

CUMULATIVE
SUPPLEMENT 9
SEPTEMBER 2002



APPROVED
DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

22nd EDITION

Department of Health and Human Services

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

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2002
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Prepared By
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

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APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

22ND EDITION

Cumulative Supplement 9

September 2002

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

22ND EDITION

**CUMULATIVE SUPPLEMENT 9
September 2002**

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, 22nd 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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.)

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 22nd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 23rd Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. 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 >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

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

| <u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u> |
|---|--|
| DANBURY PHARMACEUTICALS INC (DANBURY PHARMA) | WATSON LABORATORIES INC (WATSON LABS) |
| DURAMED PHARMACEUTICALS INC (DURAMED) | DURAMED PHARMACEUTICALS INC SUB OF BARR LABORATORIES INC (DURAMED PHARM BARR) |
| DERMIK LABORATORIES INC (DERMIK LABS) | DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS) |
| DERMIK LABORATORIES INC SUB RORER (DERMIK LABS) | DERMIK LABORATORIES DIVISION OF AVENTIS PHARMACEUTICALS INC (DERMIK LABS) |
| JANSSEN RESEARCH FDN (JANSSEN) | JANSSEN PHARMACEUTICA PRODUCTS LP (JANSSEN PHARMA) |
| JANSSEN RESEARCH FDN DIV JOHNSON AND JOHNSON (JANSSEN) | JANSSEN PHARMACEUTICA PRODUCTS LP (JANSSEN PHARMA) |
| JOHNSON AND JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT LLC (JOHNSON AND JOHNSON) | ORTHO MCNEIL PHARMACEUTICAL INC (ORTHO MCNEIL PHARM) |
| MCNEIL CONSUMER HEALTHCARE DIVISION (MCNEIL CONS) | MCNEIL CONSUMER AND SPECIALTY PHARMACEUTICALS DIVISION MCNEIL PPC (MCNEIL CONS SPECLT) |
| MOVA PHARMACEUTICALS CORPORATION (MOVA) | CLONMEL HEALTHCARE LTD (CLONMEL HLTH) |
| NMC LABORATORIES INC | ALPHARMA US PHARMACEUTICAL DIV (ALPHARMA US PAHRM) |
| PARKE DAVIS PHARMACEUTICALS LTD (PARKE DAVIS PHARMS) | PFIZER PHARMACEUTICALS LTD (PFIZER PHARM LTD) |
| RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE (JOHNSON RW) | ORTHO MCNEIL PHARMACEUTICAL INC (ORTHO MCNEIL PHARM) |
| RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW) | ORTHO MCNEIL PHARMACEUTICAL INC (ORTHO MCNEIL PHARM) |
| THAMES PHARMACAL COMPANY INC (THAMES) | TARO PHARMACEUTICALS NORTH AMERICA INC (TARO PHARMS US) |
| WHITEHALL LABORATORIES INC DIV AMERICAN HOME PRODUCTS CORP (WHITEHALL LABS) | WYETH CONSUMER HEALTHCARE (WYETH CONS) |
| WHITEHALL ROBINS HEALTHCARE (WHITEHALL LABS) | WYETH CONSUMER HEALTHCARE (WYETH CONS) |

1.3 WAIVED EXCLUSIVITY

Waived exclusivity - If a new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (Act) qualifies for exclusivity under sections 505(c)(3)(D) and 505(j)(5)(D), the exclusivity is listed in the Patent and Exclusivity Section of the Orange Book. If a drug product has received this exclusivity, the FDA will delay the approval of a 505(b)(2) application or an abbreviated new drug application (ANDA) under section 505(j) of the Act until the expiration of the exclusivity. If the listed drug is also protected by one or more patents, the approval date for the 505(b)(2) application or ANDA will be determined by the latest expiring patent or exclusivity listed in the Orange Book.

However, the holder of the NDA may waive its exclusivity as to any or all 505(b)(2) and ANDA applications referencing the protected drug product. If an NDA sponsor waives its right to the exclusivity protection, qualified 505(b)(2) or ANDA applications may be approved without regard to the NDA holder's exclusivity. An NDA for which the holder has waived its exclusivity as to all 505(b)(2) and ANDA applications will be coded with a W in the Patent and Exclusivity Section of the Orange Book and be referred to this section. The applicant referencing this listed drug should indicate in the exclusivity statement that the holder of the listed drug has waived its exclusivity.

1.4 AVAILABILITY OF THE EDITION

The 22nd 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 \$105.00 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 22nd annual edition of the 2001 Orange Book Patent and Exclusivity List is at <http://www.fda.gov/cder/orange/22bookpub.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 Patent Term Extension and new Patents, Docket Number *95S-0117, is at <http://www.fda.gov/cder/orange/docket.pdf>. It is updated monthly as soon as available and as otherwise needed.

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 2001) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

| CATEGORIES COUNTED | DEC 2001 | MAR 2002 | JUN 2002 | SEP 2002 |
|---------------------------------|--------------|--------------|--------------|--------------|
| DRUG PRODUCTS LISTED | 10166 | 10357 | 10193 | 10329 |
| SINGLE SOURCE | 2665 (26.2%) | 2645 (25.5%) | 2400 (23.5%) | 2399 (23.2%) |
| MULTISOURCE | 7391 (72.7%) | 7602 (73.4%) | 7687 (75.4%) | 7824 (75.7%) |
| THERAPEUTICALLY EQUIVALENT | 7105 (69.9%) | 7309 (70.6%) | 7402 (72.6%) | 7549 (73.1%) |
| NOT THERAPEUTICALLY EQUIVALENT | 286 (2.8%) | 293 (2.8%) | 285 (2.8%) | 275 (2.7%) |
| EXCEPTIONS ¹ | 110 (1.1%) | 110 (1.1%) | 106 (1.0%) | 106 (1.0%) |
| NEW MOLECULAR ENTITIES APPROVED | 10 | 1 | 5 | 5 |
| NUMBER OF APPLICANTS | 574 | 574 | 574 | 582 |

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

1.6 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Approval number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

| | |
|------|---|
| NEWA | New drug product approval usually in the supplement month. |
| CAHN | Applicant holder firm name has changed. |
| CDFR | Change. Dosage Form; Route of Administration. |
| CFTG | Change. A first time generic for the innovator product. A TE Code is added. |
| CMFD | Change. The product is moved from the Discontinued Section due to a change in marketing status. |
| CPOT | Change. Potency amount/unit. |
| CRLD | Change. Reference Listed Drug. |
| CTEC | Change. Therapeutic Equivalence Code. |
| CTNA | Change. Trade Name. |
| DISC | Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition. |
| WDAG | Withdrawn. The applicant holder has notified the FDA in writing that the product is no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section. |
| WDRP | Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition. |

ACEBUTOLOL HYDROCHLORIDE

CAPSULE; ORAL
SECTRAL
AB ESP PHARMA EQ 200MG BASE N18917 001 DEC 28, 1984 JUL CAHN
AB + EQ 400MG BASE N18917 003 DEC 28, 1984 JUL CAHN

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL
ACETAMINOPHEN, BUTALBITAL, CAFFEINE, AND CODEINE PHOSPHATE
AB VINTAGE PHARMS 325MG;50MG;40MG;30MG N75929 001 APR 22, 2002 APR NEWA

ACETAMINOPHEN; CODEINE PHOSPHATE

CAPSULE; ORAL
PHENAPHEN W/ CODEINE NO. 2
@ ROBINS AH 325MG;15MG N84444 001 MAY DISC
SOLUTION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
AA + ALPHARMA 120MG/5ML;12MG/5ML N85861 001 MAY CRLD
TYLENOL W/ CODEINE
@ JOHNSON RW 120MG/5ML;12MG/5ML N85057 001 MAY DISC
TABLET; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE
AA ABLE 300MG;30MG N40452 001 AUG 01, 2002 AUG NEWA
AA 300MG;60MG N40459 001 AUG 01, 2002 AUG NEWA
@ PUREPAC PHARM 300MG;60MG N86683 001 MAY DISC

ACETAMINOPHEN; HYDROCODONE BITARTRATE

SOLUTION; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA KV PHARM 500MG/15ML;7.5MG/15ML N40366 001 JAN 23, 2002 JAN NEWA
TABLET; ORAL
AA + MALLINCKRODT 660MG;10MG N40084 003 JUL 29, 1996 JUL CTNA
AA UCB 500MG;10MG N40210 001 AUG 13, 1997 JUN CAHN
NORCO
AA + WATSON LABS 325MG;5MG N40099 001 JUN 25, 1997 MAY CTNA

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
ACETAMINOPHEN AND PENTAZOCINE HCL
AB AMIDE PHARM 650MG;EQ 25MG BASE N76202 001 AUG 02, 2002 AUG NEWA

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL
DARVOCET
@ AAIPHARMA LLC 325MG;32.5MG N16844 001 JUN CAHN

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
DARVOCET-N 100
AB + AAIPHARMA LLC 650MG;100MG N17122 002 JUN CAHN
DARVOCET-N 50
AB AAIPHARMA LLC 325MG;50MG N17122 001 JUN CAHN

ACYCLOVIR

TABLET; ORAL

ACYCLOVIR

| | | | | | | |
|----|---------------|-------|------------|--------------|-----|------|
| AB | NEOSAN PHARMS | 400MG | N74946 001 | NOV 19, 1997 | JUL | CAHN |
| AB | | 800MG | N74946 002 | NOV 19, 1997 | JUL | CAHN |

>A> ADEFOVIR DIPIVOXIL

>A> TABLET; ORAL

>A> HEP SERA

>A> + GILEAD 10MG

N21449 001 SEP 20, 2002 SEP NEWA

ALBUMIN CHROMATED CR-51 SERUM

INJECTABLE; INJECTION

CHROMALBIN

@ ISO TEX 100uCi/VIAL

N17835 001 JUN DISC

ALBUMIN IODINATED I-125 SERUM

INJECTABLE; INJECTION

RADIOIODINATED SERUM ALBUMIN (HUMAN) IHSA I 125

@ MALLINCKRODT 6.67uCi/ML

N17844 003 JUN DISC

@ 100uCi/ML

N17844 002 JUN DISC

ALBUTEROL

AEROSOL, METERED; INHALATION

PROVENTIL

BN + SCHERING 0.09MG/INH

N17559 001 JUN CRLD

ALBUTEROL SULFATE

AEROSOL, METERED; INHALATION

PROVENTIL-HFA

BX + 3M EQ 0.09MG BASE/INH

N20503 001 AUG 15, 1996 MAR CTEC

VENTOLIN HFA

BX + GLAXOSMITHKLINE EQ 0.09MG BASE/INH

N20983 001 APR 19, 2001 MAR CTEC

TABLET, EXTENDED RELEASE; ORAL

>A> ALBUTEROL SULFATE

>A> AB SIDMAK LABS EQ 4MG BASE

N76130 002 SEP 26, 2002 SEP NEWA

>A> AB EQ 8MG BASE

N76130 003 SEP 26, 2002 SEP NEWA

VOLMAX

>D> BC + MURO EQ 4MG BASE

N19604 002 DEC 23, 1992 SEP CFTG

>A> AB + EQ 4MG BASE

N19604 002 DEC 23, 1992 SEP CFTG

>D> + EQ 8MG BASE

N19604 001 DEC 23, 1992 SEP CFTG

>A> AB + EQ 8MG BASE

N19604 001 DEC 23, 1992 SEP CFTG

ALFENTANIL HYDROCHLORIDE

INJECTABLE; INJECTION

ALFENTA

AP + GD SEARLE LLC EQ 0.5MG BASE/ML

N19353 001 DEC 29, 1986 JUL CAHN

ALGLUCERASE

INJECTABLE; INJECTION

CEREDASE

@ GENZYME 10 UNITS/ML

N20057 004 MAY 08, 1992 JUN DISC

ALLOPURINOL SODIUM

INJECTABLE; INJECTION

ALOPRIM

+ DSM PHARMS

EQ 500MG BASE/VIAL

N20298 001 MAY 17, 1996 JUN CAHN

ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE

INJECTABLE; INJECTION

INFUVITE ADULT

+ SABEX 2002

2 IU/ML;20MG/ML;12UGM/ML;40
IU/ML;1UGM/ML;3MG/ML;80UGM/ML;8MG/M
L;0.8MG/ML;0.72MG/ML;0.6MG/ML;600
IU/ML

N21163 001 MAY 18, 2000 AUG CTNA

MULTI-12

+ SABEX 2002

2 IU/ML;20MG/ML;12UGM/ML;40
IU/ML;1UGM/ML;3MG/ML;80UGM/ML;8MG/M
L;0.8MG/ML;0.72MG/ML;0.6MG/ML;600
IU/ML

N21163 001 MAY 18, 2000 APR CAHN

ALPROSTADIL

INJECTABLE; INJECTION

CAVERJECT

PHARMACIA AND UPJOHN

0.01MG/VIAL
0.02MG/VIAL

N21212 001 JUN 11, 2002 JUN NEWA

N21212 002 JUN 11, 2002 JUN NEWA

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

AMANTADINE HCL

>A> AA CAROLINA MEDCL

50MG/5ML

N75819 001 SEP 11, 2002 SEP NEWA

AMIFOSTINE

INJECTABLE; INJECTION

ETHYOL

@ MEDIMMUNE ONCOLOGY

375MG/VIAL

N20221 002 SEP 10, 1999 JUN DISC

AMINO ACIDS

INJECTABLE; INJECTION

AMINOSYN 7%

@ ABBOTT

7% (7GM/100ML)

N17673 002 JUN DISC

AMINOSYN 8.5%

@ ABBOTT

8.5% (8.5GM/100ML)

N17673 004 JUN DISC

AMINOSYN II 3.5%

@ ABBOTT

3.5% (3.5GM/100ML)

N19438 001 APR 03, 1986 JUN DISC

BRANCHAMIN 4%

@ BAXTER HLTHCARE

4% (4GM/100ML)

N18678 001 SEP 28, 1984 JUN DISC

AMLEXANOX

PASTE; DENTAL

APHTHASOL

+ GLAXOSMITHKLINE CONS

5%

N20511 001 DEC 17, 1996 JUL CAHN

AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHLORIDE

CAPSULE; ORAL

LOTREL

NOVARTIS

+

EQ 5MG BASE;20MG

N20364 004 MAR 03, 1995 AUG CRLD

EQ 10MG BASE;20MG

N20364 005 JUN 20, 2002 AUG NEWA

AMMONIUM LACTATE

CREAM; TOPICAL

AMMONIUM LACTATE

AB CLAY PARK

EQ 12% BASE

N75774 001 MAY 01, 2002 MAY NEWA

LAC-HYDRIN

AB + WESTWOOD SQUIBB

EQ 12% BASE

N20508 001 AUG 29, 1996 MAY CFTG

LOTION; TOPICAL

AMMONIUM LACTATE

AB PADDOCK

EQ 12% BASE

N75575 001 JUN 11, 2002 JUN NEWA

LAC-HYDRIN

AB + WESTWOOD SQUIBB

EQ 12% BASE

N19155 001 APR 24, 1985 JUN CFTG

AMOXICILLIN

TABLET, CHEWABLE; ORAL

AMOXICILLIN

@ APOTHECON

125MG

N64131 001 MAY 06, 1996 JUL DISC

@

250MG

N64131 002 MAY 06, 1996 JUL DISC

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB GENEVA PHARMS

200MG/5ML;EQ 28.5MG BASE/5ML

N65066 001 JUN 05, 2002 JUN NEWA

AB

400MG/5ML;EQ 57MG BASE/5ML

N65066 002 JUN 05, 2002 JUN NEWA

AUGMENTIN '200'

AB GLAXOSMITHKLINE

200MG/5ML;EQ 28.5MG BASE/5ML

N50725 001 MAY 31, 1996 JUN CFTG

AUGMENTIN '400'

AB GLAXOSMITHKLINE

400MG/5ML;EQ 57MG BASE/5ML

N50725 002 MAY 31, 1996 JUN CFTG

400MG/5ML;EQ 57MG BASE/5ML

N50725 002 MAY 31, 1996 FEB CRLD

TABLET; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB GENEVA PHARMS

500MG;EQ 125MG BASE

N65064 001 MAR 15, 2002 MAR NEWA

AB

875MG;EQ 125MG BASE

N65063 001 MAR 14, 2002 MAR NEWA

>A> AB RANBAXY

875MG;EQ 125MG BASE

N65102 001 SEP 17, 2002 SEP NEWA

AUGMENTIN '500'

AB GLAXOSMITHKLINE

500MG;EQ 125MG BASE

N50564 002 AUG 06, 1984 MAR CFTG

AUGMENTIN '875'

AB + GLAXOSMITHKLINE

875MG;EQ 125MG BASE

N50720 001 FEB 13, 1996 MAR CFTG

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

AB GENEVA PHARMS

200MG;EQ 28.5MG BASE

N65065 001 APR 18, 2002 APR NEWA

AB

400MG;EQ 57MG BASE

N65065 002 APR 18, 2002 APR NEWA

AUGMENTIN '200'

AB GLAXOSMITHKLINE

200MG;EQ 28.5MG BASE

N50726 001 MAY 31, 1996 APR CFTG

AUGMENTIN '400'

AB + GLAXOSMITHKLINE

400MG;EQ 57MG BASE

N50726 002 MAY 31, 1996 APR CFTG

AMOXICILLIN; CLAVULANATE POTASSIUM

>A> TABLET, EXTENDED RELEASE; ORAL
 >A> AUGMENTIN XR
 >A> + GLAXOSMITHKLINE 1GM;62.5MG N50785 001 SEP 25, 2002 SEP NEWA

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE;
DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | | |
|--|---------------|-----------------------------|------------|--------------|-----|------|
| ADDERALL XR 10 | SHIRE PHARM | 2.5MG;2.5MG;2.5MG;2.5MG | N21303 001 | OCT 11, 2001 | AUG | CAHN |
| ADDERALL XR 15 | SHIRE LABS | 3.75MG;3.75MG;3.75MG;3.75MG | N21303 006 | MAY 22, 2002 | JUN | NEWA |
| | SHIRE PHARM | 3.75MG;3.75MG;3.75MG;3.75MG | N21303 006 | MAY 22, 2002 | AUG | CAHN |
| ADDERALL XR 20 | SHIRE PHARM | 5MG;5MG;5MG;5MG | N21303 002 | OCT 11, 2001 | AUG | CAHN |
| ADDERALL XR 25 | SHIRE LABS | 6.25MG;6.25MG;6.25MG;6.25MG | N21303 004 | MAY 22, 2002 | JUN | NEWA |
| | SHIRE PHARM | 6.25MG;6.25MG;6.25MG;6.25MG | N21303 004 | MAY 22, 2002 | AUG | CAHN |
| ADDERALL XR 30 | + SHIRE PHARM | 7.5MG;7.5MG;7.5MG;7.5MG | N21303 003 | OCT 11, 2001 | AUG | CAHN |
| ADDERALL XR 5 | SHIRE LABS | 1.25MG;1.25MG;1.25MG;1.25MG | N21303 005 | MAY 22, 2002 | JUN | NEWA |
| | SHIRE PHARM | 1.25MG;1.25MG;1.25MG;1.25MG | N21303 005 | MAY 22, 2002 | AUG | CAHN |
| TABLET; ORAL | | | | | | |
| ADDERALL 10 | SHIRE LABS | 2.5MG;2.5MG;2.5MG;2.5MG | N11522 007 | FEB 13, 1996 | FEB | CFTG |
| ADDERALL 20 | | | | | | |
| AB SHIRE LABS | | 5MG;5MG;5MG;5MG | N11522 008 | FEB 13, 1996 | FEB | CFTG |
| ADDERALL 30 | | | | | | |
| AB + SHIRE LABS | | 7.5MG;7.5MG;7.5MG;7.5MG | N11522 010 | MAY 12, 1997 | FEB | CFTG |
| ADDERALL 5 | | | | | | |
| AB SHIRE LABS | | 1.25MG;1.25MG;1.25MG;1.25MG | N11522 009 | MAY 12, 1997 | FEB | CFTG |
| DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE | | | | | | |
| AB BARR | | 1.25MG;1.25MG;1.25MG;1.25MG | N40422 001 | FEB 11, 2002 | FEB | NEWA |
| | | 2.5MG;2.5MG;2.5MG;2.5MG | N40422 002 | FEB 11, 2002 | FEB | NEWA |
| | | 5MG;5MG;5MG;5MG | N40422 003 | FEB 11, 2002 | FEB | NEWA |
| | | 7.5MG;7.5MG;7.5MG;7.5MG | N40422 004 | FEB 11, 2002 | FEB | NEWA |
| AB COREPHARMA | | 1.25MG;1.25MG;1.25MG;1.25MG | N40444 001 | JUN 19, 2002 | JUN | NEWA |
| | | 2.5MG;2.5MG;2.5MG;2.5MG | N40444 002 | JUN 19, 2002 | JUN | NEWA |
| | | 5MG;5MG;5MG;5MG | N40444 003 | JUN 19, 2002 | JUN | NEWA |
| | | 7.5MG;7.5MG;7.5MG;7.5MG | N40444 004 | JUN 19, 2002 | JUN | NEWA |
| >A> AB EON | | 1.25MG;1.25MG;1.25MG;1.25MG | N40470 001 | SEP 27, 2002 | SEP | NEWA |
| | | 2.5MG;2.5MG;2.5MG;2.5MG | N40439 001 | JUN 14, 2002 | JUN | NEWA |
| | | 5MG;5MG;5MG;5MG | N40439 002 | JUN 14, 2002 | JUN | NEWA |
| | | 7.5MG;7.5MG;7.5MG;7.5MG | N40439 003 | JUN 14, 2002 | JUN | NEWA |

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

ABELCET

>A> + ELAN PHARMS 5MG/ML N50724 001 NOV 20, 1995 JAN CAHN

AMPHOTERICIN B

SUSPENSION; ORAL

FUNGIZONE

@ BRISTOL MYERS SQUIBB 100MG/ML

N50341 003

JUN DISC

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

AMPICILLIN AND SULBACTAM

| | | | | | | |
|------|-------------|-------------------------------------|------------|--------------|-----|------|
| AP | ESI LEDERLE | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | N65074 001 | MAR 19, 2002 | MAR | NEWA |
| AP | | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | N65074 002 | MAR 19, 2002 | MAR | NEWA |
| AP | | EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL | N65076 001 | MAR 19, 2002 | MAR | NEWA |
| | UNASYN | | | | | |
| AP + | PFIZER | EQ 1GM BASE/VIAL;EQ 500MG BASE/VIAL | N50608 002 | DEC 31, 1986 | MAR | CFTG |
| AP + | | EQ 2GM BASE/VIAL;EQ 1GM BASE/VIAL | N50608 001 | DEC 31, 1986 | MAR | CFTG |
| AP + | | EQ 10GM BASE/VIAL;EQ 5GM BASE/VIAL | N50608 005 | DEC 10, 1993 | MAR | CFTG |

AMPRENAVIR

CAPSULE; ORAL

AGENERASE

@ GLAXOSMITHKLINE

50MG

N21007 001 APR 15, 1999 MAY DISC

@

150MG

N21007 002 APR 15, 1999 MAY DISC

SOLUTION; ORAL

@ GLAXOSMITHKLINE

15MG/ML

N21039 001 APR 15, 1999 MAY DISC

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID;NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K

INJECTABLE; IV (INFUSION)

INFUVITE PEDIATRIC

| | | | | | |
|--------------|---|------------|--------------|-----|------|
| + SABEX 2002 | 80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14M G/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/VIA L;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL | N21265 001 | FEB 21, 2001 | APR | CAHN |
|--------------|---|------------|--------------|-----|------|

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

FOR SOLUTION; IV (INFUSION)

M.V.I. PEDIATRIC

| | | | | | |
|-------------|--|------------|--------------|-----|------|
| + AAIPHARMA | 80MG/VIAL;0.02MG/VIAL;0.001MG/VIAL; 5MG/VIAL;0.01MG/VIAL;0.14MG/VIAL;17 MG/VIAL;0.2MG/VIAL;1MG/VIAL;1.4MG/V IAL;EQ 1.2MG BASE/VIAL;0.7MG/VIAL;7MG/VIAL | N18920 001 | SEP 21, 2000 | JUL | CAHN |
|-------------|--|------------|--------------|-----|------|

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

INJECTABLE; INJECTION

M.V.I.-12

AP + AAIPHARMA 10MG/ML;0.006MG/ML;0.5UGM/ML;1.5MG/

ML;20
IU/ML;0.04MG/ML;4MG/ML;0.4MG/ML;0.3
6MG/ML;0.3MG/ML;330 UNITS/ML;
IU/ML

N08809 004 AUG 08, 1985 JUL CAHN

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

| | | | | |
|--------------------|-------------------|--|--|----------------------------------|
| CAPSULE; ORAL | | | | |
| DARVON COMPOUND | | | | |
| + AAIPHARMA LLC | 389MG;32.4MG;32MG | | | N10996 006 MAR 08, 1983 JUN CAHN |
| DARVON COMPOUND-65 | | | | |
| AA + AAIPHARMA LLC | 389MG;32.4MG;65MG | | | N10996 007 MAR 08, 1983 JUN CAHN |

ASPIRIN; PENTAZOCINE HYDROCHLORIDE

| | | | | |
|---------------------|----------------------|--|--|---------------------|
| TABLET; ORAL | | | | |
| TALWIN COMPOUND | | | | |
| @ SANOFI SYNTHELABO | 325MG;EQ 12.5MG BASE | | | N16891 001 JUN DISC |

ASPIRIN; PROPOXYPHENE HYDROCHLORIDE

| | | | | |
|-----------------|------------|--|--|---------------------|
| CAPSULE; ORAL | | | | |
| DARVON W/ ASA | | | | |
| + AAIPHARMA LLC | 325MG;65MG | | | N10996 005 JUN CAHN |

ASPIRIN; PROPOXYPHENE NAPSYLATE

| | | | | |
|-----------------|-------------|--|--|---------------------|
| CAPSULE; ORAL | | | | |
| DARVON-N W/ ASA | | | | |
| @ AAIPHARMA LLC | 325MG;100MG | | | N16829 001 JUN CAHN |
| TABLET; ORAL | | | | |
| @ AAIPHARMA LLC | 325MG;100MG | | | N16863 001 JUN CAHN |

ATROPINE; PRALIDOXIME CHLORIDE

| | | | | |
|---------------------------|-----------------------|--|--|----------------------------------|
| INJECTABLE; INTRAMUSCULAR | | | | |
| ATNAA | | | | |
| + @ US ARMY | 2.1MG/0.7ML;600MG/2ML | | | N21175 001 JAN 17, 2002 JAN NEWA |
| @ | 2.1MG/0.7ML;600MG/2ML | | | N21175 001 JAN 17, 2002 FEB NEWA |

AZELASTINE HYDROCHLORIDE

| | | | | |
|----------------------------|-------|--|--|----------------------------------|
| SOLUTION/DROPS; OPHTHALMIC | | | | |
| OPTIVAR | | | | |
| + MURO | 0.05% | | | N21127 001 MAY 22, 2000 MAY CAHN |

AZITHROMYCIN DIHYDRATE

| | | | | |
|--------------|---------------|--|--|----------------------------------|
| TABLET; ORAL | | | | |
| ZITHROMAX | | | | |
| + PFIZER | EQ 500MG BASE | | | N50784 001 MAY 24, 2002 MAY NEWA |

AZTREONAM

| | | | | |
|------------------------|------------|--|--|----------------------------------|
| INJECTABLE; INJECTION | | | | |
| AZACTAM | | | | |
| @ BRISTOL MYERS SQUIBB | 500MG/VIAL | | | N50580 001 DEC 31, 1986 JUN DISC |
| @ | 1GM/VIAL | | | N50580 002 DEC 31, 1986 JUN DISC |
| @ | 2GM/VIAL | | | N50580 003 DEC 31, 1986 JUN DISC |

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

BACITRACIN ZINC AND POLYMYXIN B SULFATE

AT ALTANA 500 UNITS/GM;10,000 UNITS/GM N65022 001 FEB 27, 2002 FEB NEWA

BENDROFLUMETHIAZIDE

TABLET; ORAL

NATURETIN-10

@ APOTHECON 10MG N12164 003 JUN DISC

NATURETIN-5

+ APOTHECON 5MG N12164 002 JUN CRLD

BENZONATATE

CAPSULE; ORAL

TESSALON

+ FOREST LABS 200MG N11210 003 JUN 25, 1999 MAR NEWA

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE

GEL; TOPICAL

DUAC

+ STIEFEL 5%;EQ 1% BASE N50741 001 AUG 26, 2002 AUG NEWA

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

| | | | | | | |
|----------|------------|-------|------------|--------------|-----|------|
| AA | COREPHARMA | 0.5MG | N72264 001 | FEB 27, 1989 | MAY | CAHN |
| AA | | 1MG | N72265 001 | FEB 27, 1989 | MAY | CAHN |
| AA | | 2MG | N72266 001 | FEB 27, 1989 | MAY | CAHN |
| AA + | PAR PHARM | 0.5MG | N88877 001 | APR 11, 1985 | AUG | CRLD |
| AA + | | 1MG | N88894 001 | APR 11, 1985 | AUG | CRLD |
| AA + | | 2MG | N88895 001 | APR 11, 1985 | AUG | CRLD |
| COGENTIN | | | | | | |
| @ | MERCK | 0.5MG | N09193 004 | | AUG | DISC |
| @ | | 1MG | N09193 003 | | AUG | DISC |
| @ | | 2MG | N09193 002 | | AUG | DISC |

BENZYL PENICILLOYL-POLYLYSINE

INJECTABLE; INJECTION

PRE-PEN

+ SCHWARZ PHARMA 60UMOLAR N50114 001 JUL CAHN

BETAMETHASONE DIPROPIONATE

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

| | | | | | | |
|-----------|----------|---------------|------------|--------------|-----|------|
| AB + | FOUGERA | EQ 0.05% BASE | N19141 001 | SEP 04, 1984 | AUG | CRLD |
| DIPROSONE | | | | | | |
| @ | SCHERING | EQ 0.05% BASE | N17691 001 | | AUG | DISC |

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

CREAM; TOPICAL

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE

AB ALPHARMA US PHARM EQ 0.05% BASE;1% N76002 001 AUG 02, 2002 AUG NEWA

BETAXOLOL HYDROCHLORIDE; CHLORTHALIDONE

TABLET; ORAL
KERLEDEX
 @ LOREX 5MG;12.5MG N19807 001 OCT 30, 1992 JUN DISC
 @ 10MG;12.5MG N19807 002 OCT 30, 1992 JUN DISC

BETAXOLOL HYDROCHLORIDE; PILOCARPINE HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETOPTIC PILO
 @ ALCON EQ 0.25% BASE;1.75% N20619 001 APR 17, 1997 JUN DISC

BIPERIDEN LACTATE

INJECTABLE; INJECTION
AKINETON
 @ ABBOTT 5MG/ML N12418 002 JUN DISC

BITOLTEROL MESYLATE

AEROSOL, METERED; INHALATION
TORNALATE
 @ SANOFI SYNTHELABO 0.37MG/INH N18770 001 DEC 28, 1984 JUN DISC
 SOLUTION; INHALATION
 @ SANOFI SYNTHELABO 0.2% N19548 001 FEB 19, 1992 JUN DISC

BRIMONIDINE TARTRATE

SOLUTION/DROPS; OPHTHALMIC
ALPHAGAN
 @ ALLERGAN 0.2% N20613 001 SEP 06, 1996 AUG DISC

BROMOCRIPTINE MESYLATE

TABLET; ORAL
BROMOCRIPTINE MESYLATE
 AB LEK SVCS EQ 2.5MG BASE N74631 001 JAN 13, 1998 JAN CMFD
 PARLODEL
 AB + NOVARTIS EQ 2.5MG BASE N17962 001 JAN CFTG

BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE

SYRUP; ORAL
BROMANYL
 @ ALPHARMA 12.5MG/5ML;10MG/5ML N88343 001 AUG 15, 1984 MAY DISC

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
BUPIVACAINE HCL KIT
 @ ABBOTT 0.075% N19978 001 SEP 03, 1992 JUN DISC
 @ 0.114% N19978 002 SEP 03, 1992 JUN DISC
 @ 0.23% N19978 003 SEP 03, 1992 JUN DISC
 BUPIVACINE HCL PRESERVATIVE FREE
 AP INTL MEDICATED 0.25% N76012 001 JAN 09, 2002 JAN NEWA
 AP 0.5% N76012 002 JAN 09, 2002 JAN NEWA
 AP 0.75% N76012 003 JAN 09, 2002 JAN NEWA

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 WELLBUTRIN SR
 GLAXOSMITHKLINE 150MG
 + 200MG

N20358 003 OCT 04, 1996 JUL CRLD
 N20358 004 JUN 14, 2002 JUL NEWA

BUSPIRONE HYDROCHLORIDE

CAPSULE; ORAL
 BUSPAR
 @ BRISTOL MYERS SQUIBB 5MG
 @ 7.5MG
 @ 10MG
 @ 15MG

N21190 001 DEC 20, 2000 JUN DISC
 N21190 002 DEC 20, 2000 JUN DISC
 N21190 003 DEC 20, 2000 JUN DISC
 N21190 004 DEC 20, 2000 JUN DISC

TABLET; ORAL
 BUSPIRONE HCL

| | | | | | | |
|----|-----------------|------|------------|--------------|-----|------|
| AB | EGIS | 5MG | N75119 001 | MAR 14, 2002 | MAR | NEWA |
| AB | | 10MG | N75119 002 | MAR 14, 2002 | MAR | NEWA |
| AB | GENEVA PHARMS | 5MG | N75413 001 | MAR 19, 2002 | MAR | NEWA |
| AB | | 10MG | N75413 002 | MAR 19, 2002 | MAR | NEWA |
| AB | | 15MG | N75413 003 | MAR 19, 2002 | MAR | NEWA |
| AB | KV PHARM | 5MG | N75572 001 | FEB 27, 2002 | FEB | NEWA |
| AB | | 10MG | N75572 002 | FEB 27, 2002 | FEB | NEWA |
| AB | | 15MG | N75572 003 | FEB 27, 2002 | FEB | NEWA |
| AB | MYLAN | 5MG | N75272 001 | MAR 01, 2002 | MAR | NEWA |
| AB | | 10MG | N75272 002 | MAR 01, 2002 | MAR | NEWA |
| AB | | 30MG | N76008 001 | JUN 28, 2001 | MAY | CAHN |
| AB | PAR PHARM | 5MG | N75467 001 | FEB 28, 2002 | FEB | NEWA |
| AB | | 10MG | N75467 003 | FEB 28, 2002 | FEB | NEWA |
| AB | | 15MG | N75467 004 | FEB 28, 2002 | FEB | NEWA |
| AB | PHARMEX PRODS | 5MG | N75388 001 | MAY 09, 2002 | MAY | NEWA |
| AB | | 10MG | N75388 002 | MAY 09, 2002 | MAY | NEWA |
| AB | | 15MG | N75388 003 | MAY 09, 2002 | MAY | NEWA |
| AB | TEVA | 5MG | N75022 001 | FEB 28, 2002 | FEB | NEWA |
| AB | | 10MG | N75022 002 | FEB 28, 2002 | FEB | NEWA |
| AB | | 15MG | N75022 003 | FEB 28, 2002 | FEB | NEWA |
| AB | TORPHARM | 5MG | N75521 001 | APR 05, 2002 | APR | NEWA |
| AB | | 10MG | N75521 002 | APR 05, 2002 | APR | NEWA |
| AB | | 15MG | N75521 003 | APR 05, 2002 | APR | NEWA |
| AB | ZENITH GOLDLINE | 5MG | N75385 001 | MAR 01, 2002 | MAR | NEWA |
| AB | | 10MG | N75385 002 | MAR 01, 2002 | MAR | NEWA |
| AB | | 15MG | N75385 003 | MAR 01, 2002 | MAR | NEWA |

BUTORPHANOL TARTRATE

SPRAY, METERED; NASAL
 BUTORPHANOL TARTRATE

AB ROXANE 1MG/SPRAY

N75824 001 MAR 12, 2002 MAR NEWA

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL
 ERCATAB
 + GENEVA PHARMS 100MG;1MG

N84294 001 JUN CTEC

CAFFEINE; ERGOTAMINE TARTRATE

TABLET; ORAL
WIGRAINE
@ ORGANON 100MG;1MG N86562 001 JUN DISC

CALCIFEDIOL

CAPSULE; ORAL
CALDEROL
@ ORGANON 0.02MG N18312 001 JUN DISC
@ 0.05MG N18312 002 JUN DISC

CALCIPOTRIENE

OINTMENT; TOPICAL
DOVONEX
+ BRISTOL MYERS SQUIBB 0.005% N20273 001 DEC 29, 1993 FEB CAHN
SOLUTION; TOPICAL
+ BRISTOL MYERS SQUIBB 0.005% N20611 001 MAR 03, 1997 FEB CAHN

CAPTOPRIL

TABLET; ORAL
CAPOTEN
AB PAR PHARM 12.5MG N18343 005 JAN 17, 1985 MAY CAHN
AB 25MG N18343 002 MAY CAHN
@ 37.5MG N18343 006 SEP 17, 1986 MAY CAHN
AB 50MG N18343 001 MAY CAHN
@ 75MG N18343 007 JUN 13, 1995 MAY CAHN
AB + 100MG N18343 003 MAY CAHN
@ 150MG N18343 004 JUN 13, 1995 MAY CAHN

CARBAMAZEPINE

CAPSULE, EXTENDED RELEASE; ORAL
CARBATROL
>D> @ SHIRE LABS 100MG N20712 003 SEP 30, 1997 SEP CMFD
@ 100MG N20712 003 DEC 22, 1999 JUL DISC
>D> @ 200MG N20712 001 SEP 30, 1997 SEP CMFD
@ 200MG N20712 001 SEP 30, 1997 JUL DISC
>D> @ 300MG N20712 002 SEP 30, 1997 SEP CMFD
@ 300MG N20712 002 SEP 30, 1997 JUL DISC
>A> + SHIRE PHARM 100MG N20712 003 SEP 30, 1997 SEP CMFD
>A> + 200MG N20712 001 SEP 30, 1997 SEP CMFD
>A> + 300MG N20712 002 SEP 30, 1997 SEP CMFD

SUSPENSION; ORAL
CARBAMAZEPINE
AB MORTON GROVE 100MG/5ML N75714 001 JUN 05, 2002 JUN NEWA
TABLET; ORAL
AB APOTEX 200MG N75948 001 FEB 27, 2002 FEB NEWA
TABLET, CHEWABLE; ORAL
+ TARO PHARM IND 200MG N75687 002 JUL 29, 2002 JUL NEWA

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL

AT NOVEX 1% N76097 001 FEB 06, 2002 FEB NEWA

CEFACLOR

TABLET, EXTENDED RELEASE; ORAL

CECLOR CD

@ LILLY EQ 375MG BASE

N50673 001 JUN 28, 1996 JUN DISC

CEFACLOR

>A> TEVA EQ 375MG BASE

N65058 001 SEP 04, 2002 SEP NEWA

>A> AB EQ 500MG BASE

N65058 002 SEP 04, 2002 SEP NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

DURICEF

@ GALEN CHEM EQ 250MG BASE

N50512 002 MAY CAHN

@ WARNER CHILCOTT EQ 250MG BASE

N50512 002 JUL CAHN

AB + EQ 500MG BASE

N50512 001 JUL CAHN

FOR SUSPENSION; ORAL

GALEN CHEM EQ 125MG BASE/5ML

N50527 002 MAY CAHN

EQ 250MG BASE/5ML

N50527 003 MAY CAHN

+ EQ 500MG BASE/5ML

N50527 001 MAY CAHN

WARNER CHILCOTT EQ 125MG BASE/5ML

N50527 002 JUL CAHN

EQ 250MG BASE/5ML

N50527 003 JUL CAHN

+ EQ 500MG BASE/5ML

N50527 001 JUL CAHN

TABLET; ORAL

AB + GALEN CHEM EQ 1GM BASE

N50528 001 MAY CAHN

AB + WARNER CHILCOTT EQ 1GM BASE

N50528 001 JUL CAHN

CEFAMANDOLE NAFATE

INJECTABLE; INJECTION

MANDOL

@ LILLY EQ 10GM BASE/VIAL

N50504 004 JUN DISC

CEFORANIDE

INJECTABLE; INJECTION

PRECEF

@ BRISTOL 500MG/VIAL

N50554 001 MAY 24, 1984 JUN DISC

@ 1GM/VIAL

N50554 002 MAY 24, 1984 JUN DISC

@ 2GM/VIAL

N50554 003 MAY 24, 1984 JUN DISC

@ 10GM/VIAL

N50554 004 MAY 24, 1984 JUN DISC

@ 20GM/VIAL

N50554 005 MAY 24, 1984 JUN DISC

CEFPODOXIME PROXETIL

FOR SUSPENSION; ORAL

CEFPODOXIME PROXETIL

AB RANBAXY EQ 50MG BASE/5ML

N65082 001 MAY 31, 2002 MAY NEWA

AB EQ 100MG BASE/5ML

N65082 002 MAY 31, 2002 MAY NEWA

VANTIN

AB PHARMACIA AND UPJOHN EQ 50MG BASE/5ML

N50675 001 AUG 07, 1992 MAY CFTG

AB + EQ 100MG BASE/5ML

N50675 002 AUG 07, 1992 MAY CFTG

CEFTIZOXIME SODIUM
INJECTABLE; INJECTION

CEFIZOK

@ FUJISAWA HLTHCARE

EQ 500MG BASE/VIAL

N50560 001 SEP 15, 1983 JUL DISC

FEB NEWA

CEFTRIAXONE SODIUM; LIDOCAINE
INJECTABLE; INJECTION

ROCEPHIN KIT

@ HLR

@

EQ 500MG BASE/VIAL;1%

N50585 007 MAY 08, 1996 JUN DISC

N50585 006 MAY 08, 1996 JUN DISC

JUN DISC

SEP NEWA

SEP NEWA

CEFUROXIME AXETIL
TABLET; ORAL

CEFTIN

AB GLAXOSMITHKLINE

EQ 125MG BASE

N50605 001 DEC 28, 1987 FEB CFTG

AB

EQ 250MG BASE

N50605 002 DEC 28, 1987 FEB CFTG

AB +

EQ 500MG BASE

N50605 003 DEC 28, 1987 FEB CFTG

MAY CAHN

JUL CAHN

JUL CAHN

MAY CAHN

MAY CAHN

MAY CAHN

CELECOXIB

CAPSULE; ORAL

CELEBREX

GD SEARLE LLC

200MG

N20998 002 DEC 31, 1998 AUG CRLD

+ 400MG

N20998 003 AUG 29, 2002 AUG NEWA

MAY CAHN

JUL CAHN

CEPHALEXIN

FOR SUSPENSION; ORAL

CEPHALEXIN

@ TEVA

EQ 125MG BASE/5ML

N62873 001 MAY 23, 1988 APR DISC

@

EQ 250MG BASE/5ML

N62867 001 APR 15, 1988 APR DISC

JUN DISC

TABLET; ORAL

TEVA

EQ 500MG BASE

N63024 001 JAN 12, 1989 JUN CTEC

KEFLET

@ LILLY

EQ 500MG BASE

N50440 001 JUN DISC

@

EQ 1GM BASE

N50440 002 JUL DISC

JUN DISC

JUN DISC

JUN DISC

JUN DISC

CEPHALOGLYCIN

CAPSULE; ORAL

KAFOCIN

@ LILLY

250MG

N50219 001 MAY DISC

MAY NEWA

MAY NEWA

MAY DISC

MAY DISC

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION

KEFLIN

@ LILLY

EQ 20GM BASE/VIAL

N50482 007 JUN DISC

MAY NEWA

MAY CFTG

MAY CFTG

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION

CEFADYL

APOTHECON

EQ 500MG BASE/VIAL

N62961 001 SEP 20, 1988 JUN DISC

@

EQ 1GM BASE/VIAL

N62961 002 SEP 20, 1988 JUN DISC

@

EQ 2GM BASE/VIAL

N62961 003 SEP 20, 1988 JUN DISC

@

EQ 4GM BASE/VIAL

N62961 004 SEP 20, 1988 JUN DISC

CERIVASTATIN SODIUM

TABLET; ORAL

BAYCOL

@ BAYER

0.2MG

N20740 003 JUN 26, 1997 JAN DISC

@

0.3MG

N20740 004 JUN 26, 1997 JAN DISC

@

0.4MG

N20740 005 MAY 24, 1999 JAN DISC

@

0.8MG

N20740 006 JUL 24, 2000 JAN DISC

CHLORAMPHENICOL

FOR SOLUTION; OPHTHALMIC

CHLOROMYCETIN

@ PARKEDALE

25MG/VIAL

N50143 001

JUL DISC

CHLORAMPHENICOL PALMITATE

SUSPENSION; ORAL

CHLOROMYCETIN PALMITATE

@ PARKE DAVIS

EQ 150MG BASE/5ML

N50152 001

JUN DISC

CHLORAMPHENICOL; HYDROCORTISONE ACETATE

FOR SUSPENSION; OPHTHALMIC

CHLOROMYCETIN HYDROCORTISONE

@ PARKEDALE

12.5MG/VIAL;25MG/VIAL

N50202 001

JUL DISC

CHLORMEZANONE

TABLET; ORAL

TRANCOPAL

@ SANOFI SYNTHELABO

100MG

N11467 003

JUN DISC

@

200MG

N11467 005

JUN DISC

CHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

CHLOROTHIAZIDE AND RESERPINE

@ WEST WARD

250MG;0.125MG

N88557 001 DEC 22, 1983 AUG DISC

@

500MG;0.125MG

N88365 001 DEC 22, 1983 AUG DISC

CHLOROTHIAZIDE-RESERPINE

@ MYLAN

250MG;0.125MG

N87744 001 MAY 06, 1982 AUG DISC

@

500MG;0.125MG

N87745 001 MAY 06, 1982 AUG DISC

CHLORPHENESIN CARBAMATE

TABLET; ORAL

MAOLATE

@ PHARMACIA AND UPJOHN

400MG

N14217 002

JUN DISC

CHLORPROMAZINE HYDROCHLORIDE

| | | | |
|---------------------------------|-------|------------|----------|
| CAPSULE, EXTENDED RELEASE; ORAL | | | |
| THORAZINE | | | |
| @ GLAXOSMITHKLINE | 30MG | N11120 016 | JUN DISC |
| @ | 75MG | N11120 017 | JUN DISC |
| @ | 150MG | N11120 018 | JUN DISC |

CHLORPROPAMIDE

| | | | |
|----------------|-------|----------------------------------|--|
| TABLET; ORAL | | | |
| CHLORPROPAMIDE | | | |
| @ LEDERLE | 100MG | N89561 001 SEP 04, 1987 MAY DISC | |
| @ | 250MG | N89562 001 SEP 04, 1987 MAY DISC | |

CHLORTETRACYCLINE HYDROCHLORIDE

| | | | |
|----------------------|----|------------|----------|
| OINTMENT; OPHTHALMIC | | | |
| AUREOMYCIN | | | |
| @ LEDERLE | 1% | N50404 001 | JUN DISC |

CHLORTHALIDONE; RESERPINE

| | | | |
|------------------|--------------|------------|----------|
| TABLET; ORAL | | | |
| DEMI-REGROTOL | | | |
| @ AVENTIS PHARMS | 25MG;0.125MG | N15103 002 | JUL DISC |
| REGROTOL | | | |
| @ AVENTIS PHARMS | 50MG;0.25MG | N15103 001 | JUL DISC |

COLESTYRAMINE

| | | | |
|--------------|----------------|----------------------------------|--|
| TABLET; ORAL | | | |
| QUESTRAN | | | |
| @ APOTHECON | EQ 800MG RESIN | N73403 002 DEC 27, 1999 JUN DISC | |

CHORIOGONADOTROPIN ALFA

| | | | |
|-----------------------|-------------|----------------------------------|--|
| INJECTABLE; INJECTION | | | |
| OIDREL | | | |
| + SERONO INC | 0.25MG/VIAL | N21149 001 SEP 20, 2000 FEB CAHN | |

CHYMOPAPAIN

| | | | |
|-----------------------|------------------|----------------------------------|--|
| INJECTABLE; INJECTION | | | |
| CHYMODIACTIN | | | |
| @ ABBOTT | 4,000 UNITS/VIAL | N18663 002 AUG 21, 1984 JUN DISC | |

CHYMOTRYPSIN

| | | | |
|--------------------------|----------------|------------|----------|
| FOR SOLUTION; OPHTHALMIC | | | |
| ZOLYSE | | | |
| @ ALCON | 750 UNITS/VIAL | N11903 001 | JUN DISC |

CICLOPIROX

| | | | |
|-------------------|----|----------------------------------|--|
| SOLUTION; TOPICAL | | | |
| PENLAC | | | |
| + DERMIC LABS | 8% | N21022 001 DEC 17, 1999 JUN CAHN | |

CIMETIDINE

TABLET; ORAL
 CIMETIDINE

| | | | | | | |
|----|---------------|-------|------------|--------------|-----|------|
| AB | LEK LJUBLJANA | 300MG | N74250 002 | JUN 29, 1995 | FEB | CMFD |
| AB | | 400MG | N74250 003 | JUN 29, 1995 | FEB | CMFD |
| AB | | 800MG | N74250 004 | JUN 29, 1995 | FEB | CMFD |

CINOXACIN

CAPSULE; ORAL
 CINOBAC

| | | | | |
|---------|-------|------------|-----|------|
| @ LILLY | 250MG | N18067 001 | JUN | DISC |
| @ | 500MG | N18067 002 | JUN | DISC |

CLADRIBINE

INJECTABLE; INJECTION
 LEUSTATIN
 + ORTHO BIOTECH

| | | | | | |
|--|--------|------------|--------------|-----|------|
| | 1MG/ML | N20229 001 | FEB 26, 1993 | MAR | CAHN |
|--|--------|------------|--------------|-----|------|

CLARITHROMYCIN

FOR SUSPENSION; ORAL
 BIAxin
 @ ABBOTT

| | | | | | |
|--|-----------|------------|--------------|-----|------|
| | 187MG/5ML | N50698 003 | SEP 30, 1998 | JUN | DISC |
|--|-----------|------------|--------------|-----|------|

CLINDAMYCIN PHOSPHATE

LOTION; TOPICAL
 CLEOCIN T

| | | | | | |
|---------------------------|------------|------------|--------------|-----|------|
| AB + PHARMACIA AND UPJOHN | EQ 1% BASE | N50600 001 | MAY 31, 1989 | JAN | CFTG |
| CLINDAMYCIN PHOSPHATE | | | | | |
| AB ALTANA | EQ 1% BASE | N65067 001 | JAN 31, 2002 | JAN | NEWA |
| SWAB; TOPICAL | | | | | |
| AT CLAY PARK | EQ 1% BASE | N65049 001 | MAY 25, 2000 | FEB | CDFR |

CLOBETASOL PROPIONATE

GEL; TOPICAL
 EMBELINE

| | | | | | |
|----------------|-------|------------|--------------|-----|------|
| AB HEALTHPOINT | 0.05% | N76141 001 | APR 12, 2002 | APR | NEWA |
|----------------|-------|------------|--------------|-----|------|

CLOFAZIMINE

CAPSULE; ORAL
 LAMPRENE

| | | | | | |
|------------|-------|------------|--------------|-----|------|
| @ NOVARTIS | 100MG | N19500 001 | DEC 15, 1986 | JUN | DISC |
|------------|-------|------------|--------------|-----|------|

CLONAZEPAM

TABLET; ORAL
 KLONOPI^N

| | | | | | |
|---|---------|------------|--------------|-----|------|
| @ ROCHE | 0.125MG | N17533 005 | APR 09, 1997 | JUN | DISC |
| @ | 0.25MG | N17533 006 | APR 09, 1997 | JUN | DISC |
| TABLET, ORALLY DISINTEGRATING; ORAL | | | | | |
| KLONOPI ^N RAPIDLY DISINTEGRATING | | | | | |
| @ ROCHE | 0.125MG | N20813 001 | DEC 23, 1997 | JUN | DISC |
| @ | 0.25MG | N20813 002 | DEC 23, 1997 | JUN | DISC |
| @ | 0.5MG | N20813 003 | DEC 23, 1997 | JUN | DISC |

| | | | | | |
|---|-----|------------|--------------|-----|------|
| @ | 1MG | N20813 004 | DEC 23, 1997 | JUN | DISC |
| @ | 2MG | N20813 005 | DEC 23, 1997 | JUN | DISC |

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

TRANXENE

| | | | | | |
|--------------|-------------------|---------|------------|-----|------|
| >D> | @ ABBOTT | 3.75MG | N17105 001 | SEP | CAHN |
| >D> | @ | 7.5MG | N17105 002 | SEP | CAHN |
| >D> | @ | 15MG | N17105 003 | SEP | CAHN |
| >A> | @ OVATION PHARMS | 3.75MG | N17105 001 | SEP | CAHN |
| >A> | @ | 7.5MG | N17105 002 | SEP | CAHN |
| >A> | @ | 15MG | N17105 003 | SEP | CAHN |
| TABLET; ORAL | | | | | |
| >D> | AB ABBOTT | 3.75MG | N17105 006 | SEP | CAHN |
| >D> | AB | 7.5MG | N17105 007 | SEP | CAHN |
| >D> | AB + | 15MG | N17105 008 | SEP | CAHN |
| >A> | AB OVATION PHARMS | 3.75MG | N17105 006 | SEP | CAHN |
| >A> | AB | 7.5MG | N17105 007 | SEP | CAHN |
| >A> | AB + | 15MG | N17105 008 | SEP | CAHN |
| TRANXENE SD | | | | | |
| >D> | ABBOTT | 11.25MG | N17105 005 | SEP | CAHN |
| >D> | + | 22.5MG | N17105 004 | SEP | CAHN |
| >A> | OVATION PHARMS | 11.25MG | N17105 005 | SEP | CAHN |
| >A> | + | 22.5MG | N17105 004 | SEP | CAHN |

CLOZAPINE

TABLET; ORAL

CLOZARIL

| | | | | | | |
|----|----------|-------|------------|--------------|-----|------|
| AB | NOVARTIS | 25MG | N19758 001 | SEP 26, 1989 | MAY | CRLD |
| AB | + | 100MG | N19758 002 | SEP 26, 1989 | MAY | CRLD |

COLCHICINE; PROBENECID

TABLET; ORAL

COL-PROBENECID

| | | | | | | |
|------------|-------|-------------|-------------|------------|-----|------|
| BP | + | WATSON LABS | 0.5MG;500MG | N84279 001 | JUN | CRLD |
| COLBENEMID | | | | | | |
| @ | MERCK | | 0.5MG;500MG | N12383 001 | JUN | DISC |

COLESEVELAM HYDROCHLORIDE

CAPSULE; ORAL

WELCHOL

| | | | | | | |
|---|--------|-------|------------|--------------|-----|------|
| @ | SANKYO | 375MG | N21141 001 | MAY 26, 2000 | JUN | DISC |
|---|--------|-------|------------|--------------|-----|------|

CORTICOTROPIN

INJECTABLE; INJECTION

CORTICOTROPIN

| | | | | | |
|-----------------|-------------------|-------------|------------|-----|------|
| + | ORGANICS LAGRANGE | 40 UNITS/ML | N10831 001 | AUG | CRLD |
| H.P. ACTHAR GEL | | | | | |
| @ | QUESTCOR PHARMS | 40 UNITS/ML | N08372 006 | JUL | DISC |

CORTISONE ACETATE

INJECTABLE; INJECTION

CORTONE

@ MERCK

@

25MG/ML

N07110 002

JUN DISC

50MG/ML

N07110 003

JUN DISC

CROMOLYN SODIUM

SOLUTION; INHALATION

CROMOLYN SODIUM

AN NOVEX 10MG/ML

N75333 001 APR 30, 2002 APR NEWA

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58

N/A; N/A

DICOPAC KIT

@ AMERSHAM HLTH

N/A;N/A;N/A

N17406 001

FEB DISC

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; INTRINSIC FACTOR

N/A; N/A

CYANOCOBALAMIN CO 57 SCHILLING TEST KIT

@ MALLINCKRODT

0.1MG;0.5uCi;60MG

N16635 001

JUN DISC

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

FLEXERIL

@ MCNEIL CONS SPECLT

5MG

N17821 001

JUN CAHN

AB +

10MG

N17821 002

JUN CAHN

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYCLOPHOSPHAMIDE

AP BAXTER HLTHCARE

100MG/VIAL

N88371 001 JUL 03, 1986 JUN CAHN

AP

200MG/VIAL

N88372 001 JUL 03, 1986 JUN CAHN

AP

500MG/VIAL

N88373 001 JUL 03, 1986 JUN CAHN

AP

1GM/VIAL

N88374 001 SEP 24, 1986 JUN CAHN

CYCLOSPORINE

CAPSULE; ORAL

CYCLOSPORINE

AB1 ABBOTT

25MG

N65003 001 MAY 12, 2000 MAY CTEC

BX

50MG

N65003 002 MAY 12, 2000 MAY CTEC

AB1

100MG

N65003 003 MAY 12, 2000 MAY CTEC

AB1 EON

25MG

N65017 002 JAN 13, 2000 MAY CTEC

AB1

100MG

N65017 001 JAN 13, 2000 MAY CTEC

AB1 SIDMAK LABS

25MG

N65044 002 DEC 20, 2000 MAY CTEC

AB1

100MG

N65044 001 DEC 20, 2000 MAY CTEC

AB2 TORPHARM

25MG

N65040 001 MAY 09, 2002 MAY CTEC

AB2

100MG

N65040 002 MAY 09, 2002 MAY CTEC

NEORAL

AB1 NOVARTIS

25MG

N50715 001 JUL 14, 1995 MAY CTEC

AB1 +

100MG

N50715 002 JUL 14, 1995 MAY CTEC

SANDIMMUNE

AB2 NOVARTIS

25MG

N50625 001 MAR 02, 1990 MAY CTEC

| | | |
|---|-----------------------|----------------------------------|
| AB2 + | 100MG | N50625 002 MAR 02, 1990 MAY CTEC |
| SOLUTION; ORAL CYCLOSPORINE | | |
| AB ABBOTT | 100MG/ML | N65025 001 MAR 03, 2000 JAN CMFD |
| <u>CYTARABINE</u> | | |
| INJECTABLE; INJECTION CYTARABINE | | |
| + FAULDING | 100MG/ML | N75383 001 NOV 22, 1999 AUG CPOT |
| <u>DALFOPRISTIN; QUINUPRISTIN</u> | | |
| INJECTABLE; IV (INFUSION) SYNERCID | | |
| + AVENTIS | 350MG/VIAL;150MG/VIAL | N50748 001 SEP 21, 1999 JUN CRLD |
| @ | 420MG/VIAL;180MG/VIAL | N50748 002 AUG 24, 2000 JUN DISC |
| <u>DANAPAROID SODIUM</u> | | |
| INJECTABLE; INJECTION ORGARAN | | |
| @ ORGANON | 750 UNITS/0.6ML | N20430 001 DEC 24, 1996 JUN DISC |
| <u>DEFEROXAMINE MESYLATE</u> | | |
| INJECTABLE; INJECTION DESFERAL | | |
| + NOVARTIS | 2GM/VIAL | N16267 002 MAY 25, 2000 FEB CPOT |
| <u>DEMECARIUM BROMIDE</u> | | |
| SOLUTION/DROPS; OPHTHALMIC HUMORSOL | | |
| @ MERCK | 0.125% | N11860 002 JUN DISC |
| @ | 0.25% | N11860 001 JUN DISC |
| <u>DEMECTOCYCLINE HYDROCHLORIDE</u> | | |
| TABLET; ORAL DECLOMYCIN | | |
| @ LEDERLE | 75MG | N50261 001 JUN DISC |
| <u>DESLORATADINE</u> | | |
| TABLET, ORALLY DISINTEGRATING; ORAL CLARINEX | | |
| + SCHERING | 5MG | N21312 001 JUN 26, 2002 JUN NEWA |
| <u>DESMOPRESSIN ACETATE</u> | | |
| SOLUTION; NASAL CONCENTRAID | | |
| @ FERRING | 0.01% | N19776 001 DEC 26, 1990 JUN DISC |
| DDAVP | | |
| >D BX + AVENTIS | 0.01% | N17922 001 SEP CTEC |
| >A + | 0.01% | N17922 001 SEP CTEC |
| >A> SPRAY; NASAL | | |
| >A> DESMOPRESSIN ACETATE | | |
| >A+ FERRING | 0.01MG/SPRAY | N21333 001 SEP 16, 2002 SEP NEWA |

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL
 DDAVP
 @ AVENTIS 0.01MG/SPRAY N17922 002 FEB 06, 1989 MAY DISC
 AB + BAUSCH AND LOMB 0.01MG/SPRAY N74830 001 JAN 25, 1999 MAY CRLD

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28
 KARIVA
 AB BARR 0.15MG;0.02MG;0.01MG N75863 001 APR 05, 2002 APR NEWA
 MIRCETTE
 AB + ORGANON 0.15MG;0.02MG;0.01MG N20713 001 APR 22, 1998 APR CFTG

DESONIDE

LOTION; TOPICAL
 DESONIDE
 AB ALTANA 0.05% N75860 001 MAR 19, 2002 MAR NEWA
 DESOWEN
 AB + GALDERMA LABS LP 0.05% N72354 001 JAN 24, 1992 MAR CFTG

DESOKSIMETASONE

OINTMENT; TOPICAL
 DESOXIMETASONE
 @ ALTANA 0.25% N73440 001 APR 01, 1998 MAY DISC

DEXAMETHASONE

AEROSOL; TOPICAL
 DECASPRAY
 @ MERCK 0.04% N12731 002 JUN DISC
 TABLET; ORAL
 DEXAMETHASONE
 @ WATSON LABS 0.25MG N85455 001 AUG DISC
 @ 0.5MG N85458 001 AUG DISC
 @ 1.5MG N85456 001 AUG DISC

DEXAMETHASONE ACETATE

INJECTABLE; INJECTION
 DECADRON-LA
 @ MERCK EQ 8MG BASE/ML N16675 001 APR DISC
 DEXAMETHASONE ACETATE
 @ STERIS EQ 8MG BASE/ML N84315 001 APR DISC
 @ EQ 16MG BASE/ML N87711 001 MAY 24, 1982 APR DISC

DEXAMETHASONE SODIUM PHOSPHATE

OINTMENT; OPHTHALMIC
 MAXIDEX
 @ ALCON EQ 0.05% PHOSPHATE N83342 001 JUN DISC

DEXAMETHASONE SODIUM PHOSPHATE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

DECADRON W/ XYLOCAINE

@ MERCK

EQ 4MG PHOSPHATE/ML;10MG/ML

N13334 002

JUN DISC

DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

DEXEDRINE

| | | | | | |
|---------------------------|-----------------|------|------------|--------------|----------|
| AB + | GLAXOSMITHKLINE | 5MG | N17078 001 | JAN | CFTG |
| AB + | | 10MG | N17078 002 | JAN | CFTG |
| AB + | | 15MG | N17078 003 | JAN | CFTG |
| DEXTROAMPHETAMINE SULFATE | | | | | |
| AB | BARR | 5MG | N76137 001 | JAN 18, 2002 | JAN NEWA |
| AB | | 10MG | N76137 002 | JAN 18, 2002 | JAN NEWA |
| AB | | 15MG | N76137 003 | JAN 18, 2002 | JAN NEWA |
| TABLET; ORAL | | | | | |
| AA | MALLINCKRODT | 5MG | N40436 001 | JAN 29, 2002 | JAN NEWA |
| AA | | 10MG | N40436 002 | JAN 29, 2002 | JAN NEWA |

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

DIATRIZOATE MEGLUMINE

@ BRACCO

76%

N10040 017

JUN DISC

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

RENOVIST

@ BRACCO

34.3%;35%

N10040 020

JUN DISC

RENOVIST II

@ BRACCO

28.5%;29.1%

N10040 019

JUN DISC

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

HYPaque

@ AMERSHAM HLTH

25%

N09561 003

JUN DISC

SOLUTION; ORAL, RECTAL

@ AMERSHAM HLTH

40%

N11386 003

JUL DISC

SOLUTION; URETERAL

HYPAQUE SODIUM 20%

@ AMERSHAM HLTH

20%

N09561 002

JUN DISC

DIAZOXIDE

CAPSULE; ORAL

PROGLYCEM

@ BAKER NORTON

50MG

N17425 001

JUN DISC

DICLOFENAC POTASSIUM

TABLET; ORAL

DICLOFENAC POTASSIUM

| | | | | | |
|----|--------------|------|------------|--------------|----------|
| AB | MUTUAL PHARM | 50MG | N75470 001 | FEB 21, 2002 | FEB NEWA |
|----|--------------|------|------------|--------------|----------|

DICLOFENAC SODIUM

| | | |
|--|----------------------------------|----------------------------------|
| GEL; TOPICAL SOLARAZE | + BIOGLAN PHARMA 3% | N21005 001 OCT 16, 2000 JUL CAHN |
| TABLET, DELAYED RELEASE; ORAL DICLOFENAC SODIUM | | |
| AB ALPHAPHARM 50MG | N75281 002 FEB 12, 2002 FEB NEWA | |
| AB 75MG | N75281 003 FEB 12, 2002 FEB NEWA | |
| TABLET, EXTENDED RELEASE; ORAL | | |
| AB PUREPAC PHARM 100MG | N75910 001 JAN 07, 2002 JAN NEWA | |

DICUMAROL

| | | |
|---------------------------|---------------------|--|
| TABLET; ORAL DICUMAROL | | |
| @ ABBOTT 25MG | N05545 003 JUN DISC | |

DIENESTROL

| | | |
|------------------------------|---------------------|--|
| CREAM; VAGINAL DIENESTROL | | |
| + ORTHO MCNEIL 0.01% | N06110 005 JUN CAHN | |

DIGOXIN

| | | |
|-------------------------|----------------------------------|--|
| TABLET; ORAL DIGOXIN | | |
| AB STEVENS J 0.125MG | N76268 001 JUL 26, 2002 JUL NEWA | |
| AB 0.25MG | N76268 002 JUL 26, 2002 JUL NEWA | |

DIHYDROERGOTAMINE MESYLATE

| | | |
|------------------------------------|----------------------------------|--|
| INJECTABLE; INJECTION D.H.E. 45 | | |
| XCEL PHARMS 1MG/ML | N05929 001 JUN CAHN | |
| SPRAY, METERED; NASAL MIGRANAL | | |
| + XCEL PHARM 0.5MG/INH | N20148 001 DEC 08, 1997 JUL CAHN | |

DILTIAZEM HYDROCHLORIDE

| | | |
|-----------------------------------|----------------------------------|--|
| INJECTABLE; INJECTION CARDIZEM | | |
| AP + BIOVAIL 5MG/ML | N20027 001 OCT 24, 1991 JUN CAHN | |
| + 25MG/VIAL | N20027 003 AUG 18, 1995 JUN CAHN | |
| DILTIAZEM HCL | | |
| + GENESIA SICOR PHARMS 10MG/ML | N74894 002 APR 19, 2002 APR NEWA | |

DILTIAZEM MALATE; ENALAPRIL MALEATE

| | | |
|--|----------------------------------|--|
| TABLET, EXTENDED RELEASE; ORAL TECZEM | | |
| + BIOVAIL EQ 180MG HCL;5MG | N20507 001 OCT 04, 1996 JUN CAHN | |

DIMYRISTOYL LECITHIN; PERFLEXANE

| | | |
|---|----------------------------------|--|
| INJECTABLE; INTRAVENOUS IMAGENT | | |
| + ALLIANCE PHARM 0.92MG/VIAL;0.092MG/VIAL | N21191 001 MAY 31, 2002 MAY NEWA | |

DIPHENHYDRAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DIPHENHYDRAMINE HCL

JUL CAHN AP AM PHARM PARTNERS 50MG/ML N40466 001 MAY 28, 2002 MAY NEWA

DIPHENIDOL HYDROCHLORIDE

TABLET; ORAL

VONTROL

@ GLAXOSMITHKLINE

EQ 25MG BASE

N16033 001

JUN DISC

JAN NEWA

DIVALPROEX SODIUM

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

ABBOTT

EQ 250MG VALPROIC ACID

N21168 002 MAY 31, 2002 JUL NEWA

JUN DISC

DONEPEZIL HYDROCHLORIDE

TABLET; ORAL

ARICEPT

EISAI MEDCL RES

5MG

N20690 002 NOV 25, 1996 MAY CAHN

+

10MG

N20690 001 NOV 25, 1996 MAY CAHN

DOXEPIPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIPIN HCL

@ LEDERLE

EQ 10MG BASE

N71685 001 JAN 05, 1988 MAY DISC

@

EQ 25MG BASE

N71686 001 JAN 05, 1988 MAY DISC

@

EQ 50MG BASE

N71673 001 JAN 05, 1988 MAY DISC

@

EQ 75MG BASE

N71674 001 JAN 05, 1988 MAY DISC

@

EQ 100MG BASE

N71675 001 JAN 05, 1988 MAY DISC

@

EQ 150MG BASE

N71676 001 JAN 05, 1988 MAY DISC

JUN CAHN

CREAM; TOPICAL

ZONALON

+ BIOGLAN PHARMS

5%

N20126 001 APR 01, 1994 JUN CAHN

JUL CAHN

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

PERIOSTAT

@ COLLAGENEX

EQ 20MG BASE

N50744 001 SEP 30, 1998 JUN DISC

JUN CAHN

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE AND DROPERIDOL

+ ABBOTT

2.5MG/ML;EQ 0.05MG BASE/ML

N71982 001 MAY 04, 1988 JUN CTEC

@ ASTRazeneca

2.5MG/ML;EQ 0.05MG BASE/ML

N72026 001 APR 13, 1989 JUN DISC

JUN CAHN

ECHOTHIOPHATE IODIDE

FOR SOLUTION; OPHTHALMIC

PHOSPHOLINE IODIDE

@ AYERST

0.03%

N11963 002

JUN DISC

@

0.06%

N11963 004

JUN DISC

@

0.25%

N11963 003

JUN DISC

MAY NEWA

EDETADE DISODIUM

INJECTABLE; INJECTION

EDETADE DISODIUM

AP PHARMAFORCE 150MG/ML

N40437 001 JUL 09, 2002 JUL NEWA

EFAVIRENZ

TABLET; ORAL

SUSTIVA

BRISTOL MYERS SQUIBB 300MG

+ 600MG

N21360 001 FEB 01, 2002 FEB NEWA

N21360 002 FEB 01, 2002 FEB NEWA

EFLORNITHINE HYDROCHLORIDE

CREAM; TOPICAL

VANIQA

+ WOMEN FIRST HLTHCARE 13.9%

N21145 001 JUL 27, 2000 JUL CAHN

ENALAPRIL MALEATE

TABLET; ORAL

VASOTEC

AB BIOVAIL 2.5MG

N18998 005 JUL 26, 1988 MAY CAHN

AB 5MG

N18998 001 DEC 24, 1985 MAY CAHN

AB 10MG

N18998 002 DEC 24, 1985 MAY CAHN

AB + 20MG

N18998 003 DEC 24, 1985 MAY CAHN

ENALAPRIL MALEATE; HYDROCHLORTIAZIDE

TABLET; ORAL

VASERETIC

AB BIOVAIL 5MG;12.5MG

N19221 003 JUL 12, 1995 MAY CAHN

AB + 10MG;25MG

N19221 001 OCT 31, 1986 MAY CAHN

ENALAPRILAT

INJECTABLE; INJECTION

VASOTEC

AP + BIOVAIL 1.25MG/ML

N19309 001 FEB 09, 1988 MAY CAHN

ENOXACIN

TABLET; ORAL

PENETREX

@ AVENTIS 200MG

N19616 004 DEC 31, 1991 JUN DISC

@ 400MG

N19616 005 DEC 31, 1991 JUN DISC

ENOXAPARIN SODIUM

INJECTABLE; SUBCUTANEOUS

LOVENOX

@ AVENTIS 90MG/0.6ML

N20164 006 JUN 02, 2000 JUN DISC

EPINEPHRINE

INJECTABLE; INJECTION

SUS-PHRINE SULFITE-FREE

@ FORREST LABS 1.5MG/AMP

N07942 003 FEB 05, 1999 JUN DISC

@ 5MG/ML

N07942 001 JUN DISC

EPINEPHRINE

INJECTABLE; INTRAMUSCULAR

EPI E Z PEN JR

@ MERIDIAN MEDCL TECHN 0.15MG/DELIVERY

N19430 004 AUG 03, 1995 JUN DISC

EPIPEN E Z PEN

@ MERIDIAN MEDCL TECHN 0.3MG/DELIVERY

N19430 003 AUG 03, 1995 JUN DISC

>A> EPLERENONE

TABLET; ORAL

INSPRA

>A> GD SEARLE LLC 25MG

N21437 001 SEP 27, 2002 SEP NEWA

>A> + 50MG

N21437 002 SEP 27, 2002 SEP NEWA

>A> + 100MG

N21437 003 SEP 27, 2002 SEP NEWA

EROSARTAN MESYLATE

TABLET; ORAL

TEVETEN

BIOVAIL PHARMS EQ 300MG BASE

N20738 004 DEC 22, 1997 JUN CAHN

EQ 400MG BASE

N20738 005 DEC 22, 1997 JUN CAHN

+ EQ 600MG BASE

N20738 006 MAY 27, 1999 JUN CAHN

EROSARTAN MESYLATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

TEVETEN HCT

BIOVAIL PHARMS 600MG;12.5MG

N21268 001 NOV 01, 2001 JUN CAHN

+ 600MG;25MG

N21268 002 NOV 01, 2001 JUN CAHN

EPTIFIBATIDE

INJECTABLE; INJECTION

INTEGRILIN

+ MILLENNIUM PHARMS 2MG/ML

N20718 001 MAY 18, 1998 FEB CAHN

+ 75MG/100ML

N20718 002 MAY 18, 1998 FEB CAHN

ERGOLOID MESYLATES

CAPSULE; ORAL

HYDERGINE LC

@ NOVARTIS 1MG

N18706 001 JAN 18, 1983 JUN DISC

SOLUTION; ORAL

HYDERGINE

@ NOVARTIS 1MG/ML

N18418 001 JUN DISC

ERYTHROMYCIN

GEL; TOPICAL

E-GLADES

AT GLADES PHARMS 2%

N65009 001 MAR 18, 2002 MAR NEWA

ESCITALOPRAM OXALATE

TABLET; ORAL

LEXAPRO

FOREST LABS 5MG

N21323 001 AUG 14, 2002 AUG NEWA

10MG

N21323 002 AUG 14, 2002 AUG NEWA

+ 20MG N21323 003 AUG 14, 2002 AUG NEWA

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

ALORA

| | | | |
|--------------|-------------|--------------|----------------------------------|
| BX | WATSON LABS | 0.025MG/24HR | N20655 004 APR 05, 2002 MAY CMS1 |
| BX | | 0.025MG/24HR | N20655 004 APR 16, 2002 APR NEWA |
| TABLET; ORAL | | | |
| ESTRADIOL | | | |
| AB | USL PHARMA | 0.5MG | N40297 001 APR 17, 2002 APR NEWA |
| AB | | 1MG | N40297 002 APR 17, 2002 APR NEWA |
| AB | | 2MG | N40297 003 APR 17, 2002 APR NEWA |

ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL

ACTIVELLA

| | | |
|----------------|-----------|----------------------------------|
| + NOVO NORDISK | 1MG;0.5MG | N20907 001 NOV 18, 1998 JUN CTNA |
|----------------|-----------|----------------------------------|

ESTRADIOL; NORGESTIMATE

TABLET; ORAL

ORTHO-PREFEST

| | | |
|---------------|----------------|----------------------------------|
| + KING PHARMS | 1MG;1MG;0.09MG | N21040 001 OCT 22, 1999 MAY CAHN |
|---------------|----------------|----------------------------------|

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTIN

| | | |
|--------------------|-------|----------------------------------|
| DURAMED | 0.3MG | N20992 001 JUN 21, 2002 AUG CAHN |
| DURAMED PHARM BARR | 0.3MG | N20992 001 JUN 21, 2002 JUL NEWA |

ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE

TABLET; ORAL-28

PREMPHASE (PREMARIN;CYCRIN 14/14)

| | | |
|----------------|---------------------|----------------------------------|
| @ WYETH AYERST | 0.625MG;0.625MG;5MG | N20303 002 DEC 30, 1994 JUN DISC |
|----------------|---------------------|----------------------------------|

PREMPRO (PREMARIN;CYCRIN)

| | | |
|----------------|-----------------------------|----------------------------------|
| @ WYETH AYERST | 0.625MG;0.625MG;2.5MG;2.5MG | N20303 001 DEC 30, 1994 JUN DISC |
|----------------|-----------------------------|----------------------------------|

ESTROGENS, CONJUGATED; MEPROBAMATE

TABLET; ORAL

PMB 200

| | | |
|----------------|--------------|---------------------|
| @ WYETH AYERST | 0.45MG;200MG | N10971 005 JUN DISC |
|----------------|--------------|---------------------|

PMB 400

| | | |
|----------------|--------------|---------------------|
| @ WYETH AYERST | 0.45MG;400MG | N10971 003 JUN DISC |
|----------------|--------------|---------------------|

ETHCHLORVYNOL

CAPSULE; ORAL

PLACIDYL

| | | |
|----------|-------|---------------------|
| @ ABBOTT | 200MG | N10021 007 JUN DISC |
| @ | 500MG | N10021 002 JUN DISC |
| @ | 750MG | N10021 010 JUN DISC |

2002 AUG NEWA

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

ALESSE

| | | | |
|---------------|------------------------|------------------------------|--|
| 2002 MAY CMS1 | AB + WYETH AYERST | 0.02MG;0.1MG 0.02MG;0.1MG | N20683 001 MAR 27, 1997 MAR CTEC N20683 001 MAR 27, 1997 MAY CTEC |
| 2002 APR NEWA | AB1 + AVIANE-21 | DURAMED PHARM BARR | N75796 002 APR 30, 2001 MAR CTEC |
| | AB1 LESSINA-21 | 0.02MG;0.1MG | |
| 2002 APR NEWA | AB2 BARR | 0.02MG;0.1MG | N75803 001 MAR 20, 2002 MAR NEWA |
| 2002 APR NEWA | LEVILITE | | |
| 2002 APR NEWA | AB2 + BERLEX LABS | 0.02MG;0.1MG | N20860 001 JUL 13, 1998 MAR CTEC |
| | PORTIA-21 | | |
| | AB BARR | 0.03MG;0.15MG | N75866 001 MAY 23, 2002 MAY NEWA |
| | TABLET; ORAL-28 | | |
| | ALESSE | | |
| 1998 JUN CTNA | AB1 WYETH AYERST | 0.02MG;0.1MG | N20683 002 MAR 27, 1997 MAR CTEC |
| | AVIANE-28 | | |
| | AB1 DURAMED PHARM BARR | 0.02MG;0.1MG | N75796 001 APR 30, 2001 MAR CTEC |
| | LESSINA-28 | | |
| | AB BARR | 0.02MG;0.1MG | N75803 002 MAR 20, 2002 MAR NEWA |
| | LEVILITE | | |
| | AB BERLEX LABS | 0.02MG;0.1MG | N20860 002 JUL 13, 1998 MAR CTEC |
| | PORTIA-28 | | |
| | AB BARR | 0.03MG;0.15MG | N75866 002 MAY 23, 2002 MAY NEWA |

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORTREL 0.5/35-21

| | | | |
|---------------|-------------------------|--|----------------------------------|
| 2002 JUL NEWA | AB BARR | 0.035MG;0.5MG | N72692 001 FEB 28, 1992 AUG CTNA |
| | AB BARR | 0.035MG;1MG | N72693 001 FEB 28, 1992 AUG CTNA |
| 1994 JUN DISC | NORTREL 7/7/7 | | |
| 1994 JUN DISC | AB BARR | 0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .75MG | N75478 001 AUG 30, 2002 AUG NEWA |
| | AB + ORTHO MCNEIL PHARM | 0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .75MG | N18985 001 APR 04, 1984 AUG CFTG |
| | TABLET; ORAL-28 | | |
| JUN DISC | NORTREL 0.5/35-28 | | |
| JUN DISC | AB BARR | 0.035MG;0.5MG | N72695 001 FEB 28, 1992 AUG CTNA |
| | AB BARR | 0.035MG;1MG | N72696 001 FEB 28, 1992 AUG CTNA |
| | NORTREL 7/7/7 | | |
| | AB BARR | 0.035MG,0.035MG,0.035MG;0.5MG,0.75M G,1MG | N75478 002 AUG 30, 2002 AUG NEWA |
| JUN DISC | AB ORTHO-NOVUM 7/7/7-28 | | |
| JUN DISC | AB ORTHO MCNEIL PHARM | 0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .75MG | N18985 002 APR 04, 1984 AUG CFTG |
| JUN DISC | | | |

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21

ESTROSTEP 21

@ PARKE DAVIS

0.02MG;0.03MG;0.035MG;1MG;1MG;1MG

N20130 001 OCT 09, 1996 JUN DISC

ETHINYL ESTRADIOL; NORGESTIMATE

TABLET; ORAL-28

ORTHO CYCLEN-28

| | | | |
|-----|-----------------------|-------------------------------------|----------------------------------|
| >D> | ORTHO MCNEIL PHARM | 0.035MG;0.25MG | N19653 002 DEC 29, 1989 SEP CFTG |
| >A> | AB + | 0.035MG;0.25MG | N19653 002 DEC 29, 1989 SEP CFTG |
| | ORTHO TRI-CYCLEN | | |
| >D> | ORTHO MCNEIL PHARM | 0.035MG,0.035MG,0.035MG;0.18MG,0.21 | N19697 001 JUL 03, 1992 SEP CRLD |
| | | 5MG,0.25MG | |
| >A> | + + | 0.035MG,0.035MG,0.035MG;0.18MG,0.21 | N19697 001 JUL 03, 1992 SEP CRLD |
| | | 5MG,0.25MG | |
| | ORTHO TRI-CYCLEN LO | | |
| | + JOHNSON AND JOHNSON | 0.025MG,0.025MG,0.025MG;0.18MG,0.25 | N21241 001 AUG 22, 2002 AUG NEWA |
| | | MG,0.215MG | |
| >A> | SPRINTEC | | |
| >A> | AB BARR | 0.035MG;0.25MG | N75804 001 SEP 25, 2002 SEP NEWA |

ETHOTOIN

TABLET; ORAL

PEGANONE

+ ABBOTT

@

250MG

N10841 001

JUN CRLD

500MG

N10841 003

JUN DISC

ETIDOCAINE HYDROCHLORIDEINJECTABLE; INJECTIONDURANEST

+ ASTRazeneca

1%

N17751 005

SEP DISC

@

1%

N17751 005

SEP DISC

ETODOLAC

CAPSULE; ORAL

ETODOLAC

AB NEOSAN PHARMS

300MG

N74929 001 JAN 30, 1998 JUL CAHN

TABLET; ORAL

AB NEOSAN PHARMS

400MG

N74927 001 OCT 30, 1997 JUL CAHN

TABLET, EXTENDED RELEASE; ORAL

AB EON

400MG

N75943 001 JUL 26, 2002 JUL NEWA

AB

500MG

N75943 002 JUL 26, 2002 JUL NEWA

AB

600MG

N75943 003 JUL 26, 2002 JUL NEWA

FAMOTIDINE

INJECTABLE; INJECTION

FAMOTIDINE

AP APOTEX

10MG/ML

N75942 001 AUG 02, 2002 AUG NEWA

AP BAXTER HLTHCARE

10MG/ML

N75799 001 APR 30, 2002 APR NEWA

FAMOTIDINE PRESERVATIVE FREE

AP APOTHECON

10MG/ML

N75708 001 APR 16, 2001 MAR WDAG

AP BAXTER HLTHCARE

10MG/ML

N75789 001 APR 30, 2002 APR NEWA

FENOFIBRATE

CAPSULE; ORAL

FENOFIBRATE (MICRONIZED)

| | | | | | | | | | |
|-----|------|-----|----|---------------------|-------|------------|--------------|-----|------|
| JUN | DISC | >A> | AB | TEVA | 67MG | N75753 001 | SEP 03, 2002 | SEP | NEWA |
| | | | AB | | 134MG | N75753 002 | APR 09, 2002 | APR | NEWA |
| | | | AB | | 200MG | N75753 003 | APR 09, 2002 | APR | NEWA |
| | | | | TRICOR (MICRONIZED) | | | | | |
| SEP | CFTG | >D> | | ABBOTT | 67MG | N19304 002 | FEB 09, 1998 | SEP | CFTG |
| SEP | CFTG | >A> | AB | | 67MG | N19304 002 | FEB 09, 1998 | SEP | CFTG |
| | | | AB | | 134MG | N19304 003 | JUN 30, 1999 | APR | CFTG |
| | | | AB | + | 200MG | N19304 004 | JUN 30, 1999 | APR | CFTG |

FENOPROFEN CALCIUM

CAPSULE; ORAL

NALFON

| | | | | | | | | | |
|-----|------|----|---|------------|---------------|------------|--|-----|------|
| SEP | CRLD | AB | + | RANBAXY | EQ 300MG BASE | N17604 002 | | JUN | CAHN |
| | | | | NALFON 200 | | | | | |
| AUG | NEWA | AB | | RANBAXY | EQ 200MG BASE | N17604 003 | | JUN | CAHN |

FENTANYL CITRATE

TROCHE/LOZENGE; ORAL

FENTANYL

| | | | | | | | | |
|-----|------|----------|--|---------------|------------|--------------|-----|------|
| JUN | CRLD | @ ANESTA | | EQ 0.1MG BASE | N20195 007 | OCT 30, 1995 | JUN | DISC |
| JUN | DISC | @ | | EQ 0.2MG BASE | N20195 001 | OCT 04, 1993 | JUN | DISC |
| | | @ | | EQ 0.3MG BASE | N20195 002 | OCT 04, 1993 | JUN | DISC |
| | | @ | | EQ 0.4MG BASE | N20195 003 | OCT 04, 1993 | JUN | DISC |

FERRIC AMMONIUM CITRATE

FOR SOLUTION; ORAL

FERRISELTZ

| | | | | | | | | |
|-----|------|-----------------|--|--------------|------------|--------------|-----|------|
| SEP | DISC | @ AMERSHAM HLTH | | 600MG/PACKET | N20292 001 | OCT 14, 1997 | JUL | DISC |
|-----|------|-----------------|--|--------------|------------|--------------|-----|------|

| | | | | | | | | | |
|-----|------|--|--|--|--|--|--|--|--|
| SEP | DISC | | | | | | | | |
|-----|------|--|--|--|--|--|--|--|--|

FLOXURIDINE

INJECTABLE; INJECTION

FUDR

| | | | | | | | | | |
|-----|------|----|---|----------|------------|------------|--|-----|------|
| JUL | CAHN | AP | + | FAULDING | 500MG/VIAL | N16929 001 | | APR | CAHN |
|-----|------|----|---|----------|------------|------------|--|-----|------|

FLUDEOXYGLUCOSE, F-18

INJECTABLE; INJECTION

FLUDEOXYGLUCOSE F 18

| | | | | | | | | |
|-----|------|--------------------|--|------------|------------|--------------|-----|------|
| JUL | CAHN | @ DOWNSTATE CLINCL | | 4-40mCi/ML | N20306 001 | AUG 19, 1994 | JUL | DISC |
|-----|------|--------------------|--|------------|------------|--------------|-----|------|

| | | | | | | | | | |
|-----|------|--|--|--|--|--|--|--|--|
| JUL | CAHN | | | | | | | | |
|-----|------|--|--|--|--|--|--|--|--|

FLUDROCORTISONE ACETATE

TABLET; ORAL

FLORINEF

| | | | | | | | | | |
|-----|------|----|---|-------------|-------|------------|--|-----|------|
| AUG | NEWA | AB | + | KING PHARMS | 0.1MG | N10060 001 | | MAR | CFTG |
|-----|------|----|---|-------------|-------|------------|--|-----|------|

| | | | | | | | | | |
|-----|------|--|--|-------------------------|--|--|--|--|--|
| APR | NEWA | | | FLUDROCORTISONE ACETATE | | | | | |
|-----|------|--|--|-------------------------|--|--|--|--|--|

| | | | | | | | | | |
|-----|------|----|--|------------|-------|------------|--------------|-----|------|
| MAR | WDAG | AB | | IMPAX LABS | 0.1MG | N40431 001 | MAR 18, 2002 | MAR | NEWA |
|-----|------|----|--|------------|-------|------------|--------------|-----|------|

| | | | | | | | | | |
|-----|------|--|--|--|--|--|--|--|--|
| APR | NEWA | | | | | | | | |
|-----|------|--|--|--|--|--|--|--|--|

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 9 - SEP 2002

FLUNISOLIDE

| | | | |
|-----------------------|---------------|------------|--------------|
| SPRAY, METERED; NASAL | | | |
| FLUNISOLIDE | | | |
| AB BAUSCH AND LOMB | 0.025MG/SPRAY | N74805 001 | FEB 20, 2002 |
| NASALIDE | | | |
| AB + IVAX RES | 0.025MG/SPRAY | N18148 001 | |

FLUOCINOLONE ACETONIDE

| | | | |
|--------------------|-------|------------|--------------|
| CREAM; TOPICAL | | | |
| SYNALAR-HP | | | |
| @ MEDICIS | 0.2% | N16161 002 | |
| SOLUTION; TOPICAL | | | |
| FLUONID | | | |
| @ ALLERGAN HERBERT | 0.01% | N87158 001 | MAR 17, 1983 |

FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN

| | | | |
|----------------|----------------|------------|--------------|
| CREAM; TOPICAL | | | |
| TRI-LUMA | | | |
| + HILL DERMAC | 0.01%;4%;0.05% | N21112 001 | JAN 18, 2002 |

FLUOCINONIDE

| | | | |
|------------------------------|-------|------------|--------------|
| CREAM; TOPICAL | | | |
| FLUOCINONIDE EMULSIFIED BASE | | | |
| AB TEVA | 0.05% | N72490 001 | FEB 07, 1989 |

FLUOXETINE HYDROCHLORIDE

| | | | |
|-----------------------|--------------|------------|--------------|
| CAPSULE; ORAL | | | |
| FLUOXETINE | | | |
| AB ALPHAPHARM | EQ 10MG BASE | N75577 001 | JAN 29, 2002 |
| AB | EQ 20MG BASE | N75577 002 | JAN 29, 2002 |
| AB BARR | EQ 10MG BASE | N74803 002 | JAN 30, 2002 |
| AB CARLSBAD | EQ 10MG BASE | N76022 001 | JAN 30, 2002 |
| AB | EQ 20MG BASE | N76022 002 | JAN 30, 2002 |
| AB DR REDDYS LABS INC | EQ 10MG BASE | N75465 001 | JAN 29, 2002 |
| AB | EQ 20MG BASE | N75465 002 | JAN 29, 2002 |
| AB EON | EQ 10MG BASE | N75807 001 | JAN 29, 2002 |
| AB | EQ 20MG BASE | N75807 002 | JAN 29, 2002 |
| AB IVAX PHARMS | EQ 10MG BASE | N75245 002 | JAN 31, 2002 |
| AB | EQ 20MG BASE | N75245 001 | JAN 31, 2002 |
| AB MALLINCKRODT | EQ 10MG BASE | N75658 001 | JAN 29, 2002 |
| AB | EQ 20MG BASE | N75658 002 | JAN 29, 2002 |
| AB MUTUAL PHARMA | EQ 10MG BASE | N75787 001 | JAN 29, 2002 |
| AB | EQ 20MG BASE | N75787 002 | JAN 29, 2002 |
| AB MYLAN | EQ 10MG BASE | N75207 001 | JAN 30, 2002 |
| AB | EQ 20MG BASE | N75207 002 | JAN 30, 2002 |
| AB RANBAXY | EQ 10MG BASE | N76165 001 | FEB 01, 2002 |
| AB | EQ 20MG BASE | N76165 002 | FEB 01, 2002 |
| AB SIDMAK LABS | EQ 10MG BASE | N76001 001 | JAN 29, 2002 |
| AB | EQ 20MG BASE | N76001 002 | JAN 29, 2002 |
| AB SIEGFRIED | EQ 10MG BASE | N75464 001 | JAN 30, 2002 |
| AB | EQ 20MG BASE | N75464 002 | JAN 30, 2002 |
| AB TEVA | EQ 10MG BASE | N75452 001 | JAN 29, 2002 |

| | | | | | |
|-----|------|-----|---|--|--|
| | | AB | WATSON LABS | EQ 20MG BASE EQ 40MG BASE EQ 10MG BASE EQ 20MG BASE | N75452 002 JAN 29, 2002 JAN NEWA N75452 003 JAN 29, 2002 JAN NEWA N75662 001 JAN 29, 2002 JAN NEWA N75662 002 JAN 29, 2002 JAN NEWA |
| FEB | NEWA | AB | FLUOXETINE HCL GENEVA PHARMS | EQ 20MG BASE EQ 40MG BASE | N75049 002 JAN 29, 2002 JAN NEWA N75049 003 JAN 29, 2002 JAN NEWA |
| FEB | CTEC | AB | SOLUTION; ORAL FLUOXETINE ALPHARMA | EQ 20MG BASE/5ML EQ 20MG BASE/5ML | N75690 001 JAN 31, 2002 JAN NEWA N75920 001 JAN 29, 2002 JAN NEWA |
| JUN | DISC | AA | MALLINCKRODT | EQ 20MG BASE/5ML | N75292 001 FEB 07, 2002 FEB NEWA |
| | | AA | NOVEX | EQ 20MG BASE/5ML | N76015 001 JAN 30, 2002 JAN NEWA |
| | | AA | PHARM ASSOC | EQ 20MG BASE/5ML | |
| MAY | DISC | | FLUOXETINE HCL HI TECH PHARMA | EQ 20MG BASE/5ML | N75525 001 JUN 27, 2002 JUN NEWA |
| | | AA | MORTON GROVE | EQ 20MG BASE/5ML | N75514 001 AUG 29, 2002 AUG NEWA |
| | | | TABLET; ORAL BARR | EQ 10MG BASE | N75810 001 FEB 01, 2002 FEB NEWA |
| JAN | NEWA | AB | DR REDDYS LABS INC | EQ 10MG BASE | N76006 001 JAN 30, 2002 JAN NEWA |
| | | AB | EON | EQ 10MG BASE | N76024 001 JAN 29, 2002 JAN NEWA |
| | | AB | TEVA | EQ 10MG BASE | N75872 001 JAN 29, 2002 JAN NEWA |
| | | AB | ZENITH GOLDLINE | EQ 10MG BASE | N75865 001 FEB 28, 2002 FEB NEWA |
| AUG | CTNA | | <u>FLUPHENAZINE ENANTHATE</u> INJECTABLE; INJECTION PROLIXIN ENANTHATE @ APOTHECON | 25MG/ML | N16110 001 JUN DISC |
| | | | <u>FLUVOXAMINE MALEATE</u> TABLET; ORAL FLUVOXAMINE MALEATE | | |
| JAN | NEWA | AB | + EON | 100MG | N75888 003 NOV 29, 2000 MAY CRLD |
| JAN | NEWA | AB | MUTUAL PHARM | 25MG | N76125 001 APR 29, 2002 APR NEWA |
| JAN | NEWA | AB | | 50MG | N76125 002 APR 29, 2002 APR NEWA |
| JAN | NEWA | AB | | 100MG | N76125 003 APR 29, 2002 APR NEWA |
| JAN | NEWA | >A> | AB TEVA | 25MG | N75893 001 SEP 10, 2002 SEP NEWA |
| JAN | NEWA | >A> | AB | 50MG | N75893 002 SEP 10, 2002 SEP NEWA |
| JAN | NEWA | >A> | AB | 100MG | N75893 003 SEP 10, 2002 SEP NEWA |
| JAN | NEWA | | LUVOX | | |
| JAN | NEWA | | @ SOLVAY | 25MG | N20243 001 DEC 05, 1994 MAY DISC |
| JAN | NEWA | | @ | 50MG | N20243 002 DEC 05, 1994 MAY DISC |
| JAN | NEWA | | @ | 100MG | N20243 003 DEC 05, 1994 MAY DISC |
| JAN | NEWA | | <u>FOLIC ACID</u> | | |
| JAN | NEWA | | TABLET; ORAL FOLIC ACID | | |
| FEB | NEWA | AA | + WATSON LABS | 1MG | N80680 001 FEB CAHN |
| FEB | NEWA | | | | |
| JAN | NEWA | | <u>FOLLITROPIN ALFA/BETA</u> INJECTABLE; INJECTION GONAL-F @ SERONO | 37.5 IU/VIAL | N20378 003 MAY 25, 2000 JUN DISC |
| JAN | NEWA | | | | |
| JAN | NEWA | | | | |
| JAN | NEWA | | | | |
| JAN | NEWA | | | | |

FULVESTRANT

INJECTABLE; INTRAMUSCULAR
FASLODEX
+ ASTRazeneca 50MG/ML

N21344 001 APR 25, 2002 APR NEWA

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE
@ SHIRE LABS 50MG/15ML
TABLET; ORAL
@ SHIRE LABS 100MG

N11323 002 JUL DISC

N11270 002 JUL DISC

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION
NEOSCAN
@ AMERSHAM HLTH 2mCi/ML

N17655 001 JUN DISC

GALLIUM NITRATE

INJECTABLE; INJECTION
GANITE
@ GENTA 25MG/ML

N19961 002 JAN 17, 1991 JUL CAHN

GLATIRAMER ACETATE

FOR SOLUTION; SUBCUTANEOUS
COPAXONE
+ TEVA 20MG/VIAL
INJECTABLE; SUBCUTANEOUS
+ TEVA 20MG/ML

N20622 001 DEC 20, 1996 JUN CDFR

N20622 002 FEB 12, 2002 JUN NEWA

GLIPIZIDE

TABLET, EXTENDED RELEASE; ORAL
GLUCOTROL XL
PFIZER 2.5MG
5MG

N20329 003 AUG 10, 1999 FEB CRLD

N20329 001 APR 26, 1994 FEB CRLD

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION
GLUCAGON
@ LILLY EQ 1MG BASE/VIAL

N12122 001 JUN DISC

GLYBURIDE

TABLET; ORAL
GLYBURIDE
AB COREPHARMA 1.25MG
AB 2.5MG
AB 5MG

N76257 001 JUN 27, 2002 JUN NEWA

N76257 002 JUN 27, 2002 JUN NEWA

N76257 003 JUN 27, 2002 JUN NEWA

GONADORELIN ACETATE

INJECTABLE; INJECTION
LUTREPULSE KIT
@ FERRING 0.8MG/VIAL
@ 3.2MG/VIAL

N19687 001 OCT 10, 1989 JUL DISC

N19687 002 OCT 10, 1989 JUN DISC

GONADORELIN HYDROCHLORIDE

INJECTABLE; INJECTION

FACTREL

@ WYETH AYERST

EQ 0.5MG BASE/VIAL

N18123 003 SEP 30, 1982 JUN DISC

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

A.P.L.

@ WYETH AYERST

20,000 UNITS/VIAL

N17055 003 JUN DISC

CHORIONIC GONADOTROPIN

@ STERIS

2,000 UNITS/VIAL

N17016 011 FEB 16, 1990 JUN DISC

GRANISETRON HYDROCHLORIDE

SOLUTION; ORAL

KYTRIL

@ ROCHE

EQ 2MG BASE/10ML

N21238 001 JUN 27, 2001 JUN DISC

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

GRISACTIN

@ WYETH AYERST

500MG

N60212 001 MAY DISC

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

GRISACTIN ULTRA

@ WYETH AYERST

165MG

N62438 001 NOV 17, 1983 MAY DISC

@

330MG

N62438 002 NOV 17, 1983 MAY DISC

GUANADREL SULFATE

TABLET; ORAL

HYLOREL

@ PHARMACIA AND UPJOHN

10MG

N18104 001 DEC 29, 1982 JUN DISC

@

25MG

N18104 002 DEC 29, 1982 JUN DISC

GUANETHIDINE MONOSULFATE

TABLET; ORAL

ISMELIN

@ NOVARTIS

EQ 10MG SULFATE

N12329 001 JUN DISC

@

EQ 25MG SULFATE

N12329 002 JUN DISC

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

TENEX

AB ESP PHARMA

EQ 1MG BASE

N19032 001 OCT 27, 1986 APR CAHN

AB +

EQ 2MG BASE

N19032 002 NOV 07, 1988 APR CAHN

@

EQ 3MG BASE

N19032 003 NOV 07, 1988 APR CAHN

HALOPERIDOL

TABLET; ORAL

HALDOL

@ ORTHO MCNEIL

0.5MG

N15921 001 AUG DISC

@

1MG

N15921 002 AUG DISC

| | | | |
|-----------------|------|------------|-----------------------|
| @ | 2MG | N15921 003 | AUG DISC |
| @ | 5MG | N15921 004 | AUG DISC |
| @ | 10MG | N15921 005 | AUG DISC |
| @ | 20MG | N15921 006 | FEB 02, 1982 AUG DISC |
| HALOPERIDOL | | | |
| + GENEVA PHARMS | 20MG | N71211 001 | MAR 11, 1988 AUG CRLD |

HALOPERIDOL LACTATE

| | | | |
|-------------------|----------------|------------|-----------------------|
| CONCENTRATE; ORAL | | | |
| HALDOL | | | |
| @ ORTHO MCNEIL | EQ 2MG BASE/ML | N15922 001 | AUG DISC |
| HALOPERIDOL | | | |
| @ ALPHARMA | EQ 2MG BASE/ML | N70318 001 | APR 11, 1986 MAY DISC |
| AA + TEVA | EQ 2MG BASE/ML | N71015 001 | AUG 25, 1987 AUG CRLD |

HALOTHANE

| | | | |
|--------------------|--------|------------|----------|
| LIQUID; INHALATION | | | |
| FLUOTHANE | | | |
| @ WYETH AYERST | 99.99% | N11338 001 | APR DISC |
| HALOTHANE | | | |
| AN + ABBOTT | 99.99% | N83254 001 | APR CTEC |

HEPARIN SODIUM

| | | | |
|------------------------|-------------------|------------|-----------------------|
| INJECTABLE; INJECTION | | | |
| HEP-LOCK | | | |
| AP + ELKINS SINK | 10 UNITS/ML | N17037 007 | JUN CRLD |
| AP + | 100 UNITS/ML | N17037 006 | JUN CRLD |
| HEPARIN LOCK FLUSH | | | |
| @ WYETH AYERST | 10 UNITS/ML | N17007 008 | JUN DISC |
| @ | 100 UNITS/ML | N17007 009 | JUN DISC |
| HEPARIN SODIUM | | | |
| AP + ABBOTT | 2,500 UNITS/ML | N88099 001 | APR 28, 1983 JUN CRLD |
| AP + AM PHARM PARTNERS | 20,000 UNITS/ML | N17029 004 | JUN CRLD |
| @ WYETH AYERST | 1,000 UNITS/ML | N17007 001 | JUN DISC |
| @ | 2,500 UNITS/ML | N17007 007 | JUN DISC |
| @ | 5,000 UNITS/ML | N17007 002 | JUN DISC |
| @ | 5,000 UNITS/0.5ML | N17007 010 | JUN DISC |
| @ | 7,500 UNITS/ML | N17007 003 | JUN DISC |
| @ | 10,000 UNITS/ML | N17007 004 | JUN DISC |
| @ | 20,000 UNITS/ML | N17007 006 | JUN DISC |

HEXACHLOROPHENONE

| | | | |
|--------------------|-------|------------|----------|
| SOAP; TOPICAL | | | |
| GAMOPHEN | | | |
| @ ARBROOK | 2% | N06270 003 | JUN DISC |
| SPONGE; TOPICAL | | | |
| E-Z SCRUB | | | |
| @ BECTON DICKINSON | 450MG | N17452 001 | JUN DISC |

HISTRELIN ACETATE

| | | | |
|-----------------------|------------------|------------|-----------------------|
| INJECTABLE; INJECTION | | | |
| SUPPRELIN | | | |
| @ SHIRE LABS | EQ 0.2MG BASE/ML | N19836 001 | DEC 24, 1991 JUL DISC |

| | | | | | | | |
|------|------|------|--|-------------|--------------|------------|--------------|
| AUG | DISC | | EQ 0.5MG BASE/ML | N19836 002 | DEC 24, 1991 | JUL | DISC |
| AUG | DISC | | EQ 1MG BASE/ML | N19836 003 | DEC 24, 1991 | JUL | DISC |
| AUG | DISC | | | | | | |
| 1982 | AUG | DISC | | | | | |
| | | | <u>HYDROCHLOROTHIAZIDE</u> | | | | |
| | | | CAPSULE; ORAL | | | | |
| 1988 | AUG | CRLD | HYDROCHLOROTHIAZIDE | | | | |
| | | | >A> AB VINTAGE PHARMS | 12.5MG | | N75907 001 | SEP 17, 2002 |
| | | | >D> TABLET; ORAL | | | | SEP NEWA |
| | | | >D> ESIDRIX | | | | |
| | | | >D> AB + NOVARTIS | 100MG | | N11793 009 | SEP DISC |
| | | | >A> AB @ | 100MG | | N11793 009 | SEP DISC |
| | | | >A> AB + | 100MG | | N11793 009 | MAR CRLD |
| 1986 | MAY | DISC | HYDROCHLOROTHIAZIDE | | | | |
| 1987 | AUG | CRLD | >D> AB IVAX PHARMS | 100MG | | N85022 001 | SEP CRLD |
| | | | >D> AB + | 100MG | | N85022 001 | SEP CRLD |
| | | | >D> AB LEDERLE | 100MG | | N87060 001 | SEP DISC |
| | | | >A> AB @ | 100MG | | N87060 001 | SEP DISC |
| | | | >A> AB VINTAGE PHARMS | 25MG | | N40412 001 | MAR 29, 2002 |
| | | | >A> AB | 50MG | | N40412 002 | MAR 29, 2002 |
| | | | >D> AB WATSON LABS | 100MG | | N81190 001 | JAN 24, 1992 |
| | | | >A> AB | 100MG | | N81190 001 | JAN 24, 1992 |
| | | | HYDRODIURIL | | | | |
| | | | @ MERCK | 25MG | | N11835 003 | MAR DISC |
| | | | @ | 50MG | | N11835 006 | MAR DISC |
| | | | @ | 100MG | | N11835 007 | MAR DISC |
| JUN | CRLD | | >D> ORETIC | | | | |
| JUN | CRLD | | >D> AB ABBOTT | 25MG | | N11971 001 | SEP DISC |
| | | | >A> AB | 25MG | | N11971 001 | SEP DISC |
| JUN | DISC | | | | | | |
| JUN | DISC | | <u>HYDROCHLOROTHIAZIDE; LISINOPRIL</u> | | | | |
| | | | TABLET; ORAL | | | | |
| 1983 | JUN | CRLD | LISINOPRIL AND HYDROCHLOROTHIAZIDE | | | | |
| JUN | CRLD | | AB EON | 12.5MG;10MG | | N76262 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N76262 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N76262 003 | JUL 01, 2002 |
| JUN | DISC | | AB GENEVA PHARMS TECH | 12.5MG;10MG | | N75926 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N75926 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N75926 003 | JUL 01, 2002 |
| JUN | DISC | | AB IVAX PHARMS | 12.5MG;10MG | | N75776 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N75776 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N75776 003 | JUL 01, 2002 |
| JUN | DISC | | AB MYLAN | 12.5MG;10MG | | N76113 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N76113 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N76113 003 | JUL 01, 2002 |
| JUN | DISC | | AB PUREPAC PHARM | 12.5MG;10MG | | N76230 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N76230 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N76230 003 | JUL 01, 2002 |
| JUN | DISC | | AB RANBAXY | 12.5MG;10MG | | N76007 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N76007 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N76007 003 | JUL 01, 2002 |
| JUN | DISC | | AB TEVA | 12.5MG;10MG | | N75869 001 | JUL 01, 2002 |
| JUN | DISC | | AB | 12.5MG;20MG | | N75869 002 | JUL 01, 2002 |
| JUN | DISC | | AB | 25MG;20MG | | N75869 003 | JUL 01, 2002 |
| 1991 | JUL | DISC | | | | | |

| | | | | | | |
|----|-------------|-------------|------------|--------------|-----|------|
| AB | WATSON LABS | 12.5MG;20MG | N76194 001 | JUL 01, 2002 | JUL | NEWA |
| AB | | 12.5MG;10MG | N76194 003 | JUL 01, 2002 | JUL | NEWA |
| AB | | 25MG;20MG | N76194 002 | JUL 01, 2002 | JUL | NEWA |
| AB | WEST WARD | 12.5MG;10MG | N76265 001 | JUL 08, 2002 | JUL | NEWA |
| AB | | 12.5MG;20MG | N76265 002 | JUL 08, 2002 | JUL | NEWA |
| AB | | 25MG;20MG | N76265 003 | JUL 08, 2002 | JUL | NEWA |

HYDROCHLOROTHIAZIDE; MOXIPRIL HYDROCHLORIDE

TABLET; ORAL

UNIRETIC

SCHWARZ PHARMA 12.5MG;15MG

N20729 003 FEB 14, 2002 JUN NEWA

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

INDERIDE LA 120/50

@ WYETH AYERST 50MG;120MG

N19059 002 JUL 03, 1985 JUN DISC

INDERIDE LA 160/50

@ WYETH AYERST 50MG;160MG

N19059 003 JUL 03, 1985 JUN DISC

INDERIDE LA 80/50

@ WYETH AYERST 50MG;80MG

N19059 001 JUL 03, 1985 JUN DISC

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDROPRES 25

@ MERCK 25MG;0.125MG

N11958 002 JUN DISC

HYDROPRES 50

@ MERCK 50MG;0.125MG

N11958 003 JUN DISC

>D> HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

>D> SYRUP; ORAL

>D> CODAMINE

>D> AA ALPHARMA 5MG/5ML;25MG/5ML

N75103 001 SEP 29, 2000 SEP DISC

>A> @ 5MG/5ML;25MG/5ML

N75103 001 SEP 29, 2000 SEP DISC

>D> HYCOMINE

>D> AA + ENDO PHARMS 5MG/5ML;25MG/5ML

N19410 001 AUG 17, 1990 SEP DISC

>A> @ 5MG/5ML;25MG/5ML

N19410 001 AUG 17, 1990 SEP DISC

>D> HYCOMINE PEDIATRIC

>D> ENDO PHARMS 2.5MG/5ML;12.5MG/5ML

N19411 001 AUG 17, 1990 SEP DISC

>A> @ 2.5MG/5ML;12.5MG/5ML

N19411 001 AUG 17, 1990 SEP DISC

HYDROCORTISONE

TABLET; ORAL

CORTEF

+ PHARMACIA AND UPJOHN 5MG

N08697 003 MAY CRLD

BP + 10MG

N08697 001 MAY CRLD

BP + 20MG

N08697 002 MAY CRLD

HYDROCORTISONE ACETATE

CREAM; TOPICAL

MICORT-HC

+ FERNDALE LABS 2%

N40398 001 MAR 29, 2002 MAR NEWA

HYDROCORTISONE ACETATE

INJECTABLE; INJECTION

HYDROCORTISONE ACETATE

| | | | | |
|--------------|---------|------------|-----|------|
| + STERIS | 25MG/ML | N83128 001 | JUN | CRLD |
| HYDROCORTONE | | | | |
| @ MERCK | 25MG/ML | N08228 001 | JUN | DISC |
| @ | 50MG/ML | N08228 004 | JUN | DISC |

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

LOCOID

| | | | | | |
|-----------------|------|------------|--------------|-----|------|
| + FERNDALE LABS | 0.1% | N18514 001 | MAR 31, 1982 | MAR | CAHN |
| + FERNDALE LABS | 0.1% | N20769 001 | SEP 08, 1997 | MAR | CAHN |

OINTMENT; TOPICAL

LOCOID

| | | | | | |
|-----------------|------|------------|--------------|-----|------|
| + FERNDALE LABS | 0.1% | N18652 001 | OCT 29, 1982 | MAR | CAHN |
|-----------------|------|------------|--------------|-----|------|

HYDROCORTISONE; TETRACYCLINE HYDROCHLORIDE

OINTMENT; OPHTHALMIC

ACHROMYCIN

| | | | | |
|-----------|---------|------------|-----|------|
| @ LEDERLE | 1.5%;1% | N50272 001 | JUN | DISC |
|-----------|---------|------------|-----|------|

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL

| | | | | | |
|----------------------------------|--------------|------------|--------------|-----|------|
| RESERPINE AND HYDROFLUMETHIAZIDE | | | | | |
| @ PAR PHARM | 50MG;0.125MG | N88907 001 | SEP 20, 1985 | AUG | DISC |
| SALUTENSIN-DEMI | | | | | |
| @ SHIRE LABS | 25MG;0.125MG | N12359 004 | | JUL | DISC |

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC

| | | | | | |
|-----------|----|------------|--|-----|------|
| PAREDRINE | | | | | |
| @ AKORN | 1% | N00004 004 | | JUN | DISC |

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION

| | | | | | |
|------------------------------|----------|------------|--|-----|------|
| HYDROXYPROGESTERONE CAPROATE | | | | | |
| @ STERIS | 250MG/ML | N17439 002 | | JUN | DISC |

HYDROXYZINE HYDROCHLORIDE

SYRUP; ORAL

| | | | | | |
|-------------------|----------|------------|--------------|-----|------|
| HYDROXYZINE HCL | | | | | |
| AA VINTAGE PHARMS | 10MG/5ML | N40391 001 | APR 10, 2002 | APR | NEWA |

IBUPROFEN

| | | | | | |
|------------------------|---------|------------|--------------|-----|------|
| SUSPENSION/DROPS; ORAL | | | | | |
| MOTRIN | | | | | |
| @ MCNEIL | 40MG/ML | N20476 001 | MAY 25, 1995 | JUN | DISC |
| TABLET; ORAL | | | | | |
| @ MCNEIL CONS SPECLT | 100MG | N20418 001 | NOV 16, 1994 | JUN | DISC |

IBUPROFEN

TABLET, CHEWABLE; ORAL

MOTRIN

| | | | | | |
|----------------------|-------|------------|--------------|-----|------|
| @ MCNEIL CONS SPECLT | 50MG | N20135 001 | NOV 16, 1994 | JUN | DISC |
| @ | 100MG | N20135 002 | NOV 16, 1994 | JUN | DISC |

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

IDAMYCIN

| | | | | | |
|---------------------------|-----------|------------|--------------|-----|------|
| AP + PHARMACIA AND UPJOHN | 5MG/VIAL | N50661 002 | SEP 27, 1990 | MAY | CFTG |
| @ | 5MG/VIAL | N50661 002 | SEP 27, 1990 | JUN | DISC |
| AP + | 10MG/VIAL | N50661 001 | SEP 27, 1990 | MAY | CFTG |
| @ | 10MG/VIAL | N50661 001 | SEP 27, 1990 | JUN | DISC |
| AP + | 20MG/VIAL | N50661 003 | APR 25, 1995 | MAY | CFTG |
| @ | 20MG/VIAL | N50661 003 | APR 25, 1995 | JUN | DISC |
| IDAMYCIN PFS | | | | | |
| AP + PHARMACIA AND UPJOHN | 1MG/ML | N50734 001 | FEB 17, 1997 | MAY | CFTG |
| IDARUBICIN HCL | | | | | |
| AP GENSIA SICOR PHARMS | 5MG/VIAL | N65037 003 | MAY 01, 2002 | MAY | NEWA |
| + | 10MG/VIAL | N65037 002 | MAY 01, 2002 | JUN | CRLD |
| AP + | 10MG/VIAL | N65037 002 | MAY 01, 2002 | MAY | NEWA |
| + | 20MG/VIAL | N65037 001 | MAY 01, 2002 | JUN | CRLD |
| AP | 20MG/VIAL | N65037 001 | MAY 01, 2002 | MAY | NEWA |
| IDARUBICIN HCL PFS | | | | | |
| AP GENSIA SICOR PHARMS | 1MG/ML | N65036 001 | MAY 01, 2002 | MAY | NEWA |

IFOSFAMIDE

INJECTABLE; INJECTION

IFSOFAMIDE

| | | | | | |
|---------------------|----------|------------|--------------|-----|------|
| + AM PHARM PARTNERS | 1GM/VIAL | N76078 001 | MAY 28, 2002 | AUG | CRLD |
| | 1GM/VIAL | N76078 001 | MAY 28, 2002 | MAY | NEWA |
| + | 3GM/VIAL | N76078 002 | MAY 28, 2002 | MAY | NEWA |

IFOSFAMIDE; MESNA

INJECTABLE; INTRAVENOUS

IFOSFAMIDE/MESNA KIT

| | | | | | |
|-----------------------|---|------------|--------------|-----|------|
| + GENSIA SICOR PHARMS | 1GM /20ML(50MG/ML);1GM /10ML(100MG/ML) | N75874 001 | FEB 26, 2002 | FEB | NEWA |
| + | 3GM /60ML(50MG/ML);1GM /10ML(100MG/ML) | N75874 002 | FEB 26, 2002 | FEB | NEWA |

INAMRINONE LACTATE

INJECTABLE; INJECTION

AMRINONE

| | | | | | |
|---------------------|----------------|------------|--------------|-----|------|
| AP + ABBOTT | EQ 5MG BASE/ML | N74616 001 | AUG 03, 1998 | JUN | CRLD |
| INOCOR | | | | | |
| @ SANOFI SYNTHELABO | EQ 5MG BASE/ML | N18700 001 | JUL 31, 1984 | JUN | DISC |

INDOCYANINE GREEN

INJECTABLE; INJECTION
CARDIO-GREEN
@ AKORN

50MG/VIAL

N11525 002

JUN DISC

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

AB PAR PHARM 25MG
AB 50MG

N18829 002 AUG 06, 1984 JUL CAHN
N18829 001 AUG 06, 1984 JUL CAHN

AB CAPSULE, EXTENDED RELEASE; ORAL
AB 75MG

N76114 001 FEB 06, 2002 FEB NEWA

SUPPOSITORY; RECTAL
INDOCIN

@ MERCK 50MG
INDOMETHEGAN

+ G AND W LABS 50MG

N17814 001 AUG 13, 1984 MAY DISC
N73314 001 AUG 31, 1992 MAY CRLD

INSULIN PORK

INJECTABLE; INJECTION
ILETIN I

@ LILLY 500 UNITS/ML

N17931 001

JUN DISC

IODIPAMIDE MEGLUMINE

INJECTABLE; INJECTION
CHOLOGRAFIN MEGLUMINE

@ BRACCO 10.3%

N09321 007

JUN DISC

IODIXANOL

INJECTABLE; INJECTION
VISIPAQUE 270

@ AMERSHAM HLTH 55%

N20808 001 AUG 29, 1997 JUN DISC

VISIPAQUE 320
@ AMERSHAM HLTH 65.2%

N20808 002 AUG 29, 1997 JUN DISC

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION
HIPPURAN I 131

@ MALLINCKRODT 0.25mCi/ML

N16666 001

JUN DISC

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION
SPECTAMINE

@ IMP 1mCi/ML

N19432 001 DEC 24, 1987 JUN DISC

IOHEXOL

INJECTABLE; INJECTION
OMNIPAQUE 210

@ AMERSHAM HLTH 45.3%

N18956 006 JUN 30, 1989 JUN DISC

SOLUTION; URETHRAL
OMNIPAQUE 70

@ AMERSHAM HLTH 15.1%

N18956 007 JUN 01, 1994 JUN DISC

IOPAMIDOL

INJECTABLE; INJECTION

IOPAMIDOL

| | | | | | |
|------------|-----|------------|--------------|-----|------|
| @ FAULDING | 61% | N74734 001 | DEC 10, 1996 | JUL | DISC |
| @ | 76% | N74734 002 | DEC 10, 1996 | JUL | DISC |
| ISOVUE-128 | | | | | |
| @ BRACCO | 26% | N18735 005 | OCT 21, 1986 | JUN | DISC |

IOPROMIDE

INJECTABLE; INJECTION

| | | | | | | |
|-----|---------------------------|----------|------------|--------------|-----|------|
| >A> | ULTRAVIST (PHARMACY BULK) | | | | | |
| >A> | + BERLEX LABS | 300MG/ML | N21425 001 | SEP 20, 2002 | SEP | NEWA |
| >A> | + | 370MG/ML | N21425 002 | SEP 20, 2002 | SEP | NEWA |

IOTHALAMATE SODIUM

INJECTABLE; INJECTION

CONRAY 325

| | | | | | |
|----------------|-------|------------|--|-----|------|
| @ MALLINCKRODT | 54.3% | N17685 001 | | JUN | DISC |
|----------------|-------|------------|--|-----|------|

OXILAN

INJECTABLE; INJECTION

| | | | | | |
|------------|-----|------------|--------------|-----|------|
| OXILAN-300 | | | | | |
| GUERBET | 62% | N20316 001 | DEC 21, 1995 | JUN | CAHN |
| OXILAN-350 | | | | | |
| GUERBET | 73% | N20316 002 | DEC 21, 1995 | JUN | CAHN |

IPODATE SODIUM

CAPSULE; ORAL

DRAGRAFIN SODIUM

| | | | | | |
|----------|-------|------------|--|-----|------|
| @ BRACCO | 500MG | N12967 001 | | JUN | DISC |
|----------|-------|------------|--|-----|------|

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPATROPIUM BROMIDE

| | | | | | |
|-----------|-------|------------|--------------|-----|------|
| AN ROXANE | 0.02% | N75867 001 | JUL 22, 2002 | JUL | NEWA |
|-----------|-------|------------|--------------|-----|------|

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION

ISOPROTERENOL HCL

| | | | | | |
|------|------------|------------|--|-----|------|
| @ 3M | 0.12MG/INH | N10375 004 | | JUN | DISC |
|------|------------|------------|--|-----|------|

ISOPROTERENOL SULFATE

AEROSOL, METERED; INHALATION

MEDIHALER-ISO

| | | | | | |
|------|------------|------------|--|-----|------|
| @ 3M | 0.08MG/INH | N10375 003 | | JUN | DISC |
|------|------------|------------|--|-----|------|

ISOSORBIDE

SOLUTION; ORAL

ISMOTIC

| | | | | | |
|---------|-------------|------------|--|-----|------|
| @ ALCON | 100GM/220ML | N17063 001 | | JUN | DISC |
|---------|-------------|------------|--|-----|------|

ISOSORBIDE DINITRATE

| | | | | | |
|---------------|------------------------|------|------------|--------------|----------|
| >D> | TABLET; ORAL | | | | |
| >D> | SORBITRATE | | | | |
| 1996 JUL DISC | BX ASTRazeneca | 5MG | N16192 001 | APR 01, 1996 | SEP DISC |
| 1996 JUL DISC | @ | 5MG | N16192 001 | APR 01, 1996 | SEP DISC |
| >A> | | 10MG | N16192 002 | APR 01, 1996 | SEP DISC |
| 1986 JUN DISC | BX @ | 10MG | N16192 002 | APR 01, 1996 | SEP DISC |
| >A> | TABLET, CHEWABLE; ORAL | | | | |
| >D> | ASTRAZENECA | 5MG | N16776 002 | APR 01, 1996 | SEP DISC |
| >D> | @ | 5MG | N16776 002 | APR 01, 1996 | SEP DISC |
| >A> | | | | | |

ISOSORBIDE MONONITRATE

| | | | | | |
|---------------|---------------|------|------------|--------------|----------|
| 2002 SEP NEWA | TABLET; ORAL | | | | |
| 2002 SEP NEWA | ISMO | | | | |
| | AB ESP PHARMA | 20MG | N19091 001 | DEC 30, 1991 | JUL CAHN |

KETOCONAZOLE

| | | | | | |
|----------|------------------|-------|------------|--------------|----------|
| JUN DISC | TABLET; ORAL | | | | |
| | KETOCONAZOLE | | | | |
| | AB NEOSAN PHARMS | 200MG | N75341 001 | JUL 27, 1999 | JUL CAHN |
| | AB TORPHARM | 200MG | N75912 001 | JAN 10, 2002 | JAN NEWA |

KETOPROFEN

| | | | | | |
|---------------|---------------------------------|-------|------------|--------------|----------|
| 1995 JUN CAHN | CAPSULE, EXTENDED RELEASE; ORAL | | | | |
| 1995 JUN CAHN | KETOPROFEN | | | | |
| | AB MYLAN | 100MG | N75679 003 | FEB 20, 2002 | FEB NEWA |
| | AB | 150MG | N75679 002 | FEB 20, 2002 | FEB NEWA |
| | AB | 200MG | N75679 001 | FEB 20, 2002 | FEB NEWA |

KETOROLAC TROMETHAMINE

| | | | | | |
|----------|------------------------|---------|------------|--------------|----------|
| JUN DISC | INJECTABLE; INJECTION | | | | |
| | KETOROLAC TROMETHAMINE | | | | |
| | AP AM PHARM PARTNERS | 15MG/ML | N75784 001 | JAN 11, 2002 | JAN NEWA |
| | AP | 30MG/ML | N75784 002 | JAN 11, 2002 | JAN NEWA |

KRYPTON, KR-81M

| | | | | | |
|---------------|-------------------------------|-----|------------|--|----------|
| 2002 JUL NEWA | GAS; INHALATION | | | | |
| | MPI KRYPTON 81M GAS GENERATOR | | | | |
| | @ AMERSHAM HLTH | N/A | N18088 001 | | JUL DISC |

JUN DISC

LABETALOL HYDROCHLORIDE

| | | | | | |
|--|-----------------------|--------|------------|--------------|----------|
| | INJECTABLE; INJECTION | | | | |
| | LABETALOL HCL | | | | |
| | AP APOTEX | 5MG/ML | N76051 001 | JUL 05, 2002 | JUL NEWA |

JUN DISC

LACTULOSE

| | | | | | |
|--|----------------|-----------|------------|--------------|----------|
| | SOLUTION; ORAL | | | | |
| | LACTULOSE | | | | |
| | AA NOVEX | 10GM/15ML | N75911 001 | FEB 21, 2002 | FEB NEWA |

JUN DISC

SOLUTION; ORAL, RECTAL

| | | | | | |
|--|------------------|-----------|------------|--|----------|
| | CEPHULAC | | | | |
| | @ AVENTIS PHARMS | 10GM/15ML | N17657 001 | | JUL DISC |

LACTULOSE

SOLUTION; ORAL, RECTAL

ENULOSE

AA + ALPHARMA 10GM/15ML

N71548 001 AUG 15, 1988 JUL CRLD

LAMOTRIGINE

TABLET, CHEWABLE; ORAL

LAMICTAL CD

+ GLAXOSMITHKLINE 25MG
@ 100MG

N20764 002 AUG 24, 1998 MAR CRLD

N20764 003 AUG 24, 1998 MAR DISC

LANSOPRAZOLE

TABLET, ORALLY DISINTEGRATING; ORAL

PREVACID

TAP PHARM 15MG
+ 30MG

N21428 001 AUG 30, 2002 AUG NEWA

N21428 002 AUG 30, 2002 AUG NEWA

LEUCOVORIN CALCIUM

TABLET; ORAL

LEUCOVORIN CALCIUM

BX XANODYNE PHARM EQ 5MG BASE
AB EQ 10MG BASE
AB EQ 15MG BASE

N18459 001 JAN 30, 1986 AUG CAHN

N71962 001 NOV 19, 1987 AUG CAHN

N71104 001 MAR 04, 1987 JUN CAHN

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS

ELIGARD

+ ATRIX 7.5MG/VIAL
+ 22.5MG/VIAL

N21343 001 JAN 23, 2002 JAN NEWA

N21379 001 JUL 24, 2002 JUL NEWA

LEVALBUTEROL HYDROCHLORIDE

SOLUTION; INHALATION

XOPENEX

+ SEPRACOR EQ 0.0105% BASE

N20837 003 JAN 30, 2002 JUN NEWA

LEVOCARNITINE

SOLUTION; ORAL

CARNITOR

@ SIGMA TAU 1GM/10ML
+ 1GM/10ML
@ 1GM/10ML

N18948 002 APR 27, 1988 JUN DISC

N19257 001 APR 10, 1986 JUL CMFD

N19257 001 APR 10, 1986 JUN DISC

LEVODOPA

TABLET; ORAL

LARODOPA

@ ROCHE 100MG
@ 250MG
@ 500MG

N16912 005

JUN DISC

N16912 003

JUN DISC

N16912 004

JUN DISC

LEVOTHYROXINE SODIUM

TABLET; ORAL

LEVO-T

| | | | | | | | |
|-----------------------------|----------|---------|--------|-----|--------------|-----|------|
| BX | MOVA | 0.025MG | N21342 | 001 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.05MG | N21342 | 002 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.075MG | N21342 | 003 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.088MG | N21342 | 004 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.1MG | N21342 | 005 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.112MG | N21342 | 006 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.125MG | N21342 | 007 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.15MG | N21342 | 008 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.175MG | N21342 | 009 | MAR 01, 2002 | MAR | NEWA |
| BX | | 0.2MG | N21342 | 010 | MAR 01, 2002 | MAR | NEWA |
| BX + | | 0.3MG | N21342 | 011 | MAR 01, 2002 | MAR | NEWA |
| <u>LEVOTHYROXINE SODIUM</u> | | | | | | | |
| AB | MYLAN | 0.025MG | N76187 | 001 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.05MG | N76187 | 002 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.075MG | N76187 | 003 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.088MG | N76187 | 004 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.1MG | N76187 | 005 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.112MG | N76187 | 006 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.125MG | N76187 | 007 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.15MG | N76187 | 008 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.175MG | N76187 | 009 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.2MG | N76187 | 010 | JUN 05, 2002 | JUN | NEWA |
| AB | | 0.3MG | N76187 | 011 | JUN 05, 2002 | JUN | NEWA |
| <u>NOVOTHYROX</u> | | | | | | | |
| BX | GENPHARM | 0.025MG | N21292 | 001 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.05MG | N21292 | 002 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.075MG | N21292 | 003 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.088MG | N21292 | 004 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.1MG | N21292 | 005 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.112MG | N21292 | 006 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.125MG | N21292 | 007 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.137MG | N21292 | 008 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.15MG | N21292 | 009 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.175MG | N21292 | 010 | MAY 31, 2002 | MAY | NEWA |
| BX | | 0.2MG | N21292 | 011 | MAY 31, 2002 | MAY | NEWA |
| BX + | | 0.3MG | N21292 | 012 | MAY 31, 2002 | MAY | NEWA |
| <u>SYNTHROID</u> | | | | | | | |
| BX | ABBOTT | 0.025MG | N21402 | 001 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.05MG | N21402 | 002 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.075MG | N21402 | 003 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.088MG | N21402 | 004 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.1MG | N21402 | 005 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.112MG | N21402 | 006 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.125MG | N21402 | 007 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.137MG | N21402 | 008 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.15MG | N21402 | 009 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.175MG | N21402 | 010 | JUL 24, 2002 | JUL | NEWA |
| BX | | 0.2MG | N21402 | 012 | JUL 24, 2002 | AUG | NEWA |
| BX + | | 0.3MG | N21402 | 011 | JUL 24, 2002 | JUL | NEWA |

LEVOTHYROXINE SODIUM

| | | | | | | |
|--------------|---------|------------|--------------|-----|------|-----|
| TABLET; ORAL | | | | | | |
| UNITHROID | | | | | | |
| AB STEVENS J | 0.025MG | N21210 001 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.05MG | N21210 002 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.075MG | N21210 003 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.088MG | N21210 004 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.1MG | N21210 005 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.112MG | N21210 006 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.125MG | N21210 007 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.15MG | N21210 008 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.175MG | N21210 009 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB | 0.2MG | N21210 010 | AUG 21, 2000 | JUN | CRLD | >A> |
| AB + | 0.3MG | N21210 011 | AUG 21, 2000 | JUN | CRLD | >A> |

LIDOCAINE

| | | | | | | |
|--------------------------------|------------|------------|--------------|-----|------|--|
| AEROSOL; ORAL | | | | | | |
| XYLOCAINE | | | | | | |
| @ ASTRazeneca | 10% | N14394 001 | | JUN | DISC | |
| FILM, EXTENDED RELEASE; Buccal | | | | | | |
| LIDOCAINE | | | | | | |
| @ NOVEN | 23MG/PATCH | N20575 001 | MAY 21, 1996 | JUN | DISC | |
| OINTMENT; TOPICAL | | | | | | |
| >D> AT FOUGERA | 5% | N80198 001 | | SEP | CRLD | |
| >A> AT + | 5% | N80198 001 | | SEP | CRLD | |
| >D> XYLOCAINE | | | | | | |
| >D> AT + ASTRazeneca | 5% | N08048 001 | | SEP | DISC | |
| >A> @ | 5% | N08048 001 | | SEP | DISC | |

LIDOCAINE HYDROCHLORIDE

| | | | | | | |
|------------------------------------|----|------------|--------------|-----|------|--|
| INJECTABLE; SPINAL | | | | | | |
| LIDOCAINE HCL 5% AND DEXTROSE 7.5% | | | | | | |
| >D> AP ABBOTT | 5% | N83914 001 | | SEP | CRLD | |
| >A> + | 5% | N83914 001 | | SEP | CRLD | |
| >D> XYLOCAINE 5% W/ GLUCOSE 7.5% | | | | | | |
| >D> AP + ASTRazeneca | 5% | N10496 002 | JUL 07, 1982 | SEP | DISC | |
| >A> @ | 5% | N10496 002 | JUL 07, 1982 | SEP | DISC | |

LINCOMYCIN HYDROCHLORIDE

| | | | | | | |
|------------------------|---------------|------------|--|-----|------|--|
| CAPSULE; ORAL | | | | | | |
| LINCOcin | | | | | | |
| @ PHARMACIA AND UPJOHN | EQ 250MG BASE | N50316 001 | | JUN | DISC | |
| @ | EQ 500MG BASE | N50316 002 | | JUN | DISC | |

LINEZOLID

| | | | | | | |
|------------------------|-------|------------|--------------|-----|------|--|
| TABLET; ORAL | | | | | | |
| ZYVOX | | | | | | |
| @ PHARMACIA AND UPJOHN | 400MG | N21130 001 | APR 18, 2000 | JUN | DISC | |

LISINOPRIL

TABLET; ORAL

LISINOPRIL

APOTEX

2.5MG

N76102 001 SEP 30, 2002 SEP NEWA

5MG

N76102 002 SEP 30, 2002 SEP NEWA

10MG

N76102 003 SEP 30, 2002 SEP NEWA

20MG

N76102 004 SEP 30, 2002 SEP NEWA

30MG

N76102 005 SEP 30, 2002 SEP NEWA

40MG

N76102 006 SEP 30, 2002 SEP NEWA

CRLD >A> AB LISINOPRIL APOTEX 2.5MG N75994 001 JUL 01, 2002 JUL NEWA

CRLD >A> AB 5MG N75994 002 JUL 01, 2002 JUL NEWA

CRLD >A> AB 10MG N75994 003 JUL 01, 2002 JUL NEWA

CRLD >A> AB 20MG N75994 004 JUL 01, 2002 JUL NEWA

CRLD >A> AB 30MG N75994 005 JUL 01, 2002 JUL NEWA

CRLD >A> AB 40MG N75994 006 JUL 01, 2002 JUL NEWA

CRLD AB EON 2.5MG N75903 001 JUL 01, 2002 JUL NEWA

CRLD AB 5MG N75903 002 JUL 01, 2002 JUL NEWA

CRLD AB 10MG N75903 003 JUL 01, 2002 JUL NEWA

CRLD AB 20MG N75903 004 JUL 01, 2002 JUL NEWA

CRLD AB 30MG N75903 005 JUL 01, 2002 JUL NEWA

CRLD AB 40MG N75903 006 JUL 01, 2002 JUL NEWA

CRLD AB GENEVA PHARMS TECH 2.5MG N75903 001 JUL 01, 2002 JUL NEWA

CRLD AB 5MG N75903 002 JUL 01, 2002 JUL NEWA

CRLD AB 10MG N75903 003 JUL 01, 2002 JUL NEWA

CRLD AB 20MG N75903 004 JUL 01, 2002 JUL NEWA

CRLD AB 30MG N75903 005 JUL 01, 2002 JUL NEWA

CRLD AB 40MG N75903 006 JUL 01, 2002 JUL NEWA

DISC AB IVAX PHARMS 2.5MG N75752 001 JUL 01, 2002 JUL NEWA

DISC AB 5MG N75752 002 JUL 01, 2002 JUL NEWA

DISC AB 10MG N75752 003 JUL 01, 2002 JUL NEWA

CRLD AB 20MG N75752 004 JUL 01, 2002 JUL NEWA

CRLD AB 30MG N75752 005 JUL 01, 2002 JUL NEWA

CRLD AB 40MG N75752 006 JUL 01, 2002 JUL NEWA

DISC AB LEK PHARM 2.5MG N75999 001 JUL 01, 2002 AUG NEWA

DISC AB 5MG N75999 002 JUL 01, 2002 AUG NEWA

DISC AB 10MG N75999 003 JUL 01, 2002 AUG NEWA

DISC AB 20MG N75999 004 JUL 01, 2002 AUG NEWA

DISC AB 30MG N75999 005 JUL 01, 2002 AUG NEWA

DISC AB 40MG N75999 006 JUL 01, 2002 AUG NEWA

CRLD AB MYLAN 2.5MG N76071 001 JUL 01, 2002 JUL NEWA

CRLD AB 5MG N76071 002 JUL 01, 2002 JUL NEWA

CRLD AB 10MG N76071 003 JUL 01, 2002 JUL NEWA

DISC AB 20MG N76071 004 JUL 01, 2002 JUL NEWA

DISC AB 30MG N76071 005 JUL 01, 2002 JUL NEWA

DISC AB 40MG N76071 006 JUL 01, 2002 JUL NEWA

AB PAR PHARM 2.5MG N75743 001 JUL 01, 2002 JUL NEWA

AB 5MG N75743 002 JUL 01, 2002 JUL NEWA

AB 10MG N75743 003 JUL 01, 2002 JUL NEWA

DISC AB 20MG N75743 004 JUL 01, 2002 JUL NEWA

DISC AB 30MG N75743 005 JUL 01, 2002 JUL NEWA

DISC AB 40MG N75743 006 JUL 01, 2002 JUL NEWA

AB PUREPAC PHARM 2.5MG N76180 001 JUL 01, 2002 JUL NEWA

AB 5MG N76180 002 JUL 01, 2002 JUL NEWA

AB 10MG N76180 003 JUL 01, 2002 JUL NEWA

DISC AB 20MG N76164 001 JUL 01, 2002 JUL NEWA

DISC AB 30MG N76164 002 JUL 01, 2002 JUL NEWA

DISC AB 40MG N76164 003 JUL 01, 2002 JUL NEWA

AB RANBAXY 2.5MG N75944 001 JUL 01, 2002 JUL NEWA

| | | | | | | |
|------------------|-------------|-------|------------|--------------|-----|------|
| AB | | 5MG | N75944 002 | JUL 01, 2002 | JUL | NEWA |
| AB | | 10MG | N75944 003 | JUL 01, 2002 | JUL | NEWA |
| AB | | 20MG | N75944 004 | JUL 01, 2002 | JUL | NEWA |
| AB | | 40MG | N75944 005 | JUL 01, 2002 | JUL | NEWA |
| AB | TEVA | 2.5MG | N75783 001 | JUL 01, 2002 | JUL | NEWA |
| AB | | 5MG | N75783 002 | JUL 01, 2002 | JUL | NEWA |
| AB | | 10MG | N75783 003 | JUL 01, 2002 | JUL | NEWA |
| AB | | 20MG | N75783 004 | JUL 01, 2002 | JUL | NEWA |
| AB | | 30MG | N75783 005 | JUL 01, 2002 | JUL | NEWA |
| AB | | 40MG | N75783 006 | JUL 01, 2002 | JUL | NEWA |
| AB | WATSON LABS | 2.5MG | N76059 001 | JUL 01, 2002 | JUL | NEWA |
| AB | | 5MG | N76059 002 | JUL 01, 2002 | JUL | NEWA |
| AB | | 10MG | N76059 003 | JUL 01, 2002 | JUL | NEWA |
| AB | | 20MG | N76059 004 | JUL 01, 2002 | JUL | NEWA |
| AB | | 30MG | N76059 005 | JUL 01, 2002 | JUL | NEWA |
| AB | | 40MG | N76059 006 | JUL 01, 2002 | JUL | NEWA |
| AB | WEST WARD | 2.5MG | N76063 001 | JUL 01, 2002 | JUL | NEWA |
| AB | | 5MG | N76063 002 | JUL 01, 2002 | JUL | NEWA |
| AB | | 10MG | N76063 003 | JUL 01, 2002 | JUL | NEWA |
| AB | | 20MG | N76063 004 | JUL 01, 2002 | JUL | NEWA |
| AB | | 40MG | N76063 005 | JUL 01, 2002 | JUL | NEWA |
| ZESTRIL | | | | | | |
| AB + ASTRazeneca | | 30MG | N19777 006 | JAN 20, 1999 | JUL | CFTG |

LITHIUM CARBONATE

| | | | | | | |
|--------------------------------|-----------|-------|------------|--------------|-----|------|
| CAPSULE; ORAL | | | | | | |
| LITHIUM CARBONATE | | | | | | |
| AB | WEST WARD | 300MG | N76243 001 | JUN 27, 2002 | JUN | NEWA |
| TABLET, EXTENDED RELEASE; ORAL | | | | | | |
| AB | BARR | 300MG | N76170 001 | JUN 10, 2002 | JUN | NEWA |
| LITHOBID | | | | | | |
| AB + SOLVAY | | 300MG | N18027 001 | | JUN | CFTG |

LOMEFLOXACIN HYDROCHLORIDE

| | | | | | | |
|--------------|--|---------------|------------|--------------|-----|------|
| TABLET; ORAL | | | | | | |
| MAXAQUIN | | | | | | |
| + PHARMACIA | | EQ 400MG BASE | N20013 001 | FEB 21, 1992 | JUL | CAHN |

LORATADINE

| | | | | | | |
|--------------|--|------|------------|--------------|-----|------|
| TABLET; ORAL | | | | | | |
| CLARITIN | | | | | | |
| + SCHERING | | 10MG | N19658 001 | APR 12, 1993 | JUL | CTEC |

LOVASTATIN

| | | | | | | |
|--------------------------------|----------|------|------------|--------------|-----|------|
| TABLET; ORAL | | | | | | |
| LOVASTATIN | | | | | | |
| AB | CARLSBAD | 10MG | N75991 001 | JUN 05, 2002 | JUN | NEWA |
| AB | | 20MG | N75991 002 | JUN 05, 2002 | JUN | NEWA |
| AB | | 40MG | N75991 003 | JUN 05, 2002 | JUN | NEWA |
| TABLET, EXTENDED RELEASE; ORAL | | | | | | |
| ALTOCOR | | | | | | |
| ANDRX | | 10MG | N21316 001 | JUN 26, 2002 | JUL | CAHN |
| | | 20MG | N21316 002 | JUN 26, 2002 | JUL | CAHN |

| | | | | | |
|------------------------------------|--|--------------------|------------|--------------|-----------------------|
| JUL NEWA | | 40MG | N21316 003 | JUN 26, 2002 | JUL CAHN |
| JUL NEWA | + | 60MG | N21316 004 | JUN 26, 2002 | JUL CAHN |
| JUL NEWA | AURA LABS | 10MG | N21316 001 | JUN 26, 2002 | JUN NEWA |
| JUL NEWA | | 20MG | N21316 002 | JUN 26, 2002 | JUN NEWA |
| JUL NEWA | | 40MG | N21316 003 | JUN 26, 2002 | JUN NEWA |
| JUL NEWA | + | 60MG | N21316 004 | JUN 26, 2002 | JUN NEWA |
| JUL NEWA | <u>LOXAPINE HYDROCHLORIDE</u> | | | | |
| JUL NEWA | CONCENTRATE; ORAL | | | | |
| JUL NEWA | LOXITANE C | | | | |
| JUL NEWA | @ WATSON LABS | EQ 25MG BASE/ML | N17658 001 | | JUL DISC |
| JUL NEWA | INJECTABLE; INJECTION | | | | |
| JUL NEWA | LOXITANE IM | | | | |
| JUL NEWA | @ WATSON LABS | EQ 50MG BASE/ML | N18039 001 | | JUL DISC |
| JUL NEWA | <u>MANGANESE CHLORIDE TETRAHYDRATE</u> | | | | |
| JUL NEWA | FOR SOLUTION; ORAL | | | | |
| JUL NEWA | LUMENHANCE | | | | |
| JUL NEWA | @ BRACCO | 3.49MG/GM | N20686 001 | DEC 19, 1997 | JUN DISC |
| JUL NEWA | <u>MASOPROCOL</u> | | | | |
| JUL NEWA | CREAM; TOPICAL | | | | |
| JUL CFTG | ACTINEX | | | | |
| JUL CFTG | @ UNIV AZ CANCER CTR | 10% | N19940 001 | SEP 04, 1992 | JUN DISC |
| <u>MAZINDOL</u> | | | | | |
| TABLET; ORAL | | | | | |
| JUN NEWA | MAZANOR | | | | |
| JUN NEWA | @ WYETH AYERST | 1MG | N17980 002 | | APR DISC |
| JUN NEWA | SANOREX | | | | |
| JUN NEWA | NOVARTIS | 1MG | N17247 001 | | APR CTEC |
| JUN CFTG | @ | 1MG | N17247 001 | | JUN DISC |
| JUN CFTG | @ | 2MG | N17247 002 | | JUN DISC |
| <u>MEDROXYPROGESTERONE ACETATE</u> | | | | | |
| TABLET; ORAL | | | | | |
| JUL CAHN | >D> | AMEN | | | |
| JUL CAHN | >D> | BP AMARIN PHARMS | 10MG | N83242 001 | SEP DISC |
| JUL CAHN | >A> | @ | 10MG | N83242 001 | SEP DISC |
| <u>MEFLOQUINE HYDROCHLORIDE</u> | | | | | |
| TABLET; ORAL | | | | | |
| JUL CTEC | LARIAM | | | | |
| JUL CTEC | AB + | ROCHE | 250MG | N19591 001 | MAY 02, 1989 FEB CFTG |
| JUL CTEC | MEFLOQUINE HCL | | | | |
| JUL CTEC | AB | GENEVA PHARMS TECH | 250MG | N76175 001 | FEB 20, 2002 FEB NEWA |
| JUN NEWA | <u>MEGESTROL ACETATE</u> | | | | |
| JUN NEWA | SUSPENSION; ORAL | | | | |
| JUN NEWA | MEGESTROL ACETATE | | | | |
| JUN NEWA | AB | ROXANE | 40MG/ML | N75997 001 | FEB 15, 2002 FEB NEWA |
| JUL CAHN | | | | | |
| JUL CAHN | | | | | |

MENOTROPINS (FSH;LH)

| | | | | |
|-----------------------|-------------------------|------------|--------------|----------|
| INJECTABLE; INJECTION | | | | |
| PERGONAL | | | | |
| BX + SERONO | 75 IU/AMP;75 IU/AMP | N17646 001 | AUG | CMFD |
| | 75 IU/AMP;75 IU/AMP | N17646 001 | JUN | DISC |
| @ | 150 IU/AMP;150 IU/AMP | N17646 002 | MAY 20, 1985 | JUN DISC |
| REPRONEX | | | | |
| + FERRING | 75 IU/VIAL;75 IU/VIAL | N21047 001 | AUG 27, 1999 | JUN CRLD |
| BX | 75 IU/VIAL;75 IU/VIAL | N21047 001 | AUG 27, 1999 | AUG CRLD |
| + | 150 IU/VIAL;150 IU/VIAL | N21047 002 | AUG 27, 1999 | JUN CRLD |

MEPERIDINE HYDROCHLORIDE

| | | | | |
|----------------|-------|------------|--------------|----------|
| TABLET; ORAL | | | | |
| MEPERIDINE HCL | | | | |
| AA CARACO | 50MG | N40446 001 | AUG 08, 2002 | AUG NEWA |
| AA | 100MG | N40446 002 | AUG 08, 2002 | AUG NEWA |

MEPERIDINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

| | | | | |
|-----------------------|-----------------|------------|--|----------|
| INJECTABLE; INJECTION | | | | |
| MEPERGAN | | | | |
| @ WYETH AYERST | 25MG/ML;25MG/ML | N11730 001 | | JUN DISC |

MEPHENTERMINE SULFATE

| | | | | |
|-----------------------|-----------------|------------|--|----------|
| INJECTABLE; INJECTION | | | | |
| WYAMINE SULFATE | | | | |
| @ WYETH AYERST | EQ 15MG BASE/ML | N08248 002 | | JUN DISC |

MEPHENYTOIN

| | | | | |
|--------------|-------|------------|--|----------|
| TABLET; ORAL | | | | |
| MESANTOIN | | | | |
| @ NOVARTIS | 100MG | N06008 001 | | JUN DISC |

MEQUINOL; TRETINOIN

| | | | | |
|-------------------|----------|------------|--------------|----------|
| SOLUTION; TOPICAL | | | | |
| SOLAGE | | | | |
| + GALDERMA LABS | 2%;0.01% | N20922 001 | DEC 10, 1999 | APR CAHN |

MESNA

| | | | | |
|-------------------------|----------|------------|--------------|----------|
| INJECTABLE; INTRAVENOUS | | | | |
| MESNEX | | | | |
| AP + BAXTER HLTHCARE | 100MG/ML | N19884 001 | DEC 30, 1988 | MAR CAHN |
| TABLET; ORAL | | | | |
| + BAXTER HLTHCARE | 400MG | N20855 001 | MAR 21, 2002 | JUN CAHN |
| + BRISTOL MYERS SQUIBB | 400MG | N20855 001 | MAR 21, 2002 | MAR NEWA |

MESORIDAZINE BESYLATE

| | | | | |
|-----------------------|-----------------|------------|--|----------|
| INJECTABLE; INJECTION | | | | |
| SERENTIL | | | | |
| @ NOVARTIS | EQ 25MG BASE/ML | N16775 001 | | JUN DISC |

MESTRANOL; NORETHINDRONE

TABLET; ORAL-28

NORINYL 1+50 28-DAY

AUG CMFD AB WATSON LABS 0.05MG;1MG N16659 001 JAN CAHN

METAPROTERENOL SULFATE

SOLUTION; INHALATION

JUN CRLD ALUPENT N17659 001 JUN DISC

AUG CRLD @ BOEHRINGER INGELHEIM 5% N17659 001 JUN DISC

JUN CRLD METAPROTERENOL SULFATE N75586 001 MAY 30, 2002 MAY NEWA

AN MORTON GROVE 0.4% N75586 002 MAY 30, 2002 MAY NEWA

AN 0.6% N75586 002 MAY 30, 2002 MAY NEWA

METAXALONE

TABLET; ORAL

SKELAXIN

AUG NEWA + ELAN PHARMS 400MG N13217 001 JUN CAHN

400MG N13217 001 AUG CRLD

+ 800MG N13217 003 AUG 30, 2002 AUG NEWA

METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLUCOPHAGE

JUN DISC AB BRISTOL MYERS SQUIBB 500MG N20357 001 MAR 03, 1995 JAN CFTG

AB 850MG N20357 002 MAR 03, 1995 JAN CFTG

AB + 1GM N20357 005 NOV 05, 1998 JAN CFTG

METFORMIN HCL N75969 001 JAN 29, 2002 JAN NEWA

AB ALPHAPHARM 500MG N75969 002 JAN 29, 2002 JAN NEWA

AB 850MG N75969 003 JAN 29, 2002 JAN NEWA

AB 1GM N75961 001 JAN 25, 2002 JAN NEWA

JUN DISC AB ANDRX PHARMS 500MG N75961 002 JAN 25, 2002 JAN NEWA

AB 850MG N75961 003 JAN 25, 2002 JAN NEWA

AB 1GM N75971 001 JAN 25, 2002 JAN NEWA

AB BARR 500MG N75971 002 JAN 25, 2002 JAN NEWA

AB 850MG N75971 003 JAN 25, 2002 JAN NEWA

AB 1GM N75971 001 JAN 25, 2002 JAN NEWA

APR CAHN AB CARACO 500MG N75967 001 JAN 29, 2002 JAN NEWA

AB 850MG N75967 002 JAN 29, 2002 JAN NEWA

AB 1GM N75967 003 JAN 29, 2002 JAN NEWA

AB EON 500MG N75965 001 JAN 25, 2002 JAN NEWA

AB 850MG N75965 002 JAN 25, 2002 JAN NEWA

AB 1GM N75965 003 JAN 25, 2002 JAN NEWA

JUN CAHN AB GENEVA PHARMS 500MG N75985 001 JAN 25, 2002 MAY CAHN

MAR NEWA AB 850MG N75985 002 JAN 25, 2002 MAY CAHN

AB 1GM N75985 003 JAN 25, 2002 MAY CAHN

AB GENEVA PHARMS TECH 500MG N75985 001 JAN 25, 2002 JAN NEWA

AB 850MG N75985 002 JAN 25, 2002 JAN NEWA

AB 1GM N75985 003 JAN 25, 2002 JAN NEWA

JUN DISC AB GENPHARM 500MG N75973 001 JAN 25, 2002 JAN NEWA

AB 850MG N75973 002 JAN 25, 2002 JAN NEWA

AB 1GM N75973 003 JAN 25, 2002 JAN NEWA

AB GOLDLINE 500MG N75972 001 JAN 24, 2002 JAN NEWA

| | | | | | | |
|----|-----------------|-------|------------|--------------|-----|------|
| AB | | 625MG | N75972 005 | JAN 24, 2002 | JAN | NEWA |
| AB | | 750MG | N75972 004 | JAN 24, 2002 | JAN | NEWA |
| AB | | 850MG | N75972 002 | JAN 24, 2002 | JAN | NEWA |
| AB | | 1GM | N75972 003 | JAN 24, 2002 | JAN | NEWA |
| AB | MUTUAL PHARMA | 500MG | N76038 001 | FEB 21, 2002 | FEB | NEWA |
| AB | | 850MG | N76038 002 | FEB 21, 2002 | FEB | NEWA |
| AB | | 1GM | N76038 003 | FEB 21, 2002 | FEB | NEWA |
| AB | MYLAN | 500MG | N75976 001 | JAN 24, 2002 | JAN | NEWA |
| AB | | 850MG | N75976 002 | JAN 24, 2002 | JAN | NEWA |
| AB | | 1GM | N75976 003 | JAN 24, 2002 | JAN | NEWA |
| AB | PUREPAC PHARM | 500MG | N76033 001 | JAN 24, 2002 | JAN | NEWA |
| AB | | 850MG | N76033 002 | JAN 24, 2002 | JAN | NEWA |
| AB | | 1GM | N76033 003 | JAN 24, 2001 | JAN | NEWA |
| AB | TEVA | 500MG | N75978 001 | JAN 25, 2002 | JAN | NEWA |
| AB | | 850MG | N75978 002 | JAN 25, 2002 | JAN | NEWA |
| AB | TORPHARM | 500MG | N75984 001 | APR 23, 2002 | APR | NEWA |
| AB | | 850MG | N75984 002 | APR 23, 2002 | APR | NEWA |
| AB | | 1GM | N75984 003 | APR 23, 2002 | APR | NEWA |
| AB | WATSON LABS | 500MG | N75979 001 | JAN 24, 2002 | JAN | NEWA |
| AB | | 850MG | N75979 002 | JAN 24, 2002 | JAN | NEWA |
| AB | | 1GM | N75979 003 | JAN 24, 2002 | JAN | NEWA |
| AB | ZENITH GOLDLINE | 500MG | N75975 001 | JAN 24, 2002 | JAN | NEWA |
| AB | | 625MG | N75975 004 | JAN 24, 2002 | JAN | NEWA |
| AB | | 750MG | N75975 005 | JAN 24, 2002 | JAN | NEWA |
| AB | | 850MG | N75975 002 | JAN 24, 2002 | JAN | NEWA |
| AB | | 1GM | N75975 003 | JAN 24, 2002 | JAN | NEWA |

METHADONE HYDROCHLORIDE

SYRUP; ORAL

DOLOPHINE HCL

@ ROXANE

10MG/30ML

N06134 004

JUL DISC

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

| | | | | | |
|--------------------------------|------------------|------|------------|-----|------|
| >D> | + ABBOTT | 5MG | N05378 002 | SEP | CAHN |
| >A> | + OVATION PHARMS | 5MG | N05378 002 | SEP | CAHN |
| TABLET, EXTENDED RELEASE; ORAL | | | | | |
| >D> | @ ABBOTT | 5MG | N05378 004 | SEP | CAHN |
| | @ | 5MG | N05378 004 | JUN | DISC |
| >D> | @ | 10MG | N05378 003 | SEP | CAHN |
| | @ | 10MG | N05378 003 | JUN | DISC |
| >D> | @ | 15MG | N05378 005 | SEP | CAHN |
| | @ | 15MG | N05378 005 | JUN | DISC |
| >A> | @ OVATION PHARMS | 5MG | N05378 004 | SEP | CAHN |
| >A> | @ | 10MG | N05378 003 | SEP | CAHN |
| >A> | @ | 15MG | N05378 005 | SEP | CAHN |

METHANTHELINE BROMIDE

TABLET; ORAL

BANTHINE

@ SHIRE LABS

50MG

N07390 001

JUL DISC

JAN NEWA
JAN NEWA
METHOHEXITAL SODIUM
INJECTABLE; INJECTION
BREVITAL SODIUM
FEB NEWA + KING PHARMS 500MG/VIAL N11559 001 FEB CAHN
FEB NEWA + 2.5GM/VIAL N11559 002 FEB CAHN
FEB NEWA + 5GM/VIAL N11559 003 FEB CAHN

JAN NEWA
JAN NEWA
METHOTREXATE SODIUM
INJECTABLE; INJECTION
FOLEX
JAN NEWA + PHARMACIA AND UPJOHN EQ 50MG BASE/VIAL N87695 002 APR 08, 1983 JUN CRLD
JAN NEWA + EQ 100MG BASE/VIAL N87695 003 APR 08, 1983 JUN CRLD
JAN NEWA METHOTREXATE SODIUM
@ LEDERLE EQ 2.5MG BASE/ML N11719 004 JUN DISC
APR NEWA @ EQ 50MG BASE/VIAL N11719 003 JUN DISC
APR NEWA @ EQ 100MG BASE/VIAL N11719 006 JUN DISC
APR NEWA TABLET; ORAL
JAN NEWA AB + CLONMEL HLTHCARE EQ 2.5MG BASE N08085 002 JUL CAHN

JAN NEWA
METHYLDOPA
SUSPENSION; ORAL
ALDOMET
JAN NEWA @ MERCK 250MG/5ML N18389 001 JUN DISC

JAN NEWA
METHYLPHENIDATE HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
METADATE CD
JUL DISC BX + CELLTECH PHARMS 20MG N21259 001 APR 03, 2001 JUN CTEC
RITALIN LA
BX NOVARTIS 20MG N21284 001 JUN 05, 2002 JUN NEWA
30MG N21284 002 JUN 05, 2002 JUN NEWA
+ 40MG N21284 003 JUN 05, 2002 JUN NEWA
TABLET; ORAL
METHYLPHENIDATE HCL
SEP CAHN AB PUREPAC PHARM 5MG N40321 001 FEB 05, 2002 FEB NEWA
SEP CAHN AB 10MG N40321 002 FEB 05, 2002 FEB NEWA
SEP CAHN AB 20MG N40321 003 FEB 05, 2002 FEB NEWA
SEP CAHN TABLET, EXTENDED RELEASE; ORAL
CONCERTA
JUN DISC + ALZA 27MG N21121 004 APR 01, 2002 JUN NEWA

SEP CAHN
JUN DISC
SEP CAHN
JUN DISC
SEP CAHN
JUN DISC
SEP CAHN
JUN DISC
SEP CAHN
SEP CAHN
METHYL PREDNISOLONE
TABLET; ORAL
METHYL PREDNISOLONE
AB GENEVA PHARMS 4MG N40194 001 OCT 31, 1997 MAY CAHN

METHYL PREDNISOLONE ACETATE
INJECTABLE; INJECTION
DEPO-MEDROL
JUL DISC > BP + PHARMACIA AND UPJOHN 80MG/ML N11757 004 SEP CTEC
> A + 80MG/ML N11757 004 SEP CTEC

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

| | | | |
|-----|----------------------------|--------|---------|
| >D> | METHYLPREDNISOLONE ACETATE | | |
| >D> | BP | STERIS | 20MG/ML |
| >A> | @ | | 20MG/ML |
| >D> | BP | | 80MG/ML |
| >A> | @ | | 80MG/ML |

METHYLTESTOSTERONE

| | | | |
|-----|--------------------|---------|------|
| >D> | TABLET; ORAL | | |
| >D> | METHYLTESTOSTERONE | | |
| >D> | BP | LANNETT | 10MG |
| >A> | @ | | 10MG |
| >D> | BP | | 25MG |
| >A> | @ | | 25MG |

METRONIDAZOLE

INJECTABLE; INJECTION

| | | |
|--------------------------------------|---------------|-------------|
| FLAGYL I.V. RTU IN PLASTIC CONTAINER | | |
| AP + | GD SEARLE LLC | 500MG/100ML |

N18353 002

JUL CAHN

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

FLAGYL I.V.

| | |
|-----------------|--------------------|
| + GD SEARLE LLC | EQ 500MG BASE/VIAL |
|-----------------|--------------------|

N18353 001

JUL CAHN

MICONAZOLE NITRATE

CREAM, INSERT; TOPICAL, VAGINAL

MONISTAT DUAL- PAK

| | | | | | |
|------------------|----------|------------|--------------|-----|------|
| @ PERSONAL PRODS | 1.2GM;2% | N20968 001 | JUN 30, 1999 | JUN | DISC |
|------------------|----------|------------|--------------|-----|------|

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL

| | | | | | | |
|-------------|-----------|----------------|------------|--------------|-----|------|
| AP | ABBOTT | EQ 1MG BASE/ML | N75857 001 | JUL 22, 2002 | JUL | NEWA |
| AP | | EQ 5MG BASE/ML | N75857 002 | JUL 22, 2002 | JUL | NEWA |
| AP | ROSS LABS | EQ 1MG BASE/ML | N75856 001 | JUN 13, 2002 | JUN | NEWA |
| AP | | EQ 5MG BASE/ML | N75856 002 | JUN 13, 2002 | JUN | NEWA |
| SYRUP; ORAL | | | | | | |
| AA | RANBAXY | EQ 2MG BASE/ML | N76058 001 | MAR 15, 2002 | MAR | NEWA |
| >D> | AA ROXANE | EQ 2MG BASE/ML | N75873 001 | APR 30, 2002 | SEP | CRLD |
| >A> | AA + | EQ 2MG BASE/ML | N75873 001 | APR 30, 2002 | SEP | CRLD |
| AA | | EQ 2MG BASE/ML | N75873 001 | APR 30, 2002 | APR | NEWA |
| VERSED | | | | | | |
| AA + | ROCHE | EQ 2MG BASE/ML | N20942 001 | OCT 15, 1998 | MAR | CFTG |
| | @ | EQ 2MG BASE/ML | N20942 001 | OCT 15, 1998 | AUG | DISC |

MIDODRINE HYDROCHLORIDE

TABLET; ORAL

PROAMATINE

| | | | | | | |
|-----|--------------|-------|------------|--------------|-----|------|
| >D> | @ SHIRE LABS | 2.5MG | N19815 001 | SEP 06, 1996 | SEP | CMFD |
|-----|--------------|-------|------------|--------------|-----|------|

| | | | | | | |
|-----|-------------|-------|------------|--------------|-----|------|
| | | 10MG | N19815 003 | MAR 20, 2002 | JUL | CRLD |
| | + | 10MG | N19815 003 | MAR 20, 2002 | JUN | NEWA |
| >A> | SHIRE PHARM | 2.5MG | N19815 001 | SEP 06, 1996 | SEP | CMFD |
| | | 5MG | N19815 002 | SEP 06, 1996 | JUN | CRLD |

MILRINONE LACTATE

INJECTABLE; INJECTION

MILRINONE LACTATE

| | | | | | | | | | |
|-----|------|---|----------------------|-------------------------|----------------|--------------|--------------|------|------|
| SEP | DISC | AP | ABBOTT | EQ 1MG BASE/ML | N75884 001 | MAY 28, 2002 | MAY | NEWA | |
| SEP | DISC | AP | AM PHARM PARTNERS | EQ 1MG BASE/ML | N75936 001 | MAY 28, 2002 | MAY | NEWA | |
| SEP | DISC | AP | BAXTER HLTHCARE CORP | EQ 1MG BASE/ML | N75852 001 | MAY 28, 2002 | MAY | NEWA | |
| SEP | DISC | AP | BEDFORD | EQ 10MG 10/ML (10MG/ML) | N75660 001 | MAY 28, 2002 | MAY | NEWA | |
| | | AP | | EQ 20MG /20ML (1MG/ML) | N75660 002 | MAY 28, 2002 | MAY | NEWA | |
| | | AP | | EQ 50MG /50ML (1MG/ML) | N75660 003 | MAY 28, 2002 | MAY | NEWA | |
| SEP | DISC | AP | ESI LEDERLE | EQ 1MG BASE/ML | N75530 001 | MAY 28, 2002 | MAY | NEWA | |
| SEP | DISC | AP | FAULDING | EQ 1MG BASE/ML | N75830 001 | MAY 28, 2002 | MAY | NEWA | |
| SEP | DISC | AP | INTL MEDICATED | EQ 1MG BASE/ML | N76013 001 | AUG 02, 2002 | AUG | NEWA | |
| | | MILRINONE LACTATE IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | | |
| | | AP | ABBOTT | EQ 20MG BASE/100ML | N75885 001 | MAY 28, 2002 | MAY | NEWA | |
| | | AP | + | EQ 40MG BASE/200ML | N75885 002 | MAY 28, 2002 | MAY | NEWA | |
| | | AP | BAXTER HLTHCARE | EQ 20MG BASE/100ML | N75834 001 | MAY 28, 2002 | MAY | NEWA | |
| | | AP | | EQ 40MG BASE/100ML | N75834 002 | MAY 28, 2002 | MAY | NEWA | |
| | | AP | | EQ 40MG BASE/200ML | N75834 002 | MAY 28, 2002 | JUN | NEWA | |
| | | AP | ESI LEDERLE | EQ 20MG BASE/100ML | N75510 001 | MAY 28, 2002 | MAY | NEWA | |
| | | MILRINONE LACTOSE IN 5% DEXTROSE | | | | | | | |
| | | AP | ESI LEDERLE | EQ 20MG BASE/100ML | N76259 001 | AUG 08, 2002 | AUG | NEWA | |
| | | PRIMACOR | | | | | | | |
| | | AP | + | SANOFI SYNTHELABO | EQ 1MG BASE/ML | N19436 001 | DEC 31, 1987 | MAY | CFTG |
| | | PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | | |
| | | AP | SANOFI SYNTHELABO | EQ 20MG BASE/100ML | N20343 003 | AUG 09, 1994 | MAY | CFTG | |
| | | AP | + | EQ 40MG BASE/100ML | N20343 004 | AUG 09, 1994 | MAY | CFTG | |
| | | AP | + | EQ 40MG BASE/200ML | N20343 004 | AUG 09, 1994 | JUN | CFTG | |

MINOCYCLINE HYDROCHLORIDE

SUSPENSION; ORAL

MINOCIN

@ LEDERLE

EQ 50MG BASE/5ML

N50445 001 JUN DISC

MISOPROSTOL

TABLET; ORAL

CYTOTEC

| | | | | | | | | |
|-----|------|-------------|---------------|-------|------------|--------------|-----|------|
| MAR | NEWA | AB | GD SEARLE LLC | 0.1MG | N19268 003 | SEP 21, 1990 | JUL | CFTG |
| SEP | CRLD | AB | + | 0.2MG | N19268 001 | DEC 27, 1988 | JUL | CFTG |
| SEP | CRLD | MISOPROSTOL | | | | | | |
| APR | NEWA | AB | IVAX PHARMS | 0.1MG | N76095 001 | JUL 10, 2002 | JUL | NEWA |
| | | AB | | 0.2MG | N76095 002 | JUL 10, 2002 | JUL | NEWA |

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION

MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER

@ ABBOTT

EQ 0.5MG BASE/ML

N20098 002 JAN 22, 1992 JUN DISC

SEP CMFD

MOMETASONE FUROATE

| | | | | | |
|--------------------|------|--|--|--------|---------------------------|
| OINTMENT; TOPICAL | | | | | |
| ELOCON | | | | | |
| AB + SCHERING | 0.1% | | | N19543 | 001 APR 30, 1987 MAR CFTG |
| MOMETASONE FUROATE | | | | | |
| AB CLAY PARK | 0.1% | | | N76067 | 001 MAR 18, 2002 MAR NEWA |

MONOCTANOIN

| | | | | | |
|----------------------------|------|--|--|--------|---------------------------|
| LIQUID; PERfusion, BILIARY | | | | | |
| MOCTANIN | | | | | |
| @ ETHITEK | 100% | | | N19368 | 001 OCT 29, 1985 JUN DISC |

MONTELUKAST SODIUM

| | | | | | |
|---------------|--------------------|--|--|--------|---------------------------|
| GRANULE; ORAL | | | | | |
| SINGULAIR | | | | | |
| + MERCK | EQ 4MG BASE/PACKET | | | N21409 | 001 JUL 26, 2002 JUL NEWA |

MORPHINE SULFATE

| | | | | | |
|---------------------------------|-------|--|--|--------|---------------------------|
| CAPSULE, EXTENDED RELEASE; ORAL | | | | | |
| AVINZA | | | | | |
| >D> ELAN PHARM | 30MG | | | N21260 | 001 MAR 20, 2002 SEP CTEC |
| >A> BX + | 30MG | | | N21260 | 001 MAR 20, 2002 SEP CTEC |
| | 30MG | | | N21260 | 001 MAR 20, 2002 MAR NEWA |
| >D> | 60MG | | | N21260 | 002 MAR 20, 2002 SEP CTEC |
| >A> BX + | 60MG | | | N21260 | 002 MAR 20, 2002 SEP CTEC |
| | 60MG | | | N21260 | 002 MAR 20, 2002 MAR NEWA |
| >D> | 90MG | | | N21260 | 003 MAR 20, 2002 SEP CRLD |
| >A> + | 90MG | | | N21260 | 003 MAR 20, 2002 SEP CRLD |
| | 90MG | | | N21260 | 003 MAR 20, 2002 MAR NEWA |
| + KADIAN | 120MG | | | N21260 | 004 MAR 20, 2002 MAR NEWA |
| >D> + FAULDING PHARMS | 30MG | | | N20616 | 004 MAR 09, 2001 SEP CTEC |
| >A> BX + | 30MG | | | N20616 | 004 MAR 09, 2001 SEP CTEC |
| >D> + | 60MG | | | N20616 | 005 MAR 09, 2001 SEP CTEC |
| >A> BX + | 60MG | | | N20616 | 005 MAR 09, 2001 SEP CTEC |

NABUMETONE

| | | | | | |
|--------------|-------|--|--|--------|---------------------------|
| TABLET; ORAL | | | | | |
| NABUMETONE | | | | | |
| AB EON | 500MG | | | N75280 | 001 FEB 25, 2002 FEB NEWA |
| AB | 750MG | | | N75280 | 002 FEB 25, 2002 FEB NEWA |
| AB INVAMED | 500MG | | | N75590 | 001 FEB 25, 2002 FEB NEWA |
| AB | 750MG | | | N75590 | 002 FEB 25, 2002 FEB NEWA |

NAFCILLIN SODIUM

| | | | | | |
|----------------|---------------|--|--|--------|--------------|
| CAPSULE; ORAL | | | | | |
| UNIPEN | | | | | |
| @ WYETH AYERST | EQ 250MG BASE | | | N50111 | 001 JUN DISC |

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

@ ABBOTT

1.5MG/ML

N20200 001 MAR 12, 1993 JUL DISC

MAR CFTG

NALIDIXIC ACID

SUSPENSION; ORAL

NEGRAM

@ SANOFI SYNTHELABO

250MG/5ML

N17430 001 JUN DISC

JUN DISC

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HCL

MALLINCKRODT

25MG

N76264 001 MAR 22, 2002 MAR NEWA

JUL NEWA

AB

50MG

N76264 002 MAR 22, 2002 MAR NEWA

+

100MG

N76264 003 MAR 22, 2002 MAR NEWA

NAPROXEN SODIUM

TABLET, EXTENDED RELEASE; ORAL

NAPRELAN

@ ELAN PHARM

EQ 750MG BASE

N20353 003 JAN 05, 1996 JUN DISC

SEP CTEC

SEP CTEC

MAR NEWA

NEOMYCIN SULFATE

SOLUTION; ORAL

MYCIFRADIN

MAR NEWA

AA +

PHARMACIA AND UPJOHN

EQ 87.5MG BASE/5ML

N50285 001 MAY CFTG

SEP CRLD

@

EQ 87.5MG BASE/5ML

N50285 001 JUN DISC

SEP CRLD

NEO-FRADIN

MAR NEWA

+ PHARMATEK

EQ 87.5MG BASE/5ML

N65010 001 MAY 23, 2002 JUN CRLD

MAR NEWA

AA

EQ 87.5MG BASE/5ML

N65010 001 MAY 23, 2002 MAY NEWA

SEP CTEC

SEP CTEC

SEP CTEC

NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

STATROL

@ ALCON

EQ 3.5MG BASE/GM;10,000 UNITS/GM

N50344 002 JUN DISC

SEP CTEC

SOLUTION/DROPS; OPHTHALMIC

@ ALCON

EQ 3.5MG BASE/ML;16,250 UNITS/ML

N50456 001 JUN DISC

NIACIN

TABLET, EXTENDED RELEASE; ORAL

NIASPIN

@ KOS

375MG

N20381 001 JUL 28, 1997 AUG DISC

+

500MG

N20381 002 JUL 28, 1997 AUG CMFD

@

500MG

N20381 002 JUL 28, 1997 JUN DISC

NIASPIN TITRATION STARTER PACK

@ KOS

375MG;500MG;750MG

N20381 005 JUL 28, 1997 JUN DISC

FEB NEWA

FEB NEWA

FEB NEWA

FEB NEWA

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC

AB1 +

BAYER

90MG

N20198 003 APR 21, 1993 AUG CTEC

JUN DISC

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | |
|------------|---------|------|--|--|--|--|--|
| NIFEDIPINE | | | | | | | |
| AB1 | BIOVAIL | 90MG | | | | | |

N76070 001 AUG 16, 2002 AUG NEWA

NILUTAMIDE

TABLET; ORAL

NILANDRON

| | | | | | | | |
|------------------|-------|--|--|--|--|--|--|
| @ AVENTIS PHARMS | 50MG | | | | | | |
| + | 150MG | | | | | | |

| | | | | | | | |
|------------|--------------|-----|------|--|--|--|--|
| N20169 001 | SEP 19, 1996 | JUN | DISC | | | | |
| N20169 002 | APR 30, 1999 | JUL | CMFD | | | | |

NISOLDIPINE

TABLET, EXTENDED RELEASE; ORAL

SULAR

| | | | | | | | |
|--------------------|------|--|--|--|--|--|--|
| + FIRST HORIZON | 10MG | | | | | | |
| | 20MG | | | | | | |
| + | 30MG | | | | | | |
| + | 40MG | | | | | | |
| + WHITEHALL ROBINS | 10MG | | | | | | |
| | 20MG | | | | | | |
| + | 40MG | | | | | | |

| | | | | | | | |
|------------|--------------|-----|------|--|--|--|--|
| N20356 001 | FEB 02, 1995 | MAR | CAHN | | | | |
| N20356 002 | FEB 02, 1995 | MAR | CAHN | | | | |
| N20356 003 | FEB 02, 1995 | MAR | CAHN | | | | |
| N20356 004 | FEB 02, 1995 | MAR | CAHN | | | | |
| N20356 001 | FEB 02, 1995 | FEB | CAHN | | | | |
| N20356 002 | FEB 02, 1995 | FEB | CAHN | | | | |
| N20356 004 | FEB 02, 1995 | FEB | CAHN | | | | |

NITISINONE

CAPSULE; ORAL

ORFADIN

| | | | | | | | |
|-------------------|------|--|--|--|--|--|--|
| R R REGISTRATIONS | 2MG | | | | | | |
| | 5MG | | | | | | |
| + | 10MG | | | | | | |
| SWEDISH ORPHAN | 2MG | | | | | | |
| | 5MG | | | | | | |
| + | 10MG | | | | | | |

| | | | | | | | |
|------------|--------------|-----|------|--|--|--|--|
| N21232 001 | JAN 18, 2002 | JAN | NEWA | | | | |
| N21232 002 | JAN 18, 2002 | JAN | NEWA | | | | |
| N21232 003 | JAN 18, 2002 | JAN | NEWA | | | | |
| N21232 001 | JAN 18, 2002 | MAY | CAHN | | | | |
| N21232 002 | JAN 18, 2002 | MAY | CAHN | | | | |
| N21232 003 | JAN 18, 2002 | MAY | CAHN | | | | |

NITROFURANTOIN

SUSPENSION; ORAL

FURADANTIN

| | | | | | | | |
|-----------------|----------|--|--|--|--|--|--|
| + FIRST HORIZON | 25MG/5ML | | | | | | |
|-----------------|----------|--|--|--|--|--|--|

N09175 001 JAN CAHN

NITROFURAZONE

CREAM; TOPICAL

FURACIN

| | | | | | | | |
|-------------------|------|--|--|--|--|--|--|
| @ SHIRE LABS | 0.2% | | | | | | |
| OINTMENT; TOPICAL | | | | | | | |
| >D> @ SHIRE LABS | 0.2% | | | | | | |
| @ | 0.2% | | | | | | |
| >A> + SHIRE PHARM | 0.2% | | | | | | |

| | | | | | | | |
|------------|-----|------|--|--|--|--|--|
| N83789 001 | JUL | DISC | | | | | |
| N05795 001 | SEP | CMFD | | | | | |
| N05795 001 | JUL | DISC | | | | | |
| N05795 001 | SEP | CMFD | | | | | |

NITROGLYCERIN

AEROSOL; SUBLINGUAL

NITROLINGUAL

| | | | | | | | |
|-----------------|-------------|--|--|--|--|--|--|
| @ FIRST HORIZON | 0.4MG/SPRAY | | | | | | |
| @ POHL BOSKAMP | 0.4MG/SPRAY | | | | | | |

| | | | | | | | |
|------------|--------------|-----|------|--|--|--|--|
| N18705 001 | OCT 31, 1985 | APR | CAHN | | | | |
| N18705 001 | OCT 31, 1985 | JUN | CAHN | | | | |

NITROGLYCERIN

SPRAY, METERED; SUBLINGUAL
 NITROLINGUAL PUMPSPRAY
 + FIRST HORIZON 0.4MG/SPRAY N18705 002 JAN 10, 1997 APR CAHN
 + POHL BOSKAMP 0.4MG/SPRAY N18705 002 JAN 10, 1997 JUN CAHN
 TABLET; SUBLINGUAL
 NITROSTAT
 PFIZER PHARMS 0.4MG N21134 002 MAY 01, 2000 JUN CAHN

NIZATIDINE

CAPSULE; ORAL
 AXID
 AB LILLY 150MG N19508 001 APR 12, 1988 JUL CFTG
 AB + 300MG N19508 002 APR 12, 1988 JUL CFTG
 AB RELIANT PHARMS 150MG N19508 001 APR 12, 1988 AUG CAHN
 AB + 300MG N19508 002 APR 12, 1988 AUG CAHN
 NIZATIDINE
 AB EON 150MG N76178 001 JUL 05, 2002 JUL NEWA
 AB 300MG N76178 002 JUL 05, 2002 JUL NEWA
 AB GENPHARM 150MG N75934 001 JUL 09, 2002 JUL NEWA
 AB 300MG N75934 002 JUL 09, 2002 JUL NEWA
 AB MYLAN 150MG N75806 001 JUL 05, 2002 JUL NEWA
 AB 300MG N75806 002 JUL 05, 2002 JUL NEWA
 >AB AB TEVA 150MG N75668 001 SEP 12, 2002 SEP NEWA
 >AB AB 300MG N75668 002 SEP 12, 2002 SEP NEWA
 AB WATSON LABS 150MG N75616 001 JUL 09, 2002 JUL NEWA
 AB 300MG N75616 002 JUL 09, 2002 JUL NEWA
 AB ZENITH GOLDLINE 150MG N75461 001 JUL 08, 2002 JUL NEWA
 AB 300MG N75461 002 JUL 08, 2002 JUL NEWA

NORETHINDRONE

TABLET; ORAL
 NOR-QD
 + WATSON LABS (UTAH) 0.35MG N17060 001 MAY CAHN

NORTRIPTYLINE HYDROCHLORIDE

SOLUTION; ORAL
 AVENTYL HCL
 AA + RANBAXY EQ 10MG BASE/5ML N14685 001 JUN CAHN

NOVOBIOCIN SODIUM

CAPSULE; ORAL
 ALBAMYCIN
 @ PHARMACIA AND UPJOHN EQ 250MG BASE N50339 001 JUN DISC

NYSTATIN

TABLET; ORAL
 NILSTAT
 @ LEDERLE 500,000 UNITS N61151 001 JUN DISC

NYSTATIN

TABLET; VAGINAL

NILSTAT

@ LEDERLE

100,000 UNITS

N61325 001

JUL DISC

OFLOXACIN

INJECTABLE; INJECTION

FLOXIN

AP + JOHNSON RW
@ ORTHO MCNEIL PHARM

40MG/ML

N20087 003 MAR 31, 1992 JAN CFTG
N20087 002 MAR 31, 1992 JUL DISC

OFLOXACIN

AP BEDFORD

40MG/ML

N75762 001 JAN 16, 2002 JAN NEWA

OLMESARTAN MEDOXOMIL

TABLET; ORAL

BENICAR

SANKYO
+
5MG
20MG
40MGN21286 001 APR 25, 2002 APR NEWA
N21286 003 APR 25, 2002 APR NEWA
N21286 004 APR 25, 2002 APR NEWAOXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

SANOFI
+
50MG/VIAL
100MG/VIALN21492 001 AUG 09, 2002 AUG NEWA
N21492 002 AUG 09, 2002 AUG NEWAOXANDROLONE

TABLET; ORAL

OXANDRIN

BIO TECH GEN
+
2.5MG
10MGN13718 001 JUN CRLD
N13718 002 NOV 05, 2001 JUN NEWAOXaprozin

TABLET; ORAL

OXaprozin

AB CARACO
AB IVAX PHARMS
AB TEVA
600MG
600MG
600MGN75844 001 JAN 03, 2002 JAN NEWA
N75846 001 MAY 13, 2002 MAY NEWA
N75849 001 JUL 03, 2002 JUL NEWAPACLITAXEL

INJECTABLE; INJECTION

PACLITAXEL

AP ABBOTT
AP NAPRO
6MG/ML
6MG/MLN76131 001 MAY 08, 2002 MAY NEWA
N76233 001 AUG 01, 2002 AUG NEWAPAMIDRONATE DISODIUM

INJECTABLE; INJECTION

PAMIDRONATE DISODIUM

AP AESGEN
AP
30MG/VIAL
90MG/VIALN75594 001 MAY 06, 2002 MAY NEWA
N75594 002 MAY 06, 2002 MAY NEWA

| | | | | | | |
|----------------------------------|---------------------|--------------------|------------|--------------|-----|------|
| AP | AM PHARM PARTNERS | 30MG/VIAL | N75773 001 | MAY 06, 2002 | MAY | NEWA |
| AP | | 30MG /10ML(3MG/ML) | N76207 001 | MAY 17, 2002 | MAY | NEWA |
| AP | | 90MG/VIAL | N75773 002 | MAY 06, 2002 | MAY | NEWA |
| AP | | 90MG /10ML(9MG/ML) | N76207 002 | MAY 17, 2002 | MAY | NEWA |
| AP | BEDFORD | 30MG /10ML(3MG/ML) | N21113 001 | MAR 04, 2002 | MAY | CDFR |
| AP + | | 90MG /10ML(9MG/ML) | N21113 002 | MAR 04, 2002 | MAY | CDFR |
| AP | FAULDING | 30MG /10ML(3MG/ML) | N75841 001 | JUN 27, 2002 | JUN | NEWA |
| AP | | 60MG /10ML(6MG/ML) | N75841 002 | JUN 27, 2002 | JUN | NEWA |
| AP | | 90MG /10ML(9MG/ML) | N75841 003 | JUN 27, 2002 | JUN | NEWA |
| AP | GENSIA SICOR PHARMS | 30MG /10ML(3MG/ML) | N76153 001 | MAR 27, 2002 | MAY | CDFR |
| AP | | 90MG /10ML(9MG/ML) | N76153 002 | MAR 27, 2002 | MAY | CDFR |
| INJECTABLE; IV (INFUSION) | | | | | | |
| AP | BEDFORD | 30MG /10ML(3MG/ML) | N21113 001 | MAR 04, 2002 | MAR | NEWA |
| AP + | | 90MG /10ML(9MG/ML) | N21113 002 | MAR 04, 2002 | MAR | NEWA |
| AP | GENSIA SICOR PHARMS | 30MG /10ML(3MG/ML) | N76153 001 | MAR 27, 2002 | MAR | NEWA |
| AP | | 90MG /10ML(9MG/ML) | N76153 002 | MAR 27, 2002 | MAR | NEWA |

PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

| | | | | | | |
|---------------|---|--|------------|--------------|-----|------|
| CAPSULE; ORAL | | | | | | |
| COTAZYM | | | | | | |
| © ORGANON | 30,000USP UNITS;8,000USP UNITS;30,000USP UNITS | | | | | |
| | | | N20580 001 | DEC 09, 1996 | JUN | DISC |

PARAMETHADIONE

| | | | | | | |
|---------------|-------|--|------------|--|-----|------|
| CAPSULE; ORAL | | | | | | |
| PARADIONE | | | | | | |
| © ABBOTT | 150MG | | N06800 003 | | JUN | DISC |
| © | 300MG | | N06800 001 | | JUN | DISC |

PENICILLIN G POTASSIUM

| | | | | | | |
|------------------------|-----------------------|--|------------|--------------|-----|------|
| INJECTABLE; INJECTION | | | | | | |
| PENICILLIN G POTASSIUM | | | | | | |
| AP GENEVA PHARMS | 1,000,000 UNITS/VIAL | | N65079 001 | AUG 30, 2002 | AUG | NEWA |
| AP | 5,000,000 UNITS/VIAL | | N65079 002 | AUG 30, 2002 | AUG | NEWA |
| AP | 20,000,000 UNITS/VIAL | | N65079 003 | AUG 30, 2002 | AUG | NEWA |

PENICILLIN V POTASSIUM

| | | | | | | |
|--------------------|-------------------|--|------------|--|-----|------|
| FOR SOLUTION; ORAL | | | | | | |
| PEN-VEE K | | | | | | |
| © WYETH AYERST | EQ 125MG BASE/5ML | | N60007 001 | | MAY | DISC |
| © | EQ 250MG BASE/5ML | | N60007 002 | | MAY | DISC |

PENTAGASTRIN

| | | | | | | |
|-----------------------|-----------|--|------------|--|-----|------|
| INJECTABLE; INJECTION | | | | | | |
| PEPTAVLON | | | | | | |
| © WYETH AYERST | 0.25MG/ML | | N17048 001 | | APR | DISC |

PENTOSAN POLYSULFATE SODIUM

| | | | | | | |
|-----------------------|-------|--|------------|--------------|-----|------|
| CAPSULE; ORAL | | | | | | |
| ELMIRON | | | | | | |
| + JOHNSON AND JOHNSON | 100MG | | N20193 001 | SEP 26, 1996 | JUL | CAHN |

PHENACEMIDE

TABLET; ORAL

PHENURONE

© ABBOTT

500MG

N07707 001

JUN DISC

PHENAZOPYRIDINE HYDROCHLORIDE; SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM AND PENAZOPYRIDINE HCL

© ABLE

200MG;800MG;160MG

N21105 001 JUN 26, 2001 JUN DISC

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

AA MIKART

35MG

N89452 001 OCT 30, 1991 MAR CMFD

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA VINTAGE PHARMS

37.5MG

N40377 001 JAN 04, 2002 JAN NEWA

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

PREFRIN-A

© ALLERGAN

0.12%;0.1%

N07953 001

JUN DISC

PHENYTOIN

SUSPENSION; ORAL

PHENTYTOIN

AB MORTON GROVE

125MG/5ML

N40420 001 APR 19, 2002 APR NEWA

PILOCARPINE

DRUG DELIVERY SYSTEM; OPHTHALMIC

OCUSERT PILO-40

© AKORN

11MG

N17548 001

JUN DISC

INSERT, EXTENDED RELEASE; OPHTHALMIC

OCUSERT PILO-20

© AKORN

5MG

N17431 001

JUN DISC

PIPECURONIUM BROMIDE

INJECTABLE; INJECTION

ARDUAN

© ORGANON

10MG/VIAL

N19638 001 JUN 26, 1990 JUN DISC

PODOFILOX

SOLUTION; TOPICAL

CONDYLOX

AT + PADDICK

0.5%

N19795 001 DEC 13, 1990 JAN CFTG

PODOFILOX

AT PADDICK

0.5%

N75600 001 JAN 29, 2002 JAN NEWA

| | | | | | |
|----------|--------------|---|------------------|--------------|-----------------------|
| | | <u>POTASSIUM CHLORIDE</u> | | | |
| | | TABLET, EXTENDED RELEASE; ORAL | | | |
| JUN DISC | | <u>POTASSIUM CHLORIDE</u> | | | |
| AB | ANDRX PHARMS | 10MEQ | N75604 001 | APR 10, 2002 | APR NEWA |
| AB | | 20MEQ | N75604 002 | APR 10, 2002 | APR NEWA |
| AB | KV PHARM | 20MEQ | N76044 001 | APR 05, 2002 | APR NEWA |
| | | <u>PRAVASTATIN SODIUM</u> | | | |
| JUN DISC | | TABLET; ORAL | | | |
| | | <u>PRAVACHOL</u> | | | |
| | | BRISTOL MYERS SQUIBB | 40MG | N19898 004 | MAR 22, 1993 MAR CRLD |
| | | + 80MG | | | |
| | | | | | |
| MAR CMFD | | <u>PREDNICARBATE</u> | | | |
| | | CREAM; TOPICAL | | | |
| | | DERMATOP | | | |
| | | + DERMIC LABS | 0.1% | N20279 001 | OCT 29, 1993 JUN CAHN |
| | | OINTMENT; TOPICAL | | | |
| | | + DERMIC LABS | 0.1% | N19568 001 | SEP 23, 1991 JUN CAHN |
| | | <u>PREDNISOLONE</u> | | | |
| | | SYRUP; ORAL | | | |
| JUN DISC | | <u>PREDNISOLONE</u> | | | |
| AA | KV PHARM | 15MG/5ML | N40364 001 | APR 10, 2002 | APR NEWA |
| | | <u>PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM</u> | | | |
| | | OINTMENT; OPHTHALMIC | | | |
| APR NEWA | | METIMYD | | | |
| | | @ SCHERING | 0.5%;10% | N10210 002 | SEP 09, 1984 JUL DISC |
| | | VASOCIDIN | | | |
| | | + NOVARTIS | 0.5%;10% | N88791 001 | OCT 05, 1984 AUG CRLD |
| | | SUSPENSION; OPHTHALMIC | | | |
| JUN DISC | | ISOPTO CETAPRED | | | |
| | | @ ALCON | 0.25%;10% | N87547 001 | JUN DISC |
| | | SUSPENSION/DROPS; OPHTHALMIC | | | |
| JUN DISC | | METIMYD | | | |
| | | @ SCHERING | 0.5%;10% | N10210 001 | JUL DISC |
| | | <u>PREDNISOLONE SODIUM PHOSPHATE</u> | | | |
| | | SOLUTION; ORAL | | | |
| JUN DISC | | ORAPRED | | | |
| | | AA + ASCENT PEDS | EQ 15MG BASE/5ML | N75117 001 | DEC 14, 2000 JUL CFTG |
| | | PEDIAPRED | | | |
| JAN CFTG | | AA + CELLTECH PHARMS | EQ 5MG BASE/5ML | N19157 001 | MAY 28, 1986 JUN CFTG |
| | | <u>PREDNISOLONE SODIUM PHOSPHATE</u> | | | |
| | | AA MORTON GROVE | EQ 5MG BASE/5ML | N75099 001 | JUN 28, 2002 JUN NEWA |
| | | AA WE PHARMS | EQ 15MG BASE/5ML | N75250 001 | JUL 12, 2002 JUL NEWA |
| | | <u>PREDNISOLONE TEBUTATE</u> | | | |
| | | INJECTABLE; INJECTION | | | |
| JAN NEWA | | HYDELTRA-TBA | | | |
| | | @ MERCK | 20MG/ML | N10562 001 | JUN DISC |

PREDNISONE

| | | | | | |
|-----|----------------|------|------------|--------------|----------|
| >D> | TABLET; ORAL | | | | |
| >D> | PREDNISONE | | | | |
| >D> | BX LANNETT | 5MG | N80514 001 | SEP | DISC |
| >A> | @ | 5MG | N80514 001 | SEP | DISC |
| AB | VINTAGE PHARMS | 5MG | N40256 001 | JUL 12, 2002 | JUL NEWA |
| AB | | 10MG | N40256 002 | JUL 12, 2002 | JUL NEWA |

PRIMIDONE

| | | | | | |
|------------------|-----------|--|------------|-----|------|
| SUSPENSION; ORAL | | | | | |
| MYSOLINE | | | | | |
| @ XCEL PHARMS | 250MG/5ML | | N10401 001 | JUL | DISC |

PROCHLORPERAZINE MALEATE

| | | | | | |
|---------------------------------|--------------|--|------------|--------------|----------|
| CAPSULE, EXTENDED RELEASE; ORAL | | | | | |
| COMPATINE | | | | | |
| @ GLAXOSMITHKLINE | EQ 10MG BASE | | N11000 001 | JUN | DISC |
| + | EQ 10MG BASE | | N21019 001 | OCT 06, 1999 | JUN CRLD |
| @ | EQ 15MG BASE | | N11000 002 | | JUN DISC |
| + | EQ 15MG BASE | | N21019 002 | OCT 06, 1999 | JUN CRLD |
| @ | EQ 30MG BASE | | N11000 003 | | JUN DISC |

PROGESTERONE

| | | | | | |
|--|------|--|------------|-----|------|
| INSERT, EXTENDED RELEASE; INTRAUTERINE | | | | | |
| PROGESTASERT | | | | | |
| @ ALZA | 38MG | | N17553 001 | JUN | DISC |

PROMAZINE HYDROCHLORIDE

| | | | | | |
|-----------------------|---------|--|------------|-----|------|
| INJECTABLE; INJECTION | | | | | |
| SPARINE | | | | | |
| @ WYETH AYERST | 50MG/ML | | N10349 006 | JUN | DISC |
| TABLET; ORAL | | | | | |
| @ WYETH AYERST | 25MG | | N10348 001 | JUN | DISC |
| @ | 50MG | | N10348 002 | JUN | DISC |

PROMETHAZINE HYDROCHLORIDE

| | | | | | |
|------------------------|----------|--|------------|--------------|----------|
| INJECTABLE; INJECTION | | | | | |
| PROMETHAZINE HCL | | | | | |
| AP GENSIA SICOR PHARMS | 25MG/ML | | N40454 001 | AUG 22, 2002 | AUG NEWA |
| AP | 50MG/ML | | N40454 002 | AUG 22, 2002 | AUG NEWA |
| SUPPOSITORY; RECTAL | | | | | |
| PHENERGAN | | | | | |
| AB + WYETH AYERST | 25MG | | N10926 001 | | FEB CTEC |
| PROMETHAZINE HCL | | | | | |
| AB G AND W LABS | 25MG | | N40428 001 | FEB 05, 2002 | FEB NEWA |
| SYRUP; ORAL | | | | | |
| PHENERGAN FORTIS | | | | | |
| @ WYETH AYERST | 25MG/5ML | | N08381 003 | | JUN DISC |

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL
PROPAFENONE HCL

| | | | | | |
|-------------|-------|------------|--------------|-----|------|
| AB KV PHARM | 150MG | N76193 001 | FEB 07, 2002 | FEB | NEWA |
| AB | 225MG | N76193 002 | FEB 07, 2002 | FEB | NEWA |
| AB | 300MG | N76193 003 | FEB 07, 2002 | FEB | NEWA |

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
DARVON

| | | | | |
|-----------------|------|------------|-----|------|
| AA + AAI PHARMA | 32MG | N10997 001 | JUN | CAHN |
| AA + | 65MG | N10997 003 | JUN | CAHN |

PROPOXYPHENE NAPSYLATE

SUSPENSION; ORAL
DARVON-N

| | | | | |
|---------------------------------|----------|------------|-----|------|
| + NEOSAN PHARMS | 50MG/5ML | N16861 001 | JUN | CAHN |
| TABLET; ORAL + AAIPHARMA LLC | 100MG | N16862 002 | JUN | CAHN |

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

| | | | | | |
|-----------------|------|------------|--------------|-----|------|
| @ LEDERLE | 60MG | N71495 001 | DEC 31, 1987 | FEB | DISC |
| @ | 80MG | N70128 001 | JUL 30, 1985 | MAY | CAHN |
| @ | 90MG | N71496 001 | DEC 31, 1987 | FEB | DISC |
| @ PUREPAC PHARM | 10MG | N70814 001 | NOV 03, 1986 | MAY | DISC |
| @ | 20MG | N70815 001 | NOV 03, 1986 | MAY | DISC |
| @ | 40MG | N70816 001 | NOV 03, 1986 | MAY | DISC |
| @ | 60MG | N70817 001 | NOV 03, 1986 | MAY | DISC |
| @ | 80MG | N70757 001 | NOV 03, 1986 | MAY | DISC |

PYRAZINAMIDE

TABLET; ORAL
PYRAZINAMIDE

| | | | | |
|--------------|-------|------------|-----|------|
| AB + CLONMEL | 500MG | N80157 001 | JUL | CAHN |
|--------------|-------|------------|-----|------|

QUINETHAZONE

TABLET; ORAL
HYDROMOX

| | | | | |
|-----------|------|------------|-----|------|
| @ LEDERLE | 50MG | N13264 001 | APR | DISC |
|-----------|------|------------|-----|------|

RABEPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
ACIPHEX

| | | | | | |
|-------------------|------|------------|--------------|-----|------|
| @ EISAI MEDCL RES | 10MG | N20973 001 | MAY 29, 2002 | JUL | DISC |
| + | 20MG | N20973 002 | AUG 19, 1999 | MAY | CAHN |
| + @ | 20MG | N20973 002 | AUG 19, 1999 | JUL | CMFD |
| @ | 20MG | N20973 002 | AUG 19, 1999 | JUN | DISC |

RANITIDINE HYDROCHLORIDE

| | | | | | |
|--------------------|---------------|--------|-----|--------------|----------|
| CAPSULE; ORAL | | | | | |
| RANITIDINE HCL | | | | | |
| AB + GENEVA PHARMS | EQ 300MG BASE | N74655 | 002 | OCT 22, 1997 | AUG CRLD |
| ZANTAC 300 | | | | | |
| @ GLAXOSMITHKLINE | EQ 300MG BASE | N20095 | 002 | MAR 08, 1994 | AUG DISC |

RAPACURONIUM BROMIDE

| | | | | | |
|-----------------------|------------|--------|-----|--------------|----------|
| INJECTABLE; INJECTION | | | | | |
| RAPLON | | | | | |
| @ ORGANON | 100MG/VIAL | N20984 | 001 | AUG 18, 1999 | JUN DISC |
| @ | 200MG/VIAL | N20984 | 002 | AUG 18, 1999 | JUN DISC |

RIMANTADINE HYDROCHLORIDE

| | | | | | |
|-----------------|-------|--------|-----|--------------|----------|
| TABLET; ORAL | | | | | |
| RIMANTADINE HCL | | | | | |
| AB IMPAX LABS | 100MG | N76132 | 001 | AUG 30, 2002 | AUG NEWA |

RISEDRONATE SODIUM

| | | | | | |
|--------------------|------|--------|-----|--------------|----------|
| TABLET; ORAL | | | | | |
| ACTONEL | | | | | |
| PROCTER AND GAMBLE | 30MG | N20835 | 001 | MAR 27, 1998 | JUL CRLD |
| + | 35MG | N20835 | 003 | MAY 25, 2002 | JUL NEWA |

RITONAVIR

| | | | | | |
|---------------|-------|--------|-----|--------------|----------|
| CAPSULE; ORAL | | | | | |
| NORVIR | | | | | |
| @ ABBOTT | 100MG | N20680 | 001 | MAR 01, 1996 | JUN DISC |
| + | 100MG | N20945 | 001 | JUN 29, 1999 | JUN CRLD |

ROCURONIUM BROMIDE

| | | | | | |
|-----------------------|---------|--------|-----|--------------|----------|
| INJECTABLE; INJECTION | | | | | |
| ZEMURON | | | | | |
| @ ORGANON | 10MG/ML | N20214 | 002 | MAR 17, 1994 | JUN DISC |

SECOBARBITAL SODIUM

| | | | | | |
|----------------|-------|--------|-----|--------------|----------|
| CAPSULE; ORAL | | | | | |
| SECONAL SODIUM | | | | | |
| + RANBAXY | 50MG | N86101 | 001 | OCT 03, 1983 | JUN CAHN |
| AA + | 100MG | N86101 | 002 | OCT 03, 1983 | JUN CAHN |

SECRETIN

| | | | | | |
|---------------------------|------------|--------|-----|--------------|----------|
| FOR SOLUTION; INTRAVENOUS | | | | | |
| SECREFLO | | | | | |
| + CHIRHOCLIN | 16UGM/VIAL | N21209 | 001 | APR 04, 2002 | APR NEWA |

SELEGILINE HYDROCHLORIDE

| | | | | | |
|---------------------|-----|--------|-----|--------------|----------|
| CAPSULE; ORAL | | | | | |
| SELEGILINE HCL | | | | | |
| AB CLONMEL HLTHCARE | 5MG | N75352 | 001 | NOV 30, 1998 | JUN CAHN |
| TABLET; ORAL | | | | | |
| AB CLONMEL HLTHCARE | 5MG | N74641 | 001 | AUG 02, 1996 | APR CAHN |

| | | | | | |
|----------|---|-------------------|------------|--------------|----------|
| AB | SIEGFRIED | 5MG | N74672 001 | APR 01, 1997 | AUG CAHN |
| AUG CRLD | <u>SELENIUM SULFIDE</u> LOTION/SHAMPOO; TOPICAL SELSUN | | | | |
| AUG DISC | AT + CHATTEM | 2.5% | N07936 001 | | AUG CAHN |
| JUN DISC | <u>SELENOMETHIONINE, SE-75</u> INJECTABLE; INJECTION SELENOMETHIONINE SE 75 | | | | |
| JUN DISC | @ CIS | 500uCi/ML | N17322 001 | | JUN DISC |
| AUG NEWA | <u>SEVOFLURANE</u> LIQUID; INHALATION SEVOFLURANE | | N75895 001 | JUL 02, 2002 | SEP NEWA |
| >A> | AN BAXTER HLTHCARE | 100% | | | |
| >D> | ULTANE | | | | |
| >D> | + ABBOTT | 100% | N20478 001 | JUN 07, 1995 | SEP CFTG |
| >A> | AN + | 100% | N20478 001 | JUN 07, 1995 | SEP CFTG |
| JUL CRLD | <u>SIMETHICONE-CELLULOSE</u> SUSPENSION; ORAL SONORX | | | | |
| JUL NEWA | @ BRACCO | 7.5MG/ML | N20773 001 | OCT 29, 1998 | JUN DISC |
| JUN DISC | <u>SIROLIMUS</u> TABLET; ORAL RAPAMUNE | | | | |
| JUN CRLD | + WYETH AYERST | 1MG | N21110 001 | AUG 25, 2000 | JUN NEWA |
| JUN DISC | <u>SODIUM BENZOATE; SODIUM PHENYLACETATE</u> SOLUTION; ORAL UCEPHAN | | | | |
| JUN CRLD | @ B BRAUN | 100MG/ML;100MG/ML | N19530 001 | DEC 23, 1987 | JUN DISC |
| JUN DISC | <u>SODIUM IODIDE, I-131</u> CAPSULE; ORAL IODOTOPE | | | | |
| JUN CAHN | @ BRACCO | 1-150mCi | N10929 003 | | JUN DISC |
| JUN CAHN | SOLUTION; ORAL @ BRACCO | 7-106mCi/BOT | N10929 002 | | JUN DISC |
| APR NEWA | <u>SODIUM OXYBATE</u> SOLUTION; ORAL XYREM | | | | |
| APR NEWA | + ORPHAN MEDCL | 500MG/ML | N21196 001 | JUL 17, 2002 | JUL NEWA |
| JUN CAHN | <u>SOMATROPIN RECOMBINANT</u> INJECTABLE; INJECTION NORDITROPIN | | | | |
| JUN CAHN | @ NOVO NORDISK | 4MG/VIAL | N19721 001 | MAY 08, 1995 | JUN DISC |
| APR CAHN | @ | 8MG/VIAL | N19721 002 | MAY 08, 1995 | JUN DISC |

| | | | | | | |
|---------------------------------------|--|----------------------|--------------------|--------|------|--------------|
| <u>SOMATROPIN RECOMBINANT</u> | | | | | | |
| INJECTABLE; INJECTION | | | | | | |
| NUTROPIN AQ PEN | | | | | | |
| BX | + | GENENTECH SAIZEN | 5MG/ML | N20522 | 002 | APR 22, 2002 |
| >A> | BX | + | 8.8MG/VIAL | N19764 | 003 | AUG 29, 2000 |
| >D> | INJECTABALE; INTRAMUSCULAR, SUBCUTANEOUS SAIZEN | | | SEP | CDFR | |
| >D> | + | SERONO SEROSTIM | 8.8MG/VIAL | N19764 | 003 | AUG 29, 2000 |
| BX | + | SERONO | 4MG/VIAL | N20604 | 003 | JUL 25, 1997 |
| BX | | | 6MG/VIAL | N20604 | 001 | AUG 23, 1996 |
| >A> | BX | + | 8.8MG/VIAL | N20604 | 004 | SEP 06, 2001 |
| >D> | SEROSTIM IN PLASTIC CONTAINER | | | SEP | CTNA | |
| >D> | BX | + | 8.8MG/VIAL | N20604 | 004 | SEP 06, 2001 |
| BX | + | SERONO TEV-TROVIN | 8.8MG/VIAL | N20604 | 004 | SEP 06, 2001 |
| BX | + | BIO TECH GEN | 5MG/ML | N19774 | 002 | JAN 04, 2002 |
| <u>SOTALOL HYDROCHLORIDE</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| SOTALOL HCL | | | | | | |
| >A> | AB | APOTEX | 80MG | N76140 | 001 | SEP 26, 2002 |
| >A> | AB | | 120MG | N76140 | 002 | SEP 26, 2002 |
| >A> | AB | | 160MG | N76140 | 003 | SEP 26, 2002 |
| >A> | AB | | 240MG | N76140 | 004 | SEP 26, 2002 |
| <u>SPECTINOMYCIN HYDROCHLORIDE</u> | | | | | | |
| INJECTABLE; INJECTION | | | | | | |
| TROBICIN | | | | | | |
| @ | PHARMACIA AND UPJOHN | | EQ 4GM BASE/VIAL | N50347 | 002 | |
| | | | | | | JUN DISC |
| <u>SUCCINYLCHOLINE CHLORIDE</u> | | | | | | |
| INJECTABLE; INJECTION | | | | | | |
| QUELICIN PRESERVATIVE FREE | | | | | | |
| @ | ABBOTT | | 50MG/ML | N08845 | 002 | |
| | | | | | | JUN DISC |
| <u>SULFAMETHIZOLE</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| THIOSULFIL | | | | | | |
| @ | WYETH AYERST | | 500MG | N08565 | 004 | |
| | | | | | | JUN DISC |
| <u>SULFAMETHOXAZOLE</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| GANTANOL | | | | | | |
| @ | ROCHE | | 500MG | N12715 | 002 | |
| | | | | | | MAY CTEC |
| <u>SULFAMETHOXAZOLE; TRIMETHOPRIM</u> | | | | | | |
| SUSPENSION; ORAL | | | | | | |
| BACTRIM PEDIATRIC | | | | | | |
| @ | WOMEN FIRST HLTHCARE | | 200MG/5ML;40MG/5ML | N17560 | 002 | |
| SEPTRA | | | | | | |
| AB | + | MONARCH PHARMS | 200MG/5ML;40MG/5ML | N17598 | 001 | |
| | | | | | | APR CRLD |

SULFAPYRIDINE

TABLET; ORAL

SULFAPYRIDINE

@ LILLY

500MG

N00159 001

JUN DISC

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

AB VINTAGE PHARMS 500MG N40349 001 JAN 11, 2002 JAN NEWA
TABLET, DELAYED RELEASE; ORAL

AZULFIDINE EN-TABS

AB + PHARMACIA AND UPJOHN 500MG N07073 002 APR 06, 1983 JAN CFTG
SULFASALAZINE

AB VINTAGE PHARMS 500MG N75339 001 JAN 11, 2002 JAN NEWA

SULFISOXAZOLE ACETYL

SYRUP; ORAL

GANTRISIN

@ ROCHE

EQ 500MG BASE/5ML

N09182 002

JUN DISC

SUMATRIPTAN SUCCINATE

TABLET; ORAL

IMITREX

GLAXOSMITHKLINE EQ 50MG BASE N20132 003 JUN 01, 1995 JUN CRLD
+ EQ 100MG BASE N20132 001 JUN 01, 1995 JUN CMFDSUPROFEN

SOLUTION/DROPS; OPHTHALMIC

PROFENAL

@ ALCON

1%

N19387 001 DEC 23, 1988 JUN DISC

TAMOXIFEN CITRATE

TABLET; ORAL

NOLVADEX

+ ASTRazeneca EQ 20MG BASE N17970 002 MAR 21, 1994 AUG CTEC

TECHNETIUM TC-99M ALBUMIN COLLOID KIT

INJECTABLE; INJECTION

MICROLITE

@ CIS

N/A

N18263 001 MAR 25, 1983 JUN DISC

TECHNETIUM TC-99M ALBUMIN KIT

INJECTABLE; INJECTION

TECHNETIUM TC 99M HSA

@ AMERSHAM HLTH

N/A

N17775 001

JUL DISC

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION

RBC-SCAN

@ CADEMA

N/A

N20063 001 JUN 11, 1992 JUN DISC

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL

SODIUM PERTECHNETATE TC 99M

© MALLINCKRODT 10-60mCi/ML

N17725 001

JUN DISC

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR

SOLUTION; INJECTION, ORAL

TECHNETIUM TC 99M GENERATOR

© AMERSHAM HLTH 830-16600mCi/GENERATOR

N17693 001

JUN DISC

TEGASEROD MALEATE

TABLET; ORAL

ZELNORM

NOVARTIS

EQ 2MG BASE

N21200 001 JUL 24, 2002 AUG CPOT

2MG

N21200 001 JUL 24, 2002 JUL NEWA

+

EQ 6MG BASE

N21200 002 JUL 24, 2002 AUG CPOT

+

6MG

N21200 002 JUL 24, 2002 JUL NEWA

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HCL

AB

RANBAXY

EQ 1MG BASE

N76021 001 AUG 22, 2002 AUG NEWA

AB

EQ 2MG BASE

N76021 002 AUG 22, 2002 AUG NEWA

AB

EQ 5MG BASE

N76021 003 AUG 22, 2002 AUG NEWA

AB

EQ 10MG BASE

N76021 004 AUG 22, 2002 AUG NEWA

TERBINAFINE

GEL; TOPICAL

LAMISIL

© NOVARTIS

1%

N20846 001 APR 29, 1998 JUN DISC

TERBUTALINE SULFATE

INJECTABLE; INJECTION

BRETHINE

+ AAIPHARMA

1MG/ML

N18571 001

JUL CAHN

+ NEOSAN PHARMS

1MG/ML

N18571 001

FEB CAHN

TABLET; ORAL

AB AAIPHARMA

2.5MG

N17849 001

JUL CAHN

AB

5MG

N17849 002

JUL CAHN

AB NEOSAN PHARMS

2.5MG

N17849 001

FEB CAHN

AB

5MG

N17849 002

FEB CAHN

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL

TESTODERM TTS

BX + ALZA

5MG/24HR

N20791 001 DEC 18, 1997 JAN CTNA

TETRACYCLINE HYDROCHLORIDE

FIBER, EXTENDED RELEASE; PERIODONTAL

ACTISITE

+ ALZA

12.7MG/FIBER

N50653 001 MAR 25, 1994 FEB CAHN

TETRACYCLINE HYDROCHLORIDE

FOR SOLUTION; TOPICAL

TOPICYCLINE

@ SHIRE LABS

2.2MG/ML

N50493 001

JUL DISC

INJECTABLE; INJECTION

ACHROMYCIN

@ LEDERLE

250MG/VIAL

N50273 002

JUN DISC

+

500MG/VIAL

N50273 003

JUN CRLD

@

500MG/VIAL

N50273 003

JUL DISC

SUSPENSION; ORAL

ACHROMYCIN V

@ LEDERLE

125MG/5ML

N50263 002

APR DISC

SUMYCIN

+ APOTHECON

125MG/5ML

N60400 001

APR CTEC

TABLET; ORAL

@ PAR PHARM

50MG

N61147 003

MAY CAHN

@

100MG

N61147 002

MAY CAHN

@

250MG

N61147 001

MAY CAHN

+

500MG

N61147 004

MAY CAHN

THIETHYLPERAZINE MALATE

INJECTABLE; INJECTION

TORECAN

@ NOVARTIS

5MG/ML

N12754 002

JUN DISC

THIORIDAZINE

SUSPENSION; ORAL

MELLARIL-S

@ NOVARTIS

EQ 25MG HCL/5ML

N17923 001

JUN DISC

@

EQ 100MG HCL/5ML

N17923 002

JUN DISC

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

MELLARIL

@ NOVARTIS

30MG/ML

N11808 012

AUG DISC

@

100MG/ML

N11808 018

AUG DISC

THIORIDAZINE HCL

AA + COPLEY PHARM

30MG/ML

N89602 001 NOV 09, 1987 AUG CRLD

AA +

100MG/ML

N89603 001 NOV 09, 1987 AUG CRLD

TABLET; ORAL

MELLARIL

@ NOVARTIS

10MG

N11808 003

AUG DISC

@

15MG

N11808 016

AUG DISC

@

25MG

N11808 006

AUG DISC

@

50MG

N11808 011

AUG DISC

@

100MG

N11808 009

AUG DISC

@

150MG

N11808 017

AUG DISC

@

200MG

N11808 015

AUG DISC

THIORIDAZINE HCL

AB + GENEVA PHARMS

25MG

N88133 001 AUG 30, 1983 AUG CRLD

AB +

100MG

N88135 001 NOV 20, 1984 AUG CRLD

| | | | | | | |
|----------------------------------|--------------------|----------------|------------|--------------|-----|------|
| AB + | | 200MG | N88137 001 | SEP 17, 1986 | AUG | CRLD |
| <u>THIOTEPA</u> | | | | | | |
| INJECTABLE; INJECTION | | | | | | |
| THIOTEPA | | | | | | |
| AP | AM PHARM PARTNERS | 15MG/VIAL | N75698 001 | SEP 20, 2001 | FEB | CAHN |
| <u>THIOTHIXENE HYDROCHLORIDE</u> | | | | | | |
| CONCENTRATE; ORAL | | | | | | |
| THIOTHIXENE HCL INTENSOL | | | | | | |
| @ ROXANE | | EQ 5MG BASE/ML | N73494 001 | JUN 30, 1992 | JAN | DISC |
| <u>TIAGABINE HYDROCHLORIDE</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| GABITRIL | | | | | | |
| + CEPHALON | | 16MG | N20646 003 | SEP 30, 1997 | JUN | CRLD |
| @ | | 20MG | N20646 004 | SEP 30, 1997 | JUN | DISC |
| <u>TICLOPIDINE HYDROCHLORIDE</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| TICLOPIDINE HCL | | | | | | |
| >A> AB | CARACO | 250MG | N75526 001 | SEP 26, 2002 | SEP | NEWA |
| <u>TIMOLOL MALEATE</u> | | | | | | |
| SOLUTION; OPHTHALMIC | | | | | | |
| TIMOLOL MALEATE | | | | | | |
| >A> AT | HI TECH PHARMA | EQ 0.5% BASE | N75163 001 | SEP 10, 2002 | SEP | NEWA |
| <u>TINZAPARIN SODIUM</u> | | | | | | |
| INJECTABLE; INJECTION | | | | | | |
| INNOHEP | | | | | | |
| + LEO PHARM | | 20,000 IU/ML | N20484 001 | JUL 14, 2000 | APR | CAHN |
| + PHARMION | | 20,000 IU/ML | N20484 001 | JUL 14, 2000 | JUL | CAHN |
| <u>TIZANIDINE HYDROCHLORIDE</u> | | | | | | |
| CAPSULE; ORAL | | | | | | |
| ZANAFLEX | | | | | | |
| ELAN PHARMS | | EQ 2MG BASE | N21447 001 | AUG 29, 2002 | AUG | NEWA |
| | | EQ 4MG BASE | N21447 002 | AUG 29, 2002 | AUG | NEWA |
| + | | EQ 6MG BASE | N21447 003 | AUG 29, 2002 | AUG | NEWA |
| TABLET; ORAL | | | | | | |
| TIZANIDINE HCL | | | | | | |
| AB | DR REDDYS LABS INC | EQ 2MG BASE | N76286 001 | JUL 03, 2002 | JUL | NEWA |
| AB | | EQ 4MG BASE | N76286 002 | JUL 03, 2002 | JUL | NEWA |
| AB | EON | EQ 4MG BASE | N76280 002 | JUN 27, 2002 | JUN | NEWA |
| AB | PUREPAC PHARM | EQ 2MG BASE | N76283 001 | JUL 12, 2002 | JUL | NEWA |
| AB | | EQ 4MG BASE | N76283 002 | JUL 12, 2002 | JUL | NEWA |
| AB | TEVA | EQ 2MG BASE | N76284 001 | JUL 03, 2002 | JUL | NEWA |
| AB | | EQ 4MG BASE | N76284 002 | JUL 03, 2002 | JUL | NEWA |
| ZANAFLEX | | | | | | |
| AB | ELAN PHARMS | EQ 2MG BASE | N20397 002 | FEB 04, 2000 | AUG | CFTG |
| AB + | | EQ 4MG BASE | N20397 001 | NOV 27, 1996 | JUN | CFTG |

AUG CRLD

TOBRAMYCIN
SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN
AT NOVEX 0.3% N65087 001 FEB 25, 2002 FEB NEWA

FEB CAHN

TOBRAMYCIN SULFATE
INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

@ ASTRazeneca EQ 40MG BASE/ML N63120 001 OCT 31, 1994 FEB DISC
@ EQ 40MG BASE/ML N63122 001 OCT 31, 1994 JAN DISC

JAN DISC

TOLAZOLINE HYDROCHLORIDE
INJECTABLE; INJECTION

PRISCOLINE
@ NOVARTIS 25MG/ML N06403 005 FEB 22, 1985 JUN DISC

JUN CRLD

JUN DISC

TOPIRAMATE
TABLET; ORAL

TOPAMAX
+ JOHNSON AND JOHNSON 25MG N20505 004 DEC 24, 1996 JAN CAHN
@ 50MG N20505 005 DEC 24, 1996 JAN CAHN
100MG N20505 001 DEC 24, 1996 JAN CAHN
200MG N20505 002 DEC 24, 1996 JAN CAHN
@ 300MG N20505 003 DEC 24, 1996 JAN CAHN
@ 400MG N20505 006 DEC 24, 1996 JAN CAHN

SEP NEWA

TORSEMIDE
TABLET; ORAL

DEMADEX
AB ROCHE 5MG N20136 001 AUG 23, 1993 MAY CFTG
AB 10MG N20136 002 AUG 23, 1993 MAY CFTG
AB + 20MG N20136 003 AUG 23, 1993 MAY CFTG
AB 100MG N20136 004 AUG 23, 1993 MAY CFTG

TORSEMIDE
AB TEVA 5MG N76110 001 MAY 14, 2002 MAY NEWA
AB 10MG N76110 002 MAY 14, 2002 MAY NEWA
AB 20MG N76110 003 MAY 14, 2002 MAY NEWA
AB 100MG N76110 004 MAY 14, 2002 MAY NEWA

AUG NEWA

AUG NEWA

AUG NEWA

TRAMADOL HYDROCHLORIDE

TABLET; ORAL
TRAMADOL HCL
AB ABLE 50MG N75963 001 JUL 03, 2002 JUL NEWA
AB ASTA 50MG N75974 001 JUL 12, 2002 JUL NEWA
AB CARACO 50MG N75964 001 JUN 19, 2002 JUN NEWA
AB COREPHARMA 50MG N76003 001 JUN 20, 2002 JUN NEWA
AB EON 50MG N75968 001 JUN 25, 2002 JUN NEWA
AB MALLINCKRODT 50MG N75983 001 JUN 25, 2002 JUN NEWA
AB MUTUAL PHARM 50MG N76100 001 JUN 20, 2002 JUN NEWA
AB MYLAN 50MG N75986 001 JUN 21, 2002 JUN NEWA
AB PUREPAC PHARM 50MG N75960 001 JUN 19, 2002 JUN NEWA
AB SIDMAK LABS 50MG N75982 001 JUL 01, 2002 JUL NEWA

AUG CFTG

JUN CFTG

| | | | | | | |
|------|---------------------|-------|------------|--------------|-----|------|
| AB | TEVA | 50MG | N75977 001 | JUN 19, 2002 | JUN | NEWA |
| AB | TORPHARM | 50MG | N75981 001 | JUL 10, 2002 | JUL | NEWA |
| AB | WATSON LABS | 50MG | N75962 001 | JUN 24, 2002 | JUN | NEWA |
| | ULTRAM | | | | | |
| + AB | JOHNSON AND JOHNSON | 50MG | N20281 002 | MAR 03, 1995 | FEB | CAHN |
| | @ | 100MG | N20281 001 | MAR 03, 1995 | FEB | CAHN |
| AB + | ORTHO MCNEIL PHARM | 50MG | N20281 002 | MAR 03, 1995 | JUN | CTEC |

TREPROSTINIL SODIUM

INJECTABLE; SUBCUTANEOUS
REMODULIN

| | | | | | |
|---------------|----------|------------|--------------|-----|------|
| UNITED THERAP | 1MG/ML | N21272 001 | MAY 21, 2002 | MAY | NEWA |
| | 2.5MG/ML | N21272 002 | MAY 21, 2002 | MAY | NEWA |
| | 5MG/ML | N21272 003 | MAY 21, 2002 | MAY | NEWA |
| + | 10MG/ML | N21272 004 | MAY 21, 2002 | MAY | NEWA |

TRETINOIN

GEL; TOPICAL

RETIN-A

| | | | | | | |
|-------|---------------------|-------|------------|--------------|-----|------|
| AB + | JOHNSON AND JOHNSON | 0.01% | N17955 001 | | JUN | CFTG |
| | RETIN-A MICRO | | | | | |
| >A> + | JOHNSON AND JOHNSON | 0.04% | N20475 002 | MAY 10, 2002 | SEP | NEWA |
| | TRETINOIN | | | | | |
| AB | SPEAR PHARMS | 0.01% | N75589 001 | JUN 11, 2002 | JUN | NEWA |

TRIAMCINOLONE

TABLET; ORAL

ARISTOCORT

| | | | | | | |
|---------------------|----------------------|------------|------------|-----|------|------|
| @ FUJISAWA HLTHCARE | 1MG | N11161 009 | | JUL | DISC | |
| @ | 2MG | N11161 004 | | JUL | DISC | |
| @ | 8MG | N11161 011 | | JUL | DISC | |
| KENACORT | | | | | | |
| + | BRISTOL MYERS SQUIBB | 8MG | N11283 010 | | AUG | CTEC |

TRIAMCINOLONE ACETONIDE

INJECTABLE; INJECTION

KENALOG-10

| | | | | | | |
|----------|-------------------------|---------|------------|--------------|-----|------|
| | APOTHECON | 10MG/ML | N12041 001 | | JUN | CRLD |
| | KENALOG-40 | | | | | |
| >D> BP + | APOTHECON | 40MG/ML | N14901 001 | | SEP | CTEC |
| >A> + | | 40MG/ML | N14901 001 | | SEP | CTEC |
| BP + | | 40MG/ML | N14901 001 | | JUN | CRLD |
| >D> | TRIAMCINOLONE ACETONIDE | | | | | |
| | @ PARRELL | 3MG/ML | N19503 001 | OCT 16, 1987 | JUN | DISC |
| >D> BP | STERIS | 40MG/ML | N85825 001 | | SEP | DISC |
| >A> | @ | 40MG/ML | N85825 001 | | SEP | DISC |

SPRAY, METERED; NASAL

TRI-NASAL

| | | | | | |
|--------|--------------|------------|--------------|-----|------|
| @ MURO | 0.05MG/SPRAY | N20120 001 | FEB 04, 2000 | JUN | DISC |
|--------|--------------|------------|--------------|-----|------|

TRIAMCINOLONE DIACETATE

| | | | | |
|-----------------------|-------------------------|---------|------------|----------|
| INJECTABLE; INJECTION | | | | |
| ARISTOCORT | | | | |
| >D> | BP + LEDERLE | 40MG/ML | N12802 001 | SEP CTEC |
| >A> | + + | 40MG/ML | N12802 001 | SEP CTEC |
| >D> | TRIAMCINOLONE DIACETATE | | | |
| >D> | BP STERIS | 40MG/ML | N84072 001 | SEP DISC |
| >A> | @ | 40MG/ML | N84072 001 | SEP DISC |
| SYRUP; ORAL | | | | |
| ARISTOCORT | | | | |
| @ FUJISAWA HLTHCARE | | 2MG/5ML | N11960 004 | JUL DISC |

TRIFLUOPROMAZINE HYDROCHLORIDE

| | | | | |
|-----------------------|---------|------------|----------|--|
| INJECTABLE; INJECTION | | | | |
| VESPRIN | | | | |
| @ APOTHECON | 10MG/ML | N11325 004 | JUN DISC | |
| @ | 20MG/ML | N11325 001 | JUN DISC | |

TRILOSTANE

| | | | | |
|---------------|------|------------|--------------|----------|
| CAPSULE; ORAL | | | | |
| MODRASTANE | | | | |
| @ BIOENVISION | 30MG | N18719 002 | DEC 31, 1984 | JUN CAHN |
| @ | 60MG | N18719 001 | DEC 31, 1984 | JUN CAHN |

TRIMETHADIONE

| | | | | |
|----------------|-----------|------------|----------|--|
| CAPSULE; ORAL | | | | |
| TRIDIONE | | | | |
| @ ABBOTT | 300MG | N05856 005 | JUN DISC | |
| SOLUTION; ORAL | | | | |
| @ ABBOTT | 200MG/5ML | N05856 002 | JUN DISC | |

TRIMETHOBENZAMIDE HYDROCHLORIDE

| | | | | |
|-----------------------|----------|------------|--------------|----------|
| CAPSULE; ORAL | | | | |
| TIGAN | | | | |
| + KING PHARMS | 300MG | N17531 006 | DEC 13, 2001 | JAN NEWA |
| INJECTABLE; INJECTION | | | | |
| TRIMETHOBENZAMIDE HCL | | | | |
| @ STERIS | 100MG/ML | N87939 001 | DEC 28, 1982 | FEB DISC |

TRIMETHOPRIM

| | | | | |
|--------------|-------|------------|----------|--|
| TABLET; ORAL | | | | |
| TRIMPEX | | | | |
| @ ROCHE | 100MG | N17952 001 | AUG DISC | |

TRIOXSALEN

| | | | | |
|--------------|-----|------------|----------|--|
| TABLET; ORAL | | | | |
| TRISORALEN | | | | |
| @ ICN | 5MG | N12697 001 | JUN DISC | |

TRIPELENNAMINE CITRATE

ELIXIR; ORAL

PBZ

@ NOVARTIS

EQ 25MG HCL/5ML

N05914 004

JUN DISC

TRIPELENNAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PBZ-SR

@ NOVARTIS

100MG

N10533 001

JUN DISC

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

TABLET; VAGINAL

SULTRIN

@ ORTHO MCNEIL PHARM

184MG;143.75MG;172.5MG

N05794 002

JUN DISC

UREA, C-13

FOR SOLUTION; ORAL

PYLORI-CHEK BREATH TEST

@ ALIMENTERICS

100MG/VIAL

N20900 001 FEB 04, 1999 JUL DISC

UROFOLLITROPIN

INJECTABLE; INTRAMUSCULAR, SUBCUTANEOUS

BRAVELLE

BX + FERRING

75 IU/VIAL

N21289 001 MAY 06, 2002 MAY NEWA

INJECTABLE; SUBCUTANEOUS

FERTINEX

BX + SERONO

75 IU/AMP

N19415 005 AUG 23, 1996 MAY CTEC

@

150 IU/AMP

N19415 004 AUG 23, 1996 JUN DISC

URSODIOL

CAPSULE; ORAL

ACTIGALL

@ WATSON PHARMS

150MG

N19594 001 DEC 31, 1987 FEB CAHN

AB +

300MG

N19594 002 DEC 31, 1987 FEB CAHN

VALACYCLOVIR HYDROCHLORIDE

TABLET; ORAL

VALTREX

@ GLAXOSMITHKLINE

EQ 500MG BASE

N20487 001 JUN 23, 1995 MAR DISC

@

EQ 1GM BASE

N20487 002 JUN 23, 1995 MAR DISC

VALSARTAN

CAPSULE; ORAL

DIOVAN

@ NOVARTIS

80MG

N20665 001 DEC 23, 1996 JUN DISC

@

160MG

N20665 002 DEC 23, 1996 JUN DISC

VECURONIUM BROMIDE

INJECTABLE; INJECTION

NORCURON

@ ORGANON

20MG/VIAL

N18776 003 JAN 03, 1992 JUN DISC

ZOLMITRIPTAN

TABLET, ORALLY DISINTEGRATING; ORAL

ZOMIG-ZMT

+ ASTRazeneca

5MG

N21231 002 SEP 17, 2001 JUN NEWA

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL

ACETAMINOPHEN

COREPHARMA

650MG

N76200 001 MAR 19, 2002 MAR NEWA

17, 2001 JUN NEWA

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL

E-Z SCRUB

>D> BECTON DICKINSON 4% N73416 001 MAR 14, 2000 SEP DISC
>D> @ 4% N73416 001 MAR 14, 2000 SEP DISC

>A>

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CONTAC 12 HOUR

@ GLAXOSMITHKLINE 8MG;75MG

N18099 001 JAN DISC

PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE

@ CENT PHARMS 8MG;75MG

N18809 001 MAY 07, 1984 FEB DISC

CIMETIDINE

SUSPENSION; ORAL

>D> TAGAMET HB 200
>D> + GLAXOSMITHKLINE 200MG/20ML N20951 001 JUL 09, 1999 SEP DISC
>A> @ 200MG/20ML N20951 001 JUL 09, 1999 SEP DISC

TABLET; ORAL

CIMETIDINE

TORPHARM 200MG

N74948 002 JUL 26, 2002 JUL NEWA

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

TORPHARM 10MG

N75610 001 MAR 12, 2002 MAR NEWA

GUAIFENESIN

TABLET, EXTENDED RELEASE; ORAL

MUCINEX

ADAMS LABS 600MG

N21282 001 JUL 12, 2002 JUL NEWA

IBUPROFEN

TABLET; ORAL

IBUPROFEN

PERRIGO 200MG

N75995 001 MAR 14, 2002 MAR NEWA

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

ADVIL COLD AND SINUS

WYETH CONS 200MG;30MG

N21374 001 MAY 30, 2002 MAY NEWA

SUSPENSION; ORAL

CHILDREN'S ADVIL COLD

WYETH CONS 100MG/5ML;15MG/5ML

N21373 001 APR 18, 2002 APR NEWA

TABLET; ORAL

IBUPROFEN AND PSEUDOEPHEDRINE HCL

PHARM FORM 200MG;30MG

N75588 001 APR 08, 2002 APR NEWA

INSULIN PURIFIED PORK

INJECTABLE; INJECTION

REGULAR PURIFIED PORK INSULIN

@ NOVO NORDISK 100 UNITS/ML

N18381 001

FEB DISC

INSULIN RECOMBINANT HUMAN

INJECTABLE; INJECTION

VELOSULIN BR

+ NOVO NORDISK 100 UNITS/ML

N21028 001 JUL 19, 1999 JUN CMS2

INSULIN SUSP ISOPHANE PURIFIED PORK

INJECTABLE; INJECTION

NPH PURIFIED PORK ISOPHANE INSULIN

@ NOVO NORDISK 100 UNITS/ML

N18623 001

FEB DISC

INSULIN ZINC SUSP PURIFIED PORK

INJECTABLE; INJECTION

LENTE

@ NOVO NORDISK 100 UNITS/ML

N18383 001

FEB DISC

KETOPROFEN

TABLET; ORAL

KETOPROFEN

PERRIGO 12.5MG

N75364 001 FEB 07, 2002 FEB NEWA

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET, CHEWABLE; ORAL

LOPERAMIDE HCL AND SIMETHICONE

PERRIGO 2MG;125MG

N76029 001 AUG 30, 2002 AUG NEWA

MINOXIDIL

SOLUTION; TOPICAL

MINOXIDIL EXTRA STRENGTH (FOR MEN)

CLAY PARK 5%

N75737 001 MAR 15, 2002 MAR NEWA

NOVEX 5%

N75839 001 OCT 01, 2001 MAR CTNA

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

DR REDDYS LABS INC EQ 200MG BASE

N75168 001 JUL 28, 1998 AUG CAHN

POTASSIUM IODIDE

TABLET; ORAL

>A> THYROSafe

>A> R R REGISTRATIONS 65MG

N76350 001 SEP 10, 2002 SEP NEWA

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

SUDAFED 12 HOUR

+ WARNER LAMBERT 120MG

N73585 001 OCT 31, 1991 MAY CAHN

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

GENEVA PHARMS

EQ 75MG BASE

PERRIGO

EQ 75MG BASE

N75519 001 SEP 26, 2002 SEP NEWA

N76195 001 AUG 30, 2002 AUG NEWA

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

CUMULATIVE SUPPLEMENT NUMBER 9 SEPTEMBER '02

NO SEPTEMBER 2002 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 September 2002

| | | | |
|---|-----------------------|--|--|
| (R)-N-[2-(6-chloro-5-methoxy-1H-indol-3-yl)propyl]acetamide | DD: 10/3/2001 | Treatment of circadian rhythm sleep disorders in blind people with no light perception | Phase 2 Discovery, Inc. 3130 Highland Avenue, Third Floor Cincinnati OH 45219-2374 |
| 2-chloroethyl-3-sarcosinamide-1-nitrosourea Sarmustine | MA: DD: 11/15/2001 | Treatment for malignant glioma | Pangene Corporation 5500 Stewart Avenue Fremont CA 94538 |
| 2-chloroethyl-3-sarcosinamide-1-nitrosourea | MA: DD: 8/3/2001 | Treatment for malignant gliomas | Lawrence Panasci, MD Professor of Medicine, McGill University 3755 Cote Ste Catherine Montreal, Quebec H3T 1E2 |
| 2-methoxyestradiol | MA: DD: 7/10/2001 | Treatment of multiple myeloma | EntreMed, Inc. 9640 Medical Center Drive Rockville MD 20850 |
| Panzem | MA: DD: 9/20/2001 | Treatment for multiple myeloma | Celgene Corporation 7 Powder Horn Drive Warren NJ 07059 |
| 3-(4'aminoisoindoline-1'-one)-1-piperidine-2,6-dione Revimid (proposed) | MA: DD: 5/15/2001 | Treatment of pediatric HIV infection/AIDS | NovoMed Pharmaceuticals, Inc. P.O. Box 900 Germantown MD 20875-0900 |
| Camvirex | MA: DD: 10/19/2001 | For the intravenous treatment of moderate to severe acetaminophen overdose | Cumberland Pharmaceuticals Inc. 209 10th Street South Suite 332 Nashville TN 37203 |
| Acetadote | MA: DD: 6/13/2001 | Intrahepatic treatment of patients with moderate to severe hemophilia | Avigen, Inc. 1301 Harbor Bay |
| Adeno-associated viral vector containing the gene for human Parkway coagulation factor IX Coagulin-B | MA: | | Alameda CA 94502 |

Orphan Products Designations and Approvals List
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| | | | |
|---|----------------|---|--|
| Adeno-associated viral vector containing the gene for human coagulation factor IX | DD: 6/13/2001 | Intramuscular treatment of patients with moderate to severe hemophilia | Avigen, Inc. 1301 Harbor Bay Parkway Alameda CA 94502 |
| Coagulin-B | MA: | | |
| adenovirus-mediated herpes simplex virus-thymidine kinase gene | DD: 7/31/2001 | Use with gancyclovir in the treatment of malignant glioma | Ark Therapeutics Ltd 6 Warren Mews London W1T6AR UK |
| | MA: | | |
| albuterol | DD: 3/12/2002 | Prevention of paralysis due to spinal cord injury | MotoGen, Inc. 3 Pine View Road Mount Kisco NY 10549 |
| | MA: | | |
| Alendronate disodium | DD: 2/13/2001 | Treatment of the bone manifestations of Gaucher disease | Richard J. Wenstrup, M.D. Division of Human Genetics Children's Hospital Research Foundation Cincinnati OH 45229-3039 |
| Fosamax | MA: | | |
| Angiotensin 1-7 | DD: 8/3/2001 | Treatment of myelodysplastic syndrome | Maret Pharmaceutical Corporation 4041 MacArthur Boulevard, Suite 375 Newport Beach CA 92660 |
| MARstem | MA: | | |
| arsenic | DD: 11/2/2001 | Treatment of acute myelocytic leukemia subtypes M0, M1, M2, M4, M5, M6 and M7 | Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 |
| Trisenox | MA: | | |
| arsenic trioxide | DD: 10/18/2001 | Treatment of chronic myeloid leukemia | Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 |
| Trisenox | MA: | | |
| augmerosen | DD: 8/28/2001 | Treatment of acute myelocytic leukemia | Genta Incorporated Two Oak Way Berkeley Heights NJ 07922 |
| Genasense | MA: | | |
| augmerosen | DD: 8/28/2001 | Treatment of multiple myeloma | Genta Incorporated Two Oak Way Berkeley Heights NJ 07922 |
| Genasense | | | |

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|--|---------------|--|--|
| | MA: | | |
| augmerosen | DD: 8/28/2001 | Treatment of chronic lymphocytic leukemia | Genta Incorporated Two Oak Way Berkeley Heights NJ 07922 |
| Genasense | | | |
| | MA: | | |
| autologous antigen presenting cells pulsed with autologous tumor Ig idiotype | DD: 4/18/2002 | Treatment of multiple myeloma | Dendreon Corporation 3005 First Avenue Seattle WA 98121 |
| Mylovenge | | | |
| | MA: | | |
| autologous tumor-derived gp96 heat shock protein-peptide complex | DD: 7/11/2002 | Treatment of metastatic melanoma | Antigenics, Inc. 34 Commerce Way Woburn MA 01702 |
| Oncophage | | | |
| | MA: | | |
| autologous tumor-derived gp96 heat shock protein-peptide complex | DD: 5/10/2002 | Treatment of renal cell carcinoma | Antigenics, Inc. 34 Commerce Way Woburn MA 01702 |
| Oncophage | | | |
| | MA: | | |
| azacitidine | DD: 12/3/2001 | Treatment of myelodysplastic syndromes | Pharmion Corporation 4865 Riverbend Road Boulder CO 80301 |
| | | | |
| | MA: | | |
| aztreonam | DD: 3/12/2002 | Inhalation therapy for control of gram-negative bacteria in the respiratory tract of patients with cystic fibrosis | Corus Pharma 2025 First Ave., Suite 800 Seattle WA 98121 |
| B Lymphocyte Stimulator | | | |
| | MA: | | |
| | DD: 2/21/2001 | Treatment of common variable immunodeficiency (CVID) | Human Genome Sciences, Inc. 9410 Key West Avenue Rockville MD 20850 |
| BLyS | | | |
| | MA: | | |
| beclomethasone | DD: 8/28/2001 | Prevention of gastrointestinal graft-versus-host disease | Enteron Pharmaceuticals, Inc. 1680 Michigan Ave. Suite 700 Miami FL 33139 |
| 17,21-dipropionate | | | |
| | MA: | | |

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| | | | |
|---|--------------------------|---|---|
| Benzophenone-3, octylmethoxycinnamate, avobenzene, titanium dioxide, zinc oxide Total Block VL SPF 75 | DD: 8/13/2001 MA: | For the prevention of visible light induced skin photosensitivity as a result of porfimer sodium photodynamic therapy | Fallien Cosmeceuticals Ltd. 677 W. Dekalb Pike King of Prussia PA 19406 |
| Bioartificial liver system utilizing xenogenic hepatocytes in a hollow fiber bioreactor cartridge (BAL) | DD: 2/11/2002 MA: | Treatment of patients with acute liver failure presenting with encephalopathy deteriorating beyond Parson's grade 2 | Excorp Medical, Inc. Suite 235 7200 Hudson Blvd. Oakdale MN 55128 |
| bryostatin-1 | DD: 12/3/2001 MA: | For use in combination with paclitaxel in the treatment of esophageal cancer | GPC Biotech, Inc. 610 Lincoln Street Waltham MA 02451 |
| Busulfan | DD: 3/5/2001 MA: | Intrathecal therapy for neoplastic meningitis | SuperGen, Inc. 4140 Dublin Boulevard Dublin CA 94568 |
| Spartajet-Busulfan | DD: 1/15/2002 MA: | Management of cystic fibrosis | Boehringer Ingelheim Pharmaceuticals, Inc 900 Ridgebury Road P.O. Box 368 Ridgefield CT 06877 |
| carbamic acid, [[4-[[3-[[4-[1-(4-hydroxyphenyl)-1-me thyl-ethyl]phenoxy]methyl]phenyl]m ethoxy]-phenyl]iminomethyl]-ethyl ester | DD: 7/10/2002 MA: | For use in patients receiving high dose chemotherapy who are unable to generate an acceptable dose of peripheral blood stem cells and who have a sufficient bone marrow aspirate without morphological evidence of tumor | Aastrom Biosciences Incorporated P.O. Box 376 Ann Arbor MI 48106 |
| cells produced using the AastromReplicelle System and SC-I Therapy Kit | DD: 3/14/2002 MA: | Treatment of acute myelogenous leukemia | Ilex Products, Inc. 4545 Horizon Hill Blvd. San Antonio TX 78229- 2263 |
| clofarabine | DD: 2/7/2002 MA: | Treatment of acute lymphoblastic leukemia | Ilex Products, Inc. 4545 Horizon Hill Blvd. San Antonio TX 78229- 2263 |
| Clofarex | DD: 3/5/2001 MA: | For the treatment of Huntington's disease | Vitaline Corporation 385 Williamson Way Ashland OR 97520 |
| Coenzyme Q10 | | | |

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|--|---------------------------|---|--|
| conjugate of human transferrin and a mutant diphtheria toxin (CRM 107) | DD: 12/3/2001 MA: | Treatment of malignant tumors of the central nervous system | INTELLigene Expressions Inc. 1938-94 St. Edmonton, AB T6N 1J3 |
| creatine | DD: 2/12/2002 | Treatment of amyotrophic lateral sclerosis | Avicena Group, Inc. 580 California St. Suite 1600 San Francisco CA 94104 |
| Creapure | MA: | | |
| decitabine | DD: 9/9/2002 MA: | Treatment of sickle cell anemia | SuperGen, Inc. 4140 Dublin Blvd., Suite 200 Dublin CA 94568 |
| deferiprone | DD: 12/12/2001 MA: | Treatment of iron overload in patients with hematologic disorders requiring chronic transfusion therapy | Apotex Research Inc. 150 Signet Drive Toronto, Canada M9L 1T9 |
| Ferriprox | | | |
| DHA-paclitaxel | DD: 9/25/2001 | Treatment of pancreatic cancer | Protarga, Inc. 2200 Renaissance Blvd. Suite 450 King of Prussia PA 19406 |
| Taxoprexin | MA: | | |
| DHA-paclitaxel | DD: 10/10/2002 | Treatment of metastatic malignant melanoma | Protarga, Inc. 2200 Renaissance Boulevard Suite 450 King of Prussia PA 19406 |
| Taxoprexin | MA: | | |
| digitoxin | DD: 11/2/2001 MA: | Treatment of ovarian cancer | PrimeCyte, Inc. 130 Fifth Ave., N. Seattle WA 98109-4933 |
| digitoxin | DD: 10/18/2001 MA: | Treatment of soft tissue sarcomas | PrimeCyte, Inc. 130 Fifth Ave., N. Seattle WA 98109-4933 |
| docosahexanoic acid-paclitaxel | DD: 3/5/2001 MA: | Treatment of hormone-refractory prostate cancer. | Protarga, Inc. 1100 East Hector Street Suite 450 Conshohocken PA |
| Taxoprexin 19428-2377 | | | |

Orphan Products Designations and Approvals List
September 2002

| | | | |
|--|----------------|---|--|
| G17DT Immunogen | DD: 7/18/2002 | Treatment of gastric cancer | Aphton Corporation 26 Harter Avenue Suite 14 Woodland CA 95776 |
| | MA: | | |
| G17DT Immunogen | DD: 7/10/2002 | Treatment of adenocarcinoma of the pancreas | Aphton Corporation 26 Harter Avenue Suite 14 Woodland CA 95776 |
| | MA: | | |
| genetically engineered herpes simplex virus (G207) | DD: 4/29/2002 | Treatment of malignant glioma | MediGene, Inc. 9880 Campus Point Drive, Suite A San Diego CA 92121 |
| | MA: | | |
| Glatiramer acetate for injection sclerosis | DD: 6/5/2001 | Treatment of primary-progressive multiple sclerosis | TEVA Pharmaceuticals, USA 1090 Horsham Road North Wales PA 19454 |
| Copaxone | MA: | | |
| h5G1.1mAb | DD: 3/5/2001 | Idiopathic membranous glomerular nephropathy | Alexion Pharmaceuticals, Inc. 352 Knotter Drive Cheshire CT 06410 |
| | MA: | | |
| homoharringtonine | DD: 2/8/2002 | Treatment for chronic myelogenous leukemia | American BioScience, Inc. 2730 Wilshire Blvd. #110 Santa Monica CA 90403 |
| | MA: | | |
| Hsp E7 | DD: 3/19/2001 | Treatment of recurrent respiratory papillomatosis (RRP) | StressGen Biotechnologies, Inc. 409 2nd Avenue Suite 201 Collegeville PA 19426-2655 |
| | MA: | | |
| Hu1D10, humanized monoclonal antibody | DD: 11/28/2001 | For use in the treatment of 1D10+ B cell non-Hodgkin's lymphoma | Protein Design Labs, Inc. 34801 Campus Drive Fremont CA 94555 |
| Remitogen | MA: | | |
| human anti-transforming growth factor beta 1 monoclonal antibody | DD: 1/11/2002 | Treatment of systemic sclerosis | Genzyme Corporation One Kendall Square Cambridge MA 02139 |
| | MA: | | |

Orphan Products Designations and Approvals List
September 2002

| | | | |
|---|------------------------------------|---|---|
| human gammaglobulin | DD: 5/25/2001 MA: | Treatment for juvenile rheumatoid arthritis | Protein Therapeutics, Inc 9040 S. Rita Rd., Suite 1100 Tucson AZ 84747 |
| human gammaglobulin | DD: 9/16/2002 MA: | Treatment of gastrointestinal disturbances (to include constipation, diarrhea, and abdominal pain) associated with regression-onset autism in pediatric patients. | Protein Therapeutics, Inc. 9040 S. Rita Road Suite 1100 Tucson AZ 85747 |
| humanized monoclonal antibody against Shiga-like toxin II | DD: 9/12/2001 MA: | To prevent the development of or to decrease the incidence and severity of hemolytic uremic syndrome and associated sequelae of Shiga-like toxin-producing E. coli. | Teijin America, Inc. 600 Alexander Park Suite 304 Princeton NJ 08540 |
| hyaluronic acid | DD: 3/19/2002 MA: | Treatment of emphysema in patients due to alpha-1 antitrypsin deficiency | Exhale Therapeutics, Inc. 1301 Shoreway Road Suite 320 Belmont CA 94002 |
| I(131)-TM-601 (chlorotoxin) | DD: 2/14/2002 MA: | treatment of malignant glioma | TransMolecular, Inc. 3800 Colonnade Parkway Suite 240 Birmingham AL 35243 |
| iduronate-2-sulfatase | DD: 11/28/2001 MA: | Long term enzyme replacement therapy for patients with MPS II (Hunter Syndrome) | Transkaryotic Therapies Inc. 195 Albany Street Cambridge MA 02139 |
| IL13-PE38QQR | DD: 11/2/2001 MA: | Treatment of malignant glioma | NeoPharm, Inc. 150 Field Drive Suite 195 Lake Forest IL 60045 |
| Imatinib | DD: 1/31/2001 MA: 5/10/2001 | Treatment of chronic myelogenous leukemia | Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover NJ 07936-1080 |
| Gleevec | | | |

Orphan Products Designations and Approvals List
September 2002

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|--|-----------------------------------|---|---|
| imatinib mesylate Gleevec 1080 | DD: 11/1/2001 MA: 2/1/2002 | Treatment of gastrointestinal stromal tumors | Novartis Pharmaceuticals Corp. One Health Plaza East Hanover NJ 07936- |
| Imexon n/a | DD: 8/3/2001 MA: | Treatment of metastatic malignant melanoma | AmpliMed Corporation 2321 Camino La Zorrela Tucson AZ 85718 |
| INH-A00021 Veronate | DD: 6/13/2001 MA: | Reduction (prevention) of nosocomial bacteremia caused by staphylococci in very low birth weight infants. | Inhibitex, Inc. 8995 Westside Parkway Suite 150 Alpharetta GA 30004 |
| interferon gamma-1b Actimmune | DD: 9/12/2002 MA: | Treatment of idiopathic pulmonary fibrosis | InterMune, Inc. 3280 Bayshore Boulevard Brisbane CA 94005 |
| Interferon-alfa-1b IFRS | DD: 4/17/2001 MA: | Treatment of multiple myeloma | Ernest C.Borden Center for Cancer Drug Discovery and Development 9500 Euclid Avenue Cleveland OH 44195 |
| Intraoral fluoride releasing system L-glutamine | DD: 7/31/2001 MA: | Prevention of dental caries due to radiation-induced xerostomia in patients with head and neck cancer | Digestive Care, Inc. 1120 Win Drive Bethlehem PA 18017 |
| lactic acid bacteria (Lactobacilli, Inc. Bifidobacteria, and Steptococci) | DD: 8/1/2001 MA: | Treatment of sickle cell disease | Orphan Drugs International, LLC (d.b.a. Hope Therapeutics) PO Box 0401 Montrose CA 91021-0401 |
| | DD: 1/15/2002 MA: | Treatment of active chronic pouchitis | VSL Pharmaceuticals, 800 S. Frederick Avenue Gaithersburg MD 20877 |

Orphan Products Designations and Approvals List
September 2002

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|---|---------------|--|--|
| lactic acid bacteria (Lactobacilli, Bifidobacteria, and Streptococcus | DD: 1/15/2002 | Prevention of disease relapse in patients with chronic pouchitis species) | VSL Pharmaceuticals, Inc. 800 S. Frederick Ave. Gaithersburg MD 20877 |
| | MA: | | |
| Latrodectus immune F(ab)2 | DD: 6/18/2001 | Treatment of black widow spider envenomations | Rare Disease Therapeutics, Inc. 1101 Kermit Drive, Suite 608 Nashville TN 37217 |
| Aracmyn | MA: | | |
| lintuzumab | DD: 9/9/2002 | Treatment of acute myelogenous leukemia | Protein Design Labs, Inc. 34801 Campus Drive Fremont CA 94555 |
| Zamyl | MA: | | |
| lipase, amylase, and protease | DD: 1/23/2002 | Treatment of pancreatic insufficiency | Altus Biologics Inc. 625 Putnam Avenue Cambridge MA 02139 |
| TheraCLEC-Total | MA: | | |
| Medroxyprogesterone acetate | DD: 2/22/2001 | Treatment of immune thrombocytopenic purpura. | InKine Pharmaceutical Company, Inc. 1787 Sentry Parkway West Building 18, Suite 440 Blue Bell PA 19422 |
| Hematrol | MA: | | |
| metreleptin | DD: 8/22/2001 | Treatment of leptin deficiency secondary to generalized lipodystrophy and partial familial lipodystrophy | Amgen, Inc. One Amgen Center Drive Thousand Oaks CA 91320-1799 |
| | MA: | | |
| metreleptin | DD: 8/22/2001 | Treatment of metabolic disorders secondary to lipodystrophy | Amgen, Inc., One Amgen Center Drive Thousand Oaks CA 91320-1799 |
| | MA: | | |
| MTC-DOX for Injection | DD: 1/3/2001 | Treatment of hepatocellular carcinoma | FeRx Incorporated 4330 La Jolla Village Drive Suite #250 San Diego CA 92122 |
| | MA: | | |

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September 2002

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|--|---------------------------|---|---|
| muramyltripeptide, phosphatidyl-ethanolamine encased in multi-lamellar | DD: 6/5/2001 MA: | Treatment of children and adolescent osteosarcoma | Jenner Biotherapies, Inc. 541 Kenosa Street Walworth WI 53184 |
| N-[4-bromo-2-(1H-1,2,3,4-tetrazol-5 -yl)phenyl]-N'-[3,5-bis(trifluorometh yl)phenyl]urea | DD: 5/13/2002 MA: | Treatment of sickle cell disease | NeuroSearch A/S 93 Pederstrupvej DK-2750 Ballerup Denmark |
| N-acetylcysteine | DD: 9/9/2002 MA: | Treatment of acute liver failure | William M. Lee, MD, FACP University of Texas Southwestern Medical Center at Dallas 5323 Harry Hines Blvd Dallas TX 75390-9151 |
| nitazoxanide | DD: 10/23/2001 MA: | Treatment for intestinal amebiasis | Romark Laboratories, L.C. 6200 Courtney Campbell Causeway Suite 880 Tampa FL 33607 |
| Cryptaz | DD: 2/14/2002 MA: | Treatment of intestinal giardiasis | Romark Laboratories, L.C. 6200 Courtney Campbell Causeway Suite 880 Tampa FL 33607 |
| Cryptaz | DD: 10/19/2001 MA: | Treatment of alkaptonuria | Swedish Orphan AB Kungsgatan 37, 7th Floor SE-111 56 Stockholm, Sweden |
| Nitisinone | DD: 2/21/2001 MA: | Treatment and prevention of cerebral vasospasm following subarachnoid hemorrhage. | Thomas, MD, Jeffrey Evan Thomas Jefferson University and Wills Neurosensory Institute 834 Walnut Street, Suite 650 Philadelphia PA 19107- 5102 |
| Nitroprusside | DD: 10/18/2001 MA: | Treatment of hepatocellular carcinoma | Zarix, Inc. 1055 Westlakes Drive Suite 200 Berwyn PA 19312 |
| nolatrexed | DD: 10/18/2001 MA: | | |
| THYMITAQ | DD: 10/18/2001 MA: | | |

Orphan Products Designations and Approvals List
September 2002

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|---|----------------------|---|---|
| Novel Acting Thrombolytic (NAT) | DD: 1/26/2001 | Treatment of peripheral arterial occlusion (PAO) | Amgen, Inc. One Amgen Center Drive Thousand Oaks CA 91320-1799 |
| NZ-1002 | MA: DD: 4/11/2001 | Enzyme replacement therapy in patients patients with all subtypes of Mucopolysaccharidosis I. | Novazyme Pharmaceuticals, Inc. 800 Research Parkway Suite 200 Oklahoma City OK 73104 |
| | MA: | | |
| octavalent Psuedomonas aeruginosa O-polysaccharide-toxin A Aerugen | DD: 5/16/2002 | Prevention of Psuedomonas aeruginosa infections in patients with cystic fibrosis | Orphan Europe Immeuble "Le Wilson" 70 avenue du General de Gaulle, 92046 Paris La Defense France |
| | MA: | | |
| oglufanide disodium | DD: 9/24/2001 | Treatment of ovarian cancer | Cytran, Inc. 10230 NE Points Dr., NE Suite 530 Kirkland WA 98033-7869 |
| | MA: | | |
| p1-(uridine 5')-p4-(2'-deoxycytidine 5') tetraphosphate, tetrasodium salt | DD: 3/7/2001 | For the treatment of cystic fibrosis | Inspire Pharmaceuticals, Inc. 4222 Emperor Blvd. Suite 470 Durham NC 27703 |
| | MA: | | |
| pemetrexed disodium Alimta | DD: 8/28/2001 | Treatment of malignant pleural mesothelioma | Eli Lilly and Company Lilly Corporate Center Indianapolis IN 46285 |
| | MA: | | |
| Perflubron | DD: 4/26/2001 | Treatment of acute respiratory distress disease (ARDS) in adults | Alliance Pharmaceutical Corp. 3040 Science Park Road San Diego CA 92191 |
| LiquiVent | MA: | | |
| phenylephrine | DD: 2/14/2002 | Treatment of ileal pouch anal anastomosis related fecal incontinence | S.L.A. Pharma Unit 3, Hill Farm Industrial Estate Leavesden, Watford United Kingdom WD25 |
| 7SA | MA: | | |

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September 2002

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|--|----------------|---|---|
| Polyethylene glycol (PEG)-uricase | DD: 2/21/2001 | To control the clinical consequences of hyperuricemia in patients with severe gout in whom conventional therapy is contraindicated or has been ineffective. | Bio-Technology General Corporation 70 Wood Avenue South Iselin NJ 08830 |
| | MA: | | |
| polyinosinic-polycytidilic acid | DD: 8/2/2002 | As an adjuvant to smallpox vaccination | Ribopharm, Inc. 3203 Cleveland Ave., NW Washington DC 20008-3450 |
| Poly-ICLC | MA: | | |
| porfimer | DD: 10/19/2001 | For the ablation of High-Grade Dysplasia in Barrett's Esophagus in patients who are not considered to be candidates for esophagectomy | Axcan Scandipharm Inc. 22 Inverness Parkway Suite 310 Suite 310 Birmingham AL 35242 |
| Photofrin | MA: | | |
| Pyruvate | DD: 2/21/2001 | Treatment of interstitial lung disease. | Cellular Sciences, Inc 84 park Avenue P.O. Box 968 Flemington NJ 08822 |
| | MA: | | |
| recombinant human alpha 1-antitrypsin (rAAT) | DD: 11/20/2001 | Treatment of cystic fibrosis | Arriva Pharmaceuticals, Inc. 2020 Challenger Drive Alameda CA 94501 |
| | MA: | | |
| recombinant human alpha-1 antitrypsin (rAAT) | DD: 8/28/2001 | To delay progression of chronic obstructive pulmonary disease resulting from AAT deficiency-mediated emphysema and bronchiectasis | Baxter Healthcare Corporation 550 N. Brand Blvd. Glendale CA 91203 |
| | MA: | | |
| Recombinant Human Alpha-Fetoprotein (rhAFP) | DD: 2/22/2001 | Treatment of myasthenia gravis | Merrimack Pharmaceuticals, Inc. 101 Binney Street Cambridge MA 02142 |
| | MA: | | |
| recombinant human endostatin protein | DD: 2/21/2002 | Treatment of metastatic melanoma | EntreMed, Inc. 9640 Medical Center Drive Rockville MD 20850 |
| | MA: | | |
| recombinant human endostatin protein | DD: 8/13/2001 | Treatment of neuroendocrine tumors. | EntreMed, Inc. 9640 Medical Center Drive Rockville MD 20850 |
| | MA: | | |

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September 2002

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|---|---------------------------|---|--|
| recombinant human insulin-like growth factor-I/insulin-like growth factor binding protein-3 | DD: 5/17/2002 syndrome | Treatment of growth hormone insensitivity syndrome | Celtrix Pharmaceuticals, Inc. a subsidiary of Insmed, Inc. 4851 Lake Brook Drive Glen Allen VA 23060 |
| SomatoKine | MA: | | |
| recombinant human monoclonal antibody to hsp90 | DD: 9/16/2002 | Treatment of invasive candidiasis | NeuTec Pharma plc 2dn floor, Clinical Sciences Bldg. Central Manchester Healthcare Trust, Oxford Rd., Manchester M139WL, UK |
| Mycograb | MA: | | |
| recombinant human porphobilinogen deaminase | DD: 9/9/2002 | Treatment of acute intermittent porphyria attacks | HemeBiotech A/S Roskildevej 12C 3400 Hillerod Denmark |
| retroviral gamma-c cDNA containing vector | DD: 4/29/2002 | Treatment of X linked severe combined immune deficiency disease | AVAX technologies, Inc. 9200 Indian Creek Parkway Building 9, Suite 200 Overland Park KS |
| 66210 | MA: | | |
| Reviparin sodium | DD: 6/18/2001 | Long-term treatment of acute deep vein thrombosis with or without pulmonary embolism in pregnant patients | Knoll AG |
| Clivarine | MA: | | Ludwigshafen, Germany |
| Reviparin sodium | DD: 6/18/2001 | Treatment of deep vein thrombosis which may lead to pulmonary embolism in pediatric patients | Knoll AG |
| Clivarine | MA: | | Ludwigshafen, Germany |
| rituximab | DD: 3/12/2002 | Treatment of immune thrombocytopenic purpura | Genentech, Inc. 1 DNA Way South San Francisco CA 94080-4990 |
| Rituxan | MA: | | |
| rubitecan | DD: 7/17/2002 | Treatment of pediatric patients infected with human immunodeficiency virus and acquired immunodeficiency syndrome | SuperGen, Inc. 4140 Dublin Blvd. Suite 200 Dublin CA 94568 |
| S(-)-3-[3-amino-phthalimido]-glutar amide | DD: 3/14/2002 MA: | Treatment of multiple myeloma | EntreMed Incorporated 9640 Medical Center Dr. Rockville MD 20850 |

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|--|---------------|---|--|
| squalamine lactate | DD: 5/11/2001 | Treatment of ovarian cancer refractory or resistant to standard chemotherapy | Genaera Corporation 5110 Campus Drive Plymouth Meeting PA |
| 19462 | MA: | | |
| SS1(dsFv)-PE38 | DD: 2/11/2002 | Treatment of malignant mesothelioma | NeoPharm Incorporated 150 Field Drive Suite 195 Lake Forest IL 60045 |
| | MA: | | |
| SS1(dsFv)-PE38 | DD: 2/11/2002 | Treatment of epithelial ovarian cancer | NeoPharm, Inc. 150 Field Drive Suite 195 Lake Forest IL 60045 |
| | MA: | | |
| Synthetic Human Parathyroid Hormone 1-34 | DD: 1/26/2001 | Treatment of hypoparathyroidism | Orphan Pharmaceuticals, U.S., Inc. 1101 Kermit Drive, Suite 608 Nashville TN 37217 |
| | MA: | | |
| T-cell depleted stem cell enriched cellular product from peripheral b lood stem cells | DD: 11/1/2001 | Treatment of chronic granulomatous disease | Nexell Therapeutics Inc. 9 Parker Irvine CA 92618-1605 |
| | MA: | | |
| TGF(beta)2-specific GmbH phosphorothioate antisense oligodeoxynucleotide Oncomun | DD: 6/5/2002 | Treatment of malignant glioma | Antisense Pharma Josef-Engert-Str. 9 93053 Regensburg Germany |
| | MA: | | |
| Thyrotropin alfa | DD: 8/3/2001 | Treatment of well-differentiated papillary, follicular or combined papillary/follicular carcinomas of the thyroid | Genzyme Corporation One Kendall Square Cambridge MA 02139- |
| Thyrogen 1562 | MA: | | |
| tinidazole | DD: 4/18/2002 | Treatment of giardiasis | Presutti Laboratories, Inc. 1607 N. Douglas Ave. Arlington Heights IL |
| 60004 | MA: | | |
| toralizumab | DD: 3/14/2002 | Treatment of immune thrombocytopenic purpura | IDEC Pharmaceuticals Corporation 3030 Callan Road San Diego CA 92121 |
| | MA: | | |

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| tri-antennary glycotripeptide derivative of 5-fluorodeoxyuridine monophosphate | DD: 11/23/2001 Treatment for hepatocellular carcinoma | Cell Works Inc. 6200 Seaforth Street Baltimore MD 21224-6506 |
| | MA: | |
| Unconjugated Chimeric (human-murine) G250 IgG monoclonal antibody | DD: 3/22/2001 Treatment of renal cell carcinoma. | Wilex Biotechnology GmbH Grillparzerstrasse 10B 81675 Munich Germany DE |
| | MA: | |
| Vasoactive intestinal peptide | DD: 3/9/2001 Treatment of Acute Respiratory Distress Syndrome. | Sami I. Said, M.D. State University of New York at Stony Brook Health Sciences Center T17, 040 Health Sciences Center T17, 040 Stony Brook NY 11794-8172 |
| | MA: | |
| Virulizin | DD: 2/1/2001 Treatment of pancreatic cancer. | Lorus Therapeutics Inc. 7100 Woodbine Avenue, Suite 215 Markham, ON L3R 5J2 Canada |
| Virulizin | MA: | |

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

NO SEPTEMBER 2002 ADDITIONS

| APP#/PROD | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXCL USE | EXPIRES | CODE | CODE EXCLUDES | NUMBER |
|---|---------------------------------------|---------------|---------------------|--------------|--------------|------------------|------------|
| *PED and PED represent Pediatric Exclusivity DATA | | | | | | | |
| 021205 001 | ABACAVIR SULFATE;TRIZIVIR | 6417191 | MAR 28, 2016 | U-248 | | | |
| 021001 001 | ALMOTRIPATAN MAIATE;AXERET | 5565447 | OCT 15, 2013 | OCT 15, 2013 | NP | NP | 021212 002 |
| 021212 001 | ALPROSOSTADIL;CAVERJECT | 5565447 | OCT 15, 2013 | OCT 15, 2013 | NP | NP | 021212 002 |
| 021303 001 | AMPHETAMINE ASPARTATE;ADDERALL XR 10 | 6162802 | DEC 19, 2017 | U-367 | | | 021303 005 |
| 021303 002 | AMPHETAMINE ASPARTATE;ADDERALL XR 15 | 6322819 | NOV 27, 2018 | NOV 27, 2018 | NP | NP | 021303 003 |
| 021303 003 | AMPHETAMINE ASPARTATE;ADDERALL XR 20 | 6322819 | NOV 27, 2018 | NOV 27, 2018 | NP | NP | 021303 004 |
| 021303 004 | AMPHETAMINE ASPARTATE;ADDERALL XR 25 | 6322819 | NOV 27, 2018 | NOV 27, 2018 | NP | NP | 020702 004 |
| 020702 001 | ATORVASTATIN CALCIUM;LIPITOR | 6352684 | NOV 28, 2009 | NOV 28, 2009 | NP | NP | 020702 002 |
| 020702 002 | ATORVASTATIN CALCIUM;LIPITOR | 6352684 | NOV 28, 2009 | NOV 28, 2009 | NP | NP | 020702 003 |
| 020702 003 | ATORVASTATIN CALCIUM;LIPITOR | 6352684 | NOV 28, 2009 | NOV 28, 2009 | NP | NP | 020702 001 |
| 020883 001 | ARGATROBAN;ARGATROBAN | 5925760 | AUG 04, 2017 | I-352 | APR 03, 2005 | SEPT 05, 2005 | 020883 001 |
| 020883 002 | ATORVASTATIN CALCIUM;LIPITOR | 6322819 | NOV 27, 2018 | NOV 27, 2018 | NP | NP | 020702 001 |
| 020883 003 | ATORVASTATIN CALCIUM;LIPITOR | 6322819 | NOV 27, 2018 | NOV 27, 2018 | NP | NP | 020702 002 |
| 020911 001 | BECLOMETHASONE DIPROPYONATE;OVAR 80 | 6352684 | NOV 28, 2009 | NOV 28, 2009 | NP | NP | 020911 001 |
| 020911 002 | BECLOMETHASONE DIPROPYONATE;OVAR 40 | 6352684 | NOV 28, 2009 | NOV 28, 2009 | NP | NP | 020911 002 |
| 021262 001 | BRIMONIDINE TARTRATE;ALPHAGAN P | 6403649 | SEP 21, 2012 | U-446 | DBR 20, 2004 | NPP JUN 20, 2005 | 021262 001 |
| 021275 001 | BRIMONIDINE TARTRATE;ALPHAGAN | 6403649 | SEP 21, 2012 | U-446 | DBR 20, 2004 | NPP JUN 20, 2005 | 021275 001 |
| 024049 001 | BRIMONIDINE TARTRATE;ALPHAGAN | 6403649 | SEP 21, 2012 | U-446 | DBR 20, 2004 | NPP JUN 20, 2005 | 024049 001 |
| 020358 004 | BUPROPION HYDROCHLORIDE;WELLBUTRIN SR | 5358970 | AUG 12, 2013 | M-10 | JUN 11, 2004 | W JAN 19, 2005 | 020358 004 |
| 018731 001 | BUSPIRONE HYDROCHLORIDE;BUSPAR | 5427798 | AUG 12, 2013 | W | JUN 19, 2004 | W JAN 19, 2005 | 018731 001 |
| 018731 002 | BUSPIRONE HYDROCHLORIDE;BUSPAR | 5427798 | AUG 12, 2013 | W | JUN 19, 2004 | W JAN 19, 2005 | 018731 002 |

| APPL/PROD | INGREDIENT NAME; TRADE NAME | PATENT/PED EXCL USE | EXCLUS EXCILS | CODE | EXPIRES | NUMBER |
|---|--|--------------------------|--------------------------|--------------------------|--------------------------|------------|
| *PED and PED represent Pediatrictic Exclusivity | | | | | | |
| 018731 003 | BUSPIRONE HYDROCHLORIDE;BUPSPR | W | M-12 | JUL 19, 2004 | W | 018731 003 |
| 018731 004 | BUSPIRONE HYDROCHLORIDE;BUPSPR | W | M-12 | JUL 19, 2004 | W | 018731 004 |
| 020954 001 | BUSULFAN;BUSULPFX | W | M-12 | JUL 19, 2004 | W | 020954 001 |
| 019881 001 | BUTOCONAZOLE NITRATE;GYNAZOLE-1 | U-263 ODE | 5430057 SEP 30, 2013 | U-205 | 5430057 SEP 30, 2013 | 019881 001 |
| 020838 002 | CANDESARTAN CLIXETYL;ATACAND | U-3 | 5196444 JUN 04, 2012 | U-3 | 5196444 JUN 04, 2012 | 020838 002 |
| 020838 003 | CANDESARTAN CLIXETYL;ATACAND | U-3 | 5196444 JUN 04, 2012 | U-3 | 5196444 JUN 04, 2012 | 020838 003 |
| 021093 001 | CANDESARTAN CLIXETYL;ATACAND HCT | U-3 | 5196444 JUN 04, 2012 | U-3 | 5196444 JUN 04, 2012 | 021093 001 |
| 021222 001 | CEDDITOREN PIVOXIL;SECRETACE | U-3 | 5196444 JUN 04, 2012 | U-3 | 5196444 JUN 04, 2012 | 021222 001 |
| 020838 002 | CETIRIZINE HYDROCHLORIDE;ZYTRC | I-284 DEC 23, 2002 | 5760068 NOV 02, 2013 | U-19 | 5760068 NOV 02, 2013 | 020838 002 |
| 019835 001 | CETIRIZINE HYDROCHLORIDE;ZYTRC | I-299 OCT 14, 2017 | 5972986 JUN 25, 2007 | U-299 | 5972986 OCT 14, 2017 | 019835 001 |
| 020346 001 | CETIRIZINE HYDROCHLORIDE;ZYTRC | I-338 OCT 17, 2004 | 5760068 NOV 02, 2013 | U-19 | 5760068 NOV 02, 2013 | 020346 001 |
| 019835 002 | CETIRIZINE HYDROCHLORIDE;ZYTRC | I-284 DEC 23, 2002 | 5466823 NOV 30, 2013 | I-284 DEC 23, 2002 | 5466823 NOV 30, 2013 | 019835 002 |
| 020998 003 | CELBECOXIB;CELBEREX | I-364 AUG 21, 2005 | 4918068 JUN 13, 2006 | I-364 AUG 21, 2005 | 4918068 JUN 13, 2006 | 020998 003 |
| 021222 002 | CEDDITOREN PIVOXIL;ATACAND HCT | U-3 | 4839350 JUN 04, 2012 | U-3 | 4839350 JUN 04, 2012 | 021222 002 |
| 021093 004 | CANDESARTAN CLIXETYL;ATACAND | U-3 | 5196444 JUN 04, 2012 | U-3 | 5196444 JUN 04, 2012 | 021093 004 |
| 020838 001 | CANDESARTAN CLIXETYL;ATACAND | U-3 | 5196444 JUN 04, 2012 | U-3 | 5196444 JUN 04, 2012 | 020838 001 |
| 020369 001 | CITRALOPRAM HYDROBROMIDE;CILOXAN | U-223 | 4670444 DEC 09, 2003 | U-223 | 4670444 DEC 09, 2003 | 020369 001 |
| 020822 002 | CITRALOPRAM HYDROBROMIDE;CELEXA | 4525358*PED DEC 25, 2007 | 020822 002 |
| 020822 003 | CITRALOPRAM HYDROBROMIDE;CELEXA | 4525358 DEC 25, 2003 | 020822 003 |
| 021046 001 | CITRALOPRAM HYDROBROMIDE;CELEXA | NCB JAN 17, 2004 | NCB DEC 25, 2003 | NCB DEC 25, 2003 | NCB DEC 25, 2003 | 021046 001 |
| 020839 001 | CLOPIDOGREL;BISULFATE;PLAVIX | PEBD JAN 17, 2004 | 6429210 JUN 10, 2019 | PEBD JAN 17, 2004 | 6429210 JUN 10, 2019 | 020839 001 |
| 021115 001 | COLSEVELAM HYDROCHLORIDE;MELCHOL | NCB JAN 17, 2003 | 6433026 JUN 10, 2014 | NCB JUN 07, 2019 | 6433026 JUN 10, 2014 | 021115 001 |
| 021116 001 | COLSEVELAM HYDROCHLORIDE;MELCHOL | NCB JAN 17, 2003 | 6433026 JUN 10, 2014 | NCB JUN 07, 2019 | 6433026 JUN 10, 2014 | 021116 001 |
| 021141 001 | COLSEVELAM HYDROCHLORIDE;MELCHOL | NCB JAN 17, 2003 | 6433026 JUN 10, 2014 | NCB JUN 07, 2019 | 6433026 JUN 10, 2014 | 021141 001 |
| 021176 001 | COLSEVELAM HYDROCHLORIDE;MELCHOL | NCB JAN 17, 2003 | 6433026 JUN 10, 2014 | NCB JUN 07, 2019 | 6433026 JUN 10, 2014 | 021176 001 |
| 02112 001 | DESSOLARADINE;CLARINEX | PC DEB JUN 21, 2006 | 6355656 DEC 04, 2015 | PC DEB JUN 21, 2006 | 6355656 DEC 04, 2015 | 02112 001 |
| 075863 001 | DESSOESTRELL;CLARIVA | PC DEB JUN 21, 2006 | 6355656 DEC 04, 2015 | PC DEB JUN 21, 2006 | 6355656 DEC 04, 2015 | 075863 001 |
| 021191 001 | DIMYRISTOYL LECITHIN;IMAGENT | NCE MAY 31, 2007 | 6280704 JUL 30, 2013 | NCE MAY 31, 2007 | 6280704 JUL 30, 2013 | 021191 001 |
| 021278 002 | DEXMETYLPHENIDATE HYDROCHLORIDE;POCALMIN | DEBC 04, 2015 | 6355656 DEC 04, 2015 | DEBC 04, 2015 | 6355656 DEC 04, 2015 | 021278 002 |
| 021278 003 | DEXMETYLPHENIDATE HYDROCHLORIDE;POCALMIN | DEBC 04, 2015 | 6355656 DEC 04, 2015 | DEBC 04, 2015 | 6355656 DEC 04, 2015 | 021278 003 |
| 021278 001 | DEXMETYLPHENIDATE HYDROCHLORIDE;POCALMIN | DEBC 04, 2015 | 6355656 DEC 04, 2015 | DEBC 04, 2015 | 6355656 DEC 04, 2015 | 021278 001 |
| 021168 002 | DIVALPROEX SODIUM;DEPAKOTE ER | NP AUG 04, 2003 | 4913906 APR 03, 2007 | NP AUG 04, 2003 | 4913906 APR 03, 2007 | 021168 002 |
| 021168 001 | DIVALPROEX SODIUM;DEPAKOTE ER | NP AUG 04, 2003 | 4988731 JAN 29, 2008 | NP AUG 04, 2003 | 4988731 JAN 29, 2008 | 021168 001 |
| 020690 001 | DONEPERZIL HYDROCHLORIDE;ARICEPT | U-458 DEC 09, 2014 | 5720938 FEB 11, 2014 | U-458 DEC 09, 2014 | 5720938 FEB 11, 2014 | 020690 001 |
| 020690 002 | DONEPERZIL HYDROCHLORIDE;ARICEPT | U-278 DEC 09, 2014 | 5707916 FEB 11, 2014 | U-278 DEC 09, 2014 | 5707916 FEB 11, 2014 | 020690 002 |
| 021027 001 | DOXERGALCIFEROL;HECROL | U-321 AUG 17, 2010 | 5602116 FEB 11, 2014 | U-321 AUG 17, 2010 | 5602116 FEB 11, 2014 | 021027 001 |
| 021098 001 | DROSPIRENONE;VASMIN | U-1 OCT 29, 2013 | 5569652 OCT 29, 2013 | U-1 OCT 29, 2013 | 5569652 OCT 29, 2013 | 021098 001 |
| 020972 001 | EFAVIRENZ;SUSTIVA | U-321 AUG 17, 2010 | 5602116 FEB 11, 2014 | U-321 AUG 17, 2010 | 5602116 FEB 11, 2014 | 020972 001 |
| 020972 002 | EFAVIRENZ;SUSTIVA | U-321 AUG 17, 2010 | 56238695 APR 06, 2019 | U-321 AUG 17, 2010 | 56238695 APR 06, 2019 | 020972 002 |
| 020972 003 | EFAVIRENZ;SUSTIVA | U-321 AUG 17, 2010 | 6238695 APR 06, 2019 | U-321 AUG 17, 2010 | 6238695 APR 06, 2019 | 020972 003 |
| 021437 001 | EPLERENONE;INSPIRA | U-3 NOV 05, 2019 | 6410054 DEC 08, 2019 | U-3 NOV 05, 2019 | 6410054 DEC 08, 2019 | 021437 001 |
| 021437 002 | EPLERENONE;INSPIRA | U-3 NOV 05, 2019 | 6410054 DEC 08, 2019 | U-3 NOV 05, 2019 | 6410054 DEC 08, 2019 | 021437 002 |
| 021437 003 | EPLERENONE;INSPIRA | U-3 NOV 05, 2019 | 6410054 DEC 08, 2019 | U-3 NOV 05, 2019 | 6410054 DEC 08, 2019 | 021437 003 |
| 020718 001 | EPITIPIBATE;INTTEGRILIN | U-453 MAY 05, 2015 | 5747447 JUN 02, 2015 | U-453 MAY 05, 2015 | 5747447 JUN 02, 2015 | 020718 001 |
| 020718 002 | EPITIPIBATE;INTTEGRILIN | U-453 MAY 05, 2015 | 5968902 NOV 05, 2019 | U-453 MAY 05, 2015 | 5968902 NOV 05, 2019 | 020718 002 |
| 020718 003 | EPITIPIBATE;INTTEGRILIN | U-453 MAY 05, 2015 | 5968902 NOV 05, 2019 | U-453 MAY 05, 2015 | 5968902 NOV 05, 2019 | 020718 003 |
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| 021437 005 | >ADD> | | | | | |
| 021437 006 | >ADD> | | | | | |
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| APP#/PROD | INGREDIENT NAME; TRADE NAME | PATENT/PED EXCL USE | EXPIRES | CODE | CODE | EXCLUS | EXCLUS | NUMBER |
|---|--|--------------------------|---------|--------------|--------------|--------------|--------------|--------------|
| *PED and PED represent Pediatrictic Exclusivity | | | | | | | | |
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| >ADD> | 021323 001 ESCITALOPRAM OXALATE; LEXAPRO | R334712 JUN 08, 2009 | NP | AUG 14, 2005 | I-366 | AUG 29, 2005 | I-254 | AUG 16, 2003 |
| >ADD> | 021323 002 ESCITALOPRAM OXALATE; LEXAPRO | R334712*PED DEC 08, 2009 | NP | AUG 14, 2005 | I-366 | AUG 29, 2005 | I-254 | AUG 16, 2003 |
| >ADD> | 021323 003 ESCITALOPRAM OXALATE; LEXAPRO | R334712*PED DEC 08, 2009 | NP | AUG 14, 2005 | I-366 | AUG 29, 2005 | I-254 | AUG 16, 2003 |
| >ADD> | 021153 001 ESMOERPRAZOLE MAGNESIUM; NEXIUM | 6428810 NOV 03, 2019 | U-469 | | | | | |
| >ADD> | 021153 002 ESMOERPRAZOLE MAGNESIUM; NEXIUM | 6369085 MAY 25, 2018 | U-469 | | | | | |
| >ADD> | 020655 001 ESTRADIOL; ALORA | 6428810 NOV 03, 2019 | U-469 | | | | | |
| >ADD> | 020655 002 ESTRADIOL; ALORA | 6369085 MAY 25, 2018 | U-469 | | | | | |
| >ADD> | 020655 003 ESTRADIOL; ALORA | 6428810 NOV 03, 2019 | U-469 | | | | | |
| >ADD> | 021241 001 ETHINYL Estradiol; ORTHO TRI-CYCLEN 1.0 | 4616006 JUL 26, 2015 | U-112 | Np | AUG 22, 2005 | I-254 | AUG 16, 2003 | |
| >ADD> | 020538 006 ESTRADIOL; VIVELLE-DOT | 6214815 JUN 09, 2019 | U-112 | | | | | |
| >ADD> | 020538 007 ESTRADIOL; VIVELLE-DOT | 5908638 JUL 26, 2015 | U-112 | I-254 | AUG 16, 2003 | I-254 | AUG 16, 2003 | |
| >ADD> | 020538 008 ESTRADIOL; VIVELLE-DOT | 5908638 JUL 26, 2015 | U-112 | I-254 | AUG 16, 2003 | I-254 | AUG 16, 2003 | |
| >ADD> | 021241 001 ETHINYL Estradiol; ORTHO TRI-CYCLEN 1.0 | 4616006 JUL 26, 2015 | U-112 | Np | AUG 22, 2005 | I-254 | AUG 16, 2003 | |
| >ADD> | 020538 003 PENODIURATE; FENOPIRIBRATE (MICRONI | 5164190 DEC 11, 2010 | | | | | | |
| >ADD> | 020625 001 PENODIURATE; FENOPIRIBRATE (MICRONI | 4628051 SEP 26, 2003 | U-112 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020625 002 PENODIURATE; FENOPIRIBRATE (MICRONI | 6399632 MAY 11, 2012 | U-468 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020625 003 PENODIURATE; FENOPIRIBRATE (MICRONI | 4530839 SEP 26, 2003 | U-112 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020538 006 PLUXETINE HYDROCHLORIDE; PROZAC | 6214815 JUN 09, 2019 | U-112 | | | | | |
| >ADD> | 020538 007 PLUXETINE HYDROCHLORIDE; PROZAC | 5908638 JUL 26, 2015 | U-112 | I-254 | AUG 16, 2003 | I-254 | AUG 16, 2003 | |
| >ADD> | 020538 008 PLUXETINE HYDROCHLORIDE; PROZAC | 5908638 JUL 26, 2015 | U-112 | I-254 | AUG 16, 2003 | I-254 | AUG 16, 2003 | |
| >ADD> | 020974 001 PLUXETINE HYDROCHLORIDE; PROZAC | 6399632 MAY 11, 2012 | U-468 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020974 002 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020974 003 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479*PED JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 021345 001 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 021345 002 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479*PED JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 001 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 002 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
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| >ADD> | 020235 004 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 005 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 006 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 007 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 008 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 009 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 010 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
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| >ADD> | 020235 012 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 013 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 014 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 015 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 016 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 017 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 018 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 019 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 020 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 021 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 022 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
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| >ADD> | 020235 028 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
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| >ADD> | 020235 030 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 031 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 032 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
| >ADD> | 020235 033 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | U-258 | PC | SEP 15, 2002 | I-362 | JUL 29, 2005 | |
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| >ADD> | 020235 035 PLUXETINE HYDROCHLORIDE; PROZAC | 5084479 JAN 02, 2010 | | | | | | |

| APP#/PROD | NUMBER | PATENT/PED EXCL USE | EXCLUS EXCILS | CODE | EXPIRES | PATENT/PED EXCL USE | EXCLUS EXCILS | NUMBER | PATENT/PED EXCL USE | EXCLUS EXCILS | CODE | EXPIRES |
|--|--|---------------------|---------------|-------|--------------|--------------------------|---------------|--------------------------|---------------------|--------------------------|--------------|--|
| *PED and PED represent Pediatric Exclusivity | | | | | | | | | | | | |
| 018662 004 | I索特尼通;阿奇坦 | M-12 | MAY 02, 2005 | PED | NOV 02, 2005 | 6407079 | JUN 18, 2019 | 6407079 | JUN 18, 2019 | 6407079 | JUN 18, 2019 | ITRACONAZOLE;SPORANOX |
| 020596 001 | I索特尼通;阿奇坦 | M-12 | MAY 02, 2005 | PED | NOV 02, 2005 | 6407079 | JUN 18, 2019 | 6407079 | JUN 18, 2019 | 6407079 | JUN 18, 2019 | ITRACONAZOLE;SPORANOX |
| 019700 001 | Kеторол酸;特莫替胺;阿奇坦 PRESCRIPTION AND OTC DRUG PRODUCT | M-16 | FEB 08, 2005 | PED | NOV 17, 2005 | 5047407 | NOV 17, 2009 | 5047407 | NOV 17, 2009 | 5047407 | NOV 17, 2009 | KETOROLAC TROMETHAMINE;ACULAR PRESERVATIVE |
| 020811 001 | Kеторол酸;特莫替胺;阿奇坦 PATENT AND EXCLUSIVITY DATA | D-2 | JUN 24, 2005 | PED | NOV 18, 2005 | 5905082 | MAY 18, 2005 | 5047407+PED | MAY 17, 2005 | 5905082 | MAY 18, 2005 | KETOROLAC TROMETHAMINE;ACULAR PRESERVATIVE |
| 020564 001 | I阿米维杜定;比维特 PATENT AND EXCLUSIVITY DATA | M-16 | FEB 08, 2005 | PED | NOV 17, 2005 | 5905082+PED | NOV 18, 2005 | 5905082+PED | NOV 18, 2005 | 5905082+PED | NOV 18, 2005 | IAMIVUDINE;BIVIR |
| 020406 001 | I阿米维杜定;比维特 PATENT AND EXCLUSIVITY DATA | D-2 | JUN 31, 2005 | PED | NOV 12, 2005 | 5013743 | FEB 12, 2010 | 5013743 | FEB 12, 2010 | 5013743 | FEB 12, 2010 | IANSOPRAZOLE;PREVACID |
| 021343 001 | I阿米维杜定;比维特 PATENT AND EXCLUSIVITY DATA | D-2 | JUN 31, 2005 | PED | NOV 24, 2005 | 6180639 | JAN 30, 2018 | 6180639 | JAN 30, 2018 | 6180639 | JAN 30, 2018 | IANSOPRAZOLE;PREVACID |
| 020596 002 | I阿米维杜定;比维特 PATENT AND EXCLUSIVITY DATA | M-12 | MAY 02, 2005 | PED | NOV 02, 2005 | 6180639+PED | NOV 18, 2005 | 6180639+PED | NOV 18, 2005 | 6180639+PED | NOV 18, 2005 | IAMIVUDINE;BIVIR |
| 020564 003 | I阿米维杜定;比维特 PATENT AND EXCLUSIVITY DATA | M-12 | MAY 02, 2005 | PED | NOV 02, 2005 | 6180639+PED JUN 30, 2018 | U-248 | 6180639+PED JUN 30, 2018 | U-248 | 6180639+PED JUN 30, 2018 | U-248 | IAMIVUDINE;BIVIR |
| 021088 001 | I爱普洛利德;维达乌 PATENT AND EXCLUSIVITY DATA | NP | JUL 24, 2005 | NP | JUL 24, 2005 | 5599552 | OCT 04, 2011 | 5599552 | OCT 04, 2011 | 5599552 | OCT 04, 2011 | LEUPROLIDE ACETATE;ELIGARD |
| 021379 001 | I爱普洛利德;维达乌 PATENT AND EXCLUSIVITY DATA | NP | JUL 24, 2005 | NP | JUL 24, 2005 | 5278201 | JAN 11, 2011 | 5278201 | JAN 11, 2011 | 5278201 | JAN 11, 2011 | LEUPROLIDE ACETATE;VADUR |
| 020837 003 | I雷拉布特罗;氢氯雷富必奈 PATENT AND EXCLUSIVITY DATA | U-332 | JAN 30, 2005 | U-332 | JAN 30, 2005 | 5362755 | NOV 08, 2011 | 5362755 | NOV 08, 2011 | 5362755 | NOV 08, 2011 | LEVALBUTEROL HYDROCHLORIDE;XOPENEX |
| 020182 001 | I雷沃卡瑞汀;卡瑞托 PATENT AND EXCLUSIVITY DATA | U-433 | JAN 18, 2011 | U-433 | JAN 18, 2011 | 6429230 | JAN 18, 2021 | 6429230 | JAN 18, 2021 | 6429230 | JAN 18, 2021 | LEVOCARNTINE;CARNITOR |
| 020634 001 | I雷沃洛拉辛;雷瓦奥因 PATENT AND EXCLUSIVITY DATA | I-357 | APR 08, 2003 | I-357 | APR 08, 2003 | 5760090 | JAN 05, 2010 | 5760090 | JAN 05, 2010 | 5760090 | JAN 05, 2010 | LEVOPROLAXACTIN;LEVAGOINI |
| 020634 002 | I雷沃洛拉辛;雷瓦奥因 PATENT AND EXCLUSIVITY DATA | I-357 | APR 08, 2003 | I-357 | APR 08, 2003 | 5844002 | DEC 17, 2011 | 5844002 | DEC 17, 2011 | 5844002 | DEC 17, 2011 | LEVOPROLAXACTIN;LEVAGOINI |
| 020634 003 | I雷沃洛拉辛;雷瓦奥因 PATENT AND EXCLUSIVITY DATA | I-357 | APR 08, 2003 | I-357 | APR 08, 2003 | 5547994 | AUG 20, 2013 | 5547994 | AUG 20, 2013 | 5547994 | AUG 20, 2013 | LEVOPROLAXACTIN;LEVAGOINI |
| 020635 001 | I雷沃洛拉辛;雷瓦奥因 PATENT AND EXCLUSIVITY DATA | I-357 | APR 08, 2003 | I-357 | APR 08, 2003 | 6335369 | JAN 18, 2012 | 6335369 | JAN 18, 2012 | 6335369 | JAN 18, 2012 | LEVOPROLAXACTIN;LEVAGOINI IN DEXTROSE |
| 020635 002 | I雷沃洛拉辛;雷瓦奥因 PATENT AND EXCLUSIVITY DATA | I-357 | APR 08, 2003 | I-357 | APR 08, 2003 | 6083993 | JAN 05, 2012 | 6083993 | JAN 05, 2012 | 6083993 | JAN 05, 2012 | LEVOPROLAXACTIN;LEVAGOINI IN DEXTROSE |
| 020635 003 | I雷沃洛拉辛;雷瓦奥因 PATENT AND EXCLUSIVITY DATA | I-357 | APR 08, 2003 | I-357 | APR 08, 2003 | 5324519 | OCT 20, 2011 | 5324519 | OCT 20, 2011 | 5324519 | OCT 20, 2011 | LEVOPROLAXACTIN;LEVAGOINI |

| APP#/PROD | NUMBER | PATENT/PED EXCL USE | EXCLUS EXCILS | CODE | EXPIRES | PATENT/PED EXCL USE | EXCLUS EXCILS | NUMBER | PATENT/PED EXCL USE | EXCLUS EXCILS | CODE | EXPIRES |
|--|--------------------------------|---------------------|---------------|---------|--------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|----------------------------|-------------------------------------|
| *PED and PED represent Pediatric Exclusivity | | | | | | | | | | | | |
| 020818 002 | HDDROCHLOROTHIAZIDE;DIIVAN HCT | 6294197 | JUN 18, 2017 | U-3 | 5135197 | OCT 06, 2009 | 5135197 | OCT 06, 2009 | 5135197 | OCT 06, 2009 | HDDROCHLOROTHIAZIDE;HYZBAR | |
| 020387 001 | HDDROCHLOROTHIAZIDE;HYZBAR | 6294197 | JUN 18, 2017 | U-3 | 5138069 | AUG 11, 2009 | 5138069 | AUG 11, 2009 | 5138069 | AUG 11, 2009 | HDDROCHLOROTHIAZIDE;HYZBAR | |
| 020818 003 | HDDROCHLOROTHIAZIDE;HYZBAR | 5608075 | MAR 04, 2014 | 5608075 | MAR 04, 2014 | 5135197+PED | APR 11, 2010 | 5135197+PED | APR 06, 2010 | 5135197+PED | APR 06, 2010 | HDDROCHLOROTHIAZIDE;UNIRETIC |
| 020729 003 | HDDROCHLOROTHIAZIDE;UNIRETIC | 5608075 | MAR 04, 2014 | 5608075 | MAR 04, 2014 | 5138069+PED | APR 11, 2010 | 5138069+PED | APR 06, 2010 | 5138069+PED | APR 06, 2010 | HDDROCHLOROTHIAZIDE;UNIRETIC |
| 021374 001 | HBUDEPROFEN;布地奈得;鼻喷雾剂 ADDs | 5618913 | JUN 06, 2014 | NP | AUG 01, 2003 | 5360615+PED JUN 10, 2009 | IBUPROFEN;CHILDREN'S ADVIL COL |
| 020986 001 | I波司他明;依索普拉米德/MESSNA KIT | PC | OCT 05, 2002 | PC | OCT 05, 2002 | 5071643+PED JUN 10, 2008 | IPOSFAMIDE;IPOSFAMIDE/MESSNA KIT |
| 075874 001 | I波司他明;依索普拉米德/MESSNA KIT | PC | OCT 05, 2002 | PC | OCT 05, 2002 | 5348216 | JUN 10, 2017 | 5348216 | JUN 10, 2017 | 5348216 | JUN 10, 2017 | IBUPROFEN;CHILDREN'S ADVIL COL |
| 021373 001 | I布洛芬;布洛芬;维柯芬 ADDs | NP | AUG 01, 2003 | NP | AUG 01, 2003 | 4743450 | FEB 24, 2007 | 4743450 | FEB 24, 2007 | 4743450 | FEB 24, 2007 | IBUDEPROFEN;CHILDREN'S ADVIL COL |
| 020757 001 | I布雷沙坦;阿瓦普罗 ADDs | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | IRBESARTAN;AVAPRO |
| 020757 002 | I布雷沙坦;阿瓦普罗 ADDs | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | IRBESARTAN;AVAPRO |
| 020571 001 | I溴替尼;卡麦托司尔 ADDs | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | 4396598 | DEC 30, 2002 | TRINTOTECAN HYDROCHLORIDE;CAMPTOSAR |
| 018662 003 | I索特尼通;阿奇坦 ADDs | M-12 | MAJ 02, 2005 | M-12 | MAJ 02, 2005 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | I索特尼通;阿奇坦 |
| 018662 002 | I索特尼通;阿奇坦 ADDs | M-12 | MAJ 02, 2005 | M-12 | MAJ 02, 2005 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | I索特尼通;阿奇坦 |
| 020571 002 | I索特尼通;阿奇坦 ADDs | M-12 | MAJ 02, 2005 | M-12 | MAJ 02, 2005 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | I索特尼通;阿奇坦 |
| 020571 003 | I索特尼通;阿奇坦 ADDs | M-12 | MAJ 02, 2005 | M-12 | MAJ 02, 2005 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | 4396598 | APR 28, 2002 | I索特尼通;阿奇坦 |
| 020571 004 | I索特尼通;阿奇坦 ADDs</td | | | | | | | | | | | |

| APP#/PROD | INGREDIENT NAME; TRADE NAME | PATENT/PED EXCL USE | EXPIRES | CODE | EXPIRES | EXCLUS | EXCLUS | NUMBER |
|------------|--|---------------------|--------------|---------|--------------|--------------|--------------|------------|
| 021316 004 | LOVASTATIN; ALTOCOR | DEC 12, 2017 | MAR 23, 2018 | U-456 | NDF | JAN 30, 2005 | AUG 14, 2005 | 019643 002 |
| 019643 003 | LOVASTATIN; MEVACOR | PED | AUG 14, 2005 | I-350 | FEB 14, | 2005 | FEB 14, | 2005 |
| 019643 004 | LOVASTATIN; MEVACOR | PED | AUG 14, 2005 | I-350 | FEB 14, | 2005 | FEB 14, | 2005 |
| 020652 001 | MANGAFODIPIR TRISODIUM; TESLASCAN | NOV 27, 2011 | NOV 27, 2011 | 4933456 | NDF | MAR 21, 2005 | NOV 03, 2002 | 020922 001 |
| 020922 001 | MEOQUINOL; SOLAGB | PC | NCE | 6353029 | AUG 24, 2020 | PC | APR 13, 2005 | 020355 001 |
| 020355 001 | METOXICAM; MOBIC | NDF | MAR 21, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 013217 001 |
| 013217 001 | METAXALONE; SKELAXIN | PC | APR 13, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 013217 002 |
| 013217 002 | METAXALONE; SKELAXIN | PC | APR 13, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 013217 003 |
| 020357 001 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | PED | JUN 15, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 020357 002 |
| 020357 002 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | PED | JUN 15, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 020357 003 |
| 020357 003 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | PED | JUN 15, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 020357 004 |
| 020357 004 | METFORMIN HYDROCHLORIDE; GLUCOPHAGE | PED | JUN 15, 2005 | 6407128 | DEC 03, 2021 | U-189 | DEC 15, 2004 | 020357 005 |
| 021121 004 | METHYLPHENIDATE HYDROCHLORIDE; CONCERTA | JUL 12, 2002 | OCT 27, 2020 | 4519801 | W | W | W | 021121 004 |
| 021259 001 | METHYLPHENIDATE HYDROCHLORIDE; METADATE CD | SEP 16, 2003 | SEP 16, 2003 | 4612008 | W | W | W | 021259 001 |
| 021284 001 | METHYLPHENIDATE HYDROCHLORIDE; RITALIN LA | SEP 16, 2003 | SEP 16, 2003 | 4783337 | W | W | W | 021284 001 |
| 021284 002 | METHYLPHENIDATE HYDROCHLORIDE; RITALIN LA | SEP 16, 2003 | SEP 16, 2003 | 5082668 | W | W | W | 021284 002 |
| 021284 003 | METHYLPHENIDATE HYDROCHLORIDE; RITALIN LA | OCT 27, 2020 | OCT 27, 2020 | 6344215 | NP | NP | NP | 021284 003 |

PRESCRIPTION AND OTC DRUG PRODUCTS
PATENT AND EXCLUSIVITY DATA
PDED and PDED represent Pediatric Exclusivity

6-V

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

8-7

| APPL/PROD | INGREDIENT NAME; TRADE NAME | PATENT | PATENT/PED EXCL USE | EXCLUS EXCLUS | CODE | CODE | EXPIRES | EXPIRES | EXCLUS EXCLUS | NUMBER |
|---|------------------------------------|-----------|---------------------|---------------|------------------|-----------|------------------|--------------|------------------|------------|
| *PED and PED represent Pediatrictic Exclusivity | | | | | | | | | | |
| 020415 001 | MIRTAZAPINE; REMERON | M-18 | APR 09, 2005 | M-18 | APR 09, 2005 | NCE | PEB 20, 2003 | PEB 20, 2003 | NCE | 020415 001 |
| 021260 002 | MORPHINE SULFATE; AVINZA | 6066339 | NOV 25, 2017 | 6066339 | NOV 25, 2017 | NP | MAR 20, 2005 | NP | MAR 20, 2005 | 021260 002 |
| 021260 003 | MORPHINE SULFATE; AVINZA | 6066339 | NOV 25, 2017 | 6066339 | NOV 25, 2017 | NP | MAR 20, 2005 | NP | MAR 20, 2005 | 021260 003 |
| 020763 001 | NARTRIPAN HYDROCHLORIDE; MERGE | 4997841 | JUL 07, 2010 | 4997841 | JUL 07, 2010 | NP | MAR 20, 2005 | NP | MAR 20, 2005 | 020763 001 |
| 020152 001 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 5256664 | APR 28, 2002 | 020152 001 |
| 020152 002 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2003 | 4338317* | SEP 16, 2003 | 4338317* | SEP 16, 2003 | 5256664 | APR 28, 2002 | 020152 002 |
| 020152 003 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2003 | 5256664 | OCT 28, 2002 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 020152 003 |
| 020152 004 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2003 | 4338317* | SEP 16, 2003 | 4338317* | SEP 16, 2003 | 5256664 | APR 28, 2002 | 020152 004 |
| 020152 005 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2003 | 5256664 | OCT 28, 2002 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 020152 005 |
| 020152 006 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2002 | 4338317* | SEP 16, 2003 | 4338317* | SEP 16, 2003 | 5256664 | APR 28, 2002 | 020152 006 |
| 020778 001 | NEFINAVIR MESYLATE; VIRACEPT | 6162812 | OCT 07, 2013 | 6162812 | OCT 07, 2013 | 5256664* | SEP 16, 2003 | 4338317* | SEP 16, 2003 | 020778 001 |
| 020779 001 | NEFINAVIR MESYLATE; VIRACEPT | 6162812 | OCT 07, 2013 | 6162812 | OCT 07, 2013 | 5256664* | SEP 16, 2003 | 4338317* | SEP 16, 2003 | 020779 001 |
| 020381 001 | NICACIN; NIASPAN | 6406715 | OCT 31, 2017 | 6406715 | OCT 31, 2017 | 6129930 | SEP 20, 2013 | 6129930 | SEP 20, 2013 | 020381 001 |
| 020381 004 | NICACIN; NIASPAN | 6406715 | OCT 31, 2017 | 6406715 | OCT 31, 2017 | 6129930 | SEP 20, 2013 | 6129930 | SEP 20, 2013 | 020381 004 |
| 020076 005 | NICOTINE; HABITROL | D-71 | NOV 12, 2002 | D-71 | NOV 12, 2002 | NCE | APR 25, 2007 | NCE | APR 25, 2007 | 020076 005 |
| 020076 006 | NICOTINE; HABITROL | D-71 | NOV 12, 2002 | D-71 | NOV 12, 2002 | NCE | APR 25, 2007 | NCE | APR 25, 2007 | 020076 006 |
| 020076 007 | NICOTINE; HABITROL | D-71 | NOV 12, 2002 | D-71 | NOV 12, 2002 | NCE | APR 25, 2007 | NCE | APR 25, 2007 | 020076 007 |
| 020555 001 | NIZATIDINE; AXID AR | 4375547 | APR 12, 2002 | 4375547 | APR 12, 2002 | 6395292 | JAN 30, 2017 | NCE | APR 25, 2007 | 020555 001 |
| 021008 001 | NIZATIDINE; BENICAR | 6166213 | OCT 09, 2005 | 6166213 | OCT 09, 2005 | 6166213 | OCT 09, 2005 | 6166213 | OCT 09, 2005 | 021008 001 |
| 021286 001 | OMEPRAZOLE; PRILoseC | 4636499 | PED NOV 30, 2005 | 4636499 | PED NOV 30, 2005 | 4636499+P | PED APR 09, 2006 | 6166213 | PED APR 09, 2006 | 021286 001 |
| 019810 002 | OMEPRAZOLE; PRILoseC | 4636499+P | PED APR 09, 2006 | 4636499+P | PED APR 09, 2006 | 4636499+P | PED APR 09, 2006 | 4636499+P | PED APR 09, 2006 | 019810 002 |
| 019810 003 | OMEPRAZOLE; PRILoseC | 6166213 | PED APR 09, 2006 | 6166213 | PED APR 09, 2006 | 6166213 | PED APR 09, 2006 | 6166213 | PED APR 09, 2006 | 019810 003 |
| 021492 001 | OXALIPLATIN; ELOXATIN | 5338874 | APR 07, 2013 | 5338874 | APR 07, 2013 | 5290961 | JAN 12, 2013 | NCE | AUG 09, 2007 | 021492 001 |
| 021492 002 | OXALIPLATIN; ELOXATIN | 5420319 | APR 07, 2013 | 5420319 | APR 07, 2013 | 5338874 | APR 07, 2013 | NCE | AUG 09, 2007 | 021492 002 |
| 021492 003 | OXCARBAZEPINE; TRILEPTAL | 4970075 | AUG 29, 2006 | 4970075 | AUG 29, 2006 | 4970075 | OCT 26, 2007 | NCE | JAN 14, 2005 | 021492 003 |
| 021285 001 | OXCARBAZEPINE; TRILEPTAL | 5266331 | OCT 26, 2007 | 5266331 | OCT 26, 2007 | 5266331 | OCT 26, 2007 | NCE | JAN 14, 2005 | 021285 001 |
| 020553 002 | OXYCODONE HYDROCHLORIDE; OXYCONTIN | 5549912 | OCT 26, 2007 | 5549912 | OCT 26, 2007 | 5549912 | OCT 26, 2007 | NCE | JAN 14, 2005 | 020553 002 |
| 020553 003 | OXYCODONE HYDROCHLORIDE; OXYCONTIN | 5549912 | OCT 26, 2007 | 5549912 | OCT 26, 2007 | 5549912 | OCT 26, 2007 | NCE | JAN 14, 2005 | 020553 003 |
| 020553 004 | OXYCODONE HYDROCHLORIDE; OXYCONTIN | 5549912 | OCT 26, 2007 | 5549912 | OCT 26, 2007 | 5549912 | OCT 26, 2007 | NCE | JAN 14, 2005 | 020553 004 |

| APPL/PROD | INGREDIENT NAME; TRADE NAME | PATENT | PATENT/PED EXCL USE | EXCLUS EXCLUS | CODE | CODE | EXPIRES | EXPIRES | EXCLUS EXCLUS | NUMBER |
|---|---|---------|---------------------|---------------|------------------|---------|------------------|---------|---------------|------------|
| *PED and PED represent Pediatrictic Exclusivity | | | | | | | | | | |
| 021409 001 | MONTELUKAST SODIUM; SINGULAIR | 5565473 | FEB 03, 2012 | 5565473 | FEB 03, 2012 | 5565473 | FEB 03, 2012 | I-360 | JUL 17, 2005 | 021409 001 |
| 020762 001 | MOMETASONE FURANOATE MONOHYDRATE; NASONEX | 4997841 | JUL 07, 2010 | 4997841 | JUL 07, 2010 | 6066339 | NOV 25, 2017 | NP | MAR 20, 2005 | 020762 001 |
| 019297 001 | MOMETASONE HYDROCHLORIDE; NOVANTRONE | 5565473 | PED AUG 03, 2012 | 5565473 | PED AUG 03, 2012 | 5565473 | PED AUG 03, 2012 | ODR | OCT 13, 2007 | 019297 001 |
| 020415 001 | MIRTAZAPINE; REMERON | M-18 | APR 09, 2005 | M-18 | APR 09, 2005 | M-18 | APR 09, 2005 | M-18 | APR 09, 2005 | 020415 001 |
| 021260 002 | MORPHINE SULFATE; AVINZA | 6066339 | NOV 25, 2017 | 6066339 | NOV 25, 2017 | 6066339 | NOV 25, 2017 | NP | MAR 20, 2005 | 021260 002 |
| 021260 003 | MORPHINE SULFATE; AVINZA | 6066339 | NOV 25, 2017 | 6066339 | NOV 25, 2017 | 6066339 | NOV 25, 2017 | NP | MAR 20, 2005 | 021260 003 |
| 020763 001 | NARTRIPAN HYDROCHLORIDE; MERGE | 4997841 | JUL 07, 2010 | 4997841 | JUL 07, 2010 | 6066339 | NOV 25, 2017 | NP | MAR 20, 2005 | 020763 001 |
| 020152 001 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 4338317 | MAR 16, 2003 | 020152 001 |
| 020152 002 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2002 | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 020152 002 |
| 020152 003 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 020152 003 |
| 020152 004 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2002 | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 020152 004 |
| 020152 005 | NEFAZODONE HYDROCHLORIDE; SERZONE | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 020152 005 |
| 020152 006 | NEFAZODONE HYDROCHLORIDE; SERZONE | 5256664 | APR 28, 2002 | 4338317 | MAR 16, 2003 | 4338317 | MAR 16, 2003 | 5256664 | APR 28, 2002 | 020152 006 |
| 020778 001 | NEFINAVIR MESYLATE; VIRACEPT | 6162812 | OCT 07, 2013 | 6162812 | OCT 07, 2013 | 6 | | | | |

* PBD and PED represent Pediatric Exclusivity
INGREDIENT NAME, TRADE NAME
PATENT/PED EXCL. USE
NUMBER
EXPIRES
CODE
CODES
EXCLUS
EXCLUS
NUMBER
APPL/PROD

APP1/PROD INGREDIENT NAME, TRADE NAME
NUMBER PATENT/PED EXCL USE CODE EXCLUS EXPIRES
PATENT NUMBER EXPIRES CODE EXCLUS EXPIRES
***PED and PED represent PediatrxiC EXCLUSiVITY**

APP1/PROD INGREDIENT NAME; TRADE NAME NUMBER
PATENT/PED EXCL USE EXCLUS EXPIRES CODE EXPIRES
NUMBER EXCLUS EXPIRES CODE EXPIRES

**PRESCRIPTION AND OTC DRUG PRODUCTS
PATENT AND EXCLUSIVITY DATA
PDED and PBD represent Pediatric Exclusivity**

L1-W

APP#/PROD **NUMBER**
 INGREDIENT NAME; TRADE NAME
 PATENT NUMBER
 EXPIRES CODE
 EXCLUS EXCL USE
 EXCLUS EXCLUS
 EXPRIES CODE
 EXCLUS EXCL USE
 EXCLUS EXCL USE
 EXCLUS EXCL USE
 *P&D represent Pediatric Exclusivity
 PATENT AND EXCLUSIVITY DATA

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

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | EXCL USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|----------------------------------|---------------|--------------------|---------------|--------------------|----------------|
| 020629 001 | PENCICLOVIR SODIUM;DENAVIR | 5075445 | SEP 24, 2010 | | | |
| 021302 001 | PIMECROLIMUS;ELIDEL | 6352998 | OCT 26, 2015 | | | |
| | | 6352998*PED | APR 26, 2016 | | | |
| | | 6423722 | JUN 26, 2018 | | | |
| | | 6423722*PED | DEC 26, 2018 | | | |
| 021073 001 | PIOGLITAZONE HYDROCHLORIDE;ACTOS | 6303640 | AUG 09, 2016 | U-425 | | |
| 021073 002 | PIOGLITAZONE HYDROCHLORIDE;ACTOS | 6303640 | AUG 09, 2016 | U-425 | | |
| 021073 003 | PIOGLITAZONE HYDROCHLORIDE;ACTOS | 6303640 | AUG 09, 2016 | U-425 | | |
| 019898 002 | PRAVASTATIN SODIUM;PRAVACHOL | 4346227 | OCT 20, 2005 | I-281 | JUN 09, 2003 | |
| | | 5180589 | JUL 09, 2008 | I-304 | JAN 18, 2003 | |
| | | 5030447 | JUL 09, 2008 | I-287 | FEB 10, 2003 | |
| | | 5622985 | APR 22, 2014 | U-335 | I-286 JAN 18, 2003 | |
| | | 4346227*PED | APR 20, 2006 | D-51 | JAN 18, 2003 | |
| | | 5180589*PED | JAN 09, 2009 | D-70 | DEC 18, 2004 | |
| | | 5622985*PED | OCT 22, 2014 | U-335 | PED DEC 09, 2003 | |
| | | 5030447*PED | JAN 09, 2009 | PED | JUL 18, 2003 | |
| | | | | PED | JUL 18, 2003 | |
| | | | | PED | AUG 10, 2003 | |
| | | | | PED | JUN 18, 2005 | |
| | | | | PED | JUL 18, 2003 | |
| 019898 003 | PRAVASTATIN SODIUM;PRAVACHOL | 4346227 | OCT 20, 2005 | I-281 | JUN 09, 2003 | |
| | | 5030447 | JUL 09, 2008 | I-304 | JAN 18, 2003 | |
| | | 5180589 | JUL 09, 2008 | I-287 | FEB 10, 2003 | |
| | | 5622985 | APR 22, 2014 | U-335 | I-286 JAN 18, 2003 | |
| | | 4346227*PED | APR 20, 2006 | D-51 | JAN 18, 2003 | |
| | | 5180589*PED | JAN 09, 2009 | D-70 | DEC 18, 2004 | |
| | | 5622985*PED | OCT 22, 2014 | U-335 | PED DEC 09, 2003 | |
| | | 5030447*PED | JAN 09, 2009 | PED | JUL 18, 2003 | |
| | | | | PED | JUL 18, 2003 | |
| | | | | PED | AUG 10, 2003 | |
| | | | | PED | JUN 18, 2005 | |
| | | | | PED | JUL 18, 2003 | |
| 019898 004 | PRAVASTATIN SODIUM;PRAVACHOL | 4346227 | OCT 20, 2005 | I-281 | JUN 09, 2003 | |
| | | 5030447 | JUL 09, 2008 | I-304 | JAN 18, 2003 | |
| | | 5180589 | JUL 09, 2008 | I-287 | FEB 10, 2003 | |
| | | 5622985 | APR 22, 2014 | U-335 | I-286 JAN 18, 2003 | |
| | | 4346227*PED | APR 20, 2006 | D-51 | JAN 18, 2003 | |
| | | 5180589*PED | JAN 09, 2009 | D-70 | DEC 18, 2004 | |
| | | 5622985*PED | OCT 22, 2014 | U-335 | PED DEC 09, 2003 | |
| | | 5030447*PED | JAN 09, 2009 | PED | JUL 18, 2003 | |
| | | | | PED | JUL 18, 2003 | |
| | | | | PED | AUG 10, 2003 | |
| | | | | PED | JUN 18, 2005 | |
| | | | | PED | JUL 18, 2003 | |
| | | | | PED | JUN 18, 2005 | |

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

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT/PED EXPIRES | EXCL USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|----------------------------------|---------------|--------------------|---------------|-------------------|----------------|
| 019898 008 | PRAVASTATIN SODIUM;PRAVACHOL | 4346227 | OCT 20, 2005 | NS | DEC 18, 2004 | |
| | | 5030447 | JUL 09, 2008 | D-70 | DEC 18, 2004 | |
| | | 5180589 | JUL 09, 2008 | PED | JUN 18, 2005 | |
| | | 5622985 | APR 22, 2014 | U-335 | PED JUN 18, 2005 | |
| | | 4346227*PED | APR 20, 2006 | I-281 | JUN 09, 2003 | |
| | | 5180589*PED | JAN 09, 2009 | PED | DEC 09, 2003 | |
| | | 5622985*PED | OCT 22, 2014 | U-335 | D-51 JAN 18, 2003 | |
| | | 5030447*PED | JAN 09, 2009 | PED | JUL 18, 2003 | |
| | | | | I-286 | JAN 18, 2003 | |
| | | | | PED | JUL 18, 2003 | |
| | | | | I-287 | FEB 10, 2003 | |
| | | | | PED | AUG 10, 2003 | |
| | | | | I-304 | JAN 18, 2003 | |
| | | | | PED | JUL 18, 2003 | |
| 019885 001 | QUINAPRIL HYDROCHLORIDE;ACCPURIL | 4344949 | OCT 03, 2002 | U-3 | | |
| | | 4743450 | FEB 24, 2007 | | | |
| | | 5684016 | NOV 04, 2014 | U-210 | | |
| | | 5747504 | APR 10, 2005 | U-210 | | |
| | | 4344949*PED | APR 03, 2003 | U-3 | | |
| | | 4743450*PED | AUG 24, 2007 | | | |
| | | 5684016*PED | MAY 04, 2015 | U-210 | | |
| | | 5747504*PED | OCT 10, 2005 | U-210 | | |
| | | 4344949 | OCT 03, 2002 | U-3 | | |
| | | 4743450 | FEB 24, 2007 | | | |
| | | 5684016 | NOV 04, 2014 | U-210 | | |
| | | 5747504 | APR 10, 2005 | U-210 | | |
| | | 4344949*PED | APR 03, 2003 | U-3 | | |
| | | 4743450*PED | AUG 24, 2007 | | | |
| | | 5684016*PED | MAY 04, 2015 | U-210 | | |
| | | 5747504*PED | OCT 10, 2005 | U-210 | | |
| | | 4344949 | OCT 03, 2002 | U-3 | | |
| | | 4743450 | FEB 24, 2007 | | | |
| | | 5684016 | NOV 04, 2014 | U-210 | | |
| | | 5747504 | APR 10, 2005 | U-210 | | |
| | | 4344949*PED | APR 03, 2003 | U-3 | | |
| | | 4743450*PED | AUG 24, 2007 | | | |
| | | 5684016*PED | MAY 04, 2015 | U-210 | | |
| | | 5747504*PED | OCT 10, 2005 | U-210 | | |
| | | 4344949 | OCT 03, 2002 | U-3 | | |
| | | 4743450 | FEB 24, 2007 | | | |
| | | 5684016 | NOV 04, 2014 | U-210 | | |
| | | 5747504 | APR 10, 2005 | U-210 | | |
| | | 4344949*PED | APR 03, 2003 | U-3 | | |
| | | 4743450*PED | AUG 24, 2007 | | | |
| | | 5684016*PED | MAY 04, 2015 | U-210 | | |
| | | 5747504*PED | OCT 10, 2005 | U-210 | | |

A-21

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
PBD and PBD represent Pediatrictic Exclusivity

A-20

| APP#/PROD | INGREDIENT NAME; TRADE NAME | PATENT# | NUMBER | EXPIRES | CODE | CODE EXCLUS | EXPIRES |
|--|---------------------------------------|-------------|--------------|-----------|--------------|--------------|---------|
| *PDED and PDED represent Pediatrictic Exclusivity DATA | | | | | | | |
| 020895 003 | SILDENAFIL CITRATE;VIAGRA | 5250534 | MAR 27, 2012 | ODE | AUG 23, 2003 | | |
| 020572 001 | SODIUM PHENYLUTYRATES;BUPHENYL | 4795751 | FEB 04, 2010 | U-160 | U-466 NCB | JUL 24, 2007 | |
| 021075 001 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 4457942 | AUG 20, 2004 | U-136 | ODE | JUL 17, 2009 | |
| 021075 002 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 5912015 | MAR 12, 2012 | U-444 | MAR 02, 2012 | MAR 02, 2012 | |
| 020132 001 | SUMATRIPTAN SUCCINATE;IMITREX | 6368627 | MAR 02, 2012 | U-444 | 6368627 | MAR 02, 2012 | |
| 020132 002 | SUMATRIPTAN SUCCINATE;IMITREX | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020677 001 | SAPROLEXACIN;ZAGAM | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020604 004 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 4536516 | AUG 20, 2003 | U-444 | 4536516 | AUG 20, 2002 | |
| 021075 003 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 4536516-PED | FEB 20, 2003 | U-444 | 4536516-PED | FEB 20, 2002 | |
| 021200 001 | TCHASEROD MALEATE;ZELNORM | 5510353 | APR 26, 2013 | U-466 NCB | JUL 24, 2007 | | |
| 021447 001 | TIZANIDINE HYDROCHLORIDE;ZANAFLEX | 6348210 | NOV 10, 2019 | U-440 | 6348210 | NOV 10, 2019 | |
| 021447 002 | TIZANIDINE HYDROCHLORIDE;ZANAFLEX | 645557 | NOV 28, 2021 | U-445 | 645557 | NOV 28, 2021 | |
| 021228 001 | TOLCAPONE;TASMAR | 5236952 | JAN 29, 2012 | U-318 | 5236952 | JAN 29, 2012 | |
| 021228 002 | TOLTERODINE TARTRATE;DETROL LA | 555269 | NOV 05, 2013 | U-318 | 555269 | NOV 05, 2013 | |
| 021227 001 | TREPROSТИNIL SODIUM;REMUDULIN | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021227 002 | TREPROSТИNIL SODIUM;REMUDULIN | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021227 003 | TREPROSТИНІЛ СОДІУМ;РЕМДУЛІН | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021227 004 | UROPOLITROPIN;BRAVELLE | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021283 001 | VALSARTAN;DIOVAN | 6294197 | JUN 18, 2017 | U-3 | I-365 | AUG 14, | 2005 |
| 021283 002 | VALSARTAN;DIOVAN | 6294197 | JUN 18, 2017 | U-3 | I-365 | AUG 14, | 2005 |
| 020665 001 | VALSARTAN;DIOVAN | 6294197 | JUN 18, 2017 | U-3 | I-365 | AUG 14, | 2005 |
| 020593 001 | VALPROATE SODIUM;DEPACON | 5633272 | FEB 13, 2015 | U-462 | D-72 | JAN 24, 2005 | |
| 021341 002 | VALDECOXB;BEKTRA | 5879706 | JAN 19, 2016 | U-107302 | 6107302 | JAN 19, 2016 | |
| 020550 002 | VALACYCLOVIR HYDROCHLORIDE;VALTREX | 4957924 | JUN 23, 2009 | | 4957924 | JUN 23, 2009 | |
| *PDED and PDED represent Pediatrictic Exclusivity DATA | | | | | | | |
| PATENT AND OTC DRUG PRODUCT | | | | | | | |
| PRSCRIPITION AND OTC DRUG PRODUCT | | | | | | | |
| A-23 | | | | | | | |

>ADD<

| APP#/PROD | INGREDIENT NAME; TRADE NAME | PATENT# | NUMBER | EXPIRES | CODE | CODE EXCLUS | EXPIRES |
|--|---------------------------------------|---------|--------------|-----------|--------------|--------------|--------------|
| *PDED and PDED represent Pediatrictic Exclusivity DATA | | | | | | | |
| 020895 003 | SILDENAFIL CITRATE;VIAGRA | 5250534 | MAR 27, 2012 | ODE | JUL 17, 2009 | | |
| 020572 001 | SODIUM PHENYLUTYRATES;BUPHENYL | 4457942 | AUG 20, 2004 | U-136 | ODE | NCE | JUL 17, 2007 |
| 021075 001 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 021075 002 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020132 001 | SUMATRIPTAN SUCCINATE;IMITREX | 6368627 | MAR 02, 2012 | U-444 | 6368627 | MAR 02, 2012 | |
| 020132 002 | SUMATRIPTAN SUCCINATE;IMITREX | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020677 001 | SAPROLEXACIN;ZAGAM | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020604 004 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 4536516 | AUG 20, 2003 | U-444 | 4536516 | AUG 20, 2002 | |
| 021200 001 | TCHASEROD MALEATE;ZELNORM | 5510353 | APR 26, 2013 | U-466 NCB | JUL 24, 2007 | | |
| 021447 001 | TESTOPROSTONE;THALOMID TTS | 6315720 | OCT 10, 2019 | U-440 | 6315720 | OCT 10, 2019 | |
| 021447 002 | TIZANIDINE HYDROCHLORIDE;ZANAFLEX | 645557 | NOV 28, 2021 | U-445 | 645557 | NOV 28, 2021 | |
| 021447 003 | TIZANIDINE HYDROCHLORIDE;ZANAFLEX | 645557 | NOV 28, 2021 | U-445 | 645557 | NOV 28, 2021 | |
| 021228 001 | TOLCAPONE;TASMAR | 5236952 | JAN 29, 2012 | U-318 | 5236952 | JAN 29, 2012 | |
| 021228 002 | TOLTERODINE TARTRATE;DETROL LA | 555269 | NOV 05, 2013 | U-318 | 555269 | NOV 05, 2013 | |
| 021227 001 | TREPROSТИНІЛ СОДІУМ;РЕМДУЛІН | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021227 002 | TREPROSТИНІЛ СОДІУМ;РЕМДУЛІН | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021227 003 | TREPROSТИНІЛ СОДІУМ;РЕМДУЛІН | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021227 004 | UROPOLITROPIN;BRAVELLE | 5153222 | OCT 06, 2009 | U-455 NCB | MAY 21, 2009 | | |
| 021283 001 | VALSARTAN;DIOVAN | 6294197 | JUN 18, 2017 | U-3 | I-365 | AUG 14, | 2005 |
| 021283 002 | VALSARTAN;DIOVAN | 6294197 | JUN 18, 2017 | U-3 | I-365 | AUG 14, | 2005 |
| 020665 001 | VALSARTAN;DIOVAN | 6294197 | JUN 18, 2017 | U-3 | I-365 | AUG 14, | 2005 |
| 020593 001 | VALPROATE SODIUM;DEPACON | 5633272 | FEB 13, 2015 | U-462 | D-72 | JAN 24, 2005 | |
| 021341 002 | VALDECOXB;BEKTRA | 5879706 | JAN 19, 2016 | U-107302 | 6107302 | JAN 19, 2016 | |
| 020550 002 | VALACYCLOVIR HYDROCHLORIDE;VALTREX | 4957924 | JUN 23, 2009 | | 4957924 | JUN 23, 2009 | |
| *PDED and PDED represent Pediatrictic Exclusivity DATA | | | | | | | |
| PATENT AND OTC DRUG PRODUCT | | | | | | | |
| PRSCRIPITION AND OTC DRUG PRODUCT | | | | | | | |
| A-22 | | | | | | | |

>ADD<

| APP#/PROD | INGREDIENT NAME; TRADE NAME | PATENT# | NUMBER | EXPIRES | CODE | CODE EXCLUS | EXPIRES |
|--|---------------------------------------|---------|--------------|---------|--------------|--------------|--------------|
| *PDED and PDED represent Pediatrictic Exclusivity DATA | | | | | | | |
| 021196 001 | SODIUM OXYBATE;XYREM | 5250534 | MAR 27, 2012 | ODE | AUG 23, 2003 | | |
| 020572 001 | SODIUM PHENYLUTYRATES;BUPHENYL | 4457942 | AUG 20, 2004 | U-136 | ODE | NCE | JUL 17, 2007 |
| 021075 001 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 021075 002 | SOMATROPIN RECOMBINANT;NUTROPIN DEPOT | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020132 001 | SUMATRIPTAN SUCCINATE;IMITREX | 6368627 | MAR 02, 2012 | U-444 | 6368627 | MAR 02, 2012 | |
| 020132 002 | SUMATRIPTAN SUCCINATE;IMITREX | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020677 001 | SAPROLEXACIN;ZAGAM | 5912015 | MAR 12, 2012 | U-444 | 5912015 | MAR 12, 2012 | |
| 020604 004 | SOMATROPIN RECOM | | | | | | |

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, 22ND 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

- W EXCLUSIVITY ON THIS APPLICATION EXPIRING ON THIS DATE HAS BEEN WAIVED BY SPONSOR - SEE SECTION 1.3 OF SUPPLEMENT WAIVED EXCLUSIVITY

REFERENCES NEW DOSING SCHEDULE

- D-71 EIGHT WEEK DOSING REGIMEN
- D-72 INFORMATION REGARDING INCREASED RATE OF INFUSION FOR DEPACON
- D-73 ONCE A WEEK DOSING FOR THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
- D-74 ONCE A WEEK DOSING FOR THE PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
- D-75 INTERMITTENT DOSING REGIMEN, STARTING DAILY DOSE 14 DAYS PRIOR TO THE ANTICIPATED ONSET OF MENSTRUATION THROUGH THE FIRST FULL DAY OF MENSES AND REPEATING WITH EACH NEW CYCLE
- D-76 FOR USE ON AN "AS NEEDED" OR PRN BASIS FOR THE MANAGEMENT OF NASAL SYMPTOMS IN PATIENTS FOR WHOM THE DRUG IS INDICATED
- D-77 ADDITION OF 20MG AND 40MG DAILY AS OPTIONAL STARTING DOSES WITH 40MG INTENDED FOR PATIENTS WHO REQUIRE A LARGE REDUCTION IN LDL-C (MORE THAN 45%)

NEW INDICATION

- I-348 LONG-TERM, TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD (INCLUDING EMPHYSEMA AND CHRONIC BRONCHITIS)
- I-349 ACUTE CORONARY SYNDROME
- I-350 TREATMENT OF HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA IN ADOLESCENT BOYS AND GIRLS AT LEAST ONE YEAR POSTMENARCHAL, AGES 10 TO 17 YEARS, WITH A RECOMMENDED DOSING RANGE OF 10 TO 40MG ONCE DAILY
- I-351 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR ALL STRENGTHS
- I-352 ANTICOAGULANT IN PATIENTS WITH OR AT RISK FOR HEPARIN-INDUCED THROMBOCYTOPENIA UNDERGOING PERCUTANEOUS CORONARY INTERVENTIONS (PCI)
- I-353 TREATMENT OF SIGNS AND SYMPTOMS OF RHEUMATOID ARTHRITIS
- I-354 MANAGEMENT OF POST HERPETIC NEURALGIA
- I-355 PREMENSTRUAL DYSPHORIC DISORDER
- I-356 TREATMENT OF PATHOLOGICAL HYPERSECRETORY CONDITIONS, INCLUDING ZOLLINGER-ELLISON SYNDROME
- I-357 TREATMENT OF COMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS
- I-358 TREATMENT OF PANIC DISORDER
- I-359 TREATMENT OF VULVAR AND VAGINAL ATROPHY ASSOCIATED WITH THE MENOPAUSE
- I-360 TREATMENT OF NASAL SYMPTOMS OF SEASONAL AND PERENNIAL RHINITIS IN CHILDREN AGES TWO UP TO AGE THREE

- I-361 TREATMENT OF MULTIPLE MYELOMA AND DOCUMENTED BONE METASTASES FROM SOLID TUMORS, IN CONJUNCTION WITH STANDARD ANTINEOPLASTIC THERAPY. PROSTATE CANCER SHOULD HAVE PROGRESSED AFTER TREATMENT WITH AT LEAST ONE HORMONAL THERAPY
- I-362 TREATMENT OF PANIC DISORDER, WITH OR WITHOUT AGORAPHOBIA
- I-363 ADJUVANT TREATMENT OF POST MENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE EARLY BREAST CANCER
- I-364 TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA IN ADULTS
- I-365 TREATMENT OF HEART FAILURE (NYHA CLASS II-IV) IN PATIENTS WHO ARE INTOLERANT TO AN ACE INHIBITOR
- I-366 PREVENTION OF RELAPSE FOLLOWING LONG-TERM TREATMENT OF MAJOR DEPRESSIVE DISORDER

MISCELLANEOUS EXCLUSIVITY CODES

- M-15 LONGER TERM EFFICACY INFORMATION FOR RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA
- M-16 CHANGE IN WORDING OF THE PEDIATRIC SECTION OF THE PACKAGE INSERT
- M-17 INFORMATION REGARDING USE OF ULTANE IN PEDIATRIC PATIENTS WITH CONGENITAL HEART DISEASE
- M-18 INFORMATION DENOTING THE EFFICACY OF REMERON IN MAINTAINING A RESPONSE IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER (MDD)
- M-19 INFORMATION REGARDING USE IN PEDIATRIC PATIENTS TWO YEARS OF AGE AND OLDER
- M-20 LABELING REVISIONS RELATED TO MCCUNE ALBRIGHT SYNDROME

PATENT USE CODES

- U-438 TREATMENT/PREVENTION OF NEURODEGENERATIVE DISEASE
- U-439 TREATMENT OF OBESITY
- U-440 METHOD FOR TRANSDERMAL ADMINISTRATION OF A DRUG THROUGH NON-SCROTAL SKIN USING A TRANSDERMAL DRUG DELIVERY DEVICE CONTAINING THE DRUG AND HAVING AN ADHESIVE SURFACE
- U-441 METHOD OF TREATING MS BY ADMINISTERING COPAXONE
- U-442 METHOD FOR DELIVERING A DRUG TO A PATIENT IN NEED OF THE DRUG, WHILE AVOIDING THE OCCURRENCE OF AN ADVERSE SIDE EFFECT KNOWN OR SUSPECTED OF BEING CAUSED BY SAID DRUG
- U-443 MANAGEMENT OF MODERATE TO SEVERE PAIN WHEN A CONTINUOUS, AROUND-THE-CLOCK ANALGESIC IS NEEDED FOR AN EXTENDED PERIOD OF TIME
- U-444 METHOD OF TREATING
- U-445 USE AS AN ANTIMYCOTIC AGENT
- U-446 TOPICAL TREATMENT OF OCULAR HYPERTENSION AND GLAUCOMA
- U-447 METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
- U-448 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
- U-449 USE IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER WHERE THE DOSE OF LEUCOVORIN IS AT LEAST 200MG PER SQUARE METER
- U-450 INTERMEDIATE REL NICOTINIC ACID FORMULATIONS HAVING UNIQUE URINARY METAB PROFILES RESULTING FROM ABSORPTION PROFILES OF NICOTINIC ACID FROM THE INTERMEDIATE NICOTINIC ACID FORMULATIONS, SUITABLE FOR TX HYPERLIPIDEMIA FOLLOWING QD DOSING
- U-451 TREATMENT OF DEPRESSION AND GENERALIZED ANXIETY DISORDER
- U-452 USE OF LANSOPRAZOLE FOR COMBATTING DISEASES CAUSED BY THE GENUS CAMPYLOBACTER (C.PYLORI=H.PYLORI)
- U-453 TREATMENT OF PLATELET ASSOCIATED ISCHEMIC DISORDERS
- U-454 METHOD OF TX A PT SUSPECTED OF HAVING HEPATITIS C BY ADMIN, IN COMBINATION, A CONJUGATE COMPRISING PEG 12000 & INTERFERON ALFA-2B IN AN AMT OF FROM 0.5MCG/KG TO 2MCG/KG, ONCE WEEKLY, AND RIBAVIRIN
- U-455 TREATMENT OF PULMONARY HYPERTENSION WITH UT-15
- U-456 METHOD OF DECREASING THE PRODUCTION OF A-BETA USING A COMPOSITION WHICH DECREASES BLOOD CHOLESTEROL IN PATIENTS AT RISK OF OR EXHIBITING SYMPTOMS OF ALZHEIMER'S DISEASE
- U-457 METHOD OF TREATING A VAGINAL FUNGAL INFECTION IN A FEMALE HUMAN
- U-458 METHOD OF USE OF IMAGENT

- U-459 TREATMENT OF DEPRESSION AND GENERALIZED ANXIETY DISORDER
- U-460 METHOD OF TREATING PSYCHIATRIC SYMPTOMS ASSOCIATED WITH PREMENSTRUAL DISORDERS USING SERTRALINE
- U-461 METHOD OF TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER (PMDD) USING SERTRALINE
- U-462 SIGNS AND SYMPTOMS OF OSTEOARTHRITIS AND ADULT RHEUMATOID ARTHRITIS AND TREATMENT OF PRIMARY DYSMENORRHEA
- U-463 VENOGRAPHY
- U-464 PERIPHERAL ARTERIOGRAPHY
- U-465 CT IMAGING OF THE HEAD
- U-466 TREATMENT OF IRRITABLE BOWEL SYNDROME
- U-467 USE OF EPLERENONE IN COMBINATION WITH AN ANGIOTENSIN CONVERTING ENZYME (ACE) INHIBITOR FOR TREATING HYPERTENSION
- U-468 METHOD OF USING FEXOFENADINE HCL IN TREATING ALLERGIC RHINITIS
- U-469 TREATMENT OF GASTROESOPHAGEAL REFLEX DISEASE (GERD) AND ERADICATION OF H.PYLORI TO REDUCE RISK OF DUODENAL ULCER RECURRENCE

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