

CUMULATIVE
SUPPLEMENT 9
SEP'99

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

CENTER FOR DRUG EVALUATION AND RESEARCH

OFFICE OF INFORMATION TECHNOLOGY

DIVISION OF DATA MANAGEMENT AND SERVICES

1999

RM
301.45
.A66
1999
Oct
Suppl

Prepared By
Division of Data Management and Services
Office of Information Technology
Center for Drug Evaluation and Research
Food and Drug Administration

S.O.

RM301.45 .A66 1999 Oct Suppl

SU Approved drug products with
therapeutic equivalence **NOW!**
C:355661 M:174736 O:12937927
Available in March 2000

New 20th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**20TH EDITION
2000**

Library Use Only

CONTENTS

- Prescription Drug Product List
- OTC Drug Product List
- Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List
- Discontinued Drug Product List
- Orphan Drug Product Designations
- Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution
- Patent and Exclusivity Information

See Subscription Form Inside Back Cover

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

Cumulative Supplement 9

SEPTEMBER 1999

CONTENTS

	<i>PAGE</i>
1.0 INTRODUCTION	iii
1.1 How to Use the Cumulative Supplement	iii
1.2 Applicant Name Changes	iv
1.3 Diclofenac Sodium Ophthalmic Solution.....	v
1.4 Availability of the Edition	vi
1.5 Report of Counts for the Prescription Drug Product List.....	vii
2.0 DRUG PRODUCT LISTS.....	
2.1 Prescription Drug Product List.....	i
2.2 OTC Drug Product List	54
2.3 Drug Products with Approval under Section 505 of the Act	
Administered by the Center for Biologics Evaluation and Research List.....	57
2.4 Orphan Product Designations and Approvals List	58
2.5 Drug Products Which Must Demonstrate in vivo Bioavailability	
Only if Product Fails to Achieve Adequate Dissolution	72
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Patent and Exclusivity Terms	73
B. Patent and Exclusivity Lists.....	76

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

19TH EDITION

**CUMULATIVE SUPPLEMENT 9
SEPTEMBER 1999**

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, 19th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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

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

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

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

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 19th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 20th Edition.

1.2 APPLICANT NAME CHANGES

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

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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

ASTRA PHARMACEUTICALS LP
(ASTRA PHARMS)

ASTRA ZENECA LP
(ASTRA ZENECA)

PENEDERM INC
(PENEDERM)

BERTEK PHARMACEUTICALS
(BERTEK PHARMS)

SANOFI PHARMACEUTICALS INC
(SANOFI)

SANOFI SYNTHELABO INC
(SANOFI SYNTHELABO)

1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

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

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

1.4 AVAILABILITY OF THE EDITION

The 19th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

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

The telephone number to charge your subscription is 202-512-1800. The cost is \$90.00 annually.

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

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

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

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

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

The 19th annual edition of the 1998 Orange Book Patent and Exclusivity List is at
<http://www.fda.gov/cder/orange/19bookpub.pdf>.

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

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

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1998) 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 1998</u>	<u>MAR 1999</u>	<u>JUN 1999</u>	<u>SEP 1999</u>
DRUG PRODUCTS LISTED	9923	9975	10009	9939
SINGLE SOURCE	2504 (25.2%)	2520 (25.3%)	2523 (25.2%)	2257 (25.7%)
MULTISOURCE	7308 (73.6%)	7344 (73.6%)	7375 (73.7%)	7271 (73.2%)
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)	6969 (69.9%)	7012 (70.1%)	6923 (69.7%)
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)	375 (3.8%)	363 (3.6%)	348 (3.5%)
EXCEPTIONS	111 (1.1%)	111 (1.1%)	111 (1.1%)	111 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	10	3	5	13
NUMBER OF APPLICANTS	563	570	568	572

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

ACYCLOVIR

CAPSULE; ORAL
ACYCLOVIR
STASON

200MG

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

N75090 001
JAN 26, 1999

TABLET; ORAL
ACYCLOVIR
CARLSBAD

400MG

N75382 001
APR 30, 1999
N75382 002
APR 30, 1999

800MG

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR
ABBOTT

EQ 50MG BASE/ML

N75114 001
JUL 26, 1999

ACYCLOVIR SODIUM
+ AM PHARM PARTNERS

EQ 50MG BASE/ML

N74930 001
MAY 13, 1998
N74930 001
MAY 13, 1998
N75065 001
FEB 25, 1999

ACYCLOVIR SODIUM
MERIDIAN MEDCL TECHN

EQ 50MG BASE/ML

ALBUTEROL

AEROSOL, METERED; INHALATION
ALBUTEROL
MEDEVA

0.09MG/INH

N72273 001
AUG 14, 1996
N72273 001
AUG 14, 1996

MEDEVA PHARMS MA

0.09MG/INH

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE
HI TECH PHARMA

EQ 0.083% BASE

N75063 001
FEB 09, 1999

SYRUP; ORAL
ALBUTEROL SULFATE
UDL

EQ 2MG BASE/5ML

N75262 001
MAR 30, 1999

ALBUTEROL SULFATE

SYRUP; ORAL
ALBUTEROL
GLAXO WELLCOME

EQ 2MG BASE/5ML

N19621 001
JUN 10, 1987
N19621 001
JUN 10, 1987

ALCOHOL; DEXTROSE

INJECTABLE; INJECTION
ALCOHOL 5% IN DEXTROSE
BAXTER HEALTHCARE

5% IN WATER
5ML/100ML; 5GM/100ML
5ML/100ML; 5GM/100ML

N83256 001
N83256 001

ALITRETINOLIN

GEL; TOPICAL
PANRETIN
+ LIGAND

EQ 0.1% BASE

N20886 001
FEB 02, 1999

ALLOPURINOL

TABLET; ORAL
ZYLOPRIM
FARO PHARMS

100MG
300MG
100MG
300MG

N16084 001
N16084 002
N16084 001
N16084 002

ALLOPURINOL SODIUM

INJECTABLE; INJECTION
ALOPRIM
+ CATALYTICA PHARMS

EQ 500MG BASE/VIAL

N20298 001
MAY 17, 1996

ZYLOPRIM

+ CATALYTICA PHARMS

EQ 500MG BASE/VIAL

N20298 001
MAY 17, 1996

ALPHA-TOCOPHEROL; ASCORBIC ACID; BIOTIN, D-; CHOLECALCIFEROL;
CYANOCOBALAMIN; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID;
PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A

INJECTABLE; INJECTION
CERNEVIT-12
+ BAXTER HLTHCARE

11.2 IU/VIAL; 125MG/VIAL; 60 UGM/VIAL;
200 IU/VIAL; 5.5MG/VIAL; 414 UGM/VIAL;
46MG/VIAL; 17.25MG/VIAL; 4.53MG/VIAL;
4.14MG/VIAL; 3.51MG/VIAL;
3,500 IU/VIAL
N20924 001
APR 06, 1999

N18116 002
N18116 001
N18116 002

ALPRAZOLAM

CONCENTRATE; ORAL
ALPRAZOLAM
ROXANE

1MG/ML
1MG/ML

N74312 001
OCT 31, 1993
N74312 001
OCT 31, 1993

N18498 001
N18498 001

SOLUTION; ORAL
ALPRAZOLAM
ROXANE

0.5MG/5ML
0.5MG/5ML

N74314 001
OCT 31, 1993
N74314 001
OCT 31, 1993

N20221 002
SEP 10, 1999

TABLET; ORAL
ALPRAZOLAM
ALPHAPHARM

2MG

N74046 004
MAY 07, 1997

ALPROSTADIL

INJECTABLE; INJECTION
ALPROSTADIL
GENSIA SICOR PHARMS

0.5MG/ML

N75196 001
APR 30, 1999

INJECTABLE; INJECTION
AMINESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE
FRESENIUS KABI

5.2%

N18901 001
APR 06, 1984
N18901 001
APR 06, 1984

PHARMACIA AND UPJOHN

5.2%

NEOPHAM 6.4%
@ FRESENIUS KABI

6.4%

N18792 001
JAN 17, 1984
N18792 001
JAN 17, 1984

PHARMACIA AND UPJOHN

6.4%

NOVAMINE 11.4%
FRESENIUS KABI

11.4%

N17957 003
AUG 09, 1982
N17957 003
AUG 09, 1982

PHARMACIA AND UPJOHN

11.4%

NOVAMINE 15%
FRESENIUS KABI

15%

N17957 004
NOV 28, 1986

AMCINONIDE

CREAM; TOPICAL
CYCLOCORT
@ FUJISAWA HLTHCARE

0.025%

AMCINONIDE

CREAM; TOPICAL
CYCLOCORT

+ FUJISAWA HLTHCARE

0.1%

0.025%

0.1%

N18116 002
N18116 001
N18116 002

LOTION; TOPICAL
CYCLOCORT

+ FUJISAWA HLTHCARE

0.1%

0.1%

N19729 001
JUN 13, 1988
N19729 001
JUN 13, 1988

OINTMENT; TOPICAL
CYCLOCORT

+ FUJISAWA HLTHCARE

0.1%

0.1%

N18498 001
N18498 001

AMIFOSTINE

INJECTABLE; INJECTION
ETHYOL

US BIOSCIENCE

375MG/VIAL

N20221 002
SEP 10, 1999

AMINO ACIDS

INJECTABLE; INJECTION
AMINESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE
FRESENIUS KABI

5.2%

N18901 001
APR 06, 1984
N18901 001
APR 06, 1984

PHARMACIA AND UPJOHN

5.2%

NEOPHAM 6.4%
@ FRESENIUS KABI

6.4%

N18792 001
JAN 17, 1984
N18792 001
JAN 17, 1984

PHARMACIA AND UPJOHN

6.4%

NOVAMINE 11.4%
FRESENIUS KABI

11.4%

N17957 003
AUG 09, 1982
N17957 003
AUG 09, 1982

PHARMACIA AND UPJOHN

11.4%

NOVAMINE 15%
FRESENIUS KABI

15%

N17957 004
NOV 28, 1986

AMINO ACIDS

INJECTABLE; INJECTION

NOVAMINE 15%
PHARMACIA AND UPJOHN 15%

N17957 004
NOV 28, 1986

NOVAMINE 8.5%
@ FRESenius KABI 8.5%

N17957 002
AUG 09, 1982
N17957 002
AUG 09, 1982

PHARMACIA AND UPJOHN 8.5%

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

INJECTABLE; INJECTION

VEINAMINE 8%

@ FRESenius KABI

8%; 61MG/100ML; 211MG/100ML; N17957 001
56MG/100ML; 388MG/100ML
8%; 61MG/100ML; 211MG/100ML;
56MG/100ML; 388MG/100ML N17957 001

PHARMACIA AND UPJOHN

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE
SMITH AND NEPHEW

N88749 001
MAY 30, 1985
N88749 001
MAY 30, 1985

25MG/ML

25MG/ML

AMIODARONE HYDROCHLORIDE

TABLET; ORAL

AMIODARONE HCL
ALPHAPHARM

N75188 001
FEB 24, 1999
N74895 001
APR 16, 1999

200MG

200MG

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

AMITRIPTYLINE HCL
STERIS

N85594 001

10MG/ML

AMITRIPTYLINE HYDROCHLORIDE

INJECTABLE; INJECTION

AMITRIPTYLINE HCL

@ STERIS

ELAVIL

* ZENECA

+

10MG/ML

10MG/ML

10MG/ML

TABLET; ORAL

AMITRIPTYLINE HCL

COPLEY PHARM

10MG

25MG

50MG

75MG

100MG

150MG

10MG

25MG

50MG

75MG

100MG

150MG

ENDEP

ROCHE

10MG

25MG

50MG

75MG

100MG

10MG

25MG

50MG

75MG

100MG

N85594 001

N12704 001

N12704 001

N88421 001

APR 30, 1984

N88422 001

APR 30, 1984

N88423 001

APR 30, 1984

N88424 001

APR 30, 1984

N88425 001

APR 30, 1984

N88426 001

APR 30, 1984

N88421 001

APR 30, 1984

N88422 001

APR 30, 1984

N88423 001

APR 30, 1984

N88424 001

APR 30, 1984

N88425 001

APR 30, 1984

N88426 001

APR 30, 1984

N83639 001

N83639 002

N83639 003

N83639 004

N83639 005

N83639 001

N83639 002

N83639 003

N83639 004

N83639 005

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

RANBAXY

250MG

N65016 001

APR 08, 1999

500MG

N65016 002

APR 08, 1999

POWDER FOR RECONSTITUTION; ORAL

AMOXIL

SMITHKLINE BEECHAM

200MG/5ML

N50760 001

APR 15, 1999

400MG/5ML

N50760 002

APR 15, 1999

TABLET, CHEWABLE; ORAL

AMOXIL

SMITHKLINE BEECHAM

200MG

N50761 001

APR 15, 1999

400MG

N50761 002

APR 15, 1999

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

AMPHOTEC

+ ALZA

50MG/VIAL

N50729 001

NOV 22, 1996

100MG/VIAL

N50729 002

NOV 22, 1996

50MG/VIAL

N50729 001

NOV 22, 1996

100MG/VIAL

N50729 002

NOV 22, 1996

AMPRENAVIR

CAPSULE; ORAL

AGENERASE

GLAXO WELLCOME

50MG

N21007 001

APR 15, 1999

150MG

N21007 002

APR 15, 1999

SOLUTION; ORAL

AGENERASE

+ GLAXO WELLCOME

15MG/ML

N21039 001

APR 15, 1999

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

INJECTABLE; INJECTION

KABIVITE PED F + W KIT

+ FRESENIUS KABI

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

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

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

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

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

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

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

DEC 29, 1993

* PHARMACIA AND UPJOHN

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

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

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

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

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

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

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

DEC 29, 1993

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE

AB ENDO PHARMS

325MG; 50MG; 40MG; 30MG

N75351 001

MAR 05, 1999

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE CITRATE, ASPIRIN, AND CAFFEINE

AB STEVENS J

385MG; 30MG; 25MG

N74988 001

APR 30, 1999

770MG; 60MG; 50MG

N74988 002

APR 30, 1999

ASTEMIZOLE

TABLET; ORAL

HISMAL

* JANSSEN

10MG

N19402 001

DEC 29, 1988

BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE

AB ALTANA EQ 0.05% BASE

N75373 001
JUN 22, 1999

2%

N19215 001
NOV 25, 1985

BETAMETHASONE VALERATE

AEROSOL; TOPICAL
LUXIQ
+ CONNETICS

EQ 0.12% BASE

N20934 001
FEB 28, 1999

CAFFEINE CITRATE

> ADD >

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

WELLBUTRIN

* GLAXO WELLCOME

N20358 001
OCT 04, 1996

50MG

OCT 04, 1996

100MG

N20358 002
OCT 04, 1996

150MG

N20358 003
OCT 04, 1996

WELLBUTRIN SR

+ GLAXO WELLCOME

N20358 001
OCT 04, 1996

50MG

OCT 04, 1996

100MG

N20358 002
OCT 04, 1996

150MG

N20358 003
OCT 04, 1996

BUSULFAN

INJECTABLE; INJECTION

BUSULFEX

6MG/ML

N20954 001
FEB 04, 1999

2%

BUTOCONAZOLE NITRATE

CREAM; VAGINAL

FEMSTAT

* SYNTEX

N19215 001
NOV 25, 1985

2%

BUTOCONAZOLE NITRATE

CREAM; VAGINAL

FEMSTAT

@ SYNTEX

2%

N19215 001
NOV 25, 1985

FEMSTAT ONE

+ KV PHARM

2%

N19881 001
FEB 07, 1997

* SYNTEX

2%

N19881 001
FEB 07, 1997

SOLUTION; INTRAVENOUS, ORAL

CAFCIT

+ OPR DEVELOP LP

EQ 10MG BASE/ML

N20793 001
SEP 21, 1999

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM
CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM
CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

ENDOSOL EXTRA

AKORN

AT

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;

0.2MG/ML; 0.38MG/ML; 2.1MG/ML;

7.14MG/ML; 0.42MG/ML

N20079 001
NOV 27, 1991

ALLERGAN

AT

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;

0.2MG/ML; 0.38MG/ML; 2.1MG/ML;

7.14MG/ML; 0.42MG/ML

N20079 001
NOV 27, 1991

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM
CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

ISOLYTE R W/ DEXTROSE 5% IN PLASTIC CONTAINER

B BRAUN

37MG/100ML; 5GM/100ML; 31MG/100ML;

120MG/100ML; 330MG/100ML;

88MG/100ML

N18271 001

37MG/100ML; 5GM/100ML; 31MG/100ML;

120MG/100ML; 330MG/100ML;

88MG/100ML

N18271 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION
ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER
B. BRAUN

35MG/100ML; 5GM/100ML; 30MG/100ML;
74MG/100ML; 640MG/100ML; 500MG/100ML;
74MG/100ML
35MG/100ML; 5GM/100ML; 30MG/100ML;
74MG/100ML; 640MG/100ML; 500MG/100ML;
74MG/100ML
JAN 17, 1983
N18269 002
JAN 17, 1983
N18269 002
JAN 17, 1983

CARBENICILLIN DISODIUM

INJECTABLE; INJECTION

* GEOPEN
* ROBERIG

EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 5GM BASE/VIAL
EQ 10GM BASE/VIAL
EQ 30GM BASE/VIAL
EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 5GM BASE/VIAL
EQ 10GM BASE/VIAL
EQ 30GM BASE/VIAL

N50306 001
N50306 004
N50306 002
N50306 006
N50306 007
N50306 001
N50306 004
N50306 002
N50306 006
N50306 007

CAPECITABINE

TABLET; ORAL
XELODA

HLR
ROCHE

N20896 001
APR 30, 1998
N20896 001
APR 30, 1998

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

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA
MYLAN

50MG; 200MG

N75091 001
SEP 30, 1999

AB + SINEMET CR
+ DUPONT PHARMS

50MG; 200MG
50MG; 200MG

N19856 001
MAY 30, 1991
N19856 001
MAY 30, 1991

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

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

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50MG; 200MG

N19856 001
MAY 30, 1991

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50MG; 200MG

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MAY 30, 1991

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50MG; 200MG

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MAY 30, 1991

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AB +

50MG; 200MG

N19856 001
MAY 30, 1991

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AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

> DLT >

AB +

50MG; 200MG

N19856 001
MAY 30, 1991

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '99 - SEP '99

Ceftazidime (Arginine Formulation)

INJECTABLE; INJECTION

PENTACEF
SMITHKLINE BEECHAM

10GM/VIAL

6GM/VIAL

1GM/VIAL

1GM/VIAL

2GM/VIAL

2GM/VIAL

6GM/VIAL

10GM/VIAL

N64008 002

MAR 31, 1992

N64008 001

MAR 31, 1992

N63322 001

NOV 07, 1995

N64006 001

MAR 31, 1992

N63322 002

NOV 07, 1995

N64006 002

MAR 31, 1992

N64008 001

MAR 31, 1992

N64008 002

MAR 31, 1992

TABLET; ORAL

BAYCOL

* BAYER

0.3MG

0.3MG

0.4MG

N20740 004
JUN 26, 1997N20740 004
JUN 26, 1997N20740 005
MAY 24, 1999N20740 005
MAY 24, 1999Chlordiazepoxide Hydrochloride

CAPSULE; ORAL

A-POXIDE

* ABBOTT

* ABBOTT

* ABBOTT

* ABBOTT

* ABBOTT

* ABBOTT

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> DLT >
> ADD >Cephalexin

CAPSULE; ORAL

CEPHALEXIN

RANBAXY

EQ 250MG BASE

EQ 500MG BASE

N65007 001

SEP 16, 1999

N65007 002

SEP 16, 1999

> DLT >
> ADD >> DLT >
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> ADD >Cephalothin Sodium

INJECTABLE; INJECTION

CEPHALOTHIN SODIUM

ABBOTT

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

EQ 1GM BASE/VIAL

EQ 2GM BASE/VIAL

N62547 001

SEP 11, 1985

N62547 002

SEP 11, 1985

N62547 001

SEP 11, 1985

N62547 002

SEP 11, 1985

> DLT >
> ADD >> DLT >
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> ADD >Chlorotrianisene

CAPSULE; ORAL

CHLOROTRIANISENE

BANNER PHARMACEUTICALS

TACE

* HORCHST MARION RSSIL

* HORCHST MARION RSSIL

* HORCHST MARION RSSIL

* HORCHST MARION RSSIL

* HORCHST MARION RSSIL

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> ADD >> DLT >
> ADD >Chlorpromazine Hydrochloride

CONCENTRATE; ORAL

CHLORPROMAZINE HCL

PHARM ASSOC

100MG/ML

> DLT >
> ADD >> DLT >
> ADD >> DLT >
> ADD >> DLT >
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> ADD >> DLT >
> ADD >N40224 001
JAN 26, 1999N84652 001
N84652 001N88102 004
N88102 004N87228 001
N87228 001
N83082 002
SEP 17, 1999N85517 001
N85517 001
N86217 001
N86217 001

CROMOLYN SODIUM

SOLUTION; INHALATION

CROMOLYN SODIUM

ALPHARMA

10MG/ML

N75067 001

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AN

ALPHARMA

10MG/ML

N75175 001

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

SOLUTION/DROPS; OPHTHALMIC

CROMOLYN SODIUM

ALCON

4%

N75282 001

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AN

ALCON

4%

N75088 001

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CROTAMITON

LOTION; TOPICAL

CROTAN

GAUDERMA

SUMMERS

10%

N87204 001

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYANOCOBALAMIN

INJECTABLE; INJECTION

RUVIDE

SAVAGE LABS

1MG/ML

N80570 002

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYCLOPHOSPHAMIDE

TABLET; ORAL

CYCLOPHOSPHAMIDE

ROXANE

25MG

N40032 001

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYTOSOL

BRISTOL MYERS SQUIBB

25MG

N12141 002

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYTOSOL

BRISTOL MYERS SQUIBB

25MG

N12141 002

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYTOSOL

BRISTOL MYERS SQUIBB

25MG

N12141 002

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYTOSOL

BRISTOL MYERS SQUIBB

25MG

N12141 002

> DLT >

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

> ADD >
> ADD >

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

MD PHARM

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

NOV 10, 1982

AA

CYPROHEPTADINE HCL

4MG

N87566 001

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

MAXITROL

AT + FALCON PHARMS

0.1%; EQ 3.5MG BASE/ML;
10,000 UNITS/ML

N50023 002

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DECADRON

AP * MERCK

EQ 24MG PHOSPHATE/ML
EQ 24MG PHOSPHATE/ML

N12071 004
N12071 004

+ DEXAMETHASONE SODIUM PHOSPHATE

AP STERIS

EQ 4MG PHOSPHATE/ML
EQ 24MG PHOSPHATE/ML

N83702 001
N85606 001

AP

EQ 4MG PHOSPHATE/ML
EQ 24MG PHOSPHATE/ML

N83702 001
N85606 001

DEXTRAMPHETAMINE SULFATE

TABLET; ORAL

DEXTRAMPHETAMINE SULFATE

AA ENDO PHARMS 5MG

N40299 001
MAY 13, 1999

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 25%

ABBOTT

250MG/ML

N19445 002
NOV 23, 1998

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC

CONTAINER

B BRAUN

2.5GM/100ML; 450MG/100ML
2.5GM/100ML; 450MG/100ML

N18030 001
N18030 001

DEXTROSE 5% AND SODIUM
CHLORIDE 0.11% IN PLASTIC

B BRAUN

5GM/100ML; 110MG/100ML
5GM/100ML; 110MG/100ML

N18030 005
N18030 005

DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC

B BRAUN

5GM/100ML; 200MG/100ML
5GM/100ML; 200MG/100ML

N18030 004
N18030 004

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC

CONTAINER
B BRAUN
5GM/100ML; 200MG/100ML
5GM/100ML; 330MG/100ML

N18030 004
N18030 003

DEXTROSE 5% AND SODIUM
CHLORIDE 0.45% IN PLASTIC

CONTAINER
B BRAUN
5GM/100ML; 450MG/100ML
5GM/100ML; 450MG/100ML

N18030 002
N18030 002

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

MD-76

MALLINCKRODT

66%; 10%
66%; 10%

N87073 001
N87073 001

DIAZEPAM

GEL; RECTAL

DIASAT

* ATHENA

2.5MG/0.5ML

N20648 001
JUL 29, 1997

5MG/ML

N20648 002
JUL 29, 1997

10MG/2ML

N20648 003
JUL 29, 1997

15MG/3ML

N20648 004
JUL 29, 1997

20MG/4ML

N20648 005
JUL 29, 1997

2.5MG/0.5ML

N20648 001
JUL 29, 1997

5MG/ML

N20648 002
JUL 29, 1997

10MG/2ML

N20648 003
JUL 29, 1997

15MG/3ML

N20648 004
JUL 29, 1997

20MG/4ML

N20648 005
JUL 29, 1997

INJECTABLE; INJECTION

DIAZEPAM

STERIS

5MG/ML

N70911 001
AUG 28, 1986

> ADD >
> ADD >
> ADD >

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

AB3 + CARDERM 180MG
 AB3 + 240MG
 AB3 + 300MG
 BC + 120MG
 BC + 180MG
 BC + 240MG
 BC + 300MG

CARTIA XT
 ANDRX PHARMS

AB3 120MG
 AB3 180MG
 AB3 240MG
 AB3 300MG

@

@

@

@

DILTIAZEM HCL
 BIOVAIL

> ADD > AB1 60MG
 > ADD > AB1 90MG
 > ADD > AB1 120MG

INJECTABLE; INJECTION

DILTIAZEM HCL
 APOTEX

> ADD > AP 5MG/ML
 > ADD > AP 5MG/ML

MERIDIAN MEDCL TECHN

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL
 PUREPAC PHARM

> DLT > AA 25MG
 > DLT > AA 50MG
 > ADD > @ 25MG
 > ADD > @ 50MG

N20062 002
 DEC 27, 1991
 N20062 003
 DEC 27, 1991
 N20062 004
 DEC 27, 1991
 N20062 001
 AUG 10, 1992
 N20062 002
 DEC 27, 1991
 N20062 003
 DEC 27, 1991
 N20062 004
 DEC 27, 1991

ELIXIR; ORAL

HYDRAMINE
 ALPHARMA

AA 12.5MG/5ML
 @ 12.5MG/5ML

DIPIVEFRIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

DIPIVEFRIN HCL
 ALCON

AT 0.1%
 AT 0.1%

N74752 002
 JUL 09, 1998
 N74752 001
 JUL 09, 1998
 N74752 003
 JUL 09, 1998
 N74752 004
 JUL 09, 1998
 N74752 002
 JUL 09, 1998
 N74752 001
 JUL 09, 1998
 N74752 003
 JUL 09, 1998
 N74752 004
 JUL 09, 1998

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE
 PUREPAC PHARM

AB 25MG
 AB 50MG
 @ 25MG
 @ 50MG
 > DLT > AB 25MG
 > DLT > AB 50MG
 > ADD > @ 25MG
 > ADD > @ 50MG

N74845 001
 SEP 15, 1999
 N74845 002
 SEP 15, 1999
 N74845 003
 SEP 15, 1999

DIRITHROMYCIN

TABLET, DELAYED RELEASE; ORAL
 DYNABAC

@ 250MG
 + LILLY RES LABS 250MG

N75375 001
 SEP 30, 1999
 N75106 001
 APR 29, 1999

N85156 001
 N85156 001
 N85156 001
 N85156 001

N80763 002
 N80763 002

N73636 001
 JUN 30, 1994
 N73636 001
 JUN 30, 1994

N89425 001
 JUL 12, 1990
 N89426 001
 JUL 12, 1990
 N89425 001
 JUL 12, 1990
 N89426 001
 JUL 12, 1990

N50678 001
 JUN 19, 1995
 N50678 001
 JUN 19, 1995

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL
SMITH AND NEPHEW

AP 40MG/ML
AP 80MG/ML
40MG/ML
80MG/ML

N70046 001
AUG 29, 1985
N70047 001
AUG 29, 1985
N70046 001
AUG 29, 1985
N70047 001
AUG 29, 1985

TABLET, EXTENDED RELEASE; ORAL
BENDECTIN
@ HOECHST MARION RSSL 10MG;10MG

N10598 002

PROPERIDOL

INJECTABLE; INJECTION

PROPERIDOL
SOLOPAK

AP 2.5MG/ML
AP 2.5MG/ML
2.5MG/ML
2.5MG/ML

N71754 001
SEP 06, 1988
N71755 001
SEP 06, 1988
N71754 001
SEP 06, 1988
N71755 001
SEP 06, 1988

2.5 UGM

N20862 001
JUN 09, 1999

AP STERIS

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION
DOXIL
+ ALZA
* SEQUUS

N50718 001
NOV 17, 1995
N50718 001
NOV 17, 1995

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
@ PUREPAC PHARM

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

N62479 001
DEC 23, 1983
N62479 002
DEC 23, 1983
N62479 001
DEC 23, 1983
N62479 002
DEC 23, 1983

TABLET, EXTENDED RELEASE; ORAL
LEXCEL
+ ASTRAZENECA 5MG;2.5MG

N20668 002
OCT 28, 1998

EPINEPHRINE

INJECTABLE; INJECTION

SUS-PHRINE
FOREST LABS

SUS-PHRINE SULFITE-FREE
FOREST LABS 1.5MG/AMP

N07942 001
N07942 003
FEB 05, 1999

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

VIVELLE-DOTAB NOVARTIS 0.1MG/24HRN20538 004
JUL 31, 1996

TABLET; ORAL

ESTRADIOLAB MYLAN

0.5MG

N40326 001

APR 21, 1999

1MG

N40326 002

APR 21, 1999

2MG

N40326 003

APR 21, 1999

TABLET; VAGINAL

VAGIFEM

+ NOVO NORDISK

25 UGM

N20908 001

MAR 26, 1999

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTINDURAMED

0.9MG

N20992 003

MAR 24, 1999

0.625MG

N20992 002

MAR 24, 1999

0.9MG

N20992 003

MAR 24, 1999

ESTRONE

INJECTABLE; INJECTION

NATURAL ESTROGENIC SUBSTANCE-ESTRONE

+ STERIS

2MG/ML

N85237 001

NOV 23, 1982

2MG/ML

N85237 001

NOV 23, 1982

ESTROPIPATE

CREAM; VAGINAL

OGEN

+ ABBOTT

1.5MG/GM

N84710 001

ESTROPIPATE

CREAM; VAGINAL

OGEN

+ PHARMACIA AND UPJOHN 1.5MG/GM

N84710 001

TABLET; ORAL

ESTROPIPATEAB MYLAN

0.75MG

N40359 001

AUG 26, 1999

1.5MG

N40359 002

AUG 26, 1999

3MG

N40359 003

AUG 26, 1999

0.75MG

N83220 001

N83220 001

1.5MG

N83220 002

N83220 002

3MG

N83220 003

N83220 003

6MG

N83220 004

N83220 004

ETHCHLORVYNOL

CAPSULE; ORAL

ETHCHLORVYNOL

BANNER PHARMACEUTICALS

200MG

N84463 002

500MG

N84463 003

750MG

N84463 004

100MG

N84463 001

100MG

N84463 001

200MG

N84463 002

500MG

N84463 003

750MG

N84463 004

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

LEVILITE

BERLEX LABS

0.02MG;0.1MG

N20860 001

JUL 13, 1998

ETRETINATE

CAPSULE; ORAL

TEGISON
ROCHE

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

10MG

25MG

10MG

25MG

N19369 001
SEP 30, 1986
N19369 002
SEP 30, 1986
N19369 001
SEP 30, 1986
N19369 002
SEP 30, 1986

CAPSULE; ORAL

PROZAC
* LILLY

EQ 20MG BASE

EQ 20MG BASE

EQ 40MG BASE

EQ 60MG BASE

N18936 001
DEC 29, 1987
N18936 001
DEC 29, 1987
N18936 003
JUN 15, 1999
N18936 004
JUN 15, 1999

FERRIC SODIUM GLUCONATE

INJECTABLE; INJECTION

FERRLECIT

+ R AND D LABS

62.5MG/5ML

TABLET; ORAL

PROZAC
LILLY

EQ 10MG BASE

EQ 20MG BASE

EQ 10MG BASE

EQ 20MG BASE

N20974 001
MAR 09, 1999
N20974 002
MAR 09, 1999
N20974 001
MAR 09, 1999
N20974 002
MAR 09, 1999

FLUOCINONIDE

ointment; TOPICAL

FLUOCINONIDE

TARO

0.05%

N75008 001
JUN 30, 1999

FOLIC ACID

TABLET; ORAL

FOLIC ACID
VINTAGE PHARMS

1MG
1MG

N86296 001
N86296 001

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

BIGMAR

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

50MG/ML

N40291 001
MAR 24, 1999
N88767 001
DEC 28, 1984
N89434 001
MAR 26, 1987
N88767 001
DEC 28, 1984
N89434 001
MAR 26, 1987

INJECTABLE; INJECTION

FUROSEMIDE

ABBOTT

10MG/ML

10MG/ML

10MG/ML

10MG/ML

10MG/ML

10MG/ML

N75241 001
MAY 28, 1999
N70078 001
FEB 05, 1986
N70078 001
FEB 05, 1986
N70019 001
SEP 22, 1986
N70604 001
JAN 02, 1987
N70019 001
SEP 22, 1986

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
 @ STERIS

10MG/ML
 N70604 001
 JAN 02, 1987

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

GALLAMINE TRIETHIODIDE

INJECTABLE; INJECTION
 FLAXEDIL
 * DAVIS AND GECK
 *
 @
 @

20MG/ML
 100MG/ML
 20MG/ML
 100MG/ML

N07842 001
 N07842 002
 N07842 001
 N07842 002

EQ 10MG BASE/ML
 EQ 40MG BASE/ML
 EQ 10MG BASE/ML
 EQ 40MG BASE/ML

N62289 001
 N62289 002
 N62289 001
 N62289 002

BRISTAGEN

BRISTOL

EQ 40MG BASE/ML
 EQ 40MG BASE/ML

N62288 001
 N62288 001

GENTAMICIN SULFATE

SOLOPAK

EQ 10MG BASE/ML

N62507 001

* DAVIS AND GECK

@

@

N07842 001
 N07842 002
 N07842 001
 N07842 002

EQ 10MG BASE/ML
 EQ 40MG BASE/ML

N62507 001
 N62507 002
 N62507 001
 N62507 002

GALLIUM NITRATE

INJECTABLE; INJECTION
 GANITE
 * SOLOPAK
 *

25MG/ML
 25MG/ML

N19961 002
 JAN 17, 1991
 N19961 002
 JAN 17, 1991

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE

ALCON
 FALCON PHARMS

EQ 0.3% BASE
 EQ 0.3% BASE

N62196 001
 N62196 001

GANIRELIX ACETATE

INJECTABLE; INJECTION
 ANTAGON
 + ORGANON INC

EQ 250 UGM BASE/0.5ML
 JUL 29, 1999

N21057 001
 JUL 29, 1999

TABLET; ORAL

GLUCOTROL
 PFIZER

2.5MG

N17783 003

MAY 11, 1993

N17783 003
 MAY 11, 1993

GEMFIBROZIL

TABLET; ORAL

GEMFIBROZIL
 PUREPAC PHARM

600MG

600MG

N74360 001
 AUG 31, 1994
 N74360 001
 AUG 31, 1994

> DLT >

> DLT >

> ADD >

> ADD >

TABLET, EXTENDED RELEASE; ORAL

GLUCOTROL XL

+ PFIZER

2.5MG

N20329 003

AUG 10, 1999

GLYBURIDE

TABLET; ORAL

GLYBURIDE (MICRONIZED)

MOVA

4.5MG

N74591 003

DEC 22, 1997

GLYBURIDETABLET; ORAL
GLYBURIDE (MICRONIZED)

<u>AB</u>	MOVA	<u>4.5MG</u>	N74591 003 DEC 22, 1987
<u>AB</u>	MYLAN	<u>6MG</u>	N74792 003 AUG 17, 1999
<u>AB</u>	NOVOPHARM	<u>1.5MG</u>	N74686 001 APR 20, 1999
<u>AB</u>		<u>3MG</u>	N74686 002 APR 20, 1999
<u>AB</u>		<u>4.5MG</u>	N74686 003 APR 20, 1999
<u>AB</u>		<u>6MG</u>	N74686 004 APR 20, 1999

GLYCOPYRROLATE

INJECTABLE; INJECTION

GLYCOPYRROLATE

<u>AP</u>	STERIS	<u>0.2MG/ML</u>	N86947 001 JUN 24, 1983
®		0.2MG/ML	N86947 001 JUN 24, 1983

TABLET; ORAL

ROBINUL	1MG
+ HORIZON PHARM	1MG
* ROBIN'S AH	
ROBINUL FORTE	2MG
+ HORIZON PHARM	2MG
* ROBIN'S AH	

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

<u>AT</u>	NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN	0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML	N62788 001 JUN 11, 1987
®		0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML	N62788 001 JUN 11, 1987

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

<u>AO</u>	GENSIA SICOR PHARMS	<u>EQ 50MG BASE/ML</u>	N75393 001 MAY 11, 1999
<u>AO</u>		<u>EQ 100MG BASE/ML</u>	N75393 002 MAY 11, 1999

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

<u>AP</u>	SOLEPAC	<u>EQ 5MG BASE/ML</u>	N70801 001 DEC 14, 1987
<u>AP</u>		<u>EQ 5MG BASE/ML</u>	N70864 001 DEC 14, 1987
®		<u>EQ 5MG BASE/ML</u>	N70801 001 DEC 14, 1987
®		<u>EQ 5MG BASE/ML</u>	N70864 001 DEC 14, 1987
<u>AP</u>	STERIS	<u>EQ 5MG BASE/ML</u>	N70713 001 MAY 17, 1988
<u>AP</u>		<u>EQ 5MG BASE/ML</u>	N70744 001 MAY 17, 1988
®		<u>EQ 5MG BASE/ML</u>	N70713 001 MAY 17, 1988
®		<u>EQ 5MG BASE/ML</u>	N70744 001 MAY 17, 1988

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

<u>AP</u>	SMITH AND NEPHEW	<u>10 UNITS/ML</u>	N88458 001 JUL 26, 1984
<u>AP</u>		<u>10 UNITS/ML</u>	N88580 001 OCT 25, 1984
<u>AP</u>		<u>100 UNITS/ML</u>	N88460 001 JUL 26, 1984
<u>AP</u>		<u>100 UNITS/ML</u>	N88581 001 OCT 25, 1984
®		<u>10 UNITS/ML</u>	N88458 001 JUL 26, 1984
®		<u>10 UNITS/ML</u>	N88580 001 OCT 25, 1984

HEPARIN SODIUMINJECTABLE; INJECTIONHEPARIN LOCK FLUSH
@ SMITH AND NEPHEW

100 UNITS/ML

N88460 001
JUL 26, 1984

100 UNITS/ML

N88581 001
OCT 25, 1984AP SOLOPAK

100 UNITS/ML

N88459 001
JUL 26, 1984

100 UNITS/ML

N88459 001
JUL 26, 1984HEPARIN SODIUM

@ SMITH AND NEPHEW

1,000 UNITS/ML

N88239 001
JUL 26, 1984

1,000 UNITS/ML

N88239 001
JUL 26, 1984HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATESYRUP; ORALAA HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

1.5MG/5ML; 5MG/5ML

N40285 001
JUL 19, 1999HYDRALAZINE HYDROCHLORIDEINJECTABLE; INJECTIONHYDRALAZINE HCLAP * LUITPOLD

20MG/ML

N40136 001
JUN 30, 1997

20MG/ML

N40136 001
JUN 30, 1997AP SOLOPAK

20MG/ML

N88517 001
AUG 22, 1985

20MG/ML

N88517 001
AUG 22, 1985HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDECAPSULE; ORALAB HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

@ SOLVAY

25MG; 25MG

N87608 001
FEB 08, 1982

50MG; 50MG

N87213 001
FEB 08, 1982HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDECAPSULE; ORALHYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

@ SOLVAY

25MG; 25MG

N87608 001
FEB 08, 1982

@

50MG; 50MG

N87213 001
FEB 08, 1982HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINETABLET; ORAL

RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

BP SOLVAY

25MG; 15MG; 0.1MG

N88376 001
OCT 28, 1983

@

25MG; 15MG; 0.1MG

N88376 001
OCT 28, 1983HYDROCHLOROTHIAZIDETABLET; ORALHYDROCHLOROTHIAZIDE

MAST MM

25MG

> DLT >

50MG

> DLT >

25MG

> ADD >

50MG

> ADD >

N86192 001

N86192 002

N86192 001

N86192 002

HYDROCHLOROTHIAZIDE; IRBESARTANTABLET; ORAL

AVALIDE

@ SANOFI SYNTHELABO

12.5MG; 75MG

N20758 001
SEP 30, 1997

12.5MG; 150MG

N20758 002
SEP 30, 1997

12.5MG; 300MG

N20758 003
AUG 31, 1998

+

AVAPRO HCT

@ SANOFI

12.5MG; 75MG

N20758 001
SEP 30, 1997

12.5MG; 150MG

N20758 002
SEP 30, 1997

HYDROCHLOROTHIAZIDE, TRIAMTERENE

CAPSULE; ORAL

AB TRIAMTERENE AND HYDROCHLOROTHIAZIDE
DURAMED 25MG; 37.5MG

N75052 001
JUN 18, 1999

CREAM; TOPICAL

AB HYDROCORTISONE ACETATE
+ FERNDAL LABS 2.5%

N40259 001
JUL 29, 1999

HYDROCORTISONE

CREAM; TOPICAL

AT HYDROCORTISONE
G AND W LABS

> DLT > AT 1%
> ADD > AT 1%

N84059 001
N84059 001

ENEMA; RECTAL

CORTENEMA

AB HYDROCORTISONE
BR + SOLVAY 100MG/60ML

N16199 001
N16199 001

AB HYDROCORTISONE
BR COPLE PHARM 100MG/60ML

N74171 001
MAY 27, 1994
N74171 001
MAY 27, 1994

LOTION; TOPICAL

DERMACORT
SOLVAY

AT HYDROCORTISONE
AT 0.5%
@ 1%
@ 0.5%
@ 1%
AT 2.5%

N84573 002
N86462 001
N84573 002
N86462 001

THAMES

N40247 001
JUL 23, 1999

SOLUTION; TOPICAL

TEXACORT

AT HYDROCORTISONE
+ BIOGLAN PHAR 1%
+ 2.5%

N80425 001
N81271 001

GENDERM

APR 17, 1992
N81271 001

MEDICIS

APR 17, 1992
N80425 001

HYDROCORTISONE ACETATE

CREAM; TOPICAL

AB HYDROCORTISONE ACETATE
+ FERNDAL LABS 2.5%

N40259 001
JUL 29, 1999

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

AP HYDROCORTISONE SODIUM SUCCINATE
STERIS EQ 100MG BASE/VIAL

> DLT > AP EQ 100MG BASE/VIAL
> ADD > AP EQ 250MG BASE/VIAL
@ AP EQ 500MG BASE/VIAL
@ AP EQ 1GM BASE/VIAL

N84737 002
N84738 001
N84737 001
N84747 001
N84748 001

EQ 100MG BASE/VIAL

EQ 100MG BASE/VIAL

EQ 250MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 100MG BASE/VIAL

EQ 250MG BASE/VIAL

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC

AT HYDROXYAMPHETAMINE HYDROBROMIDE
+ AKORN 1%
+ PHARMICS 1%

N00004 004
N00004 004

HYDROXYUREA

CAPSULE; ORAL

HYDROXYUREA

AB HYDROXYUREA
PAR PHARM 500MG

N75340 001
FEB 24, 1999

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

SOLOPAK

AP HYDROXYZINE HCL
AP 25MG/ML
AP 50MG/ML
AP 50MG/ML
@ 25MG/ML
@ 50MG/ML

N87591 001
N87593 001
N87595 001
N87591 001
N87593 001

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
@ SOLOPAK

50MG/ML

N87595 001

IBUPROFEN

SUSPENSION; ORAL
MOTRIN

AB * MCNEIL

100MG/5ML

N19842 001
SEP 19, 1989

AB + MCNEIL CONS

100MG/5ML

N19842 001
SEP 19, 1989

TABLET; ORAL
IBUPROFEN

AB NORTON HN

400MG

AB

600MG

AB

800MG

AB

400MG

ZENITH GOLDLINE

AB

600MG

AB

800MG

AB

MOTRIN
MCNEIL

300MG

400MG

600MG

800MG

AB

100MG

300MG

400MG

600MG

800MG

AB MCNEIL CONS

300MG

400MG

600MG

800MG

AB

100MG

300MG

400MG

600MG

800MG

100MG

TABLET, CHEWABLE; ORAL
MOTRIN
MCNEIL

50MG

N20135 001
NOV 16, 1994

IBUPROFEN

TABLET, CHEWABLE; ORAL
MOTRIN

* MCNEIL

100MG

N20135 002
NOV 16, 1994

MCNEIL CONS

50MG

N20135 001
NOV 16, 1994

+

100MG

N20135 002
NOV 16, 1994

IMIGLUCERASE

INJECTABLE; INJECTION
CEREZYME

* GENZYME

200 UNITS/VIAL

N20367 001
MAY 23, 1994

200 UNITS/VIAL

N20367 001
MAY 23, 1994

400 UNITS/VIAL

N20367 002
SEP 22, 1999

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL
INDOCIN SR

EON

75MG

N74464 001
MAY 28, 1998

AB * MERCK

75MG

N18185 001
FEB 23, 1982

75MG

N18185 001
FEB 23, 1982

INDOMETHACIN
EON LABS MFG

75MG

N74464 001
MAY 28, 1998

INSULIN HUMAN

INJECTABLE; INJECTION
VELOSULIN BR

+ NOVO NORDISK

100 UNITS/ML

N21028 001
JUL 19, 1999

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
IPRATROPIUM BROMIDE
ALPHARMA

0.02%

N75111 001
APR 22, 1999

ISONIAZID; RIFAMPIN

CAPSULE; ORAL
RIFAMATE
* DOV PHARM
+ HOECHST MARION RSSL

150MG;300MG
150MG;300MG

N61884 001
N61884 001

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL
INTL MEDICATION

0.08%
0.1%

0.1%
0.152%

0.167%
0.25%

0.25%
0.25%

0.08%
0.08%

0.1%
0.17%

0.25%
0.25%

0.08%
0.1%

0.17%
0.25%

0.08%
0.1%

0.17%
0.25%

ISOETHARINE HCL S/F
DEX

N86651 002
N86651 003

N86651 003
N86651 005

N86651 005
N86651 007

N86651 007
N86651 002

N89817 001
NOV 22, 1988

N89818 001
NOV 22, 1988

N89819 001
NOV 22, 1988

N89820 001
NOV 22, 1988

N89817 001
NOV 22, 1988

N89818 001
NOV 22, 1988

N89819 001
NOV 22, 1988

N89820 001
NOV 22, 1988

TABLET; ORAL
SORBITRATE
ZENECA

30MG

30MG

N88124 001
AUG 21, 1990
N88124 001
AUG 21, 1990

ISOTRETINOIN

CAPSULE; ORAL
ACCUTANE
HLR

10MG

20MG

40MG

10MG

20MG

40MG

N18662 002
MAY 07, 1982
N18662 004
MAR 28, 1983
N18662 003
MAY 07, 1982
N18662 002
MAY 07, 1982
N18662 004
MAR 28, 1983
N18662 003
MAY 07, 1982

ITRACONAZOLE

INJECTABLE; INJECTION
SPORANOX
+ JANSSEN

10MG/ML

N20966 001
MAR 30, 1999

ISOFLURANE

LIQUID; INHALATION

FORANE
* BAXTER PHARM PROD
* ORMEDA

99.9%
99.9%

N17624 001
N17624 001

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE
SOLOPAK

EQ 75MG BASE/2ML

N62605 003
FEB 26, 1986

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

SOLOPAK

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

EQ 75MG BASE/2ML

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

N62605 001

FEB 26, 1986

N62605 002

FEB 26, 1986

N62605 003

FEB 26, 1986

N62605 001

FEB 26, 1986

N62605 002

FEB 26, 1986

KETOCONAZOLE

TABLET; ORAL

KETOCONAZOLE

APPLIED ANAL

200MG

MUTUAL PHARMA

200MG

NOVOPHARM

200MG

SIDMAK LABS CA

200MG

TARO

200MG

TEVA

200MG

NIZORAL

+ JANSSEN

200MG

200MG

N75341 001

JUL 27, 1999

N75314 001

JUN 15, 1999

N74971 001

JUN 15, 1999

N75362 001

JUN 15, 1999

N75319 001

JUN 15, 1999

N75273 001

JUN 15, 1999

N18533 001

N18533 001

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

KETOPROFEN

ANDRX PHARMS

100MG

150MG

200MG

ORUVAIL

WYETH AYERST

100MG

N75270 002

MAR 24, 1999

N75270 003

MAR 24, 1999

N75270 001

MAR 24, 1999

N19816 003

FEB 08, 1995

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL

ORUVAIL

WYETH AYERST

150MG

100MG

150MG

N19816 002

FEB 08, 1995

N19816 003

FEB 08, 1995

N19816 002

FEB 08, 1995

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

KETOROLAC TROMETHAMINE

ABBOTT

15MG/ML

AP

ABBOTT

30MG/ML

AP

BEDFORD

15MG/ML

AP

BEDFORD

30MG/ML

AP

BEDFORD

30MG/ML

AP

BEDFORD

30MG/ML

TABLET; ORAL

KETOROLAC TROMETHAMINE

SIDMAK LABS CA

10MG

AB

N74993 001

JAN 27, 1999

N74993 002

JAN 27, 1999

N75222 001

APR 26, 1999

N75222 002

APR 26, 1999

N75228 001

APR 26, 1999

KETOTIFEN FUMARATE

SOLUTION/DROPS; OPHTHALMIC

ZADITOR

+ CIBA

EQ 0.025% BASE

N21066 001

JUL 02, 1999

N75303 001

MAY 28, 1999

N75242 001

SEP 30, 1999

LABETALOL HYDROCHLORIDE

TABLET; ORAL
LABETALOL HCL
MUTUAL PHARM

AB 100MG N75215 001
AB 200MG N75215 002
AB 300MG N75215 003
JUL 29, 1999
JUL 29, 1999
JUL 29, 1999

TRANDATE
FARO PHARMS

AB 100MG N18716 001
AB 200MG N18716 002
AB 300MG N18716 003
AB 400MG N18716 004
MAY 24, 1985
AUG 01, 1984
AUG 01, 1984
AUG 01, 1984
AUG 01, 1984

AB GLAXO WELLCOME

AB 100MG N18716 001
AB 200MG N18716 002
AB 300MG N18716 003
AB 400MG N18716 004
MAY 24, 1985
AUG 01, 1984
AUG 01, 1984
AUG 01, 1984

LACTULOSE

SOLUTION; ORAL
LACTULOSE
PACO

AA 10GM/15ML N73160 001
10GM/15ML N73160 001
AUG 25, 1992
AUG 25, 1992

SOLUTION; ORAL, RECTAL
LACTULOSE
PACO

AA 10GM/15ML N72029 001
10GM/15ML N72029 001
AUG 25, 1992
AUG 25, 1992

LAMIVUDINE

SOLUTION; ORAL
EPIVIR-HBV
* GLAXO WELLCOME

5MG/ML N20596 002
5MG/ML N20596 002
5MG/ML N21004 001
DEC 08, 1998
DEC 08, 1998
DEC 08, 1998

TABLET; ORAL
EPIVIR-HBV
* GLAXO WELLCOME

100MG N20564 002
100MG N20564 002
100MG N21003 001
DEC 08, 1998
DEC 08, 1998
DEC 08, 1998

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
* ABBOTT

AP EQ 10MG BASE/ML N40147 001
AP EQ 200MG BASE/VIAL N40056 001
JUN 25, 1997
MAY 23, 1995

LEUCOVORIN CALCIUM PRESERVATIVE FREE
* ABBOTT

AP EQ 10MG BASE/ML N40147 001
AP EQ 200MG BASE/VIAL N40056 001
AP EQ 10MG BASE/ML N40286 001
AP EQ 200MG BASE/VIAL N40258 001
JUN 25, 1997
MAY 23, 1995
FEB 26, 1999
FEB 26, 1999
FEB 26, 1999
FEB 26, 1999
JUN 28, 1999

TABLET; ORAL
LEUCOVORIN CALCIUM
INVAMED

AB EQ 15MG BASE N75327 001
MAR 24, 1999

AB WELLCOVORIN
GLAXO WELLCOME

AB EQ 5MG BASE N18342 001
JUL 08, 1983

LEUCOVORIN CALCIUM

TABLET; ORAL

WELLCOVORINAB * GLAXO WELLCOMEEQ 25MG BASEN18342 002

JUL 08, 1983

EQ 5MG BASE

N18342 001

JUL 08, 1983

EQ 25MG BASE

N18342 002

JUL 08, 1983

LEVALBUTEROL HYDROCHLORIDE

SOLUTION; INHALATION

XOPENEX

+ SEPRACOR

EQ 0.021% BASE

N20837 001

MAR 25, 1999

EQ 0.042% BASE

N20837 002

MAR 25, 1999

LEVOBUPIVACaine HYDROCHLORIDE

INJECTABLE; INJECTION

CHIROCAINE

DARWIN DISCOVERY

EQ 2.5MG BASE/ML

N20997 001

AUG 05, 1999

EQ 5MG BASE/ML

N20997 002

AUG 05, 1999

EQ 7.5MG BASE/ML

N20997 003

AUG 05, 1999

LEVONORGESTREL

TABLET; ORAL

PLAN B

+ WOMENS CAPITAL

0.75MG

N21045 001

JUL 28, 1999

LIDOCAINE

FILM, EXTENDED RELEASE; TOPICAL

LIDODERM

+ TEIKOKU PHARMA USA

N20612 001

MAR 19, 1999

LIDOCAINE

FILM, EXTENDED RELEASE; TRANSDERMAL

LIDODERM

* HIND HLTHCARE

700MG/12HRN20612 001

MAR 19, 1999

LIDOCAINE; PRILCAINE

AEROSOL; TOPICAL

EMLA

* ASTRA PHARMS

2.5%; 2.5%N20962 001

FEB 04, 1998

DISC; TOPICAL

EMLA

+ ASTRAZENECA

2.5%; 2.5%N20962 001

FEB 04, 1998

LISINOPRIL

TABLET; ORAL

ZESTRIL

ZENECA

30MGN19777 006

JAN 20, 1999

LITHIUM CARBONATE

CAPSULE; ORAL

LITHONATESOLVAY

a

300MG300MGN16782 001N16782 001

TABLET; ORAL

LITHIUM CARBONATE

PFIZER

+ LITHOTABS* SOLVAY

c

300MG300MGN16834 001N16834 001300MG300MGN16980 001N16980 001LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

IMODIUM

* JANSSEN

2MGN17694 001

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

IMODIUM

@ JANSSEN

AB + MCNEIL CONS

2MG
2MG
2MGN17690 001
N17694 001
N17690 001LORACARBEEF

CAPSULE; ORAL

LORABID

KING PHARMS

200MG

N50668 001

400MG

DEC 31, 1991

200MG

N50668 001

400MG

DEC 31, 1991

400MG

N50668 002

400MG

APR 05, 1996

POWDER FOR RECONSTITUTION; ORAL

LORABID

KING PHARMS

100MG/5ML

N50667 001

200MG/5ML

DEC 31, 1991

100MG/5ML

N50667 001

200MG/5ML

DEC 31, 1991

200MG/5ML

N50667 002

200MG/5ML

DEC 31, 1991

LOTEPREDNOL ETABONATE

SUSPENSION/DROPS; OPHTHALMIC

LOTEMAX

* PHARMOS

0.5%

N20841 001

0.5%

MAR 09, 1998

0.5%

N20841 001

0.5%

MAR 09, 1998

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE;
MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE;
SODIUM PHOSPHATE, DIBASIC

INJECTABLE; INJECTION

ISOLYTE S PH 7.4 IN PLASTIC CONTAINER

B BRAUN

30MG/100ML; 37MG/100ML; 0.82MG/100ML;
30MG/100ML; 37MG/100ML; 500MG/100ML;
370MG/100ML; 530MG/100ML; 500MG/100ML;
12MG/100ML

N19006 001

APR 04, 1984

30MG/100ML; 37MG/100ML; 0.82MG/100ML;

370MG/100ML; 530MG/100ML; 500MG/100ML;

12MG/100ML

N19006 001

APR 04, 1984

MALATHION

LOTION; TOPICAL

OVIDE

@ MEDICIS

0.5%

N18613 001

AUG 02, 1982

0.5%

N18613 001

AUG 02, 1982

MANNITOL

INJECTABLE; INJECTION

MANNITOL 25%

STERIS

12.5GM/50ML

N87460 001

JUN 27, 1983

N87460 001

JUN 27, 1983

MEBENDAZOLE

TABLET, CHEWABLE; ORAL

VERMOX

* JANSSEN

100MG

N17481 001

N17481 001

MECLOCYCLINE SULFOSALICYLATE

CREAM; TOPICAL

MECLAN

* JOHNSON AND JOHNSON 1%

N50518 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE SODIUM SUCCINATE
 @ STERIS EQ 125MG BASE/VIAL
 @ EQ 500MG BASE/VIAL
 @ EQ 1GM BASE/VIAL

N87030 001
 JUL 22, 1982
 N88523 001
 JUL 24, 1984
 N88524 001
 JUL 24, 1984

INJECTABLE; INJECTION
FLAGYL I.V. RTU IN PLASTIC CONTAINER
 * SCS 500MG/100ML
METRONIDAZOLE
 STERIS 500MG/100ML
 @ 500MG/100ML

N18857 001
 N70170 001
 APR 01, 1986
 N70170 001
 APR 01, 1986

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL
 SMITH AND NEPHEW EQ 5MG BASE/ML
 @ EQ 5MG BASE/ML

N70623 001
 MAR 02, 1987
 N70623 001
 MAR 02, 1987

INSERT, CREAM; VAGINAL, TOPICAL
 MONISTAT DUAL- PAK
 + ADVANCED CARE PRODS 1.2GM, 2%

N20968 001
 JUN 30, 1999

METOLAZONE

TABLET; ORAL

ZAROXOLYN
 MEDEVA 2.5MG
 + 2.5MG

N17386 001
 N17386 001

TAMPON; VAGINAL
 MONISTAT 5
 * ADVANCED CARE PRODS 100MG

N18592 001
 OCT 27, 1989
 N18592 001
 OCT 27, 1989

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE
 PUREPAC PHARM 50MG
 @ 100MG
 @ 50MG
 @ 100MG

N74380 001
 JUL 29, 1994
 N74380 002
 JUL 29, 1994
 N74380 001
 JUL 29, 1994
 N74380 002
 JUL 29, 1994

MIGLITOL
 TABLET; ORAL
 GLYSET
 BAYER 25MG
 50MG
 100MG

N20882 001
 DEC 18, 1996
 N20882 002
 DEC 18, 1996
 N20882 003
 DEC 18, 1996
 N20882 001
 DEC 18, 1996
 N20882 002
 DEC 18, 1996

METRONIDAZOLE

INJECTABLE; INJECTION

FLAGYL I.V. RTU IN PLASTIC CONTAINER
 AP + BAXTER HLTHCARE 500MG/100ML

PHARMACIA AND UPJOHN 25MG
 50MG

N18657 001

NANDROLONE PHENPROPIONATE

INJECTABLE; INJECTION

NANDROLONE PHENPROPIONATE

@ STERIS 25MG/ML

@ 50MG/ML

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

N86386 001
JUN 17, 1983
N87488 001
JUN 17, 1983

N20750 001
OCT 01, 1997

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

NAPHAZOLINE HCL

AKORN 0.1%

TAYLOR 0.1%

N83590 001
N83590 001

15MG/5ML; 3.75MG/5ML;
600MG/5ML
15MG/5ML; 3.75MG/5ML;
600MG/5ML

N08378 003
N08378 003

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

NAPROXEN

AB SIDWAK LABS CA 375MG

AB 500MG

N75337 001
MAY 26, 1999
N75337 002
MAY 26, 1999

FILM, EXTENDED RELEASE; TRANSDERMAL

PROSTEP

* ELAN PHARM 11MG/24HR

* 22MG/24HR

@ 11MG/24HR

@ 22MG/24HR

N19983 001
JAN 28, 1992
N19983 002
JAN 28, 1992
N19983 001
JAN 28, 1992
N19983 002
JAN 28, 1992

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

AB PUREPAC PHARM EQ 250MG BASE

AB EQ 500MG BASE

@ EQ 250MG BASE

@ EQ 500MG BASE

N74319 001
MAR 20, 1995
N74319 002
MAR 20, 1995
N74319 001
MAR 20, 1995
N74319 002
MAR 20, 1995

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN

AP SMITH AND NEPHEW

@ 5MG/ML

N70633 001
JUN 19, 1986
N70633 001
JUN 19, 1986

NEDOCROMIL SODIUM

SOLUTION; INHALATION

TILADE

* RHONE POULENC RORER 0.5%

2%

2%

N87355 001
JUL 08, 1988
N87355 001
JUL 08, 1988

NITROGLYCERIN

SPRAY, METERED; SUBLINGUAL
NITROLINGUAL PUMPSPRAY
+ POHL BOSKAMP 0.4MG/SPRAY

N18705 002
JAN 10, 1997

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE
AB KIEL 100MG

N40249 001
JAN 29, 1999

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
PRILOSEC
* ASTRA PHARMS 10MG
ASTRAZENECA 10MG

N19810 003
OCT 05, 1995
N19810 003
OCT 05, 1995

OXYBUTYNIN CHLORIDE

SYRUP; ORAL
OXYBUTYNIN CHLORIDE
AA MIKART 5MG/5ML

N75039 001
JAN 29, 1999

ONDANSETRON

TABLET, ORALLY DISINTEGRATING; ORAL
ZOFRAN ODT
GLAXO WELLCOME
+ EQ 4MG BASE
EQ 8MG BASE

N20781 001
JAN 27, 1999
N20781 002
JAN 27, 1999

ONDANSETRON HYDROCHLORIDE

TABLET; ORAL
ZOFRAN
* GLAXO WELLCOME EQ 8MG BASE
EQ 8MG BASE
+ EQ 24MG BASE

N20103 002
DEC 31, 1992
N20103 002
DEC 31, 1992
N20103 003
AUG 27, 1999

ORLISTAT

CAPSULE; ORAL
XENICAL
+ ROCHE

120MG

N20766 001
APR 23, 1999

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE

OINTMENT; OTIC
TERRAMYCIN W/ POLYMYXIN
* PFIZER EQ 5MG BASE/GM;
10,000 UNITS/GM;
EQ 5MG BASE/GM;
10,000 UNITS/GM;
@

N61841 001
N61841 001

OXYTETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION
TERRAMYCIN
* PFIZER EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL
@

N60586 001
N60586 002
N60586 001
N60586 002

EQ 125MG BASE/5ML
EQ 125MG BASE/5ML

N60595 001
N60595 001

N20897 003
JUN 22, 1999

OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE

TABLET, VAGINAL
TERRAMYCIN-POLYMYXIN
* PFIZER

EQ 100MG BASE;
100,000 UNITS
EQ 100MG BASE;
100,000 UNITS

N61009 001
N61009 001

N16832 002
N16832 003
N16832 001
N16832 002
N16832 003
N16832 001

37.5MG
75MG
18.75MG
37.5MG
75MG
18.75MG

PAROXETINE HYDROCHLORIDE

CAPSULE, ORAL
PAXIL
SMITHKLINE BEECHAM

EQ 10MG BASE

N20885 001
OCT 09, 1998

EQ 20MG BASE

N20885 002
OCT 09, 1998

EQ 30MG BASE

N20885 003
OCT 09, 1998

EQ 40MG BASE

N20885 004
OCT 09, 1998

EQ 10MG BASE

N20885 001
OCT 09, 1998

EQ 20MG BASE

N20885 002
OCT 09, 1998

EQ 30MG BASE

N20885 003
OCT 09, 1998

EQ 40MG BASE

N20885 004
OCT 09, 1998

PEMOLINE
COPLEY PHARM

N75030 001
JAN 29, 1999

N75030 002
JAN 29, 1999

N75286 002
JUN 30, 1999

N75286 003
JUN 30, 1999

37.5MG

75MG

37.5MG

75MG

PENTAZOCINE HYDROCHLORIDE

TABLET, ORAL
TALWIN 50
@ SANOFI SYNTHELABO
@ STERLING WINTHROP

> ADD >
> DLT >
EQ 50MG BASE
EQ 50MG BASE

N16732 001
N16732 001

TABLET, EXTENDED RELEASE; ORAL

PAXIL CR
+ SMITHKLINE BEECHAM

N20936 001
FEB 16, 1999
N20936 002
FEB 16, 1999

N75093 001
AUG 10, 1999
N74874 001
MAY 25, 1999
N75199 001
SEP 03, 1999
N75191 001
JUN 09, 1999
N74962 001
MAR 31, 1999

400MG

400MG

400MG

400MG

FEMIOLOAST POTASSIUM

SOLUTION/DROPS; OPHTHALMIC
ALAMAST
+ SANTEN

N21079 001
SEP 24, 1999

N74962 001
MAR 31, 1999

400MG

400MG

400MG

400MG

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

PERINDOPRIL ERBUMINE

TABLET; ORAL

ACEON

@ HUESCHEN

2MG

@

4MG

@

8MG

@ SOLVAY

2MG

@

4MG

@

8MG

N20184 001

DEC 30, 1993

N20184 002

DEC 30, 1993

N20184 003

DEC 30, 1993

N20184 001

DEC 30, 1993

N20184 002

DEC 30, 1993

N20184 003

DEC 30, 1993

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA + EON

30MG

N86945 001

JUL 20, 1983

PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

AP STERIS

50MG/ML

50MG/ML

N85434 001

N85434 001

PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

ACTOS

TAKEDA

EQ 15MG BASE

N21073 001

JUL 15, 1999

EQ 30MG BASE

N21073 002

JUL 15, 1999

EQ 45MG BASE

N21073 003

JUL 15, 1999

POLYETHYLENE GLYCOL 3350

POWDER FOR RECONSTITUTION; ORAL

MIRALAX

+ BRAINTREE

17GM/SCOOPFUL

N20698 001

FEB 18, 1999

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC

TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE

AT ALCON

10,000 UNITS/ML;

EQ 1MG BASE/ML

N64211 001

APR 13, 1998

10,000 UNITS/ML;

EQ 1MG BASE/ML

N64211 001

APR 13, 1998

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL

PHENAZINE

MAST WM

35MG

35MG

35MG

35MG

35MG

35MG

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

TABLET; ORAL

PHENAZINE

MAST WM

35MG

35MG

35MG

35MG

35MG

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

FASTIN

+ SMITHKLINE BEECHAM

30MG

30MG

30MG

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

PHENTERMINE HCL

EON

30MG

N86945 001

JUL 20, 1983

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

MICRO-K

AB KV PHARM

AB ROBINSON AH

AB MICRO-K 10

AB + KV PHARM

AB ROBINSON AH

8MEQ

9MEQ

10MEQ

10MEQ

N18238 001

N18238 001

N18238 002

MAY 14, 1984

N18238 002

MAY 14, 1984

GRANULE, FOR RECONSTITUTION ER; ORAL

MICRO-K LS

AB KV PHARM

AB ROBINSON AH

20MEQ/PACKET

20MEQ/PACKET

N19561 003

AUG 26, 1988

N19561 003

AUG 26, 1988

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

AB AN PHARM PARTNERS

AB MILES

AB STERIS

3MEQ/ML

3MEQ/ML

4MEQ/ML

4MEQ/ML

2MEQ/ML

2MEQ/ML

2MEQ/ML

2MEQ/ML

3MEQ/ML

2MEQ/ML

2MEQ/ML

2MEQ/ML

2MEQ/ML

2MEQ/ML

3MEQ/ML

N80225 003

N80225 003

N80195 004

N80195 004

N80195 004

N86208 001

N89163 001

MAR 10, 1988

N89421 001

JAN 02, 1987

N86210 001

N86208 001

N89163 001

MAR 10, 1988

N89421 001

JAN 02, 1987

N86210 001

POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE

INJECTABLE; INJECTION

THAM-E

AB ABBOTT

AB

370MG/VIAL; 1.75GM/VIAL;

36GM/VIAL

370MG/VIAL; 1.75GM/VIAL;

36GM/VIAL

POTASSIUM CITRATE

POWDER FOR RECONSTITUTION; ORAL

POTASSIUM CITRATE

AB MISSION PHARMA

AB

AB UNIV TX

AB

10MEQ/PACKET

20MEQ/PACKET

10MEQ/PACKET

20MEQ/PACKET

N19647 002

OCT 13, 1988

N19647 001

OCT 13, 1988

N19647 002

OCT 13, 1988

N19647 001

OCT 13, 1988

POVIDONE-IODINE

SOLUTION/DROPS; OPHTHALMIC

BETADINE

+ ALCON UNIVERSAL

* PURDUE FREDERICK

5%

5%

N18634 001

DEC 17, 1986

N18634 001

DEC 17, 1986

PRazosin HYDROCHLORIDE

CAPSULE; ORAL

PRazosin HCL

ZENITH GOLDLINE

EQ 2MG BASE

EQ 2MG BASE

EQ 5MG BASE

EQ 5MG BASE

N71995 001

MAY 16, 1989

N71995 001

SEP 12, 1988

N71745 001

MAY 16, 1989

N71745 001

SEP 12, 1988

PREDNISOLONE

SYRUP; ORAL

PREDNISOLONE

AA HALSEY

AA UDL

15MG/5ML

15MG/5ML

N40287 001

MAY 28, 1999

N40323 001

MAY 13, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HCL
GRANULET PHARMSEQ 150MG BASEN74488 001
JUL 31, 1997EQ 300MG BASEN74488 002
JUL 31, 1997EQ 150MG BASEN74488 001
JUL 31, 1997EQ 300MG BASEN74488 002
JUL 31, 1997EQ 150MG BASEN75180 001
JAN 28, 1999EQ 300MG BASEN75180 002
JAN 28, 1999

SOLUTION; ORAL

NORVIR
+ ABBOTT

80MG/ML

N20659 001
MAR 01, 1996ROFECOXIB

SUSPENSION; ORAL

VIOXX
MERCK

12.5MG/5ML

N21052 001
MAY 20, 1999

25MG/5ML

N21052 002
MAY 20, 1999RAPACURONIUM BROMIDE

INJECTABLE; INJECTION

RAPLON
ORGANON

100MG/VIAL

N20984 001
AUG 18, 1999

200MG/VIAL

N20984 002
AUG 18, 1999

TABLET; ORAL

VIOXX
MERCK

12.5MG

N21042 001
MAY 20, 1999

25MG

N21042 002
MAY 20, 1999RISPERIDONE

TABLET; ORAL

RISPERDAL
JANSSEN

0.25MG

N20272 008
MAY 10, 1999

0.5MG

N20272 007
JAN 27, 1999

TABLET; ORAL

REQUIP
SMITHKLINE BEECHAM

EQ 3MG BASE

N20658 006
JAN 27, 1999

EQ 4MG BASE

N20658 007
JAN 27, 1999RITONAVIR

CAPSULE; ORAL

NORVIR
ABBOTT

100MG

N20945 001
JUN 29, 1999

SOLUTION; ORAL

NORVIR
ABBOTT

80MG/ML

N20659 001
MAR 01, 1996ROSIGLITAZONE MALEATE

TABLET; ORAL

AVANDIA
SMITHKLINE BEECHAM

EQ 2MG BASE

N21071 002
MAY 25, 1999

EQ 4MG BASE

N21071 003
MAY 25, 1999

EQ 8MG BASE

N21071 004
MAY 25, 1999

SAQUINAVIR

CAPSULE; ORAL
FORTOVASE
+ HLR

200MG
200MG

N20828 001
NOV 07, 1997
N20828 001
NOV 07, 1997

3GM/TEASPOONFUL
3GM/TEASPOONFUL

N20573 001
APR 30, 1996
N20573 001
APR 30, 1996

SAQUINAVIR MESYLATE

CAPSULE; ORAL
INVIRASE
+ HLR

EQ 200MG BASE
EQ 200MG BASE

N20628 001
DEC 06, 1995
N20628 001
DEC 06, 1995

N20572 001
MAY 13, 1996
N20572 001
MAY 13, 1996

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
ELDEPRYL
+ SOMERSET

5MG
5MG

N19334 001
JUN 05, 1989
N19334 001
JUN 05, 1989

N19640 005
FEB 04, 1999
N19640 006
FEB 04, 1999
N19640 007
FEB 04, 1999

SILVER SULFADIAZINE

CREAM; TOPICAL
THERMAZENE
KENDALL LP

1%
1%

N18810 001
DEC 23, 1985
N18810 001
DEC 23, 1985

N17643 001
N17643 001
N18449 001
N20248 001
AUG 07, 1996
N18449 001
N20248 001
AUG 07, 1996

SIRIOLIMUS

SOLUTION; ORAL
RAPAMUNE
+ WYETH AYERST

1MG/ML

N21083 001
SEP 15, 1999

N19942 001
DEC 30, 1993
N19942 001
DEC 30, 1993

SPIRONOLACTONE

TABLET; ORAL

ALDACTONE
SEARLE

AB	50MG	N12151 008	> ADD >
AB	100MG	DEC 30, 1982	> ADD >
AB	50MG	N12151 010	> DLT >
AB	100MG	DEC 30, 1983	> ADD >
AB	50MG	N12151 008	> DLT >
AB	100MG	DEC 30, 1982	> ADD >
AB	50MG	N12151 010	> DLT >
AB	100MG	DEC 30, 1983	> ADD >

SPIRONOLACTONE
MUTUAL PHARM

AB	50MG	N89424 002	> ADD >
AB	100MG	AUG 11, 1999	> ADD >
AB	25MG	N89424 003	> DLT >
AB	50MG	AUG 11, 1999	> ADD >
AB	100MG	N87998 001	> DLT >
AB	25MG	OCT 14, 1983	> ADD >
AB	50MG	N40353 001	> DLT >
AB	100MG	JUL 29, 1999	> ADD >
AB	25MG	N40353 002	> DLT >
AB	50MG	JUL 29, 1999	> ADD >
AB	100MG	N87998 001	> DLT >
AB	25MG	OCT 14, 1983	> ADD >

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SODIUM SULFACETAMIDE

AT	10%	N83021 001	> ADD >
AT	15%	N83021 002	> ADD >
AT	30%	N83021 003	> DLT >
AT	10%	N83021 001	> ADD >
AT	15%	N83021 002	> DLT >
AT	30%	N83021 003	> ADD >

SULFACETAMIDE SODIUM

AT	10%	N40215 001	> ADD >
AT	30%	MAY 25, 1999	> ADD >
AT	10%	N40216 001	> DLT >
AT	30%	MAY 25, 1999	> ADD >

SULFADIAZINE

TABLET; ORAL

SULFADIAZINE
EON

AB	500MG	N40091 001	> DLT >
AB	500MG	JUL 29, 1994	> DLT >

SULFADIAZINE

TABLET; ORAL

SULFADIAZINE

AB	500MG	N40091 001	> ADD >
AB	500MG	JUL 29, 1994	> ADD >
AB	500MG	N80081 001	> DLT >
AB	500MG	N80081 001	> ADD >
AB	500MG	N80084 001	> DLT >
AB	500MG	N80084 001	> ADD >

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AP	80MG/ML; 16MG/ML	N71556 001	> ADD >
AP	80MG/ML; 16MG/ML	DEC 29, 1987	> ADD >
AP	80MG/ML; 16MG/ML	N71556 001	> DLT >
AP	80MG/ML; 16MG/ML	DEC 29, 1987	> ADD >

TACROLIMUS

CAPSULE; ORAL

PROGRAF

* FUJISAWA HLTHCARE

EQ	1MG BASE	N50708 001	> ADD >
EQ	0.5MG BASE	APR 08, 1994	> ADD >
EQ	1MG BASE	N50708 003	> DLT >
EQ	1MG BASE	AUG 24, 1998	> ADD >
EQ	1MG BASE	N50708 001	> DLT >
EQ	1MG BASE	APR 08, 1994	> ADD >

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

A-N STANNOUS AGGREGATED ALBUMIN

* NORTH AM CHEMS

* SYNCOR PHARMS

PULMOLITE

CIS

DUPONT PHARMS

BS	N/A	N17916 001	> ADD >
BS	N/A	N17916 001	> DLT >
BS	N/A	N17776 001	> ADD >
BS	N/A	N17776 001	> DLT >

TECHNETIUM TC-99M ALBUMIN COLLOID KIT

INJECTABLE; INJECTION MICROLITE CIS	N/A
DUPONT PHARMS	N/A

TECHNETIUM TC-99M DEPREOTIDE

INJECTABLE; INJECTION
NEO TEST KIT
+ DIATIDE
N/A

TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION	N/A
HEPATOLITE	N/A
CIS	
DUPONT PHARMS	N/A

TECHNETIUM TC-99M LIDO-FENIN KIT

INJECTABLE; INJECTION TECHNISCAN HIDA DRAXIMAGE	N/A	N/A
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TECHNETIUM TC-99M MEDRONATE KIT

[illegible]

TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

INJECTABLE; INJECTION	
PYROLITE	
CIS	N/A
DUPONT PHARMS	N/A
	N17684 001
	N17684 003

TEMOZOLOMIDE

CAPSULE; ORAL	
TEMODAR	
SCHERING	
SMG	N21029 001
	AUG 11, 1999
20MG	N21029 002
	AUG 11, 1999
100MG	N21029 003
	AUG 11, 1999
250MG	N21029 004
	AUG 11, 1999

TERBUTALINE SULFATE

INJECTABLE; INJECTION		
<u>AP</u>	<u>BRETHINE</u>	
+	<u>NOVARTIS</u>	
+		
	<u>BRICANYL</u>	
+	<u>HOECHST MARION RESSL</u>	
<u>AP</u>	[®]	

	TABLET; ORAL			N17849 001
BP	BRETHINE		2.5MG	N17849 002
BP	NOVARTIS	*	5MG	N17849 001
			2.5MG	N17849 002
		+	5MG	
	BRICANYL			
	HOECHST MARION RSSL		2.5MG	N17618 001
BP			5MG	N17618 002
BP			2.5MG	N17618 001
		@	5MG	N17618 002
		@		

N17972 001
N17972 001

N21012 001
AUG 03, 1999

N18467 001
MAR 16, 1982
N18467 001
MAR 16, 1982

N18489 001
OCT 31, 1986
N18489 001
OCT 31, 1986

N17972 001
N17972 001

TERIPARATIDE ACETATEINJECTABLE; INJECTION

PARATHAR
+ RHONE POULENC ROGER 200 UNITS/VIAL
@ 200 UNITS/VIAL

N19498 001
DEC 23, 1987
N19498 001
DEC 23, 1987

THEOPHYLLINECAPSULE, EXTENDED RELEASE; ORAL

THEOCLEAR L.A.-260
BC * CENT PHARMS 260MG
@ SCHWARZ PHARMA 260MG

N85569 002
MAY 27, 1982
N85569 002
MAY 27, 1982

TESTOSTERONE ENANTHATEINJECTABLE; INJECTION

TESTOSTERONE ENANTHATE
STERIS

100MG/ML
100MG/ML

N85599 001
N85599 001

INJECTABLE; INJECTION

THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER
@ B BRAUN 40MG/100ML
@ MCGAW 40MG/100ML
THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER
@ B BRAUN 80MG/100ML
@ MCGAW 80MG/100ML
THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER
@ B BRAUN 160MG/100ML
@ MCGAW 160MG/100ML

N19083 001
NOV 07, 1984
N19083 001
NOV 07, 1984
N19083 002
NOV 07, 1984
N19083 002
NOV 07, 1984
N19083 003
NOV 07, 1984
N19083 003
NOV 07, 1984

TETRACYCLINE HYDROCHLORIDECAPSULE; ORALTETRACYCLINE HCL

PUREPAC PHARM

250MG
500MG
250MG
500MG

N60290 001
N60290 002
N60290 001
N60290 002

TETRACYN

PFIPHARMECS

250MG
500MG
250MG
500MG

N60082 003
N60082 004
N60082 003
N60082 004

SYRUP; ORAL

AQUAPHYLLIN

FERNDAL LABS

80MG/15ML
80MG/15ML

N87917 001
JAN 18, 1983
N87917 001
JAN 18, 1983

THEOPHYLLINECAPSULE; ORAL

BRONKODYL

@ SANOFI SYNTHELABO

100MG
200MG
100MG
200MG

N85264 001
N85264 002
N85264 001
N85264 002

TABLET, EXTENDED RELEASE; ORAL

SUSTAIRE

ROERIG

100MG
300MG
100MG
300MG

N85665 001
N85665 002
N85665 001
N85665 002

CAPSULE, EXTENDED RELEASE; ORAL

THEOCLEAR L.A.-130

@ CENT PHARMS

130MG

N85569 001
MAY 27, 1982

@ SCHWARZ PHARMA

130MG

N85569 001
MAY 27, 1982

THIOTHIXENE HYDROCHLORIDECONCENTRATE; ORAL

THIOTHIXENE HCL

ALPHARMA

EQ 5MG BASE/ML

N70969 001
OCT 16, 1987

EQ 5MG BASE/ML

N70969 001
OCT 16, 1987

TIAGABINE HYDROCHLORIDE

TABLET; ORAL
GABITRIL
+ ABBOTT

2MG

N20646 005
APR 16, 1999

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLID
@ ROCHE

125MG

N19979 001
MAR 24, 1993

250MG

N19979 002
OCT 31, 1991

125MG

N19979 001
MAR 24, 1993

250MG

N19979 002
OCT 31, 1991

@
* SYNTEX USA

TICLOPIDINE HCL

EON

250MG

N75326 001
AUG 20, 1999

GENPHARM

250MG

N75161 001
SEP 13, 1999

INVAMED

250MG

N75318 001
AUG 20, 1999

PUREPAC PHARM

250MG

N75253 001
AUG 20, 1999

TEVA

250MG

N75149 001
AUG 20, 1999

TORPHARM

250MG

N75089 001
JUL 01, 1999

> ADD >
> ADD >

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC

TIMOLOL MALEATE

ALCON

EQ 0.25% BASE

N20963 001
OCT 21, 1998

EQ 0.5% BASE

N20963 002
OCT 21, 1998

EQ 0.25% BASE

N20963 001
OCT 21, 1998

EQ 0.5% BASE

N20963 002
OCT 21, 1998

FALCON PHARMS

EQ 0.25% BASE

N20963 001
OCT 21, 1998

FALCON PHARMS

EQ 0.5% BASE

N20963 002
OCT 21, 1998

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

ADV REMEDIES

EQ 0.5% BASE

N74466 001
MAR 25, 1997

EQ 0.5% BASE

N74466 001
MAR 25, 1997

EQ 0.25% BASE

N74261 001
APR 28, 1995

EQ 0.5% BASE

N74262 001
APR 28, 1995

EQ 0.25% BASE

N74261 001
APR 28, 1995

EQ 0.5% BASE

N74262 001
APR 28, 1995

@ FALCON PHARMS

@

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC

TOBREX

0.3%

N50541 001
N50541 001

* ALCON

0.3%

N50541 001
N50541 001

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

EQ 40MG BASE/ML

N64026 001
MAY 31, 1994

EQ 40MG BASE/ML

N64026 001
MAY 31, 1994

TOPOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

HYCAMTIN

+ SMITHKLINE

EQ 4MG BASE/VIAL

N20671 001
MAY 28, 1996

EQ 4MG BASE/VIAL

N20671 001
MAY 28, 1996

* SMITHKLINE BEECHAM

EQ 4MG BASE/VIAL

N20671 001
MAY 28, 1996

TRICHLORMETHIAZIDE

TABLET; ORAL

> DLT >
> DLT >
> ADD >

TRICHLORMAS

MAST MM

4MG
4MG

N86259 001
N86259 001

POWDER FOR RECONSTITUTION; ORAL
PYLORI-CHEK BREATH TEST
+ ALIMENTERICIS 100MG/VIAL

N20900 001
FEB 04, 1999

TRIHENYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL

TRIHENYPHENIDYL HCL

MIKART

2MG/5ML

N40251 001
SEP 27, 1999

SOLUTION;
VALSTAR PRESERVATIVE FREE
+ ANTHRA 40MG/ML

N20892 001
SEP 25, 1998

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

SMITH AND NEPHEW

100MG/ML

N88360 001
APR 04, 1986
N88360 001
APR 04, 1986

100MG/ML

SOLUTION; INTRAVESICAL
VALSTAR PRESERVATIVE FREE
+ ANTHRA 40MG/ML

N20892 001
SEP 25, 1998

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

ESI LEDERLE

10MG/VIAL

N75218 001
AUG 23, 1999

20MG/VIAL

N75218 002
AUG 23, 1999

GENSIA

10MG/VIAL

N74688 001
AUG 25, 1999

20MG/VIAL

N74688 002
AUG 25, 1999

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERAPAMIL HCL

MYLAN

120MG

N75138 001
APR 20, 1999

180MG

N75138 002
APR 20, 1999

240MG

N75138 003
APR 20, 1999

VERELAN

* ELAN

120MG

N19614 001
MAY 29, 1990

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

TROPICAMIDE

STERIS

0.5%

N89171 001
DEC 28, 1990

0.5%

N89171 001
DEC 28, 1990

ZALEPLON

CAPSULE; ORAL
SONATA
+ WYETH AYERST

10MG

N20859 002
AUG 13, 1999

ZANAMIVIR

CAPSULE; INHALATION
RELENZA
+ GLAXO WELLCOME

5MG

N21036 001
JUL 26, 1999

ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACEPHEN

+ G AND W LABS

120MG

325MG

+ *

650MG

120MG

325MG

650MG

ACETAMINOPHEN

ASCENT PEDS

120MG

325MG

650MG

120MG

+ UPSHER SMITH

325MG

650MG

INFANTS' FEVERALL

ASCENT PEDS

80MG

80MG

UPSHER SMITH

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CONTAC

+ SMITHKLINE

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

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8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

8MG;75MG

CIMETIDINE

SUSPENSION; ORAL

TAGAMET HB 200

+ SMITHKLINE BEECHAM

200MG/20ML

200MG/20ML

200MG/20ML

200MG/20ML

200MG/20ML

200MG/20ML

200MG/20ML

200MG/20ML

200MG/20ML

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200MG/20ML

200MG/20ML

200MG/20ML

N18060 001

N18060 003

DEC 18, 1986

N18060 002

N18060 001

N18060 003

DEC 18, 1986

N18060 002

N18337 003

SEP 12, 1983

N18337 002

N18337 001

N18337 003

SEP 12, 1983

N18337 002

N18337 001

N18337 004

AUG 26, 1992

N18337 004

AUG 26, 1992

N18337 004

AUG 26, 1992

N18337 004

AUG 26, 1992

N18099 001

N18099 001

PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

N18809 001

MAY 07, 1984

SUPPOSITORY; RECTAL

ACEPHEN

+ G AND W LABS

120MG

325MG

+ *

650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

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650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

SUPPOSITORY; RECTAL

ACEPHEN

+ G AND W LABS

120MG

325MG

+ *

650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

325MG

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650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

325MG

650MG

120MG

325MG

IBUPROFEN

SUSPENSION; ORAL
IBUPROFEN
ALPHARMA

100MG/5ML

N74916 001
APR 30, 1999

TABLET; ORAL
IBUPROFEN
LNK

200MG

N75010 001

MAR 01, 1999

200MG

N75139 001

MAR 01, 1999

NORTON HN

200MG

N71144 001

JAN 20, 1987

200MG

N72901 001

DEC 19, 1991

200MG

N72903 001

DEC 19, 1991

ZENITH GOLDLINE

200MG

N71144 001

JAN 20, 1987

200MG

N72901 001

DEC 19, 1991

200MG

N72903 001

DEC 19, 1991

JUNIOR STRENGTH IBUPROFEN
PERRIGO

100MG

N75367 001

APR 22, 1999

IBUPROFEN POTASSIUM

CAPSULE; ORAL
PROVEL

+ NOVARTIS

200MG

N20402 001

APR 20, 1995

200MG

N20402 001

APR 20, 1995

+ WHITEHALL ROBINS

INSULIN ZINC SUSP PURIFIED BEEF

INJECTABLE; INJECTION
LEVELE ILETIN II

+ BILLY

@

100 UNITS/ML

100 UNITS/ML

N18477 001

N18477 001

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
M-ZOLE 3 COMBINATION PACK
ALPHARMA US PHARM

2%, 200MG

N74926 001
APR 16, 1999

MICONAZOLE NITRATE COMBINATION PACK
PERRIGO

2%, 200MG

N75329 001
APR 20, 1999

SUPPOSITORY; VAGINAL
MICONAZOLE NITRATE
ALPHARMA US PHARM

100MG

N73507 001
NOV 19, 1993

100MG

N73507 001
NOV 19, 1993

NMC

MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)

2%

N75357 001
JUL 30, 1999

MINOXIDIL (FOR WOMEN)
PERRIGO

2%

N75357 002
JUL 30, 1999

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM
GRANTHEC

EQ 200MG BASE

N74635 001
JAN 13, 1997

EQ 200MG BASE

N74635 001
JAN 13, 1997

NOVOPHARM NC

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
PROSTEP

+ ELAN PHARM

11MG/24HR

N19983 003
DEC 23, 1998

+

22MG/24HR

N19983 004
DEC 23, 1998

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL
NICOTINE POLACRILEX
WATSON LAB

EQ 2MG BASE
EQ 4MG BASE

N74507 001
MAR 15, 1999
N74707 001
MAR 19, 1999

NONOXYNOL-9

SPONGE; VAGINAL
TODAY

@ ALLENDALE PHARMS
@ WHITEHALL ROBINS

1GM
1GM

N18683 001
APR 01, 1983
N18683 001
APR 01, 1983

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL
PERRIGO

N75153 001
FEB 26, 1999

RANITIDINE HYDROCHLORIDE

TABLET, ORAL
RANITIDINE HCL
NOVOPHARM

EQ 75MG BASE
EQ 75MG BASE

N75094 001
JUN 21, 1999
N75132 001

RANBAXY
ZANTAC 75
+ GLAXO WELLCOME

EQ 75MG BASE
EQ 75MG BASE

N20520 001
DEC 19, 1995
N20520 001

+ WARNER LAMBERT

EQ 75MG BASE

DEC 19, 1995

TERBINAFINE HYDROCHLORIDE

CREAM; TOPICAL
LAMISIL
+ NOVARTIS

1*

N20980 001
MAR 09, 1999

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

CUMULATIVE SUPPLEMENT NUMBER 9 SEP '99

NO SEPTEMBER 1999 APPROVALS

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

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
111Indium pentetreotide TN= SomatoTher	Treatment of somatostatin receptor positive neuroendocrine tumors.	Louisiana State University Medical Center Foundation 1600 Canal St. 10th Floor New Orleans, LA 70112 DD=06/10/1999
166Ho-DOTMP TN=	Treatment of multiple myeloma.	NeoRx Corporation 410 W. Harrison Seattle, WA 98119 DD=02/10/1999
506U78 TN=	Treatment of chronic lymphocytic leukemia.	Glaxo Wellcome, Inc. Five Moore Dr. P.O. Box 13398 Durham, NC 27709 DD=09/02/1999
6-hydroxymethyla cylfulvene TN=	Treatment of histologically confirmed advanced or metastatic pancreatic cancer.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=04/06/1999
6-hydroxymethyla cylfulvene TN=	Treatment of ovarian cancer.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=07/06/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
6-hydroxymethyla cylfulvene TN=	Treatment of renal cell carcinoma.	MGI Pharma, Inc. 6300 West Old Shakoppe Rd. Suite 110 Bloomington, MN 55438 DD=07/27/1999
Alitretinoin TN= Panretin	Topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998 MA=02/02/1999
Amifostine TN= Ethyol	Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street, Suite 400 Conshohocken, PA 19428 DD=05/12/1998 MA=06/24/1999
Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized TN= Humate-P	Treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric patients.	Centeon Pharma GmbH Emil-von-Behring-Stras se 76 35041 Marburg Germany DD=10/16/1992 MA=04/01/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Artesunate TN=	Treatment of malaria.	World Health Organisation Special Programme for Research and Training in Tropical Diseases Via Appia Geneva 27, Switzerland DD=07/19/1999
Atovaquone TN= Mepron	Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm3.	Glaxo Wellcome Research and Development 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=08/14/1991 MA=01/05/1999
Autologous DNP-conjugated tumor vaccine TN= M-Vax	For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).	Avax Technologies, Inc. 4520 Main St. Suite 930 Kansas City, MO 64111 DD=02/23/1999
Azathioprine TN= Imuran	Treatment of oral manifestations of graft-versus-host disease.	Oral Solutions, Inc. 787 Seventh Ave., 48th Floor New York, NY 10019 DD=09/14/1999
Beraprost TN=	Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).	United Therapeutics Corporation 68 T.W. Alexander Drive, PO Box 14186 Research Triangle Park, NC 27709 DD=04/29/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Bexarotene TN= Targretin	Treatment of cutaneous T-cell lymphoma.	Ligand Pharmaceuticals, Inc. 10275 Science Center Dr. San Diego, CA 92121 DD=06/18/1999
Bleomycin TN= Blenoxane	Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999
Busulfan TN= Busulfex	As preparative therapy in the treatment of malignancies with bone marrow transplantation.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=07/28/1994 MA=02/04/1999
CT-2584 mesylate TN=	Treatment of adult soft tissue sarcoma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Suite 400 Seattle, WA 98119 DD=04/16/1999
CT-2584 mesylate TN=	Treatment of malignant mesothelioma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Seattle, WA 98119 DD=04/16/1999
Caffeine TN= Cafcit	Treatment of apnea of prematurity.	O.P.R. Development, L.P. 1501 Wakarusa Drive Lawrence, KS 66047 DD=09/20/1988 MA=09/21/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Coagulation factor VIIa (recombinant) TN= NovoSeven	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.	Novo Nordisk Pharmaceuticals, Inc. 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=06/06/1988 MA=03/25/1999
Cytarabine liposomal TN= DepoCyt	Treatment of neoplastic meningitis.	DepoTech Corporation 10450 Science Center Drive San Diego, CA 92121 DD=06/02/1993 MA=04/01/1999
Decitabine TN=	Treatment of myelodysplastic syndromes.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999
Decitabine TN=	Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999
Denileukin diftitox TN= Ontak	Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/1996 MA=02/05/1999
Doxorubicin liposome TN= Doxil	Treatment of ovarian cancer.	Alza Corporation 1550 Plymouth St. PO Box 7210 Mountain View, CA 94039 DD=11/04/1998 MA=06/28/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Epirubicin TN= Ellence	Treatment of breast cancer.	Pharmacia & Upjohn Company 0634-298-113 7000 Portage Rd. Kalamazoo, MI 49001 DD=09/14/1999 MA=09/15/1999
Epoprostenol TN= Flolan	Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.	Glaxo Wellcome Inc. Five Moore Dr. PO Box 13398 Research Triangle Park, NC 27709 DD=03/22/1999
Etanercept TN= Enbrel	Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=10/27/1998 MA=05/27/1999
Etanercept TN= Enbrel	Treatment of Wegener's granulomatosis.	Stone, MD, MPH, John H. Johns Hopkins Vasculitis Center, Division of Rheumatology 1830 East Monument St., Suite 7500 Baltimore, MD 21205 DD=04/06/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Fluoxetine TN= Prozac	Treatment of autism.	Hollander, MD, Eric Mt. Sinai School of Medicine, Dept. of Psychiatry Box 1230, One Gustave L. Levy Place New York, NY 10029 DD=04/30/1999
Guanfacine TN= Tenex	Treatment of fragile X syndrome.	Watson Laboratories, Inc. 311 Bonnie Circle PO Box 1900 Corona, CA 91718 DD=08/05/1999
HLA-B7/Beta2M DNA Lipid (DMRIE/DOPE) Complex TN= Allovectin-7	Treatment of invasive and metastatic melanoma (Stages II, III, and IV).	Vical Incorporated 9373 Towne Centre Dr., Suite 100 San Diego, CA 92121 DD=09/30/1999
Humanized MAb (IDEC-131) to CD40L TN=	Treatment of systemic lupus erythematosus.	Idec Pharmaceuticals Corporation 3030 Callan Rd. San Diego, CA 92121 DD=02/09/1999
Interferon beta-1a (recombinant human) TN= Avonex	Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) TN= 131IchTNT-1	Treatment of glioblastoma multiforme and anaplastic astrocytoma.	Techniclone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Japanese encephalitis vaccine (live, attenuated) TN=	Prevention of Japanese encephalitis.	Boran Pharmaceuticals 3F, Koryo Academytel, 437-3 Ahyun-Dong, Mapo-Gu, Seoul 121-010 South Korea DD=05/19/1999
L-5-hydroxytrypt ophan TN=	Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA 91718 DD=01/20/1999
Lactic acid TN= Aphthaid	Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients.	Frontier Pharmaceutical, Inc. SUNY Farmingdale Conklin Hall Farmingdale, NY 11735 DD=06/29/1999
Lidocaine patch 5% TN= Lidoderm Patch	For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.	Hind Health Care, Inc. 3707 Williams Rd., Suite 101 San Jose, CA 95117 DD=10/24/1995 MA=03/19/1999
Liposomal-cis-bi s-neodecanoato-t rans-R,R-1,2-dia minocyclohexane- Pt (II) TN=	Treatment of malignant mesothelioma.	Aronex Pharmaceuticals, Inc. 8707 Technolgoy Forest Place The Woodlands, TX 77381 DD=09/01/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Lisofylline TN=	Treatment of patients undergoing induction therapy for acute myeloid leukemia.	Cell Therapeutics, Inc. 201 Elliot Ave. W., Suite 400 Seattle, WA 98119 DD=06/10/1999
Marijuana TN=	Treatment of HIV-associated wasting syndrome.	Multidisciplinary Association for Psychedelic Studies, Inc. 3 Francis St. Belmont, MA 02478 DD=05/25/1999
Mitoxantrone TN= Novantrone	Treatment of secondary-progressive multiple sclerosis.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=08/13/1999
Mitoxantrone TN= Novantrone	Treatment of progressive-relapsing multiple sclerosis.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=08/13/1999
Murine MAb to polymorphic epithelial mucin, human milk fat globule 1 TN= Theragyn	Adjuvant treatment of ovarian cancer.	Antisoma West Africa House Hanger Lane London W5 3QR, UK DD=03/22/1999
N-acetylgalactosamine-4-sulfatase, recombinant human TN=	Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=02/17/1999

Orphan Product Designations and Approvals List

September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine TN= MEDI-491	Prevention of transient aplastic crisis in patients with sickle cell anemia.	MedImmune, Inc. 35 West Watkins Mill Rd. Gaithersburg, MD 20878 DD=05/07/1999
Peginterferon alfa-2a TN= PEGASYS	Treatment of chronic myelogenous leukemia.	Hoffman-La Roche Inc. 340 Kingsland St. Nutley, NJ 07110 DD=09/30/1999
Pegylated arginine deiminase TN= Hepacid	Treatment of hepatocellular carcinoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=03/26/1999
Pegylated arginine deiminase TN= Melanocid	Treatment of invasive malignant melanoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=04/12/1999
Polyethylene glycol-modified uricase TN= Zurase	Prophylaxis of hyperuricemia in cancer patients prone to develop tumor lysis syndrome during chemotherapy.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=09/14/1999
Recombinant human C1-esterase inhibitor TN=	Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel, Belgium DD=02/23/1999

Orphan Product Designations and Approvals List September 1999

Name	Indication Designated	Sponsor & Address
Generic Name		DD= Date Designated
TN=Trade Name		MA=Marketing Approval
Recombinant human C1-esterase inhibitor TN=	Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel, Belgium DD=02/23/1999
Recombinant human insulin-like growth factor-I/insulin-like growth factor binding protein-3 TN=	Treatment of major burns that require hospitalization.	Celtrix Pharmaceuticals, Inc. 3055 Patrick Henry Dr. Santa Clara, CA 95054 DD=06/15/1999
Recombinant human nerve growth factor TN=	Treatment of HIV-associated sensory neuropathy.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=04/16/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of solid organ transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of pancreatic islet cell transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Rifalazil TN=	Treatment of pulmonary tuberculosis.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=04/13/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
SCH 58500 TN=	Treatment of primary ovarian cancer.	Schering Corporation 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=04/12/1999
Sodium 1,3-propanedisul fonate TN=	Treatment of secondary amyloidosis.	Neurochem, Inc. 7220 Frederick Banting, Suite 100 Saint-Laurent, Quebec Canada H4S 2A1 DD=04/06/1999
Sodium dichloroacetate TN= Ceresine	Treatment of severe head injury.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=06/14/1999
Somatropin [rDNA] TN= Genotropin	Treatment of short stature in patients with Prader-Willi syndrome.	Pharmacia & Upjohn 7000 Portage Rd. 0633-298-113 Kalamazoo, MI 49001 DD=07/06/1999
Synthetic human secretin TN=	For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 1550 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic human secretin TN=	For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999

Orphan Product Designations and Approvals List September 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Synthetic human secretin TN=	For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic porcine secretin TN=	For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Synthetic porcine secretin TN=	For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Synthetic porcine secretin TN=	For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Temozolomide TN= Temodar	Treatment of recurrent malignant glioma.	Schering-Plough Research Institute 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=10/05/1998 MA=08/11/1999
Thalidomide TN= Thalomid	Treatment of Crohn's disease.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=04/06/1999

Orphan Product Designations and Approvals List September 1999

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

Tobramycin TN= Tobl	Treatment of bronchiectasis patients infected with Pseudomonas aeruginosa.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=06/18/1999
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Transgenic human alpha 1 antitrypsin TN=	Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland U.K. DD=05/19/1999
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Yttrium-90 radiolabeled humanized monoclonal anti-carcinoembr yonic antigen IgG antibody TN= Cea-Cide	Treatment of ovarian carcinoma.	Immunomedics, Inc. 300 American Rd. Morris Plains, NJ 07950 DD=08/03/1999
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DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY ONLY
IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO SEPTEMBER 1999 ADDITIONS

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 19TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

NP* NEW PRODUCT (MINT FLAVORED)

REFERENCES

NEW DOSING SCHEDULE

D-50 INFORMATION FOR USE OF CORVERT IN POST-CARDIAC SURGERY PATIENTS

NEW INDICATION

- I-250 PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C
- I-251 TREATMENT OF GENERALIZED ANXIETY DISORDER
- I-252 NEW COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS METFORMIN
- I-253 COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS INSULIN
- I-254 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS (LOSS OF BONE MASS)
- I-255 PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP)
- I-256 USE IN TREATMENT OF SMALL CELL LUNG CANCER SENSITIVE DISEASE AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY
- I-257 TREATMENT OF CHRONIC HEPATITIS B ASSOCIATED WITH EVIDENCE OF HEPATITIS B VIRAL REPLICATION AND ACTIVE LIVER INFLAMMATION
- I-258 FOR PERENNIAL NONALLERGIC RHINITIS FOR AGES FOUR AND ABOVE
- I-259 PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT), WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY
- I-260 EXPANDED PEDIATRIC USE IN CHILDREN YOUNGER THAN ONE MONTH OF AGE TO BIRTH (WITH A GESTATIONAL AGE OF 37 WEEKS OR GREATER)
- I-261 TREATMENT OF SOCIAL ANXIETY DISORDER
- I-262 TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE AND FOR THE PREVENTION OF EXERCISE INDUCED BRONCHOSPASM IN CHILDREN AGES 4-12
- I-263 TREATMENT OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION FOR THE PREVENTION OF ISCHEMIC COMPLICATIONS IN PATIENTS ON CONCURRENT ASPIRIN THERAPY
- I-264 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH RADIATION, INCLUDING TOTAL BODY IRRADIATION (TBI) AND FRACTIONATED ABDOMINAL RADIATION
- I-265 TREATMENT OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS 6 YEARS AND OLDER
- I-266 USE OF TOPAMAX AS ADJUNCTIVE THERAPY IN PEDIATRIC PATIENTS AGES 2-16 YEARS WITH PARTIAL ONSET SEIZURES
- I-267 USE IN PEDIATRIC PATIENTS 3 MONTHS OLD AND OLDER-FOR CORTICOSTEROID-RESPONSIVE DERMATOSES
- I-268 PROPHYLAXIS AND CHRONIC TREATMENT OF ASTHMA IN PATIENTS 7-11 YEARS OF AGE

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

- I-269 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH HIGHLY EMETOGENIC CANCER CHEMOTHERAPY, INCLUDING CISPLATIN
- I-270 ADJUVANT TREATMENT OF NODE-POSITIVE BREAST CANCER ADMINISTERED SEQUENTIALLY TO STANDARD DOXORUBICIN-CONTAINING COMBINATION CHEMOTHERAPY
- I-271 TREATMENT OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
- I-272 TREATMENT OF GLUCOCORTICOID-INDUCED OSTEOPOROSIS IN MEN AND WOMEN RECEIVING GLUCOCORTICOID IN A DAILY DOSE EQUIVALENT TO 7.5MG OR GREATER OF PREDNISONE AND WHO HAVE LOW BONE MINERAL DENSITY
- I-273 ADJUNCT TO DIET TO INCREASE HDL-C IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA (HETEROZYGOUS FAMILIAL AND NONFAMILIAL) AND MIXED DYSLIPIDEMIA (FREDERICKSON TYPES IIA AND IIB)
- I-274 USE OF TOPAMAX AS ADJUNCTIVE THERAPY IN THE TREATMENT OF PRIMARY GENERALIZED TONIC-CLONIC SEIZURES

REFERENCES

MISCELLANEOUS EXCLUSIVITY CODES

- M-1 INFORMATION REGARDING SUPERIORITY CLAIM OVER RANITIDINE FOR DAY AND NIGHT HEARTBURN ADDED TO CLINICAL STUDIES SECTION

PATENT USE CODE

- U-254 USE OF AGGRASTAT IN COMBINATION WITH HEPARIN
- U-255 IMPROVED WAKEFULNESS IN PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY
- U-256 TREATMENT OF HIV INFECTION IN COMBINATION WITH ONE OR MORE ADDITIONAL HIV ANTIVIRAL AGENTS
- U-257 TREATMENT OF HIV INFECTION
- U-258 TREATMENT OF NEURODEGENERATIVE DISEASES
- U-259 TREATMENT OF ANDROGENIC ALOPECIA BY ORAL ADMINISTRATION OF DRUG SUBSTANCE
- U-260 REDUCTION OF INTRAOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION WHO ARE INTOLERANT OF OTHER IOP LOWERING MEDICATIONS OR INSUFFICIENTLY RESPONSIVE TO ANOTHER IOP LOWERING MEDICATION
- U-261 TREATING BENIGN PROSTATIC HYPERPLASIA WITH A GENUS OF COMPOUNDS, INCLUDING FINASTERIDE
- U-262 TREATING BENIGN PROSTATIC HYPERTROPHY WITH FINASTERIDE
- U-263 METHOD OF TREATING A MALIGNANT CONDITION THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING LEUKEMIA OR LYMPHOMA IN A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVENOUS ADMINISTRATION OF BUSULFAN.
- U-264 METHOD OF TREATING A MALIGNANT DISEASE THROUGH PARENTERAL ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN.
- U-265 USE AS A LAXATIVE
- U-266 OSTEOARTHRITIS
- U-267 METHOD FOR PREVENTING HEARTBURN
- U-268 ACROMEGALY
- U-269 EXCESS GH-SECRETION OR GASTRO-INTESTINAL DISORDERS
- U-270 METHOD FOR IMPROVING THE TIME FOR ADMINISTRATION OR THE TIME BETWEEN CHANGES OF GIVING SETS FOR THE DRUG PRODUCT
- U-271 METHOD OF TREATING TUMORS
- U-272 METHOD OF TREATING CARCINOMA

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

U-273	CUTANEOUS T-CELL LYMPHOMA
U-274	ZANAMIVIR FOR INHALATION
U-275	METHOD OF USE OF THE DRUG SUBSTANCE
U-276	METHOD OF USE OF LEVOBUPIVACAINE
U-277	NEUROLOGICAL AND OTHER DISORDERS (TREATMENT OF EPILEPSY, BID ORAL DOSING)
U-278	METHOD OF USE OF THE INDICATION OF THE DRUG PRODUCT
U-279	METHOD OF USE OF THE APPROVED PRODUCT
U-280	TREATING PRECIPITATED ACUTE URINARY RETENTION WITH FINASTERIDE
U-281	ANTIMYCOTIC USES, SPECIFICALLY, TREATMENT OF ONYCHOMYCOSIS
U-282	METHOD OF TREATING BACTERIAL INFECTIONS
U-283	METHOD FOR TREATING MENOPAUSAL SYMPTOMS IN A POSTMENOPAUSAL FEMALE

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020482 004	ACARBOSE; PRECOSE	4717720	MAY 31, 2010	U-134	I-252	SEP 29, 2001
020338 001	ADAPALENE; DIFFERIN	RE34440	MAR 31, 2010	U-275	I-253	SEP 29, 2001
020380 001	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010	U-134		
		RE34440	MAY 31, 2010	U-275		
020760 001	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE FREE	5164402	NOV 17, 2009	U-282		
		5164402	JUN 15, 2015	U-282		
020760 002	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE FREE	5164402	NOV 17, 2009	U-282		
		5763454	JUN 15, 2015	U-282		
020503 001	ALBUTEROL SULFATE; PROVENTIL-HFA	4594359	JUN 10, 2003		I-262	JUN 02, 2002
019621 001	ALBUTEROL SULFATE; VENTOLIN				I-272	JUN 16, 2002
>ADD>	ALENDRONATE SODIUM; FOSAMAX				I-272	JUN 16, 2002
>ADD>	ALENDRONATE SODIUM; FOSAMAX				I-272	JUN 16, 2002
>ADD>	ALITRETINOIN; PANRETIN				ODE	FEB 02, 2006
					NCE	FEB 02, 2004
020221 001	AMIFOSTINE; ETHYOL				ODE	JUN 24, 2006
020508 001	AMMONIUM LACTATE; LAC-HYDRIN				PED	FEB 29, 2000
021007 001	AMPRENAVIR; AGENERA				NCE	APR 15, 2004
021007 002	AMPRENAVIR; AGENERA				NCE	APR 15, 2004
020702 001	ATORVASTATIN CALCIUM; LIPITOR	5585397	DEC 17, 2013		NCE	APR 15, 2004
>ADD>	ATORVASTATIN CALCIUM; LIPITOR	5969156	JUL 08, 2016			
>ADD>	ATORVASTATIN CALCIUM; LIPITOR	5969156	JUL 08, 2016			
>ADD>	ATORVASTATIN CALCIUM; LIPITOR	5969156	JUL 08, 2016			
020702 003	ATORVASTATIN CALCIUM; LIPITOR					
020500 001	ATOVAQUONE; MEPRON					
020746 001	BUDESONIDE; RHINOCORT AQUA				ODE	JAN 05, 2006
020746 002	BUDESONIDE; RHINOCORT AQUA				I-255	JAN 05, 2002
020711 002	BUPROPION HYDROCHLORIDE; ZYBAN				NDF	OCT 01, 2002
020711 003	BUPROPION HYDROCHLORIDE; ZYBAN				NDF	OCT 01, 2002
020954 001	BUSULFAN; BUSULFEX	5763493	AUG 12, 2013			
		5763493	AUG 12, 2013			
		5430057	SEP 30, 2013	U-263	ODE	FEB 04, 2006
		5559148	MAY 24, 2015	U-264	NDF	FEB 04, 2002
020793 001	CAFFEINE CITRATE; CAFKIT	5759565	JUN 02, 2015		NE	SEP 21, 2002
020313 002	CALCITONIN, SALMON; MICALCIN	5472949	DEC 14, 2013	U-271		
020896 001	CAPECITABINE; XELODA	4966891	NOV 08, 2008	U-272		
		5472949	DEC 14, 2013	U-271		
020896 002	CAPECITABINE; XELODA	4966891	NOV 08, 2008	U-272		
020712 001	CARBAMAZEPINE; CARBATROL	5912013	JUN 15, 2016	U-277		
020712 002	CARBAMAZEPINE; CARBATROL	5912013	JUN 15, 2016	U-277		
020998 001	CELECOXIB; CELEBREX	5760068	JUN 02, 2015	U-19		
		5466823	NOV 30, 2013			
020998 002	CELECOXIB; CELEBREX	5563165	NOV 30, 2013			
		5760068	JUN 02, 2015	U-19		
		5466823	NOV 30, 2013			
		5563165	NOV 30, 2013			
020740 005	CERIVASTATIN SODIUM; BAYCOL	5006530	JAN 17, 2009		NS	MAY 24, 2002
		5177080	NOV 26, 2011			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020638 001	CIDOFOVIR; VISTIDE	5142051	JUN 26, 2010			
020863 001	CILOSTAZOL; PLETAL	4277479	AUG 29, 2000		NCE	JAN 15, 2004
020863 002	CILOSTAZOL; PLETAL	4277479	AUG 29, 2000		NCE	JAN 15, 2004
019537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	DEC 09, 2003	U-36		
		5286754	FEB 15, 2011			
020767 001	CISAPRIDE MONOHYDRATE; PROPULSID QUICKSOLV	5648093	JUL 15, 2014			
021041 001	CYTARABINE; DEPOCYT				ODE	APR 01, 2006
					NP	APR 01, 2002
020287 001	DALTEPARIN SODIUM; FRAGMIN				I-263	MAY 25, 2002
020287 003	DALTEPARIN SODIUM; FRAGMIN				I-259	MAR 30, 2002
020287 004	DALTEPARIN SODIUM; FRAGMIN				I-263	MAY 25, 2002
					I-259	MAR 30, 2002
017922 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
017922 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
017922 003	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
018938 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
018938 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
019955 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
019955 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013			
074752 001	DILTIAZEM HYDROCHLORIDE; CARTIA XT				PC	DEC 20, 1999
074752 003	DILTIAZEM HYDROCHLORIDE; CARTIA XT				PC	DEC 20, 1999
074752 004	DILTIAZEM HYDROCHLORIDE; CARTIA XT				PC	DEC 20, 1999
020449 001	DOCETAXEL; TAXOTERE	4814470	MAY 14, 2010			
		5438072	NOV 22, 2013			
		5698582	JUL 03, 2012			
		5714512	JUL 03, 2012			
>ADD>					NCE	OCT 01, 2004
>ADD>					NCE	OCT 01, 2004
>ADD>					NCE	OCT 01, 2004
020931 001	DOFETILIDE; TIKOSYN	4797413	APR 28, 2008			
020931 002	DOFETILIDE; TIKOSYN	4619939	OCT 28, 2003			
020931 003	DOFETILIDE; TIKOSYN	5602116	APR 03, 2115	U-278	NCE	JUN 09, 2004
020869 001	DORZOLAMIDE HYDROCHLORIDE; COSOPT	5707980	FEB 11, 2117	U-278		
020862 001	DOXERCALCIFEROL; HECTOROL				ODE	JUN 28, 2006
050718 001	DOXORUBICIN HYDROCHLORIDE; DOXIL	5811423	AUG 07, 2012	U-256		
020972 001	EFAVIRENZ; SUSTIVA	5519021	MAY 21, 2013			
		5663169	SEP 02, 2014	U-257		
020972 002	EFAVIRENZ; SUSTIVA	5811423	AUG 07, 2012	U-256		
		5519021	MAY 21, 2013			
		5663169	SEP 02, 2014	U-257		
020972 003	EFAVIRENZ; SUSTIVA	5519021	MAY 21, 2013			
		5663169	SEP 02, 2014	U-257		
>ADD>					ODE	SEP 15, 2006
050778 001	EPIRUBICIN HYDROCHLORIDE; ELLENCE	5811423	AUG 07, 2012	U-256		
020375 001	ESTRADIOL; CLIMARA				I-254	MAR 05, 2002
020375 002	ESTRADIOL; CLIMARA				I-254	MAR 05, 2002
020375 003	ESTRADIOL; CLIMARA				I-254	MAR 05, 2002

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020375 004	ESTRADIOL; CLIMARA	5223261	JUN 29, 2010		I-254	MAR 05, 2002
021040 002	ESTRADIOL; ORTHO-PREFEST				NP	OCT 22, 2002
020908 001	ESTRADIOL; VAGIFEM				NP	MAR 26, 2002
020992 002	ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN				NP	MAR 24, 2002
020992 003	ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN				NP	MAR 24, 2002
020527 001	ESTROGENS, CONJUGATED; PREMPRO 14/14					
020527 003	ESTROGENS, CONJUGATED; PREMPRO 14/14					
021065 001	ETHINYL ESTRADIOL; FEMHRT	RE36247	MAY 02, 2006			
021065 002	ETHINYL ESTRADIOL; FEMHRT	4826831	MAY 02, 2006			
021065 003	ETHINYL ESTRADIOL; FEMHRT	5547948	JAN 17, 2015			
020584 003	ETODOLAC; LODINE XL	RE36247	MAY 02, 2006			
020363 001	FAMCICLOVIR; FAMVIR	5208225	MAY 04, 2010	U-283 NP		OCT 15, 2002
020363 003	FAMCICLOVIR; FAMVIR	5208225	MAY 04, 2010	U-283 NP		OCT 15, 2002
020325 001	FAMOTIDINE; PEPCID AC	5208225	MAY 04, 2010	U-283 NP		OCT 15, 2002
020801 001	FAMOTIDINE; PEPCID AC	5208225	MAY 04, 2010			
		4966768	OCT 30, 2007			
		5246937	SEP 21, 2010	U-96		
		5246937	SEP 21, 2010	U-96		
		5854267	DEC 29, 2015	U-267		
		5667794	MAY 02, 2015			
		5854267	DEC 29, 2015	U-267		
		5075114	DEC 24, 2008			
		4895726	JAN 19, 2009			
019304 002	FENOFIBRATE; TRICOR (MICRONIZED)					
020747 001	FENTANYL CITRATE; ACTIQ				NP	NOV 04, 2001
020747 002	FENTANYL CITRATE; ACTIQ				NP	NOV 04, 2001
020747 003	FENTANYL CITRATE; ACTIQ				NP	NOV 04, 2001
020747 004	FENTANYL CITRATE; ACTIQ				NP	NOV 04, 2001
020747 005	FENTANYL CITRATE; ACTIQ				NP	NOV 04, 2001
020747 006	FENTANYL CITRATE; ACTIQ				NP	NOV 04, 2001
020955 001	FERRIC SODIUM GLUCONATE; FERRELECIT				NCE	FEB 18, 2004
020625 001	FEKOFENADINE HYDROCHLORIDE; ALLEGRA					
020788 001	FINASTERIDE; PROPECIA					
020180 001	FINASTERIDE; PROSCAR					
019452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTHIE/FS	5855912	FEB 28, 2015			
020101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	5738872	FEB 28, 2015			
020974 001	FLUOXETINE HYDROCHLORIDE; PROZAC	5571817	NOV 05, 2013	U-259		
020974 002	FLUOXETINE HYDROCHLORIDE; PROZAC	5886184	NOV 19, 2012	U-262		
		4760071	JUN 19, 2006			
		5886184	NOV 19, 2012			
		4377584	MAR 22, 2000	U-261		
		5942519	OCT 23, 2018	U-280		
		4626549	DEC 02, 2003		I-265	AUG 18, 2002
		4626549	DEC 02, 2003	U-84		
		4626549	DEC 02, 2003	U-154		
		4314081	FEB 02, 2001	U-154		
		4626549	DEC 02, 2003	U-84		
		4626549	DEC 02, 2003	U-154		
		4314081	FEB 02, 2001			
019958 001	FLUTICASONE PROPIONATE; CUTIVATE					
020121 001	FLUTICASONE PROPIONATE; FLONASE					
020882 001	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000		I-267	JUN 17, 2002
020882 002	GABAPENTIN; NEURONTIN	5084479	JAN 02, 2010		I-258	DEC 11, 2001
		4087544	JAN 16, 2000	U-106		
		5084479	JAN 02, 2010	U-258		
		4087544	JAN 16, 2000	U-106		
		5084479	JAN 02, 2010	U-258		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021057 001	GANIRELIX ACETATE; ANTAGON	4801577	FEB 05, 2007		NCE	JUL 29, 2004
020509 001	GEMCITABINE HYDROCHLORIDE; GEMZAR	5767082	JUN 16, 2015			
020509 002	GEMCITABINE HYDROCHLORIDE; GEMZAR	4808614	MAY 15, 2010			
020496 001	GLIMEPIRIDE; AMARYL	4808614	MAY 15, 2010			
020496 002	GLIMEPIRIDE; AMARYL	4379785	APR 06, 2005	U-118		
020496 003	GLIMEPIRIDE; AMARYL	4379785	APR 06, 2005	U-118		
020305 001	GRANISETRON HYDROCHLORIDE; KYTRIL	4379785	APR 06, 2005	U-118		
020305 002	GRANISETRON HYDROCHLORIDE; KYTRIL				I-264	JUL 27, 2002
020758 003	HYDROCHLOROTHIAZIDE; AVALIDE	5270317	MAR 20, 2011		I-264	JUL 27, 2002
020491 001	IBUTILIDE FUMARATE; CORVERT				NCE	SEP 30, 2002
020723 001	IMIQUIMOD; ALDARA	4689338	AUG 25, 2009	U-172	D-50	MAY 13, 2002
021028 001	INSULIN HUMAN; VELOSULIN BR				NP	JUL 19, 2002
020083 001	ITRACONAZOLE; SPORANOX	4791111	DEC 23, 2005			
020657 001	ITRACONAZOLE; SPORANOX	4791111	DEC 23, 2005			
020966 001	ITRACONAZOLE; SPORANOX	4791111	DEC 23, 2005			
		4267179	JUN 23, 2000			
021066 001	KETOTIFEN FUMARATE; ZADITOR				NCE	JUL 02, 2004
020564 001	LAMIVUDINE; EPIVIR	5905082	MAY 18, 2016			
021003 001	LAMIVUDINE; EPIVIR-HBV	5047407	FEB 08, 2009		I-257	DEC 08, 2001
		5532246	JUL 02, 2013	U-250		
021004 001	LAMIVUDINE; EPIVIR-HBV	5905082	MAY 18, 2016			
		5047407	MAY 18, 2016		I-257	DEC 08, 2001
		5532246	JUL 02, 2013	U-250		
020764 001	LAMOTRIGINE; LAMICTAL CD				I-247	DEC 14, 2001
020764 002	LAMOTRIGINE; LAMICTAL CD				I-247	DEC 14, 2001
020764 003	LAMOTRIGINE; LAMICTAL CD				I-247	DEC 14, 2001
020406 001	LANSOPRAZOLE; PREVACID	5905082	MAY 18, 2016		M-1	JUL 06, 2002
020406 002	LANSOPRAZOLE; PREVACID	5047407	FEB 08, 2009		M-1	JUL 06, 2002
020597 001	LATANOPROST; XALATAN	5532246	JUL 02, 2013			
020517 002	LEUPROLIDE ACETATE; LUPRON DEPOT-4	5296504	MAR 22, 2011	U-260		
020837 001	LEVABUTEROL HYDROCHLORIDE; XOPENEX	5422368	MAR 22, 2011	U-260		
020837 002	LEVABUTEROL HYDROCHLORIDE; XOPENEX	4599353	JUL 28, 2006	U-260		
020997 001	LEVOBUPIVACINE HYDROCHLORIDE; XIPENEX	4652441	NOV 01, 2004		NP	MAR 25, 2002
020997 002	LEVOBUPIVACINE HYDROCHLORIDE; XIPENEX				NP	MAR 25, 2002
020997 003	LEVOBUPIVACINE HYDROCHLORIDE; XIPENEX	5708011	OCT 13, 2014	U-276		
020997 004	LEVOBUPIVACINE HYDROCHLORIDE; XIPENEX	5708011	OCT 13, 2014	U-276		
021045 001	LEVONORGESTREL; PLAN B	5708011	OCT 13, 2014	U-276		
019941 001	LIDOCAINE; EMLA				NP	JUL 28, 2002
020612 001	LIDOCAINE; LIDODERM				I-260	MAR 11, 2002
019777 006	LISINAPRIL; ZESTRIL				ODE	MAR 19, 2006
019643 002	LOVASTATIN; MEVACOR	4374829	DEC 30, 2001			
019643 003	LOVASTATIN; MEVACOR	4231938	JUN 15, 2001		I-250	MAR 11, 2002
019643 004	LOVASTATIN; MEVACOR	4231938	JUN 15, 2001		I-250	MAR 11, 2002
021047 001	MENTROPINS (FSH; LH); REPRONEX	4231938	JUN 15, 2001		NP	AUG 27, 2002
021047 002	MENTROPINS (FSH; LH); REPRONEX				NP	AUG 27, 2002
020357 003	METFORMIN HYDROCHLORIDE; GLUCOPHAGE				NCE	MAR 03, 2000
020357 004	METFORMIN HYDROCHLORIDE; GLUCOPHAGE				NCE	MAR 03, 2000

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PRESCRIPTION AND OTC DRUG PRODUCT
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<u>>ADD></u>						
020357 005	METFORMIN HYDROCHLORIDE; GLUCOPHAGE	4845075	APR 11, 2009		NCE	MAR 03, 2000
020969 001	METHOXSALEN; UVADEX	5036102	JUL 30, 2008	U-273	NP	FEB 25, 2002
		4999375	MAR 12, 2008			
020968 001	MICONAZOLE NITRATE; MONISTAT DUAL- PAK	5514698	MAR 21, 2014		NP	JUN 30, 2002
020682 001	MIGLITOL; GLYSET	4639436	JAN 27, 2009	U-111		
020682 002	MIGLITOL; GLYSET	4639436	JAN 27, 2009	U-111		
020682 003	MIGLITOL; GLYSET	4639436	JAN 27, 2009	U-111		
020717 001	MODAFINIL; PROVIGIL	4177290	MAR 09, 1999			
		5618845	OCT 06, 2014	U-255		
		4927855	MAY 22, 2007	U-255		
020717 002	MODAFINIL; PROVIGIL	4177290	MAR 09, 1999			
		5618845	OCT 06, 2014	U-255		
		4927855	MAY 22, 2007	U-255		
018612 003	NICOTINE POLACRILEX; NICORETTE (MINT)	5656255	AUG 12, 2014		NP*	DEC 23, 2001
020066 003	NICOTINE POLACRILEX; NICORETTE (MINT)	5688530	NOV 18, 2014		NP*	DEC 23, 2001
020385 001	NICOTINE; NICOTROL	4395403	NOV 21, 2002			
021008 001	OCTREOTIDE ACETATE; SANDOSTATIN LAR	538739	JUL 23, 2013	U-268 ODE		NOV 25, 2005
		5639480	JUN 17, 2014	U-269		
		5922338	JUL 13, 2016			
021008 002	OCTREOTIDE ACETATE; SANDOSTATIN LAR	5222682	JUL 13, 2016			
		5688530	NOV 18, 2014	U-268 ODE		NOV 25, 2005
		4395403	NOV 21, 2002	U-269		
		538739	JUL 23, 2013			
		5639480	JUN 17, 2014			
		5922338	JUL 13, 2016			
021008 003	OCTREOTIDE ACETATE; SANDOSTATIN LAR	5222682	JUL 13, 2016			
		5688530	NOV 18, 2014	U-268 ODE		NOV 25, 2005
		4395403	NOV 21, 2002	U-269		
		538739	JUL 23, 2013			
		5639480	JUN 17, 2014			
		5922338	JUL 13, 2016			
020103 001	ONDANSETRON HYDROCHLORIDE; ZOFTRAN	5922682	JUL 13, 2016			
020103 002	ONDANSETRON HYDROCHLORIDE; ZOFTRAN	5688530	NOV 18, 2014	U-268 ODE		NOV 25, 2005
020766 001	ORLISTAT; XENICAL	4395403	NOV 21, 2002	U-269		
020897 001	OXYBUTYRIN CHLORIDE; DITROPAN XL	538739	JUL 23, 2013			
		5639480	JUN 17, 2014			
		5922338	JUL 13, 2016			
		5922682	JUL 13, 2016			
		4783337	SEP 16, 2003		I-269	AUG 27, 2002
		5674895	MAY 22, 2015		I-269	AUG 27, 2002
		5082668	SEP 16, 2003		NCE	APR 23, 2004
		5840754	MAY 22, 2015		NP	DEC 16, 2001
		4612008	SEP 16, 2003			
		4519801	JUL 12, 2002			
		5912268	MAY 22, 2015			
		5840754	MAY 22, 2015			
		5674895	MAY 22, 2015			
		5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4519801	JUL 12, 2002			
		5912268	MAY 22, 2015			
020897 002	OXYBUTYRIN CHLORIDE; DITROPAN XL	5840754	MAY 22, 2015		NP	DEC 16, 2001
		5674895	MAY 22, 2015			
		5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4519801	JUL 12, 2002			
		5912268	MAY 22, 2015			

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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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021073 002	PIOGLITAZONE HYDROCHLORIDE; ACTOS	4444779	JUL 27, 1999		NCE	JUL 15, 2004
021073 003	PIOGLITAZONE HYDROCHLORIDE; ACTOS	4687777	JAN 17, 2006			
		4444779	JUL 27, 1999		NCE	JUL 15, 2004
		4687777	JAN 17, 2006			
020698 001	POLYETHYLENE GLYCOL 3350; MIRALAX	5710183	JUL 14, 2015	U-265 NP		FEB 18, 2002
019627 002	PROPOFOL; DIPRIVAN	5714520	MAR 22, 2015			
		5714520*PED	SEP 22, 2015			
		5731355	MAR 22, 2015	U-217		
		5731355*PED	SEP 22, 2015			
		5731356	MAR 22, 2015	U-217		
		5731356*PED	SEP 22, 2015			
		5908869	MAR 22, 2015	U-218		
		5908869*PED	SEP 22, 2015			
		5908869	MAR 22, 2015	U-270		
		5908869*PED	SEP 22, 2015			
075102 001	PROPOFOL; PROPOFOL				PC	OCT 17, 1999
020639 004	QUETIAPINE FUMARATE; SEROQUEL	4879288	MAR 20, 2007		NCE	SEP 26, 2002
020973 002	RABEPRAZOLE SODIUM; ACIPHEX				NCE	AUG 19, 2004
020815 001	RALOXIFENE HYDROCHLORIDE; EVISTA				I-271	SEP 30, 2002
075094 001	RANITIDINE HYDROCHLORIDE; RANITIDINE HCL				PC	JAN 14, 2000
020984 001	RAPACURONIUM BROMIDE; RAPLON	5418226	APR 14, 2013		NCE	AUG 18, 2004
020984 002	RAPACURONIUM BROMIDE; RAPLON	5418226	APR 14, 2013		NCE	AUG 18, 2004
020903 001	RIBAVIRIN; REBETOL	5914128	DEC 22, 2017			
020272 007	RISPERIDONE; RISPERDAL	5158952	OCT 27, 2009	U-90 D-37		OCT 17, 2000
		4804663	DEC 29, 2007	U-90		
		5158952	OCT 27, 2009	U-90 D-37		OCT 17, 2000
020272 008	RISPERIDONE; RISPERDAL	5948436	SEP 13, 2013			
020680 001	RITONAVIR; NORVIR	5457895	OCT 01, 2013			
020865 001	RIZATRIPTAN BENZOATE; MAXALT-MLT	5457895	OCT 01, 2013			
020865 002	RIZATRIPTAN BENZOATE; MAXALT-MLT	5474995	JUN 24, 2013	U-266 NCE		MAY 20, 2004
021042 001	ROFECOXIB; VIOXX	5691374	NOV 25, 2017			
021042 002	ROFECOXIB; VIOXX	5474995	JUN 24, 2013	U-266 NCE		MAY 20, 2004
021052 001	ROFECOXIB; VIOXX	5691374	NOV 25, 2017			
021052 002	ROFECOXIB; VIOXX	5474995	JUN 24, 2013	U-266 NCE		MAY 20, 2004
021052 002	ROFECOXIB; VIOXX	5691374	NOV 25, 2017			
021071 002	ROSIGLITAZONE MALEATE; AVANDIA				NCE	MAY 25, 2004
021071 003	ROSIGLITAZONE MALEATE; AVANDIA				NCE	MAY 25, 2004
021071 004	ROSIGLITAZONE MALEATE; AVANDIA				NCE	MAY 25, 2004
019766 001	SIMVASTATIN; ZOCOR				I-273	AUG 05, 2002
019766 002	SIMVASTATIN; ZOCOR				I-273	AUG 05, 2002
019766 003	SIMVASTATIN; ZOCOR				I-273	AUG 05, 2002
019766 004	SIMVASTATIN; ZOCOR				I-273	AUG 05, 2002
019766 005	SIMVASTATIN; ZOCOR				I-273	AUG 05, 2002
021083 001	SIROLIMUS; RAPAMUNE				NCE	SEP 15, 2004
019640 005	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				I-182	DEC 30, 1999
					ODE	DEC 30, 2003
019640 006	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				I-182	DEC 30, 1999
					ODE	DEC 30, 2003

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
019640 007	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				I-182	DEC 30, 1999
021012 001	TECHNETIUM TC-99M DEPREOTIDE; NEO TECH KIT				ODE	DEC 30, 2003
021029 001	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010		NCE	AUG 03, 2004
021029 002	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010		NCE	AUG 11, 2004
021029 003	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010		NCE	AUG 11, 2006
021029 004	TEMOZOLOMIDE; TEMODAR	5260291	NOV 09, 2010		NCE	AUG 11, 2006
074823 001	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL				ODE	AUG 11, 2004
074823 002	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL				NCE	AUG 11, 2004
074823 003	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL				PC	FEB 09, 2000
074823 004	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL				PC	FEB 09, 2000
020539 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	4680291	JUL 14, 2004	U-281	PC	FEB 09, 2000
020749 001	TERBINAFINE HYDROCHLORIDE; LAMISIL					
020980 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	4680291	JUL 14, 2004	U-73	NCE	DEC 30, 1999
020846 001	TERBINAFINE; LAMISIL	4755534	DEC 30, 2006	U-73	NCE	DEC 30, 1999
019762 001	TESTOSTERONE; TESTODERM				NP	APR 29, 2001
019762 002	TESTOSTERONE; TESTODERM				NCE	DEC 30, 1999
020646 005	TIAGABINE HYDROCHLORIDE; GABITRIL	5840327	AUG 15, 2016			
020912 001	TIROFIBAN HYDROCHLORIDE; AGGRASTAT	5840327	AUG 15, 2016			
020913 001	TIROFIBAN HYDROCHLORIDE; AGGRASTAT	5010090	OCT 07, 2008			
020505 001	TOPIRAMATE; TOPAMAX	5354760	MAR 24, 2012			
020505 002	TOPIRAMATE; TOPAMAX	5292756	MAY 14, 2012			
020505 003	TOPIRAMATE; TOPAMAX	5880136	SEP 27, 2010	U-230		
020505 004	TOPIRAMATE; TOPAMAX	5292756	MAY 14, 2012	U-230		
020505 005	TOPIRAMATE; TOPAMAX	5880136	SEP 27, 2010	U-254		
020505 006	TOPIRAMATE; TOPAMAX					
020844 001	TOPIRAMATE; TOPAMAX SPRINKLE					
020844 002	TOPIRAMATE; TOPAMAX SPRINKLE					
020844 003	TOPIRAMATE; TOPAMAX SPRINKLE					
020671 001	TOPOTECAN HYDROCHLORIDE; HYCAMTIN					
020759 001	TROVAFLOXACIN MESYLATE; TROVAN					
		5164402	NOV 17, 2009	U-282		
		5763454	JUN 15, 2015	U-282		

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020759 002	TROVAFLOXACIN MESYLATE; TROVAN	5164402	NOV 17, 2009	U-282		
020900 001	UREA, C-13; PYLORI-CHEK BREATH TEST	5763454	JUN 15, 2015	U-282	NCE	SEP 17, 2001
020699 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-251	MAR 11, 2002
020699 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-251	MAR 11, 2002
020699 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-251	MAR 11, 2002
020699 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR				I-251	MAR 11, 2002
019614 004	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	JUN 19, 2007			
020943 001	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007			
020943 002	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007			
020943 003	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007			
020547 001	ZAFIRLUKAST; ACCOLATE					
020859 001	ZALEPLON; SONATA	4626538	JUN 23, 2003		I-268	SEP 17, 2002
020859 002	ZALEPLON; SONATA	4626538	JUN 23, 2003		NCE	AUG 13, 2004
021036 001	ZANAMIVIR; RELENZA	D379506	MAY 27, 2011		NCE	AUG 13, 2004
		4778054	OCT 18, 2005			
		4811731	JUL 29, 2006			
		5035237	JUL 30, 2008			
		5360817	NOV 01, 2011			
		5648379	JUL 15, 2014	U-274		
		4627432	DEC 09, 2003			

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