

# **APPROVED DRUG PRODUCTS**

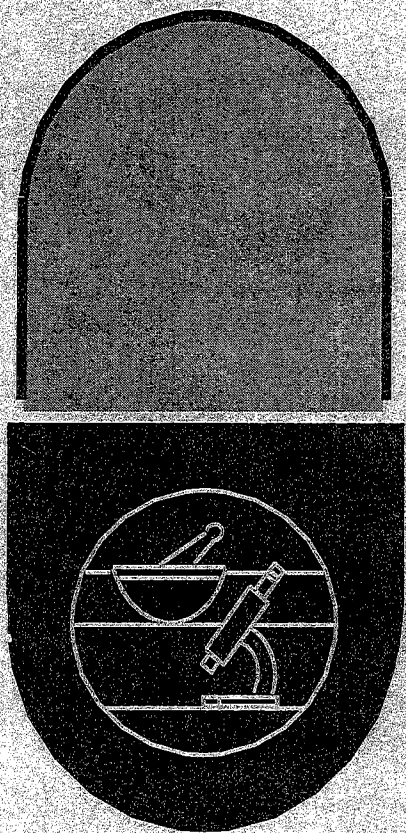
## **With Therapeutic Equivalence Evaluations**



**The "Orange Book"**

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**CUMULATIVE  
SUPPLEMENT 12  
DECEMBER 2000**



# **APPROVED DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**20<sup>TH</sup> EDITION**

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

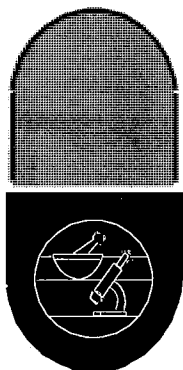
**2000**



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### **APPROVED DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**21<sup>ST</sup> EDITION  
2001**

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

**20TH EDITION**

**Cumulative Supplement 12**

**December 2000**

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**20TH EDITION**

**CUMULATIVE SUPPLEMENT 12  
DECEMBER 2000**

**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, 20th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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.)

New additions 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.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >DLT> (DELETE) to the left of the line. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition.

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 20th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st Edition.

## 1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When

this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

#### APPLICANT NAME CHANGES

##### FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)

##### NEW APPLICANT NAME (NEW ABBREVIATED NAME)

GALDERMA LABS INC  
(GALDERMA)

GALDERMA LABORATORIES LP  
(GALDERMA LABS LP)

GLOBAL PHARMACEUTICAL CORP  
(GLOBAL PHARM)

IMPAX LABORATORIES INC  
(IMPAX LABS)

HOECHST MARION ROUSSEL INC  
(HOECHST MARION RSSL)

AVENTIS PHARMACEUTICALS INC  
(AVENTIS PHARMS)

RHONE POULENC RORER PHARMACEUTICALS INC  
(RHONE POULENCE RORER)

AVENTIS PHARMACEUTICALS PRODUCTS INC  
(AVENTIS PHARM PROD)

ROCHE GLOBAL DEVELOPMENT  
(ROCHE GLOBAL)

ROCHE GLOBAL A DIVISION OF SYNTEX (USA) LLC  
(ROCHE GLOBAL DEV)

SYNTEX (USA) INC  
(SYNTEX)

SYNTEX (USA) LLC  
(SYNTEX (USA) LLC)

SYNTEX FP INC  
(SYNTEX)

SYNTEX (USA) LLC  
(SYNTEX (USA) LLC)

SYNTEX LABORATORIES INC  
SUB SYNTEX CORP  
(SYNTEX)

SYNTEX (USA) LLC  
(SYNTEX (USA) LLC)

SYNTEX USA INC  
(SYNTEX)

SYNTEX (USA) LLC  
(SYNTEX (USA) LLC)

TAP HOLDINGS INC  
(TAP HOLDINGS)

TAP PHARMACEUTICAL PRODUCTS INC  
(TAP PHARM)

ZENECA INC  
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP  
(ASTRAZENECA PHARMS)

ZENECA LTD  
(ZENECA)

ASTRAZENECA UK LTD  
(ASTRAZENECA UK)

ZENECA PHARMACEUTICALS DIV ZENECA INC  
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP  
(ASTRAZENECA PHARMS)

### 1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Falcon Pharms' (Alcon) NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

### 1.4 AVAILABILITY OF THE EDITION

The 20th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents  
Government Printing Office  
P.O. Box 371954  
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is \$101.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at <http://www.fda.gov/cder/ob>. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at <http://www.fda.gov/cder/orange/adp.htm>.

The Internet version of the hard copy monthly supplement is at <http://www.fda.gov/cder/orange/supplement/cspreface.htm>. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product data at <http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at <http://www.fda.gov/cder/orange/20bookpub.pdf>.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at <http://www.fda.gov/cder/orange/supplement/patents.pdf>.

The Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:  
<http://www.fda.gov/cder/orange/patdecl.pdf>  
<http://www.fda.gov/cder/orange/patdecl.html>

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

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

### **DESCRIPTION OF REPORT**

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 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 1999) 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 1999</u> | <u>JUN 2000</u> | <u>SEP 2000</u> | <u>DEC 2000</u> |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| DRUG PRODUCTS LISTED            | 10045           | 10186           | 10332           | 10360           |
| SINGLE SOURCE                   | 2599 (25.9%)    | 2617 (25.7%)    | 2662 (25.8%)    | 2682 (25.9%)    |
| MULTISOURCE                     | 7335 (73.0%)    | 7458 (73.2%)    | 7560 (73.2%)    | 7568 (73.1%)    |
| THERAPEUTICALLY EQUIVALENT      | 6986 (69.5%)    | 7132 (70.0%)    | 7238 (70.1%)    | 7257 (70.0%)    |
| NOT THERAPEUTICALLY EQUIVALENT  | 349 (3.5%)      | 326 (3.2%)      | 322 (3.1%)      | 311 (3.0%)      |
| EXCEPTIONS <sup>1</sup>         | 111 (1.1%)      | 111 (1.1%)      | 110 (1.1%)      | 110 (1.1%)      |
| NEW MOLECULAR ENTITIES APPROVED | 0               | 11              | 7               | 2               |
| NUMBER OF APPLICANTS            | 576             | 580             | 587             | 594             |

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



PRESCRIPTION DRUG PRODUCT LIST  
20TH EDITION  
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'2000 - DEC'2000

1-1

ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE

TABLET; ORAL  
TRIZIVIR

+ GLAXO WELLCOME EQ 300MG BASE;150MG;300MG N21205 001  
NOV 14, 2000

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL

PHRENILIN FORTE

AB + AMARIN PHARMS 650MG;50MG N88831 001

JUN 19, 1985

AB \* CARRICK 650MG;50MG N88831 001

JUN 19, 1985

TABLET; ORAL

PHRENILIN

AB + AMARIN PHARMS 325MG;50MG N87811 001

JUN 19, 1985

AB \* CARRICK 325MG;50MG N87811 001

JUN 19, 1985

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA AMARIN PHARMS 120MG/5ML;12MG/5ML N86024 001

AA CARRICK 120MG/5ML;12MG/5ML N86024 001

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE NO. 4

AA ROXANE 300MG;60MG N84667 001

@ 300MG;60MG

N84667 001

ACETAMINOPHEN W/ CODEINE NO. 2

AA ROXANE 300MG;15MG N84659 001

@ 300MG;15MG

N84659 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA BARR 500MG;2.5MG N40307 001

JUL 26, 2000

AA 500MG;5MG N40308 001

JUL 26, 2000

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA BARR 500MG;7.5MG N40307 002

JUL 26, 2000

AA 500MG;10MG N40309 001

JUL 26, 2000

AA 650MG;7.5MG N40307 003

JUL 26, 2000

AA 650MG;10MG N40307 004

JUL 26, 2000

AA 750MG;7.5MG N40308 002

JUL 26, 2000

AA MALLINCKRODT 325MG;5MG N40409 001

OCT 20, 2000

AA 325MG;7.5MG N40405 001

SEP 08, 2000

AA 325MG;10MG N40400 001

JUL 26, 2000

AA + UCB 325MG;7.5MG N40248 001

APR 28, 2000

AA 325MG;10MG N40248 002

APR 28, 2000

\* 325MG;7.5MG N40248 001

APR 28, 2000

AA VINTAGE PHARMS 325MG;10MG N40355 001

MAY 31, 2000

AA 500MG;10MG N40356 001

MAY 31, 2000

AA 660MG;10MG N40358 001

MAY 31, 2000

AA WATSON LABS 660MG;10MG N40094 003

AUG 08, 2000

AA LORTAB 325MG;5MG N40099 001

JUN 25, 1997

AA + UCB 325MG;5MG N40099 001

JUN 25, 1997

\* 325MG;5MG N40099 001

JUN 25, 1997

AA NORCO 325MG;10MG N40148 001

FEB 14, 1997

AA + WATSON LABS 325MG;10MG N40148 001

FEB 14, 1997

\* 325MG;10MG N40148 001

FEB 14, 1997

ALPROSTADIL

## INJECTABLE; INJECTION

EDEX

|         |    |                |              |              |
|---------|----|----------------|--------------|--------------|
| > DLT > | AP | SCHWARZ PHARMA | 0.005MG/VIAL | N20649 001   |
| > DLT > |    |                |              | JUN 12, 1997 |
| > ADD > | @  |                | 0.005MG/VIAL | N20649 001   |
| > ADD > |    |                |              | JUN 12, 1997 |
| > ADD > | +  |                | 0.01MG/VIAL  | N20649 005   |
| > ADD > |    |                |              | JUL 30, 1998 |
| > ADD > | +  |                | 0.02MG/VIAL  | N20649 006   |
| > ADD > |    |                |              | JUL 30, 1998 |
| > ADD > | +  |                | 0.04MG/VIAL  | N20649 007   |
| > ADD > |    |                |              | JUL 30, 1998 |

ALTRETAMINE

## CAPSULE; ORAL

HEXALEN

|                      |      |              |
|----------------------|------|--------------|
| * MEDIMMUNE ONCOLOGY | 50MG | N19926 001   |
|                      |      | DEC 26, 1990 |
| + MGI PHARMA         | 50MG | N19926 001   |
|                      |      | DEC 26, 1990 |

AMANTADINE HYDROCHLORIDE

## CAPSULE; ORAL

AMANTADINE HCL

|    |                    |       |              |
|----|--------------------|-------|--------------|
| AB | GENEVA PHARMS TECH | 100MG | N71293 001   |
|    |                    |       | FEB 18, 1987 |
| AB | INVAMED            | 100MG | N71293 001   |
|    |                    |       | FEB 18, 1987 |

AMIFOSTINE

## INJECTABLE; INJECTION

ETHYOL

|                      |            |              |
|----------------------|------------|--------------|
| + MEDIMMUNE ONCOLOGY | 500MG/VIAL | N20221 001   |
|                      |            | DEC 08, 1995 |
| * US BIOSCIENCE      | 500MG/VIAL | N20221 001   |
|                      |            | DEC 08, 1995 |

AMIKACIN SULFATE

## INJECTABLE; INJECTION

AMIKACIN SULFATE

|    |             |                  |              |
|----|-------------|------------------|--------------|
| AP | ASTRAZENECA | EQ 50MG BASE/ML  | N63167 001   |
|    |             |                  | DEC 14, 1995 |
| AP |             | EQ 250MG BASE/ML | N63169 001   |
|    |             |                  | DEC 14, 1995 |
| @  |             | EQ 50MG BASE/ML  | N63167 001   |
|    |             |                  | DEC 14, 1995 |
| @  |             | EQ 250MG BASE/ML | N63169 001   |
|    |             |                  | DEC 14, 1995 |

AMINO ACIDS

## INJECTABLE; INJECTION

NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER

|                 |     |              |
|-----------------|-----|--------------|
| BAXTER HLTHCARE | 15% | N20107 001   |
|                 |     | FEB 05, 1993 |
| @               | 15% | N20107 001   |
|                 |     | FEB 05, 1993 |

TROPHAMINEB BRAIN

|   |    |              |
|---|----|--------------|
|   | 6% | N19018 001   |
|   |    | JUL 20, 1984 |
| + | 6% | N19018 001   |
|   |    | JUL 20, 1984 |

TROPHAMINE 10%B BRAIN

|   |     |              |
|---|-----|--------------|
|   | 10% | N19018 003   |
|   |     | SEP 07, 1988 |
| + | 10% | N19018 003   |
|   |     | SEP 07, 1988 |

AMINOPHYLLINE

## TABLET; ORAL

AMINOPHYLLINE

|    |              |       |            |
|----|--------------|-------|------------|
| AB | GLOBAL PHARM | 100MG | N84574 001 |
| AB |              | 200MG | N84575 001 |
| @  | IMPAX LABS   | 100MG | N84574 001 |
| @  |              | 200MG | N84576 001 |

AMIODARONE HYDROCHLORIDE

## TABLET; ORAL

AMIODARONE HCL

|       |       |              |
|-------|-------|--------------|
| + BON | 400MG | N75315 002   |
|       |       | JUN 30, 2000 |

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

|    |                  |       |
|----|------------------|-------|
| AB | MD PHARM         | 10MG  |
| AB |                  | 25MG  |
| AB |                  | 50MG  |
| AB |                  | 75MG  |
| AB |                  | 100MG |
| AB |                  | 150MG |
| @  | MEDEVA PHARMS CA | 10MG  |
| @  |                  | 25MG  |
| @  |                  | 50MG  |
| @  |                  | 75MG  |
| @  |                  | 100MG |
| @  |                  | 150MG |
| AB | PUREPAC PHARM    | 10MG  |
| AB |                  | 25MG  |
| AB |                  | 50MG  |
| AB |                  | 75MG  |
| AB |                  | 100MG |
| @  |                  | 10MG  |
| @  |                  | 25MG  |
| @  |                  | 50MG  |
| @  |                  | 75MG  |
| @  |                  | 100MG |
| AB | ROXANE           | 10MG  |
| AB |                  | 25MG  |
| AB |                  | 50MG  |
| AB |                  | 75MG  |
| AB |                  | 100MG |
| @  |                  | 10MG  |
| @  |                  | 25MG  |
| @  |                  | 50MG  |
| @  |                  | 75MG  |
| @  |                  | 100MG |

|              |     |
|--------------|-----|
| N85864       | 001 |
| N85935       | 001 |
| N85936       | 001 |
| N86337       | 001 |
| N86336       | 001 |
| N86335       | 001 |
| N85864       | 001 |
| N85935       | 001 |
| N85936       | 001 |
| N86337       | 001 |
| N86336       | 001 |
| N86335       | 001 |
| N88075       | 001 |
| SEP 16, 1983 |     |
| N88076       | 001 |
| MAY 20, 1983 |     |
| N88077       | 001 |
| SEP 16, 1983 |     |
| N88078       | 001 |
| SEP 16, 1983 |     |
| N88079       | 001 |
| SEP 16, 1983 |     |
| N88075       | 001 |
| SEP 16, 1983 |     |
| N88076       | 001 |
| MAY 20, 1983 |     |
| N88077       | 001 |
| SEP 16, 1983 |     |
| N88078       | 001 |
| SEP 16, 1983 |     |
| N88079       | 001 |
| SEP 16, 1983 |     |
| N86002       | 001 |
| N85944       | 001 |
| N85945       | 001 |
| N86004       | 001 |
| N86003       | 001 |
| N86002       | 001 |
| N85944       | 001 |
| N85945       | 001 |
| N86004       | 001 |
| N86003       | 001 |

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

|    |       |           |
|----|-------|-----------|
| AB | MYLAN | 10MG; 2MG |
| AB | +     | 10MG; 2MG |
| AB |       | 10MG; 4MG |
| AB | +     | 10MG; 4MG |
| AB |       | 25MG; 2MG |
| AB | +     | 25MG; 2MG |
| AB |       | 25MG; 4MG |
| AB | +     | 25MG; 4MG |
| AB |       | 50MG; 4MG |
| AB | +     | 50MG; 4MG |

|              |     |
|--------------|-----|
| N70336       | 001 |
| NOV 10, 1988 |     |
| N70336       | 001 |
| NOV 10, 1988 |     |
| N71442       | 001 |
| NOV 10, 1988 |     |
| N71442       | 001 |
| NOV 10, 1988 |     |
| N70337       | 001 |
| NOV 10, 1988 |     |
| N70337       | 001 |
| NOV 10, 1988 |     |
| N70338       | 001 |
| NOV 10, 1988 |     |
| N70338       | 001 |
| NOV 10, 1988 |     |
| N71443       | 001 |
| NOV 10, 1988 |     |
| N71443       | 001 |
| NOV 10, 1988 |     |

AMOXAPINE

TABLET; ORAL

AMOXAPINE

|    |             |       |
|----|-------------|-------|
| AB | WATSON LABS | 150MG |
| AB | +           | 150MG |
| AB | ASENDIN     | 25MG  |
| AB | LEDERLE     | 50MG  |
| AB |             | 100MG |
| AB | *           | 150MG |
| @  |             | 25MG  |
| @  |             | 50MG  |
| @  |             | 100MG |
| @  |             | 150MG |

|              |     |
|--------------|-----|
| N72421       | 001 |
| MAY 11, 1989 |     |
| N72421       | 001 |
| MAY 11, 1989 |     |
| N18021       | 001 |
| N18021       | 002 |
| N18021       | 003 |
| N18021       | 004 |
| N18021       | 001 |
| N18021       | 002 |
| N18021       | 003 |
| N18021       | 004 |

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

|    |       |           |
|----|-------|-----------|
| AB | MYLAN | 125MG/5ML |
|----|-------|-----------|

|        |     |
|--------|-----|
| N62090 | 001 |
|--------|-----|

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

|           |              |                  |                   |
|-----------|--------------|------------------|-------------------|
| <u>AB</u> | <u>MYLAN</u> | <u>250MG/5ML</u> | <u>N62090 002</u> |
| @         |              | 125MG/5ML        | N62090 001        |
| @         |              | 250MG/5ML        | N62090 002        |

TABLET; ORAL

AMOXICILLIN

|           |                |              |                   |
|-----------|----------------|--------------|-------------------|
| <u>AB</u> | <u>RANBAXY</u> | <u>500MG</u> | <u>N65059 001</u> |
|           |                |              | NOV 24, 2000      |
| <u>AB</u> |                | <u>875MG</u> | <u>N65059 002</u> |
|           |                |              | NOV 24, 2000      |
| <u>AB</u> | <u>TEVA</u>    | <u>500MG</u> | <u>N65056 001</u> |
|           |                |              | SEP 18, 2000      |
| <u>AB</u> |                | <u>875MG</u> | <u>N65056 002</u> |
|           |                |              | SEP 18, 2000      |

AMOXIL

|           |                           |              |                   |
|-----------|---------------------------|--------------|-------------------|
| <u>AB</u> | <u>SMITHKLINE BEECHAM</u> | <u>500MG</u> | <u>N50754 002</u> |
|           |                           |              | JUL 10, 1998      |
| <u>AB</u> | <u>+</u>                  | <u>875MG</u> | <u>N50754 001</u> |
|           |                           |              | JUL 10, 1998      |
|           |                           | <u>500MG</u> | <u>N50754 002</u> |
|           |                           |              | JUL 10, 1998      |
|           |                           | <u>875MG</u> | <u>N50754 001</u> |
|           |                           |              | JUL 10, 1998      |

TABLET, CHEWABLE; ORAL

AMOXICILLIN

|           |                |              |                   |
|-----------|----------------|--------------|-------------------|
| <u>AB</u> | <u>RANBAXY</u> | <u>200MG</u> | <u>N65060 001</u> |
|           |                |              | NOV 29, 2000      |
| <u>AB</u> |                | <u>400MG</u> | <u>N65060 002</u> |
|           |                |              | NOV 29, 2000      |

AMOXIL

|           |                           |              |                   |
|-----------|---------------------------|--------------|-------------------|
| <u>AB</u> | <u>SMITHKLINE BEECHAM</u> | <u>200MG</u> | <u>N50761 001</u> |
|           |                           |              | APR 15, 1999      |
| <u>AB</u> | <u>+</u>                  | <u>400MG</u> | <u>N50761 002</u> |
|           |                           |              | APR 15, 1999      |
|           |                           | <u>200MG</u> | <u>N50761 001</u> |
|           |                           |              | APR 15, 1999      |
|           |                           | <u>400MG</u> | <u>N50761 002</u> |
|           |                           |              | APR 15, 1999      |

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL

AUGMENTIN '500'

|                             |                            |                   |
|-----------------------------|----------------------------|-------------------|
| <u>* SMITHKLINE BEECHAM</u> | <u>500MG;EQ 125MG BASE</u> | <u>N50564 002</u> |
|                             |                            | AUG 06, 1984      |
|                             | <u>500MG;EQ 125MG BASE</u> | <u>N50564 002</u> |
|                             |                            | AUG 06, 1984      |

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

ADDERALL 12.5

SHIRE

|                          |              |
|--------------------------|--------------|
| 3.125MG;3.125MG;3.125MG; |              |
| 3.125MG                  | N11522 012   |
|                          | AUG 31, 2000 |

ADDERALL 15

SHIRE

|                       |              |
|-----------------------|--------------|
| 3.75MG;3.75MG;3.75MG; |              |
| 3.75MG                | N11522 013   |
|                       | AUG 31, 2000 |

ADDERALL 7.5

+ SHIRE

|                          |              |
|--------------------------|--------------|
| 1.875MG;1.875MG;1.875MG; |              |
| 1.875MG                  | N11522 011   |
|                          | AUG 31, 2000 |

AMPICILLIN SODIUM

INJECTABLE; INJECTION

TOTACILLIN-N

|           |                           |                         |                   |
|-----------|---------------------------|-------------------------|-------------------|
| <u>AP</u> | <u>SMITHKLINE BEECHAM</u> | <u>EQ 1GM BASE/VIAL</u> | <u>N62727 001</u> |
|           |                           |                         | DEC 19, 1986      |
| <u>AP</u> |                           | <u>EQ 2GM BASE/VIAL</u> | <u>N62727 002</u> |
|           |                           |                         | DEC 19, 1986      |
| @         |                           | EQ 1GM BASE/VIAL        | N62727 001        |
| @         |                           | EQ 2GM BASE/VIAL        | DEC 19, 1986      |
|           |                           |                         | N62727 002        |
|           |                           |                         | DEC 19, 1986      |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMPICILLIN TRIHYDRATE

|           |              |                      |                   |
|-----------|--------------|----------------------|-------------------|
| <u>AB</u> | <u>MYLAN</u> | <u>EQ 250MG BASE</u> | <u>N61755 001</u> |
| <u>AB</u> |              | <u>EQ 500MG BASE</u> | <u>N61755 002</u> |
| @         |              | EQ 250MG BASE        | N61755 001        |

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMPICILLIN TRIHYDRATE

@ MYLAN EQ 500MG BASE N61755 002

POWDER FOR RECONSTITUTION; ORAL

TOTACILLIN

|         |    |                    |                   |            |
|---------|----|--------------------|-------------------|------------|
| > DLT > | AB | SMITHKLINE BEECHAM | EQ 125MG BASE/5ML | N62223 001 |
| > DLT > | AB |                    | EQ 250MG BASE/5ML | N62223 002 |
| > ADD > | @  |                    | EQ 125MG BASE/5ML | N62223 001 |
| > ADD > | @  |                    | EQ 250MG BASE/5ML | N62223 002 |

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

AGRYLIN

ROBERTS LABS EQ 0.5MG BASE N20333 001

\* EQ 1MG BASE N20333 002

SHIRE EQ 0.5MG BASE N20333 001

+ EQ 1MG BASE N20333 002

MAR 14, 1997

ARDEPARIN SODIUM

INJECTABLE; INJECTION

NORMIFLO

\* WYETH AYERST 5,000 UNITS/0.5ML N20227 002

\* 10,000 UNITS/0.5ML N20227 001

+ 5,000 UNITS/0.5ML N20227 002

+ 10,000 UNITS/0.5ML N20227 001

MAY 23, 1997

ARGATROBAN

INJECTABLE; INJECTION

ACOVA

+ TX BIOTECH 100MG/ML N20883 001

JUN 30, 2000

ARSENIC TRIOXIDE

INJECTABLE; INJECTION

TRISENOX

+ CELL THERAP 1MG/ML

N21248 001

SEP 25, 2000

ARTICAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

SEPTOCAINE

+ DEPROCO 4%;EQ 0.01MG BASE/ML N20971 001

APR 03, 2000

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E

INJECTABLE; INJECTION

KABI VITE PED F + N KIT

\* FRESNIUS KABI N/A, 80MG/VIAL; N/A, 0.02MG/VIAL; N/A,

0.001MG/VIAL; 400 IU/10ML; N/A; N/A,

0.14MG/VIAL; N/A, 17MG/VIAL; N/A,

5MG/VIAL; 0.2MG/10ML; N/A; N/A,

1MG/VIAL; N/A, 1.4MG/VIAL; N/A,

1.2MG/VIAL; EQ 2,300 UNITS BASE/10ML,

N/A; 7 IU/10ML; N/A N20176 001

DEC 29, 1993

VITAPED

@ FRESNIUS KABI

N/A, 80MG/VIAL; N/A, 0.02MG/VIAL; N/A,

0.001MG/VIAL; 400 IU/10ML; N/A; N/A,

0.14MG/VIAL; N/A, 17MG/VIAL; N/A,

5MG/VIAL; 0.2MG/10ML; N/A; N/A,

1MG/VIAL; N/A, 1.4MG/VIAL; N/A,

1.2MG/VIAL; EQ 2,300 UNITS BASE/10ML,

N/A; 7 IU/10ML; N/A N20176 001

DEC 29, 1993

ASPIRIN; METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL AND ASPIRIN

AB MCNEIL 325MG; 400MG

N89193 001

@ 325MG; 400MG

FEB 12, 1986

N89193 001

FEB 12, 1986

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

OXYCODONE AND ASPIRIN (HALF-STRENGTH)

|           |               |                            |                     |
|-----------|---------------|----------------------------|---------------------|
| <u>AA</u> | <u>ROXANE</u> | <u>325MG;2.25MG;0.19MG</u> | <u>N87742 001</u>   |
|           |               |                            | <u>JUN 04, 1982</u> |
|           | @             | 325MG;2.25MG;0.19MG        | N87742 001          |
|           |               |                            | <u>JUN 04, 1982</u> |

ATENOLOL

TABLET; ORAL

ATENOLOL

|           |                           |              |                     |
|-----------|---------------------------|--------------|---------------------|
| <u>AB</u> | <u>GENEVA PHARMS TECH</u> | <u>25MG</u>  | <u>N74265 001</u>   |
|           |                           |              | <u>FEB 28, 1994</u> |
| <u>AB</u> |                           | <u>50MG</u>  | <u>N74265 002</u>   |
|           |                           |              | <u>FEB 28, 1994</u> |
| <u>AB</u> |                           | <u>100MG</u> | <u>N74265 003</u>   |
|           |                           |              | <u>FEB 28, 1994</u> |
| <u>AB</u> | <u>INVAMED</u>            | <u>25MG</u>  | <u>N74265 001</u>   |
|           |                           |              | <u>FEB 28, 1994</u> |
| <u>AB</u> |                           | <u>50MG</u>  | <u>N74265 002</u>   |
|           |                           |              | <u>FEB 28, 1994</u> |
| <u>AB</u> |                           | <u>100MG</u> | <u>N74265 003</u>   |
|           |                           |              | <u>FEB 28, 1994</u> |

ATORVASTATIN CALCIUM

TABLET; ORAL

LIPITOR

|   |                                          |                     |
|---|------------------------------------------|---------------------|
|   | <u>PFIZER IRELAND PHARM EQ 40MG BASE</u> | <u>N20702 003</u>   |
|   |                                          | <u>DEC 17, 1996</u> |
| + | <u>EQ 80MG BASE</u>                      | <u>N20702 004</u>   |
|   |                                          | <u>APR 07, 2000</u> |
| * | <u>WARNER LAMBERT EXPOR EQ 40MG BASE</u> | <u>N20702 003</u>   |
|   |                                          | <u>DEC 17, 1996</u> |

ATOVAQUONE; PROGUANIL HYDROCHLORIDE

TABLET; ORAL

MALARONE

|   |                           |                    |                     |
|---|---------------------------|--------------------|---------------------|
| + | <u>GLAXO WELLCOME</u>     | <u>250MG;100MG</u> | <u>N21078 001</u>   |
|   |                           |                    | <u>JUL 14, 2000</u> |
|   | <u>MALARONE PEDIATRIC</u> |                    |                     |
| + | <u>GLAXO WELLCOME</u>     | <u>62.5MG;25MG</u> | <u>N21078 002</u>   |
|   |                           |                    | <u>JUL 14, 2000</u> |

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL

MOTOFEN

|   |                              |                      |                   |
|---|------------------------------|----------------------|-------------------|
| + | <u>AMARIN PHARMS</u>         | <u>0.025MG;1MG</u>   | <u>N17744 002</u> |
| * | <u>CARRICK</u>               | <u>0.025MG;1MG</u>   | <u>N17744 002</u> |
|   | <u>MOTOFEN HALF-STRENGTH</u> |                      |                   |
| @ | <u>AMARIN PHARMS</u>         | <u>0.025MG;0.5MG</u> | <u>N17744 001</u> |
| @ | <u>CARRICK</u>               | <u>0.025MG;0.5MG</u> | <u>N17744 001</u> |

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

|           |                  |                      |                     |
|-----------|------------------|----------------------|---------------------|
| <u>AA</u> | <u>ABLE</u>      | <u>0.025MG;2.5MG</u> | <u>N40395 001</u>   |
|           |                  |                      | <u>NOV 27, 2000</u> |
| <u>AA</u> | <u>PAR PHARM</u> | <u>0.025MG;2.5MG</u> | <u>N40357 001</u>   |
|           |                  |                      | <u>MAY 02, 2000</u> |

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON-PLUS

|   |                          |                          |                     |
|---|--------------------------|--------------------------|---------------------|
| + | <u>BAXTER PHARM PROD</u> | <u>0.14MG/ML;10MG/ML</u> | <u>N19677 001</u>   |
|   |                          |                          | <u>NOV 06, 1991</u> |
| + |                          | <u>0.14MG/ML;10MG/ML</u> | <u>N19678 001</u>   |
|   |                          |                          | <u>NOV 06, 1991</u> |
| * | <u>OHMEDA</u>            | <u>0.14MG/ML;10MG/ML</u> | <u>N19677 001</u>   |
|   |                          |                          | <u>NOV 06, 1991</u> |
| * |                          | <u>0.14MG/ML;10MG/ML</u> | <u>N19678 001</u>   |
|   |                          |                          | <u>NOV 06, 1991</u> |

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIVAR

|   |             |              |                     |
|---|-------------|--------------|---------------------|
| + | <u>ASTA</u> | <u>0.05%</u> | <u>N21127 001</u>   |
|   |             |              | <u>MAY 22, 2000</u> |

BALSALAZIDE DISODIUM

CAPSULE; ORAL

COLAZAL

|   |              |              |                     |
|---|--------------|--------------|---------------------|
| + | <u>SALIX</u> | <u>750MG</u> | <u>N20610 001</u>   |
|   |              |              | <u>JUL 18, 2000</u> |

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40

+ 3M 0.04MG/INH

N20911 002

SEP 15, 2000

QVAR 80

+ 3M 0.08MG/INH

N20911 001

SEP 15, 2000

> ADD > BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE> ADD >

GEL; TOPICAL

> ADD >

BENZACLIN

> ADD >

+ DERMIK LABS 5%;EQ 1% BASE

N50756 001

DEC 21, 2000

> ADD >BENZOYL PEROXIDE; ERYTHROMYCIN

GEL; TOPICAL

BENZAMYCIN PAK

+ DERMIK LABS 5%;3%

N50769 001

NOV 27, 2000

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA GENEVA PHARMS TECH 0.5MG

AA 1MG

AA 2MG

AA INVAMED 0.5MG

AA 1MG

AA 2MG

N72264 001

FEB 27, 1989

N72265 001

FEB 27, 1989

N72266 001

FEB 27, 1989

N72264 001

FEB 27, 1989

N72265 001

FEB 27, 1989

N72266 001

FEB 27, 1989

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

LOTION; TOPICAL

LOTRISONE

+ SCHERING PLOUGH RES EQ 0.05% BASE;1%

N20010 001

DEC 08, 2000

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAXOLOL

AT

AKORN

EQ 0.5% BASE

N75386 001

JUN 30, 2000

AT

NOVEX

EQ 0.5% BASE

N75446 001

SEP 28, 2000

BETOPTIC

AT

+ ALCON

EQ 0.5% BASE

N19270 001

AUG 30, 1985

\*

EQ 0.5% BASE

N19270 001

AUG 30, 1985

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

URECHOLINE

\* MERCK

5MG/ML

N06536 001

@

5MG/ML

N06536 001

TABLET; ORAL

BETHANECHOL CHLORIDE

AA

DANBURY PHARMA

10MG

N84408 001

AA

25MG

N84441 001

AA

50MG

N87444 001

@

10MG

N84408 001

@

25MG

N84441 001

@

50MG

N87444 001

DUVOID

AA

ROBERTS LABS

10MG

N86262 001

AA

25MG

N86263 001

AA

50MG

N85882 003

@

10MG

N86262 001

@

25MG

N86263 001

@

50MG

N85882 003

MYOTONACHOL

AA

GLENWOOD

5MG

N84188 001

AA

10MG

N84188 003

AA

25MG

N84188 004

BETHANECHOL CHLORIDE

|                    |                  |      |              |
|--------------------|------------------|------|--------------|
| TABLET, ORAL       |                  |      |              |
| <u>MYOTONACHOL</u> |                  |      |              |
| @                  | GLENWOOD         | 5MG  | N84188 001   |
| @                  |                  | 10MG | N84188 003   |
| @                  |                  | 25MG | N84188 004   |
| <u>URECHOLINE</u>  |                  |      |              |
| AA                 | * MERCK          | 5MG  | N06536 003   |
| AA                 | *                | 10MG | N06536 002   |
| AA                 | *                | 25MG | N06536 004   |
| AA                 | *                | 50MG | N06536 005   |
| @                  |                  | 5MG  | N06536 003   |
| @                  |                  | 10MG | N06536 002   |
| @                  |                  | 25MG | N06536 004   |
| @                  |                  | 50MG | N06536 005   |
| +                  | ODYSSEY PHARMS   | 5MG  | N89095 001   |
|                    |                  |      | DEC 19, 1985 |
| +                  |                  | 10MG | N88440 001   |
|                    |                  |      | MAY 29, 1984 |
| +                  |                  | 25MG | N88441 001   |
|                    |                  |      | MAY 29, 1984 |
| +                  |                  | 50MG | N89096 001   |
|                    |                  |      | DEC 19, 1985 |
| AA                 | * SIDMAK LABS NJ | 5MG  | N89095 001   |
| AA                 | *                | 10MG | DEC 19, 1985 |
| AA                 | *                | 25MG | N88440 001   |
| AA                 | *                | 50MG | MAY 29, 1984 |
| AA                 | *                |      | N88441 001   |
| AA                 | *                |      | MAY 29, 1984 |
| AA                 | *                |      | N89096 001   |
| AA                 | *                |      | DEC 19, 1985 |

BEXAROTENE

|              |        |    |              |
|--------------|--------|----|--------------|
| GEL; TOPICAL |        |    |              |
| TARGRETIN    |        |    |              |
| +            | LIGAND | 1% | N21056 001   |
|              |        |    | JUN 28, 2000 |

BISOPROLOL FUMARATE

|                            |     |     |              |
|----------------------------|-----|-----|--------------|
| TABLET, ORAL               |     |     |              |
| <u>BISOPROLOL FUMARATE</u> |     |     |              |
| AB                         | EON | 5MG | N75643 001   |
|                            |     |     | NOV 16, 2000 |

BISOPROLOL FUMARATE

|                            |         |      |              |
|----------------------------|---------|------|--------------|
| TABLET, ORAL               |         |      |              |
| <u>BISOPROLOL FUMARATE</u> |         |      |              |
| AB                         | EON     | 10MG | N75643 002   |
|                            |         |      | NOV 16, 2000 |
| <u>ZEBETA</u>              |         |      |              |
| AB                         | LEDERLE | 5MG  | N19982 002   |
|                            |         |      | JUL 31, 1992 |
| AB                         | +       | 10MG | N19982 001   |
|                            |         |      | JUL 31, 1992 |
|                            |         | 5MG  | N19982 002   |
|                            |         |      | JUL 31, 1992 |
|                            |         | 10MG | N19982 001   |
|                            |         |      | JUL 31, 1992 |

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

|                                                    |    |                    |               |
|----------------------------------------------------|----|--------------------|---------------|
| TABLET, ORAL                                       |    |                    |               |
| <u>BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE</u> |    |                    |               |
| > ADD >                                            | AB | APOTHECON          | 2.5MG; 6.25MG |
|                                                    |    |                    | N75642 002    |
|                                                    |    |                    | DEC 27, 2000  |
| > ADD >                                            | AB |                    | 5MG; 6.25MG   |
|                                                    |    |                    | N75642 001    |
|                                                    |    |                    | DEC 27, 2000  |
| > ADD >                                            | AB |                    | 10MG; 6.25MG  |
|                                                    |    |                    | N75642 003    |
|                                                    |    |                    | DEC 27, 2000  |
| > ADD >                                            | AB | CHELSEA LABS       | 2.5MG; 6.25MG |
|                                                    |    |                    | N75469 001    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB |                    | 5MG; 6.25MG   |
|                                                    |    |                    | N75469 002    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB |                    | 10MG; 6.25MG  |
|                                                    |    |                    | N75469 003    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB | EON                | 2.5MG; 6.25MG |
|                                                    |    |                    | N75579 001    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB |                    | 5MG; 6.25MG   |
|                                                    |    |                    | N75579 002    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB |                    | 10MG; 6.25MG  |
|                                                    |    |                    | N75579 003    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB | GENEVA PHARMS TECH | 2.5MG; 6.25MG |
|                                                    |    |                    | N75527 001    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB |                    | 5MG; 6.25MG   |
|                                                    |    |                    | N75527 003    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB |                    | 10MG; 6.25MG  |
|                                                    |    |                    | N75527 002    |
|                                                    |    |                    | SEP 25, 2000  |
| > ADD >                                            | AB | INVAMED            | 2.5MG; 6.25MG |
|                                                    |    |                    | N75527 001    |
|                                                    |    |                    | SEP 25, 2000  |
| > DLT >                                            | AB |                    | 5MG; 6.25MG   |
|                                                    |    |                    | N75527 003    |
|                                                    |    |                    | SEP 25, 2000  |
| > DLT >                                            | AB |                    |               |
|                                                    |    |                    |               |

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

BISOPROLOL FUMARATE AND HYDROCHLOROTHIAZIDE

|         |    |                 |               |              |
|---------|----|-----------------|---------------|--------------|
| > DLT > | AB | INVAMED         | 10MG; 6.25MG  | N75527 002   |
| > DLT   |    |                 |               | SEP 25, 2000 |
|         | AB | MYLAN           | 2.5MG; 6.25MG | N75768 001   |
|         |    |                 |               | SEP 25, 2000 |
|         | AB |                 | 5MG; 6.25MG   | N75768 002   |
|         |    |                 |               | SEP 25, 2000 |
|         | AB |                 | 10MG; 6.25MG  | N75768 003   |
|         |    |                 |               | SEP 25, 2000 |
|         | AB | PUREPAC PHARM   | 2.5MG; 6.25MG | N75672 001   |
|         |    |                 |               | SEP 25, 2000 |
|         | AB |                 | 5MG; 6.25MG   | N75672 002   |
|         |    |                 |               | SEP 25, 2000 |
|         | AB |                 | 10MG; 6.25MG  | N75672 003   |
|         |    |                 |               | SEP 25, 2000 |
|         | AB | ZENITH GOLDLINE | 2.5MG; 6.25MG | N75632 001   |
|         |    |                 |               | SEP 27, 2000 |
|         | AB |                 | 5MG; 6.25MG   | N75632 002   |
|         |    |                 |               | SEP 27, 2000 |
|         | AB |                 | 10MG; 6.25MG  | N75632 003   |
|         |    |                 |               | SEP 27, 2000 |
|         | AB | ZIAC            |               |              |
|         |    | LEDERLE         | 2.5MG; 6.25MG | N20186 003   |
|         |    |                 |               | MAR 26, 1993 |
|         | AB |                 | 5MG; 6.25MG   | N20186 001   |
|         |    |                 |               | MAR 26, 1993 |
|         | AB | +               | 10MG; 6.25MG  | N20186 002   |
|         |    |                 |               | MAR 26, 1993 |
|         |    |                 | 2.5MG; 6.25MG | N20186 003   |
|         |    |                 |               | MAR 26, 1993 |
|         |    |                 | 5MG; 6.25MG   | N20186 001   |
|         |    |                 |               | MAR 26, 1993 |
|         |    |                 | 10MG; 6.25MG  | N20186 002   |
|         |    |                 |               | MAR 26, 1993 |

> ADD > BIVALIRUDIN

|         |                         |            |              |
|---------|-------------------------|------------|--------------|
| > ADD > | INJECTABLE; INTRAVENOUS |            |              |
| > ADD > | ANGIOMAX                |            |              |
| > ADD > | + MEDS (TMC)            | 250MG/VIAL | N20873 001   |
| > ADD > |                         |            | DEC 15, 2000 |

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN

|    |                     |                       |              |
|----|---------------------|-----------------------|--------------|
| AP | FAULDING            | EQ 15 UNITS BASE/VIAL | N65031 001   |
|    |                     |                       | MAR 10, 2000 |
| AP |                     | EQ 30 UNITS BASE/VIAL | N65031 002   |
|    |                     |                       | MAR 10, 2000 |
| AP | GENSIA SICOR PHARMS | EQ 15 UNITS BASE/VIAL | N65033 001   |
|    |                     |                       | JUN 27, 2000 |
| AP |                     | EQ 30 UNITS BASE/VIAL | N65033 002   |
|    |                     |                       | JUN 27, 2000 |

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

|    |             |         |              |
|----|-------------|---------|--------------|
| AP | ASTRAZENECA | 50MG/ML | N71151 001   |
|    |             |         | AUG 10, 1987 |
| @  |             | 50MG/ML | N71151 001   |
|    |             |         | AUG 10, 1987 |

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

DIMETANE DC

|    |             |                                  |              |
|----|-------------|----------------------------------|--------------|
| AA | * ROBINS AM | 2MG/5ML; 10MG/5ML;<br>12.5MG/5ML | N11694 006   |
|    |             |                                  | MAR 29, 1984 |
| @  |             | 2MG/5ML; 10MG/5ML;<br>12.5MG/5ML | N11694 006   |
|    |             |                                  | MAR 29, 1984 |

MYPHETANE DC

|    |              |                                  |              |
|----|--------------|----------------------------------|--------------|
| AA | NORTON GROVE | 2MG/5ML; 10MG/5ML;<br>12.5MG/5ML | N88904 001   |
|    |              |                                  | FEB 21, 1985 |

|    |   |                                  |              |
|----|---|----------------------------------|--------------|
| AA | + | 2MG/5ML; 10MG/5ML;<br>12.5MG/5ML | N88904 001   |
|    |   |                                  | FEB 21, 1985 |

BUDESONIDESUSPENSION; INHALATION  
PULMICORT RESPULES

|             |            |              |
|-------------|------------|--------------|
| ASTRAZENECA | 0.25MG/2ML | N20929 001   |
|             |            | AUG 08, 2000 |

BUDESONIDE

SUSPENSION; INHALATION  
PULMICORT RESPULES  
+ ASTRAZENECA

0.5MG/2ML

N20929 002  
AUG 08, 2000  
N20929 003  
AUG 08, 2000

@

1MG/2ML

BUPROPION HYDROCHLORIDE

TABLET; ORAL  
BUPROPION HCL

AB EON 75MG

N75613 002  
OCT 10, 2000

AB 100MG

N75613 001  
OCT 10, 2000

AB GENEVA PHARMS TECH 75MG

N75584 001  
FEB 07, 2000

AB 100MG

N75584 002  
FEB 07, 2000

AB INVAMED 75MG

N75584 001  
FEB 07, 2000

AB 100MG

N75584 002  
FEB 07, 2000

AB MYLAN 75MG

N75491 001  
APR 17, 2000

AB 100MG

N75491 002  
APR 17, 2000

BUSPIRONE HYDROCHLORIDE

&gt; ADD &gt;

CAPSULE; ORAL

&gt; ADD &gt;

BUSPAR

&gt; ADD &gt;

BRISTOL MYERS SQUIBB 5MG

&gt; ADD &gt;

7.5MG

&gt; ADD &gt;

10MG

&gt; ADD &gt;

15MG

&gt; ADD &gt;

+

&gt; ADD &gt;

&gt; ADD &gt;

TABLET; ORAL

BUSPAR

\* BRISTOL MYERS SQUIBB 15MG

N18731 003  
APR 22, 1996

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR

@ BRISTOL MYERS SQUIBB 10MG

N18731 004

APR 22, 1996

15MG

N18731 003

APR 22, 1996

+

30MG

N18731 004

APR 22, 1996

BUTABARBITAL SODIUM

ELIXIR; ORAL

BUTABARB

AA

ALPHARMA

10MG/5ML

N85873 001

@

30MG/5ML

N85873 001

BUTISOL SODIUM

AA

\* WALLACE LABS

30MG/5ML

N85380 001

+

30MG/5ML

N85380 001

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

BUTORPHANOL TARTRATE

AP

ABBOTT

1MG/ML

N75559 001

MAR 20, 2000

AP

2MG/ML

N75559 002

MAR 20, 2000

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

CAFERGOT

BR

\* NOVARTIS

100MG; 2MG

N09000 002

+

100MG; 2MG

N09000 002

MIGERGOT

BR

G AND W LABS

100MG; 2MG

N86557 001

OCT 04, 1983

@

100MG; 2MG

N86557 001

OCT 04, 1983

CALCIUM CHLORIDE

INJECTABLE; INJECTION

CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER  
+ ABBOTT 100MG/MLN21117 001  
JAN 28, 2000CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC

CARDIOPLEGIC IN PLASTIC CONTAINERAT BAXTER HLTHCARE 17.6MG/100ML;325.3MG/100ML;  
119.3MG/100ML;643MG/100ML N75323 001  
APR 21, 2000PLEGISOL IN PLASTIC CONTAINERAT + ABBOTT 17.6MG/100ML;325.3MG/100ML;  
119.3MG/100ML;643MG/100ML N18608 001  
FEB 26, 1982  
\* 17.6MG/100ML;325.3MG/100ML;  
119.3MG/100ML;643MG/100ML N18608 001  
FEB 26, 1982CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

CALCIUM GLUCEPTATE

\* ABBOTT

EQ 90MG CALCIUM/5ML N80001 001  
EQ 90MG CALCIUM/5ML N80001 001CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ATACAND HCT

ASTRAZENECA

16MG;12.5MG

N21093 001

SEP 05, 2000

+

32MG;12.5MG

N21093 002

SEP 05, 2000

CANDICIDIN

OINTMENT; VAGINAL

VANOSID

@ AVENTIS PHARMS

0.6MG/GM

N61596 001

\* HOECHST MARION RESE

0.6MG/GM

N61596 001

CANDICIDIN

TABLET; VAGINAL

VANOSID

@ AVENTIS PHARMS

3MG

N61613 001

\* HOECHST MARION RESE

3MG

N61613 001

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

AB DANBURY PHARMA 50MG;25MG

N74832 001

DEC 29, 1997

@

50MG;25MG

N74832 001

DEC 29, 1997

CARBAMAZEPINE

SUSPENSION; ORAL

CARBAMAZEPINE

AB TARO 100MG/5ML

N75875 001

DEC 21, 2000

TEGRETOL

AB + NOVARTIS 100MG/5ML

N18927 001

DEC 18, 1987

\*

100MG/5ML

N18927 001

DEC 18, 1987

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

AB TARO PHARM INDS 100MG

N75687 001

OCT 24, 2000

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

AB WATSON LABS 10MG;100MG

N73381 001

SEP 28, 1993

AB 25MG;100MG

N73382 001

SEP 28, 1993

AB 25MG;250MG

N73383 001

SEP 28, 1993

@

10MG;100MG

N73381 001

SEP 28, 1993

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

@ WATSON LABS 25MG;100MG

N73382 001

SEP 28, 1993

@ 25MG;250MG

N73383 001

SEP 28, 1993

TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA

AB MYLAN 25MG;100MG

N75091 002

APR 21, 2000

SINEMET CR

AB DUPONT PHARMS 25MG;100MG

N19856 002

DEC 24, 1992

25MG;100MG

N19856 002

DEC 24, 1992

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

AA COREPHARMA 350MG

N40397 001

SEP 21, 2000

CARMUSTINE

IMPLANT; INTRACRANIAL

GLIADEL

\* AVANTIS 7.7MG

N20637 001

SEP 23, 1996

+ GUILFORD PHARMS 7.7MG

N20637 001

SEP 23, 1996

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL

AT ALCON 1%

N75476 001

JAN 03, 2000

AT BAUSCH AND LOMB 1%

N75546 001

JAN 20, 2000

OCUPRESS

AT + CIBA 1%

N19972 001

MAY 23, 1990

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OCUPRESS

\* CIBA 1%

N19972 001

MAY 23, 1990

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN AND DEXTROSE

+ B BRAUN EQ 500MG BASE/VIAL

N50779 001

JUL 27, 2000

+ EQ 1GM BASE/VIAL

N50779 002

JUL 27, 2000

CEFAZOLIN SODIUM

AP AM PHARM PARTNERS EQ 1MG BASE/VIAL

N64169 002

AUG 14, 1998

AP EQ 1GM BASE/VIAL

N64169 002

AUG 14, 1998

CEFDINIR

CAPSULE; ORAL

OMNICEF

+ ABBOTT 300MG

N50739 001

DEC 04, 1997

\* PARKE DAVIS 300MG

N50739 001

DEC 04, 1997

POWDER FOR RECONSTITUTION; ORAL

OMNICEF

+ ABBOTT 125MG/5ML

N50749 001

DEC 04, 1997

\* PARKE DAVIS 125MG/5ML

N50749 001

DEC 04, 1997

CEFMETAZOLE SODIUM

INJECTABLE; INJECTION

ZEPAZONE

\* PHARMACIA AND UPJOHN EQ 1GM BASE/VIAL

N50637 001

DEC 11, 1989

\* EQ 2GM BASE/VIAL

N50637 002

DEC 11, 1989

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

&gt; DLT &gt;

CEFMETAZOLE SODIUM

|         |                               |                  |              |
|---------|-------------------------------|------------------|--------------|
| > ADD > | INJECTABLE; INJECTION         |                  |              |
| > ADD > | ZEFAZONE                      |                  |              |
| > ADD > | + PHARMACIA AND UPJOHN        | EQ 1GM BASE/VIAL | N50637 001   |
| > ADD > |                               |                  | DEC 11, 1989 |
| > ADD > | @                             | EQ 2GM BASE/VIAL | N50637 002   |
| > ADD > |                               |                  | DEC 11, 1989 |
| > DLT > | ZEFAZONE IN PLASTIC CONTAINER |                  |              |
| > DLT > | PHARMACIA AND UPJOHN          | EQ 20MG BASE/ML  | N50683 001   |
| > DLT > |                               |                  | DEC 29, 1992 |
| > DLT > |                               | EQ 40MG BASE/ML  | N50683 002   |
| > DLT > |                               |                  | DEC 29, 1992 |
| > ADD > | @                             | EQ 20MG BASE/ML  | N50683 001   |
| > ADD > |                               |                  | DEC 29, 1992 |
| > ADD > | @                             | EQ 40MG BASE/ML  | N50683 002   |
| > ADD > |                               |                  | DEC 29, 1992 |

CEFOTAXIME SODIUM

|                       |                       |                    |              |
|-----------------------|-----------------------|--------------------|--------------|
| INJECTABLE; INJECTION |                       |                    |              |
| <u>CEFOTAXIME</u>     |                       |                    |              |
| AP                    | AM PHARM PARTNERS     | EQ 500MG BASE/VIAL | N64200 001   |
|                       |                       |                    | MAR 24, 2000 |
| AP                    |                       | EQ 1GM BASE/VIAL   | N64200 002   |
|                       |                       |                    | MAR 24, 2000 |
| AP                    |                       | EQ 2GM BASE/VIAL   | N64200 003   |
|                       |                       |                    | MAR 24, 2000 |
| AP                    |                       | EQ 10GM BASE/VIAL  | N64201 001   |
|                       |                       |                    | MAR 24, 2000 |
|                       | +                     | EQ 20GM BASE/VIAL  | N64201 002   |
|                       |                       |                    | MAR 24, 2000 |
| <u>CLAFORAN</u>       |                       |                    |              |
| AP                    | + AVENTIS PHARMS      | EQ 500MG BASE/VIAL | N50547 001   |
| AP                    | +                     | EQ 1GM BASE/VIAL   | N50547 002   |
| AP                    | +                     | EQ 2GM BASE/VIAL   | N50547 003   |
| AP                    | +                     | EQ 10GM BASE/VIAL  | N50547 004   |
|                       |                       |                    | DEC 29, 1983 |
|                       | + HOECHST MARION ROSS | EQ 500MG BASE/VIAL | N50547 001   |
|                       |                       | EQ 1GM BASE/VIAL   | N50547 002   |
|                       |                       | EQ 2GM BASE/VIAL   | N50547 003   |
|                       |                       | EQ 10GM BASE/VIAL  | N50547 004   |
|                       |                       |                    | DEC 29, 1983 |

CEFOXITIN SODIUM

|                                 |                   |                   |              |
|---------------------------------|-------------------|-------------------|--------------|
| INJECTABLE; INJECTION           |                   |                   |              |
| <u>CEFOXITIN</u>                |                   |                   |              |
| AP                              | AM PHARM PARTNERS | EQ 1GM BASE/VIAL  | N65012 001   |
|                                 |                   |                   | JUL 03, 2000 |
| AP                              |                   | EQ 2GM BASE/2VIAL | N65012 002   |
|                                 |                   |                   | JUL 03, 2000 |
| AP                              |                   | EQ 10GM BASE/VIAL | N65011 001   |
|                                 |                   |                   | JUL 03, 2000 |
| AP                              | ESI LEDERLE       | EQ 1GM BASE/VIAL  | N65051 001   |
|                                 |                   |                   | SEP 11, 2000 |
| AP                              |                   | EQ 2GM BASE/VIAL  | N65051 002   |
|                                 |                   |                   | SEP 11, 2000 |
| AP                              |                   | EQ 10GM BASE/VIAL | N65050 001   |
|                                 |                   |                   | SEP 11, 2000 |
| <u>MEFOXIN</u>                  |                   |                   |              |
| AP                              | + MERCK           | EQ 1GM BASE/VIAL  | N50517 001   |
| AP                              |                   | EQ 1GM BASE/VIAL  | N62757 001   |
|                                 |                   |                   | JAN 08, 1987 |
| AP                              | +                 | EQ 2GM BASE/VIAL  | N50517 002   |
| AP                              |                   | EQ 2GM BASE/VIAL  | N62757 002   |
|                                 |                   |                   | JAN 08, 1987 |
| AP                              | +                 | EQ 10GM BASE/VIAL | N50517 003   |
|                                 | *                 | EQ 1GM BASE/VIAL  | N50517 001   |
|                                 | *                 | EQ 1GM BASE/VIAL  | N62757 001   |
|                                 | *                 | EQ 2GM BASE/VIAL  | N50517 002   |
|                                 | *                 | EQ 2GM BASE/VIAL  | N62757 002   |
|                                 | *                 | EQ 10GM BASE/VIAL | N50517 003   |
|                                 | *                 | EQ 10GM BASE/VIAL | N50517 003   |
|                                 | *                 |                   | JAN 08, 1987 |
|                                 | *                 |                   | N50517 003   |
|                                 | *                 |                   | N50517 003   |
| <u>CEFTIBUTEN DIHYDRATE</u>     |                   |                   |              |
| CAPSULE; ORAL                   |                   |                   |              |
| CEDAX                           |                   |                   |              |
|                                 | + BIOVAIL         | EQ 400MG BASE     | N50685 002   |
|                                 |                   |                   | DEC 20, 1995 |
|                                 | * SCHERING PLOUGH | EQ 400MG BASE     | N50685 002   |
|                                 |                   |                   | DEC 20, 1995 |
| POWDER FOR RECONSTITUTION; ORAL |                   |                   |              |
| CEDAX                           |                   |                   |              |
|                                 | BIOVAIL           | EQ 90MG BASE/5ML  | N50686 001   |
|                                 |                   |                   | DEC 20, 1995 |
|                                 | +                 | EQ 180MG BASE/5ML | N50686 002   |
|                                 |                   |                   | DEC 20, 1995 |

CEFTIBUTEN DIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

CEDAX

|                   |                   |              |
|-------------------|-------------------|--------------|
| * SCHERING PLOUGH | EQ 90MG BASE/5ML  | N50585 001   |
|                   |                   | DEC 20, 1995 |
| *                 | EQ 150MG BASE/5ML | N50585 002   |
|                   |                   | DEC 20, 1995 |

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

|         |                    |              |
|---------|--------------------|--------------|
| + HLR   | EQ 250MG BASE/VIAL | N50585 001   |
|         |                    | DEC 21, 1984 |
|         | EQ 250MG BASE/VIAL | N63239 001   |
|         |                    | AUG 13, 1993 |
| +       | EQ 500MG BASE/VIAL | N50585 002   |
|         |                    | DEC 21, 1984 |
|         | EQ 500MG BASE/VIAL | N63239 002   |
|         |                    | AUG 13, 1993 |
| +       | EQ 1GM BASE/VIAL   | N50585 003   |
|         |                    | DEC 21, 1984 |
|         | EQ 1GM BASE/VIAL   | N62654 002   |
|         |                    | APR 30, 1987 |
|         | EQ 1GM BASE/VIAL   | N63239 003   |
|         |                    | AUG 13, 1993 |
| +       | EQ 2GM BASE/VIAL   | N50585 004   |
|         |                    | DEC 21, 1984 |
|         | EQ 2GM BASE/VIAL   | N62654 003   |
|         |                    | APR 30, 1987 |
| +       | EQ 10GM BASE/VIAL  | N50585 005   |
|         |                    | DEC 21, 1984 |
| * ROCHE | EQ 250MG BASE/VIAL | N50585 001   |
|         |                    | DEC 21, 1984 |
|         | EQ 250MG BASE/VIAL | N63239 001   |
|         |                    | AUG 13, 1993 |
| *       | EQ 500MG BASE/VIAL | N50585 002   |
|         |                    | DEC 21, 1984 |
|         | EQ 500MG BASE/VIAL | N63239 002   |
|         |                    | AUG 13, 1993 |
| *       | EQ 1GM BASE/VIAL   | N50585 003   |
|         |                    | DEC 21, 1984 |
|         | EQ 1GM BASE/VIAL   | N62654 002   |
|         |                    | APR 30, 1987 |
|         | EQ 1GM BASE/VIAL   | N63239 003   |
|         |                    | AUG 13, 1993 |

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

|         |                                           |              |
|---------|-------------------------------------------|--------------|
| * ROCHE | EQ 2GM BASE/VIAL                          | N50585 004   |
|         |                                           | DEC 21, 1984 |
|         | EQ 2GM BASE/VIAL                          | N62654 003   |
|         |                                           | APR 30, 1987 |
| *       | EQ 10GM BASE/VIAL                         | N50585 005   |
|         |                                           | DEC 21, 1984 |
|         | ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER |              |
| @ HLR   | EQ 10MG BASE/ML                           | N50624 001   |
|         |                                           | FEB 11, 1987 |
| +       | EQ 20MG BASE/ML                           | N50624 002   |
|         |                                           | FEB 11, 1987 |
| +       | EQ 40MG BASE/ML                           | N50624 003   |
|         |                                           | FEB 11, 1987 |
| * ROCHE | EQ 10MG BASE/ML                           | N50624 001   |
|         |                                           | FEB 11, 1987 |
| *       | EQ 20MG BASE/ML                           | N50624 002   |
|         |                                           | FEB 11, 1987 |
| *       | EQ 40MG BASE/ML                           | N50624 003   |
|         |                                           | FEB 11, 1987 |

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION

ROCEPHIN KIT

|         |                               |              |
|---------|-------------------------------|--------------|
| + HLR   | EQ 1GM BASE/VIAL, N/A; N/A,   |              |
|         | 1%                            | N50585 006   |
|         |                               | MAY 08, 1996 |
| +       | EQ 500MG BASE/VIAL, N/A; N/A, |              |
|         | 1%                            | N50585 007   |
|         |                               | MAY 08, 1996 |
| * ROCHE | EQ 1GM BASE/VIAL, N/A; N/A,   |              |
|         | 1%                            | N50585 006   |
|         |                               | MAY 08, 1996 |
| *       | EQ 500MG BASE/VIAL, N/A; N/A, |              |
|         | 1%                            | N50585 007   |
|         |                               | MAY 08, 1996 |

CEFUROXIME SODIUM

INJECTABLE; IM - IV

CEFUROXIME SODIUM

|    |        |                    |              |
|----|--------|--------------------|--------------|
| AB | MARSAM | EQ 750MG BASE/VIAL | N64035 001   |
|    |        |                    | FEB 26, 1993 |

CEFUROXIME SODIUM

INJECTABLE; INJECTION

CEFUROXIME SODIUM

|    |         |                    |              |
|----|---------|--------------------|--------------|
| AP | MARISAN | EQ 750MG BASE/VIAL | N64035 001   |
|    |         |                    | FEB 26, 1993 |

|    |         |                    |              |
|----|---------|--------------------|--------------|
| AB | KEFUROX | EQ 750MG BASE/VIAL | N62592 001   |
|    | LILLY   |                    | JAN 10, 1986 |

INJECTABLE; INTRAVENOUS

KEFUROX

|    |       |                    |              |
|----|-------|--------------------|--------------|
| AP | LILLY | EQ 750MG BASE/VIAL | N62592 001   |
|    |       |                    | JAN 10, 1986 |

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

KEFLEX

|    |       |                   |            |
|----|-------|-------------------|------------|
| AB | LILLY | EQ 125MG BASE/5ML | N50406 001 |
| AB | *     | EQ 250MG BASE/5ML | N50406 002 |
| AB | *     | EQ 250MG BASE/5ML | N62117 003 |
| AB | +     | EQ 250MG BASE/5ML | N62117 003 |
|    | @     | EQ 125MG BASE/5ML | N50406 001 |
|    | @     | EQ 250MG BASE/5ML | N50406 002 |

CERIVASTATIN SODIUM

TABLET; ORAL

BAYCOL

|   |       |       |              |
|---|-------|-------|--------------|
| * | BAYER | 0.4MG | N20740 004   |
|   |       |       | MAY 24, 1999 |
|   |       | 0.4MG | N20740 005   |
|   |       |       | MAY 24, 1999 |
| + |       | 0.8MG | N20740 006   |
|   |       |       | JUL 24, 2000 |

CETRORELIX

INJECTABLE; INJECTION

CETROTIDE

|   |      |                   |              |
|---|------|-------------------|--------------|
| * | ASTA | EQ 0.25MG BASE/ML | N21197 001   |
|   |      |                   | AUG 11, 2000 |
| * |      | EQ 3MG BASE/ML    | N21197 002   |
|   |      |                   | AUG 11, 2000 |

CETRORELIX

INJECTABLE; INJECTION

CETROTIDE

|   |            |                   |              |
|---|------------|-------------------|--------------|
| + | SERONO INC | EQ 0.25MG BASE/ML | N21197 001   |
|   |            |                   | AUG 11, 2000 |
| + |            | EQ 3MG BASE/ML    | N21197 002   |
|   |            |                   | AUG 11, 2000 |

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL

EVOXAC

|   |           |              |              |
|---|-----------|--------------|--------------|
| + | SNOWBRAND | EQ 30MG BASE | N20989 002   |
|   |           |              | JAN 11, 2000 |

CHENODIOL

TABLET; ORAL

CHENIX

|   |                   |       |              |
|---|-------------------|-------|--------------|
| @ | AXCAN             | 250MG | N18513 002   |
|   |                   |       | JUL 28, 1983 |
| @ | AXCAN SCANDIPHARM | 250MG | N18513 002   |
|   |                   |       | JUL 28, 1983 |

CHLORAMPHENICOL

SOLUTION/DROPS; OPHTHALMIC

OPHTHOCHLOR

|    |          |      |            |
|----|----------|------|------------|
| AT | PARKDALE | 0.5% | N61220 001 |
|    | @        | 0.5% | N61220 001 |

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL

CHLORHEXIDINE GLUCONATE

|    |       |       |              |
|----|-------|-------|--------------|
| AT | NOVEX | 0.12% | N75561 001   |
|    |       |       | NOV 14, 2000 |

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

|    |              |     |            |
|----|--------------|-----|------------|
| AA | GLOBAL PHARM | 4MG | N80809 001 |
|----|--------------|-----|------------|

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

@ IMPAX LABS

4MG

N80809 001

CHORIOGONADOTROPIN ALFA

INJECTABLE; INJECTION

OVIDREL

+ SERONO

0.25MG/VIAL

N21149 001

SEP 20, 2000

CICLOPIROX

CREAM; TOPICAL

LOPROX

+ AVENTIS PHARMS

0.77%

N18748 001

DEC 30, 1982

LOTION; TOPICAL

LOPROX

+ AVENTIS PHARMS

0.77%

N19824 001

DEC 30, 1988

CICLOPIROX OLAMINE

CREAM; TOPICAL

LOPROX

\* HOECHST MARION RSCL 1%

N18748 001

DEC 30, 1982

LOTION; TOPICAL

LOPROX

\* HOECHST MARION RSCL 1%

N19824 001

DEC 30, 1988

CIMETIDINE

TABLET; ORAL

CIMETIDINE

AB ROXANE

300MG

N74361 001

DEC 23, 1994

AB

400MG

N74361 002

DEC 23, 1994

CIMETIDINE

TABLET; ORAL

CIMETIDINE

AB ROXANE

300MG

N74371 001

DEC 23, 1994

@

300MG

N74361 001

@

400MG

DEC 23, 1994

N74361 002

@

800MG

DEC 23, 1994

N74371 001

DEC 23, 1994

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL

CIMETIDINE HCL

AA NOVEX

EQ 300MG BASE/5ML

N75560 001

MAR 15, 2000

CISAPRIDE MONOHYDRATE

SUSPENSION; ORAL

PROPULSID

\* JANSSEN

EQ 1MG BASE/ML

N20398 001

SEP 15, 1995

@

EQ 1MG BASE/ML

N20398 001

SEP 15, 1995

TABLET; ORAL

PROPULSID

\* JANSSEN

EQ 10MG BASE

N20210 001

JUL 29, 1993

\*

EQ 20MG BASE

N20210 002

DEC 23, 1993

@

EQ 10MG BASE

N20210 001

JUL 29, 1993

@

EQ 20MG BASE

N20210 002

DEC 23, 1993

CISPLATIN

INJECTABLE; INJECTION

CISPLATIN

AP BEDFORD

1MG/ML

N75036 001

NOV 07, 2000

CISPLATIN

INJECTABLE; INJECTION

|           |                     |                  |              |
|-----------|---------------------|------------------|--------------|
| <u>AP</u> | <u>CISPLATIN</u>    | <u>10MG/VIAL</u> | N74713 001   |
|           | BEDFORD             |                  | NOV 14, 2000 |
| <u>AP</u> |                     | <u>50MG/VIAL</u> | N74713 002   |
|           |                     |                  | NOV 14, 2000 |
| <u>AP</u> | GENSIA SICOR PHARMS | <u>1MG/ML</u>    | N74814 001   |
|           |                     |                  | MAY 16, 2000 |
| <u>AP</u> | PHARMACHEMIE        | <u>1MG/ML</u>    | N74656 001   |
|           |                     |                  | MAY 16, 2000 |
| <u>AP</u> | <u>PLATINOL</u>     | <u>10MG/VIAL</u> | N18057 001   |
|           | + BRISTOL MYERS     |                  |              |
| <u>AP</u> |                     | <u>50MG/VIAL</u> | N18057 002   |
|           |                     |                  |              |
|           |                     | <u>10MG/VIAL</u> | N18057 001   |
|           |                     | <u>50MG/VIAL</u> | N18057 002   |

CITALOPRAM HYDROBROMIDETABLET; ORAL  
CELEXA

|   |             |              |              |
|---|-------------|--------------|--------------|
|   | FOREST LABS | EQ 40MG BASE | N20822 003   |
|   |             |              | JUL 17, 1998 |
|   |             | EQ 40MG BASE | N20822 004   |
|   |             |              | JUL 17, 1998 |
|   |             | EQ 10MG BASE | N20822 001   |
|   |             |              | APR 27, 2000 |
| + |             | EQ 40MG BASE | N20822 003   |
|   |             |              | JUL 17, 1998 |
| @ |             | EQ 60MG BASE | N20822 004   |
|   |             |              | JUL 17, 1998 |

CLADRIBINE

INJECTABLE; INJECTION

|           |                   |               |              |
|-----------|-------------------|---------------|--------------|
| <u>AP</u> | <u>CLADRIBINE</u> | <u>1MG/ML</u> | N75405 001   |
|           | BEDFORD           |               | FEB 28, 2000 |

CLARITHROMYCINTABLET; ORAL  
BIAXIN

|        |       |              |
|--------|-------|--------------|
| ABBOTT | 250MG | N50662 001   |
|        |       | OCT 31, 1991 |

CLARITHROMYCINTABLET; ORAL  
BIAXIN

|          |       |              |
|----------|-------|--------------|
| + ABBOTT | 250MG | N50662 001   |
|          |       | OCT 31, 1991 |

TABLET, EXTENDED RELEASE; ORAL  
BIAXIN XL

|          |       |              |
|----------|-------|--------------|
| + ABBOTT | 500MG | N50775 001   |
|          |       | MAR 03, 2000 |

CLEMASTINE FUMARATE

SYRUP; ORAL

|           |                            |                          |              |
|-----------|----------------------------|--------------------------|--------------|
| <u>AA</u> | <u>CLEMASTINE FUMARATE</u> | <u>EQ 0.5MG BASE/5ML</u> | N75703 001   |
|           | NOVEX                      |                          | NOV 27, 2000 |

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

|           |                        |                   |              |
|-----------|------------------------|-------------------|--------------|
| <u>AB</u> | <u>CLEOCIN T</u>       | <u>EQ 1% BASE</u> | N50615 001   |
|           | + PHARMACIA AND UPJOHN |                   | JAN 07, 1987 |
|           |                        | EQ 1% BASE        | N50615 001   |
|           |                        |                   | JAN 07, 1987 |

|           |                              |                   |              |
|-----------|------------------------------|-------------------|--------------|
| <u>AB</u> | <u>CLINDAMYCIN PHOSPHATE</u> | <u>EQ 1% BASE</u> | N64160 001   |
|           | ALTANA                       |                   | JAN 28, 2000 |
| BT        | TARGET RES                   | EQ 1% BASE        | N50782 001   |
|           |                              |                   | NOV 27, 2000 |

INJECTABLE; INJECTION

|           |                              |                         |              |
|-----------|------------------------------|-------------------------|--------------|
| <u>AP</u> | <u>CLINDAMYCIN PHOSPHATE</u> | <u>EQ 150MG BASE/ML</u> | N62928 001   |
|           | ASTRAZENECA                  |                         | FEB 13, 1989 |
|           |                              | EQ 150MG BASE/ML        | N62928 001   |
|           |                              |                         | FEB 13, 1989 |

SOLUTION; TOPICAL

|           |                              |                   |              |
|-----------|------------------------------|-------------------|--------------|
| <u>AT</u> | <u>CLINDAMYCIN PHOSPHATE</u> | <u>EQ 1% BASE</u> | N65049 001   |
|           | CLAY PARK                    |                   | MAY 25, 2000 |

CLOBETASOL PROPIONATE

AEROSOL; TOPICAL  
OLUX FOAM  
+ CONNETICS 0.05%

CREAM; TOPICAL  
CLOBETASOL PROPIONATE  
AB2 TARO 0.05%

GEL; TOPICAL  
CLOBETASOL PROPIONATE  
AB ALTANA 0.05%

SOLUTION; TOPICAL  
CLOBETASOL PROPIONATE  
> ADD > AT THAMES 0.05%  
> ADD >

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL  
CLOMIPRAMINE HCL  
> ADD > AB GENEVA PHARMS TECH 25MG  
> ADD >  
> ADD > AB 50MG  
> ADD >  
> ADD > AB 75MG  
> ADD >  
> DLT > AB INVAMED 25MG  
> DLT >  
> DLT > AB 50MG  
> DLT >  
> DLT > AB 75MG  
> DLT >

CLONAZEPAM

TABLET; ORAL  
CLONAZEPAM  
> ADD > AB GENEVA PHARMS TECH 0.5MG  
> ADD >  
> ADD > AB 1MG  
> ADD >

N21142 001  
MAY 26, 2000

N75633 001  
MAY 17, 2000

N75368 001  
FEB 15, 2000

N75363 001  
DEC 29, 2000

N74953 001  
JUN 25, 1997  
N74953 002  
JUN 25, 1997  
N74953 003  
JUN 25, 1997  
N74953 001  
JUN 25, 1997  
N74953 002  
JUN 25, 1997  
N74953 003  
JUN 25, 1997

> ADD > AB  
> ADD >  
> DLT > AB  
> DLT >  
> DLT > AB  
> DLT >  
> DLT > AB  
> DLT >

CLONAZEPAM

TABLET; ORAL  
CLONAZEPAM  
GENEVA PHARMS TECH 2MG  
INVAMED 0.5MG  
1MG  
2MG  
TORPHARM 0.5MG  
1MG  
2MG

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL  
CLORAZEPATE DIPOTASSIUM  
AB TARO 3.75MG  
AB 7.5MG  
AB 15MG

CLOTRIMAZOLE

TABLET; VAGINAL  
MYCELEX-G  
\* BAYER 500MG  
@ 500MG

CLOXACILLIN SODIUM

CAPSULE; ORAL  
CLOXACILLIN SODIUM  
AB \* APOTHECON EQ 250MG BASE  
AB \* EQ 500MG BASE  
@ EQ 250MG BASE

N74925 003  
SEP 30, 1997  
N74925 001  
SEP 30, 1997  
N74925 002  
SEP 30, 1997  
N74925 003  
SEP 30, 1997  
N75468 001  
OCT 06, 2000  
N75468 002  
OCT 06, 2000  
N75468 003  
OCT 06, 2000

N75731 003  
APR 27, 2000  
N75731 002  
APR 27, 2000  
N75731 001  
APR 27, 2000

N19069 001  
APR 19, 1985  
N19069 001  
APR 19, 1985

N61452 001  
N61452 002  
N61452 001

CLOXACILLIN SODIUM

|                           |                    |               |
|---------------------------|--------------------|---------------|
| CAPSULE; ORAL             |                    |               |
| <u>CLOXACILLIN SODIUM</u> |                    |               |
| @ APOTHECON               |                    |               |
|                           | EQ 500MG BASE      | N61452 002    |
| <u>CLOXAPEN</u>           |                    |               |
| AB                        | SMITHKLINE BEECHAM | EQ 500MG BASE |
| AB                        | +                  | EQ 500MG BASE |
|                           |                    | N61806 002    |

CLOZAPINE

|                  |               |              |
|------------------|---------------|--------------|
| TABLET; ORAL     |               |              |
| <u>CLOZAPINE</u> |               |              |
| AB               | GENEVA PHARMS | 25MG         |
|                  |               | N74546 001   |
|                  |               | AUG 30, 1996 |
| AB               |               | 100MG        |
|                  |               | N74546 002   |
|                  |               | AUG 30, 1996 |
| @                |               | 25MG         |
|                  |               | N74546 001   |
| @                |               | 100MG        |
|                  |               | AUG 30, 1996 |
|                  |               | N74546 002   |
|                  |               | AUG 30, 1996 |

COLESEVELAM HYDROCHLORIDE

|                |        |              |
|----------------|--------|--------------|
| CAPSULE; ORAL  |        |              |
| <u>WELCHOL</u> |        |              |
| *              | GELTEK | 375MG        |
|                |        | N21141 001   |
|                |        | MAY 26, 2000 |
| +              | SANKYO | 375MG        |
|                |        | N21141 001   |
|                |        | MAY 26, 2000 |

|                |        |              |
|----------------|--------|--------------|
| TABLET; ORAL   |        |              |
| <u>WELCHOL</u> |        |              |
| *              | GELTEK | 625MG        |
|                |        | N21176 001   |
|                |        | MAY 26, 2000 |
| +              | SANKYO | 625MG        |
|                |        | N21176 001   |
|                |        | MAY 26, 2000 |

COPPER

|                                   |                    |              |
|-----------------------------------|--------------------|--------------|
| INTRAUTERINE DEVICE; INTRAUTERINE |                    |              |
| COPPER T MODEL TCU 380A           |                    |              |
| *                                 | JOHNSON RN         | 309MG/COPPER |
|                                   |                    | N18680 001   |
|                                   |                    | NOV 15, 1984 |
| +                                 | POPULATION COUNCIL | 309MG/COPPER |
|                                   |                    | N18680 001   |
|                                   |                    | NOV 15, 1984 |

CORTISONE ACETATE

|                          |              |            |
|--------------------------|--------------|------------|
| TABLET; ORAL             |              |            |
| <u>CORTISONE ACETATE</u> |              |            |
| BB                       | GLOBAL PHARM | 25MG       |
|                          | @ IMPAX LABS | 25MG       |
|                          |              | N09458 001 |
|                          |              | N09458 001 |

CROMOLYN SODIUM

|                    |        |              |
|--------------------|--------|--------------|
| CONCENTRATE; ORAL  |        |              |
| <u>GASTROCHROM</u> |        |              |
| *                  | MEDEVA | 100MG/5ML    |
|                    |        | N20479 001   |
|                    |        | FEB 29, 1996 |

## SOLUTION; INHALATION

CROMOLYN SODIUM

|         |    |                 |         |
|---------|----|-----------------|---------|
| > ADD > | AN | BAUSCH AND LOMB | 10MG/ML |
| > ADD > | AN | STERIPAK        | 10MG/ML |
|         | AN | WARRICK PHARMS  | 10MG/ML |

N75585 001  
DEC 21, 2000  
N75271 001  
JAN 18, 2000  
N75437 001  
APR 21, 2000

## SOLUTION, CONCENTRATE; ORAL

GASTROCHROM

|   |        |           |
|---|--------|-----------|
| + | MEDEVA | 100MG/5ML |
|---|--------|-----------|

N20479 001  
FEB 29, 1996

CYANOCOBALAMIN

## INJECTABLE; INJECTION

CYANOCOBALAMIN

|    |                     |            |
|----|---------------------|------------|
| @  | AVENTIS PHARMS      | 1MG/ML     |
| AP | HOECHST MARION RESE | 1MG/ML     |
|    |                     | N80564 001 |
|    |                     | N80564 001 |

CYCLOBENZAPRINE HYDROCHLORIDE

## TABLET; ORAL

CYCLOBENZAPRINE HCL

|    |                    |              |
|----|--------------------|--------------|
| AB | GENEVA PHARMS TECH | 10MG         |
| AB | INVAMED            | 10MG         |
|    |                    | N73683 001   |
|    |                    | FEB 26, 1993 |
|    |                    | N73683 001   |
|    |                    | FEB 26, 1993 |

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL

AT ALCON UNIVERSAL 1%

AT STERIS 1%

N89162 001

JAN 24, 1991

N89162 001

JAN 24, 1991

CYCLOSPORINE

CAPSULE; ORAL

CYCLOSPORINE

AB ABBOTT 25MG

AB 50MG

AB 100MG

50MG

AB EON 25MG

AB 100MG

&gt; ADD &gt; AB SIDMAK LABS 25MG

&gt; ADD &gt; AB 100MG

&gt; ADD &gt; AB 100MG

&gt; ADD &gt; AB 100MG

NEORAL

AB NOVARTIS 25MG

AB 50MG

AB + 100MG

BX 25MG

BX 100MG

@ 50MG

SOLUTION; ORAL

CYCLOSPORINE

AB ABBOTT 100MG/ML

N65003 001

MAY 12, 2000

N65003 002

MAY 12, 2000

N65003 003

MAY 12, 2000

N65003 002

MAY 12, 2000

N65017 002

JAN 13, 2000

N65017 001

JAN 13, 2000

N65044 002

DEC 20, 2000

N65044 001

DEC 20, 2000

N50715 001

JUL 14, 1995

N50715 003

JUL 14, 1995

N50715 002

JUL 14, 1995

N50715 001

JUL 14, 1995

N50715 002

JUL 14, 1995

N50715 003

JUL 14, 1995

N65025 001

MAR 03, 2000

CYCLOSPORINE

SOLUTION; ORAL

CYCLOSPORINE

@ ABBOTT

100MG/ML

N65025 001

MAR 03, 2000

NEORAL

AB \* NOVARTIS

100MG/ML

N50716 001

JUL 14, 1995

+

100MG/ML

N50716 001

JUL 14, 1995

SANGCYA

AB SANGSTAT MEDCL

100MG/ML

N64195 001

OCT 31, 1998

@

100MG/ML

N64195 001

OCT 31, 1998

DACARBAZINE

INJECTABLE; INJECTION

DACARBAZINE

AP GENSLA SICOR PHARMS 500MG/VIAL

N75259 001

SEP 22, 2000

DALFOPRISTIN; QUINUPRISTIN

INJECTABLE; INJECTION

SYNERCID

RHONE-POULENC RORER

350MG/VIAL

EQ 150MG BASE/VIAL

N50747 001

SEP 21, 1999

350MG/VIAL

EQ 150MG BASE/VIAL

N50748 001

SEP 21, 1999

INJECTABLE; IV (INFUSION)

SYNERCID

AVENTIS

350MG/VIAL; 150MG/VIAL

N50748 001

SEP 21, 1999

+

420MG/VIAL; 180MG/VIAL

N50748 002

AUG 24, 2000

DAUNORUBICIN CITRATE

INJECTABLE, LIPOSOMAL; INJECTION

DAUNOXOME

+ GILEAD EQ 2MG BASE/ML

N50704 002

APR 08, 1996

\* NEXSTAR EQ 2MG BASE/ML

N50704 002

APR 08, 1996

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DAUNORUBICIN HCL

AP + BEDFORD EQ 5MG BASE/ML

N50731 001

JAN 30, 1998

\* EQ 5MG BASE/ML

N50731 001

JAN 30, 1998

AP GENSLA SICOR PHARMS EQ 5MG BASE/ML

N65035 001

JAN 24, 2000

+ EQ 50MG BASE/VIAL

N64212 002

MAY 03, 1999

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE, ORAL

DECLONICIN

\* LEDERLE 150MG

N50262 001

@ 150MG

N50262 001

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

DESMOPRESSIN ACETATE

AP ABBOTT 0.004MG/ML

N75220 001

AUG 28, 2000

AP BEDFORD 0.004MG/ML

N74575 001

FEB 18, 2000

DESMOPRESSIN ACETATE PRESERVATIVE FREE

AP BEDFORD 0.004MG/ML

N74574 001

FEB 18, 2000

SPRAY, METERED; NASAL

STIMATE

+ AVENTIS BEHRING 0.15MG/SPRAY

N20355 001

MAR 07, 1994

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

STIMATE

\* CENTRON 0.15MG/SPRAY

N20355 001

MAR 07, 1994

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

CYCLESSA

+ ORGANON INC 0.1MG, 0.125MG, 0.15MG; 0.025MG,  
0.025MG, 0.025MG

N21090 001

DEC 20, 2000

MIRCETTE

\* ORGANON 0.15MG; 0.02MG

N20713 001

APR 22, 1998

+ 0.15MG, N/A; 0.02MG, 0.01MG

N20713 001

APR 22, 1998

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

BP GLOBAL PHARM 0.75MG

N85376 001

@ IMPAX LABS 0.75MG

N85376 001

BP DEXONE 1.5

SOLVAY 1.5MG

N84990 001

@ 1.5MG

N84990 001

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

AT ALCON UNIVERSAL 0.1%; EQ 3.5MG BASE/ML;

N62721 001

10,000 UNITS/ML

NOV 17, 1986

AT STERIS 0.1%; EQ 1.5MG BASE/ML;

N62721 001

10,000 UNITS/ML

NOV 17, 1986

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC

DEXAMETHASONE SODIUM PHOSPHATE

AT ALCON UNIVERSAL EQ 0.1% PHOSPHATE N88771 001  
JAN 16, 1985

SOLUTION/DROPS; OPHTHALMIC, OTIC

DEXAMETHASONE SODIUM PHOSPHATE

AT STERIS EQ 0.1% PHOSPHATE N88771 001  
JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN SULFATE AND DEXAMETHASONE SODIUM PHOSPHATE

> DLT >  
> DLT >  
> DLT >  
> DLT >  
> ADD >  
> ADD >  
> ADD >  
AT BAUSCH AND LOMB EQ 0.1% PHOSPHATE; N64055 001  
EQ 3.5MG BASE/ML OCT 30, 1995  
@ EQ 0.1% PHOSPHATE;  
EQ 3.5MG BASE/ML N64055 001  
OCT 30, 1995

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT ALCON UNIVERSAL EQ 0.1% PHOSPHATE;  
EQ 3.5MG BASE/ML N62714 001  
JUL 21, 1986  
AT STERIS EQ 0.1% PHOSPHATE;  
EQ 3.5MG BASE/ML N62714 001  
JUL 21, 1986

DEZOCINE

INJECTABLE; INJECTION

DALGAN

\* ASTRAZENECA 5MG/ML N19082 001  
DEC 29, 1989  
\* 10MG/ML N19082 002  
DEC 29, 1989  
\* 15MG/ML N19082 003  
DEC 29, 1989  
@ 5MG/ML N19082 001  
DEC 29, 1989  
@ 10MG/ML N19082 002  
DEC 29, 1989  
@ 15MG/ML N19082 003  
DEC 29, 1989

DIAZEPAM

INJECTABLE; INJECTION

DIZAC

@ PHARMACIA AND UPJOHN 5MG/ML

N19287 001  
JUN 18, 1993

INJECTABLE; INTRAVENOUS

DIZAC

\* PHARMACIA AND UPJOHN 5MG/ML

N19287 001  
JUN 18, 1993

TABLET; ORAL

DIAZEPAM

|    |        |      |                            |
|----|--------|------|----------------------------|
| AB | ROXANE | 2MG  | N70356 001<br>JUN 17, 1986 |
| AB |        | 5MG  | N70357 001<br>JUN 17, 1986 |
| AB |        | 10MG | N70358 001<br>JUN 17, 1986 |
| @  |        | 2MG  | N70356 001<br>JUN 17, 1986 |
| @  |        | 5MG  | N70357 001<br>JUN 17, 1986 |
| @  |        | 10MG | N70358 001<br>JUN 17, 1986 |

DICLOFENAC POTASSIUM

TABLET; ORAL

DICLOFENAC POTASSIUM

|    |                    |      |                            |
|----|--------------------|------|----------------------------|
| AB | GENEVA PHARMS TECH | 50MG | N75229 001<br>NOV 20, 1998 |
| AB | ENVAMED            | 50MG | N75229 001<br>NOV 20, 1998 |

DICLOFENAC SODIUM

GEL; TOPICAL

SOLARAZE

+ SKYEPHARMA 3%

N21005 001  
OCT 16, 2000

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

|    |               |                   |                            |
|----|---------------|-------------------|----------------------------|
| AB | FALCON PHARMS | 0.1% <sup>†</sup> | N20808 001<br>MAY 04, 1998 |
|----|---------------|-------------------|----------------------------|

<sup>†</sup> SEE SECTION 1.3 OF INTRODUCTION

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

@ FALCON PHARMS 0.1%

N20809 001  
MAY 04, 1998VOLTAREN

AB \* CIBA 0.1%

N20037 001

+ 0.1%

MAR 28, 1991

N20037 001

MAR 28, 1991

TABLET, EXTENDED RELEASE; ORAL

DICLOFENAC SODIUM

AB BIOVAIL 100MG

N75492 001

FEB 11, 2000

VOLTAREN-XR

AB + NOVARTIS 100MG

N20254 001

MAR 08, 1996

\* 100MG

N20254 001

MAR 08, 1996

DIDANOSINECAPSULE, DELAYED REL PELLETS; ORAL  
VIDEX EC

+ BRISTOL MYERS SQUIBB 125MG

N21183 001

OCT 31, 2000

+ 200MG

N21183 002

OCT 31, 2000

+ 250MG

N21183 003

OCT 31, 2000

+ 400MG

N21183 004

OCT 31, 2000

DIENESTROL

SUPPOSITORY; VAGINAL

DV

@ AVENTIS PHARMS 0.7MG

N83517 001

\* HOECHST MARION REEL 0.7MG

N83517 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

AA MD PHARM 25MG

N85544 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

@ MEDEVA PHARMS CA 25MG

N85544 001

DIETHYLSTILBESTROL DIPHOSPHATE

INJECTABLE; INJECTION

STILPHOSTROL

\* BAYER

250MG/5ML

N10010 001

@

250MG/5ML

N10010 001

TABLET; ORAL

STILPHOSTROL

\* BAYER

50MG

N10010 002

@

50MG

N10010 002

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

AB TARO 0.05%

N75508 001  
APR 24, 2000DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

AB3 BIOVAIL 120MG

N20939 001

JAN 28, 2000

AB3 180MG

N20939 002

JAN 28, 2000

AB3 240MG

N20939 003

JAN 28, 2000

AB3 300MG

N20939 004

JAN 28, 2000

&gt; ADD &gt; AB2 TORPHARM 120MG

N74943 003

DEC 19, 2000

&gt; ADD &gt; AB2 180MG

N74943 002

DEC 19, 2000

&gt; ADD &gt; AB2 240MG

N74943 001

AUG 06, 1998

&gt; ADD &gt; AB2 240MG

&gt; ADD &gt; AB2 240MG

&gt; DLT &gt; DILTIAZEM XR

&gt; DLT &gt; AB TORPHARM 240MG

N74943 001

AUG 06, 1998

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION

DILTIAZEM HCL

|    |        |        |              |
|----|--------|--------|--------------|
| AP | ABBOTT | 5MG/ML | N75004 001   |
|    |        |        | FEB 16, 2000 |

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL

TIAMATE

|   |                     |              |              |
|---|---------------------|--------------|--------------|
| * | HOECHST MARION RESE | EQ 120MG HCL | N20506 001   |
|   |                     |              | OCT 04, 1996 |
| * |                     | EQ 180MG HCL | N20506 002   |
|   |                     |              | OCT 04, 1996 |
| * |                     | EQ 240MG HCL | N20506 003   |
|   |                     |              | OCT 04, 1996 |
| + | MERCK               | EQ 120MG HCL | N20506 001   |
|   |                     |              | OCT 04, 1996 |
| + |                     | EQ 180MG HCL | N20506 002   |
|   |                     |              | OCT 04, 1996 |
| + |                     | EQ 240MG HCL | N20506 003   |
|   |                     |              | OCT 04, 1996 |

DILTIAZEM MALATE; ENALAPRIL MALEATE

TABLET, EXTENDED RELEASE; ORAL

TECZEM

|   |                |                  |              |
|---|----------------|------------------|--------------|
| * | AVENTIS PHARMS | EQ 180MG HCL;5MG | N20507 001   |
|   |                |                  | OCT 04, 1996 |
| + | MERCK          | EQ 180MG HCL;5MG | N20507 001   |
|   |                |                  | OCT 04, 1996 |

DIMETHYL SULFOXIDE

SOLUTION; INTRAVESICAL

RIMSO-50

|         |          |     |            |
|---------|----------|-----|------------|
| > DLT > | RES INDS | 50% | N17788 001 |
| > ADD > | +        | 50% | N17788 001 |

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

|    |              |      |            |
|----|--------------|------|------------|
| AA | GLOBAL PHARM | 25MG | N80807 001 |
|----|--------------|------|------------|

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

|    |              |      |            |
|----|--------------|------|------------|
| AA | GLOBAL PHARM | 50MG | N80807 002 |
|    | IMPAX LABS   | 25MG | N80807 001 |
|    | @            | 50MG | N80807 002 |

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

|    |               |      |              |
|----|---------------|------|--------------|
| AB | PUREPAC PHARM | 75MG | N89427 001   |
|    | @             | 75MG | JUL 12, 1990 |
|    |               |      | N89427 001   |
|    |               |      | JUL 12, 1990 |

DISULFIRAM

TABLET; ORAL

ANTABUSE

|    |                |       |            |
|----|----------------|-------|------------|
| BX | WYETH AYERST   | 250MG | N07883 003 |
| BX | *              | 500MG | N07883 002 |
|    | @              | 250MG | N07883 003 |
|    | @              | 500MG | N07883 002 |
| BX | DISULFIRAM     | 500MG | N86890 001 |
| BX | DANBURY PHARMA | 500MG | N86890 001 |
| BX | +              | 500MG | N86890 001 |

DIVALPROEX SODIUM

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

|   |        |                        |              |
|---|--------|------------------------|--------------|
| + | ABBOTT | EQ 500MG VALPROIC ACID | N21168 001   |
|   |        |                        | AUG 04, 2000 |

DOXAZOSIN MESYLATE

TABLET; ORAL

CARDURA

|    |   |        |             |              |
|----|---|--------|-------------|--------------|
| AB | + | PFIZER | EQ 1MG BASE | N19668 001   |
|    |   |        |             | NOV 02, 1990 |
| AB |   |        | EQ 2MG BASE | N19668 002   |
|    |   |        |             | NOV 02, 1990 |

DOXAZOSIN MESYLATE

## TABLET; ORAL

CARDURA

AB PFIZER

EQ 4MG BASE

N19668 003

&gt; DLT &gt;

NOV 02, 1990

&gt; DLT

AB

EQ 8MG BASE

N19668 004

&gt; DLT &gt;

NOV 02, 1990

&gt; DLT &gt;

\*

EQ 1MG BASE

N19668 001

&gt; DLT &gt;

NOV 02, 1990

&gt; DLT &gt;

EQ 2MG BASE

N19668 002

NOV 02, 1990

EQ 4MG BASE

N19668 003

NOV 02, 1990

EQ 8MG BASE

N19668 004

NOV 02, 1990

DOXAZOSIN MESYLATE

## CHELSEA LABS

AB

EQ 1MG BASE

N75426 001

OCT 18, 2000

AB

EQ 2MG BASE

N75426 002

OCT 18, 2000

AB

EQ 4MG BASE

N75426 003

OCT 18, 2000

AB

EQ 8MG BASE

N75426 004

OCT 18, 2000

AB

EON

EQ 1MG BASE

N75646 001

OCT 18, 2000

AB

EQ 2MG BASE

N75646 002

OCT 18, 2000

AB

EQ 4MG BASE

N75646 003

OCT 18, 2000

AB

EQ 8MG BASE

N75646 004

OCT 18, 2000

&gt; ADD &gt;

AB

GENEVA PHARMS TECH

EQ 1MG BASE

N75432 001

OCT 18, 2000

&gt; ADD &gt;

AB

EQ 2MG BASE

N75432 002

OCT 18, 2000

&gt; ADD &gt;

AB

EQ 4MG BASE

N75432 003

OCT 18, 2000

&gt; ADD &gt;

AB

EQ 8MG BASE

N75432 004

OCT 18, 2000

AB

GENPHARM

EQ 1MG BASE

N75466 001

OCT 18, 2000

AB

EQ 2MG BASE

N75466 002

OCT 18, 2000

AB

EQ 4MG BASE

N75466 003

OCT 18, 2000

AB

EQ 8MG BASE

N75466 004

OCT 18, 2000

DOXAZOSIN MESYLATE

## TABLET; ORAL

DOXAZOSIN MESYLATE

AB INVAMED

EQ 1MG BASE

N75432 001

OCT 18, 2000

EQ 2MG BASE

N75432 002

OCT 18, 2000

EQ 4MG BASE

N75432 003

OCT 18, 2000

AB

KV PHARM

EQ 1MG BASE

N75609 001

OCT 18, 2000

AB

EQ 2MG BASE

N75609 002

OCT 18, 2000

AB

EQ 4MG BASE

N75609 003

OCT 18, 2000

AB

EQ 8MG BASE

N75609 004

OCT 18, 2000

AB

MYLAN

EQ 1MG BASE

N75509 001

OCT 19, 2000

AB

EQ 2MG BASE

N75509 002

OCT 19, 2000

AB

EQ 4MG BASE

N75509 003

OCT 19, 2000

AB

EQ 8MG BASE

N75509 004

OCT 19, 2000

AB

PUREPAC PHARM

EQ 1MG BASE

N75574 001

OCT 18, 2000

AB

EQ 2MG BASE

N75574 002

OCT 18, 2000

AB

EQ 4MG BASE

N75574 003

OCT 18, 2000

AB

EQ 8MG BASE

N75574 004

OCT 18, 2000

AB

TEVA

EQ 1MG BASE

N75536 001

OCT 18, 2000

AB

EQ 2MG BASE

N75536 002

OCT 18, 2000

AB

EQ 4MG BASE

N75536 003

OCT 18, 2000

AB

EQ 8MG BASE

N75536 004

OCT 18, 2000

AB

TORPHARM

EQ 1MG BASE

N75580 001

OCT 18, 2000

AB

EQ 2MG BASE

N75580 002

OCT 18, 2000

AB

EQ 4MG BASE

N75580 003

OCT 18, 2000

DOXAZOSIN MESYLATE

TABLET; ORAL

DOXAZOSIN MESYLATE

AB TORPHARM EQ 8MG BASE

AB ZENITH GOLDLINE EQ 1MG BASE

AB EQ 2MG BASE

AB EQ 4MG BASE

AB EQ 8MG BASE

N75580 004  
OCT 18, 2000

N75453 001  
OCT 18, 2000

N75453 002  
OCT 18, 2000

N75453 003  
OCT 18, 2000

N75453 004  
OCT 18, 2000

> ADD >  
> ADD

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

AB PAR PHARM EQ 100MG BASE

AB RANBAXY EQ 50MG BASE

AB EQ 100MG BASE

AB MONODOX  
OCLASSEN EQ 50MG BASE

AB + EQ 100MG BASE

N65055 002  
DEC 01, 2000

N65053 001  
NOV 22, 2000

N65053 002  
NOV 22, 2000

N50641 002  
FEB 10, 1992

N50641 001  
DEC 29, 1989

N50641 002  
FEB 10, 1992

N50641 001  
DEC 29, 1989

DOXEPIH HYDROCHLORIDECREAM; TOPICAL  
ZONALON

+ BIOGLAN PHAR 5%

\* MEDICIS 5%

N20126 001  
APR 01, 1994

N20126 001  
APR 01, 1994

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

TABLET; ORAL  
DOXYCYCLINE  
PAR PHARM

EQ 50MG BASE

EQ 100MG BASE

N65070 001  
DEC 15, 2000

N65070 002  
DEC 15, 2000

DOXERCALCIFEROLINJECTABLE; INJECTION  
HECTOROL

+ BONE CARE 2 UGM/ML

N21027 001  
APR 06, 2000

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

AP ASTRAZENECA 2.5MG/ML

AP 2.5MG/ML

AP 2.5MG/ML

@ 2.5MG/ML

@ 2.5MG/ML

@ 2.5MG/ML

N72018 001  
OCT 20, 1988

N72019 001  
OCT 19, 1988

N72021 001  
OCT 19, 1988

N72018 001  
OCT 20, 1988

N72019 001  
OCT 19, 1988

N72021 001  
OCT 19, 1988

DOXYCYCLINECAPSULE; ORAL  
DOXYCYCLINE

AB EON EQ 50MG BASE

AB EQ 100MG BASE

AB HALSEY EQ 50MG BASE

AB EQ 100MG BASE

> ADD > AB PAR PHARM EQ 50MG BASE

> ADD >

N65032 001  
JUN 30, 2000

N65032 002  
JUN 30, 2000

N65041 001  
APR 28, 2000

N65041 002  
APR 28, 2000

N65055 001  
DEC 01, 2000

EFLORNITHINE HYDROCHLORIDE

CREAM; TOPICAL  
 VANIQ  
 + WESTWOOD SQUIBB CLTN 13.9%

N21145 001  
 JUL 27, 2000

ENALAPRIL MALEATE

TABLET; ORAL  
ENALAPRIL MALEATE

|           |               |              |
|-----------|---------------|--------------|
| <u>AB</u> | APOTHECON     | <u>2.5MG</u> |
| <u>AB</u> |               | <u>5MG</u>   |
| <u>AB</u> |               | <u>10MG</u>  |
| <u>AB</u> |               | <u>20MG</u>  |
| <u>AB</u> | CHELSEA LABS  | <u>2.5MG</u> |
| <u>AB</u> |               | <u>5MG</u>   |
| <u>AB</u> |               | <u>10MG</u>  |
| <u>AB</u> |               | <u>20MG</u>  |
| <u>AB</u> | EON           | <u>2.5MG</u> |
| <u>AB</u> |               | <u>5MG</u>   |
| <u>AB</u> |               | <u>10MG</u>  |
| <u>AB</u> |               | <u>20MG</u>  |
| <u>AB</u> | GENEVA PHARMS | <u>2.5MG</u> |
| <u>AB</u> |               | <u>5MG</u>   |
| <u>AB</u> |               | <u>10MG</u>  |
| <u>AB</u> |               | <u>20MG</u>  |
| <u>AB</u> | GENPHARM      | <u>2.5MG</u> |
| <u>AB</u> |               | <u>5MG</u>   |

N75583 001  
 AUG 22, 2000  
 N75583 002  
 AUG 22, 2000  
 N75583 003  
 AUG 22, 2000  
 N75583 004  
 AUG 22, 2000  
 N75501 001  
 AUG 22, 2000  
 N75501 002  
 AUG 22, 2000  
 N75501 003  
 AUG 22, 2000  
 N75501 004  
 AUG 22, 2000  
 N75621 001  
 AUG 22, 2000  
 N75621 002  
 AUG 22, 2000  
 N75621 003  
 AUG 22, 2000  
 N75621 004  
 AUG 22, 2000  
 N75048 001  
 AUG 22, 2000  
 N75048 002  
 AUG 22, 2000  
 N75048 003  
 AUG 22, 2000  
 N75048 004  
 AUG 22, 2000  
 N75472 001  
 AUG 22, 2000  
 N75472 002  
 AUG 22, 2000

ENALAPRIL MALEATE

TABLET; ORAL  
ENALAPRIL MALEATE

|           |                    |              |
|-----------|--------------------|--------------|
| <u>AB</u> | GENPHARM           | <u>10MG</u>  |
| <u>AB</u> |                    | <u>20MG</u>  |
| <u>AB</u> | KRKA DD NOVO MESTO | <u>2.5MG</u> |
| <u>AB</u> |                    | <u>5MG</u>   |
| <u>AB</u> |                    | <u>10MG</u>  |
| <u>AB</u> |                    | <u>20MG</u>  |
| <u>AB</u> | LEK PHARM          | <u>2.5MG</u> |
| <u>AB</u> |                    | <u>5MG</u>   |
| <u>AB</u> |                    | <u>10MG</u>  |
| <u>AB</u> |                    | <u>20MG</u>  |
| <u>AB</u> | MYLAN              | <u>2.5MG</u> |
| <u>AB</u> |                    | <u>5MG</u>   |
| <u>AB</u> |                    | <u>10MG</u>  |
| <u>AB</u> |                    | <u>20MG</u>  |
| <u>AB</u> | RANBAXY            | <u>2.5MG</u> |
| <u>AB</u> |                    | <u>5MG</u>   |
| <u>AB</u> |                    | <u>10MG</u>  |
| <u>AB</u> |                    | <u>20MG</u>  |
| <u>AB</u> | TEVA               | <u>2.5MG</u> |
| <u>AB</u> |                    | <u>5MG</u>   |
| <u>AB</u> |                    | <u>10MG</u>  |
| <u>AB</u> |                    | <u>20MG</u>  |

N75472 003  
 AUG 22, 2000  
 N75472 004  
 AUG 22, 2000  
 N75370 001  
 AUG 22, 2000  
 N75370 002  
 AUG 22, 2000  
 N75369 001  
 AUG 22, 2000  
 N75369 002  
 AUG 22, 2000  
 N75496 001  
 AUG 22, 2000  
 N75496 002  
 AUG 22, 2000  
 N75459 001  
 AUG 22, 2000  
 N75459 002  
 AUG 22, 2000  
 N75480 001  
 AUG 22, 2000  
 N75480 002  
 AUG 22, 2000  
 N75480 003  
 AUG 22, 2000  
 N75480 004  
 AUG 22, 2000  
 N75556 001  
 AUG 22, 2000  
 N75556 002  
 AUG 22, 2000  
 N75556 003  
 AUG 22, 2000  
 N75556 004  
 AUG 22, 2000  
 N75479 001  
 AUG 22, 2000  
 N75479 002  
 AUG 22, 2000  
 N75479 003  
 AUG 22, 2000  
 N75479 004  
 AUG 22, 2000

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

|           |                         |              |
|-----------|-------------------------|--------------|
| <u>AB</u> | WOCKHARDT               | <u>2.5MG</u> |
| <u>AB</u> |                         | <u>5MG</u>   |
| <u>AB</u> |                         | <u>10MG</u>  |
| <u>AB</u> |                         | <u>20MG</u>  |
| <u>AB</u> | ZENITH GOLDLINE         | <u>2.5MG</u> |
| <u>AB</u> |                         | <u>5MG</u>   |
| <u>AB</u> |                         | <u>10MG</u>  |
| <u>AB</u> |                         | <u>20MG</u>  |
| <u>AB</u> | <u>VASOTEC</u><br>MERCK | <u>2.5MG</u> |
| <u>AB</u> |                         | <u>5MG</u>   |
| <u>AB</u> |                         | <u>10MG</u>  |
| <u>AB</u> | +                       | <u>20MG</u>  |
|           |                         | <u>2.5MG</u> |
|           |                         | <u>5MG</u>   |
|           |                         | <u>10MG</u>  |
|           |                         | <u>20MG</u>  |

ENALAPRILAT

INJECTABLE; INJECTION

ENALAPRILAT

|           |         |                  |
|-----------|---------|------------------|
| <u>AP</u> | ABBOTT  | <u>1.25MG/ML</u> |
| <u>AP</u> |         | <u>1.25MG/ML</u> |
| <u>AP</u> | BEDFORD | <u>1.25MG/ML</u> |

N75483 001  
AUG 22, 2000  
N75483 002  
AUG 22, 2000  
N75483 003  
AUG 22, 2000  
N75483 004  
AUG 22, 2000  
N75482 001  
AUG 22, 2000  
N75482 002  
AUG 22, 2000  
N75482 003  
AUG 22, 2000  
N75482 004  
AUG 22, 2000

N18998 005  
JUL 26, 1988  
N18998 001  
DEC 24, 1985  
N18998 002  
DEC 24, 1985  
N18998 003  
DEC 24, 1985  
N18998 005  
JUL 26, 1988  
N18998 001  
DEC 24, 1985  
N18998 002  
DEC 24, 1985  
N18998 003  
DEC 24, 1985

ENALAPRILAT

INJECTABLE; INJECTION

ENALAPRILAT

|           |                           |                  |
|-----------|---------------------------|------------------|
| <u>AP</u> | FAULDING                  | <u>1.25MG/ML</u> |
| <u>AP</u> | GENSIA SICOR PHARMS       | <u>1.25MG/ML</u> |
| <u>AP</u> | <u>VASOTEC</u><br>+ MERCK | <u>1.25MG/ML</u> |
|           |                           | <u>1.25MG/ML</u> |

ENFLURANE

LIQUID; INHALATION

ETHRANE

|           |   |                   |              |
|-----------|---|-------------------|--------------|
| <u>AN</u> | + | BAXTER PHARM PROD | <u>99.9%</u> |
| <u>AN</u> | * | CHIMEDA           | <u>99.9%</u> |

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL

ERGOMAR

|           |   |                                |            |
|-----------|---|--------------------------------|------------|
| <u>AA</u> |   | <u>LOTUS BIOCHEM</u>           | <u>2MG</u> |
|           | + |                                | 2MG        |
| <u>AA</u> |   | <u>ERGOSTAT</u><br>PARKE DAVIS | <u>2MG</u> |
|           | @ |                                | 2MG        |
| <u>AA</u> | * | <u>WICKETTES</u><br>ORGANON    | <u>2MG</u> |
|           | @ |                                | 2MG        |

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

|           |  |                 |             |
|-----------|--|-----------------|-------------|
| <u>AT</u> |  | <u>ALPHARMA</u> | <u>1.5%</u> |
|-----------|--|-----------------|-------------|

N75571 001  
AUG 22, 2000  
N75578 001  
AUG 22, 2000

N19309 001  
FEB 09, 1988  
N19309 001  
FEB 09, 1988

N17087 001  
N17087 001

N87693 001  
FEB 24, 1983  
N87693 001  
FEB 24, 1983

N88337 001  
JUN 08, 1984  
N88337 001  
JUN 08, 1984

N86750 001  
JUL 29, 1982  
N86750 001  
JUL 29, 1982

N63328 001  
APR 19, 1982

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

@ ALPHARMA

1.5%

N62328 001  
APR 19, 1982SANSACAT GALDERMA LABS2%N62522 001  
JAN 24, 1985AT HEALTHPOINT2%N62522 001  
JAN 24, 1985ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

PEDIAMYCINAB ROSS LABS

EQ 200MG BASE/5ML

N62305 001

@

EQ 200MG BASE/5ML

N62305 001

SUSPENSION/DROPS; ORAL

PEDIAMYCIN

\* ROSS LABS

EQ 100MG BASE/2.5ML

N62305 002

@

EQ 100MG BASE/2.5ML

N62305 002

TABLET, CHEWABLE; ORAL

PEDIAMYCINAB ROSS LABS

EQ 200MG BASE

N62306 001

@

EQ 200MG BASE

N62306 001

ESTRADIOL

CREAM; VAGINAL

ESTRACE

\* BRISTOL MYERS SQUIBB 0.01%

N86069 001

+ WARNER CHILCOTT 0.01%

N86069 001

JAN 31, 1984  
JAN 31, 1984

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARAAB + BERLEX LABS

0.05MG/24HR

N20375 001

DEC 22, 1994

AB +

0.1MG/24HR

N20375 002

DEC 22, 1994

BX \*

0.05MG/24HR

N20375 001

DEC 22, 1994

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARABX \* BERLEX LABS

0.1MG/24HR

N20375 002

DEC 22, 1994

ESTRADIOLBX CYGNUS CA

0.05MG/24HR

N21048 001

SEP 20, 1999

BX

0.075MG/24HR

N21048 002

SEP 20, 1999

BX

0.1MG/24HR

N21048 003

SEP 20, 1999

@ JOHNSON RW

0.05MG/24HR

N21048 001

SEP 20, 1999

@

0.075MG/24HR

N21048 002

SEP 20, 1999

@

0.1MG/24HR

N21048 003

SEP 20, 1999

AB MYLAN TECHNOLOGIES

0.05MG/24HR

N75233 001

FEB 24, 2000

AB

0.1MG/24HR

N75182 001

FEB 24, 2000

VIVELLE

+ NOVARTIS

0.025MG/24HR

N20323 005

AUG 16, 2000

TABLET; ORAL

ESTRADIOLAB APPLIED ANAL

0.5MG

N40138 001

JAN 30, 1998

AB

1MG

N40138 002

JAN 30, 1998

AB

2MG

N40138 003

JAN 30, 1998

AB

ENDEAVOR

0.5MG

N40138 001

JAN 30, 1998

AB

1MG

N40138 002

JAN 30, 1998

AB

2MG

N40138 003

JAN 30, 1998

ESTRADIOL CYPIONATE; MEDROXYPROGESTERONE ACETATE

INJECTABLE; INTRAMUSCULAR

LUNELLE

+ PHARMACIA AND UPJOHN 5MG/0.5ML; 25MG/0.5ML

N20874 001

OCT 05, 2000

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTIN

\* DURAMED

0.9MG

N20992 003

MAR 24, 1999

0.9MG

N20992 003

MAR 24, 1999

+

1.25MG

N20992 004

MAR 13, 2000

ESTROGENS, ESTERIFIED

TABLET; ORAL

ESTRATAB

BP \* SOLVAY

2.5MG

N81857 001

@

2.5MG

N83857 001

MENEST

BP \* MONARCH PHARMS

2.5MG

N84949 001

+

2.5MG

N84949 001

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

\* CYPROS

50MG/ML

N19357 001

DEC 22, 1988

+

QUESTCOR PHARM

50MG/ML

N19357 001

DEC 22, 1988

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

TRIVORA-21

AB SEARLE

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,

0.125MG

N74538 001

DEC 18, 1997

AB WATSON LABS

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,

0.125MG

N74538 001

DEC 18, 1997

TABLET; ORAL-28

TRIVORA-28

AB SEARLE

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,

0.125MG

N74538 002

DEC 18, 1997

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28

TRIVORA-28

AB

WATSON LABS

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,

0.125MG

N74538 002

DEC 18, 1997

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

MODICON 21

AB

JOHNSON RW

0.035MG, 0.5MG

N17488 001

AB

+

0.035MG, 0.5MG

N17488 001

OVCON-35

\* BRISTOL MYERS SQUIBB

0.035MG, 0.4MG

N18127 001

+ WARNER CHILCOTT

0.035MG, 0.4MG

N18127 001

OVCON-50

@ BRISTOL MYERS SQUIBB

0.05MG, 1MG

N18128 001

@ WARNER CHILCOTT

0.05MG, 1MG

N18128 001

TABLET; ORAL-28

OVCON-35

BRISTOL MYERS SQUIBB

0.035MG, 0.4MG

N17716 001

WARNER CHILCOTT

0.035MG, 0.4MG

N17716 001

OVCON-50

BRISTOL MYERS SQUIBB

0.05MG, 1MG

N17576 001

WARNER CHILCOTT

0.05MG, 1MG

N17576 001

ETHOSUXIMIDE

SYRUP; ORAL

ETHOSUXIMIDE

AA

PHARM ASSOC

250MG/5ML

N40253 001

NOV 22, 2000

ETODOLAC

CAPSULE; ORAL

ETODOLAC

&gt; ADD &gt;

AB

GENEVA PHARMS TECH

200MG

N74942 001

&gt; ADD &gt;

&gt; ADD &gt;

AB

300MG

SEP 30, 1997

N74942 002

&gt; ADD &gt;

&gt; DLT &gt;

AB

INVAMED

200MG

SEP 30, 1997

N74942 001

&gt; DLT &gt;

SEP 30, 1997

ETODOLAC

## CAPSULE; ORAL

ETODOLAC

|         |    |          |       |              |
|---------|----|----------|-------|--------------|
| > DLT > | AB | INVAMED  | 300MG | N74542 002   |
| > DLT   |    |          |       | SEP 30, 1997 |
|         | AB | TORPHARM | 200MG | N75419 001   |
|         |    |          |       | JUL 28, 2000 |
|         | AB |          | 300MG | N75419 002   |
|         |    |          |       | JUL 28, 2000 |

## TABLET; ORAL

ETODOLAC

|    |                    |       |              |
|----|--------------------|-------|--------------|
| AB | GENEVA PHARMS TECH | 400MG | N74846 001   |
|    |                    |       | FEB 28, 1997 |
| AB | INVAMED            | 400MG | N74846 001   |
|    |                    |       | FEB 28, 1997 |
| AB | TARO PHARM INDS    | 500MG | N75074 002   |
|    |                    |       | APR 25, 2000 |

## TABLET, EXTENDED RELEASE; ORAL

ETODOLAC

|    |                |       |              |
|----|----------------|-------|--------------|
| AB | POINT HOLDINGS | 400MG | N75696 001   |
|    |                |       | JUL 31, 2000 |
| AB | TEVA           | 500MG | N75665 002   |
|    |                |       | JUL 31, 2000 |
| AB |                | 600MG | N75665 001   |
|    |                |       | JUL 31, 2000 |
| AB | WHITNEY PHARMS | 400MG | N75696 001   |
|    |                |       | JUL 31, 2000 |

LODINE XL

|    |                |       |              |
|----|----------------|-------|--------------|
| AB | + WYETH AYERST | 400MG | N20584 001   |
|    |                |       | OCT 25, 1996 |
| AB | +              | 500MG | N20584 003   |
|    |                |       | JAN 20, 1998 |
| AB | +              | 600MG | N20584 002   |
|    |                |       | OCT 25, 1996 |
| *  |                | 400MG | N20584 001   |
|    |                |       | OCT 25, 1996 |
| *  |                | 500MG | N20584 003   |
|    |                |       | JAN 20, 1998 |
| *  |                | 600MG | N20584 002   |
|    |                |       | OCT 25, 1996 |

FENOLDOPAM MESYLATE

## INJECTABLE; INJECTION

## CORLOPAM

|   |             |                 |              |
|---|-------------|-----------------|--------------|
| + | ABBOTT      | EQ 10MG BASE/ML | N19922 001   |
|   |             |                 | SEP 23, 1997 |
| * | ELAN PHARMA | EQ 10MG BASE/ML | N19922 001   |
|   |             |                 | SEP 23, 1997 |

FENOPROFEN CALCIUM

## CAPSULE; ORAL

FENOPROFEN CALCIUM

|    |             |               |              |
|----|-------------|---------------|--------------|
| AB | WATSON LABS | EQ 200MG BASE | N72294 001   |
|    |             |               | AUG 17, 1988 |
| AB |             | EQ 300MG BASE | N72293 001   |
|    |             |               | AUG 17, 1988 |
| @  |             | EQ 200MG BASE | N72294 001   |
|    |             |               | AUG 17, 1988 |
| @  |             | EQ 300MG BASE | N72293 001   |
|    |             |               | AUG 17, 1988 |

## TABLET; ORAL

FENOPROFEN CALCIUM

|    |             |               |              |
|----|-------------|---------------|--------------|
| AB | WATSON LABS | EQ 600MG BASE | N72165 001   |
|    |             |               | AUG 17, 1988 |
| @  |             | EQ 600MG BASE | N72165 001   |
|    |             |               | AUG 17, 1988 |

FENTANYL CITRATE

## INJECTABLE; INJECTION

SUBLIMAZE PRESERVATIVE FREE

|    |             |                   |            |
|----|-------------|-------------------|------------|
| AP | + AKORN MFG | EQ 0.05MG BASE/ML | N16619 001 |
| AP | * JANSSEN   | EQ 0.05MG BASE/ML | N16619 001 |

FEXOFENADINE HYDROCHLORIDE

## TABLET; ORAL

## ALLEGRA

|   |                |       |              |
|---|----------------|-------|--------------|
|   | AVENTIS PHARMS | 30MG  | N20872 001   |
|   |                |       | FEB 25, 2000 |
|   |                | 60MG  | N20872 002   |
|   |                |       | FEB 25, 2000 |
| + |                | 180MG | N20872 004   |
|   |                |       | FEB 25, 2000 |

FLOXURIDINE

INJECTABLE; INJECTION

AP FLOXURIDINE  
BEDFORD

500MG/VIAL

N75387 001  
APR 16, 2000 > ADD >  
> ADD >

FUDR

AP + ROCHE  
\*500MG/VIAL  
500MG/VIALN16929 001  
N16929 001FLUCONAZOLE

TABLET; ORAL

DIFLUCAN  
PFIZER

150MG

N20322 001  
JUN 10, 1994  
N19949 004  
JUN 30, 1994

150MG

FLUMAZENIL

INJECTABLE; INJECTION

ROMAZICON  
+ HLR

0.1MG/ML

N20073 001  
DEC 20, 1991

\* ROCHE

0.1MG/ML

N20073 001  
DEC 20, 1991FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUONID

AT ALLERGAN HERBERT

0.025%

N87156 002  
SEP 06, 1984

@

0.025%

N87156 002  
SEP 06, 1984

OINTMENT; TOPICAL

FLUONID

AT ALLERGAN HERBERT

0.025%

N87157 001  
SEP 06, 1984

@

0.025%

N87157 001  
SEP 06, 1984

SOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE

AT BAUSCH AND LOMB

0.01%

N40059 001  
DEC 20, 1993FLUOCINOLONE ACETONIDE

SOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE

@ BAUSCH AND LOMB 0.01%

N40059 001  
DEC 20, 1993FLUOROURACIL

CREAM; TOPICAL

FLUOROURACIL  
+ DERMIK LABS

0.5%

N20985 001  
OCT 27, 2000

INJECTABLE; INJECTION

FLUOROURACIL

AP BIGMAR

50MG/ML

N40379 001  
NOV 15, 2000

AP GENSIA SICOR PHARMS

50MG/ML

N40333 001  
JAN 27, 2000

AP

50MG/ML

N40334 001  
FEB 25, 2000FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

SARAFEM  
LILLY

EQ 10MG BASE

N18936 007  
JUL 06, 2000

+

EQ 20MG BASE

N18936 008  
JUL 06, 2000FLURANDRENOLIDE

LOTION; TOPICAL

FLURANDRENOLIDE

AT ALPHARMA

0.05%

N87203 001  
APR 29, 1982

@

0.05%

N87203 001  
APR 29, 1982> DLT >  
> DLT >

FLUTICASONE PROPIONATE

POWDER; INHALATION

FLOVENT DISKUS 100

+ GLAXO 0.1MG/INH

N20833 002

SEP 29, 2000

FLOVENT DISKUS 250

+ GLAXO 0.25MG/INH

N20833 003

SEP 29, 2000

FLOVENT DISKUS 50

+ GLAXO 0.05MG/INH

N20833 001

SEP 29, 2000

FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE

POWDER; INHALATION

ADVAIR DISKUS 100/50

+ GLAXO WELLCOME 0.1MG/INH;  
EQ 0.05MG BASE/INH

N21077 001

AUG 24, 2000

ADVAIR DISKUS 250/50

+ GLAXO WELLCOME 0.25MG/INH;  
EQ 0.05MG BASE/INH

N21077 002

AUG 24, 2000

ADVAIR DISKUS 500/50

+ GLAXO WELLCOME 0.5MG/INH;  
EQ 0.05MG BASE/INH

N21077 003

AUG 24, 2000

FLUVASTATIN SODIUM

TABLET, EXTENDED RELEASE; ORAL

LESCOL XL

+ NOVARTIS 80MG

N21192 001

OCT 06, 2000

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATEAB EON 25MG

N75888 001

NOV 29, 2000

AB 50MG

N75888 002

NOV 29, 2000

AB 100MG

N75888 003

NOV 29, 2000

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATEAB MYLAN 25MG

N75889 001

NOV 29, 2000

AB 50MG

N75889 002

NOV 29, 2000

AB 100MG

N75889 003

NOV 29, 2000

> ADD > AB PUREPAC PHARM 25MG

N75901 001

DEC 28, 2000

> ADD > AB 50MG

N75901 002

DEC 28, 2000

> ADD > AB 100MG

N75901 003

DEC 28, 2000

> ADD > AB 100MG

N75901 003

DEC 28, 2000

LUVOXAB SOLVAY 25MG

N20243 001

DEC 05, 1994

AB 50MG

N20243 002

DEC 05, 1994

AB + 100MG

N20243 003

DEC 05, 1994

25MG

N20243 001

DEC 05, 1994

50MG

N20243 002

DEC 05, 1994

100MG

N20243 003

DEC 05, 1994

FOLLITROPIN ALFA/BETA

INJECTABLE; INJECTION

GONAL-F

SERONO

37.5 IU/VIAL

N20378 003

MAY 25, 2000

FURAZOLIDONE

SUSPENSION; ORAL

FUROXONE

\* ROBERTS LABS 50MG/15ML

N11323 002

+ SHIRE 50MG/15ML

N11323 002

TABLET; ORAL

FUROXONE

\* ROBERTS LABS 100MG

N11270 002

FURAZOLIDONE

TABLET; ORAL  
FUROXONE  
+ SHIRE

100MG

N11270 002

FUROSEMIDE

INJECTABLE; INJECTION  
FUROSEMIDE

AP ASTRAZENECA

10MG/ML

N70095 001

AP

10MG/ML

SEP 09, 1985

N70096 001

SEP 09, 1985

@

10MG/ML

N70095 001

SEP 09, 1985

@

10MG/ML

N70096 001

SEP 09, 1985

GABAPENTIN

SOLUTION; ORAL  
NEURONTIN

\* PARKE DAVIS

250MG/5ML

N21129 001

MAR 02, 2000

@

250MG/5ML

N21129 001

MAR 02, 2000

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION  
MAGNEVIST

+ BERLEX LABS

469.01MG/ML

N21037 001

MAR 10, 2000

GEMFIBROZIL

TABLET; ORAL  
GEMFIBROZIL

AB WATSON LABS

600MG

N74156 001

OCT 24, 1994

@

600MG

N74156 001

OCT 24, 1994

GEMTUZUMAB OZOGAMICIN

INJECTABLE; INJECTION  
MYLOTARG

+ WYETH AYERST

5MG/VIAL

N21174 001

MAY 17, 2000

GENTAMICIN SULFATE

INJECTABLE; INJECTION

GARAMYCIN

AP \* SCHERING

EQ 10MG BASE/ML

N61739 001

@

EQ 10MG BASE/ML

N61739 001

GENTAMICIN SULFATE

AP ELKINS SINN

EQ 10MG BASE/ML

N62251 002

AP +

EQ 10MG BASE/ML

N62251 002

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

AT ALCON UNIVERSAL

EQ 0.3% BASE

N62523 001

AT STERIS

EQ 0.3% BASE

NOV 25, 1985

N62523 001

NOV 25, 1985

GLUTETHIMIDE

TABLET; ORAL  
GLUTETHIMIDE

@ MD PHARM

500MG

N85171 001

@ MEDEVA PHARMS CA

500MG

N85171 001

GLYBURIDE

TABLET; ORAL

GLYBURIDE (MICRONIZED)

AB AVENTIS PHARMS

6MG

N20055 003

MAR 08, 2000

&gt; ADD &gt;

AB GENEVA PHARMS TECH

1.5MG

N75174 001

&gt; ADD &gt;

&gt; ADD &gt;

AB

3MG

JUN 22, 1998

N75174 002

&gt; ADD &gt;

&gt; DLT &gt;

AB INVAMED

1.5MG

JUN 22, 1998

N75174 001

&gt; DLT &gt;

&gt; DLT &gt;

AB

3MG

JUN 22, 1998

N75174 002

&gt; DLT &gt;

JUN 22, 1998

GLYBURIDE; METFORMIN HYDROCHLORIDETABLET; ORAL  
GLUCOVANCE

BRISTOL MYERS SQUIBB 1.25MG;250MG

N21178 001

JUL 31, 2000

2.5MG;500MG

N21178 002

JUL 31, 2000

+

5MG;500MG

N21178 003

JUL 31, 2000

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN

AT IPHARM

0.025MG/ML;EQ 1.75MG BASE/ML

10,000 UNITS/ML

N62818 001

OCT 11, 1988

@

0.025MG/ML;EQ 1.75MG BASE/ML;

10,000 UNITS/ML

N62818 001

OCT 11, 1988

GREPAFLOXACIN HYDROCHLORIDE

TABLET; ORAL

RAXAR

GLAXO WELLCOME

EQ 200MG BASE

N20695 001

NOV 06, 1997

EQ 400MG BASE

N20695 002

MAY 14, 1998

\*

EQ 600MG BASE

N20695 003

MAY 14, 1998

OTSUKA

EQ 200MG BASE

N20695 001

NOV 06, 1997

EQ 400MG BASE

N20695 002

MAY 14, 1998

+

EQ 600MG BASE

N20695 003

MAY 14, 1998

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

GRIFULVIN V

AB J AND J

250MG

N60618 002

AB

500MG

N60618 003

125MG

N60618 001

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

GRIFULVIN V

@ J AND J

125MG

N60618 001

@

250MG

N60618 002

@

500MG

N60618 003

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

GRIS-PEG

AB ALLERGAN HERBERT

125MG

N50475 001

AB

250MG

N50475 002

AB

PEDINOL

125MG

N50475 001

AB

250MG

N50475 002

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

AO

APOTEX

EQ 50MG BASE/ML

N75440 001

FEB 28, 2000

AO

EQ 100MG BASE/ML

N75440 002

FEB 28, 2000

AO

KING PHARMS

EQ 50MG BASE/ML

N75176 001

FEB 09, 2000

AO

EQ 100MG BASE/ML

N75176 002

FEB 09, 2000

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

AP

SMITH AND NEPHEW

10 UNITS/ML

N87904 001

APR 20, 1983

AP

100 UNITS/ML

N87906 001

APR 20, 1983

@

10 UNITS/ML

N87904 001

APR 20, 1983

@

100 UNITS/ML

N87906 001

APR 20, 1983

\* STERIS

100 UNITS/ML

N17064 001

@

100 UNITS/ML

N17064 001

HEPARIN SODIUM

AP

STERIS

5,000 UNITS/ML

N17064 003

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

|    |        |                 |            |
|----|--------|-----------------|------------|
| AP | STERIS | 10,000 UNITS/ML | N17064 004 |
| AP |        | 20,000 UNITS/ML | N17064 005 |
| AP |        | 40,000 UNITS/ML | N17064 006 |
| @  |        | 5,000 UNITS/ML  | N17064 003 |
| @  |        | 10,000 UNITS/ML | N17064 004 |
| @  |        | 20,000 UNITS/ML | N17064 005 |
| @  |        | 40,000 UNITS/ML | N17064 006 |

HEXACHLOROPHENEAEROSOL; TOPICAL  
SEPTISOL

@ VESTAL LABS 0.23% N17424 001

DISC; TOPICAL  
SEPTISOL

\* VESTAL LABS 0.23% N17424 001

HISTRELIN ACETATEINJECTABLE; INJECTION  
SUPPRELIN

|   |              |                  |            |
|---|--------------|------------------|------------|
| * | ROBERTS LABS | EQ 0.2MG BASE/ML | N19836 001 |
| * |              | EQ 0.5MG BASE/ML | N19836 002 |
| * |              | EQ 1MG BASE/ML   | N19836 003 |
| + | SHIRE        | EQ 0.2MG BASE/ML | N19836 001 |
| + |              | EQ 0.5MG BASE/ML | N19836 002 |
| + |              | EQ 1MG BASE/ML   | N19836 003 |

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

TABLET; ORAL

HOMATROPINE METHYLBROMIDE AND HYDROCODONE BITARTRATE

|         |    |             |            |              |
|---------|----|-------------|------------|--------------|
| > ADD > | AA | AMIDE PHARM | 1.5MG; 5MG | N40295 001   |
| > ADD > |    |             |            | DEC 01, 2000 |

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

|    |                     |          |            |
|----|---------------------|----------|------------|
| AP | GENSIA SICOR PHARMS | 20MG/ML  | N40373 001 |
| AP | +                   | LUITPOLD | 20MG/ML    |
| *  |                     | 20MG/ML  | N40136 001 |

FEB 23, 2000  
N40136 001  
JUN 30, 1997  
N40136 001  
JUN 30, 1997

TABLET; ORAL

HYDRALAZINE HCL

|    |              |      |            |
|----|--------------|------|------------|
| AA | GLOBAL PHARM | 25MG | N84922 001 |
| @  | IMPAX LABS   | 25MG | N84922 001 |

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

APRESAZIDE

|    |            |             |            |
|----|------------|-------------|------------|
| AB | * NOVARTIS | 100MG; 50MG | N84811 001 |
| @  |            | 100MG; 50MG | N84811 001 |

|    |            |             |              |
|----|------------|-------------|--------------|
| AB | HYDRA-ZIDE | 100MG; 50MG | N88961 001   |
|    | PAR PHARM  |             | OCT 21, 1985 |

+ 100MG; 50MG

N88961 001  
OCT 21, 1985  
N88961 001  
OCT 21, 1985HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

|    |       |             |            |
|----|-------|-------------|------------|
| AB | MYLAN | 12.5MG      | N75640 001 |
| AB | +     | WATSON LABS | 12.5MG     |
| *  |       | 12.5MG      | N20504 001 |

JAN 28, 2000  
N20504 001  
DEC 27, 1996  
N20504 001  
DEC 27, 1996

TABLET; ORAL

HYDROCHLOROTHIAZIDE

|    |              |       |            |
|----|--------------|-------|------------|
| AB | GLOBAL PHARM | 100MG | N85098 001 |
| @  | IMPAX LABS   | 100MG | N85098 001 |

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUMTABLET; ORAL  
HYZAAR

\* MERCK

12.5MG;50MG

12.5MG;50MG

+

25MG;100MG

N20387 001

APR 28, 1995

N20387 001

APR 28, 1995

N20387 002

NOV 10, 1998

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB WATSON LABS

15MG;250MG

N71920 001

AUG 29, 1988

AB

25MG;250MG

N71921 001

AUG 29, 1988

AB

30MG;500MG

N71922 001

AUG 29, 1988

AB

50MG;500MG

N71923 001

AUG 29, 1988

@

15MG;250MG

N71920 001

AUG 29, 1988

@

25MG;250MG

N71921 001

AUG 29, 1988

@

30MG;500MG

N71922 001

AUG 29, 1988

@

50MG;500MG

N71923 001

AUG 29, 1988

HYDROCHLOROTHIAZIDE; TELMISARTAN

TABLET; ORAL

MICARDIS HCT

BOEHRINGER INGELHEIM 12.5MG;40MG

N21162 001

NOV 17, 2000

+

12.5MG;80MG

N21162 002

NOV 17, 2000

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

CODAMINE

AA ALPHARMA

5MG/5ML; 25MG/5ML

N75103 001

SEP 29, 2000

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

HYCOMINE

AA + ENDO PHARMS

5MG/5ML; 25MG/5ML

N19410 001

AUG 17, 1990

\*

5MG/5ML; 25MG/5ML

N19410 001

AUG 17, 1990

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

AT ZENITH GOLDLINE

1%

N85733 001

@

1%

N85733 001

MOGENIC HC

AT ZENITH GOLDLINE

1%

N87427 001

APR 04, 1988

@

1%

N87427 001

APR 04, 1988

NUTRACORT

AT GALDERMA LABS

0.5%

N80442 002

AT

1%

N80442 003

AT

HEALTHPOINT

1%

N80442 003

@

0.5%

N80442 002

GEL; TOPICAL

NUTRACORT

@ GALDERMA LABS

1%

N84698 001

@ HEALTHPOINT

1%

N84698 001

EENECORT

\* ALLERGAN HERBERT

1%

N88215 001

JUN 05, 1984

@

1%

N88215 001

JUN 06, 1984

LOTION; TOPICAL

HYDROCORTISONE

AT ALTANA

2.5%

N40351 001

JUL 25, 2000

NUTRACORT

AT GALDERMA LABS

0.5%

N80443 002

AT

1%

N80443 003

AT

2.5%

N87644 001

AUG 24, 1982

AT

HEALTHPOINT

1%

N80443 003

AT

2.5%

N87644 001

AUG 24, 1982

HYDROCORTISONE

LOTION; TOPICAL  
NUTRACORT  
 @ HEALTHPOINT

0.5%

N80443 002

OINTMENT; TOPICAL  
HYDROCORTISONE  
 THAMES

2.5%

N40310 001  
 DEC 29, 2000

> ADD >  
 > ADD >

HYTONE

AT \* DERMIK LABS

1%

N80474 003

AT \*

2.5%

N80474 004

@

1%

N80474 003

@

2.5%

N80474 004

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT ALCON UNIVERSAL

1%;EQ 3.5MG BASE/ML;  
 10,000 UNITS/ML

N62874 001  
 MAY 11, 1988

AT STERIS

1%;EQ 3.5MG BASE/ML;  
 10,000 UNITS/ML

N62874 001  
 MAY 11, 1988

SUSPENSION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT ALCON UNIVERSAL

1%;EQ 3.5MG BASE/ML;  
 10,000 UNITS/ML

N62488 001  
 NOV 06, 1985

AT STERIS

1%;EQ 3.5MG BASE/ML;  
 10,000 UNITS/ML

N62488 001  
 NOV 06, 1985

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

EPIFOAM

BX SCHWARZ PHARMA

1%;1%

N86457 001

PROCTOFOAM HC

BX SCHWARZ PHARMA

1%;1%

N86195 001

DISC; TOPICAL

EPIFOAM

BX SCHWARZ PHARMA

1%;1%

N86457 001

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

DISC; TOPICAL

PROCTOFOAM HC

BX SCHWARZ PHARMA

1%;1%

N86195 001

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

LOCOID

@ GALDERMA LABS

0.1%

N18795 001

JAN 07, 1983

@ YAMANOUCHI

0.1%

N18795 001

JAN 07, 1983

LOCOID LIPOCREAM

YAMANOUCHI

0.1%

N20769 001

SEP 08, 1997

+

0.1%

N20769 001

SEP 08, 1997

OINTMENT; TOPICAL

LOCOID

@ GALDERMA LABS

0.1%

N19106 001

JUL 03, 1984

@ YAMANOUCHI

0.1%

N19106 001

JUL 03, 1984

SOLUTION; TOPICAL

LOCOID

@ GALDERMA LABS

0.1%

N19819 001

SEP 15, 1988

@ YAMANOUCHI

0.1%

N19819 001

SEP 15, 1988

HYDROCORTISONE VALERATE

CREAM; TOPICAL

HYDROCORTISONE VALERATE

AB CLAY PARK

0.2%

N75666 001

MAY 24, 2000

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

AB GENEVA PHARMS TECH 200MG

N40150 001  
 JAN 27, 1996

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATEAB INVAMED 250MGN40150 001  
JAN 27, 1996HYDROXYUREA

CAPSULE; ORAL

HYDROXYUREAAB BARR 250MGN75143 002  
SEP 21, 2000AB DURAMED 250MGN75020 002  
JUN 26, 2000AB + 250MGN75020 002  
JUN 26, 2000

TABLET; ORAL

HYDROXYUREA

+ BARR 1GM

N75734 001  
AUG 29, 2000INAMRINONE LACTATE

INJECTABLE; INJECTION

AMRINONEAP BEDFORD EQ 5MG BASE/MLN75513 001  
MAY 09, 2000AMRINONE LACTATEAP BAXTER PHARM PROD EQ 5MG BASE/MLN75542 001  
MAY 10, 2000INDOMETHACIN

CAPSULE; ORAL

INDOMETHACINAB WATSON LABS 25MGN70529 001  
OCT 18, 1985AB 50MGN70530 001  
OCT 18, 1985

@ 25MG

N70529 001  
OCT 18, 1985

@ 50MG

N70530 001  
OCT 18, 1985INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION

NOVOLOG

+ NOVO NORDISK 100 UNITS/ML

N20986 001  
JUN 07, 2000INSULIN GLARGINE

INJECTABLE; INJECTION

LANTUS

+ AVENTIS PHARMS 100 UNITS/ML

N21081 001  
APR 20, 2000INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION

HUMALOG MIX 50/50+ LILLY 50 UNITS/ML; 50 UNITS/ML N21018 001  
DEC 22, 1999HUMALOG MIX 75/25+ LILLY 25 UNITS/ML; 75 UNITS/ML N21017 001  
DEC 22, 1999INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION

HUMALOG MIX 50/50\* LILLY 100 UNITS/ML N21019 001  
DEC 22, 1999HUMALOG MIX 75/25\* LILLY 100 UNITS/ML N21017 001  
DEC 22, 1999INULIN

INJECTABLE; INJECTION

INULIN AND SODIUM CHLORIDE

\* CYPROS 100MG/ML N02282 001

+ QUESTCOR PHARM 100MG/ML N02282 001

IOPAMIDOL

INJECTABLE; INJECTION

IOPAMIDOL-200  
AP COOK IMAGING 41%

N74881 001  
 JUL 28, 2000

IOPAMIDOL-250  
AP COOK IMAGING 51%

N74881 002  
 JUL 28, 2000

IOPAMIDOL-300  
AP COOK IMAGING 61%

N74881 003  
 JUL 28, 2000

IOPAMIDOL-370  
AP COOK IMAGING 76%

N74881 004  
 JUL 28, 2000

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION

GLOFIL-125

CYPRON

QUESTCOR PHARM

250-300 uCi/ML

250-300 uCi/ML

N17279 001

N17279 001

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

AN STERIPAK 0.02%

N75313 001  
 FEB 07, 2000

IRON SUCROSE

INJECTABLE; INTRAVENOUS

VENOFER

+ LUITPOLD

EQ 20MG BASE/ML

N21135 001  
 NOV 06, 2000

ISOCARBOXAZID

TABLET; ORAL

MARPLAN

+ OXFORD PHARM

10MG

N11961 001

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

BRONKOSOL

AN \* SANOFI SYNTHELABO

1%

N12339 008

@

1%

N12339 008

ISOETHARINE HCL

AN \* ASTRA PHARMS

0.125%

N89615 001

@

0.167%

JUN 13, 1991

@

0.062%

N89616 001

@

0.062%

JUN 13, 1991

@

0.2%

N89617 001

@

0.25%

JUN 13, 1991

@

0.062%

N89618 001

@

0.125%

JUN 13, 1991

@

0.167%

N89614 001

@

0.2%

N89615 001

@

0.25%

JUN 13, 1991

@

0.062%

N89616 001

@

0.125%

JUN 13, 1991

@

0.167%

N89617 001

@

0.2%

JUN 13, 1991

@

0.25%

N89618 001

@

0.062%

JUN 13, 1991

@

0.125%

N89614 001

@

0.167%

N89615 001

@

0.2%

JUN 13, 1991

@

0.25%

N89616 001

@

0.062%

N89617 001

@

0.125%

N89618 001

@

0.167%

JUN 13, 1991

@

0.2%

N86651 003

@

0.25%

N86651 005

@

1%

N86651 006

@

0.077%

N86651 007

@

0.08%

N86651 008

@

0.143%

N86651 001

@

0.077%

N86651 002

@

0.1%

N86651 003

@

0.143%

N86651 004

@

0.167%

N86651 005

@

0.2%

N86651 006

@

0.25%

N86651 007

@

1%

N86651 008

@

0.1%

N87396 001

@

0.125%

N87025 001

@

0.167%

N88226 001

@

0.2%

SEP 16, 1983

N87324 001

ISOETHARINE HYDROCHLORIDE

| SOLUTION; INHALATION   |               |               |                     |
|------------------------|---------------|---------------|---------------------|
| <u>ISOETHARINE HCL</u> |               |               |                     |
| <u>AN</u>              | <u>ROXANE</u> | <u>0.25%</u>  | <u>N88275 001</u>   |
|                        |               |               | <u>JUN 03, 1983</u> |
| <u>AN</u>              |               | <u>1%</u>     | <u>N86899 001</u>   |
| <u>AN</u>              | <u>+</u>      | <u>1%</u>     | <u>N86899 001</u>   |
|                        | <u>@</u>      | <u>0.1%</u>   | <u>N87396 001</u>   |
|                        | <u>@</u>      | <u>0.125%</u> | <u>N87025 001</u>   |
|                        | <u>+</u>      | <u>0.167%</u> | <u>N88226 001</u>   |
|                        |               |               | <u>SEP 16, 1983</u> |
|                        | <u>+</u>      | <u>0.2%</u>   | <u>N87324 001</u>   |
|                        | <u>@</u>      | <u>0.25%</u>  | <u>N88275 001</u>   |
|                        |               |               | <u>JUN 03, 1983</u> |

ISOETHARINE MESYLATE

| AEROSOL, METERED, INHALATION |                          |                   |                   |
|------------------------------|--------------------------|-------------------|-------------------|
| BRONKOMETER                  |                          |                   |                   |
| <u>*</u>                     | <u>SANOPI SYNTHELABO</u> | <u>0.34MG/INH</u> | <u>N12339 007</u> |
| <u>@</u>                     |                          | <u>0.34MG/INH</u> | <u>N12339 007</u> |

ISOFLURANE

| LIQUID; INHALATION |                      |              |                     |
|--------------------|----------------------|--------------|---------------------|
| <u>ISOFLURANE</u>  |                      |              |                     |
| <u>AN</u>          | <u>RHODIA</u>        | <u>99.9%</u> | <u>N74502 001</u>   |
|                    |                      |              | <u>JUN 27, 1995</u> |
| <u>AN</u>          | <u>RHONE POULENC</u> | <u>99.9%</u> | <u>N74502 001</u>   |
|                    |                      |              | <u>JUN 27, 1995</u> |

ISOPROTERENOL HYDROCHLORIDE

| AEROSOL, METERED; INHALATION |                          |                    |                   |
|------------------------------|--------------------------|--------------------|-------------------|
| ISUPREL                      |                          |                    |                   |
| <u>*</u>                     | <u>SANOPI SYNTHELABO</u> | <u>0.103MG/INH</u> | <u>N11178 001</u> |
| <u>@</u>                     |                          | <u>0.103MG/INH</u> | <u>N11178 001</u> |
| SOLUTION; INHALATION         |                          |                    |                   |
| ISUPREL                      |                          |                    |                   |
| <u>*</u>                     | <u>SANOPI SYNTHELABO</u> | <u>0.5%</u>        | <u>N06327 002</u> |
| <u>*</u>                     |                          | <u>1%</u>          | <u>N06327 003</u> |
| <u>@</u>                     |                          | <u>0.5%</u>        | <u>N06327 002</u> |
| <u>@</u>                     |                          | <u>1%</u>          | <u>N06327 003</u> |

ISOSORBIDE DINITRATE

| TABLET, EXTENDED RELEASE; ORAL |                       |             |                     |
|--------------------------------|-----------------------|-------------|---------------------|
| <u>ISORDIL</u>                 |                       |             |                     |
| <u>AB</u>                      | <u>* WYETH AVERST</u> | <u>40MG</u> | <u>N12882 001</u>   |
|                                |                       |             | <u>JUL 29, 1988</u> |
|                                | <u>@</u>              | <u>40MG</u> | <u>N12882 001</u>   |
|                                |                       |             | <u>JUL 29, 1988</u> |
| <u>ISOSORBIDE DINITRATE</u>    |                       |             |                     |
| <u>AB</u>                      | <u>INWOOD LABS</u>    | <u>40MG</u> | <u>N40009 001</u>   |
|                                |                       |             | <u>DEC 30, 1998</u> |
|                                | <u>+</u>              | <u>40MG</u> | <u>N40009 001</u>   |
|                                |                       |             | <u>DEC 30, 1998</u> |

ISOSORBIDE MONONITRATE

| TABLET; ORAL                   |                          |              |                     |
|--------------------------------|--------------------------|--------------|---------------------|
| <u>ISOSORBIDE MONONITRATE</u>  |                          |              |                     |
| <u>AB</u>                      | <u>WEST WARD</u>         | <u>20MG</u>  | <u>N75361 001</u>   |
|                                |                          |              | <u>OCT 05, 2000</u> |
| TABLET, EXTENDED RELEASE; ORAL |                          |              |                     |
| <u>IMDUR</u>                   |                          |              |                     |
| <u>AB</u>                      | <u>+</u> <u>SCHERING</u> | <u>120MG</u> | <u>N20225 003</u>   |
|                                |                          |              | <u>MAR 30, 1995</u> |
|                                | <u>*</u>                 | <u>120MG</u> | <u>N20225 003</u>   |
|                                |                          |              | <u>MAR 30, 1995</u> |
| <u>ISOSORBIDE MONONITRATE</u>  |                          |              |                     |
| <u>AB</u>                      | <u>DEXCEL LTD</u>        | <u>60MG</u>  | <u>N75522 001</u>   |
|                                |                          |              | <u>APR 17, 2000</u> |
| <u>AB</u>                      | <u>KREMERS URBAN</u>     | <u>30MG</u>  | <u>N75155 002</u>   |
|                                |                          |              | <u>JAN 13, 2000</u> |
| <u>AB</u>                      |                          | <u>120MG</u> | <u>N75155 003</u>   |
|                                |                          |              | <u>AUG 04, 2000</u> |
| <u>AB</u>                      | <u>KV PHARM</u>          | <u>30MG</u>  | <u>N75395 001</u>   |
|                                |                          |              | <u>MAR 16, 2000</u> |
| <u>AB</u>                      |                          | <u>60MG</u>  | <u>N75395 002</u>   |
|                                |                          |              | <u>MAR 16, 2000</u> |
| <u>AB</u>                      |                          | <u>120MG</u> | <u>N75395 003</u>   |
|                                |                          |              | <u>MAR 16, 2000</u> |
| <u>AB</u>                      | <u>ZENITH GOLDLINE</u>   | <u>60MG</u>  | <u>N75448 001</u>   |
|                                |                          |              | <u>JUN 19, 2000</u> |

IVERMECTIN

TABLET; ORAL  
STROMECTOL  
MERCK

3MG

N50742 002  
OCT 08, 1998

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

AP PHARMAFATE

EQ 75MG BASE/2ML

N62668 001  
MAY 07, 1987

APEQ 500MG BASE/2ML

N62672 001  
MAY 07, 1987

APEQ 1GM BASE/3ML

N62669 001  
MAY 07, 1987

@

EQ 75MG BASE/2ML

N62668 001  
MAY 07, 1987

@

EQ 500MG BASE/2ML

N62672 001  
MAY 07, 1987

@

EQ 1GM BASE/3ML

N62669 001  
MAY 07, 1987

KETOCONAZOLE

CREAM; TOPICAL

KETOCONAZOLEAB TEVA2%

N75581 001  
APR 25, 2000

NIZORALAB + MCNEIL CONS2%

N19084 001  
DEC 31, 1985

\*

2%

N19084 001  
DEC 31, 1985

SHAMPOO; TOPICAL

NIZORAL

\* JANSSEN

2%

N19927 001  
AUG 31, 1990

+ MCNEIL CONS

2%

N19927 001  
AUG 31, 1990

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINEAP

APOTHECON

15MG/ML

N75348 001  
NOV 28, 2000  
N75348 002  
NOV 28, 2000

AP30MG/ML

TABLET; ORAL

KETOROLAC TROMETHAMINEAB

ROXANE

10MG

N74790 001  
JUN 26, 1997  
N74790 001  
JUN 26, 1997

@

10MG

LACTULOSE

SOLUTION; ORAL

AA

DUPHALAC

10GM/15ML

N72372 001  
MAR 22, 1989

SOLVAY

@

10GM/15ML

N72372 001  
MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM PRESERVATIVE FREEAP

+ ABBOTT

EQ 10MG BASE/ML

N40147 001  
JUN 25, 1997  
N40147 001  
JUN 25, 1997

\*

EQ 10MG BASE/MLAP

BEDFORD

EQ 10MG BASE/ML

N40347 001  
APR 25, 2000  
N40335 001  
APR 20, 2000

APEQ 350MG BASE/VIALWELLCOVORINAP

GLAXO WELLCOME

EQ 100MG BASE/VIAL

N89834 001  
JAN 23, 1989  
N89834 001  
JAN 23, 1989

@

EQ 100MG BASE/VIAL

TABLET; ORAL

LEUCOVORIN CALCIUM> ADD > AB

GENEVA PHARMS TECH

EQ 15MG BASE

N75327 001  
MAR 24, 1999

&gt; ADD &gt;

LEUCOVORIN CALCIUMTABLET; ORAL  
LEUCOVORIN CALCIUM

|         |                     |                     |              |
|---------|---------------------|---------------------|--------------|
| AB      | * <u>LEUCOVORIN</u> | <u>EQ 15MG BASE</u> | N71104 001   |
|         |                     |                     | MAR 04, 1987 |
| AB      |                     | <u>EQ 15MG BASE</u> | N71104 001   |
|         |                     |                     | MAR 04, 1987 |
| > DLT > | AB                  | <u>EQ 15MG BASE</u> | N75327 001   |
| > DLT > |                     |                     | MAR 24, 1999 |
|         | AB                  | <u>EQ 25MG BASE</u> | N72736 001   |
|         |                     |                     | FEB 22, 1993 |
|         | AB                  | <u>EQ 25MG BASE</u> | N72736 001   |
|         |                     |                     | FEB 22, 1993 |

LEUPROLIDE ACETATEIMPLANT; IMPLANTATION  
VIADUR  
+ ALZA

EQ 65MG BASE

N21088 001  
MAR 03, 2000INJECTABLE; INJECTION  
LEUPROLIDE ACETATEAP GENSLA SICOR PHARMS 1MG/0.2MLN75471 001  
OCT 25, 2000LEVOBETAXOLOL HYDROCHLORIDESUSPENSION/DROPS; OPHTHALMIC  
BETAXON

+ ALCON EQ 0.5% BASE

N21114 001  
FEB 23, 2000LEVOBUNOLOL HYDROCHLORIDESOLUTION/DROPS; OPHTHALMIC  
LEVOBUNOLOL HCLAT NOVEX 0.25%N75473 001  
AUG 03, 2000AT 0.5%N75475 001  
AUG 03, 2000LEVOPUPIVACAINE HYDROCHLORIDEINJECTABLE; INJECTION  
CHIROCAINE

PURDUE PHARMA EQ 2.5MG BASE/ML

N20997 001

AUG 05, 1999

EQ 5MG BASE/ML

N20997 002

AUG 05, 1999

EQ 7.5MG BASE/ML

N20997 003

AUG 05, 1999

PURDUE PHARMA LP EQ 2.5MG BASE/ML

N20997 001

AUG 05, 1999

EQ 5MG BASE/ML

N20997 002

AUG 05, 1999

EQ 7.5MG BASE/ML

N20997 003

AUG 05, 1999

LEVOFLOXACINSOLUTION/DROPS; OPHTHALMIC  
QUIXIN

+ SANTEN 0.5%

N21199 001  
AUG 18, 2000

TABLET; ORAL

LEVAQUIN

\* JOHNSON RW 500MG

N20634 002

DEC 20, 1996

500MG

N20634 002

DEC 20, 1996

+ 750MG

N20634 003

SEP 08, 2000

LEVONORGESTREL

&gt; ADD &gt;

INTRAUTERINE DEVICE; INTRAUTERINE

&gt; ADD &gt;

MIRENA

&gt; ADD &gt;

+ BERLEX LABS 52MG

N21225 001  
DEC 08, 2000

&gt; ADD &gt;

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

AB + ICN 2MG

N08720 001  
DEC 19, 1991

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

\* KEN

2MG

N08720 001  
DEC 19, 1991LEVORPHANOL TARTRATE

AB ROXANE

2MG

N74278 001  
MAR 31, 2000LEVOTHYROXINE SODIUM

TABLET; ORAL

UNITHROID

STEVENS J

0.025MG

N21210 001  
AUG 21, 2000

0.05MG

N21210 002  
AUG 21, 2000

0.075MG

N21210 003  
AUG 21, 2000

0.088MG

N21210 004  
AUG 21, 2000

0.1MG

N21210 005  
AUG 21, 2000

0.112MG

N21210 006  
AUG 21, 2000

0.125MG

N21210 007  
AUG 21, 2000

0.15MG

N21210 008  
AUG 21, 2000

0.175MG

N21210 009  
AUG 21, 2000

0.2MG

N21210 010  
AUG 21, 2000

+

0.3MG

N21210 011  
AUG 21, 2000LINEZOLID

GRANULE, FOR RECONSTITUTION; ORAL

ZYVOX

+ PHARMACIA AND UPJOHN 100MG/5ML

N21132 001  
APR 18, 2000

INJECTABLE; INJECTION

ZYVOX

+ PHARMACIA AND UPJOHN 200MG/100ML

N21131 001  
APR 18, 2000LINEZOLID

TABLET; ORAL

ZYVOX

PHARMACIA AND UPJOHN 400MG

N21130 001

APR 18, 2000

+

600MG

N21130 002

APR 18, 2000

LOPINAVIR; RITONAVIR

CAPSULE; ORAL

KALETRA

+ ABBOTT

133.3MG;33.3MG

N21226 001

SEP 15, 2000

SOLUTION; ORAL

KALETRA

+ ABBOTT

80MG/ML;20MG/ML

N21251 001

SEP 15, 2000

LORAZEPAM

INJECTABLE; INJECTION

LORAZEPAM

AP

MOVA

2MG/ML

N74793 001

MAR 16, 2000

AP

4MG/ML

N74793 002

MAR 16, 2000

MAGNESIUM SULFATE

INJECTABLE; INJECTION

MAGNESIUM SULFATE

AP

ABBOTT

500MG/ML

N75151 001

APR 25, 2000

AP

+ AM PHARM PARTNERS

500MG/ML

N19316 001

SEP 08, 1986

\*

500MG/ML

N19316 001

SEP 08, 1986

MASOPROCOLCREAM; TOPICAL  
ACTINEX

|         |                      |     |              |
|---------|----------------------|-----|--------------|
| > DLT > | * SCHWABZ PHARMA     | 10% | N19940 001   |
| > DLT > |                      |     | SEP 04, 1992 |
| > ADD > | + UNIV AZ CANCER CTR | 10% | N19940 001   |
| > ADD > |                      |     | SEP 04, 1992 |

MEDROXYPROGESTERONE ACETATETABLET; ORAL  
AMEN

|    |               |      |            |
|----|---------------|------|------------|
| BP | AMARIN PHARMS | 10MG | N83242 001 |
| BP | CARNICK       | 10MG | N83242 001 |
| BP | CURRETAR      | 10MG | N85686 001 |
| BP | SOLVAY        | 10MG | N85686 001 |
|    | @             | 10MG |            |

MEGESTROL ACETATETABLET; ORAL  
MEGESTROL ACETATE

|    |              |      |              |
|----|--------------|------|--------------|
| AB | PHARMACHEMIE | 40MG | N74745 001   |
|    |              |      | FEB 27, 1998 |
| AB | TEVA         | 40MG | N74745 001   |
|    |              |      | FEB 27, 1998 |

MELOXICAMTABLET; ORAL  
MOBIC

|                        |       |              |
|------------------------|-------|--------------|
| + BOEHRINGER INGELHEIM | 7.5MG | N20938 001   |
|                        |       | APR 13, 2000 |

MENOTROPINS (FSH; LH)INJECTABLE; INJECTION  
MENOTROPINS  
@ FERRING

|                        |                          |
|------------------------|--------------------------|
| 75 IU/VIAL; 75 IU/VIAL | N73598 001               |
|                        | JAN 30, 1997             |
| @                      | 150 IU/VIAL; 150 IU/VIAL |
|                        | N73599 001               |
|                        | JAN 30, 1997             |

|    |          |                        |              |
|----|----------|------------------------|--------------|
| AB | REPRONEX | 75 IU/VIAL; 75 IU/VIAL | N73598 001   |
|    | FERRING  |                        | JAN 30, 1997 |

MENOTROPINS (FSH; LH)

INJECTABLE; INJECTION

|    |          |                          |              |
|----|----------|--------------------------|--------------|
| AB | REPRONEX | 150 IU/VIAL; 150 IU/VIAL | N73599 001   |
|    | FERRING  |                          | JAN 30, 1997 |

MEPERIDINE HYDROCHLORIDETABLET; ORAL  
MEPERIDINE HCL  
MALLINCKRODT

|    |  |       |              |
|----|--|-------|--------------|
| AA |  | 50MG  | N40352 001   |
|    |  |       | JUN 13, 2000 |
| AA |  | 100MG | N40352 002   |
|    |  |       | JUN 13, 2000 |

MEPHENTERMINE SULFATEINJECTABLE; INJECTION  
WYAMINE SULFATE

|                |                 |            |
|----------------|-----------------|------------|
| * WYETH AYERST | EQ 30MG BASE/ML | N08248 001 |
| @              | EQ 30MG BASE/ML | N08248 001 |

MEPROBAMATETABLET; ORAL  
MEPROBAMATE

|    |        |       |            |
|----|--------|-------|------------|
| AA | LANBET | 200MG | N14882 002 |
| AA |        | 400MG | N14882 001 |
|    | @      | 200MG | N14882 002 |
|    | @      | 400MG | N14882 001 |

MESALAMINECAPSULE, EXTENDED RELEASE; ORAL  
PENTASA

|                |       |              |
|----------------|-------|--------------|
| * ROBERTS LABS | 250MG | N20049 001   |
|                |       | MAY 10, 1993 |
| + SHIRE        | 250MG | N20049 001   |
|                |       | MAY 10, 1993 |

SUPPOSITORY, RECTAL  
ROWASA

|          |       |              |
|----------|-------|--------------|
| * SOLVAY | 500MG | N19919 001   |
|          |       | DEC 18, 1990 |

MESALAMINESUPPOSITORY, RECTAL

ROWASA

@ SOLVAY

500MG

N19919 001  
DEC 18, 1990MESTRANOL; NORETHINDRONE

## TABLET; ORAL-20

NORINYL

@ SEARLE

@ WATSON LABS

0.1MG; 2MG

0.1MG; 2MG

N13625 004  
N13625 004

## TABLET; ORAL-21

NORINYL 1+50 21-DAY

SEARLE

WATSON LABS

0.05MG; 1MG

0.05MG; 1MG

N13625 002  
N13625 002METAPROTERENOL SULFATE

## SOLUTION; INHALATION

ALUPENT

\* BOEHRINGER INGELHEIM

+

METAPROTERENOL SULFATE

ASTRA PHARMS

5%

5%

N17659 001

N17659 001

0.4%

0.6%

N71275 001

JUL 27, 1988

N71018 001

JUL 27, 1988

@ ASTRAZENECA

0.4%

N71275 001

JUL 27, 1988

@

0.6%

N71018 001

JUL 27, 1988

PROMETA

MURO

5%

N73340 001

MAR 30, 1992

@

5%

N73340 001

MAR 30, 1992

## SYRUP; ORAL

METAPROTERENOL SULFATE

NOVEX

10MG/5ML

N75235 001

JAN 27, 2000

PROMETA

MURO

10MG/5ML

N72023 001

SEP 15, 1988

METAPROTERENOL SULFATE

## SYRUP; ORAL

PROMETA

@ MURO

10MG/5ML

N72023 001  
SEP 15, 1988METFORMIN HYDROCHLORIDE

## TABLET, EXTENDED RELEASE; ORAL

GLUCOPHAGE XR

+ BRISTOL MYERS SQUIBB 500MG

N21202 001  
OCT 13, 2000METHANTHELINE BROMIDE

## TABLET; ORAL

BANTHINE

\* ROBERTS LABS

+ SHIRE

50MG

50MG

N07390 001

N07390 001

METHICILLIN SODIUMINJECTABLE, INJECTION

STAPHICILLIN

\* APOTHECON

+

+

+

@

@

@

EQ 900MG BASE/VIAL

EQ 3.6GM BASE/VIAL

EQ 5.4GM BASE/VIAL

EQ 900MG BASE/VIAL

EQ 3.6GM BASE/VIAL

EQ 5.4GM BASE/VIAL

N61449 001

N61449 002

N61449 003

N61449 001

N61449 002

N61449 003

METHIMAZOLE

## TABLET; ORAL

METHIMAZOLE

APPLIED ANAL

5MG

N40320 001

MAR 11, 2000

AB

10MG

N40320 002

MAR 11, 2000

AB

GENPHARM

5MG

N40350 001

MAR 29, 2000

AB

10MG

N40350 002

MAR 29, 2000

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

AB JONES PHARMA

5MG

N40320 001

MAR 31, 2000

AB 10MG

N40320 002

MAR 31, 2000

TAPAZOLE

AB LILLY

5MG

N07517 002

AB + 10MG

N07517 004

AB 5MG

N07517 002

\* 10MG

N07517 004

&gt; ADD &gt;

&gt; ADD &gt;

&gt; DLT &gt;

&gt; DLT &gt;

METHOXYFLURANE

LIQUID, INHALATION

PENTHRANE

\* ABBOTT

@

99.9%

99.9%

N13056 001

N13056 001

METHSCOPOLAMINE BROMIDE

TABLET; ORAL

PAMINE

AA + BRADLEY PHARMS

2.5MG

N08848 001

AA \* KENWOOD LABS

2.5MG

N08848 001

&gt; ADD &gt;

&gt; DLT &gt;

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CONCERTA

+ ALZA

18MG

N21121 001

AUG 01, 2000

+

36MG

N21121 002

AUG 01, 2000

+

54MG

N21121 003

DEC 08, 2000

&gt; ADD &gt;

&gt; ADD &gt;

METADATE ER

AB + MEDEVA

10MG

N40306 001

OCT 20, 1999

AB 10MG

N40306 001

OCT 20, 1999

METHYLIN ER

AB MALLINCKRODT

10MG

N75629 001

MAY 09, 2000

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

METHYLIN ER

AB MALLINCKRODT

20MG

N75629 002

MAY 09, 2000

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

AB GENEVA PHARMS TECH

4MG

N40194 001

OCT 31, 1997

AB INVAMED

4MG

N40194 001

OCT 31, 1997

METHYLTESTOSTERONE

TABLET; ORAL

ORETON METHYL

BP SCHERING

10MG

N03158 001

BP 25MG

N03158 002

@

10MG

N03158 001

@

25MG

N03158 002

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

AB WATSON LABS

EQ 10MG BASE

N70645 001

@

EQ 10MG BASE

N70645 001

MAY 11, 1987

METOPROLOL TARTRATE

TABLET; ORAL

LOPRESSOR

AB \* NOVARTIS

50MG

N17963 001

AB 50MG

50MG

N17963 001

MICONAZOLE NITRATEINSERT, CREAM; VAGINAL, TOPICAL  
MONISTAT DUAL- PAK

\* ADVANCED CARE PRODS 1.2GM, 2%

+ PERSONAL PRODS 1.2GM, 2%

TAMPON; VAGINAL  
MONISTAT 5

\* ADVANCED CARE PRODS 100MG

@ PERSONAL PRODS 100MG

N20968 001

JUN 30, 1999

N20968 001

JUN 30, 1999

N18592 001

OCT 27, 1989

N18592 001

OCT 27, 1989

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL

ABBOTT

EQ 1MG BASE/ML

N75293 001

JUN 20, 2000

EQ 1MG BASE/ML

N75409 002

JUN 20, 2000

EQ 5MG BASE/ML

N75293 002

JUN 20, 2000

EQ 5MG BASE/ML

N75409 001

JUN 20, 2000

EQ 1MG BASE/ML

N75154 002

JUN 20, 2000

EQ 5MG BASE/ML

N75154 001

JUN 20, 2000

EQ 1MG BASE/ML

N75637 001

OCT 31, 2000

EQ 5MG BASE/ML

N75637 002

OCT 31, 2000

EQ 1MG BASE/ML

N75620 001

NOV 01, 2000

EQ 5MG BASE/ML

N75620 002

NOV 01, 2000

EQ 5MG BASE/ML

N75641 001

OCT 19, 2000

EQ 5MG BASE/ML

N75263 001

JUN 26, 2000

EQ 1MG BASE/ML

N75324 001

JUN 20, 2000

EQ 5MG BASE/ML

N75324 002

JUN 20, 2000

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCLAP

BEDFORD

EQ 1MG BASE/ML

N75247 002

JUN 23, 2000

APEQ 5MG BASE/ML

N75247 001

JUN 23, 2000

APEQ 5MG BASE/ML

N75249 001

JUN 23, 2000

AP

BEN VENUE

EQ 1MG BASE/ML

N75421 002

JUN 20, 2000

APEQ 5MG BASE/ML

N75421 001

JUN 20, 2000

APEQ 5MG BASE/ML

N75455 001

JUN 20, 2000

AP

ESI LEDERLE

EQ 1MG BASE/ML

N75243 001

JUN 20, 2000

APEQ 5MG BASE/ML

N75243 002

JUN 20, 2000

AP

FAULDING

EQ 1MG BASE/ML

N75396 001

JUN 20, 2000

APEQ 5MG BASE/ML

N75396 002

JUN 20, 2000

APEQ 5MG BASE/ML

N75484 001

JUN 20, 2000

AP

TAYLOR

EQ 5MG BASE/ML

N75481 001

JUN 30, 2000

AP

TAYLOR PHARMA

EQ 1MG BASE/ML

N75494 001

JUN 30, 2000

APEQ 5MG BASE/ML

N75494 002

JUN 30, 2000

VERSEDAP

+ HLR

EQ 1MG BASE/ML

N18654 002

MAY 26, 1987

AP

+

EQ 5MG BASE/ML

N18654 001

DEC 20, 1985

AP

\* ROCHE

EQ 1MG BASE/ML

N18654 002

MAY 26, 1987

AP

\*

EQ 5MG BASE/ML

N18654 001

DEC 20, 1985

MIFEPRISTONE

TABLET; ORAL

MIFEPREX

+ POPULATION COUNCIL 200MG

N20687 001

SEP 28, 2000

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCIN

|    |                        |               |              |
|----|------------------------|---------------|--------------|
| AB | * LEADERLE             | EQ 100MG BASE | N50649 002   |
|    |                        |               | MAY 31, 1990 |
| AB |                        | EQ 100MG BASE | N50649 002   |
|    |                        |               | MAY 31, 1990 |
|    | <u>MINOCYCLINE HCL</u> |               |              |
| AB | * DANBURY PHARMA       | EQ 75MG BASE  | N63065 002   |
|    |                        |               | JUN 10, 1999 |
| AB |                        | EQ 75MG BASE  | N63065 002   |
|    |                        |               | JUN 10, 1999 |
| AB |                        | EQ 100MG BASE | N63065 001   |
|    |                        |               | DEC 30, 1991 |
| AB | +                      | EQ 100MG BASE | N63065 001   |
|    |                        |               | DEC 30, 1991 |
| AB | RANBAXY                | EQ 50MG BASE  | N65062 001   |
|    |                        |               | NOV 30, 2000 |
| AB |                        | EQ 75MG BASE  | N65062 002   |
|    |                        |               | NOV 30, 2000 |
| AB |                        | EQ 100MG BASE | N65062 003   |
|    |                        |               | NOV 30, 2000 |

MIRTAZAPINE

TABLET; ORAL

REMERON

|         |         |      |              |
|---------|---------|------|--------------|
| > DLT > | ORGANON | 15MG | N20415 001   |
| > DLT > |         |      | JUN 14, 1996 |
| > DLT > | *       | 45MG | N20415 003   |
| > DLT > |         |      | MAR 17, 1997 |
| > ADD > | +       | 15MG | N20415 001   |
| > ADD > |         |      | JUN 14, 1996 |
| > ADD > |         | 45MG | N20415 003   |
| > ADD > |         |      | MAR 17, 1997 |

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL

SINGULAIR

MERCK

|             |              |
|-------------|--------------|
| EQ 4MG BASE | N20830 002   |
|             | MAR 03, 2000 |

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

|    |                    |       |              |
|----|--------------------|-------|--------------|
| AB | ENDO PHARMS        | 100MG | N75295 004   |
|    |                    |       | SEP 15, 2000 |
| AB |                    | 200MG | N75295 005   |
|    |                    |       | SEP 15, 2000 |
| AB | ESI LEADERLE       | 15MG  | N75407 001   |
|    |                    |       | JAN 28, 2000 |
|    | <u>NABUMETONE</u>  |       |              |
|    | TABLET; ORAL       |       |              |
|    | <u>NABUMETONE</u>  |       |              |
| AB | COPLEY PHARM       | 750MG | N75179 001   |
|    |                    |       | JUN 06, 2000 |
| AB | TEVA               | 500MG | N75189 001   |
|    |                    |       | MAY 26, 2000 |
|    | <u>RELAFEN</u>     |       |              |
| AB | SMITHKLINE BEECHAM | 500MG | N19583 001   |
|    |                    |       | DEC 24, 1991 |
| AB | +                  | 750MG | N19583 002   |
|    |                    |       | DEC 24, 1991 |
|    |                    | 500MG | N19583 001   |
|    |                    |       | DEC 24, 1991 |
|    | *                  | 750MG | N19583 002   |
|    |                    |       | DEC 24, 1991 |

NADOLOL

TABLET; ORAL

CORGARD

|    |           |      |            |
|----|-----------|------|------------|
| AB | APOTHECON | 40MG | N18063 001 |
| AB | +         | 40MG | N18063 001 |

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NALLPEN

|    |                    |                  |              |
|----|--------------------|------------------|--------------|
| AB | SMITHKLINE BEECHAM | EQ 1GM BASE/VIAL | N62755 001   |
|    |                    |                  | DEC 19, 1986 |
| AB |                    | EQ 2GM BASE/VIAL | N62755 002   |
|    |                    |                  | DEC 19, 1986 |
|    | @                  | EQ 1GM BASE/VIAL | N62755 001   |
|    |                    |                  | DEC 19, 1986 |

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NALLPEN

@ SMITHKLINE BEECHAM EQ 2GM BASE/VIAL

N62755 002  
DEC 19, 1986

TABLET; ORAL

UNIPEN\* WYETH AYERST  
@EQ 500MG BASE  
EQ 500MG BASEN50462 001  
N50462 001NALMEFENE HYDROCHLORIDEINJECTABLE; INJECTION  
REVEK

+ BAXTER PHARM PROD

EQ 0.1MG BASE/ML

N20459 001  
APR 17, 1995

+

EQ 1MG BASE/ML

N20459 002  
APR 17, 1995

\* OHMEDA

EQ 0.1MG BASE/ML

N20459 001  
APR 17, 1995

\*

EQ 1MG BASE/ML

N20459 002  
APR 17, 1995NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

AP ASTRAZENCA

0.02MG/ML

N72081 001  
APR 11, 1989

AP

0.4MG/ML

N72086 001  
APR 11, 1989

AP

1MG/ML

N72091 001  
APR 11, 1989

@

0.02MG/ML

N72081 001  
APR 11, 1989

@

0.4MG/ML

N72086 001  
APR 11, 1989

@

1MG/ML

N72091 001  
APR 11, 1989NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

AB

RANBAXY

EQ 0.5MG BASE;  
EQ 50MG BASEN75523 001  
MAR 17, 2000NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HCL

AB

EON

50MG

N75434 001  
MAR 08, 2000NAPROXEN

TABLET, DELAYED RELEASE; ORAL

NAPROXEN

AB

GENEVA PHARMS TECH

375MG

N75061 001  
FEB 18, 1998

AB

500MG

N75061 002  
FEB 18, 1998

AB

INVAMED

375MG

N75061 001  
FEB 18, 1998

AB

500MG

N75061 002  
FEB 18, 1998

&gt; ADD &gt;

NATEGLINIDE

&gt; ADD &gt;

TABLET; ORAL

&gt; ADD &gt;

STARLIX

&gt; ADD &gt;

NOVARTIS

60MG

&gt; ADD &gt;

+

120MG

&gt; ADD &gt;

N21204 001  
DEC 22, 2000  
N21204 002  
DEC 22, 2000NIACIN

TABLET; ORAL

NIACIN

AA

GLOBAL PHARM

500MG

N83115 001

@ IMPAX LABS

500MG

N83115 001

NIACOR

AA

UPSHER SMITH

500MG

N40378 001  
MAY 03, 2000

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

ADALAT CCAB + BAYER 30MGBC \* 30MGNIFEDIPINE> ADD > AB BIOVAIL 30MG> ADD > 30MG> ADD > AB 60MG> ADD > 60MGAB 60MGAB ELAN PHARM 30MGPROCARDIA XLAB + PFIZER 60MGBC \* 60MGNILUTAMIDE

TABLET; ORAL

NILANDRON> ADD > AVENTIS PHARMS 50MG> ADD > 50MG> ADD > + 150MG> ADD > \* HOECHST MARION RSSE 50MG> DLT > 50MG> DLT > 50MGNITROFURAZONE

CREAM; TOPICAL

FURACIN

\* ROBERTS LABS 0.2%

+ SHIRE 0.2%

OINTMENT; TOPICAL

FURACINAT \* ROBERTS LABS 0.2%AT + SHIRE 0.2%

N20198 001

APR 21, 1993

N20198 001

APR 21, 1993

N75269 001

DEC 04, 2000

N75269 002

DEC 04, 2000

N75289 001

SEP 27, 2000

N75128 001

MAR 10, 2000

N19684 002

SEP 06, 1989

N19684 002

SEP 06, 1989

N20169 001

SEP 19, 1996

N20169 002

APR 30, 1999

N20169 001

SEP 19, 1996

N83789 001

N83789 001

N05795 001

N05795 001

NITROGLYCERIN

INJECTABLE; INJECTION

NITRO IVAP \* BOHL BOSKAMP 5MG/ML

@ 5MG/ML

TABLET; SUBLINGUAL

NITROSTAT

PARKE DAVIS 0.3MG

0.4MG

0.6MG

+

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL

NORTRIPTYLINE HCL

GENEVA PHARMS TECH EQ 10MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 75MG BASE

INVAMED EQ 10MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 75MG BASE

TARO EQ 10MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 75MG BASE

N18672 002

AUG 10, 1983

N18672 002

AUG 30, 1983

N21134 001

MAY 01, 2000

N21134 002

MAY 01, 2000

N21134 003

MAY 01, 2000

N74835 001

JUN 30, 1997

N74835 002

JUN 30, 1997

N74835 003

JUN 30, 1997

N74835 004

JUN 30, 1997

N74835 001

JUN 30, 1997

N74835 002

JUN 30, 1997

N74835 003

JUN 30, 1997

N74835 004

JUN 30, 1997

N75520 004

MAY 08, 2000

N75520 003

MAY 08, 2000

N75520 001

MAY 08, 2000

N75520 002

MAY 08, 2000

NORTRIPTYLINE HYDROCHLORIDE

SOLUTION; ORAL  
NORTRIPTYLINE HCL  
AA PHARM ASSOC EQ 10MG BASE/5ML N75606 001  
 AUG 28, 2000

NYSTATIN

TABLET; VAGINAL  
NYSTATIN  
AT ODYSSEY PHARMS 100,000 UNITS N62615 001  
 OCT 17, 1985  
AT SIRMAL LABS NJ 100,000 UNITS N62615 001  
 OCT 17, 1985

OCTREOTIDE ACETATE

INJECTABLE; INJECTION  
 SANDOSTATIN  
 NOVARTIS EQ 0.2MG BASE/ML N19667 004  
 JUN 12, 1991  
EQ 1MG BASE/ML N19667 005  
 JUN 12, 1991  
 + EQ 0.2MG BASE/ML N19667 004  
 JUN 12, 1991  
 + EQ 1MG BASE/ML N19667 005  
 JUN 12, 1991  
 SANDOSTATIN LAR  
 NOVARTIS EQ 10MG BASE/VIAL N21008 001  
 NOV 25, 1998  
EQ 20MG BASE/VIAL N21008 002  
 NOV 25, 1998  
 + EQ 10MG BASE/VIAL N21008 001  
 NOV 25, 1998  
 + EQ 20MG BASE/VIAL N21008 002  
 NOV 25, 1998

OLANZAPINE

TABLET; ORAL  
 ZYPREXA  
 LILLY 2.5MG N20592 001  
 SEP 30, 1996  
 \* 10MG N20592 004  
 SEP 30, 1996

OLANZAPINE

TABLET; ORAL  
 ZYPREXA  
 \* LILLY 15MG N20592 005  
 SEP 09, 1997  
 + 2.5MG N20592 001  
 SEP 30, 1996  
10MG N20592 004  
 SEP 30, 1996  
 + 15MG N20592 005  
 SEP 09, 1997

TABLET, ORALLY DISINTEGRATING; ORAL  
 ZYPREXA ZYDIS  
 LILLY 5MG N21086 001  
 APR 06, 2000

10MG N21086 002  
 APR 06, 2000  
15MG N21086 003  
 APR 06, 2000  
 + 20MG N21086 004  
 APR 06, 2000

ORLISTAT

CAPSULE; ORAL  
 XENICAL  
 + HLR 120MG N20766 001  
 APR 23, 1999  
 \* ROCHE 120MG N20766 001  
 APR 23, 1999

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL  
ORPHENADRINE CITRATE  
AB EON 100MG N40327 001  
 FEB 15, 2000  
AB GENEVA PHARMS TECH 100MG N40284 001  
 JUN 19, 1998  
AB IMPAX PHARM 100MG N40368 001  
 JUN 23, 2000  
AB INVAMED 100MG N40284 001  
 JUN 19, 1998

## OXCARBAZEPINE

|              |       |              |
|--------------|-------|--------------|
| TABLET; ORAL |       |              |
| TRILEPTAL    |       |              |
| NOVARTIS     | 300MG | N21014 002   |
|              |       | JAN 14, 2000 |
| +            | 600MG | N21014 003   |
|              |       | JAN 14, 2000 |

OXYBUTYNIN CHLORIDE

| TABLET, EXTENDED RELEASE; ORAL |               |            |                     |
|--------------------------------|---------------|------------|---------------------|
| <u>DITROPAN XL</u>             |               |            |                     |
| <u>AB</u>                      | <u>* ALZA</u> | <u>5MG</u> | <u>N20897 001</u>   |
|                                |               |            | <u>DEC 16, 1998</u> |
| +                              |               | 5MG        | N20897 001          |
|                                |               |            | DEC 16, 1998        |

OXYCODONE HYDROCHLORIDE

|                                |                  |       |              |
|--------------------------------|------------------|-------|--------------|
| TABLET; ORAL                   |                  |       |              |
| ROXICODONE                     |                  |       |              |
|                                | ROXANE           | 15MG  | N21011 001   |
|                                |                  |       | AUG 31, 2000 |
| +                              |                  | 30MG  | N21011 002   |
|                                |                  |       | AUG 31, 2000 |
| TABLET, EXTENDED RELEASE; ORAL |                  |       |              |
| OXYCONTIN                      |                  |       |              |
| EX                             | * PURDUE PHARMA  | 10MG  | N20553 001   |
|                                |                  |       | DEC 12, 1995 |
| +                              | PURDUE PHARMA LP | 10MG  | N20553 001   |
|                                |                  |       | DEC 12, 1995 |
| +                              |                  | 160MG | N20553 005   |
|                                |                  |       | MAR 15, 2000 |
| ROXICODONE                     |                  |       |              |
| EX                             | ROXANE           | 10MG  | N20932 001   |
|                                |                  |       | OCT 26, 1998 |
| *                              |                  | 10MG  | N20932 002   |
|                                |                  |       | OCT 26, 1998 |
| @                              |                  | 10MG  | N20932 001   |
|                                |                  |       | OCT 26, 1998 |
| @                              |                  | 30MG  | N20932 002   |
|                                |                  |       | OCT 26, 1998 |

PACLITAXEL

INJECTABLE; INJECTION

PACLITAXEL

AP BAKER NORTON 6MG/ML

N75184 001  
SEP 15, 2000TAXOL

AP + BRISTOL MYERS SQUIBB 6MG/ML

N20262 001  
DEC 29, 1992

\* 6MG/ML

N20262 001  
DEC 29, 1992PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

PROTONIX

+ WYETH AYERST EQ 40MG BASE

N20987 001  
FEB 02, 2000PAROXETINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PAXIL CR

+ SMITHKLINE BEECHAM EQ 37.5MG BASE

N20936 003  
DEC 06, 2000> ADD >  
> ADD >PEMOLINE

TABLET; ORAL

PEMOLINE

AB AMIDE PHARM 18.75MG

N75595 001  
FEB 28, 2000

AB 37.5MG

N75595 002  
FEB 28, 2000

AB 75MG

N75595 003  
FEB 28, 2000

AB COPLE PHARM 18.75MG

N75030 003  
FEB 22, 2000

AB GENEVA PHARMS TECH 18.75MG

N75286 001  
DEC 27, 1999

AB 37.5MG

N75286 002  
JUN 30, 1999

AB 75MG

N75286 003  
JUN 30, 1999

AB INVAMED 18.75MG

N75286 001  
DEC 27, 1999PEMOLINE

TABLET; ORAL

PEMOLINE

AB INVAMED 37.5MG

N75286 002  
JUN 30, 1999

AB 75MG

N75286 003  
JUN 30, 1999

AB VINTAGE PHARMS 18.75MG

N75328 001  
APR 19, 2000

AB 37.5MG

N75328 002  
APR 19, 2000

AB 75MG

N75328 003  
APR 19, 2000

AB WATSON LABS 37.5MG

N75287 002  
SEP 18, 2000

AB 75MG

N75287 003  
SEP 18, 2000

TABLET, CHEWABLE; ORAL

CYLERT

AB + ABBOTT 37.5MG

N17703 001  
N17703 001

\* 37.5MG

PEMOLINE

AB AMIDE PHARM 37.5MG

N75678 001  
JUL 26, 2000

AB COPLE PHARM 37.5MG

N75555 001  
FEB 18, 2000PENICILLIN G BENZATHINE

INJECTABLE; INJECTION

BICILLIN L-A

BC + KING PHARMS 600,000 UNITS/ML

N50141 001

+ 300,000 UNITS/ML

N50141 003

BC + WYETH AYERST 600,000 UNITS/ML

N50141 001

\* 300,000 UNITS/ML

N50141 003

PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE

INJECTABLE; INJECTION

BICILLIN C-R

+ KING PHARMS 150,000 UNITS/ML;

N50138 002

+ 150,000 UNITS/ML

+ 300,000 UNITS/ML;

N50138 001

+ 300,000 UNITS/ML

PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE

INJECTABLE; INJECTION

BICILLIN C-R

|                |                  |            |
|----------------|------------------|------------|
| * WYETH AYERST | 150,000 UNITS/ML |            |
|                | 150,000 UNITS/ML | N50138 002 |
| *              | 300,000 UNITS/ML |            |
|                | 300,000 UNITS/ML | N50138 001 |

BICILLIN C-R 900/300

|                |                    |            |
|----------------|--------------------|------------|
| + KING PHARMS  | 900,000 UNITS/2ML; |            |
|                | 300,000 UNITS/2ML  | N50138 003 |
| * WYETH AYERST | 900,000 UNITS/2ML  |            |
|                | 300,000 UNITS/2ML  | N50138 003 |

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

WYCILLIN

|                 |                  |            |
|-----------------|------------------|------------|
| AP KING PHARMS  | 300,000 UNITS/ML | N60101 002 |
| AP              | 600,000 UNITS/ML | N60101 001 |
| AP WYETH AYERST | 300,000 UNITS/ML | N60101 002 |
| AP              | 600,000 UNITS/ML | N60101 001 |

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTACARINAT

|                 |            |              |
|-----------------|------------|--------------|
| AP ARMOUR PHARM | 300MG/VIAL | N73447 001   |
|                 |            | APR 28, 1994 |
| @               | 300MG/VIAL | N73447 001   |
|                 |            | APR 28, 1994 |

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

PENTOXIFYLLINE

|                |       |              |
|----------------|-------|--------------|
| AB IMPAX LABS  | 400MG | N75093 001   |
|                |       | AUG 10, 1999 |
| AB IMPAX PHARM | 400MG | N75093 001   |
|                |       | AUG 10, 1999 |

PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL

SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS

|           |         |              |
|-----------|---------|--------------|
| + US ARMY | 50%;50% | N21084 001   |
|           |         | FEB 17, 2000 |

PERGOLIDE MESYLATE

TABLET; ORAL

PERMAX

LILLY

|   |                |              |
|---|----------------|--------------|
|   | EQ 0.05MG BASE | N19385 001   |
|   |                | DEC 30, 1988 |
| * | EQ 1MG BASE    | N19385 003   |
|   |                | DEC 30, 1988 |
| + | EQ 0.05MG BASE | N19385 001   |
|   |                | DEC 30, 1988 |
|   | EQ 1MG BASE    | N19385 003   |
|   |                | DEC 30, 1988 |

PERINDOPRIL ERBUMINE

TABLET; ORAL

ACEON

@ SOLVAY

|               |     |              |
|---------------|-----|--------------|
|               | 2MG | N20184 001   |
|               |     | DEC 30, 1993 |
| *             | 4MG | N20184 002   |
|               |     | DEC 30, 1993 |
| @             | 8MG | N20184 003   |
|               |     | DEC 30, 1993 |
| SOLVAY PHARMA | 2MG | N20184 001   |
|               |     | DEC 30, 1993 |
|               | 4MG | N20184 002   |
|               |     | DEC 30, 1993 |
| +             | 8MG | N20184 003   |
|               |     | DEC 30, 1993 |

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

|                  |      |            |
|------------------|------|------------|
| AA AMARIN PHARMS | 35MG | N85272 001 |
| AA               | 35MG | N85272 001 |
| AA CAM-METRAZINE | 35MG | N83922 001 |
| AA               | 35MG | N83922 001 |

PHENDIMETRAZINE TARTRATE

|                      |                |      |            |
|----------------------|----------------|------|------------|
| TABLET; ORAL         |                |      |            |
| <u>CAM-METRAZINE</u> |                |      |            |
| AA                   | + CAMALL       | 35MG | N83922 001 |
|                      | <u>PLEGINE</u> |      |            |
| AA                   | * NYETH AYERST | 35MG | N12248 001 |
|                      | @              | 35MG | N12248 001 |

PHYTONADIONE

|                       |       |           |            |
|-----------------------|-------|-----------|------------|
| INJECTABLE; INJECTION |       |           |            |
| <u>KONAKION</u>       |       |           |            |
| BP                    | ROCHE | 1MG/0.5ML | N11745 001 |
| BP                    |       | 10MG/ML   | N11745 003 |
|                       | @     | 1MG/0.5ML | N11745 001 |
|                       | @     | 10MG/ML   | N11745 003 |

PIROXICAM

|                  |        |      |              |
|------------------|--------|------|--------------|
| CAPSULE; ORAL    |        |      |              |
| <u>PIROXICAM</u> |        |      |              |
| AB               | ROXANE | 10MG | N73651 001   |
|                  |        |      | FEB 26, 1993 |
| AB               |        | 20MG | N73651 002   |
|                  |        |      | FEB 26, 1993 |
|                  | @      | 10MG | N73651 001   |
|                  | @      | 20MG | N73651 002   |
|                  |        |      | FEB 26, 1993 |

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

|                                 |    |                |                                    |
|---------------------------------|----|----------------|------------------------------------|
| POWDER FOR RECONSTITUTION; ORAL |    |                |                                    |
| <u>COLYTE WITH FLAVOR PACKS</u> |    |                |                                    |
| > ADD >                         | AA | SCHWARZ PHARMA | 240GM/BOT; 2.98GM/BOT; 6.72GM/BOT; |
| > ADD >                         |    |                | 5.84GM/BOT; 22.72GM/BOT            |
| > ADD >                         |    |                | N18983 012                         |
| > ADD >                         |    |                | OCT 08, 1998                       |

PORFIMER SODIUM

|                       |                     |           |              |
|-----------------------|---------------------|-----------|--------------|
| INJECTABLE; INJECTION |                     |           |              |
| <u>PHOTOFIN</u>       |                     |           |              |
|                       | + AXCAN SCANDIPHARM | 75MG/VIAL | N20451 001   |
|                       |                     |           | DEC 27, 1995 |

PORFIMER SODIUM

|                       |       |           |              |
|-----------------------|-------|-----------|--------------|
| INJECTABLE; INJECTION |       |           |              |
| <u>PHOTOFIN</u>       |       |           |              |
|                       | * QLT | 75MG/VIAL | N20451 001   |
|                       |       |           | DEC 27, 1995 |

POTASSIUM CHLORIDE

|                                |              |       |              |
|--------------------------------|--------------|-------|--------------|
| TABLET, EXTENDED RELEASE; ORAL |              |       |              |
| <u>K-DUR 10</u>                |              |       |              |
| AB                             | + KEY PHARMS | 10MEQ | N19439 002   |
|                                |              |       | JUN 13, 1986 |
| BC                             | *            | 10MEQ | N19439 002   |
|                                |              |       | JUN 13, 1986 |
| <u>KLOR-CON M10</u>            |              |       |              |
| AB                             | UPSHER SMITH | 10MEQ | N74726 002   |
|                                |              |       | AUG 09, 2000 |

PREDNISOLONE

|                     |                 |          |              |
|---------------------|-----------------|----------|--------------|
| SYRUP; ORAL         |                 |          |              |
| <u>PREDNISOLONE</u> |                 |          |              |
| AA                  | COPLY PHARM     | 15MG/5ML | N40322 001   |
|                     |                 |          | JAN 19, 2000 |
| TABLET; ORAL        |                 |          |              |
| <u>PREDNISOLONE</u> |                 |          |              |
| BX                  | GLOBAL PHARM    | 5MG      | N80780 001   |
|                     | @ IMPAX LABS    | 5MG      | N80780 001   |
| BX                  | PHOENIX LABS NY | 5MG      | N80322 001   |
|                     | @               | 5MG      | N80322 001   |
| BX                  | ROXANE          | 5MG      | N80327 002   |
|                     | @               | 5MG      | N80327 002   |

PREDNISOLONE SODIUM PHOSPHATE

|                |  |               |                  |
|----------------|--|---------------|------------------|
| SOLUTION; ORAL |  |               |                  |
| <u>ORAPRED</u> |  |               |                  |
| > ADD >        |  | + ASCENT PEDS | EQ 15MG BASE/5ML |
| > ADD >        |  |               | N75117 001       |
| > ADD >        |  |               | DEC 14, 2000     |

SOLUTION/DROPS; OPHTHALMIC

|                                      |                 |                    |              |
|--------------------------------------|-----------------|--------------------|--------------|
| <u>PREDNISOLONE SODIUM PHOSPHATE</u> |                 |                    |              |
| AT                                   | ALCON UNIVERSAL | EQ 0.11% PHOSPHATE | N81043 001   |
|                                      |                 |                    | OCT 24, 1991 |

PREDNISOLONE SODIUM PHOSPHATE

|                                      |                 |                           |              |
|--------------------------------------|-----------------|---------------------------|--------------|
| SOLUTION/DROPS; OPHTHALMIC           |                 |                           |              |
| <u>PREDNISOLONE SODIUM PHOSPHATE</u> |                 |                           |              |
| <u>AT</u>                            | ALCON UNIVERSAL | <u>EQ 0.9% PHOSPHATE</u>  | N81044 001   |
|                                      |                 |                           | OCT 24, 1991 |
| <u>AT</u>                            | STERIS          | <u>EQ 0.11% PHOSPHATE</u> | N81043 001   |
|                                      |                 |                           | OCT 24, 1991 |
| <u>AT</u>                            |                 | <u>EQ 0.9% PHOSPHATE</u>  | N81044 001   |
|                                      |                 |                           | OCT 24, 1991 |

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

|                                                               |                 |                                |              |
|---------------------------------------------------------------|-----------------|--------------------------------|--------------|
| SOLUTION/DROPS; OPHTHALMIC                                    |                 |                                |              |
| <u>SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE</u> |                 |                                |              |
| <u>AT</u>                                                     | ALCON UNIVERSAL | <u>EQ 0.23% PHOSPHATE; 10%</u> | N73630 001   |
|                                                               |                 |                                | MAY 27, 1993 |
| <u>AT</u>                                                     | STERIS          | <u>EQ 0.23% PHOSPHATE; 10%</u> | N73630 001   |
|                                                               |                 |                                | MAY 27, 1993 |

PREDNISONE

|                    |                  |         |              |
|--------------------|------------------|---------|--------------|
| SYRUP; ORAL        |                  |         |              |
| <u>LIQUID PRED</u> |                  |         |              |
|                    | * MURG           | 5MG/5ML | N87611 002   |
|                    |                  |         | SEP 07, 1982 |
|                    | @                | 5MG/5ML | N87611 002   |
|                    |                  |         | SEP 07, 1982 |
| TABLET; ORAL       |                  |         |              |
| <u>PREDNICEN-M</u> |                  |         |              |
| <u>AB</u>          | CENT PHARMS      | 5MG     | N84655 001   |
|                    | @ SCHWARZ PHARMA | 5MG     | N84655 001   |
| <u>PREDNISONE</u>  |                  |         |              |
| <u>AB</u>          | GLOBAL PHARM     | 5MG     | N80782 001   |
|                    | @ IMPAX LABS     | 5MG     | N80782 001   |
| <u>BX</u>          | PHOENIX LABS NY  | 5MG     | N80121 001   |
| <u>BX</u>          |                  | 20MG    | N83807 001   |
|                    | @                | 5MG     | N80321 001   |
|                    | @                | 20MG    | N83807 001   |

PRIMIDONE

|                 |               |      |            |
|-----------------|---------------|------|------------|
| TABLET; ORAL    |               |      |            |
| <u>MYSOLINE</u> |               |      |            |
|                 | * ELAN PHARMA | 50MG | N09170 003 |

PRIMIDONE

|                 |             |      |            |
|-----------------|-------------|------|------------|
| TABLET; ORAL    |             |      |            |
| <u>MYSOLINE</u> |             |      |            |
|                 | ELAN PHARMA | 50MG | N09170 003 |

PROCAINAMIDE HYDROCHLORIDE

|                                |            |       |              |
|--------------------------------|------------|-------|--------------|
| TABLET, EXTENDED RELEASE; ORAL |            |       |              |
| <u>PROCAN SR</u>               |            |       |              |
| <u>AB</u>                      | * PARKDALE | 500MG | N86065 001   |
| <u>AB</u>                      | *          | 750MG | N87510 001   |
|                                |            |       | APR 01, 1982 |
| <u>AB</u>                      | *          | 1GM   | N88489 001   |
|                                |            |       | JAN 16, 1985 |
|                                | @          | 500MG | N86065 001   |
|                                | @          | 750MG | N87510 001   |
|                                | @          | 1GM   | APR 01, 1982 |
|                                |            |       | N88489 001   |
|                                |            |       | JAN 16, 1985 |

PROCHLORPERAZINE

|                     |         |      |              |
|---------------------|---------|------|--------------|
| SUPPOSITORY; RECTAL |         |      |              |
| <u>COMPRO</u>       |         |      |              |
| <u>AB</u>           | PADDOCK | 25MG | N40246 001   |
|                     |         |      | JUN 28, 2000 |

PROGESTERONE

|                   |                 |       |              |
|-------------------|-----------------|-------|--------------|
| CAPSULE; ORAL     |                 |       |              |
| <u>PROMETRIUM</u> |                 |       |              |
|                   | SCHERING PLOUGH | 100MG | N19781 001   |
|                   |                 |       | MAY 14, 1998 |
|                   |                 | 200MG | N19781 002   |
|                   |                 |       | OCT 15, 1999 |
|                   | *               | 300MG | N19781 003   |
|                   |                 |       | OCT 15, 1999 |
|                   | UNIMED PHARMS   | 100MG | N19781 001   |
|                   |                 |       | MAY 14, 1998 |
|                   | +               | 200MG | N19781 002   |
|                   | @               | 300MG | OCT 15, 1999 |
|                   |                 |       | N19781 003   |
|                   |                 |       | OCT 15, 1999 |

INJECTABLE; INJECTION

|                     |           |         |            |
|---------------------|-----------|---------|------------|
| <u>PROGESTERONE</u> |           |         |            |
| > DLT >             | <u>AC</u> | * BILLY | 50MG/ML    |
|                     |           |         | N09238 001 |

PROGESTERONE

INJECTABLE; INJECTION

|                |           |                     |                |            |
|----------------|-----------|---------------------|----------------|------------|
| > <u>ADD</u> > |           | <u>PROGESTERONE</u> |                |            |
|                |           | @ LILLY             | 50MG/ML        | N09238 001 |
| > <u>DLT</u> > | <u>AO</u> | * STERIS            | <u>50MG/ML</u> | N17362 002 |
| > <u>ADD</u> > |           | +                   | 50MG/ML        | N17362 002 |

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

|  |           |                         |                |              |
|--|-----------|-------------------------|----------------|--------------|
|  | <u>AP</u> | <u>PROMETHAZINE HCL</u> | <u>25MG/ML</u> | N40372 001   |
|  |           | ABBOTT                  |                | JUN 08, 2000 |
|  | <u>AP</u> |                         | <u>50MG/ML</u> | N40372 002   |
|  |           |                         |                | JUN 08, 2000 |

SUPPOSITORY; RECTAL  
PHENERGAN

|                |           |              |      |            |
|----------------|-----------|--------------|------|------------|
| > <u>DLT</u> > | <u>BR</u> | WYETH AYERST | 25MG | N10926 001 |
| > <u>ADD</u> > | BR        | +            | 25MG | N10926 001 |

TABLET; ORAL

|                |           |                         |             |              |
|----------------|-----------|-------------------------|-------------|--------------|
|                | <u>BP</u> | <u>PROMETHAZINE HCL</u> | <u>25MG</u> | N84214 002   |
| > <u>DLT</u> > |           | GLOBAL PHARM            |             | JUL 07, 1982 |
| > <u>DLT</u> > |           |                         |             | N84214 002   |
| > <u>ADD</u> > |           | @ IMPAX LABS            | 25MG        | JUL 07, 1982 |
| > <u>ADD</u> > |           |                         |             |              |

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL

|  |           |                        |              |              |
|--|-----------|------------------------|--------------|--------------|
|  | <u>AB</u> | <u>PROPAFENONE HCL</u> | <u>150MG</u> | N75203 001   |
|  |           | WATSON LABS            |              | OCT 24, 2000 |
|  | <u>AB</u> |                        | <u>225MG</u> | N75203 002   |
|  |           |                        |              | OCT 24, 2000 |
|  | <u>AB</u> | <u>RYTHMOL</u>         | <u>150MG</u> | N19151 001   |
|  |           | KNOLL PHARM            |              | NOV 27, 1989 |
|  | <u>AB</u> |                        | <u>225MG</u> | N19151 003   |
|  |           |                        |              | NOV 20, 1992 |
|  |           |                        | <u>150MG</u> | N19151 001   |
|  |           |                        |              | NOV 27, 1989 |
|  |           |                        | <u>225MG</u> | N19151 003   |
|  |           |                        |              | NOV 20, 1992 |

PROPANTHELINE BROMIDE

TABLET; ORAL

|           |   |              |       |            |
|-----------|---|--------------|-------|------------|
|           |   | PRO-BANTHINE |       |            |
| <u>BP</u> | * | ROBERTS LABS | 7.5MG | N08732 003 |
| <u>BP</u> | * |              | 15MG  | N08732 002 |
| <u>BP</u> | + | SHIRE        | 7.5MG | N08732 003 |
| <u>BP</u> | + |              | 15MG  | N08732 002 |

PROPACACINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC

|  |           |                        |             |              |
|--|-----------|------------------------|-------------|--------------|
|  | <u>AT</u> | <u>PROPACACINE HCL</u> | <u>0.5%</u> | N40277 001   |
|  |           | TAYLOR PHARMA          |             | MAR 16, 2000 |

PROPOFOL

INJECTABLE; INJECTION

|  |           |                     |                |              |
|--|-----------|---------------------|----------------|--------------|
|  | <u>AB</u> | <u>PROPOFOL</u>     | <u>10MG/ML</u> | N75392 001   |
|  |           | GENSIA SICOR PHARMS |                | SEP 19, 2000 |

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

|  |           |                        |               |              |
|--|-----------|------------------------|---------------|--------------|
|  | <u>AP</u> | <u>INDERAL</u>         | <u>1MG/ML</u> | N16419 001   |
|  |           | WYETH AYERST           |               | N16419 001   |
|  |           | *                      | <u>1MG/ML</u> |              |
|  | <u>AP</u> | <u>PROPRANOLOL HCL</u> | <u>1MG/ML</u> | N75792 001   |
|  |           | BEDFORD                |               | AUG 29, 2000 |

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL

|  |  |                       |     |            |
|--|--|-----------------------|-----|------------|
|  |  | VENTAIRE              |     |            |
|  |  | @ AVENTIS PHARMS      | 2MG | N83459 001 |
|  |  | * ROECHST MARION RSSL | 2MG | N83459 001 |

PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

|  |           |                 |            |            |
|--|-----------|-----------------|------------|------------|
|  | <u>AB</u> | <u>VIVACTIL</u> | <u>5MG</u> | N15012 001 |
|  |           | MERCK           |            |            |

PROTRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

VIVACTIL

|    |             |      |            |
|----|-------------|------|------------|
| AB | * MERCK     | 10MG | N16012 002 |
| AB | SIDMAK LABS | 5MG  | N16012 001 |
| AB | +           | 10MG | N16012 002 |

QUINIDINE POLYGALACTURONATE

TABLET; ORAL

CARDIOQUIN

|  |                    |       |            |
|--|--------------------|-------|------------|
|  | * PURDUE FREDERICK | 275MG | N11642 002 |
|  | @                  | 275MG | N11642 002 |

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

|    |           |       |            |
|----|-----------|-------|------------|
| AB | PHARMAYTE | 200MG | N84627 001 |
|    | @         | 200MG | N84627 001 |

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL

RANITIDINE HCL

|         |    |                    |               |              |
|---------|----|--------------------|---------------|--------------|
| > DLT > | AB | CHEMINOR DRUGS     | EQ 150MG BASE | N75742 001   |
| > DLT > |    |                    |               | NOV 29, 2000 |
| > DLT > | AB |                    | EQ 300MG BASE | N75742 002   |
| > DLT > |    |                    |               | NOV 29, 2000 |
| > ADD > | AB | DR REDDYS LABS LTD | EQ 150MG BASE | N75742 001   |
| > ADD > |    |                    |               | NOV 29, 2000 |
| > ADD > | AB |                    | EQ 300MG BASE | N75742 002   |
| > ADD > |    |                    |               | NOV 29, 2000 |
|         | AB | GENPHARM           | EQ 150MG BASE | N75564 001   |
|         |    |                    |               | OCT 27, 2000 |
|         | AB |                    | EQ 300MG BASE | N75564 002   |
|         |    |                    |               | OCT 27, 2000 |

TABLET; ORAL

RANITIDINE

|    |         |               |              |
|----|---------|---------------|--------------|
| AB | RANBAXY | EQ 150MG BASE | N75439 001   |
|    |         |               | APR 19, 2000 |
| AB |         | EQ 300MG BASE | N75439 002   |
|    |         |               | APR 19, 2000 |

RESERPINE

TABLET; ORAL

RESERPINE

|    |              |        |            |
|----|--------------|--------|------------|
| BP | GLOBAL PHARM | 0.1MG  | N09627 001 |
| BP |              | 0.25MG | N09627 002 |
|    | @ IMPAX LABS | 0.1MG  | N09627 001 |
|    | @            | 0.25MG | N09627 002 |

RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

|  |                    |     |              |
|--|--------------------|-----|--------------|
|  | PROCTER AND GAMBLE | 5MG | N20835 002   |
|  |                    |     | APR 14, 2000 |

RIVASTIGMINE TARTRATE

CAPSULE; ORAL

EXELON

NOVARTIS

|               |              |
|---------------|--------------|
| EQ 1.5MG BASE | N20823 003   |
|               | APR 21, 2000 |
| EQ 3MG BASE   | N20823 004   |
|               | APR 21, 2000 |
| EQ 4.5MG BASE | N20823 005   |
|               | APR 21, 2000 |
| EQ 6MG BASE   | N20823 006   |
|               | APR 21, 2000 |

SOLUTION; ORAL

EXELON

+ NOVARTIS

|                |              |
|----------------|--------------|
| EQ 2MG BASE/ML | N21025 001   |
|                | APR 21, 2000 |

ROFECOXIB

TABLET; ORAL

VIOXX

\* MERCK

|      |              |
|------|--------------|
| 25MG | N21042 002   |
|      | MAY 20, 1999 |
| 25MG | N21042 002   |
|      | MAY 20, 1999 |
| 50MG | N21042 003   |
|      | FEB 25, 2000 |

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

|           |                         |             |                   |
|-----------|-------------------------|-------------|-------------------|
| <u>AT</u> | <u>SELENIUM SULFIDE</u> | <u>2.5%</u> | <u>N85777 001</u> |
|           | <u>ZENITH GOLDLINE</u>  |             |                   |
| @         |                         | 2.5%        | N85777 001        |

SEVELAMER HYDROCHLORIDETABLET; ORAL  
RENAGEL  
GELTEX

400MG

N21179 001

JUL 12, 2000

+ 800MG

N21179 002

JUL 12, 2000

SIROLIMUSTABLET; ORAL  
RAPAMUNE

+ WYETH AYERST 1MG

N21110 001

AUG 25, 2000

SODIUM FLUORIDE, F-18INJECTABLE; INTRAVENOUS  
FLUORINE F-18

@ NYCOMED AMERSHAM 2mCi/ML

N17042 001

SODIUM IODIDE, I-131CAPSULE; ORAL  
IODOTOPE

BRACCO 1-130mCi N10929 001

1-150mCi N10929 003

+ 1-130mCi N10929 001

+ 1-150mCi N10929 003

SODIUM IODIDE I 131

CIS 100 uCi N17316 002

+ 100 uCi N17316 002

+ MALLINCKRODT 15-100 uCi N16517 002

+ 0.8-100mCi N16517 001

+ 15-100 uCi N16517 002

+ 0.8-100mCi N16517 001

SODIUM IODIDE, I-131

SOLUTION; ORAL

IODOTOPE

BRACCO

7-106mCi/BOT

N10929 002

7-106mCi/BOT N10929 002

+ SODIUM IODIDE I 131

CIS

50mCi/ML

N17315 001

+ 50mCi/ML N17315 001

+ MALLINCKRODT 3.5-150mCi/VIAL N16515 001

3.5-150mCi/VIAL N16515 001

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE

TABLET; ORAL

VISICOL

+ INKINE 0.398GM;1.102GM

N21097 001

SEP 21, 2000

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION

NORDITROPIN

NOVO NORDISK

5MG/1.5ML

N21148 001

JUN 20, 2000

10MG/1.5ML N21148 002

JUN 20, 2000

+ 15MG/1.5ML N21148 003

JUN 20, 2000

SOTALOL HYDROCHLORIDE

TABLET; ORAL

BETAPACE

AB BERLEX LABS

80MG

N19865 001

OCT 30, 1992

AB 120MG N19865 005

APR 20, 1994

AB + 160MG N19865 002

OCT 30, 1992

AB 240MG N19865 003

OCT 30, 1992

80MG N19865 001

OCT 30, 1992

SOTALOL HYDROCHLORIDE

TABLET; ORAL

BETAPACEBERLEX LABS120MG160MG240MG

BETAPACE AF

BERLEX LABS

80MG

120MG

160MG

SOTALOL HCLEON80MG120MG160MG240MGGENPHARM80MG120MG160MG240MGIMPAX PHARM80MG120MG160MG240MGMYLAN80MG120MG160MG> ADD >  
> ADD >  
> ADD >  
> ADD >  
> ADD >  
> ADD >N19865 005APR 20, 1994N19865 002OCT 30, 1992N19865 003OCT 30, 1992N21151 001FEB 22, 2000N21151 002FEB 22, 2000N21151 003FEB 22, 2000N75366 001MAY 01, 2000N75366 002MAY 01, 2000N75366 003MAY 01, 2000N75366 004MAY 01, 2000N75237 001MAY 01, 2000N75237 002MAY 01, 2000N75237 003MAY 01, 2000N75237 004MAY 01, 2000N75663 001NOV 07, 2000N75663 002NOV 07, 2000N75663 003NOV 07, 2000N75663 004NOV 07, 2000N75725 001DEC 19, 2000N75725 002DEC 19, 2000N75725 003DEC 19, 2000

&gt; ADD &gt;

&gt; ADD

SOTALOL HYDROCHLORIDE

TABLET; ORAL

SOTALOL HCLMYLAN240MGTEVA80MGAB120MGAB160MGAB240MGABWATSON LABS80MGAB120MGAB160MGAB240MGSTRONTIUM CHLORIDE, SR-89

INJECTABLE; INJECTION

METASTRONNYCOMED AMERSHAM1mCi/ML

+

1mCi/MLSULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

OCUSULF-10ATMIZA PHARMS USA10%ATOPTOICS10%OCUSULF-30@ MIZA PHARMS USA30%@ OPTOICS30%SULFACETAMIDE SODIUMATALCON UNIVERSAL10%ATSTERIS10%N75725 004DEC 19, 2000N75429 001MAY 01, 2000N75429 002MAY 01, 2000N75429 003MAY 01, 2000N75429 004MAY 01, 2000N75238 001JUL 13, 2000N75238 002JUL 13, 2000N75238 003JUL 13, 2000N75238 004JUL 13, 2000N20134 001JUN 18, 1993N20134 001JUN 18, 1993N80660 001N80660 001N80660 002N80660 002N89560 001OCT 18, 1988N89560 001OCT 18, 1988

SULFISOXAZOLE

|              |                      |              |                   |
|--------------|----------------------|--------------|-------------------|
| TABLET; ORAL |                      |              |                   |
| <u>AB</u>    | <u>SULFISOXAZOLE</u> | <u>500MG</u> | <u>N80109 001</u> |
|              | GLOBAL PHARM         | 500MG        | N80109 001        |
|              | @ IMPAX LABS         |              |                   |

TACRINE HYDROCHLORIDE

|               |                    |              |              |
|---------------|--------------------|--------------|--------------|
| CAPSULE; ORAL |                    |              |              |
| COGNEX        |                    |              |              |
|               | FIRST HORIZON      | EQ 10MG BASE | N20070 001   |
|               |                    |              | SEP 09, 1993 |
|               |                    | EQ 20MG BASE | N20070 002   |
|               |                    |              | SEP 09, 1993 |
|               |                    | EQ 30MG BASE | N20070 003   |
|               |                    |              | SEP 09, 1993 |
|               |                    | EQ 40MG BASE | N20070 004   |
|               |                    |              | SEP 09, 1993 |
| +             |                    | EQ 10MG BASE | N20070 001   |
|               | PARKE DAVIS PHARMS |              | SEP 09, 1993 |
|               |                    | EQ 20MG BASE | N20070 002   |
|               |                    |              | SEP 09, 1993 |
|               |                    | EQ 30MG BASE | N20070 003   |
|               |                    |              | SEP 09, 1993 |
| *             |                    | EQ 40MG BASE | N20070 004   |
|               |                    |              | SEP 09, 1993 |

TACROLIMUS

|         |                   |       |              |
|---------|-------------------|-------|--------------|
| > ADD > | 0INTMENT; TOPICAL |       |              |
| > ADD > | PROTOPIC          |       |              |
| > ADD > | FUJISAWA HLTHCARE | 0.03% | N50777 001   |
| > ADD > |                   |       | DEC 08, 2000 |
| > ADD > | +                 | 0.1%  | N50777 002   |
| > ADD > |                   |       | DEC 08, 2000 |

TAMOXIFEN CITRATE

|                   |                |              |              |
|-------------------|----------------|--------------|--------------|
| TABLET; ORAL      |                |              |              |
| TAMOXIFEN CITRATE |                |              |              |
|                   | @ MYLAN        | EQ 10MG BASE | N74732 001   |
|                   |                |              | JUN 26, 2000 |
|                   | @ PHARMACHEMIE | EQ 10MG BASE | N74539 001   |
|                   |                |              | MAY 31, 2000 |

> ADD >  
> ADD >

TAZAROTENE

|                |          |       |              |
|----------------|----------|-------|--------------|
| CREAM; TOPICAL |          |       |              |
| TAZORAC        |          |       |              |
|                | ALLERGAN | 0.05% | N21184 001   |
|                |          |       | SEP 29, 2000 |
| +              |          | 0.1%  | N21184 002   |
|                |          |       | SEP 29, 2000 |

TECHNETIUM TC-99M SULFUR COLLOID KIT

|                              |                  |     |            |
|------------------------------|------------------|-----|------------|
| SOLUTION; INJECTION, ORAL    |                  |     |            |
| <u>TECHNETIUM TC 99M TSC</u> |                  |     |            |
| <u>AP</u>                    | NYCOMED AMERSHAM | N/A | N17784 001 |
|                              | @                | N/A | N17784 001 |

TELMISARTAN

|              |                           |  |              |
|--------------|---------------------------|--|--------------|
| TABLET; ORAL |                           |  |              |
| MICARDIS     |                           |  |              |
| +            | BOEHRINGER INGELHEIM 20MG |  | N20850 003   |
|              |                           |  | APR 04, 2000 |

TERAZOSIN HYDROCHLORIDE

|                      |                    |                     |              |
|----------------------|--------------------|---------------------|--------------|
| CAPSULE; ORAL        |                    |                     |              |
| <u>TERAZOSIN HCL</u> |                    |                     |              |
| <u>AB</u>            | INVAMED            | <u>EQ 1MG BASE</u>  | N75667 001   |
|                      |                    |                     | JUL 28, 2000 |
| <u>AB</u>            |                    | <u>EQ 2MG BASE</u>  | N75667 002   |
|                      |                    |                     | JUL 28, 2000 |
| <u>AB</u>            |                    | <u>EQ 5MG BASE</u>  | N75667 003   |
|                      |                    |                     | JUL 28, 2000 |
| <u>AB</u>            |                    | <u>EQ 10MG BASE</u> | N75667 004   |
|                      |                    |                     | JUL 28, 2000 |
| <u>AB</u>            | MYLAN              | <u>EQ 1MG BASE</u>  | N75140 002   |
|                      |                    |                     | FEB 11, 2000 |
| <u>AB</u>            |                    | <u>EQ 2MG BASE</u>  | N75140 003   |
|                      |                    |                     | FEB 11, 2000 |
| <u>AB</u>            |                    | <u>EQ 5MG BASE</u>  | N75140 001   |
|                      |                    |                     | FEB 11, 2000 |
| <u>AB</u>            |                    | <u>EQ 10MG BASE</u> | N75140 004   |
|                      |                    |                     | FEB 11, 2000 |
| <u>AB</u>            | MYLAN TECHNOLOGIES | <u>EQ 1MG BASE</u>  | N75384 001   |
|                      |                    |                     | DEC 01, 2000 |

TERAZOSIN HYDROCHLORIDE

## CAPSULE; ORAL

TERAZOSIN HCL

|         |    |                    |                     |              |
|---------|----|--------------------|---------------------|--------------|
| > ADD > | AB | MYLAN TECHNOLOGIES | <u>EQ 2MG BASE</u>  | N75384 002   |
| > ADD   |    |                    |                     | DEC 01, 2000 |
| > ADD > | AB |                    | <u>EQ 5MG BASE</u>  | N75384 003   |
| > ADD > |    |                    |                     | DEC 01, 2000 |
| > ADD > | AB |                    | <u>EQ 10MG BASE</u> | N75384 004   |
| > ADD > |    |                    |                     | DEC 01, 2000 |

## TABLET; ORAL

TERAZOSIN HCL

|    |                 |                     |              |
|----|-----------------|---------------------|--------------|
| AB | INVAMED         | <u>EQ 1MG BASE</u>  | N74657 001   |
|    |                 |                     | APR 28, 2000 |
| AB |                 | <u>EQ 2MG BASE</u>  | N74657 002   |
|    |                 |                     | APR 28, 2000 |
| AB |                 | <u>EQ 5MG BASE</u>  | N74657 003   |
|    |                 |                     | APR 28, 2000 |
| AB |                 | <u>EQ 10MG BASE</u> | N74657 004   |
|    |                 |                     | APR 28, 2000 |
| AB | NOVOPHARM       | <u>EQ 1MG BASE</u>  | N74446 001   |
|    |                 |                     | MAY 18, 2000 |
| AB |                 | <u>EQ 2MG BASE</u>  | N74446 002   |
|    |                 |                     | MAY 18, 2000 |
| AB |                 | <u>EQ 5MG BASE</u>  | N74446 003   |
|    |                 |                     | MAY 18, 2000 |
| AB |                 | <u>EQ 10MG BASE</u> | N74446 004   |
|    |                 |                     | MAY 18, 2000 |
| AB | ZENITH GOLDLINE | <u>EQ 1MG BASE</u>  | N74530 001   |
|    |                 |                     | APR 21, 2000 |
| AB |                 | <u>EQ 2MG BASE</u>  | N74530 002   |
|    |                 |                     | APR 21, 2000 |
| AB |                 | <u>EQ 5MG BASE</u>  | N74530 003   |
|    |                 |                     | APR 21, 2000 |
| AB |                 | <u>EQ 10MG BASE</u> | N74530 004   |
|    |                 |                     | APR 21, 2000 |

TERBUTALINE SULFATE

## AEROSOL, METERED; INHALATION

BRETHAIRE

NOVARTIS

@

0.2MG/INH

0.2MG/INH

N18762 001

AUG 17, 1984

N18762 001

AUG 17, 1984

TESTOSTERONEFILM, EXTENDED RELEASE; TRANSDERMAL  
ANDRODERM

|    |                 |            |              |
|----|-----------------|------------|--------------|
| BX | * THERATECH     | 5MG/24HR   | N20489 002   |
|    |                 |            | MAY 02, 1997 |
|    | *               | 2.5MG/24HR | N20489 001   |
|    |                 |            | SEP 29, 1995 |
| BX | + WATSON LABS   | 5MG/24HR   | N20489 002   |
|    |                 |            | MAY 02, 1997 |
|    | +               | 2.5MG/24HR | N20489 001   |
|    |                 |            | SEP 29, 1995 |
|    | GEL; TOPICAL    |            |              |
|    | ANDROGEL        |            |              |
|    | + UNIMED PHARMS | 1%         | N21015 001   |
|    |                 |            | FEB 28, 2000 |

THEOPHYLLINE

## CAPSULE, EXTENDED RELEASE; ORAL

SLO-PHYLLIN

@ AVENTIS

60MG

N85206 001

MAY 24, 1982

@

125MG

N85203 001

MAY 24, 1982

@

250MG

N85205 001

MAY 24, 1982

BC RHONE-POULENC RORER 125MG

N85203 001

MAY 24, 1982

BC 250MG

N85205 001

MAY 24, 1982

60MG

N85206 001

MAY 24, 1982

THIAMINE HYDROCHLORIDE

## INJECTABLE; INJECTION

BETALIN S

|    |         |          |            |
|----|---------|----------|------------|
| AP | * LILLY | 100MG/ML | N80853 001 |
|    | @       | 100MG/ML | N80853 001 |

THIAMINE HCL

|    |                   |          |            |
|----|-------------------|----------|------------|
| AP | AM PHARM PARTNERS | 100MG/ML | N80556 001 |
| AP | +                 | 100MG/ML | N80556 001 |

TIAGABINE HYDROCHLORIDE

|              |          |      |              |
|--------------|----------|------|--------------|
| TABLET; ORAL |          |      |              |
| GABITRIL     |          |      |              |
| > DLT >      | ABBOTT   | 4MG  | N20646 001   |
| > DLT >      |          |      | SEP 30, 1997 |
| > DLT >      |          | 12MG | N20646 002   |
| > DLT >      |          |      | SEP 30, 1997 |
| > DLT >      |          | 16MG | N20646 003   |
| > DLT >      |          |      | SEP 30, 1997 |
| > DLT >      | *        | 20MG | N20646 004   |
| > DLT >      |          |      | SEP 30, 1997 |
| > ADD >      | CEPHALON | 4MG  | N20646 001   |
| > ADD >      |          |      | SEP 30, 1997 |
| > ADD >      |          | 12MG | N20646 002   |
| > ADD >      |          |      | SEP 30, 1997 |
| > ADD >      |          | 16MG | N20646 003   |
| > ADD >      |          |      | SEP 30, 1997 |
| > ADD >      | +        | 20MG | N20646 004   |
| > ADD >      |          |      | SEP 30, 1997 |

TICLOPIDINE HYDROCHLORIDE

|                 |                |                    |              |
|-----------------|----------------|--------------------|--------------|
| TABLET; ORAL    |                |                    |              |
| TICLOPIDINE HCL |                |                    |              |
| AB              | DANBURY PHARMA | 250MG              | N75309 001   |
|                 |                |                    | APR 26, 2000 |
| > ADD >         | AB             | GENEVA PHARMS TECH | 250MG        |
| > ADD >         |                |                    | N75318 001   |
| > DLT >         | AB             | INVANCE            | 250MG        |
| > DLT >         |                |                    | AUG 20, 1999 |
|                 |                |                    | N75318 001   |
|                 |                |                    | AUG 28, 1999 |

TIMOLOL MALEATE

|                            |           |               |              |
|----------------------------|-----------|---------------|--------------|
| SOLUTION/DROPS; OPHTHALMIC |           |               |              |
| TIMOLOL MALEATE            |           |               |              |
| AT                         | NOVEX     | EQ 0.25% BASE | N75411 001   |
|                            |           |               | SEP 08, 2000 |
| AT                         |           | EQ 0.5% BASE  | N75412 001   |
|                            |           |               | SEP 08, 2000 |
| TABLET; ORAL               |           |               |              |
| TIMOLOL MALEATE            |           |               |              |
| AB                         | NOVOPHARM | 5MG           | N72648 001   |
|                            |           |               | JUN 16, 1993 |
| AB                         |           | 10MG          | N72649 001   |
|                            |           |               | JUN 16, 1993 |

TIMOLOL MALEATE

|                 |           |      |              |
|-----------------|-----------|------|--------------|
| TABLET; ORAL    |           |      |              |
| TIMOLOL MALEATE |           |      |              |
| AB              | NOVOPHARM | 20MG | N72650 001   |
|                 |           |      | JUN 16, 1993 |
| @               |           | 5MG  | N72648 001   |
|                 |           |      | JUN 16, 1993 |
| @               |           | 10MG | N72649 001   |
|                 |           |      | JUN 16, 1993 |
| @               |           | 20MG | N72650 001   |
|                 |           |      | JUN 16, 1993 |

TINZAPARIN SODIUM

|                       |               |              |              |
|-----------------------|---------------|--------------|--------------|
| INJECTABLE; INJECTION |               |              |              |
| INNOHEP               |               |              |              |
| +                     | DUPONT PHARMA | 20,000 IU/ML | N20484 001   |
|                       |               |              | JUL 14, 2000 |

TIZANIDINE HYDROCHLORIDE

|              |             |             |              |
|--------------|-------------|-------------|--------------|
| TABLET; ORAL |             |             |              |
| ZANAFLEX     |             |             |              |
|              | ELAN PHARMA | EQ 2MG BASE | N20397 002   |
|              |             |             | FEB 04, 2000 |

TOLBUTAMIDE

|              |              |       |            |
|--------------|--------------|-------|------------|
| TABLET; ORAL |              |       |            |
| TOLBUTAMIDE  |              |       |            |
| AB           | CHELSEA LABS | 500MG | N86109 001 |
| AB           | +            | 500MG | N86109 001 |
| AB           | * BON        | 500MG | N12678 001 |
|              | @            | 500MG | N12678 001 |

TOLTERODINE TARTRATE

|                                 |   |                          |              |
|---------------------------------|---|--------------------------|--------------|
| CAPSULE, EXTENDED RELEASE; ORAL |   |                          |              |
| DETROL LA                       |   |                          |              |
| > ADD >                         | + | PHARMACIA AND UPJOHN 2MG | N21228 001   |
| > ADD >                         |   |                          | DEC 22, 2000 |
| > ADD >                         | + | 4MG                      | N21228 002   |
| > ADD >                         |   |                          | DEC 22, 2000 |

TOPIRAMATECAPSULE; ORAL  
TOPAMAX SPRINKLE  
JOHNSON RW

25MG

N20844 002

OCT 26, 1998

\*

50MG

N20844 003

OCT 26, 1998

+

25MG

N20844 002

OCT 26, 1998

@

50MG

N20844 003

OCT 26, 1998

TORSEMIDETABLET; ORAL  
DEMADEX  
ROCHE

20MG

N20136 003

AUG 23, 1993

\*

100MG

N20136 004

AUG 23, 1993

+

20MG

N20136 003

AUG 23, 1993

100MG

N20136 004

AUG 23, 1993

> DLT >  
> DLT >  
> DLT >  
> DLT >  
> ADD >  
> ADD >  
> ADD >  
> ADD >TRETINOINCREAM; TOPICAL  
RENOVA  
+ JOHNSON AND JOHNSON 0.02%

N21108 001

AUG 31, 2000

GEL; TOPICAL  
RETIN-A

AB + JOHNSON AND JOHNSON 0.025%

N17579 002

BT \* 0.025%

N17579 002

AB TRETINOIN

AB SPEAR PHARMS 0.025%

N75529 001

FEB 22, 2000

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

AT FLUTEX  
ZENITH GOLDLINE 0.025%

N85539 001

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

AT FLUTEX  
ZENITH GOLDLINE

0.1%

N85539 002

AT

0.5%

N85539 003

@

0.025%

N85539 001

@

0.1%

N85539 002

@

0.5%

N85539 003

TRIATEX

AT ZENITH GOLDLINE

0.025%

N87430 001

AT

0.1%

NOV 01, 1988

AT

0.1%

N87429 001

AT

0.5%

NOV 01, 1988

TRIATEX

AT ZENITH GOLDLINE

0.025%

NOV 01, 1988

TRIATEX

@

0.025%

N87430 001

@

0.1%

NOV 01, 1988

@

0.5%

NOV 01, 1988

OINTMENT; TOPICAL

AT ARISTOCORT A  
\* FUJISAWA HEALTHCARE

0.5%

N80745 003

AT

0.5%

N80745 003

FLUTEX

AT \* ZENITH GOLDLINE

0.025%

N87375 001

AT

0.1%

NOV 01, 1988

AT

0.1%

N87377 001

AT

0.5%

NOV 01, 1988

FLUTEX

@

0.025%

N87375 001

@

0.1%

NOV 01, 1988

@

0.5%

NOV 01, 1988

@

0.5%

NOV 01, 1988

@

0.5%

NOV 01, 1988

@

0.5%

NOV 01, 1988

KENALOG

AT \* APOTHECON

0.025%

N11600 003

AT

0.025%

N11600 003

AT

0.1%

N11600 001

AT

0.1%

N11600 001

TRIAMCINOLONE ACETONIDE

AT \* ALTANA

0.025%

N85691 001

AT

0.025%

N85691 001

AT

0.1%

N85691 003

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE

|    |           |        |            |
|----|-----------|--------|------------|
| AT | ALTANA    | 0.1%   | N85691 003 |
| AT | *         | 0.5%   | N85691 002 |
| AT |           | 0.5%   | N85691 002 |
| AT | CLAY PARK | 0.025% | N87356 001 |
| AT | +         | 0.025% | N87356 001 |
| AT |           | 0.1%   | N87357 001 |
| AT | +         | 0.1%   | N87357 001 |
| AT |           | 0.5%   | N87385 001 |
| AT | +         | 0.5%   | N87385 001 |

SPRAY, METERED; NASAL

TRI-NASAL

+ MURO 0.05MG/SPRAY

N20120 001  
FEB 04, 2000TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

|    |                |              |              |
|----|----------------|--------------|--------------|
| AB | ZENTH GOLDLINE | EQ 1MG BASE  | N87612 001   |
|    |                |              | NOV 19, 1982 |
| AB |                | EQ 2MG BASE  | N87613 001   |
|    |                |              | NOV 19, 1982 |
| AB |                | EQ 5MG BASE  | N87328 001   |
|    |                |              | NOV 19, 1982 |
| AB |                | EQ 10MG BASE | N87614 001   |
|    |                |              | NOV 19, 1982 |
| @  |                | EQ 1MG BASE  | N87612 001   |
|    |                |              | NOV 19, 1982 |
| @  |                | EQ 2MG BASE  | N87613 001   |
|    |                |              | NOV 19, 1982 |
| @  |                | EQ 5MG BASE  | N87328 001   |
|    |                |              | NOV 19, 1982 |
| @  |                | EQ 10MG BASE | N87614 001   |
|    |                |              | NOV 19, 1982 |

TRIHXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHXYPHENIDYL HCL

|    |           |     |              |
|----|-----------|-----|--------------|
| AA | WEST WARD | 2MG | N40337 002   |
|    |           |     | FEB 16, 2000 |

TRIHXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHXYPHENIDYL HCL

|    |           |     |              |
|----|-----------|-----|--------------|
| AA | WEST WARD | 5MG | N40337 001   |
|    |           |     | FEB 16, 2000 |

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL

PRIMSOL

ASCENT PDS

|   |  |                  |              |
|---|--|------------------|--------------|
|   |  | EQ 25MG BASE/5ML | N74374 001   |
|   |  |                  | JUN 23, 1995 |
| + |  | EQ 25MG BASE/5ML | N74374 001   |
|   |  |                  | JUN 23, 1995 |
| + |  | EQ 50MG BASE/5ML | N74973 001   |
|   |  |                  | JAN 24, 2000 |

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION

NEUTREXIN

|   |                    |                   |              |
|---|--------------------|-------------------|--------------|
| + | MEDIMMUNE ONCOLOGY | EQ 25MG BASE/VIAL | N20326 001   |
|   |                    |                   | DEC 17, 1993 |
| * | US BIOSCIENCE      | EQ 25MG BASE/VIAL | N20326 001   |
|   |                    |                   | DEC 17, 1993 |

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION

TRELSTAR DEPOT

|   |                 |                     |              |
|---|-----------------|---------------------|--------------|
| + | DEBIO RECHERCHE | EQ 3.75MG BASE/VIAL | N20715 001   |
|   |                 |                     | JUN 15, 2000 |

TROGLITAZONE

TABLET; ORAL

PRELAY

SANKYO

|    |  |       |              |
|----|--|-------|--------------|
| AB |  | 200MG | N20719 001   |
|    |  |       | JAN 29, 1997 |
| AB |  | 300MG | N20719 003   |
|    |  |       | AUG 04, 1997 |
| AB |  | 400MG | N20719 002   |
|    |  |       | JAN 29, 1997 |

TROGLITAZONETABLET, ORALPRELAY

@ SANKYO

200MG

N20719 001

JAN 29, 1997

@

300MG

N20719 003

AUG 04, 1997

@

400MG

N20719 002

JAN 29, 1997

REGLULINAB

PARKE DAVIS PHARMS

200MG

N20720 001

JAN 29, 1997

AB300MG

N20720 003

AUG 04, 1997

AB400MG

N20720 002

JAN 29, 1997

@

200MG

N20720 001

JAN 29, 1997

@

300MG

N20720 003

AUG 04, 1997

@

400MG

N20720 002

JAN 29, 1997

TROPICAMIDESOLUTION/DROPS; OPHTHALMICTROPICACYLAT

AKORN

0.5%

N40314 001

SEP 29, 2000

AT1%

N40315 001

SEP 29, 2000

TROPICAMIDEAT

ALCON UNIVERSAL

1%

N89172 001

DEC 28, 1990

AT

MIZA PHARMS USA

0.5%

N87636 001

JUL 30, 1982

AT1%

N87637 001

AUG 09, 1982

AT

OPTORICS

0.5%

N87638 001

JUL 30, 1982

AT1%

N87637 001

AUG 09, 1982

AT

STERIS

1%

N49172 001

DEC 28, 1990

UNOPROSTONE ISOPROPYLSOLUTION/DROPS; OPHTHALMICRESCULA

+ CIBA

0.15%

N21214 001

AUG 03, 2000

UREA, C-13POWDER FOR RECONSTITUTION; ORALHELICOSOLEX

\* METABOLIC SOLUTIONS

125MG/VIAL

N21092 001

DEC 17, 1999

+

125MG/VIAL

N21092 001

DEC 17, 1999

UROFOLLITROPININJECTABLE, INTRAMUSCULARFERTINEX

\* SERONO

75 IU/AMP

N19415 002

SEP 18, 1986

\*

150 IU/AMP

N19415 003

SEP 18, 1986

METRODIN

@ SERONO

75 IU/AMP

N19415 002

SEP 18, 1986

@

150 IU/AMP

N19415 003

SEP 18, 1986

URSODIOLCAPSULE, ORALACTIGALLAB

+ NOVARTIS

300MG

N19594 002

DEC 31, 1987

\*

300MG

N19594 002

DEC 31, 1987

URSODIOLAB

AMIDE PHARM

300MG

N75517 001

MAR 14, 2000

AB

COPLEY PHARM

300MG

N75592 001

MAY 25, 2000

TABLET, ORALURSO

\* AXCAN

250MG

N20675 001

DEC 10, 1997

URSODIOLTABLET; ORAL  
URSO

+ AXCAN SCANDIPHARM 250MG

N20675 001  
DEC 10, 1997VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

> ADD > AA PHARM ASSOC 250MG/5ML  
 > ADD >  
 > ADD > AA UDL 250MG/5ML  
 > ADD >

N75379 001  
DEC 15, 2000  
N75782 001  
DEC 22, 2000

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDEAP BEDFORD 10MG/VIALAP 20MG/VIAL

N75549 001  
JUN 13, 2000  
N75549 002  
JUN 13, 2000

VERAPAMIL HYDROCHLORIDETABLET, EXTENDED RELEASE; ORAL  
COVERA-HSBC SEARLE 180MG

BC + 180MG

BC 240MG

BC + 240MG

N20552 001  
FEB 26, 1996  
N20552 001  
FEB 26, 1996  
N20552 002  
FEB 26, 1996  
N20552 002  
FEB 26, 1996

VERTEPORFININJECTABLE; INJECTION  
VISUDYNE

+ QLT 15MG/VIAL

N21119 001  
APR 12, 2000

VITAMIN A

CAPSULE; ORAL

AQUASOL AAA + ASTRAZENECA

\*

@

@

VITAMIN AAA GLOBAL PHARM

@ IMPAX LABS

AA WEST WARD

+

50,000 USP UNITS

25,000 USP UNITS

25,000 USP UNITS

50,000 USP UNITS

50,000 USP UNITS

50,000 USP UNITS

50,000 USP UNITS

50,000 USP UNITS

N83080 001

N83080 002

N83080 002

N83080 001

N80952 001

N80952 001

N80985 001

N80985 001

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN AAA GLOBAL PHARMAA

@ IMPAX LABS

@

EQ 50,000 UNITS BASE

EQ 50,000 UNITS BASE

EQ 50,000 UNITS BASE

EQ 50,000 UNITS BASE

N80953 001

N80955 001

N80953 001

N80955 001

WARFARIN SODIUM

TABLET; ORAL

WARFARIN SODIUM

GENEVA PHARMS TECH

> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> ADD > AB> ADD >> DLT > AB> DLT >

1MG

2MG

2.5MG

3MG

4MG

5MG

6MG

7.5MG

10MG

1MG

N40196 001

SEP 30, 1997

N40196 002

SEP 30, 1997

N40196 003

SEP 30, 1997

N40196 008

JUL 26, 2000

N40196 004

SEP 30, 1997

N40196 005

SEP 30, 1997

N40196 009

JUL 26, 2000

N40196 006

SEP 30, 1997

N40196 007

SEP 30, 1997

N40196 001

SEP 30, 1997

WARFARIN SODIUM

TABLET; ORAL

WARFARIN SODIUM

|         |    |         |       |              |
|---------|----|---------|-------|--------------|
| > DLT > | AB | INVAMED | 2MG   | N40196 002   |
| > DLT > |    |         |       | SEP 30, 1997 |
| > DLT > | AB |         | 2.5MG | N40196 003   |
| > DLT > |    |         |       | SEP 30, 1997 |
| > DLT > | AB |         | 4MG   | N40196 004   |
| > DLT > |    |         |       | SEP 30, 1997 |
| > DLT > | AB |         | 5MG   | N40196 005   |
| > DLT > |    |         |       | SEP 30, 1997 |
| > DLT > | AB |         | 7.5MG | N40196 006   |
| > DLT > |    |         |       | SEP 30, 1997 |
| > DLT > | AB |         | 10MG  | N40196 007   |
| > DLT > |    |         |       | SEP 30, 1997 |

XENON, XE-133

GAS; INHALATION

XENON XE 133

|    |                  |            |            |
|----|------------------|------------|------------|
| AA | NYCOMED AMERSHAM | 10mCi/VIAL | N17687 002 |
| AA |                  | 20mCi/VIAL | N17687 003 |
|    |                  | 1 CI/AMP   | N17256 002 |
| @  |                  | 1 CI/AMP   | N17256 002 |
| @  |                  | 10mCi/VIAL | N17687 002 |
| @  |                  | 20mCi/VIAL | N17687 003 |

ZAFIRLUKAST

TABLET; ORAL

ACCOLATE

ASTRAZENECA

10MG

N20547 003  
SEP 17, 1999

ZOLMITRIPTAN

TABLET; ORAL

ZOMIG

ASTRAZENECA

2.5MG

N20768 001  
NOV 25, 1997

+

5MG

N20768 002  
NOV 25, 1997

ZENNECA

2.5MG

N20768 001  
NOV 25, 1997

ZOLMITRIPTAN

TABLET; ORAL

ZOMIG

\* ZENNECA

5MG

N20768 002  
NOV 25, 1997

ZONISAMIDE

CAPSULE; ORAL

ZONEGRAN

+ DAINIPPON

100MG

N20789 001  
MAR 27, 2000

## OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'2000 - DEC'2000

ACETAMINOPHEN

SUPPOSITORY; RECTAL  
ACETAMINOPHEN  
ROXANE

120MG

N71010 001

MAY 12, 1987

650MG

N71011 001

MAY 12, 1987

@ 120MG

N71010 001

MAY 12, 1987

@ 650MG

N71011 001

MAY 12, 1987

TABLET, EXTENDED RELEASE; ORAL  
ACETAMINOPHEN  
PERRIGO

650MG

N75077 001

FEB 25, 2000

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL  
FOAMICON

GENEVA PHARMS TECH 80MG;20MG

N72687 001

JUN 28, 1989

INVAMED 80MG;20MG

N72687 001

JUN 28, 1989

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL  
8-HOUR BAYER

\* BAYER 650MG

N16030 001

@ 650MG

N16030 001

MEASURIN

\* BAYER 650MG

N16030 002

@ 650MG

N16030 002

AVOBENZONE; PADIMATE O

LOTION, TOPICAL  
PHOTOPLEX

@ ALLERGAN HERBERT 3%; 7%

N19459 001

SEP 10, 1988

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL  
DIMETANE

@ WHITEHALL ROBINS 12MG

N10799 011

JUN 10, 1983

DINETAPP

\* WHITEHALL ROBINS 12MG

N10799 011

JUN 10, 1983

CALCIUM CARBONATE, PRECIPITATED; FAMOTIDINE; MAGNESIUM HYDROXIDE

TABLET, CHEWABLE; ORAL  
PEPCID COMPLETE

+ MERCK 800MG;10MG;165MG

N20958 001

OCT 16, 2000

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL  
E-Z SCRUB

BECTON DICKINSON 4%

N73416 001

MAR 14, 2000

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SOLUTION, TOPICAL  
CHLORAPREP

\* MEDI FLEX HOSP 2%; 70%

N20832 001

JUL 14, 2000

SPONGE; TOPICAL  
CHLORAPREP

+ MEDI FLEX HOSP 2%; 70%

N20832 001

JUL 14, 2000

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
CONTAC

@ SMITHKLINE 8MG; 75MG

N18099 001

+ 8MG; 75MG

N18099 001

## OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'2000 - DEC'2000

CIMETIDINE

|                                      |                  |                                                  |
|--------------------------------------|------------------|--------------------------------------------------|
| TABLET; ORAL<br>CIMETIDINE<br>LEINER | 200MG            | N74961 001<br>JUN 19, 1998                       |
| <del>NOVOPHARM</del>                 | <del>200MG</del> | <del>N74961 001</del><br><del>JUN 19, 1998</del> |
| <del>PERRIGO</del>                   | <del>100MG</del> | <del>N74972 001</del><br><del>JUN 19, 1998</del> |
| @                                    | 100MG            | N74972 001<br>JUN 19, 1998                       |

CLOTRIMAZOLE

|                                           |    |                            |
|-------------------------------------------|----|----------------------------|
| CREAM; VAGINAL<br>TRIVAGIZOLE 3<br>+ TARO | 2% | N21143 001<br>APR 12, 2000 |
|-------------------------------------------|----|----------------------------|

DOCOSANOL

|                                      |     |                            |
|--------------------------------------|-----|----------------------------|
| CREAM; TOPICAL<br>ABREVA<br>* AVANIR | 10% | N20941 001<br>JUL 25, 2000 |
| + SMITHKLINE BEECHAM                 | 10% | N20941 001<br>JUL 25, 2000 |

IBUPROFEN

|                                          |                  |                                                  |
|------------------------------------------|------------------|--------------------------------------------------|
| CAPSULE; ORAL<br>IBUPROFEN<br>PHARM FORM | 200MG            | N74782 001<br>JUL 06, 1998                       |
| +                                        | 200MG            | N74782 001<br>JUL 06, 1998                       |
| TABLET; ORAL<br>IBUPROFEN<br>LEINER      | 200MG            | N74931 001<br>JUL 20, 1998                       |
| <del>NOVOPHARM</del>                     | <del>200MG</del> | <del>N74931 001</del><br><del>JUL 20, 1998</del> |
| MOTRIN IB<br>MCNEIL                      | 200MG            | N19012 003<br>DEC 17, 1990                       |

IBUPROFEN

|                                                  |                  |                                                  |
|--------------------------------------------------|------------------|--------------------------------------------------|
| TABLET; ORAL<br>MOTRIN MIGRAINE PAIN<br>+ MCNEIL | 200MG            | N19012 004<br>FEB 25, 2000                       |
| <del>MUPRIN</del><br><del>MCNEIL</del>           | <del>200MG</del> | <del>N19012 003</del><br><del>JUL 29, 1987</del> |
|                                                  | 200MG            | N19012 002<br>JUL 29, 1987                       |

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

|                                                             |                     |                            |
|-------------------------------------------------------------|---------------------|----------------------------|
| SUSPENSION; ORAL<br>CHILDREN'S MOTRIN COLD<br>+ MCNEIL CONS | 100MG/5ML; 15MG/5ML | N21128 001<br>AUG 01, 2000 |
|-------------------------------------------------------------|---------------------|----------------------------|

IBUPROFEN POTASSIUM

|                                                                  |       |                            |
|------------------------------------------------------------------|-------|----------------------------|
| CAPSULE; ORAL<br>ADVIL MIGRAINE LIQUI-GELS<br>+ WHITEHALL ROBINS | 200MG | N20402 002<br>MAR 16, 2000 |
|------------------------------------------------------------------|-------|----------------------------|

LOPERAMIDE HYDROCHLORIDE

|                                              |                    |                                                  |
|----------------------------------------------|--------------------|--------------------------------------------------|
| SOLUTION; ORAL<br>LOPERAMIDE HCL<br>ALPHARMA | 1MG/5ML            | N73187 001<br>SEP 15, 1992                       |
| @                                            | 1MG/5ML            | N73187 001<br>SEP 15, 1992                       |
| <del>WATSON LABS</del>                       | <del>1MG/5ML</del> | <del>N73062 001</del><br><del>MAY 28, 1993</del> |
| @                                            | 1MG/5ML            | N73062 001<br>MAY 28, 1993                       |
| TABLET; ORAL<br>LOPERAMIDE HCL<br>LEINER     | 2MG                | N73254 001<br>JUL 30, 1993                       |
| <del>NOVOPHARM INC</del>                     | <del>2MG</del>     | <del>N73254 001</del><br><del>JUL 30, 1993</del> |

## OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'2000 - DEC'2000

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL  
LOPERAMIDE HCL  
PERRIGO 2MG  
N75232 001  
JAN 06, 2000

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET; ORAL  
IMODIUM ADVANCED  
MCNEIL CONS 2MG;125MG  
N21140 001  
NOV 30, 2000

MINOXIDIL

SOLUTION; TOPICAL  
MINOXIDIL EXTRA STRENGTH (FOR MEN)  
ALPHARMA 5%  
N75518 001  
NOV 17, 2000  
TEVA 5%  
N75619 001  
NOV 17, 2000

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC  
VISINE-A  
AKORN 0.025%;0.3%  
N20485 001  
JAN 31, 1996  
PFIZER 0.025%;0.3%  
N20485 001  
JAN 31, 1996

NAPROXEN SODIUM

TABLET; ORAL  
NAPROXEN SODIUM  
LEINER EQ 200MG BASE  
N74635 001  
JAN 13, 1997  
NOVOPHARM NC EQ 200MG BASE  
N74635 001  
JAN 13, 1997

NONOXYNOL-9

AEROSOL; VAGINAL  
DELPHEN  
@ ORTHO 12.5%  
@ PERSONAL PRODS 12.5%  
N14349 002  
N14349 002

PERMETHRIN

LOTION; TOPICAL  
PERMETHRIN  
ALPHARMA 1%  
N75014 001  
MAR 28, 2000

PIPERONYL BUTOXIDE; PYRETHRINS

AEROSOL; TOPICAL  
RID MOUSSE  
+ PFIZER 4%;EQ 0.33% BASE  
N21043 001  
MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL  
RANITIDINE  
CHELSEA LABS EQ 75MG BASE  
N75212 001  
JAN 14, 2000  
CHEMINOR DRUGS EQ 75MG BASE  
N75294 001  
MAR 28, 2000  
DR REDDYS LABS LTD EQ 75MG BASE  
N75294 001  
MAR 28, 2000  
GENPHARM EQ 75MG BASE  
N75497 001  
JAN 14, 2000  
LEINER EQ 75MG BASE  
N75094 001  
JUN 21, 1999  
RANBAXY EQ 75MG BASE  
N75132 001  
JAN 14, 2000  
EQ 75MG BASE  
N75254 001  
JAN 14, 2000  
TORPHARM EQ 75MG BASE  
N75167 001  
MAY 04, 2000  
ZENITH GOLDLINE EQ 75MG BASE  
N75296 001  
JAN 14, 2000  
RANITIDINE HCL  
NOVOPHARM EQ 75MG BASE  
N75094 001  
JUN 21, 1999

## OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'2000 - DEC'2000

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT, ORAL

ZANTAC 75

\* GLAXO WELLCOME

EQ 75MG BASE

N20745 001

@ WARNER LAMBERT

EQ 75MG BASE

FEB 26, 1998

N20745 001

FEB 26, 1998

TERBINAFINE HYDROCHLORIDE

SOLUTION, TOPICAL

LAMISIL AT

+ NOVARTIS

1%

N21124 001

MAR 17, 2000

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

**CUMULATIVE SUPPLEMENT NUMBER 12 DECEMBER '00**

**NO DECEMBER 2000 APPROVALS**

**This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.**

**Orphan Products Designations and Approvals List  
January through December 2000**

| Name:                                                                                       | Indication Designated:                                                           | Sponsor & Address                                                                                            |
|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| Generic Name                                                                                |                                                                                  | DD=Date Designated                                                                                           |
| TN=Trade Name                                                                               |                                                                                  | MA=Marketing Approval                                                                                        |
| 1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate<br>TN= | Treatment of hormone refractory prostate carcinoma.                              | Cell Therapeutics, Inc.<br>201 Elliott Avenue West<br>Suite 400<br>Seattle WA 98119<br>DD= 1/18/00      MA=  |
| 3-(3,5-Dimethyl-1H-2-methylthylene)-1,3-dihydro-indazole<br>ol-2-one<br>TN=                 | Treatment of von Hippel-Lindau disease.                                          | Sugan, Inc.<br>230 East Grand Ave.<br>South San Francisco CA 94080<br>DD= 3/23/00      MA=                   |
| Abetimus<br>TN=                                                                             | Treatment of lupus nephritis.                                                    | La Jolla Pharmaceutical Co.<br>6455 Nancy Ridge Dr.<br>San Diego CA 92121<br>DD= 7/28/00      MA=            |
| Angiotensin 1-7<br>TN=                                                                      | Treatment of neutropenia associated with autologous bone marrow transplantation. | Maret Pharmaceuticals<br>4041 MacArthur Blvd.<br>Suite 375<br>Newport Beach CA 92660<br>DD= 2/16/00      MA= |
| Anti-thymocyte Globulin (Rabbitt)<br>TN=Thymoglobulin                                       | Treatment of myelodysplastic syndrome (MDS)                                      | SangStat Medical Corporation<br>6300 Dumbarton Circle<br>Fremont CA 94555<br>DD= 9/6/00      MA=             |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name        | Indication Designated:                           | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                       |
|-----------------------------------------------|--------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| arsenic trioxide<br>TN=Atrivex                | Treatment of myelodysplastic syndrome.           | Cell Therapeutics, Inc.<br>201 Elliott Avenue West<br>Suite 400<br>Seattle WA 98119<br>DD= 7/17/00 MA= |
| Arsenic trioxide<br>TN=Atrivex                | Treatment of multiple myeloma.                   | Cell Therapeutics, Inc.<br>201 Elliott Ave. West, Suite 400<br>Seattle WA 98119<br>DD= 4/28/00 MA=     |
| Bis(4-fluorophenyl)phenyl<br>acetamide<br>TN= | Treatment of sickle cell disease.                | ICAgen Inc.<br>Ion Channel Advances<br>PO Box 14487<br>Durham NC 27709<br>DD= 3/2/00 MA=               |
| Bosentan<br>TN=                               | Treatment of pulmonary arterial hypertension.    | Actelion Life Sciences Ltd.<br>1840 Gateway Dr.<br>2nd Floor<br>San Mateo CA 94404<br>DD= 10/6/00 MA=  |
| Brimonidine<br>TN=Alphagan                    | Treatment of anterior ischemic optic neuropathy. | Allergan, Inc.<br>2525 Dupont Dr.<br>P.O. Box 19534<br>Irvine CA 92623-9534<br>DD= 2/7/00 MA=          |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name                           | Indication Designated:                                                                                           | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                     |
|------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| Calfactant<br>TN=Infasurf                                        | Acute respiratory distress syndrome (ARDS)                                                                       | ONY, Inc.<br>Baird Research Park<br>1576 Sweet Home Road<br>Amherst NY 14228<br>DD= 9/5/00 MA=                       |
| Carmustine<br>TN=                                                | Treatment of intracranial malignancies.                                                                          | Direct Therapeutics, Inc.<br>1001 Bayhill Dr., Suite 100<br>San Bruno CA 94066<br>DD= 7/3/00 MA=                     |
| Centruroides immune F(ab)2<br>TN=Alacramyn                       | Treatment of scorpion envenomations requiring medical attention.                                                 | Silanes Laboratories S.A. de C.V.<br>Amores #1034 Col Del Valle<br>C.P. 03100 Mexico D.F.<br>DD= 6/12/00 MA=         |
| Cetuximab<br>TN=                                                 | Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor. | ImClone Systems Incorporated<br>Branchburg Corporate Center<br>22 Chubb Way<br>Somerville NJ 08876<br>DD= 7/3/00 MA= |
| Chimeric (human-murine) G250 IgG monoclonal antibody<br>TN=      | Treatment of renal cell carcinoma.                                                                               | Wilex Biotechnology GmbH<br>Grillparzerstrasse 10B<br>81675 Munich<br>Germany DE<br>DD= 7/24/00 MA=                  |
| Chimeric, humanized monoclonal antibody to staphylococcus<br>TN= | Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams or less) infants.               | Biosynexus, Inc.<br>9610 Medical Center Drive<br>Suite 100<br>Rockville MD 20850<br>DD= 8/3/00 MA=                   |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name                                                                         | Indication Designated:                                        | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                               |
|----------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| Cisplatin/epinephrine<br>TN=IntraDose                                                                          | Treatment of squamous cell carcinoma of the head and neck.    | Matrix Pharmaceutical, Inc.<br>34700 Campus Drive<br>Fremont CA 94555-3612<br>DD= 4/3/00 MA=                                   |
| Cisplatin/epinephrine<br>TN=IntraDose                                                                          | Treatment of metastatic malignant melanoma.                   | Matrix Pharmaceutical, Inc.<br>34700 Campus Drive<br>Fremont CA 94555-3612<br>DD= 9/7/00 MA=                                   |
| Cyclosporine in combination with omega-3 polyunsaturated fatty acids<br>TN=                                    | Prevention of solid organ graft rejection.                    | RTP Pharma Corporation<br>200 Westpark Corporate Center<br>4364 South Alston Avenue<br>Durham NC 27713-2280<br>DD= 12/6/00 MA= |
| Deoxyribose, phosphorothioate<br>TN=                                                                           | Treatment of advanced malignant melanoma (Stages II,III, IV). | Genta, Inc.<br>99 Hayden Ave., Suite 200<br>Lexington MA 02421-7966<br>DD= 7/31/00 MA=                                         |
| DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2<br>TN=Leuvectin | Treatment of renal cell carcinoma.                            | Vical Incorporated<br>9373 Towne Center Dr.<br>Suite 100<br>San Diego CA 92121-3088<br>DD= 4/28/00 MA=                         |
| DNP-Modified autologous tumor vaccine<br>TN=O-Vax                                                              | Adjuvant therapy for the treatment of ovarian cancer          | AVAX Technologies, Inc.<br>4520 Main Street<br>Suite 930<br>Kansas City MO 64111<br>DD= 9/21/00 MA=                            |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name                                                                                                                | Indication Designated:                                                                                   | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Ethyl eicosapentaenoate<br>TN=                                                                                                                        | Treatment of Huntington's disease.                                                                       | Laxdale Ltd.<br>Kings Park House, Laurelhill<br>Polmaise Road, Stirling FK7 9JQ<br>United Kingdom UK<br>DD= 4/6/00 MA= |
| Flucinolone<br>TN=                                                                                                                                    | Treatment uveitis involving the<br>posterior segment of the eye.                                         | Bausch & Lomb Pharmaceuticals,<br>8500 Hidden River Parkway<br>Tampa FL 33637<br>DD= 7/31/00 MA=                       |
| Fluorouracil<br>TN=                                                                                                                                   | Treatment of glioblastoma<br>multiforme.                                                                 | Ethypharm SA<br>194 Bureaux de la Colline -<br>92213 Saint-Cloud Cedex<br>France FR<br>DD= 6/29/00 MA=                 |
| Gavilimomab<br>TN=                                                                                                                                    | Acute graft-versus-host disease<br>(aGVHD)                                                               | Abgenix, Inc.<br>7601 Dumbarton Circle<br>Fremont CA 94555<br>DD= 11/20/00 MA=                                         |
| Gene plasmid hVEGF165<br>driven by human<br>cytomegalovirus, and<br>[2,3-bis(oleoyl)propyl]t<br>rimethyl ammonium and<br>dioleoyl phosphatidyl<br>TN= | Prevention of complications due to<br>neointimal hyperplasia disease in<br>certain vascular anastomoses. | Eurogene Ltd.<br>6 Warren Mews<br>London W1P 5DJ UK<br>DD= 10/24/00 MA=                                                |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name                 | Indication Designated:                                                                                                                   | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                                      |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Meropenem<br>TN=Merrem IV                              | Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms. | Zeneca Pharmaceuticals<br>1800 Concord Pike<br>PO Box 15437<br>Wilmington DE 19850-5437<br>DD= 4/27/00 MA=                            |
| N-acetylcysteinate<br>TN=Nacystelyn Dry Powder         | For the management of cystic fibrosis                                                                                                    | Galephar Pharmaceutical Research,<br>Road 198, No. 100 km. 14.7<br>Juncos Industrial Park<br>Juncos PR 00777-3873<br>DD= 12/27/00 MA= |
| Natural human lymphoblastoid interferon-alpha<br>TN=   | Treatment of Behcet's disease.                                                                                                           | Amarillo Biosciences, Inc.<br>800 West Ninth Avenue<br>Amarillo TX 79101-3206<br>DD= 1/18/00 MA=                                      |
| Natural human lymphoblastoid interferon-alpha<br>TN=   | Treatment of papillomavirus warts in the oral cavity of HIV positive patients.                                                           | Amarillo Biosciences. Inc.<br>800 West 9th Avenue<br>Amarillo TX 79101<br>DD= 8/10/00 MA=                                             |
| Omega-3 (n-3) polyunsaturated fatty acids<br>TN=Omacor | Treatment of IgA nephropathy.                                                                                                            | Pronova Biocare, AS<br>PO Box 420<br>1327 Lysaker<br>Norway<br>DD= 5/4/00 MA=                                                         |
| Phenylbutyrate<br>TN=                                  | Treatment of acute promyelocytic leukemia.                                                                                               | Elan Corporation<br>1300 Gould Dr.<br>Gainesville GA 30504<br>DD= 1/19/00 MA=                                                         |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name                                         | Indication Designated:                                                                                                                                | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                  |
|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Recombinant<br>glycine2-human<br>glucagon-like peptide-2<br>TN=                | Treatment of short bowel syndrome.                                                                                                                    | NPS Allelix Corp.<br>6850 Goreway Dr.<br>Mississauga, Ontario<br>L4V 1V7 Canada CA<br>DD= 6/29/00 MA=             |
| Recombinant human<br>antithrombin III<br>TN=                                   | Treatment of antithrombin III<br>dependent heparin resistance<br>requiring anticoagulation.                                                           | AT III LLC<br>c/o Genzyme Corporation<br>15 Pleasant St. Connector, P.O.<br>Framingham MA 01701<br>DD= 4/6/00 MA= |
| Recombinant human highly<br>phosphorylated acid<br>alpha-glucosidase<br>TN=TBD | For enzyme replacement therapy in<br>patients with all subtypes of<br>glycogen storage disease type II<br>(GSDII, Pompe Disease)                      | Novazyme Pharmaceuticals, Inc.<br>800 Research Parkway<br>Suite 200<br>Oklahoma City OK 73104<br>DD= 9/20/00 MA=  |
| Recombinant human<br>insulin-like growth<br>factor-I<br>TN=PV802               | Treatment of short-bowel syndrome<br>as a result of resection of the<br>small bowel or as a result of<br>congenital dysfunction of the<br>intestines. | GroPep Pty Ltd.<br>Gate 11, Victoria Dr.<br>Adelaide SA 5000<br>Australia AU<br>DD= 2/16/00 MA=                   |
| Recombinant urate<br>oxidase<br>TN=                                            | Treatment of malignancy-associated<br>or chemotherapy-induced<br>hyperuricemia.                                                                       | Sanofi-Synthelabo Research<br>9 Great Valley Parkway<br>Malvern PA 19355<br>DD= 10/11/00 MA=                      |
| Recombinant urate<br>oxidase<br>TN=                                            | Prophylaxis of chemotherapy-induced<br>hyperuricemia.                                                                                                 | Sanofi-Synthelabo Research<br>9 Great Valley Parkway<br>Malvern PA 19355<br>DD= 10/11/00 MA=                      |

# Orphan Products Designations and Approvals List

## January through December 2000

|               |                        |                       |
|---------------|------------------------|-----------------------|
| Name:         |                        | Sponsor & Address     |
| Generic Name  |                        | DD=Date Designated    |
| TN=Trade Name | Indication Designated: | MA=Marketing Approval |

|                                           |                                                                                                                    |                                                                                                                  |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| Remacemide<br>TN=Ecovia                   | Treatment of Huntington's disease.                                                                                 | AstraZeneca LP<br>725 Chesterbrook Blvd.<br>Wayne PA 19087-5677<br>DD= 3/6/00 MA=                                |
| rSP-C lung surfactant<br>TN=Venticute     | Treatment of adult respiratory distress syndrome.                                                                  | Byk Gulden Pharmaceuticals<br>Byk-Gulden StraBe 2<br>78467 Konstanz<br>Germany DE<br>DD= 4/3/00 MA=              |
| SB-408075<br>TN=                          | For pancreatic cancer                                                                                              | SmithKline Beecham Pharmaceuticals<br>1250 S. Collegeville Road<br>Collegeville PA 19426-0989<br>DD= 12/7/00 MA= |
| Soluble complement receptor type 1<br>TN= | Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.                  | Avant Immunotherapeutics, Inc.<br>119 Fourth Ave.<br>Needham MA 02494-2725<br>DD= 3/6/00 MA=                     |
| somatropin [rDNA]<br>TN=Genotropin        | Treatment of growth failure in children who were born small for gestational age.                                   | Pharmacia and Upjohn Company<br>7000 Portage Road<br>Kalamazoo MI 49001<br>DD= 12/27/00 MA=                      |
| Synthetic human secretin<br>TN=           | For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion. | ChiRhoClin, Inc.<br>15500 Gallaudet Ave.<br>Silver Spring MD 20905-4176<br>DD= 3/7/00 MA=                        |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name                                  | Indication Designated:                                                                                                      | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                   |
|-------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|
| Synthetic porcine<br>secretin<br>TN=                                    | For use in conjunction with<br>diagnostic procedures for<br>pancreatic disorders to increase<br>pancreatic fluid secretion. | ChiRhoClin, Inc.<br>15500 Gallaudet Ave.<br>Silver Spring MD 20905-4176<br>DD= 3/7/00 MA=                          |
| Technetium Tc 99m<br>pterotetramide<br>TN=                              | For the identification of ovarian<br>carcinomas.                                                                            | Endocyte, Inc.<br>1205 Kent Ave.<br>Lafayette IN 47906<br>DD= 2/16/00 MA=                                          |
| Technetium Tc99m<br>rh-Annexin V<br>TN=Apomate                          | Diagnosis or assessment of<br>rejection status in heart,<br>heart-lung, single lung, or<br>bilateral lung transplants.      | Theseus Imaging Corporation<br>124 Mount Auburn Street<br>Suite 200 North<br>Cambridge MA 02138<br>DD= 11/3/00 MA= |
| Tetraiodothyroacetic<br>acid<br>TN=                                     | Suppression of thyroid stimulating<br>hormone in patients with<br>well-differentiated cancer of the<br>thyroid gland.       | Danforth, Jr., MD, Elliot<br>University of Vermont<br>84 Beartown Rd.<br>Underhill VT 05489<br>DD= 5/1/00 MA=      |
| Thymalfasin<br>TN=Zadaxin                                               | Treatment of hepatocellular<br>carcinoma.                                                                                   | SciClone Pharmaceuticals, Inc.<br>901 Mariner's Blvd., Suite 205<br>San Mateo CA 94404<br>DD= 3/6/00 MA=           |
| Tiazofurin<br>(2-Beta-D-ribofuranosyl-<br>4-thiazolecarboxamide)<br>TN= | Chronic myelogenous leukemia (CML)                                                                                          | ICN Pharmaceuticals, Inc. (ICN)<br>3300 Hyland Avenue<br>Costa Mesa CA 92626<br>DD= 12/27/00 MA=                   |

# Orphan Products Designations and Approvals List

## January through December 2000

| Name:<br>Generic Name<br>TN=Trade Name | Indication Designated:                                                          | Sponsor & Address<br>DD=Date Designated<br>MA=Marketing Approval                                                          |
|----------------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Trimetrexate<br>TN=Neutrexin           | Treatment of metastatic osteogenic sarcoma.                                     | Medimmune Oncology, Inc.<br>One Tower Bridge<br>100 Front St., Suite 400<br>West Conshohocken PA 19428<br>DD= 8/10/00 MA= |
| Vapreotide<br>TN=Octastatin            | Treatment of gastrointestinal and pancreatic fistulas.                          | Debiopharm S.A.<br>17 rue des Terreaux<br>CH-1000 Lausanne 9<br>Switzerland CH<br>DD= 1/10/00 MA=                         |
| Vapreotide<br>TN=Octastatin            | Prevention of early postoperative complications following pancreatic resection. | Debiopharm S.A.<br>17 rue des Terreaux<br>CH-1000 Lausanne 9<br>Switzerland CH<br>DD= 3/6/00 MA=                          |
| Vapreotide<br>TN=Octastatin            | Treatment of esophageal variceal hemorrhage patients with portal hypertension.  | Debiopharm S.A.<br>17 rue des Terreaux<br>CH-1000 Lausanne 9<br>Switzerland CH<br>DD= 1/10/00 MA=                         |
| vigabatrin<br>TN=Sabril                | Treatment of infantile spasms.                                                  | Aventis Pharmaceuticals Inc.<br>P.O. Box 9627<br>Kansas City MO 64137<br>DD= 6/12/00 MA=                                  |

Orphan Products Designations and Approvals List  
January through December 2000

Name:

Generic Name

TN=Trade Name

Indication Designated:

Sponsor &amp; Address

DD=Date Designated

MA=Marketing Approval

Zoledronate

TN=Zometa, Zabel

Treatment of tumor induced  
hypercalcemia.

Novartis Pharmaceuticals Corp.

59 Route 10

East Hanover NJ 07936-1080

DD= 8/18/00 MA=

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

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**NO DECEMBER 2000 ADDITIONS**

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME                  | PATENT<br>NUMBER            | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|----------------------------------------------|-----------------------------|----------------------------|--------------|----------------|-------------------|
| >ADD>               | 021205 001                                   | ABACAVIR SULFATE; TRIZIVIR  | 5034394*PED                | DEC 26, 2009 | NCE            | NOV 17, 2000      |
| >ADD>               |                                              |                             | 5047407*PED                | MAY 17, 2010 | NCE            | DEC 17, 2003      |
| >ADD>               |                                              |                             | 5905082*PED                | NOV 18, 2016 | PED            | MAY 17, 2001      |
| >ADD>               |                                              |                             | 5089500*PED                | DEC 26, 2009 | U-248 PED      | JUN 17, 2004      |
|                     |                                              |                             | 5034394                    | JUN 26, 2009 |                |                   |
|                     |                                              |                             | 5089500                    | JUN 26, 2009 | U-248          |                   |
|                     |                                              |                             | 5047407                    | NOV 17, 2009 |                |                   |
|                     |                                              |                             | 5905082                    | MAY 18, 2016 |                |                   |
|                     |                                              |                             | 4724232                    | SEP 17, 2005 |                |                   |
|                     |                                              |                             | 4818538                    | SEP 17, 2005 |                |                   |
|                     |                                              |                             | 4833130                    | SEP 17, 2005 |                |                   |
|                     |                                              |                             | 4837208                    | SEP 17, 2005 |                |                   |
|                     |                                              |                             | 4828838                    | SEP 17, 2005 |                |                   |
| 075077 001          | ACETAMINOPHEN; ACETAMINOPHEN                 |                             |                            |              | PC             | NOV 12, 2000      |
| 020338 001          | ADAPALENE; DIFFERIN                          | 4717720                     | MAY 31, 2010               |              |                |                   |
| 020380 001          | ADAPALENE; DIFFERIN                          | 4717720                     | MAY 31, 2010               |              |                |                   |
| 020748 001          | ADAPALENE; DIFFERIN                          | 4717720                     | MAY 31, 2010               |              | NCE            | MAY 31, 2001      |
|                     |                                              | RE34440                     | MAY 31, 2010               | U-275        | NDF            | MAY 26, 2003      |
| 020760 001          | ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE | 6080756                     | JUL 05, 2016               |              |                |                   |
| 020760 002          | ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE | 6080756                     | JUL 05, 2016               |              |                |                   |
| 020560 001          | ALENDRONATE SODIUM; FOSAMAX                  | 6008207                     | JUN 06, 2015               | U-303        | M-3            | NOV 24, 2002      |
|                     |                                              | 6090410                     | DEC 02, 2012               |              | I-309          | SEP 29, 2003      |
| 020560 002          | ALENDRONATE SODIUM; FOSAMAX                  | 6008207                     | JUN 06, 2015               | U-303        | M-3            | NOV 24, 2002      |
|                     |                                              | 6090410                     | DEC 02, 2012               |              |                |                   |
| 020560 003          | ALENDRONATE SODIUM; FOSAMAX                  | 6008207                     | JUN 06, 2015               | U-303        | M-3            | NOV 24, 2002      |
|                     |                                              | 6090410                     | DEC 02, 2012               |              |                |                   |
| >ADD>               | 020560 004                                   | ALENDRONATE SODIUM; FOSAMAX | 6090410                    | DEC 02, 2012 | NS             | OCT 20, 2003      |
| >ADD>               |                                              |                             | 5994329                    | JUL 17, 2018 | D-61           | OCT 20, 2003      |
|                     |                                              |                             | 6015801                    | JUL 17, 2018 | U-353 D-62     | OCT 20, 2003      |
|                     |                                              |                             | 4621077                    | AUG 06, 2007 | U-114          |                   |
|                     |                                              |                             | 5358941                    | DEC 02, 2012 |                |                   |
|                     |                                              |                             | 5681590                    | DEC 02, 2012 |                |                   |
|                     |                                              |                             | 5804570                    | FEB 17, 2015 |                |                   |
|                     |                                              |                             | 5849726                    | JUN 06, 2015 |                |                   |
|                     |                                              |                             | 6008207                    | JUN 06, 2015 |                |                   |
| >ADD>               | 020560 005                                   | ALENDRONATE SODIUM; FOSAMAX | 6090410                    | DEC 02, 2012 | NS             | OCT 20, 2003      |
|                     |                                              |                             | 6015801                    | JUL 17, 2018 | U-353 D-61     | OCT 20, 2003      |
|                     |                                              |                             | 4621077                    | AUG 06, 2007 | U-114 D-62     | OCT 20, 2003      |
|                     |                                              |                             | 5358941                    | DEC 02, 2012 |                |                   |
|                     |                                              |                             | 5681590                    | DEC 02, 2012 |                |                   |
|                     |                                              |                             | 5804570                    | FEB 17, 2015 |                |                   |
|                     |                                              |                             | 5849726                    | JUN 06, 2015 |                |                   |
|                     |                                              |                             | 5994329                    | JUL 17, 2018 |                |                   |
|                     |                                              |                             | 6008207                    | JUN 06, 2015 |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME          | PATENT<br>NUMBER               | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------|--------------------------------|----------------------------|--------------|----------------|-------------------|
| 021107 001          | ALOSETRON HYDROCHLORIDE; LOTRONEX    |                                |                            |              | NCE            | FEB 09, 2005      |
| 018276 001          | ALPRAZOLAM; XANAX                    | 4508726                        | SEP 16, 2002               | U-46         |                |                   |
| 018276 002          | ALPRAZOLAM; XANAX                    | 4508726                        | SEP 16, 2002               | U-46         |                |                   |
| 018276 003          | ALPRAZOLAM; XANAX                    | 4508726                        | SEP 16, 2002               | U-46         |                |                   |
| 018276 004          | ALPRAZOLAM; XANAX                    | 4508726                        | SEP 16, 2002               | U-46         |                |                   |
| 020221 001          | AMIFOSTINE; ETHYOL                   |                                |                            |              | I-283          | JUN 24, 2002      |
| 020221 002          | AMIFOSTINE; ETHYOL                   |                                |                            |              | I-283          | JUN 24, 2002      |
| >ADD>               | 020364 002                           | AMLODIPINE BESYLATE; LOTREL    | 6162802                    | DEC 19, 2017 | U-367          |                   |
| >ADD>               | 020364 003                           | AMLODIPINE BESYLATE; LOTREL    | 6162802                    | DEC 19, 2017 | U-367          |                   |
| >ADD>               | 020364 004                           | AMLODIPINE BESYLATE; LOTREL    | 6162802                    | DEC 19, 2017 | U-367          |                   |
| 020508 001          | AMMONIUM LACTATE; LAC-HYDRIN         |                                |                            |              | M-4            | AUG 25, 2003      |
| >ADD>               |                                      |                                |                            |              | PED            | FEB 25, 2004      |
| 021007 001          | AMPRENAVIR; AGENERASE                | 5723490                        | MAR 03, 2013               | U-257        |                |                   |
|                     |                                      | 5646180                        | JUL 08, 2014               | U-257        |                |                   |
|                     |                                      | 5585397                        | DEC 17, 2013               |              |                |                   |
| 021007 002          | AMPRENAVIR; AGENERASE                | 5723490                        | MAR 03, 2015               | U-257        |                |                   |
|                     |                                      | 5646180                        | JUL 08, 2014               | U-257        |                |                   |
|                     |                                      | 5585397                        | DEC 17, 2013               |              |                |                   |
| 021039 001          | AMPRENAVIR; AGENERASE                | 5723490                        | MAR 03, 2015               | U-257        |                |                   |
|                     |                                      | 5646180                        | JUL 08, 2014               | U-257        |                |                   |
| 020541 001          | ANASTROZOLE; ARIMIDEX                | RE36617                        | DEC 27, 2009               |              | I-312          | SEP 01, 2003      |
| 020883 001          | ARGATROBAN; ACOVA                    |                                |                            |              | NCE            | JUN 30, 2005      |
| 021248 001          | ARSENIC TRIOXIDE; TRISENOX           |                                |                            |              | ODE            | SEP 25, 2007      |
|                     |                                      |                                |                            |              | NCE            | SEP 25, 2005      |
|                     |                                      |                                |                            |              | NC             | APR 03, 2003      |
| 020971 001          | ARTICAINE HYDROCHLORIDE; SEPTOCAINE  |                                |                            |              |                |                   |
| >ADD>               | 020702 001                           | ATORVASTATIN CALCIUM; LIPITOR  | 6126971                    | JAN 19, 2013 |                |                   |
| >ADD>               | 020702 002                           | ATORVASTATIN CALCIUM; LIPITOR  | 6126971                    | JAN 19, 2013 |                |                   |
| >ADD>               | 020702 003                           | ATORVASTATIN CALCIUM; LIPITOR  | 6126971                    | JAN 19, 2013 |                |                   |
| >ADD>               | 020702 004                           | ATORVASTATIN CALCIUM; LIPITOR  | 6126971                    | JAN 19, 2013 | NCE            | DEC 17, 2001      |
|                     |                                      | 4681893                        | SEP 24, 2009               | U-161        | I-281          | DEC 02, 2002      |
|                     |                                      | 5273995                        | DEC 28, 2010               | U-162        | I-218          | JUL 10, 2001      |
|                     |                                      | 5686104                        | NOV 11, 2014               | U-213        | I-219          | JUL 10, 2001      |
|                     |                                      | 5969166                        | JUL 08, 2016               |              |                |                   |
| >ADD>               | 021078 001                           | ATOVAQUONE; MALARONE           | 6166046                    | NOV 25, 2013 |                |                   |
| >ADD>               | 021078 002                           | ATOVAQUONE; MALARONE PEDIATRIC | 6166046                    | NOV 25, 2013 |                |                   |
| 021127 001          | AZELASTINE HYDROCHLORIDE; OPTIVAR    | 5164194                        | NOV 01, 2010               |              | NCE            | NOV 01, 2001      |
|                     |                                      | 5164194*                       | MAY 01, 2011               |              | NDF            | MAY 22, 2003      |
|                     |                                      |                                |                            |              | PED            | MAY 01, 2002      |
|                     |                                      |                                |                            |              | PED            | NOV 22, 2003      |
|                     |                                      |                                |                            |              | NCE            | JUL 18, 2005      |
| 020610 001          | BALSALAZIDE DISODIUM; COLAZAL        | 4412992                        | JUL 08, 2001               |              |                |                   |
| 020911 002          | BECLOMETHASONE DIPROPIONATE; QVAR 40 | 5776432                        | JUL 07, 2015               |              |                |                   |
|                     |                                      | 5605674                        | FEB 25, 2014               |              |                |                   |
|                     |                                      | 5695743                        | JUL 06, 2010               |              |                |                   |
|                     |                                      | 5683677                        | NOV 04, 2014               |              |                |                   |
|                     |                                      | 5766573                        | NOV 28, 2009               | U-356        |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME          | PATENT<br>NUMBER               | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------|--------------------------------|----------------------------|--------------|----------------|-------------------|
| 020911 001          | BECLOMETHASONE DIPROPIONATE;QVAR 80  | 5776432                        | JUL 07, 2015               |              |                |                   |
|                     |                                      | 5605674                        | FEB 25, 2014               |              |                |                   |
|                     |                                      | 5695743                        | JUL 06, 2010               |              |                |                   |
|                     |                                      | 5683677                        | NOV 04, 2014               |              |                |                   |
|                     |                                      | 5766573                        | NOV 28, 2009               | U-356        |                |                   |
| 020010 001          | BETAMETHASONE DIPROPIONATE;LOTRISONE |                                |                            |              | NP             | DEC 08, 2003      |
| 021055 001          | BEXAROTENE;TARGRETIN                 |                                |                            |              | ODE            | DEC 29, 2006      |
| 021056 001          | BEXAROTENE;TARGRETIN                 |                                |                            |              | NCE            | DEC 29, 2004      |
|                     |                                      |                                |                            |              | NDF            | JUN 28, 2003      |
| 019982 001          | BISOPROLOL FUMARATE;ZEBETA           | 4258062                        | MAR 24, 2000               | U-63         |                |                   |
|                     |                                      | 4258062*PED                    | SEP 24, 2000               | U-63         |                |                   |
| 019982 002          | BISOPROLOL FUMARATE;ZEBETA           | 4258062                        | MAR 24, 2000               | U-63         |                |                   |
|                     |                                      | 4258062*PED                    | SEP 24, 2000               | U-63         |                |                   |
| 020186 001          | BISOPROLOL FUMARATE;ZIAC             | 4258062                        | MAR 24, 2000               | U-63         |                |                   |
|                     |                                      | 4258062*PED                    | SEP 24, 2000               | U-63         |                |                   |
| 020186 002          | BISOPROLOL FUMARATE;ZIAC             | 4258062                        | MAR 24, 2000               | U-63         |                |                   |
|                     |                                      | 4258062*PED                    | SEP 24, 2000               | U-63         |                |                   |
| 020186 003          | BISOPROLOL FUMARATE;ZIAC             | 4258062                        | MAR 24, 2000               | U-63         |                |                   |
|                     |                                      | 4358062*PED                    | SEP 24, 2000               | U-63         |                |                   |
| >ADD>               | 020873 001                           | BIVALIRUDIN;ANGIOMAX           |                            |              | NCE            | DEC 15, 2005      |
|                     | 050443 002                           | BLEOMYCIN SULFATE;BLENOXANE    |                            |              | ODE            | FEB 20, 2003      |
|                     | 020929 001                           | BUDESONIDE;PULMICORT RESPULES  | 4787536                    | FEB 27, 2006 | NDF            | AUG 08, 2003      |
|                     | 020929 002                           | BUDESONIDE;PULMICORT RESPULES  | 4787536                    | FEB 27, 2006 | NDF            | AUG 08, 2003      |
|                     | 020711 002                           | BUPROPION HYDROCHLORIDE;ZYBAN  |                            |              | D-54           | SEP 10, 2002      |
|                     | 020711 003                           | BUPROPION HYDROCHLORIDE;ZYBAN  |                            |              | D-54           | SEP 10, 2002      |
| >ADD>               | 018731 001                           | BUSPIRONE HYDROCHLORIDE;BUSPAR | 6150365*PED                | FEB 05, 2020 | U-361          |                   |
|                     |                                      | 4182763                        | MAY 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646                        | MAY 14, 2008               |              |                |                   |
|                     |                                      | 4182763*PED                    | NOV 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646*PED                    | NOV 14, 2008               |              |                |                   |
|                     |                                      | 6150365                        | AUG 05, 2019               | U-361        |                |                   |
| >ADD>               | 018731 002                           | BUSPIRONE HYDROCHLORIDE;BUSPAR | 6150365*PED                | FEB 05, 2020 | U-13           |                   |
|                     |                                      | 4182763                        | MAY 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646                        | MAY 14, 2008               |              |                |                   |
|                     |                                      | 4182763*PED                    | NOV 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646*PED                    | NOV 14, 2008               |              |                |                   |
|                     |                                      | 6150365                        | AUG 05, 2019               | U-361        |                |                   |
| >ADD>               | 018731 003                           | BUSPIRONE HYDROCHLORIDE;BUSPAR | 6150365*PED                | FEB 05, 2020 | U-13           |                   |
|                     |                                      | 5015646                        | MAY 14, 2008               |              |                |                   |
|                     |                                      | 4182763                        | MAY 22, 2000               | U-13         |                |                   |
|                     |                                      | 4182763*PED                    | NOV 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646*PED                    | NOV 14, 2008               |              |                |                   |
|                     |                                      | 6150365                        | AUG 05, 2019               | U-361        |                |                   |
| >ADD>               | 018731 004                           | BUSPIRONE HYDROCHLORIDE;BUSPAR | 6150365*PED                | FEB 05, 2020 | U-13           |                   |
|                     |                                      | 4182763                        | MAY 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646                        | MAY 14, 2008               |              |                |                   |
|                     |                                      | 4182763*PED                    | NOV 22, 2000               | U-13         |                |                   |
|                     |                                      | 5015646*PED                    | NOV 14, 2008               | U-13         |                |                   |
|                     |                                      | 6150365                        | AUG 05, 2019               | U-361        |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME | PATENT<br>NUMBER                                 | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-----------------------------|--------------------------------------------------|----------------------------|--------------|----------------|-------------------|
| >ADD>               | 021190 001                  | BUSPIRONE HYDROCHLORIDE; BUSPAR                  | 5015646                    | MAY 14, 2008 |                |                   |
| >ADD>               |                             |                                                  | 5015646*PED                | NOV 14, 2008 |                |                   |
| >ADD>               | 021190 002                  | BUSPIRONE HYDROCHLORIDE; BUSPAR                  | 5015646*PED                | NOV 14, 2008 |                |                   |
| >ADD>               |                             |                                                  | 5015646                    | MAY 14, 2008 |                |                   |
| >ADD>               | 021190 003                  | BUSPIRONE HYDROCHLORIDE; BUSPAR                  | 5015646                    | MAY 14, 2008 |                |                   |
| >ADD>               |                             |                                                  | 5015646*PED                | NOV 14, 2008 |                |                   |
| >ADD>               | 021190 004                  | BUSPIRONE HYDROCHLORIDE; BUSPAR                  | 5015646                    | MAY 14, 2008 |                |                   |
| >ADD>               |                             |                                                  | 5015646*PED                | NOV 14, 2008 |                |                   |
|                     | 020793 001                  | CAFFEINE CITRATE; CAFKIT                         |                            |              | ODE            | SEP 21, 2006      |
|                     | 020313 002                  | CALCITONIN, SALMON; MIACALCIN                    | 5759565                    | MAR 31, 2015 |                |                   |
|                     | 018874 001                  | CALCITRIOL; CALCIJEX                             | 6051567                    | AUG 02, 2019 |                |                   |
|                     | 018874 002                  | CALCITRIOL; CALCIJEX                             | 6051567                    | AUG 02, 2019 |                |                   |
|                     | 020958 001                  | CALCIUM CARBONATE, PRECIPITATED; PEPCID COMPLETE | 5229137                    | MAY 16, 2012 | U-349 NC       | OCT 15, 2003      |
|                     |                             |                                                  | 4283408                    | OCT 15, 2000 | PED            | APR 15, 2004      |
|                     |                             |                                                  | 5817340                    | DEC 01, 2012 |                |                   |
|                     |                             |                                                  | 5989588                    | SEP 30, 2015 | U-349          |                   |
|                     |                             |                                                  | 5989588*PED                | MAR 30, 2018 | U-349          |                   |
|                     |                             |                                                  | 4283408*PED                | APR 15, 2001 |                |                   |
|                     |                             |                                                  | 5229137*PED                | NOV 16, 2012 |                |                   |
|                     |                             |                                                  | 5817340*PED                | JUN 01, 2013 |                |                   |
|                     | 021093 001                  | CANDESARTAN CILEXETIL; ATACAND HCT               | 5705517                    | APR 18, 2011 | U-3 NCE        | JUN 04, 2003      |
|                     |                             |                                                  | 5721263                    | FEB 24, 2015 | U-3 NC         | SEP 05, 2003      |
|                     |                             |                                                  | 5958961                    | JUN 06, 2014 | U-3            |                   |
|                     |                             |                                                  | 5196444                    | APR 18, 2011 | U-3            |                   |
|                     |                             |                                                  | 5534534                    | JUL 09, 2013 |                |                   |
|                     |                             |                                                  | 5703110                    | APR 18, 2011 | U-3            |                   |
|                     | 021093 002                  | CANDESARTAN CILEXETIL; ATACAND HCT               | 5705517                    | APR 18, 2011 | U-3 NCE        | JUN 04, 2003      |
|                     |                             |                                                  | 5721263                    | FEB 24, 2015 | U-3 NC         | SEP 05, 2003      |
|                     |                             |                                                  | 5958961                    | JUN 06, 2014 | U-3            |                   |
|                     |                             |                                                  | 5196444                    | APR 18, 2011 | U-3            |                   |
|                     |                             |                                                  | 5534534                    | JUL 09, 2013 |                |                   |
|                     |                             |                                                  | 5703110                    | APR 18, 2011 | U-3            |                   |
|                     | 020896 001                  | CAPECITABINE; XELODA                             | 4966891                    | JAN 13, 2011 | U-272          |                   |
|                     | 020896 002                  | CAPECITABINE; XELODA                             | 4966891                    | JAN 13, 2011 | U-272          |                   |
|                     | 020297 001                  | CARVEDILOL; COREG                                | 5902821                    | FEB 07, 2016 | U-313          |                   |
|                     | 020297 002                  | CARVEDILOL; COREG                                | 5902821                    | FEB 07, 2016 | U-313          |                   |
|                     | 020297 003                  | CARVEDILOL; COREG                                | 5902821                    | FEB 07, 2016 | U-313          |                   |
|                     | 020297 004                  | CARVEDILOL; COREG                                | 5902821                    | FEB 07, 2016 | U-313          |                   |
|                     | 020740 001                  | CERIVASTATIN SODIUM; BAYCOL                      |                            |              | D-59           | JUL 21, 2003      |
|                     |                             |                                                  |                            |              | I-303          | JUL 21, 2003      |
|                     | 020740 002                  | CERIVASTATIN SODIUM; BAYCOL                      |                            |              | D-59           | JUL 21, 2003      |
|                     |                             |                                                  |                            |              | I-303          | JUL 21, 2003      |
|                     | 020740 003                  | CERIVASTATIN SODIUM; BAYCOL                      |                            |              | D-59           | JUL 21, 2003      |
|                     |                             |                                                  |                            |              | I-303          | JUL 21, 2003      |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME        | PATENT<br>NUMBER                   | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|------------------------------------|------------------------------------|----------------------------|--------------|----------------|-------------------|
| 020740 004          | CERIVASTATIN SODIUM;BAYCOL         |                                    |                            |              | D-59           | JUL 21, 2003      |
| 020740 005          | CERIVASTATIN SODIUM;BAYCOL         |                                    |                            |              | I-303          | JUL 21, 2003      |
| 020740 006          | CERIVASTATIN SODIUM;BAYCOL         | 5006530                            | JAN 17, 2009               |              | D-59           | JUL 21, 2003      |
|                     |                                    | 5177080                            | JAN 26, 2011               |              | I-303          | JUL 21, 2003      |
| 021197 001          | CETRORELIX;CETROTIDE               | 4800191                            | JUL 17, 2007               |              | NS             | JUL 21, 2003      |
| 021197 002          | CETRORELIX;CETROTIDE               | 5198533                            | JUL 17, 2007               |              | NCE            | AUG 11, 2005      |
| 020989 002          | CEVIMELINE HYDROCHLORIDE;EVOXAC    | 4800191                            | JUL 17, 2007               |              | NCE            | AUG 11, 2005      |
|                     |                                    | 5198533                            | JUL 17, 2007               |              |                |                   |
|                     |                                    | 4855290                            | AUG 08, 2006               |              | NCE            | JAN 11, 2005      |
|                     |                                    | 5340821                            | AUG 23, 2011               | U-309        |                |                   |
|                     |                                    | 5580880                            | JUN 06, 2015               | U-310        |                |                   |
| 020832 001          | CHLORHEXIDINE GLUCONATE;CHLORAPREP |                                    |                            |              | NC             | JUL 14, 2003      |
| 021149 002          | CHORIOGONADOTROPIN ALFA;OVIDREL    | 5767251                            | JUN 16, 2015               |              | NP             | SEP 20, 2003      |
| 020780 001          | CIPROFLOXACIN;CIPRO                | 6136347                            | JAN 06, 2013               | U-362        |                |                   |
| 020780 002          | CIPROFLOXACIN;CIPRO                | 6136347                            | JAN 06, 2013               | U-362        |                |                   |
| 020822 001          | CITALOPRAM HYDROBROMIDE;CELEXA     |                                    |                            |              | NCE            | JUL 17, 2003      |
| 021046 001          | CITALOPRAM HYDROBROMIDE;CELEXA     |                                    |                            |              | NCE            | JUL 17, 2003      |
| 021142 001          | CLOBETASOL PROPIONATE;OLUX FOAM    |                                    |                            |              | NDF            | MAY 26, 2003      |
| 021143 001          | CLOTRIMAZOLE;TRIVAGIZOLE 3         |                                    |                            |              | NP             | NOV 24, 2001      |
| 021141 001          | COLESEVELAM HYDROCHLORIDE;WELCHOL  | 5624963                            | APR 29, 2014               | U-323        | NCE            | MAY 26, 2005      |
|                     |                                    | 5679717                            | APR 29, 2014               | U-323        |                |                   |
|                     |                                    | 5693675                            | DEC 02, 2014               |              |                |                   |
|                     |                                    | 5607669                            | JUN 10, 2014               | U-323        |                |                   |
|                     |                                    | 5917007                            | APR 29, 2014               | U-323        |                |                   |
|                     |                                    | 5919832                            | JUN 10, 2014               |              |                |                   |
| 021176 001          | COLESEVELAM HYDROCHLORIDE;WELCHOL  | 5919832                            | JUN 10, 2014               |              | NCE            | MAY 26, 2005      |
|                     |                                    | 5917007                            | APR 29, 2014               | U-323        |                |                   |
|                     |                                    | 5607669                            | JUN 10, 2014               | U-323        |                |                   |
|                     |                                    | 5693675                            | DEC 02, 2014               |              |                |                   |
|                     |                                    | 5679717                            | APR 29, 2014               | U-323        |                |                   |
|                     |                                    | 5624963                            | APR 29, 2014               | U-323        |                |                   |
| 020287 001          | DALTEPARIN SODIUM;FRAGMIN          |                                    |                            |              | D-60           | AUG 03, 2003      |
| 020287 003          | DALTEPARIN SODIUM;FRAGMIN          |                                    |                            |              | D-60           | AUG 03, 2003      |
| 020287 004          | DALTEPARIN SODIUM;FRAGMIN          |                                    |                            |              | D-60           | AUG 03, 2003      |
| >ADD>               | 021090 001                         | DESOGESTREL;CYCLESSA               | 4616006                    | OCT 07, 2003 | NP             | DEC 20, 2003      |
| >ADD>               |                                    |                                    | 4544554                    | SEP 26, 2003 |                |                   |
| >ADD>               |                                    |                                    | 4628051                    | SEP 26, 2003 |                |                   |
|                     | 020713 001                         | DESOGESTREL;MIRCETTE               | RE35724                    | OCT 20, 2008 |                |                   |
|                     | 020212 001                         | DEXRAZOXANE HYDROCHLORIDE;ZINECARD | 5242901                    | SEP 07, 2010 | U-339          |                   |
|                     |                                    |                                    | 4963551                    | DEC 21, 2007 |                |                   |
|                     |                                    |                                    | 4275063                    | JUN 23, 2003 |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME            | PATENT<br>NUMBER                         | PATENT/PED EXCL USE<br>EXPIRES               | EXCLUS<br>CODE               | EXCLUS<br>EXPIRES                                |
|---------------------|----------------------------------------|------------------------------------------|----------------------------------------------|------------------------------|--------------------------------------------------|
| 020212 002          | DEXRAZOXANE HYDROCHLORIDE; ZINECARD    | 5242901<br>4963551<br>4275063            | SEP 07, 2010<br>DEC 21, 2007<br>JUN 23, 2003 | U-339                        |                                                  |
| 020154 002          | DIDANOSINE; VIDEK                      |                                          |                                              | D-58                         | OCT 28, 2002                                     |
| 020154 003          | DIDANOSINE; VIDEK                      |                                          |                                              | D-58                         | OCT 28, 2002                                     |
| 020154 004          | DIDANOSINE; VIDEK                      | 5616566                                  | AUG 29, 2006                                 | U-180                        | D-58 OCT 28, 2002                                |
| 020154 005          | DIDANOSINE; VIDEK                      |                                          |                                              | D-58                         | OCT 28, 2002                                     |
| 020154 006          | DIDANOSINE; VIDEK                      |                                          |                                              | NS                           | OCT 28, 2002                                     |
| 021183 001          | DIDANOSINE; VIDEK EC                   |                                          |                                              | D-58                         | OCT 28, 2002                                     |
| 021183 002          | DIDANOSINE; VIDEK EC                   |                                          |                                              | NDF                          | OCT 31, 2003                                     |
| 021183 003          | DIDANOSINE; VIDEK EC                   |                                          |                                              | NDF                          | OCT 31, 2003                                     |
| 021183 004          | DIDANOSINE; VIDEK EC                   |                                          |                                              | NDF                          | OCT 31, 2003                                     |
| 020939 001          | DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL | 5288505<br>5529791                       | JUN 26, 2011<br>JUN 25, 2013                 |                              |                                                  |
| 020939 002          | DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL | 5288505<br>5529791                       | JUN 26, 2011<br>JUN 25, 2013                 |                              |                                                  |
| 020939 003          | DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL | 5288505<br>5529791                       | JUN 26, 2011<br>JUN 25, 2013                 |                              |                                                  |
| 020939 004          | DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL | 5288505<br>5529791                       | JUN 26, 2011<br>JUN 25, 2013                 |                              |                                                  |
| >ADD>               | 020401 001                             | DILTIAZEM HYDROCHLORIDE; TIAZAC          | 6162463                                      | APR 28, 2018                 |                                                  |
| >ADD>               | 020401 002                             | DILTIAZEM HYDROCHLORIDE; TIAZAC          | 6162463                                      | APR 28, 2018                 |                                                  |
| >ADD>               | 020401 003                             | DILTIAZEM HYDROCHLORIDE; TIAZAC          | 6162463                                      | APR 28, 2018                 |                                                  |
| >ADD>               | 020401 004                             | DILTIAZEM HYDROCHLORIDE; TIAZAC          | 6162463                                      | APR 28, 2018                 |                                                  |
| >ADD>               | 020401 005                             | DILTIAZEM HYDROCHLORIDE; TIAZAC          | 6162463                                      | APR 28, 2018                 |                                                  |
| >ADD>               | 020401 006                             | DILTIAZEM HYDROCHLORIDE; TIAZAC          | 6162463                                      | APR 28, 2018                 |                                                  |
|                     | 021168 001                             | DIVALPROEX SODIUM; DEPAKOTE ER           | 4988731<br>4913906                           | JAN 29, 2008<br>APR 03, 2007 | NP AUG 04, 2003                                  |
|                     | 020941 001                             | DOCOSANOL; ABREVA                        |                                              |                              | NCE JUL 25, 2005                                 |
|                     | 020931 001                             | DOFETILIDE; TIKOSYN                      | 6124363                                      | OCT 09, 2018                 |                                                  |
|                     | 020931 002                             | DOFETILIDE; TIKOSYN                      | 6124363                                      | OCT 09, 2018                 |                                                  |
|                     | 020931 003                             | DOFETILIDE; TIKOSYN                      | 6124363                                      | OCT 09, 2018                 |                                                  |
| >ADD>               | 020623 001                             | DOLASETRON MESYLATE MONOHYDRATE; ANZEMET | 4906775<br>4906775                           | JUL 02, 2011<br>JUL 02, 2011 |                                                  |
| >ADD>               | 020623 002                             | DOLASETRON MESYLATE MONOHYDRATE; ANZEMET | 4906775<br>4906775                           | JUL 02, 2011<br>JUL 02, 2011 |                                                  |
| >ADD>               | 020624 001                             | DOLASETRON MESYLATE MONOHYDRATE; ANZEMET | 4906775                                      | JUL 02, 2011                 |                                                  |
|                     | 020690 001                             | DONEPEZIL HYDROCHLORIDE; ARICEPT         | 6140321                                      | JUN 07, 2014                 |                                                  |
|                     | 020690 002                             | DONEPEZIL HYDROCHLORIDE; ARICEPT         | 6140321                                      | JUN 07, 2014                 |                                                  |
|                     | 020869 001                             | DORZOLAMIDE HYDROCHLORIDE; COSOPT        | 4797413<br>4619939                           | APR 28, 2008<br>OCT 28, 2003 | U-103<br>U-104                                   |
|                     | 021027 001                             | DOXERCALCIFEROL; HECTOROL                | 5602116<br>5707980                           | APR 03, 2115<br>FEB 11, 2117 | U-321 NDF APR 06, 2003<br>U-321 NCE JUN 09, 2004 |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME        | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 021145 001          | EFLORNITHINE HYDROCHLORIDE; VANIQA | 4413141          | NOV 01, 2000               |             | NP             | JUL 27, 2003      |
|                     |                                    | 4720489          | JAN 19, 2005               | U-334       |                |                   |
|                     |                                    | 5648394          | JUL 15, 2014               | U-334       |                |                   |
| 019221 001          | ENALAPRIL MALEATE; VASERETIC       | 4472380          | SEP 18, 2001               |             |                |                   |
|                     |                                    | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
|                     |                                    | 4472380*PED      | MAR 18, 2002               |             |                |                   |
| 019221 003          | ENALAPRIL MALEATE; VASERETIC       | 4472380          | SEP 18, 2001               |             |                |                   |
|                     |                                    | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
|                     |                                    | 4472380*PED      | MAR 18, 2002               |             |                |                   |
| 018998 001          | ENALAPRIL MALEATE; VASOTEC         | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
| 018998 002          | ENALAPRIL MALEATE; VASOTEC         | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
| 018998 003          | ENALAPRIL MALEATE; VASOTEC         | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
| 018998 005          | ENALAPRIL MALEATE; VASOTEC         | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
| 019309 001          | ENALAPRILAT; VASOTEC               | 4374829          | FEB 22, 2000               |             |                |                   |
|                     |                                    | 4374829*PED      | AUG 22, 2000               |             |                |                   |
| 020164 001          | ENOXAPARIN SODIUM; LOVENOX         |                  |                            |             | I-315          | NOV 17, 2003      |
| 020164 002          | ENOXAPARIN SODIUM; LOVENOX         |                  |                            |             | I-315          | NOV 17, 2003      |
| 020164 003          | ENOXAPARIN SODIUM; LOVENOX         |                  |                            |             | I-315          | NOV 17, 2003      |
| 020164 004          | ENOXAPARIN SODIUM; LOVENOX         |                  |                            |             | I-315          | NOV 17, 2003      |
| 020164 005          | ENOXAPARIN SODIUM; LOVENOX         |                  |                            |             | I-315          | NOV 17, 2003      |
| 020444 001          | EPOPROSTENOL SODIUM; FLOLAN        |                  |                            |             | ODE            | APR 14, 2007      |
|                     |                                    |                  |                            |             | I-296          | APR 14, 2003      |
| 020444 002          | EPOPROSTENOL SODIUM; FLOLAN        |                  |                            |             | ODE            | APR 14, 2007      |
|                     |                                    |                  |                            |             | I-296          | APR 14, 2003      |
| 020874 001          | ESTRADIOL CYPIONATE; LUNELLE       |                  |                            |             | NP             | OCT 05, 2003      |
| 020907 001          | ESTRADIOL; ACTIVELLE               | RE36247          | MAY 02, 2006               |             | I-295          | APR 11, 2003      |
| 020655 001          | ESTRADIOL; ALORA                   | 5122383          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5227169          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5212199          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5164190          | DEC 11, 2010               |             |                |                   |
| 020655 002          | ESTRADIOL; ALORA                   | 5122383          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5227169          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5212199          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5164190          | DEC 11, 2010               |             |                |                   |
| 020655 003          | ESTRADIOL; ALORA                   | 5122383          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5227169          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5212199          | MAY 17, 2011               |             |                |                   |
|                     |                                    | 5164190          | DEC 11, 2010               |             |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME | PATENT<br>NUMBER                             | PATENT/PED EXCL USE<br>EXPIRES CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-----------------------------|----------------------------------------------|-------------------------------------|----------------|-------------------|
| 021040 001          | ESTRADIOL; ORTHO-PREFEST    | 5108995                                      | APR 28, 2009                        | U-311          |                   |
|                     |                             | 5382573                                      | JAN 17, 2012                        |                |                   |
| 020323 001          | ESTRADIOL; VIVELLE          |                                              |                                     | I-254          | AUG 16, 2003      |
| 020323 002          | ESTRADIOL; VIVELLE          |                                              |                                     | I-254          | AUG 16, 2003      |
| 020323 003          | ESTRADIOL; VIVELLE          |                                              |                                     | I-254          | AUG 16, 2003      |
| 020323 004          | ESTRADIOL; VIVELLE          |                                              |                                     | I-254          | AUG 16, 2003      |
| 020323 005          | ESTRADIOL; VIVELLE          |                                              |                                     | NS             | AUG 16, 2003      |
|                     |                             | 4994278                                      | MAR 04, 2008                        | I-254          | AUG 16, 2003      |
|                     |                             | 5300291                                      | APR 05, 2011                        |                |                   |
|                     |                             | 4814168                                      | MAR 04, 2008                        |                |                   |
|                     |                             | 4994267                                      | MAR 04, 2008                        |                |                   |
|                     |                             | 5474783                                      | DEC 12, 2012                        |                |                   |
|                     |                             | 5656286                                      | AUG 12, 2014                        |                |                   |
|                     |                             | 5958446                                      | DEC 12, 2012                        |                |                   |
|                     |                             | 6024976                                      | JAN 07, 2014                        |                |                   |
| >ADD>               | 020538 001                  | ESTRADIOL; VIVELLE-DOT                       |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               | 020538 002                  | ESTRADIOL; VIVELLE-DOT                       |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               | 020538 003                  | ESTRADIOL; VIVELLE-DOT                       |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               | 020538 004                  | ESTRADIOL; VIVELLE-DOT                       |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
| >ADD>               |                             |                                              |                                     |                |                   |
|                     | 020992 002                  | ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN  | 5908638                             |                |                   |
|                     | 020992 003                  | ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN  | 5908638                             |                |                   |
| >ADD>               | 020992 004                  | ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN  | 5908638                             | JUL 26, 2015   | NP MAR 24, 2002   |
| >ADD>               | 020303 001                  | ESTROGENS, CONJUGATED; PREMPRO (PREMARIN; CY | RE36247                             | MAY 02, 2006   | U-284             |
| >ADD>               | 020527 001                  | ESTROGENS, CONJUGATED; PREMPRO 14/14         | RE36247                             | MAY 02, 2006   | U-284             |
| >ADD>               | 020527 003                  | ESTROGENS, CONJUGATED; PREMPRO 14/14         | RE36247                             | MAY 02, 2006   | U-284             |
| >ADD>               | 075665 001                  | ETODOLAC; ETODOLAC                           |                                     |                | PC FEB 13, 2001   |
| >ADD>               | 075665 002                  | ETODOLAC; ETODOLAC                           |                                     |                | PC FEB 13, 2001   |
|                     | 075696 001                  | ETODOLAC; ETODOLAC                           |                                     |                | PC FEB 04, 2001   |
|                     | 020584 001                  | ETODOLAC; LODINE XL                          | 4966768*PED                         | APR 30, 2008   |                   |
|                     |                             |                                              | 4966768                             | OCT 30, 2007   |                   |
|                     | 020584 002                  | ETODOLAC; LODINE XL                          | 4966768*PED                         | APR 30, 2008   |                   |
|                     |                             |                                              | 4966768                             | OCT 30, 2007   |                   |
|                     | 020584 003                  | ETODOLAC; LODINE XL                          | 4966768*PED                         | APR 30, 2008   |                   |
|                     |                             |                                              | 4966768                             | OCT 30, 2007   |                   |
|                     | 019462 001                  | FAMOTIDINE; PEPCID                           | 4283408                             | OCT 15, 2000   |                   |
|                     |                             |                                              | 4283408*PED                         | APR 15, 2001   |                   |
|                     | 019462 002                  | FAMOTIDINE; PEPCID                           | 4283408                             | OCT 15, 2000   |                   |
|                     |                             |                                              | 4283408*PED                         | APR 15, 2001   |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME        | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 019510 001          | FAMOTIDINE;PEPCID                  | 4283408          | OCT 15, 2000               |             |                |                   |
| 019527 001          | FAMOTIDINE;PEPCID                  | 4283408*PED      | APR 15, 2001               |             |                |                   |
| 020325 001          | FAMOTIDINE;PEPCID AC               | 4283408          | OCT 15, 2000               |             |                |                   |
|                     |                                    | 4283408*PED      | APR 15, 2001               |             |                |                   |
|                     |                                    | 4283408          | OCT 15, 2000               |             |                |                   |
|                     |                                    | 5667794          | MAY 02, 2015               | U-205       | D-47           | NOV 09, 2001      |
|                     |                                    | 5854267          | DEC 29, 2015               | U-267       | PED            | MAY 09, 2002      |
|                     |                                    | 4283408*PED      | APR 15, 2001               |             |                |                   |
|                     |                                    | 5667794*PED      | NOV 02, 2015               | U-205       |                |                   |
|                     |                                    | 5854267*PED      | JUN 29, 2016               | U-267       |                |                   |
| 020801 001          | FAMOTIDINE;PEPCID AC               | 5667794          | MAY 02, 2015               |             |                |                   |
|                     |                                    | 4283408          | OCT 15, 2000               |             |                |                   |
|                     |                                    | 5854267          | DEC 29, 2015               | U-267       |                |                   |
|                     |                                    | 5075114          | DEC 24, 2008               |             |                |                   |
|                     |                                    | 4283408*PED      | APR 15, 2001               |             |                |                   |
|                     |                                    | 5075114*PED      | JUN 24, 2009               |             |                |                   |
|                     |                                    | 5667794*PED      | NOV 02, 2015               |             |                |                   |
|                     |                                    | 5854267*PED      | JUN 29, 2016               |             |                |                   |
| >ADD>               | 020902 001                         | 5854267          | DEC 29, 2015               | U-368       |                |                   |
| >ADD>               |                                    | 5854267*PED      | JUN 29, 2016               | U-368       |                |                   |
| >ADD>               |                                    | 5667794          | MAY 02, 2015               | U-368       |                |                   |
| >ADD>               |                                    | 5667794*PED      | NOV 02, 2015               | U-368       |                |                   |
| >ADD>               |                                    | 4820524*PED      | AUG 20, 2007               |             |                |                   |
| >ADD>               |                                    | 4820524          | FEB 20, 2007               |             |                |                   |
|                     |                                    | 4283408          | OCT 15, 2000               |             |                |                   |
|                     |                                    | 4283408*PED      | APR 15, 2001               |             |                |                   |
| 019510 004          | FAMOTIDINE;PEPCID PRESERVATIVE     | 4283408          | OCT 15, 2000               |             |                |                   |
| 020249 001          | FAMOTIDINE;PEPCID PRESERVATIVE     | 4283408*PED      | APR 15, 2001               |             |                |                   |
| 020752 001          | FAMOTIDINE;PEPCID RPD              | 4283408          | OCT 15, 2000               |             |                |                   |
| 020752 002          | FAMOTIDINE;PEPCID RPD              | 4283408*PED      | APR 15, 2001               |             |                |                   |
|                     |                                    | 4283408          | OCT 15, 2000               |             |                |                   |
| 019304 002          | FENOFIBRATE;TRICOR (MICRONIZED)    | 4283408*PED      | APR 15, 2001               |             |                |                   |
| 019304 003          | FENOFIBRATE;TRICOR (MICRONIZED)    |                  |                            |             | I-298          | APR 24, 2003      |
| 019304 004          | FENOFIBRATE;TRICOR (MICRONIZED)    |                  |                            |             | I-298          | APR 24, 2003      |
| 020625 001          | FEXOFENADINE HYDROCHLORIDE;ALLEGRA | 6037353          | MAR 14, 2017               | U-138       |                |                   |
|                     |                                    | 6113942          | FEB 28, 2015               |             |                |                   |
| 020872 001          | FEXOFENADINE HYDROCHLORIDE;ALLEGRA | 5578610          | NOV 26, 2013               | U-139       | NDF            | FEB 25, 2003      |
|                     |                                    | 5932247          | FEB 28, 2015               |             | NCE            | JUL 25, 2001      |
|                     |                                    | 5855912          | FEB 28, 2015               |             |                |                   |
|                     |                                    | 4254129          | FEB 17, 2001               | U-139       |                |                   |
|                     |                                    | 6037353          | MAR 14, 2017               | U-138       |                |                   |
|                     |                                    | 6113942          | FEB 28, 2015               |             |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME           | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|---------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020872 002          | FEXOFENADINE HYDROCHLORIDE; ALLEGRA   | 5578610          | NOV 26, 2013               | U-139       | NDF            | FEB 25, 2003      |
|                     |                                       | 5932247          | FEB 28, 2015               |             | NCE            | JUL 25, 2001      |
|                     |                                       | 5855912          | FEB 28, 2015               |             |                |                   |
|                     |                                       | 4254129          | FEB 17, 2001               | U-139       |                |                   |
|                     |                                       | 6037353          | MAR 14, 2017               | U-138       |                |                   |
|                     |                                       | 6113942          | FEB 28, 2015               |             |                |                   |
| 020872 004          | FEXOFENADINE HYDROCHLORIDE; ALLEGRA   | 5578610          | NOV 26, 2013               | U-139       | NDF            | FEB 25, 2003      |
|                     |                                       | 5932247          | FEB 28, 2015               |             | NCE            | JUL 25, 2001      |
|                     |                                       | 5855912          | FEB 28, 2015               |             |                |                   |
|                     |                                       | 4254129          | FEB 17, 2001               | U-139       |                |                   |
|                     |                                       | 6037353          | MAR 14, 2017               | U-138       |                |                   |
|                     |                                       | 6113942          | FEB 28, 2015               |             |                |                   |
| 020786 001          | FEXOFENADINE HYDROCHLORIDE; ALLEGRA-D | 6037353          | MAR 14, 2017               | U-138       |                |                   |
|                     |                                       | 6039974          | JUL 31, 2018               |             |                |                   |
|                     |                                       | 6113942          | FEB 28, 2015               |             |                |                   |
| 019949 004          | FLUCONAZOLE; DIFLUCAN                 | 4416682          | JUN 02, 2001               |             |                |                   |
|                     |                                       | 4404216          | JAN 29, 2004               |             |                |                   |
| 020985 001          | FLUOROURACIL; FLUOROURACIL            |                  |                            |             | NP             | OCT 27, 2003      |
| 018936 001          | FLUOXETINE HYDROCHLORIDE; PROZAC      | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                       | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                       | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
| 018936 003          | FLUOXETINE HYDROCHLORIDE; PROZAC      | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                       | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
| 018936 004          | FLUOXETINE HYDROCHLORIDE; PROZAC      | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                       | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
| 018936 006          | FLUOXETINE HYDROCHLORIDE; PROZAC      | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                       | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
| 020101 001          | FLUOXETINE HYDROCHLORIDE; PROZAC      | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                       | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                       | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
|                     |                                       | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |

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|---------------------|----------------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020974 001          | FLUOXETINE HYDROCHLORIDE; PROZAC             | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                              | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                              | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                              | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                              | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
|                     |                                              | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |
| 020974 002          | FLUOXETINE HYDROCHLORIDE; PROZAC             | 4626549          | DEC 02, 2003               | U-84        |                |                   |
|                     |                                              | 4626549          | DEC 02, 2003               | U-154       |                |                   |
|                     |                                              | 4314081          | FEB 02, 2001               |             |                |                   |
|                     |                                              | 4314081*PED      | AUG 02, 2001               |             |                |                   |
|                     |                                              | 4626549*PED      | JUN 02, 2004               | U-84        |                |                   |
|                     |                                              | 4626549*PED      | JUN 02, 2004               | U-154       |                |                   |
| 018936 007          | FLUOXETINE HYDROCHLORIDE; SARAFEM            | 4971998          | NOV 20, 2007               | U-338       | NP             | JUL 06, 2003      |
|                     |                                              | 5114976          | MAY 19, 2009               | U-341       | PED            | JUN 06, 2004      |
|                     |                                              | 5744501          | MAY 19, 2009               | U-342       |                |                   |
|                     |                                              | 4971998*PED      | MAY 20, 2008               | U-338       |                |                   |
|                     |                                              | 5114976*PED      | NOV 19, 2009               | U-341       |                |                   |
|                     |                                              | 5744501*PED      | NOV 19, 2009               | U-342       |                |                   |
| 018936 008          | FLUOXETINE HYDROCHLORIDE; SARAFEM            | 4971998          | NOV 20, 2007               | U-338       | NP             | JUL 06, 2003      |
|                     |                                              | 5114976          | MAY 19, 2009               | U-341       | PED            | JAN 06, 2004      |
|                     |                                              | 5744501          | MAY 19, 2009               | U-342       |                |                   |
|                     |                                              | 4971998*PED      | MAY 20, 2008               | U-338       |                |                   |
|                     |                                              | 5114976*PED      | NOV 19, 2009               | U-341       |                |                   |
|                     |                                              | 5744501*PED      | NOV 19, 2009               | U-342       |                |                   |
| 021077 001          | FLUTICASONE PROPIONATE; ADVAIR DISKUS 100/50 | 4335121          | NOV 14, 2003               |             | NC             | AUG 24, 2003      |
|                     |                                              | 5270305          | SEP 07, 2010               |             |                |                   |
|                     |                                              | 4992474          | FEB 12, 2008               | U-211       |                |                   |
|                     |                                              | 5225445          | FEB 12, 2008               | U-211       |                |                   |
|                     |                                              | 5126375          | FEB 12, 2008               |             |                |                   |
| 021077 002          | FLUTICASONE PROPIONATE; ADVAIR DISKUS 250/50 | 4335121          | NOV 14, 2003               |             | NC             | AUG 24, 2003      |
|                     |                                              | 5270305          | SEP 07, 2010               |             |                |                   |
|                     |                                              | 4992474          | FEB 12, 2008               | U-211       |                |                   |
|                     |                                              | 5225445          | FEB 12, 2008               | U-211       |                |                   |
|                     |                                              | 5126375          | FEB 12, 2008               |             |                |                   |
| 021077 003          | FLUTICASONE PROPIONATE; ADVAIR DISKUS 500/50 | 4335121          | NOV 14, 2003               |             | NC             | AUG 24, 2003      |
|                     |                                              | 5270305          | SEP 07, 2010               |             |                |                   |
|                     |                                              | 4992474          | FEB 12, 2008               | U-211       |                |                   |
|                     |                                              | 5225445          | FEB 12, 2008               | U-211       |                |                   |
|                     |                                              | 5126375          | FEB 12, 2008               |             |                |                   |
| 021192 001          | FLUVASTATIN SODIUM; LESCOL XL                |                  |                            |             | NDF            | OCT 06, 2003      |
| 020378 001          | FOLLITROPIN ALFA/BETA; GONAL-F               |                  |                            |             | ODE            | MAY 24, 2007      |
|                     |                                              |                  |                            |             | I-306          | MAY 24, 2003      |
| 020378 002          | FOLLITROPIN ALFA/BETA; GONAL-F               |                  |                            |             | ODE            | MAY 24, 2007      |
|                     |                                              |                  |                            |             | I-306          | MAY 24, 2003      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME   | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020378 003          | FOLLITROPIN ALFA/BETA;GONAL-F | 4589402          | JUL 26, 2004               | U-242       | I-306          | MAY 24, 2003      |
| >ADD>               |                               | 5767251          | JUN 16, 2015               |             | ODE            | MAY 24, 2007      |
| >ADD>               |                               |                  |                            |             | ODE            | DEC 08, 2007      |
| 020696 001          | FOMEPIZOLE;ANTIZOL            |                  |                            |             | I-319          | DEC 08, 2003      |
| 020235 001          | GABAPENTIN;NEURONTIN          | 4087544          | JAN 16, 2000               | U-86        | PED            | MAR 29, 2002      |
|                     |                               | 5084479          | JAN 02, 2010               | U-125       | D-43           | SEP 29, 2001      |
|                     |                               | 4894476*PED      | NOV 02, 2008               |             | I-311          | OCT 12, 2003      |
|                     |                               | 4087544*PED      | JUL 16, 2000               | U-86        |                |                   |
|                     |                               | 5084479*PED      | JUL 02, 2010               | U-125       |                |                   |
|                     |                               | 4894476          | MAY 02, 2008               |             |                |                   |
|                     |                               | 6054482          | APR 25, 2017               |             |                |                   |
|                     |                               | 6054482*PED      | OCT 25, 2017               |             |                |                   |
| 020235 002          | GABAPENTIN;NEURONTIN          | 4894476          | MAY 02, 2008               |             | PED            | MAR 29, 2002      |
|                     |                               | 5084479          | JAN 02, 2010               | U-125       | D-43           | SEP 29, 2001      |
|                     |                               | 4087544          | JAN 16, 2000               | U-86        | I-311          | OCT 12, 2003      |
|                     |                               | 5084479*PED      | JUL 02, 2010               | U-125       |                |                   |
|                     |                               | 4894476*PED      | NOV 02, 2008               |             |                |                   |
|                     |                               | 4087544*PED      | JUL 16, 2000               | U-86        |                |                   |
|                     |                               | 6054482          | APR 25, 2017               |             |                |                   |
|                     |                               | 6054482*PED      | OCT 25, 2017               |             |                |                   |
| 020235 003          | GABAPENTIN;NEURONTIN          | 4087544          | JAN 16, 2000               | U-86        | PED            | MAR 29, 2002      |
|                     |                               | 5084479          | JAN 02, 2010               | U-125       | D-43           | SEP 29, 2001      |
|                     |                               | 4894476          | MAY 02, 2008               |             | I-311          | OCT 12, 2003      |
|                     |                               | 4087544*PED      | JUL 16, 2000               | U-86        |                |                   |
|                     |                               | 5084479*PED      | JUL 02, 2010               |             |                |                   |
|                     |                               | 4894476*PED      | NOV 02, 2008               |             |                |                   |
|                     |                               | 6054482          | APR 25, 2017               |             |                |                   |
|                     |                               | 6054482*PED      | OCT 25, 2017               |             |                |                   |
| 020882 001          | GABAPENTIN;NEURONTIN          | 4087544          | JAN 16, 2000               | U-106       | I-311          | OCT 12, 2003      |
|                     |                               | 4894476          | MAY 02, 2008               |             |                |                   |
|                     |                               | 5084479          | JAN 02, 2010               | U-258       |                |                   |
|                     |                               | 5084479*PED      | JUL 02, 2010               | U-258       |                |                   |
|                     |                               | 4087544*PED      | JUL 16, 2000               | U-106       |                |                   |
|                     |                               | 4894476*PED      | NOV 02, 2008               |             |                |                   |
|                     |                               | 6054482          | APR 25, 2017               |             |                |                   |
|                     |                               | 6054482*PED      | OCT 25, 2017               |             |                |                   |
| 020882 002          | GABAPENTIN;NEURONTIN          | 4087544          | JAN 16, 2000               | U-106       | I-311          | OCT 12, 2003      |
|                     |                               | 4894476          | MAY 02, 2008               |             |                |                   |
|                     |                               | 5084479          | JAN 02, 2010               | U-258       |                |                   |
|                     |                               | 4087544*PED      | JUL 16, 2000               | U-106       |                |                   |
|                     |                               | 4894476*PED      | NOV 02, 2008               |             |                |                   |
|                     |                               | 5084479*PED      | JUL 02, 2010               | U-258       |                |                   |
|                     |                               | 6054482          | APR 25, 2017               |             |                |                   |
|                     |                               | 6054482*PED      | OCT 25, 2017               |             |                |                   |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME          | PATENT<br>NUMBER | PATENT/PED EXCL USE<br>EXPIRES CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------|------------------|-------------------------------------|----------------|-------------------|
| 021129 001          | GABAPENTIN; NEURONTIN                |                  |                                     | I-311          | OCT 12, 2003      |
| 021037 001          | GADOPENTETATE DIMEGLUMINE; MAGNEVIST | 5362475          | NOV 08, 2011                        |                |                   |
|                     |                                      | 5560903          | OCT 01, 2013                        |                |                   |
|                     |                                      | 4647447          | MAR 03, 2004                        |                |                   |
|                     |                                      | 4957939          | MAR 03, 2004                        |                |                   |
|                     |                                      | 4963344          | MAR 03, 2004                        |                |                   |
| 020460 002          | GANCICLOVIR; CYTOVENE                | 4507305          | MAY 21, 2001                        | U-64           |                   |
|                     |                                      | 4423050          | MAY 21, 2001                        | U-64           |                   |
|                     |                                      | 4355032          | JUN 23, 2003                        | U-64           |                   |
|                     |                                      | 4642346          | JUN 24, 2005                        |                |                   |
| 021174 001          | GEMTUZUMAB OZOGAMICIN; MYLOTARG      | 5606040          | FEB 25, 2014                        | ODE            | MAY 17, 2007      |
|                     |                                      | 5693762          | DEC 02, 2014                        | NCE            | MAY 17, 2005      |
|                     |                                      | 5739116          | APR 14, 2015                        |                |                   |
|                     |                                      | 5767285          | JUN 16, 2015                        |                |                   |
|                     |                                      | 5773001          | JUN 30, 2015                        | U-320          |                   |
|                     |                                      | 4970198          | NOV 30, 2007                        |                |                   |
|                     |                                      | 5079233          | JAN 07, 2009                        |                |                   |
|                     |                                      | 5585089          | DEC 17, 2013                        |                |                   |
|                     |                                      | 5981589          | MAY 24, 2014                        |                |                   |
| 020622 001          | GLATIRAMER ACETATE; COPAXONE         | 6054430          | MAY 24, 2014                        |                |                   |
| 021178 001          | GLYBURIDE; GLUCOVANCE                |                  |                                     | NC             | JUL 31, 2003      |
| 021178 002          | GLYBURIDE; GLUCOVANCE                |                  |                                     | NC             | JUL 31, 2003      |
| 021178 003          | GLYBURIDE; GLUCOVANCE                |                  |                                     | NC             | JUL 31, 2003      |
| 020125 001          | HYDROCHLOROTHIAZIDE; ACCURETIC       |                  |                                     | NC             | DEC 28, 2002      |
| 020125 002          | HYDROCHLOROTHIAZIDE; ACCURETIC       |                  |                                     | NC             | DEC 28, 2002      |
| 020125 003          | HYDROCHLOROTHIAZIDE; ACCURETIC       |                  |                                     | NC             | DEC 28, 2002      |
| 020387 002          | HYDROCHLOROTHIAZIDE; HYZAAR          | 5138069          | AUG 11, 2009                        |                |                   |
|                     |                                      | 5153197          | OCT 06, 2009                        | U-3            |                   |
| 021162 001          | HYDROCHLOROTHIAZIDE; MICARDIS HCT    | 5591762          | JAN 07, 2014                        | U-3            | NC NOV 17, 2003   |
| 021162 002          | HYDROCHLOROTHIAZIDE; MICARDIS HCT    | 5591762          | JAN 07, 2014                        | U-3            | NC NOV 17, 2003   |
| 019778 001          | HYDROCHLOROTHIAZIDE; PRINZIDE        | 4374829          | DEC 29, 2001                        |                |                   |
| 019778 002          | HYDROCHLOROTHIAZIDE; PRINZIDE        | 4374829          | DEC 29, 2001                        |                |                   |
| 019778 003          | HYDROCHLOROTHIAZIDE; PRINZIDE        | 4374829          | DEC 29, 2001                        | U-3            |                   |
| >ADD> 019888 001    | HYDROCHLOROTHIAZIDE; ZESTORETIC      | 4374829          | DEC 29, 2001                        | U-3            |                   |
| >ADD> 019888 002    | HYDROCHLOROTHIAZIDE; ZESTORETIC      | 4374829          | DEC 29, 2001                        | U-3            |                   |
| >ADD> 019888 003    | HYDROCHLOROTHIAZIDE; ZESTORETIC      | 4374829          | DEC 29, 2001                        | U-3            |                   |
| 019771 001          | IBUPROFEN; ADVIL COLD AND SINUS      | 4552899          | APR 09, 2004                        |                |                   |
|                     |                                      | 4552899*PED      | OCT 09, 2004                        |                |                   |
| 021128 001          | IBUPROFEN; CHILDREN'S MOTRIN CO      |                  |                                     | NP             | AUG 01, 2003      |
| >ADD> 019012 004    | IBUPROFEN; MOTRIN MIGRAINE PAIN      |                  |                                     | NP             | FEB 26, 2003      |
| >ADD> 020491 001    | IBUTILIDE FUMARATE; CORVERT          | 5155268          | DEC 28, 2009                        |                |                   |
| 019763 003          | IFOSFAMIDE; IFEX/MESNEX KIT          | 4220660          | MAR 06, 2001                        | U-21           |                   |
|                     |                                      | 5696172          | OCT 06, 2013                        |                |                   |
| 019763 004          | IFOSFAMIDE; IFEX/MESNEX KIT          | 4220660          | MAR 06, 2001                        | U-21           |                   |
|                     |                                      | 5696172          | OCT 06, 2013                        |                |                   |

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|---------------------|--------------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020986 001          | INSULIN ASPART RECOMBINANT;NOVOLOG         |                  |                            |             | NCE            | JUN 07, 2005      |
| 021081 001          | INSULIN GLARGINE;LANTUS                    |                  |                            |             | PED            | OCT 20, 2005      |
| 020563 001          | INSULIN LISPRO;HUMALOG                     |                  |                            |             | NCE            | APR 20, 2005      |
| 021018 001          | INSULIN LISPRO;HUMALOG MIX 50/50           |                  |                            |             | D-56           | APR 04, 2003      |
| 021017 001          | INSULIN LISPRO;HUMALOG MIX 75/25           | 5474978          | JUN 16, 2014               |             | NC             | DEC 22, 2002      |
|                     |                                            | 5747642          | JUN 16, 2014               |             |                |                   |
|                     |                                            | 5461031          | JUN 16, 2014               |             |                |                   |
|                     |                                            | 5514646          | MAY 07, 2013               |             |                |                   |
| 020563 002          | INSULIN LISPRO;HUMALOG PEN                 | 5474978          | JUN 16, 2014               |             | D-56           | APR 04, 2003      |
|                     |                                            | 5514646          | MAY 07, 2013               | U-111       | NCE            | JUN 14, 2001      |
| 020571 001          | IRINOTECAN HYDROCHLORIDE;CAMPTOSAR         |                  |                            |             | I-299          | APR 20, 2003      |
| 021135 001          | IRON SUCROSE;VENOFER                       |                  |                            |             | NP             | NOV 07, 2003      |
| 020966 001          | ITRACONAZOLE;SPORANOX                      | 4727064          | FEB 23, 2005               |             |                |                   |
| 019084 001          | KETOCONAZOLE;NIZORAL                       | 4942162          | FEB 11, 2003               |             |                |                   |
| 020811 001          | KETOROLAC TROMETHAMINE;ACULAR PRESERVATIVE | 4454151          | MAR 22, 2002               |             |                |                   |
| 020857 001          | LAMIVUDINE;COMBIVIR                        | 4828838*PED      | MAR 17, 2006               |             | NCE            | NOV 17, 2000      |
|                     |                                            | 4833130*PED      | MAR 17, 2006               |             | PED            | MAY 17, 2001      |
|                     |                                            | 4837208          | SEP 17, 2005               |             |                |                   |
|                     |                                            | 5047407*PED      | AUG 08, 2009               |             |                |                   |
|                     |                                            | 4724232*PED      | MAR 17, 2006               |             |                |                   |
|                     |                                            | 4818538*PED      | MAR 17, 2006               |             |                |                   |
|                     |                                            | 5859021*PED      | NOV 15, 2012               | U-248       |                |                   |
|                     |                                            | 5905082*PED      | NOV 18, 2016               | U-248       |                |                   |
|                     |                                            | 6113920          | OCT 23, 2017               | U-257       |                |                   |
|                     |                                            | 6113920*PED      | APR 23, 2018               | U-257       |                |                   |
|                     |                                            | 4724232          | SEP 17, 2005               |             |                |                   |
|                     |                                            | 4818538          | SEP 17, 2005               |             |                |                   |
|                     |                                            | 4828838          | SEP 17, 2005               |             |                |                   |
|                     |                                            | 4833130          | SEP 17, 2005               |             |                |                   |
|                     |                                            | 5047407          | FEB 08, 2009               |             |                |                   |
|                     |                                            | 5859021          | MAY 15, 2012               | U-248       |                |                   |
|                     |                                            | 5905082          | MAY 18, 2016               | U-248       |                |                   |
|                     |                                            | 4837208*PED      | MAR 17, 2006               |             |                |                   |
| 020564 001          | LAMIVUDINE;EPIVIR                          | 5047407          | NOV 17, 2009               |             | NCE            | NOV 17, 2000      |
|                     |                                            | 5905082          | MAY 18, 2016               |             | PED            | MAY 17, 2001      |
|                     |                                            | 5905082*PED      | NOV 18, 2016               |             |                |                   |
|                     |                                            | 5047407*PED      | MAY 17, 2010               |             |                |                   |
| 020596 001          | LAMIVUDINE;EPIVIR                          | 5047407          | NOV 17, 2009               |             | NCE            | NOV 17, 2000      |
|                     |                                            | 6004968          | MAR 20, 2018               |             | PED            | MAY 17, 2001      |
|                     |                                            | 6004968*PED      | SEP 20, 2018               |             |                |                   |
|                     |                                            | 5047407*PED      | MAY 17, 2010               |             |                |                   |
| 021003 001          | LAMIVUDINE;EPIVIR-HBV                      | 5047407          | FEB 08, 2009               |             | I-257          | DEC 08, 2001      |
|                     |                                            | 5532246          | JUL 02, 2013               | U-250       | PED            | JUN 08, 2002      |
|                     |                                            | 5905082          | MAY 18, 2016               |             |                |                   |
|                     |                                            | 5047407*PED      | AUG 08, 2009               |             |                |                   |
|                     |                                            | 5532246*PED      | JAN 02, 2014               | U-250       |                |                   |
|                     |                                            | 5905082*PED      | NOV 18, 2016               |             |                |                   |

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|---------------------|--------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 021004 001          | LAMIVUDINE; EPIVIR-HBV               | 5047407          | FEB 08, 2009               |             | NCE            | NOV 17, 2000      |
|                     |                                      | 5532246          | JUL 02, 2013               | U-250       | I-257          | DEC 08, 2001      |
|                     |                                      | 6004968          | MAR 20, 2018               |             | PED            | MAY 17, 2001      |
|                     |                                      | 5047407*PED      | AUG 08, 2009               |             | PED            | JUN 08, 2002      |
|                     |                                      | 5532246*PED      | JAN 02, 2014               | U-250       |                |                   |
|                     |                                      | 6004968*PED      | SEP 20, 2018               |             |                |                   |
| 020406 001          | LANSOPRAZOLE; PREVACID               |                  |                            |             | I-316          | NOV 30, 2003      |
| 020406 002          | LANSOPRAZOLE; PREVACID               |                  |                            |             | I-316          | NOV 30, 2003      |
| >ADD> 020726 001    | LETROZOLE; FEMARA                    |                  |                            |             | I-318          | JAN 10, 2004      |
| >ADD> 021088 001    | LEUPROLIDE ACETATE; VIADUR           |                  |                            |             | NP             | MAR 03, 2003      |
|                     |                                      | 6156331          | JAN 30, 2017               |             |                |                   |
|                     |                                      | 5728396          | JAN 30, 2017               | U-316       |                |                   |
|                     |                                      | 5932547          | JUN 13, 2017               |             |                |                   |
|                     |                                      | 5985305          | JAN 30, 2017               |             |                |                   |
|                     |                                      | 6113938          | JUL 24, 2018               |             |                |                   |
|                     |                                      | 6124261          | JUN 13, 2017               |             |                |                   |
|                     |                                      | 6132420          | JAN 30, 2017               |             |                |                   |
| 020837 001          | LEVALBUTEROL HYDROCHLORIDE; XOPENEX  | 5362755          | NOV 08, 2011               | U-332       |                |                   |
|                     |                                      | 5547994          | AUG 20, 2013               | U-332       |                |                   |
|                     |                                      | 5760090          | JAN 05, 2010               | U-332       |                |                   |
|                     |                                      | 5844002          | JAN 05, 2010               | U-332       |                |                   |
| 020837 002          | LEVALBUTEROL HYDROCHLORIDE; XOPENEX  | 5362755          | NOV 08, 2011               | U-332       |                |                   |
|                     |                                      | 5547994          | AUG 20, 2013               | U-332       |                |                   |
|                     |                                      | 5760090          | JAN 05, 2010               | U-332       |                |                   |
|                     |                                      | 5844002          | JAN 05, 2010               | U-332       |                |                   |
| >ADD> 021114 001    | LEVOBETAXOLOL HYDROCHLORIDE; BETAXON | 4911920          | MAR 27, 2007               | U-369       | NP             | FEB 23, 2003      |
| >ADD> 020634 001    | LEVOFLOXACIN; LEVAQUIN               | 5540918          | JUL 30, 2013               |             |                |                   |
| >ADD> 020634 002    | LEVOFLOXACIN; LEVAQUIN               | 5053407          | DEC 20, 2010               |             | I-305          | FEB 02, 2003      |
| >ADD> 020634 003    | LEVOFLOXACIN; LEVAQUIN               | 5053407          | DEC 20, 2010               |             | I-305          | FEB 02, 2003      |
| >ADD> 020635 001    | LEVOFLOXACIN; LEVAQUIN               | 5053407          | DEC 20, 2010               |             | I-305          | FEB 02, 2003      |
| >ADD> 020635 002    | LEVOFLOXACIN; LEVAQUIN IN DEXTROSE   | 5053407          | DEC 20, 2010               |             | I-305          | FEB 02, 2003      |
| >ADD> 020635 003    | LEVOFLOXACIN; LEVAQUIN IN DEXTROSE   | 5053407          | DEC 20, 2010               |             | I-305          | FEB 02, 2003      |
| 021199 001          | LEVOFLOXACIN; QUIXIN                 | 4382892          | SEP 02, 2003               |             | NDF            | AUG 18, 2003      |
|                     |                                      | 5503407          | OCT 01, 2008               |             |                |                   |
|                     |                                      | 4551456          | NOV 14, 2003               |             |                |                   |
|                     |                                      | 5053407          | OCT 01, 2008               |             |                |                   |
| 021225 001          | LEVONORGESTREL; MIRENA               |                  |                            |             | NP             | DEC 06, 2003      |
| 019941 001          | LIDOCAINE; EMLA                      |                  |                            |             | I-314          | JAN 28, 2003      |
| 020612 001          | LIDOCAINE; LIDODERM                  |                  |                            |             | NP             | MAR 19, 2002      |
| 021130 001          | LINEZOLID; ZYVOX                     | 5688792          | NOV 18, 2014               | U-319       | NCE            | APR 18, 2005      |
| 021130 002          | LINEZOLID; ZYVOX                     | 5688792          | NOV 18, 2014               | U-319       | NCE            | APR 18, 2005      |
| 021131 001          | LINEZOLID; ZYVOX                     | 5688792          | NOV 18, 2014               | U-319       | NCE            | APR 18, 2005      |
| 021132 001          | LINEZOLID; ZYVOX                     | 5688792          | NOV 18, 2014               | U-319       | NCE            | APR 18, 2005      |
| 019558 001          | LISINAPRIL; PRINIVIL                 | 4374829          | DEC 29, 2001               |             |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME                | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 019558 002          | LISINOPRIL; PRINIVIL                       | 4374829          | DEC 29, 2001               |             |                |                   |
| 019558 003          | LISINOPRIL; PRINIVIL                       | 4374829          | DEC 29, 2001               |             |                |                   |
| 019558 004          | LISINOPRIL; PRINIVIL                       | 4374829          | DEC 29, 2001               |             |                |                   |
| 019558 006          | LISINOPRIL; PRINIVIL                       | 4374829          | DEC 29, 2001               |             |                |                   |
| >ADD> 019777 001    | LISINOPRIL; ZESTRIL                        | 4374829          | DEC 29, 2001               |             | I-288          | FEB 07, 2003      |
| >ADD> 019777 002    | LISINOPRIL; ZESTRIL                        | 4374829          | DEC 29, 2001               |             | I-288          | FEB 07, 2003      |
| >ADD> 019777 003    | LISINOPRIL; ZESTRIL                        | 4374829          | DEC 29, 2001               |             | I-288          | FEB 07, 2003      |
| >ADD> 019777 004    | LISINOPRIL; ZESTRIL                        | 4374829          | DEC 29, 2001               |             | I-288          | FEB 07, 2003      |
| >ADD> 019777 005    | LISINOPRIL; ZESTRIL                        | 4374829          | DEC 29, 2001               |             | I-288          | FEB 07, 2003      |
| >ADD> 019777 006    | LISINOPRIL; ZESTRIL                        | 4374829          | DEC 29, 2001               |             | I-288          | FEB 07, 2003      |
| >ADD> 021140 001    | LOPERAMIDE HYDROCHLORIDE; IMODIUM ADVANCED | 5612054          | SEP 28, 2010               |             |                |                   |
|                     |                                            | 5248505          | SEP 28, 2010               |             |                |                   |
| 021226 001          | LOPINAVIR; KALETRA                         | 5914332          | DEC 13, 2015               | U-351       | NC             | SEP 15, 2003      |
|                     |                                            | 5635523          | JUN 30, 2014               | U-352       | NCE            | MAR 01, 2001      |
|                     |                                            | 5541206          | JUL 30, 2013               | U-348       |                |                   |
|                     |                                            | 5674882          | OCT 07, 2014               | U-344       |                |                   |
|                     |                                            | 5886036          | DEC 29, 2012               | U-345       |                |                   |
|                     |                                            | 6037157          | JUN 26, 2016               | U-346       |                |                   |
|                     |                                            | 5846987          | DEC 29, 2012               | U-350       |                |                   |
|                     |                                            | 5648497          | JUL 15, 2014               |             |                |                   |
| 021251 001          | LOPINAVIR; KALETRA                         | 5541206          | JUL 30, 2013               | U-348       | NC             | SEP 15, 2003      |
|                     |                                            | 5914332          | DEC 13, 2005               | U-351       | NCE            | MAR 01, 2001      |
|                     |                                            | 5635523          | JUN 03, 2014               | U-352       |                |                   |
|                     |                                            | 5846987          | DEC 29, 2012               | U-350       |                |                   |
|                     |                                            | 5648497          | JUL 15, 2014               |             |                |                   |
|                     |                                            | 5674882          | OCT 07, 2014               | U-344       |                |                   |
|                     |                                            | 5886036          | DEC 29, 2012               | U-345       |                |                   |
|                     |                                            | 6037157          | JUN 26, 2016               | U-346       |                |                   |
| 019658 001          | LORATADINE; CLARITIN                       | 4282233          | JUN 19, 2002               | U-77        |                |                   |
|                     |                                            | 4659716          | APR 21, 2004               | U-142       |                |                   |
|                     |                                            | 4863931          | SEP 15, 2008               |             |                |                   |
|                     |                                            | 4282233*PED      | DEC 19, 2002               | U-77        |                |                   |
|                     |                                            | 4659716*PED      | OCT 21, 2004               | U-142       |                |                   |
|                     |                                            | 4863931*PED      | MAR 15, 2009               |             |                |                   |
| 020641 001          | LORATADINE; CLARITIN                       | 4659716          | APR 21, 2004               | U-142       |                |                   |
|                     |                                            | 4282233          | JUN 19, 2002               | U-77        |                |                   |
|                     |                                            | 4863931          | SEP 15, 2008               |             |                |                   |
|                     |                                            | 4659716*PED      | OCT 21, 2004               | U-142       |                |                   |
|                     |                                            | 4863931*PED      | MAR 15, 2009               |             |                |                   |
|                     |                                            | 4282233*PED      | DEC 19, 2002               | U-77        |                |                   |
|                     |                                            | 6132758          | JUN 01, 2018               |             |                |                   |
| 020704 001          | LORATADINE; CLARITIN REDITABS              | 4659716          | APR 21, 2004               | U-142       |                |                   |
|                     |                                            | 4282233          | JUN 19, 2002               | U-77        |                |                   |
|                     |                                            | 4371516          | FEB 01, 2000               |             |                |                   |
|                     |                                            | 4863931          | SEP 15, 2008               |             |                |                   |
|                     |                                            | 4659716*PED      | OCT 21, 2004               | U-142       |                |                   |
|                     |                                            | 4282233*PED      | DEC 19, 2002               | U-77        |                |                   |
|                     |                                            | 4371516*PED      | AUG 01, 2000               |             |                |                   |
|                     |                                            | 4863931*PED      | MAR 15, 2009               |             |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME    | PATENT<br>NUMBER                    | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------|-------------------------------------|----------------------------|--------------|----------------|-------------------|
| 019670 001          | LORATADINE; CLARITIN-D         | 4282233                             | JUN 19, 2002               | U-77         |                |                   |
|                     |                                | 4659716                             | APR 21, 2004               | U-142        |                |                   |
|                     |                                | 4863931                             | SEP 15, 2008               |              |                |                   |
|                     |                                | 4282233*PED                         | DEC 19, 2002               | U-77         |                |                   |
|                     |                                | 4659716*PED                         | OCT 21, 2004               | U-142        |                |                   |
|                     |                                | 4863931*PED                         | MAR 15, 2009               |              |                |                   |
| 020470 001          | LORATADINE; CLARITIN-D 24 HOUR | 4659716                             | APR 21, 2004               | U-142        |                |                   |
|                     |                                | 4282233                             | JUN 19, 2002               | U-77         |                |                   |
|                     |                                | 5314697*PED                         | APR 23, 2013               |              |                |                   |
|                     |                                | 4863931                             | SEP 15, 2008               |              |                |                   |
|                     |                                | 4659716*PED                         | OCT 21, 2004               | U-142        |                |                   |
|                     |                                | 4282233*PED                         | DEC 19, 2002               | U-77         |                |                   |
|                     |                                | 4863931*PED                         | MAR 15, 2009               |              |                |                   |
|                     |                                | 5314697                             | APR 23, 2013               |              |                |                   |
| >ADD>               | 020803 001                     | LOTEPREDNOL ETABONATE; ALREX        | 4996335                    |              |                |                   |
| >ADD>               | 020583 001                     | LOTEPREDNOL ETABONATE; LOTEMAX      | 4996335                    |              |                |                   |
|                     | 020938 001                     | MELOXICAM; MOBIC                    |                            |              |                |                   |
|                     | 020049 001                     | MESALAMINE; PENTASA                 | 4980173                    | JAN 29, 2002 | U-78           |                   |
|                     | 019884 001                     | MESNA; MESNEX                       | 5696172                    | OCT 06, 2013 |                |                   |
|                     | 020357 001                     | METFORMIN HYDROCHLORIDE; GLUCOPHAGE |                            |              |                |                   |
|                     |                                |                                     |                            |              | NCE            | APR 13, 2005      |
|                     |                                |                                     |                            |              | PED            | SEP 03, 2000      |
|                     |                                |                                     |                            |              | NCE            | MAR 03, 2000      |
|                     |                                |                                     |                            |              | I-307          | OCT 22, 2001      |
|                     |                                |                                     |                            |              | PED            | APR 22, 2002      |
|                     |                                |                                     |                            |              | PED            | JUN 15, 2004      |
|                     |                                |                                     |                            |              | I-320          | DEC 15, 2003      |
|                     |                                |                                     |                            |              | PED            | SEP 03, 2000      |
|                     |                                |                                     |                            |              | NCE            | MAR 03, 2000      |
|                     |                                |                                     |                            |              | I-307          | OCT 22, 2001      |
|                     |                                |                                     |                            |              | PED            | SEP 03, 2000      |
|                     |                                |                                     |                            |              | PED            | APR 22, 2002      |
|                     |                                |                                     |                            |              | PED            | JUN 15, 2004      |
|                     |                                |                                     |                            |              | I-320          | DEC 15, 2003      |
|                     |                                |                                     |                            |              | NCE            | MAR 03, 2000      |
|                     |                                |                                     |                            |              | I-307          | OCT 22, 2001      |
|                     |                                |                                     |                            |              | PED            | SEP 03, 2000      |
|                     |                                |                                     |                            |              | PED            | APR 22, 2002      |
|                     |                                |                                     |                            |              | PED            | JUN 15, 2004      |
|                     |                                |                                     |                            |              | I-320          | DEC 15, 2003      |
|                     |                                |                                     |                            |              | PED            | SEP 03, 2000      |
|                     |                                |                                     |                            |              | NCE            | MAR 03, 2000      |
|                     |                                |                                     |                            |              | I-307          | OCT 22, 2001      |
|                     |                                |                                     |                            |              | PED            | APR 22, 2002      |
|                     |                                |                                     |                            |              | PED            | JUN 15, 2004      |
|                     |                                |                                     |                            |              | I-320          | DEC 15, 2003      |
|                     |                                |                                     |                            |              | NCE            | MAR 03, 2000      |
|                     |                                |                                     |                            |              | I-307          | OCT 22, 2001      |
|                     |                                |                                     |                            |              | PED            | APR 22, 2002      |
|                     |                                |                                     |                            |              | PED            | JUN 15, 2004      |
|                     |                                |                                     |                            |              | I-320          | DEC 15, 2003      |
|                     |                                |                                     |                            |              | NCE            | MAR 03, 2000      |
|                     |                                |                                     |                            |              | I-307          | OCT 22, 2001      |
|                     |                                |                                     |                            |              | PED            | APR 22, 2002      |
|                     |                                |                                     |                            |              | PED            | JUN 15, 2004      |
|                     |                                |                                     |                            |              | I-320          | DEC 15, 2003      |

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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME             | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-----------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| >ADD> 021202 001    | METFORMIN HYDROCHLORIDE; GLUCOPHAGE XR  | 5082668          | SEP 16, 2003               |             | NDF            | OCT 13, 2003      |
| >ADD> 021121 001    | METHYLPHENIDATE HYDROCHLORIDE; CONCERTA | 4783337          | SEP 16, 2003               |             | NP             | AUG 01, 2003      |
| >ADD>               |                                         | 4612008          | SEP 16, 2003               |             |                |                   |
| >ADD>               |                                         | 4519801          | JUL 12, 2002               |             |                |                   |
| >ADD> 021121 002    | METHYLPHENIDATE HYDROCHLORIDE; CONCERTA | 5082668          | SEP 16, 2003               |             | NP             | AUG 01, 2003      |
| >ADD>               |                                         | 4783337          | SEP 16, 2003               |             |                |                   |
| >ADD>               |                                         | 4612008          | SEP 16, 2003               |             |                |                   |
| >ADD>               |                                         | 4519801          | JUL 12, 2002               |             |                |                   |
| >ADD> 021121 003    | METHYLPHENIDATE HYDROCHLORIDE; CONCERTA | 5082668          | SEP 16, 2003               |             |                |                   |
| >ADD>               |                                         | 4783337          | SEP 16, 2003               |             |                |                   |
| >ADD>               |                                         | 4612008          | SEP 16, 2003               |             |                |                   |
| >ADD>               |                                         | 4519801          | JUL 12, 2002               |             |                |                   |
| >ADD>               |                                         | 4517179          | APR 29, 2003               |             |                |                   |
| >ADD> 019532 001    | METOLAZONE; MYKROX                      | 5840744          | JAN 15, 2008               | U-370       |                |                   |
| 020208 001          | METRONIDAZOLE; METROGEL-VAGINAL         |                  |                            |             |                |                   |
| 019815 001          | MIDODRINE HYDROCHLORIDE; PROAMATINE     |                  |                            |             | ODE            | SEP 06, 2003      |
| 019815 002          | MIDODRINE HYDROCHLORIDE; PROAMATINE     |                  |                            |             | ODE            | SEP 06, 2003      |
| 020687 001          | MIFEPRISTONE; MIFEPREX                  | 4386085          | JAN 08, 2002               |             | NCE            | SEP 28, 2005      |
|                     |                                         | 4447424          | JAN 08, 2002               |             |                |                   |
|                     |                                         | 4626531          | OCT 12, 2004               |             |                |                   |
| >ADD> 020415 001    | MIRTAZAPINE; REMERON                    | 5977099          | JUN 16, 2017               |             |                |                   |
| >ADD> 020415 002    | MIRTAZAPINE; REMERON                    | 5977099          | JUN 16, 2017               |             |                |                   |
| >ADD> 020415 003    | MIRTAZAPINE; REMERON                    | 5977099          | JUN 16, 2017               |             |                |                   |
| >ADD> 021208 001    | MIRTAZAPINE; REMERON                    | 5977099          | JUN 26, 2017               |             |                |                   |
| >ADD> 021208 002    | MIRTAZAPINE; REMERON                    | 5977099          | JUN 16, 2017               |             |                |                   |
| >ADD> 021208 003    | MIRTAZAPINE; REMERON                    | 5977099          | JUN 16, 2017               |             |                |                   |
| 021120 001          | MITOXANTRONE HYDROCHLORIDE; NOVANTRONE  |                  |                            |             | ODE            | OCT 13, 2007      |
| 020762 001          | MOMETASONE FUROATE MONOHYDRATE; NASONEX | 6127353          | OCT 03, 2017               |             |                |                   |
| 020830 002          | MONTELUKAST SODIUM; SINGULAIR           | 5565473          | NOV 30, 2010               | U-228       | I-300          | MAR 03, 2003      |
|                     |                                         |                  |                            |             | NS             | MAR 03, 2003      |
|                     |                                         |                  |                            |             | NCE            | FEB 20, 2003      |
| 019516 001          | MORPHINE SULFATE; MS CONTIN             | 4366310          | DEC 10, 2000               |             |                |                   |
| 019516 002          | MORPHINE SULFATE; MS CONTIN             | 4366310          | DEC 10, 2000               |             |                |                   |
| 019516 003          | MORPHINE SULFATE; MS CONTIN             | 4366310          | DEC 10, 2000               |             |                |                   |
| 019516 004          | MORPHINE SULFATE; MS CONTIN             | 4366310          | DEC 10, 2000               |             |                |                   |
| 019516 005          | MORPHINE SULFATE; MS CONTIN             | 4366310          | DEC 10, 2000               |             |                |                   |
| >ADD> 021204 001    | NATEGLINIDE; STARLIX                    |                  |                            |             | NCE            | DEC 22, 2005      |
| >ADD> 021204 002    | NATEGLINIDE; STARLIX                    |                  |                            |             | NCE            | DEC 22, 2005      |
| 020152 001          | NEFAZODONE HYDROCHLORIDE; SERZONE       | 5256664          | APR 28, 2012               |             |                |                   |
| 020152 002          | NEFAZODONE HYDROCHLORIDE; SERZONE       | 5256664          | APR 28, 2012               |             |                |                   |
| 020152 003          | NEFAZODONE HYDROCHLORIDE; SERZONE       | 5256664          | APR 28, 2012               |             |                |                   |
| 020152 004          | NEFAZODONE HYDROCHLORIDE; SERZONE       | 5256664          | APR 28, 2012               |             |                |                   |
| 020152 005          | NEFAZODONE HYDROCHLORIDE; SERZONE       | 5256664          | APR 28, 2012               |             |                |                   |
| 020152 006          | NEFAZODONE HYDROCHLORIDE; SERZONE       | 5256664          | APR 28, 2012               |             |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-----------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020381 001          | NIACIN;NIASPAN              | 6080428          | MAY 27, 2017               | U-331       |                |                   |
|                     |                             | 6129930          | SEP 20, 2013               | U-354       |                |                   |
| 020381 002          | NIACIN;NIASPAN              | 6080428          | MAY 27, 2017               | U-331       |                |                   |
|                     |                             | 6129930          | SEP 20, 2013               | U-354       |                |                   |
| 020381 003          | NIACIN;NIASPAN              | 6080428          | MAY 27, 2017               | U-331       |                |                   |
|                     |                             | 6129930          | SEP 20, 2013               | U-354       |                |                   |
| 020381 004          | NIACIN;NIASPAN              | 6080428          | MAY 27, 2017               | U-331       |                |                   |
|                     |                             | 6129930          | SEP 20, 2013               | U-354       |                |                   |
| 020381 005          | NIACIN;NIASPAN TITRATION ST | 6080428          | MAY 27, 2017               | U-331       |                |                   |
| 020076 001          | NICOTINE;HABITROL           | 5834011          | MAY 01, 2007               | U-355       |                |                   |
| 020076 002          | NICOTINE;HABITROL           | 5834011          | MAY 01, 2007               | U-355       |                |                   |
| 020076 003          | NICOTINE;HABITROL           | 5834011          | MAY 01, 2007               | U-355       |                |                   |
| 020076 004          | NICOTINE;HABITROL           | 5834011          | MAY 01, 2007               | U-355       |                |                   |
| 020076 005          | NICOTINE;HABITROL           | 5834011          | MAY 01, 2007               | U-355       |                |                   |
| 020076 006          | NICOTINE;HABITROL           | 5834011          | MAY 01, 2007               | U-355       |                |                   |
| 020536 001          | NICOTINE;NICOTROL           | 5501236          | JUN 08, 2010               |             |                |                   |
|                     |                             | 6098632          | JUN 08, 2010               |             |                |                   |
| 020714 001          | NICOTINE;NICOTROL           | 6098632          | JUN 08, 2010               |             |                |                   |
| 021134 001          | NITROGLYCERIN;NITROSTAT     |                  |                            |             | NDF            | MAY 01, 2003      |
| 021134 002          | NITROGLYCERIN;NITROSTAT     |                  |                            |             | NDF            | MAY 01, 2003      |
| 021134 003          | NITROGLYCERIN;NITROSTAT     |                  |                            |             | NDF            | MAY 01, 2003      |
| 019921 001          | OFLOXACIN;OCUFLOX           | 4382892          | SEP 02, 2003               |             |                |                   |
|                     |                             | 4551456          | NOV 14, 2003               | U-80        |                |                   |
| 020592 001          | OLANZAPINE;ZYPREXA          | 5817656          | APR 23, 2011               | U-360       | I-297          | MAR 17, 2003      |
|                     |                             | 5817657          | APR 23, 2011               | U-363       | I-313          | NOV 09, 2003      |
|                     |                             | 5627178          | APR 23, 2011               | U-364       |                |                   |
|                     |                             | 5817655          | APR 23, 2011               | U-364       |                |                   |
| 020592 002          | OLANZAPINE;ZYPREXA          | 5817656          | APR 23, 2011               | U-360       | I-297          | MAR 17, 2003      |
|                     |                             | 5817657          | APR 23, 2011               | U-363       | I-313          | NOV 09, 2003      |
|                     |                             | 5627178          | APR 23, 2011               | U-364       |                |                   |
|                     |                             | 5817655          | APR 23, 2011               | U-364       |                |                   |
| 020592 003          | OLANZAPINE;ZYPREXA          | 5817656          | APR 23, 2011               | U-360       | I-297          | MAR 17, 2003      |
|                     |                             | 5817657          | APR 23, 2011               | U-363       | I-313          | NOV 09, 2003      |
|                     |                             | 5627178          | APR 23, 2011               | U-364       |                |                   |
|                     |                             | 5817655          | APR 23, 2011               | U-364       |                |                   |
| 020592 004          | OLANZAPINE;ZYPREXA          | 5817656          | APR 23, 2011               | U-360       | I-297          | MAR 17, 2003      |
|                     |                             | 5817657          | APR 23, 2011               | U-363       | I-313          | NOV 09, 2003      |
|                     |                             | 5627178          | APR 23, 2011               | U-364       |                |                   |
|                     |                             | 5817655          | APR 23, 2011               | U-364       |                |                   |
| 020592 005          | OLANZAPINE;ZYPREXA          | 5817656          | APR 23, 2011               | U-360       | I-297          | MAR 17, 2003      |
|                     |                             | 5817657          | APR 23, 2011               | U-363       | I-313          | NOV 09, 2003      |
|                     |                             | 5627178          | APR 23, 2011               | U-364       |                |                   |
|                     |                             | 5817655          | APR 23, 2011               | U-364       |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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|---------------------|------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020592 006          | OLANZAPINE; ZYPREXA                | 5817656          | APR 23, 2011               | U-360       | I-297          | MAR 17, 2003      |
|                     |                                    | 5817657          | APR 23, 2011               | U-363       | I-313          | NOV 09, 2003      |
|                     |                                    | 5627178          | APR 23, 2011               | U-364       |                |                   |
|                     |                                    | 5817655          | APR 23, 2011               | U-364       |                |                   |
| 021086 001          | OLANZAPINE; ZYPREXA ZYDIS          | 5457895          | SEP 30, 2013               |             | NCE            | SEP 30, 2001      |
|                     |                                    | 5229382          | APR 23, 2011               | U-324       |                |                   |
|                     |                                    | 5605897          | FEB 25, 2014               | U-325       |                |                   |
|                     |                                    | 5627178          | APR 23, 2011               | U-326       |                |                   |
|                     |                                    | 5736541          | MAR 24, 2015               | U-328       |                |                   |
|                     |                                    | 5817655          | APR 23, 2011               | U-327       |                |                   |
|                     |                                    | 5817656          | APR 23, 2011               | U-326       |                |                   |
| 021086 002          | OLANZAPINE; ZYPREXA ZYDIS          | 5457895          | SEP 30, 2013               |             | NCE            | SEP 30, 2001      |
|                     |                                    | 5229382          | APR 23, 2011               | U-324       |                |                   |
|                     |                                    | 5605897          | FEB 25, 2014               | U-325       |                |                   |
|                     |                                    | 5627178          | APR 23, 2011               | U-326       |                |                   |
|                     |                                    | 5736541          | MAR 24, 2015               | U-328       |                |                   |
|                     |                                    | 5817655          | APR 23, 2011               | U-327       |                |                   |
|                     |                                    | 5817656          | APR 23, 2011               | U-326       |                |                   |
| 021086 003          | OLANZAPINE; ZYPREXA ZYDIS          | 5457895          | SEP 30, 2013               |             | NCE            | SEP 30, 2001      |
|                     |                                    | 5736541          | MAR 24, 2015               | U-328       |                |                   |
|                     |                                    | 5817655          | APR 23, 2011               | U-327       |                |                   |
|                     |                                    | 5817656          | APR 23, 2011               | U-326       |                |                   |
|                     |                                    | 5229382          | APR 23, 2011               | U-324       |                |                   |
|                     |                                    | 5605897          | FEB 25, 2014               | U-325       |                |                   |
|                     |                                    | 5627178          | APR 23, 2011               | U-326       |                |                   |
| 021086 004          | OLANZAPINE; ZYPREXA ZYDIS          | 5457895          | SEP 30, 2013               |             | NCE            | SEP 30, 2001      |
|                     |                                    | 5229382          | APR 23, 2011               | U-324       |                |                   |
|                     |                                    | 5605897          | FEB 25, 2014               | U-325       |                |                   |
|                     |                                    | 5627178          | APR 23, 2011               | U-326       |                |                   |
|                     |                                    | 5736541          | MAR 24, 2015               | U-328       |                |                   |
|                     |                                    | 5817655          | APR 23, 2011               | U-327       |                |                   |
|                     |                                    | 5817656          | APR 23, 2011               | U-326       |                |                   |
| 020688 001          | OLOPATADINE HYDROCHLORIDE; PATANOL |                  |                            |             | I-301          | MAR 20, 2003      |
| 019715 001          | OLSALAZINE SODIUM; DIPENTUM        | 4559330          | JUL 31, 2004               | U-58        |                |                   |
| 020103 001          | ONDANSETRON HYDROCHLORIDE; ZOFTRAN | 5344658          | SEP 06, 2011               |             |                |                   |
| 020103 002          | ONDANSETRON HYDROCHLORIDE; ZOFTRAN | 5344658          | SEP 06, 2011               |             |                |                   |
| 020103 003          | ONDANSETRON HYDROCHLORIDE; ZOFTRAN | 5344658          | SEP 06, 2011               |             | I-269          | AUG 27, 2002      |
|                     |                                    | 5578628          | JUN 24, 2006               | U-44        |                |                   |
|                     |                                    | 4753789          | JUN 24, 2006               | U-44        |                |                   |
|                     |                                    | 4695578          | JAN 25, 2005               |             |                |                   |
| 020605 001          | ONDANSETRON HYDROCHLORIDE; ZOFTRAN | 4695578          | JAN 25, 2005               | U-183       |                |                   |
| 020781 001          | ONDANSETRON; ZOFTRAN ODT           | 5955488          | NOV 14, 2015               |             |                |                   |
|                     |                                    | 6063802          | NOV 14, 2015               |             |                |                   |
|                     |                                    | 5578628          | JUN 24, 2006               | U-330       |                |                   |
|                     |                                    | 4695578          | JAN 25, 2005               | U-330       |                |                   |
|                     |                                    | 4753789          | JUN 24, 2006               | U-329       |                |                   |

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\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME     | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|---------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020781 002          | ONDANSETRON; ZOFTRAN ODT        | 5955488          | NOV 14, 2015               |             |                |                   |
|                     |                                 | 6063802          | NOV 14, 2015               |             |                |                   |
|                     |                                 | 5578628          | JUN 24, 2006               | U-330       |                |                   |
|                     |                                 | 4695578          | JAN 25, 2005               | U-330       |                |                   |
|                     |                                 | 4753789          | JUN 24, 2006               | U-330       |                |                   |
|                     |                                 | 6004996          | JAN 06, 2018               |             |                |                   |
| 020766 001          | ORLISTAT; XENICAL               |                  |                            |             |                |                   |
| >ADD> 021087 001    | OSELTAMIVIR PHOSPHATE; TAMIFLU  |                  |                            |             | I-317          | NOV 17, 2003      |
| 021014 001          | OXCARBAZEPINE; TRILEPTAL        |                  |                            |             | NCE            | JAN 14, 2005      |
| 021014 002          | OXCARBAZEPINE; TRILEPTAL        |                  |                            |             | NCE            | JAN 14, 2005      |
| 021014 003          | OXCARBAZEPINE; TRILEPTAL        |                  |                            |             | NCE            | JAN 14, 2005      |
| 075184 001          | PACLITAXEL; PACLITAXEL          |                  |                            |             | PC             | APR 21, 2001      |
| 020262 001          | PACLITAXEL; TAXOL               | 6096331          | FEB 22, 2013               |             | D-57           | JUN 20, 2003      |
| 020987 001          | PANTOPRAZOLE SODIUM; PROTONIX   | 4758579          | JUL 19, 2005               |             | NCE            | FEB 02, 2005      |
| 020819 001          | PARICALCITOL; ZEMPLAR           | 5246925          | SEP 21, 2010               | U-314       |                |                   |
|                     |                                 | 5587497          | DEC 24, 2013               |             |                |                   |
|                     |                                 | 6136799          | APR 08, 2018               |             |                |                   |
| >ADD> 020031 001    | PAROXETINE HYDROCHLORIDE; PAXIL | 6172233          | JAN 15, 2018               |             |                |                   |
|                     |                                 | 6063927          | APR 23, 2019               |             |                |                   |
|                     |                                 | 6080759          | MAY 19, 2015               |             |                |                   |
|                     |                                 | 6113944          | DEC 14, 2014               |             |                |                   |
|                     |                                 | 6121291          | MAR 17, 2017               | U-286       |                |                   |
|                     |                                 | 6133289          | MAY 19, 2015               | U-358       |                |                   |
| >ADD> 020031 002    | PAROXETINE HYDROCHLORIDE; PAXIL | 6172233          | JAN 15, 2018               |             |                |                   |
|                     |                                 | 6063927          | APR 23, 2019               |             |                |                   |
|                     |                                 | 6080759          | MAY 19, 2015               |             |                |                   |
|                     |                                 | 6113944          | DEC 14, 2014               |             |                |                   |
|                     |                                 | 6121291          | MAR 17, 2017               | U-286       |                |                   |
|                     |                                 | 6133289          | MAY 19, 2015               | U-358       |                |                   |
| >ADD> 020031 003    | PAROXETINE HYDROCHLORIDE; PAXIL | 6172233          | JAN 15, 2018               |             |                |                   |
|                     |                                 | 6063927          | APR 23, 2019               |             |                |                   |
|                     |                                 | 6080759          | MAY 19, 2015               |             |                |                   |
|                     |                                 | 6113944          | DEC 14, 2014               |             |                |                   |
|                     |                                 | 6121291          | MAR 17, 2017               | U-286       |                |                   |
|                     |                                 | 6133289          | MAY 19, 2015               | U-358       |                |                   |
| 020031 004          | PAROXETINE HYDROCHLORIDE; PAXIL | 6063927          | APR 23, 2019               |             |                |                   |
|                     |                                 | 6080759          | MAY 19, 2015               |             |                |                   |
|                     |                                 | 6113944          | DEC 14, 2014               |             |                |                   |
|                     |                                 | 6133289          | MAY 15, 2015               | U-358       |                |                   |
| >ADD> 020031 005    | PAROXETINE HYDROCHLORIDE; PAXIL | 6172233          | JAN 15, 2018               |             |                |                   |
|                     |                                 | 6063927          | APR 23, 2019               |             |                |                   |
|                     |                                 | 6080759          | MAY 19, 2015               |             |                |                   |
|                     |                                 | 6113944          | DEC 14, 2014               |             |                |                   |
|                     |                                 | 6121291          | MAR 17, 2017               | U-286       |                |                   |
|                     |                                 | 6133289          | MAY 15, 2015               | U-358       |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
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\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME                              | PATENT<br>NUMBER                                    | PATENT/PED EXCL<br>EXPIRES                                                   | USE<br>CODE    | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|----------------------------------------------------------|-----------------------------------------------------|------------------------------------------------------------------------------|----------------|----------------|-------------------|
| >ADD> 020710 001    | PAROXETINE HYDROCHLORIDE; PAXIL                          | 6172233<br>6063927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-358 |                |                   |
| >ADD> 020885 001    | PAROXETINE HYDROCHLORIDE; PAXIL                          | 6172233<br>6063927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-358 |                |                   |
| >ADD> 020885 002    | PAROXETINE HYDROCHLORIDE; PAXIL                          | 6172233<br>6063927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-358 |                |                   |
| >ADD> 020885 003    | PAROXETINE HYDROCHLORIDE; PAXIL                          | 6172233<br>6063927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-358 |                |                   |
| >ADD> 020885 004    | PAROXETINE HYDROCHLORIDE; PAXIL                          | 6172233<br>6062927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-358 |                |                   |
| >ADD> 020936 001    | PAROXETINE HYDROCHLORIDE; PAXIL CR                       | 6172233<br>6063927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-358 |                |                   |
| >ADD> 020936 002    | PAROXETINE HYDROCHLORIDE; PAXIL CR                       | 6172233<br>6063927<br>6080759<br>6121291<br>6133289 | JAN 15, 2018<br>APR 23, 2019<br>MAY 19, 2015<br>MAR 17, 2017<br>MAY 19, 2015 | U-286<br>U-286 |                |                   |
| >ADD> 020936 003    | PAROXETINE HYDROCHLORIDE; PAXIL CR                       | 5607979                                             | MAY 30, 2015                                                                 |                | NDF            | FEB 16, 2002      |
| 021084 001          | PERFLUOROPOLYMETHYLISOPROPYL ETHER; SKIN EXPOSURE REDUCT | 6048901                                             | APR 20, 2019                                                                 | U-343          | NCE            | FEB 17, 2005      |
| 020698 001          | POLYETHYLENE GLYCOL 3350; MIRALAX                        | 5622985                                             | APR 22, 2014                                                                 | U-335          | I-281          | JUN 09, 2003      |
| 019898 002          | PRAVASTATIN SODIUM; PRAVACHOL                            |                                                     |                                                                              |                | I-304          | JAN 18, 2003      |
|                     |                                                          |                                                     |                                                                              |                | I-287          | FEB 10, 2003      |
|                     |                                                          |                                                     |                                                                              |                | I-286          | JAN 18, 2003      |
|                     |                                                          |                                                     |                                                                              |                | D-51           | JAN 18, 2003      |
| 019898 003          | PRAVASTATIN SODIUM; PRAVACHOL                            | 5622985                                             | APR 22, 2014                                                                 | U-335          | I-281          | JUN 09, 2003      |
|                     |                                                          |                                                     |                                                                              |                | I-304          | JAN 18, 2003      |
|                     |                                                          |                                                     |                                                                              |                | I-287          | FEB 10, 2003      |
|                     |                                                          |                                                     |                                                                              |                | I-286          | JAN 18, 2003      |
|                     |                                                          |                                                     |                                                                              |                | D-51           | JAN 18, 2003      |

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|---------------------|-------------------------------|------------------------------------------|----------------------------|--------------|------------------------------------------------|----------------------------------------------------------------------------------------------|
| 019898 004          | PRAVASTATIN SODIUM; PRAVACHOL | 5622985                                  | APR 22, 2014               | U-335        | I-281<br>I-304<br>I-287<br>I-286<br>D-51<br>PC | JUN 09, 2003<br>JAN 18, 2003<br>FEB 10, 2003<br>JAN 18, 2003<br>JAN 18, 2003<br>JUL 02, 2001 |
| >ADD>               | 075117 001                    | PREDNISOLONE SODIUM PHOSPHATE; ORAPRED   | 4448774                    | DEC 22, 2002 |                                                |                                                                                              |
|                     | 019157 001                    | PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED | 4587258                    | JAN 27, 2005 |                                                |                                                                                              |
|                     | 019901 001                    | RAMIPRIL; ALTACE                         | 5061722                    | OCT 19, 2008 | U-3                                            | I-310 OCT 04, 2003                                                                           |
|                     | 019901 002                    | RAMIPRIL; ALTACE                         | 4587258                    | JAN 27, 2005 |                                                |                                                                                              |
|                     | 019901 003                    | RAMIPRIL; ALTACE                         | 5061722                    | OCT 19, 2008 | U-3                                            | I-310 OCT 04, 2003                                                                           |
|                     | 019901 004                    | RAMIPRIL; ALTACE                         | 4587258                    | JAN 27, 2005 |                                                |                                                                                              |
|                     | 020630 001                    | REMIFENTANIL HYDROCHLORIDE; ULTIVA       | 5019583*PED                | AUG 15, 2009 |                                                |                                                                                              |
|                     |                               |                                          | 5466700                    | AUG 30, 2013 | U-156                                          | NPP OCT 15, 2002                                                                             |
|                     |                               |                                          | 5019583                    | FEB 15, 2009 |                                                | PED APR 15, 2003                                                                             |
|                     |                               |                                          | 5466700*PED                | MAR 01, 2014 | U-156                                          | PED JAN 12, 2002                                                                             |
|                     | 020630 002                    | REMIFENTANIL HYDROCHLORIDE; ULTIVA       | 5019583                    | FEB 15, 2009 |                                                | NCE JUL 12, 2001                                                                             |
|                     |                               |                                          | 5466700                    | AUG 30, 2013 | U-156                                          | NPP OCT 15, 2002                                                                             |
|                     |                               |                                          | 5019583*PED                | AUG 15, 2009 |                                                | PED APR 15, 2003                                                                             |
|                     |                               |                                          | 5466700*PED                | MAR 01, 2014 |                                                | PED JAN 12, 2002                                                                             |
|                     | 020630 003                    | REMIFENTANIL HYDROCHLORIDE; ULTIVA       | 5019583                    | FEB 15, 2009 |                                                | NCE JUL 12, 2001                                                                             |
|                     |                               |                                          | 5466700                    | AUG 30, 2013 | U-156                                          | NPP OCT 15, 2002                                                                             |
|                     |                               |                                          | 5019583*PED                | AUG 15, 2009 |                                                | PED APR 15, 2003                                                                             |
|                     |                               |                                          | 5466700*PED                | MAR 01, 2014 | U-156                                          | PED JAN 12, 2002                                                                             |
|                     | 020903 001                    | RIBAVIRIN; REBETOL                       | 6051252                    | DEC 22, 2017 |                                                |                                                                                              |
| >ADD>               | 020835 001                    | RISEDRONATE SODIUM; ACTONEL              | 6096342                    | MAR 12, 2017 |                                                | I-292 APR 14, 2003                                                                           |
| >ADD>               |                               |                                          | 6165513                    | JUN 10, 2018 |                                                | I-291 APR 14, 2003                                                                           |
|                     |                               |                                          |                            |              |                                                | I-290 APR 14, 2003                                                                           |
|                     |                               |                                          |                            |              |                                                | I-293 APR 14, 2003                                                                           |
| >ADD>               | 020835 002                    | RISEDRONATE SODIUM; ACTONEL              | 6096342                    | MAR 12, 2017 |                                                | I-292 APR 14, 2003                                                                           |
| >ADD>               |                               |                                          | 6165513                    | JUN 10, 2018 |                                                | NCE MAR 27, 2003                                                                             |
|                     |                               |                                          | 5583122                    | DEC 10, 2013 | U-222                                          | I-291 APR 14, 2003                                                                           |
|                     |                               |                                          |                            |              |                                                | I-293 APR 14, 2003                                                                           |
|                     |                               |                                          |                            |              |                                                | I-290 APR 14, 2003                                                                           |
| 020588 001          | RISPERIDONE; RISPERDAL        | 5453425                                  | JUL 11, 2014               |              |                                                |                                                                                              |
|                     |                               | 5616587                                  | JUL 11, 2014               |              |                                                |                                                                                              |
| 020659 001          | RITONAVIR; NORVIR             | 6037157                                  | JUN 26, 2016               |              |                                                |                                                                                              |
|                     |                               | 5674882                                  | OCT 07, 2014               |              |                                                |                                                                                              |
|                     |                               | 5886036                                  | DEC 29, 2012               |              |                                                |                                                                                              |
| 020945 001          | RITONAVIR; NORVIR             | 5648497                                  | JUL 15, 2014               |              | NCE                                            | MAR 01, 2001                                                                                 |
|                     |                               | 5846987                                  | DEC 29, 2012               | U-347        |                                                |                                                                                              |
|                     |                               | 5541206                                  | JUL 30, 2013               | U-348        |                                                |                                                                                              |
|                     |                               | 5635523                                  | JUN 03, 2014               | U-347        |                                                |                                                                                              |

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|---------------------|------------------------------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020823 003          | RIVASTIGMINE TARTRATE; EXELON                  | 4948807          | AUG 14, 2007               | U-322       | NCE            | APR 21, 2005      |
|                     |                                                | 5602176          | FEB 11, 2014               | U-322       |                |                   |
| 020823 004          | RIVASTIGMINE TARTRATE; EXELON                  | 4948807          | AUG 14, 2007               | U-322       | NCE            | APR 21, 2005      |
|                     |                                                | 5602176          | FEB 11, 2014               | U-322       |                |                   |
| 020823 005          | RIVASTIGMINE TARTRATE; EXELON                  | 4948807          | AUG 14, 2007               | U-322       | NCE            | APR 21, 2005      |
|                     |                                                | 5602176          | FEB 11, 2014               | U-322       |                |                   |
| 020823 006          | RIVASTIGMINE TARTRATE; EXELON                  | 4948807          | AUG 14, 2007               | U-322       | NCE            | APR 21, 2005      |
|                     |                                                | 5602176          | FEB 11, 2014               | U-322       |                |                   |
| 021025 001          | RIVASTIGMINE TARTRATE; EXELON                  | 4948807          | AUG 14, 2007               | U-322       | NCE            | APR 21, 2005      |
|                     |                                                | 5602176          | FEB 11, 2014               | U-322       |                |                   |
| 020864 001          | RIZATRIPTAN BENZOATE; MAXALT                   | 5602162          | FEB 11, 2014               |             |                |                   |
| 020864 002          | RIZATRIPTAN BENZOATE; MAXALT                   | 5602162          | FEB 11, 2014               |             |                |                   |
| 021042 001          | ROFECOXIB; VIOXX                               | 6063811          | MAY 16, 2017               | U-266       |                |                   |
| 021042 002          | ROFECOXIB; VIOXX                               | 6063811          | MAY 16, 2017               | U-266       |                |                   |
| 021042 003          | ROFECOXIB; VIOXX                               |                  |                            |             | NCE            | MAY 20, 2004      |
| 021052 001          | ROFECOXIB; VIOXX                               | 6063811          | MAY 16, 2017               | U-266       |                |                   |
| 021052 002          | ROFECOXIB; VIOXX                               | 6063811          | MAY 16, 2017               | U-266       |                |                   |
| 020533 001          | ROPIVACAINE HYDROCHLORIDE MONOHYDRATE; NAROPIN |                  |                            |             | D-64           | NOV 02, 2003      |
| 020533 003          | ROPIVACAINE HYDROCHLORIDE MONOHYDRATE; NAROPIN |                  |                            |             | D-64           | NOV 02, 2003      |
| 020533 004          | ROPIVACAINE HYDROCHLORIDE MONOHYDRATE; NAROPIN |                  |                            |             | D-64           | NOV 02, 2003      |
| 020533 005          | ROPIVACAINE HYDROCHLORIDE MONOHYDRATE; NAROPIN |                  |                            |             | D-64           | NOV 02, 2003      |
| 021071 002          | ROSIGLITAZONE MALEATE; AVANDIA                 | 5002953          | AUG 30, 2008               | U-329       | I-289          | APR 03, 2003      |
|                     |                                                | 5741803          | APR 21, 2015               | U-329       |                |                   |
| 021071 003          | ROSIGLITAZONE MALEATE; AVANDIA                 | 5002953          | AUG 30, 2008               | U-329       | I-289          | APR 03, 2003      |
|                     |                                                | 5741803          | APR 21, 2015               | U-329       |                |                   |
| 021071 004          | ROSIGLITAZONE MALEATE; AVANDIA                 | 5002953          | AUG 30, 2008               | U-329       | I-289          | APR 03, 2003      |
|                     |                                                | 5741803          | APR 21, 2015               | U-329       |                |                   |
| >ADD> 020236 001    | SALMETEROL XINAFOATE; SEREVENT                 |                  |                            |             | M-5            | JUN 30, 2003      |
| >ADD> 020692 001    | SALMETEROL XINAFOATE; SEREVENT                 |                  |                            |             | M-5            | JUN 30, 2003      |
| 020990 001          | SERTRALINE HYDROCHLORIDE; ZOLOFT               | 4536518          | DEC 30, 2005               | U-286       |                |                   |
|                     |                                                | 4940731          | AUG 30, 2009               | U-312       |                |                   |
| 021179 001          | SEVELAMER HYDROCHLORIDE; RENAGEL               | 5496545          | AUG 11, 2013               | U-246       | NCE            | OCT 30, 2003      |
|                     |                                                | 5667775          | SEP 16, 2014               | U-246       |                |                   |
| 021179 002          | SEVELAMER HYDROCHLORIDE; RENAGEL               | 5496545          | AUG 11, 2013               | U-246       | NCE            | OCT 30, 2003      |
|                     |                                                | 5667775          | SEP 16, 2014               | U-246       |                |                   |
| 020478 001          | SEVOFLURANE; ULTANE                            | 5990176          | JAN 27, 2017               |             | NCE            | JUN 07, 2000      |
|                     |                                                | 6074668          | JAN 09, 2018               |             | PED            | DEC 07, 2000      |
|                     |                                                | 5990176*PED      | JUL 27, 2017               |             |                |                   |
|                     |                                                | 6074668*PED      | JUL 09, 2018               |             |                |                   |
| 021097 001          | SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; VISICOL  | 5616346          | APR 01, 2017               | U-359       | NP             | SEP 21, 2003      |
| 020280 006          | SOMATROPIN RECOMBINANT; GENOTROPIN             | 4968299          | JUN 28, 2008               |             | I-302          | JUN 20, 2003      |
|                     |                                                |                  |                            |             | ODE            | JUN 20, 2007      |
| 020280 007          | SOMATROPIN RECOMBINANT; GENOTROPIN             | 4968299          | JUN 28, 2008               |             | I-302          | JUN 20, 2003      |
|                     |                                                |                  |                            |             | ODE            | JUN 20, 2007      |

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|---------------------|----------------------------------------------|------------------|-------------------------------------|----------------|-------------------|
| 020280 001          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 002          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 003          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 004          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT |                  |                                     | I-302          | JUN 20, 2000      |
|                     |                                              |                  |                                     | ODE            | JUN 20, 2007      |
| 020280 005          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 008          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 009          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 010          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 011          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5716338          | FEB 10, 2015                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5435076          | APR 16, 2013                        | ODE            | JUN 20, 2007      |
| 020280 012          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 020280 013          | SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT | 5435076          | APR 16, 2013                        | I-302          | JUN 20, 2003      |
|                     |                                              | 5716338          | FEB 10, 2015                        | ODE            | JUN 20, 2007      |
| 019721 001          | SOMATROPIN RECOMBINANT; NORDITROPIN          | 5633352          | MAY 27, 2014                        |                |                   |
| 019721 002          | SOMATROPIN RECOMBINANT; NORDITROPIN          | 5633352          | MAY 27, 2014                        |                |                   |
| 019676 001          | SOMATROPIN RECOMBINANT; NUTROPIN             |                  |                                     | D-55           | APR 13, 2003      |
|                     |                                              |                  |                                     | M-2            | DEC 01, 2002      |
| 019676 002          | SOMATROPIN RECOMBINANT; NUTROPIN             |                  |                                     | D-55           | APR 13, 2003      |
|                     |                                              |                  |                                     | M-2            | DEC 01, 2002      |
| 020522 001          | SOMATROPIN RECOMBINANT; NUTROPIN AQ          |                  |                                     | D-55           | APR 13, 2003      |
|                     |                                              |                  |                                     | M-2            | DEC 01, 2002      |
| 021075 001          | SOMATROPIN RECOMBINANT; NUTROPIN DEPOT       | 6051259          | DEC 02, 2012                        | U-340          |                   |
| 021075 002          | SOMATROPIN RECOMBINANT; NUTROPIN DEPOT       | 6051259          | DEC 02, 2012                        | U-340          |                   |
| 021075 003          | SOMATROPIN RECOMBINANT; NUTROPIN DEPOT       | 6051259          | DEC 02, 2012                        | U-340          |                   |
| 021151 001          | SOTALOL HYDROCHLORIDE; BETAPACE AF           |                  |                                     | NP             | FEB 22, 2003      |
| 021151 002          | SOTALOL HYDROCHLORIDE; BETAPACE AF           |                  |                                     | NP             | FEB 22, 2003      |
| 021151 003          | SOTALOL HYDROCHLORIDE; BETAPACE AF           |                  |                                     | NP             | FEB 22, 2003      |
| 007073 002          | SULFASALAZINE; AZULFIDINE EN-TABS            |                  |                                     | I-308          | AUG 18, 2003      |
| 021184 001          | TAZAROTENE; TAZORAC                          |                  |                                     | NCE            | JUN 13, 2002      |
|                     |                                              |                  |                                     | NDF            | SEP 29, 2003      |
| 021184 002          | TAZAROTENE; TAZORAC                          |                  |                                     | NCE            | JUN 13, 2002      |
|                     |                                              |                  |                                     | NDF            | SEP 29, 2003      |
| 020256 001          | TECHNETIUM TC-99M BICISATE KIT; NEUROLITE    | 5431900          | JUL 11, 2012                        | U-336          |                   |
| 019785 001          | TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE  | 4894445          | JAN 16, 2007                        | U-337          |                   |
|                     |                                              | 5324824          | JAN 16, 2007                        |                |                   |
|                     |                                              | 4885100          | SEP 11, 2007                        |                |                   |
|                     |                                              | 4988827          | JAN 29, 2008                        |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME              | PATENT<br>NUMBER                  | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|------------------------------------------|-----------------------------------|----------------------------|--------------|----------------|-------------------|
| 019785 003          | TECHNETIUM TC-99M SESTAMIBI KIT;MIRALUMA | 4452774                           | SEP 09, 2004               |              |                |                   |
|                     |                                          | 4894445                           | JAN 16, 2007               | U-337        |                |                   |
|                     |                                          | 5324824                           | JAN 16, 2007               |              |                |                   |
|                     |                                          | 4885100                           | SEP 11, 2007               |              |                |                   |
|                     |                                          | 4988827                           | JAN 29, 2008               |              |                |                   |
| 021124 001          | TERBINAFINE HYDROCHLORIDE;LAMISIL AT     | 4680291                           | JUL 14, 2004               | U-73         |                |                   |
|                     |                                          | 4755534                           | DEC 30, 2006               | U-73         |                |                   |
|                     |                                          | 5681849                           | OCT 28, 2014               |              |                |                   |
| 021015 001          | TESTOSTERONE;ANDROGEL                    |                                   |                            |              | NDF            | FEB 28, 2003      |
| >ADD>               | 020785 001                               | THALIDOMIDE;THALOMID              | 6045501                    | AUG 28, 2018 | U-371          |                   |
| >ADD>               | 020963 001                               | TIMOLOL MALEATE;TIMOLOL MALEATE   | 6174524                    | MAR 26, 2019 |                |                   |
| >ADD>               | 020963 002                               | TIMOLOL MALEATE;TIMOLOL MALEATE   | 6174524                    | MAR 26, 2019 |                |                   |
|                     | 020484 001                               | TINZAPARIN SODIUM;INNOHEP         |                            |              | NCE            | JUL 14, 2005      |
| >ADD>               | 020912 001                               | TIROFIBAN HYDROCHLORIDE;AGGRASTAT | 6136794                    | JAN 29, 2019 |                |                   |
| >ADD>               | 020913 001                               | TIROFIBAN HYDROCHLORIDE;AGGRASTAT | 6136794                    | JAN 29, 2019 |                |                   |
|                     | 020771 001                               | TOLTERODINE TARTRATE;DETROL       | 5559269                    | MAY 05, 2015 | U-318          |                   |
|                     | 020771 002                               | TOLTERODINE TARTRATE;DETROL       | 5559269                    | MAY 05, 2015 | U-318          |                   |
| >ADD>               | 021228 001                               | TOLTERODINE TARTRATE;DETROL LA    | 5382600                    | JAN 17, 2012 | NDF            | DEC 22, 2003      |
| >ADD>               |                                          |                                   |                            |              | NCE            | MAR 25, 2003      |
| >ADD>               | 021228 002                               | TOLTERODINE TARTRATE;DETROL LA    | 5382600                    | JAN 17, 2012 | NDF            | DEC 22, 2003      |
| >ADD>               |                                          |                                   |                            |              | NCE            | MAR 25, 2003      |
| 020281 001          | TRAMADOL HYDROCHLORIDE;ULTRAM            |                                   |                            |              | PED            | SEP 03, 2000      |
|                     |                                          |                                   |                            |              | PED            | FEB 21, 2002      |
|                     |                                          |                                   |                            |              | NCE            | MAR 03, 2000      |
|                     |                                          |                                   |                            |              | D-44           | AUG 21, 2001      |
| 020281 002          | TRAMADOL HYDROCHLORIDE;ULTRAM            |                                   |                            |              | PED            | FEB 21, 2002      |
|                     |                                          |                                   |                            |              | PED            | SEP 03, 2000      |
|                     |                                          |                                   |                            |              | NCE            | MAR 03, 2000      |
|                     |                                          |                                   |                            |              | D-44           | AUG 21, 2001      |
|                     |                                          |                                   |                            |              | D-63           | DEC 23, 2002      |
|                     |                                          |                                   |                            |              | PED            | JUN 23, 2003      |
| >ADD>               |                                          |                                   |                            |              | NP             | AUG 31, 2003      |
| 021108 001          | TRETINOIN;RENOVA                         |                                   |                            |              |                |                   |
| 074973 001          | TRIMETHOPRIM HYDROCHLORIDE;PRIMSOL       | 5763449                           | AUG 07, 2016               |              |                |                   |
|                     |                                          | 5962461                           | AUG 07, 2016               |              |                |                   |
| 020326 001          | TRIMETREXATE GLUCURONATE;NEUTREXIN       | 6017922                           | MAY 18, 2018               |              |                |                   |
| 020326 002          | TRIMETREXATE GLUCURONATE;NEUTREXIN       | 6017922                           | MAY 18, 2018               |              |                |                   |
| 020715 001          | TRIPTORELIN PAMOATE;TRELSTAR DEPOT       | 5134122                           | JUL 20, 2010               |              | NCE            | JUN 15, 2005      |
|                     |                                          | 5225205                           | JUL 20, 2010               |              |                |                   |
|                     |                                          | 5192741                           | MAR 09, 2010               |              |                |                   |
| 020719 001          | TROGLITAZONE;PRELAY                      | 6046202                           | SEP 15, 2013               | U-317        |                |                   |
| 020719 002          | TROGLITAZONE;PRELAY                      | 6046202                           | SEP 15, 2013               | U-317        |                |                   |
| 020719 003          | TROGLITAZONE;PRELAY                      | 6046202                           | SEP 15, 2013               | U-317        |                |                   |
| 020720 001          | TROGLITAZONE;REZULIN                     | 6046202                           | SEP 15, 2013               | U-317        |                |                   |
| 020720 002          | TROGLITAZONE;REZULIN                     | 6046202                           | SEP 15, 2013               | U-317        |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME    | PATENT<br>NUMBER                    | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE  | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|--------------------------------|-------------------------------------|----------------------------|--------------|----------------|-------------------|
| 020720 003          | TROGLITAZONE; REZULIN          | 6046202                             | SEP 15, 2013               | U-317        |                |                   |
| 020759 001          | TROVAFLOXACIN MESYLATE; TROVAN | 5164402                             | DEC 18, 2011               | U-282        |                |                   |
| 020759 002          | TROVAFLOXACIN MESYLATE; TROVAN | 5164402                             | DEC 18, 2011               | U-282        |                |                   |
| 021214 001          | UNOPROSTONE ISOPROPYL; RESCULA | 5001153                             | SEP 19, 2008               |              | NCE            | AUG 03, 2005      |
|                     |                                | 5151444                             | MAR 19, 2008               | U-333        |                |                   |
|                     |                                | 5166178                             | NOV 24, 2009               | U-333        |                |                   |
|                     |                                | 5212200                             | MAY 18, 2010               | U-333        |                |                   |
|                     |                                | 5208256                             | MAY 21, 2011               | U-333        |                |                   |
|                     |                                | 5221763                             | JUN 22, 2010               |              |                |                   |
| >ADD>               | 020487 001                     | VALACYCLOVIR HYDROCHLORIDE; VALTREX | 4957924                    | JUN 23, 2009 |                |                   |
| >ADD>               |                                |                                     | 4567182                    | JAN 28, 2003 |                |                   |
| >ADD>               |                                |                                     | 5879706                    | JAN 19, 2016 |                |                   |
| >ADD>               |                                |                                     | 6107302                    | JAN 19, 2016 |                |                   |
| >ADD>               | 020487 002                     | VALACYCLOVIR HYDROCHLORIDE; VALTREX | 4567182                    | JAN 28, 2003 |                |                   |
| >ADD>               |                                |                                     | 5879706                    | JAN 19, 2016 |                |                   |
| >ADD>               |                                |                                     | 6107302                    | JAN 19, 2016 |                |                   |
| >ADD>               |                                |                                     | 4957924                    | JUN 23, 2009 |                |                   |
|                     | 020552 001                     | VERAPAMIL HYDROCHLORIDE; COVERA-HS  | 5232705                    | AUG 31, 2010 |                |                   |
|                     |                                |                                     | 5200196                    | JAN 22, 2008 |                |                   |
|                     |                                |                                     | 5141752                    | JUN 27, 2006 |                |                   |
|                     |                                |                                     | 5082668                    | JAN 21, 2009 |                |                   |
|                     |                                |                                     | 5030456                    | NOV 07, 2008 |                |                   |
|                     |                                |                                     | 4946687                    | OCT 02, 2007 |                |                   |
|                     |                                |                                     | 5785994                    | OCT 22, 2009 | U-315          |                   |
|                     |                                |                                     | 6096339                    | APR 04, 2017 | U-365          |                   |
|                     |                                |                                     | 6146662                    | NOV 14, 2017 | U-366          |                   |
|                     | 020552 002                     | VERAPAMIL HYDROCHLORIDE; COVERA-HS  | 5232705                    | AUG 31, 2010 |                |                   |
|                     |                                |                                     | 5200196                    | JAN 22, 2008 |                |                   |
|                     |                                |                                     | 5141752                    | JUN 27, 2006 |                |                   |
|                     |                                |                                     | 5082668                    | JAN 21, 2009 |                |                   |
|                     |                                |                                     | 5030456                    | NOV 07, 2008 |                |                   |
|                     |                                |                                     | 4946687                    | OCT 02, 2007 |                |                   |
|                     |                                |                                     | 5785994                    | OCT 22, 2009 | U-315          |                   |
|                     |                                |                                     | 6096339                    | APR 04, 2017 | U-365          |                   |
|                     |                                |                                     | 6146662                    | NOV 14, 2017 | U-366          |                   |
|                     | 021119 001                     | VERTEPORFIN; VISUDYNE               | 5707608                    | AUG 02, 2015 |                | NCE               |
|                     |                                |                                     | 6074666                    | FEB 05, 2012 |                | APR 12, 2005      |
|                     |                                |                                     | 4920143                    | APR 24, 2007 |                |                   |
|                     |                                |                                     | 5095030                    | APR 24, 2007 |                |                   |
|                     |                                |                                     | 5214036                    | MAY 25, 2010 |                |                   |
|                     |                                |                                     | 5770619                    | JAN 06, 2015 | U-357          |                   |
|                     |                                |                                     | 5798349                    | AUG 25, 2015 | U-357          |                   |
|                     |                                |                                     | 5756541                    | MAR 11, 2016 | U-357          |                   |
|                     | 020547 001                     | ZAFIRLUKAST; ACCOLATE               | 5583152                    | SEP 26, 2010 |                |                   |
|                     |                                |                                     | 6143775                    | DEC 11, 2011 |                |                   |

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

| APPL/PROD<br>NUMBER | INGREDIENT NAME; TRADE NAME | PATENT<br>NUMBER | PATENT/PED EXCL<br>EXPIRES | USE<br>CODE | EXCLUS<br>CODE | EXCLUS<br>EXPIRES |
|---------------------|-----------------------------|------------------|----------------------------|-------------|----------------|-------------------|
| 020547 003          | ZAFIRLUKAST; ACCOLATE       | 4859692          | SEP 26, 2010               |             | NCE            | SEP 26, 2001      |
|                     |                             | 5294636          | DEC 11, 2011               |             | I-268          | SEP 17, 2002      |
|                     |                             | 5319097          | DEC 11, 2011               |             | NS             | SEP 17, 2002      |
|                     |                             | 5482963          | JAN 09, 2013               |             |                |                   |
|                     |                             | 5583152          | SEP 26, 2010               |             |                |                   |
|                     |                             | 5612367          | MAR 18, 2014               |             |                |                   |
|                     |                             | 6143775          | DEC 11, 2011               |             |                |                   |
|                     |                             |                  |                            | U-189       |                |                   |
| 021036 001          | ZANAMIVIR; RELENZA          |                  |                            |             | I-294          | APR 26, 2003      |
| 020789 001          | ZONISAMIDE; ZONEGRAN        |                  |                            |             | NCE            | MAR 27, 2005      |

## PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 20TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

### ABBREVIATIONS

**NPP**      **NEW PATIENT POPULATION**

### REFERENCES

#### *NEW DOSING SCHEDULE*

**D-51**      **OPTIONAL STARTING DOSE OF 40MG/DAY**  
**D-52**      **ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY**  
**D-53**      **USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE**  
**D-54**      **USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS**  
**D-55**      **ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)**  
**D-56**      **ADDITION OF POSTPRANDIAL DOSING**  
**D-57**      **3-HOUR INFUSION OF TAXOL GIVEN EVERY THREE WEEKS AT A DOSE OF 175MG/M2 FOLLOWED BY CISPLATIN AT A DOSE OF 75MG/M2 FOR THE FIRST-LINE TREATMENT OF ADVANCED OVARIAN CANCER**  
**D-58**      **CHANGE IN DOSING INTERVAL TO ONCE-DAILY ADMINISTRATION**  
**D-59**      **REDUCTION OF ELEVATED LDL-C IN A NEW, HIGHER STRENGTH TABLET, 0.8MG, AND FOR EXTENSION OF THE DOSAGE RANGE TO 0.8MG DAILY**  
**D-60**      **ADDITION OF A POST-OPERATIVE DOSING REGIMEN**  
**D-61**      **ONCE WEEKLY DOSING FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS**  
**D-62**      **ONCE WEEKLY DOSING FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS**  
**D-63**      **TO ALLOW A TITRATION DOSING REGIMEN USING A 25MG DOSE**  
**D-64**      **INCREASING DOSAGE FOR NERVE BLOCK ANESTHESIA USING NAROPIN 7.5MG/ML AND FOR EXTENDING THE DURATION OF TREATMENT FOR POSTOPERATIVE ANALGESIA USING NAROPIN 2MG/ML**

#### *NEW INDICATION*

**I-283**      **TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS**  
**I-286**      **TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III**  
**I-287**      **USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH**  
**I-288**      **CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINAPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE**

## PATENT AND EXCLUSIVITY TERMS

### NEW INDICATION

- I-289      USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL
- I-290      TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS
- I-291      PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
- I-292      TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
- I-293      TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS
- I-294      TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS
- I-295      PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS
- I-296      LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY
- I-297      SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
- I-298      TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA
- I-299      USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM
- I-300      PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE
- I-301      TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS
- I-302      TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME
- I-303      INCREASING HDL-CHOLESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS
- I-304      TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV
- I-305      TREATMENT OF LEVOFLOXACIN SUSCEPTIBLE STRAINS OF PENICILLIN-RESISTANT STREPTOCOCCUS PNEUMONIAE IN PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA
- I-306      INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE
- I-307      NEW COMBINATION USE OF METFORMIN AND INSULIN IN TYPE 2 DIABETES
- I-308      TREATMENT OF PEDIATRIC PATIENTS WITH POLYARTICULAR COURSE JUVENILE RHEUMATOID ARTHRITIS WHO RESPONDED INADEQUATELY TO SALICYLATES OR OTHER NSAIDS
- I-309      INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS
- I-310      REDUCTION IN RISK OF MYOCARDIAL INFARCTION, STROKE, AND DEATH FROM CARDIOVASCULAR CAUSES
- I-311      ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL SEIZURES IN PEDIATRIC PATIENTS AGE 3 TO 12 YEARS
- I-312      FIRST LINE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE OR HORMONE RECEPTOR UNKNOWN LOCALLY ADVANCED OR METASTATIC BREAST CANCER
- I-313      EXTENSION OF INDICATION TO PROVIDE FOR MAINTENANCE OF RESPONSE
- I-314      TOPICAL ANESTHETIC FOR SUPERFICIAL MINOR SURGERY OF GENITAL MUCOUS MEMBRANES AND AS AN ADJUNCT FOR LOCAL INFILTRATION ANESTHESIA IN GENITAL MUCOUS MEMBRANES
- I-315      THROMBOPROPHYLAXIS OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN MEDICAL PATIENTS WHO ARE AT RISK FOR THROMBOEMBOLIC COMPLICATIONS DUE TO SEVERELY RESTRICTED MOBILITY DURING ACUTE ILLNESS
- I-316      TREATMENT OF NSAID-ASSOCIATED GASTRIC ULCER PATIENTS WHO CONTINUE NSAID USE AND REDUCING RISK OF NSAID-ASSOCIATED GASTRIC ULCERS IN PATIENTS WITH HISTORY OF DOCUMENTED GASTRIC ULCER WHO REQUIRE USE OF AN NSAID
- I-317      PROPHYLAXIS OF INFLUENZA IN ADULTS AND ADOLESCENTS 13 YEARS AND OLDER
- I-318      FIRSTLINE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE OR HORMONE RECEPTOR UNKNOWN LOCALLY ADVANCED OR METASTATIC BREAST CANCER

## PATENT AND EXCLUSIVITY TERMS

### *NEW INDICATION*

- I-319**      **USE FOR SUSPECTED OR CONFIRMED METHANOL POISONING, EITHER ALONE OR IN COMBINATION WITH HEMODIALYSIS**  
**I-320**      **TREATMENT OF TYPE 2 DIABETES IN PEDIATRIC PATIENTS (AGES 10-16 YEARS)**

### *MISCELLANEOUS EXCLUSIVITY CODES*

- M-2**      **APPROVAL FOR ADDITION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE**  
**M-3**      **ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN**  
**M-4**      **CHANGES TO PEDIATRIC USE SECTION TO PROVIDE INFORMATION REGARDING SAFETY AND EFFICACY IN PEDIATRIC PATIENTS AS YOUNG AS 2 YEARS OLD**  
**M-5**      **INFORMATION REGARDING EFFECTS IN PATIENTS WITH ASTHMA ON CONCOMITANT INHALED CORTICOSTEROIDS IN CLINICAL PHARMACOLOGY SECTION**

### *PATENT USE CODE*

- U-266**      **RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS; MANAGEMENT OF ACUTE PAIN IN ADULTS; TREATMENT OF PRIMARY DYSMENORRHEA**  
**U-309**      **TREATING SJOEGREN SYNDROME**  
**U-310**      **TREATMENT OF XEROSTOMIA**  
**U-311**      **HORMONE REPLACEMENT**  
**U-312**      **PANIC DISORDER OBSSSSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER**  
**U-313**      **TREATMENT OF CONGESTIVE HEART FAILURE**  
**U-314**      **METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY**  
**U-315**      **METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT**  
**U-316**      **METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER**  
**U-317**      **METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE**  
**U-318**      **TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE**  
**U-319**      **TREATMENT OF MICROBIAL INFECTIONS**  
**U-320**      **INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA**  
**U-321**      **REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS**  
**U-322**      **TREATMENT OF ALZHEIMER'S DEMENTIA**  
**U-323**      **USE AS A BILE ACID SEQUESTRANT**  
**U-324**      **METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE**  
**U-325**      **METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE**  
**U-326**      **METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER**  
**U-327**      **METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE**

## PATENT AND EXCLUSIVITY TERMS

### PATENT USE CODE

- U-328 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH
- U-329 USE OF AVANDIA AS MONOTHERAPY, IN COMBINATION WITH METFORMIN, AND IN COMBINATION WITH SULFONYLUREAS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
- U-330 TREATMENT OF NAUSEA AND VOMITING
- U-331 METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
- U-332 TREATMENT OR PREVENTION OF BRONCHOSPASM
- U-333 METHOD OF TREATING OCULAR HYPERTENSION
- U-334 TREATMENT OF EXCESSIVE FEMALE FACIAL HAIR
- U-335 USE OF PRAVASTATIN SODIUM FOR SECONDARY PREVENTION OF CORONARY EVENTS IN MEN AND WOMEN WHO HAVE HAD A MYOCARDIAL INFARCTION AND HAVE NORMAL CHOLESTEROL LEVELS
- U-336 DIAGNOSTIC RADIOIMAGING
- U-337 USE OF CARDIOLITE/MIRALUMA KIT FOR THE PREPARATION OF TC99M SESTAMIBI
- U-338 METHODS FOR TREATING DISTURBANCES OF MOOD, DISTURBANCES OF APPETITE, DEPRESSED MOOD, OR CARBOHYDRATE CRAVING ALL ASSOCIATED WITH PREMENSTRUAL SYNDROME
- U-339 PREVENTION OF CARDIO-TOXICITY CAUSED BY THE ADMINISTRATION OF DOXORUBICIN
- U-340 THE LONG TERM TREATMENT OF GROWTH FAILURE DUE TO LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION IN CHILDREN
- U-341 METHOD FOR ENHANCING THE TREATMENT OF ... LATE LUTEAL PHASE DYSPHORIC DISORDER
- U-342 METHOD FOR TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER
- U-343 REDUCTION OF INTESTINAL GAS, CRAMPING AND ANORECTAL IRRITATION
- U-344 METHOD FOR INHIBITING HIV INFECTION BY ADMINISTERING RITONAVIR IN COMBINATION WITH ANOTHER HIV PROTEASE INHIBITOR
- U-345 RITONAVIR AND ANOTHER HIV PROTEASE INHIBITOR FOR CONCOMITANT ADMINISTRATION FOR THE TREATMENT OF AN HIV INFECTION
- U-346 METHOD FOR INHIBITING CYTOCHROME P450 MONOOXYGENASE WITH RITONAVIR AND A METHOD FOR IMPROVING THE PHARMCOKINETICS OF A DRUG THAT IS METABOLIZED BY CYTOCHROME P450 MONOOXYGENASE BY ADMIN THE DRUG AND RITONAVIR
- U-347 METHOD OF USE IN COMBINATION WITH REVERSE TRANSCRIPTASE INHIBITORS
- U-348 METHOD OF USE FOR INHIBITING HIV INFECTION
- U-349 METHOD OF USE WHICH IS SUBJECT OF THE APPLICATION
- U-350 PREPARATION OF A PHARMACEUTICAL COMPOSITION FOR CONCOMITANT ADMIN WITH A REVERSE TRANSCRIPTASE INHIBITOR
- U-351 INHIBITING PROTEASE WITH LOPINAVIR AND INHIBITING AN HIV INFECTION WITH LOPINAVIR
- U-352 INHIBITING HIV INFECTION BY ADMINISTERING RITONAVIR IN COMBINATION WITH A REVERSE TRANSCRIPTASE INHIBITOR
- U-353 PREVENTION AND TREATMENT OF OSTEOPOROSIS
- U-354 METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID WITHOUT CAUSING TREATMENT- LIMITING ELEVATIONS IN URIC ACID OR GLUCOSE LEVELS OR CAUSING LIVER DAMAGE, BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT

## PATENT AND EXCLUSIVITY TERMS

### PATENT USE CODE

- U-355 METHOD OF ASSISTING PERSON TO QUIT SMOKING...TRANSDERMALLY ADMIN NICOTINE VIA..  
PATCH ADHERED TO SKIN AT DOSING RATE APPROX SAME AS ABSORBED FROM SMOKING
- U-356 DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A.
- U-357 USE OF THE DRUG PRODUCT IN PHOTODYNAMIC THERAPEUTIC PROTOCOLS FOR THE TREATMENT  
OF AGE-RELATED MACULAR DEGENERATION AND RELATED CONDITIONS INVOLVING UNWANTED  
NEOVASCULATURE IN THE EYE
- U-358 DEPRESSION, OBSESSIVE COMPULSIVE DISORDER, PANIC DISORDER AND SOCIAL ANXIETY  
DISORDER
- U-359 METHOD OF USE OF VISICOL
- U-360 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF PATHOLOGICAL  
PSYCHOLOGICAL CONDITIONS INCLUDING MENTAL DISORDERS EMPLOYING OLANZAPINE AS PER  
THE INDICATION WHICH IS THE SUBJECT MATTER OF THIS SNDA-011
- U-361 MANAGEMENT OF ANXIETY DISORDERS AND THE SHORT-TERM RELIEF OF THE SYMPTOMS OF  
ANXIETY
- U-362 USE OF APPROVED FORMULATIONS TO TREAT ALL APPROVED DISEASE INDICATIONS
- U-363 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF PATHOLOGICAL  
PSYCHOLOGICAL CONDITIONS THAT RELATE TO THE USE OF A PSYCHOACTIVE SUBSTANCE  
EMPLOYING OLANZAPINE AS PER THE INDICATION WHICH IS THE SUBJECT MATER OF THIS  
SNDA-011
- U-364 TREATING A PATIENT SUFFERING FROM OR SUSCEPTIBLE TO ANY NUMBER OF LISTED CONDITIONS  
INCLUDING PSYCHOSIS, EMPLOYING OLANZAPINE AS PER THE INDICATION WHICH IS THE  
SUBJECT MATTER OF THIS SNDA-011
- U-365 METHOD FOR THE TREATMENT OF CARDIOVASCULAR DISEASE THROUGH THE ADMINISTRATION  
OF A CALCIUM BLOCKING VASODILATOR IN OUR EXTENDED, CONTROLLED RELEASE  
FORMULATION
- U-366 METHOD FOR THE TREATMENT OF CARDIOVASCULAR DISEASE THROUGH THE ADMINISTRATION  
OF A CALCIUM BLOCKING VASODILATOR IN A DELAYED RELEASE FORMULATION
- U-367 TREATMENT OF CARDIOVASCULAR DISORDERS
- U-368 HEARTBURN
- U-369 METHOD OF CONTROLLING AND LOWERING INTRAOCULAR PRESSURE
- U-370 INTRAVAGINAL TREATMENT OF VAGINAL INFECTIONS WITH BUFFERED METRONIDAZOLE  
COMPOSITIONS
- U-371 APPROVAL FOR MARKETING ONLY UNDER A SPECIAL RESTRICTION PROGRAM APPROVED BY FDA  
CALLED "SYSTEM FOR THALIDOMIDE EDUCATION AND PRESCRIBING SAFETY" (S.T.E.P.S.)





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