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CUMULATIVE
SUPPLEMENT 11
NOVEMBER 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

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**

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

20TH EDITION

Cumulative Supplement 11

November 2000

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

CUMULATIVE SUPPLEMENT 11
NOVEMBER 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 20th 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 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 LIST

COUNTS 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%)
MULTI-SOURCE	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	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).

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

1-2

ACETAMINOPHEN, OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

AA OXYCODONE AND ACETAMINOPHEN
BARR 500MG; 5MG

N40304 001
OCT 02, 2000

ACETAMINOPHEN, PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

AB PENTAZOCINE HCL AND ACETAMINOPHEN
WATSON LABS 650MG; EQ 25MG BASE

N74699 001
MAR 24, 2000

TALACEN

AB + SANOFI SYNTHELABO 650MG; EQ 25MG BASE

* 650MG; EQ 25MG BASE

ADAPALENE

CREAM; TOPICAL
DIFFERIN
+ GALDERMA LABS LP

0.1%

N20748 001
MAY 26, 2000

ACETOHEXAMIDE

TABLET; ORAL

AB ACETOHEXAMIDE
BARR 500MG

N70870 001
FEB 09, 1987

AB + 500MG

N70870 001
FEB 09, 1987

AB DYNELOR
AB LILLY

250MG
500MG
250MG
500MG

N13378 002
N13378 001
N13378 002
N13378 001

ACYCLOVIR

CAPSULE; ORAL

AB ACYCLOVIR
ROXANE 200MG

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

@

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

AP ACYCLOVIR SODIUM
APOTHECON EQ 500MG BASE/VIAL

N74897 001
FEB 27, 1998

AP EQ 1GM BASE/VIAL

N74897 002
FEB 27, 1998

@ EQ 500MG BASE/VIAL

N74897 001
FEB 27, 1998

@ EQ 1GM BASE/VIAL

N74897 002
FEB 27, 1998

ALBUMIN HUMAN

INJECTABLE; INJECTION

OPTISON
+ MALLINCKRODT

10MG/ML

N20899 001
DEC 31, 1997

* MOLECULAR BIOSYSTEMS 10MG/ML

N20899 001
DEC 31, 1997

ALBUTEROL

AEROSOL, METERED; INHALATION

AB ALBUTEROL
MEDISOL 0.09MG/INH

N74072 001
AUG 01, 1996

AB SIDMAK LABS CA 0.09MG/INH

N74072 001
AUG 01, 1996

ALBUTEROL SULFATE

SOLUTION; INHALATION

AN ALBUTEROL SULFATE
BAUSCH AND LOWE EQ 0.083% BASE

N75358 001
MAR 29, 2000

ALBUTEROL SULFATE

SYRUP; ORAL

ALBUTEROL SULFATE
WATSON LABS

EQ 2MG BASE/5ML
EQ 2MG BASE/5ML

N73165 001
APR 29, 1993
N73165 001
APR 29, 1993

TABLET; ORAL

ALBUTEROL SULFATE
MD PHARM

EQ 2MG BASE
EQ 4MG BASE
EQ 2MG BASE
EQ 4MG BASE

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

MEDEVA PHARMS CA

ALENDRONATE SODIUM

TABLET; ORAL

POSAMAX
MERCK

EQ 40MG BASE
EQ 35MG BASE
EQ 40MG BASE
EQ 70MG BASE

N20560 002
SEP 29, 1995
N20560 004
OCT 20, 2000
N20560 002
SEP 29, 1995
N20560 005
OCT 20, 2000

ALOSETRON HYDROCHLORIDE

TABLET; ORAL

LOTROX
GLAXO WELLCOME

EQ 1MG BASE

N21107 001
FEB 09, 2000

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

0.25MG
0.5MG
1MG
0.25MG
0.5MG
1MG

N74199 001
OCT 19, 1993
N74199 002
OCT 19, 1993
N74199 003
OCT 19, 1993
N74199 001
OCT 19, 1993
N74199 002
OCT 19, 1993
N74199 003
OCT 19, 1993

ALTRETAMINE

CAPSULE; ORAL

HEXALEN

* MEDIMUNE ONCOLOGY

+ MGI PHARMA

50MG
50MG

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

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

AMANTADINE HCL

GENEVA PHARMS TECH

100MG

N71293 001
FEB 18, 1987

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

<u>AMANTADINE HYDROCHLORIDE</u>					
AB	CAPSULE; ORAL AMANTADINE HCL INVARMED	100MG	N71293 001 FEB 18, 1987	10%	N19018 003 SEP 07, 1988
<u>AMIFOSTINE</u>					
AB	INJECTABLE; INJECTION ETHYOL + MEDIMUNE ONCOLOGY * US BIOSCIENCE	500MG/VIAL 500MG/VIAL	N20221 001 DEC 08, 1995 N20221 001 DEC 08, 1995		
<u>AMIKACIN SULFATE</u>					
AB	INJECTABLE; INJECTION AMIKACIN SULFATE ASTRAZENECA	EQ 50MG BASE/ML EQ 250MG BASE/ML EQ 50MG BASE/ML EQ 250MG BASE/ML	N63167 001 DEC 14, 1995 N63169 001 DEC 14, 1995 N63167 001 DEC 14, 1995 N63169 001 DEC 14, 1995		N75315 002 JUN 30, 2000
<u>AMINO ACIDS</u>					
AB	INJECTABLE; INJECTION TROPHAMINE 10% B BRAUN	10%	N71293 001 FEB 18, 1987	10%	N19018 003 SEP 07, 1988
<u>AMINOPHYLLINE</u>					
AB	TABLET; ORAL AMINOPHYLLINE GLOBAL PHARM	100MG 200MG 100MG 200MG	N20221 001 DEC 08, 1995 N20221 001 DEC 08, 1995		N84574 001 N84576 001 N84574 001 N84576 001
<u>AMIODARONE HYDROCHLORIDE</u>					
AB	TABLET; ORAL AMIODARONE HCL + EON	400MG	N63167 001 DEC 14, 1995 N63169 001 DEC 14, 1995 N63167 001 DEC 14, 1995 N63169 001 DEC 14, 1995		
<u>AMITRIPTYLINE HYDROCHLORIDE</u>					
AB	TABLET; ORAL AMITRIPTYLINE HCL MD PHARM	10MG 25MG 50MG 75MG 100MG 150MG 10MG 25MG 50MG 75MG 100MG 150MG 10MG 25MG 50MG 75MG 100MG 150MG 10MG	N20107 001 FEB 05, 1993 N20107 001 FEB 05, 1993 N19018 001 JUL 20, 1984 N19018 001 JUL 20, 1984 N19018 003 SEP 07, 1988		N85864 001 N85935 001 N85936 001 N86337 001 N86336 001 N86335 001 N85864 001 N85935 001 N85936 001 N86337 001 N86336 001 N86335 001 N85864 001 N85935 001 N85936 001 N86337 001 N86336 001 N86335 001 N88075 001 SEP 16, 1983 N88076 001 MAY 20, 1983 N88077 001 SEP 16, 1983
<u>AMINO ACIDS</u>					
AB	INJECTABLE; INJECTION NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER BAXTER HLTHCARE	15%	N20107 001 FEB 05, 1993 N20107 001 FEB 05, 1993 N19018 001 JUL 20, 1984 N19018 001 JUL 20, 1984 N19018 003 SEP 07, 1988		
<u>AMINO ACIDS</u>					
AB	TROPHAMINE B BRAUN	6%	N19018 001 JUL 20, 1984 N19018 001 JUL 20, 1984 N19018 003 SEP 07, 1988		
<u>AMINO ACIDS</u>					
AB	TROPHAMINE 10% B BRAUN	10%	N19018 003 SEP 07, 1988		

MAX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

[illegible]

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE
SACCHARATE; DEXTROAMPHETAMINE SULFATE

AMOXICILLIN

TABLET; ORAL

AMOXICILLIN

TEVA

AB

875MG

N65056 002
SEP 18, 2000

AB

AMOXIL
SMITHKLINE BEECHAM

500MG

N50754 002
JUL 10, 1998

AB

AB +

875MG

N50754 001
JUL 10, 1998

AB

500MG

N50754 002
JUL 10, 1998

AB

875MG

N50754 001
JUL 10, 1998

TABLET, CHEWABLE; ORAL

AMOXICILLIN

PANBAXY

> ADD >

> ADD >

> ADD >

> ADD >

AB

200MG

N65060 001
NOV 29, 2000

AB

400MG

N65060 002
NOV 29, 2000

AB

AMOXIL
SMITHKLINE BEECHAM

200MG

N50761 001
APR 15, 1999

AB

AB +

400MG

N50761 002
APR 15, 1999

AB

200MG

N50761 001
APR 15, 1999

AB

400MG

N50761 002
APR 15, 1999

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ATENOLOL

TABLET; ORAL

ATENOLOL

GENEVA PHARMS TECH

25MGABN74265 001
FEB 28, 199450MGABN74265 002
FEB 28, 1994100MGABN74265 003
FEB 28, 1994

INVAMED

25MGABN74265 001
FEB 28, 199450MGABN74265 002
FEB 28, 1994100MGABN74265 003
FEB 28, 1994ATORVASTATIN CALCIUM

TABLET; ORAL

LIPITOR

PFIZER IRELAND PHARM EQ 40MG BASE

EQ 80MG BASE

+

EQ 40MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

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WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

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WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

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WARNER LAMBERT EXPOR EQ 40MG BASE

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WARNER LAMBERT EXPOR EQ 40MG BASE

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WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

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WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

EQ 80MG BASE

+

WARNER LAMBERT EXPOR EQ 40MG BASE

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL

MOTOFEN HALF-STRENGTH

@ CARRICK

0.025MG;0.5MG

N17744 001

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

ABLE

0.025MG;2.5MG

N40395 001

NOV 27, 2000

N40357 001

MAY 02, 2000

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON-PLUS

+ BAXTER PHARM PROD

0.14MG/ML;10MG/ML

N19677 001

NOV 06, 1991

N19678 001

NOV 06, 1991

N19677 001

NOV 06, 1991

N19678 001

NOV 06, 1991

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIVAR

+ ASTA

0.05%

N21127 001

MAY 22, 2000

BALSALAZIDE DISODIUM

CAPSULE; ORAL

COLAZAL

+ SALIX

750MG

N20610 001

JUL 18, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE
 BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE
 HYDROCHLORIDE

TABLET; ORAL
 ZIAC
 LEDELF
 5MG; 6.25MG
 10MG; 6.25MG
 N20186 001
 MAR 26, 1993
 N20186 002
 MAR 26, 1993
 N20186 001
 MAR 26, 1993
 N20186 002
 MAR 26, 1993
 SYRUP; ORAL
 MYPHETANE DC
 AA + MORTON GROVE
 2MG/5ML; 10MG/5ML;
 12.5MG/5ML
 N88904 001
 FEB 21, 1985

BUDESONIDE
 SUSPENSION; INHALATION
 PULMICORT RESPULES
 ASTRAZENECA
 0.25MG/2ML
 0.5MG/2ML
 1MG/2ML
 N20929 001
 AUG 08, 2000
 N20929 002
 AUG 08, 2000
 N20929 003
 AUG 08, 2000

BUPROPION HYDROCHLORIDE
 TABLET; ORAL
 BUPROPION HCL
 EON
 AB
 75MG
 N75613 002
 OCT 10, 2000
 AB
 100MG
 N75613 001
 OCT 10, 2000
 AB
 75MG
 GENEVA PHARMS TECH
 N75584 001
 FEB 07, 2000
 AB
 100MG
 N75584 002
 FEB 07, 2000
 AB
 75MG
 INVAMED
 N75584 001
 FEB 07, 2000
 AB
 100MG
 N75584 002
 FEB 07, 2000
 AB
 75MG
 MYLAN
 N75491 001
 APR 17, 2000
 AB
 100MG
 N75491 002
 APR 17, 2000

BRETYLIUM TOSYLATE
 INJECTABLE; INJECTION
 BRETYLIUM TOSYLATE
 ASTRAZENECA
 50MG/ML
 50MG/ML
 N71151 001
 AUG 10, 1987
 N71151 001
 JUN 27, 2000
 N71151 001
 AUG 10, 1987

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE
 HYDROCHLORIDE
 SYRUP; ORAL
 DIMETANE-DC
 AA + 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

BUSPIRONE HYDROCHLORIDE
 TABLET; ORAL
 BUSPAR
 * BRISTOL MYERS SQUIBB
 15MG
 N18731 003
 APR 22, 1996

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR
® BRISTOL MYERS SQUIBB 30MG

15MG

30MG

N18731 004
APR 22, 1996
N18731 003
APR 22, 1996
N18731 004
APR 22, 1996

+

BUTABARBITAL SODIUM

ELIXIR; ORAL

BUTABARB
® ALPHARMA

30MG/5ML
30MG/5ML

AA

30MG/5ML

AA

30MG/5ML

30MG/5ML

+

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

BUTORPHANOL TARTRATE

ABBOTT

1MG/ML

2MG/ML

N7559 001

MAR 20, 2000

N7559 002

MAR 20, 2000

CAFFEINE, ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

CAFERGOT

BR * NOVARTIS

+

MIGERGOT

BR G AND W LABS

100MG; 2MG

100MG; 2MG

100MG; 2MG

100MG; 2MG

®

N09000 002

N09000 002

N86557 001

OCT 04, 1983

N86557 001

OCT 04, 1983

CALCIUM CHLORIDE

INJECTABLE; INJECTION

CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER

+ ABBOTT

N21117 001
JAN 28, 2000

CALCIUM CHLORIDE, MAGNESIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC

CARDIOPLEGIC IN PLASTIC CONTAINER

BAXTER HLTHCARE

AT

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

PLEGISOL IN PLASTIC CONTAINER

+ ABBOTT

AT

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

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

CALCIUM GLUCEPTATE

+ ABBOTT

®

EQ 90MG CALCIUM/5ML

EQ 90MG CALCIUM/5ML

N80001 001

N80001 001

CANDESARTAN CILEXETIL, HYDROCHLOROTHAZIDE

TABLET; ORAL

ATACAND HCT

ASTRAZENECA

16MG; 12.5MG

32MG; 12.5MG

N21093 001

SEP 05, 2000

N21093 002

SEP 05, 2000

CANDICIDIN

OINTMENT; VAGINAL

VANOBID

® AVENTIS PHARMS

* HOECHST MARION RSL

0.6MG/GM

0.6MG/GM

N61596 001

N61596 001

CEFAZOLIN SODIUM

INJECTABLE; INJECTION
CEFAZOLIN SODIUM
AM PHARM PARTNERS

AP EQ 1MG BASE/VIAL
AP EQ 1GM BASE/VIAL

N64169 002
AUG 14, 1998
N64169 002
AUG 14, 1998

CEFOTAXIME SODIUM

INJECTABLE; INJECTION
CLAFORAN
+ HOECHST MARION RSSL

EQ 2GM BASE/VIAL
EQ 10GM BASE/VIAL

N50547 003
N50547 004
DEC 29, 1983

CEFDINIR

CAPSULE; ORAL
OMNICEF
+ ABBOTT

300MG
300MG
PARKE DAVIS

N50739 001
DEC 04, 1997
N50739 001
DEC 04, 1997

POWDER FOR RECONSTITUTION; ORAL
OMNICEF
+ ABBOTT

125MG/5ML
125MG/5ML
PARKE DAVIS

N50749 001
DEC 04, 1997
N50749 001
DEC 04, 1997

CEFOTAXIME SODIUM

INJECTABLE; INJECTION
CEFOTAXIME
AM PHARM PARTNERS

AP EQ 500MG BASE/VIAL
AP EQ 1GM BASE/VIAL
AP EQ 2GM BASE/VIAL
AP EQ 10GM BASE/VIAL
EQ 20GM 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

CEFOXITIN SODIUM

INJECTABLE; INJECTION
CEFOXITIN
AM PHARM PARTNERS

AP EQ 1GM BASE/VIAL
AP EQ 2GM BASE/2VIAL
AP EQ 10GM BASE/VIAL
AP EQ 1GM BASE/VIAL
AP EQ 2GM BASE/VIAL
AP EQ 10GM BASE/VIAL

N65012 001
JUL 03, 2000
N65012 002
JUL 03, 2000
N65011 001
JUL 03, 2000
N65051 001
SEP 11, 2000
N65051 002
SEP 11, 2000
N65050 001
SEP 11, 2000

MEFOXIN
+ MERCK

AP EQ 1GM BASE/VIAL
AP EQ 1GM BASE/VIAL
AP EQ 2GM BASE/VIAL
AP EQ 2GM BASE/VIAL
AP EQ 10GM BASE/VIAL
AP EQ 1GM BASE/VIAL
AP EQ 1GM BASE/VIAL
AP EQ 2GM BASE/VIAL
AP EQ 2GM BASE/VIAL
EQ 10GM BASE/VIAL

N50517 001
N62757 001
JAN 08, 1987
N50517 002
N62757 002
JAN 08, 1987
N50517 003
N50517 001
N62757 001
JAN 08, 1987
N50517 002
N62757 002
JAN 08, 1987
N50517 003

CLAFORAN

+ AVENTIS PHARMS

AP EQ 500MG BASE/VIAL
AP EQ 1GM BASE/VIAL
AP EQ 2GM BASE/VIAL
AP EQ 10GM BASE/VIAL
EQ 500MG BASE/VIAL
EQ 1GM BASE/VIAL

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

CERTIBUTEN DIHYDRATE

CAPSULE; ORAL
CEDAX
+ BIOVAIL

EQ 400MG BASE

N50685 002
DEC 20, 1995

> ADD >
> ADD >

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL

CEDAX

* SCHERING PLOUGH

EQ 400MG BASE

N50685 002
DEC 20, 1995> DLT >
> DLT >

POWDER FOR RECONSTITUTION; ORAL

CEDAX

BIOVAIL

EQ 90MG BASE/5ML

N50686 001

DEC 20, 1995

EQ 180MG BASE/5ML

N50686 002

DEC 20, 1995

EQ 90MG BASE/5ML

N50686 001

DEC 20, 1995

EQ 180MG BASE/5ML

N50686 002

DEC 20, 1995

> ADD >
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> DLT >
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> DLT >
> DLT >CEFTIRAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

+ HLR

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

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

> ADD >
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> DLT >CEFTIRAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

ROCHE

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

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

CEFTIRAXONE SODIUM, LIDOCAINE

INJECTABLE; INJECTION

ROCEPHIN KIT

+ HLR

EQ 1GM BASE/VIAL, N/A; N/A,

N50585 006

MAY 08, 1996

EQ 500MG BASE/VIAL, N/A; N/A,

N50585 007

MAY 08, 1996

EQ 1GM BASE/VIAL, N/A; N/A,

N50585 006

MAY 08, 1996

EQ 500MG BASE/VIAL, N/A; N/A,

N50585 007

MAY 08, 1996

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

CHLORPHENIRAMINE MALEATE

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

N80809 001
 N80809 001

AB
 AB

400MG
 800MG

N74361 002
 DEC 23, 1994
 N74371 001
 DEC 23, 1994
 N74361 001
 DEC 23, 1994
 N74361 002
 DEC 23, 1994
 N74371 001
 DEC 23, 1994

CHORIOGONADOTROPIN ALFA

INJECTABLE; INJECTION
 OVIDREL
 + SERONO

N21149 001
 SEP 20, 2000

300MG

400MG

800MG

CICLOPIROX

CREAM; TOPICAL
 LOPROX
 + AVENTIS PHARMS

N18748 001
 DEC 30, 1982

EQ 300MG BASE/5ML

N75560 001
 MAR 15, 2000

LOTION; TOPICAL
 LOPROX
 + AVENTIS PHARMS

N19824 001
 DEC 30, 1988

EQ 1MG BASE/ML

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

CICLOPIROX OLAMINE

CREAM; TOPICAL
 LOPROX
 + HOECHST MARION RSSEL

N18748 001
 DEC 30, 1982

EQ 10MG BASE

N20210 001
 JUL 29, 1993

LOTION; TOPICAL
 LOPROX
 + HOECHST MARION RSSEL

N19824 001
 DEC 30, 1988

EQ 20MG BASE

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

CIMETIDINE

TABLET; ORAL
CIMETIDINE
 ROXANE

N74361 001
 DEC 23, 1994

300MG

TABLET; ORAL
 PROPULSID
 JANSSEN

EQ 10MG BASE

N20210 001
 JUL 29, 1993

*
 JANSSEN

EQ 20MG BASE

N20210 001
 JUL 29, 1993

*
 JANSSEN

EQ 10MG BASE

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

*
 JANSSEN

EQ 20MG BASE

N20210 001
 JUL 29, 1993

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

CLOBETASOL PROPIONATE

AEROSOL; TOPICAL
OLUX FOAM
+ CONNETICS

0.05%

N21142 001
MAY 26, 2000

CLOTIMAZOLE

TABLET; VAGINAL
MYCELEX-G
* BAYER

500MG

N19069 001
APR 19, 1985

CREAM; TOPICAL
CLOBETASOL PROPIONATE

TARO

0.05%

N75633 001
MAY 17, 2000

GEL; TOPICAL
CLOBETASOL PROPIONATE

ALTANA

0.05%

N75368 001
FEB 15, 2000

EQ 250MG BASE

EQ 500MG BASE

EQ 250MG BASE

EQ 500MG BASE

N61452 001
N61452 002
N61452 001
N61452 002
N61806 002
N61806 002

CLONAZEPAM

TABLET; ORAL
CLONAZEPAM
TORPHARM

0.5MG

N75468 001
OCT 06, 2000
N75468 002
OCT 06, 2000
N75468 003
OCT 06, 2000

1MG

2MG

CLOZAPINE

TABLET; ORAL
CLOZAPINE
GENEVA PHARMS

25MG

100MG

25MG

100MG

N74546 001
AUG 30, 1996
N74546 002
AUG 30, 1996
N74546 001
AUG 30, 1996
N74546 002
AUG 30, 1996

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM
TARO

3.75MG

7.5MG

15MG

N75731 003
APR 27, 2000
N75731 002
APR 27, 2000
N75731 001
APR 27, 2000

COLESEVELAM HYDROCHLORIDE

CAPSULE; ORAL
WELCHOL
* GELTEX

375MG

375MG

N21141 001
MAY 26, 2000
N21141 001
MAY 26, 2000

CLOTIMAZOLE

TABLET; VAGINAL
MYCELEX-G
* BAYER

500MG

TABLET; ORAL
WELCHOL
* GELTEX

625MG

N21176 001
MAY 26, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

CYCLOSPORINE

CAPSULE; ORAL

NEORAL

AB + NOVARTIS

BX

EX

100MG

25MG

100MG

50MG

N50715 002
JUL 14, 1995
N50715 001
JUL 14, 1995
N50715 002
JUL 14, 1995
N50715 003
JUL 14, 1995

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

N50748 001
SEP 21, 1999
N50748 002
AUG 24, 2000

350MG/VIAL; 150MG/VIAL
420MG/VIAL; 180MG/VIAL

DALFOPRISTIN; QUINUPRISTININJECTABLE; IV (INFUSION)
SYNERCID

AVENTIS

+

DAUNORUBICIN CITRATE

INJECTABLE; LIPOSOMAL; INJECTION

DAUNOXOME

+ GILEAD

+ NEXSTAR

N50704 002
APR 08, 1996
N50704 002
APR 08, 1996

EQ 2MG BASE/ML
EQ 2MG BASE/ML

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DAUNORUBICIN HCL

+ BEDFORD

AP

N50731 001
JAN 30, 1998
N50731 001
JAN 30, 1998
N50731 001
JAN 24, 2000
N64212 002
MAY 03, 1999

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

EQ 5MG BASE/ML
EQ 50MG BASE/VIAL

AP

GENSIA SICOR PHARMS

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

DECIOMYCIN

+ LEDERLE

®

N75259 001
SEP 22, 2000

150MG
150MG

N50262 001
N50262 001

DALFOPRISTIN; QUINUPRISTIN

INJECTABLE; INJECTION

SYNERCID

PHONE FOULENC RORER

N50747 001
SEP 21, 1999

N50748 001
SEP 21, 1999

350MG/VIAL;
EQ 150MG BASE/VIAL

350MG/VIAL;
EQ 150MG BASE/VIAL

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

INJECTABLE; INJECTION

DESMOPRESSIN ACETATE

+ ABBOTT

AP

0.004MG/ML

N75220 001
AUG 28, 2000

DACARBAZINE

INJECTABLE; INJECTION

DACARBAZINE

GENSIA SICOR PHARMS

500MG/VIAL

N75259 001
SEP 22, 2000

AP

DALFOPRISTIN; QUINUPRISTIN

INJECTABLE; INJECTION

SYNERCID

PHONE FOULENC RORER

N50747 001
SEP 21, 1999

N50748 001
SEP 21, 1999

350MG/VIAL;
EQ 150MG BASE/VIAL

350MG/VIAL;
EQ 150MG BASE/VIAL

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

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

1-22

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DESMOPRESSIN ACETATE

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

0.15MG/SPRAY

N20355 001
MAR 07, 1994

0.15MG/SPRAY

N20355 001
MAR 07, 1994

* CENTRON

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

MIRCETTE

* ORGAFON

0.15MG;0.02MG

N20713 001
APR 22, 1998

0.15MG,N/A;0.02MG,0.01MG

N20713 001
APR 22, 1998

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

BP GLOBAL PHARM

@ IMPAX LABS

DEXONE 1.5

SOLVAY

@

0.75MG

0.75MG

1.5MG

1.5MG

N85376 001

N85376 001

N84990 001

N84990 001

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

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

NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT

ALCON UNIVERSAL

EQ 0.1% PHOSPHATE;
EQ 3.5MG BASE/ML

N62714 001
JUL 21, 1986

STERIS

EQ 0.1% PHOSPHATE;
EQ 3.5MG BASE/ML

N62714 001
JUL 21, 1986

DEZOCINE

INJECTABLE; INJECTION

DALGAN

* ASTRAZENECA

5MG/ML

N19082 001

DEC 29, 1989

10MG/ML

N19082 002

DEC 29, 1989

15MG/ML

N19082 003

DEC 29, 1989

5MG/ML

N19082 001

DEC 29, 1989

10MG/ML

N19082 002

DEC 29, 1989

15MG/ML

N19082 003

DEC 29, 1989

DIAZEPAM

INJECTABLE; INJECTION

DIZAC

@ PHARMACIA AND UPJOHN 5MG/ML

N19287 001

JUN 18, 1993

DIAZEPAM

INJECTABLE; INTRAVENOUS
DIZAC
* PHARMACIA AND UPJOHN 5MG/ML

N19287 001
JUN 18, 1993

TABLET; ORAL

DIAZEPAM
ROXANE

AB 2MG

AB 5MG

AB 10MG

@ 2MG

@ 5MG

@ 10MG

N70356 001
JUN 17, 1986
N70357 001
JUN 17, 1986
N70358 001
JUN 17, 1986
N70356 001
JUN 17, 1986
N70357 001
JUN 17, 1986
N70358 001
JUN 17, 1986

DICLOFENAC POTASSIUM

TABLET; ORAL
DICLOFENAC POTASSIUM
GENEVA PHARMS TECH

AB 50MG

AB 50MG

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

DICLOFENAC SODIUM

GEL; TOPICAL
SOLARAZE
+ SKYEPHARMA

3†

N21005 001
OCT 16, 2000

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM
FALCON PHARMS

AB 0.1†

@ 0.1†

VOLTAREN
* CIBA

0.1†

N20809 001
MAY 04, 1998
N20809 001
MAY 04, 1998
N20837 001
MAR 28, 1991

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
VOLTAREN
+ CIBA

0.1†

N20037 001
MAR 28, 1991

TABLET, EXTENDED RELEASE; ORAL

DICLOFENAC SODIUM
BIOVAIL

AB 100MG

AB 100MG

AB 100MG

* 100MG

N75492 001
FEB 11, 2000
N20254 001
MAR 08, 1996
N20254 001
MAR 08, 1996

DIDANOSINE

CAPSULE, DELAYED REL PELLETS; ORAL
VIDEX EC

+ BRISTOL MYERS SQUIBB 125MG

+ 200MG

+ 250MG

+ 400MG

N21183 001
OCT 31, 2000
N21183 002
OCT 31, 2000
N21183 003
OCT 31, 2000
N21183 004
OCT 31, 2000

DIENESTROL

SUPPOSITORY; VAGINAL

DV
@ AVENTIS PHARMS 0.7MG
* HOBCHST MARION ESSIL 0.7MG

N83517 001
N83517 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL
MC PHARM
@ MEDEVA PHARMS CA

25MG
25MG

N85544 001
N85544 001

† SEE SECTION 1.3 OF INTRODUCTION

DIETHYLSTILBESTROL DIPHOSPHATE

INJECTABLE; INJECTION

STILPHOSTROL

* BAYER

250MG/5ML
250MG/5ML

N10010 001
N10010 001

TABLET; ORAL

STILPHOSTROL

* BAYER

50MG
50MG

N10010 002
N10010 002

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

TARO

0.05%

N75508 001
APR 24, 2000

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

BIOVAIL

N20939 001
JAN 28, 2000
N20939 002
JAN 28, 2000
N20939 003
JAN 28, 2000
N20939 004
JAN 28, 2000

120MG
180MG
240MG
300MG

INJECTABLE; INJECTION

DILTIAZEM HCL

ABBOTT

5MG/ML

N75004 001
FEB 16, 2000

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL

TIAMATE

* HOECHST MARION RSSL

EQ 120MG HCL

*

EQ 180MG HCL

N20506 001
OCT 04, 1996
N20506 002
OCT 04, 1996

> DLT >
> DLT >

BX

ANTABUSE

250MG

WYETH AVERST

N07883 003

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL

TIAMATE

* HOECHST MARION RSSL

EQ 240MG HCL

+

MERCK

EQ 120MG HCL

+

EQ 180MG HCL

+

EQ 240MG HCL

N20506 003
OCT 04, 1996
N20506 001
OCT 04, 1996
N20506 002
OCT 04, 1996
N20506 003
OCT 04, 1996

DILTIAZEM MALATE; ENALAPRIL MALEATE

TABLET, EXTENDED RELEASE; ORAL

TECZEM

* AVENTIS PHARMS

EQ 180MG HCL; 5MG

+

MERCK

EQ 180MG HCL; 5MG

N20507 001
OCT 04, 1996
N20507 001
OCT 04, 1996

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

GLOBAL PHARM

25MG
50MG
25MG
50MG

NA

NA

IMPAX LABS

®

N80807 001
N80807 002
N80807 001
N80807 002

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

PUREPAC PHARM

75MG

®

75MG

N89427 001
JUL 12, 1990
N89427 001
JUL 12, 1990

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

DOXAZOSIN MESYLATE

DISULFIRAM

TABLET; ORAL

ANTABUSE

* WYETH AYERST

500MG

250MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

500MG

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500MG

500MG

500MG

500MG

500MG

500MG

DIVALPROEX SODIUM

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

* ABBOTT

EQ 500MG VALPROIC ACID

N71168 001

AUG 04, 2000

DOXAZOSIN MESYLATE

TABLET; ORAL

CARDURA

* PFIZER

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

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EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

DOXAZOSIN MESYLATE

CHELSEA LABS

AB

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TABLET; ORAL

DOXAZOSIN MESYLATE

EON

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

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EQ 8MG BASE

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EQ 4MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 4MG BASE

EQ 8MG BASE

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

N75646 002

OCT 18, 2000

N75646 003

OCT 18, 2000

N75646 004

OCT 18, 2000

N75646 001

OCT 18, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

EFLORNITHINE HYDROCHLORIDE

CREAM; TOPICAL

VANIQ

+ WESTWOOD SQUIBB CLTN 13.9%

N21145 001
JUL 27, 2000

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
APOTHECON

AB	2.5MG	N75583 001	AB	10MG	N75472 003
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75583 002	AB	2.5MG	N75370 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75583 003	AB	10MG	N75369 001
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75583 004	AB	2.5MG	N75496 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75501 001	AB	10MG	N75459 001
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75501 002	AB	2.5MG	N75480 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75501 003	AB	10MG	N75480 003
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75501 004	AB	2.5MG	N75556 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75621 001	AB	10MG	N75556 003
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75621 002	AB	2.5MG	N75479 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75621 003	AB	10MG	N75479 002
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75621 004	AB	2.5MG	N75479 003
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75048 001	AB	10MG	N75479 004
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75048 002	AB	2.5MG	N75479 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75048 003	AB	10MG	N75479 002
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75048 004	AB	2.5MG	N75479 003
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75472 001	AB	10MG	N75479 004
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75472 002	AB	2.5MG	N75479 001
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75472 003	AB	10MG	N75479 002
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000
AB	10MG	N75472 004	AB	2.5MG	N75479 003
AB	20MG	AUG 22, 2000	AB	5MG	AUG 22, 2000
AB	2.5MG	N75472 005	AB	10MG	N75479 004
AB	5MG	AUG 22, 2000	AB	20MG	AUG 22, 2000

CHELSEA LABS

EON

GENEVA PHARMS

RANBAXY

TEVA

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
GENPHARM

AB	10MG	N75472 003
AB	20MG	AUG 22, 2000
AB	2.5MG	N75370 001
AB	5MG	AUG 22, 2000
AB	10MG	N75369 001
AB	20MG	AUG 22, 2000
AB	2.5MG	N75496 001
AB	5MG	AUG 22, 2000
AB	10MG	N75459 001
AB	20MG	AUG 22, 2000
AB	2.5MG	N75480 001
AB	5MG	AUG 22, 2000
AB	10MG	N75480 003
AB	20MG	AUG 22, 2000
AB	2.5MG	N75556 001
AB	5MG	AUG 22, 2000
AB	10MG	N75556 003
AB	20MG	AUG 22, 2000
AB	2.5MG	N75479 001
AB	5MG	AUG 22, 2000
AB	10MG	N75479 002
AB	20MG	AUG 22, 2000
AB	2.5MG	N75479 003
AB	5MG	AUG 22, 2000
AB	10MG	N75479 004
AB	20MG	AUG 22, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

1-28

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
WOCKHARDT

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
WOCKHARDT

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

ENALAPRILAT

INJECTABLE; INJECTION
ENALAPRILAT
FAULDING

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

N75571 001

AUG 22, 2000

N75578 001

AUG 22, 2000

N75578 001

AUG 22, 2000

N19309 001

FEB 09, 1988

N19309 001

FEB 09, 1988

N19309 001

FEB 09, 1988

N17087 001

N17087 001

N87693 001

FEB 24, 1983

N87693 001

FEB 24, 1983

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
WOCKHARDT

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
WOCKHARDT

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

ENALAPRILAT

INJECTABLE; INJECTION
ENALAPRILAT
FAULDING

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

AP 1.25MG/ML

N75571 001

AUG 22, 2000

N75578 001

AUG 22, 2000

N75578 001

AUG 22, 2000

N19309 001

FEB 09, 1988

N19309 001

FEB 09, 1988

N19309 001

FEB 09, 1988

N17087 001

N17087 001

N87693 001

FEB 24, 1983

N87693 001

FEB 24, 1983

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

N88337 001

JUN 08, 1984

ENALAPRIL MALEATE

TABLET; ORAL
ENALAPRIL MALEATE
WOCKHARDT

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

AB 5MG

AB 10MG

AB 20MG

AB 2.5MG

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL
CENESTIN
* DURAMED
0.9MG
MAR 24, 1999
N20992 003
0.9MG
MAR 24, 1999
N20992 003
1.25MG
MAR 13, 2000
N20992 004

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

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-28
TRIVORA-28
WATSON LABS
AB
0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 002
DEC 18, 1997

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
MODICON 21
JOHNSON RW
+ OVCN-35
* BRISTOL MYERS SQUIBB
+ WARNER CHILCOTT
OVCN-50
* BRISTOL MYERS SQUIBB
@ WARNER CHILCOTT
0.035MG; 0.5MG
0.035MG; 0.5MG
N17488 001
N17488 001
N18127 001
N18127 001
N18128 001
N18128 001

> DLT >
> ADD >

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
* CYPROS
+ QUESTCOR PHARM
50MG/ML
50MG/ML
DEC 22, 1988
N19357 001
DEC 22, 1988
N19357 001
DEC 22, 1988
N19357 001

N19357 001
DEC 22, 1988
N19357 001
DEC 22, 1988
N19357 001

TABLET; ORAL-28

OVCN-35
BRISTOL MYERS SQUIBB
WARNER CHILCOTT
OVCN-50
BRISTOL MYERS SQUIBB
WARNER CHILCOTT
0.035MG; 0.4MG
0.035MG; 0.4MG
0.05MG; 1MG
0.05MG; 1MG
N17716 001
N17716 001
N17576 001
N17576 001

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
TRIVORA-21
SEARLE
AB
0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 001
DEC 18, 1997
0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 001
DEC 18, 1997
0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 002
DEC 18, 1997

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 001
DEC 18, 1997
0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 001
DEC 18, 1997
0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,
0.125MG
N74538 002
DEC 18, 1997

> ADD >
> ADD >

ETHOSUXIMIDE
SYRUP; ORAL
ETHOSUXIMIDE
PHARM ASSOC
250MG/5ML

ETODOLAC

CAPSULE; ORAL
ETODOLAC
TORPHARM
AB
200MG
AB
300MG

N75419 001
JUL 28, 2000
N75419 002
JUL 28, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

ETODOLACTABLET; ORALETODOLAC

AB GENEVA PHARMS TECH 400MG
 AB INVAMED 400MG
 AB TARO PHARM INDS 500MG

N74846 001
 FEB 28, 1997
 N74846 001
 FEB 28, 1997
 N75074 002
 APR 25, 2000

TABLET, EXTENDED RELEASE; ORALETODOLACPOINT HOLDINGS

> ADD > AB 400MG
 > ADD > AB 500MG
 > ADD > AB 600MG
 > DLT > AB 400MG
 > DLT > AB 400MG

WHITNEY PHARMSLODINE XL+ WYETH AYERST

AB 400MG
 AB 500MG
 AB 600MG
 AB 400MG
 AB 500MG
 AB 600MG

N20584 001
 OCT 25, 1996
 N20584 003
 JAN 20, 1998
 N20584 002
 OCT 25, 1996
 N20584 001
 OCT 25, 1996
 N20584 003
 JAN 20, 1998
 N20584 002
 OCT 25, 1996

FENOLDOPAM MESYLATEINJECTABLE; INJECTIONCORLOPAM+ ABBOTT+ ELAN PHARMA

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

N19922 001
 SEP 23, 1997
 N19922 001
 SEP 23, 1997

FENOPROFEN CALCIUMCAPSULE; ORALFENOPROFEN CALCIUMWATSON LABS

AB EQ 200MG BASE
 AB EQ 300MG BASE
 @ EQ 200MG BASE
 @ EQ 300MG BASE

N72294 001
 AUG 17, 1988
 N72293 001
 AUG 17, 1988
 N72294 001
 AUG 17, 1988
 N72293 001
 AUG 17, 1988

TABLET; ORALFENOPROFEN CALCIUMWATSON LABS

AB EQ 600MG BASE
 @ EQ 600MG BASE

N72165 001
 AUG 17, 1988
 N72165 001
 AUG 17, 1988

FENTANYL CITRATEINJECTABLE; INJECTIONSUBLIMAZE PRESERVATIVE FREE

AP AKORN MFG EQ 0.05MG BASE/ML
 AP JANSSEN EQ 0.05MG BASE/ML

N16619 001
 N16619 001

FEXOFENADINE HYDROCHLORIDETABLET; ORALALLEGRAAVENTIS PHARMS

30MG
 60MG
 180MG

N20872 001
 FEB 25, 2000
 N20872 002
 FEB 25, 2000
 N20872 004
 FEB 25, 2000

+

FLOXURIDINEINJECTABLE; INJECTIONFLOXURIDINEBEDFORD

500MG/VIAL

N75387 001

APR 16, 2000

AP

500MG/VIAL

N16929 001

AP

500MG/VIAL

N16929 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

1-34

GABAPENTIN

SOLUTION; ORAL
NEURONTIN
+ PARKE DAVIS

250MG/5ML

250MG/5ML

N21129 001

MAR 02, 2000

N21129 001

MAR 02, 2000

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST
+ BERLEX LABS

469.01MG/ML

N21037 001

MAR 10, 2000

GEMFIBROZIL

TABLET; ORAL
GEMFIBROZIL
AB WATSON LABS

600MG

600MG

N74156 001

OCT 24, 1994

N74156 001

OCT 24, 1994

GEMTIZUMAB OZOGAMICIN

INJECTABLE; INJECTION
MYLOTARG
+ WYETH AYERST

5MG/VIAL

N21174 001

MAY 17, 2000

GENTAMICIN SULFATE

INJECTABLE; INJECTION
GARAMYCIN
AP SCHERING

EQ 10MG BASE/ML

EQ 10MG BASE/ML

N61739 001

N61739 001

EQ 10MG BASE/ML

EQ 10MG BASE/ML

N62251 002

N62251 002

GENTAMICIN SULFATE

ELKINS STINN

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

ALCON UNIVERSAL

EQ 0.3% BASE

N62523 001

NOV 25, 1985

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

AT STERIS

EQ 0.3% BASE

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

6MG

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

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;

10,000 UNITS/ML

N62818 001

OCT 11, 1988

0.025MG/ML; EQ 1.75MG BASE/ML;

10,000 UNITS/ML

N62818 001

OCT 11, 1988

GREPAFLOXACIN HYDROCHLORIDE

TABLET; ORAL

RAXAR

GLAXO WELLCOME

EQ 200MG BASE

EQ 400MG BASE

EQ 600MG BASE

EQ 200MG BASE

EQ 400MG BASE

EQ 600MG BASE

OTSUKA

N20695 001

NOV 06, 1997

N20695 002

MAY 14, 1998

N20695 003

MAY 14, 1998

N20695 001

NOV 06, 1997

N20695 002

MAY 14, 1998

N20695 003

MAY 14, 1998

GRISEOFULVIN, MICROCRYSTALLINE

TABLET; ORAL

GRIFULVIN V

J AND J

250MG

500MG

125MG

125MG

250MG

500MG

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL

GRIS-PEG

ALLERGAN HERBERT

125MG

250MG

125MG

250MG

PEDINOL

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

APOTEX

EQ 50MG BASE/ML

EQ 100MG BASE/ML

N75440 001

FEB 28, 2000

N75440 002

FEB 28, 2000

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

KING PHARMS

EQ 50MG BASE/ML

EQ 100MG BASE/ML

N75176 001

FEB 09, 2000

N75176 002

FEB 09, 2000

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

SMITH AND NEPHEW

10 UNITS/ML

100 UNITS/ML

N87904 001

APR 20, 1983

N87906 001

APR 20, 1983

N87904 001

APR 20, 1983

N87906 001

APR 20, 1983

N17064 001

APR 20, 1983

N17064 001

N17064 003

N17064 004

N17064 005

N17064 006

N17064 003

N17064 004

N17064 005

N17064 006

HEXACHLOROPHENE

AEROSOL; TOPICAL

SEPTISOL

@ VESTAL LABS

0.23%

DISC; TOPICAL

SEPTISOL

* VESTAL LABS

0.23%

N17424 001

HISTRELIN ACETATE

INJECTABLE; INJECTION

* ROBERTS LABS

EQ 0.2MG BASE/ML
EQ 0.5MG BASE/ML
EQ 1MG BASE/ML
EQ 0.2MG BASE/ML
EQ 0.5MG BASE/ML
EQ 1MG BASE/ML

N19836 001
DEC 24, 1991
N19836 002
DEC 24, 1991
N19836 003
DEC 24, 1991
N19836 001
DEC 24, 1991
N19836 002
DEC 24, 1991
N19836 003
DEC 24, 1991

12.5MG

N75640 001
JAN 28, 2000

12.5MG

N20504 001
DEC 27, 1996
N20504 001
DEC 27, 1996

100MG
100MG

N85098 001
N85098 001

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

* GENSLA SICOR PHARMS

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

N40373 001
FEB 23, 2000
N40136 001
JUN 30, 1997
N40136 001
JUN 30, 1997

12.5MG; 50MG

12.5MG; 50MG

25MG; 100MG

N20387 001
APR 28, 1995
N20387 001
APR 28, 1995
N20387 002
NOV 10, 1998

TABLET; ORAL

* GLOBAL PHARM

25MG
25MG

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE
WATSON LABS

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

* NOVARTIS

100MG; 50MG
100MG; 50MG
100MG; 50MG
100MG; 50MG

N71920 001
AUG 29, 1988
N71921 001
AUG 29, 1988
N71922 001
AUG 29, 1988
N71923 001
AUG 29, 1988
N71920 001
AUG 29, 1988
N71921 001
AUG 29, 1988
N71922 001
AUG 29, 1988

15MG; 250MG

25MG; 250MG

30MG; 500MG

50MG; 500MG

15MG; 250MG

25MG; 250MG

30MG; 500MG

@

@

@

INAMRINONE LACTATE

INJECTABLE; INJECTION
AMRINONE LACTATE
 BAXTER PHARM PROD

EQ 5MG BASE/ML

N75542 001
 MAY 10, 2000

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN
 WATSON LABS

25MG

N70529 001
 OCT 18, 1985

50MG

N70530 001
 OCT 18, 1985

25MG

N70529 001
 OCT 18, 1985

50MG

N70530 001
 OCT 18, 1985

INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION
 NOVOLOG
 + NOVO NORDISK

100 UNITS/ML

N20986 001
 JUN 07, 2000

INSULIN GLARGINE

INJECTABLE; INJECTION
 LANTUS
 + AVENTIS PHARMS

100 UNITS/ML

N21081 001
 APR 20, 2000

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
 HUMALOG MIX 50/50
 + LILLY

50 UNITS/ML; 50 UNITS/ML

N21018 001
 DEC 22, 1999

HUMALOG MIX 75/25

25 UNITS/ML; 75 UNITS/ML

N21017 001
 DEC 22, 1999

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
 HUMALOG MIX 50/50
 + LILLY

100 UNITS/ML

N21018 001
 DEC 22, 1999

HUMALOG MIX 75/25

100 UNITS/ML

N21017 001
 DEC 22, 1999

INULIN

INJECTABLE; INJECTION
 INULIN AND SODIUM CHLORIDE
 + CYPROS
 + QUESTCOR PHARM

100MG/ML

N02282 001

100MG/ML

N02282 001

IOPAMIDOL

INJECTABLE; INJECTION
 IOPAMIDOL-200
 COOK IMAGING

41%

N74881 001
 JUL 28, 2000

IOPAMIDOL-250

51%

N74881 002
 JUL 28, 2000

IOPAMIDOL-300

61%

N74881 003
 JUL 28, 2000

IOPAMIDOL-370

76%

N74881 004
 JUL 28, 2000

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
 GLOFIL-125
 CYPROS
 QUESTCOR PHARM

250-300 uCi/ML

N17279 001

250-300 uCi/ML

N17279 001

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
 IPRATROPIUM BROMIDE
 AN STERIPAK

0.02%

N75313 001
 FEB 07, 2000

[illegible]

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION

ISUPREL
+ SANOFI SYNTHELABO 0.103MG/INH
N11178 001
N11178 001

SOLUTION; INHALATION

ISUPREL 0.5%
+ SANOFI SYNTHELABO 1%
N06327 002
N06327 003
N06327 002
N06327 003

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

ISOSORBIDE MONONITRATE

KREMERS URBAN 120MG

AB N11178 001

KV PHARM 30MG

AB N06327 002

SANOFI SYNTHELABO 60MG

AB N06327 003

ZENITH GOLDLINE 120MG

AB N06327 003

ZENITH GOLDLINE 60MG

ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL

ISORDIL 40MG

AB + WYETH AYERST 40MG

N12882 001

JUL 29, 1988

ISOSORBIDE DINITRATE

INWOOD LABS 40MG

AB + 40MG

N40009 001

DEC 30, 1998

ISOSORBIDE MONONITRATE

TABLET, ORAL

ISOSORBIDE MONONITRATE

WEST WARD 20MG

AB N75361 001

OCT 05, 2000

TABLET, EXTENDED RELEASE; ORAL

IMDUR 120MG

AB + SCHERING 120MG

N20225 003

MAR 30, 1995

DEXCEL LTD 60MG

AB N75522 001

APR 17, 2000

KREMERS URBAN 30MG

AB N75155 002

JAN 13, 2000

IVERMECTIN

TABLET, ORAL

STROMECTOL

MERCK 3MG

N50742 002

OCT 08, 1998

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

PHARMAFAIR

AP EQ 75MG BASE/2ML

AP EQ 500MG BASE/2ML

AP EQ 1GM BASE/3ML

EQ 75MG BASE/2ML

EQ 500MG BASE/2ML

EQ 1GM BASE/3ML

KETOCONAZOLE

CREAM; TOPICAL

KETOCONAZOLE

TEVA 2%

AB N75581 001

APR 25, 2000

N75155 003
AUG 04, 2000
N75395 001
MAR 16, 2000
N75395 002
MAR 16, 2000
N75395 003
MAR 16, 2000
N75448 001
JUN 19, 2000

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

N75581 001
APR 25, 2000

KETOCONAZOLE

CREAM; TOPICAL
NIZORAL

AB + MCNEIL CONS

2%

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

SHAMPOO; TOPICAL
NIZORAL

+ JANSSEN

2%

N19227 001
AUG 31, 1990
N19227 001
AUG 31, 1990

+ MCNEIL CONS

2%

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION
KETOROLAC TROMETHAMINE

AP

APOTHECON

15MG/ML

N75348 001
NOV 28, 2000
N75348 002
NOV 28, 2000

30MG/ML

TABLET; ORAL
KETOROLAC TROMETHAMINE

AB

ROXANE

10MG

N74790 001
JUN 26, 1997
N74790 001
JUN 26, 1997

10MG

LACTULOSE

SOLUTION; ORAL
DUPELAC

AA SOLVAY

10GM/15ML

10GM/15ML

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

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM PRESERVATIVE FREE

AP

ABBOTT

EQ 10MG BASE/ML

N40147 001
JUN 25, 1997

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM PRESERVATIVE FREE

+ ABBOTT

EQ 10MG BASE/ML

N40147 001
JUN 25, 1997

AP BEDFORD

EQ 10MG BASE/ML

N40347 001
APR 25, 2000

AP

EQ 350MG BASE/VIAL

N40335 001
APR 20, 2000

WELLCOVORIN

GLAXO WELLCOME

EQ 100MG BASE/VIAL

N89834 001
JAN 23, 1989

AP

EQ 100MG BASE/VIAL

TABLET; ORAL
LEUCOVORIN CALCIUM

AB

IMMUNEX

EQ 15MG BASE

N71104 001
MAR 04, 1987

AB

EQ 15MG BASE

N71104 001
MAR 04, 1987

AB

ROXANE

EQ 25MG BASE

N72736 001
FEB 22, 1993

AB

EQ 25MG BASE

N72736 001
FEB 22, 1993

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION
VIADUR

+ ALZA

EQ 65MG BASE

N21088 001
MAR 03, 2000

INJECTABLE; INJECTION
LEUPROLIDE ACETATE

AP

GENSIA SICOR PHARMS

1MG/0.2ML

N75471 001
OCT 25, 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% N75473 001

AT 0.5% N75475 001

AUG 03, 2000
AUG 03, 2000

LEVOPUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHIROCAINE

FURDUE PHARMA

EQ 2.5MG BASE/ML

EQ 5MG BASE/ML

EQ 7.5MG BASE/ML

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

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

AB + ICN

2MG

2MG

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

LEVORPHANOL TARTRATE

AB ROXANE

2MG

N74278 001
MAR 31, 2000

LEVOTHYROXINE SODIUM

TABLET; ORAL

UNITHRD

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 11 / JAN'2000 - NOV'2000

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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

CAPSULE; ORAL

KALETRA

+ ABBOTT

133.3MG; 33.3MG

SOLUTION; ORAL

KALETRA

+ ABBOTT

N21226 001
SEP 15, 2000

80MG/ML; 20MG/ML

LORAZEPAM

INJECTABLE; INJECTION

LORAZEPAM

MOVIA

N74793 001
MAR 16, 2000
N74793 002
MAR 16, 2000

2MG/ML

4MG/ML

MAGNESIUM SULFATE

INJECTABLE; INJECTION

MAGNESIUM SULFATE

ABBOTT

500MG/ML

500MG/ML

500MG/ML

N75151 001
APR 25, 2000
N19316 001
SEP 08, 1986
N19316 001
SEP 08, 1986

AP + AM PHARM PARTNERS

+

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL

AMEN

BP AMARIN PHARMS 10MG
BP CARRICK 10MG
BP CURRETAS 10MG
BP SOLVAY 10MG

N83242 001
N83242 001

N85686 001
N85686 001

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

PHARMACHENIE

AB

10MG

AB TEVA 40MG

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

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

REPRONEX

FERRING

AB

AB

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

MALLINCKRODT

AA

50MG

N40352 001
JUN 13, 2000

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL
MALLINCKRODT

100MG

N40352 002
JUN 13, 2000

AB
NORINYL 1+50 21-DAY
SEARLE
WATSON LABS

N13625 002
N13625 002

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION
WYAMINE SULFATE
* WYETH AYERST

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

N08248 001
N08248 001

AN
* BOEHRINGER INGELHEIM
5%
5%

N17659 001
N17659 001

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE
LANNETT

200MG
400MG
200MG
400MG

N14882 002
N14882 001
N14882 002
N14882 001

AN
ASTRAZENECA
0.4%
0.4%
0.6%

N71275 001
JUL 27, 1988
N71018 001
JUL 27, 1988
N71275 001
JUL 27, 1988
N71018 001
JUL 27, 1988

MESALAMINE

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

250MG
250MG

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

SYRUP; ORAL
METAPROTERENOL SULFATE
NOVEX

10MG/5ML

N75235 001
JAN 27, 2000

SUPPOSITORY; RECTAL
ROWASA
* SOLVAY

500MG
500MG

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

10MG/5ML
10MG/5ML

N72023 001
SEP 15, 1988
N72023 001
SEP 15, 1988

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
NORINYL
* SEARLE
* WATSON LABS

0.1MG; 2MG
0.1MG; 2MG

N21202 001
OCT 13, 2000

TABLET, EXTENDED RELEASE; ORAL
GLUCOPHAGE XR
+ BRISTOL MYERS SQUIBB 500MG

METFORMIN HYDROCHLORIDE

NALMEFENE HYDROCHLORIDEINJECTABLE; INJECTION
REVEX

+ BAXTER PHARM PROD

+
+ OHWEDA

EQ 0.1MG BASE/ML

EQ 1MG BASE/ML

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
N20459 002
APR 17, 1995N75061 001
FEB 18, 1998
N75061 002
FEB 18, 1998
N75061 001
FEB 18, 1998
N75061 002
FEB 18, 1998NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL
ASTRAZENECAAP
AP
AP

0.02MG/ML

0.4MG/ML

1MG/ML

0.02MG/ML

0.4MG/ML

1MG/ML

N72081 001
APR 11, 1989
N72086 001
APR 11, 1989
N72091 001
APR 11, 1989
N72081 001
APR 11, 1989
N72086 001
APR 11, 1989
N72091 001
APR 11, 1989N83115 001
N83115 001
N40378 001
MAY 03, 2000NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

RANBAXY

EQ 0.5MG BASE;

EQ 50MG BASE

AB

N75523 001
MAR 17, 2000NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HCL

EON

50MG

N75434 001
MAR 08, 2000NAPROXEN

TABLET, DELAYED RELEASE; ORAL

NAPROXEN
GENEVA PHARMS TECH

AB

375MG

AB

500MG

AB

375MG

AB

500MG

INVAMED

NIACIN

TABLET; ORAL

NIACIN
GLOBAL PHARM

IMPAX LABS

NIACOR

UPSHER SMITH

AA

500MG

AA

500MG

AA

500MG

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC

+ BAYER

AB

30MG

BC

30MG

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

BIOVAIL

AB

60MG

ELAN PHARM

AB

30MG

PROCARDIA XL

AB

60MG

+ PFIZER

BC

60MG

N75289 001
SEP 27, 2000
N75128 001
MAR 10, 2000
N19684 002
SEP 06, 1989
N19684 002
SEP 06, 1989NITROFURAZONE

CREAM; TOPICAL

FURACIN

+ ROBERTS LABS

0.2%

N83789 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

1-50

NITROFURAZONE

CREAM; TOPICAL
FURACIN
+ SHIRE

0.2%

N83789 001

ointment; TOPICAL
FURACIN

AT * ROBERTS LABS
AT * SHIRE

0.2%
0.2%

N05795 001
N05795 001

NITROGLYCERIN

INJECTABLE; INJECTION
NITRO IV
AP * POHL BOSKAMP

5MG/ML

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

AP

@

TABLET; SUBLINGUAL
NITROSTAT
PARKE DAVIS

0.3MG

0.4MG

0.6MG

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

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL
TARO

AB EQ 10MG BASE

AB EQ 25MG BASE

AB EQ 50MG BASE

AB EQ 75MG BASE

SOLUTION; ORAL

AA NORTRIPTYLINE HCL
PHARM ASSOC

EQ 10MG BASE/5ML

N75606 001
AUG 28, 2000

NYSTATIN

TABLET; VAGINAL
NYSTATIN
ODYSSEY PHARMS

AT

100,000 UNITS

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

AT SIDMAK LABS NJ

100,000 UNITS

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN
NOVARTIS

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

SANDOSTATIN LAR
NOVARTIS

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

OLANZAPINE

TABLET; ORAL
ZYPREXA
LILLY

2.5MG

10MG

15MG

2.5MG

10MG

15MG

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

OLANZAPINE

TABLET, ORALLY DISINTEGRATING; ORAL
ZYPREXA ZYDIS
LILLY

5MG
10MG
15MG
20MG

+

ORLISTAT

CAPSULE; ORAL
XENICAL
+ HLR

120MG
120MG

* ROCHE

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

AB EON 100MG
AB GENEVA PHARMS TECH 100MG
AB IMPAX PHARM 100MG
AB INVRMED 100MG

OXACILLIN SODIUM

INJECTABLE; INJECTION
BACTOCILL
AP + SMITHKLINE BEECHAM

AP + SMITHKLINE BEECHAM EQ 500MG BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 1GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 2GM BASE/VIAL

OXACILLIN SODIUM

INJECTABLE; INJECTION
BACTOCILL
AP + SMITHKLINE BEECHAM

AP + SMITHKLINE BEECHAM EQ 4GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 10GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 500MG BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 1GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 2GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 4GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 10GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 500MG BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 10GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 4GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 10GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 500MG BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 10GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 4GM BASE/VIAL
AP + SMITHKLINE BEECHAM EQ 10GM BASE/VIAL

N61334 008
MAR 26, 1982
N61334 010
MAR 26, 1982
N61334 009
MAR 26, 1982
N61334 006
MAR 26, 1982
N61334 007
MAR 26, 1982
N61334 008
MAR 26, 1982
N61334 010
MAR 26, 1982
N61490 002
MAR 26, 1982
N61490 002
MAR 26, 1982
N61490 006
MAY 09, 1991
N61490 006
MAY 09, 1991
N62856 005
OCT 26, 1988
N62856 005
OCT 26, 1988
N62856 005
OCT 26, 1988

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL
NOVARTIS

150MG
300MG
600MG

N21014 001
JAN 14, 2000
N21014 002
JAN 14, 2000
N21014 003
JAN 14, 2000
N21014 000
JAN 14, 2000

OXYBUTYRIN CHLORIDE

TABLET, EXTENDED RELEASE; ORAL
DITROPAN XL
AB + ALZA

5MG
5MG

N20897 001
DEC 16, 1998
N20897 001
DEC 16, 1998
N20897 001
DEC 16, 1998

OXYCODONE HYDROCHLORIDE

TABLET; ORAL
ROXICODONE
ROXANE

15MG
30MG

+

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN

BX * PURDUE PHARMA

10MG

+

PURDUE PHARMA LP

10MG

+

160MG

ROXICODONE
ROXANE

10MG

+

30MG

@

10MG

@

30MG

PACLITAXEL

INJECTABLE; INJECTION

PACLITAXEL

AP * BAKER NORTON

6MG/ML

TAXOL

AP * BRISTOL MYERS SQUIBB

6MG/ML

+

6MG/ML

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
PROTONIX

+

WYETH AYERST

EQ 40MG BASE

N20987 001

FEB 02, 2000

PEMOLINE

TABLET; ORAL
PEMOLINE

AB AMIDE PHARM

18.75MG

AB

N21011 001

AUG 31, 2000

AB

N21011 002

AUG 31, 2000

AB

75MG

AB COPLEY PHARM

18.75MG

AB

N20553 001

DEC 12, 1995

AB

N20553 001

DEC 12, 1995

AB

N20553 005

MAR 15, 2000

AB

75MG

AB INVAMED

18.75MG

AB

N20932 001

OCT 26, 1998

AB

N20932 002

OCT 26, 1998

AB

37.5MG

AB

N20932 001

OCT 26, 1998

AB

75MG

AB VINTAGE PHARMS

18.75MG

AB

N20932 002

OCT 26, 1998

AB

37.5MG

AB

37.5MG

AB WATSON LABS

37.5MG

AB

75MG

TABLET, CHEWABLE; ORAL

CYLERT

+ ABBOTT

+

PEMOLINE

AB AMIDE PHARM

37.5MG

AB

N17703 001

SEP 18, 2000

AB

37.5MG

AB COPLEY PHARM

37.5MG

AB

N75678 001

JUL 26, 2000

AB

N75555 001

FEB 18, 2000

N75595 001

FEB 28, 2000

N75595 002

FEB 28, 2000

N75595 003

FEB 28, 2000

N75030 003

FEB 22, 2000

N75286 001

DEC 27, 1999

N75286 002

JUN 30, 1999

N75286 003

JUN 30, 1999

N75286 001

DEC 27, 1999

N75286 002

JUN 30, 1999

N75286 003

JUN 30, 1999

N75328 001

APR 19, 2000

N75328 002

APR 19, 2000

N75328 003

APR 19, 2000

N75287 002

SEP 18, 2000

N75287 003

SEP 18, 2000

N17703 001

SEP 18, 2000

N75678 001

JUL 26, 2000

N75555 001

FEB 18, 2000

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

AMARIN PHARMS

CARRICK

CAM-METRAZINE

CANALI

AA

AA

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AA

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TABLET, EXTENDED RELEASE; ORAL

K-DUR 10

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N19439 002

JUN 13, 1986

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JUN 13, 1986

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JUN 13, 1986

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N19439 002

TABLET, EXTENDED RELEASE; ORAL

K-DUR 10

AB

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RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN' 2000 - NOV' 2000

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUMSOLUTION/DROPS; OPHTHALMIC

AT STERIS SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE
EQ 0.23% PHOSPHATE; 10% N73630 001
MAY 27, 1993

PREDNISONESYRUP; ORAL

* LIQUID PRED
* NURO

5MG/5ML N87611 002
SEP 07, 1982
5MG/5ML N87611 002
SEP 07, 1982

TABLET; ORALPREDNIGEN-N

AB CENT PHARMS
@ SCHWARZ PHARMA

5MG N84655 001
5MG N84655 001

PREDNISONE

AB GLOBAL PHARM
@ IMPAX LABS

5MG N80782 001

BX PHOENIX LABS NY

5MG N80321 001
20MG N83807 001
5MG N80321 001
20MG N83807 001

PRIMIDONE

@

TABLET; ORALMYSOLENE

* ELAN PHARMA

50MG N09170 003
50MG N09170 003

> DLT >
 > ADD >

PROCAINAMIDE HYDROCHLORIDETABLET, EXTENDED RELEASE; ORALPROCAN SR

* PARKEDALE

AB 500MG N86065 001
AB 750MG N87510 001
AB 1GM APR 01, 1982
AB 500MG N88489 001
AB 500MG JAN 16, 1985
@ N86065 001

PROCAINAMIDE HYDROCHLORIDETABLET, EXTENDED RELEASE; ORALPROCAN SR

@ PARKEDALE

750MG N87510 001
1GM APR 01, 1982
1GM N88489 001
@ JAN 16, 1985

PROCHLORPERAZINESUPPOSITORY; RECTALCOMPRO

AB PADDOCK

25MG N40246 001
JUN 28, 2000

PROGESTERONECAPSULE; ORALPROMETRIUM

SCHERING PLOUGH

100MG N19781 001
200MG MAY 14, 1998
300MG N19781 002
100MG OCT 15, 1999
200MG N19781 003
300MG OCT 15, 1999
100MG N19781 001
200MG MAY 14, 1998
300MG N19781 002
100MG OCT 15, 1999
200MG N19781 003
300MG OCT 15, 1999

UNIMED PHARMS

+

@

PROMETHAZINE HYDROCHLORIDEINJECTABLE; INJECTIONPROMETHAZINE HCL

AB ABBOTT

25MG/ML N40372 001
50MG/ML JUN 08, 2000
50MG/ML N40372 002
50MG/ML JUN 08, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

1-56

PROPAPENONE HYDROCHLORIDE

TABLET; ORAL
PROPAPENONE HCL

AB WATSON LABS 150MG
AB 225MG
BYTHMOL
KNOLL PHARM 150MG
AB 225MG

N75203 001
OCT 24, 2000
N75203 002
OCT 24, 2000
N19151 001
NOV 27, 1989
N19151 003
NOV 20, 1992
N19151 001
NOV 27, 1989
N19151 003
NOV 20, 1992

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
INDERAL

* WYETH AYERST 1MG/ML
PROPRANOLOL HCL
AP BEDFORD 1MG/ML

N16419 001
N75792 001
AUG 29, 2000

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL
VENTAIRE

* AVENTIS PHARMS 2MG
* HOECHST MARION RSSL 2MG

N83459 001
N83459 001

PROPANTHELINE BROMIDE

TABLET; ORAL
PRO-BANTHINE

BP ROBERTS LABS
BP 7.5MG
BP 15MG
BP 7.5MG
BP 15MG

N08732 003
N08732 002
N08732 003
N08732 002

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

TABLET; ORAL
VIVACTIL

* MERCK 5MG
SIDMAK LABS CA 10MG
+ 5MG
+ 10MG

N16012 001
N16012 002
N16012 001
N16012 002

PROPACARINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC
PROPACARINE HCL

AT TAYLOR PHARMA 0.5%

N40277 001
MAR 16, 2000

QUINIDINE POLYGALACTURONATE

TABLET; ORAL
CARDIOQUIN

* PURDUE FREDERICK 275MG
275MG

N11642 002
N11642 002

PROPOFOL

INJECTABLE; INJECTION
PROPOFOL

AB GENSLA SICOR PHARMS 10MG/ML

N75392 001
SEP 19, 2000

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

AB PHARMAVITE 200MG
200MG

N84627 001
N84627 001

PROPRANOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
INDERAL

AP WYETH AYERST 1MG/ML

CAPSULE; ORAL
RANITIDINE HCL

* CHEMINOR DRUGS EQ 150MG BASE

N16419 001
> ADD >
> ADD >

N75742 001
NOV 29, 2000

RANITIDINE HYDROCHLORIDE

> ADD >
> ADD

AB RANITIDINE HCL
CAPSULE; ORAL
CHEMINOR DRUGS
AB EQ 300MG BASE
AB EQ 150MG BASE
AB EQ 300MG BASE

AB RANBAXY
TABLET; ORAL
RANITIDINE
AB EQ 150MG BASE
AB EQ 300MG BASE

N75742 002
NOV 29, 2000
N75564 001
OCT 27, 2000
N75564 002
OCT 27, 2000

N75439 001
APR 19, 2000
N75439 002
APR 19, 2000

N21025 001
APR 21, 2000

RIVASTIGMINE TARTRATE

SOLUTION; ORAL
EXELON
+ NOVARTIS
EQ 2MG BASE/ML

ROFECOXIB
TABLET; ORAL
VIOXX
* MERCK
25MG
25MG
50MG

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

RESERPINE

TABLET; ORAL
RESERPINE
GLOBAL PHARM
BP
BP
@ IMPAX LABS
@

0.1MG
0.25MG
0.1MG
0.25MG

N09627 001
N09627 002
N09627 001
N09627 002

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE
AT
ZENITH GOLDLINE
2.5%
2.5%

N85777 001
N85777 001

RISEDRONATE SODIUM

TABLET; ORAL
ACTONEL
PROCTER AND GAMBLE

5MG

N20835 002
APR 14, 2000

SEVELAMER HYDROCHLORIDE

TABLET; ORAL
RENAGEL
GELTEX
400MG
800MG

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

RIVASTIGMINE TARTRATE

CAPSULE; ORAL
EXELON
NOVARTIS

EQ 1.5MG BASE
EQ 3MG BASE
EQ 4.5MG BASE
EQ 6MG BASE

N20823 003
APR 21, 2000
N20823 004
APR 21, 2000
N20823 005
APR 21, 2000
N20823 006
APR 21, 2000

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

10MG/1.5ML

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

SODIUM IODIDE, I-131

CAPSULE; ORAL
IODOTOPE
BRACCO

1-130mCi
1-150mCi
1-130mCi
1-150mCi
100 uCi
100 uCi
15-100 uCi
0.8-100mCi
15-100 uCi
0.8-100mCi

N10929 001
N10929 003
N10929 001
N10929 003
N17316 002
N17316 002
N16517 002
N16517 001
N16517 002
N16517 001

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE
BERLEX LABS

AB
AB
AB
AB

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

SOLUTION; ORAL
IODOTOPE
BRACCO

7-106mCi/BOT
7-106mCi/BOT
50mCi/ML
50mCi/ML
3.5-150mCi/VIAL
3.5-150mCi/VIAL

N10929 002
N10929 002
N17315 001
N17315 001
N16515 001
N16515 001

BETAPACE AF
BERLEX LABS

80MG
120MG
160MG

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

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

TABLET; ORAL
VISICOL
+ INKINE

0.398GM; 1.102GM

N21097 001
SEP 21, 2000

SOTALOL HCL
EON

AB
AB
AB
AB
AB

80MG
120MG
160MG
240MG
80MG

N75366 001
MAY 01, 2000
N75366 002
MAY 01, 2000
N75366 003
MAY 01, 2000
N75366 004
MAY 01, 2000
N75237 001
MAY 01, 2000

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION
NORDITROPIN
NOVO NORDISK

5MG/1.5ML

N21148 001
JUN 20, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL

ANDRODERM

BX * THERATECH 5MG/24HR

* 2.5MG/24HR

BX + WATSON LABS 5MG/24HR

+ 2.5MG/24HR

GEL; TOPICAL

ANDROGEL

+ UNIMED PHARMS 1*

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

N21015 001
FEB 28, 2000

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLOPIDINE HCL

AB DANBURY PHARMA 250MG

N75309 001
APR 26, 2000

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE

AT NOVEX EQ 0.25% BASE

N75411 001
SEP 08, 2000
N75412 001
SEP 08, 2000

AT EQ 0.5% BASE

TABLET; ORAL

TIMOLOL MALEATE

AB NOVOPHARM 5MG

AB 10MG

AB 20MG

N72648 001
JUN 16, 1993
N72649 001
JUN 16, 1993
N72650 001
JUN 16, 1993
N72648 001
JUN 16, 1993
N72649 001
JUN 16, 1993
N72650 001
JUN 16, 1993

CAPSULE, EXTENDED RELEASE; ORAL

SLO-PHYLLIN

@ AVENTIS

60MG

@ 125MG

@ 250MG

BC RHONE POULENC RORER 125MG

BC 250MG

60MG

N85206 001
MAY 24, 1982
N85203 001
MAY 24, 1982
N85205 001
MAY 24, 1982
N85203 001
MAY 24, 1982
N85205 001
MAY 24, 1982
N85206 001
MAY 24, 1982

TINZAPARIN SODIUM

INJECTABLE; INJECTION

INNOHEP

+ DUPONT PHARMA 20,000 IU/ML

N20484 001
JUL 14, 2000

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

BETALIN S

AP * LILLY

100MG/ML

100MG/ML

THIAMINE HCL

AM PHARM PARTNERS

100MG/ML

100MG/ML

TABLET; ORAL
ZANAFLEX
ELAN PHARMA
EQ 2MG BASE

N20397 002
FEB 04, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

1-62

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

CHELSEA LABS

AB 500MG
AB 500MG
AB 500MG
AB 500MG
EON
EON

TOPIRAMATE

CAPSULE; ORAL

TOPAMAX SPRINKLE

JOHNSON RW

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

25MG
50MG
25MG
50MG

N86109 001
N86109 001
N12678 001
N12678 001

N20844 002
OCT 26, 1998
N20844 003
OCT 26, 1998
N20844 002
OCT 26, 1998
N20844 003
OCT 26, 1998

TRETINOIN

CREAM; TOPICAL

RENOVA

+ JOHNSON AND JOHNSON 0.02%

GEL; TOPICAL

RETIN-A

+ JOHNSON AND JOHNSON

AB 0.025%
BT 0.025%
AB 0.025%

N17579 002
N17579 002
N75529 001
FEB 22, 2000

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

FLUTEX

ZENITH GOLDLINE

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

N85539 001
N85539 002
N85539 003
N85539 001
N85539 002

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

FLUTEX

+ ZENITH GOLDLINE

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

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

OINTMENT; TOPICAL

ARISTOCORT A

+ FUJISAWA HUTHCARE

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

N80745 003
N80745 003

FLUTEX

+ ZENITH GOLDLINE

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

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

KENALOG

+ APOTHECON

AT 0.025%
AT 0.025%
AT 0.1%
AT 0.1%

N11600 003
N11600 003
N11600 001
N11600 001

FLUTEX

+ ALTANA

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

N85691 001
N85691 001
N85691 003
N85691 003
N85691 002
N85691 002
N87356 001

CLAY PARK

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE

AT + CLAY PARK 0.025%
 AT 0.1%
 AT 0.1%
 AT 0.5%
 AT 0.5%

SPRAY, METERED; NASAL

TRI-NASAL

+ MURO 0.05MG/SPRAY

N87356 001
 N87357 001
 N87357 001
 N87385 001
 N87385 001

N20120 001
 FEB 04, 2000

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

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL

PRIMSOL

ASCENT PEDS

+

+

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION

NEUTREXIN

+ MEDIMMUNE ONCOLOGY

* US BIOSCIENCE

N20326 001
 DEC 17, 1993
 N20326 001
 DEC 17, 1993

EQ 25MG BASE/VIAL
 EQ 25MG BASE/VIAL

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION

TRELSTAR DEPOT

+ DEBIO RECHERCHE

EQ 3.75MG BASE/VIAL

N20715 001
 JUN 15, 2000

TROGLITAZONE

TABLET; ORAL

FRELAY

SANKYO

200MG

300MG

400MG

200MG

300MG

400MG

200MG

REGULIN
 PARKE DAVIS PHARMS

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

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

ZENITH GOLDLINE

EQ 1MG BASE

EQ 2MG BASE

EQ 5MG BASE

EQ 10MG BASE

EQ 1MG BASE

EQ 2MG BASE

EQ 5MG BASE

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

TRIHENXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHENXYPHENIDYL HCL

WEST WARD

2MG

5MG

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

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

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TROGLITAZONE

TABLET; ORAL

<u>AB</u>	<u>REZULIN</u>	<u>PARKE DAVIS PHARMS</u>	<u>300MG</u>	<u>N20720 003</u>	<u>> DLT ></u>	<u>BX</u>	<u>* METABOLIC SOLUTIONS</u>	<u>125MG/VIAL</u>	<u>N21892 001</u>
<u>AB</u>			<u>400MG</u>	<u>AUG 04, 1997</u>	<u>> DLT ></u>				<u>DEC 17, 1999</u>
				<u>N20720 002</u>	<u>> ADD ></u>				<u>N21092 001</u>
				<u>JAN 29, 1997</u>	<u>> ADD ></u>				<u>DEC 17, 1999</u>
				<u>N20720 001</u>					
				<u>JAN 29, 1997</u>					
				<u>N20720 003</u>					
				<u>AUG 04, 1997</u>					
				<u>N20720 002</u>					
				<u>JAN 29, 1997</u>					

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC

<u>AT</u>	<u>TROPICACYL</u>	<u>AKORN</u>	<u>0.5%</u>	<u>N40314 001</u>	<u>> DLT ></u>				<u>N19415 002</u>
<u>AT</u>				<u>SEP 29, 2000</u>	<u>> DLT ></u>				<u>SEP 18, 1986</u>
				<u>N40315 001</u>	<u>> DLT ></u>				<u>N19415 003</u>
				<u>SEP 29, 2000</u>	<u>> DLT ></u>				<u>SEP 18, 1986</u>

TROPICAMIDE

ALCON UNIVERSAL

<u>AT</u>			<u>1%</u>	<u>N89172 001</u>	<u>> DLT ></u>				<u>N19415 002</u>
<u>AT</u>				<u>DEC 28, 1990</u>	<u>> DLT ></u>				<u>SEP 18, 1986</u>
<u>AT</u>				<u>N87636 001</u>	<u>> DLT ></u>				<u>N19415 003</u>
<u>AT</u>				<u>JUL 30, 1982</u>	<u>> DLT ></u>				<u>SEP 18, 1986</u>
<u>AT</u>				<u>N87637 001</u>	<u>> DLT ></u>				
<u>AT</u>				<u>AUG 09, 1982</u>	<u>> DLT ></u>				
<u>AT</u>				<u>N87636 001</u>	<u>> DLT ></u>				
<u>AT</u>				<u>JUL 30, 1982</u>	<u>> DLT ></u>				
<u>AT</u>				<u>N87637 001</u>	<u>> DLT ></u>				
<u>AT</u>				<u>AUG 09, 1982</u>	<u>> DLT ></u>				
<u>AT</u>				<u>N89172 001</u>	<u>> DLT ></u>				
<u>AT</u>				<u>DEC 28, 1990</u>	<u>> DLT ></u>				

UNOPROSTONE ISOPROPYL

SOLUTION/DROPS; OPHTHALMIC

	<u>RESCULA</u>	<u>+ CIBA</u>	<u>0.15%</u>	<u>N21214 001</u>	<u>> DLT ></u>				<u>N20675 001</u>
				<u>AUG 03, 2000</u>	<u>> DLT ></u>				<u>DEC 10, 1997</u>

UREA, C-13

POWDER FOR RECONSTITUTION; ORAL

HELICOSOL

<u>> DLT ></u>	<u>BX</u>	<u>* METABOLIC SOLUTIONS</u>	<u>125MG/VIAL</u>	<u>N21892 001</u>
<u>> DLT ></u>				<u>DEC 17, 1999</u>
<u>> ADD ></u>				<u>N21092 001</u>
<u>> ADD ></u>				<u>DEC 17, 1999</u>

UROFOLLITROPIN

INJECTABLE; INTRAMUSCULAR

<u>> DLT ></u>	<u>FERTINEX</u>	<u>* SERONO</u>	<u>75 IU/AMP</u>	<u>N19415 002</u>
<u>> DLT ></u>				<u>SEP 18, 1986</u>
<u>> DLT ></u>				<u>N19415 003</u>
<u>> DLT ></u>				<u>SEP 18, 1986</u>
<u>> DLT ></u>				
<u>> ADD ></u>	<u>METRODIN</u>	<u>@ SERONO</u>	<u>75 IU/AMP</u>	<u>N19415 002</u>
<u>> ADD ></u>				<u>SEP 18, 1986</u>
<u>> ADD ></u>				<u>N19415 003</u>
<u>> ADD ></u>				<u>SEP 18, 1986</u>

URSODIOL

CAPSULE; ORAL

<u>AB</u>	<u>ACTIGALL</u>	<u>* NOVARTIS</u>	<u>300MG</u>	<u>N19594 002</u>
				<u>DEC 31, 1987</u>
				<u>N19594 002</u>
				<u>DEC 31, 1987</u>
<u>AB</u>	<u>URSODIOL</u>	<u>AMIDE PHARM</u>	<u>300MG</u>	<u>N75517 001</u>
				<u>MAR 14, 2000</u>
<u>AB</u>	<u>COPLEY PHARM</u>		<u>300MG</u>	<u>N75592 001</u>
				<u>MAY 25, 2000</u>

TABLET; ORAL

URSO

<u>+</u>	<u>AXCAN</u>	<u>250MG</u>	<u>N20675 001</u>
<u>+</u>	<u>AXCAN SCANDIPHARM</u>	<u>250MG</u>	<u>DEC 10, 1997</u>

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

VECURONIUM BROMIDE

INJECTABLE; INJECTION

VECURONIUM BROMIDE

BEDFORD

10MG/VIAL

N75549 001
JUN 13, 2000

20MG/VIAL

N75549 002
JUN 13, 2000

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

GLOBAL PHARM

EQ 50,000 UNITS BASE
EQ 50,000 UNITS BASE
EQ 50,000 UNITS BASE
EQ 50,000 UNITS BASE

N80953 001
N80955 001
N80953 001
N80955 001

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

COVERA-HS

SEARLE

180MG

N20552 001
FEB 26, 1996

180MG

N20552 001
FEB 26, 1996

240MG

N20552 002
FEB 26, 1996

240MG

N20552 002
FEB 26, 1996

WARFARIN SODIUM

TABLET; ORAL

WARFARIN SODIUM

INVAMED

3MG

N40196 008
JUL 26, 2000

6MG

N40196 009
JUL 26, 2000

XENON, XE-133

GAS; INHALATION

XENON XE 133

NYCONED AMERSHAM

10mCi/VIAL
20mCi/VIAL
1 Ci/AMP
1 Ci/AMP
10mCi/VIAL
20mCi/VIAL

N17687 002
N17687 003
N17256 002
N17256 002
N17687 002
N17687 003

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

N21119 001
APR 12, 2000

15MG/VIAL

VERTEPORFIN

INJECTABLE; INJECTION

VISUDYNE

+ QLT

VITAMIN A

CAPSULE; ORAL

AQUASOL A

ASTRAZENECA

50,000 USP UNITS
35,000 USP UNITS
25,000 USP UNITS
50,000 USP UNITS

N83080 001
N83080 002
N83080 002
N83080 001

TABLET; ORAL

ACCOLATE

ASTRAZENECA

10MG

N20547 003
SEP 17, 1999

ZOLMITRIPTAN

TABLET; ORAL

ZOMIG

ASTRAZENECA

2.5MG

N20768 001
NOV 25, 1997
N20768 002
NOV 25, 1997

5MG

+

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

1-66

ZOLMITRIPTAN

TABLET; ORAL
ZOMIG
ZENBICA

*

2.5MG

5MG

N20768 001
NOV 25, 1997
N20768 002
NOV 25, 1997

ZONISAMIDE

CAPSULE; ORAL
ZONEGRAN
+ DAINIPPON

100MG

N20789 001
MAR 27, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACETAMINOPHEN
ROXANE

120MG

650MG

120MG

650MG

N71010 001
MAY 12, 1987
N71011 001
MAY 12, 1987
N71010 001
MAY 12, 1987
N71011 001
MAY 12, 1987

TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN
PERRIGO

650MG

N75077 001
FEB 25, 2000

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
FOAMICON
GENEVA PHARMS TECH
INVAMED

80MG; 20MG

80MG; 20MG

N72687 001
JUN 28, 1989
N72687 001
JUN 28, 1989

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER

650MG

650MG

650MG

650MG

N16030 001
N16030 001
N16030 002
N16030 002

AVOBENZONE; PADIMATE O

LOTION; TOPICAL
PHOTOPLEX
ALLERGAN HERBERT

3%; 7%

N19459 001
SEP 30, 1988

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
DIMETANE
WHITEHALL ROBINS

12MG

12MG

N10799 011
JUN 10, 1983

N10799 011
JUN 10, 1983

CALCIUM CARBONATE, PRECIPITATED; FAMOTIDINE; MAGNESIUM HYDROXIDE

TABLET, CHEWABLE; ORAL
PEPCID COMPLETE
+ MERCK

800MG; 10MG; 165MG

N20958 001
OCT 16, 2000

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
E-Z SCRUB
BECTON DICKINSON

4%

N73416 001
MAR 14, 2000

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SOLUTION; TOPICAL
CHLORAPREP
+ MEDI FLEX HOSP

2%; 70%

N20832 001
JUL 14, 2000

SPONGE; TOPICAL
CHLORAPREP
+ MEDI FLEX HOSP

2%; 70%

N20832 001
JUL 14, 2000

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CONTAC
+ SMITHKLINE

8MG; 75MG
8MG; 75MG

N18099 001
N18099 001

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

2-2

CIMETIDINE

TABLET; ORAL
CIMETIDINE
LEINER

200MG

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

NOVOPHARM
PERRIGO

200MG

200MG

100MG

100MG

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

TABLET; ORAL
MOTRIN MIGRAINE PAIN
MCNEIL

200MG

200MG

200MG

200MG

N19012 004
FEB 25, 2000
N19012 003
JUL 29, 1987
N19012 002
JUL 29, 1987

CLOTRIMAZOLE

CREAM; VAGINAL
TRIVAGIZOLE 3
+ TARO

2*

N21143 001
APR 12, 2000

N21128 001
AUG 01, 2000

DOCOSANOL

CREAM; TOPICAL
ABREVA
+ AVAMIR

10*

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

N73187 001
SEP 15, 1992
N73187 001
SEP 15, 1992
N73062 001
MAY 28, 1993
N73062 001
MAY 28, 1993

IBUPROFEN

CAPSULE; ORAL
IBUPROFEN
PHARM FORM

200MG

200MG

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

N73254 001
JUL 30, 1993
N73254 001
JUL 30, 1993
N75232 001
JAN 06, 2000

TABLET; ORAL
IBUPROFEN
LEINER

200MG

200MG

N74931 001
JUL 20, 1998
N74931 001
JUL 20, 1998

MOTRIN IB
MCNEIL

200MG

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

2MG; 125MG

N21140 001
NOV 30, 2000

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

SUSPENSION; ORAL
CHILDREN'S MOTRIN COLD
+ MCNEIL CONS

100MG/5ML; 15MG/5ML

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
ALPHARMA

1MG/5ML

1MG/5ML

1MG/5ML

1MG/5ML

WATSON LABS

TABLET; ORAL
LOPERAMIDE HCL
LEINER

2MG

2MG

2MG

N73254 001
JUL 30, 1993
N73254 001
JUL 30, 1993
N75232 001
JAN 06, 2000

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET; ORAL
IMODIUM ADVANCED
MCNEIL CONS

2MG; 125MG

N21140 001
NOV 30, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 11 / JAN'2000 - NOV'2000

MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL EXTRA STRENGTH (FOR MEN)
ALPHARMA

5%

TEVA

5%

N75518 001
NOV 17, 2000
N75619 001
NOV 17, 2000

4%;EQ 0.33% BASE

N21043 001
MAR 07, 2000

NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
VISINE-A

0.025%;0.3%

AKORN

0.025%;0.3%

PFIZER

N20485 001
JAN 31, 1996
N20485 001
JAN 31, 1996

EQ 75MG BASE

N75212 001
JAN 14, 2000

CHELSEA LABS

EQ 75MG BASE

N75294 001
MAR 28, 2000

GENPHARM

EQ 75MG BASE

N75497 001
JAN 14, 2000

LEINER

EQ 75MG BASE

N75094 001
JUN 21, 1999

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM
LEINER

EQ 200MG BASE

N75132 001
JAN 14, 2000

NOVOPHARM NC

EQ 200MG BASE

N74635 001
JAN 13, 1997
N74635 001
JAN 13, 1997

EQ 75MG BASE

N75167 001
MAY 04, 2000

NONOXYNOL-9

AEROSOL; VAGINAL
DOLFIN
@ ORTHO
@ PERSONAL PRODS

12.5%
12.5%

N14349 002
N14349 002

EQ 75MG BASE

N20745 001
FEB 26, 1998
N20745 001
FEB 26, 1998

PERMETHRIN

LOTION; TOPICAL
PERMETHRIN
ALPHARMA

1%

N75014 001
MAR 28, 2000

SOLUTION; TOPICAL
LAMISIL AT
+ NOVARTIS

1%

N21124 001
MAR 17, 2000

PIPERONYL BUTOXIDE; PYRETHRINS

AEROSOL; TOPICAL
RID MOUSE
+ PFIZER

4%;EQ 0.33% BASE

N21043 001
MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

EQ 75MG BASE

N75212 001
JAN 14, 2000

CHEMINOR DRUGS

EQ 75MG BASE

N75294 001
MAR 28, 2000

GENPHARM

EQ 75MG BASE

N75497 001
JAN 14, 2000

LEINER

EQ 75MG BASE

N75094 001
JUN 21, 1999

RANBAXY

EQ 75MG BASE

N75132 001
JAN 14, 2000

TORPHARM

EQ 75MG BASE

N75254 001
JAN 14, 2000

ZENITH GOLDLINE

EQ 75MG BASE

N75167 001
MAY 04, 2000

RANITIDINE HCL

EQ 75MG BASE

N75296 001
JAN 14, 2000

NOVOPHARM

EQ 75MG BASE

N75094 001
JUN 21, 1999

TABLET, EFFERVESCENT; ORAL

ZANTAC 75

EQ 75MG BASE

N20745 001
FEB 26, 1998
N20745 001
FEB 26, 1998

* GLAXO WELLCOME

EQ 75MG BASE

N20745 001
FEB 26, 1998
N20745 001
FEB 26, 1998

© WARNER LAMBERT

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

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

CUMULATIVE SUPPLEMENT NUMBER 11 NOVEMBER '00

NO NOVEMBER 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 November 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 prostate carcinoma. nthine 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 disease. -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=
ABX-CBL (Murine IgM Monoclonal Antibody) TN=	Acute graft-versus-host disease (aGVHD)	Abgenix, Inc. 7601 Dumbarton Circle Fremont CA 94555 DD= 11/20/00 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 November 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 Corporation 6300 Dumbarton Circle Freemont CA 94555 DD= 9/6/00 MA=
Arsenic trioxide TN=Atrivex	Treatment of multiple myeloma.	Cell Therapeutics, Inc. 201 Elliott Ave. West, Suite Seattle WA 98119 DD= 4/28/00 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=
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=
Bosentan TN=	Treatment of pulmonary arterial hypertension.	Actelion Life Sciences Ltd. 1840 Gateway Dr. 2nd Floor San Mateo CA 94404 DD= 10/6/00 MA=

Orphan Products Designations and Approvals List

January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
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=
Calfactant TN=Infasurf	Acute respiratory distress syndrome (ARDS)	ONY, Inc. Baird Research Park 1576 Sweet Home Road Amherst NY 14228 DD= 9/5/00 MA=
Carmustine TN=	Treatment of intracranial malignancies.	Direct Therapeutics, Inc. 1001 Bayhill Dr., Suite 100 San Bruno CA 94066 DD= 7/3/00 MA=
Centruroides 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=
Cetuximab 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) G250 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 November 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, Inc. 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, Inc. 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=
DNP-Modified autologous tumor vaccine TN=O-Vax	Adjuvant therapy for the treatment of ovarian cancer	AVAX Technologies, Inc. 4520 Main Street Suite 930 Kansas City MO 64111 DD= 9/21/00 MA=

Orphan Products Designations and Approvals List

January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Ethyl eicosapentaenoate TN=	Treatment of Huntington's disease.	Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA=
Flucinolone TN=	Treatment uveitis involving the posterior segment of the eye.	Bausch & Lomb 8500 Hidden River Parkway Tampa FL 33637 DD= 7/31/00 MA=
Fluorouracil TN=	Treatment of glioblastoma multiforme.	Ethypharm SA 194 Bureaux de la Colline - 92213 Saint-Cloud Cedex France FR DD= 6/29/00 MA=
Gene plasmid hVEGF165 driven by human cytomegalovirus, and [2,3-bis(oleoyl)propyl]tri methyl ammonium and dioleoyl phosphatidyl TN=	Prevention of complications due to neointimal hyperplasia disease in certain vascular anastomoses.	Eurogene Ltd. 6 Warren Mews London W1P 5DJ UK DD= 10/24/0 MA=
h5G1.1-mAb TN=	Treatment of 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 November 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 Biopharmaceuticals Textile House, 2 Koifman St. 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 Lane 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., Suite Wilmington DE 19808 DD= 8/3/00 MA=
Hypericin TN=	Treatment of cutaneous T-cell lymphoma.	Nexell Therapeutics, Inc. 2751 Centerville Rd., Suite Wilmington DE 19808 DD= 2/7/00 MA=
IL-4 Pseudomonas Toxin Fusion Protein (IL-4 (38-37) -PE38KDEL) TN=	Treatment of astrocytic glioma.	Neurocrine Biosciences, Inc. 10555 Science Center Dr. San Diego CA 92121 DD= 4/6/00 MA=

Orphan Products Designations and Approvals List

January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Iodine I 131 bis(indium-diethylenetriam inepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab') ₂ bispecific monoclonal antibody TN= 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 TN=Ipstyl	Treatment for acromegly	IPSEN, Inc. 27 Maple Street Milford MA 01757 DD= 9/11/00 MA=
Levodopa and carbidopa TN=Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215 DD= 1/18/00 MA=
Liposomal nystatin TN=Nyotran	Treatment of invasive fungal infections.	Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands TX 77381-1191 DD= 6/13/00 MA=
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 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=

Orphan Products Designations and Approvals List
January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
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=
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=
Recombinant glycine2-human glucagon-like peptide-2 TN=	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 TN=	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=

Orphan Products Designations and Approvals List

January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Recombinant human highly phosphorylated acid alpha-glucosidase TN=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 TN=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=
Recombinant urate oxidase TN=	Treatment of malignancy-associated or chemotherapy-induced hyperuricemia.	Sanofi-Synthelabo Research 9 Great Valley Parkway Malvern PA 19355 DD= 10/11/00 MA=
Recombinant urate oxidase TN=	Prophylaxis of chemotherapy-induced hyperuricemia.	Sanofi-Synthelabo Research 9 Great Valley Parkway Malvern PA 19355 DD= 10/11/00 MA=
Remacemide TN=Ecovia	Treatment of Huntington's disease.	AstraZeneca LP 725 Chesterbrook Blvd. Wayne PA 19087-5677 DD= 3/6/00 MA=
rSP-C lung surfactant TN=Venticute	Treatment of adult respiratory distress syndrome.	Byk Gulden Pharmaceuticals Byk-Gulden StraBe 2 78467 Konstanz Germany DE DD= 4/3/00 MA=

Orphan Products Designations and Approvals List

January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
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 20905-4176 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 20905-4176 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=
Technetium Tc99m rh-Annexin V TN=Apomate	Diagnosis or assessment of rejection status in heart, heart-lung, single lung, or bilateral lung transplants.	Theseus Imaging Corporation 124 Mount Auburn Street Suite 200 North Cambridge MA 02138 DD= 11/3/00 MA=
Tetraiodothyroacetic 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=

Orphan Products Designations and Approvals List

January through November 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
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=
Vapreotide 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=
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=
Vapreotide 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=
vigabatrin TN=Sabril	Treatment of infantile spasms.	Aventis Pharmaceuticals Inc. P.O. Box 9627 Kansas City MO 64137 DD= 6/12/00 MA=

Orphan Products Designations and Approvals List
January through November 2000

Name:

Generic Name

TN=Trade Name

Indication Designated:

Sponsor & Address

DD=Date Designated

MA=Marketing Approval

Zoledronate

TN=Zometa, Zabel

Treatment of tumor induced
hypercalcemia.

Novartis Pharmaceuticals

59 Route 10

East Hanover NJ 07936-1080

DD= 8/18/00

MA=

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

NO NOVEMBER 2000 ADDITIONS

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>						
021205 001	ABACAVIR SULFATE;TRIZIVIR	5034394	JUN 26, 2009			
>ADD>		5089500	JUN 26, 2009			
>ADD>		5047407	NOV 17, 2009			
>ADD>		5905082	MAY 18, 2016			
>ADD>		4724232	SEP 17, 2005			
>ADD>		4818538	SEP 17, 2005			
>ADD>		4833130	SEP 17, 2005			
>ADD>		4837208	SEP 17, 2005			
>ADD>		4828838	SEP 17, 2005			
075077 001	ACETAMINOPHEN;ACETAMINOPHEN					
020338 001	ADAPALENE;DIFFERIN	4717720	MAY 31, 2010			
020380 001	ADAPALENE;DIFFERIN	4717720	MAY 31, 2010			
020748 001	ADAPALENE;DIFFERIN	4717720	MAY 31, 2010			
020760 001	ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE	RE34440	MAY 31, 2010			
020760 002	ALATROFLOXACIN MESYLATE;TROVAN PRESERVATIVE	6080756	JUL 05, 2016			
020560 001	ALENDRONATE SODIUM;FOSAMAX	6080756	JUL 05, 2016			
		6008207	JUN 06, 2015			
020560 002	ALENDRONATE SODIUM;FOSAMAX	6090410	DEC 02, 2012			
		6008207	JUN 06, 2015			
020560 003	ALENDRONATE SODIUM;FOSAMAX	6090410	DEC 02, 2012			
		6008207	JUN 06, 2015			
020560 004	ALENDRONATE SODIUM;FOSAMAX	6090410	DEC 02, 2012			
		6015801	JUL 17, 2018			
		4621077	AUG 06, 2007			
		5358941	DEC 02, 2012			
		5681590	DEC 02, 2012			
		5804570	FEB 17, 2015			
		5849726	JUN 06, 2015			
		5943329	JUL 17, 2018			
		6008207	JUN 06, 2015			
020560 005	ALENDRONATE SODIUM;FOSAMAX	6015801	JUL 17, 2018			
		4621077	AUG 06, 2007			
		5358941	DEC 02, 2012			
		5681590	DEC 02, 2012			
		5804570	FEB 17, 2015			
		5849726	JUN 06, 2015			
		5943329	JUL 17, 2018			
		6008207	JUN 06, 2015			
021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX					
018276 001	ALPRAZOLAM;XANAX	4508726	SEP 16, 2002			
018276 002	ALPRAZOLAM;XANAX	4508726	SEP 16, 2002			
018276 003	ALPRAZOLAM;XANAX	4508726	SEP 16, 2002			
018276 004	ALPRAZOLAM;XANAX	4508726	SEP 16, 2002			
020221 001	AMIFOSTINE;ETHYOL					

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
>ADD>	020221 002 AMIFOSTINE; ETHYOL	5723490	MAR 03, 2013	U-257	I-283	JUN 24, 2002
	020508 001 AMMONIUM LACTATE; LAC-HYDRIN	5646180	JUL 08, 2014	U-257	M-4	AUG 25, 2003
	021007 001 AMPRENAVIR; AGENERASE	5585397	DEC 17, 2013			
	021007 002 AMPRENAVIR; AGENERASE	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		
		RE36617	DEC 27, 2009			
>ADD>	020541 001 ANASTROZOLE; ARIMIDEX	4681893	SEP 24, 2009	U-161	I-312	SEP 01, 2003
	020883 001 ARGATROBAN; ACOVA	5273995	DEC 28, 2010	U-162	NCE	JUN 30, 2005
	021248 001 ARSENIC TRIOXIDE; TRISENOX	5686104	NOV 11, 2014	U-213	ODE	SEP 25, 2007
	020971 001 ARTICAINE HYDROCHLORIDE; SEPTOCAINE	5969166	JUL 08, 2016		NCE	SEP 25, 2005
	020702 004 ATORVASTATIN CALCIUM; LIPITOR	5164194	NOV 01, 2010		NC	APR 03, 2003
		5164194*	MAY 01, 2011		NCE	DEC 17, 2001
	021127 001 AZELASTINE HYDROCHLORIDE; OPTIVAR	4412992	JUL 08, 2001		I-281	DEC 02, 2002
		5776432	JUL 07, 2015		I-218	JUL 10, 2001
		5605674	FEB 25, 2014		I-219	JUL 10, 2001
	020610 001 BALSALAZIDE DISODIUM; COLAZAL	5695743	JUL 06, 2010		NCE	NOV 01, 2001
	020911 002 BECLMETHASONE DIPROPIONATE; QVAR 40	5683677	NOV 04, 2014		NDF	MAY 22, 2003
		5766573	NOV 28, 2009		PED	MAY 01, 2002
	020911 001 BECLMETHASONE DIPROPIONATE; QVAR 80	5766573	NOV 28, 2009		PED	NOV 22, 2003
					NCE	JUL 18, 2005
>ADD>	020010 001 BETAMETHASONE DIPROPIONATE; LOTRISONE	4258062	MAR 24, 2000		NP	DEC 08, 2003
	021055 001 BEXAROTENE; TARGRETIN	4258062*	SEP 24, 2000		ODE	DEC 29, 2006
	021056 001 BEXAROTENE; TARGRETIN	4258062	MAR 24, 2000		NCE	DEC 29, 2004
	019982 001 BISOPROLOL FUMARATE; ZEBETA	4258062*	SEP 24, 2000		NDF	JUN 28, 2003
	019982 002 BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000			
	020186 001 BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 2000			
		4258062*	SEP 24, 2000			

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
021093 002	CANDESARTAN CILEXETIL; ATACAND HCT	5705517 5721263 5958961 5196444 5534534 5703110 4966891 5902821 5902821 5902821 5902821	APR 18, 2011 FEB 24, 2015 JUN 06, 2014 APR 18, 2011 JUL 09, 2013 APR 18, 2011 JAN 13, 2011 JAN 13, 2011 FEB 07, 2016 FEB 07, 2016 FEB 07, 2016 FEB 07, 2016	U-3 U-3 U-3 U-3 U-3 U-272 U-272 U-313 U-313 U-313 U-313	NCE NC	JUN 04, 2003 SEP 05, 2003
020896 001	CAPECITABINE; XELODA	5703110	APR 18, 2011	U-3	NCE	JUN 04, 2003
020896 002	CAPECITABINE; XELODA	4966891	JAN 13, 2011	U-272	NC	SEP 05, 2003
020297 001	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020297 002	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020297 003	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020297 004	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020740 001	CERIVASTATIN SODIUM; BAYCOL	5902821	FEB 07, 2016	U-313		
020740 002	CERIVASTATIN SODIUM; BAYCOL				D-59	JUL 21, 2003
020740 003	CERIVASTATIN SODIUM; BAYCOL				I-303	JUL 21, 2003
020740 004	CERIVASTATIN SODIUM; BAYCOL				I-303	JUL 21, 2003
020740 005	CERIVASTATIN SODIUM; BAYCOL				D-59	JUL 21, 2003
020740 006	CERIVASTATIN SODIUM; BAYCOL				I-303	JUL 21, 2003
021197 001	CETRORELIX; CETROTIDE	5006530 5177080	JAN 17, 2009 JAN 26, 2011		D-59	JUL 21, 2003
021197 002	CETRORELIX; CETROTIDE	4800191 5198533 4800191 5198533 4855290 5340821 5580880	JUL 17, 2007 JUL 17, 2007 JUL 17, 2007 JUL 17, 2007 AUG 08, 2006 AUG 23, 2011 JUN 06, 2015		I-303	JUL 21, 2003
020989 002	CEVIMELINE HYDROCHLORIDE; EVOXAC			U-309 U-310	NS NCE	JUL 21, 2003 AUG 11, 2005
020832 001	CHLORHEXIDINE GLUCONATE; CHLORAPREP	5767251	JUN 16, 2015	NC	NC	JUL 14, 2003
021149 002	CHORIOGNADOTROPIN ALFA; OVIDREL	6136347	JAN 06, 2013	NP	NP	SEP 20, 2003
020780 001	CIPROFLOXACIN; CIPRO	6136347	JAN 06, 2013	U-362 U-362	U-362	
020780 002	CIPROFLOXACIN; CIPRO				NCE	JUL 17, 2003
020822 001	CITALOPRAM HYDROBROMIDE; CELEXA				NCE	JUL 17, 2003
021046 001	CITALOPRAM HYDROBROMIDE; CELEXA				NDF	MAY 26, 2003
021142 001	CLOBETASOL PROPIONATE; OLUX FOAM				NP	NOV 24, 2001
021143 001	CLOTRIMAZOLE; TRIVAGIZOLE 3				NP	MAY 26, 2005
021141 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	5624963 5679717 5693675 5607669 5917007 5919832	APR 29, 2014 APR 29, 2014 DEC 02, 2014 JUN 10, 2014 APR 29, 2014 JUN 10, 2014	U-323 U-323 U-323 U-323 U-323 U-323	NCE	

>ADD>
>ADD>

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
021176 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	5919832 5917007 5607669 5693675 5679717 5624963	JUN 10, 2014 APR 29, 2014 JUN 10, 2014 DEC 02, 2014 APR 29, 2014 APR 29, 2014	U-323 U-323	NCE	MAY 26, 2005
020287 001	DALTEPARIN SODIUM; FRAGMIN	RE35724	OCT 20, 2008	U-339	D-60	AUG 03, 2003
020287 003	DALTEPARIN SODIUM; FRAGMIN	5242901	SEP 07, 2010		D-60	AUG 03, 2003
020287 004	DALTEPARIN SODIUM; FRAGMIN	4963551	DEC 21, 2007		D-60	AUG 03, 2003
020713 001	DESOGESTREL; MIRCETTE	4275063	JUN 23, 2003	U-339		
020212 001	DEXRAZOXANE HYDROCHLORIDE; ZINECARD	5242901	SEP 07, 2010			
020212 002	DEXRAZOXANE HYDROCHLORIDE; ZINECARD	4963551	DEC 21, 2007			
020154 002	DIDANOSINE; VIDEX	4275063	JUN 23, 2003			
020154 003	DIDANOSINE; VIDEX					
020154 004	DIDANOSINE; VIDEX					
020154 005	DIDANOSINE; VIDEX					
020154 006	DIDANOSINE; VIDEX					
021183 001	DIDANOSINE; VIDEX EC					
021183 002	DIDANOSINE; VIDEX EC					
021183 003	DIDANOSINE; VIDEX EC					
021183 004	DIDANOSINE; VIDEX EC					
020939 001	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 002	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 003	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 004	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
021168 001	DIVALPROEX SODIUM; DEPAKOTE ER					
020941 001	DOCOSANOL; ABREVA					
020931 001	DOPETILIDE; TIKOSYN					
020931 002	DOPETILIDE; TIKOSYN					
020931 003	DOPETILIDE; TIKOSYN					
020623 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET					
020623 002	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET					
020624 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET					
020690 001	DONEPEZIL HYDROCHLORIDE; ARICEPT					
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>ADD>						
>ADD>						
>ADD>						
021183 001	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
021183 002	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
021183 003	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
021183 004	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 001	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 002	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 003	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
020939 004	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL					
021168 001	DIVALPROEX SODIUM; DEPAKOTE ER					
020941 001	DOCOSANOL; ABREVA					
020931 001	DOPETILIDE; TIKOSYN					
020931 002	DOPETILIDE; TIKOSYN					
020931 003	DOPETILIDE; TIKOSYN					
020623 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET					
020623 002	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET					
020624 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET					
020690 001	DONEPEZIL HYDROCHLORIDE; ARICEPT					
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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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020690 002	DONEPEZIL HYDROCHLORIDE; ARICEPT	6140321	JUN 07, 2014			
020869 001	DORZOLAMIDE HYDROCHLORIDE; COSOPT	4797413	APR 28, 2008	U-103		
021027 001	DOXERCALCIFEROL; HECTOROL	4619939	OCT 28, 2003	U-104		
021145 001	EFLORNITHINE HYDROCHLORIDE; VANIQA	5602116	APR 03, 2115	U-321	NDF	APR 06, 2003
		5707980	FEB 11, 2117	U-321	NCE	JUN 09, 2004
		4413141	NOV 01, 2000	NP	NP	JUL 27, 2003
		4720489	JAN 19, 2005	U-334		
		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*PED	MAR 18, 2002			
		4374829	FEB 22, 2000			
		4374829*PED	AUG 22, 2000			
018998 001	ENALAPRIL MALEATE; VASOTEC	4472380	SEP 18, 2001			
018998 002	ENALAPRIL MALEATE; VASOTEC	4374829	FEB 22, 2000			
018998 003	ENALAPRIL MALEATE; VASOTEC	4374829*PED	AUG 22, 2000			
018998 005	ENALAPRIL MALEATE; VASOTEC	4374829	FEB 22, 2000			
019309 001	ENALAPRILAT; VASOTEC	4374829*PED	AUG 22, 2000			
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020164 001	ENOXAPARIN SODIUM; LOVENOX	4374829	FEB 22, 2000		I-315	NOV 17, 2003
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020164 002	ENOXAPARIN SODIUM; LOVENOX	4374829*PED	AUG 22, 2000		I-315	NOV 17, 2003
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020164 003	ENOXAPARIN SODIUM; LOVENOX	4374829	FEB 22, 2000		I-315	NOV 17, 2003
>ADD>						
020164 004	ENOXAPARIN SODIUM; LOVENOX	4374829*PED	AUG 22, 2000		I-315	NOV 17, 2003
>ADD>						
020164 005	ENOXAPARIN SODIUM; LOVENOX	4374829	FEB 22, 2000		ODE	APR 14, 2007
>ADD>						
020444 001	EPIDROSTENOL SODIUM; FLOLAN	4374829*PED	AUG 22, 2000		I-296	APR 14, 2003
020444 002	EPIDROSTENOL SODIUM; FLOLAN	4374829*PED	AUG 22, 2000		ODE	APR 14, 2007
020874 001	ESTRADIOL CYPIONATE; LUNELLE				I-296	APR 14, 2003
020907 001	ESTRADIOL; ACTIVELLE				NP	OCT 05, 2003
020655 001	ESTRADIOL; ALORA	RE36247	MAY 02, 2006		I-295	APR 11, 2003
>ADD>		5122383	MAY 17, 2011			
		5227169	MAY 17, 2011			
		5212199	MAY 17, 2011			
		5164190	DEC 11, 2010			
		5122383	MAY 17, 2011			
		5227169	MAY 17, 2011			
020655 002	ESTRADIOL; ALORA	5164190	DEC 11, 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
020902 001	FAMOTIDINE;PEPCID AC	5854267 5854267*PED 5677794 5677794*PED 4283408 4283408*PED 4283408 4283408*PED 4283408 4283408*PED 4283408 4283408*PED 4283408 4283408*PED	JUN 02, 2015 DEC 02, 2015 MAY 02, 2015 NOV 02, 2015 OCT 15, 2000 APR 15, 2001 OCT 15, 2000 APR 15, 2001 OCT 15, 2000 APR 15, 2001 OCT 15, 2000 APR 15, 2001 OCT 15, 2000 APR 15, 2001			
019510 004	FAMOTIDINE;PEPCID PRESERVATIVE					
020249 001	FAMOTIDINE;PEPCID PRESERVATIVE					
020752 001	FAMOTIDINE;PEPCID RPD					
020752 002	FAMOTIDINE;PEPCID RPD					
019304 002	FENOPIBRATE;TRICOR (MICRONIZED)					
019304 003	FENOPIBRATE;TRICOR (MICRONIZED)					
019304 004	FENOPIBRATE;TRICOR (MICRONIZED)					
020625 001	PEXOFENADINE HYDROCHLORIDE;ALLEGRA					
020872 001	PEXOFENADINE HYDROCHLORIDE;ALLEGRA					
020872 002	PEXOFENADINE HYDROCHLORIDE;ALLEGRA					
020872 004	PEXOFENADINE HYDROCHLORIDE;ALLEGRA					
020786 001	PEXOFENADINE HYDROCHLORIDE;ALLEGRA-D					
019949 004	FLUCONAZOLE;DIFLUCAN					
020985 001	FLUOROURACIL;FLUOROURACIL					
018936 001	FLUOXETINE HYDROCHLORIDE;PROZAC					
		6037353 6113942 5578610 5932247 5855912 4254129 6037353 6113942 5578610 5932247 5855912 4254129 6037353 6113942 6037353 6039974 6113942 4416682 4404216 4626549 4314081 4626549 4314081*PED 4626549*PED 4626549*PED	MAR 14, 2017 FEB 28, 2015 NOV 26, 2013 FEB 28, 2015 FEB 28, 2015 FEB 17, 2001 MAR 14, 2017 FEB 28, 2015 NOV 26, 2013 FEB 28, 2015 FEB 28, 2015 FEB 17, 2001 MAR 14, 2017 FEB 28, 2015 MAR 14, 2017 JUL 31, 2018 FEB 28, 2015 JUN 02, 2001 JAN 29, 2004 DEC 02, 2003 FEB 02, 2001 DEC 02, 2003 AUG 02, 2001 JUN 02, 2004 JUN 02, 2004	U-138 U-139 NDF NCE U-139 U-138 U-139 NDF NCE U-139 U-138 U-139 NDF NCE U-139 U-138 U-139 U-138 NP U-154 U-84 U-154 U-84	I-298 APR 24, 2003 I-298 APR 24, 2003 I-298 APR 24, 2003 FEB 25, 2003 JUL 25, 2001 FEB 25, 2003 JUL 25, 2001 FEB 25, 2003 JUL 25, 2001 OCT 27, 2003 FEB 25, 2001 DEC 02, 2003 AUG 02, 2001 JUN 02, 2004 JUN 02, 2004	

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
018936 003	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
		4626549	DEC 02, 2003	U-154		
		4626549	DEC 02, 2003	U-84		
		4314081*PED	AUG 02, 2001			
		4626549*PED	JUN 02, 2004	U-154		
018936 004	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549*PED	JUN 02, 2004	U-84		
		4314081	FEB 02, 2001			
		4314081*PED	AUG 02, 2001			
		4626549	DEC 02, 2003	U-154		
		4626549	DEC 02, 2003	U-84		
018936 006	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003	U-154		
		4314081	FEB 02, 2001	U-84		
		4314081*PED	AUG 02, 2001			
		4626549*PED	JUN 02, 2004	U-154		
		4626549*PED	JUN 02, 2004	U-84		
020101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
		4626549	DEC 02, 2003	U-84		
		4626549	DEC 02, 2003	U-154		
		4314081*PED	AUG 02, 2001			
		4626549*PED	JUN 02, 2004	U-154		
020974 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003	U-84		
		4626549	DEC 02, 2003	U-154		
		4314081	FEB 02, 2001			
		4314081*PED	AUG 02, 2001			
		4626549*PED	JUN 02, 2004	U-84		
020974 002	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549*PED	JUN 02, 2004	U-154		
		4626549	DEC 02, 2003	U-84		
		4626549	DEC 02, 2003	U-154		
		4314081	FEB 02, 2001			
		4314081*PED	AUG 02, 2001			
018936 007	FLUOXETINE HYDROCHLORIDE; SARAFEM	4626549*PED	JUN 02, 2004	U-84		
		4626549*PED	JUN 02, 2004	U-154		
		4971998	NOV 20, 2007	U-84		
		5114976	MAY 19, 2009	U-154		
		5744501	MAY 19, 2009	U-84		
018936 008	FLUOXETINE HYDROCHLORIDE; SARAFEM	4971998*PED	MAY 20, 2008	U-154		
		5114976*PED	NOV 19, 2009	U-338 NP		JUL 06, 2003
		5744501*PED	NOV 19, 2009	U-341 PED		JUN 06, 2004
		4971998	NOV 20, 2007	U-338		
		5114976	MAY 19, 2009	U-341		
		5744501	MAY 19, 2009	U-342		
		4971998*PED	MAY 20, 2008	U-338 NP		JUL 06, 2003
		5114976*PED	MAY 20, 2008	U-341 PED		JAN 06, 2004
		4971998	NOV 20, 2007	U-342		
		5744501*PED	NOV 19, 2009	U-338		

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
021077 001	FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
>ADD>		5270305	SEP 07, 2010			
>ADD>		4992474	FEB 12, 2008	U-211		
>ADD>		5225445	FEB 12, 2008	U-211		
>ADD>		5126375	FEB 12, 2008			
021077 002	FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
>ADD>		5270305	SEP 07, 2010			
>ADD>		4992474	FEB 12, 2008	U-211		
>ADD>		5225445	FEB 12, 2008	U-211		
>ADD>		5126375	FEB 12, 2008			
021077 003	FLUTICASONE PROPIONATE;ADVAIR DISKUS 500/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
>ADD>		5270305	SEP 07, 2010			
>ADD>		4992474	FEB 12, 2008	U-211		
>ADD>		5225445	FEB 12, 2008	U-211		
>ADD>		5126375	FEB 12, 2008			
021192 001	FLUVASTATIN SODIUM; LESCOL XL				NDF	OCT 06, 2003
020378 001	FOLLITROPIN ALFA/BETA; GONAL-F				ODE	MAY 24, 2007
020378 002	FOLLITROPIN ALFA/BETA; GONAL-F				I-306	MAY 24, 2003
020378 003	FOLLITROPIN ALFA/BETA; GONAL-F				ODE	MAY 24, 2007
020235 001	GABAPENTIN; NEURONTIN	4589402	JUL 26, 2004	U-242	I-306	MAY 24, 2003
		5767251	JUN 16, 2015		ODE	MAY 24, 2007
		4087544	JAN 16, 2000	U-86	PED	MAY 24, 2007
		5084479	JAN 02, 2010	U-125	D-43	MAR 29, 2002
		4894476*	NOV 02, 2008	U-86	I-311	SEP 29, 2001
		4087544*	JUL 16, 2000			OCT 12, 2003
		5084479*	JUL 02, 2010			
		4894476*	MAY 02, 2008			
		6054482	APR 25, 2017			
		6054482*	OCT 25, 2017			
020235 002	GABAPENTIN; NEURONTIN	4894476	MAY 02, 2008		PED	MAR 29, 2002
		5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
		4087544	JAN 16, 2000	U-86	I-311	OCT 12, 2003
		5084479*	JUL 02, 2010			
		4894476*	NOV 02, 2008			
		4087544*	JUL 16, 2000			
		6054482	APR 25, 2017			
		6054482*	OCT 25, 2017			
020235 003	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
		5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
		4894476	MAY 02, 2008		I-311	OCT 12, 2003
		4087544*	JUL 16, 2000			
		5084479*	JUL 02, 2010			
		4894476*	NOV 02, 2008			
		6054482	APR 25, 2017			
		6054482*	OCT 25, 2017			

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 EXCLUS CODE EXPIRES
>ADD> >ADD>					
021162 001	HYDROCHLOROTHIAZIDE; MICARDIS HCT	5591762	JAN 07, 2014	U-3	NC NOV 17, 2003
021162 002	HYDROCHLOROTHIAZIDE; MICARDIS HCT	5591762	JAN 07, 2014	U-3	NC NOV 17, 2003
019778 001	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001		
019778 002	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001	U-3	
019778 003	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001		
019771 001	IBUPROFEN; ADVIL COLD AND SINUS	4552899	APR 09, 2004		
		4552899*PED	OCT 09, 2004		
021128 001	IBUPROFEN; CHILDREN'S MOTRIN CO	4220660	MAR 06, 2001	U-21	NP AUG 01, 2003
019763 003	IFOSFAMIDE; IFEX/MESNEX KIT	5696172	OCT 06, 2013		
019763 004	IFOSFAMIDE; IFEX/MESNEX KIT	4220660	MAR 06, 2001	U-21	
		5696172	OCT 06, 2013		
020986 001	INSULIN ASPART RECOMBINANT; NOVOLOG				
021081 001	INSULIN GLARGINE; LANTUS				
020563 001	INSULIN LISPRO; HUMALOG				
021018 001	INSULIN LISPRO; HUMALOG MIX 50/50				
021017 001	INSULIN LISPRO; HUMALOG MIX 75/25				
>ADD> >ADD> >ADD> >ADD>					
020563 002	INSULIN LISPRO; HUMALOG PEN	5474978	JUN 16, 2014	U-111	NCE JUN 07, 2005
		5747642	JUN 16, 2014		PED OCT 20, 2005
		5461031	JUN 16, 2014		NCE APR 20, 2005
		5514646	MAY 07, 2013		D-56 APR 04, 2003
		5474978	JUN 16, 2014		NC DEC 22, 2002
		5514646	MAY 07, 2013		
020571 001	IRINOTECAN HYDROCHLORIDE; CAMPTOSAR	4727064	FEB 23, 2005		
021135 001	IRON SUCROSE; VENOFER	4942162	FEB 11, 2003		
020966 001	ITRACONAZOLE; SPORANOX	4454151	MAR 22, 2002		
019084 001	KETOCONAZOLE; NIZORAL	482838	PED MAR 17, 2006		
020811 001	KETOROLAC TROMETHAMINE; ACULAR PRESERVATIVE	4833130	PED MAR 17, 2006		
020857 001	LAMIVUDINE; COMBIVIR	4837208	SEP 17, 2005		
		5047407	PED AUG 08, 2009		
		4724232	PED MAR 17, 2006		
		4818538	PED MAR 17, 2006		
		5859021	PED NOV 15, 2012		
		5905082	PED NOV 18, 2016		
		6113920	OCT 23, 2017		
		6113920	PED APR 23, 2018		
		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		

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
020564 001	LAMIVUDINE; EPIVIR	5047407 5905082 5905082*PED 5047407*PED 5047407 6004968 6004968*PED 5047407*PED 5047407 5532246 5905082 5047407*PED 5532246*PED 5905082*PED 5047407 5532246 6004968 5532246*PED 6004968*PED	NOV 17, 2009 MAY 18, 2016 NOV 18, 2016 MAY 17, 2010 NOV 17, 2009 MAR 20, 2018 SEP 20, 2018 MAY 17, 2010 FEB 08, 2009 JUL 02, 2013 MAY 18, 2016 AUG 08, 2009 JAN 02, 2014 NOV 18, 2016 FEB 08, 2009 JUL 02, 2013 MAR 20, 2018 AUG 08, 2009 JAN 02, 2014 SEP 20, 2018		NCE PED	NOV 17, 2000 MAY 17, 2001
020596 001	LAMIVUDINE; EPIVIR				NCE PED	NOV 17, 2000 MAY 17, 2001
021003 001	LAMIVUDINE; EPIVIR-HBV				I-257 PED	DEC 08, 2001 JUN 08, 2002
021004 001	LAMIVUDINE; EPIVIR-HBV					
020406 001	LANSOPRAZOLE; PREVACID				NCE	NOV 17, 2000
020406 002	LANSOPRAZOLE; PREVACID				I-257 PED	DEC 08, 2001 MAY 17, 2001
021088 001	LEUPROLIDE ACETATE; VIADUR				PED	JUN 08, 2002
>ADD> >ADD>						
020837 001	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5728396 5932547 5985305 6113938 6124261 6132420 5362755 5547994 5760090 5844002	JAN 30, 2017 JUN 13, 2017 JAN 30, 2017 JUL 24, 2018 JUN 13, 2017 JAN 30, 2017 NOV 08, 2011 AUG 20, 2013 JAN 05, 2010 JAN 05, 2010 NOV 08, 2011 AUG 20, 2013 JAN 05, 2010 JAN 05, 2010		I-316 I-316 NP	NOV 30, 2003 NOV 30, 2003 MAR 03, 2003
020837 002	LEVALBUTEROL HYDROCHLORIDE; XOPENEX					
021114 001	LEVOBETAXOLOL HYDROCHLORIDE; BETAXON					
020634 001	LEVOFLOXACIN; LEVAQUIN				NP	FEB 23, 2003
020634 002	LEVOFLOXACIN; LEVAQUIN				I-305	FEB 02, 2003
020635 001	LEVOFLOXACIN; LEVAQUIN				I-305	FEB 02, 2003
020635 002	LEVOFLOXACIN; LEVAQUIN IN DEXTROSE				I-305	FEB 02, 2003
020635 003	LEVOFLOXACIN; LEVAQUIN IN DEXTROSE				I-305	FEB 02, 2003
021199 001	LEVOFLOXACIN; QUIXIN				NDF	AUG 18, 2003
4382892			SEP 02, 2003			
5503407			OCT 01, 2008			
4551456			NOV 14, 2003			
5053407			OCT 01, 2008			

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 EXCLUS CODE EXPIRES
021202 001	METFORMIN HYDROCHLORIDE; GLUCOPHAGE XR				NDF OCT 13, 2003
021121 001	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA				NP AUG 01, 2003
021121 002	METHYLPHENIDATE HYDROCHLORIDE; CONCERTA				NP AUG 01, 2003
019532 001	METOLAZONE; MYKROX	4517179	APR 29, 2003		
019815 001	MIDODRINE HYDROCHLORIDE; PROMMATINE	4386085	JAN 08, 2002		ODE SEP 06, 2003
019815 002	MIDODRINE HYDROCHLORIDE; PROMMATINE	4447424	JAN 08, 2002		ODE SEP 06, 2003
020687 001	MIPEPRISTONE; MIFEPRX	4626531	OCT 12, 2004		NCE SEP 28, 2005
021120 001	MITOXANTHONE HYDROCHLORIDE; NOVANTHONE	6127353	OCT 03, 2017		ODE OCT 13, 2007
020762 001	MOMETASONE FURATE 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	
		6129930	SEP 20, 2013	U-354	
020381 002	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331	
020381 003	NIACIN; NIASPAN	6129930	SEP 20, 2013	U-354	
		6080428	MAY 27, 2017	U-331	
020381 004	NIACIN; NIASPAN	6129930	SEP 20, 2013	U-354	
		6080428	MAY 27, 2017	U-331	
020381 005	NIACIN; NIASPAN TITRATION ST	6129930	SEP 20, 2013	U-354	
020076 001	NICOTINE; HABITROL	5834011	MAY 01, 2007	U-331	
020076 002	NICOTINE; HABITROL	5834011	MAY 01, 2007	U-355	
020076 003	NICOTINE; HABITROL	5834011	MAY 01, 2007	U-355	
020076 004	NICOTINE; HABITROL	5834011	MAY 01, 2007	U-355	
020076 005	NICOTINE; HABITROL	5834011	MAY 01, 2007	U-355	
020076 006	NICOTINE; HABITROL	5834011	MAY 01, 2007	U-355	
020536 001	NICOTINE; NICOTROL	5501236	JUN 08, 2010	U-355	
		6098632	JUN 08, 2010		
020714 001	NICOTINE; NICOTROL				NDF MAY 01, 2003
021134 001	NITROGLYCERIN; NITROSTAT	6098632	JUN 08, 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 EXCLUS CODE EXPIRES
020031 003	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6121291 6133289 6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAR 17, 2017 MAY 19, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020031 004	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-358	
020031 005	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020710 001	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020885 001	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020885 002	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020885 003	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020885 004	PAROXETINE HYDROCHLORIDE; PAXIL	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020936 001	PAROXETINE HYDROCHLORIDE; PAXIL CR	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
020936 002	PAROXETINE HYDROCHLORIDE; PAXIL CR	6063927 6080759 6113944 6133289 6063927 6080759 6113944 6133289	APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 15, 2015 APR 23, 2019 MAY 19, 2015 DEC 14, 2014 MAY 19, 2015	U-286 U-358	
021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER; SKIN EXPOSURE REDUCT	5607979 6133289 6048901	MAY 19, 2015 MAY 19, 2015 APR 20, 2019	U-286 U-343	NCE FEB 17, 2005
020698 001	POLYETHYLENE GLYCOL 3350; MIRALAX				

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			
020659 001	RITONAVIR; NORVIR	5615587	JUL 11, 2014			
		6037157	JUN 26, 2016			
		5674882	OCT 07, 2014			
020945 001	RITONAVIR; NORVIR	5886036	DEC 29, 2012			
		5648497	JUL 15, 2014			
		5846987	DEC 29, 2012			
		5541206	JUL 30, 2013			
		5635523	JUN 03, 2014			
020823 003	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007			
020823 004	RIVASTIGMINE TARTRATE; EXELON	5602176	FEB 11, 2014			
020823 005	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007			
		5602176	FEB 11, 2014			
020823 006	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007			
		5602176	FEB 11, 2014			
021025 001	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007			
		5602176	FEB 11, 2014			
020864 001	RIZATRIPTAN BENZOATE; MAXALT	4948807	AUG 14, 2007			
020864 002	RIZATRIPTAN BENZOATE; MAXALT	5602176	FEB 11, 2014			
021042 001	ROFECOXIB; VIOXX	5602162	FEB 11, 2014			
021042 002	ROFECOXIB; VIOXX	5602162	FEB 11, 2014			
021042 003	ROFECOXIB; VIOXX	6063811	MAY 16, 2017			
021052 001	ROFECOXIB; VIOXX	6063811	MAY 16, 2017			
021052 002	ROFECOXIB; VIOXX	6063811	MAY 16, 2017			
020533 001	ROPIVACAINES HYDROCHLORIDE MONOHYDRATE; NAROPIN					
020533 003	ROPIVACAINES HYDROCHLORIDE MONOHYDRATE; NAROPIN					
020533 004	ROPIVACAINES HYDROCHLORIDE MONOHYDRATE; NAROPIN					
020533 005	ROPIVACAINES HYDROCHLORIDE MONOHYDRATE; NAROPIN					
021071 002	ROSIGLITAZONE MALEATE; AVANDIA					
021071 003	ROSIGLITAZONE MALEATE; AVANDIA					
021071 004	ROSIGLITAZONE MALEATE; AVANDIA					
020990 001	SERTRALINE HYDROCHLORIDE; ZOLOFT					
021179 001	SEVELAMER HYDROCHLORIDE; RENAGEL					
021179 002	SEVELAMER HYDROCHLORIDE; RENAGEL					
020478 001	SEVOFLURANE; ULTANE					

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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
021097 001	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS; VISICOL	5616346	APR 01, 2017	U-359	NP	SEP 21, 2003
020280 006	SOMATROPIN RECOMBINANT; GENOTROPIN	4968299	JUN 28, 2008		I-302 ODE	JUN 20, 2003 JUN 20, 2007
020280 007	SOMATROPIN RECOMBINANT; GENOTROPIN	4968299	JUN 28, 2008		I-302 ODE	JUN 20, 2003 JUN 20, 2007
020280 001	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013		I-302	JUN 20, 2003
020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015		ODE	JUN 20, 2007
020280 002	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013		I-302	JUN 20, 2003
020280 003	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	FEB 10, 2015		ODE	JUN 20, 2007
020280 003	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	APR 16, 2013		I-302	JUN 20, 2003
020280 004	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	FEB 10, 2015		ODE	JUN 20, 2007
020280 004	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	APR 16, 2013		I-302	JUN 20, 2003
020280 005	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	FEB 10, 2015		ODE	JUN 20, 2007
020280 008	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013		I-302	JUN 20, 2003
020280 009	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015		ODE	JUN 20, 2007
020280 010	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013		I-302	JUN 20, 2003
020280 010	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015		ODE	JUN 20, 2007
020280 011	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013		I-302	JUN 20, 2003
020280 012	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015		ODE	JUN 20, 2007
020280 013	SOMATROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076	APR 16, 2013		I-302	JUN 20, 2003
019721 001	SOMATROPIN RECOMBINANT; NORDITROPIN	5716338	FEB 10, 2015		ODE	JUN 20, 2007
019721 002	SOMATROPIN RECOMBINANT; NORDITROPIN	5435076	APR 16, 2013		I-302	JUN 20, 2003
019676 001	SOMATROPIN RECOMBINANT; NUTROPIN	5435076	FEB 10, 2015		ODE	JUN 20, 2007
019676 002	SOMATROPIN RECOMBINANT; NUTROPIN	5716338	APR 16, 2013		I-302	JUN 20, 2003
020522 001	SOMATROPIN RECOMBINANT; NUTROPIN AQ	5633352	MAY 27, 2014		ODE	JUN 20, 2007
021075 001	SOMATROPIN RECOMBINANT; NUTROPIN DEPOT	5633352	MAY 27, 2014		D-55	APR 13, 2003
021075 002	SOMATROPIN RECOMBINANT; NUTROPIN DEPOT				M-2	DEC 01, 2002
021075 003	SOMATROPIN RECOMBINANT; NUTROPIN DEPOT				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					
021184 001	TAZAROTENE; TAZORAC					
		6051259	DEC 02, 2012	U-340		
		6051259	DEC 02, 2012	U-340		
		6051259	DEC 02, 2012	U-340		
					NP	FEB 22, 2003
					NP	FEB 22, 2003
					NP	FEB 22, 2003
					I-308	AUG 18, 2003
					NCE	JUN 13, 2002
					NDF	SEP 29, 2003

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021214 001	UNOPROSTONE ISOPROPYL; RESCULA	5001153 5151444 5166178 5212200 5208256 5221763 6096339 6146662 5232705 5200196 5141752 5082668 5030456 4946687 5785994 6096339 6146662 5232705 5200196 5141752 5082668 5030456 4946687 5785994 5707608 6074666 4920143 5095030 5214036 5770619 5798349 5756541 6143775 583152 6143775 4859692 5294636 5319097 5482963 583152 5612367	SEP 19, 2008 MAR 19, 2008 NOV 24, 2009 MAY 18, 2010 MAY 21, 2011 JUN 22, 2010 APR 04, 2017 NOV 14, 2017 AUG 31, 2010 JAN 22, 2008 JUN 27, 2006 JAN 21, 2009 NOV 07, 2008 OCT 02, 2007 OCT 22, 2009 APR 04, 2017 NOV 14, 2017 AUG 31, 2010 JAN 22, 2008 JUN 27, 2006 JAN 21, 2009 NOV 07, 2008 OCT 02, 2007 OCT 22, 2009 APR 04, 2017 NOV 14, 2017 AUG 31, 2010 JAN 22, 2008 JUN 27, 2006 JAN 21, 2009 NOV 07, 2008 OCT 02, 2007 OCT 22, 2009 AUG 02, 2015 FEB 05, 2012 APR 24, 2007 APR 24, 2007 MAY 25, 2010 JAN 06, 2015 AUG 25, 2015 MAR 11, 2016 DEC 11, 2011 SEP 26, 2010 DEC 11, 2011 SEP 26, 2010 DEC 11, 2011 DEC 11, 2011 JAN 09, 2013 SEP 26, 2010 MAR 18, 2014	U-333 U-333 U-333 U-333 U-333 U-365 U-366	NCE	AUG 03, 2005
>ADD> >ADD>	VERAPAMIL HYDROCHLORIDE; COVERA-HS					
020552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS					
>ADD> >ADD>	VERAPAMIL HYDROCHLORIDE; COVERA-HS					
021119 001	VERTEPORFIN; VISUDYNE					
>ADD> >ADD>	ZAFIRLUKAST; ACCOLATE					
020547 003	ZAFIRLUKAST; ACCOLATE					
>ADD> >ADD>	ZANAMIVIR; RELENZA					
020789 001	ZONISAMIDE; ZONEGRAN					

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
- D-63 TO ALLOW A TITRATION DOSING REGIMEN USING A 25MG DOSE
- D-64 INCREASING DOSAGE FOR NERVE BLOCK ANESTHESIA USING NAROPIN 7.5MG/ML AND FOR EXTENDING THE DURATION OF TREATMENT FOR POSTOPERATIVE ANALGESIA USING NAROPIN 2MG/ML

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 LISINOPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

- 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
- 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
- I-311 ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL SEIZURES IN PEDIATRIC PATIENTS AGE 3 TO 12 YEARS
- I-312 FIRST LINE TREATMENT OF POSTMENOPAUSAL WOMEN WITH HORMONE RECEPTOR POSITIVE OR HORMONE RECEPTOR UNKNOWN LOCALLY ADVANCED OR METASTATIC BREAST CANCER
- I-313 EXTENSION OF INDICATION TO PROVIDE FOR MAINTENANCE OF RESPONSE
- I-314 TOPICAL ANESTHETIC FOR SUPERFICIAL MINOR SURGERY OF GENITAL MUCOUS MEMBRANES AND AS AN ADJUNCT FOR LOCAL INFILTRATION ANESTHESIA IN GENITAL MUCOUS MEMBRANES
- I-315 THROMBOPROPHYLAXIS OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN MEDICAL PATIENTS WHO ARE AT RISK FOR THROMBOEMBOLIC COMPLICATIONS DUE TO SEVERELY RESTRICTED MOBILITY DURING ACUTE ILLNESS
- I-316 TREATMENT OF NSAID-ASSOCIATED GASTRIC ULCER PATIENTS WHO CONTINUE NSAID USE AND REDUCING RISK OF NSAID-ASSOCIATED GASTRIC ULCERS IN PATIENTS WITH HISTORY OF DOCUMENTED GASTRIC ULCER WHO REQUIRE USE OF AN NSAID

PATENT AND EXCLUSIVITY TERMS

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
- M-4 CHANGES TO PEDIATRIC USE SECTION TO PROVIDE INFORMATION REGARDING SAFETY AND EFFICACY IN PEDIATRIC PATIENTS AS YOUNG AS 2 YEARS OLD

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
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- 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
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PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

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U-342	METHOD FOR TREATMENT OF LATE LUTEAL PHASE DYSPHORIC DISORDER
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U-353	PREVENTION AND TREATMENT OF OSTEOPOROSIS
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U-355	METHOD OF ASSISTING PERSON TO QUIT SMOKING...TRANSDERMALLY ADMIN NICOTINE VIA.. PATCH ADHERED TO SKIN AT DOSING RATE APPROX SAME AS ABSORBED FROM SMOKING
U-356	DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A.
U-357	USE OF THE DRUG PRODUCT IN PHOTODYNAMIC THERAPEUTIC PROTOCOLS FOR THE TREATMENT OF AGE-RELATED MACULAR DEGENERATION AND RELATED CONDITIONS INVOLVING UNWANTED NEOVASCULATURE IN THE EYE
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PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

- U-361 MANAGEMENT OF ANXIETY DISORDERS AND THE SHORT-TERM RELIEF OF THE SYMPTOMS OF ANXIETY
- U-362 USE OF APPROVED FORMULATIONS TO TREAT ALL APPROVED DISEASE INDICATIONS
- U-363 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF PATHOLOGICAL PSYCHOLOGICAL CONDITIONS THAT RELATE TO THE USE OF A PSYCHOACTIVE SUBSTANCE EMPLOYING OLANZAPINE AS PER THE INDICATION WHICH IS THE SUBJECT MATTER OF THIS SNDA-011
- U-364 TREATING A PATIENT SUFFERING FROM OR SUSCEPTIBLE TO ANY NUMBER OF LISTED CONDITIONS INCLUDING PSYCHOSIS, EMPLOYING OLANZAPINE AS PER THE INDICATION WHICH IS THE SUBJECT MATTER OF THIS SNDA-011
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