

# **APPROVED DRUG PRODUCTS**

## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

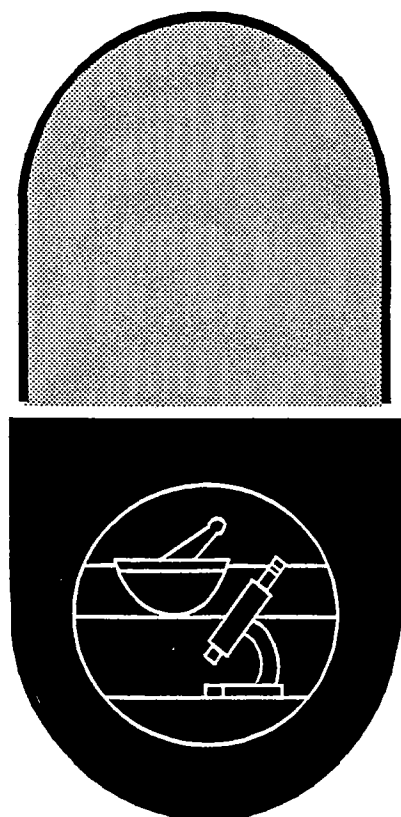
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HFD-603  
DB HARE

MPN-2/286

**CUMULATIVE  
SUPPLEMENT 12**

**JAN'92-DEC'92**



**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**12<sup>TH</sup> EDITION**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION**

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**12TH EDITION**

**Cumulative Supplement 12**

**December 1992**

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**APPROVED DRUG PRODUCTS**  
**with**  
**THERAPEUTIC EQUIVALENCE EVALUATIONS**  
  
**12TH EDITION**  
  
**CUMULATIVE SUPPLEMENT 12**

**DECEMBER 1992**

**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, 12th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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. A newly approved product is also identified by a lozenge (⌘) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "Ⓢ" symbol to designate their non-marketed status.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

## 1.2 CEFADROXIL/CEFADROXIL HEMIHYDRATE ACTIVE INGREDIENT HEADING

The active ingredient heading Cefadroxil/Cefadroxil Hemihydrate replaces the active ingredient heading Cefadroxil which is currently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, 12th Edition. All products which are listed under Cefadroxil (which is understood to be the monohydrate form) in the 12th Edition will now be listed along with the newly approved duplicate drug products under the new active ingredient, Cefadroxil/Cefadroxil Hemihydrate.

## 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.

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

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

### APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

BARNES HIND PHARMACEUTICALS INC  
(BARNES HIND)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

SOLA BARNES HIND  
(SOLA BARNES HIND)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

BEECHAM LABORATORIES DIV OF  
BEECHAM INC  
(BEECHAM)

SMITHKLINE BEECHAM  
PHARMACEUTICALS  
(SMITHKLINE BEECHAM)

DELMED INC  
(DELMED)

FRESENIUS USA INC  
(FRESENIUS)

MERCK SHARP AND DOHME RESEARCH LABS  
DIV MERCK AND CO INC  
(MSD)

MERCK RESEARCH LABORATORIES  
DIV MERCK AND CO INC  
(MERCK)

NORWICH EATON PHARMS INC  
SUB PROCTOR & GAMBLE CO  
(NORWICH EATON)

PROCTER & GAMBLE PHARMACEUTICALS INC  
(P&G)

OFFICE SURGEON GENERAL DEPT ARMY  
(DEPT ARMY)

OFFICE SURGEON GENERAL DEPT ARMY  
(US ARMY)

RECKITT AND COLMAN PHARMACEUTICALS INC  
(R & C)

RECKITT AND COLMAN PHARMACEUTICALS INC  
(RECKITT AND COLMAN)

SCHWARZ PHARMACEUTICALS INC  
(SCHWARZ)

SCHWARZ PHARMACEUTICALS INC  
(SCHWARZ PHARMA)

SMITH KLINE AND FRENCH LABS  
DIV SMITHKLINE BECKMAN CORP  
(SKF)

SMITHKLINE BEECHAM  
PHARMACEUTICALS  
(SMITHKLINE BEECHAM)

SOLOPAK LABORATORIES  
(SOLOPAK)

SMITH AND NEPHEW SOLOPAK  
DIVISION OF SMITH AND NEPHEW  
(SMITH NEPHEW SOLOPAK)

VICKS HEALTH CARE DIV RICHARDSON VICKS INC  
(VICKS HLTH CARE)

VICKS HEALTH CARE DIV RICHARDSON VICKS INC  
(VICKS HEALTH CARE)

WHITBY PHARMACEUTICALS INC  
(WHITBY PHARMS)

WHITBY PHARMACEUTICALS INC  
(WHITBY)

US CHEMICAL MARKETING GROUP INC  
(US CHEM MKTG)

US CHEMICAL MARKETING GROUP INC  
(US CHEM)



## 1.5 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

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

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

### USP MONOGRAPH TITLE ADDITIONS OR CHANGES

#### FORMER USP MONOGRAPH TITLE (FORMER ADP DOSAGE FORM; ROUTE)

ACETAMINOPHEN AND CODEINE  
PHOSPHATE ELIXIR  
(ELIXIR; ORAL)

LACTULOSE SYRUP  
(SYRUP; ORAL)

LACTULOSE SYRUP  
(SYRUP; ORAL, RECTAL)

NONE  
(SYRUP; ORAL)

OXTRIPHYLLINE ELIXIR  
(ELIXIR; ORAL)

#### NEW USP MONOGRAPH TITLE (NEW ADP DOSAGE FORM; ROUTE)

ACETAMINOPHEN AND CODEINE  
PHOSPHATE SOLUTION  
(SOLUTION; ORAL)

LACTULOSE SOLUTION  
(SOLUTION; ORAL)

LACTULOSE SOLUTION  
(SOLUTION; ORAL, RECTAL)

METOCLOPRAMIDE ORAL  
SOLUTION  
(SOLUTION; ORAL)

OXTRIPHYLLINE SOLUTION  
(SOLUTION; ORAL)

## **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 1991) 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

| <u>CATEGORIES COUNTED</u>       | <u>DEC 1991</u> | <u>JUN 1992</u> | <u>SEP 1992</u> | <u>DEC 1992</u> |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| DRUG PRODUCTS LISTED            | 9584            | 9476            | 9501            | 9488            |
| SINGLE SOURCE                   | 2187 (22.8%)    | 2227 (23.5%)    | 2227 (23.4%)    | 2245 (23.7%)    |
| MULTISOURCE                     | 7397 (77.2%)    | 7249 (76.5%)    | 7274 (76.6%)    | 7243 (76.3%)    |
| THERAPEUTICALLY EQUIVALENT      | 6580 (68.7%)    | 6494 (68.5%)    | 6518 (68.6%)    | 6516 (68.6%)    |
| NOT THERAPEUTICALLY EQUIVALENT  | 664 ( 6.9%)     | 595 ( 6.3%)     | 590 ( 6.2%)     | 577 ( 6.1%)     |
| EXCEPTIONS <sup>1</sup>         | 153 ( 1.6%)     | 160 ( 1.7%)     | 166 ( 1.8%)     | 150 ( 1.6%)     |
| NEW MOLECULAR ENTITIES APPROVED | --              | 2               | 8               | 10              |
| NUMBER OF APPLICANTS            | 430             | 455             | 471             | 477             |

<sup>1</sup> Amino acid-containing products of varying composition (see Introduction, page xvi of the List).



PRESCRIPTION DRUG PRODUCT LIST  
12TH EDITION  
CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'92 - DEC'92

1

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL  
> DLT > /BANCAP/  
> DLT > /AA/ /3/ /FOREST/PHARMS/ /325MG;50MG/ /N88889/001/  
> DLT > /JAN/16./1986/  
> ADD > @ FOREST PHARMS 325MG;50MG N88889 001  
> ADD > JAN 16, 1986

TABLET; ORAL  
BUTAPAP  
AB MIKART 325MG;50MG N89987 001  
OCT 26, 1992  
AB 650MG;50MG N89988 001  
OCT 26, 1992  
SEDAPAP  
AB + MAYRAND 650MG;50MG N88944 001  
OCT 17, 1985

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL  
FIORICET W/ CODEINE  
+ SANDOZ 325MG;50MG;40MG;30MG N20232 001  
JUL 30, 1992

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL  
ACETAMINOPHEN AND CODEINE PHOSPHATE  
AA MIKART 120MG/5ML;12MG/5ML N89450 001  
OCT 27, 1992  
ACETAMINOPHEN AND CODEINE PHOSPHATE  
AA PHARM BASICS 120MG/5ML;12MG/5ML N87006 001  
/AA/ /HYAPAP AND CODEINE/ /120MG/5ML;12MG/5ML/ /N87006/001/  
/AA/ /PHARM BASICS/

TABLET; ORAL  
ACETAMINOPHEN AND CODEINE PHOSPHATE  
/AA/ /CHARLOTTE/ /300MG;15MG/ /N89990/001/  
/AA/ /300MG;30MG/ /SEP/30./1988/  
/AA/ /300MG;60MG/ /N89805/001/  
/AA/ /300MG;60MG/ /SEP/30./1988/  
@ EON LABS 300MG;15MG N87433 001  
@ 300MG;30MG N85917 001  
@ 300MG;60MG N87423 001

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL  
ACETAMINOPHEN AND CODEINE PHOSPHATE  
AA GENEVA 300MG;30MG N81250 001  
JUL 16, 1992  
AA 300MG;60MG N81249 001  
JUL 16, 1992  
> DLT > /3/ /PARKE/DAVIS/ /300MG;15MG/ /N85492/001/  
> DLT > /3/ /300MG;30MG/ /N85218/002/  
AA VINTAGE 300MG;15MG N89990 001  
SEP 30, 1988  
AA 300MG;30MG N89805 001  
SEP 30, 1988  
AA 300MG;60MG N89828 001  
SEP 30, 1988  
/3/ /VITARINE/ /300MG;15MG/ /N87433/001/  
/3/ /300MG;30MG/ /N85917/001/  
/3/ /300MG;60MG/ /N87423/001/  
> ADD > @ WARNER CHILCOTT 300MG;15MG N85992 001  
> ADD > @ 300MG;30MG N85218 002  
ACETAMINOPHEN W/ CODEINE PHOSPHATE  
/AA/ /CHELSEA/ /300MG;15MG/ /N87277/001/  
/AA/ /300MG;30MG/ /MAY/26./1982/  
/AA/ /300MG;60MG/ /N87276/001/  
/AA/ /300MG;60MG/ /MAY/26./1982/  
@ CHELSEA 300MG;15MG N87275/001/  
@ 300MG;30MG N87277 001  
@ 300MG;60MG N87276 001  
@ 300MG;60MG N87275 001  
MAY 26, 1982

ACETAMINOPHEN; HYDROCODONE BITARTRATE

ELIXIR; ORAL  
HYDROCODONE BITARTRATE AND ACETAMINOPHEN  
MIKART 500MG/15ML;5MG/15ML N81226 001  
OCT 27, 1992  
500MG/15ML;5MG/15ML N89557 001  
APR 29, 1992  
500MG/15ML;7.5MG/15ML N81051 001  
AUG 28, 1992

TABLET; ORAL  
/AA/ /HYCOPAP/ /500MG;5MG/ /N89971/001/  
/AA/ /CHARLOTTE/ /DEC/02./1988/

ACETAMINOPHEN; HYDROCODONE BITARTRATE

## TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

|      |                                                 |                  |                |
|------|-------------------------------------------------|------------------|----------------|
| /AA/ | /CHARLOTTE/                                     | /500MG;5MG/      | /N89831/001/   |
|      |                                                 |                  | /SEP/07./1988/ |
| AA   | MIKART                                          | 500MG;5MG        | N89697 001     |
|      |                                                 |                  | JAN 28, 1992   |
|      |                                                 | 650MG;10MG       | N81223 001     |
|      |                                                 |                  | MAY 29, 1992   |
| /B*/ | /PHARM/BASICS/                                  | /500MG;5MG/      | /N89291/001/   |
|      |                                                 |                  | /MAY/29./1987/ |
|      | PHARM BASICS                                    | 500MG;5MG        | N89291 001     |
|      |                                                 |                  | MAY 29, 1987   |
|      |                                                 |                  | N89831 001     |
| AA   | <u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u> | <u>500MG;5MG</u> | SEP 07, 1988   |
|      | VINTAGE                                         |                  | N89971 001     |
| AA   |                                                 | 500MG;5MG        | DEC 02, 1988   |

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

## TABLET; ORAL

PROPOXYPHENE HCL AND ACETAMINOPHEN

|      |         |              |              |
|------|---------|--------------|--------------|
| AA   | MYLAN   | 650MG;65MG   | N83978 001   |
|      |         | 325MG;32MG   | N83689 001   |
| /AA/ | /MYLAN/ | /650MG;65MG/ | /N83978/001/ |
|      |         | /325MG;32MG/ | /N83689/001/ |

ACETIC ACID, GLACIAL

## SOLUTION/DROPS; OTIC

|      |              |      |                |
|------|--------------|------|----------------|
| /AI/ | /BOROFAIR/   | /2%/ | /N88606/001/   |
|      | /PHARMAFAIR/ |      | /AUG/21./1985/ |

ACETIC ACID, GLACIAL; ALUMINUM ACETATE

## SOLUTION/DROPS; OTIC

|    |                 |            |              |
|----|-----------------|------------|--------------|
| AI | <u>BOROFAIR</u> |            | N88606 001   |
|    | PHARMAFAIR      | 2%;0.79%   | AUG 21, 1985 |
| AI | <u>DOMEBORO</u> |            | N84476 001   |
|    | MILES           | 2%;0.79%   | /N84476/001/ |
|    |                 | /2%;0.79%/ |              |

ACETOHEXAMIDE

## TABLET; ORAL

ACETOHEXAMIDE

|      |                |         |                |
|------|----------------|---------|----------------|
| /B*/ | /PHARM/BASICS/ | /250MG/ | /N70753/001/   |
|      |                |         | /NOV/03./1986/ |
| /B*/ |                | /500MG/ | /N70754/001/   |
|      |                |         | /NOV/03./1986/ |
|      | PHARM BASICS   | 250MG   | N70753 001     |
|      |                |         | NOV 03, 1986   |
|      |                | 500MG   | N70754 001     |
|      |                |         | NOV 03, 1986   |

ACETYLCYSTEINE

## SOLUTION; INHALATION, ORAL

ACETYLCYSTEINE

|      |                   |       |                |
|------|-------------------|-------|----------------|
| AN   | CETUS BEN VENUE   | 10%   | N72323 001     |
|      |                   |       | APR 30, 1992   |
| AN   |                   | 20%   | N72324 001     |
|      |                   |       | APR 30, 1992   |
| AN   | ROXANE            | 10%   | N72621 001     |
|      |                   |       | SEP 30, 1992   |
| AN   |                   | 20%   | N72622 001     |
|      |                   |       | SEP 30, 1992   |
|      |                   |       | N13601 002     |
| AN   | <u>MUCOMYST</u>   | 10%   | N13601 001     |
| AN   | APOTHECON         | 20%   | /N13601/001/   |
| /AN/ | /HEAD/JOHNSON/    | /10%/ | /N13601/001/   |
| /AN/ |                   | /20%/ |                |
|      | <u>MUCOSIL-10</u> |       | N70575 001     |
| AN   | DEY               | 10%   | OCT 14, 1986   |
|      |                   |       | N70576 001     |
| AN   | <u>MUCOSIL-20</u> | 20%   | OCT 14, 1986   |
|      |                   |       | N70575/001/    |
| /AN/ | /MUCOSIL-10/      | /10%/ | /OCT/14./1986/ |
|      | /DEY/             |       |                |
| /AN/ | /MUCOSIL-20/      | /20%/ | /N70576/001/   |
|      | /DEY/             |       | /OCT/14./1986/ |

ALBUTEROL SULFATE

## SOLUTION; INHALATION

ALBUTEROL SULFATE

|    |     |                 |              |
|----|-----|-----------------|--------------|
| AN | DEY | EQ 0.083% BASEM | N72652 001   |
|    |     |                 | FEB 21, 1992 |

ALBUTEROL SULFATE

## SOLUTION; INHALATION

AN PROVENTIL EQ 0.083% BASE N19243 002  
SCHERING JAN 14, 1987

AN VENTOLIN EQ 0.083% BASE N19773 001  
GLAXO APR 23, 1992

## SYRUP; ORAL

AA ALBUTEROL SULFATE EQ 2MG BASE/5ML N73419 001  
LEMMON MAR 30, 1992

## TABLET; ORAL

AB ALBUTEROL SULFATE EQ 2MG BASE N73120 001  
MD PHARM SEP 29, 1992  
AB EQ 4MG BASE N73121 001  
SEP 29, 1992

## TABLET, EXTENDED RELEASE; ORAL

> ADD > AB PROVENTIL EQ 4MG BASE N19383 001  
> ADD > + SCHERING JUL 13, 1987  
> ADD >  
> ADD > VOLMAX  
> ADD > AB GLAXO EQ 4MG BASE N19604 002  
> ADD > DEC 23, 1992  
> ADD > + EQ 8MG BASE N19604 001  
> ADD > DEC 23, 1992

ALGLUCERASE

## INJECTABLE; INJECTION

CEREDASE 10 UNITS/ML N20057 004  
GENZYME MAY 08, 1992

ALLOPURINOL

## TABLET; ORAL

AB ALLOPURINOL 100MG N18241 001  
BOLAR NOV 16, 1984  
2 BOLAR 100MG N18241 001  
NOV 16, 1984

AMIKACIN SULFATE

## INJECTABLE; INJECTION

AP AMIKACIN EQ 50MG BASE/ML N63274 001  
ELKINS SINN MAY 18, 1992  
AP EQ 250MG BASE/ML N63275 001  
MAY 18, 1992

AMIKIN

AP BRISTOL EQ 50MG BASE/ML N50495 001  
AP EQ 50MG BASE/ML N62562 001  
SEP 20, 1984  
AP EQ 250MG BASE/ML N50495 002  
AP EQ 250MG BASE/ML N62562 002  
SEP 20, 1984

AMINO ACIDS; DEXTROSE

## INJECTABLE; INJECTION

/AMINOSYN/4.25%/W/DEXTROSE/25%/IN/PLASTIC/CONTAINER/  
/ABBOTT/ 4.25%;25GM/100ML N19119 001  
2 ABBOTT 4.25%;25GM/100ML N19119 001  
OCT 11, 1984

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE

## /INJECTABLE; INJECTION/

/AMINOSYN/3.5%/N/  
/ABBOTT/ 3.5%;21MG/100ML;128MG/100ML;  
234MG/100ML N17789 001  
3.5%;21MG/100ML;128MG/100ML;  
234MG/100ML N17789 001

AMINOPHYLLINE

## INJECTABLE; INJECTION

> ADD > AP AMINOPHYLLINE 25MG/ML N87200 001  
> ADD > AP FUJISAWA 25MG/ML N87886 001  
> ADD > AUG 30, 1983  
> DLT > AP /LYPHOMED/ 25MG/ML N87200 001  
/AP/ 25MG/ML N87256 001  
JAN 06, 1982  
> DLT > AP 25MG/ML N87886 001  
> DLT > 2 LYPHOMED 25MG/ML N87250 001  
JAN 06, 1982

AMITRIPTYLINE HYDROCHLORIDE

## TABLET; ORAL

/AB/ /AMITRIL/  
/AB/ /WARNER/CHILCOTT/ /10MG/  
/AB/ /25MG/  
/AB/ /50MG/  
/AB/ /75MG/  
/AB/ /100MG/  
/AB/ /150MG/  
Q WARNER CHILCOTT 10MG  
Q 25MG  
Q 50MG  
Q 75MG  
Q 100MG  
Q 150MG

## AMITRIPTYLINE HCL

/BP/ /PAR/ /10MG/ /N88697/001/  
/BP/ /25MG/ /SEP/25./1984/  
/BP/ /50MG/ /N88698/001/  
/BP/ /75MG/ /SEP/25./1984/  
/BP/ /100MG/ /N88699/001/  
/BP/ /150MG/ /SEP/25./1984/  
/N88700/001/  
/SEP/25./1984/  
/N88701/001/  
/SEP/25./1984/  
/N88702/001/  
/SEP/25./1984/  
Q PAR 10MG N88697 001  
Q 25MG SEP 25, 1984 N88698 001  
Q 50MG SEP 25, 1984 N88699 001  
Q 75MG SEP 25, 1984 N88700 001  
Q 100MG SEP 25, 1984 N88701 001  
Q 150MG SEP 25, 1984 N88702 001

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

## TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL  
/B\*/ /PHARM/BASICS/ /EQ/12.5MG/BASE;5MG/ /N70477/001/  
/B\*/ /EQ/25MG/BASE;10MG/ /JAN/12./1988/  
/N70478/001/  
/JAN/12./1988/  
Q PHARM BASICS EQ 12.5MG BASE;5MG N70477 001  
Q EQ 25MG BASE;10MG JAN 12, 1988  
N70478 001  
JAN 12, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

## TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL  
/2/CHELSEA/ /50MG;4MG/ /N71558/001/  
/MAR/02./1987/

AMLODIPINE BESYLATE

## TABLET; ORAL

NORVASC  
+ PFIZER EQ 10MG BASEM N19787 003  
JUL 31, 1992  
EQ 2.5MG BASEM N19787 001  
JUL 31, 1992  
EQ 5MG BASEM N19787 002  
JUL 31, 1992

AMOXAPINE

## TABLET; ORAL

AMOXAPINE  
AB DANBURY 25MG N72688 001  
AUG 28, 1992  
AB 50MG N72689 001  
AUG 28, 1992  
AB 100MG N72690 001  
AUG 28, 1992  
AB 150MG N72691 001  
AUG 28, 1992



AMOXICILLIN

## CAPSULE; ORAL

POLYMOX

AB BRISTOL MYERS

250MG

N63099 001

MAR 20, 1992

AB

500MG

N63099 002

MAR 20, 1992

/AB/ /UTIMOX/

/PARKE/DAVIS/

/250MG/

/N62107/001/

/AB/

/500MG/

/N62107/002/

a PARKE DAVIS

250MG

N62107 001

a

500MG

N62107 002

## POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

/AB/ /CLONMEL/

/125MG/5ML/

/N62927/001/

/NOV/25./1988/

/AB/

/250MG/5ML/

/N62927/002/

/NOV/25./1988/

BX CLONMEL

125MG/5ML

N62927 001

NOV 25, 1988

BX

250MG/5ML

N62927 002

NOV 25, 1988

/AB/ /UTIMOX/

/PARKE/DAVIS/

/125MG/5ML/

/N62127/001/

/AB/

/250MG/5ML/

/N62127/002/

a PARKE DAVIS

125MG/5ML

N62127 001

a

250MG/5ML

N62127 002

## TABLET, CHEWABLE; ORAL

AMOXICILLIN

&gt; ADD &gt; AB

BIOCRAFT

250MG

N64013 001

DEC 22, 1992

&gt; ADD &gt;

AMOXIL

&gt; ADD &gt; AB

+ SMITHKLINE BEECHAM

250MG

N50542 001

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

## CAPSULE, EXTENDED RELEASE; ORAL

&gt; DLT &gt;

/BIPHETAMINE/7.5/

/EQ/3.75MG/BASE/

&gt; DLT &gt;

/FISONS/

/EQ/3.75MG/BASE/

&gt; DLT &gt;

a FISONS

EQ 3.75MG BASE;

&gt; ADD &gt;

EQ 3.75MG BASE

&gt; ADD &gt;

/N10093/009/

N10093 009

AMPHOTERICIN B

## INJECTABLE; INJECTION

AMPHOTERICIN B

&gt; ADD &gt; AP

FUJISAWA

50MG/VIAL

N62728 001

&gt; ADD &gt;

&gt; DLT &gt; /AP/

/LITHOMED/

/50MG/VIAL/

APR 13, 1987

/N62728/001/

&gt; DLT &gt;

AP

PHARMA TEK

50MG/VIAL

/APR/13./1987/

N63206 001

APR 29, 1992

AMPICILLIN SODIUM

## INJECTABLE; INJECTION

POLYCILLIN-N

/AP/

/BRISTOL/

/EQ/125MG BASE/VIAL/

/N50309/001/

/AP/

/BRISTOL/

/EQ/250MG BASE/VIAL/

/N50309/002/

/AP/

/BRISTOL/

/EQ/500MG BASE/VIAL/

/N50309/003/

/AP/

/BRISTOL/

/EQ/1GM BASE/VIAL/

/N50309/004/

/AP/

/BRISTOL/

/EQ/2GM BASE/VIAL/

/N50309/005/

a BRISTOL

EQ 125MG BASE/VIAL

N50309 001

a

EQ 250MG BASE/VIAL

N50309 002

a

EQ 500MG BASE/VIAL

N50309 003

a

EQ 1GM BASE/VIAL

N50309 004

a

EQ 2GM BASE/VIAL

N50309 005

AMPICILLIN/AMPICILLIN TRIHYDRATE

## CAPSULE; ORAL

/AB/

/AMCILL/

/EQ/250MG BASE/

/N62041/001/

/AB/

/PARKE/DAVIS/

/EQ/500MG BASE/

/N62041/002/

/AB/

a PARKE DAVIS

EQ 250MG BASE

N62041 001

a

EQ 500MG BASE

N62041 002

POLYCILLIN

/AB/

/BRISTOL/

/EQ/250MG BASE/

/N50310/001/

/AB/

/BRISTOL/

/EQ/250MG BASE/

/N61392/001/

AB

+ BRISTOL

EQ 250MG BASE

N61392 001

/AB/

/BRISTOL/

/EQ/500MG BASE/

/N50310/002/

a

EQ 250MG BASE

N50310 001

a

EQ 500MG BASE

N50310 002

## POWDER FOR RECONSTITUTION; ORAL

/AB/

/AMCILL/

/EQ/125MG BASE/5ML/

/N62030/001/

/AB/

/PARKE/DAVIS/

/EQ/250MG BASE/5ML/

/N62030/002/

a

EQ 125MG BASE/5ML

N62030 001

a

EQ 250MG BASE/5ML

N62030 002

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

|                   |                    |              |
|-------------------|--------------------|--------------|
| <u>POLYCILLIN</u> |                    |              |
| /AB/ /BRISTOL/    | /EQ 100MG BASE/ML/ | /N50308/004/ |
| /AB/              | /EQ 100MG BASE/ML/ | /N61394/001/ |
| 3 BRISTOL         | EQ 100MG BASE/ML   | N50308 004   |
|                   | EQ 100MG BASE/ML   | N61394 001   |

AMPICILLIN/AMPICILLIN TRIHYDRATE; PROBENECID

POWDER FOR RECONSTITUTION; ORAL

|                       |                     |              |
|-----------------------|---------------------|--------------|
| <u>POLYCILLIN-PRB</u> |                     |              |
| /AB/ /BRISTOL/        | /EQ 3.5GM BASE/BOT/ | /N50457/001/ |
| /AB/                  | /1GM/BOT/           | /N61898/001/ |
| AB + BRISTOL          | EQ 3.5GM BASE/BOT;  | N61898 001   |
| 3                     | 1GM/BOT             | N50457 001   |
|                       | EQ 3.5GM BASE/BOT;  |              |
|                       | 1GM/BOT             |              |

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

|                                          |                   |              |
|------------------------------------------|-------------------|--------------|
| <u>BUTALBITAL; ASPIRIN AND CAFFEINE/</u> |                   |              |
| /AB/ /CHELSEA/                           | /325MG;50MG;40MG/ | /N86231/002/ |
| 3 CHELSEA                                | 325MG;50MG;40MG   | FEB 12, 1985 |

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

|         |                                         |               |
|---------|-----------------------------------------|---------------|
| > DLT > | /ORPHENADRINE/COMPOUND/                 |               |
| > DLT > | /3/EON/LABS/                            | /N71564/001/  |
| > DLT > |                                         | /JUN/23/1988/ |
| > DLT > | /ORPHENADRINE/COMPOUND/DOUBLE STRENGTH/ |               |
| > DLT > | /3/EON/LABS/                            | /N71565/001/  |
| > DLT > |                                         | /JUN/23/1988/ |

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

|                                 |                     |               |
|---------------------------------|---------------------|---------------|
| <u>PROPOXYPHENE COMPOUND 65</u> |                     |               |
| AA EON LABS                     | 389MG;32.4MG;65MG   | N80044 002    |
|                                 |                     | SEP 16, 1983  |
| /AA/ /VITARINE/                 | /189MG;32.4MG;65MG/ | /N80044/002/  |
|                                 |                     | /SEP/16/1983/ |

ASPIRIN; MEPROBAMATETABLET; ORAL  
MEPRO-ASPIRIN  
3 EON LABS

|              |               |               |
|--------------|---------------|---------------|
|              | 325MG;200MG   | N89127 001    |
|              |               | MAR 02, 1987  |
| /3/VITARINE/ | /325MG;200MG/ | /N89127/001/  |
|              |               | /MAR/02/1987/ |

ATENOLOL

TABLET; ORAL

|                         |       |              |
|-------------------------|-------|--------------|
| <u>ATENOLOL</u>         |       |              |
| AB APOTHECON            | 50MG  | N73317 001   |
|                         |       | MAR 20, 1992 |
| AB                      | 100MG | N73318 001   |
|                         |       | MAR 20, 1992 |
| AB GENEVA               | 25MG  | N74052 001   |
|                         |       | MAY 01, 1992 |
| AB IPR                  | 25MG  | N73646 001   |
|                         |       | JUL 31, 1992 |
| AB LEDERLE              | 25MG  | N74099 001   |
|                         |       | APR 28, 1992 |
| AB MYLAN                | 50MG  | N73456 001   |
|                         |       | JAN 24, 1992 |
| AB                      | 100MG | N73457 001   |
|                         |       | JAN 24, 1992 |
| AB SCHIAPPARELLI SEARLE | 50MG  | N73676 001   |
|                         |       | OCT 30, 1992 |
| AB                      | 100MG | N73676 002   |
|                         |       | OCT 30, 1992 |
| <u>TENORMIN</u>         |       |              |
| AB ICI                  | 25MG  | N18240 004   |
|                         |       | APR 09, 1990 |

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

|                                    |              |               |
|------------------------------------|--------------|---------------|
| <u>ATENOLOL AND CHLORTHALIDONE</u> |              |               |
| AB DANBURY                         | 50MG;25MG    | N73665 001    |
|                                    |              | JUL 02, 1992  |
| AB                                 | 100MG;25MG   | N73665 002    |
|                                    |              | JUL 02, 1992  |
| <u>TENORETIC 100</u>               |              |               |
| AB + ICI                           | 100MG;25MG   | N18760 001    |
|                                    |              | JUN 08, 1984  |
| /AB/ /3/STUART/                    | /100MG;25MG/ | /N18760/001/  |
|                                    |              | /JUN/08/1984/ |
| <u>TENORETIC 50</u>                |              |               |
| AB ICI                             | 50MG;25MG    | N18760 002    |
|                                    |              | JUN 08, 1984  |

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL  
TENORETIC 50  
 /AA/ /STUART/ /50MG;25MG/ /N18768/001/  
 /JUN/88:/1984/

ATOVAQUONE

TABLET; ORAL  
 MEPRON  
 + BURROUGHS WELLCOME 250MG  
 N20259 001  
 NOV 25, 1992

ATROPINE SULFATE

/AEROSOL;/METERED;/INHALATION/  
 /ATROPINE/SULFATE/  
 /US/ARMY/ /EQ/0.36MG/BASE/INH/ /N20056/001/  
 2 US ARMY EQ 0.36MG BASE/INH /SEP/19:/1998/  
 N20056 001  
 SEP 19, 1990

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

SOLUTION; ORAL  
 /COLONATO/  
 > DLT > /AA/ /WALLACE/ /0.025MG/5ML;2.5MG/5ML/ /N85735/001/  
 > DLT > /AA/ 2 WALLACE 0.025MG/5ML;2.5MG/5ML N85735 001  
 > ADD > /COLONATO/  
 /AA/ /BARRE/ /0.025MG/5ML;2.5MG/5ML/ /N85746/001/  
 2 BARRE 0.025MG/5ML;2.5MG/5ML N85746 001

TABLET; ORAL  
 /COLONATO/  
 > DLT > /AA/ /WALLACE/ /0.025MG;2.5MG/ /N85737/001/  
 > DLT > /AA/ 2 WALLACE 0.025MG;2.5MG N85737 001  
 > ADD > /COLONATO/

DIPHENOXYLATE HCL AND ATROPINE SULFATE  
 /AA/ /CHELSEA/ /0.025MG;2.5MG/ /N85876/001/  
 2 CHELSEA 0.025MG;2.5MG N85876 001  
 DIPHENOXYLATE HCL W/ ATROPINE SULFATE  
 2 EON LABS 0.025MG;2.5MG N86173 001  
 /2/ATROPINE/ /0.025MG;2.5MG/ /N86173/001/

> DLT >  
 > DLT >  
 > DLT >  
 > DLT >

/AZITHROMYCIN/

/CAPSULE;/ORAL/  
 /ZITHROMAX/  
 + /PFIZER/ /250MG/ /N50670/001/  
 /NOV/91:/1991/

AZITHROMYCIN DIHYDRATE

CAPSULE; ORAL  
 ZITHROMAX  
 + PFIZER EQ 250MG BASE N50670 001  
 NOV 01, 1991

AZLOCILLIN SODIUM

INJECTABLE; INJECTION  
 AZLIN  
 /MILES/ /EQ/3GM/BASE/VIAL/ /N62388/001/  
 2 MILES EQ 3GM BASE/VIAL /SEP/88:/1988/  
 N62388 002  
 SEP 08, 1982  
 /EQ/3GM/BASE/VIAL/ /N62417/001/  
 2 EQ 3GM BASE/VIAL /OCT/12:/1982/  
 N62417 002  
 OCT 12, 1982

BACLOFEN

INJECTABLE; INJECTION  
 LIORESAL  
 MEDTRONIC 0.5MG/ML N20075 001  
 2MG/ML JUN 17, 1992  
 N20075 002  
 JUN 17, 1992

TABLET; ORAL

BACLOFEN  
 AB BIOCRRAFT 10MG N73043 001  
 AB 20MG N73044 001  
 FEB 27, 1992  
 /2/EON/LABS/ /10MG/ /N71901/001/  
 /APR/13:/1988/  
 /2/ /20MG/ /N71902/001/  
 /APR/13:/1988/

BACLOFEN

TABLET; ORAL

BACLOFEN

/B\*/ /PHARM/BASICS/

/10MG/

/N71260/001/

/MAY/06/1988/

/B\*/

/20MG/

/N71261/001/

/MAY/06/1988/

Q PHARM BASICS

10MG

N71260 001

Q

20MG

MAY 06, 1988

N71261 001

MAY 06, 1988

BENZAEPRII HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

LOTENSIN HCT

+ CIBA

20MG;25MGX

N20033 003

MAY 19, 1992

5MG;6.25MGX

N20033 001

MAY 19, 1992

10MG;12.5MGX

N20033 002

MAY 19, 1992

20MG;12.5MGX

N20033 004

MAY 19, 1992

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA MUTUAL PHARM

1MGX

N81264 001

JAN 23, 1992

AA

2MGX

N81265 001

JAN 23, 1992

/B\*/ /PHARM/BASICS/

/0.5MG/

/N89211/001/

/JUN/14/1988/

/B\*/

/1MG/

/N89212/001/

/JUN/14/1988/

/B\*/

/2MG/

/N89213/001/

/JUN/14/1988/

Q PHARM BASICS

0.5MG

N89211 001

JUN 14, 1988

Q

1MG

N89212 001

JUN 14, 1988

Q

2MG

N89213 001

JUN 14, 1988

BETAMETHASONE BENZOATE

&gt; DLT &gt;

/OINTMENT; TOPICAL/

&gt; DLT &gt;

/UTICORT/

&gt; DLT &gt;

/S//PARKE/DAVIS/

/0.025%/

/N18089/001/

&gt; ADD &gt;

Q PARKE DAVIS

0.025%

N18089 001

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

&gt; DLT &gt;

/B\*/ /CLAY/PARK/

/EQ/0.05%/BASE/

/N72536/001/

&gt; DLT &gt;

Q CLAY PARK

EQ 0.05% BASE

/JAN/31/1990/

&gt; ADD &gt;

AB TARO

EQ 0.05% BASEM

N72536 001

AB TARO

EQ 0.05% BASEM

JAN 31, 1990

N73552 001

APR 30, 1992

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

&gt; DLT &gt;

/B\*/ /CLAY/PARK/

/EQ/0.05%/BASE/

/N72526/001/

&gt; DLT &gt;

Q CLAY PARK

EQ 0.05% BASE

/JAN/31/1990/

&gt; ADD &gt;

Q CLAY PARK

EQ 0.05% BASE

N72526 001

&gt; ADD &gt;

JAN 31, 1990

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE

/AB/

/PHARMAFAIR/

/EQ/0.1% BASE/

/N70485/001/

Q PHARMAFAIR

EQ 0.1% BASE

/MAY/29/1987/

N70485 001

MAY 29, 1987

OINTMENT; TOPICAL

BETAMETHASONE VALERATE

/AB/

/CLAY/PARK/

/EQ/0.1% BASE/

/N71478/001/

B\* CLAY PARK

EQ 0.1% BASE

/DEC/23/1987/

N71478 001

DEC 23, 1987

/AB/

/PHARMAFAIR/

/EQ/0.1% BASE/

/N70486/001/

Q PHARMAFAIR

EQ 0.1% BASE

/MAY/29/1987/

N70486 001

MAY 29, 1987

BETAXOLOL HYDROCHLORIDE; CHLORTHALIDONE

TABLET; ORAL  
KERLEDEX  
+ LOREX

10MG;12.5MG  
5MG;12.5MG

N19807 002  
OCT 30, 1992  
N19807 001  
OCT 30, 1992

BETHANECHOL CHLORIDE

TABLET; ORAL  
BETHANECHOL CHLORIDE  
EON LABS

5MG  
10MG  
10MG  
25MG  
25MG

&gt; ADD &gt;

/2/ VITARINE/

&gt; DLT &gt;

/2/ 5MG/  
/2/ 10MG/  
/2/ 10MG/  
/2/ 25MG/  
/2/ 25MG/

N84353 001  
N84378 001  
N84379 001  
N84383 001  
N84384 001  
N84353/001/  
N84378/001/  
N84379/001/  
N84383/001/  
N84384/001/

> DLT > /AP/  
> ADD >  
> DLT >  
> DLT > /AP/  
> ADD >

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

/AP/ /LYPHOMED/

/50MG/ML/

2 LYPHOMED

50MG/ML

/N70134/001/  
/FEB/12/1986/  
N70134 001  
FEB 12, 1986

BROMPHENIRAMINE MALEATE

INJECTABLE; INJECTION

BROMPHENIRAMINE MALEATE

&gt; DLT &gt; /AP/

/STERIS/

/10MG/ML/

&gt; ADD &gt;

STERIS

10MG/ML

&gt; DLT &gt;

/DINETANE-TEN/

&gt; DLT &gt; /AP/

/ROBINS/

/10MG/ML/

&gt; ADD &gt;

2 WYETH AYERST

10MG/ML

/N83821/001/  
N83821 001  
/N11418/002/  
N11418 002

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/

/PIONEER/PHARMS/

/4MG/

2 PIONEER PHARMS

4MG

/N88604/001/  
/JUL/13/1984/  
N88604 001  
JUL 13, 1984

BISOPROLOL FUMARATE

TABLET; ORAL  
ZEBETA  
+ LEDERLE

10MG  
5MG

N19982 001  
JUL 31, 1992  
N19982 002  
JUL 31, 1992

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPIVACAINE HCL KIT

ABBOTT

0.075%  
0.114%  
0.23%

N19978 001  
SEP 03, 1992  
N19978 002  
SEP 03, 1992  
N19978 003  
SEP 03, 1992

BITOLTEROL MESYLATE

SOLUTION; INHALATION  
TORNALATE

/STERLING/

/0.22%/

STERLING WINTHROP

0.2%

/N19548/001/  
/FEB/19/1992/  
N19548 001  
FEB 19, 1992

BUTABARBITAL SODIUM

> DLT >  
> DLT >  
> DLT >  
> DLT >  
> DLT >  
> DLT >  
> ADD >  
> ADD >  
> ADD >  
> ADD >

/CAPSULE; ORAL/

/BUTICAPS/

/WALLACE/

/15MG/  
/30MG/  
/50MG/  
/100MG/

2 WALLACE

15MG

2

30MG

2

50MG

2

100MG

/N85381/001/  
/N85381/002/  
/N85381/003/  
/N85381/004/  
N85381 001  
N85381 002  
N85381 003  
N85381 004

BUTABARBITAL SODIUM

## TABLET; ORAL

## BUTABARBITAL SODIUM

2 EON LABS

15MG

N85938 001

&gt; ADD &gt;

2

30MG

N85934 001

&gt; ADD &gt;

1/2 VITARINE/

1/15MG/

/N85938/001/

&gt; ADD &gt;

1/2

1/30MG/

/N85934/001/

&gt; ADD &gt;

SODIUM BUTABARBITAL

/AA/

WEST WARD

1/15MG/

/N85418/001/

&gt; ADD &gt;

/AA/

WEST WARD

1/30MG/

/N85432/001/

&gt; ADD &gt;

2 WEST WARD

15MG

N85418 001

&gt; ADD &gt;

2

30MG

N85432 001

&gt; ADD &gt;

BUTORPHANOL TARTRATE

## SPRAY, METERED; NASAL

## STADOL

+ BRISTOL MYERS SQUIBB 1MG/INH

N19890 001

&gt; ADD &gt;

DEC 12, 1991

&gt; ADD &gt;

1/1MG/1INH/

/N19890/001/

&gt; ADD &gt;

/DEC/12./1991/

&gt; ADD &gt;

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

## SOLUTION; INTRAPERITONEAL

Delflex W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS

18.4MG/100ML;1.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20171 001

&gt; ADD &gt;

AUG 19, 1992

&gt; ADD &gt;

Delflex W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS

18.4MG/100ML;2.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20171 002

&gt; ADD &gt;

AUG 19, 1992

&gt; ADD &gt;

Delflex W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS

18.4MG/100ML;4.25GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20171 003

&gt; ADD &gt;

AUG 19, 1992

&gt; ADD &gt;

&gt; ADD &gt;

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

BAXTER

18.3MG/100ML;1.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20183 001

&gt; ADD &gt;

DEC 04, 1992

&gt; ADD &gt;

&gt; ADD &gt;

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

## SOLUTION; INTRAPERITONEAL

DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

BAXTER

18.3MG/100ML;2.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20183 002

DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

BAXTER

18.3MG/100ML;3.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20183 003

DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

BAXTER

18.3MG/100ML;4.25GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20183 004

DEC 04, 1992

DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

BAXTER

25.7MG/100ML;1.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20163 001

DEC 04, 1992

DIANEAL PD-2 W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

BAXTER

25.7MG/100ML;2.5GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20163 002

DEC 04, 1992

DIANEAL PD-2 W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

BAXTER

25.7MG/100ML;4.25GM/100ML;

5.08MG/100ML;538MG/100ML;

448MG/100MLM

N20163 003

DEC 04, 1992

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER

AP

MCGAM

33MG/100ML;5GM/100ML;30MG/100ML;

860MG/100MLM

N20000 001

APR 17, 1992

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

RINGER'S IN PLASTIC CONTAINER

AP

MCGAM

33MG/100ML;30MG/100ML;

860MG/100MLM

N20002 001

APR 17, 1992

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE  
 /AB/ /PARKE/DAVIS/ /200MG/  
 /B\*/ /PHARM/BASICS/ /200MG/  
 2 PHARM BASICS 200MG  
 2 WARNER CHILCOTT 200MG

TABLET, CHEWABLE; ORAL

EPITOL  
 AB LEMMON 100MG

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA  
 AB LEMMON 10MG;100MG  
 AB 25MG;100MG  
 AB 25MG;250MG  
SINEMET  
 AB MSD 10MG;100MG  
 AB 25MG;100MG  
 AB + 25MG;250MG

/N70429/001/  
 /JAN/02./1987/  
 /N70300/001/  
 /MAY/15./1986/  
 N70300 001  
 MAY 15, 1986  
 N70429 001  
 JAN 02, 1987

N73524 001  
 JUL 29, 1992

N73618 001  
 AUG 28, 1992  
 N73589 001  
 AUG 28, 1992  
 N73607 001  
 AUG 28, 1992

N17555 001  
 N17555 003  
 N17555 002

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL  
 2 EON LABS 350MG  
 /B\*/ /VITAFINE/ /350MG/

N89566 001  
 AUG 30, 1988  
 /N89566/001/  
 /AUG/30./1988/

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL  
 AB ZENITH EQ 500MG BASE N62766 001  
 /2/ /EQ/500MG/BASE/ /MAR/03./1987/  
 /N62766/001/

TABLET; ORAL

CEFADROXIL  
 AB ZENITH EQ 1GM BASE N62774 001  
 /2/ /EQ/1GM/BASE/ /APR/08./1987/  
 /N62774/001/

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

ZOLICEF  
 > ADD > AP APOTHECON EQ 500MG BASE/VIAL N62831 001  
 > ADD > EQ 1GM BASE/VIAL N62831 002  
 > ADD > EQ 10GM BASE/VIAL N62831 003  
 > ADD > SEP 25, 1992  
 > DLT > /AB/ /BRISTOL/MYERS/ /EQ/500MG/BASE/VIAL/ /N62831/001/  
 > DLT > /DEC/09./1988/  
 > DLT > /AB/ /EQ/1GM/BASE/VIAL/ /N62831/002/  
 > DLT > /DEC/09./1988/

CEFMETAZOLE SODIUM

INJECTABLE; INJECTION

ZEFAZONE IN PLASTIC CONTAINER  
 > ADD > UPJOHN EQ 20MG BASE/ML N50683 001  
 > ADD > EQ 40MG BASE/ML N50683 002  
 > ADD > DEC 29, 1992

CEFPODOXIME PROXETIL

GRANULE, FOR RECONSTITUTION; ORAL

> DLT > /BANAN/  
 > DLT > /AB/ /SANKYO/ /EQ/50MG/BASE/5ML/ /N50688/002/  
 > DLT > /AUG/07./1992/  
 > DLT > /AB/ /EQ/100MG/BASE/5ML/ /N50688/001/  
 > DLT > /AUG/07./1992/

CEFPODOXIME PROXETIL

## GRANULE, FOR RECONSTITUTION; ORAL

|         |          |                      |                |
|---------|----------|----------------------|----------------|
| > DLT > | /BANAN/  |                      |                |
| > ADD > | 3 SANKYO | EQ 50MG BASE/5MLM    | N50688 002     |
| > ADD > |          |                      | AUG 07, 1992   |
| > ADD > | 3        | EQ 100MG BASE/5MLM   | N50688 001     |
| > ADD > |          |                      | AUG 07, 1992   |
| > DLT > | /VANTIN/ |                      |                |
| > DLT > | /UPJOHN/ | /EQ 50MG BASE/5MLM/  | /N50675/001/   |
| > DLT > | /AB/     |                      | /AUG/07./1992/ |
| > DLT > | /AB/     | /EQ 100MG BASE/5MLM/ | /N50675/002/   |
| > DLT > |          |                      | /AUG/07./1992/ |
| > ADD > | + UPJOHN | EQ 100MG BASE/5MLM   | N50675 002     |
| > ADD > |          |                      | AUG 07, 1992   |
| > ADD > |          | EQ 50MG BASE/5MLM    | N50675 001     |
| > ADD > |          |                      | AUG 07, 1992   |

## TABLET; ORAL

|         |          |                 |                |
|---------|----------|-----------------|----------------|
| > DLT > | /BANAN/  |                 |                |
| > DLT > | /SANKYO/ | /EQ 100MG BASE/ | /N50687/001/   |
| > DLT > | /AB/     |                 | /AUG/07./1992/ |
| > DLT > | /AB/     | /EQ 200MG BASE/ | /N50687/002/   |
| > DLT > |          |                 | /AUG/07./1992/ |
| > ADD > | 3 SANKYO | EQ 100MG BASEM  | N50687 001     |
| > ADD > |          |                 | AUG 07, 1992   |
| > ADD > | 3        | EQ 200MG BASEM  | N50687 002     |
| > ADD > |          |                 | AUG 07, 1992   |
| > DLT > | /VANTIN/ |                 |                |
| > DLT > | /UPJOHN/ | /EQ 100MG BASE/ | /N50674/001/   |
| > DLT > | /AB/     |                 | /AUG/07./1992/ |
| > DLT > | /AB/     | /EQ 200MG BASE/ | /N50674/002/   |
| > DLT > |          |                 | /AUG/07./1992/ |
| > ADD > | + UPJOHN | EQ 200MG BASEM  | N50674 002     |
| > ADD > |          |                 | AUG 07, 1992   |
| > ADD > |          | EQ 100MG BASEM  | N50674 001     |
| > ADD > |          |                 | AUG 07, 1992   |

CEFPROZIL

## PONDER FOR RECONSTITUTION; ORAL

|                                  |                |
|----------------------------------|----------------|
| CEFZIL                           |                |
| + BRISTOL MYERS SQUIBB 250MG/5ML | N50665 002     |
|                                  | DEC 23, 1991   |
| /250MG/5ML/                      | /N50665/002/   |
|                                  | /DEC/23./1991/ |

CEFPROZIL

## TABLET; ORAL

## CEFZIL

+ BRISTOL MYERS SQUIBB 500MG

/500MG/

N50664 002  
DEC 23, 1991  
/N50664/002/  
/DEC/23./1991/

CEFTAZIDIME

## INJECTABLE; INJECTION

## /CEPTAZ/

/GLAXO/

/500MG/VIAL/

/1GM/VIAL/

/2GM/VIAL/

/10GM/VIAL/

/N50646/001/  
/SEP/27./1990/  
/N50646/002/  
/SEP/27./1990/  
/N50646/003/  
/SEP/27./1990/  
/N50646/004/  
/SEP/27./1990/

CEFTAZIDIME (ARGININE FORMULATION)

## INJECTABLE; INJECTION

## /CEPTAZ/

AP GLAXO

1GM/VIAL

N50646 002  
SEP 27, 1990

AP

2GM/VIAL

N50646 003  
SEP 27, 1990

AP

10GM/VIAL

N50646 004  
SEP 27, 1990

500MG/VIAL

N50646 001  
SEP 27, 1990

PENTACEF

AP SMITHKLINE BEECHAM

1GM/VIALM

N64006 001  
MAR 31, 1992

AP

2GM/VIALM

N64006 002  
MAR 31, 1992

AP

10GM/VIALM

N64008 002  
MAR 31, 1992

6GM/VIALM

N64008 001  
MAR 31, 1992



CEFTIZOXIME SODIUMINJECTABLE; INJECTION  
CEFIZOX

|         |                                             |                    |                |
|---------|---------------------------------------------|--------------------|----------------|
| > ADD > | FUJISAWA                                    | EQ 1GM BASE/VIAL   | N50560 002     |
| > ADD > |                                             |                    | SEP 15, 1983   |
| > ADD > |                                             | EQ 2GM BASE/VIAL   | N50560 003     |
| > ADD > |                                             |                    | SEP 15, 1983   |
| > DLT > | /SKF/                                       | /EQ 1GM BASE/VIAL/ | /N50560/002/   |
| > DLT > |                                             |                    | /SEP 15, 1983/ |
| > DLT > |                                             | /EQ 2GM BASE/VIAL/ | /N50560/003/   |
| > DLT > |                                             |                    | /SEP 15, 1983/ |
| > ADD > | CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER |                    |                |
| > ADD > | FUJISAWA                                    | EQ 20MG BASE/ML    | N50589 001     |
| > ADD > |                                             |                    | OCT 03, 1984   |
| > ADD > |                                             | EQ 40MG BASE/ML    | N50589 002     |
| > ADD > |                                             |                    | OCT 03, 1984   |
| > DLT > | /SKF/                                       | /EQ 20MG BASE/ML/  | /N50589/001/   |
| > DLT > |                                             |                    | /OCT 03, 1984/ |
| > DLT > |                                             | /EQ 40MG BASE/ML/  | /N50589/002/   |
| > DLT > |                                             |                    | /OCT 03, 1984/ |

CEFTRIAXONE SODIUMINJECTABLE; INJECTION  
ROCEPHIN

|         |                      |                |
|---------|----------------------|----------------|
| /ROCHE/ | /EQ 250MG BASE/VIAL/ | /N62510/001/   |
|         |                      | /MAR 12, 1985/ |
| 2 ROCHE | EQ 250MG BASE/VIAL   | N62510 001     |
|         |                      | MAR 12, 1985   |
|         | /EQ 500MG BASE/VIAL/ | /N62510/002/   |
|         |                      | /MAR 12, 1985/ |
| 2       | EQ 500MG BASE/VIAL   | N62510 002     |
|         |                      | MAR 12, 1985   |
|         | /EQ 1GM BASE/VIAL/   | /N62510/003/   |
|         |                      | /MAR 12, 1985/ |
| 2       | EQ 1GM BASE/VIAL     | N62510 003     |
|         |                      | MAR 12, 1985   |

CEPHALEXIN

## CAPSULE; ORAL

|         |                      |                 |
|---------|----------------------|-----------------|
| > DLT > | /CEPHALEXIN/HYDRATE/ |                 |
| > DLT > | /2/EON LABS/         | /EQ 250MG BASE/ |
| > DLT > | /2/                  | /EQ 500MG BASE/ |
|         |                      | /N62159/001/    |
|         |                      | /N62159/002/    |

CEPHAPIRIN SODIUM

## INJECTABLE; INJECTION

## CEFADYL

|      |                   |                      |                |
|------|-------------------|----------------------|----------------|
| /AP/ | /BRISTOL/         | /EQ 20GM BASE/VIAL/  | /N50446/004/   |
|      | BRISTOL           | EQ 20GM BASE/VIAL    | N50446 004     |
| /AP/ | CEPHAPIRIN SODIUM | /EQ 500MG BASE/VIAL/ | /N62720/001/   |
|      | ELKINS/SINN/      |                      | /JUL 02, 1987/ |
| /AP/ |                   | /EQ 1GM BASE/VIAL/   | /N62720/002/   |
|      |                   |                      | /JUL 02, 1987/ |
| /AP/ |                   | /EQ 2GM BASE/VIAL/   | /N62720/003/   |
|      |                   |                      | /JUL 02, 1987/ |
| /AP/ |                   | /EQ 20GM BASE/VIAL/  | /N62720/004/   |
|      |                   |                      | /JUL 02, 1987/ |
| 2    | ELKINS SINN       | EQ 500MG BASE/VIAL   | N62720 001     |
|      |                   |                      | JUL 02, 1987   |
| 2    |                   | EQ 1GM BASE/VIAL     | N62720 002     |
|      |                   |                      | JUL 02, 1987   |
| 2    |                   | EQ 2GM BASE/VIAL     | N62720 003     |
|      |                   |                      | JUL 02, 1987   |
| 2    |                   | EQ 20GM BASE/VIAL    | N62720 004     |
|      |                   |                      | JUL 02, 1987   |

CEPHRADINE

|         |                |            |
|---------|----------------|------------|
| > DLT > | /TABLET; ORAL/ |            |
| > DLT > | /VELOSEF/      |            |
| > DLT > | /SQUIBB/       | /1GM/      |
| > ADD > | 2 SQUIBB       | 1GM        |
|         |                | N50530 001 |

CHLORAMPHENICOL SODIUM SUCCINATE

## INJECTABLE; INJECTION

## CHLORAMPHENICOL SODIUM SUCCINATE

|         |      |            |                    |                |
|---------|------|------------|--------------------|----------------|
| > ADD > | AP   | FUJISAWA   | EQ 1GM BASE/VIAL   | N62365 001     |
| > ADD > |      |            |                    | AUG 25, 1982   |
| > DLT > | /AP/ | /LYPHOMED/ | /EQ 1GM BASE/VIAL/ | /N62365/001/   |
| > DLT > |      |            |                    | /AUG 25, 1982/ |

CHLORDIAZEPOXIDE HYDROCHLORIDE

## CAPSULE; ORAL

## CHLORDIAZEPOXIDE HCL

|   |          |      |            |
|---|----------|------|------------|
| 2 | EON LABS | 5MG  | N84919 001 |
| 2 |          | 10MG | N84920 001 |
| 2 |          | 25MG | N84823 001 |

CHLORDIAZEPOXIDE HYDROCHLORIDE

## CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AB/ /PARKE/DAVIS/ /5MG/  
 /AB/ / /10MG/  
 /AB/ / /25MG/  
 @ PARKE DAVIS 5MG  
 @ 10MG  
 @ 25MG  
 > DLT > /AB/ /PIONEER/PHARMS/ /10MG/  
 > DLT >  
 > ADD > @ PIONEER PHARMS 10MG  
 > ADD >  
 /AB/ /VITARINE/ /5MG/  
 /AB/ / /10MG/  
 /AB/ / /25MG/  
 /AB/ /WEST/WARD/ /5MG/  
 /AB/ / /10MG/  
 /AB/ / /25MG/  
 @ WEST WARD 5MG  
 @ 10MG  
 @ 25MG

CHLOROQUINE PHOSPHATE

## TABLET; ORAL

CHLOROQUINE PHOSPHATE

/AA/ /WEST/WARD/ /EQ 150MG BASE/  
 @ WEST WARD EQ 150MG BASE

CHLOROTHIAZIDE

## TABLET; ORAL

CHLOROTHIAZIDE

@ EON LABS 250MG  
 /@/ /VITARINE/ /250MG/

CHLORPHENIRAMINE MALEATE

## TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/AA/ /PIONEER/PHARMS/ /4MG/  
 @ PIONEER PHARMS 4MG

/N85163/001/  
 /N84598/001/  
 /N85164/001/  
 N85163 001  
 N84598 001  
 N85164 001  
 /N89533/001/  
 /JUL/15./1988/  
 N89533 001  
 JUL 15, 1988  
 /N84419/001/  
 /N84420/001/  
 /N84823/001/  
 /N85014/001/  
 /N85000/001/  
 /N85294/001/  
 N85014 001  
 N85000 001  
 N85294 001

/N83082/001/  
 N83082 001

/N88556/001/  
 /JUL/13./1984/  
 N88556 001  
 JUL 13, 1984

CHLORPROPAMIDE

## TABLET; ORAL

CHLORPROPAMIDE

@ EON LABS 250MG  
 /B\*/ /PHARM/BASICS/ /100MG/  
 /B\*/ / /250MG/  
 @ PHARM BASICS 100MG  
 @ 250MG  
 /@/ /VITARINE/ /250MG/

N84669 001  
 /N88788/001/  
 /AUG/30./1984/  
 /N88788/001/  
 /AUG/30./1984/  
 N88708 001  
 AUG 30, 1984  
 N88709 001  
 AUG 30, 1984  
 /N84669/001/

CHLORTHALIDONE

## TABLET; ORAL

CHLORTHALIDONE

AB EON LABS 50MG  
 /AB/ /PIONEER/PHARMS/ /50MG/  
 @ PIONEER PHARMS 50MG  
 /AB/ /VITARINE/ /50MG/  
 /AB/ /WARNER/CHILCOTT/ /25MG/  
 /AB/ / /50MG/  
 @ WARNER CHILCOTT 25MG  
 @ 50MG

N87118 001  
 /N89541/001/  
 /JUL/21./1988/  
 N89591 001  
 JUL 21, 1988  
 /N87118/001/  
 /N87515/001/  
 /JAN/24./1983/  
 /N87516/001/  
 /FEB/09./1983/  
 N87515 001  
 JAN 24, 1983  
 N87516 001  
 FEB 09, 1983

THALITONE

/AB/ /BOEHRINGER/INGELHEIM/ /25MG/  
 / /15MG/  
 BX HORUS 25MG  
 15MG

/N88051/001/  
 /NOV/12./1982/  
 /N19574/001/  
 /DEC/20./1988/  
 N88051 001  
 NOV 12, 1982  
 N19574 001  
 DEC 20, 1988

CHYMOTRYPSIN

## POWDER FOR RECONSTITUTION; OPHTHALMIC

/ALPHA/ CHYNAR/  
 /AT/ /BARNES/HIND/ /150 UNITS/VIAL/  
 @ SOLA BARNES HIND 750 UNITS/VIAL

/N11837/001/  
 N11837 001

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC

|           |                               |                                         |                                 |
|-----------|-------------------------------|-----------------------------------------|---------------------------------|
| <u>AA</u> | <u>ZOLYSE</u><br><u>ALCON</u> | <u>750 UNITS/VIAL</u><br>750 UNITS/VIAL | <u>N11903/001</u><br>N11903 001 |
|-----------|-------------------------------|-----------------------------------------|---------------------------------|

CINOXACIN

CAPSULE; ORAL

|           |                              |              |              |
|-----------|------------------------------|--------------|--------------|
| <u>AB</u> | <u>CINOBAC</u><br>LILLY      | <u>250MG</u> | N18067 001   |
| <u>AB</u> | <u>+</u>                     | <u>500MG</u> | N18067 002   |
| <u>AB</u> | <u>CINOXACIN</u><br>BIOCRAFT | <u>250MG</u> | N73005 001   |
|           |                              |              | FEB 28, 1992 |
| <u>AB</u> |                              | <u>500MG</u> | N73006 001   |
|           |                              |              | FEB 28, 1992 |

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE

SOLUTION; IRRIGATION

RENACIDIN

|                      |                                                           |                                 |
|----------------------|-----------------------------------------------------------|---------------------------------|
| <u>GUARDIAN LABS</u> | <u>6.602GM/100ML; 198MG/100ML</u><br><u>3.177GM/100ML</u> | <u>N19481/001</u><br>N19481 001 |
|                      |                                                           | OCT 02, 1990                    |

CLEMASTINE FUMARATE

SYRUP; ORAL

CLEMASTINE FUMARATE

|           |                                |                          |                                 |
|-----------|--------------------------------|--------------------------|---------------------------------|
| <u>AA</u> | <u>COPLEY</u>                  | <u>EQ 0.5MG BASE/5ML</u> | N73095 001                      |
|           |                                |                          | APR 21, 1992                    |
| <u>AA</u> | <u>TAVIST</u><br><u>DORSEY</u> | <u>EQ 0.5MG BASE/5ML</u> | <u>N18675/001</u><br>N18675 001 |
|           |                                |                          | JUN 28, 1985                    |
| <u>AA</u> | <u>SANDOZ</u>                  | <u>EQ 0.5MG BASE/5ML</u> |                                 |

CLEMASTINE FUMARATE

TABLET; ORAL

CLEMASTINE FUMARATE

|                      |                                  |               |                     |
|----------------------|----------------------------------|---------------|---------------------|
| <u>AB</u>            | <u>LEMMON</u>                    | <u>2.68MG</u> | N73283 001          |
|                      |                                  |               | JAN 31, 1992        |
| <u>&gt; DLT &gt;</u> |                                  | <u>1.34MG</u> | <u>N73282/001</u>   |
| <u>&gt; DLT &gt;</u> |                                  |               | <u>JAN 31, 1992</u> |
| <u>&gt; ADD &gt;</u> | <u>3</u>                         | <u>1.34MG</u> | N73282 001          |
| <u>&gt; ADD &gt;</u> |                                  |               | JAN 31, 1992        |
| <u>AB</u>            | <u>TAVIST</u><br><u>+ SANDOZ</u> | <u>2.68MG</u> | N17661 001          |
| <u>AB</u>            | <u>TAVIST-1</u><br><u>DORSEY</u> | <u>1.34MG</u> | <u>N17661/002</u>   |
|                      | <u>3 SANDOZ</u>                  | <u>1.34MG</u> | N17661 002          |

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDETAVIST; EXTENDED RELEASE; ORAL

|                 |                          |                     |
|-----------------|--------------------------|---------------------|
| <u>TAVIST</u>   | <u>EQ 1MG BASE; 75MG</u> | <u>N18298/001</u>   |
| <u>3 SANDOZ</u> |                          | <u>DEC 15, 1982</u> |
|                 | <u>EQ 1MG BASE; 75MG</u> | N18298 001          |
|                 |                          | DEC 15, 1982        |

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

|                      |                      |                      |                     |
|----------------------|----------------------|----------------------|---------------------|
| <u>&gt; DLT &gt;</u> | <u>GUARDIAN LABS</u> | <u>EQ 75MG BASE</u>  | <u>N62910/001</u>   |
| <u>&gt; DLT &gt;</u> |                      |                      | <u>JUL 05, 1988</u> |
| <u>&gt; DLT &gt;</u> | <u>3</u>             | <u>EQ 150MG BASE</u> | <u>N62910/002</u>   |
| <u>&gt; DLT &gt;</u> |                      |                      | <u>JUL 05, 1988</u> |

CLINDAMYCIN PALMITATE HYDROCHLORIDE

POWDER FOR RECONSTITUTION; ORAL

CLEOCIN

|                      |                 |                         |                     |
|----------------------|-----------------|-------------------------|---------------------|
| <u>&gt; DLT &gt;</u> | <u>UPJOHN</u>   | <u>EQ 75MG BASE/5ML</u> | <u>N61827/001</u>   |
| <u>&gt; DLT &gt;</u> |                 | <u>EQ 75MG BASE/5ML</u> | <u>N62644/001</u>   |
| <u>&gt; DLT &gt;</u> |                 |                         | <u>APR 07, 1986</u> |
| <u>&gt; ADD &gt;</u> | <u>3 UPJOHN</u> | <u>EQ 75MG BASE/5ML</u> | N61827 001          |
| <u>&gt; ADD &gt;</u> |                 | <u>EQ 75MG BASE/5ML</u> | N62644 001          |
| <u>&gt; ADD &gt;</u> |                 |                         | APR 07, 1986        |

CLINDAMYCIN PHOSPHATE

CREAM; VAGINAL  
CLEOCIN  
+ UPJOHN

EQ 2% BASEM

N50680 001  
AUG 11, 1992

INJECTABLE; INJECTION

CLEOCIN PHOSPHATE

> DLT > /AP/ /UPJOHN/ /EQ 150MG BASE/ML/ /N61839/001/  
> ADD > @ UPJOHN EQ 150MG BASE/ML N61839 001

CLINDAMYCIN PHOSPHATE

AP GENSLA EQ 150MG BASE/MLM N63282 001

> DLT > /AP/ /SMITH/NEBHEW/SOLOPAK/ /EQ 150MG BASE/ML/ /N62819/001/  
> DLT > /MAR/15/1988/

> ADD > AP SOLOPAK EQ 150MG BASE/ML N62819 001

> ADD > /SMITH/NEBHEW/SOLOPAK/ /EQ 150MG BASE/ML/ /N62852/001/  
> DLT > /MAR/17/1988/

> DLT > AP SOLOPAK EQ 150MG BASE/ML N62852 001

> ADD > AP SOLOPAK EQ 150MG BASE/ML N62852 001

> ADD > AP SOLOPAK EQ 150MG BASE/ML N62852 001

SOLUTION; TOPICAL

CLINDA-DERM

AT PADDOCK EQ 1% BASEM

N63329 001  
SEP 30, 1992

CLIOQUINOL; HYDROCORTISONE

/CREAM; TOPICAL/  
/VIOFORM-HYDROCORTISONE/  
/CIBA/ /1%:0.5%/  
/3%:1%/  
/N10412/002/  
/N10412/001/

/OINTMENT; TOPICAL/  
/VIOFORM-HYDROCORTISONE/  
/CIBA/ /1%:0.5%/  
/3%:1%/  
/N10412/004/  
/N10412/003/

CLIOQUINOL; NYSTATIN

/OINTMENT; TOPICAL/  
/NYSTAFORM/  
/MILES/ /10MG/GM/  
/100,000 UNITS/GM/  
10MG/GM;  
100,000 UNITS/GM

/N50235/001/  
N50235 001

CLOFIBRATE

CAPSULE; ORAL  
CLOFIBRATE

AB PHARMACAPS 500MG

N73396 001  
MAR 20, 1992

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL  
CLORAZEPATE DIPOTASSIUM

/B\*/ /PHARM/BASICS/ /3.75MG/

/B\*/ /7.5MG/

/B\*/ /15MG/

@ PHARM BASICS 3.75MG

@ 7.5MG

@ 15MG

/N71242/001/  
/MAY/20/1987/  
/N71243/001/  
/MAY/20/1987/  
/N71244/001/  
/MAY/20/1987/  
N71242 001  
MAY 20, 1987  
N71243 001  
MAY 20, 1987  
N71244 001  
MAY 20, 1987

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/ /WARNER/CHILCOTT/ /3.75MG/

/AB/ /7.5MG/

/AB/ /15MG/

@ WARNER CHILCOTT 3.75MG

@ 7.5MG

@ 15MG

/N71828/001/  
/MAR/03/1988/  
/N71829/001/  
/MAR/03/1988/  
/N71830/001/  
/MAR/03/1988/  
N71828 001  
MAR 03, 1988  
N71829 001  
MAR 03, 1988  
N71830 001  
MAR 03, 1988

CLOTRIMAZOLE

CREAM; TOPICAL

LOTREDITH

/AT/ /SCHERING/ /1%/  
BX + SCHERING 1%

MYCELEX

/AT/ /MILES/ /1%/  
BX MILES 1%

/N17619/001/  
N17619 001

/N18183/001/  
N18183 001

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE;  
TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL  
/AA/ /HISTAFED O/  
/AA/ /CENCI/ /10MG/5ML; 30MG/5ML/  
/1.25MG/5ML/ /N89018/001/  
/JUL/23/1986/

TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES W/ CODEINE  
AA CENCI 10MG/5ML; 30MG/5ML;  
1.25MG/5ML N89018 001  
JUL 23, 1986

COLCHICINE; PROBENECID

TABLET; ORAL  
/BP/ /PROBENEC/ /0.5MG; 500MG/  
/BP/ /CHELSEA/ 0.5MG; 500MG /N85552/001/  
3 CHELSEA N85552 001

PROBENECID AND COLCHICINE  
/BP/ /EON LABS/ /0.5MG; 500MG/  
3 EON LABS 0.5MG; 500MG /N86130/001/  
N86130 001

CYANOCOBALAMIN

INJECTABLE; INJECTION  
CYANOCOBALAMIN  
> ADD > AP FUJISAMA 1MG/ML N83075 001  
/BP/ /LUITPOLD/ /0.03MG/ML/ /N80668/001/  
3 LUITPOLD 0.03MG/ML N80668 001  
> DLT > /BP/ /LYPHOMED/ /1MG/ML/ /N83075/001/  
> DLT > /BP/ /SOLLOPAK/ /1MG/ML/ /N87551/001/  
> DLT > /FEB/29/1984/ N87551 001  
> ADD > AP SOLOPAK MEDCL 1MG/ML N87551 001  
> ADD > FEB 29, 1984

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC  
CYCLOPENTOLATE HCL  
/BP/ /BARNES HIND/ /1% /N84863/001/  
3 SOLA BARNES HIND 1% N84863 001

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL  
CYPROHEPTADINE HCL  
/AA/ /PIONEER/PHARMS/ /4MG/ /N87839/001/  
3 PIONEER PHARMS 4MG /FEB/08/1984/  
N87839 001  
FEB 08, 1984

DACARBAZINE

INJECTABLE; INJECTION  
/BP/ /DACARBAZINE/ /100MG/VIAL/ /N70962/001/  
/BP/ /LYPHOMED/ /200MG/VIAL/ /AUG/28/1986/  
/N70990/001/  
/AUG/28/1986/

3 LYPHOMED 100MG/VIAL N70962 001  
AUG 28, 1986  
3 200MG/VIAL N70990 001  
AUG 28, 1986

DTIC-DOME  
/BP/ /MILES/ /100MG/VIAL/ /N17575/001/  
/BP/ /200MG/VIAL/ /N17575/002/  
100MG/VIAL N17575 001  
200MG/VIAL N17575 002

DESFLURANE

LIQUID; INHALATION  
SUPRANE  
+ ANAQUEST 99.9% N20118 001  
SEP 18, 1992

DESIPRAMINE HYDROCHLORIDETABLET; ORAL  
DESIPRAMINE HCL

AB EON LABS 25MG  
AB 50MG  
AB 75MG  
AB 100MG  
> DLT > /2/ /10MG/  
> DLT > /2/ /150MG/  
> DLT > /2/ /25MG/  
> DLT > /2/ /50MG/  
> DLT > /2/ /75MG/  
> DLT > /2/ /100MG/  
a PHARM BASICS 25MG  
a 50MG  
a 75MG  
a 100MG  
/AB/ /VITARINE/ /25MG/  
/AB/ /50MG/  
/AB/ /75MG/  
/AB/ /100MG/

N71601 001  
JUN 05, 1987  
N71588 001  
JUN 05, 1987  
N71602 001  
OCT 05, 1987  
N71766 001  
OCT 05, 1987  
/N7161/001/  
/FEB/03./1988/  
/N72254/001/  
/FEB/03./1988/  
/N71864/001/  
/SEP/09./1987/  
/N71865/001/  
/SEP/09./1987/  
/N71866/001/  
/SEP/09./1987/  
/N71867/001/  
/SEP/09./1987/  
N71864 001  
SEP 09, 1987  
N71865 001  
SEP 09, 1987  
N71866 001  
SEP 09, 1987  
N71867 001  
SEP 09, 1987  
/N71601/001/  
/JUN/05./1987/  
/N71588/001/  
/JUN/05./1987/  
/N71602/001/  
/OCT/05./1987/  
/N71766/001/  
/OCT/05./1987/

DESOGESTREL; ETHINYL ESTRADIOL

&gt; ADD &gt; TABLET; ORAL-28

> ADD > DESOREN

&gt; ADD &gt; AB ORGANON

&gt; ADD &gt;

> ADD > ORTHO-CEPT

&gt; ADD &gt; AB JOHNSON RW

&gt; ADD &gt;

0.15MG;0.03MG

N20071 002  
DEC 10, 1992

0.15MG;0.03MG

N20301 002  
DEC 14, 1992DESONIDE

CREAM; TOPICAL

DESONIDE

AB COPLEY

AB TARO

0.05%

0.05%

N74027 001  
SEP 28, 1992  
N73548 001  
JUN 30, 1992

LOTION; TOPICAL

DESOMEN

OWEN GALDERMA

0.05%

N72354 001  
JAN 24, 1992DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

&gt; ADD &gt; AP

&gt; DLT &gt; AP

FUJISAWA

/LYPHONED/

EQ 4MG PHOSPHATE/ML

/EQ 4MG PHOSPHATE/ML/

N84916 001  
/N84916/001/

SOLUTION/DROPS; OPHTHALMIC

DEXAIR

/BAUSCH AND LOMB/

/EQ 0.1%/PHOSPHATE/

PHARMAFAIR

EQ 0.1% PHOSPHATE

/N88433/001/  
/DEC/15./1983/  
N88433 001  
DEC 15, 1983> ADD > DESOGESTREL; ETHINYL ESTRADIOL

&gt; ADD &gt; TABLET; ORAL-21

> ADD > DESOREN

&gt; ADD &gt; AB + ORGANON

&gt; ADD &gt;

> ADD > ORTHO-CEPT

&gt; ADD &gt; AB JOHNSON RW

&gt; ADD &gt;

0.15MG;0.03MG

N20071 001  
DEC 10, 1992

0.15MG;0.03MG

N20301 001  
DEC 14, 1992DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

&gt; ADD &gt; AP

&gt; ADD &gt;

&gt; ADD &gt; AP

&gt; ADD &gt;

BAXTER

50M/100ML

50MG/ML

N20179 001  
DEC 07, 1992  
N20179 002  
DEC 07, 1992

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 3.3% AND SODIUM  
CHLORIDE 0.3% IN PLASTIC CONTAINER  
MCGAW 3.3GM/100ML; 75MG/100ML;  
300MG/100ML N19630 049  
MAY 07, 1992

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 3.3% AND SODIUM  
CHLORIDE 0.3% IN PLASTIC CONTAINER  
MCGAW 3.3GM/100ML; 110MG/100ML;  
300MG/100ML N19630 050  
MAY 07, 1992

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 3.3% AND SODIUM  
CHLORIDE 0.3% IN PLASTIC CONTAINER  
MCGAW 3.3GM/100ML; 150MG/100ML;  
300MG/100ML N19630 051  
MAY 07, 1992

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 3.3% AND SODIUM  
CHLORIDE 0.3% IN PLASTIC CONTAINER  
MCGAW 3.3GM/100ML; 220MG/100ML;  
300MG/100ML N19630 052  
MAY 07, 1992

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 3.3% AND SODIUM  
CHLORIDE 0.3% IN PLASTIC CONTAINER  
MCGAW 3.3GM/100ML; 300MG/100ML;  
300MG/100ML N19630 053  
MAY 07, 1992

DIAZEPAM

## INJECTABLE; INJECTION

> DLT > / AB / / LEDERLE / / 5MG/ML / / N71308/001 /  
> DLT > / JUL/17/1987 /  
> ADD > @ LEADERLE 5MG/ML N71308 001  
> ADD > JUL 17, 1987  
> DLT > / AB / / PARKE/DAVIS / / 5MG/ML / / N71613/001 /  
> DLT > / OCT/22/1987 /  
> DLT > / AB / / 5MG/ML / / N71614/001 /  
> DLT > / OCT/22/1987 /  
> ADD > @ WARNER CHILCOTT 5MG/ML N71613 001  
> ADD > OCT 22, 1987  
> ADD > @ 5MG/ML N71614 001  
> ADD > OCT 22, 1987

DIAZEPAM

## TABLET; ORAL

/ AB / / PARKE/DAVIS / / 2MG / / N70209/001 /  
/ SEP/04/1985 /  
/ AB / / 5MG / / N70210/001 /  
/ SEP/04/1985 /  
/ AB / / 10MG / / N70222/001 /  
/ SEP/04/1985 /  
/ AB / / PIONEER/PHARMS / / 2MG / / N70787/001 /  
/ AUG/02/1988 /  
/ AB / / 5MG / / N70788/001 /  
/ AUG/02/1988 /  
/ AB / / 10MG / / N70776/001 /  
/ AUG/02/1988 /  
@ PIONEER PHARMS 2MG N70787 001  
AUG 02, 1988  
@ 5MG N70788 001  
AUG 02, 1988  
@ 10MG N70776 001  
AUG 02, 1988  
@ WARNER CHILCOTT 2MG N70209 001  
SEP 04, 1985  
@ 5MG N70210 001  
SEP 04, 1985  
@ 10MG N70222 001  
SEP 04, 1985

DIAZOXIDE

## INJECTABLE; INJECTION

/ AB / / LYPHOMED / / 15MG/ML / / N71519/001 /  
/ AUG/26/1987 /  
@ LYPHOMED 15MG/ML N71519 001  
AUG 26, 1987

DICLOFENAC SODIUM

## TABLET, DELAYED RELEASE; ORAL

VOLTAREN  
+ GEIGY 25MG N19201 001  
JUL 28, 1988  
+ 50MG N19201 002  
JUL 28, 1988  
/ 25MG / / N19201/001 /  
/ JUL/28/1988 /  
/ 50MG / / N19201/002 /  
/ JUL/28/1988 /

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL  
DIETHYLPROPION HCL  
3 EON LABS  
/3/21/1989/

25MG  
/25MG/

N85916 001  
/N85916/001/

DIFLORASONE DIACETATE

CREAM; TOPICAL  
FLORONE  
BX + UPJOHN  
PSORCON  
BX DERMIK

0.05%

N17741 001

0.052M

N20205 001  
NOV 20, 1992

DIFLUNISAL

TABLET; ORAL  
DIFLUNISAL  
AB LEMMON

250MG

N73679 001  
JUL 31, 1992

AB 500MG

N73673 001  
JUL 31, 1992

AB ROXANE 250MG

N73562 001  
NOV 27, 1992

AB 500MG

N73563 001  
NOV 27, 1992

AB DOLOBID  
MSD 250MG

N18445 001  
APR 19, 1982

AB + 500MG

N18445 002  
APR 19, 1982

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
CARDIZEM CD

BC + MARION MERRELL DOW 180MG

N20062 002  
DEC 27, 1991

BC + 240MG

N20062 003  
DEC 27, 1991

+ 120MG

N20062 001  
AUG 10, 1992

+ 300MG

N20062 004  
DEC 27, 1991

/300MG/

/N20062/004/  
/DEC/27/1991/

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
CARDIZEM SR

+ MARION MERRELL DOW 60MG

N19471 001

JAN 23, 1989

+ 90MG

N19471 002

JAN 23, 1989

/60MG/

/N19471/001/

/90MG/

/JAN/23/1989/

/N19471/002/

/JAN/23/1989/

DILACOR XR  
BC RHONE POULENC RORER 180MG

N20092 002

MAY 29, 1992

BC 240MG

N20092 003

MAY 29, 1992

3 120MG

N20092 001

MAY 29, 1992

INJECTABLE; INJECTION  
CARDIZEM

MARION MERRELL DOW 5MG/ML

N20027 001

OCT 24, 1991

/25MG/5ML/

/N20027/001/

/50MG/5ML/

/OCT/24/1991/

/N20027/002/

/OCT/24/1991/

TABLET; ORAL

CARDIZEM

AB MARION MERRELL DOW 30MG

N18602 001

NOV 05, 1982

AB 60MG

N18602 002

NOV 05, 1982

AB 90MG

N18602 003

DEC 08, 1986

AB + 120MG

N18602 004

DEC 08, 1986

DILTIAZEM HCL

AB COPLEY 30MG

N74067 001

NOV 05, 1992

AB 60MG

N74067 002

NOV 05, 1992

AB 90MG

N74067 003

NOV 05, 1992

AB 120MG

N74067 004

NOV 05, 1992



DILTIAZEM HYDROCHLORIDE

## TABLET; ORAL

| <u>DILTIAZEM HCL</u> |         |              |
|----------------------|---------|--------------|
| AB                   | LEDERLE | 30MG         |
| AB                   |         | 60MG         |
| AB                   |         | 90MG         |
| AB                   |         | 120MG        |
| AB                   | MYLAN   | 30MG         |
| AB                   |         | 60MG         |
| AB                   |         | 90MG         |
| AB                   |         | 120MG        |
|                      |         | N74093 001   |
|                      |         | NOV 05, 1992 |
|                      |         | N74093 002   |
|                      |         | NOV 05, 1992 |
|                      |         | N74093 003   |
|                      |         | NOV 05, 1992 |
|                      |         | N74093 004   |
|                      |         | NOV 05, 1992 |
|                      |         | N73185 001   |
|                      |         | NOV 05, 1992 |
|                      |         | N73186 001   |
|                      |         | NOV 05, 1992 |
|                      |         | N72837 001   |
|                      |         | NOV 05, 1992 |
|                      |         | N72838 001   |
|                      |         | NOV 05, 1992 |

DINOPROSTONE

|         |                   |           |              |
|---------|-------------------|-----------|--------------|
| > ADD > | GEL; ENDOCERVICAL |           |              |
| > ADD > | PREPIDIL          |           |              |
| > ADD > | + UPJOHN          | 0.5MG/3GM | N19617 001   |
| > ADD > |                   |           | DEC 09, 1992 |

DIPHENHYDRAMINE HYDROCHLORIDE

## CAPSULE; ORAL

| <u>DIPHENHYDRAMINE HCL</u> |                  |                |
|----------------------------|------------------|----------------|
| AA                         | EON LABS         | 25MG           |
| AA                         |                  | 50MG           |
| /AA/                       | /PIONEER/PHARMS/ | /25MG/         |
| /AA/                       |                  | /50MG/         |
|                            | 3 PIONEER PHARMS | 25MG           |
|                            | 3                | 50MG           |
| /AA/                       | /VITARINE/       | /25MG/         |
| /AA/                       |                  | /50MG/         |
|                            |                  | N80845 002     |
|                            |                  | N80845 001     |
|                            |                  | /N89101/001/   |
|                            |                  | /DEC/20./1985/ |
|                            |                  | /N88880/001/   |
|                            |                  | /DEC/20./1985/ |
|                            |                  | N89101 001     |
|                            |                  | DEC 20, 1985   |
|                            |                  | N88880 001     |
|                            |                  | DEC 20, 1985   |
|                            |                  | /N88845/002/   |
|                            |                  | /N88845/001/   |

DIPYRIDAMOLE

## TABLET; ORAL

| <u>DIPYRIDAMOLE</u> |        |              |
|---------------------|--------|--------------|
| AB                  | GENEVA | 50MG         |
| AB                  |        | 75MG         |
|                     |        | N87562 001   |
|                     |        | FEB 25, 1992 |
|                     |        | N87561 001   |
|                     |        | FEB 25, 1992 |

DISOPYRAMIDE PHOSPHATE

## CAPSULE; ORAL

| DISOPYRAMIDE PHOSPHATE |              |                 |
|------------------------|--------------|-----------------|
| /B*/                   | /CHELSEA/    | /EQ/100MG/BASE/ |
| /B*/                   |              | /EQ/150MG/BASE/ |
| /B*/                   | /INTERPHARM/ | /EQ/100MG/BASE/ |
| /B*/                   |              | /EQ/150MG/BASE/ |
|                        | 3 INTERPHARM | EQ 100MG BASE   |
|                        | 3            | EQ 150MG BASE   |
|                        |              | /N71020/001/    |
|                        |              | /DEC/01./1986/  |
|                        |              | /N71021/001/    |
|                        |              | /DEC/01./1986/  |
|                        |              | /N71190/001/    |
|                        |              | /JAN/15./1987/  |
|                        |              | /N71191/001/    |
|                        |              | /JAN/15./1987/  |
|                        |              | N71190 001      |
|                        |              | JAN 15, 1987    |
|                        |              | N71191 001      |
|                        |              | JAN 15, 1987    |

DOPAMINE HYDROCHLORIDE

## INJECTABLE; INJECTION

| <u>DOPAMINE HCL</u> |                   |                |
|---------------------|-------------------|----------------|
| /AP/                | /LYPHOMED/        | /40MG/ML/      |
| /AP/                |                   | /80MG/ML/      |
| /AP/                |                   | /160MG/ML/     |
|                     | 3 LYPHOMED        | 40MG/ML        |
|                     | 3                 | 80MG/ML        |
|                     | 3                 | 160MG/ML       |
| > DLT >             | /AP/              | /40MG/ML/      |
| > DLT >             | /AP/              | /40MG/ML/      |
| > DLT >             |                   |                |
| > ADD >             | 3 WARNER CHILCOTT | 40MG/ML        |
| > ADD >             | 3                 | 40MG/ML        |
| > ADD >             |                   |                |
|                     |                   | /N70058/001/   |
|                     |                   | /MAR/20./1985/ |
|                     |                   | /N70059/001/   |
|                     |                   | /MAR/20./1985/ |
|                     |                   | /N70364/001/   |
|                     |                   | /DEC/04./1985/ |
|                     |                   | N70058 001     |
|                     |                   | MAR 20, 1985   |
|                     |                   | N70059 001     |
|                     |                   | MAR 20, 1985   |
|                     |                   | N70364 001     |
|                     |                   | DEC 04, 1985   |
|                     |                   | /N18138/001/   |
|                     |                   | /N70558/001/   |
|                     |                   | /SEP/20./1985/ |
|                     |                   | N18138 001     |
|                     |                   | N70558 001     |
|                     |                   | SEP 20, 1985   |

DOXAPRAM HYDROCHLORIDE

## INJECTABLE; INJECTION

|    |                               |         |                            |
|----|-------------------------------|---------|----------------------------|
| AP | <u>DOPRAM</u><br>ROBINS       | 20MG/ML | N14879 001                 |
| AP | <u>DOXAPRAM HCL</u><br>STERIS | 20MG/ML | N73529 001<br>JAN 30, 1992 |

DOXYCYCLINE HYCLATE

## CAPSULE; ORAL

DOXYCYCLINE HYCLATE

|         |                   |                 |                |
|---------|-------------------|-----------------|----------------|
| > DLT > | /3/EON/LABS/      | /EQ 50MG BASE/  | /N62788/001/   |
| > DLT > |                   |                 | /APR/12./1988/ |
| > DLT > | /3/               | /EQ 100MG BASE/ | /N62227/001/   |
| > DLT > | /AB/ /HEATHER/    | /EQ 50MG BASE/  | /N62463/001/   |
| > DLT > |                   |                 | /DEC/07./1983/ |
| > DLT > | /AB/              | /EQ 100MG BASE/ | /N62463/002/   |
| > DLT > |                   |                 | /DEC/07./1983/ |
| > ADD > | 3 HEATHER         | EQ 50MG BASE    | N62463 001     |
| > ADD > |                   |                 | DEC 07, 1983   |
| > ADD > | 3                 | EQ 100MG BASE   | N62463 002     |
| > ADD > |                   |                 | DEC 07, 1983   |
|         | /B*/ /INTERPHARM/ | /EQ 50MG BASE/  | /N62763/001/   |
|         |                   |                 | /SEP/02./1988/ |
|         | /B*/              | /EQ 100MG BASE/ | /N62763/002/   |
|         |                   |                 | /SEP/02./1988/ |
|         | 3 INTERPHARM      | EQ 50MG BASE    | N62763 001     |
|         |                   |                 | SEP 02, 1988   |
|         | 3                 | EQ 100MG BASE   | N62763 002     |
|         |                   |                 | SEP 02, 1988   |
| /AB/    | /PARKE/DAVIS/     | /EQ 50MG BASE/  | /N62594/001/   |
| /AB/    |                   | /EQ 100MG BASE/ | /DEC/05./1985/ |
|         |                   |                 | /N62594/002/   |
|         |                   |                 | /DEC/05./1985/ |
|         | 3 WARNER CHILCOTT | EQ 50MG BASE    | N62594 001     |
|         |                   |                 | DEC 05, 1985   |
|         | 3                 | EQ 100MG BASE   | N62594 002     |
|         |                   |                 | DEC 05, 1985   |

## CAPSULE, COATED PELLETS; ORAL

DOXYCYCLINE HYCLATE

|    |        |               |                            |
|----|--------|---------------|----------------------------|
| AB | SIDMAK | EQ 100MG BASE | N63187 001<br>JUN 30, 1992 |
|----|--------|---------------|----------------------------|

DOXYCYCLINE HYCLATE

## TABLET; ORAL

DOXYCYCLINE HYCLATE

|      |                 |                 |                |
|------|-----------------|-----------------|----------------|
| /B*/ | /INTERPHARM/    | /EQ 100MG BASE/ | /N62764/001/   |
|      |                 |                 | /SEP/02./1988/ |
| 3    | INTERPHARM      | EQ 100MG BASE   | N62764 001     |
|      |                 |                 | SEP 02, 1988   |
| /AB/ | /MEDICOPHARMA/  | /EQ 100MG BASE/ | /N62538/001/   |
| /AB/ | /PARKE/DAVIS/   | /EQ 100MG BASE/ | /APR/07./1986/ |
|      |                 |                 | /N62593/001/   |
|      |                 |                 | /AUG/28./1985/ |
| AB   | VINTAGE         | EQ 100MG BASE   | N62538 001     |
|      |                 |                 | APR 07, 1986   |
| 3    | WARNER CHILCOTT | EQ 100MG BASE   | N62593 001     |
|      |                 |                 | AUG 28, 1985   |

DROPERIDOL

## INJECTABLE; INJECTION

DROPERIDOL

|      |            |            |                |
|------|------------|------------|----------------|
| /AB/ | /LYPHOMED/ | /2.5MG/ML/ | /N70992/001/   |
|      |            |            | /NOV/17./1986/ |
| /AB/ |            | /2.5MG/ML/ | /N70993/001/   |
|      |            |            | /NOV/17./1986/ |
|      | 3 LYPHOMED | 2.5MG/ML   | N70992 001     |
|      |            |            | NOV 17, 1986   |
|      | 3          | 2.5MG/ML   | N70993 001     |
|      |            |            | NOV 17, 1986   |
| /AB/ | /SOLOPAK/  | /2.5MG/ML/ | /N71750/001/   |
|      |            |            | /SEP/06./1988/ |
|      | 3 SOLOPAK  | 2.5MG/ML   | N71750 001     |
|      |            |            | SEP 06, 1988   |

ENOXACIN

## TABLET; ORAL

## PENETREX

+ PARKE DAVIS

400MG

/400MG/

N19616 005  
DEC 31, 1991  
/N19616/005/  
/DEC/31./1991/



ESTRADIOLCREAM; VAGINAL  
ESTRACE

|         |                              |               |
|---------|------------------------------|---------------|
| > ADD > | + BRISTOL MYERS SQUIBB 0.01% | N86069 001    |
| > ADD > |                              | JAN 31, 1984  |
| > DLT > | /:/MEAD/JOHNSON/             | /N86069/001/  |
| > DLT > |                              | /JAN/31/1984/ |

TABLET; ORAL  
ESTRACE

|         |                            |              |
|---------|----------------------------|--------------|
| > ADD > | + BRISTOL MYERS SQUIBB 2MG | N84500 001   |
| > ADD > |                            | N84499 001   |
| > DLT > | /:/MEAD/JOHNSON/           | /N84500/001/ |
| > DLT > |                            | /N84499/001/ |

ESTROPIPATE

## TABLET; ORAL

|      |          |              |
|------|----------|--------------|
| /AB/ | /OGEN/   |              |
| /AB/ | /ABBOTT/ | /N83220/001/ |
| /AB/ | /:/      | /N83220/002/ |
|      |          | /N83220/003/ |
|      |          | /N83220/004/ |

|    |           |        |            |
|----|-----------|--------|------------|
| AB | OGEN .625 | 0.75MG | N83220 001 |
| AB | OGEN 1.25 | 1.5MG  | N83220 002 |
| AB | OGEN 2.5  | 3MG    | N83220 003 |
|    | ABBOTT    | 6MG    | N83220 004 |

ETHINYL ESTRADIOLTABLET; ORAL  
ESTINYL

|      |            |              |
|------|------------|--------------|
| /BP/ | /SCHERING/ | /N05292/002/ |
|      | SCHERING   | N05292 002   |
| /BP/ | /FEMINONE/ | /N16649/001/ |
|      | UPJOHN     | N16649 001   |

ETHINYL ESTRADIOL; NORETHINDRONE

## TABLET; ORAL-21

|    |                   |                |              |
|----|-------------------|----------------|--------------|
| AB | GENCEPT 0.5/35-21 | 0.035MG; 0.5MG | N72692 001   |
|    | GENCON            |                | FEB 28, 1992 |

ETHINYL ESTRADIOL; NORETHINDRONE

## TABLET; ORAL-21

|      |                  |                        |               |
|------|------------------|------------------------|---------------|
| AB   | GENCEPT 1/35-21  | 0.035MG; 1MG           | N72693 001    |
|      | GENCON           |                        | FEB 28, 1992  |
| AB   | GENCEPT 10/11-21 | 0.035MG; 0.5MG AND 1MG | N72694 001    |
|      | GENCON           |                        | FEB 28, 1992  |
| /AB/ | /N.E.E. 1/35-21/ | /0.035MG; 1MG/         | /N71541/001/  |
|      | /METRONED/       |                        | /DEC/14/1987/ |
|      | 3 LPI            | 0.035MG; 1MG           | N71541 001    |
|      |                  |                        | DEC 14, 1987  |

## TABLET; ORAL-28

|      |                   |                        |               |
|------|-------------------|------------------------|---------------|
| AB   | GENCEPT 0.5/35-28 | 0.035MG; 0.5MG         | N72695 001    |
|      | GENCON            |                        | FEB 28, 1992  |
| AB   | GENCEPT 1/35-28   | 0.035MG; 1MG           | N72696 001    |
|      | GENCON            |                        | FEB 28, 1992  |
| AB   | GENCEPT 10/11-28  | 0.035MG; 0.5MG AND 1MG | N72697 001    |
|      | GENCON            |                        | FEB 28, 1992  |
| /AB/ | /N.E.E. 1/35-28/  | /0.035MG; 1MG/         | /N71542/001/  |
|      | /METRONED/        |                        | /DEC/14/1987/ |
|      | 3 LPI             | 0.035MG; 1MG           | N71542 001    |
|      |                   |                        | DEC 14, 1987  |

ETHINYL ESTRADIOL; NORGESTIMATE

## TABLET; ORAL-21

|                  |                         |              |
|------------------|-------------------------|--------------|
| ORTHO TRI-CYCLEN | 0.035MG;                |              |
| + JOHNSON RW     | 0.18MG, 0.215MG, 0.25MG | N19697 002   |
|                  |                         | JUL 03, 1992 |

## TABLET; ORAL-28

|                  |                         |              |
|------------------|-------------------------|--------------|
| ORTHO TRI-CYCLEN | 0.035MG;                |              |
| JOHNSON RW       | 0.18MG, 0.215MG, 0.25MG | N19697 001   |
|                  |                         | JUL 03, 1992 |

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

PLENDIL  
/MERCK/

/5MG/

MERCK

5MG

/10MG/

10MG

/N19834/001/  
/JUL/26./1991/  
N19834 001  
JUL 25, 1991  
/N19834/002/  
/JUL/26./1991/  
N19834 002  
JUL 25, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

/AB/ /HALSEY/

/EQ 200MG BASE/

/AB/

/EQ 300MG BASE/

a HALSEY

EQ 200MG BASE

a

EQ 300MG BASE

/AB/ /WARNER/CHILCOTT/

/EQ 200MG BASE/

/EQ 300MG BASE/

> DLT > /AB/  
> DLT >

a WARNER CHILCOTT

EQ 200MG BASE

> ADD >  
> ADD >

a

EQ 300MG BASE

TABLET; ORAL

FENOPROFEN CALCIUM

/AB/ /HALSEY/

/EQ 600MG BASE/

a HALSEY

EQ 600MG BASE

/N72357/001/  
/JUL/05./1988/  
N72357 001  
JUL 05, 1988

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE

AP STERIS

EQ 0.05MG BASE/ML

N73488 001  
JUN 30, 1992

FINASTERIDETABLET; ORAL  
PROSCAR  
+ MSD

5MG

N20180 001  
JUN 19, 1992

> ADD > FLOSEQUINAN

> ADD > TABLET; ORAL  
> ADD > MANOPLAX  
> ADD > + BOOTS

100MG

50MG

75MG

125MG

N19960 003  
DEC 30, 1992  
N19960 001  
DEC 30, 1992  
N19960 002  
DEC 30, 1992  
N19960 004  
DEC 30, 1992

> ADD >  
> ADD >

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUONID

AI ALLERGAN HERBERT

0.025%

/AI/ /HERBERT/

/0.025%/

N87156 002  
SEP 06, 1984  
/N87156/002/  
/SEP/06./1984/

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

/AB/ /CLAY/PARK/

/0.05%/

B\* CLAY PARK

0.05%

AB NMC

0.05%

/N71790/001/  
/APR/25./1988/  
N71790 001  
APR 25, 1988  
N73085 001  
FEB 14, 1992

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

/AB/ /ABIC/

/50MG/ML/

a ABIC

50MG/ML

/N88929/001/  
/MAR/04./1986/  
N88929 001  
MAR 04, 1986

FLUOROURACIL

## INJECTABLE; INJECTION

|            |           |                     |                    |                    |
|------------|-----------|---------------------|--------------------|--------------------|
| <u>ADD</u> | <u>AP</u> | <u>FLUOROURACIL</u> | <u>50MG/ML</u>     | <u>N89152/001</u>  |
|            |           | <u>LYPHOMED</u>     |                    | <u>MAR/21/1986</u> |
| <u>ADD</u> |           | <u>50MG/ML</u>      | <u>N89428/001</u>  |                    |
|            |           |                     | <u>JAN/12/1987</u> |                    |
| <u>ADD</u> |           | <u>50MG/ML</u>      | <u>N89519/001</u>  |                    |
|            |           |                     | <u>MAR/12/1987</u> |                    |
|            |           | 3 LYPHOMED          | 50MG/ML            | N89152 001         |
|            |           |                     |                    | MAR 21, 1986       |
|            |           | 3                   | 50MG/ML            | N89428 001         |
|            |           |                     |                    | JAN 12, 1987       |
|            |           | 3                   | 50MG/ML            | N89519 001         |
|            |           |                     |                    | MAR 12, 1987       |

FLUPHENAZINE DECANOATE

## INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

|            |           |                 |                |                     |
|------------|-----------|-----------------|----------------|---------------------|
| <u>ADD</u> | <u>AO</u> | <u>FUJISAWA</u> | <u>25MG/ML</u> | <u>N71413 001</u>   |
| <u>ADD</u> |           |                 |                | <u>JUL 14, 1987</u> |
| <u>DLT</u> | <u>AP</u> | <u>LYPHOMED</u> | <u>25MG/ML</u> | <u>N71413/001</u>   |
| <u>DLT</u> |           |                 |                | <u>JUL/14/1987</u>  |

FLUPHENAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

FLUPHENAZINE HCL

|            |           |                 |                 |                     |
|------------|-----------|-----------------|-----------------|---------------------|
| <u>ADD</u> | <u>AP</u> | <u>FUJISAWA</u> | <u>2.5MG/ML</u> | <u>N89556 001</u>   |
| <u>ADD</u> |           |                 |                 | <u>APR 16, 1987</u> |
| <u>DLT</u> | <u>AP</u> | <u>LYPHOMED</u> | <u>2.5MG/ML</u> | <u>N89556/001</u>   |
| <u>DLT</u> |           |                 |                 | <u>APR/16/1987</u>  |

FLURAZEPAM HYDROCHLORIDE

## CAPSULE; ORAL

FLURAZEPAM HCL

|           |                     |             |                    |
|-----------|---------------------|-------------|--------------------|
| <u>AP</u> | <u>PHARM BASICS</u> | <u>15MG</u> | <u>N70562/001</u>  |
|           |                     |             | <u>JUL/09/1987</u> |
| <u>AP</u> |                     | <u>30MG</u> | <u>N70563/001</u>  |
|           |                     |             | <u>JUL/09/1987</u> |
|           | 3 PHARM BASICS      | 15MG        | N70562 001         |
|           |                     |             | JUL 09, 1987       |
|           | 3                   | 30MG        | N70563 001         |
|           |                     |             | JUL 09, 1987       |

FOLIC ACID

## INJECTABLE; INJECTION

FOLIC ACID

|            |           |                 |               |                     |
|------------|-----------|-----------------|---------------|---------------------|
| <u>ADD</u> | <u>AP</u> | <u>FUJISAWA</u> | <u>5MG/ML</u> | <u>N89202 001</u>   |
| <u>ADD</u> |           |                 |               | <u>FEB 18, 1986</u> |
| <u>DLT</u> | <u>AP</u> | <u>LYPHOMED</u> | <u>5MG/ML</u> | <u>N89202/001</u>   |
| <u>DLT</u> |           |                 |               | <u>FEB/18/1986</u>  |

## TABLET; ORAL

FOLIC ACID

|           |                     |            |                   |
|-----------|---------------------|------------|-------------------|
| <u>AP</u> | <u>EON LABS</u>     | <u>1MG</u> | <u>N84472 001</u> |
|           |                     |            | <u>MAR/13/003</u> |
| <u>AP</u> | <u>LILLY</u>        | <u>1MG</u> | <u>N06135 003</u> |
|           |                     |            | <u>MAR/29/001</u> |
| <u>AP</u> | <u>PHOENIX LABS</u> | <u>1MG</u> | <u>N86296 001</u> |
|           |                     |            | <u>MAR/29/001</u> |
| <u>AA</u> | <u>VINTAGE</u>      | <u>1MG</u> | <u>N84472/001</u> |
|           |                     |            | <u>MAR/29/001</u> |

FURAZOLIDONE

## SUSPENSION; ORAL

FUROXONE

|           |                |                  |                   |
|-----------|----------------|------------------|-------------------|
| <u>AP</u> | <u>ROBERTS</u> | <u>50MG/15ML</u> | <u>N11323 002</u> |
|           |                |                  | <u>MAR/23/002</u> |

## TABLET; ORAL

FUROXONE

|           |                |              |                   |
|-----------|----------------|--------------|-------------------|
| <u>AP</u> | <u>ROBERTS</u> | <u>100MG</u> | <u>N11270 002</u> |
|           |                |              | <u>MAR/23/002</u> |

FUROSEMIDE

## INJECTABLE; INJECTION

FUROSEMIDE

|            |            |                 |                |                     |
|------------|------------|-----------------|----------------|---------------------|
| <u>ADD</u> | <u>AP</u>  | <u>FUJISAWA</u> | <u>10MG/ML</u> | <u>N18902 001</u>   |
| <u>ADD</u> |            |                 |                | <u>MAY 22, 1984</u> |
| <u>DLT</u> | <u>AP</u>  | <u>LYPHOMED</u> | <u>10MG/ML</u> | <u>N18507/001</u>   |
| <u>DLT</u> |            |                 |                | <u>JUL/30/1982</u>  |
| <u>DLT</u> | <u>AP</u>  |                 | <u>10MG/ML</u> | <u>N18902/001</u>   |
| <u>DLT</u> |            |                 |                | <u>MAY/22/1984</u>  |
|            | 3 LYPHOMED | 10MG/ML         | N18507 001     |                     |
|            |            |                 |                | JUL 30, 1982        |

FUROSEMIDE

## TABLET; ORAL

FUROSEMIDE

/66/ /CHelsea/

/20MG/

/N18369/001/

/MAY/14./1982/

/66/

/40MG/

/N18369/002/

/MAY/14./1982/

3 CHelsea

20MG

N18369 001

MAY 14, 1982

3

40MG

N18369 002

MAY 14, 1982

3 EON LABS

40MG

N18750 002

JUL 30, 1984

/3/511ARINE/

/40MG/

/N18750/002/

/JUL/30./1984/

GENTAMICIN SULFATE

## INJECTABLE; INJECTION

GENTAMICIN SULFATE

&gt; DLT &gt; /AP/

/LYPHOMED/

/EQ '10MG' BASE/ML/

/N62356/001/

&gt; DLT &gt;

&gt; DLT &gt; /AP/

/EQ '40MG' BASE/ML/

/MAR/04./1982/

&gt; DLT &gt;

&gt; DLT &gt; /AP/

/SMTYB/NEQBEB/SOLOPAK

/EQ '10MG' BASE/ML/

/N62356/002/

&gt; DLT &gt;

&gt; ADD &gt; AP

SOLOPAK

EQ 10MG BASE/ML

/MAR/04./1982/

&gt; ADD &gt;

&gt; DLT &gt; /AP/

/SMTYB/NEQBEB/SOLOPAK

/EQ '40MG' BASE/ML/

/N62507/001/

&gt; DLT &gt;

&gt; ADD &gt; AP

SOLOPAK

EQ 40MG BASE/ML

/JUN/06./1985/

&gt; ADD &gt;

N62507 002

JUN 06, 1985

GADOTERIDOL

## INJECTABLE; INJECTION

## PROHANCE

## SQUIBB

279.3MG/MLM

N20131 001

NOV 16, 1992

GALLIUM CITRATE, GA-67

## INJECTABLE; INJECTION

## GALLIUM CITRATE GA 67

/BS/ /DUPONT/

/2MCI/ML/

/N17478/001/

BS DUPONT MERCK

2MCI/ML

N17478 001

GENTAMICIN SULFATE

## CREAM; TOPICAL

GENTAMICIN

&gt; DLT &gt; /AT/

/THAMES/

/EQ '1MG' BASE/GM/

/N62427/001/

&gt; DLT &gt;

/MAY/26./1983/

GENTAMICIN SULFATE

## THAMES

EQ 1MG BASE/GM

N62427 001

&gt; ADD &gt; AT

MAY 26, 1983

&gt; ADD &gt;

## INJECTABLE; INJECTION

GENTAMICIN SULFATE

## FUJISAWA

EQ 10MG BASE/ML

N62356 001

&gt; ADD &gt; AP

MAR 04, 1982

&gt; ADD &gt;

EQ 40MG BASE/ML

N62356 002

&gt; ADD &gt; AP

MAR 04, 1982

&gt; ADD &gt;

GLYBURIDE

## TABLET; ORAL

## GLUBATE

BX HOECHST ROUSSEL

1.5MGm

N20055 001

BX

3MGm

APR 17, 1992

## GLYNASE

BX UPJOHN

1.5MG

N20055 002

BX +

3MG

APR 17, 1992

N20051 001

MAR 04, 1992

N20051 002

MAR 04, 1992

GLYCOPYRROLATE

## INJECTABLE; INJECTION

GLYCOPYRROLATE

&gt; ADD &gt; AP

FUJISAWA

0.2MG/ML

N88475 001

&gt; ADD &gt;

&gt; DLT &gt; /AP/

/LYPHOMED/

/0.2MG/ML/

/JUN/12./1984/

&gt; DLT &gt;

GONADORELIN ACETATE

## INJECTABLE; INJECTION

## LUTREPULSE PUMP KIT

## FERRING

0.8MG/VIAL

N19687 001

3.2MG/VIAL

OCT 10, 1989

N19687 002

OCT 10, 1989

GONADORELIN ACETATE

INJECTABLE; INJECTION  
LUTREPULSE PUMP KIT  
/JOHNSON/RH/

/0.5MG/VIAL/

/N19687/001/

HALOPERIDOL

TABLET; ORAL  
HALOPERIDOL

/AB/ /ROYCE/

/0.5MG/

/N71722/001/

/3.2MG/VIAL/

/OCT/10./1989/

/AB/

/1MG/

/DEC/24./1987/

/N19687/002/

/AB/

/2MG/

/N71723/001/

/AB/

/5MG/

/DEC/24./1987/

/AB/

/10MG/

/N71724/001/

/AB/

/20MG/

/DEC/24./1987/

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

A.P.L.

/MYETH/AYERST/  
+ MYETH AYERST

/5,000 UNITS/VIAL/

/N17055/001/

a ROYCE

0.5MG

/DEC/24./1987/

/5,000 UNITS/VIAL/

/N17055/001/

a

1MG

/N71725/001/

/10,000 UNITS/VIAL/

/N17055/002/

a

2MG

/DEC/24./1987/

/10,000 UNITS/VIAL/

/N17055/002/

a

5MG

/N71726/001/

/20,000 UNITS/VIAL/

/N17055/003/

a

10MG

/DEC/24./1987/

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

ULTRAGRIS-165

AB SIDMAK

165MG

N62645 001  
JUN 30, 1992

a

20MG

/DEC/24./1987/

ULTRAGRIS-330

AB SIDMAK

330MG

N62646 001  
JUN 30, 1992

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

/AB/ /LYPHOMED/

/EQ 5MG BASE/ML/

/N71187/001/

a LYPHOMED

EQ 5MG BASE/ML

/JAN/20./1987/

HALOFANTRINE HYDROCHLORIDE

TABLET; ORAL

HALFAN

+ SMITHKLINE BEECHAM 250MG

N20250 001  
JUL 24, 1992

&gt; DLT &gt; /AP/

/SMITH/NEEDHAM/SOLOPAK

EQ 5MG BASE/ML

/N70800/001/

&gt; DLT &gt;

&gt; ADD &gt; AP

SOLOPAK MEDCL

EQ 5MG BASE/ML

/DEC/14./1987/

&gt; ADD &gt;

/DEC/14./1987/



HEPARIN SODIUMINJECTABLE; INJECTIONHEPARIN LOCK FLUSH

|             |                                                             |                  |               |
|-------------|-------------------------------------------------------------|------------------|---------------|
| /AP/        | /LUITPOLD/                                                  | /10 UNITS/ML/    | /N89063/001/  |
|             |                                                             |                  | /OCT/09/1985/ |
| /AP/        |                                                             | /100 UNITS/ML/   | /N89064/001/  |
|             |                                                             |                  | /OCT/09/1985/ |
|             | 3 LUITPOLD                                                  | 10 UNITS/ML      | N89063 001    |
|             |                                                             |                  | OCT 09, 1985  |
|             | 3                                                           | 100 UNITS/ML     | N89064 001    |
|             |                                                             |                  | OCT 09, 1985  |
| > DLT >/AP/ | /SMITH/NEBHEM/SOLOPAK                                       | 10 UNITS/ML/     | /N87043/001/  |
| > DLT >     |                                                             |                  | /APR/26/1983/ |
| > DLT >/AP/ |                                                             | /10 UNITS/ML/    | /N88457/001/  |
| > DLT >     |                                                             |                  | /OCT/25/1984/ |
| > DLT >/AP/ |                                                             | /100 UNITS/ML/   | /N87045/001/  |
| > DLT >     |                                                             |                  | /APR/26/1983/ |
| > DLT >/AP/ |                                                             | /100 UNITS/ML/   | /N88459/001/  |
| > DLT >     |                                                             |                  | /JUL/26/1984/ |
| > ADD > AP  | SOLOPAK MEDCL                                               | 10 UNITS/ML      | N87903 001    |
| > ADD >     |                                                             |                  | APR 20, 1983  |
| > ADD > AP  |                                                             | 10 UNITS/ML      | N88457 001    |
| > ADD >     |                                                             |                  | OCT 25, 1984  |
| > ADD > AP  |                                                             | 100 UNITS/ML     | N87905 001    |
| > ADD >     |                                                             |                  | APR 20, 1983  |
| > ADD > AP  |                                                             | 100 UNITS/ML     | N88459 001    |
| > ADD >     |                                                             |                  | JUL 26, 1984  |
| /AP/        | /HEPARIN LOCK FLUSH PRESERVATIVE FREE/                      |                  |               |
| /AP/        | /LYPHOMED/                                                  | /10 UNITS/ML/    | /N17029/011/  |
|             |                                                             |                  | /SEP/22/1987/ |
| /AP/        |                                                             | /100 UNITS/ML/   | /N17029/012/  |
|             |                                                             |                  | /SEP/22/1987/ |
|             | 3 LYPHOMED                                                  | 10 UNITS/ML      | N17029 011    |
|             |                                                             |                  | SEP 22, 1987  |
|             | 3                                                           | 100 UNITS/ML     | N17029 012    |
|             |                                                             |                  | SEP 22, 1987  |
| /AP/        | /HEPARIN LOCK FLUSH PRESERVATIVE FREE IN PLASTIC CONTAINER/ |                  |               |
| /AP/        | /LYPHOMED/                                                  | /10 UNITS/ML/    | /N17029/008/  |
|             |                                                             |                  | /SEP/22/1987/ |
| /AP/        |                                                             | /100 UNITS/ML/   | /N17029/009/  |
|             |                                                             |                  | /SEP/22/1987/ |
|             | 3 LYPHOMED                                                  | 10 UNITS/ML      | N17029 008    |
|             |                                                             |                  | SEP 22, 1987  |
|             | 3                                                           | 100 UNITS/ML     | N17029 009    |
|             |                                                             |                  | SEP 22, 1987  |
| /AP/        | <u>HEPARIN SODIUM</u>                                       |                  |               |
| /AP/        | /LUITPOLD/                                                  | /1,000 UNITS/ML/ | /N87452/001/  |
|             |                                                             |                  | /OCT/31/1983/ |
|             | 3 LUITPOLD                                                  | 1,000 UNITS/ML   | N87452 001    |
|             |                                                             |                  | OCT 31, 1983  |

HEPARIN SODIUMINJECTABLE; INJECTIONHEPARIN SODIUM

|             |                                                                                 |                      |               |
|-------------|---------------------------------------------------------------------------------|----------------------|---------------|
| > DLT >/AP/ | /SMITH/NEBHEM/SOLOPAK                                                           | 1,000 UNITS/ML/      | /N87043/001/  |
| > DLT >/AP/ |                                                                                 | /5,000 UNITS/ML/     | /N87077/001/  |
| > DLT >/AP/ |                                                                                 | /10,000 UNITS/ML/    | /N87107/001/  |
| > DLT >/AP/ |                                                                                 | /5,000 UNITS/0.5ML/  | /N87395/001/  |
| > DLT >/AP/ |                                                                                 | /10,000 UNITS/0.5ML/ | /N87363/001/  |
| > ADD > AP  | SOLOPAK MEDCL                                                                   | 1,000 UNITS/ML       | N87043 001    |
| > ADD > AP  |                                                                                 | 5,000 UNITS/ML       | N87077 001    |
| > ADD > AP  |                                                                                 | 10,000 UNITS/ML      | N87107 001    |
| > ADD > AP  |                                                                                 | 5,000 UNITS/0.5ML    | N87395 001    |
| > ADD > AP  |                                                                                 | 10,000 UNITS/0.5ML   | N87363 001    |
|             | <u>HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%</u>                               |                      |               |
| /2/ABBOTT/  |                                                                                 | /10,000 UNITS/100ML/ | /N18911/006/  |
|             |                                                                                 |                      | /JAN/30/1985/ |
| AP          | ABBOTT                                                                          | 10,000 UNITS/100ML   | N18911 006    |
|             |                                                                                 |                      | JAN 30, 1985  |
|             | <u>HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>   |                      |               |
| AP          | MCGAW                                                                           | 200 UNITS/100MLM     | N19953 001    |
|             |                                                                                 |                      | JUL 20, 1992  |
|             | <u>HEPARIN SODIUM 12500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u> |                      |               |
| AP          | MCGAW                                                                           | 5,000 UNITS/100MLM   | N19802 001    |
|             |                                                                                 |                      | JUL 20, 1992  |
|             | <u>HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>           |                      |               |
| AP          | MCGAW                                                                           | 4,000 UNITS/100MLM   | N19952 001    |
|             |                                                                                 |                      | JUL 20, 1992  |
|             | <u>HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>           |                      |               |
| AP          | MCGAW                                                                           | 5,000 UNITS/100MLM   | N19952 004    |
|             |                                                                                 |                      | JUL 20, 1992  |
| AP          |                                                                                 | 10,000 UNITS/100MLM  | N19952 005    |
|             |                                                                                 |                      | JUL 20, 1992  |
|             | <u>HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u> |                      |               |
| AP          | MCGAW                                                                           | 5,000 UNITS/100MLM   | N19802 005    |
|             |                                                                                 |                      | JUL 20, 1992  |
| AP          |                                                                                 | 10,000 UNITS/100MLM  | N19802 002    |
|             |                                                                                 |                      | JUL 20, 1992  |
|             | <u>HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>  |                      |               |
|             | MCGAW                                                                           | 5,000 UNITS/100MLM   | N19802 003    |
|             |                                                                                 |                      | JUL 20, 1992  |

HISTRELIN ACETATEINJECTABLE; INJECTION  
SUPPRELIN

/JOHNSON/RW/

/EQ/0.2MG/BASE/ML/

/N19836/001/

/EQ/0.5MG/BASE/ML/

/DEC/24./1991/

/EQ/1MG/BASE/ML/

/N19836/002/

ROBERTS

EQ 0.2MG BASE/ML

/DEC/24./1991/

EQ 0.5MG BASE/ML

/N19836/003/

EQ 1MG BASE/ML

/DEC/24./1991/

HYDRALAZINE HYDROCHLORIDE

## INJECTABLE; INJECTION

## APRESOLINE

/AB/ /CIBA/

/20MG/ML/

/N08303/003/

CIBA

20MG/ML

/N08303/003/

/AB/ /HYDRALAZINE HCL/

/20MG/ML/

/N08532/001/

/LYPHOMED/

20MG/ML

/AUG/11./1987/

3 LYPHOMED

20MG/ML

/N08532/001/

/AUG/11./1987/

## TABLET; ORAL

## HYDRALAZINE HCL

/AB/ 3 EON LABS

50MG

/N85088/001/

3 VANGARD

25MG

/N87712/001/

3 VITARINE

50MG

/N85088/001/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

## CAPSULE; ORAL

/AB/ /HYDRAL/

/25MG;25MG/

/N87608/001/

/SOLVAY/

50MG;50MG/

/FEB/08./1982/

/AB/

100MG;50MG/

/N87608/001/

/AB/

100MG;50MG/

/FEB/08./1982/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

## CAPSULE; ORAL

## HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

AB SOLVAY

25MG;25MG

N87608 001

FEB 08, 1982

AB

50MG;50MG

N87213 001

FEB 08, 1982

3

100MG;50MG

N87609 001

FEB 08, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

## TABLET; ORAL

## HYDRAP-ES

3 EON LABS

25MG;15MG;0.1MG

N84876 001

3 VITARINE

25MG;15MG;0.1MG

/N84876/001/

/BP/ /RESERPINE/HYDRALAZINE/HCL/HYDROCHLOROTHIAZIDE/

/BP/ /DANBURY/

25MG;15MG;0.1MG

/N85549/001/

/BP/ /DANBURY/

25MG;15MG;0.1MG

/N87556/001/

RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

BP DANBURY

25MG;15MG;0.1MG

N85549 001

BP

25MG;15MG;0.1MG

N87556 001

HYDRALAZINE HYDROCHLORIDE; RESERPINE

## TABLET; ORAL

## DRALSERP

3 EON LABS

25MG;0.1MG

N84617 001

3 VITARINE

25MG;0.1MG

/N84617/001/

/BP/ /CIBA/

25MG;0.1MG

/N89296/004/

/BP/ /CIBA/

25MG;0.1MG

N09296 004

HYDROCHLOROTHIAZIDE

## SOLUTION; ORAL

## /HYDROCHLOROTHIAZIDE/INTENSOL/

/ROXANE/

/100MG/ML/

/N88588/001/

3 ROXANE

100MG/ML

/JUL/02./1984/

N88588 001

JUL 02, 1984

## TABLET; ORAL

## HYDROCHLOROTHIAZIDE

AB DANBURY

25MG

N81189 001

JAN 24, 1992

AB

100MG

N81190 001

JAN 24, 1992

HYDROCHLOROTHIAZIDE

## TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/ /EON LABS/ /25MG/  
 AB EON LABS 50MG  
 2 25MG  
 /AB/ /HEATHER/ /50MG/  
 2 HEATHER 50MG  
 /AB/ /VITARINE/ /50MG/  
 /AB/ /WARNER/CHILCOTT/ /25MG/  
 /AB/ /50MG/  
 2 WARNER CHILCOTT 25MG  
 2 50MG

/N83899/001/  
 N85219 001  
 N83899 001  
 /N84135/001/  
 N84135 001  
 /N85219/001/  
 /N87586/001/  
 /MAY/03./1982/  
 /N87587/001/  
 /MAY/03./1982/  
 N87586 001  
 MAY 03, 1982  
 N87587 001  
 MAY 03, 1982

HYDROCHLOROTHIAZIDE; RESERPINE

## TABLET; ORAL

HYDRO-SERP 25  
 2 EON LABS 25MG;0.125MG  
 /2/VITARINE/ /25MG;0.125MG/  
 HYDRO-SERP 50  
 2 EON LABS 50MG;0.125MG  
 /2/VITARINE/ /50MG;0.125MG/  
 /SERPASIL-ESIDRIX/#1/  
 /BP/ /CIBA/ /25MG;0.1MG/  
 2 CIBA 25MG;0.1MG  
 /SERPASIL-ESIDRIX/#2/  
 /BP/ /CIBA/ /50MG;0.1MG/  
 2 CIBA 50MG;0.1MG

N84827 001  
 /N84827/001/  
 N85213 001  
 /N85213/001/  
 /N11878/003/  
 N11878 003  
 /N11878/005/  
 N11878 005

HYDROCHLOROTHIAZIDE; TRIAMTERENE

## TABLET; ORAL

MAXZIDE-25  
 AB MYLAN 25MG;37.5MG  
TRIAMTERENE AND HYDROCHLOROTHIAZIDE  
 > DLT > /2/EON LABS/ /50MG;37.5MG/  
 > DLT >  
 AB GENEVA 25MG;37.5MG

N19129 003  
 MAY 13, 1988  
 /N71368/001/  
 /DEC/08./1987/  
 N73281 001  
 APR 30, 1992

HYDROCORTISONE

## CREAM; TOPICAL

HYDROCORTISONE

/AT/ /BAUSCH/AND/LOMB/ /12/  
 AI PHARMAFAIR 1%

/N87838/001/  
 /JUL/28./1982/  
 N87838 001  
 JUL 28, 1982

## LOTION; TOPICAL

CORTISONE

/AT/ /MILES/ /0.52/  
 /AT/ /MILES/ /12/  
 2 MILES 0.5%  
 2 1%

/N89895/003/  
 /N89895/001/  
 N09895 003  
 N09895 001

HYDROCORTISONE

/AT/ /THAMES/ /12/  
 2 THAMES 1%

/N89024/001/  
 /FEB/12./1986/  
 N89024 001  
 FEB 12, 1986

## OINTMENT; TOPICAL

HYDROCORTISONE

AT NMC 1%  
 /AT/ /HYMAC/ /12/  
 /AT/ /NMC/ /12/

N87796 001  
 OCT 13, 1982

/N87796/001/  
 /OCT/13./1982/

## SOLUTION; TOPICAL

## TEXACORT

## GENDERM

2.5%

N81271 001  
 APR 17, 1992

## TABLET; ORAL

HYCORTOLE2/VITARINEHYDROCORTISONE

2 EON LABS

/20MG/

20MG

/N80642/002/

N80642 002

&gt; DLT &gt;

&gt; DLT &gt; /TABLET;/VAGINAL/

&gt; DLT &gt;

&gt; DLT &gt; /CORTIL/

&gt; DLT &gt;

&gt; DLT &gt; /PFIPHARMECS/

&gt; ADD &gt;

2 PFIPHARMECS

/10MG/  
10MG

/N89796/001/  
 N09796 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

## SUSPENSION; OTIC

> DLT > /OTICONE/  
 > DLT > /AT/ /SCHERING/ /12;EQ 3.5MG BASE/ML/ /N61816/001/  
 > DLT > /10,000 UNITS/ML/  
 > ADD > 3 SCHERING 1%;EQ 3.5MG BASE/ML;  
 > ADD > 10,000 UNITS/ML N61816 001

HYDROCORTISONE ACETATE

## CREAM; TOPICAL

HEMSOL-HC  
 AT ABLE 1% N81274 001  
 JUN 19, 1992

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

/CREAM; /TOPICAL/  
 /NEO-CORTEF/  
 /UPJOHN/  
 3 UPJOHN /1%;EQ 3.5MG BASE/GM/ /N61049/001/  
 3 /2.5%;EQ 3.5MG BASE/GM/ /N61049/002/  
 1%;EQ 3.5MG BASE/GM N61049 001  
 2.5%;EQ 3.5MG BASE/GM N61049 002

## SUSPENSION/DROPS; OPHTHALMIC

COR-OTICIN  
 /AT/ /AKORN/ /1.5%;EQ 3.5MG BASE/ML/ /N60188/001/  
 AKORN 1.5%;EQ 3.5MG BASE/ML N60188 001  
 /NEO-CORTEF/  
 /AT/ /UPJOHN/ /0.5%;EQ 3.5MG BASE/ML/ /N60612/002/  
 /AT/ /1.5%;EQ 3.5MG BASE/ML/ /N60612/001/  
 3 UPJOHN 0.5%;EQ 3.5MG BASE/ML N60612 002  
 3 1.5%;EQ 3.5MG BASE/ML N60612 001

HYDROCORTISONE ACETATE; UREA

## CREAM; TOPICAL

/HYDROCORTISONE ACETATE/  
 /AT/ /THAMES/ /1%;10% /N89472/001/  
 /JUN/13/1988/  
 U-CORT  
 AT THAMES 1%;10% N89472 001  
 JUN 13, 1988

HYDROCORTISONE SODIUM SUCCINATE

## INJECTABLE; INJECTION

HYDROCORTISONE SODIUM SUCCINATE

/AP/ /ELKINS/SINN/ /EQ 100MG BASE/VIAL/ /N86619/001/  
 /AP/ /EQ 250MG BASE/VIAL/ /N87567/001/  
 /AP/ /EQ 500MG BASE/VIAL/ /N87568/001/  
 3 ELKINS SINN EQ 100MG BASE/VIAL N86619 001  
 3 EQ 250MG BASE/VIAL N87567 001  
 3 EQ 500MG BASE/VIAL N87568 001

HYDROFLUMETHIAZIDE; RESERPINE

## TABLET; ORAL

/HYDROFLUMETHIAZIDE/AND/RESERPINE/  
 /B\*/ /PHARM/BASICS/ /50MG;0.125MG/ /N88195/001/  
 /OCT/26/1983/  
 3 PHARM BASICS 50MG;0.125MG N88195 001  
 OCT 26, 1983

HYDROMORPHONE HYDROCHLORIDE

## SOLUTION; ORAL

> ADD > DILAUDID  
 > ADD > KNOLL 5MG/5ML N19891 001  
 > ADD > DEC 07, 1992

## TABLET; ORAL

> ADD > DILAUDID  
 > ADD > + KNOLL 8MG N19892 001  
 > ADD > DEC 07, 1992

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

## SOLUTION/DROPS; OPHTHALMIC

PAREMYD  
 ALLERGAN 1%;0.25% N19261 001  
 JAN 30, 1992

HYDROXYCHLOROQUINE SULFATE

## TABLET; ORAL

PLAQUENIL  
 + STERLING 200MG N09768 001  
 /EQ/15MG/BASE/ /N09768/001/

HYDROXYZINE HYDROCHLORIDEINJECTABLE; INJECTIONHYDROXYZINE HCL

|            |                       |         |              |
|------------|-----------------------|---------|--------------|
| > ADD > AP | FUJISAWA              | 25MG/ML | N87329 001   |
| > ADD > AP |                       | 50MG/ML | N87329 002   |
| > DLT > AP | /LYPHONED/            | 25MG/ML | /N87329/001/ |
| > DLT > AP |                       | 50MG/ML | /N87329/002/ |
| > DLT > AP | /SANTH/NEOHEN/SOLOPAK | 25MG/ML | /N86822/001/ |
| > DLT > AP |                       | 50MG/ML | /N87310/001/ |
| > DLT > AP |                       | 50MG/ML | /N87596/001/ |
| > ADD > AP | SOLOPAK MEDCL         | 25MG/ML | N86822 001   |
| > ADD > AP |                       | 50MG/ML | N87310 001   |
| > ADD > AP |                       | 50MG/ML | N87596 001   |

TABLET; ORALHYDROXYZINE HCL

|      |                |        |               |
|------|----------------|--------|---------------|
| /AB/ | /EON LABS/     | /10MG/ | /N87246/002/  |
| /AB/ |                | /25MG/ | /N85247/001/  |
| /AB/ |                | /50MG/ | /N87245/001/  |
|      | 2 EON LABS     | 10MG   | N87246 002    |
|      | 2              | 25MG   | N85247 001    |
|      | 2              | 50MG   | N87245 001    |
| /B*/ | /PHARM/BASICS/ | /10MG/ | /N89121/001/  |
| /B*/ |                | /25MG/ | /MAR/20/1986/ |
| /B*/ |                | /50MG/ | /N89122/001/  |
|      |                |        | /MAR/20/1986/ |
|      |                |        | /N89123/001/  |
|      |                |        | /MAR/20/1986/ |
|      | 2 PHARM BASICS | 10MG   | N89121 001    |
|      | 2              | 25MG   | MAR 20, 1986  |
|      | 2              | 50MG   | N89122 001    |
|      |                |        | MAR 20, 1986  |
|      |                |        | N89123 001    |
|      |                |        | MAR 20, 1986  |

HYDROXYZINE PAMOATECAPSULE; ORALHY-PAM

|      |            |               |              |
|------|------------|---------------|--------------|
| AB   | EON LABS   | EQ 25MG HCL   | N87479 001   |
| /AB/ | /VITARINE/ | /EQ 25MG HCL/ | /N87479/001/ |
| AB   | EON LABS   | EQ 50MG HCL   | N86183 001   |
| /AB/ | /VITARINE/ | /EQ 50MG HCL/ | /N86183/001/ |

IBUPROFENTABLET; ORALIBUPROFEN

|      |                |         |               |
|------|----------------|---------|---------------|
| /AB/ | /BOOTS/        | /600MG/ | /N70556/001/  |
|      |                |         | /JUN/14/1985/ |
|      | 2 BOOTS        | 600MG   | N70556 001    |
| AB   | LEMMON         | 400MG   | JUN 14, 1985  |
| AB   |                | 600MG   | N73343 001    |
|      |                |         | JUN 30, 1992  |
|      |                |         | N73344 001    |
|      |                |         | JUN 30, 1992  |
|      |                |         | N73345 001    |
|      |                |         | JUN 30, 1992  |
| /AB/ | /MEDICOPHARMA/ | /400MG/ | /N71644/001/  |
| /AB/ | /SUPERPHARM/   | /600MG/ | /FEB/01/1986/ |
|      |                |         | /N70709/001/  |
|      |                |         | APR 25, 1986  |
|      |                |         | N71644 001    |
|      |                |         | FEB 01, 1988  |
|      | 2 SUPERPHARM   | 600MG   |               |
| AB   | VINTAGE        | 400MG   |               |

IMIPRAMINE HYDROCHLORIDETABLET; ORALIMIPRAMINE HCL

|      |            |        |              |
|------|------------|--------|--------------|
| AB   | EON LABS   | 10MG   | N85200 001   |
| AB   |            | 25MG   | N84869 002   |
| AB   |            | 50MG   | N85133 001   |
| /AB/ | /VITARINE/ | /25MG/ | /N84869/001/ |
| /AB/ |            | /50MG/ | /N85133/001/ |
|      | /2/        | /10MG/ | /N85200/001/ |

INDOMETHACINCAPSULE; ORALINDOMETHACIN

|         |                  |        |               |
|---------|------------------|--------|---------------|
| > DLT > | /2/EON LABS/     | /25MG/ | /N71711/001/  |
| > DLT > |                  |        | /JUL/05/1986/ |
| > DLT > | /2/              | /50MG/ | /N71712/001/  |
| > DLT > |                  |        | /JUL/05/1986/ |
| /AB/    | /PIONEER/PHARMS/ | /25MG/ | /N70813/001/  |
| /AB/    |                  | /50MG/ | /AUG/11/1986/ |
|         |                  |        | /N70592/001/  |
|         |                  |        | /AUG/11/1986/ |
|         | 2 PIONEER PHARMS | 25MG   | N70813 001    |
|         | 2                | 50MG   | AUG 11, 1986  |
|         |                  |        | N70592 001    |
|         |                  |        | AUG 11, 1986  |

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL  
INDOMETHACIN  
 /2/EON/LABS/ /75MG/ /N1531/001/  
 > DLT > /JUL/21/1987/  
 > DLT >

SUPPOSITORY; RECTAL  
INDOCIN  
 AB + MERCK 50MG N17814 001  
 AUG 13, 1984  
INDOMETHEGAN  
 AB G AND H 50MG N73314 001  
 AUG 31, 1992

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION  
 SPECTAMINE  
 IMP 1 MCI/ML N19432 001  
 DEC 24, 1987  
 /MED/PHYSICS/ /1/MCI/ML/ /N19432/001/  
 /DEC/24/1987/

IOPAMIDOL

INJECTABLE; INJECTION  
 ISOVUE-250  
 SQUIBB 512M N18735 007  
 JUL 06, 1992

IOPHENDYLATE

/INJECTABLE; INJECTION/  
 /PANTOPAC/ /100%/ /N05319/001/  
 /LAFAYETTE/ 100% N05319 001  
 2 ALCON

IOVERSOL

INJECTABLE; INJECTION  
 OPTIRAY 300  
 MALLINCKRODT 642M N19710 004  
 JAN 22, 1992  
 OPTIRAY 350  
 MALLINCKRODT 742M N19710 005  
 JAN 22, 1992

IRON DEXTRAN

## INJECTABLE; INJECTION

/AB/ /INFERON/  
 /FISONS/ /EQ 50MG IRON/ML/ /N10787/002/  
 2 FISONS EQ 50MG IRON/ML N10787 002

IRON DEXTRAN

/BP/ /STERIS/ /EQ 50MG IRON/ML/ /N17441/001/  
 STERIS EQ 50MG IRON/ML N17441 001  
 /BP/ /PROFERDEX/ /EQ 50MG IRON/ML/ /N17807/001/  
 LOTUS EQ 50MG IRON/ML N17807 001

ISOETHARINE HYDROCHLORIDE

## SOLUTION; INHALATION

ISOETHARINE HCL

/AN/ /ARMOUR/ /0.125%/ /N87938/001/  
 /AN/ /0.167%/ /NOV/15/1982/  
 /AN/ /0.2%/ /N88470/001/  
 /AN/ /0.25%/ /MAR/14/1984/  
 /0.062%/ /N88471/001/  
 /NOV/15/1982/ /N88472/001/  
 /N87937/001/ /MAR/14/1984/  
 /NOV/15/1982/ /N87938 001  
 AN ASTRA 0.125% NOV 15, 1982  
 2 0.062% N87937 001  
 2 0.167% NOV 15, 1982  
 2 0.2% N88470 001  
 2 0.25% N88471 001  
 2 0.25% N88472 001  
 /AN/ /DEF/ /0.062%/ /N88187/001/  
 /AN/ /0.12%/ /DEC/03/1982/  
 /AN/ /0.17%/ /N87389/001/  
 /AN/ /0.25%/ /N87390/001/  
 /12/ /N88188/001/  
 2 DEY 0.08% /DEC/03/1982/ /N86763/001/  
 2 0.1% N88187 001  
 2 0.17% DEC 03, 1982  
 2 0.25% N87389 001  
 2 1% N87390 001  
 N88188 001  
 DEC 03, 1982  
 N86763 001

ISOETHARINE HYDROCHLORIDESOLUTION; INHALATION  
ISOETHARINE HCL S/FAN DEY 0.17%  
/0.17%/N89819 001  
NOV 22, 1988  
/N89819/001/  
/NOV/22./1988/ISOPROTERENOL HYDROCHLORIDESOLUTION; INHALATION  
ISOPROTERENOL HCL/AN/ /DEY/ /0.5%/  
0 DEY 0.5%/N86764/001/  
/JAN/04./1982/  
N86764 001  
JAN 04, 1982ISOETHARINE MESYLATEAEROSOL, METERED; INHALATION  
BRONKOMETER> DLT > /BN/ /STERLING/ /0.34MG/INH/  
> ADD > + STERLING 0.34MG/INH  
> DLT > /BN/ /BARRE/ /0.34MG/INH/  
> DLT >  
> ADD > 0 BARRE 0.34MG/INH  
> ADD >/N12339/007/  
N12339 007  
/N87858/001/  
/AUG/21./1984/  
N87858 001  
AUG 21, 1984ISOSORBIDE DINITRATE

TABLET; ORAL

AB ISORDIL 40MG  
MYETH AYERST  
AB SORBITRATE 20MG  
ICI  
AB 30MG  
AB 40MGN12093 001  
JUL 29, 1988  
N86405 002  
AUG 21, 1990  
N88124 001  
AUG 21, 1990  
N88125 001  
AUG 21, 1990ISONIAZID

TABLET; ORAL

> DLT > /AA/ /WALLACE/ /100MG/  
> DLT > /AA/ /300MG/  
> ADD > 0 WALLACE 100MG  
> ADD > 0 300MG  
/AA/ /CIBA/ /100MG/  
0 CIBA 300MG/N80134/003/  
/N80134/004/  
N80134 003  
N80134 004/N80935/001/  
N80935 001ISOSORBIDE MONONITRATE

TABLET; ORAL

ISMO  
+ MYETH 20MG  
/20MG/N19091 001  
DEC 30, 1991  
/N19091/001/  
/DEC/30./1991/ISONIAZIDAA EON LABS 100MG  
AA 300MG  
/AA/ /LILLY/ /100MG/  
/AA/ /300MG/  
0 LILLY 100MG  
0 300MG  
/AA/ /VITARINE/ /100MG/  
/AA/ /300MG/N08678 002  
N08678 003  
/N08499/002/  
/N08499/003/  
N08499 002  
N08499 003  
/N08678/002/  
/N08678/003/ITRACONAZOLE

CAPSULE; ORAL

SPORANOX  
+ JANSSEN 100MGN20083 001  
SEP 11, 1992KANAMYCIN SULFATE

INJECTABLE; INJECTION

AP KANAMYCIN SULFATE  
LOCH EQ 75MG BASE/2ML  
AP EQ 500MG BASE/2ML  
AP EQ 1GM BASE/3MLN63021 001  
JUL 31, 1992  
N63022 001  
JUL 31, 1992  
N63025 001  
JUL 31, 1992

KANAMYCIN SULFATE

## INJECTABLE; INJECTION

KANAMYCIN SULFATE

|              |                       |                     |                |
|--------------|-----------------------|---------------------|----------------|
| /AP/         | /LYPHOMED/            | /EQ 75MG BASE/2ML/  | /N62504/001/   |
|              |                       |                     | /APR/05./1984/ |
| /AP/         |                       | /EQ 500MG BASE/2ML/ | /N62504/002/   |
|              |                       |                     | /APR/05./1984/ |
| /AP/         |                       | /EQ 1GM BASE/3ML/   | /N62504/003/   |
|              |                       |                     | /APR/05./1984/ |
|              | Q LYPHOMED            | EQ 75MG BASE/2ML    | N62504 001     |
|              | Q                     | EQ 500MG BASE/2ML   | APR 05, 1984   |
|              | Q                     | EQ 1GM BASE/3ML     | N62504 002     |
|              |                       |                     | APR 05, 1984   |
|              |                       |                     | N62504 003     |
|              |                       |                     | APR 05, 1984   |
| > DLT > /AP/ | /SMITH/NEBBEN/SOLOPAK | /EQ 75MG BASE/2ML/  | /N62605/001/   |
| > DLT >      |                       |                     | /FEB/26./1986/ |
| > ADD > AP   | SOLOPAK               | EQ 75MG BASE/2ML    | N62605 003     |
| > ADD >      |                       |                     | FEB 26, 1986   |
| > DLT > /AP/ | /SMITH/NEBBEN/SOLOPAK | /EQ 500MG BASE/2ML/ | /N62605/001/   |
| > DLT >      |                       |                     | /FEB/26./1986/ |
| > ADD > AP   | SOLOPAK               | EQ 500MG BASE/2ML   | N62605 001     |
| > ADD >      |                       |                     | FEB 26, 1986   |
| > DLT > /AP/ | /SMITH/NEBBEN/SOLOPAK | /EQ 1GM BASE/3ML/   | /N62605/002/   |
| > DLT >      |                       |                     | /FEB/26./1986/ |
| > ADD > AP   | SOLOPAK               | EQ 1GM BASE/3ML     | N62605 002     |
| > ADD >      |                       |                     | FEB 26, 1986   |

KETOPROFEN

## CAPSULE; ORAL

KETOPROFEN

|         |    |              |      |              |
|---------|----|--------------|------|--------------|
| > ADD > | AB | BIOCRAFT     | 25MG | N73515 001   |
| > ADD > |    |              |      | DEC 22, 1992 |
| > ADD > | AB |              | 50MG | N73516 001   |
| > ADD > |    |              |      | DEC 22, 1992 |
| > ADD > | AB |              | 75MG | N73517 001   |
| > ADD > |    |              |      | DEC 22, 1992 |
| > ADD > | AB | ORUDIS       | 25MG | N18754 001   |
| > ADD > |    | NYETH AYERST |      | JUL 31, 1987 |
| > ADD > | AB |              | 50MG | N18754 002   |
| > ADD > |    |              |      | JAN 09, 1986 |
| > ADD > | AB | +            | 75MG | N18754 003   |
| > ADD > |    |              |      | JAN 09, 1986 |

KETOROLAC TROMETHAMINE

## SOLUTION/DROPS; OPHTHALMIC

## ACULAR

SYNTEX

0.5%~~M~~

N19700 001  
NOV 09, 1992

## TABLET; ORAL

## TORADOL

+ SYNTEX

10MG

N19645 001  
DEC 20, 1991  
/N19645/001/  
/DEC/20./1991/

LACTULOSE

## SYRUP; ORAL

LACTULOSE

|    |        |                        |              |
|----|--------|------------------------|--------------|
| AA | PACO   | 10GM/15ML <del>M</del> | N73160 001   |
|    |        |                        | AUG 25, 1992 |
| AA | ROXANE | 10GM/15ML <del>M</del> | N73591 001   |
|    |        |                        | MAY 29, 1992 |
| AA | UDL    | 10GM/15ML <del>M</del> | N74138 001   |
|    |        |                        | SEP 30, 1992 |

## SYRUP; ORAL, RECTAL

LACTULOSE

|    |        |                        |              |
|----|--------|------------------------|--------------|
| AA | PACO   | 10GM/15ML <del>M</del> | N72029 001   |
|    |        |                        | AUG 25, 1992 |
| AA | ROXANE | 10GM/15ML <del>M</del> | N73590 001   |
|    |        |                        | MAY 29, 1992 |

LEUCOVORIN CALCIUM

## INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

|      |            |                     |                |
|------|------------|---------------------|----------------|
| /AP/ | /ABIC/     | /EQ 3MG BASE/ML/    | /N89352/001/   |
|      |            |                     | /JUN/01./1988/ |
| /AP/ |            | /EQ 50MG BASE/VIAL/ | /N89353/001/   |
|      |            |                     | /JUN/01./1988/ |
|      | Q ABIC     | EQ 3MG BASE/ML      | N89352 001     |
|      | Q          | EQ 50MG BASE/VIAL   | JUN 01, 1988   |
|      |            |                     | N89353 001     |
|      |            |                     | JUN 01, 1988   |
| /AP/ | /LYPHOMED/ | /EQ 50MG BASE/VIAL/ | /N88939/001/   |
|      |            |                     | /DEC/01./1986/ |
|      | Q LYPHOMED | EQ 50MG BASE/VIAL   | N88939 001     |
|      |            |                     | DEC 01, 1986   |



LEVOCARNITINE

> ADD > INJECTABLE; INJECTION  
 > ADD > CARNITOR  
 > ADD > SIGMA TAU  
 > ADD >

200MG/MLM

N20182 001  
 DEC 16, 1992

SOLUTION; ORAL  
 CARNITOR

AA SIGMA TAU

1GM/10ML

N19257 001  
 APR 10, 1986

/66/ /VITACARN/  
 /MCGAW/

/1GM/10ML/

/N19257/001/  
 /APR/10/1986/

LEVODOPA

CAPSULE; ORAL

DOPAR  
 /3/ /P/AND/6/

/500MG/  
 /100MG/  
 /250MG/

/N16913/002/  
 /N16913/003/  
 /N16913/001/

+ ROBERTS

500MG  
 100MG  
 250MG

N16913 002  
 N16913 003  
 N16913 001

> DLT >  
 > ADD >  
 > DLT >  
 > ADD >

LEVORPHANOL TARTRATE

TABLET; ORAL  
 LEVO-DROMORAN  
 + ROCHE

2MG

/2MG/

N08720 001  
 DEC 19, 1991  
 /N08720/001/  
 /DEC/19/1991/

> ADD > LIDOCAINE; PRILOCAINE

> ADD > CREAM; TOPICAL  
 > ADD > EMLA  
 > ADD > + ASTRA  
 > ADD >

2.5%;2.5%

N19941 001  
 DEC 30, 1992

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

/INTL/MEDICATION/

3 INTL MEDICATION

/1GM/VIAL/

1GM/VIAL

/2GM/VIAL/

2GM/VIAL

/N18543/001/

N18543 001

/N18543/002/

N18543 002

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

200MG/100MLM

N19830 002

APR 08, 1992

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

400MG/100MLM

N19830 003

APR 08, 1992

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

800MG/100MLM

N19830 004

APR 08, 1992

LIDOCAINE HYDROCHLORIDE; OXYTETRACYCLINE

INJECTABLE; INJECTION

TERRAMYCIN

/2/ /PFIZER/

/2%;50MG/ML/

/N60567/001/

PFIZER

2%;50MG/ML

N60567 001

/2/

/2%;125MG/ML/

/N60567/002/

2%;125MG/ML

N60567 002

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

/B\*/ /PHARM/BASICS/

/300MG/

/N72542/001/  
 /FEB/01/1989/

3 PHARM BASICS

300MG

N72542 001

FEB 01, 1989

LOMEFLOXACIN HYDROCHLORIDE

TABLET; ORAL

MAXAQUIN

+ SEARLE

EQ 400MG BASEM

N20013 001

FEB 21, 1992

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

LOPERAMIDE HCL

AB GENEVA

2MG

N72993 001

AUG 28, 1992

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL  
LOPERAMIDE HCL  
 AB LEMMON 2MG  
 N73192 001  
 APR 30, 1992

LORACARBEE

CAPSULE; ORAL  
 LORABID  
 + LILLY 200MG  
 N50668 001  
 DEC 31, 1991  
 /N50668/001/  
 /DEC/31/1991/  
 /200MG/

POWDER FOR RECONSTITUTION; ORAL  
 LORABID  
 + LILLY 200MG/5ML  
 N50667 002  
 DEC 31, 1991  
 /N50667/002/  
 /DEC/31/1991/  
 /200MG/5ML/

LORAZEPAM

TABLET; ORAL  
 LORAZEPAM  
 /B\*/ /PHARM/BASICS/ /1MG/  
 /B\*/ /2MG/  
 2 PHARM BASICS 1MG  
 2 2MG  
 N70539 001  
 DEC 22, 1986  
 N70540 001  
 DEC 22, 1986  
 /N70539/001/  
 /DEC/22/1986/  
 /N70540/001/  
 /DEC/22/1986/

MANNITOL

INJECTABLE; INJECTION  
MANNITOL 25%  
 > ADD > AP FUJISAMA 12.5GM/50ML  
 > DLT > /AP/ /LYPHOMED/ /12.5GM/50ML/  
 /AP/ /12.5GM/50ML/  
 2 LYPHOMED 12.5GM/50ML  
 N80677 001  
 N86754 001  
 N86754 001

MASOPROCOL

CREAM; TOPICAL  
 ACTINEX  
 + CHEMEX 10%  
 N19940 001  
 SEP 04, 1992

MECLOFENAMATE SODIUM

CAPSULE; ORAL  
 MECLOFENAMATE SODIUM  
 /B\*/ /PHARM/BASICS/ /EQ/50MG/BASE/ /N71007/001/  
 /B\*/ /EQ/100MG/BASE/ /MAR/25/1988/  
 2 PHARM BASICS EQ 50MG BASE N71008 001  
 2 EQ 100MG BASE MAR 25, 1988  
 N71008 001  
 MAR 25, 1988

MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION  
 DEPO-PROVERA  
 UPJOHN 150MG/ML  
 N20246 001  
 OCT 29, 1992

## TABLET; ORAL

GYCRIN  
 AB MYETH AYERST 2.5MG  
 5MG  
 N81239 001  
 OCT 30, 1992  
 N81240 001  
 OCT 30, 1992  
PROVERA  
 AB UPJOHN 2.5MG  
 AB 5MG  
 N11839 001  
 N11839 003

MEFENAMIC ACID

CAPSULE; ORAL  
 MEFENAMIC ACID  
 /B\*/ /EQ/100MG/ /N71176/001/  
 > DLT > /AP/ /LABS/ /APR/21/1988/  
 > DLT >

MEGESTROL ACETATE

## TABLET; ORAL

MEGESTROL ACETATE  
 /B\*/ /PHARM/BASICS/ /20MG/  
 /B\*/ /40MG/  
 2 PHARM BASICS 20MG  
 2 40MG

/N70646/001/  
 /OCT/02/1987/  
 /N70647/001/  
 /OCT/02/1987/  
 N70646 001  
 OCT 02, 1987  
 N70647 001  
 OCT 02, 1987

MELPHALAN HYDROCHLORIDEINJECTABLE; INJECTION  
ALKERAN

BURROUGHS WELLCOME EQ 50MG BASE/VIALM

N20207 001  
 NOV 18, 1992

MEPERIDINE HYDROCHLORIDEINJECTABLE; INJECTION  
MEPERIDINE HCL

AP ABBOTT 10MG/ML N88432 001  
 AUG 16, 1984  
 /AP/ /PARKE/DAVIS/ /50MG/ML/ /N80364/002/  
 /AP/ /75MG/ML/ /N80364/003/  
 /AP/ /100MG/ML/ /N80364/001/  
 2 PARKE DAVIS 50MG/ML N80364 002  
 2 75MG/ML N80364 003  
 2 100MG/ML N80364 001  
 AP STERIS 10MG/ML N73443 001  
 MAR 17, 1992  
 AP 50MG/ML N73444 001  
 MAR 17, 1992  
 AP 100MG/ML N73445 001  
 MAR 17, 1992

MEPIVACAINE HYDROCHLORIDE

## INJECTABLE; INJECTION

/B\*/ /POLOCATNE/  
 /B\*/ /ASTRA/ /1%/  
 /B\*/ /1.5%/  
 /B\*/ /2%/  
 /DEC/01/1986/  
 /DEC/01/1986/  
 /DEC/01/1986/  
 /DEC/01/1986/

MEPIVACAINE HYDROCHLORIDE

## INJECTABLE; INJECTION

POLOCATNE-MPF

AP ASTRA 1%  
 AP 1.5%  
 AP 2%

N89406 001  
 DEC 01, 1986  
 N89408 001  
 DEC 01, 1986  
 N89409 001  
 DEC 01, 1986

MEPROBAMATE

## TABLET; ORAL

MEPROBAMATE

2 ELKINS SINN 200MG  
 2 400MG  
 AA EON LABS 200MG  
 AA 400MG  
 > DLT > /AA/ /HEATHER/ /400MG/  
 /AA/ /600MG/  
 > ADD > 2 HEATHER 400MG  
 2 600MG  
 /AA/ /ICN/ /400MG/  
 /AA/ /400MG/  
 2 ICN 200MG  
 2 400MG  
 /AA/ /PARKE/DAVIS/ /400MG/  
 /AA/ /400MG/  
 2 PARKE DAVIS 200MG  
 2 400MG  
 /2/ /QUANTUM/PHARMICS/ /400MG/  
 /2/ /400MG/  
 /AA/ /VITARINE/ /400MG/  
 /AA/ /400MG/  
 /AA/ /ZENITH/ /400MG/  
 /AA/ /400MG/  
 2 ZENITH 200MG  
 2 400MG

N15426 002  
 N15426 001  
 N14547 002  
 N14547 001  
 /N16928/003/  
 /N84329/001/  
 N16928 003  
 N84329 001  
 /N15139/006/  
 /N15139/005/  
 N15139 006  
 N15139 005  
 /N84744/001/  
 /N84744/002/  
 N84744 001  
 N84744 002  
 /N15426/002/  
 /N15426/001/  
 /N14547/002/  
 /N14547/001/  
 /N15438/001/  
 /N15438/002/  
 N15438 001  
 N15438 002

MESALAMINE

## TABLET, DELAYED RELEASE; ORAL

ASACOL  
 + P AND G 400MG

N19651 001  
 JAN 31, 1992

METAPROTERENOL SULFATE

## SOLUTION; INHALATION

METAPROTERENOL SULFATE

/AN/ /ARMOUR/ /0.42/

/AN/ /0.62/

AN ASTRA 0.4%

AN 0.6%

/DEY/ /0.33%/

a DEY 0.33%

&gt; DLT &gt; /0.5%/

&gt; DLT &gt;

&gt; ADD &gt; a 0.5%

&gt; ADD &gt;

AN PROMETA

MURO 52%

## SYRUP; ORAL

METAPROTERENOL SULFATE

AA BIOCRRAFT 10MG/5ML

AA SILARX 10MG/5ML

## TABLET; ORAL

METAPROTERENOL SULFATE

/B\*/ /PHARM/BASICS/ /10MG/

/B\*/ /20MG/

a PHARM BASICS 10MG

a 20MG

METHACYCLINE HYDROCHLORIDE

&gt; DLT &gt; /CAPSULE//ORAL/

&gt; DLT &gt; /RONDOMYCIN/

&gt; DLT &gt; /WALLACE/

&gt; DLT &gt;

&gt; ADD &gt; a WALLACE

&gt; ADD &gt; a

/EQ/280MG/BASE/

/EQ/140MG/BASE/

EQ 140MG BASE

EQ 280MG BASE

/N71275/001/

/JUL/27./1988/

/N71018/001/

/JUL/27./1988/

N71275 001

JUL 27, 1988

N71018 001

JUL 27, 1988

/N71806/001/

/AUG/05./1988/

N71806 001

AUG 05, 1988

/N71805/001/

/AUG/05./1988/

N71805 001

AUG 05, 1988

N73340 001

MAR 30, 1992

METHACYCLINE HYDROCHLORIDE

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; ADD &gt;

/SYRUP//ORAL/

/RONDOMYCIN/

/WALLACE/

a WALLACE

/EQ/70MG/BASE/5ML/

EQ 70MG BASE/5ML

/N60641/001/

N60641 003

METHADONE HYDROCHLORIDE

## TABLET, DISPERSIBLE; ORAL

METHADONE

a EON LABS

a

a

a

/VITARINE/

/a/

/a/

/a/

2.5MG

5MG

10MG

40MG

/2.5MG/

/5MG/

/10MG/

/40MG/

N17108 001

N17108 002

N17108 003

N17108 004

/N17108/001/

/N17108/002/

/N17108/003/

/N17108/004/

METHOCARBAMOL

## TABLET; ORAL

METHOCARBAMOL

AA

AA

/AA/

/AA/

EON LABS

/HEATHER/

/HEATHER/

a HEATHER

a

/AA/

/AA/

/VITARINE/

/VITARINE/

500MG

750MG

/500MG/

/750MG/

500MG

750MG

/500MG/

/750MG/

N87283 001

N87282 001

/N84675/001/

/N84924/001/

N84675 001

N84924 001

/N87283/001/

/N87282/001/

METHOTREXATE SODIUM

## INJECTABLE; INJECTION

ABITREXATE

|      |        |                      |                |
|------|--------|----------------------|----------------|
| /AP/ | /ABIC/ | /EQ 25MG BASE/ML/    | /N89161/001/   |
|      |        |                      | /MAR/10./1987/ |
| /AP/ |        | /EQ 50MG BASE/VIAL/  | /N89354/001/   |
|      |        |                      | /JUL/17./1987/ |
| /AP/ |        | /EQ 100MG BASE/VIAL/ | /N89355/001/   |
|      |        |                      | /JUL/17./1987/ |
| /AP/ |        | /EQ 250MG BASE/VIAL/ | /N89356/001/   |
|      |        |                      | /JUL/17./1987/ |

a ABIC

EQ 25MG BASE/ML N89161 001

MAR 10, 1987

a

EQ 50MG BASE/VIAL N89354 001

JUL 17, 1987

a

EQ 100MG BASE/VIAL N89355 001

JUL 17, 1987

a

EQ 250MG BASE/VIAL N89356 001

JUL 17, 1987

METHOTREXATE

|             |           |                      |              |
|-------------|-----------|----------------------|--------------|
| > DLT >/AP/ | /LEDERLE/ | /EQ 20MG BASE/VIAL/  | /N11719/001/ |
| > ADD >     | LEDERLE   | EQ 20MG BASE/VIAL    | N11719 001   |
| > DLT >     | /HEXATE/  | /EQ 20MG BASE/VIAL/  | /N86358/001/ |
| > DLT >/AP/ | /BRISTOL/ | /EQ 50MG BASE/VIAL/  | /N86358/002/ |
| > DLT >/AP/ |           | /EQ 100MG BASE/VIAL/ | /N86358/003/ |
| > DLT >/AP/ |           | /EQ 250MG BASE/VIAL/ | /N86358/004/ |
| > ADD >     | a BRISTOL | EQ 20MG BASE/VIAL    | N86358 001   |
| > ADD >     | a         | EQ 50MG BASE/VIAL    | N86358 002   |
| > ADD >     | a         | EQ 100MG BASE/VIAL   | N86358 003   |
| > ADD >     | a         | EQ 250MG BASE/VIAL   | N86358 004   |

## TABLET; ORAL

METHOTREXATE

|    |       |                |              |
|----|-------|----------------|--------------|
| AB | MYLAN | EQ 2.5MG BASEM | N81235 001   |
|    |       |                | MAY 15, 1992 |

METHOXYFLURANE

## LIQUID; INHALATION

## PENTHRANE

ABBOTT

99.9%

N13056 001

## /SOLUTION; INHALATION/

## /PENTHRANE/

/ABBOTT/

/99.9%/

/N13056/001/

METHYCLOTHIAZIDE

## TABLET; ORAL

METHYCLOTHIAZIDE

|      |                |       |                |
|------|----------------|-------|----------------|
| /B*/ | /PHARM/BASICS/ | /5MG/ | /N88745/001/   |
|      |                |       | /MAR/21./1985/ |
|      | a PHARM BASICS | 5MG   | N88745 001     |
|      |                |       | MAR 21, 1985   |

METHYLDOPA

## TABLET; ORAL

METHYLDOPA

|      |               |         |                |
|------|---------------|---------|----------------|
| /AB/ | /PARKE/DAVIS/ | /125MG/ | /N70331/001/   |
|      |               |         | /APR/15./1986/ |
| /AB/ |               | /250MG/ | /N70332/001/   |
|      |               |         | /APR/15./1986/ |
| /AB/ |               | /500MG/ | /N70333/001/   |
|      |               |         | /APR/15./1986/ |
|      | a PARKE DAVIS | 125MG   | N70331 001     |
|      |               |         | APR 15, 1986   |
|      | a             | 250MG   | N70332 001     |
|      |               |         | APR 15, 1986   |
|      | a             | 500MG   | N70333 001     |
|      |               |         | APR 15, 1986   |

METHYLPREDNISOLONE

## TABLET; ORAL

METHYLPREDNISOLONE

|             |              |     |              |
|-------------|--------------|-----|--------------|
| > DLT >/AB/ | /EON LABS/   | 4MG | N87341 001   |
| > ADD >     | /HEATHER/    | 4MG | /N85650/001/ |
|             | a HEATHER    | 4MG | N85650 001   |
|             | /S/VITARINE/ | 4MG | /N87341/001/ |

METHYLPREDNISOLONE SODIUM SUCCINATE

## INJECTABLE; INJECTION

METHYLPREDNISOLONE

|      |                                            |                      |              |
|------|--------------------------------------------|----------------------|--------------|
| /AP/ | /ELKINS/SINN/                              | /EQ 125MG BASE/VIAL/ | /N86906/002/ |
| /AP/ |                                            | /EQ 500MG BASE/VIAL/ | /N86906/003/ |
| /AP/ |                                            | /EQ 1GM BASE/VIAL/   | /N86906/004/ |
|      | a ELKINS SINN                              | EQ 125MG BASE/VIAL   | N86906 002   |
|      | a                                          | EQ 500MG BASE/VIAL   | N86906 003   |
|      | a                                          | EQ 1GM BASE/VIAL     | N86906 004   |
|      | <u>METHYLPREDNISOLONE SODIUM SUCCINATE</u> |                      |              |
| /AP/ | /ELKINS/SINN/                              | /EQ 40MG BASE/VIAL/  | /N86906/001/ |
|      | a ELKINS SINN                              | EQ 40MG BASE/VIAL    | N86906 001   |

METHYLPREDNISOLONE SODIUM SUCCINATE

## INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE

|    |        |                            |              |
|----|--------|----------------------------|--------------|
| AP | GENSIA | <u>EQ 125MG BASE/VIALM</u> | N81266 001   |
|    |        |                            | NOV 30, 1992 |
| AP |        | <u>EQ 500MG BASE/VIALM</u> | N81267 001   |
|    |        |                            | NOV 30, 1992 |
| AP |        | <u>EQ 1GM BASE/VIALM</u>   | N81268 001   |
|    |        |                            | NOV 30, 1992 |

METOCLOPRAMIDE HYDROCHLORIDE

## CONCENTRATE; ORAL

METOCLOPRAMIDE INTENSOL

|  |        |                         |              |
|--|--------|-------------------------|--------------|
|  | ROXANE | <u>EQ 10MG BASE/MLM</u> | N72995 001   |
|  |        |                         | JAN 30, 1992 |

## INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

|              |                 |                           |               |
|--------------|-----------------|---------------------------|---------------|
| AP           | CETUS BEN VENUE | <u>EQ 10MG BASE/2MLM</u>  | N72155 001    |
|              |                 |                           | MAR 30, 1992  |
| AP           |                 | <u>EQ 10MG BASE/2MLM</u>  | N72244 001    |
|              |                 |                           | MAR 30, 1992  |
| AP           |                 | <u>EQ 10MG BASE/2MLM</u>  | N72247 001    |
|              |                 |                           | MAY 18, 1992  |
| > ADD > AP   | FUJISAWA        | <u>EQ 10MG BASE/2ML</u>   | N70293 001    |
| > ADD >      |                 |                           | JAN 24, 1986  |
| > DLT > /AP/ | /LYPHOMED/      | <u>/EQ 10MG BASE/2ML/</u> | /N70293/001/  |
| > DLT >      |                 |                           | /JAN/24/1986/ |

## SOLUTION; ORAL

METOCLOPRAMIDE HCL

|    |        |                         |              |
|----|--------|-------------------------|--------------|
| AA | SILARX | <u>EQ 5MG BASE/5MLM</u> | N73680 001   |
|    |        |                         | OCT 27, 1992 |

## TABLET; ORAL

METOCLOPRAMIDE HCL

|      |                |                       |               |
|------|----------------|-----------------------|---------------|
| /B*/ | /INTERPHARM/   | <u>/EQ 10MG BASE/</u> | /N71213/001/  |
|      |                |                       | /SEP/24/1986/ |
|      | 2 INTERPHARM   | <u>EQ 10MG BASE</u>   | N71213 001    |
|      |                |                       | SEP 24, 1986  |
| /B*/ | /PHARM BASICS/ | <u>/EQ 10MG BASE/</u> | /N70339/001/  |
|      |                |                       | /JUL/29/1985/ |
|      | 2 PHARM BASICS | <u>EQ 10MG BASE</u>   | N70339 001    |
|      |                |                       | JUL 29, 1985  |

METOLAZONE

## TABLET; ORAL

|      |                        |               |              |
|------|------------------------|---------------|--------------|
| /AB/ | /DIULG/                |               |              |
| /AB/ | /SCHIAPPARELLI/SEARLE/ | <u>2.5MG/</u> | /N18535/001/ |
| /AB/ |                        | <u>5MG/</u>   | /N18535/002/ |
| /AB/ |                        | <u>10MG/</u>  | /N18535/003/ |
|      | 2 SCHIAPPARELLI SEARLE | 2.5MG         | N18535 001   |
|      | 2                      | 5MG           | N18535 002   |
|      | 2                      | 10MG          | N18535 003   |

ZAROXOLYN

|      |           |               |              |
|------|-----------|---------------|--------------|
| /AB/ | /FISONS/  | <u>2.5MG/</u> | /N17386/001/ |
| /AB/ |           | <u>5MG/</u>   | /N17386/002/ |
| /AB/ | /+ FISONS | <u>10MG/</u>  | /N17386/003/ |
|      |           | 10MG          | N17386 003   |
|      |           | 2.5MG         | N17386 001   |
|      |           | 5MG           | N17386 002   |

METOPROLOL SUCCINATE

## TABLET, EXTENDED RELEASE; ORAL

|  |           |                           |              |
|--|-----------|---------------------------|--------------|
|  | TOPROL XL |                           |              |
|  | + HASSLE  | <u>EQ 50MG TARTRATEM</u>  | N19962 001   |
|  |           |                           | JAN 10, 1992 |
|  | +         | <u>EQ 100MG TARTRATEM</u> | N19962 002   |
|  |           |                           | JAN 10, 1992 |
|  | +         | <u>EQ 200MG TARTRATEM</u> | N19962 003   |
|  |           |                           | JAN 10, 1992 |

METRONIDAZOLE

## GEL; VAGINAL

|  |           |               |              |
|--|-----------|---------------|--------------|
|  | METROGEL  |               |              |
|  | + CURATEK | <u>0.75%M</u> | N20208 001   |
|  |           |               | AUG 17, 1992 |

## INJECTABLE; INJECTION

METRONIDAZOLE

|      |            |                      |               |
|------|------------|----------------------|---------------|
| /AB/ | /LYPHOMED/ | <u>/500MG/100ML/</u> | /N70071/001/  |
|      |            |                      | /DEC/03/1984/ |
|      | 2 LYPHOMED | 500MG/100ML          | N70071 001    |
|      |            |                      | DEC 03, 1984  |

METRONIDAZOLE

|                      |            |                |
|----------------------|------------|----------------|
| TABLET; ORAL         |            |                |
| <u>METRONIDAZOLE</u> |            |                |
| AB                   | EON LABS   | 250MG          |
|                      |            | N18620 001     |
|                      |            | MAR 04, 1982   |
| AB                   |            | 500MG          |
|                      |            | N18620 002     |
|                      |            | JUN 02, 1983   |
| /AB/                 | /VITARINE/ | /250MG/        |
|                      |            | /N18620/001/   |
| /AB/                 |            | /500MG/        |
|                      |            | /MAR/04./1982/ |
|                      |            | /N18620/002/   |
|                      |            | /JUN/02./1983/ |

METRONIDAZOLE HYDROCHLORIDE

|                       |                        |                      |
|-----------------------|------------------------|----------------------|
| INJECTABLE; INJECTION |                        |                      |
| <u>FLAGYL I.V.</u>    |                        |                      |
| /AP/                  | /SCHIAPPARELLI/SEARLE/ | /EQ 500MG BASE/VIAL/ |
|                       |                        | /N18353/001/         |
|                       |                        | /N18353 001          |
|                       |                        |                      |
| /AP/                  | /SCHIAPPARELLI SEARLE  | /EQ 500MG BASE/VIAL  |
|                       |                        | /N18353/001/         |
| /AP/                  | /METRONIDAZOLE HCL/    | /EQ 500MG BASE/VIAL/ |
|                       |                        | /N70295/001/         |
|                       |                        | /OCT/15./1985/       |
|                       |                        | /N70295 001          |
|                       |                        | /OCT 15, 1985        |
|                       | Q LYPHOMED             | EQ 500MG BASE/VIAL   |

MINOCYCLINE HYDROCHLORIDE

|                        |           |                    |
|------------------------|-----------|--------------------|
| CAPSULE; ORAL          |           |                    |
| <u>MINOCYCLINE HCL</u> |           |                    |
| AB                     | BIOCRAFT  | EQ 50MG BASEM      |
|                        |           | N63011 001         |
|                        |           | MAR 02, 1992       |
| AB                     |           | EQ 100MG BASEM     |
|                        |           | N63009 001         |
|                        |           | MAR 02, 1992       |
| SUSPENSION; ORAL       |           |                    |
| <u>MINOCIN</u>         |           |                    |
|                        | + LEDERLE | EQ 50MG BASE/5ML   |
|                        |           | N50445 001         |
| /STRUP/                | /ORAL/    |                    |
| /MINOCIN/              |           |                    |
| /+//                   | /LEDERLE/ | /EQ 50MG BASE/5ML/ |
|                        |           | /N50445/001/       |

MINOXIDIL

|                  |                |                |
|------------------|----------------|----------------|
| TABLET; ORAL     |                |                |
| <u>MINOXIDIL</u> |                |                |
| /B*/             | /PHARM/BASICS/ | /2.5MG/        |
|                  |                | /N71537/001/   |
|                  |                | /DEC/16./1988/ |
|                  |                | /N71537 001    |
|                  | Q PHARM BASICS | 2.5MG          |
|                  |                | DEC 16, 1988   |
| /AB/             | /ROYCE/        | /2.5MG/        |
|                  |                | /N71799/001/   |
|                  |                | /NOV/10./1987/ |
| /AB/             |                | /10MG/         |
|                  |                | /N71796/001/   |
|                  |                | /NOV/10./1987/ |
|                  | Q ROYCE        | 2.5MG          |
|                  |                | N71799 001     |
|                  |                | NOV 10, 1987   |
|                  | Q              | 10MG           |
|                  |                | N71796 001     |
|                  |                | NOV 10, 1987   |

MIVACURIUM CHLORIDE

|                                              |                     |              |
|----------------------------------------------|---------------------|--------------|
| INJECTABLE; INJECTION                        |                     |              |
| <u>MIVACRON</u>                              |                     |              |
| BURROUGHS WELLCOME                           | EQ 2MG BASE/MLM     | N20098 001   |
|                                              |                     | JAN 22, 1992 |
| MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER |                     |              |
| BURROUGHS WELLCOME                           | EQ 0.5MG BASE/MLM   | N20098 002   |
|                                              |                     | JAN 22, 1992 |
|                                              | EQ 50MG BASE/100MLM | N20098 003   |
|                                              |                     | JAN 22, 1992 |

MONOBENZONE

|                 |       |              |
|-----------------|-------|--------------|
| CREAM; TOPICAL  |       |              |
| <u>BENOQUIN</u> |       |              |
| /ELDER/         | /20%/ | /N08173/003/ |
| ICN             | 20%   | N08173 003   |

MORPHINE SULFATE

|                         |        |              |
|-------------------------|--------|--------------|
| INJECTABLE; INJECTION   |        |              |
| <u>MORPHINE SULFATE</u> |        |              |
| AP                      | ABBOTT | 0.5MG/MLM    |
|                         |        | N19917 001   |
|                         |        | OCT 30, 1992 |
| AP                      |        | 0.5MG/MLM    |
|                         |        | N73509 001   |
|                         |        | SEP 30, 1992 |
| AP                      |        | 1MG/MLM      |
|                         |        | N19916 001   |
|                         |        | OCT 30, 1992 |
| AP                      |        | 1MG/MLM      |
|                         |        | N73510 001   |
|                         |        | SEP 30, 1992 |

NABUMETONETABLET; ORAL  
RELAFEN+ SMITHKLINE BEECHAM 750MG  
/750MG/N19583 002  
DEC 24, 1991  
/N19583/002/  
/DEC/24/1991/NAFARELIN ACETATESPRAY, METERED; NASAL  
SYNAREL  
SYNTEX

EQ 0.2MG BASE/INH

N20109 001  
FEB 26, 1992NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

/NALBUPHINE/  
/AP/ /LYPHOMED/ /10MG/ML/

/AP/ /20MG/ML/

a LYPHOMED 10MG/ML

a 20MG/ML

/N70751/001/  
/JUL/02/1986/  
/N70752/001/  
/JUL/02/1986/  
N70751 001  
JUL 02, 1986  
N70752 001  
JUL 02, 1986NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

&gt; ADD &gt; AP FUJISAWA 0.02MG/ML

&gt; ADD &gt; 0.4MG/ML

&gt; ADD &gt; 0.4MG/ML

&gt; ADD &gt; 0.4MG/ML

&gt; DLT &gt; /AP/ /LYPHOMED/ /0.02MG/ML/

&gt; DLT &gt; /0.4MG/ML/

&gt; DLT &gt; /AP/ /0.4MG/ML/

&gt; DLT &gt; /AP/ /SMITHKLINEBEECHAM/SOLOPAK/0.02MG/ML/

&gt; DLT &gt; /0.4MG/ML/

&gt; DLT &gt; /AP/ /0.4MG/ML/

&gt; DLT &gt; /0.4MG/ML/

&gt; ADD &gt; AP SOLOPAK MEDCL 0.02MG/ML

&gt; ADD &gt; 0.4MG/ML

&gt; ADD &gt; 0.4MG/ML

&gt; ADD &gt; 0.4MG/ML

N70648 001  
NOV 17, 1986  
N70649 001  
NOV 17, 1986  
/N70648/001/  
/NOV/17/1986/  
/N70649/001/  
/NOV/17/1986/  
/N71672/001/  
/NOV/17/1987/  
/N71683/001/  
/NOV/17/1987/  
N71672 001  
NOV 17, 1987  
N71683 001  
NOV 17, 1987NAPROXEN

TABLET; ORAL

NAPROSYNAB SYNTEX 250MG  
AB 375MG  
AB 500MGN17581 002  
N17581 003  
N17581 004  
APR 15, 1982NAPROXEN

AB HAMILTON 250MG

AB 375MG

AB 500MG

N74110 001  
OCT 30, 1992  
N74110 002  
OCT 30, 1992  
N74110 003  
OCT 30, 1992> ADD > NEDOCROMIL SODIUM

&gt; ADD &gt; AEROSOL, METERED; INHALATION

> ADD > TILADE  
> ADD > + FISONS 1.75MG/INH> ADD > N19660 001  
DEC 30, 1992NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATEAA EON LABS EQ 350MG BASE N61586 001  
/AA/ /VITARINE/ /EQ 350MG BASE/ /N61586/001/NEOMYCIN SULFATE; PREDNISOLONE ACETATE

/SUSPENSION/DROPS;/OPHTHALMIC/

/NEO-DELTA-CORTEF/

/UPJOHN/

a UPJOHN

/EQ/3.5MG/BASE/ML;0.25%/ /N61037/001/  
EQ 3.5MG BASE/ML;0.25% N61037 001NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE

/OINTMENT;/OPHTHALMIC/

/NEO-HYDELTRASOL/

/MSD/

a MSD

/EQ/3.5MG/BASE/GM;/ /N50378/001/  
/EQ/0.25%/PHOSPHATE/ /N50378/001/  
EQ 3.5MG BASE/GM;  
EQ 0.25% PHOSPHATE N50378 001



NIACIN

TABLET; ORAL  
NIACIN  
 AA HOCKHARDT 500MG N81134 001  
 APR 28, 1992

NICARDIPINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
 CARDENE SR  
 + SYNTAX 30MG N20005 001  
 FEB 21, 1992  
 + 45MG N20005 002  
 FEB 21, 1992  
 + 60MG N20005 003  
 FEB 21, 1992

INJECTABLE; INJECTION  
 CARDENE  
 DUPONT MERCK 2.5MG/ML N19734 001  
 JAN 30, 1992

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL  
 NICODERM  
 /BC/ /MARION/MERRELL/DOW/ /7MG/24HR/ N20165/001/  
 /NOV/07/1991/  
 BC + MARION MERRELL DOW 7MG/24HR N20165 001  
 NOV 07, 1991  
 /BC/ /14MG/24HR/ N20165/002/  
 /NOV/07/1991/  
 BC + 14MG/24HR N20165 002  
 NOV 07, 1991  
 /BC/ /21MG/24HR/ N20165/003/  
 /NOV/07/1991/  
 BC + 21MG/24HR N20165 003  
 NOV 07, 1991  
 NICOTROL  
 + KABI 5MG/16HR N20150 001  
 APR 22, 1992  
 + 10MG/16HR N20150 002  
 APR 22, 1992  
 + 15MG/16HR N20150 003  
 APR 22, 1992

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL  
 PROSTEP  
 + ELAN 11MG/24HR N19983 001  
 JAN 28, 1992  
 + 22MG/24HR N19983 002  
 JAN 28, 1992

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL  
 NICORETTE  
 + MERRELL DOW EQ 2MG BASE N18612 001  
 JAN 13, 1984  
 /EQ/2MG/BASE/ /N18612/001/  
 /JAN/13/1984/  
 NICORETTE DS  
 + MERRELL DOW EQ 4MG BASE N20066 001  
 JUN 08, 1992  
 /GUM/CHEWING;ORAL/  
 /NICORETTE/DS/  
 /+/MERRELL/DOW/ /4MG/  
 /N20066/001/  
 /JUN/08/1992/

NIFEDIPINE

CAPSULE; ORAL  
NIFEDIPINE  
 AB NOVOPHARM 10MG N72651 001  
 FEB 19, 1992  
 AB SCHERER 20MG N74045 001  
 APR 30, 1992

NITROFURANTOIN

TABLET; ORAL  
 NITROFURANTOIN  
 @ EON LABS 50MG N80043 001  
 @ 100MG N80043 002  
 /2/vitarine/ /50MG/ /N80043/001/  
 /2/ /100MG/ /N80043/002/

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

## CAPSULE, EXTENDED RELEASE; ORAL

MACROBID

+ P AND G

75MG;25MG

/75MG;25MG/

N20064 001

DEC 24, 1991

/N20064/001/  
/DEC/24/1991/NITROFURANTOIN, MACROCRYSTALLINE

## CAPSULE; ORAL

MACRODANTIN

P AND G

25MG

50MG

100MG

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

NITROFURANTOIN

DANBURY

25MG

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

N16620 003

N16620 001

N16620 002

N73696 001

DEC 31, 1992

N73696 002

DEC 31, 1992

N73696 003

DEC 31, 1992

NITROFURAZONE

/DRESSING; TOPICAL/

/FURACIN/

/AT/ /ROBERTS/

/0.22/

/N05795/001/

/NITROFURAZONE/

/AT/ /THAMES/

/0.22/

/N06156/001/

## OINTMENT; TOPICAL

FURACIN

AT ROBERTS

0.2%

N05795 001

NITROFURAZONE

AT THAMES

0.2%

N06156 001

NITROGLYCERIN

## INJECTABLE; INJECTION

NITROGLYCERIN

FUJISAWA

5MG/ML

&gt; ADD &gt; AP

&gt; ADD &gt; AP

/AP/ /LUITPOLD/

/5MG/ML/

a LUITPOLD

5MG/ML

N70077 001

DEC 13, 1985

/N71492/001/  
/MAY/24/1986/

N71492 001

MAY 24, 1988

NITROGLYCERIN

## INJECTABLE; INJECTION

NITROGLYCERIN

/LYPHONED/

/5MG/ML/

&gt; DLT &gt; /AP/

&gt; DLT &gt;

/N70077/001/

/DEC/13/1985/

NORTRIPTYLINE HYDROCHLORIDE

## CAPSULE; ORAL

NORTRIPTYLINE HCL

AB

DANBURY

EQ 10MG BASEM

N73553 001

MAR 30, 1992

AB

EQ 25MG BASEM

N73554 001

MAR 30, 1992

AB

EQ 50MG BASEM

N73555 001

MAR 30, 1992

AB

EQ 75MG BASEM

N73556 001

MAR 30, 1992

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

&gt; ADD &gt; AB

PAMELOR

AB

SANDOZ

EQ 10MG BASE

N18013 001

AB

EQ 25MG BASE

N18013 002

AB

EQ 50MG BASE

N18013 004

AB

EQ 75MG BASE

N18013 003

/BP/

/BP/

/EQ/10MG/BASE/

/EQ/25MG/BASE/

/N18013/001/

/N18013/002/

NYSTATIN

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; ADD &gt;

/LOTION; TOPICAL/

/CANDEX/

/MILES/

a MILES

/100,000/UNITS/ML/

100,000 UNITS/ML

/N50233/001/

N50233 001

## POWDER; TOPICAL

MYCOSTATIN

/SQUIBB/

WESTWOOD SQUIBB

&gt; DLT &gt;

&gt; ADD &gt;

/100,000/UNITS/GM/

100,000 UNITS/GM

/N60578/001/

N60578 001

NYSTATIN/SUPPOSITORY; VAGINAL//NYSERT//P AND G/2 P AND G/100,000 UNITS/100,000 UNITS/N50478/001/N50478 001

TABLET; ORAL

MYSTATIN/AA/ /CHELSEA/2 CHELSEA/500,000 UNITS/500,000 UNITS/N62402/001/DEC 16, 1982N62402 001DEC 16, 1982N62065 001AA EON LABS500,000 UNITS/AA/ /VITAFINE//500,000 UNITS//N62065/001/

TABLET; VAGINAL

NYSTATIN2 EON LABS/2/ VITAFINE/100,000 UNITS/100,000 UNITS/N61965 001/N61965/001/NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

/DERMACONE//AI/ /TARO//100,000 UNITS/GM; 0.1% //N62364/001/DEC 22, 1985NYSTATIN AND TRIAMCINOLONE ACETONIDE/AI/ /CLAY PARK//100,000 UNITS/GM; 0.1% //N62186/002/JUN 06, 1985B\* CLAY PARK100,000 UNITS/GM; 0.1%N62186 002JUN 06, 1985NYSTATIN AND TRIAMCINOLONE ACETONIDEAITARO100,000 UNITS/GM; 0.1%N62364 001DEC 22, 1987NYSTATIN AND TRIAMCINOLONE ACETONIDE> ADD > AITHAMES100,000 UNITS/GM; 0.1%N62347 001MAR 30, 1987> ADD >> DLT >/NYSTATIN-TRIAMCINOLONE ACETONIDE/> DLT > /AI//THAMES//100,000 UNITS/GM; 0.1% //N62347/001/MAR 30, 1987> DLT >

OINTMENT; TOPICAL

MYCOLOG-IT> DLT > /AI//SQUIBB//100,000 UNITS/GM; 0.1% //N60572/001/JUN 28, 1985> DLT >> ADD > AIWESTWOOD SQUIBB100,000 UNITS/GM; 0.1%N60572 001JUN 28, 1985> ADD >OFLOXACIN

INJECTABLE; INJECTION

FLOXINJOHNSON RW20MG/MLMN20087 002MAR 31, 199240MG/MLMN20087 003MAR 31, 1992FLOXIN IN DEXTROSE 5%JOHNSON RW400MG/100MLMN20087 001MAR 31, 1992FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINERJOHNSON RW4MG/MLMN20087 004MAR 31, 1992400MG/100MLMN20087 005MAR 31, 1992ONDANSETRON HYDROCHLORIDE> ADD >TABLET; ORAL> ADD >ZOFRAN> ADD >+ GLAXOEQ 8MG BASEMN20103 002> ADD >> ADD >EQ 4MG BASEMN20103 001> ADD >DEC 31, 1992OXAPROZIN

TABLET; ORAL

DAYPRO+ SEARLE600MGN18841 004OCT 29, 1992OXAZEPAM

CAPSULE; ORAL

OXAZEPAM/B\* /CHELSEA//1046//N71661/001//MAR 02, 1988//B\* //1546//N71662/001//MAR 02, 1988//B\* //3046//N71663/001//MAR 02, 1988/

OINTMENT; TOPICAL

OXICONAZOLE NITRATE

LOTION; TOPICAL  
OXISTAT  
+ GLAXO

EQ 1% BASEM

N20209 001  
SEP 30, 1992

OXYBUTYNIN CHLORIDE

TABLET; ORAL  
OXYBUTYNIN CHLORIDE  
/B\*/ /PHARM/BASICS/

/5MG/

a PHARM BASICS

5MG

/N70746/001/  
/MAR/10/1988/  
N70746 001  
MAR 10, 1988

> ADD > PACLITAXEL

> ADD > INJECTABLE; INJECTION  
> ADD > TAXOL  
> ADD > BRISTOL MYERS SQUIBB 6MG/MLM  
> ADD >

N20262 001  
DEC 29, 1992

PARGYLINE HYDROCHLORIDE

> DLT > /TABLET; ORAL/  
> DLT > /EUTONYL/  
> DLT > /+//ABBOTT/  
> DLT >  
> ADD > a ABBOTT  
> ADD > a

/25MG/  
/10MG/  
10MG  
25MG

/N13448/003/  
/N13448/002/  
N13448 002  
N13448 003

> ADD > PAROXETINE HYDROCHLORIDE

> ADD > TABLET; ORAL  
> ADD > PAXIL  
> ADD > + SMITHKLINE BEECHAM EQ 10MG BASEM  
> ADD >  
> ADD > EQ 50MG BASEM  
> ADD > +  
> ADD > EQ 20MG BASEM  
> ADD >  
> ADD > EQ 30MG BASEM  
> ADD >  
> ADD > EQ 40MG BASEM  
> ADD >

N20031 001  
DEC 29, 1992  
N20031 004  
DEC 29, 1992  
N20031 002  
DEC 29, 1992  
N20031 003  
DEC 29, 1992  
N20031 005  
DEC 29, 1992

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

/AP/ /PARKE/DAVIS/ /1,000,000 UNITS/VIAL/ /N62003/001/  
/AP/ /5,000,000 UNITS/VIAL/ /N62003/002/  
a PARKE DAVIS 1,000,000 UNITS/VIAL N62003 001  
a 5,000,000 UNITS/VIAL N62003 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

/BA/ /PENAPAR-VK/ /EQ 125MG BASE/5ML/ /N62002/001/  
/BA/ /PARKE/DAVIS/ /EQ 250MG BASE/5ML/ /N62002/002/  
a PARKE DAVIS EQ 125MG BASE/5ML N62002 001  
a EQ 250MG BASE/5ML N62002 002

TABLET; ORAL

/BA/ /PENAPAR-VK/ /EQ 250MG BASE/ /N62001/001/  
/BA/ /PARKE/DAVIS/ /EQ 500MG BASE/ /N62001/002/  
a PARKE DAVIS EQ 250MG BASE N62001 001  
a EQ 500MG BASE N62001 002

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTAM 300

AP FUJISAWA 300MG/VIAL N19264 001  
OCT 16, 1984

PENTAMIDINE ISETHIONATE

AP ABBOTT 300MG/VIAL N73479 001  
JUN 30, 1992

PERPHENAZINE

TABLET; ORAL  
PERPHENAZINE

/B\*/ /CHELSEA/ /4MG/ /N89700/001/  
/DEC/23/1987/

PHENDIMETRAZINE TARTRATE

## CAPSULE; ORAL

PHENDIMETRAZINE TARTRATE

|      |            |        |
|------|------------|--------|
| AA   | EON LABS   | 35MG   |
| AA   |            | 35MG   |
| AA   |            | 35MG   |
| AA   |            | 35MG   |
| /AA/ | /VITARINE/ | /35MG/ |
| /AA/ |            | /35MG/ |
| /AA/ |            | /35MG/ |
| /AA/ |            | /35MG/ |
| /AA/ |            | /35MG/ |

## CAPSULE, EXTENDED RELEASE; ORAL

PHENDIMETRAZINE TARTRATE

|      |            |         |
|------|------------|---------|
| BC   | EON LABS   | 105MG   |
| /BC/ | /VITARINE/ | /105MG/ |

## TABLET; ORAL

## ALPHAZINE

|      |                |        |
|------|----------------|--------|
| 2    | EON LABS       | 35MG   |
| /2/  | /VITARINE/     | /35MG/ |
| /AA/ | /OBÉZINE/      | /35MG/ |
| /AA/ | /PHARM/BASICS/ | /35MG/ |
| /AA/ |                | /35MG/ |
| /AA/ |                | /35MG/ |

PHENDIMETRAZINE TARTRATE

|     |          |        |
|-----|----------|--------|
| AA  | EON LABS | 35MG   |
| AA  |          | 35MG   |
| AA  |          | 35MG   |
| AA  |          | 35MG   |
| /2/ |          | /35MG/ |

PHENDIMETRAZINE TARTRATE

|    |              |      |
|----|--------------|------|
| AA | PHARM BASICS | 35MG |
| 2  |              | 35MG |
| 2  |              | 35MG |

PHENDIMETRAZINE TARTRATE

|      |            |        |
|------|------------|--------|
| /AA/ | /VITARINE/ | /35MG/ |
| /AA/ |            | /35MG/ |
| /AA/ |            | /35MG/ |
| /AA/ |            | /35MG/ |

|          |       |
|----------|-------|
| N85633   | 001   |
| N85694   | 001   |
| N85695   | 001   |
| N85702   | 001   |
| /N85633/ | /001/ |
| /N85694/ | /001/ |
| /N85695/ | /001/ |
| /N85702/ | /001/ |

|          |       |
|----------|-------|
| N18074   | 001   |
| /N18074/ | /001/ |

|          |       |
|----------|-------|
| N85034   | 001   |
| /N85034/ | /001/ |

|          |       |
|----------|-------|
| /N83805/ | /001/ |
| /N84398/ | /001/ |
| /N84399/ | /001/ |

|          |       |
|----------|-------|
| N85402   | 001   |
| N85497   | 001   |
| N85588   | 001   |
| N85830   | 001   |
| /N85830/ | /001/ |

|        |     |
|--------|-----|
| N84399 | 001 |
| N83805 | 001 |
| N84398 | 001 |

|          |       |
|----------|-------|
| /N85402/ | /001/ |
| /N85497/ | /001/ |
| /N85588/ | /001/ |

PHEENTERMINE HYDROCHLORIDE

## CAPSULE; ORAL

PHEENTERMINE HCL

|      |            |        |
|------|------------|--------|
| AA   | EON LABS   | 15MG   |
| AA   |            | 30MG   |
| AA   |            | 30MG   |
| AA   |            | 30MG   |
| AA   |            | 30MG   |
| /AA/ | /VITARINE/ | /15MG/ |
| /AA/ |            | /30MG/ |
| /AA/ |            | /30MG/ |
| /AA/ |            | /30MG/ |
| /AA/ |            | /30MG/ |
| /AA/ |            | /30MG/ |
| /AA/ |            | /30MG/ |

## TABLET; ORAL

## PHEENTERMINE HCL

|     |            |       |
|-----|------------|-------|
| 2   | EON LABS   | 8MG   |
| 2   |            | 8MG   |
| /2/ | /VITARINE/ | /8MG/ |
| /2/ |            | /8MG/ |

PHENYL BUTAZONE

## CAPSULE; ORAL

/AZOLTO/

|      |                       |         |
|------|-----------------------|---------|
| /AA/ | /RHONE/POULENC/RORER/ | /100MG/ |
|      | 2 RHONE POULENC RORER | 100MG   |

## TABLET; ORAL

/AZOLTO/

|      |                       |         |
|------|-----------------------|---------|
| /AA/ | /RHONE/POULENC/RORER/ | /100MG/ |
|      | 2 RHONE POULENC RORER | 100MG   |

PHENYTOIN

## SUSPENSION; ORAL

DILANTIN-125

|    |               |           |
|----|---------------|-----------|
| AB | + PARKE DAVIS | 125MG/5ML |
|----|---------------|-----------|

PHENYTOIN

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

|                |       |
|----------------|-------|
| N87301         | 001   |
| N86945         | 001   |
| JUL 20, 1983   |       |
| N87190         | 001   |
| N87208         | 001   |
| N87223         | 001   |
| /N87301/       | /001/ |
| /N86945/       | /001/ |
| /JUL 20, 1983/ |       |
| /N87190/       | /001/ |
| /N87208/       | /001/ |
| /N87223/       | /001/ |

|          |       |
|----------|-------|
| N85671   | 001   |
| N85689   | 001   |
| /N85671/ | /001/ |
| /N85689/ | /001/ |

|          |       |
|----------|-------|
| /N87260/ | /001/ |
| N87260   | 001   |

|          |       |
|----------|-------|
| /N87091/ | /001/ |
| N87091   | 001   |

|              |     |
|--------------|-----|
| N89892       | 001 |
| SEP 25, 1992 |     |

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

AP MARSAM 50MG/ML

N89779 001  
NOV 27, 1992  
/N88520/001/  
/DEC/17/1984/  
N88520 001  
DEC 17, 1984PIROXICAM

CAPSULE; ORAL

FELDENE

AB PFIZER 10MG

N18147 002  
APR 06, 1982  
N18147 003  
APR 06, 1982

AB + 20MG

PIROXICAM

AB COPLEY 10MG

N74103 001  
AUG 28, 1992

AB 20MG

N74103 002  
AUG 28, 1992

AB GENPHARM 10MG

N74043 001  
SEP 22, 1992

AB 20MG

N74043 002  
SEP 22, 1992

AB LEMMON 10MG

N74131 001  
DEC 11, 1992

&gt; ADD &gt; AB 20MG

N74131 002  
DEC 11, 1992

&gt; ADD &gt; AB 10MG

N74102 001  
JUL 31, 1992

AB MYLAN 20MG

N74102 002  
JUL 31, 1992

AB SCHIAPPARELLI SEARLE 10MG

N74036 001  
MAY 29, 1992

AB 20MG

N74036 002  
MAY 29, 1992POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM  
BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

CO-LAV

AA COPLEY

240GM/BOT; 2.98GM/BOT; 6.72GM/BOT;  
5.84GM/BOT; 22.72GM/BOT N73428 001  
JAN 28, 1992GO-EVAC

/AA/ /COPLEY/

/236GM/BOT; 2.97GM/BOT; 6.74GM/BOT;  
/5.86GM/BOT; 22.74GM/BOT N73433 001  
/APR/28/1992/

AA COPLEY

236GM/BOT; 2.97GM/BOT; 6.74GM/BOT;  
5.86GM/BOT; 22.74GM/BOT N73433 001  
APR 28, 1992PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL

PHENYTOIN SODIUM/BX/ /CHELSEA/ 100MG  
3 CHELSEA/N85894/001/  
N85894 001PINDOLOL

TABLET; ORAL

PINDOLOL

AB GENPHARM 5MG

N74013 001  
SEP 24, 1992

AB 10MG

N74018 001  
SEP 24, 1992

AB MYLAN 5MG

N74019 001  
SEP 03, 1992

AB 10MG

N74019 002  
SEP 03, 1992VISKEN

AB SANDOZ 5MG

N18285 001  
SEP 03, 1982

AB + 10MG

N18285 002  
SEP 03, 1982PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION

MAXAIR

3M

EQ 0.2MG BASE/INH

N20014 001  
NOV 30, 1992

POTASSIUM CHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

|           |                          |             |                            |
|-----------|--------------------------|-------------|----------------------------|
| <u>AB</u> | <u>K-LEASE</u><br>ADRIA  | <u>8MEQ</u> | N73398 001<br>JAN 28, 1992 |
| <u>AB</u> | <u>MICRO-K</u><br>ROBINS | <u>8MEQ</u> | N18238 001                 |

## INJECTABLE; INJECTION

POTASSIUM CHLORIDE

|         |           |                   |                |                     |
|---------|-----------|-------------------|----------------|---------------------|
| > ADD > | <u>AP</u> | FUJISAWA          | <u>2MEQ/ML</u> | N80225 001          |
| > ADD > | <u>AP</u> |                   | <u>3MEQ/ML</u> | N80225 003          |
| > DLT > | <u>AB</u> | <u>/LIPHOMED/</u> | <u>2MEQ/ML</u> | <u>/N80225/001/</u> |
| > DLT > | <u>AB</u> |                   | <u>3MEQ/ML</u> | <u>/N80225/003/</u> |

POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER

|           |        |                    |                            |
|-----------|--------|--------------------|----------------------------|
| <u>AP</u> | ABBOTT | <u>745MG/100ML</u> | N20161 001<br>NOV 30, 1992 |
| <u>AP</u> |        | <u>14.9MG/ML</u>   | N20161 005<br>NOV 30, 1992 |
| <u>AP</u> | BAXTER | <u>746MG/100ML</u> | N19904 005<br>DEC 17, 1990 |
| <u>AP</u> |        | <u>14.9MG/ML</u>   | N19904 001<br>DEC 26, 1989 |

POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER

|           |        |                     |                            |
|-----------|--------|---------------------|----------------------------|
| <u>AP</u> | ABBOTT | <u>1.49GM/100ML</u> | N20161 002<br>NOV 30, 1992 |
| <u>AP</u> | BAXTER | <u>1.49GM/100ML</u> | N19904 006<br>DEC 17, 1990 |

## TABLET, EXTENDED RELEASE; ORAL

KLOR-CON

|             |                       |                |                                             |
|-------------|-----------------------|----------------|---------------------------------------------|
| <u>AB</u>   | UPSHER SMITH          | <u>8MEQ</u>    | N19123 001<br>APR 17, 1986                  |
| <u>/BC/</u> |                       | <u>/8MEQ/</u>  | <u>/N19123/001/</u><br><u>/APR/17/1986/</u> |
|             | KLOTRIX               |                |                                             |
| <u>BC</u>   | APOTHECON             | <u>10MEQ</u>   | N17850 001                                  |
| <u>/BC/</u> | <u>/HEAD/JOHNSON/</u> | <u>/10MEQ/</u> | <u>/N17850/001/</u>                         |

PRAZEPAM

## CAPSULE; ORAL

|             |                                        |               |                     |
|-------------|----------------------------------------|---------------|---------------------|
| <u>/AB/</u> | <u>CENTRAX</u><br><u>/PARKE/DAVIS/</u> | <u>/5MG/</u>  | <u>/N18144/001/</u> |
| <u>/AB/</u> | <u>/+/</u>                             | <u>/10MG/</u> | <u>/N18144/002/</u> |
|             | + PARKE DAVIS                          | 10MG          | N18144 002          |
|             |                                        | 5MG           | N18144 001          |

PRAZEPAM

## CAPSULE; ORAL

|             |                                            |               |                                             |
|-------------|--------------------------------------------|---------------|---------------------------------------------|
| <u>/BX/</u> | <u>/PRAZEPAM/</u><br><u>/PHARM/BASICS/</u> | <u>/5MG/</u>  | <u>/N70427/001/</u><br><u>/NOV/06/1987/</u> |
| <u>/BX/</u> |                                            | <u>/10MG/</u> | <u>/N70428/001/</u><br><u>/NOV/06/1987/</u> |
|             | a PHARM BASICS                             | 5MG           | N70427 001<br>NOV 06, 1987                  |
|             | a                                          | 10MG          | N70428 001<br>NOV 06, 1987                  |

PRAZOSIN HYDROCHLORIDE

## CAPSULE; ORAL

|             |                                     |                      |                     |
|-------------|-------------------------------------|----------------------|---------------------|
| <u>/AB/</u> | <u>MINIPRESS</u><br><u>/PFIZER/</u> | <u>/EQ 2MG BASE/</u> | <u>/N17442/003/</u> |
| <u>AB</u>   | + PFIZER                            | EQ 2MG BASE          | N17442 003          |
| <u>/AB/</u> | <u>/+/</u>                          | <u>/EQ 5MG BASE/</u> | <u>/N17442/001/</u> |
| <u>AB</u>   |                                     | EQ 5MG BASE          | N17442 001          |

## TABLET, EXTENDED RELEASE; ORAL

## MINIPRESS XL

|          |       |                            |
|----------|-------|----------------------------|
| + PFIZER | 2.5MG | N19775 001<br>JAN 29, 1992 |
| +        | 5MG   | N19775 002<br>JAN 29, 1992 |

PREDNISOLONE

## TABLET; ORAL

|             |                                          |              |                     |
|-------------|------------------------------------------|--------------|---------------------|
| <u>/BX/</u> | <u>/DELTA-CORTEF/</u><br><u>/UPJOHN/</u> | <u>/5MG/</u> | <u>/N09987/004/</u> |
|             | a UPJOHN                                 | 5MG          | N09987 004          |

## PREDNISOLONE

|             |                                       |              |                     |
|-------------|---------------------------------------|--------------|---------------------|
| <u>/BX/</u> | <u>a EON LABS</u><br><u>/HEATHER/</u> | <u>/5MG/</u> | <u>/N84773/001/</u> |
|             | a HEATHER                             | 5MG          | N80326 001          |
| <u>/a/</u>  | <u>/VITARINE/</u>                     | <u>/5MG/</u> | <u>/N84773/001/</u> |

PREDNISOLONE ACETATEINJECTABLE; INJECTION  
PREDNISOLONE ACETATE

> DLT > /BP/ /BEL/MAR/ /50MG/ML/  
 > DLT > /BP/ /25MG/ML/  
 > ADD > 2 BEL MAR 25MG/ML  
 > ADD > 2 50MG/ML  
 > DLT > /BP/ /STERIS/ /25MG/ML/  
 > DLT > /BP/ /25MG/ML/  
 > DLT > /BP/ /50MG/ML/  
 > DLT > /BP/ /50MG/ML/  
 > ADD > STERIS 25MG/ML  
 > ADD > 25MG/ML  
 > ADD > 50MG/ML  
 > ADD > 50MG/ML

/N83738/001/  
 /N83738/001/  
 N83738 001  
 N83738 002  
 /N83398/001/  
 /N83654/001/  
 /N83764/001/  
 /N85781/001/  
 N83398 001  
 N83654 001  
 N83764 001  
 N85781 001

PROCAINAMIDE HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

/AB/ /BOLAR/ /250MG/  
 /AB/ /500MG/  
 /AB/ /750MG/  
 2 BOLAR 250MG  
 2 500MG  
 2 750MG

/N88533/001/  
 /DEC/03/1984/  
 /N88534/001/  
 /DEC/03/1984/  
 /N88535/001/  
 /NOV/03/1984/  
 N88533 001  
 DEC 03, 1984  
 N88534 001  
 DEC 03, 1984  
 N88535 001  
 NOV 03, 1984

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

## SUSPENSION/DROPS; OPHTHALMIC

/AT/ /BLEPHAMIDE/ /0.22:10%/  
 /ALLERGAN/ 0.2%;10%  
 /AT/ /PREDNISOLONE/ /0.22:10%/  
 /PHARMAFAIR/ 0.2%;10%  
 2 PHARMAFAIR

/N12813/002/  
 N12813 002  
 /N88837/001/  
 /DEC/24/1985/  
 N88837 001  
 DEC 24, 1985

## INJECTABLE; INJECTION

PROCAINE HCL

> ADD > AP FUJISAWA 1%  
 > ADD > AP 2%  
 > DLT > /AP/ /LYPHOMED/ /1%/  
 > DLT > /AP/ /2%

N80384 002  
 N80384 003  
 /N80384/002/  
 /N80384/003/

PROCAINE HYDROCHLORIDE; TETRACYCLINE HYDROCHLORIDE

## INJECTABLE; INJECTION

ACHROMYCIN

AP LEDERLE 40MG/VIAL;100MG/VIAL  
 AP 40MG/VIAL;100MG/VIAL  
 AP 40MG/VIAL;250MG/VIAL

N50267 002  
 N50276 001  
 N50267 003

TETRACYCLIN

AP PFIZER 40MG/VIAL;250MG/VIAL  
 2 40MG/VIAL;100MG/VIAL

N60285 003  
 N60285 002

PROCHLORPERAZINE EDISYLATE

## INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

/AB/ /ELKINS/SINN/ /EQ 5MG BASE/ML/  
 2 ELKINS SINN EQ 5MG BASE/ML

/N89523/001/  
 /MAY/03/1988/  
 N89523 001  
 MAY 03, 1988

PREDNISONE

## TABLET; ORAL

/BX/ /FERNISONE/ /5MG/  
 /FERNDALE/ 5MG  
 2 FERNDALE

/N83364/001/  
 N83364 001

PREDNISONE

2 EON LABS 5MG  
 RICHLYN 5MG

N84774 001  
 N80782 001  
 /N86782/001/  
 /N84774/001/

AB /BX/ /2/VITARINE/ /5MG/

PROCAINAMIDE HYDROCHLORIDE

## INJECTABLE; INJECTION

PROCAINAMIDE HCL

> DLT > /AP/ /SLOPAK/NEOWEN/SOLOPAK/500MG/ML/  
 > DLT >  
 > ADD > AP SOLOPAK MEDCL 500MG/ML  
 > ADD >

/N88532/001/  
 /MAR/04/1985/  
 N88532 001  
 MAR 04, 1985



PROCHLORPERAZINE MALEATE

TABLET; ORAL

|      |                            |                |                |
|------|----------------------------|----------------|----------------|
| /B*/ | /PROCHLORPERAZINE/MALEATE/ | /EQ/5MG/BASE/  | /N89484/001/   |
|      | /DURAMED/                  |                | /JAN/20./1987/ |
| /B*/ |                            | /EQ/10MG/BASE/ | /N89485/001/   |
|      |                            |                | /JAN/20./1987/ |
| /B*/ |                            | /EQ/25MG/BASE/ | /N89486/001/   |
|      |                            |                | /JAN/20./1987/ |
| Q    | DURAMED                    | EQ 5MG BASE    | N89484 001     |
| Q    |                            | EQ 10MG BASE   | JAN 20, 1987   |
| Q    |                            | EQ 25MG BASE   | N89485 001     |
|      |                            |                | JAN 20, 1987   |
|      |                            |                | N89486 001     |
|      |                            |                | JAN 20, 1987   |

PROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

|      |                 |           |              |
|------|-----------------|-----------|--------------|
| /AP/ | /PROMAZINE HCL/ | /25MG/ML/ | /N84510/001/ |
|      | /STERIS/        | 25MG/ML   | /N84510 001/ |
| /AP/ | /SPARINE/       | /25MG/ML/ | /N10349/000/ |
|      | /NYETH/AYERST/  | 25MG/ML   | /N10349 008/ |

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

|     |            |        |              |
|-----|------------|--------|--------------|
| Q   | EON LABS   | 25MG   | N85146 001   |
| Q   |            | 50MG   | N85146 002   |
| /3/ | /VITARINE/ | /25MG/ | /N85146/001/ |
| /3/ |            | /50MG/ | /N85146/002/ |

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL

RYTHMOL

KNOLL 225MG

N19151 003  
NOV 20, 1992

PROPANTHELINE BROMIDE

TABLET; ORAL

PROPANTHELINE BROMIDE

|      |           |        |              |
|------|-----------|--------|--------------|
| /AA/ | /HEATHER/ | /15MG/ | /N85780/001/ |
|      | Q HEATHER | 15MG   | N85780 001   |

PROPACARCAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPHTHAINE

|      |          |          |              |
|------|----------|----------|--------------|
| /AT/ | /SQUIBB/ | /5MG/ML/ | /N08883/001/ |
| AT   | SQUIBB   | 0.5%     | N08883 001   |

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

|      |                       |        |              |
|------|-----------------------|--------|--------------|
| Q    | EON LABS              | 32MG   | N84014 001   |
| Q    |                       | 65MG   | N83688 001   |
| Q    |                       | 65MG   | N83870 002   |
| Q    |                       | 65MG   | N86495 001   |
| /3/  | /VITARINE/            | /32MG/ | /N84014/001/ |
| /3/  |                       | /65MG/ | /N83688/001/ |
| /3/  |                       | /65MG/ | /N83870/002/ |
| /3/  |                       | /65MG/ | /N86495/001/ |
| /AA/ | /PROPOXYPHENE HCL 65/ | /65MG/ | /N83786/001/ |
|      | /PARKE/DAVIS/         | 65MG   | N83786 001   |
|      | Q WARNER CHILCOTT     | 65MG   |              |

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

PROPRANOLOL HCL

|         |      |                               |                |
|---------|------|-------------------------------|----------------|
| > DLT > | /AP/ | /SMITH/NEEBEN/SOLOPAK/1MG/ML/ | /N70136/001/   |
| > DLT > |      |                               | /APR/15./1986/ |
| > ADD > | AP   | SOLOPAK MEDCL                 | N70136 001     |
| > ADD > |      |                               | APR 15, 1986   |

PROPRANOLOL HYDROCHLORIDE

## TABLET; ORAL

PROPRANOLOL HCL

|              |              |        |                |
|--------------|--------------|--------|----------------|
| > DLT > /AB/ | /SCHERING/   | /10MG/ | /N70120/001/   |
| > DLT >      |              |        | /AUG/06./1985/ |
| > DLT > /AB/ |              | /20MG/ | /N70121/001/   |
| > DLT >      |              |        | /AUG/06./1985/ |
| > DLT > /AB/ |              | /40MG/ | /N70122/001/   |
| > DLT >      |              |        | /AUG/06./1985/ |
| > DLT > /AB/ |              | /60MG/ | /N70123/001/   |
| > DLT >      |              |        | /OCT/29./1986/ |
| > DLT > /AB/ |              | /80MG/ | /N70124/001/   |
| > DLT >      |              |        | /AUG/06./1985/ |
| > ADD >      | 2 SCHERING   | 10MG   | N70120 001     |
| > ADD >      |              |        | AUG 06, 1985   |
| > ADD >      | 2            | 20MG   | N70121 001     |
| > ADD >      |              |        | AUG 06, 1985   |
| > ADD >      | 2            | 40MG   | N70122 001     |
| > ADD >      |              |        | AUG 06, 1985   |
| > ADD >      | 2            | 60MG   | N70123 001     |
| > ADD >      |              |        | OCT 29, 1986   |
| > ADD >      | 2            | 80MG   | N70124 001     |
| > ADD >      |              |        | AUG 06, 1985   |
| /AB/         | /SUPERPHARM/ | /10MG/ | /N71515/001/   |
| /AB/         |              | /20MG/ | /JUN/08./1988/ |
|              |              |        | /N71516/001/   |
|              |              |        | /JUN/08./1988/ |
|              | 2 SUPERPHARM | 10MG   | N71515 001     |
|              |              |        | JUN 08, 1988   |
|              | 2            | 20MG   | N71516 001     |
|              |              |        | JUN 08, 1988   |

PROTIRELIN

## INJECTABLE; INJECTION

RELEFACT TRM

|      |                   |            |              |
|------|-------------------|------------|--------------|
| AP   | FERRING           | 0.5MG/ML   | N18087 001   |
| /AP/ | /HOECHST/ROUSSEL/ | /0.5MG/ML/ | /N18087/001/ |

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

## TABLET; ORAL

PSEUDOEPHEDRINE HCL AND TRIPROLIDINE HCL

|      |            |              |                |
|------|------------|--------------|----------------|
| AA   | EON LABS   | 60MG;2.5MG   | N88193 001     |
|      |            |              | MAY 17, 1983   |
| /AB/ | /VITARINE/ | /60MG;2.5MG/ | /N88193/001/   |
|      |            |              | /MAY/17./1983/ |

PYRAZINAMIDE

## TABLET; ORAL

PYRAZINAMIDE

|    |           |       |              |
|----|-----------|-------|--------------|
| AB | + LEDERLE | 500MG | N80157 001   |
| AB | MIKART    | 500MG | N81319 001   |
|    |           |       | JUN 30, 1992 |

PYRIDOXINE HYDROCHLORIDE

## INJECTABLE; INJECTION

PYRIDOXINE HCL

|      |            |            |              |
|------|------------|------------|--------------|
| /AP/ | /LUITPOLD/ | /100MG/ML/ | /N80669/001/ |
|      | 2 LUITPOLD | 100MG/ML   | N80669 001   |

QUINETHAZONE; RESERPINE

## /TABLET;/ORAL/

## /HYDROMOX/R/

## /LEDERLE/

## 2 LEDERLE

/50MG;0.125MG/  
50MG;0.125MG

/N13927/001/  
N13927 001

QUINIDINE SULFATE

## TABLET; ORAL

QUINIDINE SULFATE

|      |                      |         |                |
|------|----------------------|---------|----------------|
|      | 2 ELKINS SINN        | 200MG   | N83622 001     |
| AB   | EON LABS             | 200MG   | N84631 001     |
| AB   |                      | 300MG   | N88072 001     |
|      |                      |         | SEP 26, 1983   |
| /AB/ | /2/QUANTUM PHARMICS/ | /200MG/ | /N83622/001/   |
| /AB/ | /VITARINE/           | /200MG/ | /N84631/001/   |
| /AB/ |                      | /300MG/ | /N88072/001/   |
|      |                      |         | /SEP/26./1983/ |

RAUWOLFIA SERPENTINA

## TABLET; ORAL

## /RAUVERID/

## /BP/ /FOREST PHARMS/

## WOLFINA

## 2 FOREST PHARMS

/50MG/

50MG

/N89255/008/

N09255 008

RESERPINETABLET; ORAL  
RESERPINE

|      |            |          |              |         |    |
|------|------------|----------|--------------|---------|----|
| BP   | EON LABS   | 0.1MG    | N09838 001   | > ADD > | AP |
| BP   |            | 0.25MG   | N09838 002   | > ADD > |    |
| /BP/ | /VITAMINE/ | /0.1MG/  | /N09838/001/ | > ADD > | AP |
| /BP/ |            | /0.25MG/ | /N09838/002/ | > ADD > |    |
|      | /SERPATE/  |          |              |         |    |
| /BP/ | /VALE/     | /0.1MG/  | /N09453/001/ |         |    |
| /BP/ |            | /0.25MG/ | /N09453/002/ |         |    |
|      | 2 VALE     | 0.1MG    | N09453 001   |         |    |
|      | 2          | 0.25MG   | N09453 002   | > DLT > |    |

> ADD > RIFABUTIN

> ADD > CAPSULE; ORAL  
 > ADD > MYCOBUTIN  
 > ADD > + ADRIA 150MG  
 > ADD >

RITODRINE HYDROCHLORIDE

## INJECTABLE; INJECTION

|      |            |           |               |
|------|------------|-----------|---------------|
| /BP/ | /LYPHOMED/ | /10MG/ML/ | /N71188/001/  |
| /BP/ |            | /15MG/ML/ | /JUL/23/1987/ |
|      | 2 LYPHOMED | 10MG/ML   | N71188 001    |
|      | 2          | 15MG/ML   | JUL 23, 1987  |
|      |            |           | N71189 001    |
|      |            |           | JUL 23, 1987  |

SELENIUM SULFIDE

## LOTION/SHAMPOO; TOPICAL

|         |          |          |              |
|---------|----------|----------|--------------|
| > DLT > | /AT/     | /THAMES/ | /N86209/001/ |
| > ADD > | 2 THAMES | 2.5%     | N86209 001   |

SODIUM BICARBONATE; TARTARIC ACID

## GRANULE, EFFERVESCENT; ORAL

|           |                     |               |  |
|-----------|---------------------|---------------|--|
| BAROS     |                     |               |  |
| /E/2/EN/  | /460MG/GM;420MG/GM/ | /N18509/001/  |  |
|           |                     | /AUG/07/1985/ |  |
| LAFAYETTE | 460MG/GM;420MG/GM   | N18509 001    |  |
|           |                     | AUG 07, 1985  |  |

SODIUM CHLORIDE

## INJECTABLE; INJECTION

BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

|         |    |          |          |               |
|---------|----|----------|----------|---------------|
| > ADD > | AP | ABBOTT   | 9MG/ML   | N18800 001    |
|         |    |          |          | OCT 29, 1982  |
| > ADD > | AP | LYPHOMED | 9MG/ML   | N88911 001    |
|         |    |          |          | FEB 07, 1985  |
|         |    |          | /9MG/ML/ | /N88909/001/  |
|         |    | 2        | 9MG/ML   | /FEB/07/1985/ |
|         |    |          |          | N88909 001    |
|         |    |          |          | FEB 07, 1985  |
|         |    |          | /9MG/ML/ | /N88911/001/  |
|         |    | /ABBOTT/ | /9MG/ML/ | /FEB/07/1985/ |
|         |    |          |          | /N18800/001/  |
|         |    |          |          | /OCT/29/1982/ |

SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

|         |    |                                              |              |               |
|---------|----|----------------------------------------------|--------------|---------------|
| > ADD > | AP | BAXTER                                       | 900MG/100MLM | N20178 001    |
|         |    |                                              |              | DEC 07, 1992  |
| > ADD > | AP |                                              | 9MG/MLM      | N20178 002    |
|         |    |                                              |              | DEC 07, 1992  |
|         |    | /SODIUM/CHLORIDE/23.4%/IN/PLASTIC/CONTAINER/ |              |               |
|         |    | /LYPHOMED/                                   | /234MG/ML/   | /N19329/001/  |
|         |    | 2 LYPHOMED                                   | 234MG/ML     | /APR/22/1987/ |
|         |    |                                              |              | N19329 001    |
|         |    |                                              |              | APR 22, 1987  |

SODIUM LACTATE

## INJECTABLE; INJECTION

SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER

|    |       |               |              |
|----|-------|---------------|--------------|
| AP | MCGAW | 1.87GM/100MLM | N20004 001   |
|    |       |               | APR 21, 1992 |

SODIUM NITROPRUSSIDE

## INJECTABLE; INJECTION

NITROPRESS

|    |        |          |              |
|----|--------|----------|--------------|
| AP | ABBOTT | 25MG/ML  | N71961 001   |
|    |        |          | AUG 01, 1988 |
| AP | GENSIA | 25MG/MLM | N73465 001   |
|    |        |          | MAR 30, 1992 |

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL  
SODIUM POLYSTYRENE SULFONATE  
 /66/ /ROXANE/ /15GM/60ML/  
 2 ROXANE 15GM/60ML

/N88453/001/  
 /NOV/17/1983/  
 N88453 001  
 NOV 17, 1983

SODIUM THIOSULFATE

INJECTABLE; INJECTION  
 SODIUM THIOSULFATE  
 US ARMY 250MG/MLM

N20166 001  
 FEB 14, 1992

SOTALOL HYDROCHLORIDE

TABLET; ORAL  
 BETAPACE  
 + BERLEX 240MG  
 80MG  
 160MG  
 320MG

N19865 003  
 OCT 30, 1992  
 N19865 001  
 OCT 30, 1992  
 N19865 002  
 OCT 30, 1992  
 N19865 004  
 OCT 30, 1992

SPIRONOLACTONE

TABLET; ORAL  
SPIRONOLACTONE  
 /66/ /PARKE/DAVIS/ /25MG/  
 2 WARNER CHILCOTT 25MG

/N87952/001/  
 /NOV/18/1982/  
 N87952 001  
 NOV 18, 1982

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION  
 SUCCINYLCHOLINE CHLORIDE  
 /INTL/MEDICATION/ /100MG/VIAL/  
 2 INTL MEDICATION 100MG/VIAL

/N85400/001/  
 /FEB/04/1982/  
 N85400 001  
 FEB 04, 1982

/SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE/

/CREAM;/VAGINAL/  
 /SULTRIN/  
 /JOHNSON/RW/ /3.72;2.862;3.422/ /N85794/001/  
 /TABLET;/VAGINAL/  
 /SULTRIN/  
 /JOHNSON/RW/ /184MG;143.75MG;172.5MG/ /N85794/001/  
 /TRIPLE/SULFA/  
 /3/FOUSERA/ /184MG;143.75MG;172.5MG/ /N88463/001/  
 /3/PHARMADERM/ /184MG;143.75MG;172.5MG/ /JAN/03/1985/  
 /N88462/001/  
 /JAN/03/1985/

/SULFABENZAMIDE;/SULFACETAMIDE;/SULFATHIAZOLE;/UREA/

/CREAM;/VAGINAL/  
 /GYNE-SULF/  
 /AT/ /G/AND/W/ /3.72;2.862;3.422;0.642/ /N88607/001/  
 /JUN/09/1986/  
 /TRIPLE/SULFA/  
 /AT/ /CLAY/PARK/ /3.72;2.862;3.422;0.642/ /N87285/001/  
 /NOV/15/1982/  
 /AT/ /FOUSERA/ /3.72;2.862;3.422;0.642/ /N86424/001/  
 /AT/ /NMC/ /3.72;2.862;3.422;0.642/ /N87864/001/  
 /SEP/01/1982/  
 /AT/ /PHARMADERM/ /3.72;2.862;3.422;0.642/ /N87887/001/  
 /JUL/23/1982/  
 /VAGIT/IA/  
 /AT/ /LEMON/ /3.72;2.862;3.422;0.642/ /N88821/001/  
 /NOV/09/1987/

SULFAMETHIZOLE

TABLET; ORAL  
 /PROK/AB/  
 /66/ /FOREST/PHARMS/ /500MG/  
 2 FOREST PHARMS 500MG /N80273/001/

THIOSULFYL  
 /66/ /WYETH/AYERST/ /500MG/  
 + WYETH AYERST 500MG /N88565/004/

SULFAMETHOXAZOLE

## TABLET; ORAL

SULFAMETHOXAZOLE

|         |      |            |         |              |
|---------|------|------------|---------|--------------|
| > DLT > | /AB/ | /HEATHER/  | /500MG/ | /N86163/001/ |
| > ADD > |      | 3 HEATHER  | 500MG   | N86163 001   |
|         | /AB/ | /SHIONOGI/ | /500MG/ | /N87307/001/ |
|         |      | 3 SHIONOGI | 500MG   | N87307 001   |

SULFAMETHOXAZOLE; TRIMETHOPRIM

## INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

|         |                 |                   |                   |
|---------|-----------------|-------------------|-------------------|
| AP      | CETUS BEN VENUE | 80MG/ML;16MG/ML   | N72383 001        |
|         |                 |                   | APR 29, 1992      |
| > ADD > | AP              | FUJISAWA          | 80MG/ML;16MG/ML   |
| > ADD > |                 |                   | N70223 001        |
|         |                 |                   | JAN 16, 1987      |
| > DLT > | /AB/            | /LYPHONED/        | /80MG/ML;16MG/ML/ |
| > DLT > |                 |                   | /N70223/001/      |
|         | AP              | STERLING WINTHROP | 80MG/ML;16MG/ML   |
|         |                 |                   | /JAN 16, 1987/    |
|         |                 |                   | N73199 001        |
|         |                 |                   | SEP 11, 1992      |

## TABLET; ORAL

SULFAMETHOXAZOLE & TRIMETHOPRIM

|         |      |           |               |                |
|---------|------|-----------|---------------|----------------|
| > DLT > | /AB/ | /HEATHER/ | /400MG;80MG/  | /N18946/001/   |
| > DLT > |      |           |               | /AUG 10, 1984/ |
| > DLT > | /AB/ |           | /800MG;160MG/ | /N18946/002/   |
| > DLT > |      |           |               | /AUG 10, 1984/ |
| > ADD > |      | 3 HEATHER | 400MG;80MG    | N18946 001     |
| > ADD > |      |           |               | AUG 10, 1984   |
| > ADD > |      | 3         | 800MG;160MG   | N18946 002     |
| > ADD > |      |           |               | AUG 10, 1984   |

SULFAMETHOXAZOLE AND TRIMETHOPRIM

|      |              |               |                |
|------|--------------|---------------|----------------|
| AB   | EON LABS     | 400MG;80MG    | N18598 001     |
|      |              |               | MAY 19, 1982   |
| /AB/ | /INTERPHARM/ | /400MG;80MG/  | /N71299/001/   |
|      |              |               | /OCT 27, 1987/ |
| /AB/ |              | /800MG;160MG/ | /N71300/001/   |
|      |              |               | /OCT 27, 1987/ |
| B*   | INTERPHARM   | 400MG;80MG    | N71299 001     |
|      |              |               | OCT 27, 1987   |
| B*   |              | 800MG;160MG   | N71300 001     |
|      |              |               | OCT 27, 1987   |
| /AB/ | /MARTEC/     | /400MG;80MG/  | /N72408/001/   |
|      |              |               | /DEC 07, 1988/ |
|      | 3 MARTEC     | 400MG;80MG    | N72408 001     |
|      |              |               | DEC 07, 1988   |

SULFAMETHOXAZOLE; TRIMETHOPRIM

## TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

|      |                |               |                |
|------|----------------|---------------|----------------|
| /B*/ | /PHARM/BASICS/ | /400MG;80MG/  | /N70203/001/   |
|      |                |               | /NOV 08, 1985/ |
| /B*/ |                | /800MG;160MG/ | /N70204/001/   |
|      |                |               | /NOV 08, 1985/ |
|      | 3 PHARM BASICS | 400MG;80MG    | N70203 001     |
|      |                |               | NOV 08, 1985   |
|      | 3              | 800MG;160MG   | N70204 001     |
|      |                |               | NOV 08, 1985   |
| /AB/ | /VITARINE/     | /400MG;80MG/  | /N18598/001/   |
|      |                |               | /MAY 19, 1982/ |

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH

|      |            |               |                |
|------|------------|---------------|----------------|
| AB   | EON LABS   | 800MG;160MG   | N18598 004     |
|      |            |               | MAY 19, 1982   |
| /AB/ | /MARTEC/   | /800MG;160MG/ | /N72417/001/   |
|      |            |               | /DEC 07, 1988/ |
|      | 3 MARTEC   | 800MG;160MG   | N72417 001     |
|      |            |               | DEC 07, 1988   |
| /AB/ | /VITARINE/ | /800MG;160MG/ | /N18598/004/   |
|      |            |               | /MAY 19, 1982/ |

SULFASALAZINE

## TABLET; ORAL

SULFASALAZINE

|  |              |         |              |
|--|--------------|---------|--------------|
|  | 3 EON LABS   | 500MG   | N86184 001   |
|  | /3/VITARINE/ | /500MG/ | /N86184/001/ |

SULFISOXAZOLE

## TABLET; ORAL

SULFALAB

|      |               |         |              |
|------|---------------|---------|--------------|
| /AB/ | /PARKE/DAVIS/ | /500MG/ | /N84955/001/ |
|      | 3 PARKE DAVIS | 500MG   | N84955 001   |
| /AB/ | /WEST/WARD/   | /500MG/ | /N80379/001/ |
|      | 3 WEST WARD   | 500MG   | N80379 001   |

SULINDAC

## TABLET; ORAL

SULINDAC

|    |        |       |              |
|----|--------|-------|--------------|
| AB | LEMMON | 150MG | N72972 001   |
|    |        |       | FEB 28, 1992 |
| AB |        | 200MG | N72973 001   |
|    |        |       | FEB 28, 1992 |

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'92 - DEC'92

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> ADD > SUMATRIPTAN SUCCINATE

> ADD > INJECTABLE; INJECTION  
> ADD > IMITREX  
> ADD > GLAXO  
> ADD >

EQ 6MG BASE/0.5MLM

N20080 001  
DEC 28, 1992

TALBUTAL

/TABLET; ORAL/  
/LOTUSATE/  
/STERLING/  
@ STERLING

/120MG/  
120MG

/N09410/005/  
N09410 005

TECHNETIUM TC-99M ETIDRONATE KIT

INJECTABLE; INJECTION  
OSTEOSCAN  
/MALLINCKRODT/  
@ MALLINCKRODT

/N/A/  
N/A

/N17454/001/  
N17454 001

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION  
RBC-SCAN  
CADEMA

N/A

N20063 001  
JUN 11, 1992

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION  
CARDIOLITE  
/DUPONT/  
DUPONT MERCK

/N/A/  
N/A

/N19785/001/  
DEC 21, 1990  
N19785 001  
DEC 21, 1990

TEMAFLOXACIN HYDROCHLORIDE

TABLET; ORAL  
OMNIFLOX  
/+/ABBOTT/

/EQ/600MG/BASEP/  
/EQ/400MG/BASEP/

/N20043/004/  
JAN 30, 1992  
/N20043/004/  
JAN 30, 1992

TEMAFLOXACIN HYDROCHLORIDE

TABLET; ORAL  
OMNIFLOX  
@ ABBOTT  
@

EQ 400MG BASEM  
EQ 600MG BASEM

N20043 003  
JAN 30, 1992  
N20043 004  
JAN 30, 1992

TEMAZEPAM

CAPSULE; ORAL  
TEMAZEPAM

/B\*/ /PHARM/BASICS/  
/B\*/

/15MG/  
/30MG/

@ PHARM BASICS  
@

15MG  
30MG

/N70489/001/  
JUL 07, 1986  
/N70490/001/  
JUL 07, 1986  
N70489 001  
JUL 07, 1986  
N70490 001  
JUL 07, 1986

TENIPOSIDE

INJECTABLE; INJECTION  
VUMON

BRISTOL MYERS SQUIBB 10MG/MLM

N20119 001  
JUL 14, 1992

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL  
HYTRIN  
+ ABBOTT

2MG

/+/

/10MG/  
/2MG/  
10MG

N19057 002  
AUG 07, 1987  
/N19057/004/  
AUG 07, 1987  
/N19057/002/  
AUG 07, 1987  
N19057 004  
AUG 07, 1987

> ADD > TERBINAFINE HYDROCHLORIDE

> ADD > CREAM; TOPICAL  
> ADD > LAMISIL  
> ADD > + SANDOZ  
> ADD >

1/2M

N20192 001  
DEC 30, 1992

TERBUTALINE SULFATE

## INJECTABLE; INJECTION

|         |     |          |          |              |
|---------|-----|----------|----------|--------------|
| > DLT > | AB/ | BRETHINE | /1MG/ML/ | /N18571/001/ |
| > ADD > | AP  | + GEIGY  | 1MG/ML   | N18571 001   |

TESTOSTERONE ENANTHATE

## INJECTABLE; INJECTION

|      |         |            |              |
|------|---------|------------|--------------|
| AO   | GYNEX   | 200MG/ML   | N09165 003   |
|      |         | 200MG/ML   | N09165 001   |
| /AB/ | /301BB/ | /200MG/ML/ | /N09165/003/ |
| /2/  |         | /200MG/ML/ | /N09165/001/ |

TETRACYCLINE

## SYRUP; ORAL

|      |              |                    |              |
|------|--------------|--------------------|--------------|
| /AB/ | /BIOCYCLINE/ | /EQ 125MG HCL/5ML/ | /N60633/001/ |
|      | /BARRE/      |                    |              |
| AB   | TETRACYCLINE | EQ 125MG HCL/5ML   | N60633 001   |
|      | BARRE        |                    |              |

TETRACYCLINE HYDROCHLORIDE

## CAPSULE; ORAL

|      |                   |         |              |
|------|-------------------|---------|--------------|
| /AB/ | /CYCLOPAR/        | /250MG/ | /N61725/001/ |
| /AB/ | /PARKE/DAVIS/     | /250MG/ | /N62175/001/ |
| /AB/ |                   | /250MG/ | /N62332/001/ |
| /AB/ |                   | /500MG/ | /N61725/002/ |
| /AB/ |                   | /500MG/ | /N62332/002/ |
|      | 3 WARNER CHILCOTT | 250MG   | N61725 001   |
|      | 3                 | 250MG   | N62175 001   |
|      | 3                 | 250MG   | N62332 001   |
|      | 3                 | 500MG   | N61725 002   |
|      | 3                 | 500MG   | N62332 002   |

|      |              |         |              |
|------|--------------|---------|--------------|
| /AB/ | ROBITET      | /250MG/ | /N61734/001/ |
| /AB/ | /ROBINS/     | /500MG/ | /N61734/002/ |
| AB   | WYETH AYERST | 250MG   | N61734 001   |
| AB   |              | 500MG   | N61734 002   |

|         |    |           |       |            |
|---------|----|-----------|-------|------------|
| > ADD > | AB | SUMYCIN   | 250MG | N60429 001 |
| > ADD > | AB | APOTHECON | 500MG | N60429 003 |
|         | 3  |           | 100MG | N60429 002 |
|         | 3  |           | 125MG | N60429 004 |

TETRACYCLINE HYDROCHLORIDE

## CAPSULE; ORAL

|         |         |         |              |
|---------|---------|---------|--------------|
| /AB/    | SUMYCIN | /100MG/ | /N60429/002/ |
| /AB/    | /301BB/ | /125MG/ | /N60429/004/ |
| > DLT > | /AB/    | /250MG/ | /N60429/001/ |
| > DLT > | /AB/    | /500MG/ | /N60429/003/ |

TETRACYCLINE HCL

|         |                 |           |               |
|---------|-----------------|-----------|---------------|
| /AB/    | /VITARINE/      | /250MG/   | /N61471/001/  |
| AB      | EON LABS        | 250MG     | N61471 001    |
| > DLT > | /2/             | /500MG/   | /N61471/002/  |
| > DLT > |                 |           | /SEP/06/1988/ |
| > DLT > | /AB/            | /HEATHER/ | /250MG/       |
| > DLT > | /AB/            |           | /500MG/       |
| > ADD > | 3 HEATHER       | 250MG     | N61148 001    |
| > ADD > | 3               | 500MG     | N61148 002    |
| /AB/    | /MK/            | /125MG/   | /N60173/001/  |
|         | MK              | 125MG     | N60173 001    |
| /AB/    | /PARKE/DAVIS/   | /250MG/   | /N62300/001/  |
| /AB/    |                 | /500MG/   | /N62300/002/  |
| /AB/    | /RICHLYN/       | /100MG/   | /N60469/002/  |
|         | RICHLYN         | 100MG     | N60469 002    |
| AB      | WARNER CHILCOTT | 250MG     | N62300 001    |
| AB      |                 | 500MG     | N62300 002    |

INJECTABLE; INJECTION/

|      |              |              |              |
|------|--------------|--------------|--------------|
| /AP/ | /ACHROMYCIN/ | /100MG/VIAL/ | /N50267/002/ |
| /AP/ | /LEDERLE/    | /100MG/VIAL/ | /N50276/001/ |
| /AP/ |              | /250MG/VIAL/ | /N50267/003/ |
| /AP/ | /TETRACIN/   | /250MG/VIAL/ | /N60285/003/ |
| /2/  | /PFIZER/     | /100MG/VIAL/ | /N60285/002/ |

THEOPHYLLINE

## CAPSULE, EXTENDED RELEASE; ORAL

|      |                 |         |               |
|------|-----------------|---------|---------------|
| /BC/ | SOMOPHYLLIN-CRT | /50MG/  | /N61763/001/  |
|      | /FISONS/        |         | /FEB/27/1985/ |
| /BC/ |                 | /100MG/ | /N6194/001/   |
| /BC/ |                 | /200MG/ | /N60382/001/  |
|      |                 |         | /FEB/27/1985/ |
| /BC/ |                 | /250MG/ | /N6193/001/   |
| /BC/ |                 | /300MG/ | /N60383/001/  |
|      |                 |         | /FEB/27/1985/ |

THEOPHYLLINECAPSULE, EXTENDED RELEASE; ORAL  
SOMOPHYLLIN-CRT

|              |             |         |                               |
|--------------|-------------|---------|-------------------------------|
| BC           | GRAHAM LABS | 50MG    | N87763 001<br>FEB 27, 1985    |
| BC           |             | 100MG   | N87194 001                    |
| BC           |             | 200MG   | N88382 001<br>FEB 27, 1985    |
| BC           |             | 250MG   | N87193 001                    |
| BC           |             | 300MG   | N88383 001<br>FEB 27, 1985    |
| THEO-24      |             |         |                               |
| /BC/         | /SEARLE/    | /100MG/ | /N87942/001/<br>/AUG/22/1983/ |
| /BC/         |             | /200MG/ | /N87943/001/<br>/AUG/22/1983/ |
| /BC/         |             | /300MG/ | /N87944/001/<br>/AUG/22/1983/ |
|              |             | /400MG/ | /N81034/001/<br>/FEB/28/1992/ |
| BC           | WHITBY      | 100MG   | N87942 001<br>AUG 22, 1983    |
| BC           |             | 200MG   | N87943 001<br>AUG 22, 1983    |
| BC           |             | 300MG   | N87944 001<br>AUG 22, 1983    |
|              |             | 400MG   | N81034 001<br>FEB 28, 1992    |
| THEOPHYLLINE |             |         |                               |
|              | 2 EON LABS  | 260MG   | N87462 001<br>MAY 11, 1982    |
| /2/          | /VITARINE/  | /260MG/ | /N87462/001/<br>/MAY/11/1982/ |

## INJECTABLE; INJECTION

|                                                                |       |              |                            |
|----------------------------------------------------------------|-------|--------------|----------------------------|
| <u>THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |       |              |                            |
| AP                                                             | MCGAW | 40MG/100MLM  | N19826 001<br>AUG 14, 1992 |
| <u>THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |       |              |                            |
| AP                                                             | MCGAW | 80MG/100MLM  | N19826 002<br>AUG 14, 1992 |
| <u>THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |       |              |                            |
| AP                                                             | MCGAW | 160MG/100MLM | N19826 003<br>AUG 14, 1992 |
| <u>THEOPHYLLINE 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER</u>  |       |              |                            |
| AP                                                             | MCGAW | 200MG/100MLM | N19826 004<br>AUG 14, 1992 |
| <u>THEOPHYLLINE 0.32% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |       |              |                            |
| AP                                                             | MCGAW | 320MG/100MLM | N19826 006<br>AUG 14, 1992 |

THEOPHYLLINE

## INJECTABLE; INJECTION

|                                                               |       |              |                            |
|---------------------------------------------------------------|-------|--------------|----------------------------|
| <u>THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER</u> |       |              |                            |
| AP                                                            | MCGAW | 400MG/100MLM | N19826 005<br>AUG 14, 1992 |

## TABLET, EXTENDED RELEASE; ORAL

|        |                  |       |                            |
|--------|------------------|-------|----------------------------|
| T-PHYL |                  |       |                            |
| BC     | PURDUE FREDERICK | 200MG | N88253 001<br>AUG 17, 1983 |

THEO-DUR

|    |              |       |                            |
|----|--------------|-------|----------------------------|
| AB | + KEY PHARMS | 450MG | N89131 001<br>JUN 25, 1986 |
|----|--------------|-------|----------------------------|

|                   |                    |         |                               |
|-------------------|--------------------|---------|-------------------------------|
| <u>THEOCONTIN</u> |                    |         |                               |
| /BC/              | /PURDUE/FREDERICK/ | /200MG/ | /N88253/001/<br>/AUG/17/1983/ |

THEOPHYLLINE

|    |        |       |                            |
|----|--------|-------|----------------------------|
| AB | SIDMAK | 450MG | N81236 001<br>NOV 09, 1992 |
|----|--------|-------|----------------------------|

THIAMINE HYDROCHLORIDE

## INJECTABLE; INJECTION

|                     |               |            |                          |
|---------------------|---------------|------------|--------------------------|
| <u>THIAMINE HCL</u> |               |            |                          |
| /AP/                | /LUITPOLD/    | /100MG/ML/ | /N80667/001/<br>100MG/ML |
| /AP/                | /PARKE/DAVIS/ | /100MG/ML/ | /N80770/001/<br>100MG/ML |

THIORIDAZINE HYDROCHLORIDE

## TABLET; ORAL

|                         |       |         |                               |
|-------------------------|-------|---------|-------------------------------|
| <u>THIORIDAZINE HCL</u> |       |         |                               |
| /AB/                    | /PAR/ | /150MG/ | /N89764/001/<br>/FEB/09/1988/ |
| /AB/                    |       | /200MG/ | /N89765/001/<br>/FEB/09/1988/ |
|                         | 2 PAR | 150MG   | N89764 001<br>FEB 09, 1988    |
|                         | 2     | 200MG   | N89765 001<br>FEB 09, 1988    |



THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL INTENSOL

AA ROXANE EQ 5MG BASE/MLM

N73494 001

JUN 30, 1992

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

/B\*/ /PHARM/BASICS/ /5MG/

/N72001/001/

/JAN/10/1989/

/B\*/ /10MG/

/N72002/001/

/JAN/10/1989/

/B\*/ /20MG/

/N72003/001/

/JAN/10/1989/

a PHARM BASICS 5MG

N72001 001

JAN 10, 1989

a 10MG

N72002 001

JAN 10, 1989

a 20MG

N72003 001

JAN 10, 1989

TIOCONAZOLE

OINTMENT; VAGINAL

VAGISTAT-1

&gt; DLT &gt; /BRISTOL/MYERS/ /6.5%/

/N19355/001/

/DEC/30/1986/

&gt; DLT &gt;

&gt; ADD &gt; BRISTOL MYERS SQUIBB 6.5%

N19355 001

DEC 30, 1986

&gt; ADD &gt;

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

AP ABBOTT EQ 40MG BASE/MLM

N63116 001

MAY 18, 1992

AP GENSLA EQ 40MG BASE/MLM

N63100 001

JAN 30, 1992

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

/AB/ /INTERPHARM/ /250MG/

/N71270/001/

/SEP/23/1986/

/AB/ /500MG/

/N71271/001/

/SEP/23/1986/

B\* INTERPHARM 250MG

N71270 001

SEP 23, 1986

B\* 500MG

N71271 001

SEP 23, 1986

/B\*/ /PHARM/BASICS/ /100MG/

/N71355/001/

/JAN/11/1988/

/B\*/ /250MG/

/N70168/001/

/APR/02/1986/

/B\*/ /500MG/

/N70169/001/

/APR/02/1986/

a PHARM BASICS 100MG

N71355 001

JAN 11, 1988

a 250MG

N70168 001

APR 02, 1986

a 500MG

N70169 001

APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

AB EON LABS 500MG

N12678 001

/AB/ /PARKE/DAVIS/ /500MG/

/N86047/001/

a PARKE DAVIS 500MG

N86047 001

/AB/ /VITARINE/ /500MG/

/N12678/001/

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

AB BAKER CUMMINS EQ 400MG BASEM

N73392 001

JAN 24, 1992

AB GENEVA EQ 400MG BASEM

N73462 001

APR 30, 1992

AB LEMMON EQ 400MG BASEM

N73519 001

MAY 29, 1992

AB PUREPAC EQ 400MG BASEM

N73308 001

JAN 24, 1992

TOLMETIN SODIUMTABLET; ORAL  
TOLECTIN 600

AB + JOHNSON RW

EQ 600MG BASE

N17628 002  
MAR 08, 1989TOLMETIN SODIUM

AB GENEVA

EQ 200MG BASEM

N73588 001  
JUL 31, 1992

AB PUREPAC

EQ 600MG BASEM

N73527 001  
JUN 30, 1992TRAZODONE HYDROCHLORIDETABLET; ORAL  
TRAZODONE HCL

/B\*/ /PHARM/BASICS/

/50MG/

/N70491/001/  
/APR/29/1987/

/B\*/

/100MG/

/N70492/001/  
/APR/29/1987/

Q PHARM BASICS

50MG

N70491 001  
APR 29, 1987

Q

100MG

N70492 001  
APR 29, 1987TRICHLORMETHIAZIDETABLET; ORAL  
TRICHLORMETHIAZIDE

Q EON LABS

4MG

N86171 001  
/N86171/001/

/Q/VITAFINE/

/4MG/

TRIDIHEXETHYL CHLORIDE/TABLET;/ORAL/  
/PATHILON/

/LEDERLE/

/25MG/

/N09489/005/  
N09489 005

Q LEDERLE

25MG

TRIHXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

&gt; DLT &gt; /IREMIN/

&gt; DLT &gt; /66/ /SCHERING/

/4MG/

/N00381/001/  
/N00381/003/

&gt; DLT &gt; /66/

/5MG/

&gt; ADD &gt; Q SCHERING

2MG

N80381 001

&gt; ADD &gt; Q

5MG

N80381 003

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

&gt; DLT &gt; /AP/ /MYETH/AYERST/

&gt; DLT &gt;

&gt; ADD &gt; AP

SOLOPAK MEDCL

100MG/ML

&gt; ADD &gt;

/N89094/001/  
/APR/04/1986/  
N89094 001  
APR 04, 1986TRIMIPRAMINE MALEATE

CAPSULE; ORAL

SURMONTIL

/AB/ /MYETH/AYERST/

/AB/

/AB/ /3/

/EQ 25MG BASE/

/EQ 50MG BASE/

/EQ 100MG BASE/

/N16792/001/  
/N16792/002/  
/N16792/003//SEP/15/1982/  
N16792 003

+ MYETH AYERST

EQ 100MG BASE

SEP 15, 1982

EQ 25MG BASE

N16792 001

EQ 50MG BASE

N16792 002

/TRIMIPRAMINE/MALEATE/

/B\*/ /PHARM/BASICS/

/EQ 25MG/BASE/

/N71283/001/  
/DEC/08/1987/

/B\*/

/EQ 50MG/BASE/

/N71284/001/  
/DEC/08/1987/

/B\*/

/EQ 100MG/BASE/

/N71285/001/  
/DEC/08/1987/

TRIMIPRAMINE MALEATE

/Q/EON/LABS/

/EQ 25MG/BASE/

/N71832/001/  
/SEP/10/1987/

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

/Q/

/EQ 50MG/BASE/

/N71833/001/  
/SEP/10/1987/

/Q/

/EQ 100MG/BASE/

/N71834/001/  
/SEP/10/1987/

Q PHARM BASICS

EQ 25MG BASE

N71283 001  
DEC 08, 1987

Q

EQ 50MG BASE

N71284 001  
DEC 08, 1987

Q

EQ 100MG BASE

N71285 001  
DEC 08, 1987TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL

GYNE-SULF

AT G AND M

3.7%;2.86%;3.42%

N88607 001  
JUN 09, 1986SULTRIN

AT JOHNSON RW

3.7%;2.86%;3.42%

N05794 001

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL  
TRIPLE SULFA  
 AI CLAY PARK 3.7%;2.86%;3.42% N87285 001  
 NOV 15, 1982  
 AI FOUGERA 3.7%;2.86%;3.42% N86424 001  
 AI NYC 3.7%;2.86%;3.42% N87864 001  
 SEP 01, 1982  
 AI TRYSUL  
 SAVAGE 3.7%;2.86%;3.42% N87887 001  
 JUL 23, 1982  
 VAGILIA  
 3 LEMMON 3.7%;2.86%;3.42% N88821 001  
 NOV 09, 1987

TABLET; VAGINAL  
 SULTRIN  
 JOHNSON RW 184MG;143.75MG;172.5MG N05794 002  
 TRIPLE SULFA  
 3 FOUGERA 184MG;143.75MG;172.5MG N88463 001  
 JAN 03, 1985  
 3 PHARMADERM 184MG;143.75MG;172.5MG N88462 001  
 JAN 03, 1985

TRISULFAPYRIMIDINES

SUSPENSION; ORAL  
SULFALOID  
 /AB/ /FOREST/PHARMS/ /500MG/5ML/ /N86100/001/  
 3 FOREST PHARMS 500MG/5ML N80100 001

URACIL MUSTARD

CAPSULE; ORAL  
 URACIL MUSTARD  
 ROBERTS 1MG N12892 001  
 /UPJOHN/ /1MG/ /N12892/001/

VALPROIC ACID

SYRUP; ORAL  
VALPROIC ACID  
 AA COPLEY 250MG/5ML N73178 001  
 AUG 25, 1992

VANCOMYCIN HYDROCHLORIDE

## INJECTABLE; INJECTION

VANCOMYCIN HCL

AP ABBOTT EQ 500MG BASE/VIAL N62931 001  
 OCT 29, 1992  
 AP EQ 1GM BASE/VIAL N62933 001  
 OCT 29, 1992  
 > DLT > /VANDER/ /EQ 500MG BASE/VIAL/ /N62956/001/  
 > DLT > /ADRIA/ /AUG/01/1988/  
 > DLT > /EQ 1GM BASE/VIAL/ /N62956/002/  
 > DLT > /AUG/01/1988/  
 > ADD > 3 ADRIA EQ 500MG BASE/VIAL N62956 001  
 > ADD > EQ 1GM BASE/VIAL N62956 002  
 > ADD > AUG 01, 1988  
 > ADD > N62956 002  
 > ADD > AUG 01, 1988

VECURONIUM BROMIDE

## INJECTABLE; INJECTION

## NORCURON

## ORGANON

20MG/VIAL

N18776 003  
JAN 03, 1992VERAPAMIL HYDROCHLORIDE

## CAPSULE, EXTENDED RELEASE; ORAL

## VERELAN

## + ELAN

180MG

N19614 003  
JAN 09, 1992

## INJECTABLE; INJECTION

VERAPAMIL HCL

> DLT > /AP/ /SMITH/NEHEW/SOLOPAK 2.5MG/ML/ /N70695/001/  
 > DLT > /JUL/31/1987/  
 > ADD > AP SOLOPAK MEDCL 2.5MG/ML N70695 001  
 > ADD > JUL 31, 1987

## TABLET; ORAL

VERAPAMIL HCL

/B\*/ /CHELSEA/

/80MG/

/N70421/001/  
/SEP/17/1986/  
/N70422/001/  
/SEP/17/1986/  
N73168 001  
JUL 31, 1992

/B\*/

/120MG/

AB

GENEVA

40MG

VERAPAMIL HYDROCHLORIDE

## TABLET; ORAL

|         |                   |         |                |
|---------|-------------------|---------|----------------|
| > DLT > | VERAPAMIL HCL     |         |                |
| > DLT > | /2/PARKE/DAVIS/   | /80MG/  | /N70340/001/   |
| > DLT > |                   |         | /AUG/20,/1986/ |
| > DLT > | /2/               | /120MG/ | /N70341/001/   |
| > DLT > |                   |         | /AUG/20,/1986/ |
| > ADD > | 2 WARNER CHILCOTT | 80MG    | N70340 001     |
| > ADD > |                   |         | AUG 20, 1986   |
| > ADD > | 2                 | 120MG   | N70341 001     |
| > ADD > |                   |         | AUG 20, 1986   |

## TABLET, EXTENDED RELEASE; ORAL

ISOPTIN SR

|    |         |       |              |
|----|---------|-------|--------------|
| AB | + KNOLL | 240MG | N19152 001   |
|    |         |       | DEC 16, 1986 |

VERAPAMIL HCL

|    |               |       |              |
|----|---------------|-------|--------------|
| AB | BAKER CUMMINS | 240MG | N73568 001   |
|    |               |       | JUL 31, 1992 |

VINBLASTINE SULFATE

## INJECTABLE; INJECTION

|      |          |             |                |
|------|----------|-------------|----------------|
| /AP/ | /VELSAR/ |             |                |
| /AP/ | /BULL/   | /10MG/VIAL/ | /N89565/001/   |
|      |          |             | /AUG/18,/1987/ |

VINBLASTINE SULFATE

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

VINCRIStINE SULFATE

## INJECTABLE; INJECTION

VINCRIStINE SULFATE

|      |        |          |                |
|------|--------|----------|----------------|
| /AP/ | /ABIC/ | /1MG/ML/ |                |
|      |        |          | /N70873/001/   |
|      |        |          | /FEB/19,/1987/ |
|      | 2 ABIC | 1MG/ML   | N70873 001     |
|      |        |          | FEB 19, 1987   |

VITAMIN A

## CAPSULE; ORAL

AQUASOL A

|      |       |                    |              |
|------|-------|--------------------|--------------|
| AA   | ASTRA | 50,000 USP UNITS   | N83080 001   |
|      |       | 25,000 USP UNITS   | N83080 002   |
| /AA/ | /U39/ | /50,000 USP UNITS/ | /N83080/001/ |
|      |       | /25,000 USP UNITS/ | /N83080/002/ |

VITAMIN A PALMITATE

## CAPSULE; ORAL

## VITAMIN A

|             |                            |                        |              |
|-------------|----------------------------|------------------------|--------------|
|             | 2 ELKINS SINN              | EQ 50,000 UNITS BASE   | N85479 001   |
|             | /2/QUANTUM/PHARMICS/       | /EQ/50,000/UNITS/BASE/ | /N85479/001/ |
|             | <u>VITAMIN A PALMITATE</u> |                        |              |
| > DLT >/AA/ | /BANNER/                   | /EQ/50,000/UNITS/BASE/ | /N83981/001/ |
| > ADD >     | 2 BANNER GELATIN           | EQ 50,000 UNITS BASE   | N83981 001   |

WARFARIN SODIUM

## TABLET; ORAL

WARFARIN SODIUM

|      |                |         |                |
|------|----------------|---------|----------------|
| /B*/ | /PHARM/BASICS/ | /2MG/   | /N88719/001/   |
|      |                |         | /JUN/27,/1985/ |
| /B*/ |                | /2.5MG/ | /N88720/001/   |
|      |                |         | /AUG/06,/1985/ |
| /B*/ |                | /5MG/   | /N88721/001/   |
|      |                |         | /JUL/02,/1985/ |
|      | 2 PHARM BASICS | 2MG     | N88719 001     |
|      |                |         | JUN 27, 1985   |
|      | 2              | 2.5MG   | N88720 001     |
|      |                |         | AUG 06, 1985   |
|      | 2              | 5MG     | N88721 001     |
|      |                |         | JUL 02, 1985   |

XENON, XE-133

|         |                                   |                |              |
|---------|-----------------------------------|----------------|--------------|
| > DLT > | /SOLUTION;/INHALATION;/INJECTION/ |                |              |
| > DLT > | /XENESOL/                         |                |              |
| > DLT > | /MALLINCKRODT/                    | /18-25MCI/AMP/ | /N17262/002/ |
| > ADD > | 2 MALLINCKRODT                    | 18-25MCI/AMP   | N17262 002   |

ZALCITABINE

## TABLET; ORAL

## HIVID

## + ROCHE

|         |              |
|---------|--------------|
| 0.75MG  | N20199 002   |
|         | JUN 19, 1992 |
| 0.375MG | N20199 001   |
|         | JUN 19, 1992 |

> ADD > ZOLPIDEM TARTRATE> ADD > TABLET; ORAL> ADD > AMBIEN> ADD > + LOREX

10MGx

N19908 002

> ADD >

DEC 16, 1992

> ADD >

5MGx

N19908 001

> ADD >

DEC 16, 1992

ACETAMINOPHEN

SUPPOSITORY; RECTAL  
ACEPHEN

|         |           |                  |                          |
|---------|-----------|------------------|--------------------------|
| > ADD > | + G AND M | 120MG            | N18060 001               |
| > ADD > | +         | 325MG            | N18060 003               |
| > ADD > |           |                  | DEC 18, 1986             |
| > ADD > | +         | 650MG            | N18060 002               |
| > DLT > |           | <del>120MG</del> | <del>N18060/001/</del>   |
|         |           | 120MG            | N72218 001               |
|         |           |                  | MAR 27, 1992             |
| > DLT > |           | <del>120MG</del> | <del>N18060/003/</del>   |
| > DLT > |           |                  | <del>DEC 18, 1986/</del> |
|         |           | 325MG            | N72344 001               |
|         |           |                  | MAR 27, 1992             |
| > DLT > |           | <del>650MG</del> | <del>N18060/002/</del>   |
|         |           | 650MG            | N72237 001               |
|         |           |                  | MAR 27, 1992             |

> ADD > AVOBENZONE; OCTYL METHOXYCINNAMATE; OXYBENZONE

|         |                 |              |              |
|---------|-----------------|--------------|--------------|
| > ADD > | LOTION; TOPICAL |              |              |
| > ADD > | SHADE UVAGUARD  |              |              |
| > ADD > | PLOUGH          | 3%; 7.5%; 3% | N20045 001   |
| > ADD > |                 |              | DEC 07, 1992 |

BACITRACIN ZINC; LIDOCAINE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

/OINTMENT; TOPICAL/  
/LANABiotic/  
/COMBE/

|         |  |                                                   |                          |
|---------|--|---------------------------------------------------|--------------------------|
|         |  | <del>400 UNITS/GM; 40MG/GM; EQ 5MG BASE/GM/</del> | <del>N62499/001/</del>   |
|         |  | <del>5,000 UNITS/GM/</del>                        | <del>JUN 03, 1985/</del> |
| 2 COMBE |  | 400 UNITS/GM; 40MG/GM; EQ 5MG BASE/GM             | N62499 001               |
|         |  | 5,000 UNITS/GM                                    | JUN 03, 1985             |

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL  
MICROCOL

|                     |      |                          |
|---------------------|------|--------------------------|
| JOHNSON AND JOHNSON | 0.5% | N72292 001               |
|                     |      | JAN 28, 1992             |
| STERI-STAT          |      |                          |
| MATRIX MEDCL        | 4%   | N70104 001               |
|                     |      | JUL 24, 1986             |
| /MEDCL/SYSTEMS/     | 1%   | <del>N70104/001/</del>   |
|                     |      | <del>JUL 24, 1986/</del> |

CLEMASTINE FUMARATE

|         |                     |        |              |
|---------|---------------------|--------|--------------|
| > ADD > | TABLET; ORAL        |        |              |
| > ADD > | CLEMASTINE FUMARATE |        |              |
| > ADD > | LEMMON              | 1.34MG | N73282 002   |
|         |                     |        | DEC 03, 1992 |
|         | TAVIST-1            |        |              |
|         | SANDOZ              | 1.34MG | N17661 003   |
|         |                     |        | AUG 21, 1992 |

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

|                                |              |  |              |
|--------------------------------|--------------|--|--------------|
| TABLET, EXTENDED RELEASE; ORAL |              |  |              |
| TAVIST-D                       |              |  |              |
| SANDOZ                         | 1.34MG; 75MG |  | N18298 002   |
|                                |              |  | AUG 21, 1992 |

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

|                                |            |  |                          |
|--------------------------------|------------|--|--------------------------|
| TABLET, EXTENDED RELEASE; ORAL |            |  |                          |
| /RESPORAL/                     |            |  |                          |
| /PIONEER/PHARMS/               | 6MG; 120MG |  | <del>N89139/001/</del>   |
|                                |            |  | <del>JUN 16, 1988/</del> |
| 2 PIONEER PHARMS               | 6MG; 120MG |  | N89139 001               |
|                                |            |  | JUN 16, 1988             |

DIPHENHYDRAMINE HYDROCHLORIDE

|                     |            |  |              |
|---------------------|------------|--|--------------|
| SYRUP; ORAL         |            |  |              |
| DIPHENHYDRAMINE HCL |            |  |              |
| CUMBERLAND SWAN     | 12.5MG/5ML |  | N73611 001   |
|                     |            |  | AUG 20, 1992 |
| SILPHEN             |            |  |              |
| SILARX              | 12.5MG/5ML |  | N72646 001   |
|                     |            |  | FEB 27, 1992 |

DOXYLAMINE SUCCINATE

|         |                 |       |                          |
|---------|-----------------|-------|--------------------------|
| > DLT > | /CAPSULE; ORAL/ |       |                          |
| > DLT > | /UNISON/        |       |                          |
| > DLT > | /PFIZER/        | 125MG | <del>N19440/001/</del>   |
| > DLT > |                 |       | <del>FEB 05, 1986/</del> |
| > ADD > | 2 PFIZER        | 25MG  | N19440 001               |
| > ADD > |                 |       | FEB 05, 1986             |

IBUPROFEN

|         |                |         |                |
|---------|----------------|---------|----------------|
|         | TABLET; ORAL   |         |                |
|         | IBUPROFEN      |         |                |
| > DLT > | /CHELSEA/      | /200MG/ | /N76665/001/   |
| > DLT > |                |         | /MAY/07./1986/ |
|         | /MEDICOPHARMA/ | /200MG/ | /N71639/001/   |
|         |                |         | /FEB/02./1988/ |
|         | TAG            | 200MG   | N73141 001     |
|         |                |         | MAY 29, 1992   |
|         | VINTAGE        | 200MG   | N71639 001     |
|         |                |         | FEB 02, 1988   |

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

|         |              |            |              |
|---------|--------------|------------|--------------|
|         | TABLET; ORAL |            |              |
|         | SINE-AID IB  |            |              |
| > ADD > | MCNEIL       | 200MG;30MG | N19899 001   |
| > ADD > |              |            | DEC 31, 1992 |
| > ADD > |              |            |              |

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

|  |                       |                         |              |
|--|-----------------------|-------------------------|--------------|
|  | INJECTABLE; INJECTION |                         |              |
|  | HUMULIN 50/50         |                         |              |
|  | LILLY                 | 50 UNITS/ML;50 UNITS/ML | N20100 001   |
|  |                       |                         | APR 29, 1992 |

LOPERAMIDE HYDROCHLORIDE

|         |                |         |              |
|---------|----------------|---------|--------------|
|         | SOLUTION; ORAL |         |              |
|         | LOPERAMIDE HCL |         |              |
|         | BARRE          | 1MG/5ML | N73187 001   |
|         |                |         | SEP 15, 1992 |
|         | PERRIGO        | 1MG/5ML | N73243 001   |
|         |                |         | JAN 21, 1992 |
|         | ROXANE         | 1MG/5ML | N73079 001   |
|         |                |         | APR 30, 1992 |
|         | TABLET; ORAL   |         |              |
|         | LOPERAMIDE HCL |         |              |
| > ADD > | OHM            | 2MG     | N74091 001   |
| > ADD > |                |         | DEC 10, 1992 |
|         | PERRIGO        | 2MG     | N74194 001   |
|         |                |         | OCT 30, 1992 |

MICONAZOLE NITRATE

|  |                    |    |  |
|--|--------------------|----|--|
|  | CREAM; VAGINAL     |    |  |
|  | MICONAZOLE NITRATE |    |  |
|  | COPLEY             | 2% |  |

N74030 001  
OCT 30, 1992

PSEUDOEPHEDRINE HYDROCHLORIDE

|         |                                |       |  |
|---------|--------------------------------|-------|--|
|         | TABLET, EXTENDED RELEASE; ORAL |       |  |
|         | PSEUDOEPHEDRINE HCL            |       |  |
| > ADD > | ALZA                           | 240MG |  |
| > ADD > |                                |       |  |
| > ADD > |                                |       |  |

N20021 002  
DEC 15, 1992

SODIUM CHLORIDE

|  |                              |      |  |
|--|------------------------------|------|--|
|  | AEROSOL, METERED; INHALATION |      |  |
|  | BRONCHO SALINE               |      |  |
|  | BLAIREX                      | 0.9% |  |

N19912 001  
SEP 03, 1992

SODIUM MONOFLUOROPHOSPHATE

|  |                       |      |  |
|--|-----------------------|------|--|
|  | PASTE; DENTAL         |      |  |
|  | EXTRA-STRENGTH AIM    |      |  |
|  | /3/CHESEBROUGH/PONDS/ | 1.2% |  |
|  | CHESEBROUGH PONDS     | 1.2% |  |

/N19518/001/  
/JUN/03./1987/  
N19518 001  
JUN 03, 1987

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST  
CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

DEXTRAN 40, 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION  
LMD IN PLASTIC CONTAINER  
ABBOTT LABS 10GM/100ML;0.9GM/100ML N72562  
OCT 30, 1992

DEXTRAN 40, 10% IN DEXTROSE 5%

INJECTABLE; INJECTION  
LMD IN PLASTIC CONTAINER  
ABBOTT LABS 10GM/100ML;5GM/100ML N72563  
OCT 30, 1992

DEXTRAN 75 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION  
6% GENTRAN 75 AND 10% TRAVER  
TRAVENOL LABS 6GM/100ML;10GM/100ML; N08788  
0.9GM/100ML

UROKINASE

INJECTABLE; INJECTION  
BREOKINASE  
STERLING DRUG 250,000 IU/VIAL N17873



## ORPHAN DRUG PRODUCT DESIGNATIONS

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

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

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

## ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS  
[Approved for Marketing\*]  
[Exclusive Approval\*\*]

| NAME OF BIOLOGICAL                                       | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                               | SPONSOR NAME                    |
|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| GENERIC: AI-RSA<br>TRADE: NOT ESTABLISHED                | TREATMENT OF AUTOIMMUNE UVEITIS.                                                                                                                           | AUTOIMMUNE, INC                 |
| GENERIC: ALDESLEUKIN<br>TRADE: PROLEUKIN*/**             | TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.*/** [MAY 05, 1999]                                                           | CETUS                           |
| GENERIC: ANANAIN, COMOSAIN<br>TRADE: VIANAIN             | FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.                                                                                                             | GENZYME CORPORATION             |
| GENERIC: ANTIHEMOPHILIC FACTOR, HUMAN<br>TRADE: HUMATE P | TREATMENT OF PATIENTS WITH VON WILLEBRAND'S DISEASE.                                                                                                       | BEHRINGWERKE AKTIENGESELLSCHAFT |
| GENERIC: ANTITHROMBIN III<br>TRADE: THROMBATE III*/**    | USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996] | CUTTER BIOLOGICAL               |

## ORPHAN DRUG PRODUCT DESIGNATIONS

## BIOLOGICAL DESIGNATIONS

| NAME OF BIOLOGICAL                                                                     | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                                                                                   | SPONSOR NAME                    |
|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| GENERIC: BOTULINUM TOXIN TYPE A<br>TRADE: NOT ESTABLISHED                              | TREATMENT OF SYNKINETIC CLOSURE OF THE EYELID ASSOCIATED WITH VII CRANIAL NERVE ABERRANT REGENERATION.                                                                                                         | BIOPURE CORPORATION             |
| GENERIC: BOTULINUM TOXIN TYPE B<br>TRADE: NOT ESTABLISHED                              | TREATMENT OF CERVICAL DYSTONIA.                                                                                                                                                                                | ATHENA NEUROSCIENCES, INC       |
| GENERIC: CILIARY NEUROTROPHIC FACTOR<br>TRADE: NOT ESTABLISHED                         | TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.                                                                                                                                                                    | ROGENERON PHARMACEUTICALS, INC  |
| GENERIC: CILIARY NEUROTROPHIC FACTOR, RECOMBINANT HUMAN<br>TRADE: NOT ESTABLISHED      | TREATMENT OF SPINAL MUSCULAR ATROPHIES.<br>TREATMENT OF MOTOR NEURON DISEASE (INCLUDING AMYOTROPHIC LATERAL SCLEROSIS, PROGRESSIVE MUSCULAR ATROPHY, PROGRESSIVE BULBAR PALSY, AND PRIMARY LATERAL SCLEROSIS). | SYNTEX-SYNERGEN NEUROSCIENCE    |
| GENERIC: COAGULATION FACTOR IX<br>TRADE: MONONINE*/**                                  | REPLACEMENT TREATMENT AND PROPHYLAXIS OF THE HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B.<br>[AUG 20, 1999]                                                                                                      | ARMOUR PHARMACEUTICAL           |
| GENERIC: CYSTIC FIBROSIS GENE THERAPY<br>TRADE: NOT ESTABLISHED                        | TREATMENT OF CYSTIC FIBROSIS.                                                                                                                                                                                  | GENZYME CORPORATION             |
| GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR<br>TRADE: NOT ESTABLISHED | FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.                                                                                               | GENZYME CORPORATION             |
| GENERIC: C1-ESTERASE INHIBITOR, HUMAN, PASTEURIZED<br>TRADE: NOT ESTABLISHED           | PREVENTION AND/OR TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA.                                                                                                                                         | BEHRINGWERKE AKTIENGESellschaft |

## ORPHAN DRUG PRODUCT DESIGNATIONS

## BIOLOGICAL DESIGNATIONS

| NAME OF BIOLOGICAL                                                                          | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                                                                                                                                                                                                             | SPONSOR NAME                         |
|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| GENERIC: HERPES SIMPLEX VIRUS GENE<br>TRADE: NOT ESTABLISHED                                | TREATMENT OF PRIMARY AND METASTATIC BRAIN TUMORS.                                                                                                                                                                                                                                                                                        | GENETIC THERAPY, INC                 |
| GENERIC: HIV NEUTRALIZING ANTIBODIES<br>TRADE: IMMUPATH                                     | TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).                                                                                                                                                                                                                                                                                  | HEMACARE CORPORATION                 |
| GENERIC: HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN<br>TRADE: NOT ESTABLISHED             | TREATMENT OF HIV-INFECTED PREGNANT WOMEN AND INFANTS OF HIV-INFECTED MOTHERS.                                                                                                                                                                                                                                                            | NORTH AMERICAN BIOLOGICALS           |
| GENERIC: IMMUNE GLOBULIN INTRAVENOUS, HUMAN<br>TRADE: IVEEGAM, IMMUNO                       | TREATMENT OF POLYMYOSITIS/DERMATOMYOSITIS.<br>TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.                                                                                                                                                                                                                                                | IMMUNO CLINICAL RESEARCH CORPORATION |
| GENERIC: IMPORTED FIRE ANT VENOM, ALLERGENIC EXTRACT<br>TRADE: NOT ESTABLISHED              | FOR SKIN TESTING OF VICTIMS OF FIRE ANT STINGS TO CONFIRM FIRE ANT SENSITIVITY AND IF POSITIVE, FOR USE AS IMMUNOTHERAPY FOR THE PREVENTION OF IgE-MEDIATED ANAPHYLACTIC REACTIONS.                                                                                                                                                      | ALK LABORATORIES, INC                |
| GENERIC: INTERFERON (RECOMBINANT HUMAN, BETA)<br>TRADE: NOT ESTABLISHED                     | TREATMENT OF ACUTE NON-A, NON-B HEPATITIS.                                                                                                                                                                                                                                                                                               | BIOGEN, INC                          |
| GENERIC: INTERFERON BETA (RECOMBINANT)<br>TRADE: R-FRONE                                    | TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM <sup>3</sup> .                                                                                                                                                                        | SERONO LABORATORIES, INC             |
| GENERIC: INTERLEUKIN-1 RECEPTOR ANTAGONIST, HUMAN RECOMBINANT<br>TRADE: ANTRIL              | PREVENTION AND TREATMENT OF GRAFT VERSUS HOST DISEASE IN TRANSPLANT RECIPIENTS.                                                                                                                                                                                                                                                          | SYNERGEN, INC                        |
| GENERIC: PROTEIN C CONCENTRATE<br>TRADE: PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO | FOR REPLACEMENT THERAPY IN PATIENTS WITH CONGENITAL OR ACQUIRED PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF WARFARIN-INDUCED SKIN NECROSIS DURING ORAL ANTICOAGULATION. FOR REPLACEMENT THERAPY IN CONGENITAL PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF THROMBOSIS, PULMONARY EMBOLI, AND PURPURA FULMINANS. | IMMUNO CLINICAL RESEARCH CORPORATION |

## ORPHAN DRUG PRODUCT DESIGNATIONS

## BIOLOGICAL DESIGNATIONS

| NAME OF BIOLOGICAL                                                                                 | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                                                                                                                                                                                                                                                     | SPONSOR NAME                 |
|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| GENERIC: SARGRAMOSTIM<br>TRADE: LEUKINE*/**                                                        | TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.*/** [DEC 31, 1998]<br>TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA.*/** [MAR 05, 1998] | IMMUNEX                      |
| GENERIC: SECRETORY LEUKOCYTE PROTEASE INHIBITOR<br>TRADE: NOT ESTABLISHED                          | TREATMENT OF BRONCHOPULMONARY DYSPLASIA.                                                                                                                                                                                                                                                                                                                                         | SYNERGEN, INC                |
| GENERIC: TECHNETIUM TC99M MURINE MONOCLONAL ANTIBODY (IGG2A) TO BCE<br>TRADE: IMMURAID-LL-2[99mTc] | DIAGNOSTIC IMAGING IN THE EVALUATION OF THE EXTENT OF DISEASE IN PATIENTS WITH HISTOLOGICALLY CONFIRMED DIAGNOSIS OF NON-HODGKIN'S B-CELL LYMPHOMA, ACUTE B-CELL LYMPHOBLASTIC LEUKEMIA (IN CHILDREN AND ADULTS), AND CHRONIC B-CELL LYMPHOCYTIC LEUKEMIA.                                                                                                                       | IMMUNOMEDICS, INC            |
| GENERIC: TRANSFORMING GROWTH FACTOR-BETA 2<br>TRADE: NOT ESTABLISHED                               | TREATMENT OF FULL THICKNESS MACULAR HOLES.                                                                                                                                                                                                                                                                                                                                       | CELTRIX PHARMACEUTICALS, INC |

## ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS  
 [Approved for Marketing\*]  
 [Exclusive Approval\*\*]

| NAME OF DRUG                                                                                                                                 | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                                                                                                      | SPONSOR NAME                   |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| GENERIC: ALLOPURINOL SODIUM<br>TRADE: ZYLOPRIM FOR INJECTION                                                                                 | MANAGEMENT OF PATIENTS WITH LEUKEMIA, LYMPHOMA, AND SOLID TUMOR MALIGNANCIES WHO ARE RECEIVING CANCER THERAPY WHICH CAUSES ELEVATIONS OF SERUM AND URINARY URIC ACID LEVELS AND WHO CANNOT TOLERATE ORAL THERAPY.                 | BURROUGHS WELLCOME COMPANY     |
| GENERIC: ANARITIDE ACETATE<br>TRADE: AURICULIN                                                                                               | IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION.<br>TREATMENT OF PATIENTS WITH ACUTE RENAL FAILURE.                                                                                                 | SCIOS, INC                     |
| GENERIC: ARGININE BUTYRATE<br>TRADE: NOT ESTABLISHED                                                                                         | TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA-THALASSEMIA.                                                                                                                                                                        | SUSAN P. PERRINE, M.D.         |
| GENERIC: BACLOFEN (INTRATHECAL)<br>TRADE: LIORESAL                                                                                           | TREATMENT OF INTRACTABLE SPASTICITY CAUSED BY SPINAL CORD INJURY, MULTIPLE SCLEROSIS, AND OTHER SPINAL DISEASES (INCLUDING SPINAL ISCHEMIA, SPINAL TUMOR, TRANSVERSE MYELITIS, CERVICAL SPONDYLOSIS, AND DEGENERATIVE MYELOPATHY. | MEDTRONIC, INC                 |
| GENERIC: BUTYRYLCHOLINESTERASE<br>TRADE: NOT ESTABLISHED                                                                                     | FOR THE REDUCTION AND CLEARANCE OF TOXIC BLOOD LEVELS OF COCAINE ENCOUNTERED DURING A DRUG OVERDOSE.<br>TREATMENT OF POST-SURGICAL APNEA.                                                                                         | PHARMAVENE, INCORPORATED       |
| GENERIC: DAPSONE<br>TRADE: DAPSONE                                                                                                           | FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.                                                                                                                                 | JACOBUS PHARMACEUTICAL COMPANY |
| GENERIC: DIANEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS<br>TRADE: NUTRINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS | FOR USE AS A NUTRITIONAL SUPPLEMENT FOR THE TREATMENT OF MALNOURISHMENT IN PATIENTS UNDERGOING CONTINUOUS AMBULATORY PERITONEAL DIALYSIS.                                                                                         | BAXTER HEALTHCARE CORPORATION  |
| GENERIC: DIAZEPAM VISCOUS SOLUTION FOR RECTAL ADMINISTRATION<br>TRADE: DIASTAT                                                               | TREATMENT OF ACUTE REPETITIVE SEIZURES.                                                                                                                                                                                           | UPSHER SMITH LABORATORIES, INC |
| GENERIC: FIAU<br>TRADE: NOT ESTABLISHED                                                                                                      | ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.                                                                                                                                                                               | OCLASSEN PHARMACEUTICALS, INC  |

## ORPHAN DRUG PRODUCT DESIGNATIONS

## DRUG DESIGNATIONS

| NAME OF DRUG                                                        | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                                                                                                                                                                                     | SPONSOR NAME                        |
|---------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| GENERIC: HALOFANTRINE HCL<br>TRADE: HALFAN*/**                      | TREATMENT OF MILD TO MODERATE ACUTE MALARIA CAUSED BY SUSCEPTIBLE STRAINS OF P. FALCIPARUM AND P. VIVAX. [JUL 24, 1999]                                                                                                                                                                                          | SMITHKLINE BEECHAM                  |
| GENERIC: HUMAN THYROID STIMULATING HORMONE (TSH)<br>TRADE: THYROGEN | AS AN ADJUNCT IN THE DIAGNOSIS OF THYROID CANCER.                                                                                                                                                                                                                                                                | GENZYME CORPORATION                 |
| GENERIC: IDARUBICIN<br>TRADE: IDAMYCIN                              | TREATMENT OF MYELODYSPLASTIC SYNDROMES.<br>TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA.                                                                                                                                                                                                                            | ADRIA LABORATORIES                  |
| GENERIC: ISOBUTYRAMIDE<br>TRADE: ISOBUTYRAMIDE ORAL SOLUTION        | TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA THALASSEMIA SYNDROMES.                                                                                                                                                                                                                                             | SUSAN PERRINE<br>OAKLAND, CA        |
| GENERIC: L-BACLOFEN<br>TRADE: NEURALGON                             | TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.                                                                                                                                                                                                                                             | WTD, INC                            |
| GENERIC: L-THREONINE<br>TRADE: NOT ESTABLISHED                      | TREATMENT OF SPASTICITY ASSOCIATED WITH FAMILIAL SPASTIC PARAPARESIS.                                                                                                                                                                                                                                            | INTERNEURON<br>PHARMACEUTICALS, INC |
| GENERIC: LEVOCARNITINE<br>TRADE: CARNITOR*/**                       | GENETIC CARNITINE DEFICIENCY.*<br>TREATMENT OF MANIFESTATIONS OF CARNITINE DEFICIENCY IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD) WHO REQUIRE DIALYSIS.<br>PREVENTION OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY.<br>TREATMENT OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY. | SIGMA TAU                           |
| GENERIC: LEVOCARNITINE<br>TRADE: CARNITOR*/**                       | TREATMENT OF PRIMARY AND SECONDARY CARNITINE DEFICIENCY OF GENETIC ORIGIN.*/** [DEC 27, 1992]<br>*/** [DEC 16, 1999 - SECONDARY CARNITINE DEFICIENCY].                                                                                                                                                           | SIGMA TAU                           |
| GENERIC: LIOTHYRONINE SODIUM<br>TRADE: TRIOSTAT*/**                 | TREATMENT OF MYXEDEMA COMA/PRE-COMA.<br>[DEC 31, 1998]                                                                                                                                                                                                                                                           | SMITHKLINE BEECHAM                  |
| GENERIC: LOXORIBINE<br>TRADE: NOT ESTABLISHED                       | TREATMENT OF COMMON VARIABLE IMMUNODEFICIENCY.                                                                                                                                                                                                                                                                   | R.W. JOHNSON RESEARCH INSTITUTE     |

## ORPHAN DRUG PRODUCT DESIGNATIONS

## DRUG DESIGNATIONS

| NAME OF DRUG                                                                  | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                                                                                                                                             | SPONSOR NAME                       |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| GENERIC: MELPHALAN*/**<br>TRADE: ALKERAN FOR INJECTION                        | TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE.*/** [NOV 18, 1999]<br>FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION TO TREAT METASTATIC MELANOMA OF THE EXTREMITY. | BURROUGHS WELLCOME                 |
| GENERIC: MINOCYCLINE HCL<br>TRADE: MINOCIN                                    | TREATMENT OF CHRONIC MALIGNANT PLEURAL EFFUSION.                                                                                                                                                         | LEDERLE LABORATORIES               |
| GENERIC: OXALIPLATIN<br>TRADE: NOT ESTABLISHED                                | TREATMENT OF OVARIAN CANCER.                                                                                                                                                                             | AXION PHARMACEUTICALS              |
| GENERIC: PAPAVERINE (TOPICAL GEL)<br>TRADE: NOT ESTABLISHED                   | TREATMENT OF SEXUAL DYSFUNCTION IN SPINAL CORD INJURY PATIENTS.                                                                                                                                          | PHARMEDIC COMPANY                  |
| GENERIC: PARA-AMINOSALICYLIC ACID<br>TRADE: NOT ESTABLISHED                   | TREATMENT OF TUBERCULOSIS INFECTIONS.                                                                                                                                                                    | JACOBUS PHARMACEUTICAL COMPANY     |
| GENERIC: PEG-GLUCOCEREBROSIDASE<br>TRADE: NOT ESTABLISHED                     | CHRONIC ENZYME REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE WHO ARE DEFICIENT IN GLUCOCEREBROSIDASE.                                                                                           | ENZON, INCORPORATED                |
| GENERIC: PILOCARPINE HCL<br>TRADE: NOT ESTABLISHED                            | TREATMENT OF XEROSTOMIA AND KERATOCONJUNCTIVITIS SICCA IN SJOGREN'S SYNDROME PATIENTS.                                                                                                                   | MGI PHARMA, INC                    |
| GENERIC: POLYMERIC OXYGEN<br>TRADE: NOT ESTABLISHED                           | TREATMENT OF SICKLE CELL ANEMIA.                                                                                                                                                                         | CAPMED, USA                        |
| GENERIC: PPI-002<br>TRADE: NOT ESTABLISHED                                    | TREATMENT OF MALIGNANT MESOTHELIOMA.                                                                                                                                                                     | PLEXUS PHARMACEUTICALS, INC        |
| GENERIC: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODODECABORATE<br>TRADE: BOROCCELL | FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.                                                                                                                    | NEUTRON TECHNOLOGY CORPORATION     |
| GENERIC: SODIUM PHENYLBUTYRATE<br>TRADE: NOT ESTABLISHED                      | TREATMENT OF SICKLING DISORDERS, WHICH INCLUDE S-S HEMOGLOBINOPATHY, S-C HEMOGLOBINOPATHY, AND S-THALASSEMIA HEMOGLOBINOPATHY.                                                                           | JOHNS HOPKINS MEDICAL INSTITUTIONS |

## ORPHAN DRUG PRODUCT DESIGNATIONS

## DRUG DESIGNATIONS

| NAME OF DRUG                                           | DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]                                          | SPONSOR NAME                     |
|--------------------------------------------------------|---------------------------------------------------------------------------------------|----------------------------------|
| GENERIC: SOTALOL HCL<br>TRADE: BETAPACE*/**            | TREATMENT OF LIFE-THREATENING VENTRICULAR<br>TACHYARRHYTHMIAS. [OCT 30, 1999]         | BRISTOL-MYERS SQUIBB             |
| GENERIC: TENIPOSIDE<br>TRADE: VUMON*/**                | TREATMENT OF REFRACTORY CHILDHOOD ACUTE<br>LYMPHOCYTIC LEUKEMIA (ALL). [JUL 14, 1999] | BRISTOL MYERS SQUIBB             |
| GENERIC: TOPIRAMATE<br>TRADE: TOPIMAX                  | TREATMENT OF LENNOX-GASTAUT SYNDROME.                                                 | R. W. JOHNSON RESEARCH INSTITUTE |
| GENERIC: ZALCITABINE<br>TRADE: HIVID                   | TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME<br>(AIDS). [JUN 19, 1999]             | ROCHE                            |
| GENERIC: 9-CIS RETINOIC ACID<br>TRADE: NOT ESTABLISHED | TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.                                            | LIGAND PHARMACUETICALS, INC      |



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

NO DECEMBER 1992 ADDITIONS

## BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| DRUG NAME (DOSAGE FORM)                                                                             | DATE         | REVISED DATE |
|-----------------------------------------------------------------------------------------------------|--------------|--------------|
| ALPRAZOLAM (TABLET)                                                                                 | NOV 27, 1992 |              |
| CARBIDOPA AND LEVODOPA (TABLET)                                                                     | JUN 19, 1992 |              |
| CIMETIDINE (TABLET)                                                                                 | JUN 12, 1992 |              |
| CORTICOSTEROID <i>IN VITRO</i> AND <i>IN VIVO</i> INTERIM (TOPICAL)                                 | JUL 01, 1992 |              |
| DICLOFENAC SODIUM (TABLET)                                                                          | DEC 24, 1992 |              |
| DIFLUNISAL (TABLET)                                                                                 | MAY 16, 1992 |              |
| DILTIAZEM HYDROCHLORIDE (TABLET)                                                                    | MAY 16, 1992 |              |
| ESTROPIRATE (TABLET)                                                                                | AUG 26, 1992 |              |
| FLURBIPROFEN (TABLET)                                                                               | DEC 24, 1992 |              |
| GEMFIBROZIL (CAPSULE AND TABLET)                                                                    | JUN 23, 1989 | JUN 15, 1992 |
| METOPROLOL TARTRATE (TABLET)                                                                        | JUN 12, 1992 |              |
| NADOLOL (TABLET)                                                                                    | MAY 16, 1992 |              |
| NAPROXEN (TABLET)                                                                                   | JUN 12, 1992 |              |
| NORTRIPTYLINE HYDROCHLORIDE (CAPSULE)                                                               | JUN 15, 1992 |              |
| PIROXICAM (CAPSULE)                                                                                 | JUN 15, 1992 |              |
| STATISTICAL PROCEDURE FOR BIOEQUIVALENCE STUDIES USING A<br>STANDARD TWO-TREATMENT CROSSEVER DESIGN | JUL 01, 1992 |              |
| TERFENADINE (TABLET)                                                                                | JUN 12, 1992 |              |

# ANDA SUITABILITY PETITIONS

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE                          | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER     | PETITIONER | REASON FOR<br>PETITION | STATUS                   |
|----------------------------------------------------------|------------------------------|-------------------|------------|------------------------|--------------------------|
| ACETAMINOPHEN;<br>CODEINE PHOSPHATE<br>TABLET; ORAL      | 500MG<br>7.5MG               | 91 P-0514/<br>CP1 | SOFTAN     | NEW STRENGTH           | APPROVED<br>JUN 03, 1992 |
| ACETAMINOPHEN;<br>HYDROCODONE BITARTRATE<br>TABLET; ORAL | 660MG<br>10MG                | 91 P-0004/<br>CP1 | KNOLL      | NEW STRENGTH           | APPROVED<br>OCT 27, 1992 |
| ALBUTEROL SULFATE<br>CAPSULE, EXTENDED<br>RELEASE; ORAL  | EQ 4MG BASE                  | 91 P-0348/<br>CP1 | HAMER      | NEW DOSAGE<br>FORM     | APPROVED<br>MAR 17, 1992 |
| ALPRAZOLAM<br>CONCENTRATE; ORAL                          | 1MG/ML                       | 92 P-0050/<br>CP1 | ROXANE     | NEW DOSAGE<br>FORM     | APPROVED<br>DEC 15, 1992 |
| ALPRAZOLAM<br>SOLUTION; ORAL                             | 0.5MG/5ML                    | 92 P-0050/<br>CP2 | ROXANE     | NEW DOSAGE<br>FORM     | APPROVED<br>DEC 15, 1992 |
| CHLORZOXAZONE<br>TABLET; ORAL                            | 750MG                        | 91 P-0153/<br>CP1 | MIKART     | NEW STRENGTH           | APPROVED<br>JUN 03, 1992 |

## ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

| DRUG NAME<br>DOSAGE FORM; ROUTE                                                                      | STRENGTH<br>(CONTAINER SIZE)                                                                                                          | DOCKET NUMBER     | PETITIONER            | REASON FOR<br>PETITION | STATUS                   |
|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------------|------------------------|--------------------------|
| CIMETIDINE HYDROCHLORIDE<br>IN SODIUM CHLORIDE 0.9%<br>IN PLASTIC CONTAINER<br>INJECTABLE; INJECTION | EQ 90MG BASE/100ML<br>EQ 120MG BASE/100ML<br>EQ 180MG BASE/100ML<br>EQ 240MG BASE/100ML<br>EQ 360MG BASE/100ML<br>EQ 480MG BASE/100ML | 92 P-0337/<br>CP1 | ABBOTT                | NEW STRENGTH           | APPROVED<br>OCT 26, 1992 |
| HYDROCORTISONE ACETATE<br>AEROSOL; TOPICAL                                                           | 2.5%                                                                                                                                  | 92 P-0101/<br>CP1 | HOGAN & HARTSON       | NEW DOSAGE<br>FORM     | APPROVED<br>JUL 08, 1992 |
| NALBUPHINE HYDROCHLORIDE<br>INJECTABLE; INJECTION                                                    | 10MG/ML<br>(2ML/CONTAINER)                                                                                                            | 92 P-0224/CP      | STERLING              | NEW STRENGTH           | APPROVED<br>SEP 11, 1992 |
| NITROGLYCERIN<br>IN DEXTROSE 5%<br>INJECTABLE; INJECTION                                             | 5MG/ML<br>(50ML/CONTAINER)                                                                                                            | 91 P-0387/<br>CP1 | ABBOTT                | NEW STRENGTH           | APPROVED<br>FEB 18, 1992 |
| NITROGLYCERIN<br>IN DEXTROSE 5%<br>INJECTABLE; INJECTION                                             | 10MG/ML<br>(100ML/CONTAINER)                                                                                                          | 91 P-0387/<br>CP1 | ABBOTT                | NEW STRENGTH           | APPROVED<br>FEB 18, 1992 |
| PROPRANOLOL HYDROCHLORIDE<br>TABLET, EFFERVESCENT; ORAL                                              | 40MG                                                                                                                                  | 92 P-0332/<br>CP1 | FLEMININGTON<br>PHARM | NEW DOSAGE<br>FORM     | APPROVED<br>NOV 25, 1992 |
| TAMOXIFEN CITRATE<br>TABLET; ORAL                                                                    | EQ 20MG BASE                                                                                                                          | 92 P-0269/<br>CP1 | KROSS                 | NEW STRENGTH           | APPROVED<br>OCT 26, 1992 |
| TRIAZOLAM<br>SOLUTION; ORAL                                                                          | 0.125MG/5ML                                                                                                                           | 92 P-0048/<br>CP2 | ROXANE                | NEW DOSAGE<br>FORM     | APPROVED<br>SEP 11, 1992 |

## ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

| DRUG NAME<br>DOSAGE FORM; ROUTE    | STRENGTH<br>(CONTAINER SIZE) | DOCKET NUMBER     | PETITIONER | REASON FOR<br>PETITION | STATUS                 |
|------------------------------------|------------------------------|-------------------|------------|------------------------|------------------------|
| ETOPOSIDE<br>INJECTABLE; INJECTION | 20MG/ML<br>(50ML/VIAL)       | 91 P-0076/<br>CP1 | ADRIA      | NEW STRENGTH           | DENIED<br>FEB 19, 1992 |

## EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH 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-18 LOWER RECOMMENDED STARTING DOSE GUIDELINES  
D-19 BOLUS DOSING GUIDELINES

REFERENCES  
NEW INDICATION

I-67 TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER  
I-68 CENTRAL PRECOCIOUS PUBERTY  
I-69 SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFLUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY  
I-70 USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER  
I-71 VARICELLA INFECTIONS (CHICKENPOX)  
I-72 PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE  
I-73 INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES  
I-74 INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY  
I-75 TREATMENT OF ENDOSCOPICALLY DIAGNOSED EROSIVE ESOPHAGITIS  
I-76 PREVENTION OF OSTEOPOROSIS  
I-77 DERMAL INFECTIONS-TINEA PEDIS, TINEA CORPORIS, TINEA CRURIS DUE TO EPIDERMOPHYTON FLOCCOSUM  
I-78 CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY AND INTRAVENOUS EXCRETORY UROGRAPHY  
I-79 MANAGEMENT OF CHRONIC STABLE ANGINA AND ANGINA DUE TO CORONARY ARTERY SPASM  
I-80 DIAGNOSIS AND LOCALIZATION OF ISCHEMIA AND CORONARY HEART DISEASE  
I-81 PROPHYLAXIS IN DESIGNATED IMMUNOCOMPROMISED CONDITIONS TO REDUCE THE INCIDENCE OF OROPHARYNGEAL CANDIDIASIS  
I-82 TREATMENT OF TRAVELERS' DIARRHEA  
I-83 ANGIOCARDIOGRAPHY, CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY IN CHILDREN  
I-84 INTRAOPERATIVE AND POSTOPERATIVE TACHYCARDIA AND/OR HYPERTENSION  
I-85 TREATMENT OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS  
I-86 TREATMENT OF SECONDARY CARNITINE DEFICIENCY

## EXCLUSIVITY TERMS

REFERENCES  
PATENT USE CODE

U-57 OPTHALMIC USE OF NORFLOXACIN  
U-58 METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES  
U-59 METHOD OF TREATING HYPERCHOLESTEROLEMIA  
U-60 NASAL ADMINISTRATION OF BUTORPHANOL  
U-61 CEREBRAL AND PERIPHERAL ARTERIOGRAPHY AND CT IMAGING OF THE HEAD  
U-62 CORONARY ARTERIOGRAPHY, LEFT VENTRICULOGRAPHY, CT IMAGING OF THE BODY, INTRAVENOUS EXCRETORY UROGRAPHY, INTRAVENOUS DIGITAL SUBTRACTION  
ANGIOGRAPHY AND VENOGRAPHY  
U-63 ISOPRENALINE ANTAGONISM ON THE HEART RATE OR BLOOD PRESSURE  
U-64 TREATMENT OF VIRAL INFECTIONS  
U-65 METHOD OF TREATMENT OF A PATIENT INFECTED WITH HIV  
U-66 TRIPHASIC REGIMEN  
U-67 METHOD OF INDUCING ANESTHESIA IN A WARM BLOODED ANIMAL  
U-68 TREATMENT OF ACTINIC KERATOSIS  
U-69 TREATMENT OF PNEUMOCYSTIS CARINII INFECTIONS  
U-70 TREATMENT OF TRANSIENT INSOMNIA  
U-71 METHOD OF TREATMENT OF HEART FAILURE  
U-72 TREATMENT OF MIGRAINES  
U-73 METHOD OF TREATING DISEASES OR INFECTIONS CAUSED BY MYCETES

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

| APPL/PROD<br>NUMBER        | INGREDIENT NAME; TRADE NAME                       | PATENT<br>NUMBER   | PATENT<br>EXPIRES       | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|----------------------------|---------------------------------------------------|--------------------|-------------------------|-------------|----------------|-------------------|
| 20232 001                  | ACETAMINOPHEN; FIORICET W/ CODEINE                |                    |                         |             | NC             | OCT 26, 1993      |
| 18828 001                  | ACYCLOVIR; ZOVIRAX                                |                    |                         |             | I-71           | FEB 26, 1995      |
| 19909 001                  | ACYCLOVIR; ZOVIRAX                                |                    |                         |             | I-71           | FEB 26, 1995      |
| 20089 001                  | ACYCLOVIR; ZOVIRAX                                |                    |                         |             | I-71           | FEB 26, 1995      |
| 20089 002                  | ACYCLOVIR; ZOVIRAX                                |                    |                         |             | I-71           | FEB 26, 1995      |
| >ADD> 19604 002            | ALBUTEROL SULFATE; VOLMAX                         |                    |                         |             | NS             | DEC 23, 1995      |
| 19729 001                  | AMCINONIDE; CYCLOCORT                             | 4158055            | JUN 12, 1996            | U-19        |                |                   |
| >DLT> <del>16949 001</del> | <del>AMITRIPTYLINE HYDROCHLORIDE; LIMBITROL</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT> <del>16949 002</del> | <del>AMITRIPTYLINE HYDROCHLORIDE; LIMBITROL</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| 19787 001                  | AMLODIPINE BESYLATE; NORVASC                      | 4879303            | NOV 07, 2006            |             |                |                   |
|                            |                                                   | 4572909            | FEB 25, 2003            |             | NCE            | JUL 31, 1997      |
| 19787 002                  | AMLODIPINE BESYLATE; NORVASC                      | 4879303            | NOV 07, 2006            |             |                |                   |
|                            |                                                   | 4572909            | FEB 25, 2003            |             | NCE            | JUL 31, 1997      |
| 19787 003                  | AMLODIPINE BESYLATE; NORVASC                      | 4879303            | NOV 07, 2006            |             |                |                   |
|                            |                                                   | 4572909            | FEB 25, 2003            |             | NCE            | JUL 31, 1997      |
| >ADD> 20259 001            | ATOVAQUONE; MEPRON                                | 5053432            | OCT 01, 2008            |             | ODE            | NOV 25, 1999      |
|                            |                                                   | 4981874            | JAN 01, 2008            | U-69        | NCE            | NOV 25, 1997      |
| >ADD> 20045 001            | AVOBENZONE; SHADE UVAGUARD                        | 4387089            | JUN 07, 2000            |             |                |                   |
| 20075 001                  | BACLOFEN; LIORESAL                                |                    |                         |             | ODE            | JUN 17, 1999      |
|                            |                                                   |                    |                         |             | NDF            | JUN 17, 1995      |
| 20075 002                  | BACLOFEN; LIORESAL                                |                    |                         |             | ODE            | JUN 17, 1999      |
|                            |                                                   |                    |                         |             | NDF            | JUN 17, 1995      |
| 19851 001                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN                | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
| 19851 002                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN                | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
| 19851 003                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN                | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
| 19851 004                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN                | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
| 20033 001                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT            | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
|                            |                                                   |                    |                         |             | NC             | MAY 19, 1995      |
| 20033 002                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT            | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
|                            |                                                   |                    |                         |             | NC             | MAY 19, 1995      |
| 20033 003                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT            | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
|                            |                                                   |                    |                         |             | NC             | MAY 19, 1995      |
| 20033 004                  | BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT            | 4410520            | OCT 18, 2002            |             | NCE            | JUN 25, 1996      |
|                            |                                                   |                    |                         |             | NC             | MAY 19, 1995      |
| 19001 001                  | BEPRIDIL HYDROCHLORIDE; BEPADIN                   | RE30577            | JUN 08, 1995            |             | NCE            | DEC 28, 1995      |
| 19001 002                  | BEPRIDIL HYDROCHLORIDE; BEPADIN                   | RE30577            | JUN 08, 1995            |             | NCE            | DEC 28, 1995      |
| 19001 003                  | BEPRIDIL HYDROCHLORIDE; BEPADIN                   | RE30577            | JUN 08, 1995            |             | NCE            | DEC 28, 1995      |



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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME                                  | PATENT<br>NUMBER   | PATENT<br>EXPIRES       | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------------------------------|--------------------|-------------------------|-------------|----------------|-------------------|
| 19002 001           | BEPRIDIL HYDROCHLORIDE; VASCOR                               | RE30577            | JUN 08, 1995            |             | NCE            | DEC 28, 1995      |
| 19002 002           | BEPRIDIL HYDROCHLORIDE; VASCOR                               | RE30577            | JUN 08, 1995            |             | NCE            | DEC 28, 1995      |
| 19002 003           | BEPRIDIL HYDROCHLORIDE; VASCOR                               | RE30577            | JUN 08, 1995            |             | NCE            | DEC 28, 1995      |
| 19807 001           | BETAXOLOL HYDROCHLORIDE; KERLEDEX                            | 4311708            | JAN 19, 1999            | U-3         | NC             | OCT 30, 1995      |
|                     |                                                              | 4252984            | FEB 24, 1998            |             |                |                   |
| 19807 002           | BETAXOLOL HYDROCHLORIDE; KERLEDEX                            | 4311708            | JAN 19, 1999            | U-3         | NC             | OCT 30, 1995      |
|                     |                                                              | 4252984            | FEB 24, 1998            |             |                |                   |
| 19982 001           | BISOPROLOL FUMARATE; ZEBETA                                  | 4258062            | MAR 24, 1998            | U-63        | NCE            | JUL 31, 1997      |
| 19982 002           | BISOPROLOL FUMARATE; ZEBETA                                  | 4258062            | MAR 24, 1998            | U-63        | NCE            | JUL 31, 1997      |
| 19548 001           | BITOLTEROL MESYLATE; TORNALATE                               | 4336400            | JUN 22, 1999            | U-5         |                |                   |
|                     |                                                              | 4138581            | FEB 06, 1998            |             | NDF            | FEB 19, 1995      |
| 19890 001           | BUTORPHANOL TARTRATE; STADOL                                 | 4464378            | AUG 07, 2001            | U-60        | NDF            | DEC 12, 1994      |
| >DLT>               | <del>13071 007 CHLORDIAZEPOXIDE; LIBRITABS</del>             | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>13071 008 CHLORDIAZEPOXIDE; LIBRITABS</del>             | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>13071 009 CHLORDIAZEPOXIDE; LIBRITABS</del>             | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>14740 002 CHLORDIAZEPOXIDE; MENRIUM 5-2</del>           | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>14740 004 CHLORDIAZEPOXIDE; MENRIUM 5-4</del>           | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>14740 006 CHLORDIAZEPOXIDE; MENRIUM 10-4</del>          | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>17813 001 CHLORDIAZEPOXIDE; LIBRELEASE</del>            | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>12249 001 CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>12249 002 CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>12249 003 CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>12301 001 CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>12750 001 CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRAX</del>  | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| 19847 001           | CIPROFLOXACIN; CIPRO                                         | 4808583            | FEB 28, 2006            |             |                |                   |
|                     |                                                              | 4705789            | NOV 10, 2004            |             |                |                   |
|                     |                                                              | 4670444            | OCT 01, 2002            |             | NCE            | OCT 22, 1992      |
| 19857 001           | CIPROFLOXACIN; CIPRO IN DEXTROSE 5%                          | 4957922            | SEP 18, 2007            |             |                |                   |
|                     |                                                              | 4808583            | FEB 28, 2006            |             |                |                   |
|                     |                                                              | 4705789            | NOV 10, 2004            |             |                |                   |
|                     |                                                              | 4670444            | OCT 01, 2002            |             | NCE            | OCT 22, 1992      |
| 19858 001           | CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%                 | 4957922            | SEP 18, 2007            |             |                |                   |
|                     |                                                              | 4808583            | FEB 28, 2006            |             |                |                   |
|                     |                                                              | 4705789            | NOV 10, 2004            |             |                |                   |
|                     |                                                              | 4670444            | OCT 01, 2002            |             | NCE            | OCT 22, 1992      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME               | PATENT<br>NUMBER   | PATENT<br>EXPIRES       | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-------------------------------------------|--------------------|-------------------------|-------------|----------------|-------------------|
| 19537 002           | CIPROFLOXACIN HYDROCHLORIDE; CIPRO        | 4670444            | OCT 01, 2002            | U-36        | NCE            | OCT 22, 1992      |
| 19537 003           | CIPROFLOXACIN HYDROCHLORIDE; CIPRO        | 4670444            | OCT 01, 2002            | U-36        | NCE            | OCT 22, 1992      |
| 19537 004           | CIPROFLOXACIN HYDROCHLORIDE; CIPRO        | 4670444            | OCT 01, 2002            | U-36        | NCE            | OCT 22, 1992      |
| 19992 001           | CIPROFLOXACIN HYDROCHLORIDE; CILOXAN      | 4670444            | OCT 01, 2002            |             | NDF            | DEC 31, 1993      |
| >DLT>               | <del>17533 001 CLONAZEPAM; KLOXOPIN</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>17533 002 CLONAZEPAM; KLOXOPIN</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>17533 003 CLONAZEPAM; KLOXOPIN</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| 18713 001           | CLOTTRIMAZOLE; MYCELEX                    |                    |                         |             | I-81           | SEP 29, 1995      |
| 20118 001           | DESFLURANE; SUPRANE                       | 4762856            | AUG 09, 2005            | U-67        | NCE            | SEP 18, 1997      |
| >ADD>               | 20071 001 DESOGESTREL; DESOGEN            |                    |                         |             | NC             | DEC 10, 1995      |
| >ADD>               | 20071 002 DESOGESTREL; DESOGEN            |                    |                         |             | NC             | DEC 10, 1995      |
| >ADD>               | 20301 001 DESOGESTREL; ORTHO-CEPT         |                    |                         |             | NC             | DEC 10, 1995      |
| >ADD>               | 20301 002 DESOGESTREL; ORTHO-CEPT         |                    |                         |             | NC             | DEC 10, 1995      |
| >DLT>               | <del>13263 002 DIAZEPAM; VALIUM</del>     | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>13263 004 DIAZEPAM; VALIUM</del>     | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>13263 006 DIAZEPAM; VALIUM</del>     | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>16087 001 DIAZEPAM; VALIUM</del>     | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| >DLT>               | <del>18179 001 DIAZEPAM; VALRELEASE</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |             |                |                   |
| 20037 001           | DICLOFENAC SODIUM; VOLTAREN               | 4960799            | OCT 02, 2007            |             | NDF            | MAR 28, 1994      |
| 20154 002           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20154 003           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20154 004           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20154 005           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20155 003           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20155 004           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20155 005           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20155 006           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20156 001           | DIDANOSINE; VIDEX                         |                    |                         |             | D-18           | SEP 25, 1995      |
| 20027 001           | DILTIAZEM HYDROCHLORIDE; CARDIZEM         |                    |                         |             | NCE            | NOV 05, 1992      |
| 20027 002           | DILTIAZEM HYDROCHLORIDE; CARDIZEM         |                    |                         |             | NCE            | NOV 05, 1992      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME          | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 20062 001           | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5002776          | MAR 26, 2008      |             | NCE            | NOV 05, 1992      |
|                     |                                      | 4894240          | JAN 16, 2007      |             | NS             | MAY 29, 1995      |
|                     |                                      |                  |                   |             | I-79           | OCT 15, 1995      |
| 20062 002           | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5002776          | MAR 26, 2008      |             | NCE            | NOV 05, 1992      |
|                     |                                      | 4894240          | JAN 16, 2007      |             | NP             | DEC 27, 1994      |
|                     |                                      |                  |                   |             | I-79           | OCT 15, 1995      |
| 20062 003           | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5002776          | MAR 26, 2008      |             | NCE            | NOV 05, 1992      |
|                     |                                      | 4894240          | JAN 16, 2007      |             | NP             | DEC 27, 1994      |
|                     |                                      |                  |                   |             | I-79           | OCT 15, 1995      |
| 20062 004           | DILTIAZEM HYDROCHLORIDE; CARDIZEM CD | 5002776          | MAR 26, 2008      |             | NCE            | NOV 05, 1992      |
|                     |                                      | 4894240          | JAN 16, 2007      |             | NP             | DEC 27, 1994      |
|                     |                                      |                  |                   |             | I-79           | OCT 15, 1995      |
| 20092 001           | DILTIAZEM HYDROCHLORIDE; DILACOR XR  | 4839177          | JUN 13, 2006      |             | NS             | MAY 29, 1995      |
|                     |                                      |                  |                   |             | NCE            | NOV 05, 1992      |
| 20092 002           | DILTIAZEM HYDROCHLORIDE; DILACOR XR  | 4839177          | JUN 13, 2006      |             | NP             | DEC 27, 1994      |
|                     |                                      |                  |                   |             | NCE            | NOV 05, 1992      |
| 20092 003           | DILTIAZEM HYDROCHLORIDE; DILACOR XR  | 4839177          | JUN 13, 2006      |             | NP             | DEC 27, 1994      |
|                     |                                      |                  |                   |             | NCE            | NOV 05, 1992      |
| >ADD>               | 19617 001                            | 4680312          | JUL 14, 2004      |             | NDF            | DEC 09, 1995      |
| >ADD>               |                                      | 3966962          | JUN 29, 1993      |             |                |                   |
|                     | 19946 001                            | 4701460          | MAR 06, 2005      |             | NCE            | MAR 07, 1996      |
| >ADD>               | 18651 001                            |                  |                   |             | I-85           | DEC 22, 1995      |
| >ADD>               | 18651 002                            |                  |                   |             | I-85           | DEC 22, 1995      |
| >ADD>               | 18651 003                            |                  |                   |             | I-85           | DEC 22, 1995      |
| >ADD>               | 19386 001                            | 4593119          | JUN 03, 2003      |             | I-84           | DEC 18, 1995      |
| >ADD>               |                                      | 4387103          | JUN 07, 2000      | U-11        | D-19           | DEC 18, 1995      |
| >ADD>               | 19386 002                            | 4593119          | JUN 03, 2003      |             | I-84           | DEC 18, 1995      |
| >ADD>               |                                      | 4387103          | JUN 07, 2000      | U-11        | D-19           | DEC 18, 1995      |
|                     | 84499 001                            |                  |                   |             | I-76           | SEP 08, 1995      |
|                     | 84500 001                            |                  |                   |             | I-76           | SEP 08, 1995      |
|                     | 83220 001                            |                  |                   |             | I-76           | NOV 10, 1995      |
|                     | 83220 002                            |                  |                   |             | I-76           | NOV 10, 1995      |
|                     | 83220 003                            |                  |                   |             | I-76           | NOV 10, 1995      |
|                     | 83220 004                            |                  |                   |             | I-76           | NOV 10, 1995      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME         | PATENT<br>NUMBER                             | PATENT<br>EXPIRES  | USE<br>CODE             | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-------------------------------------|----------------------------------------------|--------------------|-------------------------|----------------|-------------------|
| 19697 001           | ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN | 4628051                                      | OCT 01, 2002       | U-66                    |                |                   |
|                     |                                     | 4616006                                      | OCT 07, 2003       | U-66                    |                |                   |
|                     |                                     | 4544554                                      | JUL 23, 2002       | U-66                    |                |                   |
|                     |                                     | 4027019                                      | MAY 31, 1996       |                         | NP             | JUL 03, 1995      |
| 19697 002           | ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN | 4628051                                      | OCT 01, 2002       | U-66                    |                |                   |
|                     |                                     | 4616006                                      | OCT 07, 2003       | U-66                    |                |                   |
|                     |                                     | 4544554                                      | JUL 23, 2002       | U-66                    |                |                   |
|                     |                                     | 4027019                                      | MAY 31, 1996       |                         | NP             | JUL 03, 1995      |
| 19462 001           | FAMOTIDINE; PEPCID                  | 4283408                                      | AUG 11, 2000       |                         | I-69           | DEC 10, 1994      |
| 19462 002           | FAMOTIDINE; PEPCID                  | 4283408                                      | AUG 11, 2000       |                         | I-69           | DEC 10, 1994      |
| 19527 001           | FAMOTIDINE; PEPCID                  | 4283408                                      | AUG 11, 2000       |                         | I-69           | DEC 10, 1994      |
| 19834 001           | FELODIPINE; PLENDIL                 | 4264611                                      | APR 28, 1998       |                         | NCE            | JUL 25, 1996      |
| 19834 002           | FELODIPINE; PLENDIL                 | 4264611                                      | APR 28, 1998       |                         | NCE            | JUL 25, 1996      |
| 20180 001           | FINASTERIDE; PROSCAR                | 4760071                                      | JUL 26, 2005       |                         |                |                   |
|                     |                                     | 4377584                                      | MAR 22, 2000       |                         | NCE            | JUN 19, 1997      |
| >ADD>               | 19960 001                           | FLOSEQUINAN; MANOPLAX                        | 4552884            | NOV 12, 2002            | U-71           |                   |
| >ADD>               |                                     |                                              | 4302460            | NOV 24, 1998            |                | NCE DEC 30, 1997  |
| >ADD>               | 19960 002                           | FLOSEQUINAN; MANOPLAX                        | 4552884            | NOV 12, 2002            | U-71           |                   |
| >ADD>               |                                     |                                              | 4302460            | NOV 24, 1998            |                | NCE DEC 30, 1997  |
| >ADD>               | 19960 003                           | FLOSEQUINAN; MANOPLAX                        | 4552884            | NOV 12, 2002            | U-71           |                   |
| >ADD>               |                                     |                                              | 4302460            | NOV 24, 1998            |                | NCE DEC 30, 1997  |
| >ADD>               | 19960 004                           | FLOSEQUINAN; MANOPLAX                        | 4552884            | NOV 12, 2002            | U-71           |                   |
| >ADD>               |                                     |                                              | 4302460            | NOV 24, 1998            |                | NCE DEC 30, 1997  |
|                     | 20038 001                           | FLUDARABINE PHOSPHATE; FLUDARA               | 4357324            | NOV 02, 2001            |                | NCE APR 18, 1996  |
|                     | 20101 001                           | FLUOXETINE HYDROCHLORIDE; PROZAC             | 4626549            | DEC 02, 2003            |                |                   |
|                     |                                     |                                              | 4194009            | APR 19, 1994            |                |                   |
|                     |                                     |                                              | 4018895            | APR 19, 1994            | U-12           |                   |
| >DLT>               | <del>16721 001</del>                | <del>FLURAZEPAM HYDROCHLORIDE; DALMANE</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |                |                   |
| >DLT>               | <del>16721 002</del>                | <del>FLURAZEPAM HYDROCHLORIDE; DALMANE</del> | <del>4316897</del> | <del>FEB 23, 1999</del> |                |                   |
|                     | 20068 001                           | FOSCARNET SODIUM; FOSCAVIR                   | 4771041            | JUL 29, 1997            |                |                   |
|                     |                                     |                                              | 4665062            | JUL 29, 1997            |                |                   |
|                     |                                     |                                              | 4339445            | JUL 29, 1997            | U-64           |                   |
|                     |                                     |                                              | 4215113            | JUL 29, 1997            | U-64           | NCE SEP 27, 1996  |
| 19915 002           | FOSINOPRIL SODIUM; MONOPRIL         | 4337201                                      | JUN 29, 2001       |                         | NCE            | MAY 16, 1996      |
| 19915 003           | FOSINOPRIL SODIUM; MONOPRIL         | 4337201                                      | JUN 29, 2001       |                         | NCE            | MAY 16, 1996      |
| 20131 001           | GADOTERIDOL; PROHANCE               | 4885363                                      | DEC 05, 2006       |                         | NCE            | NOV 16, 1997      |
| 19661 001           | GANCICLOVIR SODIUM; CYTOVENE        | 4507305                                      | OCT 19, 1999       | U-35                    | I-72           | MAY 15, 1995      |

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|---------------------|-------------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 20051 001           | GLYBURIDE; GLYNASE                        | 4916163          | APR 10, 2007      |             |                |                   |
|                     |                                           | 4735805          | APR 05, 2005      |             | NCE            | MAY 01, 1994      |
|                     |                                           | 3507961          | APR 21, 1992      |             | NP             | MAR 04, 1995      |
|                     |                                           | 3507954          | APR 21, 1992      |             |                |                   |
|                     |                                           | 3454635          | APR 21, 1992      |             |                |                   |
|                     |                                           | 3426067          | APR 21, 1992      |             |                |                   |
| 20051 002           | GLYBURIDE; GLYNASE                        | 4916163          | APR 10, 2007      |             |                |                   |
|                     |                                           | 4735805          | APR 05, 2005      |             | NCE            | MAY 01, 1994      |
|                     |                                           | 3507961          | APR 21, 1992      |             | NP             | MAR 04, 1995      |
|                     |                                           | 3507954          | APR 21, 1992      |             |                |                   |
|                     |                                           | 3454635          | APR 21, 1992      |             |                |                   |
|                     |                                           | 3426067          | APR 21, 1992      |             |                |                   |
| 20055 001           | GLYBURIDE; GLUBATE                        |                  |                   |             | NP             | MAR 04, 1995      |
|                     |                                           |                  |                   |             | NCE            | MAY 01, 1994      |
| 20055 002           | GLYBURIDE; GLUBATE                        |                  |                   |             | NP             | MAR 04, 1995      |
|                     |                                           |                  |                   |             | NCE            | MAY 01, 1994      |
| 19967 001           | HALOBETASOL PROPIONATE; ULTRAVATE         |                  |                   |             | D-1            | DEC 31, 1994      |
| 19968 001           | HALOBETASOL PROPIONATE; ULTRAVATE         |                  |                   |             | D-1            | DEC 31, 1994      |
| 20250 001           | HALOFANTRINE HYDROCHLORIDE; HALFAN        |                  |                   |             | NCE            | JUL 24, 1997      |
|                     |                                           |                  |                   |             | ODE            | JUL 24, 1999      |
| 19046 001           | HYDROCHLOROTHIAZIDE; NORMOZIDE            | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19046 002           | HYDROCHLOROTHIAZIDE; NORMOZIDE            | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19046 003           | HYDROCHLOROTHIAZIDE; NORMOZIDE            | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19046 004           | HYDROCHLOROTHIAZIDE; NORMOZIDE            | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19174 001           | HYDROCHLOROTHIAZIDE; TRANDATE HCT         | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19174 002           | HYDROCHLOROTHIAZIDE; TRANDATE HCT         | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19174 003           | HYDROCHLOROTHIAZIDE; TRANDATE HCT         | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19174 004           | HYDROCHLOROTHIAZIDE; TRANDATE HCT         | 4012444          | MAR 15, 1994      |             | NCE            | AUG 01, 1994      |
| 19261 001           | HYDROXYAMPHETAMINE HYDROBROMIDE; PAREMYD  |                  |                   |             | NC             | JAN 30, 1995      |
| 20100 001           | INSULIN BIOSYNTHETIC HUMAN; HUMULIN 50/50 |                  |                   |             | NP             | APR 29, 1995      |
| 18735 007           | IOPAMIDOL; ISOVUE-250                     | 4001323          | JAN 04, 1996      |             | NS             | JUL 06, 1995      |
| 19710 001           | IOVERSOL; OPTIRAY 320                     | 4396598          | OCT 26, 2002      | U-29        | I-83           | DEC 11, 1995      |
| 19710 002           | IOVERSOL; OPTIRAY 240                     |                  |                   |             | I-78           | JUL 09, 1995      |
| 19710 004           | IOVERSOL; OPTIRAY 300                     | 4396598          | OCT 26, 2002      | U-61        | NS             | JAN 22, 1995      |
| 19710 005           | IOVERSOL; OPTIRAY 350                     | 4396598          | OCT 26, 2002      | U-62        | NS             | JAN 22, 1995      |
|                     |                                           |                  |                   |             | I-74           | JAN 22, 1995      |
| 20083 001           | ITRACONAZOLE; SPORANOX                    | 4267179          | MAY 12, 1998      |             | NCE            | SEP 11, 1997      |

&gt;ADD&gt;

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME            | PATENT<br>NUMBER                          | PATENT<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES            |
|---------------------|----------------------------------------|-------------------------------------------|-------------------|--------------|----------------|------------------------------|
| 19645 001           | KETOROLAC TROMETHAMINE; TORADOL        | 4089969                                   | MAY 16, 1997      | U-55         | NDF<br>NCE     | DEC 20, 1994<br>NOV 30, 1994 |
| 19700 001           | KETOROLAC TROMETHAMINE; ACULAR         | 4089969                                   | MAY 16, 1997      |              |                |                              |
| 08107 001           | LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM |                                           |                   |              | I-70           | DEC 12, 1994                 |
| 08107 002           | LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM |                                           |                   |              | I-70           | DEC 12, 1994                 |
| 08107 004           | LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM |                                           |                   |              | I-70           | DEC 12, 1994                 |
| 08107 005           | LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM |                                           |                   |              | I-70           | DEC 12, 1994                 |
| 19732 001           | LEUPROLIDE ACETATE; LUPRON DEPOT       | 4917893                                   | MAR 24, 2004      |              |                |                              |
|                     |                                        | 4849228                                   | JUL 18, 2006      |              |                |                              |
|                     |                                        | 4728721                                   | MAR 01, 2005      |              |                |                              |
|                     |                                        | 4677191                                   | JUN 30, 2004      |              |                |                              |
|                     |                                        | 4652441                                   | MAR 24, 2004      |              |                |                              |
| 20011 001           | LEUPROLIDE ACETATE; LUPRON DEPOT       | 4917893                                   | MAR 24, 2004      |              |                |                              |
|                     |                                        | 4849228                                   | JUL 18, 2006      |              |                |                              |
|                     |                                        | 4728721                                   | MAR 01, 2005      |              |                |                              |
|                     |                                        | 4677191                                   | JUN 30, 2004      |              |                |                              |
|                     |                                        | 4652441                                   | MAR 24, 2004      |              |                |                              |
| >ADD>               | 20182 001                              | LEVOCARNITINE; CARNITOR                   |                   |              | I-86<br>ODE    | DEC 16, 1995<br>DEC 16, 1999 |
| >ADD>               |                                        |                                           |                   |              |                |                              |
| >ADD>               | 19941 001                              | LIDOCAINE; EMLA                           | 4562060           | DEC 31, 2002 |                |                              |
| >ADD>               |                                        |                                           | 4529601           | JUL 16, 2002 | NC<br>ODE      | DEC 30, 1995<br>DEC 31, 1998 |
|                     | 20105 001                              | LIOTHYRONINE SODIUM; TRIOSTAT             |                   |              |                |                              |
|                     | 20013 001                              | LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN      | 4528287           | JUL 09, 2002 | U-36<br>NCE    | FEB 21, 1997                 |
|                     | 19487 001                              | LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D     |                   |              | I-82           | NOV 23, 1995                 |
|                     | 19860 001                              | LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D     |                   |              | I-82           | NOV 23, 1995                 |
|                     | 19940 001                              | MASOPROCOL; ACTINEX                       | 5008294           | APR 15, 2008 | U-68           |                              |
|                     |                                        | 4695590                                   | SEP 22, 2004      |              | NCE<br>NP      | SEP 04, 1997<br>OCT 29, 1995 |
| >ADD>               | 20246 001                              | MEDROXYPROGESTERONE ACETATE; DEPO-PROVERA | 4997651           | MAR 05, 2008 | ODE            | NOV 18, 1999                 |
|                     | 20207 001                              | MELPHALAN HYDROCHLORIDE; ALKERAN          |                   |              | NCE            | DEC 24, 1992                 |
|                     | 19651 001                              | MESALAMINE; ASACOL                        |                   |              | NDF            | JAN 31, 1995                 |
|                     | 17659 001                              | METAPROTERENOL SULFATE; ALUPENT           |                   |              | I-67           | NOV 14, 1994                 |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME                  | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|----------------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 19962 001           | METOPROLOL SUCCINATE; TOPROL XL              | 3998790          | APR 08, 1992      |             | NE             | JAN 10, 1995      |
|                     |                                              | 3876802          | APR 08, 1992      |             |                |                   |
| 19962 002           | METOPROLOL SUCCINATE; TOPROL XL              | 3998790          | APR 08, 1992      |             | NE             | JAN 10, 1995      |
|                     |                                              | 3876802          | APR 08, 1992      |             |                |                   |
| 19962 003           | METOPROLOL SUCCINATE; TOPROL XL              | 3998790          | APR 08, 1992      |             | NE             | JAN 10, 1995      |
|                     |                                              | 3876802          | APR 08, 1992      |             |                |                   |
| 20208 001           | METRONIDAZOLE; METROGEL                      |                  |                   |             | NDF            | AUG 17, 1995      |
| 20098 001           | MIVACURIUM CHLORIDE; MIVACRON                | 4761418          | AUG 02, 2005      |             | NCE            | JAN 22, 1997      |
| 20098 002           | MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5% | 4761418          | AUG 02, 2005      |             | NCE            | JAN 22, 1997      |
| 19583 001           | NABUMETONE; RELAFEN                          | 4420639          | DEC 13, 2000      |             | NCE            | DEC 24, 1996      |
|                     |                                              | 4061779          | DEC 06, 1994      | U-19        |                |                   |
| 19583 002           | NABUMETONE; RELAFEN                          | 4420639          | DEC 13, 2000      |             | NCE            | DEC 24, 1996      |
|                     |                                              | 4061779          | DEC 06, 1994      | U-19        |                |                   |
| 19886 001           | NAFARELIN ACETATE; SYNAREL                   |                  |                   |             | I-68           | FEB 26, 1995      |
| 20109 001           | NAFARELIN ACETATE; SYNAREL                   | 4234571          | NOV 18, 1997      |             | NCE            | FEB 13, 1995      |
|                     |                                              |                  |                   |             | I-68           | FEB 26, 1995      |
| >ADD>               | 19660 001                                    | 4760072          | JUL 26, 2005      |             |                |                   |
| >ADD>               |                                              | 4474787          | OCT 02, 2001      |             | NCE            | DEC 30, 1997      |
|                     | 19734 001                                    | 3985758          | OCT 12, 1995      |             | NDF            | JAN 30, 1995      |
|                     |                                              |                  |                   |             | NCE            | DEC 21, 1993      |
|                     | 20005 001                                    | 3985758          | OCT 12, 1995      |             | NDF            | FEB 21, 1995      |
|                     |                                              |                  |                   |             | NCE            | DEC 21, 1993      |
|                     | 20005 002                                    | 3985758          | OCT 12, 1995      |             | NDF            | FEB 21, 1995      |
|                     |                                              |                  |                   |             | NCE            | DEC 21, 1993      |
|                     | 20005 003                                    | 3985758          | OCT 12, 1995      |             | NDF            | FEB 21, 1995      |
|                     |                                              |                  |                   |             | NCE            | DEC 21, 1993      |
|                     | 19983 001                                    | 4946853          | AUG 07, 2007      | U-56        | NS             | JAN 28, 1995      |
|                     | 19983 002                                    | 4946853          | AUG 07, 2007      | U-56        | NS             | JAN 28, 1995      |
|                     | 20076 001                                    | 5016652          | MAY 21, 2008      |             | NDF            | NOV 07, 1994      |
|                     | 20076 002                                    | 5016652          | MAY 21, 2008      |             | NDF            | NOV 07, 1994      |
|                     | 20076 003                                    | 5016652          | MAY 21, 2008      |             | NDF            | NOV 07, 1994      |
|                     | 20150 001                                    |                  |                   |             | NP             | APR 22, 1995      |
|                     | 20150 002                                    |                  |                   |             | NP             | APR 22, 1995      |
|                     | 20150 003                                    |                  |                   |             | NP             | APR 22, 1995      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME       | PATENT<br>NUMBER                  | PATENT<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |              |
|---------------------|-----------------------------------|-----------------------------------|-------------------|--------------|----------------|-------------------|--------------|
| 20165 001           | NICOTINE; NICODERM                | 5004610                           | APR 02, 2008      |              |                |                   |              |
|                     |                                   | 4144317                           | SEP 09, 1992      |              | NDF            | NOV 07, 1994      |              |
| 20165 002           | NICOTINE; NICODERM                | 5004610                           | APR 02, 2008      |              |                |                   |              |
|                     |                                   | 4144317                           | SEP 09, 1992      |              | NDF            | NOV 07, 1994      |              |
| 20165 003           | NICOTINE; NICODERM                | 5004610                           | APR 02, 2008      |              |                |                   |              |
|                     |                                   | 4144317                           | SEP 09, 1992      |              | NDF            | NOV 07, 1994      |              |
| 20066 001           | NICOTINE POLACRILEX; NICORETTE DS |                                   |                   |              | NP             | JUN 08, 1995      |              |
| 20064 001           | NITROFURANTOIN; MACROBID          | 4798725                           | JAN 17, 2006      |              |                |                   |              |
|                     |                                   | 4772473                           | SEP 20, 2005      |              | NDF            | DEC 24, 1994      |              |
| 19757 001           | NORFLOXACIN; CHIBROXIN            | 4551456                           | NOV 05, 2002      | U-57         |                |                   |              |
| 20087 001           | OFLOXACIN; FLOXIN IN DEXTROSE 5%  | 4382892                           | MAY 10, 2000      |              | NCE            | DEC 28, 1995      |              |
| 20087 002           | OFLOXACIN; FLOXIN                 | 4382892                           | MAY 10, 2000      |              | NCE            | DEC 28, 1995      |              |
| 20087 003           | OFLOXACIN; FLOXIN                 | 4382892                           | MAY 10, 2000      |              | NCE            | DEC 28, 1995      |              |
| 20087 004           | OFLOXACIN; FLOXIN IN DEXTROSE 5%  | 4382892                           | MAY 10, 2000      |              | NCE            | DEC 28, 1995      |              |
| 20087 005           | OFLOXACIN; FLOXIN IN DEXTROSE 5%  | 4382892                           | MAY 10, 2000      |              | NCE            | DEC 28, 1995      |              |
| 19715 001           | OLSALAZINE SODIUM; DIPENTUM       | 4559330                           | AUG 04, 2004      | U-58         | NCE            | JUL 31, 1995      |              |
| >ADD>               | 20103 001                         | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789           | JUN 28, 2005 | U-44           | NDF               | DEC 31, 1995 |
| >ADD>               |                                   |                                   | 4695578           | SEP 22, 2004 |                |                   |              |
| >ADD>               | 20103 002                         | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4753789           | JUN 28, 2005 | U-44           | NDF               | DEC 31, 1995 |
| >ADD>               |                                   |                                   | 4695578           | SEP 22, 2004 |                |                   |              |
| 18841 004           | OXAPROZIN; DAYPRO                 |                                   |                   |              | NCE            | OCT 29, 1997      |              |
| 19828 001           | OXICONAZOLE NITRATE; OXISTAT      |                                   |                   |              | NCE            | DEC 30, 1993      |              |
|                     |                                   |                                   |                   |              | I-77           | SEP 30, 1995      |              |
| 20209 001           | OXICONAZOLE NITRATE; OXISTAT      |                                   |                   |              | NP             | SEP 30, 1995      |              |
|                     |                                   |                                   |                   |              | NCE            | DEC 30, 1993      |              |
| >ADD>               | 20262 001                         | PACLITAXEL; TAXOL                 |                   |              | NCE            | DEC 29, 1997      |              |
| >ADD>               | 20031 001                         | PAROXETINE HYDROCHLORIDE; PAXIL   |                   |              | NCE            | DEC 29, 1997      |              |
| >ADD>               | 20031 002                         | PAROXETINE HYDROCHLORIDE; PAXIL   |                   |              | NCE            | DEC 29, 1997      |              |
| >ADD>               | 20031 003                         | PAROXETINE HYDROCHLORIDE; PAXIL   |                   |              | NCE            | DEC 29, 1997      |              |
| >ADD>               | 20031 004                         | PAROXETINE HYDROCHLORIDE; PAXIL   |                   |              | NCE            | DEC 29, 1997      |              |
| >ADD>               | 20031 005                         | PAROXETINE HYDROCHLORIDE; PAXIL   |                   |              | NCE            | DEC 29, 1997      |              |



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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME                                  | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 19775 001           | PAZOSIN HYDROCHLORIDE; MINIPRESS XL                          | 5082668          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4783337          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4765989          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4612008          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4327725          | MAY 04, 1999      |             |                |                   |
|                     |                                                              | 4092315          | MAY 30, 1995      |             | NDF            | JAN 29, 1995      |
| 19775 002           | PAZOSIN HYDROCHLORIDE; MINIPRESS XL                          | 5082668          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4783337          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4765989          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4612008          | SEP 16, 2003      |             |                |                   |
|                     |                                                              | 4327725          | MAY 04, 1999      |             |                |                   |
|                     |                                                              | 4092315          | MAY 30, 1995      |             | NDF            | JAN 29, 1995      |
| 19157 001           | PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED                     | 4448774          | MAY 15, 2001      |             |                |                   |
| 19627 001           | PROPOFOL; DIPRIVAN                                           | 4798846          | NOV 01, 1996      |             | I-73           | DEC 31, 1994      |
| >ADD><br>>ADD>      | 20021 002 PSEUDOEPHEDRINE HYDROCHLORIDE; PSEUDOEPHEDRINE HCL | 4801461          | MAY 05, 2004      |             |                |                   |
|                     |                                                              | 4576604          | MAR 18, 2003      |             |                |                   |
| 18703 001           | RANITIDINE HYDROCHLORIDE; ZANTAC 150                         | 4521431          | JUN 04, 2002      |             | I-75           | MAY 19, 1995      |
| 18703 002           | RANITIDINE HYDROCHLORIDE; ZANTAC 300                         | 4521431          | JUN 04, 2002      |             | I-75           | MAY 19, 1995      |
| 19675 001           | RANITIDINE HYDROCHLORIDE; ZANTAC                             | 4128658          | DEC 05, 1995      |             | I-75           | MAY 19, 1995      |
| 19766 001           | SIMVASTATIN; ZOCOR                                           | 4444784          | APR 24, 2001      | U-59        | NCE            | DEC 23, 1997      |
| 19766 002           | SIMVASTATIN; ZOCOR                                           | 4444784          | APR 24, 2001      | U-59        | NCE            | DEC 23, 1997      |
| 19766 003           | SIMVASTATIN; ZOCOR                                           | 4444784          | APR 24, 2001      | U-59        | NCE            | DEC 23, 1997      |
| 19766 004           | SIMVASTATIN; ZOCOR                                           | 4444784          | APR 24, 2001      | U-59        | NCE            | DEC 23, 1997      |
| 20166 001           | SODIUM THIOSULFATE; SODIUM THIOSULFATE                       |                  |                   |             | NCE            | FEB 14, 1997      |
| 19865 001           | SOTALOL HYDROCHLORIDE; BETAPACE                              |                  |                   |             | NCE            | OCT 30, 1997      |
|                     |                                                              |                  |                   |             | ODE            | OCT 30, 1999      |
| 19865 002           | SOTALOL HYDROCHLORIDE; BETAPACE                              |                  |                   |             | NCE            | OCT 30, 1997      |
|                     |                                                              |                  |                   |             | ODE            | OCT 30, 1999      |
| 19865 003           | SOTALOL HYDROCHLORIDE; BETAPACE                              |                  |                   |             | NCE            | OCT 30, 1997      |
|                     |                                                              |                  |                   |             | ODE            | OCT 30, 1999      |
| 19865 004           | SOTALOL HYDROCHLORIDE; BETAPACE                              |                  |                   |             | NCE            | OCT 30, 1997      |
|                     |                                                              |                  |                   |             | ODE            | OCT 30, 1999      |
| >ADD>               | 20080 001 SUMATRIPTAN SUCCINATE; IMITREX                     | 5037845          | AUG 06, 2008      | U-72        | NCE            | DEC 28, 1997      |
|                     | 20063 001 TECHNETIUM TC-99M RED BLOOD CELL KIT; RBC-SCAN     |                  |                   |             | NP             | JUN 11, 1995      |
|                     | 19785 001 TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE        |                  |                   |             | I-80           | SEP 09, 1995      |
|                     | 20043 003 TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX               | 4730000          | MAR 08, 2005      | U-36        | NCE            | JAN 30, 1997      |
|                     | 20043 004 TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX               | 4730000          | MAR 08, 2005      | U-36        | NCE            | JAN 30, 1997      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME        | PATENT<br>NUMBER | PATENT<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|------------------------------------|------------------|-------------------|-------------|----------------|-------------------|
| 20119 001           | TENIPOSIDE; VUMON                  |                  |                   |             | NCE            | JUL 14, 1997      |
|                     |                                    |                  |                   |             | ODE            | JUL 14, 1999      |
| >ADD> 20192 001     | TERBINAFINE HYDROCHLORIDE; LAMISIL | 4775534          | JUL 05, 2005      | U-73        | NCE            | DEC 30, 1999      |
| 19614 003           | VERAPAMIL HYDROCHLORIDE; VERELAN   | 4863742          | SEP 05, 2006      | U-3         | NDF            | MAY 29, 1993      |
| 20199 001           | ZALCITABINE; HIVID                 | 5028595          | JUL 02, 2008      | U-65        | NCE            | JUN 19, 1997      |
|                     |                                    | 4879277          | NOV 07, 2006      | U-65        | ODE            | JUN 19, 1999      |
| 20199 002           | ZALCITABINE; HIVID                 | 5028595          | JUL 02, 2008      | U-65        | NCE            | JUN 19, 1997      |
|                     |                                    | 4879277          | NOV 07, 2006      | U-65        | ODE            | JUN 19, 1999      |
| 19655 001           | ZIDOVUDINE; RETROVIR               | 4837208          | FEB 09, 2005      |             |                |                   |
|                     |                                    | 4833130          | FEB 09, 2005      |             | I-47           | MAY 02, 1993      |
|                     |                                    | 4828838          | FEB 09, 2005      |             | ODE            | MAR 19, 1994      |
|                     |                                    | 4724232          | FEB 09, 2005      |             | NCE            | MAR 19, 1992      |
| 19910 001           | ZIDOVUDINE; RETROVIR               | 4837208          | FEB 09, 2005      |             |                |                   |
|                     |                                    | 4833130          | FEB 09, 2005      |             | ODE            | MAR 19, 1994      |
|                     |                                    | 4818538          | FEB 09, 2005      |             | I-47           | MAY 02, 1993      |
|                     |                                    | 4724232          | FEB 09, 2005      |             | NCE            | MAR 19, 1992      |
| 19951 001           | ZIDOVUDINE; RETROVIR               | 4837208          | FEB 09, 2005      |             |                |                   |
|                     |                                    | 4833130          | FEB 09, 2005      |             | NCE            | MAR 19, 1992      |
|                     |                                    | 4818538          | FEB 09, 2005      |             |                |                   |
|                     |                                    | 4724232          | FEB 09, 2005      |             | ODE            | MAR 19, 1994      |
| >ADD> 19908 001     | ZOLPIDEM TARTRATE; AMBIEN          |                  |                   |             | NCE            | DEC 16, 1997      |
| >ADD> 19908 002     | ZOLPIDEM TARTRATE; AMBIEN          |                  |                   |             | NCE            | DEC 16, 1997      |