

CUMULATIVE
SUPPLEMENT 9
SEPTEMBER 2000

APPROVED DRUG PRODUCTS

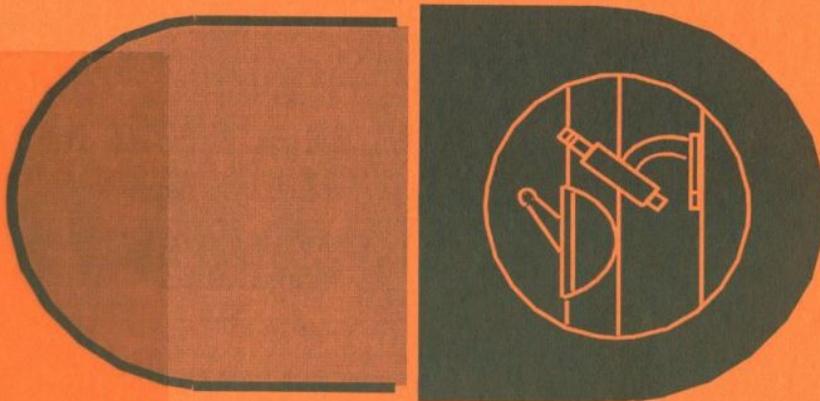
WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

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

2000

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

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New 21st Edition



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**21ST EDITION
2001**

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

Cumulative Supplement 9

September 2000

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.....	vi
1.4 Availability of the Edition.....	vi
1.5 Report of Counts for the Prescription Drug Product List.....	viii
DRUG PRODUCT LISTS	
Prescription Drug Product List.....	1-1
OTC Drug Product List	2-1
Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List.....	3-1
Orphan Product Designations and Approvals List	4-1
Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution	5-1
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Patent and Exclusivity Lists	A-1
B. Patent and Exclusivity Terms.....	B-1

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

CUMULATIVE SUPPLEMENT 9
SEPTEMBER 2000

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 20th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 20h Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st Edition.

1.2 APPLICANT NAME CHANGES

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

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

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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

GALDERMA LABS INC
(GALDERMA)

GALDERMA LABORATORIES LP
(GALDERMA LABS LP)

GLOBAL PHARMACEUTICAL CORP
(GLOBAL PHARM)

IMPAX LABORATORIES INC
(IMPAX LABS)

HOECHST MARION ROUSSEL INC
(HOECHST MARION RSSL)

AVENTIS PHARMACEUTICALS INC
(AVENTIS PHARMS)

RHONE POULENC RORER PHARMACEUTICALS INC
(RHONE POULENCE RORER)

AVENTIS PHARMACEUTICALS PRODUCTS INC
(AVENTIS PHARM PROD)

ROCHE GLOBAL DEVELOPMENT
(ROCHE GLOBAL)

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

SYNTEX (USA) INC
(SYNTEX)

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

SYNTEX FP INC
(SYNTEX)

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

SYNTEX LABORATORIES INC
SUB SYNTEX CORP
(SYNTEX)

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

SYNTEX USA INC
(SYNTEX)

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

TAP HOLDINGS INC
(TAP HOLDINGS)

TAP PHARMACEUTICAL PRODUCTS INC
(TAP PHARM)

ZENECA INC
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP
(ASTRAZENECA PHARMS)

ZENECA LTD
(ZENECA)

ASTRAZENECA UK LTD
(ASTRAZENECA UK)

ZENECA PHARMACEUTICALS DIV ZENECA INC
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP
(ASTRAZENECA PHARMS)

1.3 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%

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

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

1.4 AVAILABILITY OF THE EDITION

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

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

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

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

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

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

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

There are A
<http://www>.
are updated
Appendix A

The 20th an
<http://www>.

The current
<http://www>.

The Drug P
with all new
information
<http://www>.
<http://www>.

The current
<http://www>.

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

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

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

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

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

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1999) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LISTCOUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 1999</u>	<u>MAR 2000</u>	<u>JUN 2000</u>	<u>SEP 2000</u>
DRUG PRODUCTS LISTED	10045	10082	10186	10332
SINGLE SOURCE	2599 (25.9%)	2596 (25.7%)	2617 (25.7%)	2662 (25.8%)
MULTISOURCE	7335 (73.0%)	7375 (73.2%)	7458 (73.2%)	7560 (73.2%)
THERAPEUTICALLY EQUIVALENT	6986 (69.5%)	7040 (69.8%)	7132 (70.0%)	7238 (70.1%)
NOT THERAPEUTICALLY EQUIVALENT	349 (3.5%)	335 (3.3%)	326 (3.2%)	322 (3.1%)
EXCEPTIONS ¹	111 (1.1%)	111 (1.1%)	111 (1.1%)	110 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	0	6	11	7
NUMBER OF APPLICANTS	576	575	580	587

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

PRESCRIPTION DRUG PRODUCT LIST
20TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL

PHENILIN FORTE

AB + AMARIN PHARMS 650MG; 50MG

AB * CARRICK 650MG; 50MG

TABLET; ORAL

PHENILIN

AB + AMARIN PHARMS 325MG; 50MG

AB * CARRICK 325MG; 50MG

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL

AA ACETAMINOPHEN AND CODEINE PHOSPHATE

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

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA BARR 500MG; 2.5MG

AA 500MG; 5MG

AA 500MG; 7.5MG

AA 500MG; 10MG

AA 650MG; 7.5MG

AA 650MG; 10MG

AA 750MG; 7.5MG

AA 325MG; 7.5MG

AA 325MG; 10MG

AA 325MG; 7.5MG

AA + UCB

> ADD >

> ADD >

> ADD >

> ADD >

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA UCB 325MG; 10MG

* 325MG; 7.5MG

> DLT >

> DLT >

AA VINTAGE PHARMS

AA 325MG; 10MG

AA 500MG; 10MG

AA 660MG; 10MG

AA 660MG; 10MG

AA WATSON LABS

LORTAB

* UCB 325MG; 5MG

+ 325MG; 5MG

AA NORCO 325MG; 10MG

* 325MG; 10MG

N40248 002

APR 28, 2000

N40248 001

APR 28, 2000

N40355 001

MAY 31, 2000

N40356 001

MAY 31, 2000

N40358 001

MAY 31, 2000

N40094 003

AUG 08, 2000

N40099 001

JUN 25, 1997

N40099 001

JUN 25, 1997

N40148 001

FEB 14, 1997

N40148 001

FEB 14, 1997

N40307 001

JUL 26, 2000

N40308 001

JUL 26, 2000

N40307 002

JUL 26, 2000

N40309 001

JUL 26, 2000

N40307 003

JUL 26, 2000

N40307 004

JUL 26, 2000

N40308 002

JUL 26, 2000

N40405 001

SEP 08, 2000

N40400 001

JUL 26, 2000

N40248 001

APR 28, 2000

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE HCL AND ACETAMINOPHEN

AB WATSON LABS 650MG; EQ 25MG BASE

AB TALACEN 650MG; EQ 25MG BASE

* SANOFI SYNTHELABO 650MG; EQ 25MG BASE

* 650MG; EQ 25MG BASE

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

AB BARR 500MG

AB 500MG

N70870 001

FEB 09, 1987

N70870 001

FEB 09, 1987

N74699 001

MAR 24, 2000

N18458 001

SEP 23, 1982

N18458 001

SEP 23, 1982

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

ACETOHEXAMIDE

TABLET, ORAL

AB AB AB *
AB @
AB @

250MG
 500MG
 250MG
 500MG

N13378 002
 N13378 001
 N13378 002
 N13378 001

INJECTABLE; INJECTION
 OPTISON

* MOLECULAR BIOSYSTEMS 10MG/ML

N20899 001
 AUG 01, 1996
 DEC 31, 1997

ACYCLOVIR

CAPSULE, ORAL

AB AB *
AB @

200MG
 200MG

N74870 002
 APR 22, 1997
 N74570 002
 APR 22, 1997

AEROSOL, METERED; INHALATION

AB AB
 MEDISOL

0.09MG/INH
 0.09MG/INH

N74072 001
 AUG 01, 1996
 N74072 001
 AUG 01, 1996

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

AP AP
 APOTHECON

EQ 500MG BASE/VIAL
 EQ 1GM BASE/VIAL
 EQ 500MG BASE/VIAL
 EQ 1GM BASE/VIAL

N74897 001
 FEB 27, 1998
 N74897 002
 FEB 27, 1998
 N74897 001
 FEB 27, 1998
 N74897 002
 FEB 27, 1998

SOLUTION; INHALATION

AN AN
 BAUSCH AND LOMB

EQ 0.083% BASE

N75358 001
 MAR 29, 2000

ADAPALENE

CREAM; TOPICAL
 DIFFERIN

+ GALDERMA LABS LP

0.1%

N20748 001
 MAY 26, 2000

ALBUMIN HUMAN

INJECTABLE; INJECTION

AB AB
 OPTISON
 + MALLINCKRODT

10MG/ML

N20899 001
 DEC 31, 1997

ALOSETRON HYDROCHLORIDE

AB AB
 TABLET; ORAL
 LOTRONEX

+ GLAXO WELLCOME

EQ 1MG BASE

N21107 001
 FEB 09, 2000

AB AB
 TABLET; ORAL
 ALBUTEROL SULFATE
 MD PHARM

EQ 2MG BASE

N73120 001
 SEP 29, 1992
 N73121 001
 SEP 29, 1992
 N73120 001
 SEP 29, 1992
 N73121 001
 SEP 29, 1992

AB AB
 @ MEDEVA PHARMS CA

EQ 2MG BASE

N73120 001

@

EQ 4MG BASE

N73121 001

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

INJECTABLE; INJECTION
MULTI-12
+ SABEX
2 IU/ML; 20MG/ML; 12 UGM/ML; 40 IU/ML;
1 UGM/ML; 3MG/ML; 80 UGM/ML; 8MG/ML;
0.8MG/ML; 0.72MG/ML; 0.6MG/ML;
600 IU/ML
N21163 001
MAY 18, 2000

ALPRAZOLAM

TABLET; ORAL
ALPRAZOLAM
ROXANE

AB 0.25MG N74199 001
OCT 19, 1993
AB 0.5MG N74199 002
OCT 19, 1993
AB 1MG N74199 003
OCT 19, 1993
@ 0.25MG N74199 001
OCT 19, 1993
@ 0.5MG N74199 002
OCT 19, 1993
@ 1MG N74199 003
OCT 19, 1993

ALTRETAMINE

CAPSULE; ORAL
HEXALEN
+ MEDIMMUNE ONCOLOGY
* US BIOSCIENCE

N19926 001
DEC 26, 1990
N19926 001
DEC 26, 1990

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL
GENEVA PHARMS TECH

N71293 001
FEB 18, 1987

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL
MYLAN

N71293 001
FEB 18, 1987

AMIFOSTINE

INJECTABLE; INJECTION
ETHYOL
+ MEDIMMUNE ONCOLOGY
* US BIOSCIENCE

N20221 001
DEC 08, 1995
N20221 001
DEC 08, 1995

AMINO ACIDS

INJECTABLE; INJECTION
NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER
BAKTER HILFCARE

N20107 001
FEB 05, 1993
N20107 001
FEB 05, 1993

@
TROPHAMINE
B BRAUN

N19018 001
JUL 20, 1984
N19018 001
JUL 20, 1984

+
TROPHAMINE 10%
B BRAUN

N19018 003
SEP 07, 1988
N19018 003
SEP 07, 1988

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE
GLOBAL PHARM

N84574 001
N84574 001
N84574 001
N84574 001

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
AMIODARONE HCL
+ EON

400MG

N75315 002
JUN 30, 2000
> DLT >
> DLT >
> ADD >
> ADD >

TABLET; ORAL
AUGMENTIN '500'

* SMITHKLINE BEECHAM

500MG;EQ 125MG BASE
500MG;EQ 125MG BASE

N50564 002
AUG 06, 1984
N50564 002
AUG 06, 1984

AMOXICILLIN; CLAVULANATE POTASSIUM

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE
SACCHARATE; DEXTROAMPHETAMINE SULFATE

TABLET; ORAL
ADDERALL 12.5
SHIRE LABS
3.125MG;3.125MG;3.125MG;
3.125MG
N11522 012
AUG 31, 2000
ADDERALL 15
SHIRE LABS
3.75MG;3.75MG;3.75MG;
3.75MG
N11522 013
AUG 31, 2000
ADDERALL 7.5
+ SHIRE LABS
1.875MG;1.875MG;1.875MG;
1.875MG
N11522 011
AUG 31, 2000

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL
MD PHARM

10MG
25MG
50MG
75MG
100MG
150MG

N85864 001
N85935 001
N85936 001
N86337 001
N86338 001
N86339 001

TABLET; ORAL
ADDERALL 12.5
SHIRE LABS

ADDERALL 15
SHIRE LABS

ADDERALL 7.5
+ SHIRE LABS

AMOXICILLIN

TABLET; ORAL
AMOXICILLIN
TEVA

500MG
875MG

N65056 001
SEP 18, 2000
N65056 002
SEP 18, 2000

TABLET; ORAL
AGRYLIN
ROBERTS LABS

EQ 0.5MG BASE
EQ 1MG BASE

EQ 0.5MG BASE
EQ 0.5MG BASE
EQ 1MG BASE

AMOXIL

SMITHKLINE BEECHAM

500MG
875MG
875MG

N50754 002
JUL 10, 1998
N50754 001
JUL 10, 1998
N50754 002
JUL 10, 1998
N50754 001
JUL 10, 1998

INJECTABLE; INJECTION
NORMIFLO

+ PHARMACIA AND UPJOHN 5,000 UNITS/0.5ML

N20227 002
MAY 23, 1997

ARDEPARIN SODIUM
 INJECTABLE; INJECTION
 + PHARMACIA AND UPJOHN 10,000 UNITS/0.5ML

* WYETH AVERST
 *
 N20227 001
 MAY 23, 1997
 N20227 002
 MAY 23, 1997
 N20227 001
 MAY 23, 1997
 N20227 001
 MAY 23, 1997

ARGATROBAN
 INJECTABLE; INJECTION
 + TX BIOTECH 100MG/ML

ARSENIC TRIOXIDE
 INJECTABLE; INJECTION
 + CELL THERAP 1MG/ML

ARTICAINA HYDROCHLORIDE; EPINEPHRINE
 INJECTABLE; INJECTION
 + DEPROCO 4%;EQ 0.01MG BASE/ML

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E
 INJECTABLE; INJECTION
 + AMARIN PHARMS 0.025MG;1MG
 * CARRICK 0.025MG;1MG
 MOTOFEN HALF-STRENGTH
 @ AMARIN PHARMS 0.025MG;0.5MG
 @ CARRICK 0.025MG;0.5MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE
 TABLET; ORAL
 MOTOFEN
 + AMARIN PHARMS 0.025MG;1MG
 * CARRICK 0.025MG;1MG
 MOTOFEN HALF-STRENGTH
 @ AMARIN PHARMS 0.025MG;0.5MG
 @ CARRICK 0.025MG;0.5MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE
 TABLET; ORAL
 DIPHENOXYLATE HCL AND ATROPINE SULFATE
 PAR PHARM 0.025MG;2.5MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE
 TABLET; ORAL
 DIPHENOXYLATE HCL AND ATROPINE SULFATE
 PAR PHARM 0.025MG;2.5MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE
 TABLET; ORAL
 DIPHENOXYLATE HCL AND ATROPINE SULFATE
 PAR PHARM 0.025MG;2.5MG

N20227 001
 MAY 23, 1997
 N20227 002
 MAY 23, 1997
 N20227 001
 MAY 23, 1997
 N20227 001
 MAY 23, 1997

N20883 001
 JUN 30, 2000

N21248 001
 SEP 25, 2000

N20971 001
 APR 03, 2000

N21078 001
 JUL 14, 2000
 N21078 002
 JUL 14, 2000
 N17744 002
 N17744 002
 N17744 001
 N17744 001

N40357 001
 MAY 02, 2000

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
ENLON-PLUS

+ BAXTER PHARM PROD 0.14MG/ML; 1.0MG/ML
+ 0.14MG/ML; 1.0MG/ML
* OHMEDA 0.14MG/ML; 1.0MG/ML
* 0.14MG/ML; 1.0MG/ML

N19677 001
NOV 06, 1991
N19678 001
NOV 06, 1991
N19677 001
NOV 06, 1991
N19678 001
NOV 06, 1991

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE
GENEVA PHARMS TECH

AA 2MG
AA 0.5MG
AA 1MG
AA 2MG

N72266 001
FEB 27, 1989
N72264 001
FEB 27, 1989
N72265 001
FEB 27, 1989
N72266 001
FEB 27, 1989

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OPTIVAR

+ ASTA 0.05%

N21127 001
MAY 22, 2000

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
BETAXOLOL

AT EQ 0.5% BASE
> ADD >
> ADD >
AT AKORN
AT NOVEX
AT BETOPTIC
AT + ALCON

N75386 001
JUN 30, 2000
N75446 001
SEP 28, 2000
N19270 001
AUG 30, 1985
N19270 001
AUG 30, 1985

BALSALAZIDE DISODIUM

CAPSULE; ORAL
COLAZAL
+ SALIX

750MG

N20610 001
JUL 18, 2000

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

QVAR 40 0.04MG/INH
+ 3M
QVAR 80 0.08MG/INH
+ 3M

N20911 002
SEP 15, 2000
N20911 001
SEP 15, 2000

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

URECHOLINE

* MERCK
@ 5MG/ML
@ 5MG/ML

N06536 001
N06536 001

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

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE
GENEVA PHARMS TECH

AA 0.5MG
AA 1MG

N72264 001
FEB 27, 1989
N72265 001
FEB 27, 1989

TABLET; ORAL
BETHANECHOL CHLORIDE
DANBURY PHARMA

AA 10MG
AA 25MG
AA 50MG
@ 10MG
@ 25MG
@ 50MG
DUVOID
ROBERTS LABS

N84408 001
N84441 001
N87444 001
N84408 001
N84441 001
N87444 001
N84408 001
N84441 001
N87444 001
N86262 001
N86263 001
N85882 001
N86262 001

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

ZIAC

50MG; 6.25MG

10MG; 6.25MG

N20186 001
MAR 26, 1993
N20186 002
MAR 26, 1993

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE
HYDROCHLORIDE

SYRUP; ORAL

MYPHETANE DC

AA * MORTON GROVE

2MG/5ML; 10MG/5ML;

12.5MG/5ML

N88904 001
FEB 21, 1985

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN

FAULDING

EQ 15 UNITS BASE/VIAL

N65031 001

MAR 10, 2000

EQ 30 UNITS BASE/VIAL

N65031 002

MAR 10, 2000

EQ 15 UNITS BASE/VIAL

N65033 001

JUN 27, 2000

EQ 30 UNITS BASE/VIAL

N65033 002

JUN 27, 2000

BUDESONIDE

SUSPENSION; INHALATION

PULMICORT RESPULES

ASTRAZENECA PHARMS

0.25MG/2ML

N20929 001

AUG 08, 2000

0.5MG/2ML

N20929 002

AUG 08, 2000

1MG/2ML

N20929 003

AUG 08, 2000

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

ASTRAZENECA

50MG/ML

N71151 001

AUG 10, 1987

50MG/ML

N71151 001

AUG 10, 1987

BUPROPION HYDROCHLORIDE

TABLET; ORAL

BUPROPION HCL

INVAMED

75MG

N75584 001

FEB 07, 2000

100MG

N75584 002

FEB 07, 2000

75MG

N75491 001

APR 17, 2000

100MG

N75491 002

APR 17, 2000

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE
HYDROCHLORIDE

SYRUP; ORAL

DIMETANE-DC

ROBINS AH

2MG/5ML; 10MG/5ML;

12.5MG/5ML

N11694 006

MAR 29, 1984

2MG/5ML; 10MG/5ML;

12.5MG/5ML

N11694 006

MAR 29, 1984

2MG/5ML; 10MG/5ML;

12.5MG/5ML

N88904 001

FEB 21, 1985

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR

* BRISTOL MYERS SQUIBB

15MG

N18731 003

APR 22, 1996

30MG

N18731 004

APR 22, 1996

15MG

N18731 003

APR 22, 1996

30MG

N18731 004

APR 22, 1996

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION
BUTORPHANOL TARTRATE

AP

ABBOTT

1MG/ML

N75559 001
MAR 20, 2000

2MG/ML

N75559 002
MAR 20, 2000

CALCIUM CHLORIDE

INJECTABLE; INJECTION
CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER

+ ABBOTT

100MG/ML

N21117 001
JAN 28, 2000

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC
CARDIOLEGIC IN PLASTIC CONTAINER

AT

BAXTER HLTHCARE

17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML N75323 001
APR 21, 2000

PLEGISOL IN PLASTIC CONTAINER

AT

ABBOTT

17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML N18608 001
FEB 26, 1982

17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML N18608 001
FEB 26, 1982

CANDESARTAN CILEXETIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL
ATACAND HCT
ASTRAZENECA

> ADD >

16MG; 12.5MG

N21093 001
SEP 05, 2000

32MG; 12.5MG

N21093 002
SEP 05, 2000

CANDICIDIN

GINTMENT; VAGINAL
VANOBID
@ AVENTIS PHARMS

> ADD >

0.6MG/GM

N61596 001

CANDICIDIN

GINTMENT; VAGINAL
VANOBID

* HOECHST MARION RSSL

0.6MG/GM

N61596 001

TABLET; VAGINAL
VANOBID

@ AVENTIS PHARMS

3MG

N61613 001

* HOECHST MARION RSSL

3MG

N61613 001

CAPTOPRIL; HYDROCHLOROTHIAZIDE

TABLET; ORAL

CAPTOPRIL AND HYDROCHLOROTHIAZIDE

DANBURY PHARMA

50MG; 25MG

N74832 001

DEC 29, 1997

N74832 001

DEC 29, 1997

50MG; 25MG

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA

MYLAN

25MG; 100MG

N75091 002

APR 21, 2000

SINEMET CR

DUPONT PHARMS

25MG; 100MG

N19856 002

DEC 24, 1992

N19856 002

DEC 24, 1992

25MG; 100MG

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

COREPHARMA

350MG

N40397 001

SEP 21, 2000

> ADD >

> ADD >

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL

ALCON

1%

N75476 001

JAN 03, 2000

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL

AT BAUSCH AND LOMB 1% EQ 500MG BASE/VIAL

AT OCUPRESS 1% EQ 1GM BASE/VIAL

AT + CIBA 1% EQ 2GM BASE/VIAL

* EQ 10GM BASE/VIAL

N75546 001
JAN 20, 2000

N19972 001
MAY 23, 1990

N19972 001
MAY 23, 1990

N64201 001
MAR 24, 2000

N64201 002
MAR 24, 2000

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN AND DEXTROSE

+ B BRAUN EQ 500MG BASE/VIAL

+ EQ 1GM BASE/VIAL

CEFAZOLIN SODIUM

AM PHARM PARTNERS

AP EQ 1MG BASE/VIAL

AP EQ 1GM BASE/VIAL

N50779 001
JUL 27, 2000

N50779 002
JUL 27, 2000

N64169 002
AUG 14, 1998

N64169 002
AUG 14, 1998

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

CEFOTAXIME

AP AM PHARM PARTNERS EQ 500MG BASE/VIAL

AP EQ 1GM BASE/VIAL

AP EQ 2GM BASE/VIAL

AP EQ 10GM BASE/VIAL

+

EQ 20GM BASE/VIAL

CLAFORAN

AP AVENTIS PHARMS EQ 500MG BASE/VIAL

AP EQ 1GM BASE/VIAL

AP EQ 2GM BASE/VIAL

AP EQ 10GM BASE/VIAL

* HOECHST MARION RSSE

* EQ 500MG BASE/VIAL

* EQ 1GM BASE/VIAL

* EQ 2GM BASE/VIAL

* EQ 10GM BASE/VIAL

N64200 001
MAR 24, 2000

N64200 002
MAR 24, 2000

N64200 003
MAR 24, 2000

N64201 001
MAR 24, 2000

N64201 002
MAR 24, 2000

N64201 002
MAR 24, 2000

N50547 001
N50547 002
N50547 003
N50547 004
DEC 29, 1983

N50547 001
N50547 002
N50547 003
N50547 004
DEC 29, 1983

CEFDINIR

CAPSULE; ORAL

OMNICEF

+ ABBOTT 300MG

* PARKE DAVIS 300MG

POWDER FOR RECONSTITUTION; ORAL

OMNICEF

+ ABBOTT 125MG/5ML

* PARKE DAVIS 125MG/5ML

N50739 001
DEC 04, 1997

N50739 001
DEC 04, 1997

N50739 001
DEC 04, 1997

N50749 001
DEC 04, 1997

N50749 001
DEC 04, 1997

N50749 001
DEC 04, 1997

AP AM PHARM PARTNERS EQ 1GM BASE/VIAL

AP EQ 2GM BASE/2VIAL

AP EQ 10GM BASE/VIAL

AP ESI LEDERLE EQ 1GM BASE/VIAL

AP EQ 2GM BASE/VIAL

AP EQ 10GM BASE/VIAL

MEFOXIN

+ MERCK

AP EQ 1GM BASE/VIAL

AP EQ 1GM BASE/VIAL

AP EQ 2GM BASE/VIAL

N65012 001
JUL 03, 2000

N65012 002
JUL 03, 2000

N65011 001
JUL 03, 2000

N65011 001
JUL 03, 2000

N65051 001
SEP 11, 2000

N65051 002
SEP 11, 2000

N65050 001
SEP 11, 2000

N65050 001
SEP 11, 2000

N50517 001
JAN 08, 1987

N62757 001
JAN 08, 1987

N50517 002
JAN 08, 1987

CEFOXITIN SODIUM

INJECTABLE; INJECTION

MEFOXIN
MERCK

AP + EQ 2GM BASE/VIAL N62757 002
 AP * EQ 10GM BASE/VIAL N50517 003
 EQ 1GM BASE/VIAL N50517 001
 EQ 1GM BASE/VIAL N62757 001
 JAN 08, 1987
 EQ 2GM BASE/VIAL N50517 002
 EQ 2GM BASE/VIAL N62757 002
 JAN 08, 1987
 EQ 10GM BASE/VIAL N50517 003

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL

CEDAX

+ DJ PHARMA EQ 400MG BASE N50685 002
 * SCHERING PLOUGH EQ 400MG BASE N50685 002
 DEC 20, 1995

POWDER FOR RECONSTITUTION; ORAL

CEDAX

DJ PHARMA

+ EQ 90MG BASE/5ML N50686 001
 EQ 180MG BASE/5ML N50686 002
 DEC 20, 1995
 * SCHERING PLOUGH EQ 90MG BASE/5ML N50686 001
 * EQ 180MG BASE/5ML N50686 002
 DEC 20, 1995

CEFTRIAOXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

+ HLR

+ EQ 250MG BASE/VIAL N50585 001
 EQ 250MG BASE/VIAL N63239 001
 AUG 13, 1993
 EQ 500MG BASE/VIAL N50585 002
 EQ 500MG BASE/VIAL N63239 002
 AUG 13, 1993

CEFTRIAOXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

+ HLR

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

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

@ HLR

EQ 10MG BASE/ML N50624 001
 FEB 11, 1987
 EQ 20MG BASE/ML N50624 002
 FEB 11, 1987
 EQ 40MG BASE/ML N50624 003
 FEB 11, 1987
 EQ 10MG BASE/ML N50624 001
 FEB 11, 1987
 EQ 20MG BASE/ML N50624 002
 FEB 11, 1987
 EQ 40MG BASE/ML N50624 003
 FEB 11, 1987

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION
ROCEPHIN KIT

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

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

CETRORELIX

INJECTABLE; INJECTION

CETROTIDE
* ASTA
EQ 3MG BASE/ML
+ SERONO INC
EQ 0.25MG BASE/ML
+
EQ 3MG BASE/ML

N21197 002
AUG 11, 2000
N21197 001
AUG 11, 2000
N21197 002
AUG 11, 2000

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC
+ SNOWBRAND
EQ 30MG BASE

N20989 002
JAN 11, 2000

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

KEFLEX
* AB
* AB
* AB
* AB
+ @
@

EQ 125MG BASE/5ML
N50406 001
EQ 250MG BASE/5ML
N50406 002
EQ 250MG BASE/5ML
N62117 003
EQ 250MG BASE/5ML
N62117 003
EQ 125MG BASE/5ML
N50406 001
EQ 250MG BASE/5ML
N50406 002

TABLET; ORAL
CHENIX
@ AXCAN
250MG
@ AXCAN SCANDIPHARM
250MG

CHENODIOL

N18513 002
JUL 28, 1983
N18513 002
JUL 28, 1983

CERIVASTATIN SODIUM

TABLET; ORAL

BAYCOL
* BAYER
0.4MG
N20740 005
MAY 24, 1999
0.4MG
N20740 005
MAY 24, 1999
0.8MG
N20740 006
JUL 24, 2000

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
4MG
@ IMPAX LABS
4MG

N80809 001
N80809 001

CICLOPIROX

CREAM; TOPICAL
LOPROX
+ AVENTIS PHARMS
0.77%

N18748 001
DEC 30, 1982

CETRORELIX

INJECTABLE; INJECTION

CETROTIDE
* ASTA
EQ 0.25MG BASE/ML
N21197 001
AUG 11, 2000

LOTION; TOPICAL
LOPROX
+ AVENTIS PHARMS
0.77%

N19824 001
DEC 30, 1988

> DLT >
> DLT >

CICLOPIROX OLAMINE

CREAM; TOPICAL

LOPROX
* HOECHST MARION ROSS I*

N18748 001
DEC 30, 1982

N74656 001
MAY 16, 2000

LOTION; TOPICAL

LOPROX
* HOECHST MARION ROSS I*

N19824 001
DEC 30, 1988

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL

CIMETIDINE HCL
NOVEX

N75560 001
MAR 15, 2000

> ADD >
> ADD >

N20822 003
JUL 17, 1998
N20822 004
JUL 17, 1998
N20822 001
APR 27, 2000
N20822 003
JUL 17, 1998
N20822 004
JUL 17, 1998

CISAPRIDE MONOHYDRATE

SUSPENSION; ORAL

PROPULSID
* JANSSEN

N20398 001
SEP 15, 1995
N20398 001
SEP 15, 1995

EQ 1MG BASE/ML
EQ 1MG BASE/ML

N75405 001
FEB 28, 2000

TABLET; ORAL

PROPULSID
JANSSEN

N20210 001
JUL 29, 1993
N20210 002
DEC 23, 1993
N20210 001
JUL 29, 1993
N20210 002
DEC 23, 1993

EQ 10MG BASE
EQ 20MG BASE
EQ 10MG BASE
EQ 20MG BASE

N50662 001
OCT 31, 1991
N50662 001
OCT 31, 1991

CISPLATIN

INJECTABLE; INJECTION

CISPLATIN
GENSIA SICOR PHARMS

N74814 001
MAY 16, 2000

TABLET, EXTENDED RELEASE; ORAL
BIAIXIN XL
+ ABBOTT

N50775 001
MAR 03, 2000

CISPLATIN

INJECTABLE; INJECTION

CISPLATIN
PHARMACHEMIE

N74656 001
MAY 16, 2000

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CELEXA
FOREST LABS

EQ 40MG BASE
EQ 60MG BASE
EQ 10MG BASE
EQ 40MG BASE
EQ 60MG BASE

N20822 003
JUL 17, 1998
N20822 004
JUL 17, 1998
N20822 001
APR 27, 2000
N20822 003
JUL 17, 1998
N20822 004
JUL 17, 1998

CLADRIBINE

INJECTABLE; INJECTION

CLADRIBINE
BEDFORD

N75405 001
FEB 28, 2000

CLARITHROMYCIN

TABLET; ORAL

BIAIXIN
ABBOTT

350MG
250MG

N50662 001
OCT 31, 1991
N50662 001
OCT 31, 1991

TABLET, EXTENDED RELEASE; ORAL
BIAIXIN XL
+ ABBOTT

N50775 001
MAR 03, 2000

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL

AP + BEDFORD

EQ 5MG BASE/ML

N50731 001
 JAN 30, 1998

EQ 5MG BASE/ML

N50731 001
 JAN 30, 1998

AP GENSTA SICOR PHARMS

EQ 5MG BASE/ML

N65035 001
 JAN 24, 2000

EQ 50MG BASE/VIAL

N64212 002
 MAY 03, 1999

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

DECLEMYCIN

* LEDERLE

@

150MG

150MG

N50262 001

N50262 001

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DESMOPRESSIN ACETATE

AP ABBOTT

0.004MG/ML

N75220 001
 AUG 28, 2000

AP BEDFORD

0.004MG/ML

N74575 001
 FEB 18, 2000

DESMOPRESSIN ACETATE PRESERVATIVE FREE

AP BEDFORD

0.004MG/ML

N74574 001
 FEB 18, 2000

SPRAY, METERED; NASAL
 STIMATE

+ AVENTIS BEHRING

0.15MG/SPRAY

N20355 001
 MAR 07, 1994

* CENTEON

0.15MG/SPRAY

N20355 001
 MAR 07, 1994

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

MIRCETTE

* ORGANON

0.15MG;0.02MG

N20713 001
 APR 22, 1998

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

MIRCETTE

+ ORGANON

0.15MG,N/A;0.02MG,0.01MG N20713 001
 APR 22, 1998

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

AT ALCON UNIVERSAL

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

N62721 001
 NOV 17, 1986

AT STERIS

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

N62721 001
 NOV 17, 1986

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS, OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT ALCON UNIVERSAL EQ 0.1% PHOSPHATE

N88771 001
 JAN 16, 1985

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT STERIS EQ 0.1% PHOSPHATE

N88771 001
 JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

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

N62714 001
 JUL 21, 1986

AT STERIS EQ 0.1% PHOSPHATE;
 EQ 3.5MG BASE/ML

N62714 001
 JUL 21, 1986

DEZOCINE

INJECTABLE; INJECTION

DALGEN
 * ASTRAZENECA 5MG/ML
 * 10MG/ML
 * 15MG/ML
 @ 5MG/ML
 @ 10MG/ML
 @ 15MG/ML

N19082 001
 DEC 29, 1989
 N19082 002
 DEC 29, 1989
 N19082 003
 DEC 29, 1989
 N19082 001
 DEC 29, 1989
 N19082 002
 DEC 29, 1989
 N19082 003
 DEC 29, 1989

DIAZEPAM

INJECTABLE; INJECTION

DIZAC
 @ PHARMACIA AND UPJOHN 5MG/ML

N19287 001
 JUN 18, 1993

INJECTABLE; INTRAVENOUS

DIZAC
 * PHARMACIA AND UPJOHN 5MG/ML

N19287 001
 JUN 18, 1993

DICLOFENAC POTASSIUM

TABLET; ORAL
DICLOFENAC POTASSIUM
 @ GENEVA PHARMS TECH 50MG

AB 50MG
 AB 50MG

N75229 001
 NOV 20, 1998
 N75229 001
 NOV 20, 1998

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM
 @ FALCON PHARMS 0.1%
 @ 0.1%

AB 0.1%
 AB 0.1%

N20809 001
 MAY 04, 1998
 N20809 001
 MAY 04, 1998

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

VOLTAREN
 * CIBA 0.1%
 + 0.1%

N20037 001
 MAR 28, 1991
 N20037 001
 MAR 28, 1991

TABLET, EXTENDED RELEASE; ORAL

DICLOFENAC SODIUM
 @ BIOVAIL 100MG

N75492 001
 FEB 11, 2000

VOLTAREN-XR

+ NOVARTIS 100MG
 * 100MG

N20254 001
 MAR 08, 1996
 N20254 001
 MAR 08, 1996

DIENESTROL

SUPPOSITORY; VAGINAL

DV
 @ AVENTIS PHARMS 0.7MG
 * HOECHST MARION ESSEL 0.7MG

N83517 001
 N83517 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL
 @ MD PHARM 25MG
 @ MEDEVA PHARMS CA 25MG

N85544 001
 N85544 001

DIETHYLSTILBESTROL DIPHOSPHATE

INJECTABLE; INJECTION

* BAYER 250MG/5ML
 @ 250MG/5ML

N10010 001
 N10010 001

TABLET; ORAL

* STILPHOSTROL
 @ BAYER 50MG
 @ 50MG

N10010 002
 N10010 002

† SEE SECTION 1.3 OF INTRODUCTION

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE DIACETATE
 TARO

0.05%

N75508 001
 APR 24, 2000

N80807 002
 N80807 001
 N80807 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
 GLOBAT PHARM
 IMPAX LABS

50MG
 25MG
 50MG

N80807 002
 N80807 001
 N80807 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HCL
 BIOVAIL

120MG

N20939 001
 JAN 28, 2000

180MG

N20939 002
 JAN 28, 2000

240MG

N20939 003
 JAN 28, 2000

300MG

N20939 004
 JAN 28, 2000

N21168 001
 AUG 04, 2000

INJECTABLE; INJECTION

DILTIAZEM HCL
 ABBOTT

5MG/ML

N75004 001
 FEB 16, 2000

CREAM; TOPICAL

ZONALON
 + BIOGLAN PHAR

5%

N20126 001
 APR 01, 1994
 N20126 001
 APR 01, 1994

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
 TIAMATE

EQ 120MG HCL

N20506 001
 OCT 04, 1996

EQ 180MG HCL

N20506 002
 OCT 04, 1996

EQ 240MG HCL

N20506 003
 OCT 04, 1996

EQ 120MG HCL

N20506 001
 OCT 04, 1996

EQ 180MG HCL

N20506 002
 OCT 04, 1996

EQ 240MG HCL

N20506 003
 OCT 04, 1996

INJECTABLE; INJECTION
 HECTOROL

+ BONE CARE

2 UGM/ML

N21027 001
 APR 06, 2000

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
 GLOBAT PHARM

50MG

N80807 001

N65032 001
 JUN 30, 2000
 N65032 002
 JUN 30, 2000
 N65041 001
 APR 28, 2000
 N65041 002
 APR 28, 2000
 N50641 002
 FEB 10, 1992

EQ 50MG BASE

EQ 100MG BASE

EQ 50MG BASE

EQ 100MG BASE

EQ 50MG BASE

DOXYCYCLINE

CAPSULE; ORAL

MONODOX

AB + OCLASSEN

EQ 100MG BASE

N50641 001

DEC 29, 1989

EQ 50MG BASE

N50641 002

FEB 10, 1992

EQ 100MG BASE

N50641 001

DEC 28, 1988

EFLORNITHINE HYDROCHLORIDE

CREAM; TOPICAL

VANIQA

AB + WESTWOOD SQUIBB CLTN 13.9%

N21145 001

JUL 27, 2000

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

AB APOTHECON

2.5MG

N75583 001

AUG 22, 2000

5MG

N75583 002

AUG 22, 2000

10MG

N75583 003

AUG 22, 2000

20MG

N75583 004

AUG 22, 2000

2.5MG

N75501 001

AUG 22, 2000

5MG

N75501 002

AUG 22, 2000

10MG

N75501 003

AUG 22, 2000

20MG

N75501 004

AUG 22, 2000

2.5MG

N75621 001

AUG 22, 2000

5MG

N75621 002

AUG 22, 2000

10MG

N75621 003

AUG 22, 2000

20MG

N75621 004

AUG 22, 2000

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

AB GENEVA PHARMS

2.5MG

N75048 001

AUG 22, 2000

5MG

N75048 002

AUG 22, 2000

10MG

N75048 003

AUG 22, 2000

20MG

N75048 004

AUG 22, 2000

2.5MG

N75472 001

AUG 22, 2000

5MG

N75472 002

AUG 22, 2000

10MG

N75472 003

AUG 22, 2000

20MG

N75472 004

AUG 22, 2000

2.5MG

N75370 001

AUG 22, 2000

5MG

N75370 002

AUG 22, 2000

10MG

N75369 001

AUG 22, 2000

20MG

N75369 002

AUG 22, 2000

2.5MG

N75496 001

AUG 22, 2000

5MG

N75496 002

AUG 22, 2000

10MG

N75459 001

AUG 22, 2000

20MG

N75459 002

AUG 22, 2000

2.5MG

N75480 001

AUG 22, 2000

5MG

N75480 002

AUG 22, 2000

10MG

N75480 003

AUG 22, 2000

20MG

N75480 004

AUG 22, 2000

2.5MG

N75556 001

AUG 22, 2000

5MG

N75556 002

AUG 22, 2000

AB RANBAXY

AB MYLAN

AB LEK PHARM

AB KRKA DD NOVO MESTO

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
RANBAXY

AB 10MG N75556 003 AUG 22, 2000
 AB 20MG N75556 004 AUG 22, 2000
 AB 2.5MG N75479 001 AUG 22, 2000
 AB 5MG N75479 002 AUG 22, 2000
 AB 10MG N75479 003 AUG 22, 2000
 AB 20MG N75479 004 AUG 22, 2000
 AB 2.5MG N75483 001 AUG 22, 2000
 AB 5MG N75483 002 AUG 22, 2000
 AB 10MG N75483 003 AUG 22, 2000
 AB 20MG N75483 004 AUG 22, 2000
 AB 2.5MG N75482 001 AUG 22, 2000
 AB 5MG N75482 002 AUG 22, 2000
 AB 10MG N75482 003 AUG 22, 2000
 AB 20MG N75482 004 AUG 22, 2000

TEVA

WOCKHARDT

ZENITH GOLDLINE

VASOTEC
MERCK

AB 2.5MG N18998 005 JUL 26, 1988
 AB 5MG N18998 001 DEC 24, 1985
 AB 10MG N18998 002 DEC 24, 1985
 AB 20MG N18998 003 DEC 24, 1985
 AB 2.5MG N18998 005 JUL 26, 1988
 AB 5MG N18998 001 DEC 24, 1985
 AB 10MG N18998 002 DEC 24, 1985
 AB 20MG N18998 003 DEC 24, 1985

⊗

ENALAPRILAT

INJECTABLE; INJECTION
ENALAPRILAT
ABBOTT

AP 1.25MG/ML N75456 001 AUG 22, 2000
 AP 1.25MG/ML N75458 001 AUG 22, 2000
 AP 1.25MG/ML N75634 001 AUG 22, 2000
 AP 1.25MG/ML N75571 001 AUG 22, 2000
 AP 1.25MG/ML N75578 001 AUG 22, 2000
 AP 1.25MG/ML N19309 001 FEB 09, 1988
 AP 1.25MG/ML N19309 001 FEB 09, 1988
 AP 1.25MG/ML N19309 001 FEB 09, 1988

VASOTEC
MERCK

⊗

ENFLURANE

LIQUID; INHALATION
ETHRANE

AN 99.9% N17087 001
 AN 99.9% N17087 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL
ERGOMAR

AA 2MG N87693 001 FEB 24, 1983
 AA 2MG N87693 001 FEB 24, 1983
 AA 2MG N88337 001 JUN 08, 1984
 AA 2MG N88337 001 JUN 08, 1984
 AA 2MG N86750 001 JUL 29, 1982
 AA 2MG N86750 001 JUL 29, 1982

ERGOSTAT
PARKE DAVIS

⊗

NIGRETTES
ORGARON

⊗

ERYTHROMYCIN

SOLUTION; TOPICAL

SANSAC

* GRILDERMA LABS

2%

N62522 001

BX

ESTRADIOL

N21048 002

AT HEALTHPOINT

2%

N62522 001

BX

ESTRADIOL

N21048 003

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL

PEDIAMYCIN

* ROSS LABS

EQ 200MG BASE/5ML

N62305 001

AB

ESTRADIOL

N21048 001

SUSPENSION/DROPS; ORAL

PEDIAMYCIN

* ROSS LABS

EQ 100MG BASE/2.5ML

N62305 002

AB

ESTRADIOL

N20323 005

TABLET, CHEWABLE; ORAL

PEDIAMYCIN

* ROSS LABS

EQ 200MG BASE

N62306 001

AB

ESTRADIOL

N40138 001

ESTRADIOL

CREAM; VAGINAL

ESTRACE

* BRISTOL MYERS SQUIBB 0.01%

N86069 001

AB

ESTRADIOL

N40138 002

+ WARNER CHILCOTT 0.01%

N86069 001

AB

ESTRADIOL

N40138 003

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

+ BERLEX LABS

0.05MG/24HR

N20375 001

AB

ESTRADIOL

N40138 001

+ BERLEX LABS

0.1MG/24HR

N20375 002

AB

ESTRADIOL

N40138 002

* BERLEX LABS

0.05MG/24HR

N20375 001

BX

ESTRADIOL

N40138 001

* BERLEX LABS

0.1MG/24HR

N20375 002

BX

ESTRADIOL

N40138 003

ESTRADIOL

0.05MG/24HR

N21048 001

BX

ESTRADIOL

N21048 002

FILM, EXTENDED RELEASE; TRANSDERMAL

ESTRADIOL

* CYGNUS CA

0.075MG/24HR

N21048 002

* JOHNSON RW

0.1MG/24HR

N21048 003

* JOHNSON RW

0.05MG/24HR

N21048 001

* JOHNSON RW

0.075MG/24HR

N21048 002

* JOHNSON RW

0.1MG/24HR

N21048 003

MYLAN TECHNOLOGIES

0.05MG/24HR

N75233 001

0.1MG/24HR

N75182 001

VIVELLE

+ NOVARTIS

0.025MG/24HR

N20323 005

TABLET; ORAL

ESTRADIOL

APPLIED ANAL

0.5MG

N40138 001

APPLIED ANAL

1MG

N40138 002

APPLIED ANAL

2MG

N40138 003

ENDEAVOR

0.5MG

N40138 001

ENDEAVOR

1MG

N40138 002

ENDEAVOR

2MG

N40138 003

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

* CYPROS

50MG/ML

N19357 001

+ QUESTCOR PHARM

50MG/ML

N19357 001

QUESTCOR PHARM

DEC 22, 1988

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

TRIVORA-21

AB

SEARLE

0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG,
0.125MG
N74538 001
DEC 18, 1997

AB WATSON LABS

0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG,
0.125MG
N74538 001
DEC 18, 1997

TABLET; ORAL-28

TRIVORA-28

AB

SEARLE

0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG,
0.125MG
N74538 002
DEC 18, 1997

AB WATSON LABS

0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG,
0.125MG
N74538 002
DEC 18, 1997

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

OVCON-35

*

BRISTOL MYERS SQUIBB 0.035MG; 0.4MG

+

WARNER CHILCOTT 0.035MG; 0.4MG

@

BRISTOL MYERS SQUIBB 0.05MG; 1MG

@

WARNER CHILCOTT 0.05MG; 1MG

N18127 001
N18127 001

N18128 001
N18128 001

TABLET; ORAL-28

OVCON-35

*

BRISTOL MYERS SQUIBB 0.035MG; 0.4MG

+

WARNER CHILCOTT 0.035MG; 0.4MG

@

BRISTOL MYERS SQUIBB 0.05MG; 1MG

@

WARNER CHILCOTT 0.05MG; 1MG

N17716 001
N17716 001

N17576 001
N17576 001

ETODOLAC

CAPSULE; ORAL

ETODOLAC

AB

TORPHARM

200MG

N75419 001
JUL 28, 2000

AB

300MG

N75419 002
JUL 28, 2000

ETODOLAC

TABLET; ORAL

ETODOLAC

AB

TARO PHARM INDS

500MG

N75074 002
APR 25, 2000

TABLET, EXTENDED RELEASE; ORAL

ETODOLAC

AB

TEVA

500MG

N75665 002
JUL 31, 2000
N75665 001
JUL 31, 2000
N75696 001
JUL 31, 2000

LODINE XL

AB

+ WYETH AVERST

400MG

N20584 001
OCT 25, 1996

AB

+ WYETH AVERST

500MG

N20584 003
JAN 20, 1998

AB

+ WYETH AVERST

500MG

N20584 002
OCT 25, 1996

*

+ WYETH AVERST

400MG

N20584 001
OCT 25, 1996

*

+ WYETH AVERST

500MG

N20584 003
JAN 20, 1998

*

+ WYETH AVERST

600MG

N20584 002
OCT 25, 1996

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

CORLOPAM

+

ABBOTT

EQ 10MG BASE/ML

N19922 001
SEP 23, 1997

*

ELAN PHARMA

EQ 10MG BASE/ML

N19922 001
SEP 23, 1997

FENTANYL CITRATE

INJECTABLE; INJECTION

SUBLIMAZE PRESERVATIVE FREE

AB

+ AKORN MFG

EQ 0.05MG BASE/ML

N16619 001

AB

+ JANSSEN

EQ 0.05MG BASE/ML

N16619 001

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL
ALLEGRA
AVENTIS PHARMS

30MG N20872 001
FEB 25, 2000
60MG N20872 002
FEB 25, 2000
180MG N20872 004
FEB 25, 2000

N40334 001
FEB 25, 2000

FLOXURIDINE

INJECTABLE; INJECTION
FLOXURIDINE
BEDFORD

500MG/VIAL

N75387 001
APR 16, 2000

N18936 007
JUL 06, 2000
N18936 008
JUL 06, 2000

FUDR

AP + ROCHE

500MG/VIAL
500MG/VIAL

N16329 001
N16329 001

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
PFIZER

150MG
150MG

> ADD >
> ADD >

N20833 002
SEP 29, 2000
N20833 003
SEP 29, 2000
N20833 001
SEP 29, 2000

FLUMAZENIL

INJECTABLE; INJECTION
ROMAZICON
HLR

0.1MG/ML

N20073 001
DEC 20, 1991
N20073 001
DEC 20, 1991

N21077 001
AUG 24, 2000

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
GENSIA SICOR PHARMS

50MG/ML

N40333 001
JAN 27, 2000

N21077 002
AUG 24, 2000
N21077 003
AUG 24, 2000

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
GENSIA SICOR PHARMS

50MG/ML

AP

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL
SARAFEM
LILLY

EQ 10MG BASE
EQ 20MG BASE

FLUTICASONE PROPIONATE

POWDER; INHALATION
FLOVENT DISKUS 100

0.1MG/INH

+ GLAXO
FLOVENT DISKUS 250

0.25MG/INH

+ GLAXO
FLOVENT DISKUS 50

0.05MG/INH

FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE

POWDER; INHALATION
ADVAIR DISKUS 100/50

0.1MG/INH;
EQ 0.05MG BASE/INH

+ GLAXO WELLCOME
ADVAIR DISKUS 250/50

0.25MG/INH;
EQ 0.05MG BASE/INH

+ GLAXO WELLCOME
ADVAIR DISKUS 500/50

0.5MG/INH;
EQ 0.05MG BASE/INH

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

1-24

FOLLITROPIN ALFA/BETA

INJECTABLE; INJECTION
GONAL-F
SERONO

37.5 IU/VIAL
N20378 003
MAY 25, 2000

> ADD >
> ADD >

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE
* ROBERTS LABS
+ SHIRE LABS

50MG/15ML
50MG/15ML

N11323 002
N11323 002

TABLET; ORAL
FUROXONE
* ROBERTS LABS
+ SHIRE LABS

100MG
100MG

N11270 002
N11270 002

GABAPENTIN

SOLUTION; ORAL
NEURONTIN
+ FARKE DAVIS

250MG/5ML

N21129 001
MAR 02, 2000

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST
+ BERLEX LABS

469.01MG/ML

N21037 001
MAR 10, 2000

GEMTUZUMAB OZOGAMICIN

INJECTABLE; INJECTION
MYLOTARG
+ WYETH AYERST

5MG/VIAL

N21174 001
MAY 17, 2000

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GARAMYCIN
* SCHERING

EQ 10MG BASE/ML

N61739 001

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GARAMYCIN
* SCHERING
GENTAMICIN SULFATE
* ELKINS SINN

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

N61739 001
N62251 002
N62251 002

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

ALCON UNIVERSAL
EQ 0.3% BASE
STERIS
EQ 0.3% BASE

N62523 001
NOV 25, 1985
N62523 001
NOV 25, 1985

GLUTETHIMIDE

TABLET; ORAL
GLUTETHIMIDE
* MD PHARM
* MEDEVA PHARMS CA

500MG
500MG

N85171 001
N85171 001

GLYBURIDE

TABLET; ORAL
GLYBURIDE (MICRONIZED)
* AVENTIS PHARMS

5MG

N20055 003
MAR 08, 2000

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL
GLUCOVANCE

BRISTOL MYERS SQUIBB 1.25MG;250MG
2.5MG;500MG
5MG;500MG

N21178 001
JUL 31, 2000
N21178 002
JUL 31, 2000
N21178 003
JUL 31, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

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

GONADOTROPIN CHORIONIC RECOMBINANT HUMAN
 INJECTABLE; INJECTION
 OVIDREL
 + SERONO 0.25MG/VIAL N21149 001
 SEP 20, 2000

HALOPERIDOL DECANOATE
 INJECTABLE; INJECTION
 HALOPERIDOL DECANOATE
 APOTEX EQ 50MG BASE/ML N75440 001
 FEB 28, 2000
 EQ 100MG BASE/ML N75440 002
 FEB 28, 2000
 EQ 50MG BASE/ML N75176 001
 FEB 09, 2000
 EQ 100MG BASE/ML N75176 002
 FEB 09, 2000

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE
 SOLUTION/DROPS; OPHTHALMIC
 NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN
 IPHARM 0.025MG/ML; EQ 1.75MG BASE/ML; N62818 001
 10,000 UNITS/ML OCT 11, 1988

@ 0.025MG/ML; EQ 1.75MG BASE/ML; N62818 001
 10,000 UNITS/ML OCT 11, 1988

AT
 GREPAPFLOXACIN HYDROCHLORIDE
 TABLET; ORAL
 RAXAR
 GLAXO WELLCOME EQ 200MG BASE N20695 001
 NOV 06, 1997
 EQ 400MG BASE N20695 002
 MAY 14, 1998
 EQ 600MG BASE N20695 003
 MAY 14, 1998

* OTSUKA EQ 200MG BASE N20695 001
 NOV 06, 1997
 EQ 400MG BASE N20695 002
 MAY 14, 1998
 EQ 600MG BASE N20695 003
 MAY 14, 1998

+
 GRISEOFULVIN, ULTRAMICROCRYSTALLINE
 TABLET; ORAL
 GRIS-PEG
 ALLEGAN HERBERT 125MG N50475 001
 250MG N50475 002
 250MG N50475 001
 250MG N50475 002

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

HEPARIN SODIUM
 INJECTABLE; INJECTION
 HEPARIN LOCK FLUSH
 SMITH AND NEPHEW 10 UNITS/ML N87904 001
 APR 20, 1983
 100 UNITS/ML N87906 001
 APR 20, 1983
 10 UNITS/ML N87904 001
 APR 20, 1983
 100 UNITS/ML N87906 001
 APR 20, 1983
 100 UNITS/ML N17064 001
 APR 20, 1983
 5,000 UNITS/ML N17064 003
 10,000 UNITS/ML N17064 004
 20,000 UNITS/ML N17064 005
 40,000 UNITS/ML N17064 006
 5,000 UNITS/ML N17064 003
 10,000 UNITS/ML N17064 004
 20,000 UNITS/ML N17064 005
 40,000 UNITS/ML N17064 006

@ STERIS
 HEPARIN SODIUM
 STERIS 10 UNITS/ML N17064 001
 5,000 UNITS/ML N17064 003
 10,000 UNITS/ML N17064 004
 20,000 UNITS/ML N17064 005
 40,000 UNITS/ML N17064 006

@
 @
 @
 @
 @
 @
 @
 @

HEXACHLOROPHENE
 AEROSOL; TOPICAL
 SEPTISOL @ VESTAL LABS 0.23% N17424 001
 DISC; TOPICAL
 SEPTISOL * VESTAL LABS 0.23% N17424 001

HISTRELIN ACETATE

INJECTABLE; INJECTION

SUPPRELIN

* ROBERTS LABS

EQ 0.2MG BASE/ML

N19836 001

DEC 24, 1991

EQ 0.5MG BASE/ML

N19836 002

DEC 24, 1991

EQ 1MG BASE/ML

N19836 003

DEC 24, 1991

EQ 0.2MG BASE/ML

N19836 001

DEC 24, 1991

EQ 0.5MG BASE/ML

N19836 002

DEC 24, 1991

EQ 1MG BASE/ML

N19836 003

DEC 24, 1991

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

GENSIA SICOR PHARMS

20MG/ML

N40373 001

FEB 23, 2000

20MG/ML

N40136 001

JUN 30, 1997

20MG/ML

N40136 001

JUN 30, 1997

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

MYLAN

12.5MG

N75640 001

JAN 28, 2000

12.5MG

N20504 001

DEC 27, 1996

12.5MG

N20504 001

DEC 27, 1996

TABLET; ORAL

HYDROCHLOROTHIAZIDE

GLOBEL PHARM

@ IMPAX LABS

100MG

N85098 001

N85098 001

HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM

TABLET; ORAL

HYZAAR

* MERCK

12.5MG; 50MG

N20387 001

APR 28, 1995

12.5MG; 50MG

N20387 001

APR 28, 1995

25MG; 100MG

N20387 002

NOV 10, 1998

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

CODAMINE

ALPHARMA

5MG/5ML; 25MG/5ML

N75103 001

SEP 29, 2000

5MG/5ML; 25MG/5ML

N19410 001

AUG 17, 1990

5MG/5ML; 25MG/5ML

N19410 001

AUG 17, 1990

5MG/5ML; 25MG/5ML

N19410 001

AUG 17, 1990

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

ZENITH GOLDLINE

@

NOGENIC HC

ZENITH GOLDLINE

@

NUTRACORT

GALDERMA LABS

@

HEALTHPOINT

@

NUTRACORT

GALDERMA LABS

@

HEALTHPOINT

@

GEL; TOPICAL

NUTRACORT

@ GALDERMA LABS

@ HEALTHPOINT

LOTION; TOPICAL

HYDROCORTISONE

ALTANA

@

2.5%

N40351 001

JUL 25, 2000

HYDROCORTISONE

LOTION; TOPICAL

AT NUTRACORT
AT GALEDERMA LABS

0.5%
1%
2.5%

N80443 002
N80443 003
N87644 001
AUG 24, 1982
N80443 003
N87644 001
AUG 24, 1982
N80443 002

HEALTHPOINT

1%
2.5%

0.5%

CREAM; TOPICAL

LOCROID
GALEDERMA LABS

0.1%
0.1%

N18795 001
JAN 07, 1983
N18795 001
JAN 07, 1983
N20769 001
SEP 08, 1997
N20769 001
SEP 08, 1997

LOCROID LIPOCREAM
YAMANOUCHI

0.1%
0.1%

0.1%

N20769 001
SEP 08, 1997
N20769 001
SEP 08, 1997

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

AT NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE
ALCON UNIVERSAL

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

N62874 001
MAY 11, 1988

AT STERIS

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

N62874 001
MAY 11, 1988

SUSPENSION/DROPS; OTIC

AT NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE
ALCON UNIVERSAL

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

N62488 001
NOV 06, 1985

AT STERIS

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

N62488 001
NOV 06, 1985

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

BX SCHWARZ PHARMA
PROCTOFOAM HC

1%; 1%

N86457 001

BX SCHWARZ PHARMA

1%; 1%

N86195 001

DISC; TOPICAL

BX SCHWARZ PHARMA
PROCTOFOAM HC

1%; 1%

N86457 001

BX SCHWARZ PHARMA

1%; 1%

N86195 001

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

LOCROID
GALEDERMA LABS

0.1%
0.1%

N18795 001
JAN 07, 1983
N18795 001
JAN 07, 1983
N20769 001
SEP 08, 1997
N20769 001
SEP 08, 1997

LOCROID LIPOCREAM
YAMANOUCHI

0.1%
0.1%

0.1%

N20769 001
SEP 08, 1997
N20769 001
SEP 08, 1997

OINTMENT; TOPICAL

LOCROID
GALEDERMA LABS

0.1%
0.1%

N19106 001
JUL 03, 1984
N19106 001
JUL 03, 1984

SOLUTION; TOPICAL

LOCROID
GALEDERMA LABS

0.1%
0.1%

N19819 001
SEP 15, 1988
N19819 001
SEP 15, 1988

LOCROID

GALEDERMA LABS

0.1%

N19819 001
SEP 15, 1988

HYDROCORTISONE VALERATE

CREAM; TOPICAL

HYDROCORTISONE VALERATE
CLAY PARK

0.2%

N75666 001
MAY 24, 2000

HYDROXYUREA

CAPSULE; ORAL

HYDROXYUREA
BARR

250MG

N75143 002
SEP 21, 2000
N75020 002
JUN 26, 2000
N75020 002
JUN 26, 2000

EXPRANED

250MG

250MG

250MG

HYDROXYUREA

TABLET; ORAL
HYDROXYUREA
+ BARR

1GM
N75734 001
AUG 29, 2000

100 UNITS/ML
N21018 001
DEC 22, 1999

INAMRINONE LACTATE

INJECTABLE; INJECTION

AMRINONE
BEDFORD

EQ 5MG BASE/ML
N75513 001
MAY 09, 2000

INULIN

INJECTABLE; INJECTION

INULIN AND SODIUM CHLORIDE
* CYPROS
+ QUESTCOR PHARM

EQ 5MG BASE/ML
N75542 001
MAY 10, 2000

100MG/ML
N02282 001
N02282 001

INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION

NOVOLOG

+ NOVO NORDISK

100 UNITS/ML

N20986 001
JUN 07, 2000

INJECTABLE; INJECTION

IOPAMIDOL-200

COOK IMAGING

41%

N74881 001
JUL 28, 2000

INSULIN GLARGINE

INJECTABLE; INJECTION

LANTUS

+ AVENTIS PHARMS

100 UNITS/ML

N21081 001
APR 20, 2000

COOK IMAGING

61%

N74881 003
JUL 28, 2000

COOK IMAGING

76%

N74881 004
JUL 28, 2000

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION

HUMALOG MIX 50/50

+ LILLY

50 UNITS/ML;50 UNITS/ML

N21018 001
DEC 22, 1999

INJECTABLE; INJECTION

GLOFILL-125

CYPROS

QUESTCOR PHARM

250-300 uCi/ML

N17279 001
N17279 001

25 UNITS/ML;75 UNITS/ML

N21017 001
DEC 22, 1999

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

AN STERIPAK

0.02%

N75313 001
FEB 07, 2000

ISOCARBOXAZID

TABLET; ORAL
MAREPLAN
+ OXFORD PHARM

10MG

N11961 001

ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL

ISORBID
* WYETH AYERST

40MG

N12882 001
JUL 29, 1988

40MG

N12882 001
JUL 29, 1988

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

BRONKOSOL

* SAMOFI SYNTHELABO

1%

N12339 008

1%

N12339 008

AN *
ISOETHARINE HCL

ROXANE

1%

N86899 001

1%

N86899 001

ISOETHARINE MESYLATE

AEROSOL, METERED; INHALATION

BRONKOMETER

* SAMOFI SYNTHELABO

0.34MG/INH

N12339 007

0.34MG/INH

N12339 007

ISOFLURANE

LIQUID; INHALATION

ISOFLURANE

RHODIA

99.9%

N74502 001

99.9%

N74502 001

AN *
RHONE POULENC

JUN 27, 1995

JUN 27, 1995

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION

ISUPREL

* SAMOFI SYNTHELABO

0.103MG/INH

N11178 001

0.103MG/INH

N11178 001

SOLUTION; INHALATION

ISUPREL

* SAMOFI SYNTHELABO

0.5%

N06327 002

1%

N06327 003

0.5%

N06327 002

1%

N06327 003

TABLET, EXTENDED RELEASE; ORAL

IMDUR

AB + SCHERING

120MG

N20225 003

120MG

MAR 30, 1995

120MG

N20225 003

120MG

MAR 30, 1995

ISOSORBIDE MONONITRATE

DEXCEL LTD

60MG

N75522 001

60MG

APR 17, 2000

30MG

N75155 002

30MG

JAN 13, 2000

120MG

N75155 003

30MG

AUG 04, 2000

60MG

N75395 001

60MG

MAR 16, 2000

120MG

N75395 003

60MG

MAR 16, 2000

60MG

MAR 16, 2000

60MG

MAR 16, 2000

60MG

MAR 16, 2000

IVERMECTIN

TABLET; ORAL

STROMECTOL

MERCK

3MG

N50742 002

OCT 08, 1998

> ADD >

> ADD >

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

PHARMAPAIR

> DLT >
> ADD >

AP AP AP @ @ @

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

N62668 001
MAY 07, 1987
N62672 001
MAY 07, 1987
N62669 001
MAY 07, 1987
N62668 001
MAY 07, 1987
N62672 001
MAY 07, 1987
N62669 001
MAY 07, 1987

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM PRESERVATIVE FREE

AP + ABBOTT
*

AP BEDFORD
AP

WELLCOVORIN
GLAXO WELLCOME

@

EQ 10MG BASE/ML
EQ 10MG BASE/ML
EQ 10MG BASE/ML
EQ 350MG BASE/VIAL
EQ 100MG BASE/VIAL
EQ 100MG BASE/VIAL

N40147 001
JUN 25, 1997
N40147 001
JUN 25, 1997
N40347 001
APR 25, 2000
N40335 001
APR 20, 2000
N89834 001
JAN 23, 1989
N89834 001
JAN 23, 1989

KETOCONAZOLE

CREAM; TOPICAL

KETOCONAZOLE

TEVA

AB

2%

N75581 001
APR 25, 2000

N19084 001
DEC 31, 1985
N19084 001
DEC 31, 1985

NIZORAL

AB + MCNEIL CONS

*

SHAMPOO; TOPICAL

NIZORAL

JANSSEN

AB

2%

N19927 001
AUG 31, 1990
N19927 001
AUG 31, 1990

AB + MCNEIL CONS

*

LACTULOSE

SOLUTION; ORAL

DUPHALAC

SOLVAY

AA

10GM/15ML
10GM/15ML

N72372 001
MAR 22, 1989
N72372 001
MAR 22, 1989

TABLET; ORAL

LEUCOVORIN CALCIUM

* IMMUNEX

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

AB AB AB AB AB

EQ 15MG BASE
EQ 15MG BASE
EQ 25MG BASE
EQ 25MG BASE

N71104 001
MAR 04, 1987
N71104 001
MAR 04, 1987
N72736 001
FEB 22, 1993
N72736 001
FEB 22, 1993

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION

VIADUR

+ ALZA

EQ 65MG BASE

N21088 001
MAR 03, 2000

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

BETAXON

+ ALCON

EQ 0.5% BASE

N21114 001
FEB 23, 2000

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
LEVOBUNOLOL HCL

AT NOVEX 0.25%
AT 0.5%

N75473 001
AUG 03, 2000
N75475 001
AUG 03, 2000

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN

AB + ICN 2MG
* 2MG

N08720 001
DEC 19, 1991
N08720 001
DEC 19, 1991

AB LEVORPHANOL TARTRATE
ROXANE 2MG

N74278 001
MAR 31, 2000

LEVOBUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHIROCAINE
PURDUE PHARMA

EQ 2.5MG BASE/ML

EQ 5MG BASE/ML

EQ 7.5MG BASE/ML

PURDUE PHARMA LP

EQ 2.5MG BASE/ML

EQ 5MG BASE/ML

EQ 7.5MG BASE/ML

N20997 001
AUG 05, 1999
N20997 002
AUG 05, 1999
N20997 003
AUG 05, 1999
N20997 001
AUG 05, 1999
N20997 002
AUG 05, 1999
N20997 003
AUG 05, 1999

LEVOFLOXACIN

SOLUTION/DROPS; OPHTHALMIC
QUIXIN

+ SANTEN 0.5%

N21199 001
AUG 18, 2000

TABLET; ORAL

LEVAQUIN
* JOHNSON RW

500MG
500MG
750MG

N20634 002
DEC 20, 1996
N20634 002
DEC 20, 1996
N20634 003
SEP 08, 2000

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

LEVOTHYROXINE SODIUM

TABLET; ORAL
UNITHROID
STEVENS J

0.025MG
0.05MG
0.075MG
0.088MG
0.1MG
0.112MG
0.125MG
0.15MG
0.175MG
0.2MG
0.3MG

N21210 001
AUG 21, 2000
N21210 002
AUG 21, 2000
N21210 003
AUG 21, 2000
N21210 004
AUG 21, 2000
N21210 005
AUG 21, 2000
N21210 006
AUG 21, 2000
N21210 007
AUG 21, 2000
N21210 008
AUG 21, 2000
N21210 009
AUG 21, 2000
N21210 010
AUG 21, 2000
N21210 011
AUG 21, 2000

LINEZOLID

GRANULE, FOR RECONSTITUTION; ORAL
ZYVOX

+ PHARMACIA AND UPJOHN 100MG/5ML

N21132 001
APR 18, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

1-32

LINEZOLID

INJECTABLE; INJECTION
ZYVOX

+ PHARMACIA AND UPJOHN 200MG/100ML

N21131 001
APR 18, 2000

TABLET; ORAL
ZYVOX

PHARMACIA AND UPJOHN 400MG

N21130 001
APR 18, 2000
N21130 002
APR 18, 2000

600MG

LOPINAVIR, RITONAVIR

TABLET; ORAL
KALETRA

+ ABBOTT

133.3MG;33.3MG

N21226 001
SEP 15, 2000

SOLUTION; ORAL
KALETRA

+ ABBOTT

80MG/ML;20MG/ML

N21251 001
SEP 15, 2000

LORAZEPAM

INJECTABLE; INJECTION
LORAZEPAM

MOVIA

2MG/ML

N74793 001
MAR 16, 2000

4MG/ML

N74793 002
MAR 16, 2000

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE

ABBOTT

500MG/ML

N75151 001
APR 25, 2000

AP + AM PHARM PARTNERS

500MG/ML

N19316 001
SEP 08, 1986

500MG/ML

N19316 001
SEP 08, 1986

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL

AMEN

BP AMARIN PHARMS

10MG

BP CARRICK

10MG

N83242 001
N83242 001

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

AB PHARMACHEMIE

40MG

N74745 001
FEB 27, 1998
N74745 001
FEB 27, 1998

AB TEVA

40MG

MELOXICAM

TABLET; ORAL

MOBIC

+ BOEHRINGER INGELHEIM 7.5MG

N20938 001
APR 13, 2000

MENOTROPINS (FSH, LH)

INJECTABLE; INJECTION

MENOTROPINS

@ FERRING

75 IU/VIAL;75 IU/VIAL

N73598 001
JAN 30, 1997

150 IU/VIAL;150 IU/VIAL

N73599 001
JAN 30, 1997

REFRONEX

FERRING

75 IU/VIAL;75 IU/VIAL

N73598 001
JAN 30, 1997

150 IU/VIAL;150 IU/VIAL

N73599 001
JAN 30, 1997

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL

MEPERIDINE HCL

AA MALLINCKRODT

50MG

N40352 001
JUN 13, 2000

100MG

N40352 002
JUN 13, 2000

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION
 WYAMINE SULFATE
 * WYETH AYERTS
 @

EQ 30MG BASE/ML
 EQ 30MG BASE/ML

N08248 001
 N08248 001

AN * BOEHRINGER INGELHEIM 5%
 +
AN PROMETA 5%
 MERO 5%
 @

N17659 001
 N17659 001
 N73340 001
 MAR 30, 1992
 N73340 001
 MAR 30, 1992

MEPROBAMATE

TABLET; ORAL
AA MEPROBAMATE
AA LANNETT

200MG
 400MG
 200MG
 400MG

N14882 002
 N14882 001
 N14882 002
 N14882 001

AA SYRUP; ORAL
AA METAPROTERENOL SULFATE 10MG/5ML
 NOVEX

N75235 001
 JAN 27, 2000

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

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL
 PENTASA
 * ROBERTS LABS
 + SHIRE LABS

250MG
 250MG

N20049 001
 MAY 10, 1993
 N20049 001
 MAY 10, 1993

AB TABLET; ORAL
 BANTHINE
 * ROBERTS LABS 50MG
 + SHIRE LABS 50MG

N07390 001
 N07390 001

SUPPOSITORY; RECTAL

ROWASA
 * SOLVAY
 @

500MG
 500MG

N19919 001
 DEC 18, 1990
 N19919 001
 DEC 18, 1990

AB TABLET; ORAL
AB METHIMAZOLE 5MG
 APPLIED ANAL 10MG

N40320 001
 MAR 31, 2000
 N40320 002
 MAR 31, 2000
 N40350 001
 MAR 29, 2000
 N40350 002
 MAR 29, 2000
 N40320 001
 MAR 31, 2000
 N40320 002
 MAR 31, 2000

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
 NORINYL
 @ SEARLE
 @ WATSON LABS

0.1MG; 2MG
 0.1MG; 2MG

N13625 004
 N13625 004

TABLET; ORAL-21
 NORINYL 1+50 21-DAY
 @ SEARLE
 @ WATSON LABS

0.05MG; 1MG
 0.05MG; 1MG

N13625 002
 N13625 002

AB TABLET; ORAL-21 5MG
AB LILLY 10MG
 + 5MG
 * 10MG

N07517 002
 N07517 004
 N07517 002
 N07517 004

REPRODUCED FROM THE ORIGINAL SOURCE

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL

FAULDING

N75396 002

EQ 5MG BASE/ML

JUN 20, 2000

N75484 001

EQ 5MG BASE/ML

JUN 20, 2000

N75481 001

EQ 5MG BASE/ML

JUN 30, 2000

N75494 001

EQ 1MG BASE/ML

JUN 30, 2000

N75494 002

EQ 5MG BASE/ML

JUN 30, 2000

VERSED

HLR

EQ 1MG BASE/ML

N18654 002

MAY 26, 1987

N18654 001

EQ 5MG BASE/ML

DEC 20, 1985

N18654 002

EQ 1MG BASE/ML

MAY 26, 1987

N18654 001

EQ 5MG BASE/ML

DEC 20, 1985

> ADD >

> ADD >

> ADD >

> ADD >

MIFEPRISTONE

TABLET; ORAL

MIFEPRX

+ POPULATION COUNCIL

200MG

N20687 001

SEP 28, 2000

> ADD >

> ADD >

> ADD >

> ADD >

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HCL

AB + DANBURY PHARMA

EQ 100MG BASE

N63065 001

DEC 30, 1991

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL

SINGULAIR

MERCK

EQ 4MG BASE

N20830 002

MAR 03, 2000

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

100MG

N75295 004

SEP 15, 2000

N75295 005

SEP 15, 2000

N75407 001

JAN 28, 2000

15MG

AB ESI LEDERLE

NABUMETONE

TABLET; ORAL

NABUMETONE

COPLEY PHARM

750MG

N75179 001

JUN 06, 2000

N75189 001

MAY 26, 2000

500MG

AB TEVA

RELAFEN

SMITHKLINE BEECHAM

500MG

N19583 001

DEC 24, 1991

N19583 002

DEC 24, 1991

N19583 001

DEC 24, 1991

N19583 002

DEC 24, 1991

500MG

AB +

750MG

AB +

500MG

AB +

750MG

AB +

750MG

AB +

750MG

AB +

750MG

AB +

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCIN

AB + LEDERLE

EQ 100MG BASE

N50649 002

MAY 31, 1990

N50649 002

EQ 100MG BASE

MAY 31, 1990

EQ 75MG BASE

N63065 002

JUN 10, 1999

N63065 002

JUN 10, 1999

N63065 001

DEC 30, 1991

EQ 100MG BASE

AB

AB

AB

AB

AB

MINOCYCLINE HCL

AB + DANBURY PHARMA

EQ 75MG BASE

N63065 002

JUN 10, 1999

N63065 002

JUN 10, 1999

N63065 001

DEC 30, 1991

EQ 75MG BASE

AB

AB

AB

AB

AB

AMERICAN PHARMACEUTICAL COMPANY

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

NADOLOL

TABLET; ORAL

AB CORGARD
 AB APOTHECON
 AB +

40MG
40MG

N18063 001
 N18063 001

NAPROXEN

TABLET, DELAYED RELEASE; ORAL
NAPROXEN

AB GENEVA PHARMS TECH 375MG

N75061 001
 FEB 18, 1998
 N75061 002
 FEB 18, 1998
 N75061 001
 FEB 18, 1998
 N75061 002
 FEB 18, 1998

AB

500MG

AB

375MG

AB

500MG

INVAMED

N50452 001
 N50462 001

EQ 500MG BASE
 EQ 500MG BASE

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION
 REVEX

+ BAXTER PHARM PROD

EQ 0.1MG BASE/ML
 EQ 1MG BASE/ML

N20459 001
 APR 17, 1995
 N20459 002
 APR 17, 1995
 N20459 001
 APR 17, 1995
 N20459 002
 APR 17, 1995

EQ 0.1MG BASE/ML

EQ 1MG BASE/ML

TABLET; ORAL

AA NIACIN
GLOBAL PHARM
@ IMPAX LABS
 AA NIACOR
UPSHER SMITH

500MG
500MG
500MG

N83115 001
 N83115 001
 N40378 001
 MAY 03, 2000

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

AB PENTAZOCINE AND NALOXONE HYDROCHLORIDES
RANBAXY
 EQ 0.5MG BASE;
 EQ 50MG BASE

TABLET, EXTENDED RELEASE; ORAL
ADALAT CC
 AB + BAYER

30MG
30MG

N20198 001
 APR 21, 1993
 N20198 001
 APR 21, 1993

> ADD >
 > ADD >

N7523 001
 MAR 17, 2000

NIFEDIPINE
BIOVAIL

60MG

N75289 001
 SEP 27, 2000
 N75128 001
 MAR 10, 2000

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

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

AB NALTREXONE HCL
EON

50MG

N75434 001
 MAR 08, 2000

NITROFURAZONE

CREAM; TOPICAL
FURACIN

* ROBERTS LABS

0.2%

N83783 001

NITROFURAZONE

CREAM; TOPICAL
 FURACIN
 + SHIRE LABS
 0.2%

OINTMENT; TOPICAL
 FURACIN
 AT * ROBERTS LABS
 AT + SHIRE LABS
 0.2%

N83789 001

N03795 001
 N05795 001

AT TABLET; VAGINAL
 NYSTATIN
 ODYSSEY PHARMS
 100,000 UNITS

AT SIDMAX LABS NJ
 100,000 UNITS

N62615 001
 OCT 17, 1985
 N62615 001
 OCT 17, 1985

NITROGLYCERIN

INJECTABLE; INJECTION
 NITRO IV
 * FOHL BOSKAMP

N18672 002
 AUG 30, 1983
 N18672 002
 AUG 30, 1983

EQ 0.2MG BASE/ML
 EQ 1MG BASE/ML
 EQ 0.2MG BASE/ML
 EQ 1MG BASE/ML

N19667 004
 JUN 12, 1991
 N19667 005
 JUN 12, 1991
 N19667 004
 JUN 12, 1991
 N19667 005
 JUN 12, 1991

TABLET; SUBLINGUAL
 NITROSTAT
 PARKE DAVIS

N21134 001
 MAY 01, 2000
 N21134 002
 MAY 01, 2000
 N21134 003
 MAY 01, 2000

EQ 10MG BASE/VIAL
 EQ 20MG BASE/VIAL
 EQ 10MG BASE/VIAL
 EQ 20MG BASE/VIAL

N21008 001
 NOV 25, 1998
 N21008 002
 NOV 25, 1998
 N21008 001
 NOV 25, 1998
 N21008 002
 NOV 25, 1998

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
 NORTRIPTYLINE HCL
 TARO

N75520 004
 MAY 08, 2000
 N75520 003
 MAY 08, 2000
 N75520 001
 MAY 08, 2000
 N75520 002
 MAY 08, 2000

EQ 10MG BASE
 EQ 25MG BASE
 EQ 50MG BASE
 EQ 75MG BASE

2.5MG
 10MG
 15MG
 2.5MG

N20592 001
 SEP 30, 1996
 N20592 004
 SEP 30, 1996
 N20592 005
 SEP 08, 1997
 N20592 001
 SEP 30, 1996
 N20592 004
 SEP 30, 1996
 N20592 005
 SEP 09, 1997

SOLUTION; ORAL
 NORTRIPTYLINE HCL
 PHARM ASSOC

N75606 001
 AUG 28, 2000

EQ 10MG BASE/5ML

10MG
 15MG

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

AMERICAN PHARMACEUTICAL COMPANY

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN' 2000 - SEP' 2000

OLANZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL

ZYPREXA ZYDIS
LILLY

5MG N21086 001
APR 06, 2000
10MG N21086 002
APR 06, 2000
15MG N21086 003
APR 06, 2000
20MG N21086 004
APR 06, 2000

+

ORLISTAT

CAPSULE; ORAL
XENICAL

+ HLR

* ROCHE

120MG N20766 001
APR 23, 1999
120MG N20766 001
APR 23, 1999

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

AB EON 100MG N40327 001
FEB 15, 2000
AB GENEVA PHARMS TECH 100MG N40284 001
JUN 19, 1998
AB IMPAX PHARM 100MG N40368 001
JUN 23, 2000
AB INVAMED 100MG N40284 001
JUN 19, 1998

OXYBUTYRIN CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

DITROPAN XL

AB * ALZA

5MG N20897 001
DEC 16, 1998
5MG N20897 001
DEC 16, 1998

+

OXYCODONE HYDROCHLORIDE

TABLET; ORAL
ROXICODONE
ROXANE

15MG N21011 001
AUG 31, 2000
30MG N21011 002
AUG 31, 2000

+

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN

BX * FURBERE PHARMA

10MG N20553 001
DEC 12, 1995

+

PURDUE PHARMA LP

10MG N20553 001
DEC 12, 1995
160MG N20553 005
MAR 15, 2000

+

ROXICODONE
ROXANE

10MG N20932 001
OCT 26, 1998
30MG N20932 002
OCT 26, 1998
10MG N20932 001
OCT 26, 1998
30MG N20932 002
OCT 26, 1998

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL
NOVARTIS

150MG N21014 001
JAN 14, 2000
300MG N21014 002
JAN 14, 2000
600MG N21014 003
JAN 14, 2000

+

INJECTABLE; INJECTION

PACLITAXEL

AB BAKER NORTON

6MG/ML N75184 001
SEP 15, 2000

TAXOL

AB + BRISTOL MYERS SQUIBB

6MG/ML N20262 001
DEC 29, 1992

*

6MG/ML N20262 001
DEC 29, 1992

> ADD >

> ADD >

> ADD >

> ADD >

> DLT >

> DLT >

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
 PROTONIX
 + WYETH AYERST

EQ 40MG BASE

N20987 001
 FEB 02, 2000

37.5MG

AB COPLEY PHARM

N75555 001
 FEB 18, 2000

PEMOLINE

TABLET; ORAL

PEMOLINE
 AMIDE PHARM

18.75MG

N75595 001
 FEB 28, 2000

37.5MG

N75595 002
 FEB 28, 2000

75MG

N75595 003
 FEB 28, 2000

AB COPLEY PHARM

18.75MG

N75030 003
 FEB 22, 2000

AB GENEVA PHARMS TECH

18.75MG

N75286 001
 DEC 27, 1999

37.5MG

N75286 002
 JUN 30, 1999

75MG

N75286 003
 JUN 30, 1999

AB INVAMED

18.75MG

N75286 001
 DEC 27, 1999

37.5MG

N75286 002
 JUN 30, 1999

75MG

N75286 003
 JUN 30, 1999

AB VINTAGE PHARMS

18.75MG

N75328 001
 APR 19, 2000

37.5MG

N75328 002
 APR 19, 2000

75MG

N75328 003
 APR 19, 2000

AB WATSON LABS

37.5MG

N75287 002
 SEP 18, 2000

75MG

N75287 003
 SEP 18, 2000

TABLET, CHEWABLE; ORAL

CYLERT
 + ABBOTT

37.5MG

N17703 001
~~N17703 001~~

~~37.5MG~~

AB PEMOLINE
 AMIDE PHARM

37.5MG

N75678 001
 JUL 26, 2000

PEMOLINE

TABLET, CHEWABLE; ORAL
PEMOLINE

AB COPLEY PHARM

37.5MG

N75555 001
 FEB 18, 2000

PENICILLIN G PROCAINE

INJECTABLE; INJECTION

MYCILLIN

AP KING PHARMS

300,000 UNITS/ML

600,000 UNITS/ML

300,000 UNITS/ML

600,000 UNITS/ML

N60101 002
 N60101 001
~~N60101 002~~
~~N60101 001~~

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTACARINAT

AP ARMOUR PHARM

300MG/VIAL

300MG/VIAL

N73447 001
 APR 28, 1994
 N73447 001
 APR 28, 1994

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

PENTOXIFYLLINE

AB IMPAX LABS

400MG

N75093 001
 AUG 10, 1999

400MG

AB IMPAX PHARM

N75093 001
 AUG 10, 1999

PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL

SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE

AGENTS

+ US ARMY

50%; 50%

N21084 001
 FEB 17, 2000

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

PERINDOPRIL ERBUMINE

TABLET; ORAL

ACEON
 @ SOLVAY 2MG
 @ 4MG
 @ 8MG
 SOLVAY PHARMA 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

PIROXICAM

CAPSULE; ORAL

PIROXICAM
 ROXANE 20MG
 @ 10MG
 @ 20MG

N73651 002
 FEB 26, 1993
 N73651 001
 FEB 26, 1993
 N73651 002
 FEB 26, 1993

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

K-DUR 10
 KEY PHARMS 10MEQ
 * 10MEQ

N19439 002
 JUN 13, 1986
 N19439 002
 JUN 13, 1986

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM 35MG
 AMARIN PHARMS 35MG
 CARRICK
 CAM-METRAZINE 35MG
 CANALE 35MG
 + PLEGINE 35MG
 * WYETH AYERST 35MG
 @

N85272 001
 N85272 001
 N83922 001
 N83922 001
 N12248 001
 N12248 001

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

PHYTONADIONE

INJECTABLE; INJECTION

KONAKION
 ROCHE 1MG/0.5ML
 @ 1.0MG/ML
 @ 1MG/0.5ML
 @ 1.0MG/ML

N11745 001
 N11745 003
 N11745 001
 N11745 003

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

PIROXICAM

CAPSULE; ORAL

PIROXICAM
 ROXANE 10MG

N73651 001
 FEB 26, 1993

SOLUTION/DROPS; OPHTHALMIC
 PREDNISOLONE SODIUM PHOSPHATE
 ALCON UNIVERSAL EQ 0.11% PHOSPHATE

N81043 001
 OCT 24, 1991
 N81044 001
 OCT 24, 1991

AT EQ 0.9% PHOSPHATE
 AT EQ 0.11% PHOSPHATE

N80780 001
 N80780 001
 N80322 001
 N80322 001

N40322 001
 JAN 19, 2000

AA 15MG/5ML

TABLET; ORAL

PREDNISOLONE 5MG
 GLOBAL PHARM 5MG
 @ IMPAX LABS 5MG
 @ PHOENIX LABS NY 5MG

PREDNISOLONE SODIUM PHOSPHATE

AT EQ 0.9% PHOSPHATE
 AT EQ 0.11% PHOSPHATE

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE
 AT STERIS EQ 0.11% PHOSPHATE N81043 001
 OCT 24, 1991
 AT STERIS EQ 0.9% PHOSPHATE N81044 001
 OCT 24, 1991

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

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

PREDNISONE

SYRUP; ORAL
 LIQUID PRED
 * MURO N87611 002
 5MG/5ML
 @ N87611 002
 5MG/5ML
 SEP 07, 1982

TABLET; ORAL

PREDNICEN-M
 AB CENT PHARMS 5MG N84655 001
 @ SCHWARZ PHARMA 5MG N84655 001
 BX PREDNISONE 5MG N80321 001
 BX PHOENIX LABS NY 20MG N83807 001
 @ 5MG N80321 001
 @ 20MG N83807 001

PROCHLORPERAZINE

SUPPOSITORY; RECTAL
 COMPRO
 @ PADDOCK 25MG N40246 001
 JUN 28, 2000

PROGESTERONE

CAPSULE; ORAL
 PROMETRIUM
 SCREENING FLOWERS 100MG N19781 001
 MAY 14, 1998
 200MG N19781 002
 OCT 15, 1999
 300MG N19781 003
 OCT 15, 1999
 * UNIMED PHARMS 100MG N19781 001
 MAY 14, 1998
 + 200MG N19781 002
 OCT 15, 1999
 @ 300MG N19781 003
 OCT 15, 1999

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL
 AP ABBOTT 25MG/ML N40372 001
 JUN 08, 2000
 AP 50MG/ML N40372 002
 JUN 08, 2000

PROPANTHELINE BROMIDE

TABLET; ORAL
 PRO-BANTHINE
 BP ROBERTS LABS 7.5MG N08732 003
 BP * 15MG N08732 002
 BP + SHIRE LABS 7.5MG N08732 003
 BP + 15MG N08732 002

PROPACARINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC
PROPACARINE HCL
 AT TAYLOR PHARMA 0.5% N40277 001
 MAR 16, 2000

19990910 10:00:00 AM '15

PROPOFOL

INJECTABLE; INJECTION

PROPOFOL

* GENSLIA SICOR PHARMS

10MG/ML

N75392 001
SEP 19, 2000

EQ 300MG BASE

N75439 002
APR 19, 2000

> ADD >
> ADD >

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

INDERAL

* WYETH AYERST

1MG/ML
1MG/ML

N16419 001
N16419 001

0.1MG
0.25MG

N09627 001
N09627 002
N09627 001
N09627 002

AP *

PROPRANOLOL HCL

1MG/ML

N75792 001
AUG 29, 2000

0.1MG
0.25MG

N09627 001
N09627 002

AP *

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL

VENTAIRE

* AVENTIS PHARMS

2MG

N83459 001

5MG

N20835 002
APR 14, 2000

* HOECHST MARION ROSS

QUINIDINE POLYGALACTURONATE

TABLET; ORAL

CARDIOQUIN

* PURDUE FREDERICK

275MG

N11642 002

EQ 1.5MG BASE

N20823 003
APR 21, 2000

* PURDUE FREDERICK

+

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

* PHARMAYTE

200MG

N84627 001

SOLUTION; ORAL

N21025 001
APR 21, 2000

* PHARMAYTE

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

RANBAXY

EQ 150MG BASE

N75439 001
APR 19, 2000

EQ 2MG BASE/ML

N21025 001
APR 21, 2000

RANBAXY

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

RANBAXY

EQ 300MG BASE

N75439 002
APR 19, 2000

RESERPINE

TABLET; ORAL

RESERPINE

GLOBAL PHARM

0.1MG
0.25MG

N09627 001
N09627 002
N09627 001
N09627 002

BP

@ IMPAX LABS

0.1MG
0.25MG

N09627 001
N09627 002

@

RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

PROCTER AND GAMBLE

5MG

N20835 002
APR 14, 2000

PROCTER AND GAMBLE

RIVASTIGMINE TARTRATE

CAPSULE; ORAL

EXELON

NOVARTIS

EQ 1.5MG BASE

N20823 003
APR 21, 2000

NOVARTIS

EQ 3MG BASE

N20823 004
APR 21, 2000

NOVARTIS

EQ 4.5MG BASE

N20823 005
APR 21, 2000

NOVARTIS

EQ 6MG BASE

N20823 006
APR 21, 2000

NOVARTIS

SOLUTION; ORAL

EXELON

EQ 2MG BASE/ML

N21025 001
APR 21, 2000

NOVARTIS

ROFECOXIB

TABLET; ORAL

VIOXX
* MERCK

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

25MG
25MG
50MG

N21042 002
MAY 20, 1999
N21042 002
MAY 20, 1999
N21042 003
FEB 25, 2000

> ADD >
> ADD >

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

TABLET; ORAL
VISICOL
+
INKINE

0.398GM; 1.102GM

N21097 001
SEP 21, 2000

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION
NORDITROPIN
NOVO NORDISK

N21148 001
JUN 20, 2000
N21148 002
JUN 20, 2000
N21148 003
JUN 20, 2000

5MG/1.5ML
10MG/1.5ML
15MG/1.5ML

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL

SELENIUM SULFIDE

ZENITH COSMETICS

2.5%
2.5%

N85777 001
N85777 001

SEVELAMER HYDROCHLORIDE

TABLET; ORAL

RENAGEL
GELTEX

400MG
800MG

N21179 001
JUL 12, 2000
N21179 002
JUL 12, 2000

80MG

120MG

160MG

240MG

80MG

120MG

160MG

240MG

N19865 001
OCT 30, 1992
N19865 005
APR 20, 1994
N19865 002
OCT 30, 1992
N19865 003
OCT 30, 1992
N19865 001
OCT 30, 1992
N19865 005
APR 20, 1994
N19865 002
OCT 30, 1992
N19865 003
OCT 30, 1992

SIRROLIMUS

TABLET; ORAL
RAPAMUNE

+ WYETH AYERST

1MG

N21110 001
AUG 25, 2000

SODIUM FLUORIDE, F-18

INJECTABLE; INTRAVENOUS

FLUORINE F-18

@ NYCOMED AMERSHAM

2mCi/ML

N17042 001

BETAPACE AF
BERLEX LABS

80MG

120MG

160MG

N21151 001
FEB 22, 2000
N21151 002
FEB 22, 2000
N21151 003
FEB 22, 2000

AMERICAN PHARMACEUTICAL COMPANY

SOTALOLOL HYDROCHLORIDE

TABLET; ORAL
SOTALOLOL HCL
EON

AB	80MG	N75366 001	MAY 01, 2000
AB	120MG	N75366 002	MAY 01, 2000
AB	160MG	N75366 003	MAY 01, 2000
AB	240MG	N75366 004	MAY 01, 2000
AB	80MG	N75237 001	MAY 01, 2000
AB	120MG	N75237 002	MAY 01, 2000
AB	160MG	N75237 003	MAY 01, 2000
AB	240MG	N75237 004	MAY 01, 2000
AB	80MG	N75429 001	MAY 01, 2000
AB	120MG	N75429 002	MAY 01, 2000
AB	160MG	N75429 003	MAY 01, 2000
AB	240MG	N75429 004	MAY 01, 2000
AB	80MG	N75238 001	JUL 13, 2000
AB	120MG	N75238 002	JUL 13, 2000
AB	160MG	N75238 003	JUL 13, 2000
AB	240MG	N75238 004	JUL 13, 2000

STRONTIUM CHLORIDE, SR-89

INJECTABLE; INJECTION
METASTRON
NYCOMED AMERSHAM

1mCi/ML
1mCi/ML

+

N20134 001
JUN 18, 1993
N20134 001
JUN 18, 1993

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

AT	OCUSULF-10	10%	N80660 001	OCT 18, 1988
AT	MIZA PHARMS USA	10%	N80660 001	OCT 18, 1988
AT	OPTORICE	10%	N80660 001	OCT 18, 1988
AT	OCUSULF-30	30%	N80660 002	OCT 18, 1988
AT	MIZA PHARMS USA	30%	N80660 002	OCT 18, 1988
AT	OPTORICE	30%	N80660 002	OCT 18, 1988
AT	SULFACETAMIDE SODIUM	10%	N89560 001	OCT 18, 1988
AT	ALCON UNIVERSAL	10%	N89560 001	OCT 18, 1988
AT	STERIS	10%	N89560 001	OCT 18, 1988

TACRINE HYDROCHLORIDE

CAPSULE; ORAL
COGNEX

AT	FIRST HORIZON	EQ 10MG BASE	N20070 001	SEP 09, 1993
AT	FIRST HORIZON	EQ 20MG BASE	N20070 002	SEP 09, 1993
AT	FIRST HORIZON	EQ 30MG BASE	N20070 003	SEP 09, 1993
AT	FIRST HORIZON	EQ 40MG BASE	N20070 004	SEP 09, 1993
AT	PARKE DAVIS PHARMS	EQ 10MG BASE	N20070 001	SEP 09, 1993
AT	PARKE DAVIS PHARMS	EQ 20MG BASE	N20070 002	SEP 09, 1993
AT	PARKE DAVIS PHARMS	EQ 30MG BASE	N20070 003	SEP 09, 1993
AT	PARKE DAVIS PHARMS	EQ 40MG BASE	N20070 004	SEP 09, 1993

TAMOXIFEN CITRATE

TABLET; ORAL

AT	TAMOXIFEN CITRATE	EQ 10MG BASE	N74732 001	JUN 26, 2000
AT	MYLAN	EQ 10MG BASE	N74539 001	MAY 31, 2000
AT	PHARMACHEMIE	EQ 10MG BASE	N74539 001	MAY 31, 2000

TAZAROTENE

CREAM; TOPICAL
TAZORAC
ALLERGAN

> ADD >
0.05%
0.1%
+

N21184 001
SEP 29, 2000
N21184 002
SEP 29, 2000

TABLET; ORAL
TERAZOSIN HCL
NOVOPHARM
AB EQ 1MG BASE
AB EQ 2MG BASE
AB EQ 5MG BASE
AB EQ 10MG BASE

N74446 001
MAY 18, 2000
N74446 002
MAY 18, 2000
N74446 003
MAY 18, 2000
N74446 004
MAY 18, 2000
N74530 001
APR 21, 2000
N74530 002
APR 21, 2000
N74530 003
APR 21, 2000
N74530 004
APR 21, 2000

TELMISARTAN

TABLET; ORAL
MICARDIS
+ BOEHRINGER INGELHEIM 20MG

N20850 003
APR 04, 2000

AB ZENITH GOLDLINE
AB EQ 1MG BASE
AB EQ 2MG BASE
AB EQ 5MG BASE
AB EQ 10MG BASE

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
TERAZOSIN HCL
INVAMED

AB EQ 1MG BASE
AB EQ 2MG BASE
AB EQ 5MG BASE
AB EQ 10MG BASE
AB EQ 1MG BASE
AB EQ 2MG BASE
AB EQ 5MG BASE
AB EQ 10MG BASE

N75667 001
JUL 28, 2000
N75667 002
JUL 28, 2000
N75667 003
JUL 28, 2000
N75667 004
JUL 28, 2000
N75140 002
FEB 11, 2000
N75140 003
FEB 11, 2000
N75140 001
FEB 11, 2000
N75140 004
FEB 11, 2000

TERBUTALINE SULFATE

AEROSOL, METERED; INHALATION
BRETHAIRE
NOVARTIS

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

0.2MG/INH
0.2MG/INH

N18762 001
AUG 17, 1984
N18762 001
AUG 17, 1984

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM
THERATECH

BX 5MG/24HR
* 2.5MG/24HR
BX + WATSON LABS
+ 5MG/24HR
+ 2.5MG/24HR

N20489 002
MAY 02, 1997
N20489 001
SEP 29, 1995
N20489 002
MAY 02, 1997
N20489 001
SEP 29, 1995

TABLET; ORAL
TERAZOSIN HCL
INVAMED

AB EQ 1MG BASE
AB EQ 2MG BASE
AB EQ 5MG BASE
AB EQ 10MG BASE

N74657 001
APR 28, 2000
N74657 002
APR 28, 2000
N74657 003
APR 28, 2000
N74657 004
APR 28, 2000

GEL; TOPICAL
ANDROGEL
+ UNIMED PHARMS
1%

N21015 001
FEB 28, 2000

UNIMED PHARMS

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SLO-PHYLLIN

@ AVENTIS

60MG

N85206 001

MAY 24, 1982

125MG

N85203 001

MAY 24, 1982

250MG

N85205 001

MAY 24, 1982

125MG

N85203 001

MAY 24, 1982

250MG

N85205 001

MAY 24, 1982

N85206 001

MAY 24, 1982

60MG

BC RHONE-POULENC ROBER

BC

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

BETALIN S

@ UNILEX

100MG/ML

N80853 001

N80853 001

100MG/ML

N80556 001

N80556 001

100MG/ML

AP THIAMINE HCL

AP AM PHARM PARTNERS

AP +

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLOPIDINE HCL

DANBURY PHARMA

250MG

N75309 001

APR 26, 2000

AB

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

NOVEX

EQ 0.25% BASE

N75411 001

SEP 08, 2000

EQ 0.5% BASE

N75412 001

SEP 08, 2000

AT

AT

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

TINZAPARIN SODIUM

INJECTABLE; INJECTION

INNOHEP

+ DUPONT PHARMA

20,000 IU/ML

N20484 001

JUL 14, 2000

TIZANIDINE HYDROCHLORIDE

TABLET; ORAL

ZANAFLEX

ELAN PHARMA

EQ 2MG BASE

N20397 002

FEB 04, 2000

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

CHELSEA LABS

500MG

500MG

500MG

500MG

N86109 001

N86109 001

N12678 001

N12678 001

N12678 001

TRETINOIN

CREAM; TOPICAL

RENOVA

+ JOHNSON AND JOHNSON

0.02%

N21108 001

AUG 31, 2000

GEL; TOPICAL

RETIN-A

+ JOHNSON AND JOHNSON

0.025%

0.025%

N17579 002

N17579 002

N75529 001

FEB 22, 2000

TRETINOIN

SPEAR PHARMS

0.025%

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

FLUTEX

ZENITH GOLDLINE

0.025%

0.1%

0.5%

N85539 001

N85539 002

N85539 003

AT

AT

AT

TRIAMCINOLONE ACETONIDE

CREAM, TOPICAL

FLUTEX
 @ ZENITH GOLDLINE
 @
 @
TRIALEX
 @ ZENITH GOLDLINE

0.025%
 0.1%
 0.5%
0.025%
0.1%
0.5%

AT
AT
AT

N85539 001
 N85539 002
 N85539 003

N87430 001
 NOV 01, 1988
 N87429 001
 NOV 01, 1988
 N87428 001
 NOV 01, 1988
 N87430 001
 NOV 01, 1988
 N87429 001
 NOV 01, 1988
 N87428 001
 NOV 01, 1988

0.025%
 0.1%
 0.5%

@
 @
 @

OINTMENT; TOPICAL

ARISTOCORT A
 * FUJISAWA HEALTHCARE

0.5%
0.5%

AT
AT

N80745 003
 N80745 003

FLUTEX
 @ ZENITH GOLDLINE

0.025%
0.1%
0.5%

AT
AT

N87375 001
 NOV 01, 1988
 N87377 001
 NOV 01, 1988
 N87376 001
 NOV 01, 1988
 N87375 001
 NOV 01, 1988
 N87377 001
 NOV 01, 1988
 N87376 001
 NOV 01, 1988

0.025%
 0.1%
 0.5%

@
 @
 @

KENALOG
 * APOTHECON

0.025%
0.025%
0.1%
0.1%

AT
AT
AT
AT

N11600 003
 N11600 003
N11600 003
 N11600 001

TRIAMCINOLONE ACETONIDE

* ALTANA

0.025%
0.025%
0.1%
0.1%
0.5%

AT
AT
AT
AT
AT

N85691 001
 N85691 001
N85691 003
 N85691 003
N85691 002

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE
 0.5%
0.025%
0.025%
0.1%
0.1%
0.5%
0.5%

AT
AT
AT
AT
AT
AT
AT

N85691 002
 N87358 001
 N87356 001
 N87357 001
 N87357 001
 N87385 001
 N87385 001

SPRAY, METERED; NASAL
 TRI-NASAL

+ MURO 0.05MG/SPRAY

N20120 001
 FEB 04, 2000

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL
ZENITH GOLDLINE

AB EQ 1MG BASE
AB EQ 2MG BASE
AB EQ 5MG BASE
AB EQ 10MG BASE

N87612 001
 NOV 19, 1982
N87613 001
 NOV 19, 1982
 N87328 001
 NOV 19, 1982
N87614 001
 NOV 19, 1982
 N87612 001
 NOV 19, 1982
 N87613 001
 NOV 19, 1982
 N87328 001
 NOV 19, 1982
 N87614 001
 NOV 19, 1982

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHEXYPHENIDYL HCL
 WEST WARD

AA 2MG
AA 5MG

N40337 002
 FEB 16, 2000
 N40337 001
 FEB 16, 2000

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
 PRIMISOL
 ASCENT PRDS
 +
 +
 EQ 25MG BASE/5ML
 EQ 25MG BASE/5ML
 EQ 50MG BASE/5ML
 N74374 001
 JUN 23, 1995
 N74374 001
 JUN 23, 1995
 N74973 001
 JAN 24, 2000

TROGLITAZONE
 TABLET; ORAL
 REZULIN
 PARKE DAVIS PHARMS
 300MG
 400MG
 200MG
 300MG
 400MG
 N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
 NEUTREXIN
 + MEDIMMUNE ONCOLOGY
 * US BIOSCIENCE
 EQ 25MG BASE/VIAL
 EQ 25MG BASE/VIAL
 N20326 001
 DEC 17, 1993
 N20326 001
 DEC 17, 1993

TROPICAMIDE
 SOLUTION/DROPS; OPHTHALMIC
 TROPICACYL
 AKORN
 0.5%
 1%
 1%
 0.5%
 1%
 1%
 N40314 001
 SEP 29, 2000
 N40315 001
 SEP 29, 2000

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION
 TRELSTAR DEPOT
 + DEBIO RECHERCHE
 EQ 3.75MG BASE/VIAL
 N20715 001
 JUN 15, 2000

TROPICAMIDE
 ALCON UNIVERSAL
 MIZA PHARMS USA
 OPTOPICS
 STERIS
 UNOPROSTONE ISOPROPYL
 SOLUTION/DROPS; OPHTHALMIC
 RESCULA
 + CIBA
 0.15%
 N21214 001
 AUG 03, 2000

TROGLITAZONE

TABLET; ORAL
 PRELAY
 SANKYO
 200MG
 300MG
 400MG
 200MG
 300MG
 400MG
 N20719 001
 JAN 29, 1997
 N20719 003
 AUG 04, 1997
 N20719 002
 JAN 29, 1997
 N20719 001
 JAN 29, 1997
 N20719 003
 AUG 04, 1997
 N20719 002
 JAN 29, 1997
 N20720 001
 JAN 29, 1997
 TABLET; ORAL
 REZULIN
 PARKE DAVIS PHARMS
 200MG
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997
 N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997
 N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997
 N20720 001
 JAN 29, 1997

URSODIOL

CAPSULE; ORAL
ACTIGALL

AB + NOVARTIS

300MG

N19594 002

DEC 31, 1987

N19594 002

DEC 31, 1987

300MG

* URSODIOL

AB AMIDE PHARM

300MG

N75517 001

MAR 14, 2000

N75592 001

MAY 25, 2000

300MG

AB COPLEY PHARM

TABLET; ORAL

URSO

* AXCAN

250MG

N20675 001

DEC 10, 1997

N20675 001

DEC 10, 1997

+ AXCAN SCANDIPHARM

250MG

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

AP BEDFORD

10MG/VIAL

N75549 001

JUN 13, 2000

N75549 002

JUN 13, 2000

AP

20MG/VIAL

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

COVERA-HS

BC SEARLE

180MG

N20552 001

FEB 26, 1996

N20552 001

FEB 26, 1996

BC +

180MG

BC

240MG

N20552 002

FEB 26, 1996

N20552 002

FEB 26, 1996

BC +

240MG

VERTEPORFIN

INJECTABLE; INJECTION

VISUDYNE

+ QLT

15MG/VIAL

N21119 001

APR 12, 2000

VITAMIN A

CAPSULE; ORAL

VITAMIN A

GLOBAL PHARM

@ IMPAX LABS

50,000 USP UNITS

N80952 001

N80952 001

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

GLOBAL PHARM

@ IMPAX LABS

EQ 50,000 UNITS BASE

N80953 001

N80953 001

N80953 001

N80953 001

N80953 001

WARFARIN SODIUM

TABLET; ORAL

WARFARIN SODIUM

AB INVAMED

3MG

N40196 008

JUL 26, 2000

N40196 009

JUL 26, 2000

AB

6MG

ZAFIRLUKAST

TABLET; ORAL

ACCOLATE

ASTRAZENECA UK

10MG

N20547 003

SEP 17, 1999

ZOLMITRIPTAN

TABLET; ORAL

ZOMIG

ASTRAZENECA PHARMS

2.5MG

N20768 001

NOV 25, 1997

ASTRAZENECA PHARMACEUTICALS LIMITED

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

ZOLMITRIPTAN

TABLET; ORAL

ZOMIG

5MG

+ ASTRAZENECA PHARMS

ZENECA

2.5MG

N20768 002
NOV 25, 1997

N20768 001

NOV 25, 1997

5MG

N20768 002

NOV 25, 1997

*

ZONISAMIDE

CAPSULE; ORAL

ZONEGRAN

100MG

+ DAINIPPON

N20789 001

MAR 27, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN' 2000 - SEP' 2000

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN
PERRIGO 650MG

N75077 001
FEB 25, 2000

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CONTAC
SMITHKLINE 8MG; 75MG
+ 8MG; 75MG

N18099 001
N18099 001

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER

* BAYER 550MG
650MG

@

MEASURIN
* BAYER 550MG
650MG

N16030 001
N16030 001
N16030 002
N16030 002

TABLET; ORAL
CIMETIDINE
LEINER 200MG

200MG

NOVOPHARM

200MG

N74961 001
JUN 19, 1998
N74961 001
JUN 19, 1998

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL

DIMETANE
@ WHITEHALL ROBINS 12MG

N10799 011
JUN 10, 1983

2%

N21143 001
APR 12, 2000

DINETAPP

* WHITEHALL ROBINS 12MG

N10799 011
JUN 10, 1983

DOCOSANOL

CREAM; TOPICAL

ABREVA
* AVANIR 10%

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

N20941 001
JUL 25, 2000
N20941 001
JUL 25, 2000

SPONGE; TOPICAL

E-Z SCRUB
BECTON DICKINSON 4%

N73416 001
MAR 14, 2000

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN
PHARM FORM 200MG

> DLT >
> DLT >
> DLT >
> DLT >

SOLUTION; TOPICAL
CHLORAPREP
* MEDI FLEX HOSP 2%; 70%

N20832 001
JUL 14, 2000

N74782 001
JUL 06, 1998
N74782 001
JUL 06, 1998

SPONGE; TOPICAL

CHLORAPREP
+ MEDI FLEX HOSP 2%; 70%

N20832 001
JUL 14, 2000

TABLET; ORAL
IBUPROFEN
LEINER 200MG

N74931 001
JUL 20, 1998

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SOLUTION; TOPICAL

CHLORAPREP
* MEDI FLEX HOSP 2%; 70%

SPONGE; TOPICAL

CHLORAPREP
+ MEDI FLEX HOSP 2%; 70%

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

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'2000 - SEP'2000

Product Name	Strength	Lot/Date	Manufacturer	Strength	Lot/Date	Manufacturer
<u>IBUPROFEN</u>						
TABLET; ORAL						
IBUPROFEN	200MG	N74931 001	AEROSOL; VAGINAL			N14349 002
NOVOPHARM		JUL 20, 1998	DELFIN	12.5%		N14349 002
			@ ORTHO			
			@ PERSONAL PRODS	12.5%		
				> DLT >		
				> ADD >		
<u>IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE</u>						
SUSPENSION; ORAL						
CHILDREN'S MOTRIN COLD	100MG/5ML;15MG/5ML	N21128 001	LOTION; TOPICAL			N75014 001
+ MCNEIL CONS		AUG 01, 2000	PERMETHRIN	1%		MAR 28, 2000
			ALPHARMA			
<u>LOPERAMIDE HYDROCHLORIDE</u>						
TABLET; ORAL						
LOPERAMIDE HCL	2MG	N73254 001	AEROSOL; TOPICAL			N21043 001
LEINER		JUL 30, 1993	RID MOUSE	4%;EQ 0.33% BASE		MAR 07, 2000
NOVOPHARM NC	2MG	N73254 001	+ PFIZER			
PERRIGO	2MG	JUL 30, 1993				
		N75232 001				
		JAN 06, 2000				
<u>NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE</u>						
SOLUTION/DROPS; OPHTHALMIC						
VISINE-A	0.025%;0.3%	N20485 001	TABLET; ORAL			N75212 001
AKORN		JAN 31, 1996	RANITIDINE	EQ 75MG BASE		JAN 14, 2000
PFIZER	0.025%;0.3%	N20485 001	CHELSEA LABS	EQ 75MG BASE		N75294 001
		JAN 31, 1996	CHEMINOR DRUGS	EQ 75MG BASE		MAR 28, 2000
			GENPHARM	EQ 75MG BASE		N75497 001
			LEINER	EQ 75MG BASE		JAN 14, 2000
			RANBAXY	EQ 75MG BASE		JUN 21, 1999
			TORPHARM	EQ 75MG BASE		N75132 001
			ZENITH GOLDLINE	EQ 75MG BASE		JAN 14, 2000
				EQ 75MG BASE		N75254 001
				EQ 75MG BASE		JAN 14, 2000
				EQ 75MG BASE		MAY 04, 2000
				EQ 75MG BASE		N75296 001
				EQ 75MG BASE		JAN 14, 2000
				EQ 75MG BASE		N75094 001
				EQ 75MG BASE		JUN 21, 1999
				EQ 75MG BASE		N75132 001
				EQ 75MG BASE		JAN 14, 2000
				EQ 75MG BASE		N75254 001
				EQ 75MG BASE		JAN 14, 2000
				EQ 75MG BASE		MAY 04, 2000
				EQ 75MG BASE		N75296 001
				EQ 75MG BASE		JAN 14, 2000
				EQ 75MG BASE		N75094 001
				EQ 75MG BASE		JUN 21, 1999

RANITIDINE HYDROCHLORIDE

TABLET EFFERVESCENT, ORAL

ZANTAC 75

* GLAXO WELLCOME

@ WARNER LAMBERT

EQ 75MG BASE

EQ 75MG BASE

N20745 001

FEB 26, 1998

N20745 001

FEB 26, 1998

TERBINAFINE HYDROCHLORIDE

SOLUTION; TOPICAL

LAMISIL AT

+ NOVARTIS

1*

N21124 001

MAR 17, 2000

Product Approved as of 10/1/00

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

CUMULATIVE SUPPLEMENT NUMBER 9 SEPTEMBER '00

NO SEPTEMBER 2000 APPROVALS

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

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
1- (11-dodecylamino-10-hydr oxyundecyl) -3,7-dimethylxa nithine hydrogen methanesulfonate TN=	Treatment of hormone refractory prostate carcinoma.	Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 DD= 1/18/00 MA=
3- (3,5-Dimethyl-1H-2ylmeth ylene) -1,3-dihydro-indol-2 -one TN=	Treatment of von Hippel-Lindau disease.	Sugen, Inc. 230 East Grand Ave. South San Francisco CA 94080 DD= 3/23/00 MA=
Abetimus TN=	Treatment of lupus nephritis.	La Jolla Pharmaceutical Co. 6455 Nancy Ridge Dr. San Diego CA 92121 DD= 7/28/00 MA=
Angiotensin 1-7 TN=	Treatment of neutropenia associated with autologous bone marrow transplantation.	Maret Pharmaceuticals 4041 MacArthur Blvd. Suite 375 Newport Beach CA 92660 DD= 2/16/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Anti-thymocyte Globulin (Rabbitt) TN=Thymoglobulin	Treatment of myelodysplastic syndrome (MDS)	SangStat Medical Corporat 6300 Dumbarton Circle Freemont CA 94555 DD= 9/6/00 MA=
arsenic trioxide TN=Atrivex	Treatment of myelodysplastic syndrome.	Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 DD= 7/17/00 MA=
Arsenic trioxide TN=Atrivex	Treatment of multiple myeloma.	Cell Therapeutics, Inc. 201 Elliott Ave. West, Suite 400 Seattle WA 98119 DD= 4/28/00 MA=
Bis(4-fluorophenyl)phenyla cetamide TN=	Treatment of sickle cell disease.	ICAgen Inc. Ion Channel Advances PO Box 14487 Durham NC 27709 DD= 3/2/00 MA=
Brimonidine TN=Alphagan	Treatment of anterior ischemic optic neuropathy.	Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine CA 92623-9534 DD= 2/7/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
ic alfactant TN=Infasurf	Acute respiratory distress syndrome (ARDS)	ONY, Inc. Baird Research Park 1576 Sweet Home Road Amherst NY 14228 DD= 9/5/00 MA=
armustine TN=	Treatment of intracranial malignancies.	Direct Therapeutics, Inc. 1001 Bayhill Dr., Suite 100 San Bruno CA 94066 DD= 7/3/00 MA=
entruroides immune F(ab)2 TN=Alacramyn	Treatment of scorpion envenomations requiring medical attention.	Silanes Laboratories S.A. de Amores #1034 Col Del Valle C.P. 03100 Mexico D.F. DD= 6/12/00 MA=
etuximab TN=	Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor.	ImClone Systems Incorporated Branchburg Corporate Center 22 Chubb Way Somerville NJ 08876 DD= 7/3/00 MA=
Chimeric (human-murine) 250 IgG monoclonal antibody TN=	Treatment of renal cell carcinoma.	Wilex Biotechnology GmbH Grillparzerstrasse 10B 81675 Munich Germany DE DD= 7/24/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Chimeric, humanized monoclonal antibody to staphylococcus TN=	Prophylaxis of Staphylococcus epidermidis sepsis in low birth weight (1500 grams or less) infants.	Biosynexus, Inc. 9610 Medical Center Drive Suite 100 Rockville MD 20850 DD= 8/3/00 MA=
Cisplatin/epinephrine TN=IntraDose	Treatment of metastatic malignant melanoma.	Matrix Pharmaceutical, In 34700 Campus Drive Fremont CA 94555-3612 DD= 9/7/00 MA=
Cisplatin/epinephrine TN=IntraDose	Treatment of squamous cell carcinoma of the head and neck.	Matrix Pharmaceutical, In 34700 Campus Drive Fremont CA 94555-3612 DD= 4/3/00 MA=
Deoxyribose, phosphorothioate TN=	Treatment of advanced malignant melanoma (Stages II,III, IV).	Genta, Inc. 99 Hayden Ave., Suite 200 Lexington MA 02421-7966 DD=7/31/00 MA=
DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2 TN=Leuvectin	Treatment of renal cell carcinoma.	Vical Incorporated 9373 Towne Center Dr. Suite 100 San Diego CA 92121-3088 DD= 4/28/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name N=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
AP-Modified autologous umor vaccine N=O-Vax	Adjuvant therapy for ovarian cancer patients	AVAX Technologies, Inc. 4520 Main Street Suite 930 Kansas City MO 64111 DD= 9/21/00 MA=
c. chyl eicosapentaenoate N=	Treatment of Huntington's disease.	Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA=
c. lucinolone N=	Treatment uveitis involving the posterior segment of the eye.	Bausch & Lomb 8500 Hidden River Parkway Tampa FL 33637 DD= 7/31/00 MA=
fluorouracil N=	Treatment of glioblastoma multiforme.	Ethypharm SA 194 Bureaux de la Colline - 92213 Saint-Cloud Cedex France FR DD= 6/29/00 MA=
EG1.1-mAb N=	For patients with dermatomyositis	Alexion Pharmaceuticals, Inc. 25 Science Park Suite 360 New Haven CT 06511 DD= 9/21/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Halofuginone TN=Stenorol	Treatment of systemic sclerosis.	Collgard Biopharmaceutical Textile House, 2 Koifman s Tel-Aviv 68012 Israel IL DD= 2/7/00 MA=
Histamine TN=Maxamine	For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.	Maxim Pharmaceuticals, Inc 8899 University Center Lar Suite 400 San Diego CA 92122 DD= 2/1/00 MA=
Hydroxycobalamin TN=CYANOKIT	Treatment of acute cyanide poisoning	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 250 Minnetonka MN 55305 DD= 9/22/00 MA=
Hypericin TN=	Treatment of glioblastoma multiforme.	Nexell Therapeutics 2751 Centerville Rd., Suit Wilmington DE 19808 DD= 8/3/00 MA=
Hypericin TN=	Treatment of cutaneous T-cell lymphoma.	Nexell Therapeutics, Inc. 2751 Centerville Rd., Suit Wilmington DE 19808 DD= 2/7/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name N=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
IL-4 Pseudomonas Toxin Fusion Protein IL-4 (38-37)-PE38KDEL N=	Treatment of astrocytic glioma.	Neurocrine Biosciences, Inc. 10555 Science Center Dr. San Diego CA 92121 DD= 4/6/00 MA=
Iodine I 131 Tis (indium-diethylenetriam inepentaacetic acid) tyrosyllysine/hMN-14 m734 F(ab') ₂ bispecific monoclonal antibody N= Pentacea	Treatment of small-cell lung cancer.	IBC Pharmaceuticals, L.L.C. 300 American Rd. Morris Plains NJ 07950 DD= 2/22/00 MA=
lanreotide, Somatostatin N=Ipstyl	Treatment for acromegly	IPSEN, Inc. 27 Maple Street Milford MA 01757 DD= 9/11/00 MA=
Levodopa and carbidopa N=Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215 DD= 1/18/00 MA=
Liposomal nystatin N=Nyotran	Treatment of invasive fungal infections.	Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands TX 77381-1191 DD= 6/13/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name:	Indication Designated:	Sponsor & Address
Generic Name		DD=Date Designated
TN=Trade Name		MA=Marketing Approval
Meropenem TN=Merrem IV	Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms.	Zeneca Pharmaceuticals 1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437 DD= 4/27/00 MA=
Natural human lymphoblastoid interferon-alpha TN=	Treatment of Behcet's disease.	Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo TX 79101-3206 DD= 1/18/00 MA=
Natural human lymphoblastoid interferon-alpha TN=	Treatment of papillomavirus warts in the oral cavity of HIV positive patients.	Amarillo Biosciences, Inc. 800 West 9th Avenue Amarillo TX 79101 DD= 8/10/00 MA=
Omega-3 (n-3) polyunsaturated fatty acids TN=Omacor	Treatment of IgA nephropathy.	Pronova Biocare, AS PO Box 420 1327 Lysaker Norway DD= 5/4/00 MA=
Phenylbutyrate TN=	Treatment of acute promyelocytic leukemia.	Elan Corporation 1300 Gould Dr. Gainesville GA 30504 DD= 1/19/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name N=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
recombinant glycine2-human glucagon-like peptide-2 N=	Treatment of short bowel syndrome.	NPS Allelix Corp. 6850 Goreway Dr. Mississauga, Ontario L4V 1V7 Canada CA DD= 6/29/00 MA=
recombinant human antithrombin III N=	Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.	AT III LLC c/o Genzyme Corporation 15 Pleasant St. Connector, Framingham MA 01701 DD= 4/6/00 MA=
recombinant human highly phosphorylated acid alpha-glucosidase N=TBD	For enzyme replacement therapy in patients with all subtypes of glycogen storage disease type II (GSDII, Pompe Disease)	Novazyme Pharmaceuticals, 800 Research Parkway Suite 200 Oklahoma City OK 73104 DD= 9/20/00 MA=
recombinant human insulin-like growth factor-I N=PV802	Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines.	GroPep Pty Ltd. Gate 11, Victoria Dr. Adelaide SA 5000 Australia AU DD= 2/16/00 MA=
hemacemide N=Ecovia	Treatment of Huntington's disease.	AstraZeneca LP 725 Chesterbrook Blvd. Wayne PA 19087-5677 DD= 3/6/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
rSP-C lung surfactant TN=Venticute	Treatment of adult respiratory distress syndrome.	Byk Gulden Pharmaceutical Byk-Gulden StraBe 2 78467 Konstanz Germany DE DD= 4/3/00 MA=
Soluble complement receptor type 1 TN=	Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.	Avant Immunotherapeutics, 119 Fourth Ave. Needham MA 02494-2725 DD= 3/6/00 MA=
Synthetic human secretin TN=	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4 DD= 3/7/00 MA=
Synthetic porcine secretin TN=	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4 DD= 3/7/00 MA=
Technetium Tc 99m pterotetramide TN=	For the identification of ovarian carcinomas.	Endocyte, Inc. 1205 Kent Ave. Lafayette IN 47906 DD= 2/16/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approva
Letrodathydroacetic acid TN=	Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland.	Danforth, Jr., MD, Elliot University of Vermont 84 Beartown Rd. Underhill VT 05489 DD= 5/1/00 MA=
Thymalfasin TN=Zadaxin	Treatment of hepatocellular carcinoma.	SciClone Pharmaceuticals, 901 Mariner's Blvd., Suite San Mateo CA 94404 DD= 3/6/00 MA=
Trimetrexate TN=Neutrexin	Treatment of metastatic osteogenic sarcoma.	Medimmune Oncology, Inc. One Tower Bridge 100 Front St., Suite 400 West Conshohocken PA 19428 DD= 8/10/00 MA=
Epreotide TN=Octastatin	Treatment of esophageal variceal hemorrhage patients with portal hypertension.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 1/10/00 MA=
Epreotide TN=Octastatin	Treatment of gastrointestinal and pancreatic fistulas.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 1/10/00 MA=

Orphan Products Designations and Approvals List
January through September 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Vapreotide TN=Octastatin	Prevention of early postoperative complications following pancreatic resection.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH DD= 3/6/00 MA=
vigabatrin TN=Sabril	Treatment of infantile spasms.	Aventis Pharmaceuticals Inc. P.O. Box 9627 Kansas City MO 64137 DD= 6/12/00 MA=
Zoledronate TN=Zometa, Zabel	Treatment of tumor induced hypercalcemia.	Novartis Pharmaceuticals 59 Route 10 East Hanover NJ 07936-1000 DD= 8/18/00 MA=

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

NO SEPTEMBER 2000 ADDITIONS

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
075077 001	ACETAMINOPHEN; ACETAMINOPHEN	4717720	MAY 31, 2010		PC	NOV 12, 2000
020338 001	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010			
020380 001	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010		NCE	MAY 31, 2001
020748 001	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010		NDF	MAY 26, 2003
020760 001	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE	RE34440	MAY 31, 2010	U-275		
020760 002	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE	6080756	JUL 05, 2016			
020560 001	ALENDRONATE SODIUM; FOSAMAX	6080756	JUN 05, 2016	U-303	M-3	NOV 24, 2002
>ADD>		6090410	JUN 06, 2015		I-309	SEP 29, 2003
020560 002	ALENDRONATE SODIUM; FOSAMAX	6008207	DEC 02, 2012	U-303	M-3	NOV 24, 2002
020560 003	ALENDRONATE SODIUM; FOSAMAX	6090410	JUN 06, 2015			
020560 004	ALENDRONATE SODIUM; FOSAMAX	6008207	DEC 02, 2012	U-303	M-3	NOV 24, 2002
>ADD>		6090410	DEC 02, 2012			
>ADD>		6015801	JUL 17, 2018	U-353	NS	OCT 20, 2000
>ADD>		4621077	AUG 06, 2007	U-114	D-61	OCT 20, 2003
>ADD>		5358941	DEC 02, 2012		D-62	OCT 20, 2003
>ADD>		5681590	DEC 02, 2012			
>ADD>		5804570	FEB 17, 2015			
>ADD>		5849726	JUN 06, 2015			
>ADD>		5944329	JUL 17, 2018			
>ADD>		6008207	JUN 06, 2015			
020560 005	ALENDRONATE SODIUM; FOSAMAX	6015801	JUL 17, 2018	U-353	NS	OCT 20, 2003
>ADD>		4621077	AUG 06, 2007	U-114	D-61	OCT 20, 2003
>ADD>		5358941	DEC 02, 2012		D-62	OCT 20, 2003
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>ADD>		5944329	JUL 17, 2018			
>ADD>		6008207	JUN 06, 2015			
021107 001	ALOSETRON HYDROCHLORIDE; LOTRONEX	6015801	JUL 17, 2018	U-353	NS	OCT 20, 2003
018276 001	ALPRAZOLAM; XANAX	4621077	AUG 06, 2007	U-114	D-61	OCT 20, 2003
018276 002	ALPRAZOLAM; XANAX	4621077	AUG 06, 2007			
018276 003	ALPRAZOLAM; XANAX	5358941	DEC 02, 2012			
018276 004	ALPRAZOLAM; XANAX	5681590	DEC 02, 2012			
020221 001	AMIFOSTINE; ETHYOL	5804570	FEB 17, 2015			
020221 002	AMIFOSTINE; ETHYOL	5849726	JUN 06, 2015			
021007 001	AMPRENAVIR; AGENERASE	5944329	JUL 17, 2018			
>ADD>		6008207	JUN 06, 2015			
		4508726	SEP 16, 2002	U-46		FEB 09, 2005
		4508726	SEP 16, 2002	U-46		
		4508726	SEP 16, 2002	U-46		
		4508726	SEP 16, 2002	U-46		
021007 002	AMPRENAVIR; AGENERASE	5723490	MAR 03, 2013	U-257		JUN 24, 2002
		5646180	JUL 08, 2014	U-257		JUN 24, 2002
		5585397	DEC 17, 2013			
		5723490	MAR 03, 2015	U-257		
		5646180	JUL 08, 2014	U-257		
		5585397	DEC 17, 2013			
021039 001	AMPRENAVIR; AGENERASE	5723490	MAR 03, 2015	U-257		
		5646180	JUL 08, 2014	U-257		

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
020541 001	ANASTROZOLE; ARIMIDEX	RE36617	DEC 27, 2009		NCE	JUN 30, 2005
020883 001	ARGATROBAN; ACOVA				ODE	SEP 25, 2007
021248 001	ARSENIC TRIOXIDE; TRISENOX				NCE	SEP 25, 2005
020971 001	ARTICAINA HYDROCHLORIDE; SEPTOCAINE	5164194	NOV 01, 2010		NC	APR 03, 2003
021127 001	AZELASTINE HYDROCHLORIDE; OPTIVAR	5164194*	MAY 01, 2011		NCE	NOV 01, 2001
					NDF	MAY 22, 2003
					PED	MAY 01, 2002
020610 001	BALSALAZIDE DISODIUM; COLAZAL	4412992	JUL 08, 2001		PED	NOV 22, 2003
021055 001	BEXAROTENE; TARGRETIN				NCE	JUL 18, 2005
021056 001	BEXAROTENE; TARGRETIN				ODE	DEC 29, 2006
					NCE	DEC 29, 2004
					NDF	JUN 28, 2003
019982 001	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		
019982 002	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		
020186 001	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 2000	U-63		
020186 002	BISOPROLOL FUMARATE; ZIAC	4258062*PED	SEP 24, 2000	U-63		
020186 003	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 2000	U-63		
050443 002	BLEOMYCIN SULFATE; BLENOXANE	4258062	MAR 24, 2000	U-63		
020929 001	BUDESONIDE; PULMICORT RESPULES	4787536	FEB 27, 2006		ODE	FEB 20, 2003
020929 002	BUDESONIDE; PULMICORT RESPULES	4787536	FEB 27, 2006		NDF	AUG 08, 2003
020711 002	BUPROPION HYDROCHLORIDE; ZYBAN				D-54	SEP 10, 2002
020711 003	BUPROPION HYDROCHLORIDE; ZYBAN				D-54	SEP 10, 2002
018731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22, 2000	U-13		
018731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008	U-13		
018731 003	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763*PED	NOV 22, 2000	U-13		
018731 004	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646*PED	NOV 14, 2008	U-13		
		4182763	MAY 14, 2008	U-13		
		5015646	MAY 14, 2008	U-13		
		4182763	MAY 22, 2000	U-13		
		5015646*PED	NOV 22, 2000	U-13		
		4182763	MAY 22, 2000	U-13		
		5015646	MAY 14, 2008	U-13		
		4182763*PED	NOV 22, 2000	U-13		
		5015646*PED	NOV 14, 2008	U-13		
		4182763	MAY 22, 2000	U-13		
		5015646	MAY 14, 2008	U-13		
		4182763*PED	NOV 22, 2000	U-13		
		5015646*PED	NOV 14, 2008	U-13		

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
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020822 001	CITALOPRAM HYDROBROMIDE; CELEXA	5624963	APR 29, 2014	U-323	NCE	JUL 17, 2003
021046 001	CITALOPRAM HYDROBROMIDE; CELEXA	5679717	APR 29, 2014	U-323	NCE	JUL 17, 2003
021142 001	CLOBETASOL PROPIONATE; OLUX FOAM	5693675	DEC 02, 2014		NDF	MAY 26, 2003
021143 001	CLOTIMAZOLE; TRIVAGIZOLE 3	5607669	JUN 10, 2014	U-323	NP	NOV 24, 2001
021141 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	5917007	APR 29, 2014	U-323	NCE	MAY 26, 2005
		5919832	JUN 10, 2014			
		5919832	JUN 10, 2014			
021176 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	5917007	APR 29, 2014	U-323	NCE	MAY 26, 2005
		5607669	JUN 10, 2014	U-323		
		5693675	DEC 02, 2014			
		5679717	APR 29, 2014	U-323		
		5624963	APR 29, 2014	U-323		
020287 001	DALTEPARIN SODIUM; FRAGMIN				D-60	AUG 03, 2003
020287 003	DALTEPARIN SODIUM; FRAGMIN				D-60	AUG 03, 2003
020287 004	DALTEPARIN SODIUM; FRAGMIN				D-60	AUG 03, 2003
020713 001	DESOGESTREL; MIRCETTE	RE35724	OCT 20, 2008	U-339		
020212 001	DEXRAZOXANE HYDROCHLORIDE; ZINECARD	5242901	SEP 07, 2010			
		4963551	DEC 21, 2007			
		4275063	JUN 23, 2003			
		5242901	SEP 07, 2010	U-339		
		4963551	DEC 21, 2007			
		4275063	JUN 23, 2003			
020212 002	DEXRAZOXANE HYDROCHLORIDE; ZINECARD					
020154 002	DIDANOSINE; VIDEX	5616566	AUG 29, 2006	U-180	D-58	OCT 28, 2002
020154 003	DIDANOSINE; VIDEX				D-58	OCT 28, 2002
020154 004	DIDANOSINE; VIDEX				D-58	OCT 28, 2002
020154 005	DIDANOSINE; VIDEX				NS	OCT 28, 2002
020154 006	DIDANOSINE; VIDEX				D-58	OCT 28, 2002
020939 001	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5288505	JUN 26, 2011			
		5529791	JUN 25, 2013			
020939 002	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5288505	JUN 26, 2011			
		5529791	JUN 25, 2013			
020939 003	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5288505	JUN 26, 2011			
		5529791	JUN 25, 2013			
020939 004	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5288505	JUN 26, 2011			
		5529791	JUN 25, 2013			
021168 001	DIVALPROEX SODIUM; DEPAKOTE ER	4988731	JAN 29, 2008		NP	AUG 04, 2003
		4913906	APR 03, 2007			
020941 001	DOCOSANOL; ABREVA					
020931 001	DOFETILIDE; TIKOSYN	6124363	OCT 09, 2018		NCE	JUL 25, 2005
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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
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020931 002	DOFETILIDE;TIKOSYN	6124363	OCT 09, 2018			
020931 003	DOFETILIDE;TIKOSYN	6124363	OCT 09, 2018			
020623 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906775	MAR 06, 2007			
020623 002	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906775	MAR 06, 2007			
020624 001	DOLASETRON MESYLATE MONOHYDRATE;ANZEMET	4906775	MAR 06, 2007			
020869 001	DORZOLAMIDE HYDROCHLORIDE;COSOPT	4797413	APR 28, 2008			
		4619939	OCT 28, 2003			
021027 001	DOXERCALCIFEROL;HECTOROL	5602116	APR 03, 2115		NDF	APR 06, 2003
		5707980	FEB 11, 2117		U-321 NCE	JUN 09, 2004
021145 001	EFLORNITHINE HYDROCHLORIDE;VANIQA	4413141	NOV 01, 2000		U-321 NCE	JUL 27, 2003
		4720489	JAN 19, 2005		NP	
		5648394	JUL 15, 2014		U-334	
019221 001	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
		4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
019221 003	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
		4472380*PED	MAR 18, 2002			
		4374829	FEB 22, 2000			
018998 001	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
018998 002	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
018998 003	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
018998 005	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
019309 001	ENALAPRILAT;VASOTEC	4374829	FEB 22, 2000			
020444 001	EPOPROSTENOL SODIUM;FLOLAN	4374829	FEB 22, 2000			
020444 002	EPOPROSTENOL SODIUM;FLOLAN	4374829	FEB 22, 2000			
>ADD>						
020874 001	ESTRADIOL CYPIONATE;LUNELLE	5122383	MAY 17, 2011			
020907 001	ESTRADIOL;ACTIVELLE	5227169	MAY 17, 2011			
020655 001	ESTRADIOL;ALORA	5164190	DEC 11, 2010			
020655 002	ESTRADIOL;ALORA	5122383	MAY 17, 2011			
		5227169	MAY 17, 2011			
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		512238				

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 USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
020655 003	ESTRADIOL;ALORA	5122383	MAY 17, 2011		
		5227169	MAY 17, 2011		
		5212199	MAY 17, 2011		
		5164190	DEC 11, 2010		
		5108995	APR 28, 2009	U-311	
		5382573	JAN 17, 2012		
021040 001	ESTRADIOL;ORTHO-PREFEST				
020323 001	ESTRADIOL;VIVELLE	4994278	MAR 04, 2008		I-254 AUG 16, 2003
020323 002	ESTRADIOL;VIVELLE	5300291	APR 05, 2011		I-254 AUG 16, 2003
020323 003	ESTRADIOL;VIVELLE	4814168	MAR 04, 2008		I-254 AUG 16, 2003
020323 004	ESTRADIOL;VIVELLE	4994267	MAR 04, 2008		NS AUG 16, 2003
020323 005	ESTRADIOL;VIVELLE				I-254 AUG 16, 2003
075696 001	ETODOLAC;ETODOLAC	4966768	APR 30, 2008	PC	FEB 04, 2001
020584 001	ETODOLAC;LODINE XL	4966768	OCT 30, 2007		
020584 002	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008		
020584 003	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008		
		4966768	OCT 30, 2007		
019304 002	FENOFIBRATE;TRICOR (MICRONIZED)	4966768*PED	APR 30, 2008		
019304 003	FENOFIBRATE;TRICOR (MICRONIZED)	4966768	OCT 30, 2007		
019304 004	FENOFIBRATE;TRICOR (MICRONIZED)	4966768	OCT 30, 2007		
020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	4966768*PED	APR 30, 2008		
		4966768	OCT 30, 2007		
020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017	U-138	
		6113942	FEB 28, 2015		
		5578610	NOV 26, 2013	U-139	FEB 25, 2003
		5932247	FEB 28, 2015	NCE	JUL 25, 2001
		5855912	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		6113942	FEB 28, 2015		
020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	FEB 25, 2003
		5932247	FEB 28, 2015	NCE	JUL 25, 2001
		5855912	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		6113942	FEB 28, 2015		
020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	FEB 25, 2003
		5932247	FEB 28, 2015	NCE	JUL 25, 2001
		5855912	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		6113942	FEB 28, 2015		
		5578610	NOV 26, 2013	U-139	FEB 25, 2003
		5932247	FEB 28, 2015	NCE	JUL 25, 2001
		5855912	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		6113942	FEB 28, 2015		
		5578610	NOV 26, 2013	U-139	FEB 25, 2003
		5932247	FEB 28, 2015	NCE	JUL 25, 2001
		5855912	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		6113942	FEB 28, 2015		

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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
020786 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA-D	6037353	MAR 14, 2017	U-138		
		6039974	JUL 31, 2018			
		6113942	FEB 28, 2015			
019949 004	FLUCONAZOLE; DIFLUCAN	4416682	JUN 02, 2001			
		4404216	JAN 29, 2004			
018936 007	FLUOXETINE HYDROCHLORIDE; SARAFEM	4971998	NOV 20, 2007	U-338 NP		JUL 06, 2003
		5114976	MAY 19, 2009	U-341		
		5744501	MAY 19, 2009	U-342		
018936 008	FLUOXETINE HYDROCHLORIDE; SARAFEM	4971998	NOV 20, 2007	U-338 NP		JUL 06, 2003
		5114976	MAY 19, 2009	U-341		
		5744501	MAY 19, 2009	U-342		
021077 001	FLUTICASON PROPIONATE; ADVAIR DISKUS 100/50				NC	AUG 24, 2003
021077 002	FLUTICASON PROPIONATE; ADVAIR DISKUS 250/50				NC	AUG 24, 2003
021077 003	FLUTICASON PROPIONATE; ADVAIR DISKUS 500/50				NC	AUG 24, 2003
020378 001	FOLLITROPIN ALFA/BETA; GONAL-F				ODE	MAY 24, 2007
					I-306	MAY 24, 2003
					ODE	MAY 24, 2007
020378 002	FOLLITROPIN ALFA/BETA; GONAL-F				I-306	MAY 24, 2003
					I-306	MAY 24, 2007
020378 003	FOLLITROPIN ALFA/BETA; GONAL-F				ODE	MAY 24, 2007
					PED	MAR 29, 2002
020235 001	GABAPENTIN; NEURONTIN				U-125 D-43	SEP 29, 2001
		4589402	JUL 26, 2004	U-242		
		5767251	JUN 16, 2015			
		4087544	JAN 16, 2000	U-86		
		5084479	JAN 02, 2010	U-125		
		4894476*PED	NOV 02, 2008			
		4087544*PED	JUL 16, 2000	U-86		
		5084479*PED	JUL 02, 2010			
		4894476	MAY 02, 2008			
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			
		4894476	MAY 02, 2008			
		4894476	MAY 02, 2008			
		5084479	JAN 02, 2010			
		5084479	JAN 02, 2010			
		4087544	JAN 16, 2000			
		5084479*PED	JUL 02, 2010			
		4894476*PED	NOV 02, 2008			
		4087544*PED	JUL 16, 2000			
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017			
		4087544	JAN 16, 2000			
		5084479	JAN 02, 2010			
		4894476	MAY 02, 2008			
		4087544*PED	JUL 16, 2000			
		5084479*PED	JUL 02, 2010			
020235 002	GABAPENTIN; NEURONTIN				PED	MAR 29, 2002
					D-43	SEP 29, 2001
					U-125	
					U-86	
					U-125	
					U-86	
					U-125	
					U-86	
020235 003	GABAPENTIN; NEURONTIN				PED	MAR 29, 2002
					D-43	SEP 29, 2001
					U-125	
					U-86	

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
019778 001	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001		
019778 002	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001		
019778 003	HYDROCHLOROTHIAZIDE; PRINZIDE	4522899	APR 09, 2004	U-3	
019771 001	IBUPROFEN; ADVIL COLD AND SINUS	4552899*	OCT 09, 2004		
019763 003	IFOSFAMIDE; IFEX/MESNEX KIT	4220660	MAR 06, 2001	U-21	
019763 004	IFOSFAMIDE; IFEX/MESNEX KIT	5696172	OCT 06, 2013	U-21	
020986 001	INSULIN ASPART RECOMBINANT; NOVOLOG				NCE JUN 07, 2005
021081 001	INSULIN GLARGINE; LANTUS				PED OCT 20, 2005
020563 001	INSULIN LISPRO; HUMALOG				NCE APR 20, 2005
021018 001	INSULIN LISPRO; HUMALOG MIX 50/50				D-56 APR 04, 2003
020563 002	INSULIN LISPRO; HUMALOG PEN				NC DEC 22, 2002
020571 001	IRINOTECAN HYDROCHLORIDE; CAMPTOSAR	5474978	JUN 16, 2014	U-111	D-56 APR 04, 2003
020966 001	ITRACONAZOLE; SPORANOX	5514646	MAY 07, 2013		NCE JUN 14, 2001
019084 001	KETOCONAZOLE; NIZORAL				I-299 APR 20, 2003
020857 001	LAMIVUDINE; COMBIVIR				
		4727064	FEB 23, 2005		
		4942162	FEB 11, 2003		
		4828838*	PED MAR 17, 2006	NCE	NOV 17, 2000
		4833130*	PED MAR 17, 2006	PED	MAY 17, 2001
		4837208	SEP 17, 2005		
		5047407*	PED AUG 08, 2009		
		4724232*	PED MAR 17, 2006		
		4818538*	PED MAR 17, 2006		
		5859021*	PED NOV 15, 2012	U-248	
		5905082*	PED NOV 18, 2016	U-248	
		6113920	OCT 23, 2017	U-257	
		6113920*	PED APR 23, 2018	U-257	
		4724232	SEP 17, 2005		
		4818538	SEP 17, 2005		
		4828838	SEP 17, 2005		
		4833130	SEP 17, 2005		
		5047407	FEB 08, 2009		
		5859021	MAY 15, 2012		
		5905082	MAY 18, 2016		
		4837208*	PED MAR 17, 2006		
		5047407	NOV 17, 2009	NCE	NOV 17, 2000
	LAMIVUDINE; EPIVIR	5905082	MAY 18, 2016	PED	MAY 17, 2001
020564 001		5905082*	PED NOV 18, 2016		
		5047407*	PED MAY 17, 2010		
		5047407	NOV 17, 2009	NCE	NOV 17, 2000
		6004968	MAR 20, 2018	PED	MAY 17, 2001
020596 001		5047407*	PED MAY 17, 2010		
	LAMIVUDINE; EPIVIR	6004968*	PED SEP 20, 2018		
		5047407*	PED MAY 17, 2010		

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
019558 006	LISINAPRIL; PRINIVIL	4374829	DEC 29, 2001			
019777 001	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 002	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 003	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 004	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 005	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 006	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
021226 001	LOPINAVIR; KALETRA					
>ADD>		5914332	DEC 13, 2015	U-351		
>ADD>		5635523	JUN 30, 2014	U-352		
>ADD>		5541206	JUL 30, 2013	U-348		
>ADD>		5674882	OCT 07, 2014	U-344		
>ADD>		5886036	DEC 29, 2012	U-345		
>ADD>		6037157	JUN 26, 2016	U-346		
>ADD>		5846987	DEC 29, 2012	U-350		
>ADD>		5648497	DEC 29, 2012			
>ADD>		5541206	JUL 30, 2013	U-348		
>ADD>		5914332	DEC 13, 2005	U-351		
>ADD>		5635523	JUN 03, 2014	U-352		
>ADD>		5846987	DEC 29, 2012	U-350		
>ADD>		5648497	JUL 15, 2014			
021251 001	LOPINAVIR; KALETRA					
>ADD>		5674882	OCT 07, 2014	U-344		
>ADD>		5886036	DEC 29, 2012	U-345		
>ADD>		6037157	JUN 26, 2016	U-346		
>ADD>		4282233	JUN 19, 2002	U-77		
>ADD>		4659716	APR 21, 2004	U-142		
019658 001	LORATADINE; CLARITIN					
>ADD>		4863931	SEP 15, 2008	U-77		
>ADD>		4282233*PED	DEC 19, 2002	U-142		
>ADD>		4659716*PED	OCT 21, 2004			
>ADD>		4863931*PED	MAR 15, 2009			
>ADD>		6132758	JUN 01, 2018			
>ADD>		4659716	APR 21, 2004	U-142		
>ADD>		4282233	JUN 19, 2002	U-77		
020641 001	LORATADINE; CLARITIN					
>ADD>		4863931	SEP 15, 2008	U-142		
>ADD>		4659716*PED	OCT 21, 2004			
>ADD>		4863931*PED	MAR 15, 2009			
>ADD>		4282233*PED	DEC 19, 2002	U-77		
>ADD>		4659716	APR 21, 2004	U-142		
>ADD>		4282233	JUN 19, 2002	U-77		
>ADD>		4371516	FEB 01, 2000			
>ADD>		4863931	SEP 15, 2008			
020704 001	LORATADINE; CLARITIN REDITABS					
>ADD>		4659716*PED	OCT 21, 2004	U-142		
>ADD>		4282233*PED	DEC 19, 2002	U-77		
>ADD>		4371516*PED	AUG 01, 2000	U-77		
>ADD>		4863931*PED	MAR 15, 2009			

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
019670 001	LORATADINE; CLARITIN-D	4282233	JUN 19, 2002	U-77		
		4659716	APR 21, 2004	U-142		
		4863931	SEP 15, 2008			
		4282233*PED	DEC 19, 2002	U-77		
		4659716*PED	OCT 21, 2004	U-142		
		4863931*PED	MAR 15, 2009			
020470 001	LORATADINE; CLARITIN-D 24 HOUR	4659716	APR 21, 2004	U-142		
		4282233	JUN 19, 2002	U-77		
		5314697*PED	APR 23, 2013			
		4863931	SEP 15, 2008			
		4659716*PED	OCT 21, 2004	U-142		
		4282233*PED	DEC 19, 2002	U-77		
		4863931*PED	MAR 15, 2009			
		5314697	APR 23, 2013			
		4966335	MAR 09, 2012			
		4966335	MAR 09, 2012			
020803 001	LOTEPREDNOL ETABONATE; ALREX	4980173	JAN 29, 2002	U-78	NCE	APR 13, 2005
020583 001	LOTEPREDNOL ETABONATE; LOTEMAX	5696172	OCT 06, 2013			
020938 001	MELOXICAM; MOBIC					
020049 001	MESALAMINE; PENTASA					
019884 001	MESNA; MESNEX					
020357 001	METFORMIN HYDROCHLORIDE; GLUCOPHAGE					
020357 002	METFORMIN HYDROCHLORIDE; GLUCOPHAGE					
020357 003	METFORMIN HYDROCHLORIDE; GLUCOPHAGE					
020357 004	METFORMIN HYDROCHLORIDE; GLUCOPHAGE					
020357 005	METFORMIN HYDROCHLORIDE; GLUCOPHAGE					
021121 001	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA					
021121 002	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA					
019815 001	MIDODRINE HYDROCHLORIDE; PROAMATINE					
019815 002	MIDODRINE HYDROCHLORIDE; PROAMATINE					
020687 001	MIFEPRISTONE; MIFEPREX					
>ADD>		4386085	JAN 08, 2002			
>ADD>		4447424	JAN 08, 2002			
>ADD>		4626531	OCT 12, 2004			

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 USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
>ADD>		6127353	OCT 03, 2017		
020762 001	MOMETASONE FUROATE MONOHYDRATE; NASONEX	5565473	NOV 30, 2010	U-228 I-300	MAR 03, 2003
020830 002	MONTELUKAST SODIUM; SINGULAIR			NS	MAR 03, 2003
				NCE	FEB 20, 2003
019516 001	MORPHINE SULFATE; MS CONTIN	4366310	DEC 10, 2000		
019516 002	MORPHINE SULFATE; MS CONTIN	4366310	DEC 10, 2000		
019516 003	MORPHINE SULFATE; MS CONTIN	4366310	DEC 10, 2000		
019516 004	MORPHINE SULFATE; MS CONTIN	4366310	DEC 10, 2000		
019516 005	MORPHINE SULFATE; MS CONTIN	4366310	DEC 10, 2000		
020152 001	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012		
020152 002	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012		
020152 003	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012		
020152 004	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012		
020152 005	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012		
020152 006	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012		
020381 001	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331	
020381 002	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331	
020381 003	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331	
020381 004	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331	
020381 005	NIACIN; NIASPAN TITRATION ST	6080428	MAY 27, 2017	U-331	
>ADD>		5834011	MAY 01, 2007		
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>ADD>		5834011	MAY 01, 2007		
020536 001	NICOTINE; NICOTROL	5501236	JUN 08, 2010		
020714 001	NICOTINE; NICOTROL	6098632	JUN 08, 2010		
021134 001	NITROGLYCERIN; NITROSTAT			NDF	MAY 01, 2003
021134 002	NITROGLYCERIN; NITROSTAT			NDF	MAY 01, 2003
021134 003	NITROGLYCERIN; NITROSTAT			NDF	MAY 01, 2003
019921 001	OFLOXACIN; OCUFLOX	4382892	SEP 02, 2003		
		4551456	NOV 14, 2003	U-80	
020592 001	OLANZAPINE; ZYPREXA			I-297	MAR 17, 2003
020592 002	OLANZAPINE; ZYPREXA			I-297	MAR 17, 2003
020592 003	OLANZAPINE; ZYPREXA			I-297	MAR 17, 2003
020592 004	OLANZAPINE; ZYPREXA			I-297	MAR 17, 2003
020592 005	OLANZAPINE; ZYPREXA			I-297	MAR 17, 2003
020592 006	OLANZAPINE; ZYPREXA			I-297	MAR 17, 2003
021086 001	OLANZAPINE; ZYPREXA ZYDIS	5457895	SEP 30, 2013	NCE	SEP 30, 2001
		5229382	APR 23, 2011	U-324	
		5605897	FEB 25, 2014	U-325	
		5627178	APR 23, 2011	U-326	
		5736541	MAR 24, 2015	U-328	
		5817655	APR 23, 2011	U-327	
		5817656	APR 23, 2011	U-326	

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021086 002	OLANZAPINE; ZYPREXA ZYDIS	5457895	SEP 30, 2013	U-324	NCE	SEP 30, 2001
		5229382	APR 23, 2011	U-325		
		5605897	FEB 25, 2014	U-326		
		5627178	APR 23, 2011	U-328		
		5736541	MAR 24, 2015	U-327		
		5817655	APR 23, 2011	U-326		
		5817656	APR 23, 2011	U-328		
021086 003	OLANZAPINE; ZYPREXA ZYDIS	5457895	SEP 30, 2013	U-324	NCE	SEP 30, 2001
		5736541	MAR 24, 2015	U-327		
		5817655	APR 23, 2011	U-326		
		5817656	APR 23, 2011	U-328		
		5229382	APR 23, 2011	U-324		
		5605897	FEB 25, 2014	U-325		
		5627178	APR 23, 2011	U-326		
021086 004	OLANZAPINE; ZYPREXA ZYDIS	5457895	SEP 30, 2013	U-324	NCE	SEP 30, 2001
		5229382	APR 23, 2011	U-325		
		5605897	FEB 25, 2014	U-326		
		5627178	APR 23, 2011	U-328		
		5817655	APR 23, 2011	U-327		
		5817656	APR 23, 2011	U-326		
020688 001	OLOPATADINE HYDROCHLORIDE; PATANOL	4559330	JUL 31, 2004	U-58	I-301	MAR 20, 2003
019715 001	OLSALAZINE SODIUM; DIPENTUM	5344658	SEP 06, 2011			
020103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	5344658	SEP 06, 2011			
020103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	5344658	SEP 06, 2011			
020103 003	ONDANSETRON HYDROCHLORIDE; ZOFRAN	5578628	JUN 24, 2006	U-44	I-269	AUG 27, 2002
		4753789	JUN 24, 2006	U-44		
		4695578	JAN 25, 2005	U-183		
		4695578	JAN 25, 2005	U-183		
		5955488	NOV 14, 2015			
		6063802	NOV 14, 2015			
		5578628	JUN 24, 2006	U-330		
		4695578	JAN 25, 2005	U-330		
		4753789	JUN 24, 2006	U-329		
		5955488	NOV 14, 2015			
		6063802	NOV 14, 2015			
		5578628	JUN 24, 2006	U-330		
		4695578	JAN 25, 2005	U-330		
		4753789	JUN 24, 2006	U-330		
020781 002	ONDANSETRON; ZOFRAN ODT	6004996	JAN 06, 2018			
020605 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN					
020781 001	ONDANSETRON; ZOFRAN ODT					
020766 001	ORLISTAT; XENICAL				NCE	JAN 14, 2005
021014 001	OXCARBAZEPINE; TRILEPTAL				NCE	JAN 14, 2005
021014 002	OXCARBAZEPINE; TRILEPTAL				NCE	JAN 14, 2005
021014 003	OXCARBAZEPINE; TRILEPTAL				NCE	JAN 14, 2005

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020262 001	PACLITAXEL; TAXOL	6096331	FEB 22, 2013		D-57	JUN 20, 2003
020987 001	PANTOPRAZOLE SODIUM; PROTONIX	4758579	JUL 19, 2005		NCE	FEB 02, 2005
020819 001	PARICALCITOL; ZEMPLAR	5246925	SEP 21, 2010	U-314		
		5587497	DEC 24, 2013			
		6113944	DEC 14, 2014			
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6121291	MAR 17, 2017	U-286		
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020031 002	PAROXETINE HYDROCHLORIDE; PAXIL	6113944	DEC 14, 2014		U-286	
>ADD>		6121291	MAR 17, 2017			
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020031 003	PAROXETINE HYDROCHLORIDE; PAXIL	6113944	DEC 14, 2014		U-286	
>ADD>		6121291	MAR 17, 2017			
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020031 004	PAROXETINE HYDROCHLORIDE; PAXIL	6113944	DEC 14, 2014			
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020031 005	PAROXETINE HYDROCHLORIDE; PAXIL	6113944	DEC 14, 2014		U-286	
>ADD>		6121291	MAR 17, 2017			
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020710 001	PAROXETINE HYDROCHLORIDE; PAXIL	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020885 001	PAROXETINE HYDROCHLORIDE; PAXIL	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020885 002	PAROXETINE HYDROCHLORIDE; PAXIL	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020885 003	PAROXETINE HYDROCHLORIDE; PAXIL	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020885 004	PAROXETINE HYDROCHLORIDE; PAXIL	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020936 001	PAROXETINE HYDROCHLORIDE; PAXIL CR	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			
020936 002	PAROXETINE HYDROCHLORIDE; PAXIL CR	6121291	MAR 17, 2017		U-286	
>ADD>		6063927	APR 23, 2019			
		6080759	MAY 19, 2015			

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
021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER; SKIN EXPOSURE REDUCT	5607979	MAY 30, 2015	U-343	NCE	FEB 17, 2005
020698 001	POLYETHYLENE GLYCOL 3350; MIRALAX	6048901	APR 20, 2019	U-335	I-281	JUN 09, 2003
019898 002	PRAVASTATIN SODIUM; PRAVACHOL	5622985	APR 22, 2014		I-304	JAN 18, 2003
					I-287	FEB 10, 2003
					I-286	JAN 18, 2003
					D-51	JAN 18, 2003
019898 003	PRAVASTATIN SODIUM; PRAVACHOL	5622985	APR 22, 2014	U-335	I-281	JUN 09, 2003
					I-304	JAN 18, 2003
					I-287	FEB 10, 2003
					I-286	JAN 18, 2003
019898 004	PRAVASTATIN SODIUM; PRAVACHOL	5622985	APR 22, 2014	U-335	D-51	JAN 18, 2003
					I-281	JUN 09, 2003
					I-304	JAN 18, 2003
					I-287	FEB 10, 2003
					I-286	JAN 18, 2003
					D-51	JAN 18, 2003
>ADD>					I-310	OCT 04, 2003
>ADD>					I-310	OCT 04, 2003
>ADD>					I-310	OCT 04, 2003
>ADD>					I-310	OCT 04, 2003
>ADD>					I-310	OCT 04, 2003
>ADD>					I-310	OCT 04, 2003
019157 001	PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED	4448774	DEC 22, 2002	U-3	NPP	OCT 15, 2002
019901 001	RAMIPRIL; ALTACE	4587258	JAN 27, 2005	U-156	PED	APR 15, 2003
		5061722	OCT 19, 2008		PED	JAN 12, 2002
019901 002	RAMIPRIL; ALTACE	4587258	JAN 27, 2005	U-156	NCE	JUL 12, 2001
		5061722	OCT 19, 2008		NPP	OCT 15, 2002
019901 003	RAMIPRIL; ALTACE	4587258	JAN 27, 2005	U-156	PED	APR 15, 2003
		5061722	OCT 19, 2008		PED	JAN 12, 2002
019901 004	RAMIPRIL; ALTACE	4587258	JAN 27, 2005	U-3	NCE	JUL 12, 2001
		5061722	OCT 19, 2008		NPP	OCT 15, 2002
>ADD>					NCE	JUL 12, 2001
>ADD>					NPP	OCT 15, 2002
020630 001	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	AUG 15, 2009	U-156	PED	APR 15, 2003
		5466700	AUG 30, 2013		PED	JAN 12, 2002
		5019583	FEB 15, 2009		NCE	JUL 12, 2001
		5466700	FEB 15, 2009		NPP	OCT 15, 2002
020630 002	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5466700	MAR 01, 2014	U-156	PED	APR 15, 2003
		5019583	FEB 15, 2009		PED	JAN 12, 2002
		5466700	AUG 30, 2013		NCE	JUL 12, 2001
		5019583	FEB 15, 2009		NPP	OCT 15, 2002
020630 003	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5466700	MAR 01, 2014	U-156	PED	APR 15, 2003
		5019583	FEB 15, 2009		PED	JAN 12, 2002
		5466700	AUG 30, 2013		NCE	JUL 12, 2001
		6051252	DEC 22, 2017		NPP	OCT 15, 2002
020903 001	RIBAVIRIN; REBETOL	5019583	AUG 15, 2009	U-156	PED	APR 15, 2003
020835 001	RISEDRONATE SODIUM; ACTONEL	5466700	MAR 01, 2014	U-156	PED	JAN 12, 2002
		6051252	DEC 22, 2017		NCE	JUL 12, 2001
020835 002	RISEDRONATE SODIUM; ACTONEL	5583122	DEC 10, 2013	U-222	I-292	APR 14, 2003
					I-291	APR 14, 2003
					I-290	APR 14, 2003
					I-293	APR 14, 2003
					I-292	APR 14, 2003
					NCE	MAR 27, 2003
					I-291	APR 14, 2003
					I-293	APR 14, 2003
>ADD>					I-290	APR 14, 2003
>ADD>					I-290	APR 14, 2003
>ADD>					I-290	APR 14, 2003
>ADD>					I-290	APR 14, 2003

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020588 001	RISPERIDONE; RISPERDAL	5453425	JUL 11, 2014			
		5616587	JUL 11, 2014			
020659 001	RITONAVIR; NORVIR	6037157	JUN 26, 2016			
		5674882	OCT 07, 2014			
		5886036	DEC 29, 2012		NCE	MAR 01, 2001
020945 001	RITONAVIR; NORVIR	5648497	JUL 15, 2014	U-347		
		5846987	DEC 29, 2012	U-348		
		5541206	JUL 30, 2013	U-347		
		5635523	JUN 03, 2014	U-347		
		4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
020823 003	RIVASTIGMINE TARTRATE; EXELON	5602176	FEB 11, 2014	U-322	NCE	APR 21, 2005
020823 004	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
020823 005	RIVASTIGMINE TARTRATE; EXELON	5602176	FEB 11, 2014	U-322	NCE	APR 21, 2005
020823 006	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
021025 001	RIVASTIGMINE TARTRATE; EXELON	5602176	FEB 11, 2014	U-322	NCE	APR 21, 2005
		5602162	FEB 11, 2014	U-322	NCE	APR 21, 2005
020864 001	RIZATRIPTAN BENZOATE; MAXALT	5602162	FEB 11, 2014	U-266		
020864 002	RIZATRIPTAN BENZOATE; MAXALT	6063811	MAY 16, 2017	U-266		
021042 001	ROFECOXIB; VIOXX	6063811	MAY 16, 2017	U-266		
021042 002	ROFECOXIB; VIOXX	6063811	MAY 16, 2017	U-266		
021042 003	ROFECOXIB; VIOXX	6063811	MAY 16, 2017	U-266		
021052 001	ROFECOXIB; VIOXX	6063811	MAY 16, 2017	U-266		
021052 002	ROFECOXIB; VIOXX	6063811	MAY 16, 2017	U-266		
021071 002	ROSIGLITAZONE MALEATE; AVANDIA	6063811	MAY 16, 2017	U-266		
021071 003	ROSIGLITAZONE MALEATE; AVANDIA	6063811	MAY 16, 2017	U-266		
021071 004	ROSIGLITAZONE MALEATE; AVANDIA	6063811	MAY 16, 2017	U-266		
020990 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4940731	AUG 30, 2009	U-312		
021179 001	SEVELAMER HYDROCHLORIDE; RENAGEL	5496545	AUG 11, 2013	U-246	NCE	OCT 30, 2003
021179 002	SEVELAMER HYDROCHLORIDE; RENAGEL	5667775	SEP 16, 2014	U-246	NCE	OCT 30, 2003
		5496545	AUG 11, 2013	U-246	NCE	OCT 30, 2003
020478 001	SEVOFLURANE; ULTANE	5667775	SEP 16, 2014	U-246	NCE	OCT 30, 2003
		5990176	JAN 27, 2017	NCE		JUN 07, 2000
		6074668	JAN 09, 2018	PED		DEC 07, 2000
		5990176*PED	JUL 27, 2017			
		6074668*PED	JUL 09, 2018			
020280 006	SOMATROPIN RECOMBINANT; GENOTROPIN	4968299	JUN 28, 2008		I-302	JUN 20, 2003
					ODE	JUN 20, 2007

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
020280 007	SOMATROPIN RECOMBINANT; GENOTROPIN	4968299	JUN 28, 2008	I-302	JUN 20, 2003
020280 001	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	ODE	JUN 20, 2007
020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015	I-302	JUN 20, 2003
020280 003	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	ODE	JUN 20, 2007
020280 004	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015	I-302	JUN 20, 2003
020280 005	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	ODE	JUN 20, 2007
020280 008	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015	I-302	JUN 20, 2003
020280 009	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	ODE	JUN 20, 2007
020280 010	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015	I-302	JUN 20, 2003
020280 011	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	ODE	JUN 20, 2007
020280 012	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015	I-302	JUN 20, 2003
020280 013	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	ODE	JUN 20, 2007
019721 001	SOMATROPIN RECOMBINANT; NORDITROPIN	5716338	FEB 10, 2015	I-302	JUN 20, 2003
019721 002	SOMATROPIN RECOMBINANT; NORDITROPIN	5435076	APR 16, 2013	ODE	JUN 20, 2007
019676 001	SOMATROPIN RECOMBINANT; NUTROPIN	5716338	FEB 10, 2015	I-302	JUN 20, 2003
019676 002	SOMATROPIN RECOMBINANT; NUTROPIN	5435076	APR 16, 2013	ODE	JUN 20, 2007
020522 001	SOMATROPIN RECOMBINANT; NUTROPIN AQ	5633352	MAY 27, 2014	I-302	JUN 20, 2003
021075 001	SOMATROPIN RECOMBINANT; NUTROPIN DEPOT	6051259	DEC 02, 2012	D-55	APR 13, 2003
021075 002	SOMATROPIN RECOMBINANT; NUTROPIN DEPOT	6051259	DEC 02, 2012	M-2	DEC 01, 2002
021075 003	SOMATROPIN RECOMBINANT; NUTROPIN DEPOT	6051259	DEC 02, 2012	D-55	APR 13, 2003
021151 001	SOTALOL HYDROCHLORIDE; BETAPACE AF			M-2	DEC 01, 2002
021151 002	SOTALOL HYDROCHLORIDE; BETAPACE AF			D-55	APR 13, 2003
021151 003	SOTALOL HYDROCHLORIDE; BETAPACE AF			M-2	DEC 01, 2002
007073 002	SULFASALAZINE; AZULFIDINE EN-TABS				
020256 001	TECHNETIUM TC-99M BICISATE KIT; NEUROLITE	5431900	JUL 11, 2012	I-308	AUG 18, 2003
019785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4894445	JAN 16, 2007		
		5324824	JAN 16, 2007		
		4885100	SEP 11, 2007		
		4988827	JAN 29, 2008		

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 *PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
019785 003	TECHNETIUM TC-99M SESTAMIBI KIT; MIRALUMA	4452774 4894445 5324824	SEP 09, 2004 JAN 16, 2007 JAN 16, 2007	U-337	
021124 001	TERBINAFINE HYDROCHLORIDE; LAMISIL AT	4885100 4988827 4680291 4755534 5681849	SEP 11, 2007 JAN 29, 2008 JUL 14, 2004 DEC 30, 2006 OCT 28, 2014	U-73 U-73	
021015 001	TESTOSTERONE; ANDROGEL	5559269	MAY 05, 2015	U-318	FEB 28, 2003
020484 001	TINZAPARIN SODIUM; INNOHEP	5559269	MAY 05, 2015	U-318	JUL 14, 2005
020771 001	TOLTERODINE TARTRATE; DETROL				
020771 002	TOLTERODINE TARTRATE; DETROL				
020281 001	TRAMADOL HYDROCHLORIDE; ULTRAM				
020281 002	TRAMADOL HYDROCHLORIDE; ULTRAM				
074973 001	TRIMETHOPRIM HYDROCHLORIDE; PRIMSOLOL	5763449	AUG 07, 2016		
020326 001	TRIMETREKATE GLUCURONATE; NEUTREXIN	5962461	AUG 07, 2016		
020326 002	TRIMETREKATE GLUCURONATE; NEUTREXIN	6017922	MAY 18, 2018		
020715 001	TRIPTORELIN PAMOATE; TRELSTAR DEPOT	6017922	MAY 18, 2018		
020719 001	TROGLITAZONE; PRELAY	5134122	JUL 20, 2010		
020719 002	TROGLITAZONE; PRELAY	5225205	JUL 20, 2010		
020719 003	TROGLITAZONE; PRELAY	5132741	MAR 09, 2010		
020720 001	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317	U-317
020720 002	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317	U-317
020720 003	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317	U-317
020759 001	TROVAFLOXACIN MESYLATE; TROVAN	6046202	SEP 15, 2013	U-317	U-317
020759 002	TROVAFLOXACIN MESYLATE; TROVAN	5164402	DEC 18, 2011	U-282	U-282
021214 001	UNOPROSTONE ISOPROPYL; RESCULA	5001153	SEP 19, 2008	U-282	U-282
		5151444	MAR 19, 2008	NCE	AUG 03, 2005
		5166178	NOV 24, 2009	U-333	
		5212200	MAY 18, 2010	U-333	
		5208256	MAY 21, 2011	U-333	
		5221763	JUN 22, 2010		
		5232705	AUG 31, 2010		
020552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5200196	JAN 22, 2008		
		5141752	JUN 27, 2006		
		5082668	JAN 21, 2009		
		5030456	NOV 07, 2008		
		4946687	OCT 02, 2007		
		5785994	OCT 22, 2009	U-315	

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PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	5232705 5200196 5141752 5082668 5030456 4946687 5785994	AUG 31, 2010 JAN 22, 2008 JUN 27, 2006 JAN 21, 2009 NOV 07, 2008 OCT 02, 2007 OCT 22, 2009	U-315	NCE	APR 12, 2005
021119 001	VERTEPORFIN; VISUDYNE	5583152	SEP 26, 2010		NCE	SEP 26, 2001
020547 001	ZAFIRLUKAST; ACCOLATE	4859692	SEP 26, 2010		NCE	SEP 26, 2001
020547 003	ZAFIRLUKAST; ACCOLATE	5294636 5319097 5482963 5583152 5612367	DEC 11, 2011 DEC 11, 2011 JAN 09, 2013 SEP 26, 2010 MAR 18, 2014		I-268 NS	SEP 17, 2002 SEP 17, 2002
021036 001	ZANAMIVIR; RELENZA			U-189	I-294	APR 26, 2003
020789 001	ZONISAMIDE; ZONEGRAN				NCE	MAR 27, 2005

PATENT AND EXCLUSIVITY TERMS

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

ABBREVIATIONS

NPP **NEW PATIENT POPULATION**

REFERENCES

NEW DOSING SCHEDULE

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

NEW INDICATION

I-283 **TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS**
I-286 **TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III**
I-287 **USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH**
I-288 **CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINAPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE**
I-289 **USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL**
I-290 **TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS**
I-291 **PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS**

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

- I-292 TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
- I-293 TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS
- I-294 TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS
- I-295 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS
- I-296 LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY
- I-297 SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
- I-298 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA
- I-299 USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM
- I-300 PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE
- I-301 TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS
- I-302 TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME
- I-303 INCREASING HDL-CHOLESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS
- I-304 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV
- I-305 TREATMENT OF LEVOFLOXACIN SUSCEPTIBLE STRAINS OF PENICILLIN-RESISTANT STREPTOCOCCUS PNEUMONIAE IN PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA
- I-306 INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE
- I-307 NEW COMBINATION USE OF METFORMIN AND INSULIN IN TYPE 2 DIABETES
- I-308 TREATMENT OF PEDIATRIC PATIENTS WITH POLYARTICULAR COURSE JUVENILE RHEUMATOID ARTHRITIS WHO RESPONDED INADEQUATELY TO SALICYLATES OR OTHER NSAIDS
- I-309 INCREASE BONE MASS IN MEN WITH OSTEOPOROSIS
- I-310 REDUCTION IN RISK OF MYOCARDIAL INFARCTION, STROKE, AND DEATH FROM CARDIOVASCULAR CAUSES

MISCELLANEOUS EXCLUSIVITY CODES

- M-2 APPROVAL FOR ADDITION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE
- M-3 ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

- U-266 RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS; MANAGEMENT OF ACUTE PAIN IN ADULTS; TREATMENT OF PRIMARY DYSMENORRHEA
- U-309 TREATING SJOEGREN SYNDROME
- U-310 TREATMENT OF XEROSTOMIA
- U-311 HORMONE REPLACEMENT
- U-312 PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER
- U-313 TREATMENT OF CONGESTIVE HEART FAILURE
- U-314 METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY
- U-315 METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT
- U-316 METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER
- U-317 METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE
- U-318 TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE
- U-319 TREATMENT OF MICROBIAL INFECTIONS
- U-320 INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA
- U-321 REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS
- U-322 TREATMENT OF ALZHEIMER'S DEMENTIA
- U-323 USE AS A BILE ACID SEQUESTRANT
- U-324 METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE
- U-325 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE
- U-326 METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER
- U-327 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE
- U-328 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH
- U-329 USE OF AVANDIA AS MONOTHERAPY, IN COMBINATION WITH METFORMIN, AND IN COMBINATION WITH SULFONYLUREAS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
- U-330 TREATMENT OF NAUSEA AND VOMITING
- U-331 METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
- U-332 TREATMENT OR PREVENTION OF BRONCHOSPASM
- U-333 METHOD OF TREATING OCULAR HYPERTENSION
- U-334 TREATMENT OF EXCESSIVE FEMALE FACIAL HAIR
- U-335 USE OF PRAVASTATIN SODIUM FOR SECONDARY PREVENTION OF CORONARY EVENTS IN MEN AND WOMEN WHO HAVE HAD A MYOCARDIAL INFARCTION AND HAVE NORMAL CHOLESTEROL LEVELS
- U-336 DIAGNOSTIC RADIOIMAGING
- U-337 USE OF CARDIOLITE/MIRALUMA KIT FOR THE PREPARATION OF TC99M SESTAMIBI
- U-338 METHODS FOR TREATING DISTURBANCES OF MOOD, DISTURBANCES OF APPETITE, DEPRESSED MOOD, OR CARBOHYDRATE CRAVING ALL ASSOCIATED WITH PREMENSTRUAL SYNDROME
- U-339 PREVENTION OF CARDIO-TOXICITY CAUSED BY THE ADMINISTRATION OF DOXORUBICIN
- U-340 THE LONG TERM TREATMENT OF GROWTH FAILURE DUE TO LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION IN CHILDREN
- U-341 METHOD FOR ENHANCING THE TREATMENT OF ... LATE LUTEAL PHASE DYSPHORIC DISORDER
- U-342 METHOD FOR TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER

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- U-343 REDUCTION OF INTESTINAL GAS, CRAMPING AND ANORECTAL IRRITATION
- U-344 METHOD FOR INHIBITING HIV INFECTION BY ADMINISTERING RITONAVIR IN
COMBINATION WITH ANOTHER HIV PROTEASE INHIBITOR
- U-345 RITONAVIR AND ANOTHER HIV PROTEASE INHIBITOR FOR CONCOMITANT
ADMINISTRATION FOR THE TREATMENT OF AN HIV INFECTION
- U-346 METHOD FOR INHIBITING CYTOCHROME P450 MONOOXYGENASE WITH RITONAVIR AND
A METHOD FOR IMPROVING THE PHARMCOKINETICS OF A DRUG THAT IS
METABOLIZED BY CYTOCHROME P450 MONOOXYGENASE BY ADMIN THE DRUG AND
RITONAVIR
- U-347 METHOD OF USE IN COMBINATION WITH REVERSE TRANSCRIPTASE INHIBITORS
- U-348 METHOD OF USE FOR INHIBITING HIV INFECTION
- U-349 METHOD OF USE WHICH IS SUBJECT OF THE APPLICATION
- U-350 PREPARATION OF A PHARMACEUTICAL COMPOSITION FOR CONCOMITANT ADMIN WITH
A REVERSE TRANSCRIPTASE INHIBITOR
- U-351 INHIBITING PROTEASE WITH LOPINAVIR AND INHIBITING AN HIV INFECTION WITH
LOPINAVIR
- U-352 INHIBITING HIV INFECTION BY ADMINISTERING RITONAVIR IN COMBINATION WITH A
REVERSE TRANSCRIPTASE INHIBITOR
- U-353 PREVENTION AND TREATMENT OF OSTEOPOROSIS

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