

CUMULATIVE
SUPPLEMENT 12

JAN'93-DEC'93

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION



RM
301.45
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1993
Dec
Suppl

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

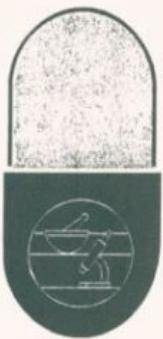
Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927 **SUBSCRIBE NOW!**

Available in March 1994

New 14th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**14TH EDITION
1994**

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

13TH EDITION

Cumulative Supplement 12

DECEMBER 1993

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

CUMULATIVE SUPPLEMENT 12

DECEMBER 1993

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, 13th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

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

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item.

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "♦" symbol to designate their non-marketed status. All products having a "♦" symbol in the 12th Cumulative Supplement of the 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

| <u>Products</u> | <u>Federal Register Reference</u> |
|--|-----------------------------------|
| Nitroglycerin (capsule, controlled release;oral) | SEP 07, 1984 (49 FR 35428) |
| Nitroglycerin (film, extended release; transdermal*) | JUL 15, 1993 (58 FR 38129) |
| Nitroglycerin (tablet, controlled release;oral) | SEP 07, 1984 (49 FR 35428) |
| Nitroglycerin (tablet, controlled release;buccal) | JUL 05, 1985 (50 FR 27688) |

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

1.3 APPLICANT NAME CHANGES

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

APPLICANT NAME CHANGES

| <u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u> |
|--|--|
| AH ROBINS CO (ROBINS) | AH ROBINS CO (ROBINS AH) |
| ALLERGAN HERBERT SKIN CARE DIV ALLERGAN INC (ALLERGAN HERBERT) | ALLERGAN HERBERT DIV ALLERGAN INC (ALLERGAN) |
| ANAQUEST DIV BOC INC (ANAQUEST) | ANAQUEST INC (ANAQUEST) then changed to OHMEDA PHARMACEUTICAL PRODUCTS DIVISION INC (OHMEDA PHARM) |
| ANAQUEST INC (ANAQUEST) | OHMEDA PHARMACEUTICAL PRODUCTS DIVISION INC (OHMEDA PHARM) |
| ASTRA PHARMACEUTICAL PRODUCTS INC (ASTRA) | ASTRA USA INC (ASTRA) |
| BAKER CUMMINS PHARMACEUTICALS INC (BAKER CUMMINS) | BAKER NORTON PHARMACEUTICALS INC (BAKER NORTON) |
| BENEDICT NUCLEAR PHARMACEUTICALS INC (BENEDICT) | NORTH AMERICAN CHEMICAL CORPORATION (NORTH AM CHEM) |
| BOLAR PHARMACEUTICAL CO INC (BOLAR) | CIRCA PHARMACEUTICALS INC (CIRCA) |
| CIS US INC (CIS) | CIS US INC (CIS) formerly (CIS US) |

APPLICANT NAME CHANGES

| <u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u> |
|--|---|
| CUTTER BIOLOGICAL DIV MILES LABORATORIES INC (CUTTER) | MILES LABORATORIES INC (MILES LABS) |
| DANBURY PHARMACAL INC (DANBURY) | DANBURY PHARMACAL INC (DANBURY PHARMA) |
| FUJISAWA PHARMACEUTICAL CO (FUJISAWA) | FUJISAWA USA INC (FUJISAWA) |
| GENSIA PHARMACEUTICAL INC (GENSIA) | GENSIA INC (GENSIA) |
| HERBERT LABORATORIES DIV SMITH KLINE AND FRENCH CO (HERBERT) | ALLERGAN HERBERT DIV ALLERGAN INC (ALLERGAN HERBERT) |
| ICI PHARMACEUTICALS GROUP DIV ICI AMERICAS (ICI) | ZENECA PHARMACEUTICALS GROUP DIV ZENECA INC (ZENECA) <i>formerly</i> ZENECA PHARMACEUTICALS GROUP |
| KABIVITRUM INC (KABIVITRUM) | KABI PHARMACIA INC (KABI) |
| LEMMON CO (LEMMON) | LEMMON CO SUB TEVA PHARMACEUTICALS (LEMMON) |
| LYPHOMED DIV FUJISAWA USA INC (LYPHOMED) | FUJISAWA USA INC (FUJISAWA) |
| OWEN GALDERMA LABORATORIES INC (OWEN GALDERMA) | GALDERMA LABORATORIES INC (GALDERMA) |
| PIONEER PHARMACEUTICALS INC (PIONEER PHARMS) | PIONEER PHARMACEUTICALS CO INC (PIONEER PHARMS) |
| ROXANE LABORATORIES INC (ROXANE) | ROXANE LABORATORIES INC (ROXANE) <i>formerly</i> (ROXANE LABS) |
| RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV MCNEILAB (JOHNSON RW) | RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIV ORTHO PHARMACEUTICAL CORP (JOHNSON RW) |

APPLICANT NAME CHANGES

| <u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u> |
|--|---|
| SCHIAPPARELLI SEARLE (SCHIAPPARELLI SEARLE) | SCS PHARMACEUTICALS (SCS PHARMS) |
| SCHWARZ PHARMA KERMERS URBAN (SCHWARZ PHARMA) | SCHWARZ PHARMA DIV KREMERS URBAN CO (SCHWARZ PHARMA) |
| SOMERSET PHARMACEUTICALS INC (SOMERSET) | SOMERSET PHARMACEUTICALS INC (SOMERSET PHARMS) |
| STERLING DRUG INC (STERLING) | STERLING WINTHROP INC (STERLING WINTHROP) |

1.4 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

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

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

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

| <u>FORMER USP MONOGRAPH TITLE (FORMER ADP DOSAGE FORM; ROUTE)</u> | <u>NEW USP MONOGRAPH TITLE (NEW ADP DOSAGE FORM; ROUTE)</u> |
|---|---|
|---|---|

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF DECEMBER 1993.

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 sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1992) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

| <u>CATEGORIES COUNTED</u> | <u>DEC 1992</u> | <u>JUN 1993</u> | <u>SEP 1993</u> | <u>DEC 1993</u> |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| DRUG PRODUCTS LISTED | 9488 | 9194 | 9140 | 9140 |
| SINGLE SOURCE | 2245 (23.7%) | 2119 (23.0%) | 2151 (23.5%) | 2144 (23.5%) |
| MULTI SOURCE | 7243 (76.3%) | 7075 (77.0%) | 6991 (76.5%) | 6996 (76.5%) |
| THERAPEUTICALLY EQUIVALENT | 6516 (68.6%) | 6357 (69.1%) | 6276 (68.7%) | 6292 (68.8%) |
| NOT THERAPEUTICALLY EQUIVALENT | 577 (6.1%) | 555 (6.1%) | 532 (5.8%) | 527 (5.8%) |
| EXCEPTIONS ¹ | 150 (1.6%) | 163 (1.8%) | 183 (2.0%) | 177 (1.9%) |
| NEW MOLECULAR ENTITIES APPROVED | — | 2 | 9 | 15 |
| NUMBER OF APPLICANTS | 477 | 508 | 515 | 526 |

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

ACETAMINOPHEN; HYDROCODONE BITARTRATE

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

2

ACETAMINOPHEN; PROPYXYPHEN NAPSYLATE

TABLET; ORAL
PROPYXYPHEN NAPSYLATE AND ACETAMINOPHEN
/466/
/HALSIEY/

/466/
/65465;160mg/
325MG;50MG

② HALSEY

EQ 500MG/VIAL
EQ 500MG/VIAL

② QUAD

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
/Acétadoláte'sodium/
/466/
/QUAD/

/466/
/ED'500MG/VIAL/
EQ 500MG/VIAL

LEDERLE
LEDERLE

EQ 500MG/VIAL
EQ 500MG/VIAL

ACETYLCHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; OPHTHALMIC
MIOTIC-E
+ TOLAB

20MG/VIAL
SEP 22, 1993

INJECTABLE; INJECTION
ZOVIRAX
+ BURROUGHS WELLCOME

EQ 1GM BASE/VIAL
EQ 250MG BASE/VIAL

②

ACYLOVIR SODIUM

N18603 002
JUN 29, 1989

N18603 003
AUG 30, 1988

ACETAZOLAMIDE SODIUM

TABLET; ORAL
ACETAZOLAMIDE SODIUM
/466/
/N9619/

/466/
/N9619/001
N9619 001

JAN 13, 1988

ACETYLPHENYL ALBUMIN

INJECTION
/Acetylphenylalb/
/466/
/QUAD/

/466/
/ED'500MG/VIAL/
EQ 500MG/VIAL

LEDERLE
LEDERLE

EQ 500MG/VIAL
EQ 500MG/VIAL

DEC 05, 1990

BC + MURO
+
DEC 23, 1992

DEC 23, 1992

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

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ALBUTEROL SULFATE

TABLET; ORAL
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/COPLEY/

/AN/
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N72105 001

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MAY 13, 1988

MAY 13, 1988

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TABLET; ORAL
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/AN/
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MAY 13, 1988

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HATSON LABS

MAY 13, 1988

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TABLET; ORAL
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MAY 13, 1988

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TABLET; ORAL
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/AN/
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MAY 13, 1988

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HATSON LABS

MAY 13, 1988

MAY 13, 1988

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TABLET; ORAL
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/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
/AN/
/COPLEY/

/AN/
/N72105/001
N72105 001

MAY 13, 1988

AA
HATSON LABS

MAY 13, 1988

MAY 13, 1988

AA
NOVOPHARM

AB

AB

AB

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM
ALPHADIAZEPAM

| | | | |
|-----------|------------|---------------|--------------|
| <u>AB</u> | ALPHAPHARM | <u>0.25MG</u> | N74046 001 |
| <u>AB</u> | | <u>0.5MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>1MG</u> | N74046 002 |
| <u>AB</u> | LEDERLE | <u>0.25MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>1MG</u> | N74046 003 |
| <u>AB</u> | | <u>2MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>0.5MG</u> | N74174 001 |
| <u>AB</u> | | <u>1MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>2MG</u> | N74174 002 |
| <u>AB</u> | PUREPAC | <u>0.25MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>0.5MG</u> | N74174 003 |
| <u>AB</u> | | <u>1MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>2MG</u> | N74342 001 |
| <u>AB</u> | ROXANE | <u>0.25MG</u> | OCT 31, 1993 |
| <u>AB</u> | | <u>0.5MG</u> | N74342 002 |
| <u>AB</u> | | <u>1MG</u> | OCT 31, 1993 |
| <u>AB</u> | | <u>2MG</u> | N74342 003 |
| <u>AB</u> | | <u>0.25MG</u> | OCT 31, 1993 |
| <u>AB</u> | | <u>0.5MG</u> | N74342 004 |
| <u>AB</u> | | <u>1MG</u> | OCT 31, 1993 |
| <u>AB</u> | | <u>2MG</u> | N74199 001 |
| <u>AB</u> | | <u>0.25MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>0.5MG</u> | N74199 002 |
| <u>AB</u> | | <u>1MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>2MG</u> | N74199 003 |
| <u>AB</u> | | <u>0.25MG</u> | OCT 19, 1993 |
| <u>AB</u> | | <u>0.5MG</u> | N74199 004 |
| <u>AB</u> | | <u>1MG</u> | OCT 19, 1993 |

AMANTADINE HYDROCHLORIDE

**SYRUP; ORAL
AMANTADINE HCl**

AMIKACIN SULFATE

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NOV 27, 1985
N18276 002
N18276 003
N18276 004

AMERICAN INSTITUTE OF MEDICAL TECHNOLOGIES

CAPSULE; ORAL

ANAVATADINE HCL
/CIRCA/
/ 66 /
a CIRCA
100MG
/100MG/
/JAN/21,1987/
N71382 001
JAN 21, 1987

AMERICAN / ERISSTOLI / BOSTON

EY ZUHIG BASE/AHL

N50495 002

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'93 - DEC'93

4

AMIKACIN SULFATE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE

INJECTABLE; INJECTION
/AMIKACIN/1% IN SODIUM CHLORIDE/10% IN PLASTIC CONTAINER/
/BAXTER/
>DLT>
>DLT>
>DLT>
>DLT>
>ADD>
>ADD>

② BRISTOL
EQ 5MG BASE/ML
NOV 30, 1987
EQ 10MG BASE/ML
NOV 30, 1987

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;
POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE

INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>
>DLT>
>DLT>
>DLT>
>ADD>

③ ABBOTT
N50618 002
NOV 30, 1987
N50618 001
NOV 30, 1987

AMINO ACIDS
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>
>DLT>
>DLT>
>DLT>

③ ABBOTT
FEB 05, 1993
N20107 001

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>
>DLT>
>DLT>

③ ABBOTT
AUG 09, 1982
N17957 002

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>

③ LYMPHOMED
JUN 17, 1986
N70522 001

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC
INJECTABLE; INJECTION
/AMINO ACIDS/10% IN PLASTIC CONTAINER/
/ABBOTT/
>DLT>

SYRUP; ORAL
AMICAR
IMMUNEX
N15250 002
N15250 003
1.25GM/5ML

AMPHETAMINE ADIPATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE
ADIPATE; DEXTROAMPHETAMINE SULFATE

AMPHOTERICIN B

| | | | |
|---|--|--|--|
| /t/ampetamine/ /adipate/ /decoese/ /lenmon/ /LENMON | CREAM; TOPICAL FUNGIZONE + APOTHECON /SQUIDPE/ | N50319 001 /N50314/661/ /3:/ | |
| ② LEMMON | INJECTABLE; INJECTION FUNGIZONE AP + APOTHECON /AP/ /SQUIDPE/ | N60517 001 /N60517/661/ /50MG/ | |
| ② | LOTION; TOPICAL FUNGIZONE + APOTHECON /SQUIDPE/ | N60570 001 /N60570/661/ /3:/ | |
| ③ | OINTMENT; TOPICAL FUNGIZONE + APOTHECON /SQUIDPE/ | N50313 001 /N50313/661/ /3:/ | |
| ② LEMMON | INJECTABLE; INJECTION AMPICILLIN SODIUM HANFORD | EQ 125MG BASE/VIAL AP EQ 250MG BASE/VIAL AP EQ 500MG BASE/VIAL AP EQ 500MG BASE/VIAL AP EQ 1GM BASE/VIAL AP EQ 1GM BASE/VIAL AP EQ 2GM BASE/VIAL AP EQ 2GM BASE/VIAL AP EQ 10GM BASE/VIAL AP EQ 10GM BASE/VIAL AP EQ 125MG BASE/VIAL AP EQ 2GM BASE/VIAL AP | N63143 001 APR 15, 1993 N63145 001 APR 15, 1993 N63146 001 APR 15, 1993 N63147 001 APR 15, 1993 N62772 001 APR 15, 1993 N63139 001 APR 15, 1993 N63140 001 APR 15, 1993 N63141 001 APR 15, 1993 N63142 001 APR 15, 1993 N62777 001 JUL 12, 1993 N62777 002 JUL 12, 1993 |
| ② FISONS | AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX /extended/release/; oral/ /BIPHENYL/12.5/ /Fisons/ ② FISONS | /Eq 6.25MG BASE/ /Eq 6.25MG BASE/ EQ 6.25MG BASE; EQ 6.25MG BASE /BIPHENYL/26/ /Eq 10MG BASE/ /Eq 10MG BASE/ EQ 10MG BASE; EQ 10MG BASE | N10093 007 N10093 003 AP IBI AP |
| ② FISONS | | | |

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM
/AP/ /LILLY//Ed '500MG BASE/VIAL/
/AP/ /Ed '1GM BASE/VIAL/
/AP/ /Ed '2GM BASE/VIAL/
/AP/ /Ed '4GM BASE/VIAL/

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 4GM BASE/VIAL

AP +

/NS0072 006

/NS1395 001

/NS1395 002

/NS1395 003

/NS1395 004

/NS1395 005

/NS1395 006

/NS1395 007

/NS1395 008

/NS1395 009

/NS1395 010

/NS1395 011

/NS1395 012

/NS1395 013

/NS1395 014

/NS1395 015

/NS1395 016

/NS1395 017

/NS1395 018

/NS1395 019

/NS1395 020

/NS1395 021

/NS1395 022

/NS1395 023

AMPICILLIN SODIUM

INJECTABLE; INJECTION

PRINCIPEN
APOTHECON

/AP/ /AP/ /AP/ /AP/

AMPICILLIN SODIUM

INJECTABLE; INJECTION

LILLY

/AP/ /AP/ /AP/ /AP/

AMPICILLIN SODIUM

INJECTABLE; INJECTION

PENBRITIN-S

/AP/ /AP/ /AP/ /AP/

AMPICILLIN SODIUM

INJECTABLE; INJECTION

UNASYN

/AP/ /AP/ /AP/ /AP/

AMPICILLIN SODIUM

INJECTABLE; INJECTION

PFIZER

/AP/ /AP/ /AP/ /AP/

AMPICILLIN SODIUM

CAPSULE; ORAL

AMPICTYLIN

/AP/ /AP/ /AP/ /AP/

AMPICILLIN/AMPICILLIN TRIHYDRATE

AMPICILLIN/AMPICEFOL IN TRIHYDRATE: PROBLEMS

| | | |
|---|--|--|
| <u>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E</u> | <u>ASPIRIN; BUTALBITAL</u> | |
| <u>/INJECTABLE; INJECTION/ /ASTRA/</u> | <u>TABLET; ORAL AXOTAL /4//APDTA/ + SAVAGE</u> | <u>/N66665/6661/ /66665/6661/ N88305 001 OCT 13, 1983</u> |
| <u>/INJECTABLE; INJECTION/ /ASTRA/</u> | <u>ASPIRIN; BUTALBITAL; CAFFINE</u> | |
| <u>③ ASTRA</u> | <u>TABLET; ORAL BUTALBITAL w/ ASPIRIN & CAFFINE /AB/ /PHARMAFAIR/</u> | <u>/N67644/6661/ /66665/6661/ N87048 002 DEC 09, 1983</u> |
| | <u>AB PHARMERAL</u> | <u>325MG; 50MG; 40MG</u> |
| | <u>AUG 08, 1985</u> | |
| <u>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E</u> | <u>BUTALBITAL, ASPIRIN AND CAFFEINE /CHELSEA/</u> | <u>/N66643/6661/ /N66643/6661/ N866237 002 MAR 23, 1984</u> |
| | <u>> DLT > AB/ > DLT > > ADD > > ADD ></u> | <u>325MG; 50MG; 40MG</u> |
| | <u>③ CHELSEA</u> | |
| | | |
| | <u>ASPIRIN; PROPOXYPHENE MAPSYLATE</u> | |
| | <u>/TABLET; ORAL/ /PARSONS/ W/ASA/ /4//LILLY/ ③ LILLY</u> | <u>/N66663/6661/ /66663/6661/ N168863 001 N168863 001</u> |
| | <u>ATENOLOL</u> | |
| | <u>TABLET; ORAL ATENOLOL</u> | <u>50MG</u> |
| | <u>AB MUTUAL PHARM</u> | |
| | <u>AUG 08, 1985</u> | |
| <u>M.V.O. 243</u> | <u>ATENOLOL</u> | |
| <u>AP FUJISAWA</u> | | |
| | <u>1.0MG/ML; 0.006MG/ML; 0.5UGM/ML; 1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML; 0.4MG/ML; 0.36MG/ML; 0.3MG/ML; 330 UNITS/ML; 1 IU/ML</u> | <u>N73475 001 MAR 30, 1993 N73476 001 MAR 30, 1993 N73315 001 MAR 28, 1993 N73316 001 MAY 28, 1993</u> |
| | <u>/66/ /5/PhDfEP/</u> | |
| | <u>KABIVIT PED F + W KIT</u> | |
| | <u>KABI</u> | |
| | <u>80MG/VIAL; 0.02MG/VIAL; 0.001MG/VIAL; 400IU/10ML; 0.14MG/VIAL; 17MG/VIAL; 5MG/VIAL; 0.2MG/10ML; 1MG/VIAL; 1.4MG/VIAL; 1.2MG/VIAL; EQ 2300 UNITS BASE/10ML; 7IU/10ML</u> | <u>100MG 50MG 100MG</u> |
| | <u>> ADD > > ADD ></u> | <u>N20176 003 DEC 29, 1993</u> |

ATENOLOL: CHLORTHALIDONE

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

12

BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFA TE

BACLOFEN

| | | | | | | |
|-------------------------|--|---|---|---|--|----------------------------|
| /61/ PHARMAFAIR | OINTMENT; OPHTHALMIC /BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFA TE/ | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 10,000 UNITS/GM | > DLT > > DLT > > DLT > > DLT > > DLT > | > DLT > > DLT > > DLT > > DLT > > DLT > | /INJECTABLE; INJECTION/ LIQUID; /HEPTANOIC/ | /6.5MG/ML/ /2.5G/ML/ |
| ③ PHARMAFAIR | OINTMENT; TOPICAL CORTISPORTH /BUTYROPHENOL/HYDROCHLORIC ACID/ | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 10,000 UNITS/GM | N62389 001 JUL 02, 1992 | > ADD > > ADD > > ADD > > ADD > | LIQUID; MEDTRONIC | 0.5MG/ML |
| /61/ BURROUGHS WELLCOME | OINTMENT; OPHTHALMIC /NEOMYCIN SULFATE; POLYMYXIN B SULFA TE/ | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 5,000 UNITS/GM | MAY 04, 1994 N50168 002 MAY 06, 1994 | > ADD > > ADD > > ADD > | SOLUTION; ORAL CHYMEX /APRIKA/ | JUN 17, 1992 |
| /61/ PHARMAFAIR | OINTMENT; OPHTHALMIC /NEOMYCIN SULFATE; POLYMYXIN B SULFA TE/ | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 5,000 UNITS/GM | SEP 06, 1995 N62281 001 SEP 06, 1995 | > ADD > > ADD > | SAVAGE | 2MG/ML |
| ③ PHARMAFAIR | OINTMENT; OPHTHALMIC BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFA TE | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 5,000 UNITS/GM | N62281 001 SEP 06, 1995 | BENTONITE; SULFUR | /POWDERS; TOPICAL/ /BENSULFOID/ /POLYTHRESE/ | JUN 17, 1992 |
| /61/ PHARMAFAIR | OINTMENT; OPHTHALMIC /BACITRACIN ZINC; HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFA TE/ | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 10,000 UNITS/GM | SEP 06, 1995 N62386 001 SEP 09, 1995 | BENTONITE | /66.64%; 33.33%; 3 POTTHRESS | JUN 17, 1992 |
| ③ PHARMADERM | OINTMENT; OPHTHALMIC BACITRACIN-NEOMYCIN-POLYMYXIN /PHARMADERM/ | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 5,000 UNITS/GM | N62386 001 SEP 09, 1995 N62167 001 | CAPSULE; ORAL BENZONATE PHARMACAPS | 100MG | NB1297 001 JAN 29, 1993 |
| ③ PHARMADERM | OINTMENT; OPHTHALMIC BENZPHEPTAMINE HYDROCHLORIDE | 400 UNITS/GM; 1/2; EQ 3.5MG BASE/GM; 5,000 UNITS/GM | N62167 001 | AA TESSALON AA FOREST LABS | 100MG | N11210 001 |
| | TABLET; ORAL DIREX | | | | | /45MG/ 2.5MG |
| | ③ UP JOHN | | | | | /45MG/ 2.5MG |
| | ③ UP JOHN | | | | | /45MG/ 2.5MG |

N11210 003

CUMULATIVE PRODUCT HST / SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

RISOBPOGI ELIMABATE: HYDROCHLOROTHIAZIDE

| TABLET; ORAL | | SYRUP; ORAL | | SYRUP; ORAL | |
|--------------|-----------|----------------------------|---------------------|-----------------------------------|-----------------------------------|
| ZIAC | + LEDERLE | N20186 002 MAR 26, 1993 | AA PENNEX PHARMS | 2MG;5ML ; 10MG;5ML; 12.5MG;5ML | 2MG;5ML ; 10MG;5ML; 12.5MG;5ML |
| | | 10MG;6.25MG + 2.5MG | | / 10MG;6.25GS / / 2.5GS;5ML / | / 10MG;6.25GS / / 2.5GS;5ML / |
| | | 2.5MG;6.25MG | | | |
| | | 5MG;6.25MG | | | |
| | | N20186 003 MAR 26, 1993 | | | |
| | | N20186 001 MAR 26, 1993 | | | |

BRETYLIUM TOSYLATE

| INJECTABLE; INJECTION | | PSEUDOEPHEDRINE HYDROCHLORIDE | |
|-----------------------|------------|-------------------------------|---|
| BRETTUM TOSYLATE | /Astra/ | /Astra/ 50MG/ML | SYRUP; ORAL METPHETANE DX PENNEX PHARMS |
| /Astra/ | N71152 001 | AUG 10, 1987 | 2MG/5ML; 10MG/5ML; 30MG/5ML |
| | | | /Astra/ /Astra/ /Astra/ |
| | | | JUN 07, 1985 |
| | | | N888811 001 |

PHENYL PROPANDI AMINE HYDROCHLORIDE

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CEFAZOLIN SODIUM

CAPSULE; ORAL
DURISTOL * BRISTOL MYERS SQUIBB EQ-500H
AB Ab //4//HEAD/Johinson/
POWDER FOR RECONSTITUTION: ORAL

CEFAMANDOLE NAFATE

INJECTABLE INJECTION

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| | |
|----------------------|----------------------------|
| /EQ/500MG/BASE/VIAL/ | /N50571/001 |
| /EQ/1GM/BASE/VIAL/ | /PFC/50/1487 |
| /EQ/2GM/BASE/VIAL/ | /PFC/50/1488 |
| EQ 500MG BASE/VIAL | N50571.001 |
| EQ 1GM BASE/VIAL | DEC 30, 1987 N50571.002 |
| EQ 2GM BASE/VIAL | DEC 30, 1987 N50571.003 |

CEFENOXIME HYDROCHLORIDE

CEFTAZIDIME SODIUMINJECTABLE; INJECTION
CEFTAZIDIME SODIUM IN PLASTIC CONTAINER

| | | | | | | |
|-----------|---------------|----------------------------|------------------------------------|----------------|---|----------------------------|
| <u>AP</u> | <u>BAXTER</u> | N63221 001 APR 29, 1993 | <u>EQ 10MG BASE/ML</u> | <u>AP</u> | <u>EQ 750MG BASE/VIAL DEFUROXIME MARSAN</u> | N64035 001 FEB 26, 1993 |
| <u>AP</u> | | N63221 002 APR 29, 1993 | <u>EQ 20MG BASE/ML</u> | <u>AP</u> | <u>EQ 1.5GM BASE/VIAL</u> | N64035 002 FEB 26, 1993 |
| <u>AP</u> | | N63221 003 APR 29, 1993 | <u>EQ 40MG BASE/ML</u> | <u>AP</u> | <u>EQ 7.5GM BASE/VIAL</u> | N64036 001 FEB 26, 1993 |
| <u>AP</u> | | N63221 004 APR 29, 1993 | <u>FORTAZ IN PLASTIC CONTAINER</u> | <u>AP</u> | <u>KEFUROM</u> | |
| <u>AP</u> | <u>GLAXO</u> | N50634 001 APR 28, 1989 | <u>EQ 10MG BASE/ML</u> | <u>LILLY</u> | <u>EQ 7.5GM BASE/VIAL</u> | N62591 003 DEC 17, 1987 |
| <u>AP</u> | | N50634 002 APR 28, 1989 | <u>EQ 20MG BASE/ML</u> | <u>ZIAZEEF</u> | <u>EQ 7.5GM BASE/VIAL</u> | |
| <u>AP</u> | | N50634 003 APR 28, 1989 | <u>EQ 40MG BASE/ML</u> | <u>GLAXO</u> | <u>EQ 7.5GM BASE/VIAL</u> | N50558 004 OCT 23, 1986 |

CEFTIZOXIME SODIUMINJECTABLE; INJECTION
CEFIZOK
FUJISAWA

| | | | | | | |
|--|--|----------------------------|-----------------------------------|-------------------------|-----------------------|---------------------|
| | | N50560 001 SEP 15, 1983 | <u>POWDER; ORAL CALCIBIND</u> | <u>/4.5G/4.5G/4.5G/</u> | <u>MISSION PHARMA</u> | <u>2.5GM/PACKET</u> |
| | | N50560 005 MAR 19, 1993 | | | | |

CEFRITIAKONE SODIUM

| | | | | | |
|---|---------------------------|------------------------------------|--|--------------------------|------------------------------------|
| <u>INJECTABLE; INJECTION ROCEPHIN ROCHE</u> | <u>EQ 250MG BASE/VIAL</u> | <u>N63239 001 AUG 13, 1993</u> | <u>CAPSULE; ORAL GEFAHIX APOTHECON</u> | <u>EQ 250MG BASE</u> | <u>N63063 001 SEP 29, 1989</u> |
| | <u>EQ 500MG BASE/VIAL</u> | <u>N63239 002 AUG 13, 1993</u> | <u>AB</u> | <u>EQ 500MG BASE</u> | <u>N63063 002 SEP 29, 1989</u> |
| | <u>EQ 1GM BASE/VIAL</u> | <u>N63239 003 AUG 13, 1993</u> | <u>AB/</u> | <u>/EQ'250MG '66\$//</u> | <u>/EQ'250MG '66\$//</u> |
| | | | <u>AB/</u> | <u>/EQ'500MG '66\$//</u> | <u>/EQ'1GM '66\$//</u> |
| | | | | <u>/EQ'250MG '66\$//</u> | <u>/EQ'250MG '66\$//</u> |

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER
/4.5G/4.5G/

| | | | | | | |
|--|------------------------|------------------------------------|-----------|---------------------------------|--------------------------|------------------------------------|
| <u>INJECTABLE; INJECTION ROCHE</u> | <u>EQ 10MG BASE/ML</u> | <u>N50624 001 FEB 11, 1987</u> | <u>AB</u> | <u>CEPHALEXIN APOTHECON</u> | <u>EQ 250MG BASE</u> | <u>N62973 001 NOV 08, 1988</u> |
| | | | | | <u>EQ 500MG BASE</u> | <u>N62974 001 NOV 23, 1988</u> |
| | | | | | <u>/EQ'250MG '66\$//</u> | <u>/EQ'500MG '66\$//</u> |
| | | | | | <u>/EQ'250MG '66\$//</u> | <u>/EQ'500MG '66\$//</u> |
| | | | | | <u>/EQ'250MG '66\$//</u> | <u>/EQ'500MG '66\$//</u> |

CHLORTHALIDONE

TABLETS: ORAL
CHLORPHENIRAMINE
 ABBOTT / ADDIT / CHELSEA / PHARMACEUTICALS

3 PHARM BASICS

CHLORTHALIDONE; METOPROLOL TARTRATE

/CAPSULE/ /ORAL/
/TOPRESSIDONE/
/+ / CIBA/

CHLOROXAZONE

TABLET; ORAL
CHLORZOXAZONE

> ADD > /AA/ /PIONEER/ /PIAVERS/ /AA/

3 PIONEER PHARMS

CHYNOOPAPAIN

INJECTABLE; INJECTION

| | | |
|---------|---------------------|-------------------------------|
| /B00TS/ | /16,000 UNITS/VIAL/ | /NIB663/001 /NOV 10, 1982/ |
| 3 BOOTS | 10,000 UNITS/VIAL | NIB663 001 NOV 10, 1982 |

CHYNOTRYPsin
NS8052 001
JUN 01, 1987

POWDER FOR RECONSTITUTION; OPTIMALIC
CATARASE

/150/UNITS/VAL/
150 UNITS/VAL
/300/UNITS/VAL/
/N18121/001
/N18121/001
/N18121/001

CISAPRIDE MONOHYDRATE

TABLET; ORAL
PROPULSID
+ JANSSEN

CLADRIBINE

N20229 001
FEB. 26, 1993
INJECTABLE; INJECTION
LEUSTATIN
+ JOHNSON & WALKER
1MG/ML

CONTINUATION

**GRANULE, FOR RECONSTITUTION; ORAL
BITAXIN**

250MG/5ML + ABBOTT
125MG/5ML

CORTICOTROPIN

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE
/HEATHER/
/BP/ 3 HEATHER

CROLYN SODIUM

SPRAY, METERED; NASAL
NASALCROM
+ FITSONS

CYANOCOBALAMIN
INJECTABLE; INJECTION
CYANOCOBALAMIN
/SELE/ DELL FUJISAMA/
/SELE/ @ FUJISAMA

CYANOCOBALAMIN

INJECTABLE; INJECTION
 /RUBATITE/
 /PE/TAD/
 /AP/
 /AP/
 /AP/
 /AP/
 /AP/
 NO8975 001
 NO8975 001
 NO8975 002
 NO8975 002

/ 114 / 115 / 116 / 117 /

| | |
|-------------------|---------------|
| /+/-KAPEL-M | /5/60/16 '5H/ |
| /+/-KLETH/AYERST/ | /12/60/5H/ |
| | /2/50/16 '5H/ |
| | 1.25MG / 5ML |
| | 2.50MG / 5ML |
| | 5.00MG / 5ML |

CYCLIZINE LACTATE
 /INJECTABLE/ ANJETOL/
 /NARZINE/
 /BENODIPS/WELLCHOL/ /SH
 a BURROUGHS WELLCOME 501
 CYCLOBENZAPRINE HYDROCHLORIDE
 N18306 001
 MAR 18, 1983

10MG

INTRODUCTION

N50508 002
N50508 003
N50508 004
N50508 005
N50508 006

/N66445/001/
N09605/001/

N73683 001
FEB 26, 1993

CYCLOPHOSPHAMIDE

INJECTABLES: INJECTION

| | | | |
|-------------------|--------------|--|--|
| <u>NEOSAR</u> | <u>ADRIA</u> | | |
| <u>100MG/VIAL</u> | | | |
| <u>200MG/VIAL</u> | | | |
| <u>500MG/VIAL</u> | | | |
| <u>1GM/VIAL</u> | | | |
| <u>2GM/VIAL</u> | | | |

CYPROHEPTADINE HYDROCHLORIDE

| | |
|--|-----------------------------------|
| SYRUP; ORAL <u>CYPROHEPTADINE HCL</u> 3 PENNEX PHARMS | / 666 / / PHARM/ 666/CS / |
| TABLET; ORAL <u>CYPROHEPTADINE HCL</u> 3 PENNEX PHARMS | / 666 / / H/ 666 / 3 PENNEX |

DESIPRAMINE HYDROCHLORIDE

③ RHONE POULENC RORER 25MG
3 3

DESLANOSIDE

zurück e

DESHOPPRESSIN ACETATE

SPRAY; METERED; NASAL

N40015 001
 APR 29, 1993
 N40015 002
 APR 29, 1993
 N40015 003
 APR 29, 1993
 N40015 004
 APR 29, 1993
 N40015 005
 APR 29, 1993
 DDAVP RHONE POULENC RORER 0.01MG/INH
DESOXYSKORTICOSTERONE PIVALATE
*/INJECTABLE/INJECTION/
 /PERCUTEN/
 /CIBA/
 @ CIBA*
 N17922 002
 FEB 06, 1989
 /N08822 001
 N08822 001

DEXAME THASONE

| | | |
|------------------------------|------------------|---|
| <u>ELIXIR; OPAL</u> | | N88997 001 |
| <u>DEXAMETHASONE</u> | | OCT 10, 1986 |
| AA BARRE | <u>0.5MG/5ML</u> | /N88997/001 /N88997/001 /N88997/001 |
| | | /01/16/1986 |
| | | |
| <u>HYDROXYCORTICOSTEROID</u> | | N88254 001 |
| <u>HYDROCORTISONE</u> | | JUL 27, 1983 |
| AA PENNEX PHARMS | <u>0.5MG/5ML</u> | /N88254/001 /N88254/001 /N88254/001 |
| | | /01/27/1983 |
| | | |
| <u>HYDROCORTISONE</u> | | N86678 001 |
| AA | <u>0.5MG/5ML</u> | /N86678/001 /N86678/001 |
| | | |
| | | |

DEXAME THASONE

DESMOPRESSIN ACETATE

SPRAY; METERED; NASAL

N40015 001
 APR 29, 1993
 N40015 002
 APR 29, 1993
 N40015 003
 APR 29, 1993
 N40015 004
 APR 29, 1993
 N40015 005
 APR 29, 1993
 DDAVP
 RHONE POULENC RORER 0.01MG/INH
DESOXYSOCORTICOSTERONE PIVALATE
*/INJECTABLE/INJECTION/
 /PERCUTEN/
 /CIBA/
 @ CIBA*
 N17922 002
 FEB 06, 1989
 /N08822 001
 N08822 001

DEXAMETHASONE

DEXCHIOPHENTRAMINE MALEATE

1262/
2024

/Nid.4561/ded/
NO9561.002

CAPSULE; C

N17425 001
BAKER NORTON SONG
11//NEDPL/NKtg/
/sphg/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '95 - DEC '95

DIAZOXIDE

INJECTABLES: INJECTION

卷之三

15MG/ML
QUAD

HYPERSTAT

SUSPENSION; ORAL
PROGLYCEM
+ BAKER NORTON

DICI QFENAC POTASSIUM

DICLOFENAC SODIUM

SCIENCETECH IN 2011

CAPSULE; ORAL
DYCELL

160254/002
160254/003
N60254 002
N60254 003

MAP 28-1991
N20037 001

10MG
PIONEER PHARMS
JAN 10, 1989

DICYCLOMINE HYDROCHLORIDE

/ 544 / 506

DICUMAROL

N61455 001
N61455 001
EQ 62.5MG BASE/5ML
ED 62.5MG BASE/5ML
DYNAPEN APOTHECON
EPISISTOL

DICLOXACILLIN SODIUM

卷之三

66

DIETHYLSТИLBESTROL

/S/PLADISTYL/ /AG/ML/
/STILBESTROL/
a SQUIBB
a

TABLET, DELAYED RELEASE; ORAL
STILBETIN
/β/ /
a SQUIBB
a

DILTIAZEM HYDROCHLORIDE

| | TABLET; ORAL <u>DILTIAZEM HCl</u> APOTHECON | | 3.0MG |
|------------|---|----|--------|
| N04056 001 | AB | AB | 6.0MG |
| N04056 002 | AB | AB | 9.0MG |
| | | | 12.0MG |
| | | | 15.0MG |
| | | | 20.0MG |
| | | | 24.0MG |

DILTIAZEM HYDROCHLORIDE

| | CAPSULE, EXTENDED RELEASE; ORAL CARDIZEM CD BC + CARDERM | | 12.0MG |
|---------|--|-----|---------|
| > ADD > | BC | BC | 18.0MG |
| > ADD > | BC | BC | 24.0MG |
| BC + | | | 30.0MG |
| > DLT > | /+/ | /+/ | 36.0MG |
| > DLT > | + / | + / | 42.0MG |
| | | | 48.0MG |
| | | | 54.0MG |
| | | | 60.0MG |
| | | | 66.0MG |
| | | | 72.0MG |
| | | | 78.0MG |
| | | | 84.0MG |
| | | | 90.0MG |
| | | | 96.0MG |
| | | | 102.0MG |
| | | | 108.0MG |
| | | | 114.0MG |
| | | | 120.0MG |

DIPHENHYDRAMINE HYDROCHLORIDE

| | CAPSULE; ORAL <u>DIPHENHYDRAMINE HCl</u> /LEFT/ | | 1.5MG |
|---------------------|---|----|----------|
| N20062 001 | AB | AB | 2.5MG |
| AUG 10, 1992 | | | 5.0MG |
| N20062 002 | AB | AB | 10.0MG |
| DEC 27, 1991 | a | a | 20.0MG |
| N20062 003 | | | 40.0MG |
| DEC 27, 1991 | | | 50.0MG |
| /N20062/ /661/ / | | | 60.0MG |
| /APC/ /1.5/ /1.5/ / | | | 70.0MG |
| N20062 004 | | | 80.0MG |
| DEC 27, 1991 | | | 90.0MG |
| /N20062/ /661/ / | | | 100.0MG |
| /APC/ /1.5/ /1.5/ / | | | 110.0MG |
| /N20062/ /661/ / | | | 120.0MG |
| /APC/ /1.5/ /1.5/ / | | | 130.0MG |
| /N20062/ /661/ / | | | 140.0MG |
| /APC/ /1.5/ /1.5/ / | | | 150.0MG |
| | | | 160.0MG |
| | | | 170.0MG |
| | | | 180.0MG |
| | | | 190.0MG |
| | | | 200.0MG |
| | | | 210.0MG |
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| | | | 970.0MG |
| | | | 980.0MG |
| | | | 990.0MG |
| | | | 1000.0MG |

| | CAPSULE, EXTENDED RELEASE; ORAL <u>DISOPYRAMIDE PHOSPHATE</u> /ED 100MG BASE/ | | EQ 100MG BASE |
|------------------|---|----|---------------|
| N20092 001 | AB | AB | 100MG |
| MAY 29, 1992 | | | 200MG |
| /N20092/ /661/ / | | | 300MG |
| /N20092/ /661/ / | | | 400MG |
| /N20092/ /661/ / | | | 500MG |
| N74079 001 | AB | KV | 600MG |
| NOV 30, 1993 | | | 900MG |
| N74079 002 | | | 1200MG |
| NOV 30, 1993 | | | 1500MG |
| N74079 003 | | | 1800MG |
| NOV 30, 1993 | | | 2100MG |
| | | | 2400MG |
| | | | 2700MG |
| | | | 3000MG |
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| | | | 4200MG |
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| | | | 61200MG |
| | | | 61500MG |
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| | | | 62100MG |
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| | | | 72900MG |
| | | | 73200MG |
| | | | 73500MG |
| | | | 73800MG |
| | | | 74100MG |
| | </ | | |

DOXEPIPIN HYDROCHLORIDE

**CONCENTRATE; ORAL
DOXYCYCLINE HCl**

PENNEX PHARMS EQ 10MG BASE/ML
AA //

/ 1951 / 26 / 1988 /

DOXYCYCLINE

CAPSULE; ORAL
DOXYCYCLINE MONOHYDRATE

+ VINTAGE

DIXYCYCLINE HYCLATE

DOXYCYCLINE HYCL

卷之三

PAR

EQ 100MG BASE

DOXY-TABS
3 BACHELIE

THEATER / BOOKS / ENTERTAINMENT / ARTS

EQ 100MG BASE

INJECTABLE TISSUE EXPANDERS

DROPERIDOL / 355

DROPERIDOL

INJECTABLE; INJECTION

| | | | |
|----------------|----------|-----------|----------|
| N71918 001 | /N71918/ | /SOLOPAK/ | 2.5MG/HL |
| JUL 20, 1988 | /AP/ | /AP/ | /AP/ |
| /N71918/ | SOLOPAK | 2.5MG/HL | 2.5MG/HL |
| /JUL 20, 1988/ | | | |

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

EFLORNITHINE HYDROCHLORIDE

ENCATINDE HYDROCHLORIDE

/kæpsjʊl/ /ɔːlɪ/ /ɛk'ærɪd/ /ə/ /brɪstɒl/

| | |
|---------------|--|
| /N18981/004 | |
| /B18981/005 | |
| /N18981/002 | |
| /DEC/24, 1986 | |
| /N18981/003 | |
| /DEC/24, 1986 | |
| N18981 002 | |
| DEC 24, 1986 | |
| N18981 003 | |
| DEC 24, 1986 | |
| N18981 004 | |
| DEC 24, 1986 | |
| 25MG | |
| 35MG | |
| 50MG | |

3 BRISTOL

2

ENOXACIN

TABLET; ORAL
PENETREX
1/4//PARKER/DRUG

RHÔNE POULENC RORER 4000MG

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX
RHONE POULENC RORER 30

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

| | | | | |
|----|-------------------|---------------|--|-----------|
| AP | STERLING MINTHROP | 0.01MS/ML; 2% | LIDOCAINE HCl/M. EPINEPHRINE /BETADINE/ | 3 BEL MAR |
| AP | | 0.02MS/ML; 2% | / | |

EPINEPHRINE; PROCAINE HYDROCHLORIDE

/INJECTABLE/ /ANESTHETIC/
/PROCOCaine/HCl/W/EPD/
/BET/HAR/

ERGOLOID MESYLATES

TABLET; ORAL
HYDERGINE
/SAH'DEE/

© SANDOZ

/6.5MG/
0.5MG

TABLET; SUBLINGUAL
HYDROGENATED ERGOT ALKALOIDS
/ZÉNITH/
666/

| | |
|---------------------|---------------|
| ERGOTAMINE TARTRATE | /N87693/061 |
| TABLET; SUBLINGUAL | /FEB 24, 1983 |
| ERGOMAR | N87693 .001 |
| /715945/ | FEB 24, 1983 |
| AA | LOTUS |
| 661 | /445/ |
| | 2MG |

| | | |
|-------------------------------------|--------|--|
| CAPSULE, DELAYED REL PELLETS; ORAL | | |
| /MERIC/SPIRANKLES/ /+//FAULDING/ | /125MG | |
| 3 FAULDING | | |
| | | |
| GEL; TOPICAL | | |
| ERTGEL /HERBERT/ | /22/ | |
| ATI + HERBERT | 22 | |
| | | |
| ERYTHROMYCIN | | |
| STIEFEL | 22 | |
| | | |
| JAN 29, 1993 | | |
| N65211 001 | | |
| OCT 21, 1987 | | |
| N50593 001 | | |
| JUL 22, 1985 | | |
| /NS65211/651/ /651/1, /1995/ | | |
| /NS65211/651/ /651/1, /1995/ | | |
| | | |
| DISPENSING STATION | | |

93

SUPPLEMENT NUMBER 12 / JAN '95 - DEC'

ERYTHROMYCINOINTMENT; OPHTHALMICERYTHROMYCIN
/P/HARM/AF/ERH/

@ PHARMADERM

/P/HARM/AF/ERH/

@ PHARMAFAIR

/P/HARM/AF/ERH/

ERYTHROMYCINTABLET, COATED PARTICLES; ORALPCE
/P/HARM/AF/ERH/

+ ABBOTT

500MG

333MG

/P/HARM/AF/ERH/

APR 05, 1984

/P/HARM/AF/ERH/

ERYTHROMYCINTABLET, COATED PARTICLES; ORAL

/P/HARM/AF/ERH/

N50611 001

SEP 26, 1983

/P/HARM/AF/ERH/

N62481 001

APR 05, 1984

/P/HARM/AF/ERH/

N62362 001

DEC 17, 1982

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL

ERYTHROMYCIN ESTOLATE

EQ 250MG BASE/5ML

/P/HARM/AF/ERH/

ERYTHROMYCIN ETHYL SUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYL SUCCINATE

EQ 250MG BASE/25ML

/P/HARM/AF/ERH/

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROMYCIN LACTOBIONATE

EQ 500MG BASE/VIAL

/P/HARM/AF/ERH/

ERYTHROMYCIN BASE/VIAL

EQ 1GM BASE/VIAL

GENSIA

EQ 1GM BASE/VIAL

/P/HARM/AF/ERH/

SWAB; TOPICALC-SOLVE²

SYOSSET

AT

/P/HARM/AF/ERH/

LYMPHOMED

AT

/P/HARM/AF/ERH/

NOV 24, 1986

N62604 001

NOV 24, 1986

N62604 002

NOV 24, 1986

JUL 30, 1993

N63253 001

N63253 002

JUL 30, 1993

/P/HARM/AF/ERH/

ESHOLOL HYDROCHLORIDE

ESTROPIPATE

ESTRADIOL

TABLET; ORAL
ESTRACE

TESTROGENS, CONJUGATED

CREAM; TOPICAL, VAGINAL
PREMARIN
+ AYERST
/ / / / / / / / / / / / / /

TABLET; ORAL
CONJUGATED ESTROGENS
1/2/100 mg

/6.645mg/
 /1.5mg/
 /1.5mg/
 /1.5mg/
 PREMARIN
 + HYETH AYERST
 /4/

NO4782 001 NO4782 002

/NOV/29./1984/

/Nb6564/681/

N20216 001
/NBS273/001

七

ETHINYL ESTRADIOL: FIBROUS FILM RATE: MORE THAN ONE ACETATE

| | | |
|---------------------------------------|--|--|
| /+/-/PARKE/DAVIS/ a PARKE DAVIS | /6'-OHESTRA- NOL/ a PARKE/DAVIS/ a PARKE DAVIS | /6'-OHESTRA- NOL/ a PARKE/DAVIS/ a PARKE DAVIS |
| | /6'-OHESTRA- NOL/ 0.05MG; 1IMG | /6'-OHESTRA- NOL/ 0.05MG; 1IMG |
| | /6'-OHESTRA- NOL/ 0.05MG; 1IMG | /6'-OHESTRA- NOL/ 0.05MG; 1IMG |
| | /6'-OHESTRA- NOL/ 0.05MG; 1IMG | /6'-OHESTRA- NOL/ 0.05MG; 1IMG |

ETHINI ESTIMATIO: EVONBEESTBEI

TABLET; ORAL-21
LEVORA 0.15/30-21
SYNTEX

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

ETHINYL ESTRADIOL; LEVONORGESTREL

> ADD > TABLET; ORAL-28
LEVORA 0.15/30-28
SYNTEX 0.035MG;0.15MG
> ADD > AB
> ADD > NORDETTE-28
HYETH AYERST 0.035MG;0.15MG
> ADD >

N73594 001
DEC 13, 1993
N18782 001
JUL 21, 1992

ETHINYL ESTRADIOL; NORETHINDRONE

> ADD > TABLET; ORAL-21
HORETHEN 1/35E-21
ROBERTS 0.035MG;1MG
/AB/ /SCHIFF APPAREL LTD/SEARLE/0.035MG;1MG/
> ADD >

N71480 001
APR 12, 1988
/N17449/061/
/APR/12/1988/
AB/ /SCHIFF APPAREL LTD/SEARLE/0.035MG;1MG/
/APR/

N71481 001
APR 12, 1988
/N17449/061/
/APR/12/1988/
AB/ /SCHIFF APPAREL LTD/SEARLE/0.035MG;1MG/
/APR/

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

> ADD > TABLET; ORAL-28
HORETHEN 1/35E-28
ROBERTS 0.035MG;1MG
/AB/ /SCHIFF APPAREL LTD/SEARLE/0.035MG;1MG/
> ADD >

N71481 001
APR 12, 1988
/N17449/061/
/APR/12/1988/
AB/ /SCHIFF APPAREL LTD/SEARLE/0.035MG;1MG/
/APR/

N71482 001
APR 12, 1988
/N17449/061/
/APR/12/1988/
AB/ /SCHIFF APPAREL LTD/SEARLE/0.035MG;1MG/
/APR/

ETHOSUXIMIDE

> ADD > SYRUP; ORAL
ETHOSUXXIDE
AA COPLEY 250MG/5ML
> ADD >

N81306 001
JUL 30, 1993
AA PARKE DAVIS 250MG/5ML
> ADD >

ETHONOFIBRATE

> ADD > TABLET; ORAL
FELBAMATE
SUSPENSION; ORAL
FELBATOL
+ WALLACE 600MG/5ML
> ADD >

N20189 003
JUL 29, 1993
FELBAMATE
SUSPENSION; ORAL
FELBATOL
+ WALLACE 600MG/5ML
> ADD >

FLUOCINOLONE ACETONIDE

> ADD > CAPSULE; ORAL
LIPIDIL
+ FOURNIER 100MG
> ADD >

N19304 001
DEC 31, 1993
N80258 001
HENTANYL CITRATE

ETHYNODIOL DIACETATE; MESTRANOL

> ADD > TABLET; ORAL-21
DOLLEN-21/
#//SEARLE/
③ SEARLE
/N16629/061/
/N16029 003
> ADD >

N16705 001
APR 20, 1987
/N19545/061/
/APR/20/1987/
> ADD >

FLUOCINOLONE ACETONIDE

> ADD > TABLET; ORAL-28
DOLLEN-28/
#//SEARLE/
③ SEARLE
/N16705/061/
/N16029 003
> ADD >

N16705 001
APR 20, 1987
/N19545/061/
/APR/20/1987/
> ADD >

FLUOXYMESTERONE

TABLET; ORAL
/An'pɪdɒfɪl/
/ɛp̩/ /ɪCN/
/ɛp̩/ a ICN

FLUOXYMESTERONE /floo'kseme'stuhron/
/flu'oksem'esuhron/

2 ICH

FLUPHENAZINE DECANOATE

**INJECTABLE; INJECTION
PROLOTOTH DECANOATE**

FLUPHENAZINE ENANTHATE
INJECTABLE; INJECTION
PROLIXIN ENANTHATE
+ APOTHECIAL
400 mg/

ELEHENEZTNE HYDROCHI DABIE

PROLDTIN CONCENTRATE; ORAL
AA 1666 /SODIUM APOTHECON

INJECTABLES: INJECTION

PROLIFERATION + APOTHECON
/AP/ /SOLIB/

FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL

/T/HE/ET:/EXTEN/DE/WE/TE/SE/1/DE/1/

| | | | |
|----------------------------|---------|--------------------|--|
| N16727 001 /N16727/d61/ | > ADD > | FLUVASTATIN SODIUM | |
| | > ADD > | CAPSULE; ORAL | |
| | > ADD > | LESCOL | |
| | > ADD > | + SANDOZ | |
| | > ADD > | EQ 40MG BASE | |
| | > ADD > | EQ 20MG BASE | |
| | > ADD > | | |
| N16110 001 /N16114/A01/ | > ADD > | | |

EDIT ACCD

INJECTABLE; INJECTION

| | | | | |
|---|-------------------------------------|-----------------------|-----------------------|--|
| N70533 001 NOV 07, 1985 <i>(N70533-001/ 07/07/1985)</i> | > <u>ADD</u> > AP > <u>ADD</u> > | LOCH | EMG/MH | NB1066 001 DEC 29, 1993 |
| TABLET; ORAL | | | | |
| FOLTO ACID /666/ | /BBOTS/ ③ PHARMER AL | /1MG/ 1MG /1MG/ | /1MG/ 1MG /1MG/ | NB4156/666/ NB4156 001 /NB4156/666/ /SE/15/1985 NB8949 001 SEP 13, 1985 |
| N81310 001 APR 29, 1993 | | | ③ PIONEER PHARMS | |
| N12145 003 <i>(N12145-003/ 29/04/1993)</i> | | | | |

/N84/56/661
N84158 001
/N86/64/661
/SEP/13/1985
N88949 001
SEP 13, 1985

GLYBURIDE

TABLET; ORAL

GLYNAZINE /glīnāzē/
glycine /glīsēn/
glycogen /glīkōjēn/
glycoside /glīkōsīd/
glycosuria /glīkōsürēə/
glycine /glīsēn/
glycogen /glīkōjēn/
glycoside /glīkōsīd/
glycosuria /glīkōsürēə/

| | | | | | |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| /1.5MG/ | /3MG/ | 6MG | 1.5MG | 3MG | 4.5MG |
| N20051/04/1992/ | N20051/04/1992/ | N20051/04/1992/ | N20051/04/1992/ | N20051/04/1992/ | N20051/04/1992/ |
| N20051 004 | N20051 001 | N20051 002 | N20051 002 | N20051 002 | N20051 003 |
| SEP 24, 1993 | MAR 04, 1992 | MAR 04, 1992 | MAR 04, 1992 | MAR 04, 1992 | SEP 24, 1992 |

GOSERELIN ACETATE

THREE WAYS TO
MANAGE YOUR
INVESTMENTS

IMPLANT; IMPLANTATION
 ZOLADEX
 + ZENECA
 EQ 3.6MG BASE
GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
 SOLUTION; DROPS; OPHTHALMIC
 $\frac{1}{6t} / \frac{1}{pOH} / \frac{1}{Ned-polyCtH}$
 $\frac{1}{10,000 UNITS/ML} / \frac{1}{10,000 UNITS/ML} / \frac{1}{10,000 UNITS/ML}$
 / 0.025MG/ML; EQ 1.75MG BASE/ML;
 3 DOM

GONADORELIN ACETATE

| | | |
|--|--------------------------|-------------------------------------|
| LUTROPULSE; INJECTION LUTROPULSE KIT + FERRING | 0.8MG/VIAL 3.2MG/VIAL | LUTROPULSE /PLMP/KIT/ +FERRINGS/ |
|--|--------------------------|-------------------------------------|

SEONABOTROPIN, CHOBITONIC

| | | | | | |
|---|--|--|--------------------|---|--|
| INJECTABLE; INJECTION CHORIOIC GONADOTROPHIN /BÉL/MAR/ 3 BEL MAR | /16,666 UNITS/VIAL/ 10,000 UNITS/VIAL/ 5,000 UNITS/VIAL 10,000 UNITS/VIAL | /N17054/661/ /N17054/662/ N17054 001 N17054 002 | > DLT > > ADD > | GUANIDINE HYDROCHLORIDE TABLET; ORAL GUANIDINE HCL /KEY/PHARM/ SCHERING | /N17054/661/ /N17054/662/ N01546 001 |
| INJECTABLE; INJECTION EOLLUTIN /EOLLUTIN/ 3 EOLLUTIN | /16,666 UNITS/VIAL/ 10,000 UNITS/VIAL/ 5,000 UNITS/VIAL | /N17054/661/ /N17054/662/ N17054 001 N17054 002 | > DLT > > ADD > | HALOFANTRINE HYDROCHLORIDE | /N17054/661/ /N17054/662/ N01546 001 |

HOSERELIN ACETATE

IMPLANT; IMPLANTATION
ZOLADEX
+//THIMERAL/CHIEM//
E4/3;SM/045E/
N19/26/001/
/DEC/26/1992/
a SMITHKLINE BEECHAM
250MHC
/JUL/24/1992/
N20250 001
JUL 24, 1992

HYDROCHLOROTHIAZIDE : LABETALOL HYDROCHLORIDE
TABLET; ORAL
HYDROCHLOROTHIAZIDE
PHARME RAL

TABLET; ORAL
HYDROCHLOROTHIAZIDE
PHARMERAL

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE
 TABLET; ORAL
MORPOZIDE
 /SCHERINGER/
 /
 /
 /
 /
 /
 /
 + SCHERING

| | | | | | | |
|------------|-------------|-------------|-------------|------------|------------|------------|
| 25MG;200MG | /25MG;100MG | /25MG;100MG | /25MG;100MG | 25MG;100MG | 25MG;200MG | 25MG;300MG |
| | /GLAXO | /GLAXO | /GLAXO | | | |
| | | | | e GLAXO | e | e |
| | | | | | | |

HYDROCHLOROTHIAZIDE: LISINOPRIL

TABLET; ORAL
PRAZILOE 10-12.5
MERCK

PROZESSID: 20-12-5
/14:54:56 / 2006/
/HERCK/ /BENEDICTE 14.2/

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL
PRINZIDE 20-25
+ MERCK

| | |
|---------------------------------|----------------|
| <u>ZESTORETIC</u> 10-12. AB | <u>ZENECA</u> |
| <u>ZESTORETIC</u> 20-12. AB | <u>ZENECA</u> |
| <u>ZESTORETIC</u> 20-25 AB | <u>ZENECA</u> |
| <u>ZESTORETIC</u> 20/12. AB/ | <u>ZENECA/</u> |
| <u>ZESTORETIC</u> 20/25 AB/ | <u>ZENECA/</u> |

TABLET: ORAL

SPINOKOACTONE TM / TITROUCH COROTONE
a UPSPHER SMITH / 25MG; 25MG;
a UPSPHER SMITH 25MG; 25MG

HYDROCHLOROTHIAZIDE; TRIAMTERENE

N19778 002
FEB 16, 1989
/N19778/6664
/FEB 16, 1989

N19778 002
FEB 16, 1989

| | |
|------------------------------|-----------------------------|
| /N19888 003 /FEB/16/1989 | NOV 18, 1993 |
| N19888 001 SEP 20, 1990 | N19888 002 JUL 20, 1989 |
| /SFR/26/1989 /JUL/26/1989 | /N19888 001 /JUL/26/1989 |

/NBB7553/001/
NBB7553 001

HYDROCORTISONE

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

/N64664/664/
NO9864/001

LOTION; TOPICAL
ACTICORT
BAKER NORTON
AT / KEY/PHACNS/
/ BALNEOL-HC/
/ SOLVNT/

OINTMENT; TOPICAL

HYDROCORTISONE ACETATE; NEOMYCIN SULFATE

RIAL CO., 1772
 /N60751/001/
 /FEB/09/1987/
 N60751 001
 FEB 09, 1987
 OINTMENT; TOPICAL
 NEO-CORTEF
 /^{1/2} SNG/
 a UP JOHN
 /^{1/2} SNG/ BASE/GM
 /^{1/2} SNG/ BASE/GM
 2.5%EQ 3.SNG BASE/GM
 a
 /N60751/001/
 /N60751/001/
 N60751 001
 /N60751/001/
 N60751 003

BX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

HYDROCHLOROTHIAZIDE : PAMOXETINE ACETATE

LOTION; TOPICAL
PRAMOSONE /fərn'däl'ē/
a FERNDALE

HYDROCORTISONE BUTYRATE
/dītrōkôrt'ēsōn büt'ērāt/
/hīdrōkôrt'ēsōn büt'ērāt/
/hīdrōkôrt'ēsōn büt'ērāt/

GALDERMA

HYDROFLUMETHIAZ

TABLET; ORAL

SALURON

AB//+/ERISTOL/

AB + ROBERTS

HYDROXYLIC ACID

HYETH AYERST
25MG/ML
50MG/ML

SYRUP; ORAL
HYDROXYZINE HCL
BARRE

10454A / 10454B
PENNEX PHARMS
10454-5H
10454C / 10454D
N11444/0001
N11449 001

| | | | |
|---------|-------|----------|--------|
| /NB6164 | /661 | NB8785 | 001 |
| /MAP31 | /1981 | FEB 03, | 1988 |
| /NB6165 | /661 | /NB6165 | /661 |
| /MAP31 | /1983 | /FEB 03, | 1/1988 |
| /NB6158 | /661 | NB7294 | 001 |
| /NB6258 | /662 | APR 12, | 1982 |
| NB6258 | 001 | /NB7164 | /661 |
| NB6258 | 002 | /APR 12, | 1/1982 |

TABLET; ORAL
HYDROXYZINE HCL
/CHELSEA/

/CHELSEA/
a CHELSEA
a a a

HYDROXYZINE PAMOATE

N86827
N86829
N86836

/N86644d/d61/
 /JUL_01/1982/
 /N86705/d61/
 /JUL_01/1982/
 N86840 001
 JUL 01, 1982
 N86705 001
 JUL 01, 1982

CAPSULE; ORAL
HYDROXYZINE PAKOATE

| | | |
|---------------|-----------|-----------|
| > DLT > ADD > | /CHELSEA/ | /CHELSEA/ |
| > DLT > | | |
| > DLT > ADD > | | |
| > DLT > | | |
| > ADD > | | |

N866840 001
N86705 001
JUL 01, 1982
JUL 01, 1982

N88184 001
MAR 31, 1983
N88185 001
MAR 31, 1983

50MG/ML

IBUPROFEN

INDOHE THACIN

INDOMETHACIN

| LACTULOSE | | SOLUTION; ORAL | | INJECTABLE; INJECTION | | LEUCOVORIN CALCIUM | | POWDER FOR RECONSTITUTION; ORAL | | TABLET; ORAL | | LEUPROLIDE ACETATE | |
|------------------------|----------------------------|----------------|--------------|-----------------------|--------|---------------------------------|--------------|---------------------------------|----|--------------|--------------------|--------------------|--|
| /66/ | /CEPHALAC/ MERRILL DOH/ | /10GM/15ML/ | /N11454/661/ | AB | GENSIA | EQ 50MG BASE/VIAL | N81278 001 | /N11454/661/ | AP | IMMUNEX | EQ 60MG BASE/VIAL | N08107 003 | |
| /66/ | /ENULOSE/ BARRE/ | /10GM/15ML/ | /N11454/661/ | AA | COPLEY | EQ 100MG BASE/VIAL | SEP 28, 1993 | /N11454/661/ | AP | IMMUNEX | EQ 100MG BASE/VIAL | SEP 28, 1993 | |
| | EVALOSE | 10GM/15ML | N73497 001 | > ADD > | | POWDER FOR RECONSTITUTION; ORAL | MAY 28, 1993 | > ADD > | | IMMUNEX | EQ 60MG BASE/VIAL | JAN 30, 1987 | |
| | | | N71841 001 | > ADD > | | LEUCOVORIN CALCIUM | SEP 22, 1988 | > DLT > | | | EQ 100MG BASE/VIAL | N81277 001 | |
| | | | SEP 22, 1988 | > DLT > | | | /N11454/661/ | | | /FOLIC ACID/ | /N11454/661/ | SEP 28, 1993 | |
| | | | /N11454/661/ | | | | /N11454/661/ | | | /FOLIC ACID/ | /N11454/661/ | | |
| | LACTULOSE | 10GM/15ML | N73686 001 | AB | + | POWDER FOR RECONSTITUTION; ORAL | MAY 28, 1993 | AB | + | IMMUNEX | EQ 10MG BASE | N71962 001 | |
| 3 PENNEX PHARMS | | 10GM/15ML | N73685 001 | BX | | LEUCOVORIN CALCIUM | MAY 28, 1993 | BX | | | EQ 10MG BASE | NOV 19, 1987 | |
| /66/ | /PHARM/BASICS/ | /10GM/15ML/ | N71548 001 | /AB/ | | | AUG 15, 1988 | /AB/ | | /FOLIC ACID/ | EQ 15MG BASE | N71104 001 | |
| | | | N71842 001 | /BX/ | | | SEP 27, 1988 | /BX/ | | /FOLIC ACID/ | EQ 5MG BASE | MAR 04, 1987 | |
| | | | N72734 001 | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | N18459 001 | |
| | LACTULOSE | 10GM/15ML | N72735 001 | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | JAN 30, 1986 | |
| 3 TECHNILAB | | 10GM/15ML | N72736 001 | | | | | | | /FOLIC ACID/ | EQ 5MG BASE | /N11454/661/ | |
| SOLUTION; ORAL, RECTAL | | | N73504 001 | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | /N11454/661/ | |
| ACTILAC | | | MAY 28, 1993 | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | /N11454/661/ | |
| TECHNILAB | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | /N11454/661/ | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | N72734 001 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | FEB 22, 1993 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | N72735 001 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | FEB 22, 1993 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | N72735 001 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | FEB 22, 1993 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | N72736 001 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | FEB 22, 1993 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | N72736 001 | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 25MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 10MG BASE | | |
| | | | | | | | | | | /FOLIC ACID/ | EQ 15MG BASE | | |
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LEUPROLIDE ACETATE

INJECTABLE; INJECTION

LUPRON DEPOT
+ TAP

3.75MG/VIAL

7.5MG/VIAL

/3.75MG/VIAL/

LUPRON DEPOT-PED
+ TAP

3.75MG/VIAL&7.5MG/VIAL

7.5MG/VIAL&7.5MG/VIAL

/3.75MG/VIAL/

7.5MG/VIAL

/3.75MG/VIAL/

LEVOCABASTINE HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

LIVOSTIN

+ IOLAB EQ 0.05% BASE

LEVOMETHADYL ACETATE HYDROCHLORIDE

CONCENTRATE; ORAL

ORLAAM

BIO DEVELOPMENT 10MG/ML

LEVONORDREPHRINE HYDROCHLORIDE; PROPOXYCAINE HYDROCHLORIDE

/INJECTABLE; INJECTION/

/RAVOCATINE AND NOXOCATINE/

/COOK/WALTE/

③ STERLING WINTRROP

0.05MG/ML; 22; 0.4%

LIDOCANE

/SUPPOSITORIES; RECTAL/

/ASTRA/

/1.69MG/

LIDOCAINE/SUPPOSITORIES; RECTAL/
/X-LIDOCANE/

③ ASTRA

100MG

N13077 001

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

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③ ABBOTT

10%

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③ BEL MAR

1%

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

LIDOCAINE HYDROCHLORIDE

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LIDOCAINE

/SUPPOSITORIES; RECTAL/

③ ASTRA

100MG

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LORATADINE

TABLET; ORAL
CLARITIN
+ SCHERRING

N19658 001
APR 12, 1993
10MG

TABLET; ORAL
LORAZEPAM

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LORAZEPA
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MAFENIDE ACETATE

CREAM; TOPICAL
SULFAMYLYON
HICKAM
4-4-6-6-1-1-1-1

MANGANESE SULFATE

INJECTION
MANGANESE SULFATE
FUJISAWA

/Lý thuyết

MANINTOL

MANHETTOL 10% IN PLAS

MAY

31

MANNITO

N19658 001
AND 12 1997

| | | |
|------------------------------|--|-------------------|
| <u>INJECTABLE; INJECTION</u> | <u>MANNITOL 20% IN PLASTIC CONTAINER</u> | <u>5GM/100ML</u> |
| <u>AP</u> | <u>MCGAN</u> | <u>20GM/100ML</u> |
| <u>AP</u> | <u>MCGAN</u> | <u>5GM/100ML</u> |

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|-------------|--------------|
| /N70675/001 | DEC 01, 1986 |
| pfc | N70676/001 |
| /N70676/001 | DEC 01, 1986 |
| pfc | N70677/001 |
| /N70677/001 | DEC 01, 1986 |
| pfc | N70678/001 |
| /N70678/001 | DEC 01, 1986 |

N119228 001
MAY 05, 1987
/N119228/001/
/N119228/05/1987/

JUL 26, 1993
N20006 003

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| <u>AP</u> | <u>AP</u> | <u>MANNITOL 20% IN PLASTIC CONTAINER MCGM</u> | <u>MANNITOL 5% IN PLASTIC CONTAINER MCGM</u> |
| <u>N2</u> | <u>JUL</u> | <u>20GM/100ML</u> | <u>5GM/100ML</u> |

| | | | |
|--------------------------|---|-----|---------------|
| <u>MASOPPROCOL</u> | CREAM; TOPICAL ACTINEX + BLOCK DRUG | 10% | /i://chEHEH// |
| <u>MEGESTROL ACETATE</u> | SUSPENSION: ORAL N1 SEP 0 /N1 /sep/ | | |

| | | | | | |
|--|----------------------------------|--|---|---|-------------------------------------|
| INJECTABLES SINKAYE ROCHE | 3 3 3 | 10MG./ML. 37.5MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | NO NO NO |
| INJECTABLES SINKAYE ROCHE | 3 3 3 | 10MG./ML. 37.5MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | NO NO NO |
| INJECTABLES SINKAYE ROCHE | 3 3 3 | 10MG./ML. 37.5MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | NO NO NO |
| INJECTABLES SINKAYE ROCHE | 3 3 3 | 10MG./ML. 37.5MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | 5MG./ML. 10MG./ML. 37.5MG./ML. | NO NO NO |

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE
 AA PENNEX PHARMS 10MG/5ML
 /66/ /PENNEX/66545/ /10MG/5ML/

N71656 001
 OCT 13, 1987
 /N71656/661/
 /OCT 13/1987/

N07390 001
 /N07390/661/

METHANTHELINE BROMIDE

TABLET; ORAL
BANTHINE
 ROBERTS
 /SCHIAPPARELLI/SERAFILO/50MG/

N07390 001
 /N07390/661/

METARAMINOL BITARTRATE

INJECTABLE; INJECTION
METARAMINOL BITARTRATE
 AP FUJISAWA EQ 10MG BASE/ML
 AP EQ 10MG BASE/ML
 /AP/ /LPHD/ EQ 10MG BASE/ML
 /AP/ EQ 10MG BASE/ML
 /EQ 10MG BASE/ML/

N80431 001
 N80722 001
 /N80431/661/
 /N80722/661/
 JUN 30, 1993
 N40001 002
 N40001 002
 JUN 30, 1993
 N40036 001
 N40036 002
 JUN 30, 1993
 N40036 002
 JUN 30, 1993

METHAZOLAMIDE

TABLET; ORAL
METHAZOLAMIDE
 AB COPLEY 25MG
 AB 50MG
 AB GENEVA 25MG
 AB 50MG
 AB NEPTAZANE 25MG
 AB LEDERLE 25MG
 AB + 50MG

N40001 001
 JUN 30, 1993
 N40001 002
 JUN 30, 1993
 N40036 001
 JUN 30, 1993
 N40036 002
 JUN 30, 1993

METHADONE HYDROCHLORIDE

TABLET; ORAL
METHADONE
 AA MALLINCKRODT 5MG
 AA 10MG
 AA N40050 001
 APR 15, 1993
 N40050 002
 APR 15, 1993
 N40050 001
 APR 15, 1993

N17058 001
 N74184 001
 APR 29, 1993

METHICILLIN SODIUM

INJECTABLE; INJECTION
STAPHICILLIN
 + APOTHECON
 +
 /BRISTOL/

EQ 900MG BASE/VIAL
 EQ 3.6GM BASE/VIAL
 EQ 5.4GM BASE/VIAL
 /Eq/5.4GM/BASE/VIAL/
 /Eq/3.6GM/BASE/VIAL/
 /Eq/5.4GM/BASE/VIAL/
 /Eq/5.4GM/BASE/VIAL/
 /Eq/5.4GM/BASE/VIAL/
 /Eq/5.4GM/BASE/VIAL/

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL
 /66/ /BETHAMPEX/
 /LEMONT/ 10MG
 @ LEMON
 /66/ /LEMONT/ 5MG
 @ LEMON /10MG/
 /66/ /REXAR/
 REXAR
 /N83889/661/
 N83889 001
 /N83889/661/
 /66/ /FERNDALE/
 @ FERNDALE
 /66/ /NYLOS TRADING/
 /PHARMA/ 750MG
 /500MG/
 /500MG/
 3 PHARMERAL
 NB4471 002
 NB4471 001

METHOCARBAMOL

TABLET; ORAL
 /66/ /DELATH/
 /66/ /FERNDALE/
 @ FERNDALE
 /66/ /NYLOS TRADING/
 /PHARMA/ 750MG
 /500MG/
 /500MG/
 3 PHARMERAL
 NB4471 002
 NB4471 001

N85454 001
 /N85454/661/
 N85454 001
 /N85454/661/
 /N8471/661/
 NB4471 002
 NB4471 001

NALOXONE HYDROCHLORIDEINJECTABLE; INJECTION

NARCAN
/A&/ /DUPONT/ /6.4H6.4H/

/A&/ /1M6.2H/ /1M6.2H/

/A&/ /1M6.2H/ /1M6.2H/

/A&/ ^③ DUPONT 0.4MG/ML

1MG/ML

NITROFURANTOIN

NOTABILITATI IN HYDROCHI OVIDE

TABLET; ORAL
NITROFURANTOIN
/ZENITH/

NITROFURANTOIN; NITROFURANTOIN; MACROCRYSTALLINE

APSULE; ORAL
MACROBID

/CAPSULE / EXTENDED RELEASE / DRUG /
/ MICRODID /
/ + / P AND S /
/ STMS : 25% /

NITROFURANTOIN: MACROCRYSTALLINE

CAPSULE; ORAL
NITROFURANTOIN
ZENITH

MITROGI VCEBTW

INJECTABLE; INJECTION
NITRO-BID
/Harrington/Harrington/bid

ବିଜ୍ଞାନ

/BRISTOL/HYDERS/SCOTT/ /100,000 UNITS/

CAPSULE; ORAL
MORTIPITYLINE HEL

| | | | |
|----|--------------|---------------------|--------------|
| AB | <u>MYLAN</u> | <u>EQ_10MG BASE</u> | N74224 001 |
| AB | | <u>EQ_25MG BASE</u> | JUL 26, 1993 |
| AB | | <u>EQ_50MG BASE</u> | N74224 002 |
| AB | | <u>EQ_75MG BASE</u> | JUL 26, 1993 |
| AB | | | N74224 003 |
| | | | JUL 26, 1993 |
| | | | N74224 004 |
| | | | JUL 26, 1993 |

N20064 001
DEC 24, 1991

/N40064/001/
/PFC/24/1991

JAN 28, 1993
N73652 001
N73671 001

N71159/001
FEB 28, 1990
N71159 001

**CREAM; TOPICAL
HYSTATH**

AT BARRE /Nashka/
AT TARO

OINTMENT; TOPICAL

N62489 001
APR 27, 1988

N61533 001
/N61533/661/
N62571 001
OCT 29, 1985
/N62571/661/
/N62571/29, 1985

MYSTIN

RX DRUG PRODUCT LIST / CLINICAL STUDY ELEMENT

| SUSPENSION; ORAL | | INJECTABLE; INJECTION | |
|------------------|---------------|----------------------------|-----------------------------|
| <u>HYSTATIN</u> | | SANDOSTATIN | |
| AA | PENNEX PHARMS | / <i>pH4t5h/β4t5t5t5/</i> | / <i>t5/t5t5h/β4t5t5t5/</i> |
| | ② | 100,000 UNITS./ML | 100,000 UNITS./ML |
| | | 100,000 UNITS./ML | 100,000 UNITS./ML |
| | | / <i>t5t5t5h/β4t5t5t5/</i> | / <i>t5t5t5h/β4t5t5t5/</i> |
| | | / <i>t5t5t5h/β4t5t5t5/</i> | / <i>t5t5t5h/β4t5t5t5/</i> |
| | | / <i>t5t5t5h/β4t5t5t5/</i> | / <i>t5t5t5h/β4t5t5t5/</i> |
| | | / <i>t5t5t5h/β4t5t5t5/</i> | / <i>t5t5t5h/β4t5t5t5/</i> |
| | | / <i>t5t5t5h/β4t5t5t5/</i> | / <i>t5t5t5h/β4t5t5t5/</i> |
| | | 100,000 UNITS./ML | 100,000 UNITS./ML |
| | | / <i>pH4t5h/β4t5t5t5/</i> | / <i>pH4t5h/β4t5t5t5/</i> |
| ③ | PHARMADERM | | |

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THEATRE CANADIEN

JUN 12, 1991
CREAM; TOPICAL

HYSTATIN AND TRIAMCINOLONE ACETONIDE

100,000 UNITS/GM; 0.1%
BANKE
N63010 001
OFLOXACIN

DEC 20, 1988

SOLUTON DROPS, OPHTHALMIC

NYSTATIN-TRIMECINOLOLNE ACETOICIDE

100,000 UNITS/GR. 0.1% HAZARD

A DHAARMIC ROMANCE 25

1990-1991
1991-1992
1992-1993
1993-1994
1994-1995
1995-1996
1996-1997
1997-1998
1998-1999
1999-2000
2000-2001
2001-2002
2002-2003
2003-2004
2004-2005
2005-2006
2006-2007
2007-2008
2008-2009
2009-2010
2010-2011
2011-2012
2012-2013
2013-2014
2014-2015
2015-2016
2016-2017
2017-2018
2018-2019
2019-2020
2020-2021
2021-2022
2022-2023
2023-2024

SOCIETY FOR POLYMER SCIENCE

CAPSULE; ORAL

HISTATIN AND TOTAMCTYLONE AND POLY-
PROSTAPHILIN

N61450 001
EQ 250MG BASE
APOTHECIAL

MAR 29, 1993
N61450 00
50-510015 BAS

> DLT > AB

/AB

NE0118 002 BASE EQ 500MG BRISOL

POWDER FOR RECONSTITUTION: ORAL

PROSTAPHILIN

N61457 001
EQ 250MG BASE/5ML
APU HECON

150104/001

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAXIL
/P/A/X/I/L
/P/E/T/H/I/L/E/E/T/H/I/L/
/E/G/J/D/H/S/B/A/S/E/
/E/G/J/S/D/H/S/B/A/S/E/
/A/

| | | |
|---|--------------------|--|
| 3 | SMITHKLINE BEECHAM | EQ 10MG BASE /EQ/40HS/BSSE/ EQ 40MG BASE EQ 50MG BASE |
| 3 | | |
| 3 | | |

/TABLET/CH4/
/BICILLIN/
/+//WYETH/Ayerst/
a WYETH AYERST

PENICILLIN G POTASSIUM

POWDER FOR RECONSTITUTION; ORAL
PENTETEETH

| | | | |
|------|-----------------------|--------------------|------------------------------------|
| /66/ | <u>BIOCRAFT</u> | /666,000 UNITS/5HL | /664,567/664/ 200,000 UNITS/5HL |
| /66/ | <u>IDENTIS '4664'</u> | /666,000 UNITS/5HL | /664,567/664/ 200,000 UNITS/5HL |
| /66/ | <u>SQUISHB/</u> | /666,000 UNITS/5HL | /664,567/664/ 200,000 UNITS/5HL |
| /66/ | <u>APOTHECON</u> | /666,000 UNITS/5HL | /664,567/664/ 400,000 UNITS/5HL |

TABLET; ORAL
PENICILLIN G POTASSIUM
© APOTHECON
SQUIBER

PENICILLIN G POTASSIUM

| TABLET; ORAL | |
|---|---|
| /AB/ /PENTI'DS '6664/ /SC17BP/ | /666,666 UNITS/ 200,000 UNITS |
| /AB/ a APOTHECON /PENTI'DS '6664/ /SC17BP/ | /250,000 UNITS/ 250,000 UNITS |
| /AB/ a APOTHECON /PENTI'DS '6664/ /SC17BP/ | /400,000 UNITS/ 400,000 UNITS |
| /AB/ a APOTHECON /PENTI'DS '6664/ /SC17BP/ | /600,000 UNITS/ 800,000 UNITS |
| /AB/ a APOTHECON /PENTI'DS '6664/ /SC17BP/ | /600,000 UNITS/ 800,000 UNITS |
| N20031 001 DEC 29, 1992 /N20031 005 /PENTI'DS '6664/ /SC17BP/ | N2155 001 Ne2155 001 N20031 005 DEC 29, 1992 N20031 006 DEC 29, 1992 |

| | | | | |
|------------------------------|---|-------------------|---------------------|--|
| <u>PENICILLIN G PROCAINE</u> | INJECTABLE; INJECTION /PENICILLIN G, S/I/ a LILLY | /300,000 UNITS/ML | <u>PENICILLIN V</u> | /PENICILLIN V POTASSIUM /125MG/0.5ML a LILLY |
| | | | | |
| | | | | |
| | | | | |

| | |
|----------------------------------|------------------|
| POUNDER FOR RECONSTITUTION; ORAL | |
| /VETENUS '1125'/ | /VETENUS '1125'/ |
| /AA/ BB/ | /AA/ BB/ |
| 3 APOTHECON | 3 APOTHECON |
| /VETENUS '1125'/ | /VETENUS '1125'/ |
| /AA/ BB/ | /AA/ BB/ |

PENICILLIN G PROCAINE

INJECTABLE; INJECTION
/64/ ~~DRUGS~~ / ~~144, \$1/~~
e LILLY

PENICILLIN V
/PENICILLIN V FOR PEDIATRIC SUSPENSION / DRUG /
LILLY / 125 MG/50 ml
125 MG/50 ml

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION: QBAI

//N621266//6661/
//N621253//6661/
N61206 001
N62153 001

//N621266//6662/
//N621253//6662/
N61206 002
N62153 002

/N62153/001/

N62153 001

N82153 001

N62153 002

/N62153/DPZ/

N62153 002

PENICILLIN V POTASSIUM

ADD > PERINDOPRIL ERBUMINE

PENTETATE CALCIUM TRISODIUM YB-169

/INJECTABLE/ INJECTION /
/STEREOTAXIC/ /B16.5/pTA/ /Anti-HL/
/SH/ 2MC/ML
② 3M

PENTOBARBITAL SODIUM

INJECTABLE; INJECTION
/PENTODIASTYL SODIUM/ /5662HL/
/ELKINS SAIN/ FORT WORTH, TEXAS

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LIQUID; ORAL
IMAGENT
+ ALLIANCE PHARM
100%

• ADD > PERINDOPRIL ERBUMINE

N17518 001

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL
STATDEX/
LEMON/
166/ 3 LEMON

TABLE I; URAL

| | | | |
|------|---|-------------------|-------------------------------|
| /AA/ | / FERNDALE / a FERNDALE | / 35MG / 3.5MG | / N836222 001 / N83655 001 |
| /BB/ | / BELFEST / a BELFEST | / 35MG / 3.5MG | / N83744 664 / N83790 002 |
| /CC/ | / SOLVAY / a SOLVAY | / 35MG / 3.5MG | / N83754 661 / N83754 001 |
| /DD/ | / METRA / a FOREST PHARMS | / 35MG / 3.5MG | / N86626 661 / N86620 001 |
| /EE/ | PHENDIETRAZINE TARTRATE / ANADOLIC / a ANABOLIC | / 35MG / 3.5MG | / N86626 661 / N86620 001 |

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'93 - DEC'93

66

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

/66/ PHENDIMETRAZINE TARTRATE
/FERNDALE//66/ 35MG
③ FERNDALE/66/ /dénéV/
③ SOLVAY/66/ TABLET; EXTENDED RELEASE; ORAL
/PREUDIN/
② BOEHRINGER INGELHEIM 75MG/66/ PHENTERMINE HYDROCHLORIDE/66/ /LEMON/
/66/ /OBESTIN-36/
/66/ /FERNDALE/
③ FERNDALE/66/ PHENTERPOTHE HCL/66/ /LEMON/66/ /PHARM/BASICS/

③ PHARM BASICS

/66/ /ZENITH/

③ ZENITH

CAPSULE; ORAL

/66/ ADIPEX-P
/66/ /LEMON//66/ /OBESTIN-36/
/66/ /FERNDALE/
③ FERNDALE/66/ 30MG/66/ /30MG/

③ DANBURY PHARMA

/66/ /30MG/

③ GENEVAV

/66/ 100MG/66/ TABLET; ORAL
/66/ /30MG/
③ GEIGYPHENYLBUTAZONE

TABLET; ORAL

/66/ PHENYLBUTAZONE
/BARR//66/ 100MG
+ BARR/66/ /CHELSEA/
③ CHELSEA/66/ /GENEVAV/
③ GENEVA/66/ TABLET; ORAL
/66/ /GEIGY/
③ GEIGY/66/ 100MG/66/ 100MG

SYRUP; ORAL

③ PENNEX PHARMS

/66/ PROMETHAZINE VC PLATE

5MG/5ML

6.25MG/5ML

/5ML

TABLET; ORAL

③ PENNEX PHARMS

/66/ PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

/66/ PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

/5ML

CAPSULE; ORAL

③ PARKE DAVIS

/66/ PHENYLBUTAZONE/66/ /GEIGY/

③ GEIGY

/66/ 100MG

> DLT >

> ADD >

PHENYTOIN SODIUM, PROMPT

| | | | |
|--|-----------------|--|------------------------|
| CAPSULE; ORAL PHENYTOIN SODIUM 1/2 PHARMACIST a PHARMERAL | 16645/ 100MG | INJECTABLE; INJECTION AQUAMEPHYTON 1/165/1ML/ 10MG/ML | 16645/1ML/ 10MG/ML |
| | | | /16645/1ML/ 10MG/ML |
| | | | /16645/1ML/ 10MG/ML |

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

| | | | | | |
|-----------------------|------------------|---------------------------------|-----------------------|--------------|---------------------|
| INJECTABLE; ORAL | PHENYTOIN SODIUM | /16645/ 100MG 3 PHARMERAI | INJECTABLE; INJECTION | AQUAMEPHYTON | /16645/ 100MG/ML |
| CAPSULE; ORAL | PHENYTOIN SODIUM | /16645/ 100MG 3 PHARMERAI | INJECTABLE; INJECTION | KONAKION | /16645/ 100MG/ML |
| INJECTABLE; INJECTION | ZOSYN | /16645/ 100MG 3 PHARMERAI | INJECTABLE; INJECTION | ROCHE | /16645/ 100MG/ML |
| INJECTABLE; INJECTION | LEDERLE | /16645/ 100MG 3 PHARMERAI | INJECTABLE; INJECTION | DTDOXICAM | |

> ADD >
> DLT >

**INJECTABLE; INJECTION
MITHRACIN**

2. ENGLISH/ITALIAN
/ ENGLISH/ITALIAN
/ N50109 001 /

POLY(ETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; UKA_L
PEG-LYTE INVAMED 236GM/1

5.86GM/BOT; 22.74GM/BOT N73098 001
AUG 31, 1993

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

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SOLUTION/DROPS; OPHTHALMIC
POLYTRIM
ALLERGAN
10,000 UNITS/ML;
EQ 1MG BASE/ML
/05/05/05/05/05/05/
/05/05/05/05/05/05/
N50567 001
OCT 20, 1988
/N50567 001/
/05/05/05/05/05/05/

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
 K-LEASE
/ADRIA/
 /AB/
 /AB/
 AB
 SAVAGE
 AB
BMEQ
/10 MEQ

INJECTABLES: INJECTION

| TABLET, EXTENDED RELEASE; ORAL | | <u>K48</u> | ALRA | <u>MEG</u> |
|--------------------------------|---------------------------------|------------|------|-------------------|
| | | | | |
| <u>AB</u> | KAON CL /ADRIA/ SAVAGE | | | /6.7MEG 6.7MEG |
| | KAON CL-10 /ADRIA/ SAVAGE | | | /10MEG 10MEG |

POTASSIUM CITRATE

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| | | | |
|----------------------------|---|---|--|
| N50567 001 OCT 20, 1988 | ③ UNIV TX <i>/PDR/PR/RECONSTITUTION; /ORAL/ /KOTASSIUM CITRATE/ /+//UNIV/TX/</i> | 10MEQ/PACKET <i>/20MEQ/PACKET/ /10MEQ/PACKET/ /20MEQ/PACKET/</i> | N19647 001 N19647 002 N19647 001 N19647 001 N19647 002 N19647 001 N19647 001 N19647 001 |
| | | 20MEQ/PACKET ③ | OCT 13, 1988 OCT 13, 1988 OCT 13, 1988 |

PRAVASTATIN SODIUM

TABLET; ORAL
 PRAVACHOL
 /#//BRISTOL/MYERS/SQUIBB/ 20MG/
 + BRISTOL MYERS SQUIBB 40MG
 20MG
 N84290 001
 N87787 001
 APR 20, 1982
 /#0421/001/
 /#0436/001/
 N80221 001
 N80236 001
 /#//31/1991/
 /#//31/1991/
 N19898 004
 MAR 22, 1993
 N19898 005
 OCT 31, 1991

PRAZEPAM
 /PRAZEPAM/
 /CAPSULES//ORAL/
 /CENTRAL/
 /+ PARKE DAVIS/
 /
 /10MG/
 /20MG/
 /
 /5MG/
 5MG
 3 PARKE DAVIS
 3
 3
 > DLT ^
 > DLT ^
 > DLT ^
 > DLT ^
 > ADD ^
 N70998 001
 JAN 25, 1993
 /N17646/661/
 N17046 001
 /N17646/662/

1/1645 /PARKE DAVIS/
CENTAX /TABELET /DRAZI /
/N17445/0001/

PREDNISONE

TABLET; ORAL
METICORTEN

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PROCAINAHIDE HYDROCHLORIDE

PROBENECID
TABLETS; ORAL
PROBENECID
PROBENECID
© CHELSEA

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PROCAINAMIDE HYDROCHLORIDE

INJECTABLES; INJECTION

ROCAINE HYDROCHLORIDE: TETRACYCLINE HYDROCHLORIDE

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RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

74

PROPRANOLOL HYDROCHLORIDE

| | | |
|--|-----------------------------------|---|
| TABLET; ORAL PROPRANOLOL HCL <u>/66/ /MYLAN/</u> | <u>/66666/</u> 60MG ② MYLAN | <u>/N72275/666/</u> N72275 001 JUN 09, 1989 |
|--|-----------------------------------|---|

PROPYLIODONE

| | | |
|--|---------------------|-----------------------------------|
| <u>/SUSPENSION/ /ANTIATRACHINAL/</u> /PIRONOSTI/ OIL/ | <u>/666/</u> 60% | <u>/N69366/666/</u> N69366 002 |
|--|---------------------|-----------------------------------|

PROTAMINE SULFATE

| | | |
|--|--------------------------------------|---|
| INJECTABLE; INJECTION PROTAMINE SULFATE <u>/66/ /QUAD/</u> | <u>/166666/</u> 10MG/ML ② QUAD | <u>/N69366/666/</u> N69366 001 MAY 30, 1986 |
|--|--------------------------------------|---|

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

| | | |
|---------------------------------------|--|---|
| SYRUP; ORAL <u>/66/ /HISTAFED/</u> | <u>/166666/666/</u> 30MG/5ML; 1.25MG/5ML ③ CENCI | <u>/N66666/666/</u> N88283 001 APR 20, 1984 |
|---------------------------------------|--|---|

PYRANTEL PAMOATE

| | | |
|---|---|-------------------------------------|
| <u>/SUSPENSION/ /PAM/</u> /ANTIPHTHAL/ | <u>/EQ/75666/666/</u> /EQ/75666/666/ | <u>/N36666/666/</u> /N36666/666/ |
|---|---|-------------------------------------|

PYRIDOSTIGMINE BROMIDE

| | | |
|---|--|-----------------------------------|
| INJECTABLE; INJECTION <u>/66/ /ESTHON/</u> | <u>/166666/</u> 5MG/ML ④ PARKE/DAY | <u>/N69436/666/</u> NO9830 001 |
|---|--|-----------------------------------|

PYRIDOSTIGMINE BROMIDE

| | | |
|---|---|-----------------------------------|
| SYRUP; ORAL MESTINON /ICN/ ROCHE | <u>/66666/666/</u> 60MG/5ML ② LILLY | <u>/N15193/666/</u> N15193 001 |
|---|---|-----------------------------------|

TABLET; ORAL

| | | |
|----------------------------|---------------------------------------|-----------------------------------|
| MESTINON /ICN/ ROCHE | <u>/66666/666/</u> 60MG ② LILLY | <u>/N69624/666/</u> NO9829 002 |
|----------------------------|---------------------------------------|-----------------------------------|

TABLET, EXTENDED RELEASE; ORAL

| | | |
|------------------------------|--|-----------------------------------|
| MESTINON /ICN/ + ROCHE | <u>/16666/666/</u> 180MG ④ ROCHE | <u>/N11665/666/</u> N11665 001 |
|------------------------------|--|-----------------------------------|

PYRIDOXINE HYDROCHLORIDE

| | | |
|--|--|--|
| INJECTABLE; INJECTION <u>/66/ /LILLY/</u> | <u>/166666/666/</u> 100MG/ML ③ LILLY | <u>/166666/666/</u> 100MG/ML ③ LILLY |
|--|--|--|

QUAZepam

| | | |
|---------------------------------------|--|-----------------------------------|
| TABLET; ORAL DORAL /166666/666/ | <u>/166666/666/</u> 15MG + WALLACE | <u>/N6761/666/</u> NB06761 001 |
|---------------------------------------|--|-----------------------------------|

QUINIDINE GLUCONATE

| | | |
|--|--|-----------------------------------|
| TABLET, EXTENDED RELEASE; ORAL /PIRAQUTIN/ /PARKE/DAY/ | <u>/166666/666/</u> 7.5MG FEB 26, 1987 | <u>/N17931/666/</u> N17931 001 |
|--|--|-----------------------------------|

QUINIDINE GLUCONATE

| | | |
|--------------------------------|-------|---------|
| TABLET, EXTENDED RELEASE; ORAL | | |
| <u>PIRAQUIN</u> | | |
| 3 WARNER CHILCOTT | 330MG | |
| | | / 33446 |
| <u>CHLORIDINE GLUCONATE</u> | | |
| <u>CHELSEA</u> | | |
| 3 CHELSEA | 324MG | |
| | | / ADD > |
| | | / ADD > |
| | | / ADD > |

RESERPINE; TRICHLORMETHIAZIDE

QUINIDINE SULFATE

SOLVAY

GUTTIDINE SULFATE
/PARKE/DAVIS/
a WARNER CHILCOTT
/A/

TABLET; ORAL
RAUDIXIN APOTHECON
50MG 100MG
500MG / 1000MG

DECEMBER

TABLET; ORAL
RESERPINE
/rɛsə'pīn/
/rɛsə'pīn/
a LEMON

RESERPINE; TRICHLORMETHIAZIDE
TABLET; ORAL
100 mg / 10 mg /
10 mg / 10 mg /
SCHERING
a

N19650 001
SER 17. 1992

SEP 17, 1993

RITODRINE HYDROCHLORIDE

PENTODRTH E HCL / 100ML
10MG/ML

/N70700//001/
/001//001/
N70700 001
OCT 06, 1986

| | | |
|--|-----------|--|
| <u>SOMATROPIN, BIOSYNTHETIC</u> | | <u>SULFACETAMIDE SODIUM</u> |
| INJECTABLE; INJECTION HUMATROPE BX + LILLY | 5MG/VIAL | OINTMENT; OPHTHALMIC <u>/SULFA¹T²A³M⁴E⁵A⁶T⁷/</u> /A ⁸ T ⁹ / /PHARMAFAIR/ N88000 001 DEC 22, 1982 |
| NUTROPIN GENENTECH BX | 5MG/VIAL | 10Z; ③ PHARMAFAIR |
| + 10MG/VIAL | 10MG/VIAL | NO20168 001 NO20168 002 NOV 17, 1993 NOV 17, 1993 NOV 17, 1993 |
| <u>SOYBEAN OIL</u> | | <u>SULFADIAZINE</u> |
| INJECTABLE; INJECTION INTRALIPID 30% KABI | 30Z; | TABLET; ORAL <u>/SULFA¹D²I³A⁴Z⁵E⁶N⁷/</u> /ABBOTT/ ③ ABBOTT |
| > <u>ADD</u> > > <u>ADD</u> > | | N19942 001 DEC 30, 1993 |
| <u>NUTRILIPID 10%</u> AP MCGAH | 10Z; | SULFADIAZINE SODIUM <u>/SULFA¹D²I³A⁴Z⁵E⁶N⁷/</u> /INJECTION/ ③ WYETH AYERST |
| <u>NUTRILIPID 20%</u> AP MCGAH | 20Z; | N19531 001 MAY 28, 1993 > <u>DLT</u> > > <u>DLT</u> > > <u>DLT</u> > > <u>ADD</u> > |
| | | N19531 002 MAY 28, 1993 ③ LEDERLE |
| <u>SPIRONOLACTONE</u> | | <u>SULFAMETHIZOLE</u> |
| TABLET; ORAL SPIRONOLACTONE ③ CHELSEA /66/ ③ UPSHER SMITH/ ③ UPSHER SMITH/ | | TABLET; ORAL <u>/THIOSULF¹YL²/</u> /WYETH AYERST/ 250MG |
| > <u>DLT</u> > > <u>ADD</u> > | | N87078 001 N87554 001 N87554 001 25MG 25MG 25MG |
| INJECTABLE; INJECTION METASTRON MEDI PHYSICS | 1MCU/ML | SULFAMETHOXAZOLE <u>/SULFA¹M²E³TOX⁴A⁵Z⁶O⁷E⁸/</u> ③ ROCHE/ ③ ROCHE |
| | | N20134 001 JUN 18, 1993 1GM |
| <u>STRONTIUM CHLORIDE, SR-89</u> | | <u>SUSPENSION; ORAL</u> |
| INJECTABLE; INJECTION METASTRON MEDI PHYSICS | 1MCU/ML | <u>TRIMETH/SULFA</u> AB BARRE |
| | | 200MG/5ML; 400MG/5ML |
| <u>SUCRALFATE</u> | | N722289 001 MAY 23, 1988 |
| > <u>ADD</u> > > <u>ADD</u> > > <u>ADD</u> > > <u>ADD</u> > | | N72398 001 MAY 23, 1988 |
| SUSPENSION; ORAL CARAFATE + MARION MERRELL DOW | 1GM/10ML | 200MG/5ML; 400MG/5ML |
| | | DEC 16, 1993 |

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL
TRIMETH-SULFA
/NASKA/
/Ab/
/Ab/

TABLET; ORAL
SULFAMETHOX

TABLE I. URAL
SULFISONAZOLE
/HEATHER/
3 HEATHER
/3/PHARMACEUTICAL/
a PHARMERAL

ELLI ETIENNE

/DANTHENYL/PHTHALINIC
/SANTHIN/
© ROCHE

TABLE I, URAL SULTINDAC

| | | | |
|------------------|------------------|------------------------------|---------------|
| | | | <u>150MG</u> |
| /466665; 66665/ | AB | MYLAN | |
| /866665; 166665/ | AB | | <u>200MG</u> |
| 400MG; 80MG | | | |
| | | <u>TACRINE HYDROCHLORIDE</u> | |
| /17d665; 6d61/ | | CAPSULE; ORAL | |
| /Nb3/61/; 1664/ | | COGNEX | |
| /17d665; 6d61/ | | + PARKE DAVIS | |
| /Nb3/61/; 1664/ | | | <u>EQ 40M</u> |
| N70002 001 | NOV 07, 1984 | | |
| | N70000 001 | | |
| | NOV 07, 1984 | | <u>EQ 10M</u> |
| | /N12665; 6d61/ | | |
| | /dc1/; 7/; 1987/ | | <u>EQ 20M</u> |
| | /N13665; 6d61/ | | |
| | /dc1/; 7/; 1987/ | | <u>EQ 30M</u> |
| | N71299 001 | | |
| | OCT 27, 1987 | | |
| | N71300 001 | | |
| | OCT 27, 1987 | | |

TAMOXIFEN CITRATE

TABLET; ORAL
NOLVADEX
1/4//STANDARD/
+ ZENECA

SULFISOXAZOLE DIOLAMINE

SULINDAC

TABLE I, URAL
SULINDAC

| | | | | |
|--------------|--------------|--|--------------|-----------------------------|
| <u>HYLAN</u> | <u>150MG</u> | CAPSULE; ORAL COGNEX + PARKE DAVIS | EQ 40MG BASE | N20070 0004 SEP 09, 1993 |
| <u>B</u> | <u>200MG</u> | | EQ 10MG BASE | N20070 001 SEP 09, 1993 |
| <u>B</u> | | | EQ 20MG BASE | N20070 002 SEP 09, 1993 |
| | | | EQ 30MG BASE | N20070 003 SEP 09, 1993 |

TAMOXIFEN CITRATE

SII E SOVRAZUE ACETI

/EQ/1GM BASE/5ML
EQ 1GM BASE/5ML

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

| | | | |
|--|---|--|--|
| INJECTABLE / INJECTION /BS / K-AM-STANNOUS AGGREGATEP / K-EPIMIN /NORTH AM CHEM / 3 NORTH AM CHEM | AN-MAA BS SORIN /TECHNETIUM/Tc/99m/MAA/ /HEU/PHYSICS/ a MEDI PHYSICS | N/A N/A N/A N/A | N11792 001 /N11792/661/ /N11773 661/ N11773 001 |
|--|---|--|--|

SULFISOXAZOLE DIOLAMINE

SULINDAC
a ROCHE
/SANTRISAN

TABLE I, URAL
SULINDAC

| | | | | |
|--------------|--------------|--|--------------|-----------------------------|
| <u>HYLAN</u> | <u>150MG</u> | CAPSULE; ORAL COGNEX + PARKE DAVIS | EQ 40MG BASE | N20070 0004 SEP 09, 1993 |
| <u>B</u> | <u>200MG</u> | | EQ 10MG BASE | N20070 001 SEP 09, 1993 |
| <u>B</u> | | | EQ 20MG BASE | N20070 002 SEP 09, 1993 |
| | | | EQ 30MG BASE | N20070 003 SEP 09, 1993 |

TAMOXIFEN CITRATE

SII E SOVRAZUE ACETI

| | | | |
|---|---|--|--|
| INJECTABLE; INJECTION <i>\$ / K-N STABLOPS AGGRESEATPE ALBUMIN /</i> <i>\$ / NORTH AM CHEM /</i> <i>a NORTH AM CHEM</i> | ANI-MAA S SORIN <i>\$ / FERCHETUM TC 99m/MAA /</i> <i>\$ / MEDI PHYSICS /</i> <i>a MEDI PHYSICS</i> | N/A N/A N/A N/A N/A | NI 17916/661 / NI 17916 001 NI 17922/661 / NI 17922 001 NI 17773/661 / NI 17773 001 |
|---|---|--|--|

TECHNETIUM TC-99M ALBUMIN MICROSPHERES KIT

TERAZOSIN HYDROCHLORIDE

DLT > DLT > DLT > ADD

TABLET: ORAL
HYTRIN
/i:/ /ɛɒp.tɪ/

TECHNETIUM TC-99M MEDBONATE KIT

TECHNETIUM Tc-99M SODIUM PERTECHNETATE GENERATOR

| EQ | SENG BASE |
|--------|-----------|
| /1616/ | |

TEMAZE PAM

CAPSULE: ORAL
TEHZAPEPAM
DANBURY PHARMA
AB 15MG 200C

TESTOSTERONE

MAY 21, 1993 N71447 001
 MAY 21, 1993 +
 FILM, EXTENDED RELEASE; TRANSDERMAL
 TESTODERM + ALZA 4MG/24HR
 + 6MG/24HR
 N19762 001 OCT 12, 1993
 N19762 002 OCT 12, 1993

INJECTABLE; INJECTION

| | | | |
|----------------|----------|---------------|--------------|
| Δ DLT > | /25MG/ML | 1/864420/001 | NB86420 001 |
| Δ DLT > | /50MG/ML | 1/864419/001 | NB86419 001 |
| Δ ADD > | | 1/864423/1983 | AUG 23, 1983 |
| Δ ADD > | | 1/864423/1983 | AUG 23, 1983 |
| Δ DLT > | | 1/864423/1983 | AUG 23, 1983 |
| Δ DLT > | | 1/864423/1983 | AUG 23, 1983 |
| Δ ADD > | | 1/864423/1983 | AUG 23, 1983 |
| Δ ADD > | | 1/864423/1983 | AUG 23, 1983 |

TESTOSTERONE CYPIONATE

INJECTABLES: INJECTION

| | | | |
|------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| DEPO-TESTOSTERONE | /səʊtə'stərən/ 3 UP JOHN | /səʊtə'stərən/ 3 UP JOHN | /stɛr'ɔɪd/ 3 STERIS |
| TESTOSTERONE CYPIONATE | /tɛstə'stərən sɪpi'ənət/ 3 ADD | /tɛstə'stərən sɪpi'ənət/ 3 ADD | /tɛstə'stərən sɪpi'ənət/ 3 ADD |

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
/Steris/
 100 mg vials
 100 mg vials
 200 mg vials
 a STERIS
 a

TESTOSTERONE PROPIONATE

| | |
|---|-----------|
| INJECTABLE; INJECTION | |
| TESTOSTERONE PROPOXATE /TÉS-tó-SE-trōn PRO-pók-sát/ /TÉS-tó-SE-trōn/PROP-o-kát/ | |
| /Ad/ /AO/ /AO/ | 3 BEL MAR |
| /AO/ /AO/ /AO/ | 3 |
| | 3 |
| > DLT > /Ad/ /AO/ /AO/ | /I/I/I/I/ |
| > ADD > | LILLY |
| | /Stéros/ |
| > DLT > /AO/ /AO/ /AO/ | |
| > DLT > /AO/ /AO/ /AO/ | |
| | STERO |

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '93 - DEC '93

TETRACYCLINE HYDROCHLORIDE

| | | | | | |
|----------------------------|---|-------------------------------------|----------------------------|------------------------------------|----------------------------|
| /N65635/661/ NB5635 001 | CAPSULE; ORAL /TRACHELL/ /RACHELL/ /AB/ BS/ | /45661/ 500MG/ 250MG 500MG | /N64401/661/ NB4401 001 | TETRACYCLINE HCL /ICN/ a ICN | /N64401/661/ NB4401 002 |
| /N65635/661/ NB5635 001 | a ANGUS | /45661/ 500MG/ 250MG 500MG | /N64401/661/ NB4401 001 | | |
| | a | | | | |
| | | | | | |

| TABLET; ORAL | SUNNYBCH | APOTHECON | |
|--------------|------------|-----------|-----------|
| AB | AB | | |
| AB | AB | | |
| N83667 001 | N83667 001 | AB | + |
| N83667 002 | N83667 002 | /S/AB/EP/ | /S/AB/EP/ |
| | | /AB/ | /AB/ |

THALLOUS CHLORIDE, Tl-201

INJECTABLE; INJECTION
 THALLOUS CHLORIDE TL 201
 /SQUIBB/
 30/EP/
 a SQUIBB
 IMCL/ML
 /NIB5461661/
 /NIB5461662/
 NIB548 001
 DEC 30, 1982

| CAPSULE, EXTENDED RELEASE; ORAL | |
|---------------------------------|--------------|
| /N80188/001 | /THE0810/ |
| N80188 003 | /THE0810/ |
| /N85490/001 | /THE0810/ |
| N85490 001 | ③ WHITBY |
| N80188 002 | /THE0810/ |
| N85490 002 | /THE0810/ |
| /N83595/001 | /THE0810/ |
| N83595 003 | ③ WHITBY |
| 25MG/ML | /46945/ |
| 100MG/ML | /46945/ |
| 25MG/ML | /46945/ |
| 25MG/ML | /46945/ |
| 50MG/ML | /46945/ |
| 50MG/ML | /46945/ |
| 100MG/ML | /46945/ |
| | 260MG |
| | 130MG |
| | MAR 20, 1985 |
| | NB5983 001 |
| | MAR 20, 1985 |
| | NB5983/001 |
| | MAR 20, 1985 |
| | NB5983/001 |

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
THEOCLEAR L.A.-130
/βc/ /CENTRAL/PHARMS/
BC + CENTRAL PHARMS 130MG

TABLET; ORAL
THEOCLEAR L.A.-260
/βc/ /CENTRAL/PHARMS/
BC + CENTRAL PHARMS 260MG

ELIXIR; ORAL
/THEOPHYL-225/
/JOHNSON/RW/
③ JOHNSON RW

THEOPHYLLINE

TABLET; ORAL
PENNEX PHARMS
/βc/ /PHARMS/βc/CS/
AA BARRE 80MG/15ML

TABLET; ORAL
QUIBRON-T
/+/-ER1510/PHFRS/
+ ROBERTS 300MG

/THEOPHYL-225/

/JOHNSON/RW/

③ JOHNSON RW

/THEOPHYL-225/

/JOHNSON/RW/

③ JOHNSON RW

THEOPHYLLINE SODIUM GLYCINATE

TABLET; ORAL
THEOPHYLLINE SODIUM GLYCINATE
/βc/ /SODIUM GLYCINATE/
③ CENTRAL PHARMS

/THEOPHYLLINE SODIUM GLYCINATE/

MAY 27, 1982
/N86569/001

/N86569/002

MAY 27, 1982
/N86569/002

</div

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'93 - DEC'93

THIORDIAZINE HYDROCHLORIDE

TABLET; ORAL

THIORDIAZINE HCl
/PAR/

/100mg/
/150mg/
/250mg/
/500mg/
/AB/

② PAR

10MG

15MG

25MG

50MG

100MG

/AB/

② ZENITH

100MG

/AB/

AT

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLID
+ SYNTEX
/DEC/

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOPTIC-XE
+ MERCK
/DEC/

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN
BAUSCH AND LOMB

0.3%

AT

THIOTEP A

INJECTABLE; INJECTION

THIOTEP A
+ IMMUNEX

/DEC/

AT

TICARCILLIN DISODIUM

INJECTABLE; INJECTION

TICARCILLIN
SMITHKLINE BEECHAM

/DEC/

AT

TOBREX

INJECTABLE; INJECTION

TOBREX
+ ALCON

/DEC/

AT

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION
TUBOCURARINE CHLORIDE
/444/
/QUAD/ /5ML/

3 QUAD 3ML/ML

AUG 12, 1988

VALPROIC ACID

CAPSULE; ORAL
VALPROIC ACID
PHARMACAPS
AB

250MG

N73484 001

JUN 29, 1993

> ADD >

TUBOCURARINE CHLORIDE

INJECTABLE; ORAL
VALPROIC ACID
/444/

TABLET; ORAL
VALPROIC ACID
/5MG/ML

3 QUAD 3MG/ML

AUG 12, 1988

VALPROIC ACID

CAPSULE; ORAL
VALPROIC ACID
PHARMACAPS
AB

250MG

N73484 001

JUN 29, 1993

> ADD >

PONDER FOR RECONSTITUTION; ORAL

VANCOGEN HCL

AB LILLY

EQ 250MG BASE/5ML

N61667 002

JUL 13, 1993

N61667 001

OCT 15, 1993

N63321 003

OCT 15, 1993

VASOPRESSIN TANNATE

INJECTABLE; INJECTION

/PITRESSIN TANNATE/

3 PARKE DAVIS

/5 PRESSOR UNITS/ML

/APR 29, 1987

/APR 29, 1987

/APR 29, 1987

VALPROIC ACID

TABLET; ORAL
VALPROIC ACID
/5MG/ML

3 QUAD 3MG/ML

AUG 12, 1988

VALPROIC ACID

CAPSULE; ORAL
VALPROIC ACID
PHARMACAPS
AB

250MG

N73484 001

JUN 29, 1993

> ADD >

VANCOMYCIN HCL IN PLASTIC CONTAINER

+ LILLY

EQ 500MG BASE/100ML

N50671 001

APR 29, 1993

TABLET; ORAL

VERAPAMIL HCL

AB

WATSON LABS

40MG

VINBLASTINE SULFATE

FUJISAMA

1MG/ML

VASOPRESSIN

/L-PHOHfP/

/L-PHOHfP/

/L-PHOHfP/

/L-PHOHfP/

/L-PHOHfP/

/L-PHOHfP/

/L-PHOHfP/

/L-PHOHfP/

VANCOMYCIN HCL

INJECTABLE; INJECTION

VANCOMYCIN HCL

AB LILLY

EQ 500MG BASE/5ML

N61667 001

JUL 13, 1993

N61667 001

OCT 15, 1993

N63321 003

OCT 15, 1993

N63321 001

OCT 15, 1993

N63321 001

OCT 15, 1993

N63321 003

OCT 15, 1993

N63321 001

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N63321 003

OCT 15, 1993

N63321 001

OCT 15, 1993

N63321 003

OCT 15, 1993

N63321 001

OCT 15, 1993

VITAMIN A PALMITATE

CAPSULE; ORAL

| | | |
|-----------------------|------------|--------------|
| EQ 50,000 UNITS BASE | N83187 001 | |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 004 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 005 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 006 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 007 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 008 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 009 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 010 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 011 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 012 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 013 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 014 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 015 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 016 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 017 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 018 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 019 |
| /EQ 50,000 UNITS BASE | N83665 001 | /N17687 020 |
| | | MEDI PHYSICS |
| | | 10MC1/VIAL |
| | | 20MC1/VIAL |

INJECTABLE: INJECTION

| | | | | | | | |
|------------------|-------------|----------------------------|-------------|----------------------------|-------------|----------------------------|-------------|
| <u>AEROSOL A</u> | /AER/ | /EQ '50;000 UNITS BASE/ML' | /N06025/001 | /EQ '50;000 UNITS BASE/ML' | /N06025/001 | /EQ '50;000 UNITS BASE/ML' | /N06019/001 |
| ASTRA | /ASTRA/ | EQ 50,000 UNITS BASE/ML | N06825 001 | ASTRA | /ASTRA/ | EQ 50,000 UNITS BASE/ML | N06819 001 |
| VITAMIN A | /VITAMIN A/ | /VITAMIN A' VITAMINATE/ | | VITAMIN A | /VITAMIN A/ | /VITAMIN A' VITAMINATE/ | |
| SAVAGE | /SAVAGE/ | AA | | SAVAGE | /SAVAGE/ | AA | |

WARFARIN SODIUM

ACETAMINOPHEN

SUPPOSITORY; RECTAL
NEOPAP /ÁlcOH/
POLYMEDICA /120MG/
N164401 001

ACETAMINOPHEN; DEXBROMPHENTRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
DRIXORAL PLUS /500MG; 120MG/
+ SCHERRING PLOUGH 500MG; 3MG; 60MG /N19453/001
MAY 22, 1987

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
/Aluminum Hydroxide/ /Magnesium Trisilicate/
/PENNEX/ /80MG; 20MG/
② PENNEX 80MG; 20MG /N89449/001
NOV 27, 1987

BACITRACIN; POLYMYXIN B SULFATE

/Aerodol/ /TOPICAL/
/Lanibiotic/ /COMBE/

/500 UNITS/GM;
5,000 UNITS/GM
② COMBE SEP 22, 1986

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
HIBISTAT /STUART/
+ ZENECA /0.5%;
N18300 001

TINCTURE; TOPICAL
HIBITANE /Stuart/
② ZENECA /0.5%;
N18049 001

CHLORPHENIRAMINE MALEATE

SUPPOSITORY; RECTAL
CHLOR-TRIMETON /SCHERING/
N16441/001 /120MG/
+ SCHERRING PLOUGH 12MG /N07638/001
N07638 002

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
DEMAZIN /SCHERING/ /4MG; 25MG/
+ SCHERRING PLOUGH 4MG; 25MG /N18556/001
MAY 14, 1984

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
/750C/001 /120MG/
② FISONS 8MG; 120MG /N18747/001
MAR 06, 1986

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
CHLOR-TRIMETON /SCHERING/ /80MG; 120MG/
+ SCHERRING PLOUGH 80MG; 120MG /N18397/001

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

/Suspension/ /Extended Release/ /80MG/
/Fisons/ /Penruoss/ /Penruoss/
② FISONS EQ 4MG MALEATE/5ML; /N18928/001
EQ 10MG BASE/5ML /AUD/14/1985/
AUG 14, 1985

/N18649/001/
N18049 001

100% PROPYLENE DIAMINE POLYISOBUTYL AMINE POLYSTIREX

CLOTRIMAZOLE

/ SUSPENSION; EXTENDED/RELEASE; ORAL/
 /ORSIN/
 /FISONS/
 /
 /ED/4Hg/MALEATE/SML;
 /ED/37.5Hg/HCL/SML/
 /
 /JAN 04/1994/
 /N/16550/0651/
 /JAN 04/1994/
 NI18050 001
 JAN 06. 1994

LOTION; TOPICAL
LOTRIMIN AF
+ SCHERING
L:
1/12/1

CLEMASTINE FUMARATE

TABLET; ORAL
CLEMASTINE FUMARATE
GENEVA

CLOTRIMAZOLE

**CREAM; TOPICAL
ANTIINFLAMMATORY**

TARO

LOTTRIMIN AF / SCHERING /

SCHERRING PL

**CREAM; VAGINAL
CLOTRIMAZOLE**

NHC

SCHERFES

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
GYNE-LOTRIMIN COMBINATION PACK
1/2;100G
+ SCHERING PLough 1/2

N18052 002
NOV 30, 1990

N120289 002
NOV 30, 1990

N70118 001
OCT 01, 1985

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 12 / DEC '93

INDIUM¹¹¹ CHLORIDE

SOLUTION; INJECTION
INDICLOR
AMERSHAM

N/A

N19862
DEC 29, 1992

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January thru November 1993]

ME
 Generic/Chemical
 - Trade Name

| INDICATION DESIGNATED | SPONSOR & ADDRESS |
|------------------------------|------------------------------|
|------------------------------|------------------------------|

| | | |
|--|--|---|
| DESULFATED HEPARIN AEROPIN | TREATMENT OF CYSTIC FIBROSIS. | KENNEDY & HOITAL, MDS. 7702 PARHAM ROAD RICHMOND VA 23294 DD 09/17/93 MA / / |
| MONOCLONAL ANTIBODY TO CD4 | FOR USE IN POST-EXPOSURE PROPHYLAXIS FOR OCCUPATIONAL EXPOSURE TO HUMAN IMMUNODEFICIENCY VIRUS. | BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 12/20/93 MA / / |
| METROXALEN DUVADEX | FOR USE IN CONJUNCTION WITH THE UVAR PHOTOPHERESIS TO TREAT DIFFUSE SYSTEMIC SCLEROSIS. | THERAKOS, INCORPORATED 201 BRANDYWINE PARKWAY WEST CHESTER PA 19380 DD 06/22/93 MA / / |
| 3-PYRIDYL(METHYL)-9-DEAZAGUANI | TREATMENT OF CUTANEOUS T-CELL LYMPHOMA. | BIOCRYST PHARMACEUTICALS, INCORPORATED 2190 PARKWAY LAKE DRIVE BIRMINGHAM AL 35244 DD 10/05/93 MA / / |
| MOSALICYLATE SODIUM | TREATMENT OF CROHN'S DISEASE. | SYNCOM PHARMACEUTICALS, INC. 155 PASSAIC AVENUE FAIRFIELD NJ 07004 DD 04/06/93 MA / / |
| MOSIDINE GABBROMICINA | TREATMENT OF TUBERCULOSIS. | KANYOK, THOMAS P. PHARM.D. UNIVERSITY OF RHODE ISLAND PROVIDENCE RI 02908-4735 DD 05/14/93 MA / / |
| MOSIDINE GABBROMICINA | TREATMENT OF MYCOBACTERIUM AVIUM COMPLEX. | KANYOK, THOMAS P. PHARM.D. UNIVERSITY OF RHODE ISLAND PROVIDENCE RI 02908-4735 DD 11/15/93 MA / / |
| NUARONE AMIO-AQUEOUS | TREATMENT OF INCESSANT VENTRICULAR TACHYCARDIA. | ACADEMIC PHARMACEUTICALS, INC. 25720 SAUNDERS ROAD NORTH LAKE FOREST IL 60045 DD 08/17/93 MA / / |
| THYMOCYTE SERUM NASHVILLE RABBIT THYMOCYTE SERUM | TREATMENT OF ALLOGRAFT REJECTION, INCLUDING SOLID ORGAN (KIDNEY, LIVER, HEART, LUNG, AND PANCREAS) AND BONE MARROW TRANSPLANTATION. | APPLIED MEDICAL RESEARCH 1600 HAYES STREET NASHVILLE TN 37203 DD 06/02/93 MA / / |
| MORPHINE HCL INJECTION | TREATMENT OF THE ON-OFF FLUCTUATIONS ASSOCIATED WITH LATE-STAGE PARKINSON'S DISEASE. | BRITANNIA PHARMACEUTICALS LTD FORUM HOUSE, BRIGHTON ROAD REDHILL, SURREY UK DD 04/22/93 MA / / |
| TAQUONE HEPRON | TREATMENT AND SUPPRESSION OF TOXOPLASMA GONDII ENCEPHALITIS. | BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / / |
| TAQUONE HEPRON | PRIMARY PROPHYLAXIS OF HIV-INFECTED PERSONS AT HIGH RISK FOR DEVELOPING TOXOPLASMA GONDII ENCEPHALITIS. | BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / / |
| FACTANT SURVANTA INTRATHECAL EXPRESS | TREATMENT OF FULL-TERM NEWBORN INFANTS WITH RESPIRATORY FAILURE CAUSED BY MECONIUM ASPIRATION SYNDROME, PERSISTENT PULMONARY HYPERTENSION OF THE NEWBORN, OR PNEUMONIA AND SEPSIS. | ROSS LABORATORIES 625 CLEVELAND AVENUE COLUMBUS OH 43215 DD 12/20/93 MA / / |

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD= Date Designated
MA= Marketing Approval

BISPECIFIC ANTIBODY 520C9x22
TN=

IN VIVO SEROTHERAPY OF PATIENTS WITH OVARIAN CANCER.

MEDAREX
12 COMMERCE AVENUE
WEST LEBANON NH 03784
DD 10/05/93 MA / /

BLEOMYCIN SULFATE
TN= BLENOXANE

TREATMENT OF MALIGNANT PLEURAL EFFUSION.

BRISTOL-MYERS SQUIBB
PO BOX 4000
PRINCETON NJ 08543-4000
DD 09/17/93 MA / /

BOVINE WHEY PROTEIN CONCENTRATE
TN= IMMUNO-C

TREATMENT OF CRYPTOSPORIDIOSIS CAUSED BY THE PRESENCE
OF CRYPTOSPORIDIUM PARVUM IN THE GASTROINTESTINAL TRACT
OF PATIENTS WHO ARE IMMUNODEFICIENT/IMMUNOCOMPROMISED
OR IMMUNOCOMPETENT.

BIMUNE SYSTEMS, INCORPORATED
40 EAST SOUTH TEMPLE SUITE 31
SALT LAKE CITY UT 84111
DD 09/30/93 MA / /

CLADRIBINE
TN= LEUSTATIN INJECTION

TREATMENT OF NON-HODGKIN'S LYMPHOMA.

R.W.JOHNSON RESEARCH INSTITUT
ROUTE 202 SOUTH, P.O. BOX 300
RARITAN NJ 08869-0602
DD 04/19/93 MA / /

COLFOSCERIL PALMITATE, CETYL
ALCOHOL, TYLOXAPOL
TN= EXOSURF

TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.

BURROUGHS WELLCOME COMPANY
3030 CORNWALLIS ROAD
RESEARCH TRIANGLE PK NC 27709
DD 01/11/93 MA / /

CY-1503
TN=

TREATMENT OF POST-ISCHEMIC REPERFUSION EDEMA FOLLOWING
SURGICAL TREATMENT FOR CHRONIC THROMBOEMBOLIC PULMONARY
HYPERTENSION.

CYTEL CORPORATION
3525 JOHN HOPKINS COURT
SAN DIEGO CA 92121
DD 12/22/93 MA / /

CYSTIC FIBROSIS TRANSMEMBRANE
CONDUCTANCE REGULATOR GENE
TN=

TREATMENT OF CYSTIC FIBROSIS.

GENETIC THERAPY, INC.
19 FIRSTFIELD ROAD
GAIITHERSBURG MD 20878
DD 01/08/93 MA / /

DEPOFOAM ENCAPSULATED CYTARABINE
TN=

TREATMENT OF NEOPLASTIC MENINGITIS.

DEPOTECH CORPORATION
11025 NORTH TORREY PINES ROAD
SUITE 100
LA JOLLA CA 92037
DD 06/02/93 MA / /

DISODIUM CLODRONATE
TN=

TREATMENT OF HYPERCALCEMIA OF MALIGNANCY.

DISCOVERY EXPERIMENTAL &
DEVELOPMENT, INC
29949 S.R. 54 WEST
WESLEY CHAPEL FL 33543
DD 06/16/93 MA / /

EPOETIN ALFA
TN=

TREATMENT OF MYELODYSPLASTIC SYNDROME.

R.W. JOHNSON RESEARCH INSTITU
ROUTE 202 SOUTH, BOX 300
RARITAN NJ 08869-0602
DD 12/20/93 MA / /

FACTOR XIII, RECOMBINANT
TN=

TREATMENT OF CONGENITAL FACTOR XIII DEFICIENCY.

ZYMOGENETICS, INC.
4225 ROOSEVELT WAY
SEATTLE WA 98105
DD 04/22/93 MA / /

HEMIN AND ZINC MESOPORPHYRIN
TN= HEMEX

TREATMENT OF ACUTE PORPHYRIC SYNDROMES.

BONKOVSKY, HERBERT L. M.D.
UNIVERSITY OF MASSACHUSETTS
MEDICAL CTR
WORCESTER MA 01655
DD 12/20/93 MA / /

HUMANIZED ANTI-TAC
TN=

PREVENTION OF ACUTE RENAL ALLOGRAFT REJECTION.

HOFFMANN-LA ROCHE, INC.
340 KINGSLAND STREET
NUTLEY NJ 07110
DD 03/05/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD = Date Designated

MA = Marketing Approval

ME
world/Chemical
Trade Name

ANIZED ANTI-TAC

PREVENTION OF ACUTE GRAFT-VS-HOST DISEASE FOLLOWING BONE MARROW TRANSPLANTATION.

HOFFMANN-LA ROCHE, INC.
340 KINGSLAND STREET
NUTLEY NJ 07110
DD 03/05/93 MA / /

HINE GLOBULIN INTRAVENOUS
(HUMAN)
GAMIMUNE N

INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS AFFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS.

MILES, INC.
4TH & PARKER STREETS
BERKELEY CA 94710
DD 02/18/93 MA / /

HINE GLOBULIN INTRAVENOUS
(HUMAN)
IMMUNE GLOBULIN INTRAVENOUS
(HUMAN) IMMUNO, IVEEGAM

TREATMENT OF PATIENTS WITH ACUTE MYOCARDITIS.

IMMUNO CLINICAL RESEARCH CORPORATION
750 LEXINGTON AVENUE
NEW YORK NY 10022
DD 11/22/93 MA / /

FERFERON BETA (RECOMBINANT
(HUMAN)

TREATMENT OF PRIMARY BRAIN TUMORS.

BIOGEN, INC.
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02142
DD 01/13/93 MA / /

ERLEUKIN-3, HUMAN,
RECOMBINANT

FOR SEQUENTIAL ADMINISTRATION WITH SARGRAMOSTIM TO ACCELERATE NEUTROPHIL AND PLATELET RECOVERY IN PATIENTS UNDERGOING AUTOLOGOUS BONE MARROW TRANSPLANTATION FOR THE TREATMENT OF HODGKIN'S DISEASE OR NON-HODGKIN'S LYMPHOMA.

SANDOZ PHARMACEUTICALS CORP.
59 ROUTE 10
EAST HANOVER NJ 07936-1080
DD 09/30/93 MA / /

CARNITINE
CARNITOR

TREATMENT OF PEDIATRIC CARDIOMYOPATHY.

SIGMA-TAU PHARMACEUTICALS, INC.
200 ORCHARD RIDGE DRIVE, SUITE 300
GAIITHERSBURG MD 20878
DD 11/17/93 MA / /

FISOMAL DAUNORUBICIN
DAUNOXOME

TREATMENT OF PATIENTS WITH ADVANCED HIV-ASSOCIATED KAPOSI'S SARCOMA.

VESTAR, INC.
650 CLIFFSIDE DRIVE
SAN DIMAS CA 91773
DD 05/14/93 MA / /

LATONIN

TREATMENT OF CIRCADIAN RHYTHM SLEEP DISORDERS IN BLIND PEOPLE WITH NO LIGHT PERCEPTION.

SACK, ROBERT, M.D.
3181 S.W. SAM JACKSON PARK ROAD
PORTLAND OR 97201-3098
DD 11/15/93 MA / /

TOTREXATE
RHEUMATREX

TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.

LEDERLE LABORATORIES
401 N. MIDDLETOWN ROAD
PEARL RIVER NY 1065-1299
DD 08/23/93 MA / /

RAFINIL

TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.

CEPHALON, INC.
145 BRANDYWINE PARKWAY
WEST CHESTER PA 19380-4245
DD 03/15/93 MA / /

COLONAL ANTIBODY FOR
IMMUNIZATION AGAINST LUPUS
NEPHRITIS

TREATMENT OF LUPUS NEPHRITIS.

MEDCLONE, INC.
2435 MILITARY AVENUE
LOS ANGELES CA 90064
DD 01/07/93 MA / /

GLOLAURIN
GLYLORIN

TREATMENT OF CONGENITAL PRIMARY ICHTHYOSIS.

CELLEGY PHARMACEUTICALS, INC.
371 BEL MARIN KEYS, SUITE 210
NOVATO CA 94949
DD 04/29/93 MA / /

OMYCIN-C

TREATMENT OF REFRACTORY GLAUCOMA AS AN ADJUNCT TO AB EXTERNO GLAUCOMA SURGERY.

IOP INCORPORATED
3100 AIRWAY AVENUE
COSTA MESA CA 92626
DD 08/20/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD = Date Designated
MA = Marketing Approval

NITRIC OXIDE
TN=

TREATMENT OF PERSISTENT PULMONARY HYPERTENSION IN THE NEWBORN.

OHMEDA PHARMACEUTICAL PRODUCTIONS
DIVISION
110 ALLEN ROAD, PO BOX 804
LIBERTY CORNER NJ 07938-0804
DD 06/22/93 MA / /

POLY I: POLY C12U
TN= AMPLIGEN

TREATMENT OF CHRONIC FATIGUE SYNDROME.

HEM PHARMACEUTICALS CORP.
ONE PENN CENTER, SUITE 660
PHILADELPHIA PA 19103
DD 12/09/93 MA / /

PRIMAQUINE PHOSPHATE
TN=

FOR USE IN COMBINATION WITH CLINDAMYCIN HYDROCHLORIDE IN THE TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA ASSOCIATED WITH ACQUIRED IMMUNODEFICIENCY SYNDROME.

STERLING WINTHROP INC.
90 PARK AVENUE
NEW YORK NY 10016
DD 07/23/93 MA / /

PROSTAGLANDIN E1
ALPHA-CYCLODEXTRIN
TN= VASOPROST

TREATMENT OF SEVERE PERIPHERAL ARTERIAL OCCLUSIVE DISEASE (CRITICAL LIMB ISCHEMIA) IN PATIENTS WHERE OTHER PROCEDURES, GRAFTS OR ANGIOPLASTY, ARE NOT INDICATED.

SCHWARZ PHARMA
5600 WEST COUNTY LINE ROAD
MEQUON WI 53092
DD 10/20/93 MA / /

PROTEIN C CONCENTRATE
TN= PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO

FOR USE IN THE PREVENTION AND TREATMENT OF PURPURA FULMINANS IN MENINGOCOCCEMIA.

IMMUNO CLINICAL RESEARCH CORP.
750 LEXINGTON AVENUE, 19TH FLOOR
NEW YORK NY 10022
DD 04/22/93 MA / /

PROTIRELIN
TN=

PREVENTION OF INFANT RESPIRATORY DISTRESS SYNDROME ASSOCIATED WITH PREMATURITY.

UCB PHARMACEUTICALS, INC.
5505-A ROBIN HOOD ROAD
NORFOLK VA 23513
DD 08/24/93 MA / /

PULMONARY SURFACTANT REPLACEMENT, PORCINE
TN= CUROSURF

FOR THE TREATMENT AND PREVENTION OF RESPIRATORY DISTRESS SYNDROME IN PREMATURE INFANTS.

CHIESI PHARMACEUTICALS, INC.
150 DANBURY ROAD
RIDGEFIELD CT 06877
DD 08/02/93 MA / /

RECOMBINANT RETROVIRAL VECTOR - GLUCOCEREBROSIDASE
TN=

FOR USE AS ENZYME REPLACEMENT THERAPY FOR PATIENTS WITH TYPES I, II, OR III GAUCHER DISEASE.

GENETIC THERAPY, INC.
19 FIRSTFIELD ROAD
GAIITHERSBURG MD 20878
DD 11/15/93 MA / /

RHO(D) IMMUNE GLOBULIN (HUMAN)
TN= WINPHO SD

TREATMENT OF IMMUNE THROMBOCYTOPENIC PURPURA.

RH PHARMACEUTICALS, INC.
104 CHANCELLOR MATHESON ROAD
WINNIPEG, MANITOBA
DD 11/09/93 MA / /

RII RETINAMIDE
TN=

TREATMENT OF MYELODYSPLASTIC SYNDROMES.

SPARTA PHARMACEUTICALS,
INCORPORATED
PO BOX 13288
RESEARCH TRIANGLE PK NC 27709
DD 05/06/93 MA / /

RILUZOLE
TN=

TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.

RHONE-POULENC RORER PHARM.
500 ARCOLA ROAD, PO BOX 1200
COLLEGEVILLE PA 19426-0107
DD 03/16/93 MA / /

ROQUINIMEX
TN= LINOMIDE

TO PROLONG TIME TO RELAPSE IN LEUKEMIA PATIENTS WHO HAVE UNDERGONE AUTOLOGOUS BONE MARROW TRANSPLANTATION.

KABI PHARMACIA, INC.
800 CENTENNIAL AVENUE
PISCATAWAY NJ 08855-1327
DD 07/01/93 MA / /

SECALCIFEROL
TN= OSTEO-D

TREATMENT OF FAMILIAL HYPOPHOSPHATEMIC RICKETS.

LEMMON COMPANY
650 CATHILL ROAD
SELLERSVILLE PA 18960
DD 07/26/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

ME
ERIC/Chemical
Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated

MA=Marketing Approval

SUM BENZOATE/SODIUM
VALACETATE

TREATMENT OF UREA CYCLE DISORDERS: CARBAMYLPHOSPHATE
SYNTETASE DEFICIENCY, ORNITHINE TRANSCARBAMYLASE
DEFICIENCY, AND ARGININOSUCCINIC ACID SYNTHETASE
DEFICIENCY.

BRUSILOW, SAUL W. M.D.
JOHNS HOPKINS MEDICAL
INSTITUTIONS
BALTIMORE MD 21205
DD 11/17/93 MA / /

SUM PHENYLBUTYRATE

TREATMENT OF UREA CYCLE DISORDERS: CARBAMYLPHOSPHATE
SYNTETASE DEFICIENCY, ORNITHINE TRANSCARBAMYLASE
DEFICIENCY, AND ARGININOSUCCINIC ACID SYNTHETASE
DEFICIENCY.

BRUSILOW, SAUL W. M.D.
JOHNS HOPKINS MEDICAL
INSTITUTIONS
BALTIMORE MD 21205
DD 11/17/93 MA / /

MITROPIN
BIOTROPIN

TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS.

BIO-TECHNOLOGY GENERAL
CORPORATION
1250 BROADWAY, 20th FLOOR
NEW YORK NY 10001
DD 02/12/93 MA / /

ALFATE

TREATMENT OF ORAL MUCOSITIS AND STOMATITIS FOLLOWING
RADIATION THERAPY FOR HEAD AND NECK CANCER.

FUISZ TECHNOLOGIES, LTD.
3810 CONCORDE PARKWAY, SUITE 100
CHANTILLY VA 22021
DD 07/15/93 MA / /

BASE (YEAST-DERIVED)
SACARASA

TREATMENT OF CONGENITAL SUCRASE-ISOMALTASE DEFICIENCY.

TREEM, WILLIAM R. M.D.
HARTFORD HOSPITAL
HARTFORD CT 06115
DD 12/10/93 MA / /

IDIOMIDE

TREATMENT OF THE CLINICAL MANIFESTATIONS OF
MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM
TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA.

CELGENE CORPORATION
7 POWDER HORN DRIVE
WARREN NJ 07059
DD 01/12/93 MA / /

EPRIFENE
ESTRINEX

TREATMENT OF DESMOID TUMORS.

ADRIA LABORATORIES
P.O. BOX 16529
COLUMBUS OH 43216-6529
DD 08/17/93 MA / /

TINOIN
TRETINOIN LF, IV

TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.

ARGUS PHARMACEUTICALS, INC.
3400 RESEARCH FOREST DRIVE
THE WOODLANDS TX 77381
DD 01/14/93 MA / /

FR NECROSIS FACTOR-BINDING
PROTEIN 1

TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED
IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH
CD4 COUNTS LESS THAN 200 CELLS PER MM³.

SERONO LABORATORIES, INC.
100 LONGWATER CIRCLE
NORWELL MA 02061
DD 01/06/93 MA / /

FR NECROSIS FACTOR-BINDING
PROTEIN II

TREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED
IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH
CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM³.

SERONO LABORATORIES, INC.
100 LONGWATER CIRCLE
NORWELL MA 02061
DD 01/06/93 MA / /

RACTIVE INTESTINAL
PEPTIDE

TREATMENT OF ACUTE ESOPHAGEAL FOOD IMPACTION.

RESEARCH TRIANGLE
PHARMACEUTICALS
200 WESTPARK CORPORATE CENTER
DURHAM NC 27713
DD 06/23/93 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical
TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD=Date Designated
MA=Marketing Approval

ME
Generic/Chemical
TN= Trade Name

Orphan Drug Approvals

ANTIHEMOPHILIC FACTOR
(RECOMBINANT)
TN= KOGENATE

PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.

MILES, INC.
4TH & PARKER STREETS
BERKELEY CA 94701
DD 09/25/89 MA 02/25/93

NUTROPIN FOR
NUTROPIN

APROTININ
TN= TRASYLOL

FOR PROPHYLACTIC USE TO REDUCE PERIOPERATIVE BLOOD LOSS AND THE HOMOLOGOUS BLOOD TRANSFUSION REQUIREMENT IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS SURGERY IN THE COURSE OF REPEAT CORONARY ARTERY BYPASS GRAFT SURGERY, AND IN SELECTED CASES OF PRIMARY CORONARY ARTERY BYPASS GRAFT SURGERY WHERE THE RISK OF BLEEDING IS ESPECIALLY HIGH (IMPAIRED HEMOSTASIS, E.G. PRESENCE OF ASPIRIN OR OTHER COAGULOPATHY) OR WHERE TRANSFUSION IS UNAVAILABLE OR UNACCEPTABLE.

MILES, INC.
400 MORGAN LANE
WEST HAVEN CT 06516
DD 11/17/93 MA 12/29/93

NEUTREXATE GL
NEUTREXIN

CLADRIBINE
TN= LEUSTATIN INJECTION

TREATMENT OF HAIRY CELL LEUKEMIA.

R.W.JOHNSON RESEARCH INSTITUTE
ROUTE 202, PO BOX 300
RARITAN NJ 08869-0602
DD 11/15/90 MA 02/26/93

DORNASE ALFA
TN= PULMOZYME

TO REDUCE MUCOUS VISCOSITY AND ENABLE THE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.

GENENTECH, INC.
460 POINT SAN BRUNO BOULEVARD
SOUTH SAN FRANCISCO CA 94080
DD 01/16/91 MA 12/30/93

FELBAMATE
TN= FELBATOL

TREATMENT OF LENNOX-GASTAUT SYNDROME.

WALLACE LABORATORIES
301B COLLEGE ROAD EAST
PRINCETON NJ 08540
DD 01/24/89 MA 07/29/93

IMMUNE GLOBULIN INTRAVENOUS
(HUMAN)
TN= GAMIMUNE N

INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS Affected WITH THE HUMAN IMMUNODEFICIENCY VIRUS.

MILES, INC.
4TH & PARKER STREETS
BERKELEY CA 94710
DD 02/18/93 MA 12/27/93

INTERFERON BETA, RECOMBINANT
HUMAN
TN=BETASERON

TREATMENT OF MULTIPLE SCLEROSIS.

CHIRON CORPORATION
4560 HORTON STREET
EMERYVILLE CA 94608
DD 11/17/88 MA 07/23/93

LEUPROLIDE ACETATE
TN= LUPRON INJECTION

TREATMENT OF CENTRAL PRECOCIOUS PUBERTY.

TAP PHARMACEUTICALS, INC.
2355 WAUKEGAN ROAD
DEERFIELD IL 60015
DD 07/25/88 MA 04/16/93

LEVOMETHADYL ACETATE
HYDROCHLORIDE
TN=ORLAAM

TREATMENT OF HEROIN ADDICTS SUITABLE FOR MAINTENANCE ON OPIATE AGONISTS.

BIODEVELOPMENT CORPORATION
1300 NORTH 17TH STREET, SUITE 300
ARLINGTON VA 22209-2306
DD 01/24/84 MA 07/09/93

LODOXAMIDE TROMETHAMINE
TN= ALOMIDE OPHTHALMIC SOLUTION

TREATMENT OF VERNAL KERATOCONJUNCTIVITIS.

ALCON LABORATORIES, INC.
6201 SOUTH FREEWAY
FORT WORTH TX 76134
DD 10/16/91 MA 09/23/93

MEGESTROL ACETATE
TN= MEGACE

TREATMENT OF PATIENTS WITH ANOREXIA, CACHEXIA, OR SIGNIFICANT WEIGHT LOSS ($=/ >10\%$ OF BASELINE BODY WEIGHT) AND CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).

BRISTOL-MYERS SQUIBB
2400 WEST LLOYD EXPRESSWAY
EVANSVILLE IN 47721-0001
DD 04/13/88 MA 09/10/93

Trade Name

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD = Date Designated
MA = Marketing Approval

Orphan Drug Approvals

NUTROPIN FOR INJECTION
NUTROPIN

TREATMENT OF GROWTH RETARDATION ASSOCIATED WITH CHRONIC
RENAL FAILURE.

GENENTECH, INC.
460 POINT SAN BRUNO BOULEVARD
SOUTH SAN FRANCISCO CA 94080
DD 08/04/89 MA 11/17/93

NEUTREXATE GLUCURONATE
NEUTREXIN

TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA
IN AIDS PATIENTS.

U.S. BIOSCIENCE, INC.
ONE TOWER BRIDGE, 100 FRONT STREET
WEST CONSHOHOCKEN PA 19428
DD 05/15/86 MA 12/17/93

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

NO DECEMBER 1993 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

| DRUG NAME (DOSAGE FORM) | DATE | REVISED DATE |
|-------------------------|------|--------------|
|-------------------------|------|--------------|

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

| | | |
|------------------------------------|--------------|--------------|
| BUMETANIDE (TABLET) | APR 23, 1993 | |
| BUSIPRONE HYDROCHLORIDE (TABLET) | AUG 13, 1993 | |
| CAPTOPRIL (TABLET) | MAY 13, 1993 | |
| CEFACLOR (CAPSULE AND SUSPENSION) | APR 23, 1993 | |
| CHOLESTERYRAMINE (POWDER) | JUL 15, 1993 | |
| DICLOFENAC SODIUM (TABLET) | DEC 24, 1992 | DEC 02, 1993 |
| GLIPIZIDE (TABLET) | APR 23, 1993 | |
| GLYBURIDE (TABLET) | APR 23, 1993 | |
| GUANABENZ ACETATE (TABLET) | APR 23, 1993 | |
| INDAPAMIDE (TABLET) | APR 23, 1993 | |
| KETOPROFEN (CAPSULE) | APR 23, 1993 | |
| ORAL EXTENDED (CONTROLLED RELEASE) | SEP 09, 1993 | |
| PINDOLOL (TABLET) | APR 23, 1993 | |
| RANITIDINE HYDROCHLORIDE (TABLET) | APR 23, 1993 | |
| TRIAZOLAM (TABLET) | DEC 24, 1992 | |

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

| DRUG NAME DOSE FORM; ROUTE | STRENGTH (CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|---|---|-------------------|------------|--|--------------------------|
| THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857. | | | | | |
| REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT. | | | | | |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE CAPSULE; ORAL | 150MG 180MG 2.5MG | 92 P-0282/ CP3 | MIKART | NEW COMBINATION | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE CAPSULE; ORAL | 150MG 180MG 5MG | 92 P-0282/ CP1 | MIKART | NEW COMBINATION | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE CAPSULE; ORAL | 150MG 180MG 7.5MG | 92 P-0282/ CP2 | MIKART | NEW COMBINATION NEW STRENGTH | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE CAPSULE; ORAL | 150MG 180MG 10MG | 92 P-0282/ CP4 | MIKART | NEW COMBINATION | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE TABLET; ORAL | 150MG 180MG 2.5MG | 92 P-0282/ CP3 | MIKART | NEW COMBINATION NEW DOSAGE FORM | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE TABLET; ORAL | 150MG 180MG 5MG | 92 P-0282/ CP1 | MIKART | NEW COMBINATION NEW DOSAGE FORM | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE TABLET; ORAL | 150MG 180MG 7.5MG | 92 P-0282/ CP2 | MIKART | NEW COMBINATION NEW DOSAGE FORM NEW STRENGTH | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; ASPIRIN; HYRDODODONE BITARTRATE TABLET; ORAL | 150MG 180MG 10MG | 92 P-0282/ CP4 | MIKART | NEW COMBINATION NEW DOSAGE FORM | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; CODEINE PHOSPHATE CAPSULE; ORAL | 500MG 45MG | 93 P-0314/ CP1 | MIKART | NEW DOSAGE FORM NEW STRENGTH | APPROVED NOV 10, 1993 |
| ACETAMINOPHEN; CODEINE PHOSPHATE TABLET; ORAL | 500MG 45MG | 93 P-0314/ CP1 | MIKART | NEW STRENGTH | APPROVED NOV 10, 1993 |
| ACYCLOVIR SODIUM INJECTABLE; INJECTION | EQ 50MG BASE/ML (10ML/VIAL) (20ML/VIAL) | 92 P-0468/ CP1 | BULL | NEW DOSAGE FORM | APPROVED SEP 01, 1993 |
| AMINOSALICYLIC ACID GRANULES, ENTERIC-COATED; ORAL | 4GM/PACKET | 92 P-0356/ CP1 | JACOBUS | NEW DOSAGE FORM NEW STRENGTH | APPROVED MAR 03, 1993 |

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

| STATUS | DRUG NAME DOSE FORM; ROUTE | STRENGTH (CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|--|--|---|-------------------|----------------------|------------------------------------|--------------------------|
| HAS DETERMINED THAT THE BLE FOR SUBMISSION AS AN ITSELF IS SUBMITTED AND CKETS MANAGEMENT BRANCH, | CARBOPLATIN INJECTABLE; INJECTION | 10MG/ML (5ML/VIAL) (15ML/VIAL) (45ML/VIAL) | 92 P-0467/ CP1 | BULL | NEW DOSAGE FORM | APPROVED MAY 20, 1993 |
| A FULL LISTING OF ANDA APPROVED NOV 10, 1993 | CHLORPROMAZINE HYDROCHLORIDE SOLUTION; ORAL | 25MG/5ML | 92 P-0284/ CP1 | UDL | NEW STRENGTH | APPROVED JAN 07, 1993 |
| APPROVED NOV 10, 1993 | CISPLATIN INJECTABLE; INJECTION | 1MG/ML (200ML/VIAL) | 93 P-0084/ CP1 | FUJISAWA | NEW STRENGTH | APPROVED NOV 10, 1993 |
| APPROVED NOV 10, 1993 | CYTARABINE INJECTABLE; INJECTION | 20MG/ML (12.5ML/VIAL) | 92 P-0381/ CP1 | BRISTOL MYERS SQUIBB | NEW DOSAGE FORM NEW STRENGTH | APPROVED MAR 18, 1993 |
| APPROVED NOV 10, 1993 | DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION | EQ 12.5MG BASE/ML (40ML/VIAL) | 92 P-0365/ CP1 | LYPHOMED | NEW STRENGTH | APPROVED FEB 11, 1993 |
| APPROVED NOV 10, 1993 | DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION | EQ 12.5MG BASE/ML (100ML/CONTAINER) | 93 P-0045/ CP1 | MARSAM | NEW STRENGTH | APPROVED SEP 10, 1993 |
| APPROVED NOV 10, 1993 | ETOPOSIDE INJECTABLE; INJECTION | 20MG/ML (12.5MG/VIAL) | 92 P-0355/ CP1 | LEDERLE | NEW STRENGTH | APPROVED JAN 07, 1993 |
| APPROVED NOV 10, 1993 | ETOPOSIDE INJECTABLE; INJECTION | 20MG/ML (50ML/CONTAINER) | 91 P-0460/ CP1 | ABBOTT | NEW STRENGTH | APPROVED FEB 11, 1993 |
| APPROVED NOV 10, 1993 | LACTULOSE CRYSTAL; ORAL | 10GM/PACKET | 92 P-0370/ CP1 | BENNETT AND COMPANY | NEW DOSAGE FORM | APPROVED JAN 07, 1993 |
| APPROVED NOV 10, 1993 | METHYLPHENIDATE HYDROCHLORIDE; TABLET, EXTENDED RELEASE; ORAL | 10MG | 92 P-0400/ CP1 | MD PHARM | NEW STRENGTH | APPROVED MAR 22, 1993 |
| APPROVED NOV 10, 1993 | PREDNISOLONE SYRUP; ORAL | 10MG/5ML | 92 P-0439/ CP1 | WE PHARMS | NEW STRENGTH | APPROVED MAY 20, 1993 |
| APPROVED NOV 10, 1993 | PREDNISONE TABLET, CHEWABLE; ORAL | 5MG 10MG | 92 P-0336/ CP1 | WE PHARMS | NEW DOSAGE FORM | APPROVED NOV 10, 1993 |
| APPROVED NOV 10, 1993 | PROPRANOLOL HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL | 10MG 20MG 60MG 80MG 90MG | 93 P-0049/ CP1 | FLEMINGTON PHARM | NEW DOSAGE FORM NEW STRENGTH | APPROVED SEP 01, 1993 |
| APPROVED NOV 10, 1993 | TERBUTALINE SULFATE INJECTABLE; INJECTION | 1MG/ML (0.25ML/CONTAINER) | 92 P-0430/ CP1 | STERLING WINTHROP | NEW STRENGTH | APPROVED MAR 18, 1993 |
| APPROVED NOV 10, 1993 | TRIMETHOPRIM SOLUTION; ORAL | 25MG/5ML | 92 P-0500/ CP1 | ASCENT PHARMS | NEW DOSAGE FORM | APPROVED MAY 20, 1993 |
| APPROVED NOV 10, 1993 | | | | | | |
| APPROVED SEP 01, 1993 | | | | | | |
| APPROVED MAR 03, 1993 | | | | | | |

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

| DRUG NAME DOSAGE FORM; ROUTE | STRENGTH (CONTAINER SIZE) | DOCKET NUMBER | PETITIONER | REASON FOR PETITION | STATUS |
|---------------------------------|------------------------------|-------------------|------------|------------------------|------------------------|
| CROTAMITON GEL; TOPICAL | 10% | 92 P-0249/ CP1 | HAMER | NEW DOSAGE FORM | DENIED NOV 10, 1993 |

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES

NEW DOSING SCHEDULE

D-20 SINGLE 32MG DOSE

REFERENCES

NEW INDICATION

- I-87 RENAL IMAGING AGENT FOR USE IN CHILDREN
- I-88 MANAGEMENT OF ENDOMETRIOSIS
- I-89 EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAIN
- I-90 INTENSIVE CARE UNIT SEDATION
- I-91 MONOTHERAPY USE FOR HYPERTENSION
- I-92 ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE
- I-93 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS
- I-94 USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITATE VISUALIZATION OF LESIONS
IN THE BODY [EXCLUDING THE HEART]
- I-95 TREATMENT OF LEFT VENTRICULAR DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION
- I-96 TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA
- I-97 ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINATION OF THE GASTROINTESTINAL TRACT
- I-98 TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE ASSOCIATED WITH CHRONIC RENAL INSUFFICIENCY

REFERENCES

PATENT USE CODE

- U-74 METHOD OF PROVIDING HYPNOTIC EFFECT
- U-75 RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
- U-76 USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM
- U-77 TREATMENT OF SYMPTOMS OF SEASONAL ALLERGIC RHINITIS
- U-78 ULCERATIVE COLITIS
- U-79 SYMPTOMATIC TREATMENT OF PATIENTS WITH NOCTURNAL HEARTBURN DUE TO GERD
- U-80 METHOD OF TREATING OCULAR BACTERIAL INFECTIONS
- U-81 RELIEF OF SYMPTOMS ASSOCIATED WITH SEASONAL ALLERGIC RHINITIS
- U-82 TREATMENT FOR DEMENTIA IN PATIENTS WITH ALZHEIMER'S DISEASE
- U-83 TREATMENT OF SEIZURES
- U-84 A METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS
- U-85 NASAL TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS SYMPTOMS
- U-86 METHOD OF TREATING CERTAIN FORMS OF EPILEPSY
- U-87 METHOD FOR NONINVASIVE ADMINISTRATION OF SEDATIVES, ANALGESICS, AND ANESTHETICS
- U-88 TREATMENT OF MODERATE PLAQUE PSORIASIS
- U-89 TREATMENT OR PROPHYLAXIS OF EMESIS
- U-90 TREATMENT OF PSYCHOTIC DISORDERS

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS EXPIRES |
|-----------------|---|---------------|----------------|----------|------------------|
| 18473 001 | ALBUTEROL; VENTOLIN | 4851229 | JUN 14, 2005 | 1-93 | JUL 20, 1994 |
| 19489 001 | ALBUTEROL SULFATE; VENTOLIN ROTACAPS | 4777049 | OCT 11, 2005 | 1-93 | JUL 20, 1994 |
| 19604 001 | ALBUTEROL SULFATE; VOLMAX | 4751071 | JUN 14, 2005 | | |
| 19604 002 | ALBUTEROL SULFATE; VOLMAX | 4851229 | JUN 14, 2005 | | |
| >ADD> >DLT> | 18276 004 ALPRAZOLAM; XANAX | 4777049 | OCT 11, 2005 | | |
| >ADD> >DLT> | 19787 001 AMLODIPINE BESYLATE; NORVASC | 4751071 | JUN 14, 2005 | | |
| >ADD> >DLT> | 19787-001 AMLODIPINE BESYLATE; NORVASC | 5061794 | OCT 29, 2008 | | |
| >ADD> >DLT> | 19787 002 AMLODIPINE BESYLATE; NORVASC | 4529009 | FEB 25, 2003 | NCE | JUL 31, 1994 |
| >ADD> >DLT> | 19787-002 AMLODIPINE BESYLATE; NORVASC | 4572909 | AUG 01, 2006 | NCE | JUL 31, 1994 |
| >ADD> >DLT> | 19787 003 AMLODIPINE BESYLATE; NORVASC | 4572909 | FEB 25, 2003 | NCE | JUL 31, 1994 |
| >ADD> >DLT> | 19787-003 AMLODIPINE BESYLATE; NORVASC | 4572909 | AUG 01, 2006 | NCE | JUL 31, 1994 |
| >ADD> | 20258 001 APRACLONIDINE HYDROCHLORIDE; IOPIDINE | 4517199 | MAY 14, 2002 | U-15 | NS JUL 31, 1994 |
| >ADD> | 20304 001 APROTININ BOVINE; TRASYLOL | 4219559 | AUG 26, 1999 | NCE | DEC 29, 1994 |
| >ADD> | 19442 001 ASTENZONE; HISMANAL | 4522807 | JUN 11, 2002 | NCE | DEC 29, 1994 |
| >ADD> | 20045 001 AVONZONE; SHADE UVAGUARD | 4387089 | JUN 07, 2002 | NC | DEC 07, 1994 |
| >ADD> | 19807 001 BETAXOLOL HYDROCHLORIDE; KERLEDEX | 4252984 | AUG 30, 1999 | | |
| >ADD> | 19807 002 BETAXOLOL HYDROCHLORIDE; KERLEDEX | 4252984 | AUG 30, 1999 | | |
| >ADD> | 19982 001 BISOPROLOL FUMARATE; ZEBETA | 4258062 | MAR 24, 2000 | U-63 | NCE JUL 31, 1997 |
| >DLT> | 19982-001 BISOPROLOL FUMARATE; ZEBETA | 4258062 | MAR 24, 1998 | U-63 | NCE JUL 31, 1997 |
| >ADD> | 19982 002 BISOPROLOL FUMARATE; ZEBETA | 4258062 | MAR 24, 2000 | U-63 | NCE JUL 31, 1997 |
| >DLT> | 19982-002 BISOPROLOL FUMARATE; ZEBETA | 4258062 | MAR 24, 1998 | U-63 | NCE JUL 31, 1997 |
| >ADD> | 20186 001 BISOPROLOL FUMARATE; ZIAC | 4258062 | MAR 24, 2000 | U-63 | NCE JUL 31, 1997 |
| >DLT> | 20186-001 BISOPROLOL FUMARATE; ZIAC | 4258062 | MAR 24, 1998 | U-63 | NCE JUL 31, 1997 |
| >ADD> | 20186 002 BISOPROLOL FUMARATE; ZIAC | 4258062 | MAR 24, 2000 | U-63 | NCE FEB 26, 1996 |
| >DLT> | 20186-002 BISOPROLOL FUMARATE; ZIAC | 4258062 | MAR 24, 1998 | U-63 | NCE JUL 31, 1997 |
| >ADD> | 20186 003 BISOPROLOL FUMARATE; ZIAC | 4258062 | MAR 24, 2000 | U-63 | NCE JUL 31, 1997 |
| >DLT> | 20186-003 BISOPROLOL FUMARATE; ZIAC | 4258062 | MAR 24, 1998 | U-63 | NCE JUL 31, 1997 |
| >ADD> | 20273 001 CALCIOPOTRIENE; DOVONEX | 4258062 | MAR 24, 1998 | U-63 | NCE FEB 26, 1996 |
| >ADD> | 20486 008 SEP 12, 2006 II-88 | | | | |

PRESCRIPITION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES | |
|---------------------|--|------------------|-------------------|-------------|----------------|-------------------|------|
| 18343 001 | CAPTOPRIL; CAPOTEN | 4105776 | AUG 08, 1995 | I-95 | SEP 23, | 1996 | |
| 18343 002 | CAPTOPRIL; CAPOTEN | 4105776 | AUG 08, 1995 | I-95 | SEP 23, | 1996 | |
| 18343 003 | CAPTOPRIL; CAPOTEN | 4105776 | AUG 08, 1995 | I-95 | SEP 23, | 1996 | |
| 18343 005 | CAPTOPRIL; CAPOTEN | 4105776 | AUG 08, 1995 | I-95 | SEP 23, | 1996 | |
| 20210 001 | CISAPRIDE MONOHYDRATE; PROPELSID | 4962115 | OCT 09, 2007 | U-79 | JUL 29, | 1998 | |
| 20210 002 | CISAPRIDE MONOHYDRATE; PROPELSID | 4962115 | OCT 09, 2007 | U-79 | JUL 29, | 1998 | |
| 20229 001 | CLADRIBINE; LEUSTATIN | | | NCE | FEB 26, | 1998 | |
| >ADD> >DLT> | 20118 001 DESFLURANE; SUPRANE 20118-001 DESFLURANE; SUPRANE | 4762856 | SEP 18,' 2006 | U-67 | NCE | SEP 18, | 1997 |
| >ADD> | 20071 001 DESOGESTRE; DESOGEN | 3927046 | NOV 19, 1995 | NCE | DEC 10, | 1995 | |
| >ADD> | 20071 002 DESOGESTRE; DESOGEN | 3927046 | NOV 19, 1995 | NC | DEC 10, | 1995 | |
| >ADD> | 20301 001 DESOGESTRE; ORTHO-CEPT | 3927046 | NOV 19, 1995 | NC | DEC 10, | 1995 | |
| >ADD> | 20301 002 DESOGESTRE; ORTHO-CEPT | 3927046 | NOV 19, 1995 | NC | DEC 10, | 1995 | |
| >ADD> | 19287 001 DIAZEPAM; DIZAC | RE32393 | SEP 18, 1996 | NDF | JUN 18, | 1996 | |
| >ADD> | 20142 001 DICLOFENAC POTASSIUM; CATAFLAM | | | NDF | NOV 24, | 1996 | |
| >ADD> | 20142 002 DICLOFENAC POTASSIUM; CATAFLAM | | | NDF | NOV 24, | 1996 | |
| >ADD> | 18723 001 DIVALPROEX SODIUM; DEPAKOTE | 5212326 | JAN 29, 2008 | ODE | DEC 22, | 1999 | |
| >ADD> | 18723 002 DIVALPROEX SODIUM; DEPAKOTE | 5212326 | JAN 29, 2008 | ODE | DEC 22, | 1999 | |
| >ADD> | 18723 003 DIVALPROEX SODIUM; DEPAKOTE | 5212326 | JAN 29, 2008 | ODE | DEC 22, | 1999 | |
| >ADD> | 19680 001 DIVALPROEX SODIUM; DEPAKOTE | 5212326 | JAN 29, 2008 | ODE | DEC 22, | 1999 | |
| >ADD> | 19794 001 DIVALPROEX SODIUM; DEPAKOTE CP | 5212326 | JAN 29, 2008 | ODE | DEC 22, | 1999 | |
| >ADD> | 19794 002 DIVALPROEX SODIUM; DEPAKOTE CP | 5212326 | JAN 29, 2008 | ODE | DEC 22, | 1999 | |
| >ADD> | 18651 001 DRONABINOL; MARINOL | | | ODE | DEC 22, | 1999 | |
| >ADD> | 18651 002 DRONABINOL; MARINOL | | | ODE | DEC 22, | 1999 | |
| >ADD> | 18651 003 DRONABINOL; MARINOL | | | ODE | DEC 22, | 1999 | |
| >ADD> | 19879 002 EFFLORITHINE HYDROCHLORIDE; ORNIDYL | 4399151 | AUG 16, 2000 | NCE | NOV 28, | 1995 | |
| >ADD> | 19616 004 ENOXACIN; PENETREX | 4359578 | NOV 16, 2001 | NCE | DEC 31, | 1996 | |
| >ADD> | 19616 005 ENOXACIN; PENETREX | 4359578 | NOV 16, 2001 | NCE | DEC 31, | 1996 | |
| >ADD> | 20164 001 ENOXAPARIN SODIUM; LOVENOX | | | NCE | MAR 29, | 1998 | |
| >ADD> | 20189 001 FELBAMATE; FELBATOL | 5082861 | JAN 21, 2009 | U-83 | ODE | JUL 29, | 2000 |
| >ADD> | 19304 001 FENOFIBRATE; LIPIDIL | 4978680 | DEC 18, 2007 | U-83 | NCE | DEC 31, | 1998 |

**PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE EXCLUS CODE | EXCLUS EXPIRES |
|------------------|---|---------------|----------------|------------------|------------------|
| >ADD> | 20195 001 FENTANYL CITRATE; FENTANYL | 4671953 | JUN 09, 2004 | U-87 | NDF OCT 04, 1996 |
| >ADD> | 20195 002 FENTANYL CITRATE; FENTANYL | 4671953 | JUN 09, 2004 | U-87 | NDF OCT 04, 1996 |
| >ADD> | 20195 003 FENTANYL CITRATE; FENTANYL | 4671953 | JUN 09, 2004 | U-87 | NDF OCT 04, 1996 |
| >ADD> | 20090 001 FLUCONAZOLE; DIFLUCAN | 4416682 | NOV 22, 2000 | | |
| >ADD> | 20090 002 FLUCONAZOLE; DIFLUCAN | 4404216 | OCT 16, 2003 | NCE JAN 29, 1995 | |
| >ADD> | | 4416682 | NOV 22, 2000 | | |
| >ADD> | | 4404216 | OCT 16, 2003 | NCE JAN 29, 1995 | |
| >ADD> | 20073 001 FLUMAZENIL; MAZICON | 4316839 | MAR 03, 2003 | NCE DEC 20, 1996 | |
| >ADD> | 18936 001 FLUORETINE HYDROCHLORIDE; PROZAC | 4626549 | DEC 02, 2003 | U-84 | |
| >ADD> | 18936 006 FLUORETINE HYDROCHLORIDE; PROZAC | 4626549 | DEC 02, 2003 | U-84 | |
| | | 4314081 | FEB 02, 2001 | | |
| | | 4194009 | APR 19, 1994 | U-12 | |
| | | 4018895 | APR 19, 1994 | U-84 | |
| | | 4626549 | DEC 02, 2003 | | |
| >ADD> | 20101 001 FLUORETINE HYDROCHLORIDE; PROZAC | 4215113 | JUN 06, 2000 | U-64 | NCE DEC 31, 1998 |
| >ADD> | 20261 001 FLUVASTATIN SODIUM; LESCOL | 4087544 | MAY 02, 1995 | U-86 | NCE DEC 31, 1998 |
| >ADD> | 20261 002 FLUVASTATIN SODIUM; LESCOL | 4024755 | MAY 17, 1994 | | SEP 27, 1996 |
| >ADD> | 20268 001 FOSCARINET SODIUM; FOSCNAVIR | 4087544 | MAY 02, 1995 | U-86 | |
| >ADD> | GABAPENTIN; NEURONTIN | 4024755 | MAY 17, 1994 | | |
| >ADD> | 20235 002 GABAPENTIN; NEURONTIN | 4087544 | MAY 02, 1995 | U-86 | |
| >ADD> | 20235 003 GABAPENTIN; NEURONTIN | 4024755 | MAY 17, 1994 | | |
| >ADD> | 20123 001 GADODIAMIDE; OMNISCAN | 4087544 | MAY 02, 1995 | U-86 | |
| >ADD> | 19596 001 GADOPENTETATE DIMEGLUMINE; MAGNEVIST | 4024755 | MAY 17, 1994 | | |
| >ADD> | 17783 003 GLIPIZIDE; GLUCOTROL | 4687659 | AUG 18, 2004 | U-76 | |
| >ADD> | 20051 003 GLYBURIDE; GLYNASE | 4957939 | MAR 03, 2004 | | |
| | | 4916163 | APR 10, 2007 | | |
| | | 4735805 | APR 05, 2005 | | |
| | | 4916163 | APR 10, 2007 | | |
| | | 4735805 | APR 05, 2005 | | |
| | | 4886808 | DEC 12, 2006 | U-89 | |
| | | | | | |
| >ADD> | 19726 001 GOSERELIN ACETATE; ZOLADEX | | | | |
| >ADD> | 20239 001 GRANISETRON HYDROCHLORIDE; KYTRIL | | | | |
| >ADD> | 19032 001 GUANFACINE HYDROCHLORIDE; TENEX | | | | |
| >ADD> | 19032 002 GUANFACINE HYDROCHLORIDE; TENEX | | | | |
| >ADD> | 19778 003 HYDROCHLORTIAZIDE; PRINZIDE 10-12.5 | | | | |
| >ADD> | 18888 003 HYDROCHLORTIAZIDE; ZESTORETIC 10-12.5 | | | | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---------------------|--|------------------|-------------------|-------------|----------------|-------------------|
| 19891 001 | HYDROMORPHONE HYDROCHLORIDE; DILAUDID | | | NCE | JAN 11, 1994 | |
| 19892 001 | HYDROMORPHONE HYDROCHLORIDE; DILAUDID | | | NDF | DEC 07, 1995 | |
| 18538 002 | INDAPAMIDE; LOZOL | | | NCE | JAN 11, 1994 | |
| 18956 001 | IOPHEXOL; OINNIPHAQUE 180 | 4250113 | DEC 26, 1999 | NCE | JUL 06, 1993 | |
| | | 4021481 | MAY 03, 1994 | NDF | DEC 07, 1995 | |
| 19710 005 | IOPERSOL; OPTIRAY 350 | | | NCE | JUL 13, 1996 | |
| 20228 001 | IPRATROPIUM BROMIDE; ATROVENT | | | NR | JUL 13, 1996 | |
| 20215 001 | ISOSORBIDE MONONITRATE; MONOKET | | | NDF | JUL 27, 1996 | |
| 20215 002 | ISOSORBIDE MONONITRATE; MONOKET | | | NCE | SEP 29, 1996 | |
| 20225 001 | ISOSORBIDE MONONITRATE; IMDUR | | | NCE | DEC 30, 1996 | |
| 20225 002 | ISOSORBIDE MONONITRATE; IMDUR | | | NS | JUN 30, 1996 | |
| 19084 001 | KETOCONAZOLE; NIZORAL | 4335125 | JUN 15, 1999 | NCE | DEC 30, 1996 | |
| 19700 001 | KETOROLAC TRIMETHAMINE; ACULAR | 5110493 | MAY 05, 2009 | U-75 | NOV 30, 1994 | |
| | | 4454151 | JUN 12, 2001 | U-75 | NOV 09, 1995 | |
| 20263 001 | LEUPROLIDE ACETATE; LUPRON | 4089969 | MAY 16, 1997 | U-75 | | |
| | | 4917893 | MAR 24, 2004 | | | |
| | | 4849228 | JUL 18, 2006 | NP | APR 16, 1996 | |
| | | 4728721 | MAR 01, 2005 | | | |
| | | 4652441 | MAR 24, 2004 | | | |
| | | 4677191 | JUN 30, 2004 | | | |
| | | 4005063 | JAN 25, 1996 | ODE | APR 16, 2000 | |
| | | 4917893 | MAR 24, 2004 | | | |
| | | 4849228 | JUL 18, 2006 | NP | APR 16, 1996 | |
| 20263 002 | LEUPROLIDE ACETATE; LUPRON DEPOT - PED | 4728721 | MAR 01, 2005 | | | |
| | | 4677191 | JUN 30, 2004 | | | |
| | | 4652441 | MAR 24, 2004 | | | |
| | | 4005063 | JAN 25, 1996 | ODE | APR 16, 2000 | |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|------------------|--|---------------|----------------|----------|--------------|----------------|
| 20263 003 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 4917893 | MAR 24, 2004 | NP | APR 16, 1996 | |
| | | 4849228 | JUL 18, 2006 | | | |
| | | 4728721 | MAR 01, 2005 | | | |
| | | 4677191 | JUN 30, 2004 | | | |
| | | 4652441 | MAR 24, 2004 | | | |
| | | 4005063 | JAN 25, 1996 | ODE | APR 16, 2000 | |
| 20263 004 | LEUPROLIDE ACETATE; LUPRON DEPOT-PED | 4917893 | MAR 24, 2004 | NP | APR 16, 1996 | |
| | | 4849228 | JUL 18, 2006 | | | |
| | | 4728721 | MAR 01, 2005 | | | |
| | | 4677191 | JUN 30, 2004 | | | |
| | | 4652441 | MAR 24, 2004 | | | |
| | | 4005063 | JAN 25, 1996 | ODE | APR 16, 2000 | |
| >ADD> | 20219 001 LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN 18948 001 LEVOCARNITINE; CARNITOR | 4005063 | JAN 25, 1996 | ODE | APR 16, 2000 | |
| | | | | NCE | NOV 10, 1998 | |
| | | | | 1-86 | DEC 16, 1995 | |
| 20315 001 | LEVOMETHADYL ACETATE HYDROCHLORIDE; ORLAAM | 4374829 | DEC 30, 2001 | ODE | DEC 16, 1999 | |
| | | 4374829 | DEC 30, 2001 | NCE | JUL 09, 1998 | |
| | | 4374829 | DEC 30, 2001 | ODE | JUL 09, 2000 | |
| 19558 001 | LISINOPRIL; PRINIVIL | 4374829 | DEC 30, 2001 | NCE | JUL 09, 1998 | |
| 19558 002 | LISINOPRIL; PRINIVIL | 4374829 | DEC 30, 2001 | ODE | JUL 09, 1998 | |
| 19558 003 | LISINOPRIL; PRINIVIL | 4374829 | DEC 30, 2001 | NCE | JUL 09, 1998 | |
| 19558 004 | LISINOPRIL; PRINIVIL | 4374829 | DEC 30, 2001 | ODE | JUL 09, 1998 | |
| 19777 001 | LISINOPRIL; ZESTRIL | 4374829 | DEC 30, 2001 | NCE | JUL 09, 1998 | |
| 19777 002 | LISINOPRIL; ZESTRIL | 4374829 | DEC 30, 2001 | ODE | JUL 09, 1998 | |
| 19777 003 | LISINOPRIL; ZESTRIL | 4374829 | DEC 30, 2001 | NCE | JUL 09, 1998 | |
| 19777 004 | LISINOPRIL; ZESTRIL | 4374829 | DEC 30, 2001 | ODE | JUL 09, 1998 | |
| 19777 005 | LISINOPRIL; ZESTRIL | 4374829 | DEC 30, 2001 | NCE | JUL 09, 1998 | |
| 20191 001 | LOOKAMIDE TROMETHAMINE; ALOMIDE | 4374829 | DEC 30, 2001 | ODE | JUL 09, 1998 | |
| 20013 001 | LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN | 4528287 | MAY 05, 2005 | U-36 | ODE | SEP 23, 2000 |
| 19658 001 | LORATADINE; CLARITIN | 4282233 | AUG 04, 1998 | U-77 | NCE | FEB 21, 1997 |
| 19940 001 | MASOPROLIC; ACTINEX | 4695590 | SEP 05, 2006 | | NCE | APR 12, 1998 |
| >ADD> | >DLT> | 6695590 | SEP 22, 2004 | | NCE | SEP 04, 1997 |
| 20264 001 | MEGESTROL ACETATE; MEGACE | 4980173 | DEC 25, 2007 | U-78 | ODE | SEP 10, 2000 |
| 20049 001 | MESALAMINE; PENTASA | 4496553 | JAN 29, 2002 | U-78 | NP | MAY 10, 1996 |

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---------------------|--|------------------|-------------------|-------------|----------------|-------------------|
| 20098 001 | MIVACURIUM CHLORIDE; MIVACRON | 4761418 | JAN 22, 2006 | NCE | JAN 22, | 1997 |
| 20098 002 | MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5% | 4761418 | JAN 22, 2006 | NCE | JAN 22, | 1997 |
| 19583 001 | NABUMETONE; RELAFEN | 4420639 | DEC 13, 2002 | NCE | DEC 24, | 1996 |
| 19583 002 | NABUMETONE; RELAFEN | 4420639 | DEC 13, 2002 | NCE | DEC 24, | 1996 |
| 20109 001 | NAFARELIN ACETATE; SYNAREL | 4234571 | NOV 18, 1999 | NCE | FEB 13, | 1995 |
| 19356 001 | NAFTIFINE HYDROCHLORIDE; NAFTIN | 4282251 | AUG 04, 2000 | NCE | MAR 01, | 1993 |
| 20150 001 | NICOTINE; NICOTROL | 4915950 | APR 10, 2007 | NP | APR 22, | 1995 |
| 20150 002 | NICOTINE; NICOTROL | 4915950 | APR 10, 2007 | NP | APR 22, | 1995 |
| 20150 003 | NICOTINE; NICOTROL | 4915950 | APR 10, 2007 | NP | APR 22, | 1995 |
| 20066 001 | NICOTINE POLACRELYX; NICORETTE DS | 4915950 | APR 10, 2007 | NP | APR 22, | 1995 |
| 20198 001 | NIFEDIPINE; ADALAT CC | 4892741 | JAN 09, 2007 | NDF | JUL 30, | 1996 |
| 20198 002 | NIFEDIPINE; ADALAT CC | 4892741 | JAN 09, 2007 | NDF | JUL 30, | 1996 |
| 20198 003 | NIFEDIPINE; ADALAT CC | 4892741 | JAN 09, 2007 | NDF | JUL 30, | 1996 |
| 19921 001 | OFLOXACIN; OCULEFOL | 4551456 | NOV 05, 2002 | U-80 | D-20 | FEB 02, 1996 |
| 20007 001 | ONDANSETRON HYDROCHLORIDE; ZOFTRAN | 4695578 | JAN 03, 2005 | NCE | 1-9 | AUG 13, 1996 |
| 20103 001 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4695578 | JAN 03, 2005 | NCE | JAN 04, | 1996 |
| 20103 002 | ONDANSETRON HYDROCHLORIDE; ZOFRAN | 4695578 | JAN 03, 2005 | NCE | JAN 04, | 1996 |
| 20036 001 | PAMIDRONATE DISODIUM; AREDIA | 3962432 | JUL 16, 1996 | U-53 | NCE | OCT 31, 1996 |
| 20036 003 | PAMIDRONATE DISODIUM; AREDIA | 4711880 | DEC 08, 2004 | NCE | OCT 31, 1996 | |
| 20036 004 | PAMIDRONATE DISODIUM; AREDIA | 3962432 | JUL 16, 1996 | U-53 | NCE | OCT 31, 1996 |
| 20091 001 | PERFLUBRON; IMAGEN | 4695578 | JAN 03, 2005 | NCE | OCT 31, | 1996 |
| >ADD> | PERINDOPRIL ERBITUME; ACEON | 4695578 | JAN 03, 2005 | NCE | OCT 31, | 1996 |
| >ADD> | PERINDOPRIL ERBITUME; ACEON | 4695578 | JAN 03, 2005 | NCE | OCT 31, | 1996 |
| >ADD> | PIRUTEROL ACETATE; MAXAIR | 4664107 | MAY 12, 2004 | NCE | OCT 31, | 1995 |
| 19795 001 | POOFILLOX; CONDYLOX | 4346227 | AUG 24, 1999 | NCE | DEC 30, | 1998 |
| 19898 004 | PRAVASTATIN SODIUM; PRAVACHOL | 4242334 | DEC 30, 1999 | U-50 | NE | SEP 23, 1994 |
| 19568 001 | PREDNICARBATE; DERMATOP | 4242334 | DEC 30, 1999 | U-50 | NE | SEP 23, 1994 |
| 20279 001 | PREDNICARBATE; DERMATOP | 4996061 | FEB 26, 2008 | 1-90 | MAR 08, | 1996 |
| 19627 001 | PROPOFOL; DIPRIVAN | 4929605 | MAY 29, 2007 | U-81 | | |
| 19664 001 | PSEUDOEPHEDRINE HYDROCHLORIDE; SELDANE-D | 4254129 | MAR 03, 1998 | U-81 | | |

PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS EXPIRES |
|------------------|--------------------------------------|---------------|----------------|----------|-------------------|
| 19885 001 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | MAY 10, 2005 | 1-92 | OCT 29, 1996 |
| 19885 002 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | MAY 10, 2005 | 1-92 | OCT 29, 1996 |
| 19885 003 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | MAY 10, 2005 | 1-92 | OCT 29, 1996 |
| 19885 004 | QUINAPRIL HYDROCHLORIDE; ACCUPRIL | 4743450 | MAY 10, 2005 | 1-92 | OCT 29, 1996 |
| 50689 001 | RIFABUTIN; MYCOPUTIN | 0DE | DEC 23, 1999 | NCE | SEP 17, 1998 |
| 19649 001 | RIMANTADINE HYDROCHLORIDE; FLUMADINE | | | NCE | SEP 17, 1998 |
| 19650 001 | RIMANTADINE HYDROCHLORIDE; FLUMADINE | | | NCE | DEC 29, 1998 |
| >ADD> | RISPERIDONE; RISPERDAL | 4804663 | FEB 14, 2006 | U-90 | NCE |
| >ADD> | RISPERIDONE; RISPERDAL | 4804663 | FEB 14, 2006 | U-90 | NCE |
| >ADD> | RISPERIDONE; RISPERDAL | 4804663 | FEB 14, 2006 | U-90 | NCE |
| >ADD> | RISPERIDONE; RISPERDAL | 4804663 | FEB 14, 2006 | U-90 | NCE |
| >ADD> | RISPERIDONE; RISPERDAL | 4804663 | FEB 14, 2006 | U-90 | NCE |
| >ADD> | RISPERIDONE; RISPERDAL | 4804663 | FEB 14, 2006 | U-90 | NCE |
| >ADD> | SERTRALINE HYDROCHLORIDE; ZOLOFT | 5248699 | SEP 28, 2010 | U-12 | DEC 29, 1998 |
| >ADD> | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4962128 | OCT 09, 2007 | 2005 | NCE |
| >ADD> | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4536518 | DEC 31, 2005 | 2005 | NCE |
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| >ADD> | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4962128 | OCT 09, 2007 | 2005 | NCE |
| >ADD> | SERTRALINE HYDROCHLORIDE; ZOLOFT | 4536518 | DEC 31, 2005 | 2005 | NCE |
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| >ADD> | SIMVASTATIN; ZOCOR | 5248699 | SEP 28, 2010 | U-12 | DEC 30, 1996 |
| 19766 001 | SIMVASTATIN; ZOCOR | 4962128 | OCT 09, 2007 | 2005 | NCE |
| 19766 002 | SIMVASTATIN; ZOCOR | 4536518 | DEC 31, 2005 | 2005 | NCE |
| 19766 003 | SIMVASTATIN; ZOCOR | 44444784 | DEC 24, 2005 | U-59 | NCE |
| 19766 004 | SIMVASTATIN; ZOCOR | 44444784 | DEC 24, 2005 | U-59 | NCE |
| 20168 001 | SOMATROPIN; BIOSYNTHETIC; NUTROPIN | 44444784 | DEC 24, 2005 | U-59 | NCE |
| >ADD> | SOMATROPIN; BIOSYNTHETIC; NUTROPIN | | | I-98 | NOV 17, 1996 |
| >ADD> | STRONTIUM CHLORIDE, SR-89; METASTRON | | | ODE | NOV 17, 2000 |
| >ADD> | SUCRALFATE; CARAFATE | | | NCE | JUN 18, 1998 |
| 19183 001 | SUFENTANIL CITRATE; SUFENTA | | | NDF | DEC 16, 1996 |
| 19050 001 | SUMATRIPTAN SUCCINATE; IMITREX | | | NR | MAR 19, 1996 |
| 20080 001 | SUMATRIPTAN SUCCINATE; IMITREX | 4816470 | MAR 28, 2006 | U-72 | I-89 MAR 19, 1996 |

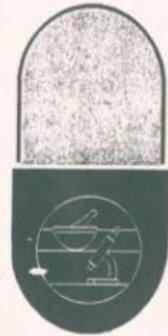
PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROO NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---------------------|---|------------------|-------------------|-------------|----------------|-------------------|
| 20070 001 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | MAR 28, 2006 | U-82 | NCE | SEP 09, 1998 |
| 20070 002 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | MAR 28, 2006 | U-82 | NCE | SEP 09, 1998 |
| 20070 003 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | MAR 28, 2006 | U-82 | NCE | SEP 09, 1998 |
| 20070 004 | TACRINE HYDROCHLORIDE; COGNEX | 4816456 | MAR 28, 2006 | U-82 | NCE | SEP 09, 1998 |
| 19882 001 | TECHNETIUM TC-99M MERTIATE KIT; TECHNESCAN MAG3 | 4730000 | JAN 30, 2006 | U-36 | NCE | NOV 27, 1995 |
| 20043 003 | TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX | 4730000 | JAN 30, 2006 | U-36 | NCE | JAN 30, 1997 |
| 20043 004 | TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX | 5211954 | MAY 18, 2010 | 1-87 | NCE | JAN 30, 1997 |
| 18163 003 | TEMAZEPAM; RESTORIL | 5030632 | JUL 09, 2008 | U-70 | NS | OCT 25, 1994 |
| 19057 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 2000 | U-3 | 1-96 | SEP 29, 1996 |
| 19057 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 2000 | U-3 | 1-96 | SEP 29, 1996 |
| 19057 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 2000 | U-3 | 1-96 | SEP 29, 1996 |
| 19057 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 2000 | U-3 | 1-96 | SEP 29, 1996 |
| 20223 001 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 2000 | U-3 | 1-96 | SEP 29, 1996 |
| 20223 002 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4112097 | SEP 05, 1995 | 1-96 | SEP 29, 1996 | |
| 20223 003 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4026894 | MAY 31, 1994 | 1-96 | SEP 29, 1996 | |
| 20223 004 | TERAZOSIN HYDROCHLORIDE; HYTRIN | 4251532 | FEB 17, 2000 | U-81 | ND | OCT 12, 1996 |
| 18949 001 | TERENADINE; SELDANE | 4251532 | FEB 17, 2000 | ND | OCT 12, 1996 | |
| 19762 001 | TESTOSTERONE; TESTODERM | 4112097 | SEP 05, 1995 | ND | OCT 12, 1996 | |
| 19762 002 | TESTOSTERONE; TESTODERM | 4026894 | MAY 31, 1994 | ND | OCT 12, 1996 | |
| 19979 001 | TICLOPIDINE HYDROCHLORIDE; TICLID | 4251532 | FEB 17, 2000 | ND | OCT 12, 1996 | |
| 20330 001 | TIMOLOL MALEATE; TIMOPTIC-XE | 4112097 | SEP 05, 1995 | ND | OCT 12, 1996 | |
| 20330 002 | TIMOLOL MALEATE; TIMOPTIC-XE | 4026894 | MAY 31, 1994 | ND | OCT 12, 1996 | |
| | | 4254129 | MAR 03, 1998 | 1-96 | SEP 29, 1996 | |
| | | 4591592 | NOV 01, 2005 | ND | OCT 12, 1996 | |
| | | 4051161 | SEP 27, 1996 | ND | OCT 12, 1996 | |
| | | 4591592 | NOV 01, 2005 | ND | OCT 12, 1996 | |
| | | 4051141 | SEP 27, 1996 | ND | OCT 12, 1996 | |

PRESSCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

| APPL/PROD NUMBER | INGREDIENT NAME; TRADE NAME | PATENT NUMBER | PATENT EXPIRES | USE CODE | EXCLUS CODE | EXCLUS EXPIRES |
|---------------------|---|------------------|-------------------|-------------|----------------|-------------------|
| 20136 001 | TORSEMIDE; DEMADEX | 4,822,807 | APR 18, 2006 | | | |
| 20136 002 | TORSEMIDE; DEMADEX | 4,018,929 | APR 19, 1994 | NCE | | AUG 23, 1998 |
| | | RE30633 | APR 19, 1994 | | | |
| | | 4,822,807 | APR 18, 2006 | | | |
| 20136 003 | TORSEMIDE; DEMADEX | 4,018,929 | APR 19, 1994 | NCE | | AUG 23, 1998 |
| | | RE30633 | APR 19, 1994 | | | |
| | | 4,822,807 | APR 18, 2006 | | | |
| 20136 004 | TORSEMIDE; DEMADEX | 4,018,929 | APR 19, 1994 | NCE | | AUG 23, 1998 |
| | | RE30633 | APR 19, 1994 | | | |
| | | 4,822,807 | APR 18, 2006 | | | |
| 20137 002 | TORSEMIDE; DEMADEX | 4,018,929 | APR 19, 1994 | NCE | | AUG 23, 1998 |
| | | RE30633 | APR 19, 1994 | | | |
| | | 4,822,807 | APR 18, 2006 | | | |
| 18207 004 | TRAZODONE HYDROCHLORIDE; DESYREL | 4,018,929 | APR 19, 1994 | NCE | | AUG 23, 1998 |
| | | RE30633 | APR 19, 1994 | | | |
| >ADD> | 19798 001 TRIAMCINOLONE ACETONIDE; NASACORT | 4,258,027 | MAR 24, 1998 | | | |
| >ADD> | 20326 001 TRIMETREXATE GLUCURONATE; NEUTREXIN | 4,215,104 | JUL 29, 1997 | | | |
| 18776 003 | VECURONIUM BROMIDE; NORCURON | 4,767,612 | AUG 30, 2005 | U-85 | MR | JUL 11, 1994 |
| | | 4,376,858 | MAR 15, 2000 | | | |
| | | 4,297,351 | OCT 27, 1998 | | | |
| >ADD> | 20151 001 VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4,237,126 | DEC 02, 1997 | | | |
| >ADD> | 20151 002 VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4,535,186 | AUG 13, 2002 | | | |
| >ADD> | 20151 003 VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4,535,186 | AUG 13, 2002 | | | |
| >ADD> | 20151 004 VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4,535,186 | AUG 13, 2002 | | | |
| >ADD> | 20151 005 VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4,535,186 | AUG 13, 2002 | | | |
| >ADD> | 20151 006 VENLAFAXINE HYDROCHLORIDE; EFFEXOR | 4,535,186 | AUG 13, 2002 | | | |
| 19908 001 | ZOLPIDEM TARTRATE; AMBIEN | 4,382,938 | MAY 10, 2000 | U-74 | NCE | DEC 16, 1997 |
| 19908 002 | ZOLPIDEM TARTRATE; AMBIEN | 4,382,938 | MAY 10, 2000 | U-74 | NCE | DEC 16, 1997 |

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