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CUMULATIVE
SUPPLEMENT 12

JAN'92-DEC'92

Library Use Only

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

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

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

PRICE REDUCTION

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\$55

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Available in March 1993

New 13th Edition



**APPROVED
DRUG PRODUCTS**

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**13TH EDITION
1993**

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See Subscription Form Inside Back Cover

January 1880

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
12TH EDITION**

Cumulative Supplement 12

December 1992

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

12TH EDITION

CUMULATIVE SUPPLEMENT 12

DECEMBER 1992

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, 12th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

Additions new to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (◊) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

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

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

1.2 CEFADROXIL/CEFADROXIL HEMIHYDRATE ACTIVE INGREDIENT HEADING

The active ingredient heading Cefadroxil/Cefadroxil Hemihydrate replaces the active ingredient heading Cefadroxil which is currently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, 12th Edition. All products which are listed under Cefadroxil (which is understood to be the monohydrate form) in the 12th Edition will now be listed along with the newly approved duplicate drug products under the new active ingredient, Cefadroxil/Cefadroxil Hemihydrate.

1.3 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

<u>Products</u>	<u>Federal Register Reference</u>
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranlycypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.4 APPLICANT NAME CHANGES

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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

BARNES HIND PHARMACEUTICALS INC
(BARNES HIND)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

SOLA BARNES HIND
(SOLA BARNES HIND)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

BEECHAM LABORATORIES DIV OF
BEECHAM INC
(BEECHAM)

DELMED INC
(DELMED)

MERCK SHARP AND DOHME RESEARCH LABS
DIV MERCK AND CO INC
(MSD)

NORWICH EATON PHARMS INC
SUB PROCTOR & GAMBLE CO
(NORWICH EATON)

OFFICE SURGEON GENERAL DEPT ARMY
(DEPT ARMY)

RECKITT AND COLMAN PHARMACEUTICALS INC
(R & C)

SCHWARZ PHARMACEUTICALS INC
(SCHWARZ)

SMITH KLINE AND FRENCH LABS
DIV SMITHKLINE BECKMAN CORP
(SKF)

SOLOPAK LABORATORIES
(SOLOPAK)

VICKS HEALTH CARE DIV RICHARDSON VICKS INC
(VICKS HLTH CARE)

WHITBY PHARMACEUTICALS INC
(WHITBY PHARMS)

US CHEMICAL MARKETING GROUP INC
(US CHEM MKTG)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

SMITHKLINE BEECHAM
PHARMACEUTICALS
(SMITHKLINE BEECHAM)

FRESENIUS USA INC
(FRESENIUS)

MERCK RESEARCH LABORATORIES
DIV MERCK AND CO INC
(MERCK)

PROCTER & GAMBLE PHARMACEUTICALS INC
(P&G)

OFFICE SURGEON GENERAL DEPT ARMY
(US ARMY)

RECKITT AND COLMAN PHARMACEUTICALS INC
(RECKITT AND COLMAN)

SCHWARZ PHARMACEUTICALS INC
(SCHWARZ PHARMA)

SMITHKLINE BEECHAM
PHARMACEUTICALS
(SMITHKLINE BEECHAM)

SMITH AND NEPHEW SOLOPAK
DIVISION OF SMITH AND NEPHEW
(SMITH NEPHEW SOLOPAK)

VICKS HEALTH CARE DIV RICHARDSON VICKS INC
(VICKS HEALTH CARE)

WHITBY PHARMACEUTICALS INC
(WHITBY)

US CHEMICAL MARKETING GROUP INC
(US CHEM)

1.5 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

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

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

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

<u>FORMER USP MONOGRAPH TITLE</u> <u>(FORMER ADP DOSAGE FORM; ROUTE)</u>	<u>NEW USP MONOGRAPH TITLE</u> <u>(NEW ADP DOSAGE FORM; ROUTE)</u>
ACETAMINOPHEN AND CODEINE PHOSPHATE ELIXIR (ELIXIR; ORAL)	ACETAMINOPHEN AND CODEINE PHOSPHATE SOLUTION (SOLUTION; ORAL)
LACTULOSE SYRUP (SYRUP; ORAL)	LACTULOSE SOLUTION (SOLUTION; ORAL)
LACTULOSE SYRUP (SYRUP; ORAL, RECTAL)	LACTULOSE SOLUTION (SOLUTION; ORAL, RECTAL)
NONE (SYRUP; ORAL)	METOCLOPRAMIDE ORAL SOLUTION (SOLUTION; ORAL)
OXTRIPHYLLINE ELIXIR (ELIXIR; ORAL)	OXTRIPHYLLINE SOLUTION (SOLUTION; ORAL)

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1991) 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 1991</u>	<u>JUN 1992</u>	<u>SEP 1992</u>	<u>DEC 1992</u>
DRUG PRODUCTS LISTED	9584	9476	9501	9488
SINGLE SOURCE	2187 (22.8%)	2227 (23.5%)	2227 (23.4%)	2245 (23.7%)
MULTISOURCE	7397 (77.2%)	7249 (76.5%)	7274 (76.6%)	7243 (76.3%)
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)	6494 (68.5%)	6518 (68.6%)	6516 (68.6%)
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)	595 (6.3%)	590 (6.2%)	577 (6.1%)
EXCEPTIONS	153 (1.6%)	160 (1.7%)	166 (1.8%)	150 (1.6%)
NEW MOLECULAR ENTITIES APPROVED	--	2	8	10
NUMBER OF APPLICANTS	430	455	471	477

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

ALBUTEROL SULFATE

SOLUTION; INHALATION

PROVENTIL

AN

SCHERING

EQ 0.083% BASE

N19243 002
JAN 14, 1987

INJECTABLE; INJECTION

AMIKACIN

AP

ELKINS SINN

EQ 50MG BASE/ML

N63274 001
MAY 18, 1992
N63275 001
MAY 18, 1992

VENTOLIN

AN

GLAXO

EQ 0.083% BASE

N19773 001
APR 23, 1992

SYRUP; ORAL

ALBUTEROL SULFATE

LEMMON

EQ 2MG BASE/5ML

N73419 001
MAR 30, 1992

AMIKIN

AP

BRISTOL

EQ 50MG BASE/ML

N50495 001
N62562 001
SEP 20, 1984

AP

EQ 250MG BASE/ML

N50495 002
N62562 002
SEP 20, 1984

TABLET; ORAL

ALBUTEROL SULFATE

MD PHARM

AB

EQ 2MG BASE

N73120 001
SEP 29, 1992

AB

EQ 4MG BASE

N73121 001
SEP 29, 1992

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

AMINO SYN 4.25% / DEXTROSE 25% / IN PLASTIC CONTAINER /
/ABBOTT /
/N19119 001 /
/OCT 11, 1984 /

3 ABBOTT

4.25%; 25GM/100ML

N19119 001
OCT 11, 1984

TABLET, EXTENDED RELEASE; ORAL

PROVENTIL

AN

SCHERING

EQ 4MG BASE

N19383 001
JUL 13, 1987

VOLMAX

GLAXO

AB

EQ 4MG BASE

N19604 002
DEC 23, 1992

+

EQ 8MG BASE

N19604 001
DEC 23, 1992

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

AMINO SYN 3.5% /
/ABBOTT /
/N17789 001 /
/3.5%; 21MG/100ML; 128MG/100ML; /
/234MG/100ML /
/N17789 001 /

3 ABBOTT

234MG/100ML

N17789 001

ALGLUCERASE

INJECTABLE; INJECTION

CEREDASE

GENZYME

10 UNITS/ML

N20057 004
MAY 08, 1992

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

BOLAR

AB

/100MG/

N16241 001
NOV 16, 1984

3 BOLAR

100MG

3 LYPHOMED

25MG/ML

N87200 001
N87886 001
AUG 30, 1983

INJECTABLE; INJECTION

AMINOPHYLLINE

FULSANA

25MG/ML

N87200 001
N87886 001
AUG 30, 1983

LYPHOMED

25MG/ML

N87200 001
N87886 001
AUG 30, 1983

25MG/ML

N87200 001
N87886 001
AUG 30, 1983

25MG/ML

N87200 001
N87886 001
AUG 30, 1983

AMOXICILLIN

CAPSULE; ORAL

POLYMOX

AB BRISTOL MYERS

250MG

AB

AB

500MG

UTIMAX/
PARKE/DAVIS/

125MG/
500MG/

AB/
AB/

3 PARKE DAVIS

250MG

3

500MG

N63099 001

MAR 20, 1992

N63099 002

MAR 20, 1992

/N62107/001/

/N62107/002/

N62107 001

N62107 002

FUJISAMA

/L'YPHOMED/

AP

PHARMA TEK

50MG/VIAL

/50MG/VIAL/

50MG/VIAL

N62728 001

APR 13, 1987

/N62728/001/

/APR 13, 1987/

N63206 001

APR 29, 1992

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

AB/
CLONNEL/

125MG/5ML/

AB/

AB/

125MG/5ML/

BX CLONNEL

125MG/5ML

BX

250MG/5ML

UTIMAX/
PARKE/DAVIS/

125MG/5ML/

250MG/5ML/

125MG/5ML

250MG/5ML

3 PARKE DAVIS

3

/N62927/001/

/NOV 25, 1988/

/N62927/002/

/NOV 25, 1988/

N62927 001

NOV 25, 1988

N62927 002

NOV 25, 1988

INJECTABLE; INJECTION

POLYCYCLIN-N

AB/
BRISTOL/

AB/

AB/

AB/

AB/

AB/

3 BRISTOL

3

3

3

3

/N50309/001/

/N50309/002/

/N50309/003/

/N50309/004/

/N50309/005/

N50309 001

N50309 002

N50309 003

N50309 004

N50309 005

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AB/
AMCILL/

AB/

AB/

AB/

AB/

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3 PARKE DAVIS

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/N62041/001/

/N62041/002/

N62041 001

N62041 002

3 BRISTOL

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RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

TENORETIC 50

/STUART/

/50MG; 25MG/

/N85735/001/
/JUN/90./1990//CAPSULE; ORAL/
/ZITHROMAX/
/PFIZER/

/250MG/

/N50670/001/
/NOV/01./1991/ATOVAQUONE

TABLET; ORAL

MEPRON

+ BURROUGHS WELLCOME 250MG

N20259 001
NOV 25, 1992AZITHROMYCIN DIHYDRATE

CAPSULE; ORAL

ZITHROMAX

+ PFIZER

EQ 250MG BASE

N50670 001
NOV 01, 1991ATROPINE SULFATE

/AEROSOL; INJECTED; INHALATION/

/ATROPINE/SULFATE/

/US ARMY/

/EQ 0.36MG/BASE/INH/

@ US ARMY

EQ 0.36MG BASE/INH

/N20056/001/
/SEP/19./1990/
N20056 001
SEP 19, 1990AZLOCILLIN SODIUM

INJECTABLE; INJECTION

AZLIN

/MILES/

@ MILES

/EQ 3GM/BASE/VIAL/

EQ 3GM BASE/VIAL

/EQ 3GM/BASE/VIAL/

EQ 3GM BASE/VIAL

/N62388/002/
/SEP/08./1982/
N62388 002
SEP 08, 1982
/N62417/002/
/OCT/12./1982/
N62417 002
OCT 12, 1982ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

SOLUTION; ORAL

/COLCHATO/

@ WALLACE

@ WALLACE

/LOMAMATE/

/BARRE/

@ BARRE

/0.025MG/5ML; 0.025MG/5ML/
0.025MG/5ML; 2.5MG/5ML
/N85735/001/
N85735 001/0.025MG/5ML; 0.025MG/5ML/
0.025MG/5ML; 2.5MG/5ML
/N85746/001/
N85746 001

TABLET; ORAL

/COLCHATO/

@ WALLACE

@ WALLACE

/0.025MG; 2.5MG/
0.025MG; 2.5MG
/N85737/001/
N85737 001DIPHENOXYLATE HCL AND ATROPINE SULFATE

/CHELSEA/

@ CHELSEA

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

@ EON LABS

/3 VITAMINE/

/0.025MG; 2.5MG/
0.025MG; 2.5MG
/N85876/001/
N85876 001/0.025MG; 2.5MG/
0.025MG; 2.5MG
/N86173/001/
N86173 001BACLOFEN

INJECTABLE; INJECTION

LIORESAL

MEDTRONIC

0.5MG/ML

2MG/ML

N20075 001
JUN 17, 1992
N20075 002
JUN 17, 1992

TABLET; ORAL

BACLOFEN

BIOCRAFT

10MG

20MG

N73043 001
FEB 27, 1992
N73044 001
FEB 27, 1992
/N71961/001/
/APR/13./1988/
/N71962/001/
/APR/13./1988/

/3/EON/LABS/

/3/

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

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/AB/ /PARKE/DAVIS/

/200MG/

/BA/ /PHARM/BASIS/

/200MG/

2 PHARM BASICS

200MG

2 WARNER CHILCOTT

200MG

TABLET, CHEWABLE; ORAL

EPITOL

AB LEMMON

100MG

/N70429/001/
/JAN/02/1987/

/N70300/001/
/MAY/15/1986/

N70300 001

MAY 15, 1986

N70429 001

JAN 02, 1987

N73524 001

JUL 29, 1992

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

AB LEMMON

10MG;100MG

25MG;100MG

25MG;250MG

10MG;100MG

25MG;100MG

25MG;250MG

10MG;100MG

25MG;100MG

25MG;250MG

SINEMET

AB MSD

AB +

N73618 001

AUG 28, 1992

N73589 001

AUG 28, 1992

N73607 001

AUG 28, 1992

N17555 001

AUG 30, 1988

N17555 003

N17555 002

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

2 EON LABS

350MG

/350MG/

/BA/ /VITAFINE/

N89566 001

AUG 30, 1988

/N89566/001/
/AUG/30/1988/

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

AB ZENITH

EQ 500MG BASE

/EQ/500MG/BASE/

/3/

TABLET; ORAL

CEFADROXIL

AB ZENITH

EQ 1GM BASE

/EQ/1GM/BASE/

/3/

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

ZOLICEF

APOTHECON

> ADD > AP

> ADD > AP

> ADD > AP

> ADD > AP

> ADD > AP

> DLT > AB/

> DLT > AB/

> DLT > AB/

> DLT > AB/

EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

EQ 10GM BASE/VIAL

/EQ/500MG BASE/VIAL/

/EQ/1GM BASE/VIAL/

/EQ/10GM BASE/VIAL/

/BRISTOL/MYERS/

N62831 001

DEC 09, 1988

N62831 002

DEC 09, 1988

N62831 003

SEP 25, 1992

/N62831/001/
/DEC/09/1988/

/N62831/002/
/DEC/09/1988/

/N62831/003/
/DEC/09/1988/

CEFMETAZOLE SODIUM

INJECTABLE; INJECTION

ZEFAZONE IN PLASTIC

UPJOHN

> ADD >

> ADD >

> ADD >

> ADD >

EQ 20MG BASE/MLM

EQ 40MG BASE/MLM

N50683 001

DEC 29, 1992

N50683 002

DEC 29, 1992

CEFDIOXIME PROXETIL

GRANULE, FOR RECONSTITUTION; ORAL

CEFDIOXIME

AB/

/BA/

/SANKYO/

/BA/

/BA/

> DLT >

> DLT >

> DLT >

> DLT >

> DLT >

/EQ/50MG BASE/5MLH/

/EQ/100MG BASE/5MLH/

/EQ/50MG BASE/5MLH/

/EQ/100MG BASE/5MLH/

/N50683/001/
/AUG/07/1992/

/N50683/001/
/AUG/07/1992/

/N50683/001/
/AUG/07/1992/

/N50683/001/
/AUG/07/1992/

N62766 001

MAR 03, 1987

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

N62774 001

APR 08, 1987

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

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION

CEFTIZOX
FUJISAWA

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

EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
/EQ/1GM/BASE/VIAL/
/EQ/2GM/BASE/VIAL/

/SKF/

CEFTIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER
FUJISAWA

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

EQ 20MG BASE/ML
EQ 40MG BASE/ML
/EQ/20MG/BASE/ML/
/EQ/40MG/BASE/ML/

/SKF/

CEFTIRAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN
/ROCHE/

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

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

3 ROCHE

3

3

CEPHALEXIN

CAPSULE; ORAL

/CEPHALEXIN/HYDRATE/
/3/EON/LABS/
/3/

> DLT >
> DLT >
> DLT >

/N62159/001/
/N62159/002/

/EQ/250MG/BASE/
/EQ/500MG/BASE/

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION

CEFADYL
/AP/
/BRISTOL/
BRISTOL

/AP/

N50560 002
SEP 15, 1983
N50560 003
SEP 15, 1983
/N50560/002/
/SEP/15/1983/
/N50560/003/
/SEP/15/1983/

EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
/EQ/1GM/BASE/VIAL/
/EQ/2GM/BASE/VIAL/

CEPHAPIRIN SODIUM
/AP/
/ELKINS/SINN/

/AP/

N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

EQ 20MG BASE/ML
EQ 40MG BASE/ML
/EQ/20MG/BASE/ML/
/EQ/40MG/BASE/ML/

/AP/

N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

3 ELKINS SINN

3

N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

3 ELKINS SINN

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N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

3 ELKINS SINN

3

N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

3 ELKINS SINN

3

N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

3 ELKINS SINN

3

N50589 001
OCT 03, 1984
N50589 002
OCT 03, 1984
/N50589/001/
/OCT/03/1984/
/N50589/002/
/OCT/03/1984/

CEPHRADINE

> DLT >
> DLT >
> DLT >
> ADD >
/TABLET/001/
/VELOSEF/
/3/SQUIBB/
3 SQUIBB

/N62510/001/
/MAR/12/1985/
N62510 001
MAR 12, 1985
/N62510/002/
/MAR/12/1985/
N62510 002
MAR 12, 1985
/N62510/003/
/MAR/12/1985/
N62510 003
MAR 12, 1985

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

/1GM/
1GM

/N50530/001/
N50530 001

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

CHLORAMPHENICOL SODIUM SUCCINATE
FUJISAWA

> ADD >

N62365 001
AUG 25, 1982
/N62365/001/
/AUG/25/1982/

EQ 1GM BASE/VIAL

/1GM/BASE/VIAL/

> DLT >

N62365 001
AUG 25, 1982
/N62365/001/
/AUG/25/1982/

EQ 1GM BASE/VIAL

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL
3 EON LABS

3

/N62159/001/
/N62159/002/

/EQ/250MG/BASE/
/EQ/500MG/BASE/

N84919 001
N84920 001
N84823 001

5MG
10MG
25MG

CHLORDIAZEPOXIDE HYDROCHLORIDECAPSULE; ORALCHLORDIAZEPOXIDE HCL

/AB/	/5MG/	/N85163/001/	/B+/	/250MG/	/N84669 001/
/AB/	/10MG/	/N84598/001/	/B+/	/100MG/	/N86708 001/
/AB/	/25MG/	/N85164/001/		/250MG/	/N86709 001/
	5MG	N85163 001			/N86709 001/
	10MG	N84598 001			/N86709 001/
	25MG	N85164 001			/N86709 001/
	/10MG/	/N85163/001/			/N86709 001/
		/JUL 15, 1984/			/N86709 001/
> DLT >		N89533 001			/N86709 001/
> DLT >		JUL 15, 1988			/N86709 001/
> ADD >		/N84519/001/			/N86709 001/
> ADD >		/N84420/001/			/N86709 001/
	/5MG/	/N84420/001/			/N86709 001/
	/10MG/	/N84420/001/			/N86709 001/
	/25MG/	/N84420/001/			/N86709 001/
	5MG	N84420 001			/N86709 001/
	10MG	N85000 001			/N86709 001/
	25MG	N85294 001			/N86709 001/
	5MG	N85014 001			/N86709 001/
	10MG	N85000 001			/N86709 001/
	25MG	N85294 001			/N86709 001/

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

CHLOROQUINE PHOSPHATETABLET; ORALCHLOROQUINE PHOSPHATE

/AB/	/150MG BASE/	/N83082 001/
	EQ 150MG BASE	

CHLOROTHIAZIDETABLET; ORALCHLOROTHIAZIDE

/AB/	/250MG/	/N85485 001/
	/250MG/	/N85485 001/

CHLORPHENIRAMINE MALEATETABLET; ORALCHLORPHENIRAMINE MALEATE

/AB/	/4MG/	/N85555/001/
		/JUL 13, 1984/
		N88556 001
		JUL 13, 1984

CHLORPHENIRAMINE MALEATE

4MG

CHLORPROPAMIDETABLET; ORALCHLORPROPAMIDE

/B+/	/250MG/	/N84669 001/
	/100MG/	/N86708 001/
/B+/	/250MG/	/N86709 001/
		/N86709 001/
	100MG	N88708 001
	250MG	AUG 30, 1984
		N88709 001
	/250MG/	AUG 30, 1984
		/N84669 001/

CHLORTHALIDONETABLET; ORALCHLORTHALIDONE

/AB/	/50MG/	/N87118 001/
/AB/	/50MG/	/N87118 001/
	50MG	JUL 21, 1988
		/N87118 001/
		/JUL 21, 1988/
		N89591 001
		JUL 21, 1988
		/N87118 001/
		/N87118 001/
		/N87118 001/
		/JAN 24, 1983/
		/N87118 001/
		/FEB 09, 1983/
		N87515 001
		JAN 24, 1983
		N87516 001
		FEB 09, 1983

CHLORTHALIDONECHLORTHALIDONE

/AB/	/25MG/	/N86651/001/
		/NOV 12, 1982/
		/N86651/001/
		/DEC 20, 1988/
		N88051 001
		NOV 12, 1982
		N19574 001
		DEC 20, 1988

CHYMOTRYPSINPOWDER FOR RECONSTITUTION; OPHTHALMIC

/AT/	/150 UNITS/VIAL/	/N11837 001/
	750 UNITS/VIAL	

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC

ZOLYTE
ALCON
/AL/

150 UNITS/VIAL
750 UNITS/VIAL

/N11903/001/
N11903 001

CINNOXACIN

POWDER; ORAL

CINNOBAC
LILLY
AB +
CINNOXACIN
BIOCRAFT
AB
AB

250MG
500MG
250MG
500MG

N18067 001
N18067 002
N73005 001
FEB 28, 1992
N73006 001
FEB 28, 1992

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE

SOLUTION; IRRIGATION
RENACIDIN
GUARDIAN/LABS

6.602GM/100ML; 198MG/100ML;
3.177GM/100ML
N19481 001
OCT 02, 1990

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE
COPLEY
AA

EQ 0.5MG BASE/5ML

N73095 001
APR 21, 1992

IAVIST
POURSEY
/AA/
AA

EQ 0.5MG BASE/5ML
EQ 0.5MG BASE/5ML

/N18675/001/
N18675 001
JUN 28, 1985

CLEMASTINE FUMARATE

TABLET; ORAL

CLEMASTINE FUMARATE
LEMMON
AB

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

2.68MG
1.34MG
1.34MG

N73283 001
JAN 31, 1992
/N17661/001/
/N17661/001/
N73282 001
JAN 31, 1992

IAVIST
AB +
SANDOZ
IAVIST-1
POURSEY
/AA/
SANDOZ

2.68MG
1.34MG
1.34MG

N17661 001
/N17661/001/
N17661 002

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET; EXTENDED RELEASE; ORAL
IAVIST
SANDOZ

EQ 1MG BASE/75MG

/N18298/001/
N18298 001
DEC 15, 1982

CLINDAMYCIN HYDROCHLORIDE

POWDER; ORAL
CLINDAMYCIN HCL
LABS
/AA/
/AA/

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

EQ 75MG BASE/5ML
EQ 75MG BASE/5ML

/N62916/001/
/N62916/001/
/N62916/001/
/N62916/001/

CLINDAMYCIN PALMITATE HYDROCHLORIDE

POWDER FOR RECONSTITUTION; ORAL

CLEOCIN
UPJOHN
SANDOZ

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

EQ 75MG BASE/5ML
EQ 75MG BASE/5ML

/N61827/001/
/N61827/001/
/N61827/001/
/N61827/001/

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE;
TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

/AA/ /HISTAFED-D/
/CENC/

/10MG/5ML; 10MG/5ML;
/1.25MG/5ML

/N89018/001/
/JUL/23/1986/

TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES W/ CODEINE

10MG/5ML; 30MG/5ML;

1.25MG/5ML

N89018 001
JUL 23, 1986

COLCHICINE; PROBENECID

TABLET; ORAL

/BP/ /PROBEN-C/
/CHELSEA/

3 CHELSEA

/0.5MG; 500MG/
0.5MG; 500MG

/N85552/001/
N85552 001

PROBENECID AND COLCHICINE

/BP/ /EON/LABS/
3 EON LABS

/0.5MG; 500MG/
0.5MG; 500MG

/N86130/001/
N86130 001

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN

/AP/ /FUJISAMA/
/LUITPOLD/
3 LUITPOLD

1MG/ML
/0.03MG/ML/
0.03MG/ML

N83075 001
/N80668/001/
N80668 001

> DLT > /AP/ /LYPHOMED/
> DLT > /AP/ /SOLPAK MEDCL/
> DLT > /AP/ /SOLPAK MEDCL

/1MG/ML/
/1MG/ML/
/1MG/ML

/N83075/001/
/N87551/001/
/FEB/29/1984/
N87551 001

> ADD > /AP/ /SOLPAK MEDCL

> ADD > /AP/ /SOLPAK MEDCL

> ADD > /AP/ /SOLPAK MEDCL

> ADD > /AP/ /SOLPAK MEDCL

> ADD > /AP/ /SOLPAK MEDCL

> ADD > /AP/ /SOLPAK MEDCL

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL

/AT/ /BARNES/HIND/
3 SOLA BARNES HIND

/12/
1%

/N84863/001/
N84863 001

CYPROHEPTADINE HYDROCHLORIDE

TABLET; ORAL

CYPROHEPTADINE HCL

/AA/ /PIONEER/PHARMS/
/4MG/

/N87839/001/
/FEB/08/1984/
N87839 001

3 PIONEER PHARMS

4MG
FEB 08, 1984

DACARBAZINE

INJECTABLE; INJECTION

/AP/ /DACARBAZINE/
/LYPHOMED/

/100MG/VIAL/
/200MG/VIAL/

/N70962/001/
/AUG/28/1986/
N70962 001

/100MG/VIAL/
/200MG/VIAL/

/100MG/VIAL/
/200MG/VIAL/

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/200MG/VIAL/

/100MG/VIAL/
/200MG/VIAL/

N20118 001
SEP 18, 1992

99.9/2M

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'92 - DEC'92

20

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL
@ EON LABS
/3/VITAFINE/

N85916 001
/N45916/001/

25MG
/25MG/

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM SR
+ MARION MERRELL DOM

60MG

N19471 001
JAN 23, 1989
N19471 002
JAN 23, 1989
/N19471/001/
/JAN/23, 1989/
/N19471/002/
/JAN/23, 1989/

DIFLORASONE DIACETATE

CREAM; TOPICAL
FLORONE
BX + UPJOHN
PSORCON
BX DERMIK

N17741 001

0.05%

N20205 001
NOV 20, 1992

0.05/M

BC
DILACOR XR
RHONE POULENC RORER

180MG

BC
240MG

DIFLUNISAL

TABLET; ORAL
DIFLUNISAL
LENNON

N73679 001
JUL 31, 1992

250MG

N73673 001
JUL 31, 1992

500MG

N73562 001
NOV 27, 1992

250MG

N73563 001
NOV 27, 1992

500MG

AB
DOLOBID
MSD

N18445 001
APR 19, 1982

250MG

N18445 002
APR 19, 1982

500MG

INJECTABLE; INJECTION
CARDIZEM
MARION MERRELL DOM

5MG/ML

/25MG/VIAL/

/50MG/VIAL/

N20027 001
OCT 24, 1991
/N20027/001/
/OCT/24, 1991/
/N20027/002/
/OCT/24, 1991/

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM CD
BC + MARION MERRELL DOM

N20062 002
DEC 27, 1991

180MG

N20062 003
DEC 27, 1991

240MG

N20062 001
AUG 10, 1992

120MG

N20062 004
DEC 27, 1991

300MG

/N20062/004/
/DEC/27, 1991/

/300MG/

TABLET; ORAL

CARDIZEM

AB
MARION MERRELL DOM

30MG

AB
60MG

AB
90MG

AB +
120MG

DILTIAZEM HCL
COPLEY

30MG

60MG

90MG

120MG

N18602 001
NOV 05, 1982
N18602 002
NOV 05, 1982
N18602 003
DEC 08, 1986
N18602 004
DEC 08, 1986

N74067 001
NOV 05, 1992
N74067 002
NOV 05, 1992
N74067 003
NOV 05, 1992
N74067 004
NOV 05, 1992

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOPRAM

ROBINS

DOXAPRAM SOL

STERIS

20MG/ML

20MG/MLM

N14879 001

N73529 001

JAN 30, 1992

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

/A/ EON/LAB/

/A/

/HEATHER/

/A/

/HEATHER/

/A/

/HEATHER/

/A/

/HEATHER/

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/A/

/HEATHER/

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/EQ/50MG/BASE/

/EQ/100MG/BASE/

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/EQ/50MG/BASE/

CAPSULE, COATED PELLETS; ORAL

DOXYCYCLINE HYCLATE

SIDMAX

AB

EQ 100MG BASEM

N63187 001

JUN 30, 1992

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE

/B*/

/INTERPHARM/

3 INTERPHARM

/MEDICOPHARM/

/PARKE/DAVIS/

AB VINTAGE

3 WARNER CHILCOTT

/EQ/100MG/BASE/

EQ 100MG BASE

/EQ/100MG/BASE/

/EQ/100MG/BASE/

/EQ/100MG/BASE/

EQ 100MG BASE

EQ 100MG BASE

/N62764/001/

/SEP/02/1988/

SEP 02, 1988

/N62764/001/

/APR/07/1986/

/N62593/001/

/AUG/28/1985/

/N62538/001/

/APR/07/1986/

/N62593/001/

/AUG/28/1985/

/N62593/001/

/AUG/28/1985/

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

/A*/

/LYPHOMED/

3 LYPHOMED

3

/2.5MG/ML/

/2.5MG/ML/

2.5MG/ML

2.5MG/ML

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

/NOV/17/1986/

/N70992/001/

N19616 005

DEC 31, 1991

/N19616/005/

/DEC/31/1991/

400MG

/400MG/

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

AP GRAHAM CHEM 0.01MG/ML; 2Z

AP 0.02MG/ML; 2Z

/AP/ /LIDOCAINE HCL/M/ /EPINEPHRINE/

/AP/ /GRAHAM/CHEM/ 0.01MG/ML; 2Z

/AP/ 0.02MG/ML; 2Z

N80504 004

OCT 19, 1983

N80504 005

OCT 19, 1983

/N80504/004/

/OCT 19, 1983/

/N80504/005/

/OCT 19, 1983/

/AI/ /SANSAC/

/OWEN/GALDERMA/

/2Z/

/N62231/001/

/JAN 24, 1985/

/AI/

/2Z/

/N50594/001/

/FEB 15, 1985/

N50594 001

FEB 15, 1985

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ALKERGOT

3 EON LABS

3

/3/ /ERGOLOID MESYLATE/

/3/

0.5MG

1MG

/0.5MG/

/1MG/

N85153 001

N87417 001

/N85153/001/

/N87417/001/

TABLET, COATED PARTICLES; ORAL

PCE

ABBOTT

500MG

N50611 002

AUG 22, 1990

ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

/SUSPENSION; /ORAL/

/ERYTHROMYCIN/

/LILLY/

/EQ 125MG BASE/5ML/

/EQ 600MG BASE/5ML/

/EQ 125MG BASE/5ML/

/EQ 600MG BASE/5ML/

/N50599/001/

/SEP 29, 1989/

N50599 001

SEP 29, 1989

3 LILLY

EQ 125MG BASE/5ML

EQ 600MG BASE/5ML

ERYTHROMYCIN

SOLUTION; TOPICAL

/G-SOLVE-2/

/SYOSSET/

/2Z/

/N62198/001/

/N62198/002/

N62198 001

N62198 002

AI SYOSSET

2Z

ERYTHROMYCIN

PHARM BASICS

2Z

/AI/ /ERYTHROMYCIN/

/PHARM/BASICS/

/2Z/

/N62231/001/

/N62231/002/

N62231 001

N62231 002

SANSAC

OWEN GALDERMA

2Z

ERYTHROMYCIN ETHYL SUCCINATE

/PARKE/DAVIS/

3 PARKE DAVIS

3

/EQ 200MG BASE/5ML/

/EQ 400MG BASE/5ML/

/EQ 400MG BASE/5ML/

/EQ 400MG BASE/5ML/

/N62231/001/

/N62231/002/

N62231 001

N62231 002

SUSPENSION; ORAL

/ERYTHROMYCIN/

/UPJOHN/

3 UPJOHN

3

/EQ 200MG BASE/5ML/

/EQ 400MG BASE/5ML/

/EQ 400MG BASE/5ML/

/EQ 400MG BASE/5ML/

/N62198/001/

/N62198/002/

N62198 001

N62198 002

/AB/

/AB/

/EQ 200MG BASE/5ML/

/EQ 400MG BASE/5ML/

/EQ 400MG BASE/5ML/

/EQ 400MG BASE/5ML/

/N62231/001/

/N62231/002/

N62231 001

N62231 002

N62522 001

JAN 24, 1985

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

/AP/ /LYPHOMED/

/50MG/ML/

/AP/

/50MG/ML/

/AP/

/50MG/ML/

3 LYPHOMED

50MG/ML

3

50MG/ML

3

50MG/ML

/N89152/001/
MAR 21, 1986
/N89428/001/
JAN 12, 1987
/N89519/001/
MAR 12, 1987

> ADD > AP
> ADD >
> DLT > /AP/ /LYPHOMED/
> DLT >

INJECTABLE; INJECTION

FOLIC ACID

FUJISAWA

5MG/ML

N89202 001
FEB 18, 1986
/N89202/001/
FEB 18, 1986

TABLET; ORAL

FOLIC ACID

3 EON LABS

/LILLY/

3 LILLY

/PHOENIX/ /AP/

AA VINTAGE

/3/VITAMINE/

1MG
/1MG/
1MG
/1MG/
1MG
/1MG/
1MG
/1MG/

N84472 001
/N85155/001/
N06135 003
/N85296/001/
N86296 001
/N84472/001/

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE DECANOATE

FUJISAWA

25MG/ML

/AP/ /LYPHOMED/

/25MG/ML/

> ADD > A0
> ADD >
> DLT > /AP/ /LYPHOMED/
> DLT >

N71413 001
JUL 14, 1987
/N71413/001/
JUL 14, 1987

50MG/15ML
/50MG/15ML/

FURAZOLIDONE

SUSPENSION; ORAL

FUROXONE

+ ROBERTS

INJECTABLE; INJECTION

FLUPHENAZINE HCL

FUJISAWA

2.5MG/ML

/AP/ /LYPHOMED/

/2.5MG/ML/

> ADD > AP
> ADD >
> DLT > /AP/ /LYPHOMED/
> DLT >

N89556 001
APR 16, 1987
/N89556/001/
APR 16, 1987

100MG
/100MG/

N11270 002
/N11270/002/

FLUPHENAZINE HYDROCHLORIDE

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

/PHARM/BASICS/

/15MG/

/PH/

/15MG/

3 PHARM BASICS

15MG

3

30MG

INJECTABLE; INJECTION

FUROSEMIDE

FUJISAWA

10MG/ML

/AP/ /LYPHOMED/

/10MG/ML/

> ADD > AP
> ADD >

/10MG/ML/

N18902 001
MAY 22, 1984
/N18902/001/
JUL 30, 1984
/N18902/001/
MAY 22, 1984
N18507 001
JUL 30, 1982

> DLT > /AP/

/10MG/ML/

> DLT >

10MG/ML

3 LYPHOMED

FUROSEMIDE

TABLET; ORAL

FUROSEMIDE

/AD/ /CHELSEA/

/40MG/

/N18369/001/

> DLT > /AP/

INJECTABLE; INJECTION

GENTAMICIN SULFATE

/LYPHONED/

/EQ 10MG BASE/ML/

/N62356/001/

/MAR/04./1982/

/EQ 40MG BASE/ML/

/N62356/002/

/MAR/04./1982/

/EQ 10MG BASE/ML/

/N62507/001/

/JUN/06./1985/

EQ 10MG BASE/ML

N62507 001

/EQ 40MG BASE/ML/

/N62507/002/

/JUN/06./1985/

EQ 40MG BASE/ML

N62507 002

EQ 40MG BASE/ML

JUN 06, 1985

EQ 40MG BASE/ML

JUN 06, 1985

GADOTERIDOL

INJECTABLE; INJECTION

PROHANCE

SQUIBB

279.3MG/MLM

N20131 001

NOV 16, 1992

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

GALLIUM CITRATE GA 67

/BS/ /DUPONT/

DUPONT MERCK

/2MG/ML/

2MG/ML

/N17478/001/

N17478 001

GENTAMICIN SULFATE

CREAM; TOPICAL

GENTAMICIN

/THAMES/

/EQ 1MG BASE/GM/

/N62427/001/

/MAR/26./1983/

> DLT > /AT/

> DLT >

INJECTABLE; INJECTION

GLYCOPYRROLATE

FUJISAMA

0.2MG/ML

N88475 001

JUN 12, 1984

/N88475/001/

/JUN/12./1984/

GENTAMICIN SULFATE

THAMES

EQ 1MG BASE/GM

N62427 001

MAY 26, 1983

> ADD > AT

> ADD >

INJECTABLE; INJECTION

GONADORELIN ACETATE

INJECTABLE; INJECTION

GENTAMICIN SULFATE

FUJISAMA

EQ 10MG BASE/ML

N62356 001

MAR 04, 1982

N62356 002

MAR 04, 1982

> ADD > AP

> ADD >

INJECTABLE; INJECTION

LUTREPULSE PUMP KIT

FERRING

0.8MG/VIAL

N19687 001

OCT 10, 1989

N19687 002

OCT 10, 1989

> ADD > AP

> ADD >

3.2MG/VIAL

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

/AP/ /LUITPOLD/ /10 UNITS/ML/ /N87043/001/

/AP/ /LUITPOLD/ /100 UNITS/ML/ /N87043/001/

3 LUITPOLD 10 UNITS/ML /N87043/001/

3 100 UNITS/ML /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

/HEPARIN LOCK FLUSH PRESERVATIVE FREE/ /N87043/001/

/LYPHOMED/ /10 UNITS/ML/ /N87043/001/

/AP/ /LYPHOMED/ /100 UNITS/ML/ /N87043/001/

3 LYPHOMED 10 UNITS/ML /N87043/001/

3 100 UNITS/ML /N87043/001/

/HEPARIN LOCK FLUSH PRESERVATIVE FREE IN PLASTIC CONTAINER/ /N87043/001/

/LYPHOMED/ /10 UNITS/ML/ /N87043/001/

/AP/ /LYPHOMED/ /100 UNITS/ML/ /N87043/001/

3 LYPHOMED 10 UNITS/ML /N87043/001/

3 100 UNITS/ML /N87043/001/

3 LYPHOMED 10 UNITS/ML /N87043/001/

3 100 UNITS/ML /N87043/001/

HEPARIN SODIUM
/LUITPOLD/

/AP/ /LUITPOLD/ /1,000 UNITS/ML/ /N87043/001/

3 LUITPOLD 1,000 UNITS/ML /N87043/001/

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

> DLT > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> DLT > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /10 UNITS/ML/ /N87043/001/

> ADD > /AP/ /SOLOPAK MEDCL /100 UNITS/ML/ /N87043/001/

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

/AP/ /ABBOTT/ /10,000 UNITS/100ML/ /N18911/006/

AP ABBOTT 10,000 UNITS/100ML /N18911/006/

HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /200 UNITS/100ML/ /N1953/001/

AP MCGAM 200 UNITS/100ML /N1953/001/

HEPARIN SODIUM 12500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/001/

AP MCGAM 5,000 UNITS/100ML /N19802/001/

HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /4,000 UNITS/100ML/ /N19952/001/

AP MCGAM 4,000 UNITS/100ML /N19952/001/

HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19952/004/

AP MCGAM 5,000 UNITS/100ML /N19952/004/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/005/

AP MCGAM 5,000 UNITS/100ML /N19802/005/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /10,000 UNITS/100ML/ /N19802/002/

AP MCGAM 10,000 UNITS/100ML /N19802/002/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/ /MCGAM/ /5,000 UNITS/100ML/ /N19802/003/

AP MCGAM 5,000 UNITS/100ML /N19802/003/

HISTRELIN ACETATE

INJECTABLE; INJECTION
SUPPRELIN
/ JOHNSON/RAJ

/EQ/0.2MG/BASE/ML/

/N19836/001/
DEC/24, 1991

/EQ/0.5MG/BASE/ML/

/N19836/002/
DEC/24, 1991

/EQ/1MG/BASE/ML/

/N19836/003/
DEC/24, 1991

ROBERTS

EQ 0.2MG BASE/ML

N19836 001
DEC 24, 1991

EQ 0.5MG BASE/ML

N19836 002
DEC 24, 1991

EQ 1MG BASE/ML

N19836 003
DEC 24, 1991HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
APRESOLINE
/ CIBA

/20MG/ML/
20MG/ML/N8532/001/
AUG 11, 1987

/AP/
/LYPHOMED/

/20MG/ML/

/N8532/001/
AUG 11, 1987

2 LYPHOMED

20MG/ML

TABLET; ORAL
HYDRALAZINE HCL
2 EON LABS

50MG

N85088 001

/25MG/

/N87712/001/
N87712 001

25MG

/N85088/001/

/50MG/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
/HYDRAL/
/SOLVAY/

/25MG;25MG/

/N87608/001/
FEB/08, 1982

/50MG;50MG/

/N87213/001/
FEB/08, 1982

/100MG;50MG/

/N87609/001/
FEB/08, 1982HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

AB

25MG;25MG

N87608 001
FEB 08, 1982

AB

50MG;50MG

N87213 001
FEB 08, 1982

2

100MG;50MG

N87609 001
FEB 08, 1982HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRAP-ES

2 EON LABS

25MG;15MG;0.1MG

N84876 001

/3-VITAMINE/
/RESERPINE/HYDRALAZINE/HCL/HYDROCHLOROTHIAZIDE/

/25MG;15MG;0.1MG/

/N84876/001/

/BP/ /DANBURY/

/25MG;15MG;0.1MG/

/N85549/001/

/BP/

/25MG;15MG;0.1MG/

/N87556/001/

RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

25MG;15MG;0.1MG

N85549 001

BP DANB-JRY

25MG;15MG;0.1MG

N87556 001

BP

25MG;15MG;0.1MG

N87556 001

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL

DRALSERP

2 EON LABS

25MG;0.1MG

N84617 001

/3-VITAMINE/
/SERPASIL-APRESOLINE

/25MG;0.1MG/

/N84617/001/

/BP/ /CIBA/

/25MG;0.1MG/

/N84617/001/

CIBA

25MG;0.1MG

N09296 004

HYDROCHLOROTHIAZIDE

SOLUTION; ORAL

/HYDROCHLOROTHIAZIDE/ANTHENSOL/

/ROXANE/

100MG/ML

/N85588/001/

/JUL/02, 1984

N85588 001

JUL 02, 1984

TABLET; ORAL

HYDROCHLOROTHIAZIDE

DANBURY

25MG

N81189 001

JAN 24, 1992

AB

100MG

N81190 001

JAN 24, 1992

INJECTABLE; INJECTION
HYDROXYZINE HCL

FUJISANA	25MG/ML 50MG/ML 25MG/ML 50MG/ML 25MG/ML 50MG/ML 25MG/ML 50MG/ML
/L.YPHONED/	
/SATAI/NEOHEN/SOLOPAK/	
SOLOPAK MEDCL	

IBU PROFEN /Bodt\$/

IBUPROFEN	/AD/	/BOOTS/	600MG
	AB	2 BOOTS	600MG
	AB	LEMON	400MG
	AB		600MG
	AB		800MG
	/AB/	/MEDICOPHARM/	400MG
	/AB/	/SUPERPHARM/	600MG
	AB	2 SUPERPHARM	600MG
	AB	VINTAGE	400MG

/N70556/001
 JUN 14, 1985
 N70556 001
 JUN 14, 1985
 N73343 001
 JUN 30, 1992
 N73344 001
 JUN 30, 1992
 N73345 001
 JUN 30, 1992
 /N71644/001/
 /FEB 01, 1988/
 /N70709/001/
 /APR 25, 1986/
 N70709 001
 APR 25, 1986
 N71644 001
 FEB 01, 1988

HYDROXYZINE HCL
/EON/LABS/

HYDROXIZINE HCL
/EON LABS/
10MG/
25MG/
50MG/
10MG
25MG
50MG
/EON LABS/
/PHARM/BASICS/
25MG/
50MG/
50MG/

TABLET; ORAL
TRIPRAMINE HCL
EON LABS

AB	EON LABS	10MG
AB		25MG
AB		50MG
AB	/VITAMINE/	25MG
AB		50MG
AB		10MG

N85200 001
N84869 002
N85133 001
~~N84869 002~~
~~N85133 001~~
~~N85200 001~~

CAPSULE; ORAL

EQ 25MG HCL	EQ 25MG HCL
EQ 50MG HCL	EQ 50MG HCL
EQ 25MG HCL	EQ 25MG HCL
EQ 50MG HCL	EQ 50MG HCL

CAPSULE; ORAL
INDOMETHACIN

> DLT	/P/EDN/LABS/	/25MG/
> DLT	/P/	/50MG/
> DLT	/AS/	/25MG/
> DLT	/AS/	/50MG/
	3 PIONEER PHARMS	25MG
	3	50MG

/N71711/001/
 /JUL/05, 1986/
 /N71712/001/
 /JUL/05, 1986/
 /N70813/001/
 /AUG/11, 1986/
 /N70592/001/
 /AUG/11, 1986/
 N70813 001
 AUG 11, 1986
 N70592 001
 AUG 11, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'92 - DEC'92

34

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN
/3/50N/LAB5/

> DLT >
> DLT >

IRON DEXTRAN

INJECTABLE; INJECTION

/AB/ /DEXTRON/
/FISONS/
3 FISONS

/N1531/001/
/JUL/21/1987/

/N10787/002/
N10787 002

SUPPOSITORY; RECTAL

INDOCIN
AB + MERCK

50MG

N17814 001
AUG 13, 1984

IRON DEXTRAN

/STERIS/
STERIS

/EQ 50MG IRON/ML/
EQ 50MG IRON/ML

/N17441/001/
N17441 001

INDOMETHACIN
G AND M

50MG

N73314 001
AUG 31, 1992

/EQ 50MG IRON/ML/
EQ 50MG IRON/ML

/N17807/001/
N17807 001

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION

SPECTAMINE
IMP

1 MCI/ML

N19432 001
DEC 24, 1987
/N19432/001/
/DEC/24/1987/

/1/MCI/ML/

/0.125Z/

/N87938/001/
NOV 15, 1982

/0.167Z/

/N88470/001/
NOV 15, 1982

/0.2Z/

/N88471/001/
MAR 14, 1984

/0.25Z/

/N88472/001/
MAR 14, 1984

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-250
SQUIBB

512M

N18735 007
JUL 06, 1992

/0.062Z/

/N87937/001/
NOV 15, 1982

/0.062Z/

/N88470/001/
NOV 15, 1982

/0.167Z/

/N88471/001/
MAR 14, 1984

/0.2Z/

/N88472/001/
MAR 14, 1984

IOPHENDYLATE

INJECTABLE; INJECTION

/PANTOPAGUE/
/LAFAYETTE/
3 ALCON

/100Z/
100Z

/N05319/001/
N05319 001

/0.08Z/

/N88187/001/
DEC 03, 1982

/0.1Z/

/N88188/001/
DEC 03, 1982

/0.17Z/

/N88189/001/
DEC 03, 1982

/0.25Z/

/N88190/001/
DEC 03, 1982

IOVERSOL

INJECTABLE; INJECTION

OPTIRAY 300
MALLINCKRODT

642M

N19710 004
JAN 22, 1992

/0.08Z/

/N88191/001/
DEC 03, 1982

/0.1Z/

/N88192/001/
DEC 03, 1982

/0.17Z/

/N88193/001/
DEC 03, 1982

/0.25Z/

/N88194/001/
DEC 03, 1982

OPTIRAY 350
MALLINCKRODT

742M

N19710 005
JAN 22, 1992

/0.08Z/

/N88195/001/
DEC 03, 1982

/0.1Z/

/N88196/001/
DEC 03, 1982

/0.17Z/

/N88197/001/
DEC 03, 1982

/0.25Z/

/N88198/001/
DEC 03, 1982

ISOETHARINE HYDROCHLORIDESOLUTION; INHALATION
ISOETHARINE HCL 5/FAN DEY
0.17%
/0.17%/
N89819 001
NOV 22, 1988
/N89819/001/
/NOV/22, 1988/ISOPROTERENOL HYDROCHLORIDESOLUTION; INHALATION
ISOPROTERENOL HCL/AN/ /DEY/
0 DEY
0.5%
/0.5%/
/N86764/001/
/JAN/04, 1982/
N86764 001
JAN 04, 1982ISOETHARINE MESYLATEAEROSOL, METERED; INHALATION
BRONCHOMETER> DLT > /BN/+/STERLING/
> ADD > + STERLING
/0.34MG/INH/
0.34MG/INH> DLT > /BN/ /BAPPE/
> DLT > /BAPPE/
> ADD > 0.34MG/INH
> ADD > 0.34MG/INH/N12339/001/
N12339 007
/N12339/007//N87858/001/
N87858 001
/N87858/001/
AUG 21, 1984ISONIAZID

TABLET; ORAL

> DLT > /AA/ /WALLACE/
> DLT > /WALLACE/
> ADD > 300MG
> ADD > 300MG> DLT > /AA/ /CIBA/
> DLT > /CIBA/
> ADD > 300MG
> ADD > 300MG/N80134/003/
N80134 003
/N80134/003/
N80134 004/N80134/004/
N80134 004
/N80134/004//N80935/001/
N80935 001
/N80935/001/ISONIAZID
EON LABSAA
/AA/ /LILLY/
/AA/ /LILLY/
> ADD > 300MG
> ADD > 300MG> DLT > /AA/ /LILLY/
> DLT > /LILLY/
> ADD > 300MG
> ADD > 300MGN08678 002
N08678 003
/N08678/002/
/N08678/002/
N08678 002
N08678 003
/N08678/002/
/N08678/002//N08678/003/
N08678 003
/N08678/003//N08678/004/
N08678 004
/N08678/004//N08678/005/
N08678 005
/N08678/005//N08678/006/
N08678 006
/N08678/006//N08678/007/
N08678 007
/N08678/007//N08678/008/
N08678 008
/N08678/008//N08678/009/
N08678 009
/N08678/009//N08678/010/
N08678 010
/N08678/010//N08678/011/
N08678 011
/N08678/011//N08678/012/
N08678 012
/N08678/012//N08678/013/
N08678 013
/N08678/013//N08678/014/
N08678 014
/N08678/014/ISOSORBIDE MONONITRATETABLET; ORAL
ISMO+ MYETH
20MG
/20MG//N80134/003/
N80134 003
/N80134/003/
N80134 004/N80134/004/
N80134 004
/N80134/004//N80935/001/
N80935 001
/N80935/001/ITRACONAZOLECAPSULE; ORAL
SPORANOX+ JANSSEN
100MG
/100MG/N08678 002
N08678 003
/N08678/002/
/N08678/002/
N08678 002
N08678 003
/N08678/002/
/N08678/002//N08678/003/
N08678 003
/N08678/003//N08678/004/
N08678 004
/N08678/004//N08678/005/
N08678 005
/N08678/005//N08678/006/
N08678 006
/N08678/006//N08678/007/
N08678 007
/N08678/007//N08678/008/
N08678 008
/N08678/008//N08678/009/
N08678 009
/N08678/009//N08678/010/
N08678 010
/N08678/010//N08678/011/
N08678 011
/N08678/011//N08678/012/
N08678 012
/N08678/012//N08678/013/
N08678 013
/N08678/013//N08678/014/
N08678 014
/N08678/014/KANAMYCIN SULFATEINJECTABLE; INJECTION
KANAMYCIN SULFATELOCH
AP
EQ 75MG BASE/2MLM
JUL 31, 1992AP
EQ 500MG BASE/2MLM
JUL 31, 1992AP
EQ 1GM BASE/3MLM
JUL 31, 1992N63021 001
JUL 31, 1992N63022 001
JUL 31, 1992N63025 001
JUL 31, 1992N12093 001
JUL 29, 1988N86405 002
AUG 21, 1990N88124 001
AUG 21, 1990N88125 001
AUG 21, 1990N19091 001
DEC 30, 1991/N19091/001/
/DEC/30, 1991/N20083 001
SEP 11, 1992N63021 001
JUL 31, 1992N63022 001
JUL 31, 1992N63025 001
JUL 31, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE
/ABP/ /LYPHOMED/

/EQ 150MG BASE/2ML/

/EQ 500MG BASE/2ML/

/EQ 1GM BASE/3ML/

3 LYPHOMED

EQ 75MG BASE/2ML

3

EQ 500MG BASE/2ML

3

EQ 1GM BASE/3ML

> DLT > /ABP/ /SHUTU/NEORHEW/SOLORAE EQ 150MG BASE/2ML/

> DLT >

> ADD > AP

> DLT > /ABP/ /SHUTU/NEORHEW/SOLORAE EQ 500MG BASE/2ML/

> DLT >

> ADD > AP

> DLT > /ABP/ /SHUTU/NEORHEW/SOLORAE EQ 1GM BASE/3ML/

> DLT >

> ADD > AP

> ADD >

KETOPROFEN

CAPSULE; ORAL

KETOPROFEN
BIOCRAFT

25MG

50MG

75MG

N73515 001
DEC 22, 1992

N73516 001
DEC 22, 1992

N73517 001
DEC 22, 1992

ORUDIS

MYETH AYERST

25MG

50MG

75MG

N18754 001
JUL 31, 1987

N18754 002
JAN 09, 1986

N18754 003
JAN 09, 1986

+

KETOROLAC TROMETHAMINE

SOLUTION/DROPS; OPHTHALMIC
ACULAR

SYNTEX

0.5/M

N19700 001
NOV 09, 1992

TABLET; ORAL
TORADOL

+ SYNTEX

10MG

/10MG/

N19645 001
DEC 20, 1991
/N19645/001/
/DEC/20,1991/

LACTULOSE

SYRUP; ORAL
LACTULOSE
PACO

AA

10GM/15MLM

N73160 001
AUG 25, 1992

AA ROXANE

AA

10GM/15MLM

N73591 001
MAY 29, 1992

AA UDL

AA

10GM/15MLM

N74138 001
SEP 30, 1992

SYRUP; ORAL, RECTAL
LACTULOSE
PACO

AA

10GM/15MLM

N72029 001
AUG 25, 1992

AA ROXANE

AA

10GM/15MLM

N73590 001
MAY 29, 1992

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
/ABP/ /ABIC/

/EQ 3MG BASE/ML/

/EQ 50MG BASE/VIAL/

3 ABIC

EQ 3MG BASE/ML

N89352 001
JUN 01, 1988

3

EQ 50MG BASE/VIAL

N89353 001
JUN 01, 1988

/ABP/ /LYPHOMED/

/EQ 50MG BASE/VIAL/

N88939 001
DEC 01, 1986

3 LYPHOMED

EQ 50MG BASE/VIAL

N88939 001
DEC 01, 1986

LEVOCARNITINE

> ADD > INJECTABLE; INJECTION

CARNITOR

SIGMA TAU

200MG/MLM

N20182 001
DEC 16, 1992

INJECTABLE; INJECTION

LIDOCAINE HCL

/INTL/MEDICATION/

3 INTL MEDICATION

/15M/VIAL/

15M/VIAL

/25M/VIAL/

25M/VIAL

/N18543/001/
N18543 001
/N18543/002/
N18543 002

SOLUTION; ORAL

CARNITOR

SIGMA TAU

1GM/10ML

N19257 001
APR 10, 1986

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

200MG/100MLM

N19830 002

AA

SIGMA TAU

/1GM/10ML/

/N19257/001/
/APR/10/1986/

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

400MG/100MLM

N19830 003

BB

/VITACARB/

/M-SAN/

LEVODOPA

CAPSULE; ORAL

DOPAR

/+/P/AND/S/

/500MG/

/100MG/

/250MG/

500MG

100MG

250MG

+ ROBERTS

> DLT >

> ADD >

> DLT >

> ADD >

/N16913/001/
N16913 001
/N16913/002/
N16913 002
/N16913/003/
N16913 003
/N16913/001/
N16913 001

/N60567/001/
N60567 001
/N60567/002/
N60567 002

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

+ ROCHE

2MG

/1MG/

N08720 001
DEC 19, 1991

/N08720/001/
/DEC/19/1991/

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

/B+/ /PHARM/BASICS/

/300MG/

3 PHARM BASICS

300MG

/N72542/001/
/FEB/01/1989/
N72542 001
FEB 01, 1989

LIDOCAINE; PRILLOCAINE

CREAM; TOPICAL

EMLA

+ ASTRA

2.5%:2.5%:2M

N19941 001
DEC 30, 1992

TABLET; ORAL

MAXAQUIN

+ SEARLE

EQ 400MG BASEM

N20013 001
FEB 21, 1992

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

LOPERAMIDE HCL

GENEVA

2MG

N72993 001
AUG 28, 1992

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

/B# / PHARM/BASICS/

/B# /

2 PHARM BASICS

2

/20MG/

/40MG/

20MG

40MG

/N70646/001/

/DEC/01/1987/

/N70647/001/

/DEC/01/1987/

N70646 001

OCT 02, 1987

MELPHALAN HYDROCHLORIDE

INJECTABLE; INJECTION

ALKERAN

BURROUGHS WELLCOME

EQ 50MG BASE/VIALM

N20207 001

NOV 18, 1992

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

ABBOTT

10MG/ML

/AP /

/AP /

/AP /

/50MG/ML/

/75MG/ML/

/100MG/ML/

N88432 001

AUG 16, 1984

/N80364/002/

/N80364/003/

/N80364/001/

N80364 002

N80364 003

N80364 001

MAR 17, 1992

MAR 17, 1992

MAR 17, 1992

N73443 001

MAR 17, 1992

MAR 17, 1992

N73445 001

MAR 17, 1992

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

POCLOCAINE/

ASTRA

/AP /

/AP /

/AP /

/12/

/1.52/

/22/

/N89406/001/

/DEC/01/1986/

/N89408/001/

/DEC/01/1986/

/N89409/001/

/DEC/01/1986/

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

POCLOCAINE-MPE

ASTRA

AP

AP

AP

12

1.52

22

N89406 001

DEC 01, 1986

N89408 001

DEC 01, 1986

N89409 001

DEC 01, 1986

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

3 ELKINS SINN

3

EON LABS

AA

AA

AA

BB

BB

> DLT >

> ADD >

200MG

400MG

200MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

N15426 002

N15426 001

N14547 002

N14547 001

N16928/003/

N16928/001/

N16928 003

N84329 001

N15139/006/

N15139/005/

N15139 006

N15139 005

N84744/001/

N84744/002/

N84744 001

N84744 002

N15426/002/

N15426/001/

N15426 001

N15426/002/

N15426/001/

N15426 001

N15426/002/

N15426/001/

N15426 001

N19651 001

JAN 31, 1992

TABLET, DELAYED RELEASE; ORAL

ASACOL

+ P AND G

400MG

MESALAMINE

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

METAPROTERENOL SULFATE

SOLUTION; INHALATION

METAPROTERENOL SULFATE

/AN/ /ARMOUR/ /0.4% /

/AN/ /0.6% /

AN ASTRA

0.4% /

AN

0.6% /

/PEX/

/0.33% /

a DEY

0.33% /

a

/0.5% /

a

0.5% /

PROMETA

5% /

MURO

5% /

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

SYRUP; ORAL

METAPROTERENOL SULFATE

AA BIOCRRAFT

10MG/5MLM

AA SILARX

10MG/5MLM

TABLET; ORAL

METAPROTERENOL SULFATE

/B# /PHARM/BASIC/ /10MG /

/B# /10MG /

a PHARM BASICS

10MG

20MG

/CAPSULE; ORAL/

/PONDICHYCN/

/WALLACE/

a WALLACE

a

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

METHACYCLINE HYDROCHLORIDE

/SYRUP; ORAL/

/PONDICHYCN/

/WALLACE/

a WALLACE

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

/N71275/001

/JUL/27/1988

/N71018/001

/JUL/27/1988

/N71275/001

/JUL/27/1988

/N71018/001

/JUL/27/1988

/N71275/001

/JUL/27/1988

/N71018/001

/JUL/27/1988

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/N71018/001

/JUL/27/1988

/N71275/001

/JUL/27/1988

/N71018/001

METHOTREXATE SODIUM

INJECTABLE; INJECTION

ABITREXATE

/ABIC/

/EQ 250MG BASE/VIAL/

/MAR/10, 1987/

/AP/

TABLET; ORAL

METHYLCLOTHIAZIDE

/PHARM/BASICS/

/5MG/

/N88745/001/

/MAR/21, 1985/

N88745 001

MAR 21, 1985

METHYLDOPA

TABLET; ORAL

METHYLDOPA

/PARKE/DAVIS/

/125MG/

/N70331/001/

/APR/15, 1986/

N70331 001

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

/EON LABS/

/4MG/

/N87341/001/

/APR/15, 1986/

N87341 001

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

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APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE

/ELKINS/SINN/

/EQ 125MG BASE/VIAL/

/N86906/002/

/APR/15, 1986/

N86906 002

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

METHOXYFLURANE

LIQUID; INHALATION

PENTHRANE

/ABBOTT/

99.9%

N13056 001

/AP/

/ELKINS/SINN/

/EQ 125MG BASE/VIAL/

/N86906/002/

/APR/15, 1986/

N86906 002

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

SOLUTION; INHALATION

PENTHRANE

/ABBOTT/

99.9%

N13056/001/

/AP/

/ELKINS/SINN/

/EQ 40MG BASE/VIAL/

/N86906/001/

/APR/15, 1986/

N86906 001

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

APR 15, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

METHYLPREDNISOLONE SODIUM SUCCINATEINJECTABLE; INJECTIONMETHYLPREDNISOLONE SODIUM SUCCINATE

AP GENISA EQ 125MG BASE/VIALM

AP EQ 500MG BASE/VIALM

AP EQ 1GM BASE/VIALM

N81266 001

NOV 30, 1992

N81267 001

NOV 30, 1992

N81268 001

NOV 30, 1992

TABLET; ORALDIULO/

/AB/ SCHIAPPARELLI/SEARLE/2.5MG/

/AB/ 5MG/

/AB/ 10MG/

a SCHIAPPARELLI SEARLE 2.5MG

a 5MG

a 10MG

/N18535/001/

/N18535/002/

/N18535/003/

N18535 001

N18535 002

N18535 003

METOCLOPRAMIDE HYDROCHLORIDECONCENTRATE; ORALMETOCLOPRAMIDE INTENSOL

ROXANE EQ 10MG BASE/MLM

N72995 001

JAN 30, 1992

ZAROXOLYN

/AB/ FISON/

/AB/ 2.5MG/

/AB/ 5MG/

/AB/ 10MG/

+ FISON

/N17386/001/

/N17386/002/

/N17386/003/

N17386 003

N17386 001

N17386 002

METOPROLOL SUCCINATEINJECTABLE; INJECTIONMETOCLOPRAMIDE HCL

CETUS BEN VENUE

EQ 10MG BASE/2MLM

N72155 001

MAR 30, 1992

EQ 10MG BASE/2MLM

N72244 001

MAR 30, 1992

EQ 10MG BASE/2MLM

N72247 001

MAY 18, 1992

EQ 10MG BASE/2MLM

N70293 001

JAN 24, 1986

EQ 10MG BASE/2MLM

/N70293/001/

/JAN/24, 1986/

> ADD > AP

> ADD >

> DLT > /AP/

> DLT >

TABLET, EXTENDED RELEASE; ORALTOPROL XL

+ HASSLE

EQ 50MG TARTRATEM

N1962 001

JAN 10, 1992

EQ 100MG TARTRATEM

N1962 002

JAN 10, 1992

EQ 200MG TARTRATEM

N1962 003

JAN 10, 1992

METRONIDAZOLEGEL; VAGINALMETROGEL

+ CURATEK

0.75/M

N20208 001

AUG 17, 1992

SOLUTION; ORALMETOCLOPRAMIDE HCL

AA SILLARX

EQ 5MG BASE/5MLM

N73680 001

OCT 27, 1992

INJECTABLE; INJECTIONMETRONIDAZOLE

/AP/ /LYPHOMED/

/500MG/100ML/

/N70071/001/

/DEC/03, 1984/

a LYPHOMED

500MG/100ML

DEC 03, 1984

TABLET; ORALMETOCLOPRAMIDE HCL

/AP/ /INTERPHARM/

/EQ/10MG/BASE/

/N71213/001/

/SEP/24, 1986/

SEP 24, 1986

EQ 10MG BASE

N71213 001

/AP/ /PHARM/BASICS/

/EQ/10MG/BASE/

/N70339/001/

/JUL/29, 1985/

EQ 10MG BASE

N70339 001

JUL 29, 1985

a PHARM BASICS

METRONIDAZOLE

TABLET; ORAL

METRONIDAZOLE

250MG

AB

EON LABS

AB

500MG

AB

EON LABS

AB

1000MG

AB

EON LABS

AB

1000MG

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EON LABS

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

NABUMETONE

TABLET; ORAL
RELAFEN
+ SMITHKLINE BEECHAM

750MG
/750MG/

N19583 002
DEC 24, 1991
/N19583/002/
/DEC/24,1991/

NAPROXEN

TABLET; ORAL
NAPROSYN
SYNTEX

250MG
375MG
500MG

N17581 002
N17581 003
N17581 004
APR 15, 1982

NAPROXEN
HAMILTON

250MG

N74110 001
OCT 30, 1992

NAFARELIN ACETATE

SPRAY, METERED; NASAL
SYNAREL
SYNTEX

EQ 0.2MG BASE/INHML

N20109 001
FEB 26, 1992

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE
/AP/ /LYPHOMED/

10MG/ML
20MG/ML

/N70751/001/
/JUL/02,1986/
/N70752/001/
/JUL/02,1986/
N70751 001
JUL 02, 1986
N70752 001
JUL 02, 1986

3 LYPHOMED

3

> ADD > NEDOCROMIL SODIUM

> ADD > AEROSOL, METERED; INHALATION

> ADD > TILADE
> ADD > + FISOONS

1.75MG/INHML

N19660 001
DEC 30, 1992

NEOMYCIN SULFATE

TABLET; ORAL
NEOMYCIN SULFATE
EON LABS

EQ 350MG BASE
/EQ 350MG BASE/

N61586 001
/N61586/001/

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL
FUJISAWA

0.02MG/ML
0.4MG/ML

N70648 001
NOV 17, 1986
N70649 001
NOV 17, 1986

/0.02MG/ML/
/0.4MG/ML/

/N70648/001/
/NOV/17,1986/
/N70649/001/
/NOV/17,1986/
/N70650/001/
/NOV/17,1986/
/N70651/001/
/NOV/17,1986/
/N70652/001/
/NOV/17,1986/

/0.02MG/ML/
/0.4MG/ML/

/N70653/001/
/NOV/17,1986/
/N70654/001/
/NOV/17,1986/
/N70655/001/
/NOV/17,1986/
/N70656/001/
/NOV/17,1986/
/N70657/001/
/NOV/17,1986/

SOLOPAK MEDCL

0.02MG/ML
0.4MG/ML

NOV 17, 1987
N71683 001
NOV 17, 1987

NEOMYCIN SULFATE; PREDNISOLONE ACETATE

/SUSPENSION/PROPS; /OPHTHALMIC/
/NEO-DELTA-CORTÉF/
/UP JOHN/
3 UP JOHN

/EQ/3.5MG/BASE/ML; 0.25% /N61037/001/
EQ 3.5MG BASE/ML; 0.25% N61037 001

NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE

/OINTMENT; /OPHTHALMIC/
/NEO-HYDELTRASOL/
/HSP/
3 MSD

/EQ/3.5MG/BASE/ML; 0.25% /N50378/001/
/EQ/0.25% /PHOSPHATE/
EQ 3.5MG BASE/GM; N50378 001
EQ 0.25% PHOSPHATE

NIACIN

TABLET; ORAL

NIACIN

AA HOCKHARDT

500MG

N81134 001
APR 28, 1992

FILM, EXTENDED RELEASE; TRANSFERMAL
PROSTEP
+ ELAN

11MG/24HR

N19983 001
JAN 28, 1992

22MG/24HR

N19983 002
JAN 28, 1992

NICARDIPINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDENE SR

+ SYNTAX

30MG

45MG

60MG

N20005 001
FEB 21, 1992
N20005 002
FEB 21, 1992
N20005 003
FEB 21, 1992

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICORETTE

+ MERRELL DOW

EQ 2MG BASE

/EQ/2MG/BASE/

N18612 001
JAN 13, 1984
/N18612/001/
/JAN/13/1984/

NICORETTE DS

+ MERRELL DOW

EQ 4MG BASE

N20066 001
JUN 08, 1992

INJECTABLE; INJECTION

CARDENE

DUPONT MERCK

2.5MG/ML

N19734 001
JAN 30, 1992

/GUM;/CHEWING;/ORAL/
/NICORETTE/DS/
/+/MERRELL/DOW/

/4MG/

/N20066/001/
/JUN/08/1992/

NICOTINE

FILM, EXTENDED RELEASE; TRANSFERMAL

NICODERM

/BC/ /MARION/MERRELL/DOW/ /7MG/24HR/

BC + MARION MERRELL DOW

7MG/24HR

/BC/ /14MG/24HR/

BC +

14MG/24HR

/BC/ /21MG/24HR/

BC +

21MG/24HR

NICOTROL

+ KABI

5MG/16HR

10MG/16HR

15MG/16HR

N80043 001
N80043 002
/N80043/001/
/N80043/002/

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

AB NOVOPHARM

10MG

N72651 001
FEB 19, 1992

20MG

N74045 001
APR 30, 1992

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

3 EON LABS

3

/3/VITARINE/

50MG

100MG

/50MG/

/100MG/

NYSTATIN

/SUPPOSITORIES/VAGINAL/
/NYSTATIN/
/P/AND/G/
@ P AND G

/100,000 UNITS/
100,000 UNITS

/N50478/001/
N50478 001

TABLET; ORAL

NYSTATIN

/AA/ /CHELSEA/

/500,000 UNITS/
500,000 UNITS

/N62402/001/
DEC 16, 1982

AA
/AA/

/500,000 UNITS/
500,000 UNITS

/N62065/001/
N62065 001

TABLET; VAGINAL

NYSTATIN

@ EON LABS

/A/ /VITARINE/

/100,000 UNITS/
100,000 UNITS

/N61965/001/
N61965 001

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

/DEBACOMB/

/AI/ /TARO/

/100,000 UNITS/GM;0.1%/
DEC/22,1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

/AI/ /CLAY/PARK/

/100,000 UNITS/GM;0.1%/
JUN/06,1985

/N62186/002/
N62186 002

B*
/AI/

100,000 UNITS/GM;0.1%
JUN 06, 1985

NYSTATIN AND TRIAMCINOLONE ACETONIDE

AI
/AI/

100,000 UNITS/GM;0.1%
DEC 22, 1987

/N62364/001/
N62364 001

NYSTATIN AND TRIAMCINOLONE ACETONIDE

THAMES

/AI/

100,000 UNITS/GM;0.1%
MAR 30, 1987

/N62347/001/
N62347 001

NYSTATIN-TRIAMCINOLONE ACETONIDE

/AI/ /THAMES/

/100,000 UNITS/GM;0.1%/
MAR/30,1987

/N62347/001/
N62347 001

ONYX-101; TOPICAL

ONYX-101

/AI/ /SQUIBB/

/100,000 UNITS/GM;0.1%/
JUN/28,1985

/N60572/001/
N60572 001

AI
/AI/

100,000 UNITS/GM;0.1%
JUN 28, 1985

/N60572/001/
N60572 001

OFLOXACIN

INJECTABLE; INJECTION

FLOXIN

JOHNSON RH

20MG/MLM

N20087 002
MAR 31, 1992

40MG/MLM

N20087 003
MAR 31, 1992

FLOXIN IN DEXTROSE 5%

JOHNSON RH

400MG/100MLM

N20087 001
MAR 31, 1992

FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

JOHNSON RH

4MG/MLM

N20087 004
MAR 31, 1992

400MG/100MLM

N20087 005
MAR 31, 1992

ONDANSETRON HYDROCHLORIDE

TABLET; ORAL

ZOFRAN

+ GLAXO

EQ 8MG BASEM

N20103 002
DEC 31, 1992

TABLET; ORAL

DAYPRO

+ SEARLE

EQ 4MG BASEM

N20103 001
DEC 31, 1992

OXAPROZIN

TABLET; ORAL

DAYPRO

+ SEARLE

600MG

N18841 004
OCT 29, 1992

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

/B*/ /CHELSEA/

/10MG/

/N71661/001/
MAR/02,1988

/B*/

/15MG/

/N71662/001/
MAR/02,1988

/B*/

/30MG/

/N71663/001/
MAR/02,1988

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'92 - DEC'92

OXICONAZOLE NITRATE

LOTION; TOPICAL
OXISTAT
+ GLAXO

EQ 1% BASEM

N20209 001
SEP 30, 1992

/N62003/001/
/N62003/002/
N62003 001
N62003 002

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE
/P# /PHARM/BASICS/
a PHARM BASICS

/5MG/

5MG

/N14746/001/
/MAR/10, 1988/
N70746 001
MAR 10, 1988

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

/PENAPAS-VK/
/PARKE/DAVIS/
/AA/
/AA/
a PARKE DAVIS
a

/EQ 125MG BASE/5ML/
/EQ 250MG BASE/5ML/
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML

/N62002/001/
/N62002/002/
N62002 001
N62002 002

> ADD > PACLITAXEL

> ADD > INJECTABLE; INJECTION
> ADD > TAXOL
> ADD > BRISTOL MYERS SQUIBB
> ADD >

6MG/MLM

N20262 001
DEC 29, 1992

TABLET; ORAL

/PENAPAS-VK/
/PARKE/DAVIS/
/AB/
/AB/
a PARKE DAVIS
a

/EQ 450MG BASE/
/EQ 500MG BASE/
EQ 450MG BASE
EQ 500MG BASE

/N62001/001/
/N62001/002/
N62001 001
N62001 002

PARGYLINE HYDROCHLORIDE

/TABLET; ORAL/
/EUTONYL/
/A/ /ABBOTT/
a ABBOTT
a

/25MG/
/10MG/
10MG
25MG

/N13448/003/
/N13448/002/
N13448 002
N13448 003

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTAM 300
FUJISAMA

300MG/VIAL

N19264 001
OCT 16, 1984

AP
PENTAMIDINE ISETHIONATE
AP ABBOTT
300MG/VIALM

N73479 001
JUN 30, 1992

PAROXETINE HYDROCHLORIDE

TABLET; ORAL
PAXIL
+ SMITHKLINE BEECHAM
+

EQ 10MG BASEM
EQ 50MG BASEM
EQ 20MG BASEM
EQ 30MG BASEM
EQ 40MG BASEM

N20031 001
DEC 29, 1992
N20031 004
DEC 29, 1992
N20031 002
DEC 29, 1992
N20031 003
DEC 29, 1992
N20031 005
DEC 29, 1992

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE
/P# /CHELSEA/

/4MG/

/N62001/001/
/DEC/23, 1987/

PHENIDIMETRAZINE TARTRATE

CAPSULE; ORAL

PHENIDIMETRAZINE TARTRATE

AA	35MG	N85633 001
AA	35MG	N85694 001
AA	35MG	N85695 001
AA	35MG	N85702 001
AA	35MG	N85633/001/
AA	35MG	N85634/001/
AA	35MG	N85695/001/
AA	35MG	N85702/001/

VITAMINE

CAPSULE, EXTENDED RELEASE; ORAL

PHENIDIMETRAZINE TARTRATE

BC	105MG	N18074 001
BC	105MG	N18074/001/

VITAMINE

TABLET; ORAL

ALPHAZINE

3 EON LABS	35MG	N85034 001
3	35MG	N85034/001/
3	35MG	N85034/001/
3	35MG	N85034/001/
3	35MG	N85034/001/
3	35MG	N85034/001/

VITAMINE

PHARM/BASICS

PHENIDIMETRAZINE TARTRATE

AA	35MG	N85402 001
AA	35MG	N85497 001
AA	35MG	N85588 001
AA	35MG	N85930 001
AA	35MG	N85402/001/
AA	35MG	N85497/001/
AA	35MG	N85588/001/
AA	35MG	N85930/001/

PHENIDIMETRAZINE TARTRATE

AA	35MG	N84399 001
AA	35MG	N83805 001
AA	35MG	N84398 001

PHENIDIMETRAZINE TARTRATE

AA	35MG	N85402/001/
AA	35MG	N85497/001/
AA	35MG	N85588/001/

VITAMINE

PHARM/BASICS

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

AA	15MG	N87301 001
AA	30MG	N86945 001
AA	30MG	N87190 001
AA	30MG	N87208 001
AA	30MG	N87223 001
AA	30MG	N87301/001/
AA	30MG	N86945/001/
AA	30MG	N87190/001/
AA	30MG	N87208/001/
AA	30MG	N87223/001/

VITAMINE

TABLET; ORAL

PHENTERMINE HCL

3 EON LABS	8MG	N85671 001
3	8MG	N85689 001
3	8MG	N85671/001/
3	8MG	N85689/001/

VITAMINE

PHENYLBUTAZONE

CAPSULE; ORAL

AA	100MG	N87260/001/
AA	100MG	N87260 001

TABLET; ORAL

AA	100MG	N87260/001/
AA	100MG	N87091 001

PHENYTOIN

SUSPENSION; ORAL

AB	125MG/5ML	N08762 001
AB	125MG/5ML	N89892 001

DILANTIN-125

PHARM/BASICS

PHENYTOIN

BARRE

PHARM/BASICS

PRAZEPAM

CAPSULE; ORAL

/BS/ /PHARM/BASICS/
/PRZEPAN/
/

1545/

/SHPI/

2 PHARM BASICS

5MG
10MG

CAPSULE; ORAL

EQ 2MG BASE
EQ 5MG BASE

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

EQ 5MG BASE
EQ 5MG BASE

TABLET, EXTENDED RELEASE; ORAL

PFIZER 2.5MG

2.5MGH
5MGH

PREDNISOLONE

TABLET; ORAL

5MG/5MG

2015

PREDNTSOL ONE

SMC

© HEATH
12/54/54

N18144 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL
/SCHERING/

> DLT > /AB/ /10MG/

> DLT > /AB/ /20MG/

> DLT > /AB/ /40MG/

> DLT > /AB/ /60MG/

> DLT > /AB/ /80MG/

> DLT > /AB/ /100MG/

> DLT > /AB/ /120MG/

> ADD > /AB/ /10MG/

> ADD > /AB/ /20MG/

> ADD > /AB/ /40MG/

> ADD > /AB/ /60MG/

> ADD > /AB/ /80MG/

> ADD > /AB/ /100MG/

> ADD > /AB/ /120MG/

> ADD > /AB/ /140MG/

> ADD > /AB/ /160MG/

> ADD > /AB/ /180MG/

> ADD > /AB/ /200MG/

> ADD > /AB/ /220MG/

> ADD > /AB/ /240MG/

> ADD > /AB/ /260MG/

> ADD > /AB/ /280MG/

> ADD > /AB/ /300MG/

> ADD > /AB/ /320MG/

> ADD > /AB/ /340MG/

> ADD > /AB/ /360MG/

> ADD > /AB/ /380MG/

> ADD > /AB/ /400MG/

/N70120/001/

/AUG 06, 1985/

/N70121/001/

/AUG 06, 1985/

/N70122/001/

/AUG 06, 1985/

/N70123/001/

/AUG 06, 1985/

/N70124/001/

/AUG 06, 1985/

/N70125/001/

/AUG 06, 1985/

/N70126/001/

/AUG 06, 1985/

/N70127/001/

/AUG 06, 1985/

/N70128/001/

/AUG 06, 1985/

/N70129/001/

/AUG 06, 1985/

/N70130/001/

/AUG 06, 1985/

/N70131/001/

/AUG 06, 1985/

/N70132/001/

/AUG 06, 1985/

/N70133/001/

/AUG 06, 1985/

TABLET; ORAL
PYRAZINAMIDE
AB + LEDERLE
AB MIKART

500MG
500MG

N80157 001
N81319 001
JUN 30, 1992

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION
PYRIDOXINE HCL
/LUITPOLD/
a LUITPOLD

/100MG/ML/
100MG/ML

QUINETHAZONE; RESERPINE

TABLET; ORAL
HYDROX/AL/
/LEDERLE/
a LEDERLE

/50MG; 0.125MG/
50MG; 0.125MG

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
a ELKINS SINN
EON LABS

200MG
200MG
300MG

N83622 001
N84631 001
N88072 001
SEP 26, 1983

/3/QUINIDINE/PHARMICS/
/VITARINE/
/AB/
/AB/

/200MG/
200MG/
300MG/

/N83622/001/
/N84631/001/
/N88072/001/
/SEP 26, 1983/

RAUMOLFIA SERPENTINA

TABLET; ORAL
/RAUMOLFIA/
/FOREST/PHARMS/
WOLFINA
a FOREST PHARMS

/50MG/
50MG

/N89255/001/
N89255 008

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

PSEUDOEPHEDRINE HCL AND TRIPROLIDINE HCL
EON LABS

60MG; 2.5MG

/60MG; 2.5MG/

N88193 001
MAY 17, 1983

/N88193/001/
/MAY 17, 1983/

/AB/ /VITARINE/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

> ADD > SUMATRIPTAN SUCCINATE

> ADD > INJECTABLE; INJECTION
 > ADD > IMITREX
 > ADD > GLAXO
 > ADD >

EQ 6MG BASE/0.5MLM

N20080 001
DEC 28, 1992

TABLET; ORAL
 OMNIFLOX
 @ ABBOTT
 @

EQ 400MG BASEM
 EQ 600MG BASEM

N20043 003
 JAN 30, 1992
 N20043 004
 JAN 30, 1992

TALBUTAL

/TABLET; ORAL/
 /LOXUSATE/
 /STERLING/
 @ STERLING

/120MG/
120MG/N09410/005/
N09410 005TEHAZEPAM

CAPSULE; ORAL
 TEHAZEPAM

/B# / PHARM/BASICS/
 /B# /

/15MG/
 /30MG/

/N70489/001/
 /JUL/07/1986/
 /N70490/001/
 /JUL/07/1986/
 N70489 001
 JUL 07, 1986
 N70490 001
 JUL 07, 1986

TECHNETIUM TC-99M ETIDRONATE KIT

INJECTABLE; INJECTION
 OSTEOSCAN
 /MALLINCKRODT/
 @ MALLINCKRODT

/N/A/
N/A/N17454/001/
N17454 001TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION
 RBC-SCAN
 CADEMA

N/A

N20063 001
JUN 11, 1992TENIPOSIDE

INJECTABLE; INJECTION
 VUMON
 BRISTOL MYERS SQUIBB

10MG/MLM

N20119 001
 JUL 14, 1992

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION
 CARDIOLITE
 /DUPONT/

N/A

N/A

/N19785/001/
 /DEC/21/1990/
 N19785 001
 DEC 21, 1990

TABLET; ORAL
 HYTRIN
 + ABBOTT

2MG
 /10MG/
 /2MG/
 10MG

N19057 002
 AUG 07, 1987
 /N19057/004/
 /AUG/07/1987/
 /N19057/002/
 /AUG/07/1987/
 N19057 004
 AUG 07, 1987

TEMAFLOXACIN HYDROCHLORIDE

TABLET; ORAL
 OMNIFLOX
 /@/ABBOTT/

/EQ/600MG/BASIS/

/EQ/600MG/BASIS/

/N20043/004/
 /JAN/30/1992/
 /N20043/003/
 /JAN/30/1992/

> ADD > TERBINAFINE HYDROCHLORIDE

CREAM; TOPICAL
 LANISIL
 + SANDOZ

1/2M

N20192 001
 DEC 30, 1992

TERBUTALINE SULFATEINJECTABLE; INJECTIONBRETHINE

/GEIGY/

> DLT > /AP/
> ADD > AP/1MG/ML/
/1MG/ML/N18571/001/
N18571 001TESTOSTERONE ENANTHATEINJECTABLE; INJECTIONDELATESTYL

a GYNEX

200MG/ML

N09165 003

200MG/ML

N09165 001

/400MG/ML/

/N09165/003/

/200MG/ML/

/N09165/001/

TETRACYCLINE

SYRUP; ORAL

/BIDDYCLINE/

/PARKE/

/EQ 125MG HCL/5ML/

/N60633/001/

TETRACYCLINE

a BARRE

EQ 125MG HCL/5ML

N60633 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

/CICLOPAB/

/PARKE/DAVIS/

/450MG/

/250MG/

/N51725/001/

/250MG/

/N51725/001/

/250MG/

/N52332/001/

/250MG/

/N51725/002/

/250MG/

/N52332/002/

a WARNER CHILCOTT

250MG

N61725 001

250MG

N62175 001

250MG

N62332 001

250MG

N61725 002

500MG

N62332 002

ROBITEL

/ROBINS/

/450MG/

/250MG/

/N51734/001/

250MG

/N51734/002/

MYETH AYERST

250MG

N61734 001

500MG

N61734 002

250MG

N60429 001

500MG

N60429 003

100MG

N60429 002

125MG

N60429 004

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

SUNYCON

/SQUIBB/

/100MG/

/125MG/

/N60429/002/

/250MG/

/250MG/

/N60429/004/

/500MG/

/500MG/

/N60429/001/

/500MG/

/500MG/

/N60429/003/

TETRACYCLINE HCL

/VITARINE/

EON LABS

/450MG/

/250MG/

/N61471/001/

/250MG/

/250MG/

/N61471 001

/500MG/

/500MG/

/N61471/002/

/500MG/

/500MG/

/SEP/06, 1988

/450MG/

/450MG/

/N61148/001/

/500MG/

/500MG/

/N61148/002/

250MG

250MG

N61148 001

500MG

500MG

N61148 002

/125MG/

/125MG/

/N60173/001/

125MG

125MG

N60173 001

/450MG/

/450MG/

/N62300/001/

/500MG/

/500MG/

/N62300/002/

/100MG/

/100MG/

/N60469/002/

100MG

100MG

N60469 002

250MG

250MG

N62300 001

500MG

500MG

N62300 002

INJECTABLE; INJECTION/ACHESON

/LEDERLE/

/100MG/VIAL/

/100MG/VIAL/

/N50267/002/

/250MG/VIAL/

/250MG/VIAL/

/N50267/001/

/250MG/VIAL/

/250MG/VIAL/

/N50267/003/

/450MG/VIAL/

/450MG/VIAL/

/N50265/003/

/200MG/VIAL/

/200MG/VIAL/

/N50265/002/

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SOMOPHYLLIN-CRT

/Fisons/

/50MG/

/50MG/

/N51763/001/

/50MG/

/50MG/

/FEB/27, 1985

/50MG/

/50MG/

/N51763/001/

/50MG/

/50MG/

/FEB/27, 1985

/250MG/

/250MG/

/N51763/001/

/50MG/

/50MG/

/FEB/27, 1985

/50MG/

/50MG/

/N51763/001/

/50MG/

/50MG/

/FEB/27, 1985

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SONOPHYLLIN-CRT

GRAHAM LABS

BC 50MG N87763 001 FEB 27, 1985

BC 100MG N87194 001

BC 200MG N88382 001

FEB 27, 1985

BC 250MG N87193 001

BC 300MG N88383 001

FEB 27, 1985

THEO-24

/BC/ /SEARLE/

/100MG/ N87444 001

/200MG/ N87443 001

/300MG/ N87444 001

/400MG/ N87444 001

BC 100MG N87942 001

BC 200MG N87943 001

BC 300MG N87944 001

400MG N81034 001

THEOPHYLLINE

3 EON LABS

/200MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

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/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

/250MG/ N87462 001

THEOPHYLLINE

INJECTABLE; INJECTION

THEOPHYLLINE 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

400MG/100ML

AP MCGAM N19826 005

AUG 14, 1992

TABLET, EXTENDED RELEASE; ORAL

T-PHYL

BC PURDUE FREDERICK

200MG

N88253 001

AUG 17, 1983

THEO-DUR

AB + KEY PHARMS

450MG

N89131 001

JUN 25, 1986

THEOCONTIN

/BC/ /PURDUE/FREDERICK/

/200MG/

N88453 001

AUG 17, 1983

THEOPHYLLINE

AB SIDHAK

450MG

N81236 001

NOV 09, 1992

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

/AB/ /LUITPOLD/

3 LUITPOLD

/AB/ /PARKE/DAVIS/

3 PARKE DAVIS

/AB/ /LUITPOLD/

/AB/ /LUITPOLD/

/AB/ /LUITPOLD/

/AB/ /LUITPOLD/

/AB/ /LUITPOLD/

/AB/ /LUITPOLD/

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/AB/ /LUITPOLD/

THIURIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIURIDAZINE HCL

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

/AB/ /PAR/

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/AB/ /PAR/

/AB/ /PAR/

N88764 001

FEB 09, 1988

N89765 001

FEB 09, 1988

N89764 001

FEB 09, 1988

N89765 001

FEB 09, 1988

N89764 001

FEB 09, 1988

N89765 001

FEB 09, 1988

N89764 001

FEB 09, 1988

N89765 001

FEB 09, 1988

N89764 001

FEB 09, 1988

N89765 001

FEB 09, 1988

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL INTENSOL

AA ROXANE

EQ 5MG BASE/MLM

N73494 001
JUN 30, 1992

TABLET; ORAL

TOLAZAMIDE

/AB/ INTERPHARM/

/250MG/

/N71270/001/
SEP 23, 1986

/AB/

/500MG/

/N71271/001/
SEP 23, 1986

B* INTERPHARM

250MG

N71270 001
SEP 23, 1986

TABLET; ORAL

TIMOLOL MALEATE

/B*/ PHARM/BASICS/

/5MG/

/B*/ PHARM/BASICS/

/100MG/

/N71355/001/
JAN 11, 1988

/B*/

/10MG/

/B*/

/250MG/

/N71356/001/
APR 02, 1986

/B*/

/20MG/

/B*/

/500MG/

/N71357/001/
APR 02, 1986

3 PHARM BASICS

5MG

3 PHARM BASICS

100MG

N71355 001
JAN 11, 1988

3

10MG

3

250MG

N70168 001
APR 02, 1986

3

20MG

3

500MG

N70169 001
APR 02, 1986

TIOCONAZOLE

OINTMENT; VAGINAL

VAGISTAT-1

/BRISTOL MYERS/

/6.5%/

/N71355/001/
DEC 30, 1986

BRISTOL MYERS SQUIBB 6.5%

AB

EON LABS

500MG

N12678 001
/N86047/001/
N86047 001

/AB/

/PARKE DAVIS/

/500MG/

/N12678/001/
N86047 001

/AB/

/VITARINE/

/500MG/

/N12678/001/
N86047 001

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

AP ABBOTT

EQ 40MG BASE/MLM

N63116 001
MAY 18, 1992

AP GENSLA

EQ 40MG BASE/MLM

N63100 001
JAN 30, 1992

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

AB

BAKER CUMMINS

EQ 400MG BASEM

N73392 001
JAN 24, 1992

AB

GENEVA

EQ 400MG BASEM

N73462 001
APR 30, 1992

AB

LEMMON

EQ 400MG BASEM

N73519 001
MAY 29, 1992

AB

PUREPAC

EQ 400MG BASEM

N73308 001
JAN 24, 1992

TOLMETIN SODIUM

TABLET; ORAL

TOLMETIN 600

AB + JOHNSON RM

TOLMETIN SODIUM

GENEVA

AB PUREPAC

EQ 600MG BASE

EQ 200MG BASEM

EQ 600MG BASEM

N17628 002

MAR 08, 1989

N73588 001

JUL 31, 1992

N73527 001

JUN 30, 1992

> DLT > /AB/

> DLT >

> ADD > AP

> ADD >

/N89644/001/

/APR/04/1986/

N89094 001

APR 04, 1986

100MG/ML

SOLOPAK MEDCL

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

/SHUTTLE/NEOHEM/SOLOPAK/100MG/ML/

100MG/ML

> DLT > /AB/

> DLT >

> ADD > AP

> ADD >

/N89644/001/

/APR/04/1986/

N89094 001

APR 04, 1986

100MG/ML

SOLOPAK MEDCL

TRIMIPRAMINE MALEATE

CAPSULE; ORAL

SURMONTIL

/AB/ /MYETH AYERST/

/AB/ /MYETH AYERST/

/AB/ /MYETH AYERST/

+ MYETH AYERST

/EQ 100MG BASE

/EQ 25MG BASE

/EQ 50MG BASE

/EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N16792/001/

/SEP 15, 1982/

N16792 003

SEP 15, 1982

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL

TRIPLE SULFA

AT CLAY PARK

3.7%; 2.86%; 3.42%

N87285 001

NOV 15, 1982

AT FOUGERA

3.7%; 2.86%; 3.42%

N86424 001

NOV 15, 1982

AT NMC

3.7%; 2.86%; 3.42%

N87864 001

SEP 01, 1982

AT SAVAGE

3.7%; 2.86%; 3.42%

N87887 001

JUL 23, 1982

VAGILIA

3.7%; 2.86%; 3.42%

N88821 001

NOV 09, 1987

3 LEMMON

3.7%; 2.86%; 3.42%

N88821 001

NOV 09, 1987

TABLET; VAGINAL

SULTRIN

JOHNSON RW

TRIPLE SULFA

3 FOUGERA

3 PHARMADERM

184MG;143.75MG;172.5MG

N05794 002

184MG;143.75MG;172.5MG

N88463 001

184MG;143.75MG;172.5MG

N88462 001

JAN 03, 1985

JAN 03, 1985

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

SULFACETAMIDE

FOREST/PHARMS

3 FOREST PHARMS

/500MG/5ML/

N80100 001

N80100 001

URACIL MUSTARD

CAPSULE; ORAL

URACIL MUSTARD

ROBERTS

/100/100/

1MG

N12892 001

N12892 001

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

COBLEY

250MG/5ML

N73178 001

AUG 25, 1992

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOMYCIN HCL

ABBOTT

AP

EQ 500MG BASE/VIAL

N62931 001

OCT 29, 1992

AP

EQ 1GM BASE/VIAL

N62933 001

OCT 29, 1992

> DLT >

/VANGOL/

/ED 500MG BASE/VIAL/

N62956 001

AUG 01, 1988

> DLT >

/ADRIA/

/ED 1GM BASE/VIAL/

N62956 002

AUG 01, 1988

> DLT >

3 ADRIA

EQ 500MG BASE/VIAL

N62956 001

AUG 01, 1988

> ADD >

3

EQ 1GM BASE/VIAL

N62956 002

AUG 01, 1988

> ADD >

3

EQ 1GM BASE/VIAL

N62956 002

AUG 01, 1988

VECURNIUM BROMIDE

INJECTABLE; INJECTION

NORCURON

ORGANON

20MG/VIAL

N18776 003

JAN 03, 1992

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN

+ ELAN

180MG

N19614 003

JAN 09, 1992

INJECTABLE; INJECTION

VERAPAMIL HCL

/SOLOPAK MEDCL

2.5MG/ML

N70695 001

JUL 31, 1987

> DLT >

/SOLOPAK MEDCL

2.5MG/ML

N70695 001

JUL 31, 1987

> DLT >

/SOLOPAK MEDCL

2.5MG/ML

N70695 001

JUL 31, 1987

> ADD >

/SOLOPAK MEDCL

2.5MG/ML

N70695 001

JUL 31, 1987

TABLET; ORAL

VERAPAMIL HCL

/GENEVA

/80MG/

N70695 001

JUL 31, 1987

> DLT >

/GENEVA

/80MG/

N70695 001

JUL 31, 1987

> DLT >

/GENEVA

/80MG/

N70695 001

JUL 31, 1987

> ADD >

/GENEVA

/80MG/

N70695 001

JUL 31, 1987

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

VERAPAMIL HCL
/3/PARKE/DAVIS/

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

/60MG/

/N70340/001/
/AUG/20, 1986/

/120MG/

/N70341/001/
/AUG/20, 1986/

3 WARNER CHILCOTT

80MG

N70340 001

3

120MG

AUG 20, 1986
N70341 001
AUG 20, 1986

TABLET, EXTENDED RELEASE; ORAL

ISOPTIN SR

AB + KNOLL

240MG

N19152 001
DEC 16, 1986

VERAPAMIL HCL

BAKER CURRINS

240MG

N73568 001
JUL 31, 1992

VINBLASTINE SULFATE

INJECTABLE; INJECTION

/AB/ /VLSAB/
/BULL/

/10MG/VIAL/

VINBLASTINE SULFATE

AB BULL

10MG/VIAL

N89565 001
AUG 18, 1987

VINCISTINE SULFATE

INJECTABLE; INJECTION

VINCISTINE SULFATE

/AB/ /ABIC/

/1MG/ML/

3 ABIC

1MG/ML

/N70873/001/
/FEB/19, 1987/

N70873 001
FEB 19, 1987

VITAMIN A

CAPSULE; ORAL

AQUASOL A

AA ASTRA

/AA/ /USV/

50,000 USP UNITS

25,000 USP UNITS

/50,000 USP UNITS/
/25,000 USP UNITS/

N83080 001

N83080 002

/N63080/001/
/N63080/002/

VITAMIN A PALMITATE

CAPSULE; ORAL

VITAMIN A

3 ELKINS SINN

/3/QUANTUM/PHARMICS/

VITAMIN A PALMITATE

/BANNER/

3 BANNER GELATIN

EQ 50,000 UNITS BASE

/EQ/50,000 UNITS BASE/

/EQ/50,000 UNITS BASE/

EQ 50,000 UNITS BASE

EQ 50,000 UNITS BASE

N85479 001

/N85479/001/

/N85479/001/

N83981 001

N83981 001

WARFARIN SODIUM

TABLET; ORAL

/WARFARIN/SODIUM/

/BAY/ /PHARM/BASICS/

/BAY/ /PHARM/BASICS/

/BAY/ /PHARM/BASICS/

/BAY/ /PHARM/BASICS/

/BAY/ /PHARM/BASICS/

/BAY/ /PHARM/BASICS/

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/BAY/ /PHARM/BASICS/

/BAY/ /PHARM/BASICS/

/N86719/001/

/JUN/27, 1985/

/N86720/001/

/AUG/06, 1985/

/N86721/001/

/JUL/02, 1985/

N88719 001

JUN 27, 1985

N88720 001

AUG 06, 1985

N88721 001

JUL 02, 1985

XENON, XE-133

/SOLUTION; INHALATION; INJECTION/

/XENON/

/XENON/

/XENON/

/XENON/

/XENON/

/XENON/

/XENON/

/XENON/

/XENON/

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/XENON/

/N17262/002/

N17262 002

N20199 002

JUN 19, 1992

N20199 001

JUN 19, 1992

> ADD > ZOLPIDEM TARTRATE

> ADD > TABLET; ORAL

> ADD > AMBIEN

> ADD > + LOREX

> ADD >

> ADD >

> ADD >

10MGH

5MGH

N19908 002

DEC 16, 1992

N19908 001

DEC 16, 1992

ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACEPHEN

+ G AND M

> ADD >

> ADD >

> ADD >

> ADD >

> DLT >

120MG

325MG

650MG

/120MG/

120MG

> DLT >

> DLT >

> DLT >

N18060 001

N18060 003

DEC 18, 1986

N18060 002

/N18060/001/

N72218 001

MAR 27, 1992

/N18060/003/

/DEC 18, 1986/

N72344 001

MAR 27, 1992

/N18060/002/

N72237 001

MAR 27, 1992

> ADD >

> ADD >

> ADD >

TABLET; ORAL

CLEMASTINE FUMARATE

LEMON

TAVIST-1

SANDOZ

1.34MG

1.34MG

N73282 002
DEC 03, 1992N17661 003
AUG 21, 1992CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST-D

SANDOZ

1.34MG; 75MG

N18298 002
AUG 21, 1992DEXBROPHENIRAMINE MALEATE; PSEUDOPHEDRINE SULFATEAVOBENZONE; OCTYL METHOXYCINNAMATE; OXYBENZONE

LOTION; TOPICAL

SHADE UVAGUARD

PLOUGH

3%; 7.5%; 5/M

N20045 001

DEC 07, 1992

> ADD >

> ADD >

> ADD >

> ADD >

TABLET, EXTENDED RELEASE; ORAL

/RESPOVAL/

/PIONEER/PHARMS/

6MG; 120MG

/N69139/001/
/JUN 16, 1988/
/N89139 001/
JUN 16, 1988BACITRACIN ZINC; LIDOCAINE; NEOMYCIN SULFATE; POLYMYXIN B

SULFATE

/OINTMENT; TOPICAL/

/LABORATORY/

/COMBE/

/400 UNITS/GM; 40MG/GM; 5MG/GM; 5MG/GM/

/5,000 UNITS/GM/

/JUN 03, 1985/

400 UNITS/GM; 40MG/GM; 5MG/GM; 5MG/GM

5,000 UNITS/GM

N62499 001

JUN 03, 1985

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

SYRUP; ORAL

DIPHENHYDRAMINE HCL

CUMBERLAND SWAN

SILPHEN

SILARX

12.5MG/5ML

12.5MG/5ML

N73611 001
AUG 20, 1992N72646 001
FEB 27, 1992CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

MICROCOL

JOHNSON AND JOHNSON 0.5/M

N72292 001

JAN 28, 1992

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

STERI-STAT

MATRIX MEDCL

/MEDCL/SYSTEMS/

4%

/4%/
/JUN 24, 1986/
/N70104/001/
/JUN 24, 1986/

N70104 001

JUL 24, 1986

/N70104/001/
/JUN 24, 1986/

/CAPSULE; ORAL/

/UNISON/

/PFIZER/

25MG

/25MG/

/N19440/001/
/FEB 05, 1986/
N19440 001
FEB 05, 1986DOXYLAMINE SUCCINATE

IBUPROFEN

TABLET; ORAL
IBUPROFEN
/CHELSEA/
/HEPACOPHARM/

> DLT >
> DLT >

/ZDMS/
/ZDMS/

TAG

200MG

VINTAGE

200MG

/N70605/001/
/MAY/07/1986/
/N71639/001/
/FEB/02/1988/
N73141 001

MAY 29, 1992

N71639 001

FEB 02, 1988

> ADD >
> ADD >
> ADD >

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL
SINE-AID IB
MCNEIL

> ADD >
> ADD >
> ADD >

200MG;30MG

N19899 001

DEC 31, 1992

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 50/50
LILLY

50 UNITS/ML;50 UNITS/ML N20100 001
APR 29, 1992

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL
LOPERAMIDE HCL
BARRE

1MG/5ML

N73187 001

SEP 15, 1992

1MG/5ML

N73243 001

JAN 21, 1992

1MG/5ML

N73079 001

APR 30, 1992

TABLET; ORAL
LOPERAMIDE HCL
OHM

2MG

N74091 001

DEC 10, 1992

2MG

N74194 001

OCT 30, 1992

PERRIGO

MICONAZOLE NITRATE

CREAM; VAGINAL
MICONAZOLE NITRATE
COPLEY

2%

N74030 001
OCT 30, 1992

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL
ALZA

240MG

N20021 002
DEC 15, 1992

SODIUM CHLORIDE

AEROSOL, METERED; INHALATION
BRONCHO SALINE
BLAIREX

0.9%

N19912 001
SEP 03, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL
EXTRA-STRENGTH AIM
/CHESTERBROUGH/PODS/

1.2%

N19518/001/
JUN/03/1987/
N19518 001
JUN 03, 1987

CHESEBROUGH PONDS

1.2%

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST
 CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '92 - DEC '92

DEXTRAN 40, 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION	
LMD IN PLASTIC CONTAINER	
ABBOTT LABS	10GM/100ML; 0.9GM/100ML
	N72562
	OCT 30, 1992

DEXTRAN 40, 10% IN DEXTROSE 5%

INJECTABLE; INJECTION	
LMD IN PLASTIC CONTAINER	
ABBOTT LABS	10GM/100ML; 5GM/100ML
	N72563
	OCT 30, 1992

DEXTRAN 75 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION	
6% GENTRAN 75 AND 10% TRAVERT	
TRAVENOL LABS	6GM/100ML; 10GM/100ML; 0.9GM/100ML
	N08788

UROKINASE

INJECTABLE; INJECTION	
BREOKINASE	
STERLING DRUG	250,000 IU/VIAL
	N17873

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: AI-RSA TRADE: NOT ESTABLISHED	TREATMENT OF AUTOIMMUNE UVEITIS.	AUTOIMMUNE, INC
GENERIC: ALDESLEUKIN TRADE: PROLEUKIN*/**	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.*/** [MAY 05, 1999]	CETUS
GENERIC: ANANAIN, COMOSAIN TRADE: VIANAIN	FOR THE ENZYMATIC DEBRIDEMENT OF SEVERE BURNS.	GENZYME CORPORATION
GENERIC: ANTIHEMOPHILIC FACTOR, HUMAN TRADE: HUMATE P	TREATMENT OF PATIENTS WITH VON WILLEBRAND'S DISEASE.	BEHRINGWERKE AKTIENGESSELLSCHAFT
GENERIC: ANTITHROMBIN III TRADE: THROMBATE III*/**	USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996]	CUTTER BIOLOGICAL

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: BOTULINUM TOXIN TYPE A TRADE: NOT ESTABLISHED	TREATMENT OF SYNKINETIC CLOSURE OF THE EYELID ASSOCIATED WITH VII CRANIAL NERVE ABERRANT REGENERATION.	BIOPURE CORPORATION
GENERIC: BOTULINUM TOXIN TYPE B TRADE: NOT ESTABLISHED	TREATMENT OF CERVICAL DYSTONIA.	ATHENA NEUROSCIENCES, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF ANYOTROPHIC LATERAL SCLEROSIS.	ROGENERON PHARMACEUTICALS, INC
GENERIC: CILIARY NEUROTROPHIC FACTOR, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	TREATMENT OF SPINAL MUSCULAR ATROPHIES. TREATMENT OF MOTOR NEURON DISEASE (INCLUDING ANYOTROPHIC LATERAL SCLEROSIS, PROGRESSIVE MUSCULAR ATROPHY, PROGRESSIVE BULBAR PALSY, AND PRIMARY LATERAL SCLEROSIS).	SYNTEX-SYNERGEN NEUROSCIENCE
GENERIC: COAGULATION FACTOR IX TRADE: MONONINE*/**	REPLACEMENT TREATMENT AND PROPHYLAXIS OF THE HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B. [AUG 20, 1999]	ARMOUR PHARMACEUTICAL
GENERIC: CYSTIC FIBROSIS GENE THERAPY TRADE: NOT ESTABLISHED	TREATMENT OF CYSTIC FIBROSIS.	GENZYME CORPORATION
GENERIC: CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR TRADE: NOT ESTABLISHED	FOR CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR PROTEIN REPLACEMENT THERAPY IN CYSTIC FIBROSIS PATIENTS.	GENZYME CORPORATION
GENERIC: C1-ESTERASE INHIBITOR, HUMAN, PASTEURIZED TRADE: NOT ESTABLISHED	PREVENTION AND/OR TREATMENT OF ACUTE ATTACKS OF HEREDITARY ANGIOEDEMA.	BEHRINGWERKE AKTIENGESSELLSCHAFT

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: HERPES SIMPLEX VIRUS GENE TRADE: NOT ESTABLISHED	TREATMENT OF PRIMARY AND METASTATIC BRAIN TUMORS.	GENETIC THERAPY, INC
GENERIC: HIV NEUTRALIZING ANTIBODIES TRADE: IMMUPATH	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	HEMACARE CORPORATION
GENERIC: HUMAN IMMUNODEFICIENCY VIRUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF HIV-INFECTED PREGNANT WOMEN AND INFANTS OF HIV-INFECTED MOTHERS.	NORTH AMERICAN BIOLOGICALS
GENERIC: IMMUNE GLOBULIN INTRAVENOUS, HUMAN TRADE: IVEEGAM, IMMUNO	TREATMENT OF POLYMYOSITIS/DERMATOMYOSITIS. TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	IMMUNO CLINICAL RESEARCH CORPORATION
GENERIC: IMPORTED FIRE ANT VENOM, ALLERGENIC EXTRACT TRADE: NOT ESTABLISHED	FOR SKIN TESTING OF VICTIMS OF FIRE ANT STINGS TO CONFIRM FIRE ANT SENSITIVITY AND IF POSITIVE, FOR USE AS IMMUNOTHERAPY FOR THE PREVENTION OF IGE-MEDIATED ANAPHYLACTIC REACTIONS.	ALK LABORATORIES, INC
GENERIC: INTERFERON (RECOMBINANT HUMAN, BETA) TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE NON-A, NON-B HEPATITIS.	BIOGEN, INC
GENERIC: INTERFERON BETA (RECOMBINANT) TRADE: R-FRONE	TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM ³ .	SERONO LABORATORIES, INC
GENERIC: INTERLEUKIN-1 RECEPTOR ANTAGONIST, HUMAN RECOMBINANT TRADE: ANTRIL	PREVENTION AND TREATMENT OF GRAFT VERSUS HOST DISEASE IN TRANSPLANT RECIPIENTS.	SYNERGEN, INC
GENERIC: PROTEIN C CONCENTRATE TRADE: PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO	FOR REPLACEMENT THERAPY IN PATIENTS WITH CONGENITAL OR ACQUIRED PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF WARFARIN-INDUCED SKIN NECROSIS DURING ORAL ANTICOAGULATION. FOR REPLACEMENT THERAPY IN CONGENITAL PROTEIN C DEFICIENCY FOR THE PREVENTION AND TREATMENT OF THROMBOSIS, PULMONARY EMBOLI, AND PURPURA FULMINANS.	IMMUNO CLINICAL RESEARCH CORPORATION

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.*/** [DEC 31, 1998] TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA.*/** [MAR 05, 1998]	IMMUNEX
GENERIC: SECRETORY LEUKOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF BRONCHOPULMONARY DYSPLASIA.	SYNERGEN, INC
GENERIC: TECHNETIUM Tc99m MURINE MONOCLONAL ANTIBODY (1GG2A) TO BCE TRADE: IMMURAD-LL-2[99mTc]	DIAGNOSTIC IMAGING IN THE EVALUATION OF THE EXTENT OF DISEASE IN PATIENTS WITH HISTOLOGICALLY CONFIRMED DIAGNOSIS OF NON-HODGKIN'S B-CELL LYMPHOMA, ACUTE B-CELL LYMPHOBLASTIC LEUKEMIA (IN CHILDREN AND ADULTS), AND CHRONIC B-CELL LYMPHOBLASTIC LEUKEMIA.	IMMUNOMEDICS, INC
GENERIC: TRANSFORMING GROWTH FACTOR-BETA 2 TRADE: NOT ESTABLISHED	TREATMENT OF FULL THICKNESS MACULAR HOLES.	CELTRIX PHARMACEUTICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALLOPURINOL SODIUM TRADE: ZYLOPRIM FOR INJECTION	MANAGEMENT OF PATIENTS WITH LEUKEMIA, LYMPHOMA, AND SOLID TUMOR MALIGNANCIES WHO ARE RECEIVING CANCER THERAPY WHICH CAUSES ELEVATIONS OF SERUM AND URINARY URIC ACID LEVELS AND WHO CANNOT TOLERATE ORAL THERAPY.	BURROUGHS WELLCOME COMPANY
GENERIC: ANARITIDE ACETATE TRADE: AURICULIN	IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION.	SCIOS, INC
GENERIC: ARGININE BUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF PATIENTS WITH ACUTE RENAL FAILURE.	SUSAN P. PERRINE, M.D.
GENERIC: BACLOFEN (INTRATHECAL) TRADE: LITORESAL	TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA-THALASSEMIA.	MEDTRONIC, INC
GENERIC: BUTYRYLCHOLINESTERASE TRADE: NOT ESTABLISHED	TREATMENT OF INTRACTABLE SPASTICITY CAUSED BY SPINAL CORD INJURY, MULTIPLE SCLEROSIS, AND OTHER SPINAL DISEASES (INCLUDING SPINAL ISCHEMIA, SPINAL TUMOR, TRANSVERSE MYELITIS, CERVICAL SPONDYLOSIS, AND DEGENERATIVE MYELOPATHY.	PHARMAVEONE, INCORPORATED
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE REDUCTION AND CLEARANCE OF TOXIC BLOOD LEVELS OF COCAINE ENCOUNTERED DURING A DRUG OVERDOSE. TREATMENT OF POST-SURGICAL APNEA.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIANEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS TRADE: NUTRINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINIT PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM. FOR USE AS A NUTRITIONAL SUPPLEMENT FOR THE TREATMENT OF MALNOURISHMENT IN PATIENTS UNDERGOING CONTINUOUS AMBULATORY PERITONEAL DIALYSIS.	BAXTER HEALTHCARE CORPORATION
GENERIC: DIAZEPAM VISCOUS SOLUTION FOR RECTAL ADMINISTRATION TRADE: DIASTAT	TREATMENT OF ACUTE REPETITIVE SEIZURES.	UPSHER SMITH LABORATORIES, INC
GENERIC: FIAU TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	OCLASSEN PHARMACEUTICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: HALOFANTRINE HCL TRADE: HALFAN*/**	TREATMENT OF MILD TO MODERATE ACUTE MALARIA CAUSED BY SUSCEPTIBLE STRAINS OF P. FALCIPARUM AND P. VIVAX. [JUL 24, 1999]	SMITHKLINE BEECHAM
GENERIC: HUMAN THYROID STIMULATING HORMONE (TSH) TRADE: THYROGEN	AS AN ADJUNCT IN THE DIAGNOSIS OF THYROID CANCER.	GENZYME CORPORATION
GENERIC: IDARUBICIN TRADE: IDAMYCIN	TREATMENT OF MYELODYSPLASTIC SYNDROMES. TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA.	ADRIA LABORATORIES
GENERIC: ISOBUTYRAMIDE TRADE: ISOBUTYRAMIDE ORAL SOLUTION	TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA THALASSEMIA SYNDROMES.	SUSAN PERRINE OAKLAND, CA
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY IN CHILDREN WITH CEREBRAL PALSY.	WTD, INC
GENERIC: L-THREONINE TRADE: NOT ESTABLISHED	TREATMENT OF SPASTICITY ASSOCIATED WITH FAMILIAL SPASTIC PARAPARESIS.	INTERNEURON PHARMACEUTICALS, INC
GENERIC: LEVOCARNITINE TRADE: CARNITOR*/**	GENETIC CARNITINE DEFICIENCY.* TREATMENT OF MANIFESTATIONS OF CARNITINE DEFICIENCY IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD) WHO REQUIRE DIALYSIS. PREVENTION OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY. TREATMENT OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY.	SIGMA TAU
GENERIC: LEVOCARNITINE TRADE: CARNITOR*/**	TREATMENT OF PRIMARY AND SECONDARY CARNITINE DEFICIENCY OF GENETIC ORIGIN.*/** [DEC 27, 1992] */** [DEC 16, 1999 - SECONDARY CARNITINE DEFICIENCY].	SIGMA TAU
GENERIC: LIOTHYRONINE SODIUM TRADE: TRIOSTAT*/**	TREATMENT OF MYXEDEMA COMA/PRE-COMA. [DEC 31, 1998]	SMITHKLINE BEECHAM
GENERIC: LOXORIBINE TRADE: NOT ESTABLISHED	TREATMENT OF COMMON VARIABLE IMMUNODEFICIENCY.	R.W. JOHNSON RESEARCH INSTITUTE

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: MELPHALAN*/** TRADE: ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE.*/** [NOV 18, 1999] FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION TO TREAT METASTATIC MELANOMA OF THE EXTREMITY.	BURROUGHS WELLCOME
GENERIC: MINOCYCLINE HCL TRADE: MINOCIN	TREATMENT OF CHRONIC MALIGNANT PLEURAL EFFUSION.	LEDERLE LABORATORIES
GENERIC: OXALIPLATIN TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CANCER.	AXION PHARMACEUTICALS
GENERIC: PAPAVERINE (TOPICAL GEL) TRADE: NOT ESTABLISHED	TREATMENT OF SEXUAL DYSFUNCTION IN SPINAL CORD INJURY PATIENTS.	PHARMEDIC COMPANY
GENERIC: PARA-AMINOSALICYLIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF TUBERCULOSIS INFECTIONS.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: PEG-GLUCOCEREBROSIDASE TRADE: NOT ESTABLISHED	CHRONIC ENZYME REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE WHO ARE DEFICIENT IN GLUCOCEREBROSIDASE.	ENZON, INCORPORATED
GENERIC: PILOCARPINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF XEROSTOMIA AND KERATOCONJUNCTIVITIS SICCA IN SJOGREN'S SYNDROME PATIENTS.	MGI PHARMA, INC
GENERIC: POLYMERIC OXYGEN TRADE: NOT ESTABLISHED	TREATMENT OF SICKLE CELL ANEMIA.	CAPMED, USA
GENERIC: PPI-002 TRADE: NOT ESTABLISHED	TREATMENT OF MALIGNANT MESOTHELIOMA.	PLEXUS PHARMACEUTICALS, INC
GENERIC: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODIOECABORATE TRADE: BOROCCELL	FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.	NEUTRON TECHNOLOGY CORPORATION
GENERIC: SODIUM PHENYLBUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF SICKLING DISORDERS, WHICH INCLUDE S-S HEMOGLOBINOPATHY, S-C HEMOGLOBINOPATHY, AND S-THALASSEMIA HEMOGLOBINOPATHY.	JOHNS HOPKINS MEDICAL INSTITUTIONS

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SOTALOL HCL TRADE: BETAPACE*/**	TREATMENT OF LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIAS. [OCT 30, 1999]	BRISTOL-MYERS SQUIBB
GENERIC: TENIPOSIDE TRADE: VUMON*/**	TREATMENT OF REFRACTORY CHILDHOOD ACUTE LYMPHOCYTIC LEUKEMIA (ALL). [JUL 14, 1999]	BRISTOL MYERS SQUIBB
GENERIC: TOPIRAMATE TRADE: TOPIMAX	TREATMENT OF LENNOX-GASTAUT SYNDROME.	R. W. JOHNSON RESEARCH INSTITUTE
GENERIC: ZALCITABINE TRADE: HIVID	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS). [JUN 19, 1999]	ROCHE
GENERIC: 9-CIS RETINOIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.	LIGAND PHARMACEUTICALS, INC

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

NO DECEMBER 1992 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALPRAZOLAM (TABLET)	NOV 27, 1992	
CARBIDOPA AND LEVODOPA (TABLET)	JUN 19, 1992	
CIMETIDINE (TABLET)	JUN 12, 1992	
CORTICOSTEROID <i>IN VITRO</i> AND <i>IN VIVO</i> INTERIM (TOPICAL)	JUL 01, 1992	
DICLOFENAC SODIUM (TABLET)	DEC 24, 1992	
DIFLUNISAL (TABLET)	MAY 16, 1992	
DILTIAZEM HYDROCHLORIDE (TABLET)	MAY 16, 1992	
ESTROPIPATE (TABLET)	AUG 26, 1992	
FLURBIPROFEN (TABLET)	DEC 24, 1992	
GENFIBROZIL (CAPSULE AND TABLET)	JUN 23, 1989	
METOPROLOL TARTRATE (TABLET)	JUN 12, 1992	
NADOLOL (TABLET)	MAY 16, 1992	
NAPROXEN (TABLET)	JUN 12, 1992	
NORTRIPTYLINE HYDROCHLORIDE (CAPSULE)	JUN 15, 1992	
PIROXICAM (CAPSULE)	JUN 15, 1992	
STATISTICAL PROCEDURE FOR BIOEQUIVALENCE STUDIES USING A STANDARD TWO-TREATMENT CROSSOVER DESIGN	JUN 15, 1992	
TERFENADINE (TABLET)	JUL 01, 1992	
	JUN 12, 1992	
		JUN 15, 1992

ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	PETITIONS APPROVED		REASON FOR PETITION	STATUS
		DOCKET NUMBER	PETITIONER		
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET; ORAL	500MG 7.5MG	91 P-0514/ CP1	SOFTAN	NEW STRENGTH	APPROVED JUN 03, 1992
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	660MG 10MG	91 P-0004/ CP1	KNOLL	NEW STRENGTH	APPROVED OCT 27, 1992
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CP1	HAMER	NEW DOSAGE FORM	APPROVED MAR 17, 1992
ALPRAZOLAM CONCENTRATE; ORAL	1MG/ML	92 P-0050/ CP1	ROXANE	NEW DOSAGE FORM	APPROVED DEC 15, 1992
ALPRAZOLAM SOLUTION; ORAL	0.5MG/5ML	92 P-0050/ CP2	ROXANE	NEW DOSAGE FORM	APPROVED DEC 15, 1992
CHLORZOXAZONE TABLET; ORAL	750MG	91 P-0153/ CP1	MIKART	NEW STRENGTH	APPROVED JUN 03, 1992

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CIMETIDINE HYDROCHLORIDE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER INJECTABLE; INJECTION	EQ 90MG BASE/100ML EQ 120MG BASE/100ML EQ 180MG BASE/100ML EQ 240MG BASE/100ML EQ 360MG BASE/100ML EQ 480MG BASE/100ML	92 P-0337/ CP1	ABBOTT	NEW STRENGTH	APPROVED OCT 26, 1992
HYDROCORTISONE ACETATE AEROSOL; TOPICAL	2.5%	92 P-0101/ CP1	HOGAN & HARTSON	NEW DOSAGE FORM	APPROVED JUL 08, 1992
MALBUPHINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (2ML/CONTAINER)	92 P-0224/CP	STERLING	NEW STRENGTH	APPROVED SEP 11, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 18, 1992
PROPRANOLOL HYDROCHLORIDE TABLET, EFFERVESCENT; ORAL	40MG	92 P-0332/ CP1	FLEMININGTON PHARM	NEW DOSAGE FORM	APPROVED NOV 25, 1992
TAMOXIFEN CITRATE TABLET; ORAL	EQ 20MG BASE	92 P-0269/ CP1	KROSS	NEW STRENGTH	APPROVED OCT 26, 1992
TRIAZOLAM SOLUTION; ORAL	0.125MG/5ML	92 P-0048/ CP2	ROXANE	NEW DOSAGE FORM	APPROVED SEP 11, 1992

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/VIAL)	91 P-0076/ Cp1	ADRIA	NEW STRENGTH	DENIED FEB 19, 1992

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 12TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW DOSING SCHEDULE

D-18 LOWER RECOMMENDED STARTING DOSE GUIDELINES
D-19 BOLUS DOSING GUIDELINES

REFERENCES
NEW INDICATION

I-67 TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER
I-68 CENTRAL PRECOCIOUS PUBERTY
I-69 SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFLUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY
I-70 USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER
I-71 VARICELLA INFECTIONS (CHICKENPOX)
I-72 PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE
I-73 INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES
I-74 INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY
I-75 TREATMENT OF ENDOSCOPICALLY DIAGNOSED EROSIVE ESOPHAGITIS
I-76 PREVENTION OF OSTEOPOROSIS
I-77 DERMAL INFECTIONS-TINEA PEDIS, TINEA CORPORIS, TINEA CRURIS DUE TO EPIDERMOPHYTON FLOCCOSUM
I-78 CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY AND INTRAVENOUS EXCRETORY UROGRAPHY
I-79 MANAGEMENT OF CHRONIC STABLE ANGINA AND ANGINA DUE TO CORONARY ARTERY SPASM
I-80 DIAGNOSIS AND LOCALIZATION OF ISCHEMIA AND CORONARY HEART DISEASE
I-81 PROPHYLAXIS IN DESIGNATED IMMUNOCOMPROMISED CONDITIONS TO REDUCE THE INCIDENCE OF OROPHARYNGEAL CANDIDIASIS
I-82 TREATMENT OF TRAVELERS' DIARRHEA
I-83 ANGIOCARDIOGRAPHY, CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY IN CHILDREN
I-84 INTRAOPERATIVE AND POSTOPERATIVE TACHYCARDIA AND/OR HYPERTENSION
I-85 TREATMENT OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS
I-86 TREATMENT OF SECONDARY CARNITINE DEFICIENCY

EXCLUSIVITY TERMS

REFERENCES

PATENT USE CODE

U-57	OPHTHALMIC USE OF NORFLOXACIN
U-58	METHOD OF TREATING INFLAMMATORY INTESTINAL DISEASES
U-59	METHOD OF TREATING HYPERCHOLESTEROLEMIA
U-60	NASAL ADMINISTRATION OF BUTORPHANOL
U-61	CEREBRAL AND PERIPHERAL ARTERIOGRAPHY AND CT IMAGING OF THE HEAD
U-62	CORONARY ARTERIOGRAPHY, LEFT VENTRICULOGRAPHY, CT IMAGING OF THE BODY, INTRAVENOUS EXCRETORY UROGRAPHY, INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY AND VENOGRAPHY
U-63	ISOPRENALINE ANTAGONISM ON THE HEART RATE OR BLOOD PRESSURE
U-64	TREATMENT OF VIRAL INFECTIONS
U-65	METHOD OF TREATMENT OF A PATIENT INFECTED WITH HIV
U-66	TRIPHASIC REGIMEN
U-67	METHOD OF INDUCING ANESTHESIA IN A WARM BLOODED ANIMAL
U-68	TREATMENT OF ACTINIC KERATOSIS
U-69	TREATMENT OF PNEUMOCYSTIS CARINII INFECTIONS
U-70	TREATMENT OF TRANSIENT INSOMNIA
U-71	METHOD OF TREATMENT OF HEART FAILURE
U-72	TREATMENT OF MIGRAINES
U-73	METHOD OF TREATING DISEASES OR INFECTIONS CAUSED BY MYCETES

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
2032 001	ACETAMINOPHEN; FIORICET W/ CODEINE	4158055	JUN 12, 1996	U-19	NC	OCT 26, 1993
18828 001	ACYCLOVIR; ZOVIRAX	4316897	FEB 23, 1999		1-71	FEB 26, 1995
19909 001	ACYCLOVIR; ZOVIRAX	4316897	FEB 23, 1999		1-71	FEB 26, 1995
20089 001	ACYCLOVIR; ZOVIRAX	4316897	FEB 23, 1999		1-71	FEB 26, 1995
20089 002	ACYCLOVIR; ZOVIRAX	4316897	FEB 23, 1999		1-71	FEB 26, 1995
19604 002	ALBUTEROL SULFATE; VOLMAX	4879303	NOV 07, 2006		NS	FEB 26, 1995
19729 001	AMCINONIDE; CYCLOCORT	4572909	FEB 25, 2003			DEC 23, 1995
16949 001	AMITRIPTYLINE HYDROCHLORIDE; LIMBITROL	4879303	NOV 07, 2006			
16949 002	AMITRIPTYLINE HYDROCHLORIDE; LIMBITROL	4879303	NOV 07, 2006			
19787 001	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
19787 002	AMLODIPINE BESYLATE; NORVASC	4879303	NOV 07, 2006		NCE	JUL 31, 1997
19787 003	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
20259 001	ATOVAQUONE; MEPRON	4879303	NOV 07, 2006		NCE	JUL 31, 1997
20045 001	AVOBENZONE; SHADE UVAGUARD	4572909	FEB 25, 2003		ODE	NOV 25, 1999
20075 001	BACLOFEN; LIORESAL	5053432	OCT 01, 2008	U-69	NCE	NOV 25, 1997
20075 002	BACLOFEN; LIORESAL	4981874	JAN 01, 2008		ODE	JUN 17, 1999
19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4387089	JUN 07, 2000		NDF	JUN 17, 1995
19851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				NDF	JUN 17, 1995
19851 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				NDF	JUN 17, 1995
19851 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				NCE	JUN 25, 1996
20033 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
20033 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NC	MAY 19, 1995
20033 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
20033 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NC	MAY 19, 1995
19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NC	MAY 19, 1995
19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
		RE30577	JUN 08, 1995		NCE	DEC 28, 1995

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19002 001	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19002 002	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19002 003	BEPRIDIL HYDROCHLORIDE; VASCOR	RE30577	JUN 08, 1995		NCE	DEC 28, 1995
19807 001	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4311708	JAN 19, 1999	U-3	NC	OCT 30, 1995
19807 002	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	FEB 24, 1998			
19882 001	BISOPROLOL FUMARATE; ZEBETA	4311708	JAN 19, 1999	U-3	NC	OCT 30, 1995
19882 002	BISOPROLOL FUMARATE; ZEBETA	4252984	FEB 24, 1998			
19548 001	BITOLTEROL MESYLATE; TORNALATE	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
19890 001	BUTORPHANOL TARTRATE; STADOL	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
13071 007	CHLORDIAZEPOXIDE; LIBRITABS	4336400	JUN 22, 1999	U-5	NDF	FEB 19, 1995
13071 008	CHLORDIAZEPOXIDE; LIBRITABS	4138581	FEB 06, 1998		NDF	DEC 12, 1994
14740 002	CHLORDIAZEPOXIDE; MENRIUM 5-2	4464378	AUG 07, 2001	U-60		
14740 004	CHLORDIAZEPOXIDE; MENRIUM 5-4	4316897	FEB 23, 1999			
14740 006	CHLORDIAZEPOXIDE; MENRIUM 10-4	4316897	FEB 23, 1999			
17413 001	CHLORDIAZEPOXIDE; LIBRELEASE	4316897	FEB 23, 1999			
12240 001	CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM	4316897	FEB 23, 1999			
12240 002	CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM	4316897	FEB 23, 1999			
12240 003	CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM	4316897	FEB 23, 1999			
12401 001	CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM	4316897	FEB 23, 1999			
12750 001	CHLORDIAZEPOXIDE HYDROCHLORIDE; LIBRIUM	4316897	FEB 23, 1999			
19847 001	CIPROFLOXACIN; CIPRO	4316897	FEB 23, 1999			
19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002		NCE	OCT 22, 1992
		4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4670444	OCT 01, 2002		NCE	OCT 22, 1992
		4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002		NCE	OCT 22, 1992

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
19992 001	CIPROFLOXACIN HYDROCHLORIDE; CILOXAN	4670444	OCT 01, 2002		NDF	DEC 31, 1993
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17533-001	CLONAZEPAM; KLOXOPIN	4316897	FEB 23, 1999			
17533-002	CLONAZEPAM; KLOXOPIN	4316897	FEB 23, 1999			
17533-003	CLONAZEPAM; KLOXOPIN	4316897	FEB 23, 1999			
18713 001	CLOTRIMAZOLE; MYCELEX					
20118 001	DESFLURANE; SUPRANE					
20071 001	DESOGESTREL; DESOGEN	4762856	AUG 09, 2005	U-67	I-81	SEP 29, 1995
20071 002	DESOGESTREL; DESOGEN				NCE	SEP 18, 1997
20301 001	DESOGESTREL; ORTHO-CEPT				NC	DEC 10, 1995
20301 002	DESOGESTREL; ORTHO-CEPT				NC	DEC 10, 1995
20301 002	DESOGESTREL; ORTHO-CEPT				NC	DEC 10, 1995
13263-002	DIAZEPAM; VALIUM					
13263-004	DIAZEPAM; VALIUM	4316897	FEB 23, 1999			
13263-006	DIAZEPAM; VALIUM	4316897	FEB 23, 1999			
16087-001	DIAZEPAM; VALIUM	4316897	FEB 23, 1999			
18179-001	DIAZEPAM; VALRELEASE	4316897	FEB 23, 1999			
20037 001	DICLOFENAC SODIUM; VOLTAREN	4960799	OCT 02, 2007		NDF	MAR 28, 1994
20154 002	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20154 003	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20154 004	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20154 005	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20155 003	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20155 004	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20155 005	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20155 006	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20156 001	DIDANOSINE; VIDEK				D-18	SEP 25, 1995
20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NCE NS	NOV 05, 1992 MAY 29, 1995
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		I-79 NCE	OCT 15, 1995 NOV 05, 1992
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NP I-79	DEC 27, 1994 OCT 15, 1995
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776 4894240	MAR 26, 2008 JAN 16, 2007		NCE NP	NOV 05, 1992 DEC 27, 1994
20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR	5002776 4894240	MAR 26, 2008 JAN 16, 2007		I-79 NCE	OCT 15, 1995 NOV 05, 1992
20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR	4839177	JUN 13, 2006		NP	DEC 27, 1994
20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR	4839177	JUN 13, 2006		NCE	NOV 05, 1992
19617 001	DINOPROSTONE; PREPIDIL	4680312 3966962 4701460	JUL 14, 2004 JUN 29, 1993 MAR 06, 2005		NP NCE NDF	DEC 27, 1994 NOV 05, 1992 DEC 09, 1995
19946 001	DOXACURIUM CHLORIDE; NUROMAX				NCE	MAR 07, 1996
18651 001	DROMABINOL; MARINOL				I-85	DEC 22, 1995
18651 002	DROMABINOL; MARINOL				I-85	DEC 22, 1995
18651 003	DROMABINOL; MARINOL				I-84	DEC 18, 1995
19386 001	ESMOLOL HYDROCHLORIDE; BREVIBLOC				D-19	DEC 18, 1995
19386 002	ESMOLOL HYDROCHLORIDE; BREVIBLOC				I-84	DEC 18, 1995
84499 001	ESTRADIOL; ESTRACE	4593119	JUN 03, 2003		D-19	DEC 18, 1995
84500 001	ESTRADIOL; ESTRACE	4387103	JUN 07, 2000	U-11	D-19	DEC 18, 1995
83220 001	ESTROPIPATE; OGEN .625	4593119	JUN 03, 2003		D-19	DEC 18, 1995
83220 002	ESTROPIPATE; OGEN 1.25	4387103	JUN 07, 2000	U-11	D-19	DEC 18, 1995
83220 003	ESTROPIPATE; OGEN 2.5				I-76	SEP 08, 1995
83220 004	ESTROPIPATE; OGEN 5				I-76	SEP 08, 1995
					I-76	NOV 10, 1995
					I-76	NOV 10, 1995
					I-76	NOV 10, 1995
					I-76	NOV 10, 1995

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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4628051	OCT 01, 2002	U-66		
		4616006	OCT 07, 2003	U-66		
		4544554	JUL 23, 2002	U-66		
		4027019	MAY 31, 1996		NP	JUL 03, 1995
19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN	4628051	OCT 01, 2002	U-66		
		4616006	OCT 07, 2003	U-66		
		4544554	JUL 23, 2002	U-66		
		4027019	MAY 31, 1996		NP	JUL 03, 1995
19462 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
19462 002	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
19527 001	FAMOTIDINE; PEPCID	4283408	AUG 11, 2000		I-69	DEC 10, 1994
19834 001	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
20180 001	FINASTERIDE; PROSCAR	4760071	JUL 26, 2005			
		4377584	MAR 22, 2000		NCE	JUN 19, 1997
19960 001	FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
		4302460	NOV 24, 1998		NCE	DEC 30, 1997
19960 002	FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
		4302460	NOV 24, 1998		NCE	DEC 30, 1997
19960 003	FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
		4302460	NOV 24, 1998		NCE	DEC 30, 1997
19960 004	FLOSEQUINAN; MANOPLAX	4552884	NOV 12, 2002	U-71		
		4302460	NOV 24, 1998		NCE	DEC 30, 1997
20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 2001		NCE	DEC 30, 1997
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4626549	DEC 02, 2003		NCE	APR 18, 1996
		4194009	APR 19, 1994			
		4018895	APR 19, 1994	U-12		
16721 001	FLURAZEPAM HYDROCHLORIDE; DALMANE	4316897	FEB 23, 1999			
16721 002	FLURAZEPAM HYDROCHLORIDE; DALMANE	4316897	FEB 23, 1999			
20068 001	FOSCARNET SODIUM; FOSCAVIR	4771041	JUL 29, 1997			
		4665062	JUL 29, 1997			
		4339445	JUL 29, 1997	U-64		
		4215113	JUL 29, 1997	U-64		
19915 002	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	SEP 27, 1996
19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	MAY 16, 1996
20131 001	GADOTERIDOL; PROHANCE	4337201	JUN 29, 2001		NCE	MAY 16, 1996
19661 001	GANCICLOVIR SODIUM; CYTOVENE	4885363	DEC 05, 2006		NCE	NOV 16, 1997
		4507305	OCT 19, 1999	U-35	I-72	MAY 15, 1995

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20051 001	GLYBURIDE; GLYNASE	4916163	APR 10, 2007			
		4735805	APR 05, 2005		NCE	MAY 01, 1994
		3507961	APR 21, 1992		NP	MAR 04, 1995
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
		3426067	APR 21, 1992			
20051 002	GLYBURIDE; GLYNASE	4916163	APR 10, 2007			
		4735805	APR 05, 2005		NCE	MAY 01, 1994
		3507961	APR 21, 1992		NP	MAR 04, 1995
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
		3426067	APR 21, 1992			
20055 001	GLYBURIDE; GLUBATE				NP	MAR 04, 1995
					NCE	MAY 01, 1994
					NP	MAR 04, 1995
20055 002	GLYBURIDE; GLUBATE				NCE	MAY 01, 1994
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
20250 001	HALOFANTRINE HYDROCHLORIDE; HALFAN				NCE	JUL 24, 1997
					ODE	JUL 24, 1999
19046 001	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19046 002	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19046 003	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19046 004	HYDROCHLOROTHIAZIDE; NORMOZIDE	4012444	MAR 15, 1994		NCE	AUG 01, 1994
119174 001	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 002	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 003	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19174 004	HYDROCHLOROTHIAZIDE; TRANDATE HCT	4012444	MAR 15, 1994		NCE	AUG 01, 1994
19261 001	HYDROXYAMPHETAMINE HYDROBROMIDE; PAREMYD	4012444	MAR 15, 1994		NCE	AUG 01, 1994
2020100 001	INSULIN BIOSYNTHETIC HUMAN; HUMULIN 50/50				NC	JAN 30, 1995
18735 007	TOPAMIDOL; ISOVUE-250	4001323	JAN 04, 1996		NP	APR 29, 1995
19710 001	TOVERSOL; OPTIRAY 320	4396598	OCT 26, 2002	U-29	NS	JUL 06, 1995
19710 002	TOVERSOL; OPTIRAY 240				I-83	DEC 11, 1995
19710 004	TOVERSOL; OPTIRAY 300	4396598	OCT 26, 2002	U-61	I-78	JUL 09, 1995
19710 005	TOVERSOL; OPTIRAY 350	4396598	OCT 26, 2002	U-62	NS	JAN 22, 1995
					NS	JAN 22, 1995
20083 001	ITRACONAZOLE; SPORANOX	4257179	MAY 12, 1998		I-74	JAN 22, 1995
					NCE	SEP 11, 1997

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF NCE	DEC 20, 1994 NOV 30, 1994
19700 001	KETOROLAC TROMETHAMINE; ACULAR	4089969	MAY 16, 1997			
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
20182 001	LEVOCARNITINE; CARNITOR				I-86 ODE	DEC 16, 1995 DEC 16, 1999
19941 001	LIDOCAINE; EMLA	4562060	DEC 31, 2002		NC	DEC 30, 1995
		4529601	JUL 16, 2002		ODE	DEC 31, 1998
20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				NCE	FEB 21, 1997
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	JUL 09, 2002	U-36	I-82	NOV 23, 1995
19487 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D				I-82	NOV 23, 1995
19860 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D					
19940 001	MASOPROCOL; ACTINEX	5008294	APR 15, 2008	U-68	NCE	SEP 04, 1997
		4695590	SEP 22, 2004		NP	OCT 29, 1995
20246 001	MEDROXYPROGESTERONE ACETATE; DEPO-PROVERA				ODE	NOV 18, 1999
20207 001	MELPHALAN HYDROCHLORIDE; ALKERAN	4997651	MAR 05, 2008		NCE	DEC 24, 1992
19651 001	MESALAMINE; ASACOL				NDF	JAN 31, 1995
17659 001	METAPROTERENOL SULFATE; ALUPENT				I-67	NOV 14, 1994

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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19962 001	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
19962 002	METOPROLOL SUCCINATE; TOPROL XL	3876802	APR 08, 1992			
19962 003	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
20208 001	METRONIDAZOLE; METROGEL	3876802	APR 08, 1992		NE	JAN 10, 1995
20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NDF	AUG 17, 1995
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	JAN 22, 1997
19583 002	NABUMETONE; RELAFEN	4061779	DEC 06, 1994	U-19	NCE	DEC 24, 1996
19886 001	NAFARELIN ACETATE; SYNAREL	4420639	DEC 13, 2000		NCE	DEC 24, 1996
20109 001	NAFARELIN ACETATE; SYNAREL	4061779	DEC 06, 1994	U-19		
19660 001	NEDOCROMIL SODIUM; TILADE	4234571	NOV 18, 1997		I-68	FEB 26, 1995
19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE	4760072	JUL 26, 2005		NCE	FEB 13, 1995
20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR	4474787	OCT 02, 2001		I-68	FEB 26, 1995
20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NCE	DEC 30, 1997
20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NDF	JAN 30, 1995
19983 001	NICOTINE; PROSTEP	3985758	OCT 12, 1995		NCE	DEC 21, 1993
19983 002	NICOTINE; PROSTEP	3985758	OCT 12, 1995		NDF	DEC 21, 1993
20076 001	NICOTINE; HABITROL	3985758	OCT 12, 1995		NCE	DEC 21, 1993
20076 002	NICOTINE; HABITROL	3985758	OCT 12, 1995		NDF	FEB 21, 1995
20076 003	NICOTINE; HABITROL	3985758	OCT 12, 1995		NCE	DEC 21, 1993
20150 001	NICOTINE; NICOTROL	3985758	OCT 12, 1995		NDF	FEB 21, 1995
20150 002	NICOTINE; NICOTROL	3985758	OCT 12, 1995		NCE	DEC 21, 1993
20150 003	NICOTINE; NICOTROL	3985758	OCT 12, 1995		NDF	DEC 21, 1993
19983 001	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
19983 002	NICOTINE; PROSTEP	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
20076 001	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20076 002	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20150 001	NICOTINE; NICOTROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20150 002	NICOTINE; NICOTROL	5016652	MAY 21, 2008		NP	APR 22, 1995
20150 003	NICOTINE; NICOTROL	5016652	MAY 21, 2008		NP	APR 22, 1995

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20165 001	NICOTINE; NICODERM	5004610	APR 02, 2008			
20165 002	NICOTINE; NICODERM	4144317	SEP 09, 1992		NDF	NOV 07, 1994
20165 003	NICOTINE; NICODERM	5004610	APR 02, 2008			
20066 001	NICOTINE POLACRILEX; NICORETTE DS	4144317	SEP 09, 1992		NDF	NOV 07, 1994
20064 001	NITROFURANTOIN; MACROBID	4798725	JAN 17, 2006		NP	JUN 08, 1995
19757 001	NORFLOXACIN; CHIBROXIN	4772473	SEP 20, 2005		NDF	DEC 24, 1994
20087 001	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4551456	NOV 05, 2002	U-57		
20087 002	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 003	OFLOXACIN; FLOXIN	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 004	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20087 005	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
19715 001	OLSALAZINE SODIUM; DIPENTUM	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
20103 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4753789	JUN 28, 2005	U-44	NDF	DEC 31, 1995
20103 002	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004	U-44	NDF	DEC 31, 1995
18841 004	OXAPROZIN; DAYPRO	4753789	JUN 28, 2005		NCE	OCT 29, 1997
19828 001	OXICONAZOLE NITRATE; OXISTAT	4695578	SEP 22, 2004		NCE	DEC 30, 1993
20209 001	OXICONAZOLE NITRATE; OXISTAT				I-77	SEP 30, 1995
20262 001	PACLITAXEL; TAXOL				NP	SEP 30, 1995
20031 001	PAROXETINE HYDROCHLORIDE; PAXIL				NCE	DEC 30, 1993
20031 002	PAROXETINE HYDROCHLORIDE; PAXIL				NCE	DEC 29, 1997
20031 003	PAROXETINE HYDROCHLORIDE; PAXIL				NCE	DEC 29, 1997
20031 004	PAROXETINE HYDROCHLORIDE; PAXIL				NCE	DEC 29, 1997
20031 005	PAROXETINE HYDROCHLORIDE; PAXIL				NCE	DEC 29, 1997

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19775 001	PRazosin Hydrochloride; MINIPRESS XL	5082668	SEP 16, 2003			
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4327725	MAY 04, 1999			
		4092315	MAY 30, 1995			
19775 002	PRazosin Hydrochloride; MINIPRESS XL	5082668	SEP 16, 2003		NDF	JAN 29, 1995
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003			
		4327725	MAY 04, 1999			
		4092315	MAY 30, 1995			
19157 001	PREDNISOLONE Sodium Phosphate; PEDIAPRED	4092315	MAY 30, 1995		NDF	JAN 29, 1995
19627 001	PROPOFOL; DIPRIVAN	4448774	MAY 15, 2001			
20021 002	PSEUDOEPHEDRINE Hydrochloride; PSEUDOEPHEDRINE HCL	4798846	NOV 01, 1996		I-73	DEC 31, 1994
		4801461	MAY 05, 2004			
		4576604	MAR 18, 2003			
18703 001	RANITIDINE Hydrochloride; ZANTAC 150	4521431	JUN 04, 2002		I-75	MAY 19, 1995
18703 002	RANITIDINE Hydrochloride; ZANTAC 300	4521431	JUN 04, 2002		I-75	MAY 19, 1995
19675 001	RANITIDINE Hydrochloride; ZANTAC	4128658	DEC 05, 1995		I-75	MAY 19, 1995
19766 001	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
20166 001	SODIUM THIOSULFATE; SODIUM THIOSULFATE	4444784	APR 24, 2001	U-59	NCE	DEC 23, 1997
19865 001	SOTALOL Hydrochloride; BETAPACE				NCE	FEB 14, 1997
					NCE	OCT 30, 1997
19865 002	SOTALOL Hydrochloride; BETAPACE				ODE	OCT 30, 1999
					NCE	OCT 30, 1997
19865 003	SOTALOL Hydrochloride; BETAPACE				ODE	OCT 30, 1999
					NCE	OCT 30, 1997
19865 004	SOTALOL Hydrochloride; BETAPACE				ODE	OCT 30, 1999
					NCE	OCT 30, 1997
20080 001	SUMATRIPTAN Succinate; IMITREX	5037845	AUG 06, 2008	U-72	ODE	OCT 30, 1999
20063 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; RBC-SCAN				NCE	DEC 28, 1997
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE				NP	JUN 11, 1995
20043 003	TEMAFLOXACIN Hydrochloride; OMNIFLOX	4730000	MAR 08, 2005	U-36	I-80	SEP 09, 1995
20043 004	TEMAFLOXACIN Hydrochloride; OMNIFLOX	4730000	MAR 08, 2005	U-36	NCE	JAN 30, 1997
					NCE	JAN 30, 1997

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20119 001	TENIPOSIDE; VUMON				NCE	JUL 14, 1997
>ADD>					ODE	JUL 14, 1999
20192 001	TERBINAFINE HYDROCHLORIDE; LAMISIL	4775534	JUL 05, 2005	U-73	NCE	DEC 30, 1999
19614 003	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
20199 001	ZALCITABINE; HIVID	5028595	JUL 02, 2008	U-65	NCE	JUN 19, 1997
		4879277	NOV 07, 2006	U-65	ODE	JUN 19, 1999
20199 002	ZALCITABINE; HIVID	5028595	JUL 02, 2008	U-65	NCE	JUN 19, 1997
		4879277	NOV 07, 2006	U-65	ODE	JUN 19, 1999
19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005		I-47	MAY 02, 1993
		4833130	FEB 09, 2005		ODE	MAR 19, 1994
		4828838	FEB 09, 2005		NCE	MAR 19, 1992
19910 001	ZIDOVUDINE; RETROVIR	4724232	FEB 09, 2005		ODE	MAR 19, 1994
		4837208	FEB 09, 2005		I-47	MAY 02, 1993
		4833130	FEB 09, 2005		NCE	MAR 19, 1992
19951 001	ZIDOVUDINE; RETROVIR	4818538	FEB 09, 2005		NCE	MAR 19, 1992
		4837208	FEB 09, 2005		ODE	MAR 19, 1994
		4833130	FEB 09, 2005		NCE	DEC 16, 1997
19908 001	ZOLPIDEM TARTRATE; AMBIEN	4818538	FEB 09, 2005		NCE	DEC 16, 1997
19908 002	ZOLPIDEM TARTRATE; AMBIEN	4724232	FEB 09, 2005		NCE	DEC 16, 1997

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