

**CUMULATIVE
SUPPLEMENT 9**

JAN'92-SEP'92

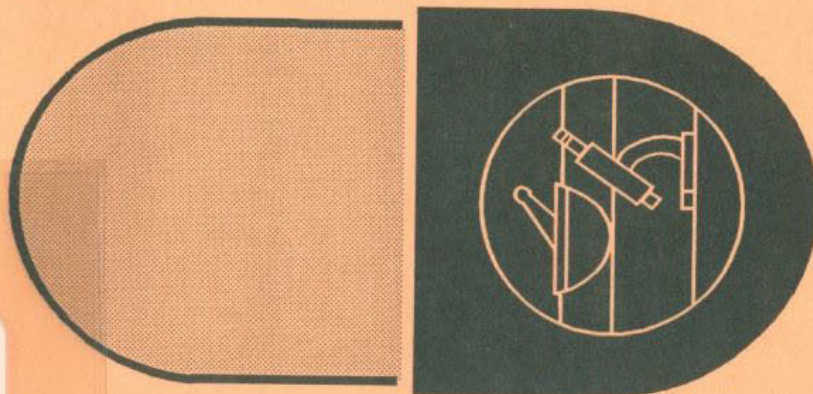
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APPROVED DRUG PRODUCTS

**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

Approved drug products with
therapeutic equivalence

C:355661 M:174736 O:12937927

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

12TH EDITION

Cumulative Supplement 9

September 1992

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

CUMULATIVE SUPPLEMENT 9

SEPTEMBER 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 Division of Blood and Blood Products and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 Division of Blood and Blood Products 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)
Tranylcypromine 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)

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)

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)

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)

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 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>MAR 1992</u>	<u>JUN 1992</u>	<u>SEP 1992</u>
DRUG PRODUCTS LISTED	9584	9473	9476	9501
SINGLE SOURCE	2187 (22.8%)	2222 (23.4%)	2227 (23.5%)	2227 (23.4%)
MULTISOURCE	7397 (77.2%)	7251 (76.6%)	7249 (76.5%)	7274 (76.6%)
THERAPEUTICALLY EQUIVALENT	6580 (68.7%)	6510 (68.7%)	6494 (68.5%)	6518 (68.6%)
NOT THERAPEUTICALLY EQUIVALENT	664 (6.9%)	592 (6.3%)	595 (6.3%)	590 (6.2%)
EXCEPTIONS ¹	153 (1.6%)	149 (1.6%)	160 (1.7%)	166 (1.8%)
NEW MOLECULAR ENTITIES APPROVED	--	4	2	8
NUMBER OF APPLICANTS	430	437	455	471

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORA
FIORICET W
+ SANDOZ

+ SANDOZ

325MG;50MG;40MG;30MGx N20232 001
JUL 30, 1992

MIKART
500MG/15ML; 5MG/15ML
500MG/15ML; 7.5MG/15ML

ETAMINOPHEN;

ELIXIR; ORAL
ACETAMINOP
PHARM BA
/MYAPAP' AND
/PHARM/BA

NE PHOSPHATE
120MG/5ML; 12MG/5ML
120MG/5ML; 12MG/5ML

N87006 001
/N87006/001/

MA	MIKART	500MG; 5MG
----	--------	------------

TABLET; ORAL
ACETAMINOPHEN
3 EON LABS
3
3
GENEVA

NE PHOSPHATE
300MG; 15MG
300MG; 30MG
300MG; 60MG
300MG; 30MG

N87433 001
N85917 001
N87423 001
N81250 001
JUL 16, 1992
N81249 001

2 PARKE DA
2
12/VITARINE
12/
12/

A	MYLAN	650MG; 65MG 325MG; 32MG
a	PROPOXYPHENE 'HOL' W/ 'A&P'	650MG; 65MG/ 325MG; 32MG/
A/	MYLAN	650MG; 65MG/ 325MG; 32MG/

ACETAMINOPHEN
/CHELSEA/

MAY/26./1982
MAY/26./1982
MAY/26./1982
MAY/26./1982

300Mg; 60Mg/
300Mg; 60Mg

> DLT > /BOROF AIR/
> DLT > /AT/ PHARMAFAIR/

3 CHelsea

N87276 001
MAY 26, 1982
N87275 001

[illegible]

ADD > AT PHARMAFAIR

	> ADD > AT	<u>MILES</u>
1		
2		
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7		
8		
9		
10		
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97		
98		
99		
100		

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

/B*/ /PHARM/BASICS/

/B*/ /50MG/

3 PHARM BASICS

250MG

3

500MG

/N70753/001/

/NOV/03,1986/

/N70754/001/

/NOV/03,1986/

NOV 03, 1986

NOV 03, 1986

ALBUTEROL SULFATE

SYRUP; ORAL

ALBUTEROL SULFATE

AA

EQ 2MG BASE/5MLM

N73419 001
MAR 30, 1992

TABLET; ORAL

ALBUTEROL SULFATE

MD PHARM

EQ 2MG BASEM

N73120 001
SEP 29, 1992

> ADD > AB

> ADD >

EQ 4MG BASEM

N73121 001
SEP 29, 1992

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

ACETYLCYSTEINE

10ZM

N72323 001

APR 30, 1992

20ZM

N72324 001

APR 30, 1992

10ZM

N72621 001

SEP 30, 1992

20ZM

N72622 001

SEP 30, 1992

ALGLUCERASE

INJECTABLE; INJECTION

CEREDASE

GENZYME

10 UNITS/MLM

N20057 004
MAY 08, 1992

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

/AB/ /BOLAR/

/100MG/

/N18241/001/

/NOV/16,1984/

N18241 001

NOV 16, 1984

3 BOLAR

100MG

AMIKACIN SULFATE

INJECTABLE; INJECTION

AMIKACIN

ELKINS SINN

EQ 50MG BASE/MLM

N63274 001

MAY 18, 1992

EQ 250MG BASE/MLM

N63275 001

MAY 18, 1992

AMIKIN

BRISTOL

EQ 50MG BASE/ML

N50495 001

N62562 001

SEP 20, 1984

EQ 250MG BASE/ML

N50495 002

N62562 002

SEP 20, 1984

N70575 001

OCT 14, 1986

N70576 001

OCT 14, 1986

/N70575/001/

/OCT/14,1986/

/N70576/001/

/OCT/14,1986/

N72652 001

FEB 21, 1992

N19243 002

JAN 14, 1987

N19773 001

APR 23, 1992

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

DEY

EQ 0.083% BASEM

N72652 001

FEB 21, 1992

PROVENTIL

SCHERING

EQ 0.083% BASE

N19243 002

JAN 14, 1987

VENTOLIN

GLAXO

EQ 0.083% BASEM

N19773 001

APR 23, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'92 - SEP'92

4

AMLODIPINE BESYLATE

TABLET; ORAL
NORVASC
+ PFIZER

EQ 10MG BASEM
EQ 2.5MG BASEM
EQ 5MG BASEM

N19787 003
JUL 31, 1992
N19787 001
JUL 31, 1992
N19787 002
JUL 31, 1992

AMOXICILLIN

POWDER FOR RECONSTITUTION; ORAL

AB/
AB/
UTIMOX/
PARKE/DAVIS/
3 PARKE DAVIS
3

125MG/5ML
250MG/5ML
125MG/5ML
250MG/5ML

N62127 001
N62127 002
N62127 001
N62127 002

AMOXAPINE

TABLET; ORAL
AMOXAPINE
DANBURY

AB
AB
AB
AB
25MG
50MG
100MG
150MG

N72688 001
AUG 28, 1992
N72689 001
AUG 28, 1992
N72690 001
AUG 28, 1992
N72691 001
AUG 28, 1992

INJECTABLE; INJECTION

AMPHOTERICIN B
PHARMA TEK

50MG/VIAL

N63206 001
APR 29, 1992

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AB/
AB/
AB/
AB/
AB/
AB/
POLYCYCLIN-N
BRISTOL/
3 BRISTOL
3
3
3

EQ 125MG BASE/VIAL
EQ 250MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL

N50309 001
N50309 002
N50309 003
N50309 004
N50309 005

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AB/
AB/
AB/
AB/
AMCILL/
PARKE/DAVIS/
3 PARKE DAVIS
3

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

N62041 001
N62041 002

POWDER FOR RECONSTITUTION; ORAL

AB/
AB/
AMOXICILLIN
CLONMEL/
3

125MG/5ML
250MG/5ML
125MG/5ML
250MG/5ML

N62927 001
NOV 25, 1988
N62927 002
NOV 25, 1988

POLYCYCLIN
BRISTOL/
3 BRISTOL
3

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

N50310 001
N50310 002

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

SOLUTION; ORAL

> DLT >
> DLT > /AA/
> ADD >

/LOMANATE/
/BARRE/
@ BARRE

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

TABLET; ORAL

BACLOFEN

/B*/ /PHARM/BASICS/
/B*/ /20MG/
@ PHARM BASICS
@
/3/VITAFINE/
/3/

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/
/CHELSEA/
@ CHELSEA
DIPHENOXYLATE HCL W/ ATROPINE SULFATE
@ EON LABS
/3/VITAFINE/
/0.025MG/5ML; 2.5MG/5ML/
0.025MG/5ML; 2.5MG/5ML

/N85876/001
N85876 001

/N86173/001
N86173 001

TABLET; ORAL

BACLOFEN

/B*/ /PHARM/BASICS/
/B*/ /20MG/
@ PHARM BASICS
@
/3/VITAFINE/
/3/

/AZITHROMYCIN/

/CAPSULE; ORAL/
/ZITHROMAX/
/P/ PFIZER/

/250MG/

/N85876/001
/NOV/01/1991/

AZITHROMYCIN DIHYDRATE

CAPSULE; ORAL
ZITHROMAX
+ PFIZER

EQ 250MG BASE

N50670 001
NOV 01, 1991

20MG; 25MG
5MG; 6.25MG
10MG; 12.5MG
20MG; 12.5MG

N20033 003
MAY 19, 1992
N20033 001
MAY 19, 1992
N20033 002
MAY 19, 1992
N20033 004
MAY 19, 1992

BACLOFEN

INJECTABLE; INJECTION

LIORESAL
MEDTRONIC

0.5MG/ML
2MG/ML

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

1MG
2MG

N81264 001
JAN 23, 1992
N81265 001
JAN 23, 1992
/N80211/001/
/JUN/14/1988/
/N80212/001/
/JUN/14/1988/
/N80213/001/
/JUN/14/1988/
N89211 001
JUN 14, 1988
N89212 001
JUN 14, 1988
N89213 001
JUN 14, 1988

TABLET; ORAL

BACLOFEN

BIOCRAFT

10MG

N73043 001
FEB 27, 1992

20MG

N73044 001
FEB 27, 1992

@ EON LABS

10MG

N71901 001
APR 13, 1988

@

20MG

N71902 001
APR 13, 1988

0.5MG
1MG
2MG

N89211 001
JUN 14, 1988
N89212 001
JUN 14, 1988
N89213 001
JUN 14, 1988

BENZAEPRIIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
LOTENSIN HCT
+ CIBA

20MG; 25MG
5MG; 6.25MG
10MG; 12.5MG
20MG; 12.5MG

N20033 003
MAY 19, 1992
N20033 001
MAY 19, 1992
N20033 002
MAY 19, 1992
N20033 004
MAY 19, 1992

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA MUTUAL PHARM

1MG
2MG

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

1MG
2MG

N81264 001
JAN 23, 1992
N81265 001
JAN 23, 1992
/N80211/001/
/JUN/14/1988/
/N80212/001/
/JUN/14/1988/
/N80213/001/
/JUN/14/1988/
N89211 001
JUN 14, 1988
N89212 001
JUN 14, 1988
N89213 001
JUN 14, 1988

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

/Ad/ /CLAY/PARK/ /Eq 0.05% BASE/

B* CLAY PARK EQ 0.05% BASE

AB TARO EQ 0.05% BASEM

/N72536/001/
/JAN/31/1990/
N72536 001
JAN 31, 1990
N73552 001
APR 30, 1992

ointment; TOPICAL

BETAMETHASONE DIPROPIONATE

/Ad/ /CLAY/PARK/ /Eq 0.05% BASE/

B* CLAY PARK EQ 0.05% BASE

/N72536/001/
/JAN/31/1990/
N72526 001
JAN 31, 1990

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE

/Ad/ /PHARMAFAIR/ /Eq 0.1% BASE/

3 PHARMAFAIR EQ 0.1% BASE

/N70485/001/
/MAY/29/1987/
N70485 001
MAY 29, 1987

ointment; TOPICAL

BETAMETHASONE VALERATE

/Ad/ /CLAY/PARK/ /Eq 0.1% BASE/

B* CLAY PARK EQ 0.1% BASE

AB /PHARMAFAIR/ /Eq 0.1% BASE/

3 PHARMAFAIR EQ 0.1% BASE

/N71478/001/
/DEC/23/1987/
N71478 001
DEC 23, 1987
/N70486/001/
/MAY/29/1987/
N70486 001
MAY 29, 1987

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

/AA/ /VITARINE/ /5MG/

/AA/ /VITARINE/ /10MG/

/AA/ /VITARINE/ /10MG/

/AA/ /VITARINE/ /25MG/

/AA/ /VITARINE/ /25MG/

3 VITARINE 5MG
3 10MG
3 10MG
3 25MG
3 25MG

/N84353/001/
/N84378/001/
/N84379/001/
/N84383/001/
/N84384/001/
/N84384/001/
N84353 001
N84378 001
N84379 001
N84383 001
N84384 001

BISOPROLOL FUMARATE

TABLET; ORAL

ZEBETA
+ LEDERLE

10MG

5MG

N19982 001
JUL 31, 1992
N19982 002
JUL 31, 1992

BITOLTEROL MESYLATE

SOLUTION; INHALATION

TORNALATE

/STERLING/MINTHROP/ /0.2% /

STERLING 0.2%

/N19548/001/
/FEB/19/1992/
N19548 001
FEB 19, 1992

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

/AB/ /LYPHOMED/ /50MG/ML/

3 LYPHOMED 50MG/ML

/N70134/001/
/FEB/12/1986/
N70134 001
FEB 12, 1986

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/ /PIONEER/PHARMS/ 4MG/

3 PIONEER PHARMS

4MG

/N88604/001/
/JUL/13/1984/
N88604 001
JUL 13, 1984

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
BUPIVACAINE HCL KIT
ABBOTT

0.075/M

0.114/M

0.23/M

N19978 001
SEP 03, 1992
N19978 002
SEP 03, 1992
N19978 003
SEP 03, 1992

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

3 EON LABS

15MG

30MG

15MG/

30MG/

30MG/

SODIUM BUTABARBITAL

/WEST/WARD/

15MG/

30MG/

15MG

30MG

/AA/
/AA/

BUTORPHANOL TARTRATE

SPRAY, METERED; NASAL
STADOL

+ BRISTOL MYERS SQUIBB 1MG/INH

1MG/INH/

N19890 001
DEC 12, 1991
/N19890/001/
/DEC/12/1991/

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL

DELFLX W/ DEXTROSE 1.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

18.4MG/100ML; 1.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N20171 001
AUG 19, 1992

DELFLX W/ DEXTROSE 2.5% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS

18.4MG/100ML; 2.5GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N20171 002
AUG 19, 1992

DELFLX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM IN PLASTIC CONTAINER

FRESENIUS

18.4MG/100ML; 4.25GM/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

N20171 003
AUG 19, 1992

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER

MCGAW

33MG/100ML; 5GM/100ML; 30MG/100ML;
860MG/100ML

AP

N20000 001
APR 17, 1992

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

RINGER'S IN PLASTIC CONTAINER

MCGAW

33MG/100ML; 30MG/100ML;
860MG/100ML

AP

N20002 001
APR 17, 1992

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/AB/ /PARKE/DAVIS/

200MG/

/B+ /PHARM/BASICS/

200MG/

3 PHARM BASICS

200MG

/N76444/001/
/JAN/02/1987/
/N76366/001/
/MAR/15/1986/
N70300 001
MAY 15, 1986

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

3 WARNER CHILCOTT

200MG

N70429 001
JAN 02, 1987

TABLET; ORAL

CEFADROXIL

AB

ZENITH

EQ 1GM BASE

/EQ/1GM/BASE/
/3/

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

TABLET, CHEWABLE; ORAL

EPITOL

AB

LEMMON

100MG

N73524 001
JUL 29, 1992

CEFDIOXIME PROXETIL

GRANULE, FOR RECONSTITUTION; ORAL

BANAH

AB

SANKYO

EQ 50MG BASE/5ML

N50688 002
AUG 07, 1992
N50688 001
AUG 07, 1992

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

AB

LEMMON

10MG;100MG

AB

25MG;100MG

AB

25MG;250MG

N73618 001
AUG 28, 1992
N73589 001
AUG 28, 1992
N73607 001
AUG 28, 1992

VANTIN

UPJOHN

EQ 50MG BASE/5ML

EQ 100MG BASE/5ML

N50675 001
AUG 07, 1992
N50675 002
AUG 07, 1992

SINEMET

AB

MSD

10MG;100MG

25MG;100MG

25MG;250MG

N17555 001
N17555 003
N17555 002

TABLET; ORAL

BANAH

AB

SANKYO

EQ 100MG BASE

N50687 001
AUG 07, 1992
N50687 002
AUG 07, 1992

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

B* EON LABS

350MG

N89566 001
AUG 30, 1988
/N89566/001/
/AUG/30./1988/

/3/ /VITAFINE/

/350MG/

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

CEFADROXIL

AB

ZENITH

EQ 500MG BASE

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

POWDER FOR RECONSTITUTION; ORAL

CEFZIL

+

BRISTOL MYERS SQUIBB 250MG/5ML

N50665 002
DEC 23, 1991
/N50665/002/
/DEC/23./1991/

CEFTAZIDIME

TABLET; ORAL

CEFTAZ

+ BRISTOL MYERS SQUIBB 500MG

/500MG/

N50664 002
DEC 23, 1991
/N50664/002/
/DEC/23,1991/

CEFTAZIDIME

INJECTABLE; INJECTION

/CEPTAZ/

/GLAXO/

/500MG/VIAL/

/1GM/VIAL/

/2GM/VIAL/

/10GM/VIAL/

/N50664/001/
/SEP/27,1990/
/N50664/002/
/SEP/27,1990/
/N50664/003/
/SEP/27,1990/
/N50664/004/
/SEP/27,1990/
/N50664/005/
/SEP/27,1990/

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION

CEPTAZ

GLAXO

1GM/VIAL

2GM/VIAL

10GM/VIAL

500MG/VIAL

N50646 002
SEP 27, 1990
N50646 003
SEP 27, 1990
N50646 004
SEP 27, 1990
N50646 001
SEP 27, 1990

PENTACEF

SMITHKLINE BEECHAM

1GM/VIAL

2GM/VIAL

10GM/VIAL

6GM/VIAL

N64006 001
MAR 31, 1992
N64006 002
MAR 31, 1992
N64008 002
MAR 31, 1992
N64008 001
MAR 31, 1992

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

ROCEPHIN

/ROCHE/

250MG

2

/EQ/250MG/BASE/VIAL/

EQ 250MG BASE/VIAL

/EQ/500MG/BASE/VIAL/

EQ 500MG BASE/VIAL

/EQ/1GM/BASE/VIAL/

EQ 1GM BASE/VIAL

/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

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

2 EON LABS

2

/AB/

/AB/

/AB/

2 PARKE DAVIS

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N84919 001
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/N84919/183/
/N84920/183/
/N84823/183/
/N84919/184/
/N84920/184/
/N84823/184/
/N84919/185/
/N84920/185/
/N84823/185/
/N84919/186/
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/N84920/195/
/N84823/195/
/N84919/196/
/N84920/196/
/N84823/196/
/N84919/197/
/N84920/197/
/N84823/197/
/N84919/198/
/N84920/198/
/N84823/198/
/N84919/199/
/N84920/199/
/N84823/199/
/N84919/200

CHLOROTHIAZIDE

TABLET; ORAL
CHLOROTHIAZIDE
@ EON LABS
/3/VITAFINE/

250MG
/250MG/

N85485 001
/N85485/001/

25MG

BX
HORUS

N88051 001
NOV 12, 1982
N19574 001
DEC 20, 1988

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
/AA/ /PIONEER/PHARMS/ /4MG/

4MG

/N88556/001/
/JUL/13/1984/
N88556 001
JUL 13, 1984

POWDER FOR RECONSTITUTION; OPHTHALMIC
/ALPHA CHYMOTRYPSIN/
/AT/ /BARNES/HIND/
@ SOLA BARNES HIND
/250 UNITS/VIAL/
750 UNITS/VIAL

/N11837/001/
N11837 001

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE
@ EON LABS
/B*/ /PHARM/BASICS/
/B*/

250MG
/250MG/
/250MG/

N84669 001
/N84669/001/
/AUG/30/1984/
/N84669/001/
/AUG/30/1984/
N88708 001
AUG 30, 1984
N88709 001
AUG 30, 1984
/N84669/001/

ZOLYSE
/AT/ /ALCON/
ALCON
/250 UNITS/VIAL/
750 UNITS/VIAL

/N11903/001/
N11903 001

CHLOROTHALIDONE

TABLET; ORAL
CHLOROTHALIDONE
@ EON LABS
/AB/ /VITAFINE/
/AB/ /WARNER/CHILCOTT/
/AB/

50MG
/50MG/
/250MG/
/50MG/

N87118 001
/N87118/001/
/N87118/001/
/JAN/24/1983/
/N87118/001/
/FEB/09/1983/
N87515 001
JAN 24, 1983
N87516 001
FEB 09, 1983

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE

SOLUTION; IRRIGATION
RENACIDIN
/GUARDIAN/LABS/

GUARDIAN LABS

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

THALITONE

/AB/ /BOEHRINGER/INGELHEIM/ /25MG/
/15MG/

SYRUP; ORAL
CLEMASTINE FUMARATE
AA
COPLEY

EQ 0.5MG BASE/5MLM
N73095 001
APR 21, 1992

CLEMASTINE FUMARATE

SYRUP; ORAL

TAVIST

> DLT > /AA/
> DLT > /PORSEY/
> ADD > AA
> ADD >

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

/N18675/001/
JUN/28/1985
N18675 001
JUN 28, 1985

EQ 2% BASEM

N50680 001
AUG 11, 1992

TABLET; ORAL

CLEMASTINE FUMARATE

LEMON

/AB/
AB

/1.34MG/

/N17661/001/
JAN/31/1992
N17661 001
JAN 31, 1992

EQ 150MG BASE/MLM

N63282 001
MAY 29, 1992

TAVIST

AB + SANDOZ

/AB/
AB

2.68MG

N17661 001

EQ 1% BASEM

N63329 001
SEP 30, 1992

TAVIST-1

PORSEY

/AB/
AB

/1.34MG/

/N17661/002/
N17661 002

EQ 1% BASEM

N10412/002/
N10412/001/

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

/TABLET; EXTENDED/RELEASE; ORAL/
/TAVIST/
/+/SANDOZ/

/EQ 1MG BASE/75MG/

/N18298/001/
DEC/15/1982

EQ 1% BASEM

N10412/004/
N10412/003/

AB

EQ 1MG BASE; 75MG

N18298 001
DEC 15, 1982

CLIOQUINOL; NYSTATIN

/OINTMENT; TOPICAL/
/NYSTAFORM/
/MILES/

EQ 10MG/GM;
100,000 UNITS/GM

N50235 001

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

AB EON LABS

/AB/
AB

EQ 75MG BASE

N62910 001
JUL 05, 1988

EQ 10MG/GM;
100,000 UNITS/GM

N50235 001

VIATRAINE

/AB/
AB

/EQ 75MG BASE/

/N62910/001/
JUL/05/1988
N62910 001
JUL 05, 1988

EQ 10MG/GM;
100,000 UNITS/GM

N50235 001

CAPSULE; ORAL

CLOFIBRATE

AB PHARMACAPS

500MG

N73396 001
MAR 20, 1992

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

/B*/ /PHARM/BASICS/ /3.75MG/

/B*/ /3.75MG/

/B*/ /15MG/

a PHARM BASICS 3.75MG

a 7.5MG

a 15MG

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/ /WARNER/CHILCOTT/ /3.75MG/

/AB/ /7.5MG/

/AB/ /15MG/

a WARNER CHILCOTT 3.75MG

a 7.5MG

a 15MG

CLOTIRIMAZOLE

CREAM; TOPICAL

LOTIRIN

/AT//S/ /SCHERING/

BX + SCHERING

MYCELEX

/AT/ /MILES/

BX MILES

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

HISTAFED-C

/CENCI/

> DLT >

> DLT >

> DLT >

> DLT >

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE;TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES M/ CODEINE

CENCI

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

1.25MG/5ML

N89018 001

JUL 23, 1986

COLCHICINE; PROBENECID

TABLET; ORAL

/PROBEN-C/

/B*/ /CHELSEA/

a CHELSEA

/0.5MG; 500MG/

0.5MG; 500MG

/N85552/001/

N85552 001

PROBENECID AND COLCHICINE

/B*/ /EON/LABS/

a EON LABS

/0.5MG; 500MG/

0.5MG; 500MG

/N86130/001/

N86130 001

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN

/AB/ /LUITPOLD/

a LUITPOLD

/0.05MG/ML/

0.03MG/ML

/N80668/001/

N80668 001

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL

/AT/ /BARNES/HIND/

a SOLA BARNES HIND

/1% /

1%

/N84863/001/

N84863 001

DACARBAZINE

INJECTABLE; INJECTION

DACARBAZINE

/AB/ /LYPHOMED/

a LYPHOMED

/100MG/VIAL/

/200MG/VIAL/

/N70962/001/

N70962 001

/AUG 28, 1986/

/N70990/001/

N70990 001

/AUG 28, 1986/

/N70962/001/

N70962 001

/AUG 28, 1986/

/N70990/001/

N70990 001

/AUG 28, 1986/

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAW

3.3GM/100ML; 110MG/100ML;
300MG/100MLM

N19630 050
MAY 07, 1992

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAW

3.3GM/100ML; 150MG/100ML;
300MG/100MLM

N19630 051
MAY 07, 1992

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAW

3.3GM/100ML; 220MG/100ML;
300MG/100MLM

N19630 052
MAY 07, 1992

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER
MCGAW

3.3GM/100ML; 300MG/100ML;
300MG/100MLM

N19630 053
MAY 07, 1992

DIAZEPAMTABLET; ORAL

DIAZEPAM
/AB/ /PIONEER/PHARMS/

/2MG/

/N70787/001/
/AUG 02, 1988/

/5MG/

/N70788/001/
/AUG 02, 1988/

/10MG/

/N70776/001/
/AUG 02, 1988/

/2MG/

/N70787/001/
/AUG 02, 1988/

/5MG/

/N70788/001/
/AUG 02, 1988/

/10MG/

/N70776/001/
/AUG 02, 1988/

/2MG/

/N70209/001/
/SEP 04, 1985/

/5MG/

/N70210/001/
/SEP 04, 1985/

/10MG/

/N70222/001/
/SEP 04, 1985/

DIAZEPAMINJECTABLE; INJECTION

DIAZEPAM

/AB/ /PARKE/DAVIS/

/5MG/ML/

/N71614/001/
/OCT 22, 1987/

/5MG/ML/

/N71613/001/
/OCT 22, 1987/

5MG/ML

N71613 001
OCT 22, 1987

5MG/ML

N71614 001
OCT 22, 1987

DICLOFENAC SODIUMTABLET, DELAYED RELEASE; ORAL

VOLTAREN

+ GEIGY

> ADD >

> ADD >

> ADD >

> ADD >

> DLT >

> DLT >

> DLT >

25MG

N19201 001
JUL 28, 1988

50MG

N19201 002
JUL 28, 1988

/25MG/

/N19201/001/
/JUL 28, 1988/

/50MG/

/N19201/002/
/JUL 28, 1988/

DIETHYLPROPION HYDROCHLORIDETABLET; ORAL

DIAZEPAM

/AB/ /PARKE/DAVIS/

/2MG/

/N70209/001/
/SEP 04, 1985/

/5MG/

/N70210/001/
/SEP 04, 1985/

/10MG/

/N70222/001/
/SEP 04, 1985/

TABLET; ORAL

DIETHYLPROPION HCL

@ EON LABS

/2-VITAFINE/

25MG

N85916 001
/N85916/001/

/25MG/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '92 - SEP '92

DIFLUNISAL

TABLET; ORAL
DIFLUNISAL
LEMMON

AB 250MG

AB 500MG

AB DOLOBID
MSD

250MG

500MG

N73679 001

JUL 31, 1992

N73673 001

JUL 31, 1992

N18445 001

APR 19, 1982

N18445 002

APR 19, 1982

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION
CARDIZEM

MARION MERRELL DOW

5MG/ML

/25MG VIAL/

/50MG VIAL/

N20027 001
OCT 24, 1991
/N86627/001/
/DEC/24, 1991/
/N86627/002/
/DEC/24, 1991/

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM CD

BC + MARION MERRELL DOW 180MG

BC + 240MG

+ 120MG

+ 300MG

/300MG/

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

EON LABS

25MG

50MG

/25MG/

/50MG/

N80845 002
N80845 001
/N89101/001/
/DEC/26, 1985/
/N88880/001/
/DEC/26, 1985/
N89101 001
DEC 20, 1985
N88880 001
DEC 20, 1985
/N88845/002/
/N88845/001/

25MG

50MG

a PIONEER PHARMS

a

/VITAMINE/

/25MG/

/50MG/

CARDIZEM SR

+ MARION MERRELL DOW

60MG

90MG

/60MG/

/90MG/

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

GENEVA

50MG

75MG

N87562 001
FEB 25, 1992
N87561 001
FEB 25, 1992

DILACOR XR

BC RHONE POULENC RORER

180MG

240MG

120MG

a

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE

/CHELSEA/

/EQ/100MG/PASE/

/EQ/150MG/PASE/

/N71626/001/
/DEC/01, 1985/
/N71621/001/
/DEC/01, 1985/

PROPERIDOLINJECTABLE; INJECTIONPROPERIDOL
LYPHOMED

> DLT > /AB/ /2.5MG/ML/
> DLT > /AB/ /2.5MG/ML/
> DLT > /AB/ /2.5MG/ML/
> DLT > /AB/ /2.5MG/ML/
> ADD >
> ADD >
> ADD >
> ADD >

3 LYPHOMED

3

SOLOPAK

3 SOLOPAK

/N76992/001/
NOV 17, 1986
/N76993/001/
NOV 17, 1986
/N76992/001/
NOV 17, 1986
/N76993/001/
NOV 17, 1986
/N71750/001/
SEP 06, 1988
/N71750/001/
SEP 06, 1988

ENOXACINTABLET; ORAL
PENETREX
+ PARKE DAVIS

400MG
/400MG/

N19616 005
DEC 31, 1991
/N19616/005/
DEC 31, 1991

ERGOLOID MESYLATESTABLET; SUBLINGUAL

ALKERGOT
3 EON LABS
3
/3/3ITAPINE/
/3/

0.5MG
1MG
/0.5MG/
/1MG/

N85153 001
N87417 001
/N85153/001/
/N87417/001/

ERGOTAMINE TARTRATETABLET; SUBLINGUAL

/ERGOTAM/
/FISONS/
/AA/

3 FISONS

/2MG/
2MG

/N87693/001/
FEB 24, 1983
/N87693/001/
FEB 24, 1983

ERYTHROMYCINSOLUTION; TOPICAL

/AT/ /C-SOLVE 2/
/AT/ /SYOSSET/

/22/

/N62468/001/
JUL 03, 1985

AT C-SOLVE-2
SYOSSET

22

N62468 001
JUL 03, 1985

AT ERYTHROMYCIN
PHARM BASICS

22

N62825 001
OCT 23, 1987

/AT/ /MYTHROMYCIN/
/PHARM/BASICS/

/22/

/N62825/001/
OCT 23, 1987

AT SANSAC

22

N62522 001
JAN 24, 1985

/AT/ /SANSAC/
/OWEN/GALDERMA/

/22/

/N62522/001/
JAN 24, 1985

TABLET, COATED PARTICLES; ORAL
PCE
ABBOTT

500MG

N50611 002
AUG 22, 1990

ERYTHROMYCIN ETHYLSUCCINATESUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE
/PARKE/DAVIS/

/EQ 200MG BASE/5ML/
/EQ 400MG BASE/5ML/
/EQ 200MG BASE/5ML/
/EQ 400MG BASE/5ML/

/N62231/001/
N62231 001
N62231 002

> DLT > /AB/
> DLT > /AB/
> ADD >
> ADD >

3 PARKE DAVIS

3

ESTROPIRATETABLET; ORAL

/AB/ /GEN/
/AB/ /ABBOTT/
/AB/ /+

/0.75MG/
/1.5MG/
/3MG/
/6MG/

/N83220/001/
N83220 001
N83220 002
N83220 003

OGEN .625

ABBOTT

0.75MG

OGEN 1.25

+ ABBOTT

1.5MG

OGEN 2.5

ABBOTT

3MG

ESTROPIPATE

TABLET; ORAL
OGEN 5
ABBOTT

ETHINYL ESTRADIOL; NORETHINDRONE

6MG
N83220 004
/AB/ /N.E.E.'11/35'28/
/N.E.E.'11/35'28/
/METFORMED/
TABLET; ORAL-28
@ LPI
0.035MG; 1MG
/0.035MG; 1MG/
/N71542/001/
/DEC/14, 1987/
N71542 001
DEC 14, 1987

ETHINYL ESTRADIOL

TABLET; ORAL
ESTINYL
/BP/ /SCHERING/
SCHERING
/BP/ /FEMINONE/
/UPJOHN/
@ UPJOHN

ETHINYL ESTRADIOL; NORGESTIMATE

/0.05MG/
0.05MG
/0.05MG/
0.05MG
/N05292/002/
N05292 002
/N16649/001/
N16649 001

TABLET; ORAL-21
ORTHO TRI-CYCLEN
+ JOHNSON RW

0.035MG;
0.18MG, 0.215MG, 0.25MG
N19697 002
JUL 03, 1992

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
GENCEPT 0.5/35-21
GENCON
AB
GENCEPT 1/35-21
GENCON
AB
GENCEPT 10/11-21
GENCON
AB

TABLET; ORAL-28
ORTHO TRI-CYCLEN
JOHNSON RW

0.035MG;
0.18MG, 0.215MG, 0.25MG
N19697 001
JUL 03, 1992

FELODIPINE

0.035MG; 0.5MG
0.035MG; 1MG
0.035MG; 0.5MG AND 1MG
/0.035MG; 1MG/
0.035MG; 1MG
/N71541/001/
/DEC/14, 1987/
N71541 001
DEC 14, 1987

TABLET, EXTENDED RELEASE; ORAL
PLENDIL
/MERCK/
MERCK

/5MG/
5MG
/10MG/
10MG
/N19834/001/
/JUL/25, 1991/
N19834 001
JUL 25, 1991
/N19834/002/
/JUL/25, 1991/
N19834 002
JUL 25, 1991

TABLET; ORAL-28
GENCEPT 0.5/35-28
GENCON
AB

FENOPROFEN CALCIUM

0.035MG; 0.5MG
0.035MG; 1MG
0.035MG; 0.5MG AND 1MG
/ED'200MG'BASE/
/ED'300MG'BASE/
EQ 200MG BASE
EQ 300MG BASE
/N72355/001/
/JUL/05, 1988/
N72355 001
JUL 05, 1988
/N72356/001/
/JUL/05, 1988/
N72356 001
JUL 05, 1988

CAPSULE; ORAL
FENOPROFEN CALCIUM
/AB/ /HALSEY/
/AB/

/ED'200MG'BASE/
/ED'300MG'BASE/
EQ 200MG BASE
EQ 300MG BASE
/N72355/001/
/JUL/05, 1988/
N72355 001
JUL 05, 1988
/N72356/001/
/JUL/05, 1988/
N72356 001
JUL 05, 1988

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '92 - SEP '92

FENOPROFEN CALCIUM

TABLET; ORAL

FENOPROFEN CALCIUM

/AB/ /HALSEY/

a HALSEY

/EQ 600MG BASE/

EQ 600MG BASE

/N7257/001/

/JUL/05/1988/

N7257 001

JUL 05, 1988

> DLT >/AP/

> DLT >

> DLT >/AP/

> DLT >

> DLT >/AP/

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

INJECTABLE; INJECTION

FLUOROURACIL

/LYPHOMED/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/50MG/ML/

/N89152/001/

/MAR/21/1986/

/N89428/001/

/JAN/12/1987/

/N89519/001/

/MAR/12/1987/

/N89152 001

MAR 21, 1986

N89428 001

JAN 12, 1987

N89519 001

MAR 12, 1987

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE

AP STERIS

EQ 0.05MG BASE/ML

N73488 001

JUN 30, 1992

FINASTERIDE

TABLET; ORAL

PROSCAR

+ MSD

5MG

N20180 001

JUN 19, 1992

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUONID

AT ALLERGAN HERBERT

0.025%

N87156 002

SEP 06, 1984

/N87156/002/

/SEP/06/1984/

/0.025%/

/AT/ /HERBERT/

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

/CLAY/PARK/

/0.05%/

/N71790/001/

/APR/25/1988/

N71790 001

APR 25, 1988

N73085 001

FEB 14, 1992

0.05%

B* CLAY PARK

0.05%

AB NMC

SUSPENSION; ORAL

FUROXONE

+ ROBERTS

50MG/15ML

/50MG/15ML/

N11323 002

/N11323/002/

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

/PHARM/BASICS/

/15MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

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/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/30MG/

/N70562/001/

/JUL/09/1987/

/N70563/001/

/JUL/09/1987/

/N70562 001

JUL 09, 1987

N70563 001

JUL 09, 1987

JUL 09, 1987

N84472 001

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

/N84472/001/

FURAZOLIDONE

TABLET; ORAL
FUROXONE
+ ROBERTS

100MG
/100MG/

N11270 002
/N11270/002/

1.5MG

BX UPJOHN

N20051 001
MAR 04, 1992
N20051 002
MAR 04, 1992

FUROSEMIDE

INJECTABLE; INJECTION

/AB/ FUROSEMIDE
/LYPHOMED/

/10MG/ML/

/N18507/001/
/JUL/30, 1982/
N18507 001
JUL 30, 1982

INJECTABLE; INJECTION
LUTREPULSE PUMP KIT
FERRING

10MG/ML

0.8MG/VIAL

N19687 001
OCT 10, 1989
N19687 002
OCT 10, 1989

TABLET; ORAL
FUROSEMIDE
/CHELSEA/

/20MG/

/N18369/001/
/MAY/14, 1982/
/N18369/002/
/MAY/14, 1982/
N18369 001
MAY 14, 1982

/JOHNSON/PH/

/0.8MG/VIAL/
/3.2MG/VIAL/

N19687 001
OCT 10, 1989
N19687 002
OCT 10, 1989
/N19687/001/
/OCT/10, 1989/
/N19687/002/
/OCT/10, 1989/

3 CHELSEA

20MG

MAY 14, 1982

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

3

40MG

MAY 14, 1982

TABLET; ORAL

3 EON LABS

40MG

MAY 14, 1982

ULTRAGRIS-165

AB

165MG

N62645 001
JUN 30, 1992

/3/VITARINE/

/40MG/

/N18750/002/
/JUL/30, 1984/
N18750 002
JUL 30, 1984

ULTRAGRIS-330

AB

330MG

N62646 001
JUN 30, 1992

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

GALLIUM CITRATE GA 67

/BS/ DUPONT/
BS DUPONT MERCK

/2MCI/ML/
2MCI/ML

/N17478/001/
N17478 001

HALOFANTRINE HYDROCHLORIDE

TABLET; ORAL

HALFAN

+ SMITHKLINE BEECHAM

250MG

N20250 001
JUL 24, 1992

GLYBURIDE

TABLET; ORAL
GLUBATE

BX HOECHST ROUSSEL

1.5MG

N20055 001
APR 17, 1992

BX

3MG

N20055 002
APR 17, 1992

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL
/ROYCE/

/AB/ /0.5MG/ /N71722/001/ /SEP/22/1987/

/AB/ /1MG/ /N71723/001/ /SEP/22/1987/

/AB/ /2MG/ /N71724/001/ /SEP/22/1987/

/AB/ /5MG/ /N71725/001/ /SEP/22/1987/

/AB/ /10MG/ /N71726/001/ /SEP/22/1987/

/AB/ /20MG/ /N71727/001/ /SEP/22/1987/

3 ROYCE

3

3

3

3

3

HALOPERIDOL LACTATE

INJECTABLE; INJECTION
HALOPERIDOL
/LYPHOMED/

/AB/ /EQ 5MG BASE/ML/ /N71187/001/ /JAN/20/1987/

3 LYPHOMED

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH
/LUITPOLD/

/AB/ /10 UNITS/ML/ /N89063/001/ /OCT/09/1985/

/AB/ /100 UNITS/ML/ /N89064/001/ /OCT/09/1985/

3 LUITPOLD

3

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH PRESERVATIVE FREE
/LYPHOMED/

/AB/ /10 UNITS/ML/ /N17029/011/ /SEP/22/1987/

/AB/ /100 UNITS/ML/ /N17029/012/ /SEP/22/1987/

3 LYPHOMED

3

HEPARIN LOCK FLUSH PRESERVATIVE FREE IN PLASTIC CONTAINER
/LYPHOMED/

/AB/ /100 UNITS/ML/ /N17029/008/ /SEP/22/1987/

/AB/ /100 UNITS/ML/ /N17029/009/ /SEP/22/1987/

3 LYPHOMED

3

HEPARIN SODIUM
/LUITPOLD/

/AB/ /1,000 UNITS/ML/ /N87452/001/ /OCT/31/1983/

3 LUITPOLD

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5%
/3/ABBOTT/

AP /10,000 UNITS/100ML/ /N18911/006/ /JAN/30/1985/

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

AP /200 UNITS/100ML/ /N19953/001/ /JUL/20/1992/

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

AP /5,000 UNITS/100ML/ /N19802/001/ /JUL/20/1992/

HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP /4,000 UNITS/100ML/ /N19952/001/ /JUL/20/1992/

HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP /5,000 UNITS/100ML/ /N19952/004/ /JUL/20/1992/

AP /10,000 UNITS/100ML/ /N19952/005/ /JUL/20/1992/

HEPARIN SODIUM

HYDRAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN

PLASTIC CONTAINER

AP MCGAM 5,000 UNITS/100MLM N19802 005

JUL 20, 1992

AP 10,000 UNITS/100MLM N19802 002

JUL 20, 1992

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN

PLASTIC CONTAINER

MCGAM 5,000 UNITS/100MLM N19802 003

JUL 20, 1992

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

APRESOLINE

/AB/

/CIBA/

CIBA

HYDRALAZINE HCL

/AB/

/LYPHOMED/

2 LYPHOMED

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

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20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

20MG/ML

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

capsule; oral

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

AB SOLVAY 25MG; 25MG N87608 001

FEB 08, 1982

AB 50MG; 50MG N87213 001

FEB 08, 1982

100MG; 50MG

N87609 001

FEB 08, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRAP-ES

2 EON LABS

/2/VITAPINE/

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

25MG; 15MG; 0.1MG

TABLET; ORAL

HYDROCHLOROTHIAZIDE

AB DANBURY

25MG

100MG

25MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

50MG

N81189 001

JAN 24, 1992

N81190 001

JAN 24, 1992

N83899 001

N85219 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

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N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

N84135 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/ /WARNER/CHILCOTT/

/AB/ /50MG/

3 WARNER CHILCOTT

3 25MG

3 50MG

/N87586/001/

/MAY/03/1982/

/N87587/001/

/MAY/03/1982/

N87586 001

MAY 03, 1982

N87587 001

MAY 03, 1982

CREAM; TOPICAL

HYDROCORTISONE

AT

PHARMAFAIR

1%

N87838 001
JUL 28, 1982

LOTION; TOPICAL

/GRIFFIN/

/MILES/

3 MILES

3

/0.5%/

/12/

0.5%

1%

/N09895/001/
/N09895/001/
N09895 003
N09895 001

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRO-SERP 25

3 EON LABS

/3/VITAFINE/

HYDRO-SERP 50

3 EON LABS

/3/VITAFINE/

/SERPASIL-ESIPRIX/1/

/BP/ /CIBA/

3 CIBA

/SERPASIL-ESIPRIX/2/

/BP/ /CIBA/

3 CIBA

25MG; 0.125MG

/25MG; 0.125MG/

50MG; 0.125MG

/50MG; 0.125MG/

25MG; 0.1MG

/25MG; 0.1MG/

50MG; 0.1MG

/50MG; 0.1MG/

N84827 001

/N84827/001/

N85213 001

/N85213/001/

N11878 003

/N11878/003/

N11878 005

/N11878/005/

ointment; topical

HYDROCORTISONE

NMC

> ADD > AT

> ADD >

> DLT >

> DLT >

N87796 001

OCT 13, 1982

/N87796/001/

/OCT/13/1982/

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

MAXZIDE-25

AB MYLAN

25MG; 37.5MG

50MG; 75MG

25MG; 37.5MG

50MG; 75MG

25MG; 37.5MG

50MG; 75MG

37.5MG; 56.25MG

75MG; 112.5MG

N19129 003

MAY 13, 1988

N71360 001

DEC 08, 1987

N73281 001

APR 30, 1992

/N71360/001/

/DEC/08/1987/

TABLET; ORAL

/HYCORTOL/

/3/VITAFINE/

HYDROCORTISONE

3 EON LABS

/20MG/

20MG

/N86642/001/
N80642 002

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HEMSOL-HC

ABLE

1%

N81274 001
JUN 19, 1992

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

/AT/ /BAUSCH/AND/LOMB/

1%

> DLT >
> DLT > /AT/

> DLT >

/HYDROCORTISONE ACETATE/

/THAMES/

/12/102/

/N89472/001/
/JUN/13/1988/

HYDROCORTISONE ACETATE; UREA

HYDROXYZINE PAMOATE

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE-HCL

/AN/ /DEY/

/AN/ /DEY/

/AN/ /DEY/

/AN/ /DEY/

/AN/ /DEY/

/AN/ /DEY/

/AN/ /DEY/

/AN/ /DEY/

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ISOSORBIDE MONONITRATE

TABLET; ORAL

ISMO

+ MYETH

20MG

/20MG/

/20MG/

/20MG/

/20MG/

/20MG/

/20MG/

/20MG/

/20MG/

/20MG/

/20MG/

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/20MG/

N19091 001
DEC 30, 1991
/N19091/001/
/DEC/30/1991/

N20083 001
SEP 11, 1992

N63021 001
JUL 31, 1992
N63022 001
JUL 31, 1992
N63025 001
JUL 31, 1992

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

N73160 001
AUG 25, 1992
N73591 001
MAY 29, 1992
N74138 001
SEP 30, 1992

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

LOCH

EQ 75MG BASE/2MLM

EQ 500MG BASE/2MLM

EQ 1GM BASE/3MLM

KEITOROLAC TROMETHAMINE

TABLET; ORAL

TORADOL

+ SYNTAX

10MG

/10MG/

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

LACTULOSE

SYRUP; ORAL

LACTULOSE

PACO

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

10GM/15MLM

N73160 001
AUG 25, 1992
N73591 001
MAY 29, 1992
N74138 001
SEP 30, 1992

ISOETHARINE HCL S/F

DEY

0.17%

/0.17%/

/0.17%/

/0.17%/

/0.17%/

/0.17%/

/0.17%/

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/0.17%/

/0.17%/

ISONIAZID

TABLET; ORAL

ISONIAZID

EON LABS

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

100MG

300MG

N08678 002
N08678 003
/N08678/002/
/N08678/003/
N08499 002
N08499 003
/N08499/002/
/N08499/003/

/N08678/001/
/JAN/04/1982/
N86764 001
JAN 04, 1982

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION

ISOPROTERENOL HCL

DEY

0.5%

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

/0.5%/

LACTULOSE

SYRUP; ORAL, RECTAL

AA LACTULOSE
PACO

AA ROXANE

10GM/15MLM

N72029 001
AUG 25, 1992
N73590 001
MAY 29, 1992

10GM/VIAL/
1GM/VIAL/
2GM/VIAL

INJECTABLE; INJECTION

LIDOCAINE HCL

/INTL/MEDICATION/
3 INTL MEDICATION

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

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

/AP/ /LYPHOMED/

3 LYPHOMED

/EQ 50MG BASE/VIAL/

EQ 50MG BASE/VIAL

/N88939/001/
DEC/01/1986/
N88939 001
DEC 01, 1986

LEVOCARNITINE

SOLUTION; ORAL

CARNITOR

AA SIGMA TAU

/VITACARN/
MCGAM/

1GM/10ML

N19257 001
APR 10, 1986

/B*/ /PHARM/BASICS/
300MG

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

LEVODOPA

CAPSULE; ORAL

DOPAR

/+//P/AND/S/

+ ROBERTS

500MG/
100MG/
250MG/
500MG
100MG
250MG

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

EQ 400MG BASEM

N20013 001
FEB 21, 1992

LEVORPHANOL TARTRATE

TABLET; ORAL

LEVO-DROMORAN

+ ROCHE

2MG

/2MG/

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

2MG

N72993 001
AUG 28, 1992
N73192 001
APR 30, 1992

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

/INTL/MEDICATION/
3 INTL MEDICATION

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

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAM

200MG/100MLM

N19830 002
APR 08, 1992

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAM

400MG/100MLM

N19830 003
APR 08, 1992

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER

AP MCGAM

800MG/100MLM

N19830 004
APR 08, 1992

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

/B*/ /PHARM/BASICS/
300MG

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

LOMEFLOXACIN HYDROCHLORIDE

TABLET; ORAL

MAXAQUIN

+ SEARLE

EQ 400MG BASEM

N20013 001
FEB 21, 1992

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

LOPERAMIDE HCL

AB GENEVA

2MG

N72993 001
AUG 28, 1992
N73192 001
APR 30, 1992

AB LEMMON

2MG

LORACARBEF

CAPSULE; ORAL
LORABID
+ LILLY

200MG
/200MG/

N50668 001
DEC 31, 1991
/N50668/001/
DEC/31,1991/

/B*/ /PHARM/BASICS/

MECLOFENAMATE SODIUM
CAPSULE; ORAL

/EQ/50MG/BASE/
/EQ/100MG/BASE/

/N71007/001/
MAR/25,1988/
/N71008/001/
MAR/25,1988/
/N71007/001/
MAR/25,1988/
/N71008/001/
MAR/25,1988/

POWDER FOR RECONSTITUTION; ORAL
LORABID
+ LILLY

200MG/5ML
/200MG/5ML/

N50667 002
DEC 31, 1991
/N50667/002/
DEC/31,1991/

MEFENAMIC ACID

CAPSULE; ORAL
MEFENAMIC ACID
EON LABS

250MG
/250MG/

N72179 001
APR 21, 1988
/N72179/001/
APR/21,1988/

LORAZEPAM

TABLET; ORAL
LORAZEPAM
/B*/ /PHARM/BASICS/

1MG
/1MG/

/N70539/001/
DEC/22,1986/
/N70540/001/
DEC/22,1986/

PHARM BASICS

2MG

N70539 001
DEC 22, 1986
N70540 001
DEC 22, 1986

MANNITOL

INJECTABLE; INJECTION
MANNITOL 25%
/LYPHOMED/

12.5GM/50ML
12.5GM/50ML

/N86754/001/
N86754 001

20MG
40MG

N70646 001
OCT 02, 1987
N70647 001
OCT 02, 1987

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

MASOPROCOL

CREAM; TOPICAL
ACTINEX
+ CHEMEX

102M

N19940 001
SEP 04, 1992

10MG/ML
50MG/ML
75MG/ML
100MG/ML
50MG/ML
75MG/ML
100MG/ML

N88432 001
AUG 16, 1984
/N88432/001/
/N88432/001/
/N88432/001/
/N88432/001/
/N88432/001/
/N88432/001/
/N88432/001/

INJECTABLE; INJECTION

MEPERIDINE HCL

AP ABBOTT

/AP/ /PARKE/DAVIS/

/AP/ /PARKE/DAVIS/

/AP/ /PARKE/DAVIS/

/AP/ /PARKE/DAVIS/

PARKE DAVIS

PARKE DAVIS

PARKE DAVIS

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

STERIS

10MG/ML

N73443 001

50MG/ML

N73444 001

100MG/ML

N73445 001

100MG/ML

N73446 001

METAPROTERENOL SULFATE

SOLUTION; INHALATION

METAPROTERENOL SULFATE

/AN/ /0.42/

/AN/ /0.62/

AN ASTRA /0.42/

AN /0.62/

/DEV/ /0.33/

DEV 0.33%

PROMETA

AN MURO 52M

AN

SYRUP; ORAL

METAPROTERENOL SULFATE

AA BIOCRIFT 10MG/5ML

AA SILARX 10MG/5ML

TABLET; ORAL

METAPROTERENOL SULFATE

/B*/ /PHARM/BASICS/ /10MS/

/B*/ /20MS/

PHARM BASICS 10MG

PHARM BASICS 20MG

TABLET; ORAL

METAPROTERENOL SULFATE

/B*/ /PHARM/BASICS/ /10MS/

/B*/ /20MS/

PHARM BASICS 10MG

PHARM BASICS 20MG

TABLET; ORAL

METAPROTERENOL SULFATE

/B*/ /PHARM/BASICS/ /10MS/

/B*/ /20MS/

PHARM BASICS 10MG

PHARM BASICS 20MG

TABLET; ORAL

METAPROTERENOL SULFATE

/B*/ /PHARM/BASICS/ /10MS/

/B*/ /20MS/

PHARM BASICS 10MG

PHARM BASICS 20MG

TABLET; ORAL

METAPROTERENOL SULFATE

/B*/ /PHARM/BASICS/ /10MS/

/B*/ /20MS/

PHARM BASICS 10MG

PHARM BASICS 20MG

TABLET; ORAL

METAPROTERENOL SULFATE

MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPIVACAINE HCL

STERIS

10MG/ML

50MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

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100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

100MG/ML

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

ELKINS SINN

EON LABS

HEATHER/

HEATHER

ICH/

ICN

ICN

PARKE/DAVIS/

PARKE DAVIS

QUANTUM/PHARMICS/

QUANTUM/PHARMICS/

VI-TARINE/

VI-TARINE/

VI-TARINE/

VI-TARINE/

VI-TARINE/

VI-TARINE/

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VI-TARINE/

METHADONE HYDROCHLORIDE

TABLET, DISPERSIBLE; ORAL

METHADONE
 3 EON LABS 2.5MG
 3 5MG
 3 10MG
 3 40MG
 3 12.5MG
 3 5MG
 3 10MG
 3 40MG

N17108 001
 N17108 002
 N17108 003
 N17108 004
 N17108 001
 N17108 002
 N17108 003
 N17108 004

/B* /
 3 PHARM BASICS
 5MG
 5MG

/N88745/001/
 /MAR 21, 1985/
 N88745 001
 MAR 21, 1985

METHOCARBAMOL

TABLET; ORAL

AA
 AA
 /AA/
 /AA/
 3 HEATHER
 3
 /AA/
 /AA/

500MG
 750MG
 500MG
 750MG
 500MG
 750MG
 500MG
 750MG

N87283 001
 N87282 001
 N84675/001/
 N84675/001/
 N84675 001
 N84924 001
 N87283/001/
 N87282/001/

/N70331/001/
 /APR 15, 1986/
 /N70332/001/
 /APR 15, 1986/
 /N70333/001/
 /APR 15, 1986/
 /N70331 001
 APR 15, 1986
 N70332 001
 APR 15, 1986
 N70333 001
 APR 15, 1986

METHOTREXATE SODIUM

TABLET; ORAL

AB
 METHOTREXATE
 MYLAN

EQ 2.5MG BASEM

N81235 001
 MAY 15, 1992

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE
 3 EON LABS
 4MG
 4MG
 /3/VITAFINE/

N87341 001
 /N87341/001/

METHOXYFLURANE

LIQUID; INHALATION
 PENTHRANE
 ABBOTT

99.9%

METOCLOPRAMIDE HYDROCHLORIDE

CONCENTRATE; ORAL

METOCLOPRAMIDE INTENSOL
 ROXANE

N13056 001

EQ 10MG BASE/MLM

N72995 001
 JAN 30, 1992

/SOLUTION; INHALATION/
 PENTHRANE/
 ABBOTT/

/99.9%/
 /N13056/001/

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL
 CETUS BEN VENUE

AP

EQ 10MG BASE/2MLM

N72155 001
 MAR 30, 1992

AP

EQ 10MG BASE/2MLM

N72244 001
 MAR 30, 1992

AP

EQ 10MG BASE/2MLM

N72247 001
 MAY 18, 1992

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL
/B*/ /INTERPHARM/
EQ 10MG BASE
/B*/ /PHARM/BASICS/
EQ 10MG BASE

/N171213/001/
/SEP/24/1986/
N71213 001
SEP 24, 1986
/N170339/001/
/JUL/29/1985/
N70339 001
JUL 29, 1985

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

METRONIDAZOLE

INJECTABLE; INJECTION
METRONIDAZOLE
/L.YPHOMED/
EQ 500MG/100ML

/N170071/001/
/DEC/03/1984/
N70071 001
DEC 03, 1984

TABLET; ORAL
METRONIDAZOLE
EON LABS

N18620 001
MAR 04, 1982
N18620 002
JUN 02, 1983
/N18520/001/
/MAR/04/1982/
/N18520/002/
/JUN/02/1983/

250MG
500MG
/250MG/
/500MG/

METOLAZONE

TABLET; ORAL
/B*/ /SCHIAPPARELLI/SEARLE/
EQ 2.5MG
/B*/ /FISONS/
EQ 5MG
/B*/ /FISONS/
EQ 10MG
EQ 2.5MG
EQ 5MG
EQ 10MG

/N18535/001/
/N18535/002/
/N18535/003/
N18535 001
N18535 002
N18535 003

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION
FLAGYL I.V.
/SCHIAPPARELLI/SEARLE/
EQ 500MG BASE/VIAL
/L.YPHOMED/
EQ 500MG BASE/VIAL

/N18353/001/
N18353 001

/N17386/001/
/N17386/002/
/N17386/003/
N17386 001
N17386 002
N17386 003

/N170295/001/
/OCT/15/1985/
N70295 001
OCT 15, 1985

EQ 500MG BASE/VIAL
EQ 500MG BASE/VIAL

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL
TOPROL XL
+ HASSLE
EQ 50MG TARTRATEM
EQ 100MG TARTRATEM
EQ 200MG TARTRATEM

N19962 001
JAN 10, 1992
N19962 002
JAN 10, 1992
N19962 003
JAN 10, 1992

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCYCLINE HCL
BIOCRAFT
EQ 50MG BASEM
EQ 100MG BASEM

N63011 001
MAR 02, 1992
N63009 001
MAR 02, 1992

METRONIDAZOLE

GEL; VAGINAL
METROGEL
+ CURATEK

SUSPENSION; ORAL
MINOCIN
+ LEDERLE

N50445 001

N20208 001
AUG 17, 1992

EQ 50MG BASE/5ML

0.75/M

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '92 - SEP '92

<u>MINOCYCLINE HYDROCHLORIDE</u>		<u>MORPHINE SULFATE</u>	
/STRUP; ORAL/ /MINOCIN/ /+/LEDERLE/	/EQ/50MG/BASE/5ML/ <		

CREAM; TOPICAL

BENOGUIN

/ELDER/

ICN

EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE/N61586 001
/N61586/001/

NEOMYCIN SULFATE

EON LABS

/AA/
/AA/
/VITAFINE/EQ 350MG BASE
/EQ 350MG BASE

NEOMYCIN SULFATE; PREDNISOLONE SODIUM PHOSPHATE

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

/DANTHRENE; DPH THALAMIC/
/NEO-HYDELTHASOL/
/MSD/

/EQ/3.5MG/BASE/GM;
/EQ/0.25% PHOSPHATE/

/N50378/001/

EQ 3.5MG BASE/GM;
EQ 0.25% PHOSPHATE

N50378 001

NIACIN

TABLET; ORAL

NIACIN

AA WOCKHARDT

500MG

N81134 001
APR 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

INJECTABLE; INJECTION

CARDENE

DUPONT MERCK

2.5MG/ML

N19734 001
JAN 30, 1992

NICOTINE

FILM, EXTENDED RELEASE; TRANSFERMAL

NICODERM

/BC/ /MARION/MERRELL/DOW/ /4MG/24HR/

BC + MARION MERRELL DOW 7MG/24HR

/BC/ /14MG/24HR/

BC + 14MG/24HR

/BC/ /21MG/24HR/

BC + 21MG/24HR

/N20165/001/
/NOV/07/1991/

N20165 001

NOV 07, 1991

/N20165/002/
/NOV/07/1991/

N20165 002

NOV 07, 1991

/N20165/003/
/NOV/07/1991/

N20165 003

NOV 07, 1991

NICOTINE

FILM, EXTENDED RELEASE; TRANSFERMAL

NICOTROL

+ KABI

+

+

+

PROSTEP

+ ELAN

+

+

11MG/24HR

22MG/24HR

N19983 001
JAN 28, 1992

N19983 002
JAN 28, 1992

N19983 003
JAN 28, 1992

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICORETTE

MERRELL DOW

NICORETTE DS

+ MERRELL DOW

+

+

EQ 2MG BASE

N18612 001
JAN 13, 1984

EQ 4MG BASE

N20066 001
JUN 08, 1992

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

/EQ/2MG/BASE/

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

NICORETTE DS

/+/MERRELL/DOW/

/4MG/

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

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

AB NOVOPHARM

AB SCHERER

10MG

20MG

N72651 001
FEB 19, 1992

N74045 001
APR 30, 1992

NITROFURANTOIN

TABLET; ORAL
NITROFURANTOIN
@ EON LABS
/A/ VITARINE/
/A/

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

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

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL
DANBURY

EQ 10MG BASEM
EQ 25MG BASEM
EQ 50MG BASEM
EQ 75MG BASEM

N73553 001
MAR 30, 1992
N73554 001
MAR 30, 1992
N73555 001
MAR 30, 1992
N73556 001
MAR 30, 1992

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE, EXTENDED RELEASE; ORAL
MACROBID
+ P AND G

75MG;25MG
/75MG;25MG/
/75MG;25MG/

N20064 001
DEC 24, 1991
/N20064/001/
/DEC/24,1991/

PAMELOR
SANDOZ

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

N18013 001
N18013 002
N18013 004
N18013 003
/N18013/001/
/N18013/002/

NITROFURAZONE

> DLT > /PRESSING; TOPICAL/
> DLT > /EUREGIN/
> DLT > /AT/ ROBERTS/
> DLT > /AT/ NITROFURAZONE/
> DLT > /AT/ THAMES/

/6.22/
/6.22/

/N05795/001/
/N05795/001/

NYSTATIN

/SUPPOSITORY; VAGINAL/
/NYSEPT/
/P/AND/G/

/100,000 UNITS/
/100,000 UNITS/

100,000 UNITS

N50478 001

ointment; TOPICAL

> ADD > FURACIN
> ADD > AT ROBERTS
> ADD > AT NITROFURAZONE
> ADD > AT THAMES

0.2%
0.2%

N05795 001
N86156 001

TABLET; ORAL
NYSTATIN
/AA/ CHELSEA/
@ CHELSEA

/500,000 UNITS/
/500,000 UNITS/

500,000 UNITS

/N62402/001/
/DEC/16,1982/
N62402 001
DEC 16, 1982
N62065 001
/N62065/001/

NITROGLYCERIN

INJECTABLE; INJECTION

/AP/ NITROGLYCERIN
/LUITPOLD/

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

5MG/ML

/N71492/001/
/MAY/24,1988/
N71492 001
MAY 24, 1988

TABLET; VAGINAL
NYSTATIN
@ EON LABS
/B/ VITARINE/

100,000 UNITS
/100,000 UNITS/

N61965 001
/N61965/001/

NYSTATIN; TRIAMCINOLONE ACETONIDE

OXYBUTYRIN CHLORIDE

CREAM; TOPICAL

TABLET; ORAL

NYSTATIN AND TRIAMCINOLONE ACETONIDE

OXYBUTYRIN CHLORIDE

/AT/ /CLAY/PARK/

/B*/ /PHARM/BASICS/

/N62186/002/ /N62186/002/

/5MG/

B* CLAY PARK

100,000 UNITS/GM; 0.1% /JUN/86, 1985/

3 PHARM BASICS

5MG

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

N70746 001
MAR 10, 1988

OFLOXACIN

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

INJECTABLE; INJECTION

FLOXIN

PENICILLIN G POTASSIUM

JOHNSON RM

/AP/ /PARK/DAVIS/

N20087 002

20MG/MLM

JOHNSON RM

3 PARKE DAVIS

MAR 31, 1992

40MG/MLM

FLOXIN IN DEXTROSE 5%

/1,000,000 UNITS/VIAL/

JOHNSON RM

3

MAR 31, 1992

400MG/100MLM

FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER

POWDER FOR RECONSTITUTION; ORAL

JOHNSON RM

3

MAR 31, 1992

4MG/MLM

400MG/100MLM

3

MAR 31, 1992

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

/B*/ /CHELSEA/

/10MG/

/B*/

/15MG/

/B*/

/30MG/

/N71661/001/

/MAR/82, 1988/

/N71662/001/

/MAR/82, 1988/

/N71663/001/

/MAR/82, 1988/

TABLET; ORAL

/PENAPAR-VK/

/PARK/DAVIS/

/EQ 125MG BASE/5ML/

3 PARKE DAVIS

/EQ 250MG BASE/5ML/

3

/EQ 500MG BASE/

TABLET; ORAL

/PENAPAR-VK/

/PARK/DAVIS/

/EQ 125MG BASE/5ML/

3 PARKE DAVIS

/EQ 250MG BASE/5ML/

3

/EQ 500MG BASE/

OXICONAZOLE NITRATE

PENTAMIDINE ISETHIONATE

LOTION; TOPICAL

INJECTABLE; INJECTION

OXISTAT

PENTAM 300

+ GLAXO

FUJISAWA

EQ 1% BASEM

300MG/VIAL

> ADD >

> ADD >

> ADD >

> ADD >

N20209 001

ABBOTT

300MG/VIALM

N19264 001
OCT 16, 1984

N73479 001
JUN 30, 1992

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE
/BX/ /CHELSEA/

/8MG/

/N84700/001/
/DEC/23/1987/

N87301 001
N87190 001
N87208 001
N87223 001
/N87301/001/
/N87190/001/
/N87208/001/
/N87223/001/

PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL
PHENDIMETRAZINE TARTRATE
EON LABS

AA 35MG
AA 35MG
AA 35MG
AA 35MG
/AA/ /VITARINE/
/AA/ /35MG/
/AA/ /35MG/
/AA/ /35MG/
/AA/ /35MG/

N85633 001
N85694 001
N85695 001
N85702 001
/N85633/001/
/N85694/001/
/N85695/001/
/N85702/001/

15MG
30MG
30MG
30MG
/15MG/
/30MG/
/30MG/
/30MG/

TABLET; ORAL
PHENDIMETRAZINE HCL
EON LABS

8MG
8MG
/8MG/
/8MG/

N85671 001
N85689 001
/N85671/001/
/N85689/001/

CAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE
EON LABS

BC 105MG
/BC/ /VITARINE/
/105MG/

N18074 001
/N18074/001/

PHENYLBUZAZONE

CAPSULE; ORAL

/AZOLIN/
/RHONE/POULENC/RORER/100MG/
/AB/ 3 RHONE POULENC RORER 100MG

/N87260/001/
N87260 001

TABLET; ORAL
ALPHAZINE
EON LABS

35MG
/35MG/

N85034 001
/N85034/001/

TABLET; ORAL

/AZOLIN/
/RHONE/POULENC/RORER/100MG/
/AB/ 3 RHONE POULENC RORER 100MG

/N87091/001/
N87091 001

/AA/ /PHARM/BASICS/
/AA/ /35MG/
/AA/ /35MG/

PHENDIMETRAZINE TARTRATE
EON LABS

AA 35MG
AA 35MG
/35MG/

N85402 001
N85830 001
/N85830/001/

SUSPENSION; ORAL

DILANTIN-125
+ PARKE DAVIS
PHENYTOIN
BARRE
> ADD > AB
> ADD >
> ADD > AB
> ADD >

N08762 001
N8982 001
SEP 25, 1992

PHENDIMETRAZINE TARTRATE
PHARM BASICS

AA 35MG
3 35MG
3 35MG

N84399 001
N83805 001
N84398 001

PHENYTOIN SODIUM, PROMPT

PHENDIMETRAZINE TARTRATE
/AA/ /VITARINE/
/35MG/

CAPSULE; ORAL
/PHENYTOIN/SODIUM/
/BX/ /CHELSEA/
3 CHELSEA

/N85894/001/
N85894 001

/100MG/
100MG

PYRAZINAMIDETABLET; ORAL
PYRAZINAMIDEAB + LEDERLE
AB MIKART500MG
500MGN80157 001
N81319 001
JUN 30, 1992TABLET; ORAL
RESERPINEBP EON LABS
BP
BP /VITAMINE/
BP/0.1MG
0.25MG
0.1MG/
0.25MG/N09838 001
N09838 002
N09838/001/
N09838/002/PYRIDOXINE HYDROCHLORIDEINJECTABLE; INJECTION
PYRIDOXINE HCL/AB/ /LUITPOLD/
3 LUITPOLD/100MG/ML/
100MG/ML/N80669/001/
N80669 001/SERPATE;/
/BP/ /VALE/
BP/ 3 VALE
3/0.1MG/
/0.25MG/
0.1MG
0.25MG/N09453/001/
/N09453/002/
N09453 001
N09453 002QUINETHAZONE; RESERPINE/TABLET; ORAL/
/HYDROX/ R/
/LEDERLE/

3 LEDERLE

50MG; 0.125MG

N13927 001

INJECTABLE; INJECTION
RIIODRINE HCL/AB/ /LUITPOLD/
/AB//10MG/ML/
/15MG/ML/
10MG/ML
15MG/ML/N71188/001/
/JUL/23/1987/
/N71188/001/
/JUL/23/1987/
N71188 001
JUL 23, 1987
N71189 001
JUL 23, 1987QUINIDINE SULFATETABLET; ORAL
QUINIDINE SULFATE3 ELKINS SINN
EON LABS200MG
200MG
300MGN83622 001
N84631 001
N88072 001> DLT >
> DLT >
> ADD >
> ADD >/3/QUANTUM/PHARMICS/
/AB/ /VITAMINE/
/AB//200MG/
/200MG/
/300MG//N83622/001/
/N84631/001/
/N88072/001/
/SEP/26/1983/

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL

BAROS

/E/2/EN/

/450MG/5M; 420MG/5M/

/N18509/001/
/AUG/07/1985/
N18509 001
AUG 07, 1985

460MG/GM; 420MG/GM

LAFAYETTE

RAUWOLFIA SERPENTINA

TABLET; ORAL

/RAUVERID/
/FOREST/PHARMS/
WOLFINA

3 FOREST PHARMS

50MG

N09255 008

SODIUM CHLORIDE

INJECTABLE; INJECTION

/SODIUM/CHLORIDE/23.4% IN PLASTIC CONTAINER/
/LUITPOLD/

3 LYPHOMED

234MG/ML

/N19329/001/
/APR/22/1987/
N19329 001
APR 22, 1987

SULFAMETHIZOLE

TABLET; ORAL

THIOSULFYL

/AB//+/WYETH/AYERST/
+ WYETH AYERST

/500MG/
500MG

SULFAMETHOXAZOLE

TABLET; ORAL

/USDA/

/AB//SHIONOGI/
@ SHIONOGI

/500MG/
500MG

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

SULFAMETHOXAZOLE AND TRIMETHOPRIM

CETUS BEN VENUE

80MG/ML; 16MG/ML

> ADD > AP

> ADD >

STERLING WINTHROP

80MG/ML; 16MG/ML

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

EON LABS

/N08565/004/
N08565 004

800MG; 160MG

AB

/AB//MARTEC/

/800MG; 160MG/

@ MARTEC

800MG; 160MG

/AB//VITAFINE/

/800MG; 160MG/

@ VITAFINE/

800MG; 160MG

/AB//VITAFINE/

/800MG; 160MG/

@ VITAFINE/

800MG; 160MG

/AB//VITAFINE/

/800MG; 160MG/

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/800MG; 160MG/

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800MG; 160MG

/AB//VITAFINE/

/800MG; 160MG/

@ VITAFINE/

800MG; 160MG

/AB//VITAFINE/

/800MG; 160MG/

@ VITAFINE/

800MG; 160MG

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION
RBC-SCAN
CADEMA

N/AM

N20063 001
JUN 11, 1992

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

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/400MG/BASIS/

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

a ABBOTT

EQ 400MG BASEM

N20043 003

JAN 30, 1992

a

EQ 600MG BASEM

N20043 004

JAN 30, 1992

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
DELATESTRYL
GYNEX

AO

200MG/ML
200MG/ML
/200MG/ML/
/200MG/ML/

N09165 003
N09165 001
/N09165/003/
/N09165/001/

TEMAZEPAM

CAPSULE; ORAL
TEMAZEPAM

/B+/ /PHARM/BASIS/

/B+/

/15MG/

/30MG/

a PHARM BASICS

15MG

N70489 001

JUL 07, 1986

a

30MG

N70490 001

JUL 07, 1986

TETRACYCLINE

SYRUP; ORAL
/BIDCYCLINE/
/BARRE/

/AB/
TETRACYCLINE
AB

/EQ 125MG HCL/5ML/

EQ 125MG HCL/5ML

/N60633/001/

N60633 001

TENIPOSIDE

INJECTABLE; INJECTION
VUMON

BRISTOL MYERS SQUIBB 10MG/MLM

/AB/
/AB/
/AB/
/AB/
/AB/

/150MG/

/250MG/

/250MG/

/500MG/

/500MG/

/250MG/

/250MG/

/500MG/

/500MG/

CAPSULE; ORAL

/CYCLOPAB/
/PARKE/DAVIS/

/N61725/001/

/N61725/001/

/N61725/001/

/N61725/002/

/N61725/002/

/N61725/001/

/N61725/001/

/N61725/002/

/N61725/002/

TETRACYCLINE HCL

EON LABS

/250MG/

/500MG/

/N61471 001

/N61471 002

SEP 06, 1988

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

3 LUITPOLD

3 PARKE/DAVIS

3 PARKE DAVIS

/100MG/ML/

100MG/ML

/100MG/ML/

100MG/ML

/N8667/001/

N8067 001

/N8670/001/

N8070 001

N63116 001

MAY 18, 1992

N63100 001

JAN 30, 1992

EQ 40MG BASE/ML

EQ 40MG BASE/ML

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

3 PAR

3

/150MG/

150MG

/200MG/

200MG

/N89764/001/

FEB 09, 1988

/N89765/001/

FEB 09, 1988

TABLET; ORAL

TOLAZAMIDE

/AB/

/AB/

B*

B*

/B*/

/B*/

/B*/

250MG

500MG

/100MG/

/250MG/

/500MG/

100MG

250MG

500MG

N73494 001

JUN 30, 1992

EQ 5MG BASE/ML

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL INTENSOL

3 ROXANE

3

EQ 5MG BASE/ML

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

3 PHARM/BASICS

3

3

3

3

3

3

3

3

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3

3

3

3

3

3

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3

/5MG/

5MG

/10MG/

10MG

/20MG/

20MG

5MG

10MG

20MG

/N72001/001/

JAN 10, 1989

/N72002/001/

JAN 10, 1989

/N72003/001/

JAN 10, 1989

N72001 001

JAN 10, 1989

N72002 001

JAN 10, 1989

N72003 001

JAN 10, 1989

TABLET; ORAL

TOLBUTAMIDE

3

3

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500MG

N12678 001

N8667/001/

N86047 001

N12678/001/

N73392 001

JAN 24, 1992

EQ 400MG BASE

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL
TRIPLE SULFA

AT CLAY PARK

AT FOUGERA

AT NHC

TRYSUL

AT SAVAGE

VAGILIA

3 LEMMON

3.7%; 2.86%; 3.42%

3.7%; 2.86%; 3.42%

3.7%; 2.86%; 3.42%

3.7%; 2.86%; 3.42%

3.7%; 2.86%; 3.42%

N87285 001
NOV 15, 1982

N86424 001
NOV 15, 1982

N87864 001
SEP 01, 1982

N87887 001
JUL 23, 1982

N88821 001
NOV 09, 1987

TABLET; VAGINAL

SULTRIN

JOHNSON RW

TRIPLE SULFA

3 FOUGERA

3 PHARMADERM

184MG;143.75MG;172.5MG

184MG;143.75MG;172.5MG

184MG;143.75MG;172.5MG

N05794 002

N88463 001
JAN 03, 1985

N88462 001
JAN 03, 1985

IRISULFAPYRIMIDINES

SUSPENSION; ORAL

SULFALDIA

FOREST PHARMS

3 FOREST PHARMS

TABLET, EXTENDED RELEASE; ORAL

ISOPTIN SR

AB + KNOLL

AB

N19152 001
DEC 16, 1986

N73568 001
JUL 31, 1992

N73568 001
JUL 31, 1992

N86166/661/
N80100 001

500MG/5ML/
500MG/5ML

VALPROIC ACID

SYRUP; ORAL

VALPROIC ACID

COPLEY

N73178 001
AUG 25, 1992

250MG/5ML

VECURIUM BROMIDE

INJECTABLE; INJECTION

NORCURON

ORGANON

N18776 003
JAN 03, 1992

20MG/VIAL

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN

+ ELAN

N19614 003
JAN 09, 1992

TABLET; ORAL

VERAPAMIL HCL

CHELSEA

AB

AB

AB

AB

AB

AB

AB

AB

AB

N73168 001
JUL 31, 1992

N73168 001
JUL 31, 1992

N73168 001
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N73168 001
JUL 31, 1992

N73168 001
JUL 31, 1992

WARFARIN SODIUM

TABLET; ORAL
/B*/ /WARFARIN/SODIUM/
/B*/ /PHARM/BASICS/

12MG/

/N88719/001/
/JUN/27/1985/

12.5MG/

/N88720/001/
/AUG/06/1985/

15MG/

/N88721/001/
/JUL/02/1985/

2 PHARM BASICS

2MG

N88719 001

2.5MG

JUN 27, 1985
N88720 001

5MG

AUG 06, 1985
N88721 001

JUL 02, 1985

ZALCITABINE

TABLET; ORAL
HIVID
+ ROCHE

0.75MGH

N20199 002

0.375MGH

JUN 19, 1992
N20199 001

JUN 19, 1992

ACETAMINOPHEN

SUPPOSITORY; RECTAL

ACEPHEN
G AND M

120MG

N72218 001

MAR 27, 1992

325MG

N72344 001

MAR 27, 1992

650MG

N72237 001

MAR 27, 1992

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

MICROCOL

JOHNSON AND JOHNSON 0.5%

N72292 001

JAN 28, 1992

STERI-STAT

MATRIX MEDCL

4%

N70104 001

JUL 24, 1986

MEDCL/SYSTEMS/

N70104/001/

JUL/24, 1986/

CLEMASTINE FUMARATE

TABLET; ORAL

TAVIST-1

SANDOZ

1.34MG

N17661 003

AUG 21, 1992

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST-D

SANDOZ

1.34MG;75MG

N18298 002

AUG 21, 1992

DEXBROMPHENTRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

RESPORAL/

PIONEER/PHARMS/

6MG;120MG/

N89139/001/

JUN/16, 1988/

3 PIONEER PHARMS

6MG;120MG

N89139 001

JUN 16, 1988

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

DIPHENHYDRAMINE HCL

CUMBERLAND SWAN

12.5MG/5ML

N73611 001

AUG 20, 1992

SILPHEN

SILARX

12.5MG/5ML

N72646 001

FEB 27, 1992

IBUPROFEN

TABLET; ORAL

IBUPROFEN

TAG

200MG

N73141 001

MAY 29, 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

PERRIGO

1MG/5ML

N73243 001

JAN 21, 1992

ROXANE

1MG/5ML

N73079 001

APR 30, 1992

SODIUM CHLORIDE

AEROSOL, METERED; INHALATION

BRONCHO SALINE

BLAIREX

0.9%

N19912 001

SEP 03, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL

EXTRA-STRENGTH AIM

/3/CHESBROUGH POND'S

11.44/

CHESBROUGH POND'S

1.2%

/N19518/001/

/JUN/03, 1987/

N19518 001

JUN 03, 1987

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '92 - SEP '92

<u>DEXTRAN, 75, 6% INVERTED SUGAR 10% IN SODIUM CHLORIDE 0.9%</u>	
<u>INJECTABLE; INJECTION</u>	
6% GENTRAN 75 AND 10% TRAVERS	N08788
TRAVENOL LABS	
6GM/100ML; 0.9GM/100ML	
0.9GM/100ML	
<u>UROKINASE</u>	
<u>INJECTABLE; INJECTION</u>	
BREOKINASE	
STERLING DRUG	N17873
250,000 IU/VIAL	

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: 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: ANTITHROMBIN III TRADE: THROMBATE III*/**	USE AS REPLACEMENT THERAPY IN CONGENITAL DEFICIENCY OF ANTITHROMBIN-III FOR PREVENTION AND TREATMENT OF OF THROMBOSIS AND PULMONARY EMBOLI. [DEC 13, 1996]	CUTTER BIOLOGICAL
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 AMYOTROPHIC LATERAL SCLEROSIS.	ROGENERON PHARMACEUTICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CILIARY NEUROTROPHIC FACTOR, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	TREATMENT OF SPINAL MUSCULAR ATROPHIES. TREATMENT OF MOTOR NEURON DISEASE (INCLUDING AMYOTROPHIC 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: 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.	ABBOTT LABORATORIES
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: 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 (IGG2A) TO BCE TRADE: IMMURATID-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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ANARITIDE ACETATE TRADE: AURICULIN	IMPROVEMENT OF EARLY RENAL ALLOGRAFT FUNCTION FOLLOWING RENAL TRANSPLANTATION. TREATMENT OF PATIENTS WITH ACUTE RENAL FAILURE.	SCIOS, INC
GENERIC: ARGININE BUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF BETA-HEMOGLOBINOPATHIES AND BETA-THALASSEMIA.	SUSAN P. PERRINE, M.D.
GENERIC: BACLOFEN (INTRATHECAL) TRADE: LIORESAL	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.	MEDTRONIC, INC
GENERIC: BUTYRYLCHOLINESTERASE TRADE: NOT ESTABLISHED	FOR THE REDUCTION AND CLEARANCE OF TOXIC BLOOD LEVELS OF COCAINE ENCOUNTERED DURING A DRUG OVERDOSE. TREATMENT OF POST-SURGICAL APNEA.	PHARMAVENE, INCORPORATED
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIAINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS TRADE: NUTRINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS	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
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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: 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
GENERIC: MELPHALAN TRADE: ALKERAN FOR INJECTION	TREATMENT OF PATIENTS WITH MULTIPLE MYELOMA FOR WHOM ORAL THERAPY IS INAPPROPRIATE. FOR USE IN HYPERTHERMIC REGIONAL LIMB PERFUSION TO TREAT METASTATIC MELANOMA OF THE EXTREMITY.	BURROUGHS WELLCOME COMPANY
GENERIC: MINOCYCLINE HCL TRADE: MINOCIN	TREATMENT OF CHRONIC MALIGNANT PLEURAL EFFUSION.	LEDERLE LABORATORIES
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: 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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: PPI-002 TRADE: NOT ESTABLISHED	TREATMENT OF MALIGNANT MESOTHELIOMA.	PLEXUS PHARMACEUTICALS, INC
GENERIC: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODODECABORATE TRADE: BOROCELL	FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.	NEUTRON TECHNOLOGY CORPORATION
GENERIC: SODIUM PHENYL BUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF SICKLING DISORDERS, WHICH INCLUDE S-S HEMOGLOBINOPATHY, S-C HEMOGLOBINOPATHY, AND S-THALASSEMIA HEMOGLOBINOPATHY.	JOHNS HOPKINS MEDICAL INSTITUTIONS
GENERIC: TENIPOSIDE TRADE: VUMON*/**	TREATMENT OF REFRACTORY CHILDHOOD ACUTE LYMPHOCYTIC LEUKEMIA (ALL). [JUL 14, 1999]	BRISTOL MYERS SQUIBB
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 SEPTEMBER 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
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	
DIFLUNISAL (TABLET)	MAY 16, 1992	
DILTIAZEM HYDROCHLORIDE (TABLET)	MAY 16, 1992	
GEMFIBROZIL (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 CROSSEVER DESIGN		
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	PETITIONS APPROVED			REASON FOR STATUS
	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET; ORAL	500MG 7.5MG	91 P-0514/ CP1	SOFTAN	APPROVED JUN 03, 1992
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CP1	HAMER	APPROVED MAR 17, 1992
CHLORZOXAZONE TABLET; ORAL	750MG	91 P-0153/ CP1	MIKART	APPROVED JUN 03, 1992
HYDROCORTISONE ACETATE AEROSOL; TOPICAL	2.5%	92 P-0101/ CP1	HOGAN & HARTSON	APPROVED JUL 08, 1992
NALBUPHINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (2ML/CONTAINER)	92 P-0224/CP	STERLING	APPROVED SEP 11, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CP1	ABBOTT	APPROVED FEB 18, 1992
TRIAZOLAM SOLUTION; ORAL	0.125MG/5ML	92 P-0048/ CP2	ROXANE	APPROVED SEP 11, 1992

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	PETITION	REASON FOR STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/VIAL)	91 P-0076/ CPI	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 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

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

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
20232 001	ACETAMINOPHEN; FIORICET W/ CODEINE			NC		OCT 26, 1993
18828 001	ACYCLOVIR; ZOVIRAX			I-71		FEB 26, 1995
19909 001	ACYCLOVIR; ZOVIRAX			I-71		FEB 26, 1995
20089 001	ACYCLOVIR; ZOVIRAX			I-71		FEB 26, 1995
20089 002	ACYCLOVIR; ZOVIRAX			I-71		FEB 26, 1995
19787 001	AMLODIPINE BESYLATE; NORVASC			I-71		FEB 26, 1995
19787 002	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003	NCE		JUL 31, 1997
19787 003	AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003	NCE		JUL 31, 1997
18240-001	ATENOLOL; TENORMIN	4572909	FEB 25, 2003	NCE		JUL 31, 1997
18240-002	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	NCE		JUL 31, 1997
18240-004	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	NCE		JUL 31, 1997
20075 001	BACLOFEN; LIORESAL	3934032	JAN 20, 1993	NCE		JUL 31, 1997
20075 002	BACLOFEN; LIORESAL			ODE		JUN 17, 1999
19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN			NDF		JUN 17, 1995
19851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN			ODE		JUN 17, 1999
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	NCE		JUN 25, 1996
20033 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002	NC		MAY 19, 1995
20033 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002	NCE		JUN 25, 1996
19001 001	BEPRIDIL HYDROCHLORIDE; BEPADIN			NC		MAY 19, 1995
19001 002	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
19001 003	BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995	NCE		DEC 28, 1995
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
19982 001	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998	NCE		DEC 28, 1995
19982 002	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998	NCE		DEC 28, 1995
19548 001	BITOLTEROL MESYLATE; TORNALATE	436400	JUN 22, 1999	NCE		JUL 31, 1997
		4138581	FEB 06, 1998	NDF		FEB 19, 1995

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
19890 001	BUTORPHANOL TARTRATE; STADOL	4464378	AUG 07, 2001	U-60	NDF	DEC 12, 1994
19847 001	CIPROFLOXACIN; CIPRO	4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	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			
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; CIPRO	4670444	OCT 01, 2002	U-36	NCE	OCT 22, 1992
20118 001	DESFLURANE; SUPRANE	4670444	OCT 01, 2002	NDF	DEC 31, 1993	
20037 001	DICLOFENAC SODIUM; VOLTAREN	4762856	AUG 09, 2005	U-67	NCE	SEP 18, 1997
20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM	4960799	OCT 02, 2007		NCE	MAR 28, 1994
20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
20062 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD				NCE	NOV 05, 1992
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NS	MAY 29, 1995
		4894240	JAN 16, 2007		NP	DEC 27, 1994
		4894240	JAN 16, 2007		NP	DEC 27, 1994
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NCE	NOV 05, 1992
		4894240	JAN 16, 2007		NP	DEC 27, 1994
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008		NCE	NOV 05, 1992
		4894240	JAN 16, 2007		NP	DEC 27, 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
19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-35	I-72	MAY 15, 1995
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
20055 002	GLYBURIDE; GLUBATE				NP	MAR 04, 1995
					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
19174 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				NC	JAN 30, 1995
20100 001	INSULIN BIOSYNTHETIC HUMAN; HUMULIN 50/50				NP	APR 29, 1995
19710 004	IOVERSOL; OPTIRAY 300	4396598	OCT 26, 2002	U-61	NS	JAN 22, 1995
19710 005	IOVERSOL; OPTIRAY 350	4396598	OCT 26, 2002	U-62	NS	JAN 22, 1995
					I-74	JAN 22, 1995
20083 001	ITRACONAZOLE; SPORANOX	4267179	MAY 12, 1998		NCE	SEP 11, 1997
19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	NDF	DEC 20, 1994
					NCE	NOV 30, 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
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM	4917893	MAR 24, 2004		I-70	DEC 12, 1994
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM	4849228	JUL 18, 2006		I-70	DEC 12, 1994
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM	4728721	MAR 01, 2005		I-70	DEC 12, 1994
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM	4677191	JUN 30, 2004		I-70	DEC 12, 1994
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4652441	MAR 24, 2004			
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
20105 001	LIOTHYRONINE SODIUM; TRIOSTAT	4528287	JUL 09, 2002	U-36	ODE	DEC 31, 1998
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	5008294	APR 15, 2008	U-68	NCE	FEB 21, 1997
19940 001	MASOPROCOL; ACTINEX	4695590	SEP 22, 2004		NCE	SEP 04, 1997
19651 001	MESALAMINE; ASACOL				NCE	DEC 24, 1992
17659 001	METAPROTERENOL SULFATE; ALUPENT				NDF	JAN 31, 1995
19962 001	METOPROLOL SUCCINATE; TOPROL XL				I-67	NOV 14, 1994
19962 002	METOPROLOL SUCCINATE; TOPROL XL	3998790	APR 08, 1992		NE	JAN 10, 1995
19962 003	METOPROLOL SUCCINATE; TOPROL XL	3876802	APR 08, 1992		NE	JAN 10, 1995
20208 001	METRONIDAZOLE; METROGEL	4761418	AUG 02, 2005		NDF	AUG 17, 1995
20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NCE	JAN 22, 1997
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4420639	DEC 13, 2000		NCE	JAN 22, 1997
19583 001	NABUMETONE; RELAFEN	4061779	DEC 06, 1994	U-19	NCE	DEC 24, 1996
19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
19886 001	NAFARELIN ACETATE; SYNAREL	4061779	DEC 06, 1994	U-19		
20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		I-68	FEB 26, 1995
					NCE	FEB 13, 1995
					I-68	FEB 26, 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
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19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NDF	JAN 30, 1995
					NCE	DEC 21, 1993
20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NDF	FEB 21, 1995
					NCE	DEC 21, 1993
20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NDF	FEB 21, 1995
					NCE	DEC 21, 1993
20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR	3985758	OCT 12, 1995		NDF	FEB 21, 1995
					NCE	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				NP	APR 22, 1995
20150 002	NICOTINE; NICOTROL				NP	APR 22, 1995
20150 003	NICOTINE; NICOTROL				NP	APR 22, 1995
20165 001	NICOTINE; NICODERM				NP	APR 22, 1995
20165 002	NICOTINE; NICODERM	5004610	APR 02, 2008		NDF	NOV 07, 1994
		4144317	SEP 09, 1992			
		5004610	APR 02, 2008		NDF	NOV 07, 1994
		4144317	SEP 09, 1992			
20165 003	NICOTINE; NICODERM	5004610	APR 02, 2008		NDF	NOV 07, 1994
		4144317	SEP 09, 1992		NP	JUN 08, 1995
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20066 001	NICOTINE POLACRILEX; NICORETTE DS	4798725	JAN 17, 2006		NDF	DEC 24, 1994
20064 001	NITROFURANTOIN; MACROBID	4772473	SEP 20, 2005			
19757 001	NORFLOXACIN; CHIBROXIN	4551456	NOV 05, 2002	U-57	NCE	DEC 28, 1995
20087 001	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4382892	MAY 10, 2000		NCE	DEC 28, 1995
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	4382892	MAY 10, 2000		NCE	DEC 28, 1995
20209 001	OXICONAZOLE NITRATE; OXISTAT	4559330	AUG 04, 2004	U-58	NCE	JUL 31, 1995
					NP	SEP 30, 1995

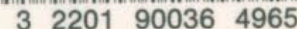
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PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		ODE	MAR 19, 1994
		4818538	FEB 09, 2005		I-47	MAY 02, 1993
		4724232	FEB 09, 2005		NCE	MAR 19, 1992
19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 09, 2005			
		4833130	FEB 09, 2005		NCE	MAR 19, 1992
		4818538	FEB 09, 2005			
		4724232	FEB 09, 2005		ODE	MAR 19, 1994

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