIAL | N62732 001 DEC 23, 1986 | |
| AP | | EQ 2GM BASE/VIAL | N61984 003 | |
| AP | | EQ 2GM BASE/VIAL | N62527 003 AUG 02, 1984 | |
| AP | | EQ 2GM BASE/VIAL | N62732 002 DEC 23, 1986 | |
| AP | | EQ 4GM BASE/VIAL | N61984 005 | |
| AP | | EQ 10GM BASE/VIAL | N62527 004 AUG 02, 1984 | |

NAFCILLIN SODIUM

| | | | | |
|---|---|---|---|---|
| AP | APOTHECON | EQ 500MG BASE/VIAL | N61984 001 | |
| AP | | EQ 500MG BASE/VIAL | N62527 001 AUG 02, 1984 | |
| AP | | EQ 1GM BASE/VIAL | N61984 002 | |
| AP | | EQ 1GM BASE/VIAL | N62527 002 AUG 02, 1984 | |
| AP | | EQ 1GM BASE/VIAL | N62732 001 DEC 23, 1986 | |
| AP | | EQ 2GM BASE/VIAL | N61984 003 | |
| AP | | EQ 2GM BASE/VIAL | N62527 003 AUG 02, 1984 | |
| AP | | EQ 2GM BASE/VIAL | N62732 002 DEC 23, 1986 | |
| AP | | EQ 4GM BASE/VIAL | N61984 005 | |
| AP | | EQ 10GM BASE/VIAL | N62527 004 AUG 02, 1984 | |

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | REVEX | | | |
| | OHMEDA | EQ 0.1MG BASE/ML | N20459 001 | APR 17, 1995 |
| + | | EQ 1MG BASE/ML | N20459 002 | APR 17, 1995 |

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **NALOXONE HCL** | | | |
| **AP** | FUJISAWA | **0.02MG/ML** | **N70648 001** | NOV 17, 1986 |
| **AP** | | **0.4MG/ML** | **N70649 001** | NOV 17, 1986 |
| @ | | 0.02MG/ML | N70648 001 | NOV 17, 1986 |
| @ | | 0.4MG/ML | N70649 001 | NOV 17, 1986 |
| **AP** | MARSAM | **0.4MG/ML** | **N71811 001** | JUL 19, 1988 |
| @ | | 0.4MG/ML | N71811 001 | JUL 19, 1988 |

NANDROLONE DECANOATE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **NANDROLONE DECANOATE** | | | |
| **AO** | AKORN | **100MG/ML** | **N87519 001** | SEP 28, 1983 |
| @ | | 100MG/ML | N87519 001 | SEP 28, 1983 |

NAPROXEN

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **NAPROXEN** | | | |
| **AB** | CHELSEA LABS | **250MG** | **N74457 001** | MAY 31, 1995 |
| **AB** | | **375MG** | **N74457 002** | MAY 31, 1995 |
| **AB** | | **500MG** | **N74457 003** | MAY 31, 1995 |

NAPROXEN

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **NAPROXEN** | | | |
| **AB** | DANBURY PHARMA | **250MG** | **N74163 001** | FEB 10, 1995 |
| **AB** | | **375MG** | **N74163 002** | FEB 10, 1995 |
| **AB** | | **500MG** | **N74163 003** | FEB 10, 1995 |
| **AB** | MOVA | **250MG** | **N74410 001** | APR 28, 1995 |
| **AB** | | **375MG** | **N74410 002** | APR 28, 1995 |
| **AB** | | **500MG** | **N74410 003** | APR 28, 1995 |
| **AB** | ZENITH LABS | **250MG** | **N74111 001** | FEB 28, 1995 |
| **AB** | | **375MG** | **N74111 002** | FEB 28, 1995 |
| **AB** | | **500MG** | **N74111 003** | FEB 28, 1995 |

NAPROXEN SODIUM

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **NAPROXEN SODIUM** | | | |
| **AB** | CHELSEA LABS | **EQ 250MG BASE** | **N74455 001** | MAY 31, 1995 |
| **AB** | | **EQ 500MG BASE** | **N74455 002** | MAY 31, 1995 |
| **AB** | PUREPAC PHARM | **EQ 250MG BASE** | **N74319 001** | MAR 20, 1995 |
| **AB** | | **EQ 500MG BASE** | **N74319 002** | MAR 20, 1995 |
| **AB** | ZENITH LABS | **EQ 250MG BASE** | **N74230 001** | MAR 14, 1995 |
| **AB** | | **EQ 500MG BASE** | **N74230 002** | MAR 14, 1995 |

NEOMYCIN SULFATE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **NEOMYCIN SULFATE** | | | |
| **AA** | BIOCRAFT | **EQ 350MG BASE** | **N60304 001** | |
| | | EQ 350MG BASE | N60304 001 | |
| **AA** | LILLY | **EQ 350MG BASE** | **N60385 001** | |

NEOMYCIN SULFATE

TABLET; ORAL
**NEOMYCIN SULFATE**

| | | | | |
|---|---|---|---|---|
| | @ LILLY | EQ 350MG BASE | N60385 001 | |

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 | + | 21MG/24HR | N20076 003 | NOV 27, 1991 |
| BC | + CIBA | 7MG/24HR | N20076 001 | NOV 27, 1991 |
| BC | + | 14MG/24HR | N20076 002 | NOV 27, 1991 |
| BC | + | 21MG/24HR | N20076 003 | NOV 27, 1991 |

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICORETTE

| | | | | |
|---|---|---|---|---|
| + | MERRELL DOW | EQ 2MG BASE | N18612 001 | JAN 13, 1984 |
| + | SMITHKLINE BEECHAM | EQ 2MG BASE | N18612 001 | JAN 13, 1984 |

NICORETTE DS

| | | | | |
|---|---|---|---|---|
| + | MERRELL DOW | EQ 4MG BASE | N20066 001 | JUN 08, 1992 |
| + | SMITHKLINE BEECHAM | EQ 4MG BASE | N20066 001 | JUN 08, 1992 |

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
ADALAT CC

| | | | | |
|---|---|---|---|---|
| > ADD > | BC + BAYER | 30MG | N20198 001 | APR 21, 1993 |
| > ADD > | BC + | 60MG | N20198 002 | APR 21, 1993 |

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
ADALAT CC

| | | | | |
|---|---|---|---|---|
| > ADD > | BC + BAYER | 90MG | N20198 003 | APR 21, 1993 |
| > ADD > | | | | |
| > DLT > | BC MILES | 30MG | N20198 001 | APR 21, 1993 |
| > DLT > | | | | |
| > DLT > | BC | 60MG | N20198 002 | APR 21, 1993 |
| > DLT > | | | | |
| > DLT > | BC | 90MG | N20198 003 | APR 21, 1993 |
| > DLT > | | | | |

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL
NISOCOR

| | | | | |
|---|---|---|---|---|
| + | BAYER | 10MG | N20356 001 | FEB 02, 1995 |
| + | | 20MG | N20356 002 | FEB 02, 1995 |
| + | | 30MG | N20356 003 | FEB 02, 1995 |
| + | | 40MG | N20356 004 | FEB 02, 1995 |
| + | ZENECA | 10MG | N20356 001 | FEB 02, 1995 |
| + | | 20MG | N20356 002 | FEB 02, 1995 |
| + | | 30MG | N20356 003 | FEB 02, 1995 |
| + | | 40MG | N20356 004 | FEB 02, 1995 |

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
**NITROFURANTOIN**

| | | | | |
|---|---|---|---|---|
| **AB** | GENEVA PHARMS | **25MG** | **N74336 001** | JAN 25, 1995 |
| **AB** | | **50MG** | **N74336 002** | JAN 25, 1995 |
| **AB** | | **100MG** | **N74336 003** | JAN 25, 1995 |

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL

NITRO-DUR

| | | | | |
|---|---|---|---|---|
| + | KEY PHARMS | 0.1MG/HR | N20145 001 | APR 04, 1995 |
| + | | 0.2MG/HR | N20145 002 | APR 04, 1995 |
| + | | 0.3MG/HR | N20145 003 | APR 04, 1995 |
| + | | 0.4MG/HR | N20145 004 | APR 04, 1995 |
| + | | 0.6MG/HR | N20145 005 | APR 04, 1995 |
| + | | 0.8MG/HR | N20145 006 | APR 04, 1995 |

INJECTABLE; INJECTION

**NITROGLYCERIN**

| | | | | |
|---|---|---|---|---|
| **AP** | **FUJISAWA** | **5MG/ML** | **N70077 001** | **DEC 13, 1985** |
| @ | | 5MG/ML | N70077 001 | DEC 13, 1985 |

**NITROSTAT**

| | | | | |
|---|---|---|---|---|
| **AP** | **PARKE DAVIS** | **5MG/ML** | **N18588 002** | **DEC 23, 1983** |
| + | | 0.8MG/ML | N18588 001 | |
| @ | | 0.8MG/ML | N18588 001 | |
| @ | | 5MG/ML | N18588 002 | DEC 23, 1983 |

**TRIDIL**

| | | | | |
|---|---|---|---|---|
| **AP** | **DUPONT MERCK** | **5MG/ML** | **N18537 001** | |
| + | | 0.5MG/ML | N18537 002 | JUN 16, 1983 |
| **AP** | **FAULDING** | **5MG/ML** | **N18537 001** | |
| + | | 0.5MG/ML | N18537 002 | JUN 16, 1983 |

NORETHINDRONE

TABLET; ORAL

NOR-Q.D.

| | | | | | |
|---|---|---|---|---|---|
| >ADD< | SEARLE | 0.35MG | N17060 001 | >ADD< | |
| >DLT< | SYNTEX | 0.35MG | N17060 001 | >ADD< | |

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

**NORTRIPTYLINE HCL**

| | | | | |
|---|---|---|---|---|
| **AB** | LEMMON | **EQ 10MG BASE** | **N74132 001** | MAR 27, 1995 |
| **AB** | | **EQ 25MG BASE** | **N74132 002** | MAR 27, 1995 |
| **AB** | | **EQ 50MG BASE** | **N74132 003** | MAR 27, 1995 |
| **AB** | | **EQ 75MG BASE** | **N74132 004** | MAR 27, 1995 |

NYSTATIN

TABLET; ORAL

**MYCOSTATIN**

| | | | | |
|---|---|---|---|---|
| **AA** | + APOTHECON | **500,000 UNITS** | **N60574 001** | |
| **AA** | + SQUIBB | **500,000 UNITS** | **N60574 001** | |

TABLET; VAGINAL

**NYSTATIN**

| | | | | |
|---|---|---|---|---|
| **AT** | LEMMON | **100,000 UNITS** | **N62502 001** | DEC 23, 1983 |
| @ | | 100,000 UNITS | N62502 001 | DEC 23, 1983 |

NYSTATIN; TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

**NYSTATIN AND TRIAMCINOLONE ACETONIDE**

| | | | | |
|---|---|---|---|---|
| **AT** | PHARMAFAIR | **100,000 UNITS/GM;0.1%** | **N62656 001** | JUL 30, 1986 |
| @ | | 100,000 UNITS/GM;0.1% | N62656 001 | JUL 30, 1986 |

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRILOSEC

| | | | | | |
|---|---|---|---|---|---|
| + | ASTRA MERCK | 10MG | N19810 003 | >ADD< | OCT 05, 1995 |

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION
ZOFRAN IN PLASTIC CONTAINER
\+ GLAXO WELLCOME — EQ 0.64MG BASE/ML — N20403 001 JAN 31, 1995

OXACILLIN SODIUM

CAPSULE; ORAL
OXACILLIN SODIUM
AB APOTHECON — EQ 250MG BASE — N61450 002
AB + EQ 500MG BASE — N61450 001
PROSTAPHLIN
AB APOTHECON — EQ 250MG BASE — N61450 002
AB + EQ 500MG BASE — N61450 001
@ — EQ 500MG BASE — N50118 002
@ BRISTOL — EQ 500MG BASE — N50118 002

POWDER FOR RECONSTITUTION; ORAL
OXACILLIN SODIUM
AA APOTHECON — EQ 250MG BASE/5ML — N61457 001
PROSTAPHLIN
AA APOTHECON — EQ 250MG BASE/5ML — N61457 001
@ — EQ 250MG BASE/5ML — N50194 001
@ BRISTOL — EQ 250MG BASE/5ML — N50194 001

OXYPHENCYCLIMINE HYDROCHLORIDE

TABLET; ORAL
DARICON
\+ PFIZER — 10MG — N11612 001
@ — 10MG — N11612 001

PENBUTOLOL SULFATE

TABLET; ORAL
LEVATOL
@ REED AND CARNRICK — 10MG — N18976 001 DEC 30, 1987
\+ 20MG — N18976 004 JAN 05, 1989
@ SPKU — 10MG — N18976 001 DEC 30, 1987
\+ 20MG — N18976 004 JAN 05, 1989

PENICILLAMINE

TABLET; ORAL
DEPEN
\+ WALLACE — 250MG — N19854 001
DEPEN 250
\+ WALLACE — 250MG — N19854 001

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM
@ CONSOLIDATED PHARM — 500,000 UNITS/VIAL — N60806 001
@ — 1,000,000 UNITS/VIAL — N60806 002
@ — 5,000,000 UNITS/VIAL — N60806 003
@ — 10,000,000 UNITS/VIAL — N60806 004
@ COPANOS — 500,000 UNITS/VIAL — N60806 001
@ — 1,000,000 UNITS/VIAL — N60806 002
@ — 5,000,000 UNITS/VIAL — N60806 003
@ — 10,000,000 UNITS/VIAL — N60806 004
AP + LILLY — 1,000,000 UNITS/VIAL — N60384 002
AP + 5,000,000 UNITS/VIAL — N60384 001
AP + 20,000,000 UNITS/VIAL — N60384 005
AP 20,000,000 UNITS/VIAL — N60601 001
\+ 200,000 UNITS/VIAL — N60384 004
\+ 500,000 UNITS/VIAL — N60384 003
@ — 200,000 UNITS/VIAL — N60384 004
@ — 500,000 UNITS/VIAL — N60384 003
@ — 1,000,000 UNITS/VIAL — N60384 002
@ — 5,000,000 UNITS/VIAL — N60384 001
@ — 20,000,000 UNITS/VIAL — N60384 005
@ — 20,000,000 UNITS/VIAL — N60601 001
PFIZERPEN
AP PFIZER — 1,000,000 UNITS/VIAL — N60657 001
AP + 1,000,000 UNITS/VIAL — N60657 001
AP 5,000,000 UNITS/VIAL — N60657 002
AP + 5,000,000 UNITS/VIAL — N60657 002
AP 20,000,000 UNITS/VIAL — N60657 003
AP + 20,000,000 UNITS/VIAL — N60657 003

TABLET; ORAL
PENICILLIN G POTASSIUM
AB DISTA — 250,000 UNITS — N60403 001
@ LILLY — 250,000 UNITS — N60403 001

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
PENICILLIN G PROCAINE

| | | | |
|---|---|---|---|
| @ | CONSOLIDATED PHARM | 300,000 UNITS/ML | N60800 001 |
| @ | | 600,000 UNITS/1.2ML | N60800 002 |
| @ | COPANOS | 300,000 UNITS/ML | N60800 001 |
| @ | | 600,000 UNITS/1.2ML | N60800 002 |

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
**PENICILLIN V POTASSIUM**

| | | | |
|---|---|---|---|
| AA | CONSOLIDATED PHARM | EQ 125MG BASE/5ML | N61529 001 |
| AA | | EQ 250MG BASE/5ML | N61529 002 |
| AA | COPANOS | EQ 125MG BASE/5ML | N61529 001 |
| AA | | EQ 250MG BASE/5ML | N61529 002 |

TABLET; ORAL
**BETAPEN-VK**

| | | | |
|---|---|---|---|
| AB | APOTHECON | EQ 250MG BASE | N61411 001 |
| AB | | EQ 500MG BASE | N61411 002 |

**PENICILLIN V POTASSIUM**

| | | | |
|---|---|---|---|
| AB | CONSOLIDATED PHARM | EQ 250MG BASE | N61528 001 |
| AB | | EQ 500MG BASE | N61528 002 |
| AB | COPANOS | EQ 250MG BASE | N61528 001 |
| AB | | EQ 500MG BASE | N61528 002 |

**VEETIDS**

| | | | |
|---|---|---|---|
| AB | APOTHECON | EQ 250MG BASE | N61411 001 |
| AB | | EQ 500MG BASE | N61411 002 |

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION
**PENTACARINAT**

| | | | |
|---|---|---|---|
| AP | ARMOUR | 300MG/VIAL | N73447 001 APR 28, 1994 |
| AP | RHONE POULENC RORER | 300MG/VIAL | N73447 001 APR 28, 1994 |

**PENTAMIDINE ISETHIONATE**

| | | | |
|---|---|---|---|
| AP | STERIS | 300MG/VIAL | N74303 001 AUG 17, 1995 |

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

| | | | |
|---|---|---|---|
| | AMARIC | 2MG | N20184 001 DEC 30, 1993 |
| | | 4MG | N20184 002 DEC 30, 1993 |
| + | | 8MG | N20184 003 DEC 30, 1993 |
| | JOHNSON RW | 2MG | N20184 001 DEC 30, 1993 |
| | | 4MG | N20184 002 DEC 30, 1993 |
| + | | 8MG | N20184 003 DEC 30, 1993 |

PHENDIMETRAZINE TARTRATE

CAPSULE, EXTENDED RELEASE; ORAL
MELFIAT-105

| | | | |
|---|---|---|---|
| @ | NUMARK | 105MG | N87487 001 OCT 13, 1982 |
| @ | SOLVAY | 105MG | N87487 001 OCT 13, 1982 |

SPRX-105

| | | | |
|---|---|---|---|
| @ | NUMARK | 105MG | N88024 001 DEC 22, 1982 |
| @ | SOLVAY | 105MG | N88024 001 DEC 22, 1982 |

TABLET; ORAL
MELFIAT

| | | | |
|---|---|---|---|
| @ | NUMARK | 35MG | N83790 002 |
| @ | SOLVAY | 35MG | N83790 002 |

PHENDIMETRAZINE TARTRATE

| | | | |
|---|---|---|---|
| @ | NUMARK | 35MG | N83790 001 |
| @ | SOLVAY | 35MG | N83790 001 |

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
**PHENTERMINE HCL**

| | | | |
|---|---|---|---|
| AA | LEMMON | 30MG | N87777 001 NOV 01, 1985 |
| @ | | 30MG | N87777 001 NOV 01, 1985 |

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | IONAMIN | | |
| | FISONS | EQ 15MG BASE | N11613 004 |
| + | | EQ 30MG BASE | N11613 002 |
| | IONAMIN-15 | | |
| | FISONS | EQ 15MG BASE | N11613 004 |
| | IONAMIN-30 | | |
| + | FISONS | EQ 30MG BASE | N11613 002 |

PINACIDIL

CAPSULE, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | PINDAC | | |
| + | LEO PHARM | 12.5MG | N19456 001 |
| | | | DEC 28, 1989 |
| + | | 25MG | N19456 002 |
| | | | DEC 28, 1989 |
| @ | | 12.5MG | N19456 001 |
| | | | DEC 28, 1989 |
| @ | | 25MG | N19456 002 |
| | | | DEC 28, 1989 |

PINDOLOL

TABLET; ORAL

| | | | |
|---|---|---|---|
| | **PINDOLOL** | | |
| **AB** | ROYCE LABS | **5MG** | **N74437 001** |
| | | | FEB 27, 1995 |
| **AB** | | **10MG** | **N74437 002** |
| | | | FEB 27, 1995 |

PIROXICAM

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | **PIROXICAM** | | |
| **AB** | ROYCE LABS | **10MG** | **N74460 001** |
| | | | SEP 29, 1995 |
| **AB** | | **20MG** | **N74460 002** |
| | | | SEP 29, 1995 |

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

POWDER FOR RECONSTITUTION; ORAL

| | | | |
|---|---|---|---|
| | NULYTELY-FLAVORED | | |
| | BRAINTREE | 420GM/BOT;1.48GM/BOT;5.72GM/BOT; 11.2GM/BOT | N19797 002 NOV 18, 1994 |

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | **COLYTE** | | |
| > DLT > | **AA** | KREMERS URBAN | **227.1GM/BOT;2.82GM/BOT;6.36GM/BOT; 5.53GM/BOT;21.5GM/BOT** | **N18983 010** JAN 31, 1989 |
| > DLT > | **AA** | | **240GM/BOT;2.98GM/BOT;6.72GM/BOT; 5.84GM/BOT;22.72GM/BOT** | **N18983 007** JUN 12, 1987 |
| > DLT > | | @ REED AND CARNRICK | 120GM/PACKET;1.49GM/PACKET; 3.36GM/PACKET;2.92GM/PACKET; 11.36GM/PACKET | N18983 005 OCT 26, 1984 |
| > DLT > | | @ | 227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET | N18983 004 OCT 26, 1984 |
| > DLT > | | @ | 360GM/PACKET;4.47GM/PACKET; 10.08GM/PACKET;8.76GM/PACKET; 34.08GM/PACKET | N18983 006 OCT 26, 1984 |
| > ADD > | **AA** | SPKU | **227.1GM/BOT;2.82GM/BOT;6.36GM/BOT; 5.53GM/BOT;21.5GM/BOT** | **N18983 010** JAN 31, 1989 |
| > ADD > | **AA** | | **240GM/BOT;2.98GM/BOT;6.72GM/BOT; 5.84GM/BOT;22.72GM/BOT** | **N18983 007** JUN 12, 1987 |
| > ADD > | | @ | 120GM/PACKET;1.49GM/PACKET; 3.36GM/PACKET;2.92GM/PACKET; 11.36GM/PACKET | N18983 005 OCT 26, 1984 |
| > ADD > | | @ | 227.1GM/PACKET;2.82GM/PACKET; 6.36GM/PACKET;5.53GM/PACKET; 21.5GM/PACKET | N18983 004 OCT 26, 1984 |

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | **COLYTE** | | |
| > ADD > | | @ SPKU | 360GM/PACKET;4.47GM/PACKET; | |
| > ADD > | | | 10.08GM/PACKET;8.76GM/PACKET; | |
| > ADD > | | | 34.08GM/PACKET | N18983 006 |
| > ADD > | | | | OCT 26, 1984 |
| | | **COLYTE-FLAVORED** | | |
| > DLT > | AA | KREMERS URBAN | 227.1GM/BOT;2.82GM/BOT;6.36GM/BOT; | |
| > DLT > | | | 5.53GM/BOT;21.5GM/BOT | N18983 008 |
| > DLT > | | | | NOV 14, 1991 |
| > DLT > | AA | | 240GM/BOT;2.98GM/BOT;6.72GM/BOT; | |
| > DLT > | | | 5.84GM/BOT;22.72GM/BOT | N18983 009 |
| > DLT > | | | | NOV 14, 1991 |
| > ADD > | AA | SPKU | 227.1GM/BOT;2.82GM/BOT;6.36GM/BOT; | |
| > ADD > | | | 5.53GM/BOT;21.5GM/BOT | N18983 008 |
| > ADD > | | | | NOV 14, 1991 |
| > ADD > | AA | | 240GM/BOT;2.98GM/BOT;6.72GM/BOT; | |
| > ADD > | | | 5.84GM/BOT;22.72GM/BOT | N18983 009 |
| > ADD > | | | | NOV 14, 1991 |
| | | **GOLYTELY** | | |
| | AA | BRAINTREE | 227.1GM/PACKET;2.82GM/PACKET; | |
| | | | 6.36GM/PACKET;5.53GM/PACKET; | |
| | | | 21.5GM/PACKET | N19011 002 |
| | | | | JUN 02, 1992 |

POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

| | | | |
|---|---|---|---|
| | MINIZIDE | | |
| | PFIZER | 0.5MG;1MG | N17986 001 |
| | | 0.5MG;2MG | N17986 002 |
| | + | 0.5MG;5MG | N17986 003 |
| | | 0.5MG;EQ 1MG BASE | N17986 001 |
| | | 0.5MG;EQ 2MG BASE | N17986 002 |
| | + | 0.5MG;EQ 5MG BASE | N17986 003 |

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **POTASSIUM CHLORIDE** | | |
| AP | AKORN | **2MEQ/ML** | **N88286 001** |
| | | | SEP 05, 1985 |
| | @ | 2MEQ/ML | N88286 001 |
| | | | SEP 05, 1985 |

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

| | | | |
|---|---|---|---|
| | KAON CL | | |
| | SAVAGE LABS | 6.7MEQ | N17046 001 |
| | @ | 6.7MEQ | N17046 001 |
| | KAON CL-10 | | |
| BC | SAVAGE LABS | 10MEQ | N17046 002 |
| | @ | 10MEQ | N17046 002 |

PREDNISOLONE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | CORTALONE | | |
| BX | HALSEY | 1MG | N80304 003 |
| BX | | 2.5MG | N80304 002 |
| BX | | 5MG | N80304 001 |
| | @ | 1MG | N80304 003 |
| | @ | 2.5MG | N80304 002 |
| | @ | 5MG | N80304 001 |
| | PREDNISOLONE | | |
| BX | SPERTI | 1MG | N80358 001 |
| | | 1MG | N80358 001 |

PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

| | | | |
|---|---|---|---|
| | **ECONOPRED PLUS** | | |
| AB | ALCON | 1% | N17469 001 |
| BX | | 1% | N17469 001 |

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | **HYDELTRASOL** | | |
| AP | + MERCK SHARP DOHME | **EQ 20MG PHOSPHATE/ML** | **N11583 002** |
| | + | EQ 20MG PHOSPHATE/ML | N11583 002 |
| | **PREDNISOLONE SODIUM PHOSPHATE** | | |
| AP | STERIS | **EQ 20MG PHOSPHATE/ML** | **N80517 001** |
| | @ | EQ 20MG PHOSPHATE/ML | N80517 001 |

PREDNISONE

TABLET; ORAL

| | | | |
|---|---|---|---|
| | CORTAN | | |
| BX | HALSEY | 20MG | N87480 001 |

PREDNISONE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | CORTAN | | | |
| | @ HALSEY | 20MG | | N87480 001 |

PROBUCOL

| | | | | |
|---|---|---|---|---|
| > DLT > | TABLET; ORAL | | | |
| > DLT > | LORELCO | | | |
| > ADD > | @ HOECHST MARION RSSL | 250MG | | N17535 001 |
| > ADD > | @ | 500MG | | N17535 002 |
| > ADD > | | | | JUL 06, 1988 |
| > DLT > | MERRELL DOW | 250MG | | N17535 001 |
| > DLT > | + | 500MG | | N17535 002 |
| > DLT > | | | | JUL 06, 1988 |

PROCAINAMIDE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PRONESTYL | | | |
| | APOTHECON | 250MG | | N17371 001 |
| | | 375MG | | N17371 002 |
| | + | 500MG | | N17371 003 |
| | SQUIBB | 250MG | | N17371 001 |
| | | 375MG | | N17371 002 |
| | + | 500MG | | N17371 003 |

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | PROCAN SR | | | |
| AB | PARKE DAVIS | 250MG | | N86468 001 |
| | @ | 250MG | | N86468 001 |
| | PRONESTYL-SR | | | |
| BC | APOTHECON | 500MG | | N87361 001 |
| BC | BRISTOL MYERS SQUIBB | 500MG | | N87361 001 |

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | PROMETHAZINE HCL | | | |
| AP | AKORN | 25MG/ML | | N83955 002 |
| AP | | 50MG/ML | | N83955 001 |
| | @ | 25MG/ML | | N83955 002 |
| | @ | 50MG/ML | | N83955 001 |

PROPANTHELINE BROMIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PROPANTHELINE BROMIDE | | | |
| AA | DANBURY PHARMA | 15MG | | N83029 002 |
| | @ | 15MG | | N83029 002 |
| AA | GLOBAL PHARMS | 15MG | | N84541 002 |
| | @ | 15MG | | N84541 002 |
| AA | TABLICAPS | 15MG | | N84428 001 |
| | @ | 15MG | | N84428 001 |

PROPARACAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | OPHTHAINE | | | |
| AT | + APOTHECON | 0.5% | | N08883 001 |
| AT | + SQUIBB | 0.5% | | N08883 001 |
| | PROPARACAINE HCL | | | |
| AT | BAUSCH AND LOMB | 0.5% | | N40074 001 |
| | | | | SEP 29, 1995 |

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | PROPRANOLOL HCL | | | |
| AB | PARKE DAVIS | 20MG | | N70439 001 |
| | | | | SEP 15, 1986 |
| AB | | 40MG | | N70440 001 |
| | | | | SEP 15, 1986 |
| AB | | 60MG | | N70441 001 |
| | | | | SEP 24, 1986 |
| AB | | 80MG | | N70442 001 |
| | | | | SEP 15, 1986 |
| AB | WARNER CHILCOTT | 10MG | | N70438 001 |
| | | | | SEP 15, 1986 |
| | @ | 10MG | | N70438 001 |
| | | | | SEP 15, 1986 |
| | @ | 20MG | | N70439 001 |
| | | | | SEP 15, 1986 |
| | @ | 40MG | | N70440 001 |
| | | | | SEP 15, 1986 |
| | @ | 60MG | | N70441 001 |
| | | | | SEP 24, 1986 |
| | @ | 80MG | | N70442 001 |
| | | | | SEP 15, 1986 |

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

| | | | |
|---|---|---|---|
| BD | LILLY | 50MG | N06213 001 |
| | @ | 50MG | N06213 001 |

PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
PROTRIPTYLINE HCL

| | | | |
|---|---|---|---|
| AB | SIDMAK LABS NJ | 5MG | N73644 001<br>AUG 24, 1995 |
| AB | | 10MG | N73645 001<br>AUG 24, 1995 |

VIVACTIL

| | | | |
|---|---|---|---|
| AB | MERCK SHARP DOHME | 5MG | N16012 001 |
| AB | + | 10MG | N16012 002 |

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL

| | | | |
|---|---|---|---|
| AP | AKORN | 100MG/ML | N87967 001<br>OCT 01, 1982 |
| | @ | 100MG/ML | N87967 001<br>OCT 01, 1982 |

QUINESTROL

TABLET; ORAL
ESTROVIS

| | | | |
|---|---|---|---|
| | + PARKE DAVIS | 0.1MG | N16768 002 |
| | @ | 0.1MG | N16768 002 |

QUINIDINE GLUCONATE

TABLET, EXTENDED RELEASE; ORAL
QUINALAN

| | | | |
|---|---|---|---|
| BC | LANNETT | 324MG | N88081 001<br>FEB 10, 1986 |
| | @ | 324MG | N88081 001<br>FEB 10, 1986 |

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

| | | | |
|---|---|---|---|
| AB | PHOENIX LABS NY | 200MG | N83963 001 |
| | @ VINTAGE PHARMS | 200MG | N83963 001 |

RAUWOLFIA SERPENTINA

TABLET; ORAL
RAUDIXIN

| | | | |
|---|---|---|---|
| BP | APOTHECON | 50MG | N08842 001 |
| BP | + | 100MG | N08842 002 |
| | @ | 50MG | N08842 001 |
| | @ | 100MG | N08842 002 |

RAUVAL

| | | | |
|---|---|---|---|
| BP | VALE | 100MG | N09108 004 |
| BP | + | 100MG | N09108 004 |

RAUWOLFIA SERPENTINA

| | | | |
|---|---|---|---|
| BP | HALSEY | 50MG | N80498 001 |
| BP | | 100MG | N80498 002 |
| | @ | 50MG | N80498 001 |
| | @ | 100MG | N80498 002 |

RITODRINE HYDROCHLORIDE

TABLET; ORAL
YUTOPAR

| | | | |
|---|---|---|---|
| | + ASTRA | 10MG | N18555 001 |
| | @ | 10MG | N18555 001 |

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM

| | | | |
|---|---|---|---|
| AA | ZENITH LABS | 100MG | N85869 001 |
| | @ | 100MG | N85869 001 |

SEVOFLURANE

LIQUID; INHALATION
ULTANE

| | | | |
|---|---|---|---|
| | ABBOTT | 100% | N20478 001<br>JUN 07, 1995 |

SILVER SULFADIAZINE

CREAM; TOPICAL
SSD AF

| | | | | | |
|---|---|---|---|---|---|
| BX | KNOLL PHARM | 1% | N18578 003<br>JUL 11, 1990 | | |

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

| | | | | | |
|---|---|---|---|---|---|
| AP | BAXTER | 9MG/ML | N16677 004<br>OCT 30, 1985 | | |
| AP | + | 9MG/ML | N16677 004<br>OCT 30, 1985 | | |

SOLUTION; IRRIGATION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

| | | | | | |
|---|---|---|---|---|---|
| AT | BAXTER | 450MG/100ML | N18497 001<br>FEB 19, 1982 | | |
| | @ | 450MG/100ML | N18497 001<br>FEB 19, 1982 | | |

SODIUM CHROMATE, CR-51

INJECTABLE; INJECTION
CHROMITOPE SODIUM

| | | | | | |
|---|---|---|---|---|---|
| | BRACCO | 200 uCi/ML | N13993 001 | | |
| | BRACCO DXS | 250 uCi/VIAL | N13993 001 | | |
| | | 1mCi/VIAL | N13993 003 | | |

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
BIO-TROPIN

| | | | | | |
|---|---|---|---|---|---|
| + | BIO TECH GEN | 4.8MG/VIAL | N19774 001<br>MAY 25, 1995 | > ADD ><br>> ADD ><br>> DLT ><br>> DLT > | |

GENOTROPIN

| | | | | | |
|---|---|---|---|---|---|
| + | PHARMACIA | 1.5MG/VIAL | N20280 004<br>AUG 24, 1995 | | |
| + | | 5.8MG/VIAL | N20280 006<br>AUG 24, 1995 | | |

NORDITROPIN

| | | | | | |
|---|---|---|---|---|---|
| + | NOVO NORDISK | 4MG/VIAL | N19721 001<br>MAY 08, 1995 | | |

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
NORDITROPIN

| | | | | | |
|---|---|---|---|---|---|
| + | NOVO NORDISK | 8MG/VIAL | N19721 002<br>MAY 08, 1995 | | |

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE

| | | | | | |
|---|---|---|---|---|---|
| | BERLEX | 120MG | N19865 005<br>APR 20, 1994 | | |
| | @ | 120MG | N19865 005<br>APR 20, 1994 | | |

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION
STREPTOMYCIN SULFATE

| | | | | | |
|---|---|---|---|---|---|
| AP | LILLY | EQ 1GM BASE/VIAL | N60107 001 | | |
| AP | | EQ 5GM BASE/VIAL | N60107 002 | | |
| | | EQ 1GM BASE/2ML | N60404 001 | | |
| | @ | EQ 1GM BASE/2ML | N60404 001 | | |
| | @ | EQ 1GM BASE/VIAL | N60107 001 | | |
| | @ | EQ 5GM BASE/VIAL | N60107 002 | | |
| AP | + PFIZER | EQ 1GM BASE/VIAL | N60076 001 | | |
| AP | + | EQ 5GM BASE/VIAL | N60076 002 | | |
| | + | EQ 1GM BASE/VIAL | N60076 001 | | |
| | + | EQ 5GM BASE/VIAL | N60076 002 | | |

SUCCIMER

CAPSULE; ORAL
CHEMET

| | | | | | |
|---|---|---|---|---|---|
| + | BOCK PHARMA | 100MG | N19998 002<br>JAN 30, 1991 | | |
| + | MCNEIL CONS PRODS | 100MG | N19998 002<br>JAN 30, 1991 | | |

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION
SUCOSTRIN

| | | | | | |
|---|---|---|---|---|---|
| AP | APOTHECON | 20MG/ML | N08847 001 | | |

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION
**SUCOSTRIN**

| | | | | |
|---|---|---|---|---|
| | @ | APOTHECON | 100MG/ML | N08847 003 |
| AP | | SQUIBB | **20MG/ML** | **N08847 001** |
| | @ | | 100MG/ML | N08847 003 |

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
**SULF-15**

| | | | | |
|---|---|---|---|---|
| >ADD< | | | | |
| >ADD< | AT | CIBA VISION | **15%** | **N89047 001** |
| >ADD< | | | | OCT 31, 1995 |

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
**TRIMETH/SULFA**

| | | | | |
|---|---|---|---|---|
| AB | | BARRE | **200MG/5ML;40MG/5ML** | **N72289 001** |
| | | | | MAY 23, 1988 |
| | @ | | 200MG/5ML;40MG/5ML | N72289 001 |
| | | | | MAY 23, 1988 |

SULFUR

POWDER; TOPICAL
BENSULFOID

| | | | |
|---|---|---|---|
| @ | POYTHRESS | 33.32% | N02918 001 |

SUMATRIPTAN SUCCINATE

TABLET; ORAL
IMITREX

| | | | |
|---|---|---|---|
| | GLAXO WELLCOME | EQ 25MG BASE | N20132 002 |
| | | | JUN 01, 1995 |
| + | | EQ 50MG BASE | N20132 003 |
| | | | JUN 01, 1995 |
| @ | | EQ 100MG BASE | N20132 001 |
| | | | JUN 01, 1995 |

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL
TECHNELITE

| | | |
|---|---|---|
| DUPONT | 0.0083-2.7 CI/GENERATOR | N17771 001 |

TECHNETIUM TC 99M GENERATOR

| | | |
|---|---|---|
| DUPONT | 0.0083-2.7 CI/GENERATOR | N17771 001 |

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM

| | | | |
|---|---|---|---|
| + | THERATECH | 2.5MG/24HR | N20489 001 |
| | | | SEP 29, 1995 |

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
**TETRACYCLINE HCL**

| | | | |
|---|---|---|---|
| AB | PVT FORM | **250MG** | **N62686 001** |
| | | | JUL 24, 1986 |
| AB | | **500MG** | **N62686 002** |
| | | | JUL 24, 1986 |
| @ | | 250MG | N62686 001 |
| | | | JUL 24, 1986 |
| @ | | 500MG | N62686 002 |
| | | | JUL 24, 1986 |

FIBER, EXTENDED RELEASE; PERIODONTAL
ACTISITE

| | | | |
|---|---|---|---|
| + | ON SITE | 12.7MG/FIBER | N50653 001 |
| | | | MAR 25, 1994 |
| + | ON SITE ALZA | 12.7MG/FIBER | N50653 001 |
| | | | MAR 25, 1994 |

OINTMENT; OPHTHALMIC
ACHROMYCIN

| | | | |
|---|---|---|---|
| + | LEDERLE | 10MG/GM | **N50266 001** |
| @ | STORZ OPHTHALM | 10MG/GM | N50266 001 |

SUSPENSION; ORAL
**ACHROMYCIN V**

| | | | |
|---|---|---|---|
| AB | + LEDERLE | **125MG/5ML** | **N50263 002** |

**SUMYCIN**

| | | | |
|---|---|---|---|
| AB | APOTHECON | **125MG/5ML** | **N60400 001** |

**TETRACYCLINE HCL**

| | | | |
|---|---|---|---|
| AB | BARRE | **125MG/5ML** | **N60633 001** |

TETRACYCLINE HYDROCHLORIDE

SUSPENSION; ORAL

| | | | | |
|---|---|---|---|---|
| | **TETRACYCLINE HCL** | | | |
| AB | MK LABS | **125MG/5ML** | **N60174 001** | |
| | @ PROTER | 125MG/5ML | N60446 001 | |
| AB | PUREPAC PHARM | **125MG/5ML** | **N60291 001** | |
| | **TETRACYN** | | | |
| AB | PFIPHARMECS | **125MG/5ML** | **N60095 001** | |
| | **TETRAMED** | | | |
| AB | ZENITH LABS | **125MG/5ML** | **N61468 001** | |

SUSPENSION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | ACHROMYCIN | | | |
| | + LEDERLE | 1% | N50268 001 | |
| | @ STORZ OPHTHALM | 1% | N50268 001 | |

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** | |

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | THEOPHYLLINE | | | |
| BC | FAULDING | 100MG | N89976 001 | JAN 04, 1995 |
| BC | | 200MG | N89977 001 | JAN 04, 1995 |
| BC | | 300MG | N89932 001 | JAN 04, 1995 |

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | LABID | | | |
| BC | + PROCTER AND GAMBLE | 250MG | N87225 001 | |
| | @ | 250MG | N87225 001 | |
| | THEOLAIR-SR | | | |
| BC | 3M | 250MG | N86363 002 | JUL 16, 1987 |

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

| | | | | |
|---|---|---|---|---|
| | THEOLAIR-SR | | | |
| | 3M | 250MG | N86363 002 | JUL 16, 1987 |
| | **THEOPHYLLINE** | | | |
| AB | INWOOD LABS | **450MG** | **N40034 001** | APR 28, 1995 |
| | UNI-DUR | | | |
| BC | + KEY PHARMS | 400MG | N89822 001 | JAN 04, 1995 |
| | + | 600MG | N89823 001 | JAN 04, 1995 |
| | UNIPHYL | | | |
| BC | PURDUE FREDERICK | 400MG | N87571 001 | SEP 01, 1982 |

THEOPHYLLINE SODIUM GLYCINATE

TABLET; ORAL

| | | | |
|---|---|---|---|
| ASBRON | | | |
| + DORSEY | EQ 150MG BASE | N85148 001 | |
| @ SANDOZ | EQ 150MG BASE | N85148 001 | |

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **THIAMINE HCL** | | | |
| AP | AKORN | **100MG/ML** | **N87968 001** | OCT 01, 1982 |
| | @ | 100MG/ML | N87968 001 | OCT 01, 1982 |

THIOTEPA

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | **THIOPLEX** | | | |
| | IMMUNEX | 15MG/VIAL | N20058 001 | DEC 22, 1994 |
| AP | LEDERLE | **15MG/VIAL** | **N20058 001** | DEC 22, 1994 |
| | **THIOTEPA** | | | |
| AP | + IMMUNEX | **15MG/VIAL** | **N11683 001** | |
| | + | 15MG/VIAL | N11683 001 | |

TIMOLOL

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | BETIMOL | | | |
| | + LEIRAS | EQ 0.25% BASE | N20439 001 | |
| | | | MAR 31, 1995 | |
| | + | EQ 0.5% BASE | N20439 002 | |
| | | | MAR 31, 1995 | |

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | |
|---|---|---|---|---|
| | **TIMOLOL MALEATE** | | | |
| **AT** | ALCON | **EQ 0.25% BASE** | **N74261 001** | |
| | | | APR 28, 1995 | |
| **AT** | | **EQ 0.5% BASE** | **N74262 001** | |
| | | | APR 28, 1995 | |
| | **TIMOPTIC** | | | |
| **AT** | + MERCK | **EQ 0.25% BASE** | **N18086 001** | |
| **AT** | + | **EQ 0.5% BASE** | **N18086 002** | |

TIOCONAZOLE

OINTMENT; VAGINAL

| | | | | |
|---|---|---|---|---|
| | VAGISTAT-1 | | | |
| | + BRISTOL MYERS | 6.5% | N19355 001 | |
| | | | DEC 30, 1986 | |
| | + BRISTOL MYERS SQUIBB | 6.5% | N19355 001 | |
| | | | DEC 30, 1986 | |

TOCAINIDE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | TONOCARD | | | |
| | ASTRA MERCK | 400MG | N18257 001 | |
| | | | NOV 09, 1984 | |
| | + | 600MG | N18257 002 | |
| | | | NOV 09, 1984 | |
| | MERCK SHARP DOHME | 400MG | N18257 001 | |
| | | | NOV 09, 1984 | |
| | + | 600MG | N18257 002 | |
| | | | NOV 09, 1984 | |

TRAMADOL HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | ULTRAM | | | |
| | + JOHNSON RW | 50MG | N20281 002 | |
| | | | MAR 03, 1995 | |
| | @ | 100MG | N20281 001 | |
| | | | MAR 03, 1995 | |

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | **TRAZODONE HCL** | | | |
| **AB** | SIDMAK LABS NJ | **150MG** | **N71525 001** | |
| | | | MAR 09, 1988 | |
| | **TRAZON-150** | | | |
| **AB** | SIDMAK LABS NJ | **150MG** | **N71525 001** | |
| | | | MAR 09, 1988 | |

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

| | | | |
|---|---|---|---|
| | **KENALOG-H** | | |
| **AT** | APOTHECON | **0.1%** | **N86240 001** |
| **AT** | WESTWOOD SQUIBB | **0.1%** | **N86240 001** |

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | KENALOG-10 | | |
| | + APOTHECON | 10MG/ML | N12041 001 |
| | + WESTWOOD SQUIBB | 10MG/ML | N12041 001 |
| | KENALOG-40 | | |
| BP | APOTHECON | 40MG/ML | N14901 001 |
| BP | WESTWOOD SQUIBB | 40MG/ML | N14901 001 |

LOTION; TOPICAL

| | | | |
|---|---|---|---|
| | **KENALOG** | | |
| **AT** | APOTHECON | **0.025%** | **N84343 001** |
| **AT** | + | **0.1%** | **N84343 002** |
| | @ | 0.025% | N11602 003 |
| | @ | 0.1% | N11602 001 |
| **AT** | WESTWOOD SQUIBB | **0.025%** | **N84343 001** |
| **AT** | + | **0.1%** | **N84343 002** |
| | @ | 0.025% | N11602 003 |
| | @ | 0.1% | N11602 001 |
| | **TRIAMCINOLONE ACETONIDE** | | |
| **AT** | BARRE | **0.025%** | **N87191 001** |
| | | | SEP 08, 1982 |

TRIAMCINOLONE ACETONIDE

LOTION; TOPICAL
**TRIAMCINOLONE ACETONIDE**
@ BARRE 0.025% N87191 001 SEP 08, 1982

OINTMENT; TOPICAL
TRIAMCINOLONE ACETONIDE IN ABSORBASE
+ CAROLINA MEDCL 0.05% N89595 001 MAR 23, 1995

PASTE; DENTAL
**KENALOG IN ORABASE**
**AT** + APOTHECON **0.1%** **N12097 001**
**AT** + SQUIBB **0.1%** **N12097 001**

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION
ARISTOCORT
BP + LEDERLE 25MG/ML N11685 003
+ 25MG/ML N11685 003
TRIAMCINOLONE DIACETATE
BP AKORN 25MG/ML N85122 001
BP 40MG/ML N86394 001
@ 25MG/ML N85122 001
@ 40MG/ML N86394 001

TRIAZOLAM

TABLET; ORAL
**TRIAZOLAM**
>ADD> **AB** CHELSEA LABS **0.125MG** **N74445 001** OCT 20, 1995
>ADD>
>ADD> **AB** **0.25MG** **N74445 002** OCT 20, 1995
>ADD>

TRICHLORMETHIAZIDE

TABLET; ORAL
NAQUA
BP SCHERING 2MG N12265 001
@ 2MG N12265 001

>ADD>
>ADD>
>ADD>

TRIFLURIDINE

SOLUTION/DROPS; OPHTHALMIC
**TRIFLURIDINE**
**AT** STERIS **1%** **N74311 001** OCT 06, 1995

**VIROPTIC**
**AT** + GLAXO WELLCOME **1%** **N18299 001**

TRILOSTANE

CAPSULE; ORAL
MODRASTANE
SANOFI WINTHROP 30MG N18719 002 DEC 31, 1984
+ 60MG N18719 001 DEC 31, 1984
@ 30MG N18719 002 DEC 31, 1984
@ 60MG N18719 001 DEC 31, 1984

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL
ASCENT EQ 25MG BASE/5ML N74374 001 JUN 23, 1995

TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL
TRIPROLIDINE HCL
+ DANBURY PHARMA 2.5MG N85094 001
@ 2.5MG N85094 001

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

SUSPENSION; ORAL
TERPONYL
+ SQUIBB 167MG/5ML;167MG/5ML; 167MG/5ML N06904 002
@ 167MG/5ML;167MG/5ML; 167MG/5ML N06904 002

TRISULFAPYRIMIDINES (SULFADIAZINE;SULFAMERAZINE;SULFAMETHAZINE)

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | **SULFA-TRIPLE #2** | | |
| AB | | GLOBAL PHARMS | 167MG;167MG;167MG | N80079 001 |
| AB | + | | 167MG;167MG;167MG | N80079 001 |
| | | **TERFONYL** | | |
| AB | + | SQUIBB | 167MG;167MG;167MG | N06904 001 |
| | @ | | 167MG;167MG;167MG | N06904 001 |

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **TUBOCURARINE CHLORIDE** | | |
| AP | + | APOTHECON | 3MG/ML | N05657 001 |
| AP | + | SQUIBB | 3MG/ML | N05657 001 |

UROFOLLITROPIN

INJECTABLE; INJECTION

| | | | |
|---|---|---|---|
| | METRODIN | | |
| | SERONO | 150 IU/AMP | N19415 003<br>SEP 18, 1986 |

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

| | | | | |
|---|---|---|---|---|
| | | VALTREX | | |
| | + | GLAXO WELLCOME | EQ 500MG BASE | N20487 001<br>JUN 23, 1995 |
| | @ | | EQ 1GM BASE | N20487 002<br>JUN 23, 1995 |

VALPROIC ACID

SYRUP; ORAL

| | | | | |
|---|---|---|---|---|
| | | **VALPROIC ACID** | | |
| AA | | HIGH TECH PHARMA | 250MG/5ML | N74060 001<br>JAN 13, 1995 |

VANCOMYCIN HYDROCHLORIDE

POWDER FOR RECONSTITUTION; ORAL

| | | | | |
|---|---|---|---|---|
| | | **VANCOCIN HCL** | | |
| AA | | LILLY | EQ 250MG BASE/5ML | N61667 002<br>JUL 13, 1983 |
| AA | + | | EQ 500MG BASE/6ML | N61667 001 |
| AB | | | EQ 250MG BASE/5ML | N61667 002<br>JUL 13, 1983 |
| | + | | EQ 500MG BASE/6ML | N61667 001 |
| | | **VANCOLED** | | |
| AA | | LEDERLE | EQ 250MG BASE/5ML | N63321 002<br>OCT 15, 1993 |
| AA | | | EQ 500MG BASE/6ML | N63321 003<br>OCT 15, 1993 |
| AB | | | EQ 250MG BASE/5ML | N63321 002<br>OCT 15, 1993 |
| | @ | | EQ 500MG BASE/6ML | N63321 003<br>OCT 15, 1993 |

VECURONIUM BROMIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **NORCURON** | | |
| AP | + | ORGANON | 10MG/VIAL | N18776 002<br>APR 30, 1984 |
| AP | + | | 20MG/VIAL | N18776 003<br>JAN 03, 1992 |
| | | **VECURONIUM BROMIDE** | | |
| AP | | STERIS | 10MG/VIAL | N74334 001<br>AUG 31, 1995 |
| AP | | | 20MG/VIAL | N74334 002<br>AUG 31, 1995 |

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | |
|---|---|---|---|---|
| | | **VERAPAMIL HCL** | | |
| AP | | BEDFORD | 2.5MG/ML | N72888 001<br>JUL 28, 1995 |

VITAMIN A

CAPSULE; ORAL

| | | | | |
|---|---|---|---|---|
| | | **VITAMIN A** | | |
| AA | | BANNER PHARMACAPS | 50,000 USP UNITS | N83973 001 |

VITAMIN A

CAPSULE; ORAL
VITAMIN A
@ BANNER PHARMACAPS 50,000 USP UNITS N83973 001

VITAMIN A PALMITATE

CAPSULE; ORAL
VITAMIN A
AA BANNER PHARMACAPS EQ 50,000 UNITS BASE N80702 001
@ EQ 50,000 UNITS BASE N80702 001
VITAMIN A PALMITATE
AA BANNER PHARMACAPS EQ 50,000 UNITS BASE N83948 001
@ EQ 50,000 UNITS BASE N83948 001

WARFARIN SODIUM

INJECTABLE; INJECTION
COUMADIN
+ DUPONT MERCK 5MG/VIAL N09218 024
FEB 07, 1995

WATER FOR INJECTION, STERILE

LIQUID; N/A
BACTERIOSTATIC WATER FOR INJECTION IN PLASTIC CONTAINER
AP FUJISAWA 100% N89099 001
DEC 29, 1987
AP 100% N89100 001
DEC 29, 1987
@ 100% N89099 001
DEC 29, 1987
@ 100% N89100 001
DEC 29, 1987

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN

| | | | |
|---|---|---|---|
| | ABLE | 120MG | N73106 001 FEB 27, 1995 |
| | | 325MG | N73107 001 FEB 27, 1995 |
| | | 650MG | N73108 001 FEB 27, 1995 |

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VASOCON-A

| | | | |
|---|---|---|---|
| + | CIBA | 0.5%;0.05% | N18746 002 JUL 11, 1994 |

BACITRACIN ZINC; POLYMYXIN B SULFATE

AEROSOL; TOPICAL
POLYSPORIN

| | | | |
|---|---|---|---|
| @ | GLAXO WELLCOME | 10,000 UNITS/GM; 2,000,000 UNITS/GM | N50167 002 MAR 01, 1985 |

CIMETIDINE

TABLET; ORAL
TAGAMET HB

| | | | |
|---|---|---|---|
| + | SMITHKLINE BEECHAM | 100MG | N20238 001 JUN 19, 1995 |

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
ANTITUSSIVE

| | | | |
|---|---|---|---|
| | PERRIGO | 12.5MG/5ML | N71292 001 APR 10, 1987 |
| @ | | 12.5MG/5ML | N71292 001 APR 10, 1987 |

BELDIN

| | | | |
|---|---|---|---|
| | HALSEY | 12.5MG/5ML | N89179 001 JUN 05, 1986 |

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
BELDIN

| | | | |
|---|---|---|---|
| @ | HALSEY | 12.5MG/5ML | N89179 001 JUN 05, 1986 |

BENYLIN

| | | | |
|---|---|---|---|
| + | PARKE DAVIS | 12.5MG/5ML | N06514 004 |
| @ | | 12.5MG/5ML | N06514 004 |

DIPHEN

| | | | |
|---|---|---|---|
| @ | MORTON GROVE | 12.5MG/5ML | N70118 001 OCT 01, 1985 |
| | PENNEX | 12.5MG/5ML | N70118 001 OCT 01, 1985 |

DIPHENHYDRAMINE HCL

| | | | |
|---|---|---|---|
| | CUMBERLAND SWAN | 12.5MG/5ML | N73611 001 AUG 20, 1992 |
| @ | | 12.5MG/5ML | N73611 001 AUG 20, 1992 |
| | HI TECH PHARMA | 12.5MG/5ML | N72416 001 SEP 28, 1990 |
| @ | | 12.5MG/5ML | N72416 001 SEP 28, 1990 |

HYDRAMINE

| | | | |
|---|---|---|---|
| | BARRE | 12.5MG/5ML | N70205 001 JAN 28, 1986 |
| @ | | 12.5MG/5ML | N70205 001 JAN 28, 1986 |

SILPHEN

| | | | |
|---|---|---|---|
| | SILARX | 12.5MG/5ML | N72646 001 FEB 27, 1992 |
| @ | | 12.5MG/5ML | N72646 001 FEB 27, 1992 |

VICKS FORMULA 44

| | | | |
|---|---|---|---|
| @ | PROCTER AND GAMBLE | 12.5MG/5ML | N70524 001 JAN 14, 1987 |
| | VICKS HLTH CARE | 12.5MG/5ML | N70524 001 JAN 14, 1987 |

FAMOTIDINE

TABLET; ORAL
PEPCID AC

| | | | |
|---|---|---|---|
| + | MERCK | 10MG | N20325 001 APR 28, 1995 |

IBUPROFEN

| | | |
|---|---|---|
| CAPSULE; ORAL | | |
| MIDOL | | |
| + WINTHROP | 200MG | N70626 001<br>SEP 02, 1987 |
| | 200MG | N71002 001<br>SEP 02, 1987 |
| @ | 200MG | N70626 001<br>SEP 02, 1987 |
| @ | 200MG | N71002 001<br>SEP 02, 1987 |
| PROVEL | | |
| + SANDOZ | 200MG | N20402 001<br>APR 20, 1995 |
| SUSPENSION; ORAL | | |
| CHILDREN'S MOTRIN | | |
| + MCNEIL CONS PRODS | 100MG/5ML | N20516 001<br>JUN 16, 1995 |
| TABLET; ORAL | | |
| MIDOL | | |
| WINTHROP | 200MG | N70591 001<br>SEP 02, 1987 |
| | 200MG | N71001 001<br>SEP 02, 1987 |
| @ | 200MG | N70591 001<br>SEP 02, 1987 |
| @ | 200MG | N71001 001<br>SEP 02, 1987 |

INSULIN PORK

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| INSULIN | | |
| + NOVO NORDISK | 100 UNITS/ML | N17926 003 |
| REGULAR INSULIN | | |
| + NOVO NORDISK | 100 UNITS/ML | N17926 003 |

INSULIN PURIFIED PORK

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| VELOSULIN | | |
| NOVO NORDISK | 100 UNITS/ML | N18193 001 |
| @ | 100 UNITS/ML | N18193 001 |

INSULIN PURIFIED PORK; INSULIN SUSP ISOPHANE PURIFIED PORK

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| INSULIN NORDISK MIXTARD (PORK) | | |
| + NOVO NORDISK | 30 UNITS/ML;70 UNITS/ML | N18195 001 |
| @ | 30 UNITS/ML;70 UNITS/ML | N18195 001 |

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| MIXTARD HUMAN 70/30 | | |
| + NOVO NORDISK | 30 UNITS/ML;70 UNITS/ML | N19585 001<br>MAR 11, 1988 |
| @ | 30 UNITS/ML;70 UNITS/ML | N19585 001<br>MAR 11, 1988 |
| NOVOLIN 70/30 | | |
| + NOVO NORDISK | 30 UNITS/ML;70 UNITS/ML | N19441 001<br>JUL 11, 1986 |
| @ | 30 UNITS/ML;70 UNITS/ML | N19441 001<br>JUL 11, 1986 |

INSULIN SUSP ISOPHANE PURIFIED BEEF

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| NPH ILETIN II | | |
| + LILLY | 100 UNITS/ML | N18479 001 |
| @ | 100 UNITS/ML | N18479 001 |

INSULIN SUSP ISOPHANE PURIFIED PORK

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| INSULIN INSULATARD NPH NORDISK | | |
| + NOVO NORDISK | 100 UNITS/ML | N18194 001 |
| @ | 100 UNITS/ML | N18194 001 |
| NPH ILETIN II (PORK) | | |
| @ LILLY | 100 UNITS/ML | N18345 001 |
| + | 100 UNITS/ML | N18345 001 |

INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

| | | |
|---|---|---|
| INJECTABLE; INJECTION | | |
| INSULATARD NPH HUMAN | | |
| + NOVO NORDISK | 100 UNITS/ML | N19449 001<br>MAY 30, 1986 |

INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION
INSULATARD NPH HUMAN

| | | | |
|---|---|---|---|
| @ | NOVO NORDISK | 100 UNITS/ML | N19449 001 MAY 30, 1986 |

INSULIN SUSP PROTAMINE ZINC PURIFIED BEEF

INJECTABLE; INJECTION
PROTAMINE ZINC AND ILETIN II

| | | | |
|---|---|---|---|
| + | LILLY | 100 UNITS/ML | N18476 001 |
| @ | | 100 UNITS/ML | N18476 001 |

PROTAMINE ZINC INSULIN

| | | | |
|---|---|---|---|
| | SQUIBB | 100 UNITS/ML | N17928 003 |
| + | | 100 UNITS/ML | N17928 003 |

> ADD > KETOPROFEN

> ADD > TABLET; ORAL
> ADD > ACTRON

| | | | |
|---|---|---|---|
| > ADD > | BAYER | 12.5MG | N20499 001 OCT 06, 1995 |

> ADD > ORUDIS KT

| | | | |
|---|---|---|---|
| > ADD > + | WHITEHALL ROBINS | 12.5MG | N20429 001 OCT 06, 1995 |

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL

| | | | |
|---|---|---|---|
| | LEMMON | 1MG/5ML | N73478 001 JUN 23, 1995 |

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE

| | | | |
|---|---|---|---|
| | LEMMON | 2% | N74136 001 JAN 04, 1995 |

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE

| | | | |
|---|---|---|---|
| | ABLE | 100MG | N73507 001 NOV 19, 1993 |

MICONAZOLE NITRATE

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE

| | | | |
|---|---|---|---|
| | NMC | 100MG | N73507 001 NOV 19, 1993 |

NAPROXEN SODIUM

TABLET; ORAL
ALEVE

| | | | |
|---|---|---|---|
| | HAMILTON PHARMS | EQ 200MG BASE | N20204 002 JAN 11, 1994 |
| + | | EQ 200MG BASE | N20204 002 JAN 11, 1994 |

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

CREAM; TOPICAL
NEOSPORIN

| | | | |
|---|---|---|---|
| @ | GLAXO WELLCOME | EQ 3.5MG BASE/GM; 10,000 UNITS/GM | N50176 002 JAN 14, 1985 |

NONOXYNOL-9

AEROSOL; VAGINAL
DELFEN

| | | | |
|---|---|---|---|
| @ | ORTHO | 12.5% | N14349 002 |

SPONGE; VAGINAL
TODAY

| | | | |
|---|---|---|---|
| @ | WHITEHALL LABS | 1GM | N18683 001 APR 01, 1983 |
| @ | WHITEHALL ROBINS | 1GM | N18683 001 APR 01, 1983 |

POTASSIUM IODIDE

SOLUTION; ORAL
POTASSIUM IODIDE

| | | | |
|---|---|---|---|
| + | ROXANE | 1GM/ML | N18551 001 FEB 19, 1982 |
| @ | | 1GM/ML | N18551 001 FEB 19, 1982 |

PYRITHIONE ZINC

LOTION; TOPICAL

| | | | |
|---|---|---|---|
| HEAD & SHOULDERS CONDITIONER | | | |
| + | PROCTER AND GAMBLE | 0.3% | N19412 002<br>MAR 10, 1986 |
| @ | | 0.3% | N19412 002<br>MAR 10, 1986 |

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 10 / OCT '95

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
6% HETASTARCH IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
ABBOTT 6GM/100ML;0.9GM/100ML N74193
JAN 30, 1995

## *LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS*
## *[January - October, 1995]*

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| ADENO-AS'TED VIRAL-BASED VECTOR CYSTIC FIBROSIS GENE THERAPY<br>TN= | TREATMENT OF CYSTIC FIBROSIS. | TARGETED GENETICS CORPORATION<br>1100 OLIVE WAY, SUITE 100<br>SEATTLE WA 98101<br>DD 02/15/95 MA / / |
| ALGLUCERASE INJECTION<br>TN= CEREDASE | REPLACEMENT THERAPY IN PATIENTS WITH TYPE II AND III GAUCHER'S DISEASE. | GENZYME CORPORATION<br>ONE KENDALL SQUARE<br>CAMBRIDGE MA 02139-1562<br>DD 07/21/95 MA / / |
| AMINOCAPROIC ACID<br>TN= | FOR THE TOPICAL TREATMENT OF TRAUMATIC HYPHEMA OF THE EYE. | ORPHAN MEDICAL<br>13911 RIDGEDALE DRIVE<br>MINNETONKA MN 55305<br>DD 01/06/95 MA / / |
| APL 400-020<br>TN= | TREATMENT OF CUTANEOUS T CELL LYMPHOMA. | APOLLON, INC.<br>ONE GREAT VALLEY PARKWAY<br>MALVERN PA 19355<br>DD 03/08/95 MA / / |
| APOMORPHINE HCL<br>TN= | TREATMENT OF ON-OFF FLUCTUATIONS ASSOCIATED WITH LATE-STAGE PARKINSON'S DISEASE. | PENTECH PHARMACEUTICALS, INC.<br>417 HARVESTER COURT<br>WHEELING IL 60090<br>DD 07/17/95 MA / / |
| BROMODEOXYURIDINE<br>TN= | RADIATION SENSITIZER IN THE TREATMENT OF PRIMARY BRAIN TUMORS. | NEOPHARM, INC.<br>225 EAST DEERPATH, SUITE 250<br>LAKE FOREST IL 60045<br>DD 09/18/95 MA / / |
| CHONDROITINASE<br>TN= | TREATMENT OF PATIENTS UNDERGOING VITRECTOMY. | STORZ OPHTHALMICS<br>AMERICAN CYANAMID COMPANY<br>PEARL RIVER NY 10965<br>DD 02/09/95 MA / / |
| CLOTRIMIDAZOLE<br>TN= | TREATMENT OF SICKLE CELL DISEASE. | BRUGNARA, CARLO M.D.<br>THE CHILDREN'S HOSPITAL<br>BOSTON MA 02115<br>DD 04/24/95 MA / / |
| CYSTIC FIBROSIS TR GENE THERAPY (RECOMBINANT ADENOVIRUS)<br>TN= ADgvCFTR.10 | TREATMENT OF CYSTIC FIBROSIS. | GENVAC, INCORPORATED<br>12111 PARKLAWN DRIVE<br>ROCKVILLE MD 20852<br>DD 03/09/95 MA / / |
| ELCATONIN<br>TN= | INTRATHECAL TREATMENT OF INTRACTABLE PAIN. | INNAPHARMA, INCORPORATED<br>75 MONTEBELLO ROAD<br>SUFFERN NY 10901<br>DD 09/25/95 MA / / |
| ENCAPSULATED PORCINE ISLET PREPARATION<br>TN= BETARX | TREATMENT OF TYPE I DIABETIC PATIENTS WHO ARE ALREADY ON IMMUNOSUPPRESSION. | VIVORX<br>3212 NEBRASKA AVENUE<br>SANTA MONICA CA 90404<br>DD 07/05/95 MA / / |
| FIBRINOGEN (HUMAN)<br>TN= | FOR THE CONTROL OF BLEEDING AND PROPHYLACTIC TREATMENT OF PATIENTS DEFICIENT IN FIBRINOGEN. | ALPHA THERAPEUTIC CORPORATION<br>5555 VALLEY BOULEVARD<br>LOS ANGELES CA 90032<br>DD 08/23/95 MA / / |
| FILGRASTIM<br>TN= NEUPOGEN | FOR USE IN THE MOBILIZATION OF PERIPHERAL BLOOD PROGENITOR CELLS FOR COLLECTION IN PATIENTS WHO WILL RECEIVE MYELOABLATIVE OR MYELOSUPPRESSIVE CHEMOTHERAPY. | AMGEN, INCORPORATED<br>1840 DEHAVILLAND DRIVE<br>THOUSAND OAKS CA 91320-1789<br>DD 07/17/95 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 |
|---|---|---|
| GABAPENTIN<br>TN= NEURONTIN | TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS. | WARNER-LAMBERT COMPANY<br>PARKE-DAVIS PHARMACEUTICAL<br>RESEARCH DIV.<br>ANN ARBOR MI 48105-2430<br>DD 07/05/95 MA / / |
| GLUTAMINE<br>TN= | FOR USE WITH HUMAN GROWTH HORMONE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE). | RESEARCH TRIANGLE<br>PHARMACEUTICALS<br>4364 SOUTH ALSTON AVENUE<br>DURHAM NC 27713<br>DD 03/06/95 MA / / |
| GLYCERYL TRIOLEATE AND GLYCERYL TRIERUCATE<br>TN= LORENZO'S OIL | TREATMENT OF ADRENOLEUKODYSTROPHY. | MOSER, HUGO W. M.D.<br>JOHNS HOPKINS UNIVERSITY<br>BALTIMORE MD 21205<br>DD 02/14/95 MA / / |
| HEPATITIS B IMMUNE GLOBULIN, INTRAVENOUS<br>TN= H-BIGIV | PROPHYLAXIS AGAINST HEPATITIS B VIRUS REINFECTION IN LIVER TRANSPLANT PATIENTS. | NORTH AMERICAN BIOLOGICS, INC.<br>16500 N.W. 15th AVENUE<br>MIAMI FL 33169<br>DD 03/08/95 MA / / |
| HUMAN GROWTH HORMONE<br>TN= | FOR USE WITH GLUTAMINE IN THE TREATMENT OF SHORT BOWEL SYNDROME (NUTRIENT MALABSORPTION FROM THE GASTROINTESTINAL TRACT RESULTING FROM AN INADEQUATE ABSORPTIVE SURFACE). | RESEARCH TRIANGLE<br>PHARMACEUTICALS<br>4364 SOUTH ALSTON AVENUE<br>DURHAM NC 27713<br>DD 03/06/95 MA / / |
| HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN<br>TN= HIVIG | TREATMENT OF HIV-INFECTED PEDIATRIC PATIENTS. | NORTH AMERICAN BIOLOGICALS, INC.<br>16500 N.W. 15TH AVENUE<br>MIAMI FL 33169<br>DD 01/04/95 MA / / |
| INTRAVITREAL GANCICLOVIR FREE ACID IMPLANT<br>TN= VITRASERT IMPLANT | TREATMENT OF CYTOMEGALOVIRUS RETINITIS. | CHIRON VISION<br>500 IOLAB DRIVE<br>CLAREMONT CA 91711<br>DD 06/07/95 MA / / |
| KL4-SURFACTANT<br>TN= | TREATMENT OF ACUTE RESPIRATORY DISTRESS SYNDROME IN ADULTS. | R.W.JOHNSON RESEARCH INSTITUTE<br>ROUTE 202, PO BOX 300<br>RARITAN NJ 08869-0602<br>DD 07/17/95 MA / / |
| KL4-SURFACTANT<br>TN= | TREATMENT OF RESPIRATORY DISTRESS SYNDROME IN PREMATURE INFANTS. | COCHRANE, CHARLES G. M.D.<br>THE SCRIPPS RESEARCH INSTITUTE<br>10666 NORTH TORREY PINES ROAD<br>IMM 12<br>LA JOLLA, CA 92037<br>DD 10/18/95 MA / / |
| LAMOTRIGINE<br>TN= LAMICTAL | TREATMENT OF LENNOX-GASTAUT SYNDROME. | BURROUGHS-WELLCOME COMPANY<br>3030 CORNWALLIS ROAD, P.O. BO<br>12700<br>RESEARCH TRIANGLE PK NC 2770<br>DD 08/23/95 MA / / |
| LIDOCAINE PATCH 5%<br>TN=LIDOCAINE PATCH | TREATMENT OF POST-HERPETIC NEURALGIA RESULTING FROM HERPES ZOSTER INFECTIONS. | HIND HEALTH CARE, INC<br>165 GIBRALTAR COURT<br>SUNNYVALE, CA 94089<br>DD 10/24/95 MA / / |
| MITOLACTOL<br>TN= | AS ADJUVANT THERAPY IN THE TREATMENT OF PRIMARY BRAIN TUMORS. | BIOPHARMACEUTICS, INC.<br>990 STATION ROAD<br>BELLPORT NY 11713<br>DD 07/12/95 MA / / |

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| MYCOBACTERIUM AVIUM SENSITIN<br>RS-10<br>TN= | FOR USE IN THE DIAGNOSIS OF INVASIVE MYCOBACTERIUM AVIUM DISEASE IN IMMUNOCOMPETENT INDIVIDUALS. | STATENS SERUMINSTITUT<br>5 ARTILLERIVEJ<br>DK-2300 COPENHAGEN S<br>DENMARK<br>DD 10/11/95 MA / / |
| NITRIC OXIDE<br>TN= | TREATMENT OF ACUTE RESPIRATORY DISTRESS SYNDROME IN ADULTS. | OHMEDA PHARMACEUTICAL PRODUCTS DIVISION<br>110 ALLEN ROAD<br>LIBERTY CORNER NJ 07938-0804<br>DD 07/10/95 MA / / |
| NTBC<br>TN= | TREATMENT OF TYROSINEMIA TYPE 1. | SWEDISH ORPHAN AB<br>ORPHAN PHARMACEUTICAL, USA, INC.<br>NASHVILLE TN 37217<br>DD 05/16/95 MA / / |
| PHENYLALANINE AMMONIA-LYASE<br>TN= PHENYLASE | TREATMENT OF HYPERPHENYLALANINEMIA. | IBEX TECHNOLOGIES, INC.<br>5485 PARE<br>MONTREAL, QUEBEC<br>DD 03/08/95 MA / / |
| PORFIROMYCIN<br>TN= | TREATMENT OF HEAD AND NECK CANCER. | ONCORX INC.<br>4 SCIENCE PARK<br>NEW HAVEN CT 06511<br>DD 09/19/95 MA / / |
| PURIFIED TYPE II COLLAGEN<br>TN= COLLORAL | TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS. | AUTOIMMUNE, INCORPORATED<br>128 SPRING STREET<br>LEXINGTON MA 02173<br>DD 02/09/95 MA / / |
| RECOMBINANT HUMAN GELSOLIN<br>TN= | TREATMENT OF ACUTE AND CHRONIC RESPIRATORY SYMPTOMS OF BRONCHIECTASIS. | BIOGEN, INCORPORATED<br>14 CAMBRIDGE CENTER<br>CAMBRIDGE MA 02142<br>DD 03/06/95 MA / / |
| RECOMBINANT HUMAN INSULIN-LIKE GROWTH FACTOR I<br>TN= | TREATMENT OF POST-POLIOMYELITIS SYNDROME. | CEPHALON, INC<br>145 BRANDYWINE PARKWAY<br>WEST CHESTER, PA 19380<br>DD 10/13/95 MA / / |
| RECOMBINANT HUMAN INSULIN-LIKE GROWTH FACTOR I<br>TN= IGEF | TREATMENT OF GROWTH HORMONE RECEPTOR DEFICIENCY. | PHARMACIA, INC.<br>PO BOX 16529<br>COLUMBUS OH 43216-6529<br>DD 06/07/95 MA / / |
| RECOMBINANT HUMAN INSULIN-LIKE GROWTH FACTOR I<br>TN= IGEF | TREATMENT OF ANTIBODY-MEDIATED GROWTH HORMONE RESISTANCE IN PATIENTS WITH ISOLATED GROWTH HORMONE DEFICIENCY IA. | PHARMACIA, INC.<br>P.O. BOX 16529<br>COLUMBUS OH 43216-6529<br>DD 06/07/95 MA / / |
| RECOMBINANT METHIONYL HUMAN STEM CELL FACTOR<br>N= | FOR USE IN COMBINATION WITH FILGRASTIM TO DECREASE THE NUMBER OF PHERESES REQUIRED TO COLLECT PERIPHERAL BLOOD PROGENITOR CELLS CAPABLE OF PROVIDING RAPID MULTI-LINEAGE HEMATOPOIETIC RECONSTITUTION FOLLOWING MYELOSUPPRESSIVE OR MYELOABLATIVE THERAPY. | AMGEN, INCORPORATED<br>1840 DEHAVILLAND DRIVE<br>THOUSAND OAKS CA 91320-1789<br>DD 07/05/95 MA / / |
| RGD0853, E1A LIPID COMPLEX<br>N= | TREATMENT OF ADVANCED OVARIAN CANCER THAT OVEREXPRESSES THE HER-2/neu ONCOGENE. | RGENE THERAPEUTICS, INC.<br>2170 BUCKTHORNE PLACE, SUITE 230<br>THE WOODLANDS TX 77380<br>DD 09/19/95 MA / / |
| RIFAPENTINE<br>N= | TREATMENT OF PULMONARY TUBERCULOSIS. | MARION MERRELL DOW INC.<br>PO BOX 9627 (PARK A)<br>KANSAS CITY MO 94137<br>DD 06/09/95 MA / / |

| NAME<br>Generic/Chemical<br>TN=Trade Name | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| RIFAPENTINE<br>TN= | TREATMENT OF MYCOBACTERIUM AVIUM COMPLEX IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME. | MARION MERRELL DOW INC.<br>PO BOX 9627 (PARK A)<br>KANSAS CITY MO 64137<br>DD 06/09/95 MA / / |
| SARGRAMOSTIM<br>TN= LEUKINE | TO REDUCE NEUTROPENIA AND LEUKOPENIA AND DECREASE THE INCIDENCE OF DEATH DUE TO INFECTION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA. | IMMUNEX CORPORATION<br>51 UNIVERSITY STREET<br>SEATTLE WA 98101<br>DD 03/06/95 MA / / |
| STERILE AEROSOL TALC<br>TN= | TREATMENT OF MALIGNANT PLEURAL EFFUSION. | BRYAN CORPORATION<br>4 PLYMPTON STREET<br>WOBURN MA 01801<br>DD 09/18/95 MA / / |
| SU-101<br>TN= | TREATMENT OF MALIGNANT GLIOMA. | SUGEN, INC.<br>515 GALVESTON DRIVE<br>REDWOOD CITY CA 94063-4720<br>DD 05/25/95 MA / / |
| SYNSORB PK<br>TN= | TREATMENT OF VEROCYTOTOXOGENIC E. COLI INFECTIONS. | SYNSORB BIOTECH INC.<br>FOURTH FLOOR, 140 4TH AVENUE SW<br>CALGARY, ALBERTA<br>DD 07/17/95 MA / / |
| THALIDOMIDE<br>TN= | TREATMENT OF SEVERE RECURRENT APHTHOUS STOMATITIS IN SEVERELY, TERMINALLY IMMUNOCOMPROMISED PATIENTS. | CELGENE CORPORATION<br>P.O. BOX 4914<br>WARREN NJ 07059<br>DD 05/01/95 MA / / |
| THALIDOMIDE<br>TN= | TREATMENT AND PREVENTION OF RECURRENT APHTHOUS ULCERS IN SEVERELY, TERMINALLY IMMUNOCPOMPROMISED PATIENTS. | ANDRULIS RESEARCH CORPORATION<br>11800 BALTIMORE AVENUE, SUITE 113<br>BELTSVILLE MD 20705<br>DD 05/15/95 MA / / |
| THALIDOMIDE<br>TN= SYNOVIR | TREATMENT OF ERYTHEMA NODOSUM LEPROSUM. | CELGENE CORPORATION<br>7 POWDER HORN DRIVE, PO BOX 4914<br>WARREN NJ 07059<br>DD 07/26/95 MA / / |
| TRISODIUM CITRATE CONCENTRATION<br>TN= HEMOCITRATE | FOR USE IN LEUKAPHERESIS PROCEDURES. | HEMOTEC MEDICAL PRODUCTS, INC.<br>BOX 19255<br>JOHNSTON RI 02919<br>DD 06/15/95 MA / / |
| TYLOXAPOL<br>TN= | TREATMENT OF CYSTIC FIBROSIS. | KENNEDY & HOIDAL, MDs<br>50 NORTH MEDICAL DRIVE, U OF UTAH<br>SALT LAKE CITY UT 84132<br>DD 03/08/95 MA / / |

| | INDICATION DESIGNATED | SPONSOR & ADDRESS<br>DD=Date Designated<br>MA=Marketing Approval |
|---|---|---|
| | Approved Orphan Products in 1995 | |
| | 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 08/03/95 |
| | FOR THE PREVENTION OF CARDIOMYOPATHY ASSOCIATED WITH DOXORUBICIN ADMINISTRATION. | PHARMACIA, INC.<br>P.O. BOX 16529<br>COLUMBUS OH 43216-6529<br>DD 12/17/91 MA 05/26/95 |
| OBULIN<br>N) | TREATMENT OF IMMUNE THROMBOCYTOPENIC PURPURA. | RH PHARMACEUTICALS, INC.<br>104 CHANCELLOR MATHESON ROAD<br>WINNIPEG, MANITOBA<br>DD 11/09/93 MA 03/24/95 |

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

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NO OCTOBER 1995 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, 15TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| | | |
|---|---|---|
| CLOZAPINE *IN VITRO* AND *IN VIVO* INTERIM (TABLET) | NOV 21, 1995 | |
| CORTICOSTEROIDS, DERMATOLOGIC *IN VIVO* (TOPICAL) | JUN 02, 1995 | |
| FLURBIPROFEN (TABLET) | DEC 24, 1992 | JUN 08, 1995 |
| NAPROXEN (TABLET) | JUN 12, 1992 | JUN 08, 1995 |
| TERFENADINE (TABLET) | JUN 12, 1992 | SEP 11, 1995 |

## ANDA SUITABILITY PETITIONS

### PETITIONS APPROVED

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT T
REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS
ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED A
REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANC
HFA-305, ROOM 1-23, PARK BUILDING, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 15TH EDITION FOR A FULL LISTING OF AN
SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR<br>PETITION | STATUS |
|---|---|---|---|---|---|
| ACETAMINOPHEN;<br>ASPIRIN;<br>CODEINE PHOSPHATE<br>TABLET; ORAL | 150MG<br>180MG<br>15MG | 94 P-0212/<br>CP1 | MIKART | NEW<br>DOSAGE FORM | APPROVED<br>JAN 19, 1995 |
| ACETAMINOPHEN;<br>ASPIRIN;<br>CODEINE PHOSPHATE<br>TABLET; ORAL | 150MG<br>180MG<br>30MG | 94 P-0211/<br>CP1 | MIKART | NEW<br>DOSAGE FORM | APPROVED<br>JAN 19, 1995 |
| ACETAMINOPHEN;<br>ASPIRIN;<br>CODEINE PHOSPHATE<br>TABLET; ORAL | 150MG<br>180MG<br>60MG | 94 P-0210/<br>CP1 | MIKART | NEW<br>DOSAGE FORM | APPROVED<br>JAN 19, 1995 |
| ACETAMINOPHEN;<br>CAFFEINE;<br>DIHYDROCODEINE BITARTRATE<br>TABLET; ORAL | 712.8MG<br>60MG<br>32MG | 93 P-0484/<br>CP1 | MIKART | NEW<br>DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>JAN 19, 1995 |
| ACETAMINOPHEN;<br>CODEINE PHOSPHATE<br>TABLET, CHEWABLE; ORAL | 120MG<br>12MG | 94 P-0182/<br>CP1 | WE PHARMS | NEW<br>DOSAGE FORM | APPROVED<br>JAN 19, 1995 |
| ALBUTEROL SULFATE<br>TABLET, CHEWABLE; ORAL | EQ 2MG BASE<br>EQ 4MG BASE | 92 P-0335/<br>CP1 | WE PHARMS | NEW<br>DOSAGE FORM | APPROVED<br>JAN 19, 1995 |
| ATRACURIUM BESYLATE<br>INJECTABLE; INJECTION | 25MG/ML | 94 P-0314/<br>CP1 | ABBOTT | NEW STRENGTH | APPROVED<br>MAY 02, 1995 |
| CALCITONIN, SALMON<br>INJECTABLE; INJECTION | 100 IU/ML<br>(0.5ML/AMP)<br>1ML/AMP) | 95 P-0080/<br>CP1 | FERRING | NEW STRENGTH | APPROVED<br>AUG 07, 1995 |
| CAPTOPRIL<br>SOLUTION; ORAL | 25MG/ML | 95 P-0008/<br>CP1 | ROXANE | NEW<br>DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>AUG 07, 1995 |
| FLUOROURACIL<br>GEL; TOPICAL | 5% | 94 P-0263/<br>CP1 | BRADLEY PHARMS | NEW<br>DOSAGE FORM | APPROVED<br>SEP 12, 1995 |
| IOPAMIDOL<br>INJECTABLE; INJECTION | 61%<br>(250ML/CONTAINER)<br>(500ML/CONTAINER) | 95 P-0073/<br>CP1 | ABBOTT | NEW STRENGTH | APPROVED<br>AUG 23, 1995 |
| IOPAMIDOL<br>INJECTABLE; INJECTION | 76%<br>(250ML/CONTAINER)<br>(500ML/CONTAINER) | 95 P-0073/<br>CP1 | ABBOTT | NEW STRENGTH | APPROVED<br>AUG 23, 1995 |
| LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION | 10MG/ML<br>(5ML/VIAL) | 94 P-0433/<br>CP2 | LEDERLE | NEW<br>DOSAGE FORM | APPROVED<br>AUG 07, 1995 |
| LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION | 10MG/ML<br>(20ML/VIAL) | 94 P-0433/<br>CP3 | LEDERLE | NEW<br>DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>AUG 07, 1995 |

## ANDA SUITABILITY PETITIONS

### PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|---|---|---|---|---|---|
| LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION | 10MG/ML<br>(35ML/VIAL) | 94 P-0433/<br>CP1 | LEDERLE | NEW<br>DOSAGE FORM | APPROVED<br>AUG 07, 1995 |
| LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION | EQ 10MG BASE/ML<br>(100MG/VIAL) | 93 P-0427/<br>CP3 | ABBOTT | NEW DOSAGE<br>FORM | APPROVED<br>JAN 19, 1995 |
| LEUCOVORIN CALCIUM<br>INJECTABLE; INJECTION | EQ 10MG BASE/ML<br>(250MG/VIAL) | 93 P-0427/<br>CP2 | ABBOTT | NEW<br>DOSAGE FORM<br>NEW STRENGTH | APPROVED<br>JAN 19, 1995 |
| LORAZEPAM<br>SOLUTION; ORAL | 0.5MG/5ML | 94 P-0199/<br>CP1 | ROXANE | NEW<br>DOSAGE FORM | APPROVED<br>FEB 07, 1995 |
| MEDROXYPROGESTERONE ACETATE<br>TABLET; ORAL | 2MG<br>4MG<br>8MG | 92 P-0452/<br>CP1 | CARNRICK | NEW STRENGTH | APPROVED<br>AUG 07, 1995 |
| METHYLPREDNISOLONE<br>TABLET, CHEWABLE; ORAL | 4MG<br>16MG<br>24MG<br>32MG | 94 P-0432/<br>CP1 | DURA PHARMS | NEW<br>DOSAGE FORM | APPROVED<br>AUG 07, 1995 |
| SULFAMETHOXAZOLE;<br>TRIMETHOPRIM<br>TABLET, CHEWABLE; ORAL | 200MG<br>40MG | 94 P-0186/<br>CP1 | DURA PHARMS | NEW<br>DOSAGE FORM | APPROVED<br>JAN 19, 1995 |
| THIORIDAZINE HYDROCHLORIDE<br>SOLUTION; ORAL | 25MG/5ML | 92 P-0283/<br>CP1 | UDL LABS | NEW STRENGTH | APPROVED<br>JAN 19, 1995 |

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

| DRUG NAME<br>DOSAGE FORM; ROUTE | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|---|---|---|---|---|---|
| HYDROMORPHONE HYDROCHLORIDE<br>INJECTABLE; INJECTION | 0.2MG/ML<br>(50ML PREFILLED SYRINGE) | 95 P-0022/<br>CP1 | ASTRA | NEW INDICATION<br>NEW ROUTE OF ADMINISTRATION<br>NEW STRENGTH | DENIED<br>SEP 07, 1995 |
| MEFLOQUINE HYDROCHLORIDE<br>TABLET; ORAL | 275MG | 94 P-0329/<br>CP1 | LACASSE | NEW DOSING REGIMEN<br>NEW STRENGTH | DENIED<br>SEP 07, 1995 |
| NICOTINE POLACRILEX<br>LOLLIPOP; ORAL | 2MG | 93 P-0414/<br>CP1 | SAVAGE | NEW DOSAGE FORM | DENIED<br>MAY 02, 1995 |
| NORETHINDRONE ACETATE<br>TABLET; ORAL | 1MG<br>2.5MG | 94 P-0446/<br>CP1 | APOTHECON | NEW INGREDIENT<br>NEW STRENGTH | DENIED<br>SEP 07, 1995 |
| SELEGILINE HYDROCHLORIDE<br>TABLET, EXTENDED RELEASE; ORAL | 10MG | 94 P-0387/<br>CP1 | PHARMAVENE | NEW DOSAGE FORM<br>NEW STRENGTH | DENIED<br>MAY 08, 1995 |
| TERFENADINE<br>TABLET, CHEWABLE: ORAL | 60MG | 94 P-0119/<br>CP1 | DURA PHARMS | NEW DOSAGE FORM | DENIED<br>AUG 23, 1995 |

## 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, 15TH 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-26 ONCE WEEKLY APPLICATION
D-27 BID DOSING IN PATIENTS 12 YEARS OF AGE AND OLDER FOR PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH MODERATELY EMETOGENIC CANCER CHEMOTHERAPY
D-28 USE OF ISOVUE-370 IN EXCRETORY UROGRAPHY AT EQUIVALENT GRAMS OF IODINE TO THE CURRENTLY APPROVED ISOVUE-250 AND ISOVUE-300

### REFERENCES
*NEW INDICATION*

I-117 TO SLOW THE PROGRESSION OF CORONARY ATHEROSCLEROSIS IN PATIENTS WITH CORONARY HEART DISEASE
I-118 PREVENTION OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, FOLLOWING KNEE REPLACEMENT SURGERY
I-119 TREATMENT OF ANEMIA CAUSED BY UTERINE LEIOMYOMATA IN WOMEN WHO FAIL IRON THERAPY
I-120 MAINTENANCE THERAPY FOR GASTRIC ULCER PATIENTS AT REDUCED DOSAGE AFTER HEALING ACUTE ULCERS
I-121 EXPANDED PATIENT POPULATION - USE IN ICU PATIENTS
I-122 PSORIASIS OF THE SCALP
I-123 RELIEF OF MILD TO MODERATE PAIN IN PATIENTS AGED 6 MONTHS AND OLDER
I-124 LEUCOCYTE LABELED SCINTIGRAPHY AS AN ADJUNCT IN THE LOCALIZATION OF INTRA-ABDOMINAL INFECTION AND INFLAMMATORY BOWEL DISEASE
I-125 EXPANSION OF CONSCIOUS SEDATION INDICATION TO INCLUDE SHORT THERAPEUTIC PROCEDURES
I-126 ADJUNCT TO THALLIUM-201 MYOCARDIAL PERFUSION IN PATIENTS UNABLE TO EXERCISE ADEQUATELY
I-127 TREATMENT OF ACYCLOVIR-RESISTANT HERPES IN IMMUNOCOMPROMISED PATIENTS
I-128 IN PATIENTS WITH CORONARY HEART DISEASE AND HYPERCHOLESTEROLEMIA: TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH; REDUCE THE RISK OF NON-FATAL MYOCARDIAL INFARCTION; REDUCE THE RISK FOR UNDERGOING MYOCARDIAL REVASCULARIZATION PROCEDURES; REDUCTION OF ELEVATED TOTAL AND LDL CHOLESTEROL LEVELS IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA (TYPES IIA AND IIB)
I-129 TREATMENT OF ALCOHOL DEPENDENCE
I-130 MAINTENANCE OF HEALING OF EROSIVE ESOPHAGITIS
I-131 PERIPHERAL ARTERIOGRAPHY
I-132 TREATMENT OF MANIC PHASE OF BIPOLAR DISORDER
I-133 MANAGEMENT OF CHRONIC STABLE ANGINA
I-134 HEART FAILURE POST MYOCARDIAL INFARCTION
I-135 BONE METASTASES ASSOCIATED WITH MULTIPLE MYELOMA
I-136 IDIOPATHIC CHRONIC URTICARIA

### REFERENCES
*PATENT USE CODE*

U-102 METHOD OF HORMONALLY TREATING MENOPAUSAL OR POST-MENOPAUSAL DISORDERS IN WOMEN
U-103 TREATMENT OF OCULAR HYPERTENSION
U-104 TREATMENT OF AQUEOUS HUMOR FORMATION AND INTRAOCULAR PRESSURE
U-105 EMESIS
U-106 TREATMENT OF EPILEPSY
U-107 TREATMENT OF HYPERTENSION AND ANGINA PECTORIS
U-108 SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER, GASTROESOPHAGEAL REFLUX DISEASE (GERD), SEVERE EROSIVE ESOPHAGITIS, POORLY RESPONSIVE SYMPTOMATIC GERD, PATHOLOGICAL HYPERSECRETORY CONDITIONS AND MAINTENANCE OF HEALING OF EROSIVE ESOPHAGITIS

## EXCLUSIVITY TERMS

## REFERENCES

*PATENT USE CODE*

| | |
|---|---|
| U-109 | USE AS AN ADJUNCT TO DIET IN THE TREATMENT OF ELEVATED TOTAL CHOLESTEROL AND LDL-C LEVELS IN PATIENTS WITH PRI HYPERCHOLESTEROLEMIA WHOSE RESPONSE TO DIETARY RESTRICTION OF SATURATED FAT AND CHOLESTEROL AND OTHER NONPHARMACOLOGICAL MEASURES HAS NOT BEEN ADEQUATE |
| U-110 | USE AS A RETRIEVABLE PESSARY |
| U-111 | DIABETES |
| U-112 | CONTRACEPTION |
| U-113 | METHOD OF CONDUCTING A RADIOLOGICAL EXAMINATION OF A PATIENT BY ADMINISTERING TO SAID PATIENT A RADIOPAQUE AM OF IOPROMIDE |
| U-114 | USE FOR INHIBITING BONE RESORPTION |
| U-115 | USE OF VASODILATORS TO EFFECT AND ENHANCE AN ERECTION (AND THUS TREAT ERECTILE DYSFUNCTION), BY INJECTION INT PENIS |

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 |
|---|---|---|---|---|---|---|---|
| | 20482 001 | ACARBOSE; PRECOSE | | | | NCE | SEP 06, 2000 |
| | 20482 002 | ACARBOSE; PRECOSE | | | | NCE | SEP 06, 2000 |
| | 19872 001 | ACETAMINOPHEN; TYLENOL | 5004613 | JUL 27, 2007 | | | |
| | | | 4968509 | NOV 06, 2007 | | | |
| | | | 4820522 | JUL 27, 2007 | | NDF | JUN 08, 1997 |
| | 19806 001 | ACRIVASTINE; SEMPREX-D | 4501893 | FEB 01, 2003 | | | |
| | 20059 001 | ADENOSINE; ADENOSCAN | | | | I-126 | MAY 18, 1998 |
| >ADD> | 18062 001 | ALBUTEROL SULFATE; PROVENTIL | 4499108 | JUN 08, 2003 | | | |
| >DLT> | ~~18062 001~~ | ~~ALBUTEROL SULFATE; PROVENTIL~~ | ~~4499108~~ | ~~FEB 12, 2002~~ | | | |
| | 19489 001 | ALBUTEROL SULFATE; VENTOLIN ROTACAPS | 4353365 | APR 24, 1998 | | | |
| | | | 4206758 | APR 24, 1998 | | | |
| | 18702 001 | ALCLOMETASONE DIPROPIONATE; ACLOVATE | 4124707 | DEC 12, 1996 | | | |
| | 18707 001 | ALCLOMETASONE DIPROPIONATE; ACLOVATE | 4124707 | DEC 12, 1996 | | | |
| | 20560 001 | ALENDRONATE SODIUM; FOSAMAX | 5358941 | DEC 02, 2012 | | | |
| | | | 4621077 | NOV 04, 2003 | U-114 | NCE | SEP 29, 2000 |
| | 20560 002 | ALENDRONATE SODIUM; FOSAMAX | 5358941 | DEC 02, 2012 | | | |
| | | | 4621077 | NOV 04, 2003 | U-114 | NCE | SEP 29, 2000 |
| >ADD> | 19353 001 | ALFENTANIL HYDROCHLORIDE; ALFENTA | 4167574 | MAY 05, 1999 | | | |
| >DLT> | ~~19353 001~~ | ~~ALFENTANIL HYDROCHLORIDE; ALFENTA~~ | ~~4167574~~ | ~~SEP 11, 1998~~ | | | |
| >ADD> | 20379 001 | ALPROSTADIL; CAVERJECT | 4127118 | MAR 16, 1997 | U-115 | NP | JUL 06, 1998 |
| >ADD> | 20379 002 | ALPROSTADIL; CAVERJECT | 4127118 | MAR 16, 1997 | U-115 | NP | JUL 06, 1998 |
| | 20377 001 | AMIODARONE HYDROCHLORIDE; CORDARONE | | | | ODE | AUG 03, 2002 |
| | | | | | | NDF | AUG 03, 1998 |
| | 19787 001 | AMLODIPINE BESYLATE; NORVASC | 4879303 | MAR 25, 2007 | | | |
| | 19787 002 | AMLODIPINE BESYLATE; NORVASC | 4879303 | MAR 25, 2007 | | | |
| | 19787 003 | AMLODIPINE BESYLATE; NORVASC | 4879303 | MAR 25, 2007 | | | |
| | 20364 002 | AMLODIPINE BESYLATE; LOTREL | 4879303 | MAR 25, 2007 | | NC | MAR 03, 1998 |
| | | | 4572909 | AUG 01, 2006 | | NCE | JUN 25, 1996 |
| | | | 4410520 | OCT 18, 2002 | | NCE | JUL 31, 1997 |
| | 20364 003 | AMLODIPINE BESYLATE; LOTREL | 4879303 | MAR 25, 2007 | | NC | MAR 03, 1998 |
| | | | 4572909 | AUG 01, 2006 | | NCE | JUN 25, 1996 |
| | | | 4410520 | OCT 18, 2002 | | NCE | JUL 31, 1997 |
| | 20364 004 | AMLODIPINE BESYLATE; LOTREL | 4879303 | MAR 25, 2007 | | NC | MAR 03, 1998 |
| | | | 4572909 | AUG 01, 2006 | | NCE | JUN 25, 1996 |
| | | | 4410520 | OCT 18, 2002 | | NCE | JUL 31, 1997 |
| >ADD> | 19155 001 | AMMONIUM LACTATE; LAC-HYDRIN | 4105783 | JAN 15, 1997 | | | |
| >DLT> | ~~19155 001~~ | ~~AMMONIUM LACTATE; LAC-HYDRIN~~ | ~~4105783~~ | ~~OCT 26, 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 |
|---|---|---|---|---|---|---|---|
| | | | 4219559 | APR 03, 2000 | | | |
| >ADD> | 19402 001 | ASTEMIZOLE; HISMANAL | 4219559 | AUG 26, 1999 | | | |
| >DLT> | 19402 001 | ASTEMIZOLE; HISMANAL | 4981874 | AUG 15, 2009 | U-69 | | |
| | 20259 001 | ATOVAQUONE; MEPRON | 5053432 | OCT 01, 2008 | | NCE | NOV 25, 1997 |
| | 20500 001 | ATOVAQUONE; MEPRON | 4981874 | AUG 15, 2009 | U-69 | NDF | FEB 08, 1998 |
| | | | 4298604 | OCT 06, 2000 | | | |
| >ADD> | 18827 001 | BETAMETHASONE DIPROPIONATE; LOTRISONE | 4298604 | NOV 03, 1998 | | | |
| >DLT> | 18827 001 | BETAMETHASONE DIPROPIONATE; LOTRISONE | 4489071 | DEC 09, 2003 | | | |
| >ADD> | 19555 001 | BETAMETHASONE DIPROPIONATE; DIPROLENE AF | 4489071 | DEC 18, 2001 | | | |
| >DLT> | 19555 001 | BETAMETHASONE DIPROPIONATE; DIPROLENE AF | 4775529 | MAY 21, 2007 | | | |
| >ADD> | 19716 001 | BETAMETHASONE DIPROPIONATE; DIPROLENE | 4775529 | OCT 04, 2005 | | | |
| >DLT> | 19716 001 | BETAMETHASONE DIPROPIONATE; DIPROLENE | | | | NCE | OCT 04, 2000 |
| >ADD> | 20498 001 | BICALUTAMIDE; CASODEX | 4507323 | JUL 25, 2004 | | | |
| | 18644 001 | BUPROPION HYDROCHLORIDE; WELLBUTRIN | 4438138 | DEC 06, 2002 | | | |
| | | | 4435449 | MAY 14, 2001 | | | |
| | | | 4425363 | MAY 14, 2001 | | | |
| | | | 4393078 | MAR 15, 2002 | | | |
| | | | 4347257 | OCT 09, 1999 | | | |
| | 18644 002 | BUPROPION HYDROCHLORIDE; WELLBUTRIN | 4507323 | JUL 25, 2004 | | | |
| | | | 4438138 | DEC 06, 2002 | | | |
| | | | 4435449 | MAY 14, 2001 | | | |
| | | | 4425363 | MAY 14, 2001 | | | |
| | | | 4393078 | MAR 15, 2002 | | | |
| | | | 4347257 | OCT 09, 1999 | | | |
| | 18644 003 | BUPROPION HYDROCHLORIDE; WELLBUTRIN | 4507323 | JUL 25, 2004 | | | |
| | | | 4438138 | DEC 06, 2002 | | | |
| | | | 4435449 | MAY 14, 2001 | | | |
| | | | 4425363 | MAY 14, 2001 | | | |
| | | | 4393078 | MAR 15, 2002 | | | |
| | | | 4347257 | OCT 09, 1999 | | | |
| | 19215 001 | BUTOCONAZOLE NITRATE; FEMSTAT | 4078071 | JUL 28, 1997 | | | |
| | 19359 001 | BUTOCONAZOLE NITRATE; FEMSTAT | 4078071 | JUL 28, 1997 | | | |
| | | | | | | NDF | AUG 17, 1998 |
| | 20313 002 | CALCITONIN, SALMON; MIACALCIN | 4105776 | FEB 13, 1996 | | | |
| | 18343 001 | CAPTOPRIL; CAPOTEN | 4105776 | FEB 13, 1996 | | | |
| | 18343 002 | CAPTOPRIL; CAPOTEN | 4105776 | FEB 13, 1996 | | | |
| | 18343 003 | CAPTOPRIL; CAPOTEN | 4105776 | FEB 13, 1996 | | | |
| | 18343 005 | CAPTOPRIL; CAPOTEN | | | | | |

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 |
|---|---|---|---|---|---|---|
| 18343 006 | CAPTOPRIL; CAPOTEN | 4105776 | FEB 13, 1996 | | | |
| 18709 001 | CAPTOPRIL; CAPOZIDE 25/15 | 4217347 | DEC 27, 1997 | | | |
| | | 4105776 | FEB 13, 1996 | | | |
| 18709 002 | CAPTOPRIL; CAPOZIDE 25/25 | 4217347 | DEC 27, 1997 | | | |
| | | 4105776 | FEB 13, 1996 | | | |
| 18709 003 | CAPTOPRIL; CAPOZIDE 50/25 | 4217347 | DEC 27, 1997 | | | |
| | | 4105776 | FEB 13, 1996 | | | |
| 18709 004 | CAPTOPRIL; CAPOZIDE 50/15 | 4217347 | DEC 27, 1997 | | | |
| | | 4105776 | FEB 13, 1996 | | | |
| 19856 001 | CARBIDOPA; SINEMET CR | 4900755 | JUN 16, 2006 | | | |
| | | 4832957 | JUN 16, 2006 | | | |
| 19856 002 | CARBIDOPA; SINEMET CR | 4900755 | JUN 16, 2006 | | | |
| | | 4832957 | JUN 16, 2006 | | | |
| 20297 001 | CARVEDILOL; COREG | | | | NCE | SEP 14, 2000 |
| 20297 002 | CARVEDILOL; COREG | | | | NCE | SEP 14, 2000 |
| 20297 003 | CARVEDILOL; COREG | | | | NCE | SEP 14, 2000 |
| 20044 001 | CETYL ALCOHOL; EXOSURF NEONATAL | 5110806 | MAY 02, 2006 | | | |
| | | 4312860 | NOV 21, 2001 | | | |
| 18663 001 | CHYMOPAPAIN; CHYMODIACTIN | 4439423 | MAY 13, 2001 | | | |
| 18663 002 | CHYMOPAPAIN; CHYMODIACTIN | 4439423 | MAY 13, 2001 | | | |
| 20238 001 | CIMETIDINE; TAGAMET HB | | | | NS | JUN 19, 1998 |
| 19847 001 | CIPROFLOXACIN; CIPRO | 4670444 | DEC 09, 2003 | | | |
| 19857 001 | CIPROFLOXACIN; CIPRO IN DEXTROSE 5% | 4670444 | DEC 09, 2003 | | | |
| 19858 001 | CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9% | 4670444 | DEC 09, 2003 | | | |
| 19537 002 | CIPROFLOXACIN HYDROCHLORIDE; CIPRO | 5286754 | FEB 15, 2011 | | | |
| | | 4670444 | DEC 09, 2003 | U-36 | | |
| 19537 003 | CIPROFLOXACIN HYDROCHLORIDE; CIPRO | 5286754 | FEB 15, 2011 | | | |
| | | 4670444 | DEC 09, 2003 | U-36 | | |
| 19537 004 | CIPROFLOXACIN HYDROCHLORIDE; CIPRO | 5286754 | FEB 15, 2011 | | | |
| | | 4670444 | DEC 09, 2003 | U-36 | | |
| 20398 001 | CISAPRIDE MONOHYDRATE; PROPULSID | | | | NCE | JUL 29, 1998 |
| 18891 001 | CLONIDINE; CATAPRES-TTS-1 | 4559222 | MAY 04, 2003 | | | |
| | | 4201211 | JUL 12, 1997 | | | |
| 18891 002 | CLONIDINE; CATAPRES-TTS-2 | 4559222 | MAY 04, 2003 | | | |
| | | 4201211 | JUL 12, 1997 | | | |
| 18891 003 | CLONIDINE; CATAPRES-TTS-3 | 4559222 | MAY 04, 2003 | | | |
| | | 4201211 | JUL 12, 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 |
|---|---|---|---|---|---|---|---|
| | 20222 001 | COLESTIPOL HYDROCHLORIDE; COLESTID | | | | NDF | JUL 19, 1997 |
| | 12142 006 | CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN | 4537883 | NOV 12, 2002 | | | |
| | 12142 007 | CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN | 4537883 | NOV 12, 2002 | | | |
| | 12142 008 | CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN | 4537883 | NOV 12, 2002 | | | |
| | 12142 009 | CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN | 4537883 | NOV 12, 2002 | | | |
| | 12142 010 | CYCLOPHOSPHAMIDE; LYOPHILIZED CYTOXAN | 4537883 | NOV 12, 2002 | | | |
| | 20287 001 | DALTEPARIN SODIUM; FRAGMIN | 4303651 | JAN 04, 2000 | | NCE | DEC 22, 1999 |
| | 19849 001 | DAPIPRAZOLE HYDROCHLORIDE; REV-EYES | 4252721 | FEB 07, 2003 | | | |
| >ADD> | 20071 001 | DESOGESTREL; DESOGEN | 3927046 | NOV 06, 1996 | | | |
| >DLT> | ~~20071 001~~ | ~~DESOGESTREL; DESOGEN~~ | ~~3927046~~ | ~~NOV 19, 1995~~ | | | |
| >ADD> | 20071 002 | DESOGESTREL; DESOGEN | 3927046 | NOV 06, 1996 | | | |
| >DLT> | ~~20071 002~~ | ~~DESOGESTREL; DESOGEN~~ | ~~3927046~~ | ~~NOV 19, 1995~~ | | | |
| >ADD> | 20301 001 | DESOGESTREL; ORTHO-CEPT | 3927046 | NOV 06, 1996 | | | |
| >DLT> | ~~20301 001~~ | ~~DESOGESTREL; ORTHO-CEPT~~ | ~~3927046~~ | ~~NOV 19, 1995~~ | | | |
| >ADD> | 20301 002 | DESOGESTREL; ORTHO-CEPT | 3927046 | NOV 06, 1996 | | | |
| >DLT> | ~~20301 002~~ | ~~DESOGESTREL; ORTHO-CEPT~~ | ~~3927046~~ | ~~NOV 19, 1995~~ | | | |
| | 20212 001 | DEXRAZOXANE HYDROCHLORIDE; ZINECARD | | | | NCE | MAY 26, 2000 |
| | | | | | | ODE | MAY 26, 2002 |
| | 20212 002 | DEXRAZOXANE HYDROCHLORIDE; ZINECARD | | | | NCE | MAY 26, 2000 |
| | | | | | | ODE | MAY 26, 2002 |
| | 20062 001 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5286497 | MAY 20, 2011 | | | |
| | 20062 002 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5286497 | MAY 20, 2011 | | | |
| | 20062 003 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5286497 | MAY 20, 2011 | | | |
| | 20062 004 | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5286497 | MAY 20, 2011 | | | |
| | 20092 001 | DILTIAZEM HYDROCHLORIDE; DILACOR XR | 4839177 | DEC 09, 2006 | | I-133 | OCT 15, 1995 |
| | 20092 002 | DILTIAZEM HYDROCHLORIDE; DILACOR XR | 4839177 | DEC 09, 2006 | | I-133 | OCT 15, 1995 |
| | 20092 003 | DILTIAZEM HYDROCHLORIDE; DILACOR XR | 4839177 | DEC 09, 2006 | | I-133 | OCT 15, 1995 |
| | 20411 001 | DINOPROSTONE; CERVIDIL | 5269321 | DEC 14, 2010 | U-110 | | |
| | | | 4931288 | JAN 16, 2007 | | NDF | MAR 30, 1998 |
| | 18723 001 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | I-132 | MAY 26, 1998 |
| | 18723 002 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | I-132 | MAY 26, 1998 |
| | 18723 003 | DIVALPROEX SODIUM; DEPAKOTE | 4988731 | JAN 29, 2008 | | I-132 | MAY 26, 1998 |
| >ADD> | 20408 001 | DORZOLAMIDE HYDROCHLORIDE; TRUSOPT | 4797413 | DEC 12, 2004 | U-103 | NCE | DEC 09, 1999 |
| >DLT> | ~~20408 001~~ | ~~DORZOLAMIDE HYDROCHLORIDE; TRUSOPT~~ | ~~4797413~~ | ~~JUN 30, 2004~~ | ~~U-103~~ | ~~NCE~~ | ~~DEC 09, 1999~~ |
| | | | 4619939 | OCT 28, 2003 | U-104 | | |
| | 19946 001 | DOXACURIUM CHLORIDE; NUROMAX | | | | I-121 | DEC 08, 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 |
|---|---|---|---|---|---|---|---|
| >ADD> | 19668 001 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | OCT 18, 2000 | | I-96 | FEB 06, 1998 |
| >DLT> | ~~19668 001~~ | ~~DOXAZOSIN MESYLATE; CARDURA~~ | ~~4188390~~ | ~~FEB 12, 1999~~ | | ~~I-96~~ | ~~FEB 06, 1998~~ |
| >ADD> | 19668 002 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | OCT 18, 2000 | | I-96 | FEB 06, 1998 |
| >DLT> | ~~19668 002~~ | ~~DOXAZOSIN MESYLATE; CARDURA~~ | ~~4188390~~ | ~~FEB 12, 1999~~ | | ~~I-96~~ | ~~FEB 06, 1998~~ |
| >ADD> | 19668 003 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | OCT 18, 2000 | | I-96 | FEB 06, 1998 |
| >DLT> | ~~19668 003~~ | ~~DOXAZOSIN MESYLATE; CARDURA~~ | ~~4188390~~ | ~~FEB 12, 1999~~ | | ~~I-96~~ | ~~FEB 06, 1998~~ |
| >ADD> | 19668 004 | DOXAZOSIN MESYLATE; CARDURA | 4188390 | OCT 18, 2000 | | I-96 | FEB 06, 1998 |
| >DLT> | ~~19668 004~~ | ~~DOXAZOSIN MESYLATE; CARDURA~~ | ~~4188390~~ | ~~FEB 12, 1999~~ | | ~~I-96~~ | ~~FEB 06, 1998~~ |
| | 20126 001 | DOXEPIN HYDROCHLORIDE; ZONALON | 4395420 | DEC 09, 2001 | U-95 | | |
| | 19221 003 | ENALAPRIL MALEATE; VASERETIC | 4472380 | SEP 18, 2001 | | | |
| | | | 4374829 | FEB 22, 2000 | | NS | JUL 12, 1998 |
| | 19616 004 | ENOXACIN; PENETREX | 4442101 | FEB 04, 2002 | | | |
| | 19616 005 | ENOXACIN; PENETREX | 4442101 | FEB 04, 2002 | | | |
| | 20164 001 | ENOXAPARIN SODIUM; LOVENOX | | | | I-118 | MAR 09, 1998 |
| | 20444 001 | EPOPROSTENOL SODIUM; FLOLAN | | | | NCE | SEP 20, 2000 |
| | 20444 002 | EPOPROSTENOL SODIUM; FLOLAN | | | | NCE | SEP 20, 2000 |
| | 18418 001 | ERGOLOID MESYLATES; HYDERGINE | 4138565 | MAY 26, 1996 | | | |
| | 18706 001 | ERGOLOID MESYLATES; HYDERGINE LC | 4366145 | JUN 24, 2001 | | | |
| | 19081 002 | ESTRADIOL; ESTRADERM | 4379454 | FEB 17, 2001 | | | |
| | 19081 003 | ESTRADIOL; ESTRADERM | 4379454 | FEB 17, 2001 | | | |
| | 20323 001 | ESTRADIOL; VIVELLE | 5300291 | APR 05, 2011 | | NS | OCT 28, 1997 |
| | | | 4994278 | MAR 04, 2008 | | | |
| | | | 4994267 | MAR 04, 2008 | | | |
| | | | 4814168 | MAR 04, 2008 | | | |
| | 20323 002 | ESTRADIOL; VIVELLE | 5300291 | APR 05, 2011 | | | |
| | | | 4994278 | MAR 04, 2008 | | | |
| | | | 4994267 | MAR 04, 2008 | | | |
| | | | 4814168 | MAR 04, 2008 | | | |
| | 20323 003 | ESTRADIOL; VIVELLE | 5300291 | APR 05, 2011 | | NS | OCT 28, 1997 |
| | | | 4994278 | MAR 04, 2008 | | | |
| | | | 4994267 | MAR 04, 2008 | | | |
| | | | 4814168 | MAR 04, 2008 | | | |
| | 20323 004 | ESTRADIOL; VIVELLE | 5300291 | APR 05, 2011 | | | |
| | | | 4994278 | MAR 04, 2008 | | | |
| | | | 4994267 | MAR 04, 2008 | | | |
| | | | 4814168 | MAR 04, 2008 | | | |
| | 20375 001 | ESTRADIOL; CLIMARA | 5223261 | JUN 29, 2010 | | D-26 | DEC 22, 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 |
|---|---|---|---|---|---|---|
| 20375 002 | ESTRADIOL; CLIMARA | 5223261 | JUN 29, 2010 | | D-26 | DEC 22, 1997 |
| | | 4436738 | MAR 15, 2002 | | | |
| 86069 001 | ESTRADIOL; ESTRACE | 4826831 | MAY 02, 2006 | U-102 | NP | DEC 30, 1997 |
| 20303 001 | ESTROGENS, CONJUGATED; PREMPRO (PREMARIN;CYCRIN 14/14) | 4390531 | AUG 10, 2001 | | | |
| 18977 001 | ETHINYL ESTRADIOL; TRI-NORINYL 21-DAY | 4390531 | AUG 10, 2001 | | | |
| 18977 002 | ETHINYL ESTRADIOL; TRI-NORINYL 28-DAY | 4628051 | SEP 26, 2003 | | | |
| 18985 001 | ETHINYL ESTRADIOL; ORTHO-NOVUM 7/7/7-21 | 4616006 | SEP 26, 2003 | | | |
| | | 4544554 | SEP 26, 2003 | | | |
| | | 4530839 | SEP 26, 2003 | | | |
| 18985 002 | ETHINYL ESTRADIOL; ORTHO-NOVUM 7/7/7-28 | 4628051 | SEP 26, 2003 | | | |
| | | 4616006 | SEP 26, 2003 | | | |
| | | 4544554 | SEP 26, 2003 | | | |
| | | 4530839 | SEP 26, 2003 | | | |
| 19697 001 | ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN | 4628051 | SEP 26, 2003 | U-66 | | |
| | | 4616006 | SEP 26, 2003 | | | |
| | | 4544554 | SEP 26, 2003 | U-66 | | |
| | | 4530839 | SEP 26, 2003 | U-112 | | |
| 19697 002 | ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN | 4628051 | SEP 26, 2003 | U-66 | | |
| | | 4616006 | SEP 26, 2003 | | | |
| | | 4544554 | SEP 26, 2003 | U-66 | | |
| | | 4530839 | SEP 26, 2003 | U-112 | | |
| 19462 001 | FAMOTIDINE; PEPCID | 4283408 | OCT 15, 2000 | | | |
| 19462 002 | FAMOTIDINE; PEPCID | 4283408 | OCT 15, 2000 | | | |
| 19510 001 | FAMOTIDINE; PEPCID | 4283408 | OCT 15, 2000 | | | |
| 19527 001 | FAMOTIDINE; PEPCID | 4283408 | OCT 15, 2000 | | | |
| 20249 001 | FAMOTIDINE; PEPCID | 4283408 | OCT 15, 2000 | | | |
| 20325 001 | FAMOTIDINE; PEPCID AC | 4283408 | OCT 15, 2000 | | NS | APR 28, 1998 |
| 20189 001 | FELBAMATE; FELBATOL | 5082861 | SEP 26, 2009 | U-83 | | |
| | | 4978680 | SEP 26, 2009 | U-83 | | |
| 20189 002 | FELBAMATE; FELBATOL | 5082861 | SEP 26, 2009 | U-83 | | |
| | | 4978680 | SEP 26, 2009 | U-83 | | |
| 20189 003 | FELBAMATE; FELBATOL | 5082861 | SEP 26, 2009 | U-83 | | |
| | | 4978680 | SEP 26, 2009 | U-83 | | |
| 19834 001 | FELODIPINE; PLENDIL | 4803081 | APR 03, 2007 | | | |
| >ADD> | | 4264611 | JUN 19, 2001 | U-3 | NCE | JUL 25, 1996 |
| >DLT> | | ~~4264611~~ | ~~APR 28, 2000~~ | ~~U-3~~ | ~~NCE~~ | ~~JUL 25, 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 |
|---|---|---|---|---|---|---|---|
| | 19834 002 | FELODIPINE; PLENDIL | | | | | |
| >ADD> | | | 4803081 | APR 03, 2007 | | | |
| >DLT> | | | 4264611 | JUN 19, 2001 | U-3 | NCE | JUL 25, 1996 |
| | | | ~~4264611~~ | ~~APR 28, 2000~~ | ~~U-3~~ | ~~NCE~~ | ~~JUL 25, 1996~~ |
| | 19834 004 | FELODIPINE; PLENDIL | | | | | |
| >ADD> | | | 4803081 | APR 03, 2007 | | | |
| >DLT> | | | 4264611 | JUN 19, 2001 | U-3 | NCE | JUL 25, 1996 |
| | | | ~~4264611~~ | ~~APR 28, 2000~~ | ~~U-3~~ | ~~NCE~~ | ~~JUL 25, 1996~~ |
| | 19813 001 | FENTANYL; DURAGESIC | 4588580 | JUL 23, 2004 | U-43 | | |
| | 19813 002 | FENTANYL; DURAGESIC | 4588580 | JUL 23, 2004 | U-43 | | |
| | 19813 003 | FENTANYL; DURAGESIC | 4588580 | JUL 23, 2004 | U-43 | | |
| | 19813 004 | FENTANYL; DURAGESIC | 4588580 | JUL 23, 2004 | U-43 | | |
| | 19960 001 | FLOSEQUINAN; MANOPLAX | 4302460 | MAR 24, 2000 | | | |
| | 19960 002 | FLOSEQUINAN; MANOPLAX | 4302460 | MAR 24, 2000 | | | |
| | 19960 003 | FLOSEQUINAN; MANOPLAX | 4302460 | MAR 24, 2000 | | | |
| | 19960 004 | FLOSEQUINAN; MANOPLAX | 4302460 | MAR 24, 2000 | | | |
| | 19949 001 | FLUCONAZOLE; DIFLUCAN | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~19949 001~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| | 19949 002 | FLUCONAZOLE; DIFLUCAN | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~19949 002~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| | 19949 003 | FLUCONAZOLE; DIFLUCAN | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~19949 003~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| | 19950 001 | FLUCONAZOLE; DIFLUCAN | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~19950 001~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| | 20090 001 | FLUCONAZOLE; DIFLUCAN | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~20090 001~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| | 20090 002 | FLUCONAZOLE; DIFLUCAN | 4416682 | JUN 02, 2001 | | | |
| >ADD> | | | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~20090 002~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| >ADD> | 20322 001 | FLUCONAZOLE; DIFLUCAN | 4404216 | JAN 29, 2004 | | | |
| >DLT> | ~~20322 001~~ | ~~FLUCONAZOLE; DIFLUCAN~~ | ~~4404216~~ | ~~OCT 16, 2003~~ | | | |
| | 20073 001 | FLUMAZENIL; ROMAZICON | 4316839 | OCT 10, 2004 | | | |
| | 18148 001 | FLUNISOLIDE; NASALIDE | 4933168 | JUN 12, 2007 | | | |

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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 |
|---|---|---|---|---|---|---|
| 18340 001 | FLUNISOLIDE; AEROBID | 4933168 | JUN 12, 2007 | | | |
| 20409 001 | FLUNISOLIDE; NASAREL | 4983595 | MAY 22, 2006 | | | |
| | | 4933168 | JUN 12, 2007 | | | |
| | | 4782047 | MAY 22, 2006 | | | |
| | | | | | I-122 | FEB 16, 1998 |
| 19452 001 | FLUOCINOLONE ACETONIDE; DERMA-SMOOTHE/FS | 4335121 | MAR 15, 2002 | | | |
| 19957 001 | FLUTICASONE PROPIONATE; CUTIVATE | 4335121 | MAR 15, 2002 | | | |
| 19958 001 | FLUTICASONE PROPIONATE; CUTIVATE | 4335121 | MAR 15, 2002 | | NCE | DEC 14, 1995 |
| 20121 001 | FLUTICASONE PROPIONATE; FLONASE | | | | NDF | OCT 19, 1997 |
| 20261 001 | FLUVASTATIN SODIUM; LESCOL | 5354772 | OCT 11, 2011 | U-109 | NCE | DEC 31, 1998 |
| 20261 002 | FLUVASTATIN SODIUM; LESCOL | 5354772 | OCT 11, 2011 | U-109 | NCE | DEC 31, 1998 |
| 20068 001 | FOSCARNET SODIUM; FOSCAVIR | 4339445 | JUL 29, 1997 | U-64 | I-127 | JUN 16, 1998 |
| 19915 002 | FOSINOPRIL SODIUM; MONOPRIL | 5006344 | JUL 10, 2009 | | | |
| | | 4384123 | DEC 04, 2000 | | I-92 | MAY 02, 1998 |
| | | 4337201 | DEC 04, 2002 | | | |
| >ADD> | | ~~4337201~~ | ~~JUN 29, 2001~~ | | | |
| >DLT> | | | | | | |
| 19915 003 | FOSINOPRIL SODIUM; MONOPRIL | 5006344 | JUL 10, 2009 | | | |
| | | 4384123 | DEC 04, 2000 | | I-92 | MAY 02, 1998 |
| | | 4337201 | DEC 04, 2002 | | | |
| >ADD> | | ~~4337201~~ | ~~JUN 29, 2001~~ | | | |
| >DLT> | | | | | | |
| 19915 004 | FOSINOPRIL SODIUM; MONOPRIL | 5006344 | JUL 10, 2009 | | | |
| | | 4384123 | DEC 04, 2000 | | I-92 | MAY 02, 1998 |
| | | 4337201 | DEC 04, 2002 | | NCE | MAY 16, 1996 |
| >ADD> | | ~~4337201~~ | ~~JUN 29, 2001~~ | | | |
| >DLT> | | | | | | |
| 20286 001 | FOSINOPRIL SODIUM; MONOPRIL-HCT | 5006344 | JUL 10, 2009 | | | |
| | | 4384123 | DEC 04, 2000 | | | |
| | | 4337201 | DEC 04, 2002 | | | |
| >ADD> | | ~~4337201~~ | ~~JUN 29, 2001~~ | | | |
| >DLT> | | | | | | |
| 20286 002 | FOSINOPRIL SODIUM; MONOPRIL-HCT | 5006344 | JUL 10, 2009 | | | |
| | | 4384123 | DEC 04, 2000 | | | |
| | | 4337201 | DEC 04, 2002 | | | |
| >ADD> | | ~~4337201~~ | ~~JUN 29, 2001~~ | | | |
| >DLT> | | | | | | |
| 20235 001 | GABAPENTIN; NEURONTIN | 4087544 | MAY 02, 1996 | U-86 | | |
| 20235 002 | GABAPENTIN; NEURONTIN | 4087544 | MAY 02, 1996 | U-86 | | |
| 20235 003 | GABAPENTIN; NEURONTIN | 4087544 | MAY 02, 1996 | U-86 | | |
| 19596 001 | GADOPENTETATE DIMEGLUMINE; MAGNEVIST | 5362475 | NOV 08, 2011 | | | |

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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 |
|---|---|---|---|---|---|---|
| 20460 001 | GANCICLOVIR; CYTOVENE | 4507305 | OCT 19, 1999 | U-64 | NDF | DEC 22, 1997 |
| | | 4355032 | JUN 23, 2003 | U-64 | | |
| | | 4507305 | MAY 21, 2001 | U-35 | | |
| | | 4423050 | MAY 21, 2001 | U-34 | | |
| 19661 001 | GANCICLOVIR SODIUM; CYTOVENE | 4355032 | JUN 23, 2003 | U-64 | | |
| | | 5091190 | JUN 18, 2008 | U-111 | | |
| | | 5082668 | SEP 16, 2003 | | | |
| | | 5024843 | SEP 05, 2009 | | | |
| | | 4612008 | SEP 16, 2003 | | | |
| 20329 001 | GLIPIZIDE; GLUCOTROL XL | 4327725 | NOV 25, 2000 | | NDF | APR 26, 1997 |
| | | 5091190 | JUN 18, 2008 | U-111 | | |
| | | 5082668 | SEP 16, 2003 | | | |
| | | 5024843 | SEP 05, 2009 | | | |
| | | 4612008 | SEP 16, 2003 | | | |
| 20329 002 | GLIPIZIDE; GLUCOTROL XL | 4327725 | NOV 25, 2000 | | NDF | APR 26, 1997 |
| | | 4100274 | APR 22, 1999 | | | |
| | | 4886808 | DEC 12, 2006 | U-105 | NCE | DEC 29, 1998 |
| | | | | | NDF | MAR 16, 1998 |
| 19726 001 | GOSERELIN ACETATE; ZOLADEX | 4138475 | SEP 14, 1997 | | | |
| 20305 001 | GRANISETRON HYDROCHLORIDE; KYTRIL | 4138475 | SEP 14, 1997 | | | |
| | | 4138475 | SEP 14, 1997 | | | |
| 19059 001 | HYDROCHLOROTHIAZIDE; INDERIDE LA 80/50 | 4444769 | JUL 27, 2002 | | | |
| 19059 002 | HYDROCHLOROTHIAZIDE; INDERIDE LA 120/50 | 4444769 | JUL 27, 2002 | | | |
| 19059 003 | HYDROCHLOROTHIAZIDE; INDERIDE LA 160/50 | 5153197 | OCT 06, 2009 | U-3 | NC | APR 28, 1998 |
| 19129 001 | HYDROCHLOROTHIAZIDE; MAXZIDE | 5138069 | AUG 11, 2009 | | NCE | APR 14, 2000 |
| 19129 003 | HYDROCHLOROTHIAZIDE; MAXZIDE-25 | 5374659 | DEC 20, 2011 | | I-123 | MAR 24, 1998 |
| 20387 001 | HYDROCHLOROTHIAZIDE; HYZAAR | 5320855 | JUN 14, 2011 | | I-123 | MAR 24, 1998 |
| | | 5215755 | JUN 01, 2010 | | NDF | NOV 16, 1997 |
| 19842 001 | IBUPROFEN; CHILDREN'S MOTRIN | 5320855 | JUN 14, 2011 | | I-123 | MAR 24, 1998 |
| 20135 001 | IBUPROFEN; MOTRIN | 5215755 | JUN 01, 2010 | | NDF | NOV 16, 1997 |
| | | | | | I-123 | MAR 24, 1998 |
| 20135 002 | IBUPROFEN; MOTRIN | 5374659 | DEC 20, 2011 | | NP | JUN 16, 1998 |
| | | 4173626 | DEC 11, 1998 | | | |
| 20418 001 | IBUPROFEN; MOTRIN | | | | ODE | MAR 25, 2001 |
| 20516 001 | IBUPROFEN; CHILDREN'S MOTRIN | 4396597 | JUL 14, 1998 | | | |
| 18185 001 | INDOMETHACIN; INDOCIN SR | 4250113 | DEC 26, 1999 | | | |
| 20084 001 | IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131 | 4001323 | NOV 24, 1997 | | | |
| 18956 007 | IOHEXOL; OMNIPAQUE 70 | | | | | |
| 18735 001 | IOPAMIDOL; ISOVUE-M 200 | | | | | |

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 |
|---|---|---|---|---|---|---|---|
| | 18735 002 | IOPAMIDOL; ISOVUE-300 | 4001323 | NOV 24, 1997 | | | |
| | 18735 003 | IOPAMIDOL; ISOVUE-370 | 4001323 | NOV 24, 1997 | | D-28 | MAY 15, 1998 |
| | 18735 004 | IOPAMIDOL; ISOVUE-M 300 | 4001323 | NOV 24, 1997 | | | |
| | 18735 007 | IOPAMIDOL; ISOVUE-250 | 4001323 | NOV 24, 1997 | | | |
| | 20327 001 | IOPAMIDOL; ISOVUE-200 | 4001323 | NOV 24, 1997 | | | |
| | 20327 002 | IOPAMIDOL; ISOVUE-250 | 4001323 | NOV 24, 1997 | | | |
| | 20327 003 | IOPAMIDOL; ISOVUE-300 | 4001323 | NOV 24, 1997 | | | |
| | 20327 004 | IOPAMIDOL; ISOVUE-370 | 4001323 | NOV 24, 1997 | | | |
| | 20220 001 | IOPROMIDE; ULTRAVIST | 4364921 | DEC 21, 1999 | U-113 | NCE | MAY 10, 2000 |
| | 20220 002 | IOPROMIDE; ULTRAVIST | 4364921 | DEC 21, 1999 | U-113 | NCE | MAY 10, 2000 |
| | 20220 003 | IOPROMIDE; ULTRAVIST | 4364921 | DEC 21, 1999 | U-113 | NCE | MAY 10, 2000 |
| | 20220 004 | IOPROMIDE; ULTRAVIST | 4364921 | DEC 21, 1999 | U-113 | NCE | MAY 10, 2000 |
| | | | | | | I-131 | JUN 21, 1998 |
| | 19710 005 | IOVERSOL; OPTIRAY 350 | | | | | |
| >ADD> | 18905 002 | IOXAGLATE MEGLUMINE; HEXABRIX | 4014986 | MAY 20, 1997 | | | |
| >DLT> | ~~18905 002~~ | ~~IOXAGLATE MEGLUMINE; HEXABRIX~~ | ~~4014986~~ | ~~MAR 29, 1996~~ | | | |
| | | | | | | NDF | OCT 20, 1998 |
| >ADD> | 20393 001 | IPRATROPIUM BROMIDE; ATROVENT | | | | NDF | OCT 20, 1998 |
| >ADD> | 20394 001 | IPRATROPIUM BROMIDE; ATROVENT | | | | NDF | AUG 12, 1996 |
| | 20225 003 | ISOSORBIDE MONONITRATE; IMDUR | | | | NCE | DEC 30, 1996 |
| | 20336 001 | ISRADIPINE; DYNACIRC CR | 4816263 | OCT 02, 2007 | U-3 | | |
| | 20336 002 | ISRADIPINE; DYNACIRC CR | 4816263 | OCT 02, 2007 | U-3 | | |
| | | | 4267179 | JUN 23, 2000 | | | |
| >ADD> | 20083 001 | ITRACONAZOLE; SPORANOX | ~~4267179~~ | ~~MAY 12, 1998~~ | | | |
| >DLT> | ~~20083 001~~ | ~~ITRACONAZOLE; SPORANOX~~ | | | | NDF | SEP 24, 1996 |
| | 19816 002 | KETOPROFEN; ORUVAIL | | | | NDF | SEP 24, 1996 |
| | 19816 003 | KETOPROFEN; ORUVAIL | 4089969 | JUL 14, 1998 | U-55 | | |
| | 19645 001 | KETOROLAC TROMETHAMINE; TORADOL | 4089969 | JUL 14, 1998 | U-55 | NR | DEC 07, 1997 |
| | 19698 001 | KETOROLAC TROMETHAMINE; TORADOL | 4089969 | JUL 14, 1998 | U-55 | NR | DEC 07, 1997 |
| | 19698 002 | KETOROLAC TROMETHAMINE; TORADOL | 4454151 | MAR 22, 2002 | U-75 | | |
| | 19700 001 | KETOROLAC TROMETHAMINE; ACULAR | 4089969 | JUL 14, 1998 | U-55 | | |
| | | | 4328213 | NOV 28, 1999 | | | |
| | 18686 001 | LABETALOL HYDROCHLORIDE; NORMODYNE | 4602017 | JUL 22, 2003 | U-106 | NCE | DEC 27, 1999 |
| | 20241 001 | LAMOTRIGINE; LAMICTAL | 4602017 | JUL 22, 2003 | U-106 | NCE | DEC 27, 1999 |
| | 20241 002 | LAMOTRIGINE; LAMICTAL | 4602017 | JUL 22, 2003 | U-106 | NCE | DEC 27, 1999 |
| | 20241 003 | LAMOTRIGINE; LAMICTAL | 4602017 | JUL 22, 2003 | U-106 | NCE | DEC 27, 1999 |
| | 20241 004 | LAMOTRIGINE; LAMICTAL | 4602017 | JUL 22, 2003 | U-106 | NCE | DEC 27, 1999 |
| | 20241 005 | LAMOTRIGINE; LAMICTAL | 4602017 | JUL 22, 2003 | U-106 | NCE | DEC 27, 1999 |
| | 20241 006 | LAMOTRIGINE; LAMICTAL | | | | | |

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 |
|---|---|---|---|---|---|---|
| 20406 001 | LANSOPRAZOLE; PREVACID | 5093132 | SEP 03, 2008 | | | |
| | | 5045321 | SEP 03, 2008 | | | |
| | | 5026560 | JUN 25, 2008 | | | |
| | | 4689333 | JUL 29, 2005 | | | |
| | | 4628098 | JUL 29, 2005 | | NCE | MAY 10, 2000 |
| 20406 002 | LANSOPRAZOLE; PREVACID | 5093132 | SEP 03, 2008 | | | |
| | | 5045321 | SEP 03, 2008 | | | |
| | | 5026560 | JUN 25, 2008 | | | |
| | | 4689333 | JUL 29, 2005 | | | |
| | | 4628098 | JUL 29, 2005 | | NCE | MAY 10, 2000 |
| 19732 001 | LEUPROLIDE ACETATE; LUPRON DEPOT | 5330767 | NOV 01, 2004 | | | |
| | | 4917893 | NOV 01, 2004 | | | |
| | | 4728721 | MAY 01, 2006 | | | |
| | | 4677191 | JUL 03, 2005 | | | |
| | | 4652441 | NOV 01, 2004 | | | |
| 20011 001 | LEUPROLIDE ACETATE; LUPRON DEPOT | 5330767 | NOV 01, 2004 | | | |
| | | 4917893 | NOV 01, 2004 | | | |
| | | 4728721 | MAY 01, 2006 | | | |
| | | 4677191 | JUL 03, 2005 | | | |
| | | 4652441 | NOV 01, 2004 | | | |
| | | 4005063 | JAN 25, 1996 | | I-119 | MAR 30, 1998 |
| 20263 001 | LEUPROLIDE ACETATE; LUPRON | 5330767 | NOV 01, 2004 | | | |
| | | 4917893 | NOV 01, 2004 | | | |
| | | 4728721 | MAY 01, 2006 | | | |
| | | 4677191 | JUL 03, 2005 | | | |
| | | 4652441 | NOV 01, 2004 | | | |
| 20263 002 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 5330767 | NOV 01, 2004 | | | |
| | | 4917893 | NOV 01, 2004 | | | |
| | | 4728721 | MAY 01, 2006 | | | |
| | | 4677191 | JUL 03, 2005 | | | |
| | | 4652441 | NOV 01, 2004 | | | |
| 20263 003 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 5330767 | NOV 01, 2004 | | | |
| | | 4917893 | NOV 01, 2004 | | | |
| | | 4728721 | MAY 01, 2006 | | | |
| | | 4677191 | JUL 03, 2005 | | | |
| | | 4652441 | NOV 01, 2004 | | | |

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 |
|---|---|---|---|---|---|---|---|
| | 20263 004 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 5330767 | NOV 01, 2004 | | | |
| | | | 4917893 | NOV 01, 2004 | | | |
| | | | 4728721 | MAY 01, 2006 | | | |
| | | | 4677191 | JUL 03, 2005 | | | |
| | | | 4652441 | NOV 01, 2004 | | | |
| | 20263 005 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 5330767 | NOV 01, 2004 | | | |
| | | | 4917893 | NOV 01, 2004 | | | |
| | | | 4849228 | JUL 18, 2006 | | | |
| | | | 4728721 | MAY 01, 2006 | | | |
| | | | 4677191 | JUL 03, 2005 | | | |
| | | | 4652441 | NOV 01, 2004 | | | |
| | | | 4005063 | JAN 25, 1996 | | | |
| | 20263 006 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 5330767 | NOV 01, 2004 | | | |
| | | | 4917893 | NOV 01, 2004 | | | |
| | | | 4849228 | JUL 18, 2006 | | | |
| | | | 4728721 | MAY 01, 2006 | | | |
| | | | 4677191 | JUL 03, 2005 | | | |
| | | | 4652441 | NOV 01, 2004 | | | |
| | | | 4005063 | JAN 25, 1996 | | | |
| | 18027 001 | LITHIUM CARBONATE; LITHOBID | 4264573 | MAY 21, 1999 | | | |
| >ADD> | 20013 001 | LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN | 4528287 | FEB 21, 2006 | U-36 | | |
| >DLT> | ~~20013 001~~ | ~~LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN~~ | ~~4528287~~ | ~~MAY 05, 2005~~ | ~~U-36~~ | | |
| >ADD> | 19658 001 | LORATADINE; CLARITIN | 4282233 | JUN 19, 2002 | U-77 | I-136 | SEP 20, 1998 |
| | 19670 001 | LORATADINE; CLARITIN-D | 4282233 | JUN 19, 2002 | | NCE | APR 12, 1998 |
| | 20386 001 | LOSARTAN POTASSIUM; COZAAR | 5153197 | OCT 06, 2009 | U-3 | | |
| | | | 5138069 | AUG 11, 2009 | | NCE | APR 14, 2000 |
| | 20386 002 | LOSARTAN POTASSIUM; COZAAR | 5153197 | OCT 06, 2009 | U-3 | | |
| | | | 5138069 | AUG 11, 2009 | | NCE | APR 14, 2000 |
| | 19643 002 | LOVASTATIN; MEVACOR | 4231938 | JUN 15, 2001 | | I-117 | FEB 08, 1998 |
| | 19643 003 | LOVASTATIN; MEVACOR | 4231938 | JUN 15, 2001 | | I-117 | FEB 08, 1998 |
| | 19643 004 | LOVASTATIN; MEVACOR | 4231938 | JUN 15, 2001 | | I-117 | FEB 08, 1998 |
| | 19940 001 | MASOPROCOL; ACTINEX | 4695590 | SEP 04, 2006 | | NCE | SEP 04, 1997 |
| | 19591 001 | MEFLOQUINE HYDROCHLORIDE; LARIAM | 4579855 | OCT 01, 2004 | | | |
| | 20207 001 | MELPHALAN HYDROCHLORIDE; ALKERAN | 4997651 | NOV 18, 2008 | | | |
| >ADD> | 19884 001 | MESNA; MESNEX | 4220660 | MAR 06, 2001 | | | |
| >DLT> | ~~19884 001~~ | ~~MESNA; MESNEX~~ | ~~4220660~~ | ~~DEC 02, 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> | 19600 001 | METHOXSALEN; OXSORALEN-ULTRA | 4454152 | DEC 21, 2001 | | | |
| >DLT> | ~~19600 001~~ | ~~METHOXSALEN; OXSORALEN-ULTRA~~ | ~~4454152~~ | ~~JUN 12, 2001~~ | | | |
| | 18029 001 | METHYLPHENIDATE HYDROCHLORIDE; RITALIN-SR | 4137300 | AUG 20, 1996 | | | |
| | 19962 001 | METOPROLOL SUCCINATE; TOPROL-XL | 5081154 | JAN 14, 2009 | | | |
| | | | 5001161 | MAR 19, 2008 | | | |
| | | | 4957745 | SEP 18, 2007 | U-107 | NE | JAN 10, 1995 |
| | 19962 002 | METOPROLOL SUCCINATE; TOPROL-XL | 5081154 | JAN 14, 2009 | | | |
| | | | 5001161 | MAR 19, 2008 | | | |
| | | | 4957745 | SEP 18, 2007 | U-107 | NE | JAN 10, 1995 |
| | 19962 003 | METOPROLOL SUCCINATE; TOPROL-XL | 5081154 | JAN 14, 2009 | | | |
| | | | 5001161 | MAR 19, 2008 | | | |
| | | | 4957745 | SEP 18, 2007 | U-107 | NE | JAN 10, 1995 |
| | 20531 001 | METRONIDAZOLE; METROCREAM | | | | NDF | SEP 20, 1998 |
| | 18654 001 | MIDAZOLAM HYDROCHLORIDE; VERSED | 4280957 | DEC 20, 1999 | | I-125 | APR 26, 1997 |
| | 18654 002 | MIDAZOLAM HYDROCHLORIDE; VERSED | 4280957 | DEC 20, 1999 | | I-125 | APR 26, 1997 |
| | 19268 001 | MISOPROSTOL; CYTOTEC | 4301146 | JUL 29, 2000 | | | |
| | 19268 003 | MISOPROSTOL; CYTOTEC | 4301146 | JUL 29, 2000 | | | |
| | 20312 001 | MOEXIPRIL HYDROCHLORIDE; UNIVASC | 4743450 | FEB 24, 2007 | | NCE | APR 19, 2000 |
| | 20312 002 | MOEXIPRIL HYDROCHLORIDE; UNIVASC | 4743450 | FEB 24, 2007 | | NCE | APR 19, 2000 |
| >ADD> | 19625 001 | MOMETASONE FUROATE; ELOCON | 4808610 | OCT 02, 2006 | | | |
| >DLT> | ~~19625 001~~ | ~~MOMETASONE FUROATE; ELOCON~~ | ~~4808610~~ | ~~FEB 28, 2006~~ | | | |
| >ADD> | 19796 001 | MOMETASONE FUROATE; ELOCON | 4775529 | MAY 21, 2007 | | | |
| >DLT> | ~~19796 001~~ | ~~MOMETASONE FUROATE; ELOCON~~ | ~~4775529~~ | ~~OCT 04, 2005~~ | | | |
| | 20459 001 | NALMEFENE HYDROCHLORIDE; REVEX | | | | NCE | APR 17, 2000 |
| | 20459 002 | NALMEFENE HYDROCHLORIDE; REVEX | | | | NCE | APR 17, 2000 |
| | 18932 001 | NALTREXONE HYDROCHLORIDE; REVIA | | | | I-129 | DEC 30, 1997 |
| | 20152 001 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2001 | | | |
| | 20152 002 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2001 | | | |
| | 20152 003 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2001 | | | |
| | 20152 004 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2001 | | | |
| | 20152 005 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2001 | | | |
| | 20152 006 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2001 | | | |
| | 19488 001 | NICARDIPINE HYDROCHLORIDE; CARDENE | 3985758 | FEB 15, 1996 | | | |
| | 19488 002 | NICARDIPINE HYDROCHLORIDE; CARDENE | 3985758 | FEB 15, 1996 | | | |
| | 19734 001 | NICARDIPINE HYDROCHLORIDE; CARDENE | 5164405 | NOV 17, 2009 | | | |
| | | | 4880823 | NOV 14, 2006 | | | |
| | | | 3985758 | FEB 15, 1996 | | | |

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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 |
|---|---|---|---|---|---|---|
| 20005 001 | NICARDIPINE HYDROCHLORIDE; CARDENE SR | 5198226 | MAR 30, 2010 | | | |
| | | 3985758 | FEB 15, 1996 | | | |
| 20005 002 | NICARDIPINE HYDROCHLORIDE; CARDENE SR | 5198226 | MAR 30, 2010 | | | |
| | | 3985758 | FEB 15, 1996 | | | |
| 20005 003 | NICARDIPINE HYDROCHLORIDE; CARDENE SR | 5198226 | MAR 30, 2010 | | | |
| | | 3985758 | FEB 15, 1996 | | | |
| 20076 001 | NICOTINE; HABITROL | 4597961 | JAN 23, 2005 | U-56 | | |
| 20076 002 | NICOTINE; HABITROL | 4597961 | JAN 23, 2005 | U-56 | | |
| 20076 003 | NICOTINE; HABITROL | 4597961 | JAN 23, 2005 | U-56 | | |
| 20150 001 | NICOTINE; NICOTROL | 4915950 | FEB 12, 2008 | | | |
| 20150 002 | NICOTINE; NICOTROL | 4915950 | FEB 12, 2008 | | | |
| 20150 003 | NICOTINE; NICOTROL | 4915950 | FEB 12, 2008 | | | |
| 20165 001 | NICOTINE; NICODERM | 5364630 | JUN 14, 2008 | | | |
| | | 5344656 | JUN 14, 2008 | | | |
| | | 5342623 | JUN 14, 2008 | | | |
| | | 5004610 | JUN 14, 2008 | | | |
| 20165 002 | NICOTINE; NICODERM | 5364630 | JUN 14, 2008 | | | |
| | | 5344656 | JUN 14, 2008 | | | |
| | | 5342623 | JUN 14, 2008 | | | |
| | | 5004610 | JUN 14, 2008 | | | |
| 20165 003 | NICOTINE; NICODERM | 5364630 | JUN 14, 2008 | | | |
| | | 5344656 | JUN 14, 2008 | | | |
| | | 5342623 | JUN 14, 2008 | | | |
| | | 5004610 | JUN 14, 2008 | | | |
| 19684 001 | NIFEDIPINE; PROCARDIA XL | 4327725 | NOV 25, 2000 | | | |
| 19684 002 | NIFEDIPINE; PROCARDIA XL | 4327725 | NOV 25, 2000 | | | |
| 19684 003 | NIFEDIPINE; PROCARDIA XL | 4327725 | NOV 25, 2000 | | | |
| 20198 001 | NIFEDIPINE; ADALAT CC | 5264446 | NOV 23, 2010 | | | |
| | | 4892741 | JUN 08, 2008 | | | |
| 20198 002 | NIFEDIPINE; ADALAT CC | 5264446 | NOV 23, 2010 | | | |
| | | 4892741 | JUN 08, 2008 | | | |
| 20198 003 | NIFEDIPINE; ADALAT CC | 5264446 | NOV 23, 2010 | | | |
| | | 4892741 | JUN 08, 2008 | | | |
| | | 4892741 | JUN 08, 2008 | | | |
| 20356 001 | NISOLDIPINE; NISOCOR | 4154839 | NOV 02, 1996 | | NCE | FEB 02, 2000 |
| | | 4892741 | JUN 08, 2008 | | | |
| 20356 002 | NISOLDIPINE; NISOCOR | 4154839 | NOV 02, 1996 | | NCE | FEB 02, 2000 |

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 |
|---|---|---|---|---|---|---|---|
| | 20356 003 | NISOLDIPINE; NISOCOR | 4892741 | JUN 08, 2008 | | | |
| | 20356 004 | NISOLDIPINE; NISOCOR | 4154839 | NOV 02, 1996 | | NCE | FEB 02, 2000 |
| | | | 4892741 | JUN 08, 2008 | | | |
| | 20064 001 | NITROFURANTOIN; MACROBID | 4154839 | NOV 02, 1996 | | NCE | FEB 02, 2000 |
| | | | 4798725 | JUN 16, 2006 | | | |
| | 20145 001 | NITROGLYCERIN; NITRO-DUR | 4772473 | JUN 16, 2006 | | | |
| | 20145 002 | NITROGLYCERIN; NITRO-DUR | 5186938 | FEB 16, 2010 | | | |
| | 20145 003 | NITROGLYCERIN; NITRO-DUR | 5186938 | FEB 16, 2010 | | | |
| | 20145 004 | NITROGLYCERIN; NITRO-DUR | 5186938 | FEB 16, 2010 | | | |
| | 20145 005 | NITROGLYCERIN; NITRO-DUR | 5186938 | FEB 16, 2010 | | | |
| | 20145 006 | NITROGLYCERIN; NITRO-DUR | 5186938 | FEB 16, 2010 | | | |
| | 19508 001 | NIZATIDINE; AXID | 5186938 | FEB 16, 2010 | | | |
| | 19508 002 | NIZATIDINE; AXID | 4375547 | APR 12, 2002 | | | |
| | 19384 002 | NORFLOXACIN; NOROXIN | 4375547 | APR 12, 2002 | | | |
| | | | 4639458 | JAN 22, 2005 | | | |
| | 19757 001 | NORFLOXACIN; CHIBROXIN | 4146719 | FEB 16, 2000 | | | |
| | | | 4551456 | NOV 14, 2003 | | | |
| >ADD> | 19667 001 | OCTREOTIDE ACETATE; SANDOSTATIN | 4146719 | FEB 16, 2000 | | | |
| >DLT> | ~~19667 001~~ | ~~OCTREOTIDE ACETATE; SANDOSTATIN~~ | 4395403 | OCT 21, 2002 | | | |
| | | | ~~4395403~~ | ~~JUL 26, 2002~~ | | | |
| >ADD> | 19667 002 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | OCT 21, 2002 | | | |
| >DLT> | ~~19667 002~~ | ~~OCTREOTIDE ACETATE; SANDOSTATIN~~ | ~~4395403~~ | ~~JUL 26, 2002~~ | | | |
| >ADD> | 19667 003 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | OCT 21, 2002 | | | |
| >DLT> | ~~19667 003~~ | ~~OCTREOTIDE ACETATE; SANDOSTATIN~~ | ~~4395403~~ | ~~JUL 26, 2002~~ | | | |
| >ADD> | 19667 004 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | OCT 21, 2002 | | | |
| >DLT> | ~~19667 004~~ | ~~OCTREOTIDE ACETATE; SANDOSTATIN~~ | ~~4395403~~ | ~~JUL 26, 2002~~ | | | |
| >ADD> | 19667 005 | OCTREOTIDE ACETATE; SANDOSTATIN | 4395403 | OCT 21, 2002 | | | |
| >DLT> | ~~19667 005~~ | ~~OCTREOTIDE ACETATE; SANDOSTATIN~~ | ~~4395403~~ | ~~JUL 26, 2002~~ | | | |
| >ADD> | 19735 001 | OFLOXACIN; FLOXIN | 4382892 | SEP 02, 2003 | | | |
| >DLT> | ~~19735 001~~ | ~~OFLOXACIN; FLOXIN~~ | ~~4382892~~ | ~~MAY 10, 2002~~ | | | |
| >ADD> | 19735 002 | OFLOXACIN; FLOXIN | 4382892 | SEP 02, 2003 | | | |
| >DLT> | ~~19735 002~~ | ~~OFLOXACIN; FLOXIN~~ | ~~4382892~~ | ~~MAY 10, 2002~~ | | | |
| >ADD> | 19735 003 | OFLOXACIN; FLOXIN | 4382892 | SEP 02, 2003 | | | |
| >DLT> | ~~19735 003~~ | ~~OFLOXACIN; FLOXIN~~ | ~~4382892~~ | ~~MAY 10, 2002~~ | | | |
| | 20087 001 | OFLOXACIN; FLOXIN IN DEXTROSE 5% | 4382892 | SEP 02, 2001 | | | |
| | 20087 002 | OFLOXACIN; FLOXIN | 4382892 | SEP 02, 2001 | | | |
| | 20087 003 | OFLOXACIN; FLOXIN | 4382892 | SEP 02, 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 |
|---|---|---|---|---|---|---|---|
| | 20087 004 | OFLOXACIN; FLOXIN IN DEXTROSE 5% | 4382892 | SEP 02, 2001 | | | |
| | 20087 005 | OFLOXACIN; FLOXIN IN DEXTROSE 5% | 4382892 | SEP 02, 2001 | | | |
| | 19810 001 | OMEPRAZOLE; PRILOSEC | 4853230 | APR 20, 2007 | U-108 | | |
| | | | 4786505 | APR 20, 2007 | U-108 | I-130 | JUN 22, 1998 |
| | | | 4255431 | APR 05, 2001 | U-108 | | |
| >ADD> | | | | | | | |
| >DLT> | | | ~~4255431~~ | ~~MAR 10, 2000~~ | ~~U-108~~ | | |
| >ADD> | 19810 003 | OMEPRAZOLE; PRILOSEC | 4853230 | APR 20, 2007 | U-108 | | |
| >ADD> | | | 4786505 | APR 20, 2007 | U-108 | | |
| >ADD> | | | 4255431 | APR 05, 2001 | U-108 | | |
| | 20007 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789 | JUN 24, 2006 | U-44 | | |
| | | | 4695578 | JAN 25, 2005 | | D-20 | FEB 02, 1996 |
| | 20103 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789 | JUN 24, 2006 | U-44 | D-27 | APR 10, 1998 |
| | | | 4695578 | JAN 25, 2005 | | NCE | JAN 04, 1996 |
| | | | | | | I-9 | APR 19, 1998 |
| | 20103 002 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789 | JUN 24, 2006 | U-44 | D-27 | APR 10, 1998 |
| | | | 4695578 | JAN 25, 2005 | | NCE | JAN 04, 1996 |
| | | | | | | I-9 | APR 19, 1998 |
| | 20403 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789 | JUN 24, 2006 | U-44 | D-20 | FEB 02, 1996 |
| | | | 4695578 | JAN 25, 2005 | | NCE | JAN 04, 1996 |
| | | | | | | I-9 | AUG 13, 1996 |
| | 19828 001 | OXICONAZOLE NITRATE; OXISTAT | 4124767 | DEC 27, 1996 | | | |
| | 20209 001 | OXICONAZOLE NITRATE; OXISTAT | 4124767 | DEC 27, 1996 | | | |
| | 20036 001 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | JUL 29, 2005 | | I-135 | SEP 01, 1998 |
| | 20036 003 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | JUL 29, 2005 | | I-135 | SEP 01, 1998 |
| | 20036 004 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | JUL 29, 2005 | | I-135 | SEP 01, 1998 |
| >ADD> | 20031 001 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | SEP 24, 2008 | U-12 | | |
| >DLT> | ~~20031 001~~ | ~~PAROXETINE HYDROCHLORIDE; PAXIL~~ | ~~4721723~~ | ~~DEC 29, 2006~~ | ~~U-12~~ | | |
| >ADD> | 20031 002 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | SEP 24, 2008 | U-12 | | |
| >DLT> | ~~20031 002~~ | ~~PAROXETINE HYDROCHLORIDE; PAXIL~~ | ~~4721723~~ | ~~DEC 29, 2006~~ | ~~U-12~~ | | |
| >ADD> | 20031 003 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | SEP 24, 2008 | U-12 | | |
| >DLT> | ~~20031 003~~ | ~~PAROXETINE HYDROCHLORIDE; PAXIL~~ | ~~4721723~~ | ~~DEC 29, 2006~~ | ~~U-12~~ | | |
| >ADD> | 20031 004 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | SEP 24, 2008 | U-12 | | |
| >DLT> | ~~20031 004~~ | ~~PAROXETINE HYDROCHLORIDE; PAXIL~~ | ~~4721723~~ | ~~DEC 29, 2006~~ | ~~U-12~~ | | |
| >ADD> | 20031 005 | PAROXETINE HYDROCHLORIDE; PAXIL | 4721723 | SEP 24, 2008 | U-12 | | |
| >DLT> | ~~20031 005~~ | ~~PAROXETINE HYDROCHLORIDE; PAXIL~~ | ~~4721723~~ | ~~DEC 29, 2006~~ | ~~U-12~~ | | |
| | 19385 001 | PERGOLIDE MESYLATE; PERMAX | 4797405 | OCT 26, 2007 | | | |
| | | | 4166182 | FEB 08, 2000 | | | |

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 |
|---|---|---|---|---|---|---|---|
| | 19385 002 | PERGOLIDE MESYLATE; PERMAX | 4797405 | OCT 26, 2007 | | | |
| | | | 4166182 | FEB 08, 2000 | | | |
| | 19385 003 | PERGOLIDE MESYLATE; PERMAX | 4797405 | OCT 26, 2007 | | | |
| | | | 4166182 | FEB 08, 2000 | | | |
| | 17850 001 | POTASSIUM CHLORIDE; KLOTRIX | 4140756 | JUN 10, 1996 | | | |
| | 18238 001 | POTASSIUM CHLORIDE; MICRO-K | 4259315 | JUN 13, 2000 | | | |
| | 18238 002 | POTASSIUM CHLORIDE; MICRO-K 10 | 4259315 | JUN 13, 2000 | | | |
| | 19561 003 | POTASSIUM CHLORIDE; MICRO-K LS | 4259315 | JUN 13, 2000 | | | |
| >ADD> | 19898 002 | PRAVASTATIN SODIUM; PRAVACHOL | 4346227 | OCT 20, 2005 | | | |
| >DLT> | ~~19898 002~~ | ~~PRAVASTATIN SODIUM; PRAVACHOL~~ | ~~4346227~~ | ~~JAN 29, 2004~~ | | | |
| >ADD> | 19898 003 | PRAVASTATIN SODIUM; PRAVACHOL | 4346227 | OCT 20, 2005 | | | |
| >DLT> | ~~19898 003~~ | ~~PRAVASTATIN SODIUM; PRAVACHOL~~ | ~~4346227~~ | ~~JAN 29, 2004~~ | | | |
| >ADD> | 19898 004 | PRAVASTATIN SODIUM; PRAVACHOL | 4346227 | OCT 20, 2005 | | | |
| >DLT> | ~~19898 004~~ | ~~PRAVASTATIN SODIUM; PRAVACHOL~~ | ~~4346227~~ | ~~JAN 29, 2004~~ | | | |
| | 19775 001 | PRAZOSIN HYDROCHLORIDE; MINIPRESS XL | 4327725 | NOV 25, 2000 | | | |
| | 19775 002 | PRAZOSIN HYDROCHLORIDE; MINIPRESS XL | 4327725 | NOV 25, 2000 | | | |
| | 19627 001 | PROPOFOL; DIPRIVAN | 4798846 | MAR 19, 1997 | | | |
| | | | 4056635 | MAR 19, 1997 | | | |
| | 18553 001 | PROPRANOLOL HYDROCHLORIDE; INDERAL LA | 4138475 | SEP 14, 1997 | | | |
| | 18553 002 | PROPRANOLOL HYDROCHLORIDE; INDERAL LA | 4138475 | SEP 14, 1997 | | | |
| | 18553 003 | PROPRANOLOL HYDROCHLORIDE; INDERAL LA | 4138475 | SEP 14, 1997 | | | |
| | 18553 004 | PROPRANOLOL HYDROCHLORIDE; INDERAL LA | 4138475 | SEP 14, 1997 | | | |
| | 19536 001 | PROPRANOLOL HYDROCHLORIDE; INDERAL | 4600708 | JUL 19, 2005 | | | |
| | 19664 001 | PSEUDOEPHEDRINE HYDROCHLORIDE; SELDANE-D | 4929605 | OCT 07, 2007 | U-81 | | |
| | | | 4254129 | APR 10, 1999 | U-81 | | |
| | 20021 002 | PSEUDOEPHEDRINE HYDROCHLORIDE; EFIDAC/24 | 4801461 | MAR 14, 2006 | | | |
| | 19885 001 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | FEB 24, 2007 | | | |
| | | | 4344949 | AUG 17, 2001 | U-3 | | |
| | 19885 002 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | FEB 24, 2007 | | | |
| | | | 4344949 | AUG 17, 2001 | U-3 | | |
| | 19885 003 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | FEB 24, 2007 | | | |
| | | | 4344949 | AUG 17, 2001 | U-3 | | |
| | 19885 004 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | FEB 24, 2007 | | | |
| | | | 4344949 | AUG 17, 2001 | U-3 | | |
| | 19901 001 | RAMIPRIL; ALTACE | 5061722 | OCT 29, 2008 | U-3 | I-134 | AUG 22, 1998 |
| | 19901 002 | RAMIPRIL; ALTACE | 5061722 | OCT 29, 2008 | U-3 | I-134 | AUG 22, 1998 |
| | 19901 003 | RAMIPRIL; ALTACE | 5061722 | OCT 29, 2008 | U-3 | I-134 | AUG 22, 1998 |

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 |
|---|---|---|---|---|---|---|
| 19901 004 | RAMIPRIL; ALTACE | 5061722 | OCT 29, 2008 | U-3 | I-134 | AUG 22, 1998 |
| 18703 001 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 4880636 | MAY 13, 2008 | | | |
| | | 4128658 | JUL 25, 1997 | | I-120 | MAR 29, 1998 |
| 18703 002 | RANITIDINE HYDROCHLORIDE; ZANTAC 300 | 4880636 | MAY 13, 2008 | | | |
| | | 4128658 | JUL 25, 1997 | | I-120 | MAR 29, 1998 |
| 19090 001 | RANITIDINE HYDROCHLORIDE; ZANTAC | 4585790 | MAY 11, 2004 | | | |
| | | 4128658 | JUL 25, 1997 | | | |
| 19593 001 | RANITIDINE HYDROCHLORIDE; ZANTAC | 4128658 | JUL 25, 1997 | | | |
| 19593 002 | RANITIDINE HYDROCHLORIDE; ZANTAC | 4585790 | APR 29, 2003 | | | |
| | | 4521431 | JUN 04, 2002 | | | |
| | | 4128658 | JUL 25, 1997 | | | |
| 19675 001 | RANITIDINE HYDROCHLORIDE; ZANTAC | 4585790 | MAY 11, 2004 | | I-120 | MAR 29, 1998 |
| | | 4128658 | JUL 25, 1997 | | | |
| 20095 001 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 5028432 | FEB 22, 2010 | | I-120 | MAR 29, 1998 |
| | | 4128658 | JUL 25, 1997 | | | |
| 20095 002 | RANITIDINE HYDROCHLORIDE; ZANTAC 300 | 5028432 | FEB 22, 2010 | | I-120 | MAR 29, 1998 |
| | | 4128658 | JUL 25, 1997 | | | |
| 20251 001 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 5102665 | JUN 23, 2009 | | I-120 | MAR 29, 1998 |
| | | 4128658 | JUL 25, 1997 | | | |
| 20251 002 | RANITIDINE HYDROCHLORIDE; ZANTAC 150 | 5102665 | JUN 23, 2009 | | I-120 | MAR 29, 1998 |
| | | 4128658 | JUL 25, 1997 | | | |
| 20214 001 | ROCURONIUM BROMIDE; ZEMURON (P/F) | 4894369 | APR 13, 2008 | | | |
| 20214 002 | ROCURONIUM BROMIDE; ZEMURON | 4894369 | APR 13, 2008 | | | |
| 20236 001 | SALMETEROL XINAFOATE; SEREVENT | 5380922 | MAY 14, 2013 | | | |
| 19839 001 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 5248699 | AUG 13, 2012 | U-12 | | |
| | | 4962128 | NOV 02, 2009 | U-12 | | |
| 19839 002 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 5248699 | AUG 13, 2012 | U-12 | | |
| | | 4962128 | NOV 02, 2009 | U-12 | | |
| 19839 003 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 5248699 | AUG 13, 2012 | U-12 | | |
| | | 4962128 | NOV 02, 2009 | U-12 | | |
| 19839 004 | SERTRALINE HYDROCHLORIDE; ZOLOFT | 5248699 | AUG 13, 2012 | U-12 | | |
| | | 4962128 | NOV 02, 2009 | U-12 | | |
| 20478 001 | SEVOFLURANE; ULTANE | | | | NCE | JUN 07, 2000 |
| 19766 001 | SIMVASTATIN; ZOCOR | | | | I-128 | JUN 30, 1998 |
| 19766 002 | SIMVASTATIN; ZOCOR | | | | I-128 | JUN 30, 1998 |
| 19766 003 | SIMVASTATIN; ZOCOR | | | | I-128 | JUN 30, 1998 |
| 19766 004 | SIMVASTATIN; ZOCOR | | | | I-128 | JUN 30, 1998 |

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 |
|---|---|---|---|---|---|---|---|
| | 19721 001 | SOMATROPIN; NORDITROPIN | | | | NS | MAY 08, 1998 |
| | 19721 002 | SOMATROPIN; NORDITROPIN | | | | NS | MAY 08, 1998 |
| | 20240 001 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | 4470972 | SEP 11, 2001 | U-3 | NCE | DEC 29, 1999 |
| | 20240 002 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | 4470972 | SEP 11, 2001 | U-3 | NCE | DEC 29, 1999 |
| | 20240 003 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | 4470972 | SEP 11, 2001 | U-3 | NCE | DEC 29, 1999 |
| | 20240 004 | SPIRAPRIL HYDROCHLORIDE; RENORMAX | 4470972 | SEP 11, 2001 | U-3 | NCE | DEC 29, 1999 |
| >ADD> | 20080 001 | SUMATRIPTAN SUCCINATE; IMITREX | 4816470 | DEC 28, 2006 | U-72 | | |
| >ADD> | 20132 001 | SUMATRIPTAN SUCCINATE; IMITREX | 5037845 | AUG 06, 2008 | U-72 | | |
| >ADD> | | | 4816470 | DEC 28, 2006 | U-72 | | |
| >ADD> | 20132 002 | SUMATRIPTAN SUCCINATE; IMITREX | 5037845 | AUG 06, 2008 | U-72 | | |
| >ADD> | | | 4816470 | DEC 28, 2006 | U-72 | | |
| >ADD> | 20132 003 | SUMATRIPTAN SUCCINATE; IMITREX | 5037845 | AUG 06, 2008 | U-72 | | |
| >ADD> | | | 4816470 | DEC 28, 2006 | U-72 | | |
| | 20070 001 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | OCT 01, 2006 | U-82 | | |
| | | | 4631286 | OCT 25, 2004 | U-97 | | |
| | 20070 002 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | OCT 01, 2006 | U-82 | | |
| | | | 4631286 | OCT 25, 2004 | U-97 | | |
| | 20070 003 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | OCT 01, 2006 | U-82 | | |
| | | | 4631286 | OCT 25, 2004 | U-97 | | |
| | 20070 004 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | OCT 01, 2006 | U-82 | | |
| | | | 4631286 | OCT 25, 2004 | U-97 | | |
| | 19829 001 | TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC | 4789736 | DEC 06, 2005 | | I-124 | APR 07, 1998 |
| | | | 4615876 | OCT 07, 2003 | | | |
| | 19981 001 | TECHNETIUM TC-99M RED BLOOD CELL KIT; ULTRATAG | 4755375 | JUL 05, 2005 | U-51 | | |
| | 19057 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | | 5294615 | APR 29, 2013 | | | |
| | | | 5212176 | JUN 29, 2010 | | | |
| | | | 4112097 | JAN 21, 1997 | U-3 | | |
| | 19057 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | | 5294615 | APR 29, 2013 | | | |
| | | | 5212176 | JUN 29, 2010 | | | |
| | | | 4112097 | JAN 21, 1997 | U-3 | | |
| | 19057 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | | 5294615 | APR 29, 2013 | | | |
| | | | 5212176 | JUN 29, 2010 | | | |
| | | | 4112097 | JAN 21, 1997 | U-3 | | |

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 |
|---|---|---|---|---|---|---|
| 19057 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | 5294615 | APR 29, 2013 | | | |
| | | 5212176 | JUN 29, 2010 | | | |
| | | 4112097 | JAN 21, 1997 | U-3 | | |
| 20347 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | 5294615 | APR 29, 2013 | | | |
| | | 5212176 | JUN 29, 2010 | | | |
| | | 4112097 | JAN 21, 1997 | | | |
| 20347 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | 5294615 | APR 29, 2013 | | | |
| | | 5212176 | JUN 29, 2010 | | | |
| | | 4112097 | JAN 21, 1997 | | | |
| 20347 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | 5294615 | APR 29, 2013 | | | |
| | | 5212176 | JUN 29, 2010 | | | |
| | | 4112097 | JAN 21, 1997 | | | |
| 20347 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 5412095 | APR 29, 2013 | | | |
| | | 5294615 | APR 29, 2013 | | | |
| | | 5212176 | JUN 29, 2010 | | | |
| | | 4112097 | JAN 21, 1997 | | | |
| 18949 001 | TERFENADINE; SELDANE | 4254129 | APR 10, 1999 | U-81 | | |
| | | | | | NS | SEP 29, 1998 |
| 20489 001 | TESTOSTERONE; ANDRODERM | 4591592 | MAY 27, 2003 | | | |
| 19979 001 | TICLOPIDINE HYDROCHLORIDE; TICLID | 4591592 | MAY 27, 2003 | | | |
| 19979 002 | TICLOPIDINE HYDROCHLORIDE; TICLID | 5231095 | JUL 27, 2010 | | NP | MAR 31, 1998 |
| 20439 001 | TIMOLOL; BETIMOL | 5231095 | JUL 27, 2010 | | NP | MAR 31, 1998 |
| 20439 002 | TIMOLOL; BETIMOL | RE34672 | AUG 11, 2006 | | | |
| 20136 001 | TORSEMIDE; DEMADEX | RE34672 | AUG 11, 2006 | | | |
| 20136 002 | TORSEMIDE; DEMADEX | RE34672 | AUG 11, 2006 | | | |
| 20136 003 | TORSEMIDE; DEMADEX | RE34672 | AUG 11, 2006 | | | |
| 20136 004 | TORSEMIDE; DEMADEX | 4861786 | JUL 08, 2007 | | | |
| 20137 002 | TORSEMIDE; DEMADEX | RE34672 | AUG 11, 2006 | | | |
| | | | | | NCE | MAR 03, 2000 |
| 20281 001 | TRAMADOL HYDROCHLORIDE; ULTRAM | | | | NCE | MAR 03, 2000 |
| 20281 002 | TRAMADOL HYDROCHLORIDE; ULTRAM | | | | | |
| 18207 003 | TRAZODONE HYDROCHLORIDE; DESYREL | 4258027 | MAR 26, 1999 | | | |
| | | 4215104 | MAR 26, 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 |
|---|---|---|---|---|---|---|---|
| | 18207 004 | TRAZODONE HYDROCHLORIDE; DESYREL | 4258027 | MAR 26, 1999 | | | |
| | | | 4215104 | MAR 26, 1999 | | | |
| | 19798 001 | TRIAMCINOLONE ACETONIDE; NASACORT | 4767612 | JAN 23, 2007 | U-85 | | |
| | 20326 001 | TRIMETREXATE GLUCURONATE; NEUTREXIN | 4694007 | MAY 20, 2006 | U-91 | | |
| | | | 4376858 | OCT 31, 2000 | | | |
| | 20487 001 | VALACYCLOVIR HYDROCHLORIDE; VALTREX | 4957924 | SEP 18, 2007 | | NE | JUN 23, 1998 |
| | 20487 002 | VALACYCLOVIR HYDROCHLORIDE; VALTREX | 4957924 | SEP 18, 2007 | | NE | JUN 23, 1998 |
| | 18776 002 | VECURONIUM BROMIDE; NORCURON | 4297351 | AUG 20, 1999 | | | |
| | | | 4237126 | AUG 20, 1999 | | | |
| | 18776 003 | VECURONIUM BROMIDE; NORCURON | 4297351 | AUG 20, 1999 | | | |
| | | | 4237126 | AUG 20, 1999 | | | |
| | 20151 001 | VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4535186 | DEC 13, 2002 | | | |
| | 20151 002 | VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4535186 | DEC 13, 2002 | | | |
| | 20151 003 | VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4535186 | DEC 13, 2002 | | | |
| | 20151 004 | VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4535186 | DEC 13, 2002 | | | |
| | 20151 005 | VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4535186 | DEC 13, 2002 | | | |
| | 20151 006 | VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4535186 | DEC 13, 2002 | | | |
| | 19614 001 | VERAPAMIL HYDROCHLORIDE; VERELAN | 4863742 | JUN 19, 2007 | U-3 | | |
| | 19614 002 | VERAPAMIL HYDROCHLORIDE; VERELAN | 4863742 | JUN 19, 2007 | U-3 | | |
| | 19614 003 | VERAPAMIL HYDROCHLORIDE; VERELAN | 4863742 | JUN 19, 2007 | U-3 | | |
| >ADD> | 20388 001 | VINORELBINE TARTRATE; NAVELBINE | 4307100 | AUG 20, 1999 | | NCE | DEC 23, 1999 |
| >DLT> | ~~20388 001~~ | ~~VINORELBINE TARTRATE; NAVELBINE~~ | ~~4307100~~ | ~~NOV 23, 2001~~ | | ~~NCE~~ | ~~DEC 23, 1999~~ |
| | 19655 001 | ZIDOVUDINE; RETROVIR | 4837208 | SEP 17, 2005 | | | |
| | | | 4833130 | SEP 17, 2005 | | | |
| | | | 4828838 | SEP 17, 2005 | | | |
| | | | 4818538 | SEP 17, 2005 | | | |
| | | | 4724232 | SEP 17, 2005 | | | |
| | 19910 001 | ZIDOVUDINE; RETROVIR | 4837208 | SEP 17, 2005 | | | |
| | | | 4833130 | SEP 17, 2005 | | | |
| | | | 4818538 | SEP 17, 2005 | | | |
| | | | 4724232 | SEP 17, 2005 | | | |
| | 19951 001 | ZIDOVUDINE; RETROVIR | 4837208 | SEP 17, 2005 | | | |
| | | | 4833130 | SEP 17, 2005 | | | |
| | | | 4818538 | SEP 17, 2005 | | | |
| | | | 4724232 | SEP 17, 2005 | | | |
| >ADD> | 19908 001 | ZOLPIDEM TARTRATE; AMBIEN | 4382938 | OCT 21, 2006 | U-74 | | |
| >DLT> | ~~19908 001~~ | ~~ZOLPIDEM TARTRATE; AMBIEN~~ | ~~4382938~~ | ~~MAY 10, 2005~~ | ~~U-74~~ | | |

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| | APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---|---|---|---|---|---|---|---|
| >ADD> | 19908 002 | ZOLPIDEM TARTRATE; AMBIEN | 4382938 | OCT 21, 2006 | U-74 | | |
| >DLT> | ~~19908 002~~ | ~~ZOLPIDEM TARTRATE; AMBIEN~~ | ~~4382938~~ | ~~MAY 10, 2005~~ | ~~U-74~~ | | |

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