

**CUMULATIVE
SUPPLEMENT 8**

JAN'94-AUG'94

APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

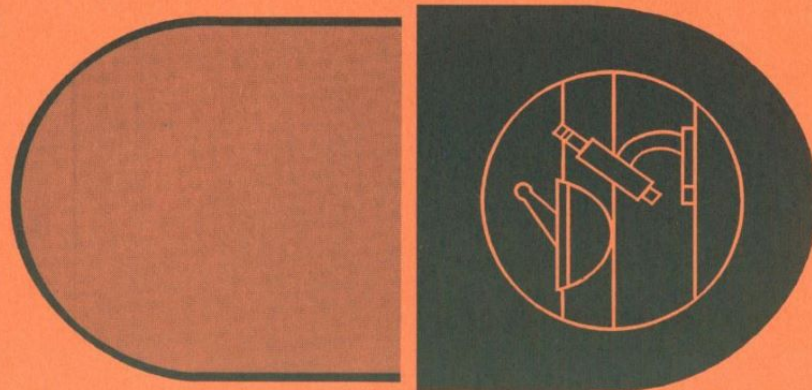
PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF MANAGEMENT

DIVISION OF DRUG INFORMATION RESOURCES



RM
301.45
.A66
1994
Aug
Suppl

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

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New 15th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**15TH EDITION
1995**

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Library Use Only

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RM301.45 .A66 1994 Aug Suppl

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

Cumulative Supplement 8

AUGUST 1994

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

14TH EDITION

CUMULATIVE SUPPLEMENT 8

AUGUST 1994

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, 14th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 14th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 15th 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. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)

NEW APPLICANT NAME (NEW ABBREVIATED NAME)

ADRIA LABORATORIES DIV ERBAMONT INC
(ADRIA)

PHARMACIA INC
(PHARMACIA)

BANNER GELATIN PRODUCTS CORP
(BANNER GELATIN)

BANNER PHARMACAPS INC
(BANNER PHARMACAPS)

CLONMEL CHEMICALS CO LTD
(CLONMEL)

CLONMEL HEALTHCARE LIMITED
(CLONMEL)

DUPONT PHARMACEUTICALS
(DUPONT)

DUPONT MERCK PHARMACEUTICALS CO
(DUPONT MERCK)

GYNEX INC
(GYNEX)

BTG PHARMACEUTICALS CORP SUB
BIOTECHNOLOGY GENERAL CORP
(BTG PHARMS)

KABI PHARMACIA INC
(KABI)

PHARMACIA INC
(PHARMACIA)

MALLINCKRODT SPECIALTY CHEMICALS CO
(MALLINCKRODT)

MALLINCKRODT CHEMICAL INC
(MALLINCKRODT)

NORTH AMERICAN CHEMICAL CORP
(NORTH AM CHEM)

GOLDEN PHARMACEUTICALS INC
(GOLDEN PHARM)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

PHARMACEUTICAL BASICS INC
(PHARM BASICS)

ROSEMONT PHARMACEUTICAL CORPORATION
(ROSEMONT PHARM)

RICHLYN LABORATORIES INC
(RICHLYN)

GLOBAL PHARMACEUTICAL CORPORATION
(GLOBAL PHARM)

SQUIBB DIAGNOSTICS
(SQUIBB)

BRACCO DIAGNOSTICS INC
(BRACCO)

1.4 NEW INDICATIONS FOR PREVIOUSLY APPROVED DRUG PRODUCTS

When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by the same firm, the application is either submitted as a supplement to the original NDA (if the clinical expertise for the review of the new indication resides in the same division that reviewed the original NDA), or as a "Type 6 NDA" and assigned a new NDA number (if the clinical expertise for the review of the new indication resides in another review division). When an application is submitted to FDA for a new indication for a drug product that duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by a different firm, the application is classified as "Type 6" and assigned a new NDA number. For administrative purposes, FDA has been listing all "Type 6 NDA's" in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, (ADP), even when the application was submitted by the original NDA holder. However, FDA has determined that the practice of listing a separate "Type 6 NDA" number in the ADP when the applicant is the original NDA holder may cause confusion to the ADP reader.

Accordingly, to prevent confusion and to eliminate duplicity of data, the approval of an application for a new indication for a previously approved drug product submitted by the original NDA holder will no longer be listed in the ADP. Any exclusivity awarded for that approval will be shown in the Patent and Exclusivity Information Addendum under the original NDA number. However, approval of an application for a new indication submitted by an applicant other than the original NDA holder will be shown in the appropriate drug product list of the ADP. Any exclusivity awarded will be shown under the NDA number of the new applicant.

All approvals of "Type 6" applications submitted by the original NDA holder currently in the ADP are listed in the table below. For reference purposes, the original NDA number is listed next to the corresponding "Type 6 NDA Number". This data ("Type 6 NDA Number") will continue to be listed in the remaining Cumulative Supplements to the 14th Edition of the ADP; but it will not appear in the 15th Edition of the ADP.

<u>TYPE 6 NDA NUMBER</u>	<u>ORIGINAL NDA NUMBER</u>	<u>ACTIVE INGREDIENT (TRADE NAME)</u>	<u>DOSAGE FORM (ROUTE)</u>
17-117	16-020	AMANTADINE HCL (SYMMETREL)	CAPSULE (ORAL)
17-118	16-023	AMANTADINE HCL (SYMMETREL)	SYRUP (ORAL)
50-697	50-662	CLARITHROMYCIN (BIAxin)	TABLET (ORAL)
19-576	19-084	KETOCONAZOLE (NIZORAL)	CREAM (TOPICAL)
19-648	19-084	KETOCONAZOLE (NIZORAL)	CREAM (TOPICAL)
18-064	18-063	NADOLOL (CORGARD)	TABLET (ORAL)
20-109	19-886	NAFARELIN ACETATE (SYNAREL)	SPRAY, METERED (NASAL)
20-223	19-057	TERAZOSIN HCL (HYTRIN)	TABLET (ORAL)

1.5 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

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

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

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

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

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

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF AUGUST 1994.

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1993) 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 1993</u>	<u>MAR 1994</u>	<u>JUN 1994</u>	<u>SEP 1994</u>
DRUG PRODUCTS LISTED	9140	9153	9079	
SINGLE SOURCE	2144 (23.5%)	2151 (23.5%)	2150 (23.7%)	
MULTISOURCE	6996 (76.5%)	7002 (76.5%)	6929 (76.3%)	
THERAPEUTICALLY EQUIVALENT	6292 (68.8%)	6306 (68.9%)	6290 (69.3%)	
NOT THERAPEUTICALLY EQUIVALENT	527 (5.8%)	513 (5.6%)	458 (5.0%)	
EXCEPTIONS ¹	177 (1.9%)	183 (2.0%)	181 (2.0%)	
NEW MOLECULAR ENTITIES APPROVED	--	6	5	
NUMBER OF APPLICANTS	526	528	490	

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

PRESCRIPTION DRUG PRODUCT LIST
14TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 8 / JAN '94 - AUG '94

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

/AB/ /MEDIGESIC PLUS/

/325MG; 50MG; 40MG/

/N89115/001/
/JAN/14, 1986/

N89115 001
JAN 14, 1986

325MG; 50MG; 40MG

@ US CHEM

ACETIC ACID; GLACIAL; ALUMINUM ACETATE

SOLUTION/DROPS; OTIC

ACETIC ACID 2% IN AQUEOUS ALUMINUM ACETATE

AT BAUSCH AND LOMB 2%; 0.79%

N40063 001
FEB 25, 1994

/AL/ /BOROFAIR/
/PHARMAFAIR/

/2%; 0.79%/

/N88606/001/
/AUG/21, 1985/

@ PHARMAFAIR 2%; 0.79%

N88606 001
AUG 21, 1985

DONEBORO

> DLT > /AL/ /MILES/
> ADD > AT + MILES

/2%; 0.79%/
2%; 0.79%

/N84476/001/
N84476 001

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

ACETYLCYSTEINE

ABBOTT

10%

N73664 001
AUG 30, 1994

20%

N74037 001
AUG 30, 1994

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

SEMPREX-D

+ BURROUGHS WELLCOME 8MG; 60MG

N19806 001
MAR 25, 1994

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

/AB/ /WARNER/CHILCOTT/

/N72817/001/
/JAN/09, 1990/

/N72818/001/
/JAN/09, 1990/

/EQ 2MG BASE/

/N72817/001/
/JAN/09, 1990/

/EQ 4MG BASE/

@ WARNER CHILCOTT

EQ 2MG BASE

N72817 001
JAN 09, 1990

EQ 4MG BASE

N72818 001
JAN 09, 1990

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

MYLAN

0.25MG

N74215 001
JAN 27, 1994

0.5MG

N74215 002
JAN 27, 1994

1MG

N74215 003
JAN 27, 1994

2MG

N74215 004
JAN 27, 1994

0.25MG

N74085 001
FEB 16, 1994

0.5MG

N74085 002
FEB 16, 1994

1MG

N74085 003
FEB 16, 1994

0.25MG

N74294 001
JUL 29, 1994

0.5MG

N74294 002
JUL 29, 1994

1MG

N74294 003
JUL 29, 1994

2MG

N74294 004
JUL 29, 1994

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKACIN

BEDFORD

EQ 50MG BASE/ML

N63313 001
APR 11, 1994

EQ 250MG BASE/ML

N63315 001
APR 11, 1994

¹DUE TO PROGRAMMING CHANGES, EACH FIELD ON A PREVIOUSLY DELETED OR CURRENTLY DELETED DRUG PRODUCT LINE HAS BEEN CHANGED TO ONLY SHOW THE OVERSTRUCK SYMBOL BEFORE AND AFTER EACH FIELD RATHER THAN OVER EACH CHARACTER OF THE ENTIRE ENTRY.

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

/POLYMOX/

/AB/ /BRISTOL/

/125MG/5ML/

/125MG/5ML/

/250MG/5ML/

/250MG/5ML/

125MG/5ML

125MG/5ML

250MG/5ML

250MG/5ML

@ APOTHECON

@

@

@

/N61851/001/

/N62323/001/

/N61851/002/

/N62323/002/

N61851 001

N62323 001

N61851 002

N62323 002

AMPHETAMINE SULFATE

/TABLET; ORAL/

/AMPHETAMINE/SULFATE/

/LANNETT/

/5MG/

/10MG/

@ LANNETT

@

/N83901/001/

/AUG/31./1984/

/N83901/002/

/AUG/31./1984/

N83901 001

AUG 31, 1984

N83901 002

AUG 31, 1984

AMPHOTERICIN B

INJECTABLE; INJECTION

AMPHOTERICIN B

/AP/ /FUJISAWA/

/50MG/VIAL/

@ FUJISAWA

50MG/VIAL

/N62728/001/

/APR/13./1987/

N62728 001

APR 13, 1987

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

POLYCILLIN

@ APOTHECON

/AB/ /BRISTOL/

/AB/

EQ 125MG BASE/5ML

EQ 250MG BASE/5ML

/EQ 125MG BASE/5ML/

/EQ 250MG BASE/5ML/

N62297 001

N62297 002

/N62297/001/

/N62297/002/

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

INJECTABLE; INJECTION

/M.V.C. 9+3/

/FUJISAWA/

/AP/

/10MG/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/ /N18440/002/

10MG/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 N18440 002

AUG 08, 1985

AUG 08, 1985

@ FUJISAWA

ATENOLOL

TABLET; ORAL

ATENOLOL

GENPHARM

AB

AB

AB

AB

AB

AB

AB

AB

AB

50MG

100MG

25MG

50MG

100MG

N74126 001

MAR 23, 1994

N74126 002

MAR 23, 1994

N74265 001

FEB 28, 1994

N74265 002

FEB 28, 1994

N74265 003

FEB 28, 1994

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

/LOFENE/

/AA/ /LANNETT/

@ LANNETT

/0.025MG; 2.5MG/

0.025MG; 2.5MG

/N85372/001/

N85372 001

BACITRACIN

OINTMENT; OPHTHALMIC

BACITRACIN

@ PHARMADERM/

@ PHARMADERM

/AL/ /PHARMAFAIR/

@ PHARMAFAIR

/500 UNITS/GM/

500 UNITS/GM

/500 UNITS/GM/

500 UNITS/GM

/N62158/001/

N62158 001

/N62453/001/

MAR/28./1984/

N62453 001

MAR 28, 1984

BACLOFEN

TABLET; ORAL

BACLOFEN

AB ROYCE

10MG

N73092 001
JAN 28, 1994

AB

20MG

N73093 001
JAN 28, 1994

BENZYL BENZOATE

/EMULSION; /TOPICAL/

/BENZYL/BENZOATE/

/+//LANNETT/

@ LANNETT

/50%/

/N84535/001/
N84535 001

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL

/DIPROLENE/

/+//SCHERING/

/EQ/0.05%/BASE/

/N19408/001/
/JAN/31,/1986/

@ SCHERING

EQ 0.05% BASE

N19408 001
JAN 31, 1986

GEL; TOPICAL

DIPROLENE

+ SCHERING

EQ 0.05% BASE

N19408 002
NOV 22, 1991

BETAMETHASONE VALERATE

OINTMENT; TOPICAL

BETAMETHASONE VALERATE

/B*/ /CLAY/PARK/

/EQ/0.1%/BASE/

/N71478/001/
/DEC/23,/1987/

@ CLAY PARK

EQ 0.1% BASE

N71478 001
DEC 23, 1987

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

/AA/

/5MG/

/N84702/001/

/AA/

/10MG/

/N84712/001/

/AA/

/25MG/

/N84074/001/

@ LANNETT

5MG

N84702 001

@

10MG

N84712 001

@

25MG

N84074 001

BROMPHENIRAMINE MALEATE, DEXTROMETHORPHAN HYDROBROMIDE,

PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

DIMETANE-DX

/AA/ /ROBINS/AH/

/2MG/5ML; 10MG/5ML;
/30MG/5ML//N11694/007/
/MAR/29,/1984/

BUDESONIDE

AEROSOL, METERED; NASAL

RHINOCORT

+ ASTRA

0.05MG/INH

N20233 001
FEB 14, 1994

BUTABARBITAL SODIUM

ELIXIR; ORAL

/BUTALAN/

/LANNETT/

@ LANNETT

/33.3MG/5ML/
33.3MG/5ML/N85880/001/
N85880 001

TABLET; ORAL

BUTISOL SODIUM

/AA/

/100MG/

/N00793/005/
N00793 005

/WALLACE/

WALLACE

100MG

/N00793/005/
N00793 005

SODIUM BUTABARBITAL

/AA/ /LANNETT/

/100MG/

/N85881/001/

@ LANNETT

100MG

N85881 001

/AA/ /ZENITH/

/30MG/

/N84040/001/

@ ZENITH

30MG

N84040 001

CAFFEINE, ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL
MIGERGOT

BR G AND W LABS

100MG; 2MG

N86557 001
OCT 04, 1983/WIGRAINE/
/BR/ /ORGANON/

/100MG; 2MG/

/N86557/001/
/OCT/04,/1983/

CALCIFEDIOL

CAPSULE; ORAL

CALDEROL

+ ORGANON

0.05MG
0.02MGN18312 002
N18312 001

CALCIFEDIOL, ANHYDROUS

/CAPSULE; /ORAL/
/CALDEROL/
/+/ /ORGANON//0.05MG/
/0.02MG//N18312/002/
/N18312/001/

CALCIUM CHLORIDE, DEXTROSE, MAGNESIUM CHLORIDE, SODIUM CHLORIDE, SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELIFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN

PLASTIC CONTAINER

AT FRESSENIUS

18.4MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20171 001
AUG 19, 1992

DELIFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN

PLASTIC CONTAINER

AT FRESSENIUS

18.4MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20171 002
AUG 19, 1992

DELIFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN

PLASTIC CONTAINER

AT FRESSENIUS

18.4MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20171 003
AUG 19, 1992

CALCIUM CHLORIDE, DEXTROSE, MAGNESIUM CHLORIDE, SODIUM CHLORIDE, SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DIANEAL LOW CALCIUM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT BAXTER

18.3MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20183 001
DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT BAXTER

18.3MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20183 002
DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT BAXTER

18.3MG/100ML; 3.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20183 003
DEC 04, 1992

DIANEAL LOW CALCIUM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT BAXTER

18.3MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20183 004
DEC 04, 1992

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

AT BAXTER

18.3MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N17512 004

INPERSOL-LC/LM W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT ABBOTT

18.4MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20374 001
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 2.5% IN PLASTIC CONTAINER

AT ABBOTT

18.4MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20374 002
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AT ABBOTT

18.4MG/100ML; 3.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20374 003
JUN 13, 1994

INPERSOL-LC/LM W/ DEXTROSE 4.25% IN PLASTIC CONTAINER

AT ABBOTT

18.4MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100MLN20374 004
JUN 13, 1994

CARBACHOL

/INJECTABLE;/INJECTION/
/CARBACHOL/
/@/PHARMAFAIR/
/MIOSTAT/
/+//ALCON/

/0.01%/

/N70292/001/
/MAY/21./1986/>_ADD->
>_ADD->

MERCK SHARP DOHME 25MG;100MG

N19856 002
DEC 24, 1992

SOLUTION; INTRAOCULAR

CARBACHOL
@ PHARMAFAIR

0.01%

N70292 001
MAY 21, 1986

MIOSTAT
+ ALCON

0.01%

N16968 001

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL
/@/ZENITH/

/EQ/500MG/BASE/

/N62766/001/
/MAR/03./1987/

AB APOTHECON
AB ZENITH

EQ 500MG BASE
EQ 500MG BASEN62291 001
N62766 001
MAR 03, 1987

CARBAMAZEPINE

SUSPENSION; ORAL
TEGRETOL

+ BASEL PHARMS

100MG/5ML

N18927 001
DEC 18, 1987
/N18927/001/
/DEC/18./1987/

/+//GEIGY/

/100MG/5ML/

POWDER FOR RECONSTITUTION; ORAL

CEFADROXIL
APOTHECON

EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 500MG BASE/5MLN62334 001
N62334 002
N62334 003

TABLET; ORAL

TEGRETOL

AB + BASEL PHARMS
/AB//+//GEIGY/

200MG
/200MG/N16608 001
/N16608/001/

TABLET, CHEWABLE; ORAL

TEGRETOL

AB + BASEL PHARMS
/AB//+//GEIGY/

100MG
/100MG/N18281 001
/N18281/001/

/EQ/1GM/BASE/

/N62774/001/
/APR/08./1987/

AB ZENITH

EQ 1GM BASE

N62774 001
APR 08, 1987

ULTRACEF
APOTHECON

EQ 1GM BASE

N62390 001
JUN 10, 1982

/AB/ /BRISTOL/

/EQ 1GM BASE/

/N62390/001/
/JUN/10./1982/

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

AB SCS

10MG;100MG

N74080 001
MAR 25, 1994

AB

25MG;100MG

N74080 002
MAR 25, 1994

AB

25MG;250MG

N74080 003
MAR 25, 1994

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM

/AP/ /FUJISAWA/
/EQ 500MG BASE/VIAL/
/NOV/17,/1986/
/AP/ /FUJISAWA/
/EQ 1GM BASE/VIAL/
/NOV/17,/1986/
/AP/ /FUJISAWA/
/EQ 10CM BASE/VIAL/
/NOV/17,/1986/
/AP/ /FUJISAWA/
/EQ 20CM BASE/VIAL/
/AUG/03,/1987/
EQ 500MG BASE/VIAL
NOV 17, 1986
EQ 1GM BASE/VIAL
NOV 17, 1986
EQ 10CM BASE/VIAL
NOV 17, 1986
EQ 20CM BASE/VIAL
NOV 17, 1986
AUG 03, 1987

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
/SEFFIN/
@ GLAXO

EQ 1GM BASE/VIAL
N62435 001
NOV 15, 1983
EQ 2GM BASE/VIAL
N62435 002
NOV 15, 1983
EQ 10CM BASE/VIAL
N62435 003
NOV 15, 1983

@ FUJISAWA

EQ 500MG BASE/VIAL

NOV 17, 1986

CHLORAMPHENICOL

ointment; OPHTHALMIC

/AI/ /CHLOROFAIR/
/1%/
@ PHARMAFAIR
1%

/N62439/001/
/APR/21,/1983/
N62439 001
APR 21, 1983

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION
CEFTIZOX

/AP/ /FUJISAWA/
EQ 1GM BASE/VIAL
MAR 31, 1994
EQ 2CM BASE/VIAL
MAR 31, 1994

SOLUTION/DROPS; OPHTHALMIC

/AI/ /CHLOROFAIR/
/0.5%/
@ PHARMAFAIR
0.5%

/N62437/001/
/APR/14,/1983/
N62437 001
APR 14, 1983

CEFUROXIME AXETIL

POWDER FOR RECONSTITUTION; ORAL
CEFTIN
+ GLAXO

EQ 125MG BASE/5ML
N50672 001
JUN 30, 1994

AT + PROCTER AND GAMBLE
0.12%

N19028 001
AUG 13, 1986

AT COLGATE PALMOLIVE
0.12%

N73695 001
JAN 14, 1994

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
/SEFFIN/
@ GLAXO/
/AP/

/EQ 1GM BASE/VIAL/
/NOV/15,/1983/
/EQ 2GM BASE/VIAL/
/NOV/15,/1983/
/EQ/10CM/BASE/VIAL/
/NOV/15,/1983/
/+

CHLORMERODRIN, HG-197

INJECTABLE; INJECTION
CHLORMERODRIN HG 197
@ BRACCO
/SQUIBB/

> ADD >
> DLT >

0.6-1.4mCi/ML
/0.6-1.4mCi/ML/
N17269 001
/N17269/001/

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE
/AP/ /DUPONT/

/EQ 150MG BASE/ML/

@ DUPONT MERCK

EQ 150MG BASE/ML

/N62908/001/
/FEB/01,/1989/

N62908 001

/AP/ /FUJISAWA/

/EQ 150MG BASE/ML/

/N62747/001/
/JUN/03,/1988/

N62747 001

@ FUJISAWA

EQ 150MG BASE/ML

>_ADD_>
>_ADD_>
>_ADD_>
>_ADD_>

SWAB; TOPICAL
CLEOCIN
UPJOHN

EQ 1% BASE

N50537 002
FEB 22, 1994

CLOBETASOL PROPIONATE

CREAM; TOPICAL
CLOBETASOL PROPIONATE
AB
COPLY

0.05%

N74087 001

>_ADD_>
>_ADD_>

AB

NMC

0.05%

N74139 001
AUG 03, 1994

TEMOVATE

AB +

0.05%

N19322 001
DEC 27, 1985

AB +

0.05%

N20340 001
JUN 17, 1994

GEL; TOPICAL
TEMOVATE
+ GLAXO

0.05%

N20337 001

APR 29, 1994

ointment; TOPICAL
CLOBETASOL PROPIONATE
AB
COPLY

0.05%

N74089 001

>_ADD_>
>_ADD_>

AB

NMC

0.05%

N74128 001
AUG 03, 1994

TEMOVATE

AB +

0.05%

N19323 001
DEC 27, 1985

CLOMIPRAMINE HYDROCHLORIDE

CAPSULE; ORAL
ANAFRANIL
+ BASEL PHARMS

75MG

N19906 003
DEC 29, 1989

25MG

N19906 001
DEC 29, 1989

50MG

N19906 002
DEC 29, 1989

/+//CIBA/

/75MG/

/N19906/003/
/DEC/29,/1989/

/25MG/

/N19906/001/
/DEC/29,/1989/

/50MG/

/N19906/002/
/DEC/29,/1989/

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE VC W/ CODEINE

AA

PENNEX

10MG/5ML; 5MG/5ML;

5.25MG/5ML

N88896 001
JAN 04, 1985

/e/

/10MG/5ML; 5MG/5ML;

/6.25MG/5ML/

/N88896/001/
/JAN/04,/1985/

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE W/ CODEINE

AA

PENNEX

10MG/5ML; 5.25MG/5ML

N88875 001
DEC 17, 1984

/e/

/10MG/5ML; 5.25MG/5ML/

/N88875/001/
/DEC/17,/1984/

COLESTIPOL HYDROCHLORIDE

TABLET; ORAL

COLESTID

UPJOHN

1GM

N20222 001
JUL 19, 1994

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

CETUS BEN VENUE

1GM/VIAL

N74245 001

AUG 31, 1994

2GM/VIAL

N74245 002

AUG 31, 1994

CYTOSAR-U

+ UPJOHN

1GM/VIAL

N16793 003

DEC 21, 1987

2GM/VIAL

N16793 004

DEC 21, 1987

DACTINOMYCIN

INJECTABLE; INJECTION

COSMEGEN

+ MERCK SHARP DOHME

/+//MSD/

0.5MG/VIAL

N50682 001

/N60467/001/

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

DESMOPRESSIN ACETATE

+ RHONE POULENC RORER

0.15MG/INH

N20355 001

MAR 07, 1994

DESONIDE

OINTMENT; TOPICAL

DESONIDE

TARO PHARMS

0.05%

N74254 001

AUG 03, 1994

DEXAMETHASONE, NEOMYCIN SULFATE, POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

DEXASPORIN

AT BAUSCH AND LOMB

0.1%; EQ 3.5MG BASE/GM;

10,000 UNITS/GM

N64063 001

JUL 25, 1994

DEXAMETHASONE SODIUM PHOSPHATE

AEROSOL; NASAL

/DECADRON/

/+//MSD/

/EQ/0.1MG/PHOSPHATE/INH/ /N14242/001/

DEXAMETHASONE SODIUM PHOSPHATE

AEROSOL; NASAL

DEXACORT

+ MEDEVA

EQ 0.1MG PHOSPHATE/INH

N14242 001

AEROSOL, METERED; INHALATION

/DECADRON/

/+//MSD/

/EQ/0.1MG/PHOSPHATE/INH/ /N13413/001/

DEXACORT

+ MEDEVA

EQ 0.1MG PHOSPHATE/INH

N13413 001

DEXTROAMPHETAMINE SULFATE

/ELIXIR; ORAL/

/DEXEDRINE/

/SMITHKLINE/BEECHAM/ /5MG/5ML/

@ SMITHKLINE BEECHAM

5MG/5ML

/N83902/001/

N83902 001

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

/AA/

/AA/

/5MG/

/10MG/

5MG

10MG

/15MG/

15MG

/N83903/001/

N83903 001

N83903 001

N83903 003

/N85652/001/

N85652 001

DEXTROMETHORPHAN HYDROBROMIDE, PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE W/ DEXTROMETHORPHAN

AA

PENNEX

15MG/5ML; 6.25MG/5ML

N88864 001

JAN 04, 1985

/N88864/001/

/JAN/04,/1985/

/@/

/15MG/5ML; 6.25MG/5ML/

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 5% IN PLASTIC CONTAINER

50MG/ML

N16730 002

AP

MCCAW

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

DIPIVEFRIN HCL

AT ALCON 0.1% N73636 001

JUN 30, 1994

PROPINE

AT + ALLERGAN 0.1% N18239 001

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT EQ 400MG BASE/100ML N20201 006

JUL 07, 1994

AP + BAXTER EQ 400MG BASE/100ML N20255 005

OCT 19, 1993

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

+ GENDERM 5% N20126 001

APR 01, 1994

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

/AP//+//ADRIA/ /200MG/100ML/ N50629/002/

MAY/03,1988/

/AP/ /200MG/100ML/ N63165/002/

JAN/30,1991/

+ ADRIA 200MG/100ML N50629 002

MAY 03, 1988

200MG/100ML N63165 002

JAN 30, 1991

ENFLURANE

LIQUID; INHALATION

ENFLURANE

AN INHALON 99.9% N74396 001

JUL 29, 1994

ERGOCALCIFEROL

CAPSULE; ORAL

/DELTA LIN/

/AA/ /LILLY/ /50,000 IU/

50,000 IU

@ LILLY

VITAMIN D

/AA/ /LANNETT/ /50,000 IU/

50,000 IU

@ LANNETT

/AA/ /WEST/WARD/ /50,000 IU/

50,000 IU

@ WEST WARD PHARM

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYC

/AB/ /PARKE/DAVIS/ /250MG/

250MG

@ PARKE DAVIS

N62546/001/

JUL/25,1985/

N62546 001

JUL 25, 1985

OINTMENT; OPHTHALMIC

ERYTHROMYCIN

AT BAUSCH AND LOMB 0.5% N64067 001

JUL 29, 1994

/AI/ /FOUGERA/ /5MG/GM/

N62447/001/

/SEP/26,1983/

AT FOUGERA 0.5% N62447 001

SEP 26, 1983

ILOTYCIN

/AI//+//DISTA/

AT + DISTA /5MG/GM/

0.5%

N50368/001/

N50368 001

JUL/21,1988/

N62957 001

JUL 21, 1988

N64039 001

JAN 27, 1994

/N62616/001/

JUL/25,1985/

N62616 001

JUL 25, 1985

ERYTHROMYCIN

TABLET, COATED PARTICLES; ORAL
PCE

+ ABBOTT

333MG

/333MG/

N50611 001

SEP 09, 1986

/N50611/001/

/SEP/09,/1986/

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

/AB/ /DISTA/

/EQ 200MG BASE/5ML/

/N62177/001/

/AB/ @ DISTA

/EQ 400MG BASE/5ML/

/N62177/002/

/AB/ @ /PHARMAFAIR/

EQ 200MG BASE/5ML

N62177 001

/AB/ @ /PHARMAFAIR/

EQ 400MG BASE/5ML

N62177 002

/AB/ >_D.L.T._>

/EQ 200MG BASE/5ML/

/N62559/001/

/AB/ >_D.L.T._>

/EQ 400MG BASE/5ML/

/MAR/15,/1985/

@ PHARMAFAIR

EQ 200MG BASE/5ML

/N62558/001/

@

EQ 400MG BASE/5ML

MAR 15, 1985

>_ADD_>

EQ 400MG BASE/5ML

N62558 001

>_ADD_>

EQ 400MG BASE/5ML

MAR 15, 1985

TABLET; ORAL

E.E.S. 400

/AB//+//ABBOTT/

/EQ 400MG BASE/

/N61905/001/

/AB/

/EQ 400MG BASE/

/N61905/002/

AB + ABBOTT

EQ 400MG BASE

/AUG/12,/1982/

@

EQ 400MG BASE

N61905 002

>_ADD_>

EQ 400MG BASE

AUG 12, 1982

N61905 001

ERYTHROMYCIN STEARATE

TABLET; ORAL

/ERYPAR/

/EQ 250MG BASE/

/N62322/001/

/AB/ /PARKE/DAVIS/

EQ 250MG BASE

N62322 001

ERYPAR

EQ 250MG BASE

/N61743/001/

@ WARNER CHILCOTT

EQ 250MG BASE

N61743 001

ERYTHROMYCIN STEARATE

/PUREPAC/

/EQ 250MG BASE/

/N61743/001/

@ PUREPAC PHARM

EQ 250MG BASE

N61743 001

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

/DELADUMONE/

/AO//+//SQUIBB/

@ SQUIBB

/4MG/ML; 90MG/ML/

4MG/ML; 90MG/ML

/N09545/001/

N09545 001

TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE

/AO/ /STERIS/

+ STERIS

/4MG/ML; 90MG/ML/

4MG/ML; 90MG/ML

/N85865/001/

N85865 001

ESTROGENS, ESTERIFIED

TABLET; ORAL

ESTRATAB

/BS/ /SOLVAY/

BS + SOLVAY

/0.625MG/

0.625MG

/N83209/001/

N83209 001

/BS/ /SOLVAY/

BS +

/2.5MG/

2.5MG

/N83857/001/

N83857 001

MENEST

/BS//SMITHKLINE/BEECHAM/

BS SMITHKLINE BEECHAM

/0.625MG/

0.625MG

/N84948/001/

N84948 001

/BS//SMITHKLINE BEECHAM/

BS

/2.5MG/

2.5MG

/N84949/001/

N84949 001

ESTRONE

INJECTABLE; INJECTION

ESTRONE

/BP/ /STERIS/

@ STERIS

/2MG/ML/

/N83397/001/

N83397 001

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

MYAMBUTOL

+ LEDERLE

/+/

400MG

/500MG/

N16320 003

/N16320/004/

@

/200MG/

/N16320/002/

@

/200MG

N16320 002

@

/400MG/

/N16320/003/

@

500MG

N16320 004

ETHINAMATE

/CAPSULE;/ORAL/

/VALMID/

/DISTA/

@ DISTA

/500MG/

/N09750/001/

N09750 001

ETHINYL ESTRADIOL, FERROUS FUMARATE, NORETHINDRONE

TABLET; ORAL-28/
/NORQUEST/FE/
/+//SYNTEX/
@ SYNTEX
/0.035MG;75MG;1MG/
/JUL/18,/1986/
N18926 001
JUL 18, 1986

AP + BRISTOL
VEPESID
INJECTABLE; INJECTION
20MG/ML
N18768 001
NOV 10, 1983

ETHINYL ESTRADIOL, NORETHINDRONE

TABLET; ORAL-21
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
/WATSON/
/0.035MG;0.5MG/AND/1MG/
/N71041/001/
/SEP/24,/1991/
N71041 001
SEP 24, 1991
WATSON LABS
0.035MG;0.5MG AND 1MG
ORTHO-NOVUM 7/14-21
AB + JOHNSON RW
0.035MG;0.5MG AND 1MG
APR 04, 1984
/0.035MG;0.5MG/AND/1MG/
/N19004/001/
/APR/04,/1984/
/e/

TABLET; ORAL
FAMVIR
+ SMITHKLINE BEECHAM
500MG
N20363 002
JUN 29, 1994

FAMOTIDINE
INJECTABLE; INJECTION
PEPCID IN PLASTIC CONTAINER
+ MERCK
0.4MG/ML
N20249 001
FEB 18, 1994

TABLET; ORAL-28
NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
/WATSON/
/0.035MG;0.5MG/AND/1MG/
/N71042/001/
/SEP/24,/1991/
N71042 001
SEP 24, 1991
WATSON LABS
0.035MG;0.5MG AND 1MG
ORTHO-NOVUM 7/14-28
AB + JOHNSON RW
0.035MG;0.5MG AND 1MG
APR 04, 1984
/0.035MG;0.5MG/AND/1MG/
/N19004/002/
/APR/04,/1984/
/e/

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
/+//PFIZER/
/50MG/
/+/
/100MG/
PFIZER
50MG
100MG
150MG
/N19949/001/
/JAN/29,/1990/
/N19949/002/
/JAN/29,/1990/
N19949 001
JAN 29, 1990
N19949 002
JAN 29, 1990
N20322 001
JUN 30, 1994

ETODOLAC

TABLET; ORAL
LODINE
+ WYETH AYERST

400MG
N18922 004
JUL 29, 1993

>_ADD_> ELUDEOXYGLUCOSE, F-18
>_ADD_> INJECTABLE; INJECTION
>_ADD_> FLUDEOXYGLUCOSE F 18
>_ADD_> + DOWNSTATE CLINCL
>_ADD_> 6.8-35.7mCi/ML
N20306 001
AUG 19, 1994

ETOPOSIDE

INJECTABLE; INJECTION
ETOPOSIDE
GENSIA

20MG/ML
N74284 001
FEB 10, 1994

FLUMAZENIL

INJECTABLE; INJECTION

/MAZICON/

/+//ROCHE/

/0.1MG/ML/

ROMAZICON

+ ROCHE

/N20073/001/
/DEC/20,/1991/0.1MG/ML
N20073 001
DEC 20, 1991/N13790/001/
N13790 001/AI//+//DISTA/
AI + LILLY
/0.05%/
0.05%

FLUOCINOLONE ACETONIDE

SOLUTION; TOPICAL

FLUOCINOLONE ACETONIDE

/AI/ /PHARMAFAIR/ /0.01%/
@ PHARMAFAIR

0.01%

/N88449/001/
/FEB/08,/1984/
N88449 001
FEB 08, 1984/N12806/004/
/N12806/001/
N12806 004
N12806 001/0.025%/
/0.05%/
0.025%
0.05%

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

/B* / /CLAY/PARK/

/0.05%/
0.05%

@ CLAY PARK

/N71790/001/
/JUL/13,/1988/
N71790 001
JUL 13, 1988N18766 002
OCT 31, 1988
N18766 003
OCT 31, 1988AB
AB +
50MG
100MG

FLUOROURACIL

INJECTABLE; INJECTION

ADRUCIL

/AP//+//ADRIA/
/AP//50MG/ML/
/50MG/ML/

AP + PHARMACIA

@

/N17959/001/
/N40023/001/
/OCT/18,/1991/
N40023 001
OCT 18, 1991
N17959 001

FLURBIPROFEN

AB MYLAN

AB

50MG
100MGN74358 001
JUN 20, 1994
N74358 002
JUN 20, 1994

FOLIC ACID

TABLET; ORAL

FOLIC ACID

/AA/ @ LANNETT/

/AA/ @ PUREPAC/

/1MG/
1MG
/1MG/
1MG/N80816/001/
N80816 001
/N80784/001/
N80784 001

FLURANDRENOLIDE

CREAM; TOPICAL

CORDRAN SP

/+//DISTA/

/+//

+ LILLY

+

/0.025%/
/0.05%/
0.025%
0.05%

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

AP MARSAM

10MG/ML

N74017 001
JUN 30, 1994

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

/AP/ /ORGANON/ /10MG/ML/ /N70017/001/ /DEC/15, /1986/

@ ORGANON N70017 001

/AP/ /WARNER/CHILCOTT/ /10MG/ML/ DEC 15, 1986

@ WARNER CHILCOTT /N18420/001/ /FEB/26, /1982/

N18420 001

FEB 26, 1982

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

GALLIUM CITRATE GA 67

BS DUPONT 2MCI/ML N17478 001

/BS/ /DUPONT/MERCK/ /2MCI/ML/ /N17478/001/

GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL

PUREPAC PHARM

> ADD > AB N74360 001

> ADD > AUG 31, 1994

GENTAMICIN SULFATE

CREAM; TOPICAL

GARAMYCIN

/AI//+//SCHERING/ /EQ 1MG BASE/GM/ /N60462/001/

AT + SCHERING EQ 0.1% BASE N60462 001

GENTAFAIR /EQ 0.1% BASE/ /N62458/001/

/AI/ /PHARMAFAIR/ /SEP/01, /1983/

@ PHARMAFAIR EQ 0.1% BASE N62458 001

SEP 01, 1983

GENTAMICIN

/CLAY/PARK/

CLAY PARK

GENTAMICIN SULFATE

/AI/ /GENTAMICIN SULFATE

AT BAUSCH AND LOMB EQ 0.1% BASE N64056 001

/AI/ /FOUGERA/ /EQ 1MG BASE/GM/ APR 29, 1994

AT FOUGERA EQ 0.1% BASE N62531/001/

N62531 001

JUL/05, /1984/

JUL 05, 1984

GENTAMICIN SULFATE

CREAM; TOPICAL

GENTAMICIN SULFATE

/AI/ /NMC/ /EQ 1MG BASE/GM/ /N62471/001/

AT NMC EQ 0.1% BASE /SEP/27, /1983/

/AI/ /THAMES/ /EQ 1MG BASE/GM/ N62471 001

AT THAMES /MAY/26, /1983/

EQ 0.1% BASE N62427 001

MAY 26, 1983

INJECTABLE; INJECTION

APOGEN

AP KING PHARMS EQ 10MG BASE/ML N62289 001

AP EQ 40MG BASE/ML N62289 002

/AP/ /SMITHKLINE/BEECHAM/ /EQ 10MG BASE/ML/ /N62289/001/

/AP/ /EQ 40MG BASE/ML/ /N62289/002/

GARAMYCIN

/AP//+//SCHERING/

/EQ 2MG BASE/ML/ /N50505/001/

INJECTABLE; INTRATHECAL

GARAMYCIN

+ SCHERING

EQ 2MG BASE/ML N50505 001

OINTMENT; OPHTHALMIC

GARAMYCIN

/AI//+//SCHERING/

AT + SCHERING

GENTACIDIN

/AI/ /IOLAB/

AT IOLAB

EQ 0.3% BASE

EQ 0.3% BASE

OINTMENT; TOPICAL

GARAMYCIN

/AI//+//SCHERING/

AT + SCHERING

GENTAFAIR

/AI/ /PHARMAFAIR/

@ PHARMAFAIR

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

EQ 0.1% BASE

GLYCOPYRROLATE

INJECTABLE; INJECTION
GLYCOPYRROLATE

/AP/ /FUJISAWA/ /0.2MG/ML/ /N88475/001/
@ FUJISAWA 0.2MG/ML JUN 12, 1984

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

/AP/ /FUJISAWA/ /5,000 UNITS/VIAL/ /N17067/001/
/AP/ /FUJISAWA/ /20,000 UNITS/VIAL/ /N17067/003/
@ FUJISAWA 5,000 UNITS/VIAL N17067 001
@ 20,000 UNITS/VIAL N17067 003

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

/NEOMYCIN SULFATE AND POLYMYXIN B SULFATE GRAMICIDIN/

/AL/ /PHARMAFAIR/ /0.025MG/ML;EQ 1.75MG BASE/ML;/ /N62383/001/
/10,000 UNITS/ML/ /AUG/31, 1982/
@ PHARMAFAIR 0.025MG/ML;EQ 1.75MG BASE/ML;
10,000 UNITS/ML N62383 001
AUG 31, 1982

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION
KYTRIL

+ SMITHKLINE BEECHAM EQ 1MG BASE/ML N20239 002
MAR 11, 1994
/+ /EQ/3MG/BASE/ML/ /N20239/001/
@ EQ 3MG BASE/ML /DEC/29, 1993/
N20239 001
DEC 29, 1993

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

AB COPLECY PHARM EQ 4MG BASE N74267 001
AB EQ 8MG BASE N74267 002
JUN 01, 1994
JUN 01, 1994

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

AB WATSON LABS EQ 4MG BASE N74025 001
FEB 28, 1994
AB EQ 8MG BASE N74025 002
FEB 28, 1994
AB WYETH AYERST EQ 4MG BASE N18587 001
SEP 07, 1982
AB + EQ 8MG BASE N18587 002
SEP 07, 1982

HEPARIN CALCIUM

INJECTABLE; INJECTION

CALCIPARINE

+ CHOAY 25,000 UNITS/ML N18237 001
/+//DUPONT/ /25,000/UNITS/ML/ /N18237/001/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/BP/ /DANBURY/PHARMA/ /25MG;15MG;0.1MG/ /N87556/001/
@ DANBURY PHARMA 25MG;15MG;0.1MG N87556 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/ /ZENITH/ /50MG/ /N84658/001/
@ ZENITH 50MG N84658 001

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL/

/NORMOZIDE/

/+//SCHERING/ /25MG;300MG/ /N19046/003/
/APR/06, 1987/
/N19046/001/ /25MG;100MG/ /N19046/001/
/APR/06, 1987/
/N19046/002/ /25MG;200MG/ /N19046/002/
/APR/06, 1987/

HYDROCHLOROTHIAZIDE, LABETALOL HYDROCHLORIDE

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

/TABLET; ORAL/
 /NORMOZIDE/
 @ SCHERING

25MG; 100MG
 25MG; 200MG
 25MG; 300MG

N19046 001
 APR 06, 1987
 N19046 002
 APR 06, 1987
 N19046 003
 APR 06, 1987

/AI/+//NUTRACORT/
 @ GALDERMA

/1%/
 1%

/N84698/001/
 N84698 001

PENECORT

/AI/ /ALLERGAN/HERBERT/

/1%/
 1%

/N88215/001/
 /JUN/06,/1984/
 N88215 001
 JUN 06, 1984

+ ALLERGAN HERBERT

HYDROCHLOROTHIAZIDE, RESERPINE

TABLET; ORAL

/BP/ /ROXANE/
 @ ROXANE
 HYDROCHLOROTHIAZIDE W/ RESERPINE
 /50MG; 0.125MG/
 50MG; 0.125MG

/N84603/001/
 N84603 001

LOTION; TOPICAL
 HYDROCORTISONE

/AI/ /CLAY/PARK/
 @ CLAY PARK

/1%/
 1%

/N85663/001/
 N85663 001

HYDROCHLOROTHIAZIDE, TRIAMTERENE

CAPSULE; ORAL

/AB/+//SMITHKLINE/BEECHAM/
 SMITHKLINE BEECHAM
 /25MG; 50MG/
 25MG; 37.5MG

/N16042/002/
 N16042 003
 MAR 03, 1994
 N16042 002

/AI/ /CLAY/PARK/
 @ CLAY PARK

/1%/
 1%

/N85028/001/
 N85028 001

/AB/ /GENEVA/PHARMS/
 + GENEVA PHARMS
 TRIAMTERENE AND HYDROCHLOROTHIAZIDE
 /25MG; 50MG/
 25MG; 50MG

/N73191/001/
 /JUL/31,/1991/
 N73191 001
 JUL 31, 1991

> DLT >
 > ADD >
 TABLET; ORAL
 HYDROCORTISONE
 /BP/ /DANBURY/PHARMA/
 @ DANBURY PHARMA
 /20MG/
 20MG
 /BP/ /INWOOD/
 @ INWOOD LABS
 /20MG/
 20MG

/N80355/001/
 N80355 001
 /N80732/001/
 N80732 001

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

/AI/ /LEMMON/
 @ LEMMON
 /AI/ /PHARMAFAIR/
 @ PHARMAFAIR

/N85191/001/
 N85191 001
 /N87838/001/
 /JUL/28,/1982/
 N87838 001
 JUL 28, 1982

/AI/ /PHARMAFAIR/
 @ PHARMAFAIR

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

/N62394/001/
 /SEP/29,/1982/
 N62394 001
 SEP 29, 1982

HYDROCORTISONE, NEOMYCIN SULFATE, POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

/NEOMYCIN SULFATE-POLYMYXIN B SULFATE-HYDROCORTISONE/
 /AI/ /PHARMAFAIR/

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

/N62394/001/
 /SEP/29,/1982/
 N62394 001
 SEP 29, 1982

SUSPENSION; OTIC

/OTICAIR/
 /AI/ /PHARMAFAIR/

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

/N62399/001/
 /NOV/18,/1982/
 N62399 001
 NOV 18, 1982

ENEMA; RECTAL

CORTENEMA

AT + SOLVAY

HYDROCORTISONE

COPLY

100MG/60ML

100MG/60ML

N16199 001

N74171 001
 MAY 27, 1994

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE
/AI/ /PARKE/DAVIS/ /1%/
@ PARKE DAVIS 1%

/N89914/001/
/JAN/03,/1989/
N89914 001
JAN 03, 1989

INJECTABLE; INJECTION
HYDROCORTISONE ACETATE
/BP/ /STERIS/
@ STERIS /50MG/ML/
50MG/ML

/N85214/001/
N85214 001

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL
LOCOID
/+/BROCADES/PHARMA/ /0.1%/
+ YAMANOUCHI 0.1%

/N18514/001/
/MAR/31,/1982/
N18514 001
MAR 31, 1982

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION
DILAUDID-HP
+ KNOLL PHARM 250MG/VIAL
>_ADD_>
>_ADD_>

N19034 002
AUG 04, 1994

OINTMENT; TOPICAL
LOCOID
/+/BROCADES/PHARMA/ /0.1%/
@ YAMANOUCHI 0.1%

/N18652/001/
/OCT/29,/1982/
N18652 001
OCT 29, 1982

SOLUTION; TOPICAL
LOCOID
/+/BROCADES/PHARMA/ /0.1%/
+ YAMANOUCHI 0.1%

/N19116/001/
/FEB/25,/1987/
N19116 001
FEB 25, 1987

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION
/DELALUTIN/
/AO//+/SQUIBB/
/AO/
/AO//+/
/AO/
@ SQUIBB
@
@
@

/N10347/004/
/N16911/001/
/N10347/002/
/N16911/002/
N10347 004
N16911 001
N10347 002
N16911 002

HYDROXYPROGESTERONE CAPROATE

/AO/ /STERIS/
AO + STERIS
/AO/
+
/125MG/ML/
125MG/ML
/250MG/ML/
250MG/ML

/N17439/001/
N17439 001
/N17439/002/
N17439 002

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
/AP/ /SMITH/NEPHEW/SOLOPAK/25MG/ML/
/AP/ /50MG/ML/
/AP/ /50MG/ML/

/N87591/001/
/N87593/001/
/N87595/001/

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT
/AP/ /ABBOTT/
/AP/
/AP/
/EQ 250MG BASE/VIAL/
/EQ 500MG BASE/VIAL/
/EQ 1GM BASE/VIAL/

@ ABBOTT EQ 250MG BASE/VIAL
@ EQ 500MG BASE/VIAL
@ EQ 1GM BASE/VIAL

/N89578/001/
/APR/11,/1989/
/N89579/001/
/APR/11,/1989/
/N89580/001/
/APR/11,/1989/
N89578 001
APR 11, 1989
N89579 001
APR 11, 1989
N89580 001
APR 11, 1989

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

SOLOPAK

25MG/ML
50MG/ML
50MG/MLN87591 001
N87593 001
N87595 001

500 UNITS/ML

N18780 004
MAR 31, 1994

/AP/ /ORGATRAK/

/AP/ /ORGANON/

/25MG/ML/

/50MG/ML/

@ ORGANON

25MG/ML

50MG/ML

/N87014/001/

/N87014/002/

N87014 001

N87014 002

INVERT SUGAR

/INJECTABLE; INJECTION/
/TRAVERT/10%/IN/PLASTIC/CONTAINER/
/BAXTER/
@ BAXTER/N16717/001/
N16717 001

TABLET; ORAL

HYDROXYZINE HCL

ROYCE

10MG

N81149 001

MAR 18, 1994

N81150 001

MAR 18, 1994

N81151 001

MAR 18, 1994

IOBENGUANE SULFATE I 131

INJECTABLE; INJECTION
IOBENGUANE SULFATE I 131
CIS

2.3mCi/ML

N20084 001
MAR 25, 1994IMIGLUCERASE

INJECTABLE; INJECTION

CEREZYME

+ GENZYME

200 UNITS/VIAL

INJECTABLE; INJECTION

RENOVUE-65

+ BRACCO

/+//SQUIBB/

>_ADD_>

>_DLT_>

N20367 001

MAY 23, 1994

65%

/65%/

N17902 001
/N17902/001/INDIUM IN-111 PENTETROTIDE KIT

INJECTABLE; INJECTION

OCTREOSCAN

MALLINCKRODT

3mCi/ML

IODIPAMIDE MEGLUMINE

INJECTABLE; INJECTION

CHOLOGRAFIN MEGLUMINE

+ BRACCO

+

/+//SQUIBB/

/+//

>_ADD_>

>_ADD_>

>_DLT_>

>_DLT_>

N20314 001

JUN 02, 1994

10.3%

52%

/10.3%/

/52%/

N09321 007
N09321 003
/N09321/007/
/N09321/003/INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

/AB/ /CHELSEA/LABS/

/25MG/

/AB/

/50MG/

@ CHELSEA LABS

25MG

@

50MG

/N18690/001/

/JUL/31,/1984/

/N18690/002/

/JUL/31,/1984/

N18690 001

JUL 31, 1984

N18690 002

JUL 31, 1984

IODIPAMIDE SODIUM

INJECTABLE; INJECTION

CHOLOGRAFIN SODIUM

@ BRACCO

/@/SQUIBB/

>_ADD_>

>_DLT_>

20%

/20%/

N09321 001
/N09321/001/

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANTREX

/AP//+//APOTHECON/
/AP/
AP + APOTHECON
/AP//+/
/AP/
AP +
/AP//+/
/AP/
AP +
/AP//+/
/AP/
AP +
EQ 75MG BASE/2ML/
EQ 75MG BASE/2ML/
EQ 75MG BASE/2ML/
EQ 500MG BASE/2ML/
EQ 500MG BASE/2ML/
EQ 1GM BASE/3ML/
EQ 1GM BASE/3ML/
EQ 1GM BASE/3ML/
EQ 75MG BASE/2ML
EQ 75MG BASE/2ML
EQ 500MG BASE/2ML
EQ 500MG BASE/2ML

/EQ 75MG BASE/2ML/
/EQ 75MG BASE/2ML/
/EQ 75MG BASE/2ML/
/EQ 500MG BASE/2ML/
/EQ 500MG BASE/2ML/
/EQ 1GM BASE/3ML/
/EQ 1GM BASE/3ML/
/EQ 1GM BASE/3ML/
/EQ 75MG BASE/2ML
/EQ 75MG BASE/2ML
/EQ 500MG BASE/2ML
/EQ 500MG BASE/2ML

/AP/ /BRISTOL/

/AP/

/AP/

KLEBIL

@ KING PHARMS

@

@

/@/SMITHKLINE/BEECHAM/

/@/

/@/

EQ 75MG BASE/2ML
EQ 500MG BASE/2ML
EQ 1GM BASE/3ML
EQ 75MG BASE/2ML/
EQ 500MG BASE/2ML/
EQ 1GM BASE/3ML/
EQ 1GM BASE/3ML/

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

ELKINS SINN

/+//IMMUNEX/

@ IMMUNEX

EQ 100MG BASE/VIAL

/EQ/3MG/BASE/ML/

EQ 3MG BASE/ML

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAGAN

AT + ALLERGAN 0.25%

AT + 0.5%

AT 0.25%

AT 0.5%

AT 0.25%

AT 0.5%

AT 0.25%

AT 0.5%

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AT 0.25%

AT 0.5%

AT 0.25%

AT 0.5%

AT 0.25%

AT 0.5%

N19814 001
JUN 28, 1989
N19219 002
DEC 19, 1985
N74307 001
MAR 04, 1994
N74326 001
MAR 04, 1994

LEVONORDEFIN, MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

/ARESTOCAINE HCL W/ LEVONORDEFIN/

/AP/ /CARLISLE/ /0.05MG/ML; 2% /

@ SOLWAY 0.05MG/ML; 2% /

/N85010/001/
N85010 001

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL

MYLOCAINE

@ PENNEX

AT 4%

@/ 4% /

PEDIATRIC LTA KIT

/AL/ /ABBOTT/ 2% /

@ ABBOTT 2%

N87881 001
NOV 18, 1982
/N87881/001/
/NOV/18,/1982/
/N88572/001/
/JUL/31,/1984/
N88572 001
JUL 31, 1984

LIOTRIX (T4,T3)

TABLET; ORAL

/EUTHROID-0.5/

@ PARKE/DAVIS/

/EUTHROID-1/

@ PARKE/DAVIS/

/EUTHROID-2/

@ PARKE/DAVIS/

/EUTHROID-3/

@ PARKE/DAVIS/

/+//PARKE/DAVIS/

@ PARKE DAVIS

N81224 001

JUN 03, 1994

/N08107/001/

N08107 001

/0.03MG; 0.0075MG/

0.03MG; 0.0075MG

/0.06MG; 0.015MG/

0.06MG; 0.015MG

/0.12MG; 0.03MG/

0.12MG; 0.03MG

/0.18MG; 0.045MG/

0.18MG; 0.045MG

/N16680/001/
N16680 001

/N16680/002/
N16680 002

/N16680/003/
N16680 003

/N16680/004/
N16680 004

LISINAPRIL

TABLET; ORAL

PRINIVIL

MERCK

2.5MG

N19558 006
JAN 28, 1994

ZESTRIL

ZENECA

2.5MG

N19777 005
APR 29, 1993

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL

/LITHOBID/

/+/CIBA/

@ CIBA

/300MG/
300MG/N18027/001/
N18027 001

LORAZEPAM

INJECTABLE; INJECTION

ATIVAN

AP + WYETH AVERST

AP +

LORAZEPAM

ABBOTT

2MG/ML
4MG/MLN18140 001
N18140 002N74280 001
MAY 27, 1994N74282 001
MAY 27, 1994N74280 002
MAY 27, 1994N74282 002
MAY 27, 1994N74276 001
APR 15, 1994N74276 002
APR 15, 1994N74243 001
APR 12, 1994N74300 001
APR 12, 1994N74243 002
APR 12, 1994

STERIS

2MG/ML

4MG/ML

STERLING WINTHROP

2MG/ML

2MG/ML

4MG/ML

LORAZEPAM

TABLET; ORAL

LORAZEPAM

/AB/ /WARNER/CHILCOTT/

/1MG/

/N71038/001/
/JAN/12,/1988/

/AB/

/2MG/

/N71039/001/
/JAN/12,/1988/

@ WARNER CHILCOTT

1MG

N71038 001

@

2MG

N71039 001

@

2MG

N71039 001

@

2MG

N71039 001

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE IN PLASTIC CONTAINER

ABBOTT

4GM/100ML

N20309 001

JUN 24, 1994

N20309 002

JUN 24, 1994

80MG/ML

MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION

DEPO-PROVERA

+ UPJOHN

150MG/ML

N20246 001

OCT 29, 1992

/N20246/001/

/OCT/29,/1992/

MEPIVACAIN HYDROCHLORIDE

INJECTABLE; INJECTION

/ARESTOCAINE HCL/

/3%/

/N84777/002/

/APR/18,/1982/

N84777 002

APR 18, 1982

@ SOLVAY

3%

MEPROBAMATE

TABLET; ORAL

/MEPRIAM/

/LEMMON/

@ LEMMON

/400MG/
400MG/N16069/001/
N16069 001

METARAMINOL BITARTRATE

INJECTABLE; INJECTION

METARAMINOL BITARTRATE

/AP/ /FUJISAWA/
@ FUJISAWA /EQ 10MG BASE/ML/
EQ 10MG BASE/ML/N80431/001/
N80431 001>_ADD_>
>_ADD_>AB
ROXANETABLET; ORAL
METHOTREXATE SODIUM

EQ 2.5MG BASE

N40054 001
AUG 01, 1994

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

AB MIKART

25MG

N40062 001
JAN 27, 1994

50MG

N40062 002
JAN 27, 1994AA
PAMINE/AA/ BRADLEY
/UPJOHN/2.5MG
/2.5MG/N08848 001
/N08848/001/

METHDILAZINE

/TABLET;/CHEWABLE;/ORAL/

/TACARYL/

@ WESTWOOD SQUIBB/
/WESTWOOD/SQUIBB/
3.6MG/ 3.6MG/N11950/009/
N11950 009

/AP/

/AP/ A-METHAPRED

/EQ 40MG BASE/VIAL/

/N89573/001/
/FEB/22,/1991/

METHDILAZINE HYDROCHLORIDE

/SYRUP;/ORAL/

/TACARYL/

@ WESTWOOD SQUIBB/
/WESTWOOD/SQUIBB/
4MG/5ML/ 4MG/5ML/N11950/007/
N11950 007

@

@ ABBOTT

EQ 40MG BASE/VIAL

FEB 22, 1991

/TABLET;/ORAL/

/TACARYL/

@ WESTWOOD SQUIBB/
/WESTWOOD/SQUIBB/
8MG/ 8MG/N11950/006/
N11950 006

/AP/

/AP/

/EQ 1GM BASE/VIAL/

/N87535/001/
/JUN/25,/1982/

METHOTREXATE SODIUM

INJECTABLE; INJECTION

FOLEX PFS

/AP/ /ADRIA/

/EQ 25MG BASE/ML/
EQ 25MG BASE/ML/N89180/001/
/JAN/03,/1986/
N89180 001
JAN 03, 1986TABLET; BUCCAL/SUBLINGUAL
METHYLTESTOSTERONE/5MG/
5MG/N83836/001/
N83836 001
/N85125/001/
N85125 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

/EQ 40MG BASE/VIAL/

/N89573/001/
/FEB/22,/1991/

/EQ 125MG BASE/VIAL/

/N89574/001/
/FEB/22,/1991/

/EQ 500MG BASE/VIAL/

/N89575/001/
/FEB/22,/1991/

EQ 40MG BASE/VIAL

@ ABBOTT

FEB 22, 1991

EQ 125MG BASE/VIAL

@

FEB 22, 1991

EQ 500MG BASE/VIAL

@

FEB 22, 1991

/METHYLPREDNISOLONE/

/EQ 500MG BASE/VIAL/

/N87535/001/
/JUN/25,/1982/

/EQ 1GM BASE/VIAL/

/N87535/002/
/JUN/25,/1982/

EQ 500MG BASE/VIAL

@ ORGANON

N87535 001
JUN 25, 1982

EQ 1GM BASE/VIAL

@

N87535 002
JUN 25, 1982

METHYLTESTOSTERONE

TABLET; ORAL

METHYLTESTOSTERONE

> DLT > /BP/ /10MG/
 > DLT > /BP/ /25MG/
 > ADD > @ DANBURY PHARMA 10MG
 > ADD > @ DANBURY PHARMA 25MG
 /BP/ /PUREPAC/ /10MG/
 /BP/ /PUREPAC/ /25MG/
 @ PUREPAC 10MG
 @ PUREPAC 25MG
 /BP/ /TABLICAPS/ /10MG/
 /BP/ /TABLICAPS/ /25MG/
 @ TABLICAPS 10MG
 @ TABLICAPS 25MG
 /BP/ /WEST/WARD/ /10MG/
 /BP/ /WEST/WARD/ /25MG/
 @ WEST WARD 10MG
 @ WEST WARD 25MG

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

MAXOLON

AB KING PHARMS EQ 10MG BASE
 /AB/ /SMITHKLINE/BEECHAM/ /EQ 10MG BASE/

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

AB APOTHECON 50MG
 AB 100MG
 AB COPLEY 50MG
 AB 100MG
 AB GENEVA PHARMS 50MG
 AB 100MG
 AB PUREPAC PHARM 50MG
 AB 100MG

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

AB WATSON LABS 50MG
 AB 100MG
 N74217 001
 MAY 27, 1994
 N74217 002
 MAY 27, 1994

MILRINONE LACTATE

> DLT > INJECTABLE; INJECTION
 > DLT > /MILRINONE/LACTATE/
 > DLT > /+//STERLING/WINTHROP/ /EQ/1MG/BASE/ML/
 > ADD > PRIMACOR
 > ADD > + STERLING WINTHROP EQ 1MG BASE/ML
 > ADD >

/N19436/001/
 /DEC/31,/1987/

N19436 001
 DEC 31, 1987

> ADD > PRIMACOR IN DEXTROSE 5% IN PLASTIC CONTAINER
 > ADD > + STERLING WINTHROP EQ 20MG BASE/100ML
 > ADD >

N20343 003
 AUG 09, 1994

N20343 001
 AUG 09, 1994

N20343 002
 AUG 09, 1994

MINOCYCLINE HYDROCHLORIDE

TABLET; ORAL

/MINOCIN/

/@/LEDERLE/

/EQ/50MG/BASE/
 /EQ/100MG/BASE/
 /@/
 MINOCYCLINE HCL
 LEDERLE

/N50451/003/
 /AUG/10,/1982/
 /N50451/002/
 /AUG/10,/1982/

N50451 003
 AUG 10, 1982
 N50451 002
 AUG 10, 1982

NADOLOL

TABLET; ORAL

CORGARD

SQUIBB

> ADD > AB 120MG
 > ADD > AB 120MG
 > ADD > AB 160MG
 > ADD > AB 160MG

N18063 003
 N18064 003
 N18063 004
 N18064 004

N74258 001
 JAN 27, 1994
 N74258 002
 JAN 27, 1994
 N74333 001
 JAN 27, 1994
 N74333 002
 JAN 27, 1994
 N73288 001
 MAR 25, 1994
 N73289 001
 MAR 25, 1994
 N74380 001
 JUL 29, 1994
 N74380 002
 JUL 29, 1994

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
HABITROL

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

NITROGLYCERIN

INJECTABLE; INJECTION

/AP/ /PARKE/DAVIS/ /5MG/ML/ /N70863/001/
NITROSTAT @ PARKE DAVIS 5MG/ML /JAN/08,1987/
@ 10MG/ML/ N70863 001
@ 10MG/ML/ /N70871/001/
@ 10MG/ML/ /JAN/08,1987/
@ 10MG/ML/ N70871 001
@ 10MG/ML/ /JAN/08,1987/
@ 10MG/ML/ /N70872/001/
@ 10MG/ML/ /JAN/08,1987/
@ 10MG/ML/ N70872 001
@ 10MG/ML/ /JAN/08,1987/
@ 10MG/ML/ N70872 001
@ 10MG/ML/ JAN 08, 1987

NITROFURANTOIN

TABLET; ORAL

/AB/ /FURALAN/ /50MG/ /N80017/001/
/AB/ /LANNETT/ /100MG/ /N80017/002/
@ LANNETT 50MG N80017 001
@ 100MG N80017 002

NORETHINDRONE

TABLET; ORAL

/NORLUTIN/ /5MG/ /N10895/002/
/+//PARKE/DAVIS/ 5MG N10895 002
@ PARKE DAVIS

NITROFURAZONE

OINTMENT; TOPICAL

NITROFURAZONE
/AI/ /LANNETT/ /0.2%/ /N84393/001/
@ LANNETT 0.2% N84393 001

NYSTATIN

SUSPENSION; ORAL

NYSTATIN
AA BAUSCH AND LOMB 100,000 UNITS/ML N64042 001
/AA/ /PHARMAFAIR/ /100,000 UNITS/ML/ FEB 28, 1994
@ PHARMAFAIR 100,000 UNITS/ML /JAN/16,1985/
N62541 001
JAN 16, 1985

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN

/AP/ /INTL/MEDICATION/ /5MG/ML/ /N70026/001/
@ INTL MEDICATION 5MG/ML /SEP/10,1985/
/NITRONAL/ /1MG/ML/ N70026 001
/+//BOSKAMP/ 1MG/ML /SEP 10, 1985
@ G POHL BOSKAMP 1MG/ML /N18672/001/
/AUG/30,1983/
/AUG 30, 1983 N18672 001

NYSTATIN, TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYCOLOG-II
AI + APOTHECON 100,000 UNITS/GM;0.1% N60576 002
AI 100,000 UNITS/GM;0.1% MAY 01, 1985
/AI//+//SQUIBB/ /100,000 UNITS/GM;0.1% /N62606 001
/AI/ /100,000 UNITS/GM;0.1% /MAY 15, 1985
/AI/ /100,000 UNITS/GM;0.1% /N60576/002/
/MAY/01,1985/
/AI/ /100,000 UNITS/GM;0.1% /N62606/001/
/MAY/15,1985/

NYSTATIN, TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

/AI/ /BARRE/ /100,000 UNITS/GM;0.1% /N63010/001/
/DEC/20,/1988/
@ BARRE 100,000 UNITS/GM;0.1% N63010 001
/B*/ /CLAY/PARK/ /100,000 UNITS/GM;0.1% /N62186/002/
/JUN/06,/1985/
@ CLAY PARK 100,000 UNITS/GM;0.1% N62186 002
/AI/ /PHARMAFAIR/ /100,000 UNITS/GM;0.1% /N62657/001/
/JUL/30,/1986/
@ PHARMAFAIR 100,000 UNITS/GM;0.1% N62657 001
JUL 30, 1986

OINTMENT; TOPICAL

NYSTATIN-TRIAMCINOLONE ACETONIDE

/AI/ /PHARMADERM/ /100,000 UNITS/GM;0.1% /N62603/001/
/OCT/09,/1985/
@ PHARMADERM 100,000 UNITS/GM;0.1% N62603 001
OCT 09, 1985

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS, ORAL

PRILOSEC

+ ASTRA MERCK

/+//MERCK/

N19810 001
SEP 14, 1989
/N19810/001/
/SEP/14,/1989/

ORPHENADRINE HYDROCHLORIDE

/TABLET;/ORAL/

/DISIPAL/

/3M/

@ 3M

/50MG/
50MG
/N10653/001/
N10653 001

PAROXETINE HYDROCHLORIDE

TABLET; ORAL

PAXIL

+ SMITHKLINE BEECHAM

EQ 30MG BASE

/EQ/30MG/BASE/

N20031 003
DEC 29, 1992
/N20031/003/
/DEC/29,/1992/

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

@ APOTHECON 1,000,000 UNITS/VIAL
@ 5,000,000 UNITS/VIAL
@ 10,000,000 UNITS/VIAL
@ 20,000,000 UNITS/VIAL
/AP/ /SQUIBB/ /1,000,000 UNITS/VIAL/
/AP/ /N60362/001/
/AP/ /N60362/003/
/AP/ /N60362/004/
/N60362/002/

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

> DLT_> /BETAPEN-VK/
> DLT_> /AA/ /BRISTOL/
> DLT_> /AA/ /EQ 125MG BASE/5ML/
> ADD_> /AA/ /EQ 250MG BASE/5ML/
> ADD_> @ APOTHECON EQ 125MG BASE/5ML
@ EQ 250MG BASE/5ML
/N61149/001/
/N61149/002/
/N61149 001
/N61149 002

TABLET; ORAL

UTICILLIN VK

/UPJOHN/

@ UPJOHN

> DLT_> /AB/ /EQ 500MG BASE/
> ADD_> EQ 500MG BASE
/N61651/002/
/N61651 002

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTACARINAT

AP RHONE POULENC RORER 300MG/VIAL

N73447 001
APR 28, 1994

PENTOBARBITAL SODIUM

CAPSULE; ORAL

/PENTOBARBITAL SODIUM/

/LANNETT/

@ LANNETT

@

/AA/ /50MG/
/AA/ /100MG/
50MG
100MG
/N85937/001/
/N85915/001/
N85937 001
N85915 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE
 /AA/ /ZENITH/
 @ ZENITH

/35MG/
 35MG

/N85611/001/
 N85611 001

TABLET; ORAL
 SALAGEN
 + MGI

5MG

N20237 001
 JAN 27, 1994
 MAR 22, 1994

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL
 /AA/ /LANNETT/
 @ LANNETT

/30MG/
 30MG

/N87022/001/
 /FEB/03, /1983/
 N87022 001
 FEB 03, 1983

TABLET; ORAL
PINDOLOL
 AB MUTUAL PHARM

5MG

N74063 001
 JAN 27, 1994
 N74063 002
 JAN 27, 1994

10MG

10MG

PHENYLEPHRINE HYDROCHLORIDE, PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PROMETHAZINE VC PLAIN
 AA PENNEX
 /@/
 5MG/5ML; 6.25MG/5ML/
 /5MG/5ML; 6.25MG/5ML/

N88897 001
 JAN 04, 1985
 /N88897/001/
 /JAN/04, /1985/

SYRUP; ORAL
 /AA/ /VERMIDOL/
 @ SOLVAY

/EQ 500MG BASE/5ML/
 EQ 500MG BASE/5ML

/N80992/001/
 N80992 001

PHENYTOIN SODIUM, PROMET

CAPSULE; ORAL
 /DIPHENYLAN/SODIUM/
 /BX/ /LANNETT/
 @ LANNETT
 @

/100MG/
 /30MG/
 30MG
 100MG

/N80857/002/
 /N80857/001/
 N80857 001
 N80857 002

CAPSULE; ORAL
PIROXICAM
 AB NOVOPHARM

10MG

N73637 001
 JAN 28, 1994
 N73638 001
 JAN 28, 1994

20MG

POTASSIUM CHLORIDEPHYTONADIONE

INJECTABLE; INJECTION
 PHYTONADIONE
 /BP/ /SMITHKLINE/BEECHAM/
 /BP/ @ SMITHKLINE BEECHAM
 @

/1MG/0.5ML/
 /10MG/ML/
 1MG/0.5ML
 10MG/ML

/N84060/001/
 /N84060/002/
 N84060 001
 N84060 002

INJECTABLE; INJECTION
POTASSIUM CHLORIDE
 /AP/ /FUJISAWA/
 @ FUJISAWA

/2MEQ/ML/

2MEQ/ML

/N87885/001/
 /FEB/03, /1983/
 N87885 001
 FEB 03, 1983

PREDNISOLONE

TABLET; ORAL
 PREDNISOLONE
 /BX/ /BUNDY/
 @ BUNDY

/5MG/
 5MG

/N83675/001/
 N83675 001

PREDNISOLONE

TABLET, ORAL
PREDNISOLONE
/BX/ /ICN/
@ ICN
/BX/ /INWOOD/
@ INWOOD
/BX/ /TABLICAPS/
@ TABLICAPS

/5MG/
5MG
/5MG/
5MG
/5MG/
5MG

/N80236/001/
N80236 001
/N80748/001/
N80748 001
/N85170/001/
N85170 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

ointment; OPHTHALMIC
METIMYD
+ SCHERING
VASOCIDIN
IOLAB

0.5%:10%
0.5%:10%

N10210 002
N88791 001
OCT 05, 1984

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
/PREDAIR FORTE/
/PHARMAFAIR/
@ PHARMAFAIR

/EQ 0.9% PHOSPHATE/
EQ 0.9% PHOSPHATE

/N88165/001/
/MAR/28, /1983/
N88165 001
MAR 28, 1983

PREDNISOLONE SODIUM PHOSPHATE

AT BAUSCH AND LOMB
EQ 0.11% PHOSPHATE
AT EQ 0.9% PHOSPHATE

N40065 001
JUL 29, 1994
N40070 001
JUL 29, 1994

PREDNISONE

TABLET, ORAL
PREDNISONE
/BX/ /BUNDY/
@ BUNDY
/BX/ /DANBURY/PHARMA/
@ DANBURY PHARMA
@ FERRANTE
@ FERRANTE
/BX/ /ICN/
@ ICN
/BX/ /INWOOD/
/BX/ /INWOOD
@ INWOOD

/5MG/
5MG
/50MG/
50MG
2.5MG
5MG
/5MG/
5MG
/1MG/
/2.5MG/
1MG
2.5MG

/N83676/001/
N83676 001
/N86867/001/
N86867 001
N80563 001
N80563 002
/N80237/001/
N80237 001
/N80328/001/
/N80306/001/
N80328 001
N80306 001

PREDNISONE

TABLET, ORAL
PREDNISONE
/BX/ /MK/LABS/
/BX/ /BX/
/BX/ /NYLOS/
@ NYLOS
/BX/ /REXALL/
@ REXALL
/BX/ /SPERTI/
/BX/ /BX/
/BX/ @ SPERTI
@

/2.5MG/
/5MG/
/5MG/
5MG
/5MG/
5MG
/1MG/
/2.5MG/
/5MG/
1MG
2.5MG
5MG
/WHITE/TOWNE/PAULSEN//20MG/
@ WHITE TOWNE PAULSEN 20MG
/1ST/TX/
@ 1ST TX 5MG

/N80563/001/
/N80563/002/
/N85115/001/
N85115 001
/N80232/001/
N80232 001
/N80359/001/
/N80359/002/
/N80359/003/
N80359 001
N80359 002
N80359 003
/N84913/002/
N84913 002
/N80371/001/
N80371 001

PROMETHAZINE HYDROCHLORIDE

SYRUP, ORAL
PROMETHAZINE PLAIN
AA PENNEX
/e/
/e/

6.25MG/5ML
/6.25MG/5ML/

N87953 001
NOV 15, 1982
/N87953/001/
/NOV/15, /1982/

TABLET, ORAL
PROMETHAZINE HCL
/BP/ /TABLICAPS/
/BP/ @ TABLICAPS
@ REMSED/
/BP/ /DUPONT/
@ DUPONT

/12.5MG/
/25MG/
12.5MG
25MG
/25MG/
25MG

/N84080/001/
/N84027/001/
N84080 001
N84027 001
/N83176/002/
N83176 002

PROPANTHELINE BROMIDE

TABLET, ORAL
PRO-BANTHINE
AA ROBERTS LABS
AA
/AA/ /SCS/
/AA/

7.5MG
15MG
/7.5MG/
/15MG/

N08732 003
N08732 002
/N08732/003/
/N08732/002/

PROPARACAINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

/AI/ /KAINAIR/ /PHARMAFAIR/ /0.5%/
@ PHARMAFAIR 0.5%

/N88087/001/
/JUN/07./1983/
N88087 001
JUN 07, 1983

TABLET, EXTENDED RELEASE; ORAL

QUINIDEX
AB + ROBINS AH 300MG
QUINIDINE SULFATE
AB COPLEY PHARM 300MG

N12796 002
N40045 001
JUN 30, 1994

PROPYLTHIOURACIL

TABLET; ORAL

PROPYLTHIOURACIL
/BD/ /DANBURY/PHARMA/
@ DANBURY PHARMA
/BD/ /LANNETT/
@ LANNETT
/BD/ /TABLICAPS/
@ TABLICAPS

/50MG/
N80932 001
/N80016/001/
N80016 001
/N80840/001/
N80840 001

EQ 150MG BASE
EQ 300MG BASE

N20095 001
MAR 08, 1994
N20095 002
MAR 08, 1994

PROTIRELIN

INJECTABLE; INJECTION

/AP/ /RELEFACT TRH/
/FERRING/LABS/
THYREL TRH
AP FERRING LABS

/N18087/001/
N18087 001

EQ 150MG BASE/PACKET

N20251 002
MAR 31, 1994

PSEUDOEPHEDRINE HYDROCHLORIDE, TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

/AA/ /ALLERFED/
/PRIVATE/FORM/
@ PRIVATE FORM

/N88860/001/
/JAN/31./1985/
N88860 001
JAN 31, 1985

10MG/ML

N20214 002
MAR 17, 1994

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL

/PYRIDOSTIGMINE/BROMIDE/
/KALI/DUPHAR/
@ SOLVAY

/N89572/001/
/NOV/27./1990/
N89572 001
NOV 27, 1990

0.5mCi/VIAL
1mCi/VIAL
2mCi/VIAL

N16224 001
N16224 002
N16224 003

ROSE BENGAL SODIUM, I-131

INJECTABLE; INJECTION

ROBENGATOPE
@ BRACCO
@
@

>_ADD->
>_ADD->
>_ADD->

ROSE BENGAL SODIUM, I-131

INJECTABLE; INJECTION

ROBENCATOPE

> DLT >
> DLT >
> DLT >

/0.5mCi/VIAL/
/1mCi/VIAL/
/2mCi/VIAL/

/N16224/001/
/N16224/002/
/N16224/003/

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

250uCi/VIAL
1mCi/VIAL
2mCi/VIAL
/250/UCI/VIAL/
/1mCi/VIAL/
/2mCi/VIAL/

N13993 001
N13993 003
N13993 002
/N13993/001/
/N13993/003/
/N13993/002/

SALMETEROL XINAFOATE

AEROSOL, METERED; INHALATION
SEREVENT

+ GLAXO

EQ 0.021MG BASE/INH

N20236 001
FEB 04, 1994

SODIUM IODIDE, I-131

CAPSULE; ORAL

IODOTOPE

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

8-100mCi
1-50mCi
/8-100/UCI/
/1-50mCi/

N10929 001
N10929 003
/N10929/001/
/N10929/003/

SECOBARBITAL SODIUM

CAPSULE; ORAL

SECOBARBITAL SODIUM

/AA/ /LANNETT/

/50MG/
/100MG/
50MG
100MG

/N85909/001/
/N85903/001/
N85909 001
N85903 001

/AA/ /LILLY/

/50MG/
50MG

/N86101/001/
/OCT/03,/1983/
N86101 001
OCT 03, 1983

SOLUTION; ORAL

IODOTOPE

> ADD >
> DLT >

7-106mCi/BOT
/7-106mCi/BOT/

N10929 002
/N10929/002/

SELENOMETHIONINE, SE-75

INJECTABLE; INJECTION

SETHOTOPE

@ BRACCO

85-550uCi/ML
/85-550/UCI/ML/

N17047 001
/N17047/001/

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION

PHOSPHOTOPE

@ BRACCO

> ADD >

1-8mCi/VIAL

N10927 001

SILVER SULFADIAZINE

DRESSING; TOPICAL

SILDIMAC

/@/BIOPLASTY/

/1%/
1%

/N19608/001/
/NOV/30,/1989/
N19608 001
NOV 30, 1989

SOLUTION; INJECTION, ORAL

PHOSPHOTOPE

/@/SQUIBB/

/1-8mCi/VIAL/

/N10927/001/

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
BERLEX

120MG

N19865 005
APR 20, 1994

TABLET; ORAL
SULFADIAZINE

> DLT > /AB/ /EON/LABS/ /500MG/
> DLT >
> ADD > AB + EON LABS 500MG
> ADD >
> DLT > /AB/ /+//LILLY/ /500MG/
> ADD > @ LILLY 500MG

/N40091/001/
/JUL/29,/1994/
N40091 001
JUL 29, 1994
/N04122/002/
N04122 002

STAVUDINE

CAPSULE; ORAL
ZERIT

+ BRISTOL MYERS SQUIBB 40MG

@

N20412 005
JUN 24, 1994
N20412 001
JUN 24, 1994
N20412 002
JUN 24, 1994
N20412 003
JUN 24, 1994
N20412 004
JUN 24, 1994

SULFAMETHOXAZOLE, TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

/AP/ /FUJISAWA/ /80MG/ML,16MG/ML/

@ FUJISAWA

80MG/ML,16MG/ML

/N70223/001/
/DEC/29,/1987/
N70223 001
DEC 29, 1987

SUSPENSION; ORAL

/BACTRIM/

/AB/ /+//ROCHE/ /200MG/5ML;40MG/5ML/
@ ROCHE 200MG/5ML;40MG/5ML

/N17560/001/
N17560 001

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION
STREPTOMYCIN SULFATE

/AP/ /PFIZER/
PFIZER

/EQ 1GM BASE/2ML/
EQ 1GM BASE/2.5ML

/N60111/001/
N60111 001

BACTRIM PEDIATRIC

/AB/ /ROCHE/

AB + ROCHE /200MG/5ML;40MG/5ML/
200MG/5ML;40MG/5ML

/N17560/002/
N17560 002

/AB/ /BARRE/

/200MG/5ML;40MG/5ML/

/N72398/001/
/MAY/23,/1988/
N72398 001
MAY 23, 1988

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

/AI/ /SULFAIR FORTE/
/PHARMAFAIR/

/30%/

@ PHARMAFAIR

/N88385/001/
/OCT/13,/1983/
N88385 001
OCT 13, 1983

/AI/ /SULFAIR-15/
/PHARMAFAIR/

/15%/

@ PHARMAFAIR

/N88186/001/
/MAY/25,/1983/
N88186 001
MAY 25, 1983

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM
/AB/ /EON/LABS/ /400MG;80MG/

@ EON LABS 400MG;80MG

/N18598/003/
/MAY/19,/1982/
N18598 003
MAY 19, 1982

/AB/ /UROPLUS DS/
/SHIONOGI/

/800MG;160MG/

/N71816/001/
/SEP/28,/1987/
N71816 001
SEP 28, 1987

/AB/ /UROPLUS SS/
/SHIONOGI/

/400MG;80MG/

/N71815/001/
/SEP/28,/1987/
N71815 001
SEP 28, 1987

@ SHIONOGI

400MG;80MG

SULFASALAZINE

SUSPENSION; ORAL

AZULFIDINE

/+//PHARMACIA/

+ PHARMACIA

@

/250MG/5ML/

250MG/5ML

250MG/5ML

/250MG/5ML/

/N18605/001/

N86983 001

N18605 001

/N86983/001/

INJECTABLE; INJECTION

RENOTEC

@ BRACCO

/SQUIBB/

>_ADD>

>_DLT>

N/A

/N/A/

N17045 001
/N17045/001/SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/AB/ /LANNETT/

@ LANNETT

/500MG/
500MG/N80085/001/
N80085 001

INJECTABLE; INJECTION

MDP-SQUIBB

BRACCO

/SQUIBB/

>_ADD> AP

>_DLT> AP/

N/A

/N/A/

N18107 001
/N18107/001/TACROLIMUS

CAPSULE; ORAL

PROGRAF

+ FUJISAWA

+

EQ 1MG BASE

N50708 001

APR 08, 1994

EQ 5MG BASE

N50708 002

APR 08, 1994

INJECTABLE; INJECTION

/OSTEOSCAN-HDP/

/MALLINCKRODT/

TECHNISCAN HDP

MALLINCKRODT

/N18321/001/

N18321 001

INJECTABLE; INJECTION

PROGRAF

+ FUJISAWA

EQ 5MG BASE/ML

N50709 001

APR 08, 1994

INJECTABLE; INJECTION

CARDIOLITE

DUPONT

/DUPONT/MERCK/

N/A

/N/A/

N19785 001
DEC 21, 1990
/N19785/001/
/DEC/21, 1990/TAMOXIFEN CITRATE

TABLET; ORAL

NOLVADEX

+ ZENECA

EQ 20MG BASE

N17970 002

MAR 21, 1994

SOLUTION; INJECTION, ORAL

TESULOID

BRACCO

/SQUIBB/

>_ADD> AP

>_DLT> AP/

N/A

/N/A/

N16923 001
/N16923/001/TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

MACROTEC

BRACCO

/SQUIBB/

N/A

/N/A/

/SYRUP; ORAL/

/ACHROMYCIN V/

/AB//+//LEDERLE/

/SUMYCIN/

/AB/ /SQUIBB/

/TETRACYCLINE/

/AB/ /BARRE/

/AB/ /MK/LABS/

/N50263/002/

/N60400/001/

/N60633/001/

/N60174/001/

/EQ 125MG HCL/5ML/

/EQ 125MG HCL/5ML/

/EQ 125MG HCL/5ML/

/EQ 125MG HCL/5ML/

TETRACYCLINE

/SYRUP; ORAL/
/TETRACYCLINE HCL/
/AB/ /PUREPAC/
/TETRACYN/
/AB/ /PFIPHARMECS/
/TETRAMED/
/AB/ /ZENITH/

/EQ 125MG HCL/5ML/
/N60291/001/
/EQ 125MG HCL/5ML/
/N60095/001/
/EQ 125MG HCL/5ML/
/N61468/001/

N87892 001
JAN 31, 1985
N89540 001
MAY 10, 1989
N87893 001
JAN 31, 1985
N87894 001
JAN 31, 1985

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
/AB/ /ICN/
@ ICN

/500MG/
500MG
/N60471/002/
N60471 002

N40052 001
FEB 14, 1994
N40052 002
FEB 14, 1994
N40052 003
FEB 14, 1993
N40052 004
FEB 14, 1994

FIBER, EXTENDED RELEASE; PERIODONTAL
ACTISITE
+ ON SITE

12.7MG/FIBER
N50653 001
MAR 25, 1994

ELIXIR; ORAL
/LANOPHYLLIN/
/AA/ /LANNETT/
@ LANNETT

/80MG/15ML/
80MG/15ML

/N84578/001/
N84578 001

SYRUP; ORAL

ACHRONYCIN V

AB + LEDERLE

SUMYCIN

AB SQUIBB

TETRACYCLINE HCL

AB BARRE

AB MK LABS

AB PUREPAC

AB TETRACYN

AB PFIPHARMECS

AB TETRAMED

AB ZENITH

125MG/5ML
N50263 002
125MG/5ML
N60400 001
125MG/5ML
N60633 001
125MG/5ML
N60174 001
125MG/5ML
N60291 001
125MG/5ML
N60095 001
125MG/5ML
N61468 001

/80MG/15ML/
80MG/15ML

/N89223/001/
/MAY/27, /1988/
N89223 001
MAY 27, 1988
N87679 001
APR 15, 1982
/N87679/001/
/APR/15, /1982/

TABLET; ORAL

/PANMYCIN/

/AB/ /UPJOHN/

@ UPJOHN

@

/500MG/
250MG
500MG
/N61705/002/
N61705 001
N61705 002

INJECTABLE; INJECTION

THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

AP BAXTER

4MG/ML

N18649 007
JUL 26, 1982

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT

4MG/ML

N19211 007
DEC 14, 1984

SUMYCIN

/AB/ /+//APOTHECON/

+ APOTHECON

/500MG/
500MG
/N61147/004/
N61147 004

THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAW

4MG/ML

N19212 003
NOV 07, 1984

SYRUP; ORAL

/ACCURBRON/

/MERRELL/DOW/

/150MG/15ML/

/N88746/001/
/NOV/22, /1985/

> DLT >

> DLT >

> DLT >

THEOPHYLLINE

> DLT >
> ADD >
> ADD >
SYRUP; ORAL
/ACCURBRON/
@ MERRELL DOW
/THEOPHYLLINE/
/AA/ /BARRE/
@ BARRE

150MG/15ML

/80MG/15ML/
80MG/15ML

N88746 001
NOV 22, 1985

/N86001/001/
N86001 001

EQ 600MG BASE

N74473 001
AUG 30, 1994

THYROGLOBULIN

TABLET; ORAL
PROLOID
/BP//+//PARKE/DAVIS/

@ PARKE DAVIS
@

@

@

@

@
THYROGLOBULIN
+ GLOBAL PHARMS
/BP/ /RICHLYN/

/65MG/
/32MG/
32MG
65MG
/100MG/
100MG
/130MG/
130MG
/200MG/
200MG
N02245/002/
N02245/005/
N02245 005
N02245 002
N02245/008/
N02245 008
N02245/010/
N02245 010
N02245/007/
N02245 007

/BP/ /MYLAN/
@ MYLAN

/N84406/001/
N84406 001

TRIAMCINOLONE ACETONIDE

AEROSOL; TOPICAL
KENALOG
+ APOTHECON
/+//WESTWOOD/SQUIBB/

0.147MG/GM
/0.147MG/GM/

N12104 001
/N12104/001/

CREAM; TOPICAL
KENALOG

AT +
AT +
AT +
/AT//+//WESTWOOD/SQUIBB/
/AT//+//
/AT//+//

0.025%
0.1%
0.5%
/0.025%/
/0.1%/
/0.5%/
N11601 003
N11601 006
N83943 001
/N11601/003/
/N11601/006/
/N83943/001/

SOLUTION/DROPS; OPHTHALMIC

TOBRAMYCIN
AT STERIS

0.3%

N63176 001
MAY 25, 1994

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE
AP APOTHECON

EQ 10MG BASE/ML

EQ 40MG BASE/ML

EQ 40MG BASE/ML

N64021 001
MAY 31, 1994
N64021 002
MAY 31, 1994
N64026 001
MAY 31, 1994

TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC
CONTAINER
+ ABBOTT

EQ 1.6MG BASE/ML

N63081 006
JUN 02, 1993

0.025%
0.1%
0.5%
/0.025%/
/0.1%/
/0.5%/
N11600 003
N11600 001
N83944 001
/N11600/003/
/N11600/001/
/N83944/001/

OINTMENT; TOPICAL
KENALOG

AT +
AT +
AT +
/AT//+//WESTWOOD/SQUIBB/
/AT//+//
/AT//+//

TRIAZOLAM

TABLET; ORAL
HALCION
UPJOHN

0.125MG
0.25MG

N17892 003
APR 26, 1985
N17892 001
NOV 15, 1982

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'94 - AUG'94

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TRIAZOLAM

TABLET; ORAL

TRIAZOLAM
ALPHAPHARM

AB 0.125MG

N74031 001
MAR 25, 1994

AB 0.25MG

N74031 002
MAR 25, 1994

AB 0.125MG

N74224 001
JUN 01, 1994

AB 0.25MG

N74224 002
JUN 01, 1994

TRIHENXYPHENIDYL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

ARTANE

/+//LEDERLE/

/N06773/010/

+ LEDERLE

N12947 001

@

5MG

N05773 010

5MG/

N12947/001/

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

TRISULFAPYRIMIDINES (SULFADIAZINE, SULFAMERAZINE, SULFAMETHAZINE)

SUSPENSION; ORAL

/LANTRISUL/

/AB/ /LANNETT/

@ LANNETT

/500MG/5ML/

167MG/5ML; 167MG/5ML;

167MG/5ML

/N80123/002/

N80123 002

TROPICANIDE

SOLUTION/DROPS; OPHTHALMIC

/MYDRIAFAIR/

/AL/ /PHARMAFAIR/

/0.5%/

/N88274/001/

/SEP/16,/1983/

/N88230/001/

/SEP/16,/1983/

N88274 001

SEP 16, 1983

N88230 001

SEP 16, 1983

/AL/ /PHARMAFAIR/

@ PHARMAFAIR

0.5%

@

1%

TROPICANIDE

AT BAUSCH AND LOMB

0.5%

N40067 001

JUL 27, 1994

AT

N40064 001

JUL 27, 1994

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ISOPTIN SR

AB + KNOLL PHARM

180MG

N19152 002
DEC 15, 1989

AB VERAPAMIL HCL

BAKER NORTON

180MG

N74330 001
JAN 31, 1994

VINBLASTINE SULFATE

INJECTABLE; INJECTION

VINBLASTINE SULFATE

/AP/ /BULL/

/10MG/VIAL/

/N89565/001/
/AUG/18,/1987/
N89565 001

AP FAULDING

10MG/VIAL

AUG 18, 1987

VINCRISTINE SULFATE

INJECTABLE; INJECTION

VINCRISTINE SULFATE

/AP/ /FUJISAWA/

/1MG/ML/

/N70411/001/
/SEP/10,/1986/
N70411 001

@ FUJISAWA

1MG/ML

SEP 10, 1986

VINCRISTINE SULFATE PFS

/AP/ /BULL/

/1MG/ML/

/N71484/001/
/APR/19,/1988/
N71484 001

AP FAULDING

1MG/ML

APR 19, 1988

ACETAMINOPHEN

SUPPOSITORY; RECTAL
INFANTS' FEVERALL
UPSHER SMITH

80MG

N18337 004
AUG 26, 1992

TABLET, EXTENDED RELEASE; ORAL
TYLENOL
+ MCNEIL

650MG

N19872 001
JUN 08, 1994

BACITRACIN

OINTMENT; TOPICAL
BACITRACIN
/COMBE/

/500/UNITS/GM/

500 UNITS/GM

/N62799/001/
MAY/14,1987/
N62799 001
MAY 14, 1987

CLOTRIMAZOLE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
MYCELEX-7 COMBINATION PACK
MILES

1%;100MG

N20389 002
JUN 23, 1994

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
/BARRE/

/12.5MG/SML/

12.5MG/SML

/N70497/001/
APR/25,1989/
N70497 001
APR 25, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN
MCNEIL

200MG

N73019 001
MAR 30, 1994

200MG

N73691 001
FEB 25, 1994

PRIVATE FORM

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
/HUMULIN/BR/
/+/LILLY/

/100/UNITS/ML/

100 UNITS/ML

@ LILLY

/N19529/001/
APR/28,1986/
N19529 001
APR 28, 1986

INSULIN SUSP ISOPHANE BEEF

INJECTABLE; INJECTION
NPH INSULIN
/+/NOVO/NORDISK/
@ NOVO NORDISK

/40/UNITS/ML/
40 UNITS/ML

/N17929/001/
N17929 001

NAPHAZOLINE HYDROCHLORIDE, PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
NAPHCON-A
+ ALCON

0.025%;0.3%

N20226 001
JUN 08, 1994

OPCON-A

+ BAUSCH AND LOMB

N20065 001
JUN 08, 1994

NAPROXEN SODIUM

TABLET; ORAL
ALEVE

HAMILTON PHARMS

EQ 200MG BASE

N20204 002
JAN 11, 1994

PERMETHRIN

LOTION; TOPICAL
NIX

/+/BURROUGHS/HELLCOME/ 1%/

+ WARNER WELLCOME

1%

/N19918/001/
MAY/02,1990/
N19918 001
MAY 02, 1990

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
EFIDAC/24

+ CIBA

240MG

N20021 002
DEC 15, 1992

PSEUDOEPHEDRINE HYDROCHLORIDE

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
/PSEUDOEPHEDRINE/HCL/
/ALZA/ /240MG/

/N20021/002/
/DEC/15./1992/

SUDAFED 12 HOUR
/+/BURROUGHS/WELLCOME/ /120MG/

/N73585/001/
/OCT/31./1991/

+ WARNER WELLCOME 120MG

N73585 001
OCT 31, 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
CUMULATIVE SUPPLEMENT NUMBER 8 / AUGUST '94

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION USP

INJECTABLE; INJECTION
BLOOD PACK UNIT CPDA-1 IN PLASTIC CONTAINER
BAXTER HLTHCARE

N940404
JUL 28, 1994

LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS
[January-August, 1994]

NAME <i>Generic/Chemical</i> <i>TN= Trade Name</i>	INDICATION DESIGNATED	SPONSOR & ADDRESS <i>DD=Date Designated</i> <i>MA=Marketing Approval</i>
8-METHOXSALEN TN= UVADEX	FOR THE PREVENTION OF ACUTE REJECTION OF CARDIAC ALLOGRAFTS.	THERAKOS, INCORPORATED 201 BRANDYWINE PARKWAY WEST CHESTER PA 19380 DD 05/12/94 MA / /
AMINOSALICYLIC ACID TN= PASER GRANULES	TREATMENT OF TUBERCULOSIS INFECTIONS.	JACOBUS PHARMACEUTICAL COMPANY 37 CLEVELAND LANE PRINCETON NJ 08540 DD 02/19/92 MA 06/30/94
AMIODARONE HCL TN= CORDARONE	FOR THE ACUTE TREATMENT AND PROPHYLAXIS OF LIFE-THREATENING VENTRICULAR TACHYCARDIA OR VENTRICULAR FIBRILLATION.	WYETH-AYERST LABORATORIES P.O. BOX 8299 PHILADELPHIA PA 19101-1245 DD 03/16/94 MA / /
AMMONIUM TETRATHIOMOLYBDATE TN=	TREATMENT OF WILSON'S DISEASE.	BREWER, GEORGE J. M.D. UNIVERSITY OF MICHIGAN MEDICAL SCHOOL ANN ARBOR MI 48109-0618 DD 01/31/94 MA / /
ANTIVENIN, POLYVALENT CROTALID (OVINE) FAB TN= CROTAB	TREATMENT OF ENVENOMATIONS INFLICTED BY NORTH AMERICAN CROTALID SNAKES.	THERAPEUTIC ANTIBODIES INC. 1500 21ST AVENUE SOUTH, SUITE 310 NASHVILLE TN 37212 DD 01/12/94 MA / /
ARGININE BUTYRATE TN=	TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA.	VERTEX PHARMACEUTICALS INC. 40 ALLSTON STREET CAMBRIDGE MA 02139-4211 DD 05/25/94 MA / /
AUTOLYMPHOCYTE THERAPY TN=	TREATMENT OF RENAL CELL CARCINOMA.	CELLCOR INCORPORATED 200 WELLS AVENUE NEWTON MA 02159 DD 07/12/94 MA / /
BETAINE TN=	TREATMENT OF HOMOCYSTEINURIA.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 05/16/94 MA / /
BOVINE IMMUNOGLOBULIN CONCENTRATE, CRYPTOSPORIDIUM PARVUM TN= SPORIDIN-G	TREATMENT AND SYMPTOMATIC RELIEF OF CRYPTOSPORIDIUM PARVUM INFECTION OF THE GASTROINTESTINAL TRACT IN IMMUNOCOMPROMISED PATIENTS.	GALAGEN, INCORPORATED 4001 LEXINGTON AVENUE NORTH ARDEN HILLS MN 55126-2998 DD 03/01/94 MA / /
BUPRENORPHINE HYDROCHLORIDE TN=	TREATMENT OF OPIATE ADDICTION IN OPIATE USERS.	RECKITT & COLMAN PHARMACEUTICALS, INC. 1901 HUGUENOT ROAD RICHMOND VA 23235 DD 06/15/94 MA / /
BUSULFAN TN=	FOR USE AS PREPARATIVE THERAPY FOR MALIGNANCIES TREATED WITH BONE MARROW TRANSPLANTATION.	SPARTA PHARMACEUTICALS, INC. P.O. BOX 13288 RESEARCH TRIANGLE PK NC 27709 DD 04/21/94 MA / /
BUSULFAN TN=	AS PREPARATIVE THERAPY IN THE TREATMENT OF MALIGNANCIES WITH BONE MARROW TRANSPLANTATION.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 07/28/94 MA / /
CCD 1042 TN=	TREATMENT OF INFANTILE SPASMS.	COCENSYS, INC. 213 TECHNOLOGY DRIVE IRVINE CA 92718 DD 05/25/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
CHIMERIC (MURINE VARIABLE, HUMAN CONSTANT) MAB TO CD20 TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	IDEC PHARMACEUTICALS CORPORATION 11011 TORREYANA ROAD SAN DIEGO CA 92121 DD 06/13/94 MA / /
CHOLINE CHLORIDE TN=	TREATMENT OF CHOLINE DEFICIENCY, SPECIFICALLY THE CHOLINE DEFICIENCY, HEPATIC STEATOSIS, AND CHOLESTASIS, ASSOCIATED WITH LONG-TERM PARENTERAL NUTRITION.	BUCHMAN, ALAN M.D. 6550 FANNIN, SUITE 1122 HOUSTON TX 77030 DD 02/10/94 MA / /
CLADRIBINE TN= LEUSTATIN	TREATMENT OF THE CHRONIC PROGRESSIVE FORM OF MULTIPLE SCLEROSIS.	BEUTLER, ERNEST M.D. 10666 NORTH TORREY PINES ROAD LA JOLLA CA 92037 DD 04/19/94 MA / /
CLONAZEPAM TN= KLOPIN	TREATMENT OF HYPEREKPLEXIA (STARTLE DISEASE).	HOFFMAN-LA ROCHE, INCORPORATED 340 KINGSLAND STREET NUTLEY NJ 07110-1199 DD 08/04/94 MA / /
CY-1899 TN=	TREATMENT OF CHRONIC ACTIVE HEPATITIS B INFECTION IN HLA-A2 POSITIVE PATIENTS.	CYTEL CORPORATION 3525 JOHN HOPKINS COURT SAN DIEGO CA 92121 DD 03/16/94 MA / /
CYSTEAMINE TN= CYSTAGON	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	MYLAN LABORATORIES, INC 781 CHESTNUT RIDGE ROAD, PO BOX 4310 MORGANTOWN WV 26504-4310 DD 01/25/91 MA 08/15/94
DEHYDROEPIANDROSTERONE TN=	TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) AND THE REDUCTION IN THE USE OF STEROIDS IN STEROID-DEPENDENT SLE PATIENTS.	GENELABS TECHNOLOGIES, INC. 505 PENOBSCOT DRIVE REDWOOD CITY CA 94063 DD 07/13/94 MA / /
DESMOPRESSIN ACETATE TN=	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD COLLEGEVILLE PA 19426 DD 01/22/91 MA 03/07/94
ELLIOTT'S B SOLUTION TN=	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIAS AND ACUTE LYMPHOBLASTIC LYMPHOMAS.	ORPHAN MEDICAL 13911 RIDGEDALE DRIVE MINNETONKA MN 55305 DD 08/24/94 MA / /
FGN-1 TN=	FOR THE SUPPRESSION AND CONTROL OF COLONIC ADENOMATOUS POLYPS IN THE INHERITED DISEASE ADENOMATOUS POLYPOSIS COLI.	CELL PATHWAYS, INC. 1700 BROADWAY, SUITE 2000 DENVER CO 80290 DD 02/14/94 MA / /
GAMMALINOLENIC ACID TN=	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	ZURIER, ROBERT B. M.D. 55 LAKE AVE. UNIV. OF MASS. MED. CTR. WORCESTER MA 01655 DD 07/27/94 MA / /
HEME ARGINATE TN= NORMOSANG	TREATMENT OF MYELODYSPLASTIC SYNDROMES.	LEIRAS, INCORPORATED 1850 CENTENNIAL PARK DRIVE, SUITE 450 RESTON VA 22091 DD 03/01/94 MA / /
I-131 RADIOLABELED B1 MONOCLONAL ANTIBODY TN=	TREATMENT OF NON-HODGKIN'S B-CELL LYMPHOMA.	COULTER CORPORATION 11800 S.W. 147 AVENUE, P.O. BOX 169015 MIAMI FL 33116-9015 DD 05/16/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
IMIGLUCERASE TN= CEREZYME	FOR REPLACEMENT THERAPY IN PATIENTS WITH TYPES I, II, AND III GAUCHER'S DISEASE.	GENZYME CORPORATION ONE KENDALL SQUARE CAMBRIDGE MA 02139 DD 11/05/91 MA 05/23/94
ISOBUTYRAMIDE TN=	TREATMENT OF SICKLE CELL DISEASE AND BETA THALASSEMIA.	VERTEX PHARMACEUTICALS INC. 40 ALLSTON STREET CAMBRIDGE MA 02139-4211 DD 05/25/94 MA / /
L-2-OXOTHIAZOLIDINE-4-CARBOXYLIC ACID TN= PROCYSTEINE	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	FREE RADICAL SCIENCES, INC. 245 FIRST STREET CAMBRIDGE MA 02142 DD 06/14/94 MA / /
L-CYSTEINE TN=	FOR THE PREVENTION AND LESSENING OF PHOTOSENSITIVITY IN ERYTHROPOIETIC PROTOPORPHYRIA.	TYSON AND ASSOCIATES 12832 SOUTH CHADRON AVENUE HAWTHORNE CA 90250 DD 05/16/94 MA / /
LIPOSOME ENCAPSULATED RECOMBINANT INTERLEUKIN-2 TN=	TREATMENT OF CANCERS OF THE KIDNEY AND RENAL PELVIS.	ONCOTHERAPEUTICS, INC. 1002 EASTPARK BOULEVARD CRANBURY NJ 08512 DD 06/20/94 MA / /
MITOGUAZONE TN=	TREATMENT OF DIFFUSE NON-HODGKIN'S LYMPHOMA, INCLUDING AIDS-RELATED DIFFUSE NON-HODGKIN'S LYMPHOMA.	CTRC RESEARCH FOUNDATION 11812 BECKET STREET POTOMAC MD 20854 DD 03/18/94 MA / /
N-TRIFLUOROACETYLADRIAMYCIN-14- VALERATE TN=	TREATMENT OF CARCINOMA IN SITU OF THE URINARY BLADDER.	ANTHRA PHARMACEUTICALS, INC. 19 CARSON ROAD PRINCETON NJ 08540 DD 05/23/94 MA / /
OXANDROLONE TN= HEPANDRIN	TREATMENT OF MODERATE/SEVERE ACUTE ALCOHOLIC HEPATITIS IN THE PRESENCE OF MODERATE PROTEIN CALORIE MALNUTRITION.	BIO-TECHNOLOGY GENERAL CORP. 70 WOOD AVENUE SOUTH ISELIN NJ 08830 DD 03/18/94 MA / /
PEGASPARGASE TN= ONCASPAR	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL).	ENZON, INC. 40 KINGSBRIDGE ROAD PISCATAWAY NJ 08854-3998 DD 10/20/89 MA 02/01/94
PILOCARPINE TN= SALAGEN	TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER.	MGI PHARMA, INC. SUITE 300 E, 9900 BREN ROAD EAST MINNEAPOLIS MN 55343-9667 DD 09/24/90 MA 03/22/94
RECOMBINANT HUMAN GELSOLIN TN=	TREATMENT OF THE RESPIRATORY SYMPTOMS OF CYSTIC FIBROSIS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02124 DD 01/12/94 MA / /
RECOMBINANT VACCINIA (HUMAN PAPILLOMAVIRUS) TN= TA-HPV	TREATMENT OF CERVICAL CANCER.	CANTAB PHARMACEUTICALS RESEARCH, LTD. 184 CAMBRIDGE SCIENCE PARK CAMBRIDGE CB4 4GN UK DD 08/24/94 MA / /
REDUCED L-GLUTATHIONE TN= CACHEXON	TREATMENT OF AIDS-ASSOCIATED CACHEXIA.	TELLURIDE PHARMACEUTICAL CORPORATION 146 FLANDERS DRIVE HILLSBOROUGH NJ 08876-4656 DD 02/14/94 MA / /

CUMULATIVE LIST OF DESIGNATIONS & APPROVALS

NAME

Generic/Chemical

TN= Trade Name

INDICATION DESIGNATED

SPONSOR & ADDRESS

DD= Date Designated

MA= Marketing Approval

RIFAMPIN, ISONIAZID,
PYRAZINAMIDE
TN= RIFATER

SHORT-COURSE TREATMENT OF TUBERCULOSIS.

MARION MERRELL DOW, INC.
P.O. BOX 9627
KANSAS CITY MO 64134-0627
DD 09/12/85 MA 05/31/94

SOMATROPIN
TN= NUTROPIN
(EXCLUSIVITY NOT APPLICABLE)

FOR USE IN THE LONG-TERM TREATMENT OF CHILDREN WHO HAVE
GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS
GROWTH HORMONE SECRETION.

GENENTECH, INC.
460 POINT SAN BRUNO BOULEVARD
SOUTH SAN FRANCISCO CA 94080
DD 03/06/87 MA 03/09/94

SULFADIAZINE
TN=

FOR USE IN COMBINATION WITH PYRIMETHAMINE FOR THE
TREATMENT OF TOXOPLASMA GONDII ENCEPHALITIS IN PATIENTS
WITH AND WITHOUT ACQUIRED IMMUNODEFICIENCY SYNDROME.

EON LABS MANUFACTURING, INC.
227-15 NORTH CONDUIT AVENUE
LAURELTON NY 11413
DD 03/14/94 MA 07/29/94

TIZANIDINE HCL
TN= ZANAFLEX

TREATMENT OF SPASTICITY ASSOCIATED WITH MULTIPLE
SCLEROSIS AND SPINAL CORD INJURY.

ATHENA NEUROSCIENCES, INC.
800F GATEWAY BOULEVARD
SOUTH SAN FRANCISCO CA 94080
DD 01/31/94 MA / /

TREOSULFAN
TN= OVASTAT

TREATMENT OF OVARIAN CANCER.

MEDAC GmbH c/o PRINCETON REG.
ASSOC.
65 SOUTH MAIN STREET
PENNINGTON NJ 08534
DD 05/16/94 MA / /

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

NO AUGUST 1994 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
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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, 14TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ALBUTEROL (METERED DOSE INHALER - <i>IN VIVO</i>)	JAN 27, 1994	
FLURBIPROFEN (TABLET)	DEC 24, 1992	FEB 04, 1994
PHENYTOIN (SUSPENSION AND CHEWABLE TABLET)	MAR 04, 1994	
PHENYTOIN SODIUM (CAPSULE, EXTENDED AND PROMPT)	MAR 04, 1994	

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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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.

ACYCLOVIR TABLET; ORAL	200MG	93 P-0339/ CP1	NOVOPHARM	NEW DOSAGE FORM	APPROVED FEB 08, 1994
ACYCLOVIR SODIUM INJECTABLE; INJECTION	25MG/ML (20ML/VIAL) (40ML/VIAL)	93 P-0469/ CP1	FAULDING	NEW DOSAGE FORM	APPROVED JUN 09, 1994
ESTRADIOL TABLET; ORAL	1.5MG	93 P-0344/ CP1	BRISTOL MYERS SQIBB	NEW STRENGTH	APPROVED JUN 08, 1994
LOPERAMIDE HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	1MG	93 P-0332/ CP1	ELLIS PHARM CONSULTING	NEW DOSAGE FORM	APPROVED FEB 08, 1994
METHYLTESTOSTERONE CAPSULE; ORAL	25MG	93 P-0459/ CP1	ICN	NEW DOSAGE FORM	APPROVED JUN 08, 1994
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	15MG 60MG 100MG	93 P-0446/ CP1	PHARMA CONSULT	NEW DOSAGE FORM	APPROVED JUN 08, 1994
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	90MG	93 P-0446/ CP1	PHARMA CONSULT	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUN 08, 1994
PREDNISONE TABLET, CHEWABLE; ORAL	1MG 2.5MG 20MG 50MG	93 P-0333/ CP1	DURA	NEW DOSAGE FORM	APPROVED JUN 08, 1994
PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE CAPSULE, EXTENDED RELEASE; ORAL	120MG 60MG	93 P-0367/ CP1	EURAND AMERICA	NEW DOSAGE FORM	APPROVED FEB 08, 1994

ERRATA

CIMETIDINE TABLET, EFFERVESCENT; ORAL	200MG 300MG 400MG 800MG	93 P-0048/ CP1*	FLEMINGTON PHARM	NEW DOSAGE FORM	APPROVED SEP 18, 1993
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*Not previously published

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, 14TH 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-21 ALTERNATIVE DOSAGE OF 300MG ONCE DAILY AFTER THE EVENING MEAL
D-22 REDUCTION IN INFUSION TIME FROM 24 TO 4 HOURS FOR THE 60MG DOSE
D-23 INCREASE MAXIMUM DOSE AND VARIATIONS IN THE DOSING REGIMEN
D-24 FOR OVARIAN CANCER THE RECOMMENDED REGIMEN IS 135MG/M² OR 175MG/M² INTRAVENOUSLY OVER THREE HOURS EVERY THREE WEEKS

REFERENCES NEW INDICATION

I-99 PEDIATRIC ANESTHESIA IN CHILDREN 3 YEARS AND OLDER
I-100 TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY
I-101 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY
I-102 TREATMENT OF OBSESSIVE-COMPULSIVE DISORDER
I-103 PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOCOMPROMISED AND CONSIDERED TO BE AT RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA
I-104 TREATMENT OF PULMONARY AND EXTRAPULMONARY ASPERGILLOSIS IN PATIENTS WHO ARE INTOLERANT OF OR WHO ARE REFRACTORY TO AMPHOTERICIN B THERAPY
I-105 TREATMENT OF METASTATIC CARCINOMA OF THE BREAST AFTER FAILURE OF FIRST-LINE OR SUBSEQUENT CHEMOTHERAPY
I-106 TREATMENT OF ACROMEGALY
I-107 VAGINAL CANDIDIASIS
I-108 EXPANDED USE-FOR ICU PATIENTS UNDERGOING LONG-TERM INFUSION DURING MECHANICAL VENTILATION
I-109 TYPHOID FEVER

REFERENCES PATENT USE CODE

U-91 ALTERNATIVE THERAPY TO TRIMETHOPRIM-SULFAMETHOXAZOLE FOR TREATMENT OF MODERATE-TO-SEVERE PNEUMOCYSTIS CARINII PNEUMONIA IN IMMUNOCOMPROMISED AND AIDS PATIENTS
U-92 TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN DEPENDENT DIABETES MELLITUS AND RETINOPATHY
U-93 USE AS AN ANTIHISTAMINE/DECONGESTANT
U-94 TREATMENT OF ADULTS WITH ADVANCED HIV INFECTION WHO ARE INTOLERANT OF APPROVED THERAPIES WITH PROVEN CLINICAL BENEFIT OR WHO HAVE EXPERIENCED SIGNIFICANT CLINICAL OR IMMUNOLOGIC DETERIORATION WHILE RECEIVING THESE THERAPIES OR FOR WHOM SUCH THERAPIES ARE CONTRAINDICATED
U-95 SHORT TERM MANAGEMENT OF MODERATE PRURITIS IN ADULTS WITH ATOPIC DERMATITIS AND LICHEN SIMPLEX CHRONICUS

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
19872 001	ACETAMINOPHEN; TYLENOL	4650807	MAR 17, 2004	U-93	NDF	JUN 08, 1997
19806 001	ACRIVASTINE; SEMPRES-D	4501893	FEB 26, 2002		NC	MAR 25, 1997
74346 001	AMINOSALICYLIC ACID; PASER				ODE	JUN 30, 2001
18700 001	AMRINONE LACTATE; INOCOR				NCE	JUL 31, 1994
20304 001	APROTININ BOVINE; TRASYLOL	4072746	JUL 31, 1998	U-7	ODE	DEC 29, 2000
18831 001	ATRACURIUM BESYLATE; TRACRIUM	4179507	DEC 18, 1996		I-108	JUN 06, 1997
20233 001	BUDESONIDE; RHINOCORT				NCE	FEB 14, 1999
18731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
18731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
18343 001	CAPTAPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 002	CAPTAPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 003	CAPTAPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 005	CAPTAPRIL; CAPOTEN	5238924	AUG 24, 2010	U-92	I-101	JAN 28, 1997
18343 006	CAPTAPRIL; CAPOTEN	4105776	AUG 08, 1995		I-101	JAN 28, 1997
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	I-95	SEP 23, 1996
>ADD>					I-66	JUL 21, 1997
>ADD>					I-109	JUL 21, 1997
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	I-66	JUL 21, 1997
>ADD>					I-109	JUL 21, 1997
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	I-66	JUL 21, 1997
>ADD>					I-109	JUL 21, 1997
20392 001	CYSTEAMINE BITARTRATE; CYSTAGON				NCE	AUG 15, 1999
>ADD>					ODE	AUG 15, 2001
20392 002	CYSTEAMINE BITARTRATE; CYSTAGON				NCE	AUG 15, 1999
>ADD>					ODE	AUG 15, 2001
20355 001	DESMOPRESSIN ACETATE; DESMOPRESSIN ACETATE				NP	MAR 07, 1997
>ADD>					ODE	MAR 07, 2001
20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		NDF	APR 01, 1997
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		I-76	SEP 08, 1995
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		NCE	JAN 31, 1996
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5286497	FEB 14, 2011		NCE	JUN 29, 1999
20126 001	DOXEPIN HYDROCHLORIDE; ZONALON	4395420	JUL 26, 2000	U-95	I-69	DEC 10, 1994
81295 001	ESTRADIOL; ESTRACE					
18922 004	ETODOLAC; LODINE	4076831	FEB 28, 1997	U-45		
20363 002	FANCICLOVIR; FAMVIR					
20249 001	FAMOTIDINE; PEPICID	4283408	AUG 11, 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
19304 001	FENOFIBRATE; LIPIDIL	4058552	NOV 15, 1994		NCE	DEC 31, 1998
19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000		I-100	DEC 30, 1996
20322 001	FLUCONAZOLE; DIFLUCAN	4552884	NOV 12, 2002		I-100	DEC 30, 1996
		4302460	NOV 24, 1998		NCE	JAN 29, 1995
					NS	JUN 30, 1997
18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4018895	APR 19, 1994	U-12	I-107	JUN 30, 1997
18936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		I-102	FEB 28, 1997
20235 001	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007		I-102	FEB 28, 1997
20235 002	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20235 003	GABAPENTIN; NEURONTIN	4894476	JAN 16, 2007			
20329 001	GLIPIZIDE; GLUCOTROL XL					
20329 002	GLIPIZIDE; GLUCOTROL XL					
19778 003	HYDROCHLOROTHIAZIDE; PRINZIDE 10-12.5				NDF	APR 26, 1997
					NDF	APR 26, 1997
19888 001	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-12.5	4472380	SEP 18, 2001	U-3	NS	NOV 18, 1996
		4374829	DEC 30, 2001			
		4472380	SEP 18, 2001			
19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20-25	4374829	DEC 30, 2001	U-3		
19888 003	HYDROCHLOROTHIAZIDE; ZESTORETIC 10-12.5	4374829	DEC 30, 2001	U-3		
		4472380	SEP 18, 2001		NS	NOV 18, 1996
20367 001	IMIGLUCERASE; CERESZYME	4374829	DEC 30, 2001	U-3		
20314 001	INDIUM IN-111 PENTETREOTIDE KIT; OCTREOSCAN				NCE	MAY 23, 1999
20084 001	IOBENGUANE SULFATE I 131; IOBENGUANE SULFATE I 131	4584187	APR 22, 2003		ODE	MAY 23, 2001
50705 001	ISONIAZID; RIFATER				NCE	JUN 02, 1999
					NCE	MAR 25, 1999
					ODE	MAY 31, 2001

>ADD>

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
20336 001	ISRADIPINE; DYNACIRC CR	5030456	JUL 09, 2008			
		4950486	AUG 21, 2007		NDF	JUN 01, 1997
		4946687	AUG 07, 2007		NCE	DEC 20, 1995
		4816263	MAR 28, 2006	U-3		
		4783337	SEP 16, 2003	U-3		
		4466972	AUG 21, 2003	U-3		
		5030456	JUL 09, 2008			
20336 002	ISRADIPINE; DYNACIRC CR	4950486	AUG 21, 2007		NDF	JUN 01, 1997
		4946687	AUG 07, 2007		NCE	DEC 20, 1995
		4816263	MAR 28, 2006	U-3		
		4783337	SEP 16, 2003	U-3		
		4466972	AUG 21, 2003	U-3		
20083 001	ITRACONAZOLE; SPORANOX				I-104	MAR 29, 1997
19816 001	KETOPROFEN; ORUVAIL	4369184	JAN 18, 2000		NDF	SEP 24, 1996
20219 001	LEVOCABASTINE HYDROCHLORIDE; LIVOSTIN	4374829	DEC 30, 2001		NCE	NOV 10, 1998
19558 006	LISINAPRIL; PRINIVIL				I-92	JUN 09, 1996
20264 001	MEGESTROL ACETATE; MEGACE	4313951	FEB 02, 2001		NDF	SEP 10, 1997
20343 001	MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5%	4313951	FEB 02, 2001			
20343 002	MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5%	4313951	FEB 02, 2001			
20343 003	MILRINONE LACTATE; PRIMACOR IN DEXTROSE 5%	4313951	FEB 02, 2001			
20065 001	NAPHAZOLINE HYDROCHLORIDE; OPCON-A				NC	JUN 08, 1997
20226 001	NAPHAZOLINE HYDROCHLORIDE; NAPHCON-A				NC	JUN 08, 1997
19667 001	OCTEOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
19667 002	OCTEOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
19667 003	OCTEOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
19667 004	OCTEOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
19667 005	OCTEOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		I-106	MAY 03, 1997
20262 001	PACLITAXEL; TAXOL				I-105	APR 13, 1997
20036 001	PAMIDRONATE DISODIUM; ARELIA	4711880	DEC 08, 2004		D-24	JUN 22, 1997
20036 003	PAMIDRONATE DISODIUM; ARELIA	4711880	DEC 08, 2004		D-22	APR 15, 1997
20036 004	PAMIDRONATE DISODIUM; ARELIA	4711880	DEC 08, 2004		D-22	APR 15, 1997
20184 001	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
20184 002	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998
20184 003	PERINDOPRIL ERBUMINE; ACEON	4508729	APR 02, 2002		NCE	DEC 30, 1998

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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
20237 001	PILOCARPINE HYDROCHLORIDE; SALAGEN	4801461	MAY 05, 2004		ODE	MAR 22, 2001
20279 001	PREDNICARBATE; DERMATOP	4576604	MAR 18, 2003		NDF	MAR 22, 1997
19627 001	PROPOFOL; DIPRIVAN	4128658	DEC 05, 1995		NDF	OCT 29, 1996
20021 002	PSEUDOEPHEDRINE HYDROCHLORIDE; EFIDAC/24	4128658	DEC 05, 1995		I-99	OCT 26, 1996
18703 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		D-21	FEB 28, 1997
18703 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008		D-21	FEB 28, 1997
19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4521431	JUN 04, 2002		I-75	MAY 19, 1995
20095 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		D-21	FEB 28, 1997
20095 002	RANITIDINE HYDROCHLORIDE; ZANTAC 300	5028432	JUL 02, 2008		I-75	MAY 19, 1995
20251 001	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4521431	JUN 04, 2002		D-21	FEB 28, 1997
20251 002	RANITIDINE HYDROCHLORIDE; ZANTAC 150	4128658	DEC 05, 1995		I-75	MAY 19, 1995
20214 001	ROCURONIUM BROMIDE; ZEMURON (P/F)	5102665	APR 07, 2009		D-21	FEB 28, 1997
20214 002	ROCURONIUM BROMIDE; ZEMURON	4521431	JUN 04, 2002		I-75	MAY 19, 1995
19766 001	SALMETEROL XINAFOATE; SEREVENT	4128658	DEC 05, 1995		D-21	FEB 28, 1997
19766 002	SIMVASTATIN; ZOCOR	4894369	JAN 16, 2007		NCE	MAR 17, 1999
19766 003	SIMVASTATIN; ZOCOR	4894369	JAN 16, 2007		NCE	MAR 17, 1999
19766 004	SIMVASTATIN; ZOCOR	4992474	FEB 12, 2008		NCE	FEB 04, 1999
19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
19865 005	SOTALOL HYDROCHLORIDE; BETAPACE	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1996
20412 001	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	D-23	APR 15, 1997
20412 002	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	D-23	APR 15, 1997
20412 003	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	OCT 30, 1997
20412 004	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	ODE	OCT 30, 1999
20412 005	STAVUDINE; ZERIT	4978655	DEC 18, 2007	U-94	NCE	JUN 24, 1999

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>						
40091 001	SULFADIAZINE; SULFADIAZINE	4209513	JUN 24, 1997		00E	JUL 29, 2001
17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-103	JAN 07, 1997
17376 002	SULFAMETHOXAZOLE; SEPTRA DS				I-103	JAN 07, 1997
17377 001	SULFAMETHOXAZOLE; BACTRIM				I-103	JAN 07, 1997
17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-103	JAN 07, 1997
17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-103	JAN 07, 1997
17598 001	SULFAMETHOXAZOLE; SEPTRA				I-103	JAN 07, 1997
17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-103	JAN 07, 1997
17970 002	TAMOXIFEN CITRATE; NOLVADEX					
19762 001	TESTOSTERONE; TESTODERM	4536516	AUG 20, 2002			
		4867982	FEB 16, 2005			
		4725439	FEB 16, 2005			
		4704282	NOV 03, 2004		NDF	OCT 12, 1996
		4867982	FEB 16, 2005			
19762 002	TESTOSTERONE; TESTODERM	4725439	FEB 16, 2005			
		4704282	NOV 03, 2004		NDF	OCT 12, 1996
20330 001	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
		4195085	MAR 25, 1997		NP	NOV 04, 1996
20330 002	TIMOLOL MALEATE; TIMOPTIC-XE	4861760	AUG 29, 2006			
		4195085	MAR 25, 1997		NP	NOV 04, 1996
20326 001	TRIMETREXATE GLUCURONATE; NEUTREXIN	4694007	SEP 15, 2004	U-91	ODE	DEC 17, 2000

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