

CUMULATIVE
SUPPLEMENT 7

JAN'92-JUL'92

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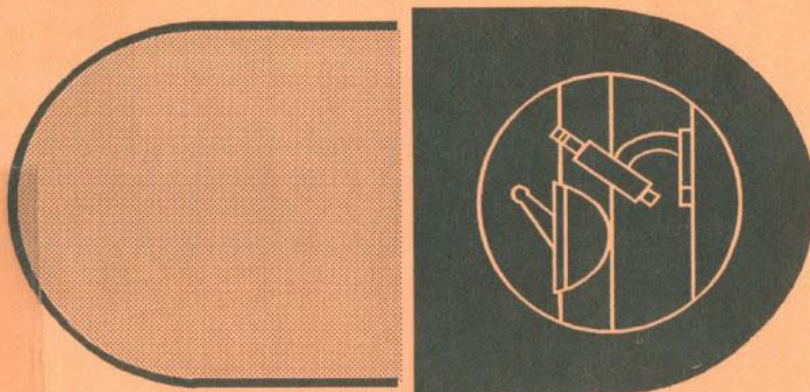
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APPROVED DRUG PRODUCTS

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 7

July 1992

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

12TH EDITION

CUMULATIVE SUPPLEMENT 7

JULY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)
Tranlycypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.4 APPLICANT NAME CHANGES

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

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

BARNES HIND PHARMACEUTICALS INC
(BARNES HIND)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

SOLA BARNES HIND
(SOLA BARNES HIND)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

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

PROCTER & GAMBLE PHARMACEUTICALS INC
(P&G)

RECKITT AND COLMAN PHARMACEUTICALS INC
(R & C)

RECKITT AND COLMAN PHARMACEUTICALS INC
(RECKITT AND COLMAN)

SOLOPAK LABORATORIES
(SOLOPAK)

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

VITARINE PHARMACEUTICALS INC
(VITARINE)

EON LABS MANUFACTURING INC
(EON LABS)

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

SEP 1992

JUN 1992

MAR 1992

DEC 1991

CATEGORIES COUNTED

DRUG PRODUCTS LISTED

SINGLE SOURCE

MULTISOURCE

THERAPEUTICALLY EQUIVALENT

NOT THERAPEUTICALLY EQUIVALENT

EXCEPTIONS¹

NEW MOLECULAR ENTITIES APPROVED

NUMBER OF APPLICANTS

9584	9473	9476	
2187 (22.8%)	2222 (23.4%)	2227 (23.5%)	
7397 (77.2%)	7251 (76.6%)	7249 (76.5%)	
6580 (68.7%)	6510 (68.7%)	6494 (68.5%)	
664 (6.9%)	592 (6.3%)	595 (6.3%)	
153 (1.6%)	149 (1.6%)	160 (1.7%)	
---	4	2	
430	437	455	

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

ALBUTEROL SULFATE

TABLET; ORAL

WERNER/CHICOTT/

N72652 001
FEB 21, 1992

EQ 0.083% BASEM

N19243 002
JAN 14, 1987

EQ 0.083% BASE

WARNER CHILCOTT

N19773 001
APR 23, 1992

EQ 0.083% BASEM

ॐ ॐ

N73419 001
MAR 30, 1992

EQ 2MG BASE/5ML₁₀₀

149/

181244

1891

1410

1491

卷一百一十五

[illegible]

/100MG/

N18241 001
NOV 16, 1984

9

01104

७

150MG

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

EQ 50MG BASE/MLM

N63275 001
MAY 18, 1992

EQ 250MG BASE/MLM

N50495 001
N62562 001
SEP 20, 1984
N50495 002
N62562 002
SEP 20, 1984

EQ 50MG BASE/ML
EQ 50MG BASE/ML

N50495 002
N62562 002
SEP 20, 1984

EQ 250MG BASE/ML
EQ 250MG BASE/ML

N83939 001
 N83937 001
 N83938 002
 N84957 001
 N85093 001
 N86295 001
 N83939 001
 N83937 001
 N83938 002
 N84957 001
 N85093 001
 N86295 001

/N88697 001
 SEP 25, 1984
 /N88698 001
 SEP 25, 1984
 /N88699 001
 SEP 25, 1984
 /N88700 001
 SEP 25, 1984
 /N88701 001
 SEP 25, 1984
 /N88702 001
 SEP 25, 1984
 /N88697 001
 SEP 25, 1984
 /N88698 001
 SEP 25, 1984
 /N88699 001
 SEP 25, 1984
 /N88700 001
 SEP 25, 1984
 /N88701 001
 SEP 25, 1984
 /N88702 001
 SEP 25, 1984

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL	
DIPHENOXYLATE HCL AND ATROPINE SULFATE	
/AA/	/CHELSEA/
3	0.025MG; 2.5MG
	0.025MG; 2.5MG
DIPHENOXYLATE HCL W/ ATROPINE SULFATE	
3	EON LABS
/3/	/VITAFINE/
> ADD >	
> DLT >	
/AZITHROMYCIN/	
/CAPSULE; ORAL/	
/ZITHROMAX/	
/3/	
/PFIZER/	
> DLT >	
> DLT >	
> DLT >	
> DLT >	
	/250MG/
	/N85676/001/
	N85876 001
	N86173 001
	/N86173/001/
	/N85676/001/
	N85876 001
	N86173 001
	/N86173/001/
	/N85676/001/
	N85876 001
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	N85876 001

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE
/AA/ /PIONEER/PHARMS/ /4MG/

3 PIONEER PHARMS

4MG

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

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

3 EON LABS

15MG

30MG

/15MG/

/30MG/

SODIUM BUTABARBITAL

/AA/ /WEST/WARD/

3 WEST WARD

3

15MG

30MG

/15MG/

/30MG/

N85938 001
N85934 001
/N85938/001/
/N85934/001/
N85934 001
/N85418/001/
/N85432/001/
N85418 001
N85432 001

TABLET, CHEWABLE; ORAL

EPITOL

LEMMON

> ADD >
> ADD >
> ADD >

100MG

N73524 001
JUL 29, 1992

BUTORPHANOL TARTRATE

SPRAY, METERED; NASAL

STADOL

+ BRISTOL MYERS SQUIBB 1MG/INH

/1MG/INH/

TABLET; ORAL

CARISOPRODOL

B* EON LABS

/B*/ /VITAMINE/

350MG

/350MG/

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

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

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

N20000 001
APR 17, 1992

CAPSULE; ORAL
CEFADROXIL
ZENITH

EQ 500MG BASE

/EQ/500MG/BASE/

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

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

RINGER'S IN PLASTIC CONTAINER

MCGAW

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

N20002 001
APR 17, 1992

TABLET; ORAL
CEFADROXIL
ZENITH

EQ 1GM BASE

/EQ/1GM/BASE/

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

CEFTAZIDIME

POWDER FOR RECONSTITUTION; ORAL

CEFTAZ
+ BRISTOL MYERS SQUIBB 250MG/5ML

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

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

/EQ/250MG/BASE/VIAL/

/N62510/001/
/MAR/12, 1985/
N62510 001

EQ 250MG BASE/VIAL

MAR 12, 1985

/EQ/500MG/BASE/VIAL/

/N62510/002/
/MAR/12, 1985/
N62510 002

EQ 500MG BASE/VIAL

MAR 12, 1985

/EQ/1GM/BASE/VIAL/

/N62510/003/
/MAR/12, 1985/
N62510 003

EQ 1GM BASE/VIAL

MAR 12, 1985

TABLET; ORAL

CEFTAZ
+ BRISTOL MYERS SQUIBB 500MG

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

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

/500MG/

CEFTAZIDIME

INJECTABLE; INJECTION

CEPTAZ
/GLAXO/

/500MG/VIAL/

/N50646/001/
/SEP/27, 1990/

/1GM/VIAL/

/N50646/002/
/SEP/27, 1990/

/2GM/VIAL/

/N50646/003/
/SEP/27, 1990/

/1GM/VIAL/

/N50646/004/
/SEP/27, 1990/

CEFTAZIDIME (ARGININE FORMULATION)

INJECTABLE; INJECTION

CEPTAZ
GLAXO

1GM/VIAL

N50646 002
SEP 27, 1990

2GM/VIAL

N50646 003
SEP 27, 1990

10GM/VIAL

N50646 004
SEP 27, 1990

500MG/VIAL

N50646 001
SEP 27, 1990

PENTACEF

SMITHKLINE BEECHAM

1GM/VIAL

N64006 001
MAR 31, 1992

2GM/VIAL

N64006 002
MAR 31, 1992

10GM/VIAL

N64008 002
MAR 31, 1992

6GM/VIAL

N64008 001
MAR 31, 1992

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

EON LABS

5MG

N84919 001

10MG

10MG

N84920 001

25MG

25MG

N84923 001

/PARKE/DAVIS/

5MG

/N85163/001/

10MG

10MG

/N85163/001/

25MG

25MG

/N85163/001/

PARKE DAVIS

5MG

N85163 001

10MG

10MG

N85163 001

25MG

25MG

N85163 001

/VITAPRINE/

5MG

/N85164/001/

10MG

10MG

/N85164/001/

25MG

25MG

/N85164/001/

WEST WARD

5MG

/N85164/001/

10MG

10MG

/N85164/001/

25MG

25MG

/N85164/001/

WEST WARD

5MG

N85014 001

10MG

10MG

N85000 001

25MG

25MG

N85294 001

CHLOROQUINE PHOSPHATE

TABLET; ORAL

CHLOROQUINE PHOSPHATE

WEST WARD

/EQ/150MG BASE/

/N83082/001/

WEST WARD

EQ 150MG BASE

N83082 001

CHLOROTHIAZIDE

TABLET; ORAL
CHLOROTHIAZIDE
EON LABS
/3/VITAFINE/

> ADD >
> DLT >
250MG
/250MG/

N85485 001
/N85485/001/

BX
THALITONE
HORUS
25MG
15MG

N88051 001
NOV 12, 1982
N19574 001
DEC 20, 1983

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
/PIONEER/PHARMS/
E PIONEER PHARMS

> DLT >
> DLT >
> ADD >
> ADD >
4MG

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

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC
/ALPHA CHYMOTRYPSIN/
/BARNES/HIND/
SOLA BARNES HIND

/61/
/150 UNITS/VIAL/
750 UNITS/VIAL
/N11837/001/
N11837 001

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE
EON LABS
/PHARM/PHARMS/
/61/

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

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

ZOLYSE
/ALCON/
ALCON

/61/
/150 UNITS/VIAL/
750 UNITS/VIAL
/N11903/001/
N11903 001

CINOXACIN

CAPSULE; ORAL
CINOBAC
LILLY
+
CINOXACIN
BIOCRAFT

AB
AB
AB
AB
250MG
500MG
250MG
500MG

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

CHLOROTHIAZIDE

TABLET; ORAL
CHLOROTHIAZIDE
EON LABS
/VITAFINE/
/WARNER/CHILCOTT/
/61/

50MG
/50MG/
/50MG/
/50MG/
25MG
50MG

N87118 001
/N87118/001/
/AUG/15, 1983/
/JAN/24, 1983/
/N87516/001/
/FEB/09, 1983/
N87516 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/
/N19481/001/
/OCT/02, 1990/
6.602GM/100ML; 198MG/100ML;
3.177GM/100ML
N19481 001
OCT 02, 1990

CLEMASTINE FUMARATE

SYRUP; ORAL
CLEMASTINE FUMARATE
COPLEY

EQ 0.5MG BASE/5ML

N73095 001
APR 21, 1992

THALITONE

/61/
/BOEHRINGER/INGELHEIM/

/N88051/001/
/NOV/12, 1982/
/N19574/001/
/DEC/20, 1983/

COLCHICINE; PROBENECID

TABLET; ORAL

PROBENECID
/BP/ /CHELSEA/
a CHELSEA

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

/N85552/001/
N85552 001

TABLET; ORAL

DESIPRAMINE HCL
/BP/ /PHARM/BASICS/
a PHARM BASICS

/25MG/
25MG

/N71864/001/
SEP 09, 1987

PROBENECID AND COLCHICINE
EON LABS

/BP/ /VITAFINE/
a VITAFINE

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

/N86130/001/
N86130 001

/75MG/
75MG

/N71866/001/
SEP 09, 1987

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN
/BP/ /LUITPOLD/
a LUITPOLD

/0.03MG/ML/
0.03MG/ML

/N80668/001/
N80668 001

/100MG/
100MG

/N71867/001/
SEP 09, 1987

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL
/BP/ /BARNES/HIND/
a SOLA BARNES HIND

/1%/
1%

/N84863/001/
N84863 001

/25MG/
25MG

/N71601/001/
JUN 05, 1987

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL
/BP/ /EON LABS/
a EON LABS

/25MG/
25MG

/N71601/001/
JUN 05, 1987

/25MG/
25MG

/N71601/001/
JUN 05, 1987

> ADD > AB
> ADD >

AB

/50MG/
50MG

/N71598/001/
JUN 05, 1987

/75MG/
75MG

/N71602/001/
OCT 05, 1987

AB

/100MG/
100MG

/N71766/001/
OCT 05, 1987

/10MG/
10MG

/N72167/001/
FEB 03, 1988

AB

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/10MG/
10MG

/N72167/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

a

/150MG/
150MG

/N72254/001/
FEB 03, 1988

/0.05%
0.05%

/N73548/001/
JUN 30, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

DEXAIR

/PARKE/DAVIS/

/EQ 0.1% PHOSPHATE/

/N76209/001/
/DEC 15, 1983/
N88433 001
DEC 15, 1983

PHARMAFAIR

EQ 0.1% PHOSPHATE

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 3.3% AND SODIUM

CHLORIDE 0.3% IN PLASTIC CONTAINER

MCGAW

3.3GM/100ML; 75MG/100ML;
300MG/100MLM
N19630 049
MAY 07, 1992

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, 1992DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

/PARKE/DAVIS/

/5MG/ML/

/N76209/001/
/DEC 15, 1983/

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

3 PARKE DAVIS

5MG/ML

/N76209/001/
/DEC 15, 1983/

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

DIAZEPAM

TABLET; ORAL

DIAZEPAM

/PARKE/DAVIS/

/4MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/4MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/4MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/5MG/

/N76209/001/
/SEP 04, 1985/

/AB/

/PARKE/DAVIS/

/10MG/

/N76209/001/
/SEP 04, 1985/

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM CD

BC + MARION MERRELL DOW 180MG
BC + 240MG
+ 300MG

CARDIZEM SR

+ MARION MERRELL DOW 60MG
+ 90MG

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

N20062 002
DEC 27, 1991
N20062 003
DEC 27, 1991
N20062 004
DEC 27, 1991
/N20062/004/
/DEC/27/1991/

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

DILACOR XR

BC RHONE POULENC RORER 180MG
BC 240MG
3 120MG

N20092 002
MAY 29, 1992
N20092 003
MAY 29, 1992
N20092 001
MAY 29, 1992

INJECTABLE; INJECTION
CARDIZEM

MARION MERRELL DOW 5MG/ML
/25MG VIAL/
/50MG VIAL/

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

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA EON LABS 25MG
AA 50MG

N80845 002
N80845 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/AA/ /PIONEER/PHARM/ /25MG/
/AA/ /50MG/

3 PIONEER PHARMS

3

/AA/ /VIAIRINE/ /25MG/
/AA/ /50MG/

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB GENEVA 50MG
AB 75MG

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

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

/B*/ /CHELSEA/ /EQ/100MG/BASE/
/B*/ /EQ/150MG/BASE/
/B*/ /INTERPHARM/ /EQ/100MG/BASE/
/B*/ /EQ/150MG/BASE/

3 INTERPHARM

3

EQ 100MG BASE
EQ 150MG BASE

/N71020/001/
/DEC/01/1986/
/N71021/001/
/DEC/01/1986/
/N7100/001/
/JAN/15/1987/
/N7101/001/
/JAN/15/1987/
N71190 001
JAN 15, 1987
N71191 001
JAN 15, 1987

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

/AP/ /LYPHOMED/

/AP/

/AP/

3 LYPHOMED

3

3

/40MG/ML/

/80MG/ML/

/160MG/ML/

40MG/ML

80MG/ML

160MG/ML

/N70058/001/

/MAR/20, 1985/

/N70059/001/

/MAR/20, 1985/

/N70364/001/

/DEC/04, 1985/

N70058 001

MAR 20, 1985

N70059 001

MAR 20, 1985

N70364 001

DEC 04, 1985

> ADD >

> ADD >

> ADD >

> ADD >

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

3 WARNER CHILCOTT

3

EQ 50MG BASE

EQ 100MG BASE

N62594 001

DEC 05, 1985

N62594 002

DEC 05, 1985

CAPSULE, COATED PELLETS; ORAL

DOXYCYCLINE HYCLATE

SIDMAK

EQ 100MG BASE

N63187 001

JUN 30, 1992

AB

TABLET; ORAL

DOXYCYCLINE HYCLATE

/B*/ /INTERPHARM/

3 INTERPHARM

/EQ/100MG/BASE/

EQ 100MG BASE

/N62764/001/

/SEP/02, 1988/

N62764 001

SEP 02, 1988

/N62593/001/

/AUG/28, 1985/

N62593 001

AUG 28, 1985

/AB/ /PARKE/DAVIS/

3 WARNER CHILCOTT

/EQ/100MG/BASE/

EQ 100MG BASE

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

3 EON LABS

3

EQ 50MG BASE

EQ 100MG BASE

N62780 001

APR 12, 1988

N6227 001

/N62763/001/

/SEP/02, 1988/

/N62763/002/

/SEP/02, 1988/

N62763 001

SEP 02, 1988

N62763 002

SEP 02, 1988

/N62594/001/

/DEC/05, 1985/

/N62594/002/

/DEC/05, 1985/

/N62780/001/

/APR/12, 1988/

/N6227/001/

> ADD >

> ADD >

> ADD >

/B*/ /INTERPHARM/

/B*/

3 INTERPHARM

3

/EQ/100MG/BASE/

EQ 50MG BASE

EQ 100MG BASE

/EQ/50MG/BASE/

/EQ/100MG/BASE/

/EQ/50MG/BASE/

/EQ/100MG/BASE/

/PARKE/DAVIS/

/AB/

/AB/

/3/ VITAFINE/

/3/

> DLT >

> DLT >

> DLT >

> DLT >

> DLT >

> DLT >

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

3 SOLOPAK

/2.5MG/ML/

2.5MG/ML

/N71750/001/

/SEP/06, 1988/

N71750 001

SEP 06, 1988

ENOXACIN

TABLET; ORAL

PENETREX

+ PARKE DAVIS

400MG

/400MG/

N19616 005

DEC 31, 1991

/N19616/005/

/DEC/31, 1991/

> ADD >

> ADD >

> DLT >

> DLT >

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

ETHINYL ESTRADIOL; NORETHINDRONE

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

0.035MG; 0.5MG

N72695 001
FEB 28, 1992

GENCEPT 1/35-28
GENCON

0.035MG; 1MG

N72696 001
FEB 28, 1992

GENCEPT 10/11-28
GENCON

0.035MG; 0.5MG AND 1MG

N72697 001
FEB 28, 1992

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

/N.E.'s' 1/35-28/
METRONED/
3 LPI

0.035MG; 1MG

/N71543/001/
DEC 14, 1987
N71542 001

ETHINYL ESTRADIOL; NORGESTIMATE

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

0.035MG;
0.18MG; 0.215MG; 0.25MG

N19697 002
JUL 03, 1992

FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE
AP
STERIS

EQ 0.05MG BASE/ML

N73488 001
JUN 30, 1992

TABLET; ORAL-28
ORTHO TRI-CYCLEN
JOHNSON RM

0.035MG;
0.18MG; 0.215MG; 0.25MG

N19697 001
JUL 03, 1992

FINASTERIDE

TABLET; ORAL
PROSCAR
+ MSD

5MG

N20180 001
JUN 19, 1992

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL
PLENDIL
/MERCK/
MERCK

5MG

10MG

/N19834/001/
JUL 25, 1991
N19834 001
JUL 25, 1991
/N19834/001/
JUL 25, 1991
N19834 002
JUL 25, 1991

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

CLAY PARK

NMC

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
/CLAY/PARK/
CLAY PARK

0.05%

0.05%

0.05%

/N71790/001/
APR 25, 1988
N71790 001
APR 25, 1988
N73085 001
FEB 14, 1992

FENOPROFEN CALCIUM

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

EQ 200MG BASE

EQ 300MG BASE

EQ 200MG BASE

EQ 300MG BASE

/N72355/001/
JUL 05, 1988
N72355 001
JUL 05, 1988
N72356 001
JUL 05, 1988

TABLET; ORAL
FENOPROFEN CALCIUM
/HALSEY/
/AB/
/AB/

EQ 600MG BASE

EQ 600MG BASE

/N72357/001/
JUL 05, 1988
N72357 001
JUL 05, 1988

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

/P4/ /PHARM/BASICS/

/15MG/

/N70562/001/

/AB/

TABLET; ORAL

FUROSEMIDE

/20MG/

/N18369/001/

/AB/

/40MG/

/N18369/002/

3 CHELSEA

20MG

/N18369/001/

3

40MG

/N18369/002/

3 EON LABS

40MG

/N18369/001/

/3/ VITAMINE/

/40MG/

/N18369/002/

3

40MG

/N18369/001/

/3/ VITAMINE/

/40MG/

/N18369/002/

3

40MG

/N18369/001/

/3/ VITAMINE/

/40MG/

/N18369/002/

3

40MG

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/N18369/002/

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40MG

/N18369/001/

/3/ VITAMINE/

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC

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

CONTAINER

MCGAW

4,000 UNITS/100MLM
N19952 001
JUL 20, 1992

HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC

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

CONTAINER

MCGAW

5,000 UNITS/100MLM
N19952 004
JUL 20, 1992

10,000 UNITS/100MLM
N19952 005
JUL 20, 1992

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN

PLASTIC CONTAINER

MCGAW

5,000 UNITS/100MLM
N19802 005
JUL 20, 1992

10,000 UNITS/100MLM
N19802 002
JUL 20, 1992

HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN

PLASTIC CONTAINER

MCGAW

5,000 UNITS/100MLM
N19802 003
JUL 20, 1992

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

APRESOLINE

CIBA

20MG/ML
N08303 003

N08303 003
AUG 11, 1987

HYDRALAZINE HCL

LYPHOMED

20MG/ML

TABLET; ORAL

EON LABS

20MG/ML

N08532 001
AUG 11, 1987

HYDRALAZINE HCL

TABLET; ORAL

EON LABS

50MG

N85088 001

HYDRALAZINE HCL

VANGARD

25MG

N87712 001

HYDRALAZINE HCL

VANGARD

50MG

N85088 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRALAZINE

SOLVAY

25MG; 25MG

N87608 001

HYDRALAZINE

SOLVAY

50MG; 50MG

N87213 001

HYDRALAZINE

SOLVAY

100MG; 50MG

N87609 001

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

SOLVAY

25MG; 25MG

N87608 001

AB

50MG; 50MG

N87213 001

AB

100MG; 50MG

N87609 001

AB

100MG; 50MG

N87608 001

AB

100MG; 50MG

N87609 001

AB

100MG; 50MG

N87608 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDRAP-ES

EON LABS

RESERPINE

25MG; 15MG; 0.1MG

N84876 001

25MG; 15MG; 0.1MG

N84876 001

HYDRALAZINE HYDROCHLORIDE; RESERPINE

TABLET; ORAL

DRALSERP

EON LABS

RESERPINE

25MG; 0.1MG

N84617 001

25MG; 0.1MG

N84617 001

SERPASIL-APRESOLINE

CIBA

RESERPINE

25MG; 0.1MG

N09296 004

25MG; 0.1MG

N09296 004

HYDROCHLOROTHIAZIDE

TABLET; ORAL

DANBURY

HYDROCHLOROTHIAZIDE

25MG

N81189 001

100MG

N81190 001

25MG

N83899 001

50MG

N85219 001

25MG

N85219 001

25MG

N85219 001

25MG

N85219 001

25MG

N85219 001

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
/HYDRO-SERP/125-1/
/B* / VITARINE/
3 VITARINE

/25MG; 0.125MG/
25MG; 0.125MG

HYDRO-SERP 50
3 EON LABS
/3 VITARINE/

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

/SERPASIL-ESIDRIX/125-1/
/B* / CIBA/
3 CIBA

/25MG; 0.1MG/
25MG; 0.1MG

/SERPASIL-ESIDRIX/125-1/
/B* / CIBA/
3 CIBA

/50MG; 0.1MG/
50MG; 0.1MG

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL
MAXIDE-25
MYLAN

25MG; 37.5MG

> ADD >
> ADD >

TRIAMTERENE AND HYDROCHLOROTHIAZIDE
EON LABS

50MG; 75MG

> DLT >
> DLT >

GENEVA
/B* / VITARINE/
/50MG; 75MG/

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE
/AT / BAUSCH/AND/LOMB/

12

AT PHARMAFAIR

12

LOTION; TOPICAL
/ODOL-ODME/
/AT / MILES/
/AT /

/0.5%/
/12/
0.5%
12

3 MILES
3

HYDROCORTISONE

SOLUTION; TOPICAL
TEXACORT
GENDERM

2.5/M

/N84827/001/
N84827 001

N81271 001
APR 17, 1992

TABLET; ORAL
/HYCORTOLE/
/3 VITARINE/

/20MG/

N85213 001
/N85213/001/

/N88844/001/

HYDROCORTISONE
3 EON LABS

20MG

N80642 002

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HEMSOL-HC
ABLE

1/M

N81274 001
JUN 19, 1992

HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL

/HYDROFLUMETHIAZIDE/AND/RESERPINE/
/B* / PHARM/BASICS/
/50MG; 0.125MG/

N19129 003
MAY 13, 1988

N71360 001
DEC 08, 1987

N73281 001
APR 30, 1992

/N71360/001/
/DEC/08, 1987/

3 PHARM BASICS

50MG; 0.125MG

/N88195/001/
/DEC/26, 1983/
N88195 001
OCT 26, 1983

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREMYD
ALLERGAN

12; 0.25/M

N19261 001
JAN 30, 1992

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL
EON LABS

10MG
25MG
50MG

/N88845/001/
/JUL/28, 1982/
N87838 001
JUL 28, 1982

N87246 002
N85247 001
N87245 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL
HYDROXYZINE HCL
/PHARM/BASICS/

AB / 10MG /
AB / 25MG /
AB / 50MG /

3 PHARM BASICS

10MG

3

25MG

3

50MG

AB / VITARINE /
AB /
AB /

10MG /
25MG /
50MG /

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HY-PAM

AB / EON LABS
AB / VITARINE /

HYDROXYZINE PAMOATE

AB / EON LABS
AB / VITARINE /

EQ 25MG HCL
EQ 25MG HCL /

EQ 50MG HCL
EQ 50MG HCL /

N87479 001
/N87479/001/

N86183 001
/N86183/001/

TABLET; ORAL
IMPAMINE HCL

EON LABS

10MG

25MG

50MG

10MG /

25MG /

50MG /

AB

> ADD >

AB

> DLT >

AB

/VITARINE /

/AB /

/AB /

/AB /

/AB /

/AB /

/AB /

/AB /

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N85200 001
N84869 002
N85133 001
/N84869/002/
/N85133/001/
/N85200/001/

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

3 EON LABS

25MG

3

50MG

/2/ VITARINE /

/2/

N71711 001
JUL 05, 1988
N71712 001
JUL 05, 1988
/N71711/001/
/N71712/001/
/N71713/001/
/N71714/001/
/N71715/001/

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

B* EON LABS

75MG

/B* / VITARINE /

/B* /

N71531 001
JUL 21, 1987
/N71531/001/
/N71532/001/
/N71533/001/

IOFETAMINE HYDROCHLORIDE I-123

INJECTABLE; INJECTION
SPECTAMINE

IMP

1 MCI/ML

/MED/PHYSICS/

/MED/PHYSICS/

N73343 001
JUN 30, 1992

N73344 001
JUN 30, 1992

N73345 001
JUN 30, 1992

N73346 001
JUN 30, 1992

N73347 001
JUN 30, 1992

N73348 001
JUN 30, 1992

N73349 001
JUN 30, 1992

N73350 001
JUN 30, 1992

N73351 001
JUN 30, 1992

N73352 001
JUN 30, 1992

N73353 001
JUN 30, 1992

N73354 001
JUN 30, 1992

N73355 001
JUN 30, 1992

IBUPROFEN

TABLET; ORAL

IBUPROFEN

LEMON

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

400MG

600MG

800MG

1000MG

1200MG

1400MG

1600MG

1800MG

2000MG

2200MG

2400MG

2600MG

2800MG

3000MG

3200MG

3400MG

3600MG

3800MG

4000MG

N19432 001
DEC 24, 1987
/N19432/001/
/N19433/001/
/N19434/001/

IOPAMIDOL

INJECTABLE; INJECTION

ISOVUE-250

SQUIBB

51/4

N18735 007
JUL 06, 1992

> ADD >
> ADD >
> ADD >

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE
LOCH

> ADD > AP
> ADD >
> ADD > AP
> ADD >
> ADD > AP
> ADD >
> ADD >

EQ 75MG BASE/2MLM
JUL 31, 1992
N63021 001
EQ 500MG BASE/2MLM
JUL 31, 1992
N63022 001
EQ 1GM BASE/3MLM
JUL 31, 1992
N63025 001

> DLT >
> DLT >
> DLT >

SOLUTION; ORAL

/1GM/10ML/
/N19543/001/
/APR/10, 1986/

KETOROLAC TROMETHAMINE

TABLET; ORAL
TORADOL
+ SYNTEX

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

10MG
/10MG/

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

CAPSULE; ORAL
DOPAR
/+/P/AND/G/

/50MG/
/10MG/
/25MG/
500MG
100MG
250MG

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

LACTULOSE

SYRUP; ORAL
LACTULOSE
AA ROXANE LABS

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

10GM/15MLM

N73591 001
MAY 29, 1992

TABLET; ORAL
LEVO-DROMORAN
+ ROCHE

2MG
/2MG/

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

SYRUP; ORAL, RECTAL
LACTULOSE
AA ROXANE LABS

10GM/15MLM

N73590 001
MAY 29, 1992

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
@ INTL MEDICATION

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

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

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
/AP/ /LYPHONED/

/EQ 50MG BASE/VIAL/

EQ 50MG BASE/VIAL

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

AP

LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER
MCGAN
200MG/100MLM

N19830 002
APR 08, 1992

AP

LIDOCAINE HCL 0.4% AND DEXTROSE 5% IN PLASTIC CONTAINER
MCGAN
400MG/100MLM

N19830 003
APR 08, 1992

LEVOCARNITINE

SOLUTION; ORAL
CARNITOR
SIGMA TAU

> ADD > AA
> ADD >

1GM/10ML

N19257 001
APR 10, 1986

AP

LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER
MCGAN
800MG/100MLM

N19830 004
APR 08, 1992

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

AP	ABBOTT	10MG/ML
> DLT >	/AP/	/50MG/ML/
	/PARKE/DAVIS/	/75MG/ML/
		/100MG/ML/
> ADD >	3 PARKE DAVIS	50MG/ML
	3	75MG/ML
	3	100MG/ML
AP	STERIS	100MG/ML
AP		50MG/ML
AP		100MG/ML

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

3	ELKINS SINN	200MG
> ADD >	3 EON LABS	400MG
> ADD >		200MG
> DLT >	/ICN/	400MG
> DLT >		200MG
> ADD >	3 ICN	400MG
> ADD >		200MG
	/PARKE/DAVIS/	400MG
		200MG
	3 PARKE DAVIS	400MG
	3	200MG
	/3/QUANTUM/PHARMICS/	400MG
	/3/	200MG
> DLT >	/3/VITARINE/	400MG
> DLT >		200MG

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

ASACOL

+ P AND G

400MG

METAPROTERENOL SULFATE

SOLUTION; INHALATION

METAPROTERENOL SULFATE

/AN/	/ARMOUR/	/0.42/
		/N71275/001/
		/JUL/27/1988/
		/N71018/001/
		/JUL/27/1988/
		/N71275/001/
	ASTRA	0.42
		JUL 27, 1988
		N71018 001
		JUL 27, 1988
	/DEY/	/0.33/
		/N71006/001/
		/AUG/05/1988/
	3 DEY	0.33
		N71806 001
		AUG 05, 1988
	PROMETA	
	MURO	52M
AN		
		N73340 001
		MAR 30, 1992

SYRUP; ORAL

METAPROTERENOL SULFATE

AA BIOCRIFT 10MG/5ML

> ADD > AA SILARX 10MG/5ML

> ADD >

TABLET; ORAL

METAPROTERENOL SULFATE

/B4/	/PHARM/PLASTICS/	/10MG/
		/N71013/001/
		/JAN/25/1988/
		/N71014/001/
		/JAN/25/1988/
	3 PHARM BASICS	10MG
		N71013 001
		JAN 25, 1988
	3	20MG
		N71014 001
		JAN 25, 1988

METHADONE HYDROCHLORIDE

TABLET, DISPERSIBLE; ORAL

MESTADONE

> ADD >	3 EON LABS	2.5MG
> ADD >	3	5MG
> ADD >	3	10MG
> ADD >	3	40MG
> DLT >	/3/VITARINE/	/2.5MG/
> DLT >		/5MG/
> DLT >		/10MG/
> DLT >		/40MG/

N19651 001

JAN 31, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL
EON LABS
AA
AA
/AA/
/AA/
/AA/
/AA/

500MG
750MG
/500MG/
/750MG/

N87283 001
N87282 001
/N87283/001/
/N87282/001/

N72995 001
JAN 30, 1992

METHOTREXATE SODIUM

TABLET; ORAL
METHOTREXATE
MYLAN
AB

EQ 2.5MG BASEM

N81235 001
MAY 15, 1992

N72155 001
MAR 30, 1992
N72244 001
MAR 30, 1992
N72247 001
MAY 18, 1992

METHYCLOTHIAZIDE

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

/5MG/

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

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

TABLET; ORAL

METOCLOPRAMIDE HCL

/B*/ /INTERPHARM/

/EQ/10MG/BASE/

3 INTERPHARM

EQ 10MG BASE

/B*/ /PHARM/BASICS/

/EQ/10MG/BASE/

3 PHARM BASICS

EQ 10MG BASE

METHYLDOPA

TABLET; ORAL
METHYLDOPA
/AB/ /PARKE/DAVIS/

/125MG/

/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

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

3 PARKE DAVIS

125MG

3

250MG

3

500MG

ZAROXOLYN

/AB/ /FISONS/

/2.5MG/

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

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE
3 EON LABS
/3/VITAPINE/

4MG
/4MG/

N87341 001
/N87341/001/

METOLAZONE

TABLET; ORAL

/AB/ /SCHIAPPARELLI/SEARLE/

/2.5MG/

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

3

5MG

3

10MG

ZAROXOLYN

/AB/ /FISONS/

/2.5MG/

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

3

5MG

3

10MG

ZAROXOLYN

/AB/ /FISONS/

/2.5MG/

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

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

METOPROLOL SUCCINATE

TABLET, EXTENDED RELEASE; ORAL

TOPROL XL
+ HASSELE

EQ 50MG TARTRATEM

N19962 001
JAN 10, 1992

EQ 100MG TARTRATEM

N19962 002
JAN 10, 1992

EQ 200MG TARTRATEM

N19962 003
JAN 10, 1992

CAPSULE; ORAL

MINOCYCLINE HCL

AB

EQ 50MG BASEM

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

AB

EQ 100MG BASEM

METRONIDAZOLE

INJECTABLE; INJECTION

METRONIDAZOLE
/LYPHOMED/

/500MG/100ML/

/N70071 001/
DEC 03, 1984

a LYPHOMED

500MG/100ML

/SYRUP; ORAL/
/MINOCIN/
/+/LEDERLE/SUSPENSION; ORAL
MINOCIN
+ LEDERLE

EQ 50MG BASE/5ML

N50445 001

MINOXIDIL

TABLET; ORAL

METRONIDAZOLE
EON LABS> ADD > AB
> ADD >
> ADD > AB
> ADD >
> DLT > /AB/
> DLT >
> DLT > /AB/

250MG

N18620 001
MAR 04, 1982

500MG

N18620 002
JUN 02, 1983

/VITARINE/

/250MG/

/N18620 001/
/MAR/04/1983/

/500MG/

/N18620 002/
/JUN/02/1983/

/B+/ /PHARM/BASICS/

/2.5MG/

/N71537 001/
/DEC/16/1983/
N71537 001

a PHARM BASICS

2.5MG

DEC 16, 1983

/AB/ /ROYCE/

/2.5MG/

/N71799 001/
/NOV/10/1987/

/AB/

/10MG/

/N71799 001/
/NOV/10/1987/

a ROYCE

2.5MG

NOV 10, 1987

a

10MG

N71796 001
NOV 10, 1987METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

FLAGYL I.V.

/SCHIAPPARELLI/SEARLE/EQ 500MG BASE/VIAL/
SCHIAPPARELLI SEARLE EQ 500MG BASE/VIAL/N18353 001/
N18353 001

AB

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION

/LYPHOMED/

/EQ 500MG BASE/VIAL/

/N70295 001/
N70295 001

a LYPHOMED

EQ 500MG BASE/VIAL

OCT 15, 1985

/METRONIDAZOLE HCL/
/LYPHOMED/

/EQ 500MG BASE/VIAL/

/N70295 001/
N70295 001

a LYPHOMED

EQ 500MG BASE/VIAL

OCT 15, 1985

MIVACRON IN DEXTROSE 5% IN PLASTIC CONTAINER
BURROUGHS WELLCOME

EQ 2MG BASE/MLM

N20098 001
JAN 22, 1992

EQ 0.5MG BASE/MLM

N20098 002
JAN 22, 1992

EQ 50MG BASE/100MLM

N20098 003
JAN 22, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

NICARDIPINE HYDROCHLORIDE

<u>NABUMETONE</u>					
TABLET; ORAL					
+ SMITHKLINE BEECHAM					
RELAFEN	750MG				
> ADD >		N19583 002			N20005 001
> ADD >		DEC 24, 1991			FEB 21, 1992
> DLT >	/750MG/	/N19583/002/			N20005 002
> DLT >		/DEC/24, 1991/			FEB 21, 1992
					N20005 003
					FEB 21, 1992

CAPSULE, EXTENDED RELEASE; ORAL
CARDENE SR
+ SYNTAX
30MG
45MG
60MG

NAFARELIN ACETATE

SPRAY, METERED; NASAL
SYNAREL
SYNTAX

INJECTABLE; INJECTION
CARDENE
DUPONT MERCK

EQ 0.2MG BASE/INH
N20109 001
FEB 26, 1992

N19734 001
JAN 30, 1992

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

/NALBUPHINE/
/LYPHOMED/
/AP/
/AP/

3 LYPHOMED

3

/10MG/ML/
/20MG/ML/
10MG/ML
20MG/ML
JUL 02, 1986
JUL 02, 1986
JUL 02, 1986

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

FILM, EXTENDED RELEASE; TRANSDERMAL

NICODERM

/MARION/MERRELL/DOM/

/7MG/24HR/

BC + MARION MERRELL DOM

7MG/24HR

/14MG/24HR/

BC +

14MG/24HR

/21MG/24HR/

BC +

21MG/24HR

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

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

EON LABS

/VITAMINE/

EQ 350MG BASE
/EQ 350MG BASE/

N61586 001
/N61586/001/

NICOTROL

+ KABI

+ +

5MG/16HR

10MG/16HR

15MG/16HR

PROSTEP

+ ELAN

+ +

11MG/24HR

22MG/24HR

NIACIN

TABLET; ORAL

NIACIN

WOCKHARDT LTD

500MG

N81134 001

APR 28, 1992

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

/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

N20150 001
APR 22, 1992
N20150 002
APR 22, 1992
N20150 003
APR 22, 1992

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

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
MORTRIPTYLINE HCL
DANBURY

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

PAMELOR
SANDOZ

10MGH

TABLET; ORAL

> DLT >
> DLT >
> DLT >

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

CAPSULE - EXTENDED RELEASE: ORAL

75MG; 25MG / 175MG; 25MG /

/AA/ NYSTATIN
 /CHELSEA/
 3 CHELSEA
 EON LABS
 /VITAPRINE
 > ADD > AA/
 > DLT > /AA/

INJECTABLE; INJECTION

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

100,000 UNITS
/100,000 UNITS/

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

NYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

HYSTATIN AND TRIAMCINOLONE ACETONIDE

DLT	>	AT	/CLAY/PARK	/100,000 UNITS/GM:0.12/	/N62186 002/
DLT	>				/JUN 06, 1985/
ADD	>	B*	CLAY PARK	100,000 UNITS/GM:0.12	N62186 002
ADD	>				JUN 06, 1985

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENTICILLIN G POTASSIUM

PERCENTAGE OF POTENTIAL	
AP/	PARKE/DAVIS/
1,000,000 UNITS/VIAL	N62003 001
5,000,000 UNITS/VIAL	N62003 002
1,000,000 UNITS/VIAL	N62003 001
5,000,000 UNITS/VIAL	N62003 002

OFLOXACIN

INJECTABLE; INJECTION

FLOXIN
JOHNSON RW

20MG/MLH	N20087 002
	MAR 31, 1992
40MG/MLH	N20087 003
	MAR 31, 1992

FLOXIN IN DEXTROSE 5%
JOHNSON RW

400MG/100MLX

FLOXIN IN DEXTROSE 5% IN PLASTIC CONTAINER
JOHNSON RW 4MG/ML[†]

4MG/MLA

400MG/100MLH

MAR 31, 1992

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

/B*	/CHELSEA/	/10MS/	/NTISSI/DDI/
/B*		/15MS/	/MAR/02/1988/
/B*		/30MS/	/NTISSI/DDI/
			/MAR/02/1988/
			/NTISSI/DDI/
			/MAR/02/1988/

PENTAMIDINE ISETHIONATE

INJECTABLE; INJECTION

PENTAM 300

NI9264 001
OCT 16, 1984

PENTAMIDINE ISETHIONATE

N73479 001
JUN 30, 1992

OXYBUTYNIN CHLORIDE

TABLET; ORAL

OXYBUTYNIN CHLORIDE

PHARM BASICS	5MG	N70746 001	MAR 10, 1988	/N70746 001/ /MAR/10, 1988/
PHARM BASICS	5MG	N70746 001	MAR 10, 1988	/N70746 001/ /MAR/10, 1988/

N70746 001
MAR 10, 1988

TABLET; ORAL

PERPHENAZINE

/B* / CHLSEA /
 /ANG /
 /N89766 / ddi /
 /DEC / 23 / 1987 /

PIROXICAM

CAPSULE; ORAL

PIROXICAM

AB SCHIAPPARELLI SEARLE 10MGH

N74036 001
MAY 29, 1992

AB 20MGH

N74036 002
MAY 29, 1992POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM
BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

CO-LAV

AA COPLEY

240GM/BOI; 2.98GM/BOI; 6.72GM/BOI;
5.84GM/BOI; 22.72GM/BOI N73428 001
JAN 28, 1992GO-EVAC
/COPIEY//44MG/BOI; 2.97GM/BOI; 6.74GM/BOI;
/5.86GM/BOI; 22.74GM/BOI N73433 001
/APR/28, 1992

AA COPLEY

236GM/BOI; 2.97GM/BOI; 6.74GM/BOI;
5.86GM/BOI; 22.74GM/BOI N73433 001
APR 28, 1992POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

AB ADRIA

N73398 001
JAN 28, 1992

AB MICRO-K

ROBINS

N18238 001

TABLET, EXTENDED RELEASE; ORAL

KLOR-CON

AB UPSHER SMITH

N19123 001
APR 17, 1986/N19123/001/
/APR/17, 1986/

/BC/

KLOTRIX

BC APOTHECON

/BC/ /NEAD/JOHNSON/

N17850 001
/N17850/001/

/BC/ 10MEQ

/N17850/001/

PRAZEPAM

CAPSULE; ORAL

CENTRAX

/AB/ /PARKE/DAVIS/

/N18144/001/
/N18144/002/
N18144 002
N18144 001

/AB/ /+ PARKE DAVIS

/5MG/
/10MG/
10MG
5MG/PRAZEPAM/;
/PHARM/BASICS//N176427/001/
/NOV/06, 1987/
/N176428/001/
/NOV/06, 1987/

/PH/

/5MG/

/PH/

/10MG/

a PHARM BASICS

5MG

a

10MG

N70427 001
NOV 06, 1987
N70428 001
NOV 06, 1987PRazosin HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

MINIPRESS XL

+ PFIZER

2.5MGH

+

5MGH

N19775 001
JAN 29, 1992
N19775 002
JAN 29, 1992PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

a EON LABS

5MG

N84773 001

/N84773/001/

N80326 001

/N84773/001/

/HEATHER/

a HEATHER

/a/VITARINE/

/5MG/

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC

BLEPHANTIDE

/ALLERGAN/

ALLERGAN

/0.22;102/
0.22;102/N12813/002/
N12813 002

/PREDNISOLONE/

/PHARM/FAIR/

a PHARMAFAIR

/0.22;102/
0.22;102/N88837/001/
/DEC/24, 1985/
N88837 001
DEC 24, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

PREDNISONE

TABLET; ORAL

/FERNISONE/
/BX/ /FERNDALE/
3 FERNDALE/5MG/
5MG/N83364/001/
N83364 001

TABLET; ORAL

COMPATINE

/SKF/

/EQ 5MG BASE/
/EQ 10MG BASE/
/EQ 25MG BASE//N10571/001/
/N10571/002/
/N10571/003/
N10571 003
N10571 001
N10571 002

PREDNISONE

3 EON LABS

RICHLYN

5MG

N84774 001

5MG

N80782 001

5MG

/N84782/001/
/N84774/001/

/3/VITARINE/

/5MG/

/N84774/001/

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

/BOLAR/

/250MG/

/N85333/001/
/DEC/03/1984/

/500MG/

/N85334/001/
/DEC/03/1984/

/750MG/

/N85335/001/
/NOV/03/1984/

3 BOLAR

250MG

N85333 001

3

500MG

DEC 03, 1984

3

750MG

DEC 03, 1984
N85335 001
NOV 03, 1984PROCAINE HYDROCHLORIDE; TETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION

ACHROMYCIN

LEDERLE

AP

AP

AP

40MG/VIAL; 100MG/VIAL

40MG/VIAL; 100MG/VIAL

40MG/VIAL; 250MG/VIAL

N50267 002

N50276 001

N50267 003

TETRACYN

PFIZER

3

40MG/VIAL; 250MG/VIAL

40MG/VIAL; 100MG/VIAL

N60285 003

N60285 002

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

3 EON LABS

/VITARINE/

> ADD >

/AA/

/AA/

/AA/

65MG

/32MG/

/32MG/

/32MG/

N83870 002

/N84014/001/

/N83668/001/

/N86495/001/

N84014 001

N83688 001

/N83870/002/

N86495 001

3 VITARINE

3

/3/

3

32MG

65MG

/65MG/

65MG

/PROPOXYPHENE HCL 65/

/PARKE/DAVIS/

3 WARNER CHILCOTT

> DLT >

> DLT >

> ADD >

/65MG/

/65MG/

65MG

/N83786/001/

N83786 001

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

3 EON LABS

/3/VITARINE/

> ADD >

/AA/

/AA/

/AA/

25MG

50MG

/25MG/

/50MG/

N85146 001

N85146 002

/N85146/001/

/N85146/002/

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

PROMETHAZINE HCL

3 EON LABS

/3/VITARINE/

> ADD >

/AA/

/AA/

/AA/

25MG

50MG

/25MG/

/50MG/

N85146 001

N85146 002

/N85146/001/

/N85146/002/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

/AB/ /SUPERPHARM/

/10MG/

/N71515/001/

/AB/

/20MG/

/N71516/001/

a SUPERPHARM

10MG

N71515 001

a

20MG

N71516 001

JUN 08, 1988

JUN 08, 1988

PROTIRELIN

INJECTABLE; INJECTION

RELEFACT TRH

FERRING

/AP/ /HÖCHST/ROUSSEL/

0.5MG/ML

N18087 001

/0.5MG/ML/

/N18087/001/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

PSEUDOEPHEDRINE HCL AND TRIPROLIDINE HCL

EON LABS

60MG; 2.5MG

N88193 001

/60MG; 2.5MG/

MAY 17, 1983

/N88193/001/

/MAY 17, 1983/

/AA/ /VITARINE/

PYRAZINAMIDE

TABLET; ORAL

PYRAZINAMIDE

AB + LEDERLE

AB MIKART

500MG

500MG

N80157 001

N81319 001

JUN 30, 1992

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

PYRIDOXINE HCL

/AB/ /LUITPOLD/

a LUITPOLD

/100MG/ML/

100MG/ML

/N80669/001/

N80669 001

QUINETHAZONE; RESERPINE

/TABLET; ORAL/

/HYDROX/AB/

/LEDERLE/

/50MG; 0.125MG/

/N13927/001/

a LEDERLE

50MG; 0.125MG

N13927 001

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

a ELKINS SINN

EON LABS

200MG

200MG

300MG

> ADD > AB

> ADD > AB

> ADD >

/a/ QUANTUM/PHARMICS/

/VITARINE/

/200MG/

/200MG/

/300MG/

> DLT > /AB/

> DLT > /AB/

> DLT >

N83622 001

N84631 001

N88072 001

SEP 26, 1983

/N83622/001/

/N84631/001/

/N88072/001/

/SEP 26, 1983/

RAUMOLFIA SERPENTINA

TABLET; ORAL

/RAUMOLFIA/

/BP/ /FOREST/PHARMS/

WOLFINA

a FOREST PHARMS

/50MG/

/N09255/008/

50MG

N09255 008

RESERPINE

TABLET; ORAL

RESERPINE

BP EON LABS

BP

/BP/ /VITARINE/

/BP/

0.1MG

0.25MG

/0.1MG/

/0.25MG/

N09838 001

N09838 002

/N09838/001/

/N09838/002/

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION
RITODRINE HCL
/AP/ /LYPHOMED/
/AP/

2 LYPHOMED
2
10MG/ML
15MG/ML

/N71188/001/
/JUL/23/1987/
/N71189/001/
/JUL/23/1987/
/N71188/001/
/JUL/23/1987/
/N71189/001/
/JUL/23/1987/

INJECTABLE; INJECTION
SODIUM THIOSULFATE
DEPT ARMY

250MG/MLM
N20166 001
FEB 14, 1992

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION
SUCCINYLCHOLINE CHLORIDE
/INTL/MEDICATION/

SODIUM CHLORIDE

INJECTABLE; INJECTION
/SODIUM/CHLORIDE/23.4% IN PLASTIC CONTAINER/
/LYPHOMED/

2 LYPHOMED
234MG/ML

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

SULFABENZAMIDE; /SULFACETAMIDE; /SULFATHIAZOLE/

/CREAM; /VAGINAL/
/SULTRIN/
/JOHNSON/RM/

/3.72; 2.86; 3.42; 0.642/
/N05794/001/

SODIUM LACTATE

INJECTABLE; INJECTION
SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER

AP MCGAW
1.87GM/100MLM

N20004 001
APR 21, 1992

/TABLET; /VAGINAL/
/SULTRIN/
/JOHNSON/RM/
/TRIPLE/SULFAL/
/2/FOUSERA/
/2/PHARMADERM/

/18.4MG; 14.3; 7.5MG; 1.72; 5MG/ /N05794/001/
/18.4MG; 14.3; 7.5MG; 1.72; 5MG/ /N05794/001/
/18.4MG; 14.3; 7.5MG; 1.72; 5MG/ /N05794/001/
/18.4MG; 14.3; 7.5MG; 1.72; 5MG/ /N05794/001/
/18.4MG; 14.3; 7.5MG; 1.72; 5MG/ /N05794/001/

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
NITROPRESS
ABBOTT

AP
25MG/ML

N71961 001
AUG 01, 1988

SODIUM NITROPRUSSIDE
GENSIA

AP
25MG/MLM

N73465 001
MAR 30, 1992

SODIUM POLYSTYRENE SULFONATE

SUSPENSION; ORAL, RECTAL

/AA/ /ROXANE/
SODIUM POLYSTYRENE SULFONATE
/1.5GM/60ML/

2 ROXANE
15GM/60ML

/N08453/001/
/NOV/17/1983/
/N08453 001
NOV 17, 1983

SULFABENZAMIDE; /SULFACETAMIDE; /SULFATHIAZOLE; /UREA/

/CREAM; /VAGINAL/
/GYN-SULF/
/5/AND/W/

/3.72; 2.86; 3.42; 0.642/
/N08667/001/
/JUN/09/1986/

/TRIPLE SulfA/
/CLAY/PARK/

/3.72; 2.86; 3.42; 0.642/
/N07285/001/
/NOV/15/1982/

/AT/ /FOUSERA/
/AT/ /NMC/

/3.72; 2.86; 3.42; 0.642/
/N06424/001/
/3.72; 2.86; 3.42; 0.642/
/N07864/001/

/AT/ /PHARMADERM/

/3.72; 2.86; 3.42; 0.642/
/N07887/001/
/JUL/23/1982/

/AT/ /VAGILIA/
/LENNON/

/3.72; 2.86; 3.42; 0.642/
/N08883/001/
/NOV/09/1987/

SULFAMETHIZOLESULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

/AB/ PROCLAR
FOREST PHARMS/
@ FOREST PHARMS/500MG/
500MG/N80273/001/
N80273 001> DLT > /AB/
> DLT >

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM
/VITARINE/
/400MG;80MG//N18598/001/
/MAY/19/1982/THIOSULFIL/AB/ +/MYETH/AYERST/
+ MYETH AYERST/500MG/
500MG/N08565/004/
N08565 004> ADD > /AB/
> ADD >

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH
/MARTEC/
/800MG;160MG//N18598/004/
MAY 19, 1982SULFAMETHOXAZOLE

TABLET; ORAL

> DLT > /AB/ URONAL
> DLT > /SHIONOGI/
> ADD > @ SHIONOGI/500MG/
500MG/N87307/001/
N87307 001> DLT > /AB/
> DLT >

TABLET; ORAL

SULFASALAZINE
/VITARINE/
/800MG;160MG//N18598/004/
MAY 19, 1982SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION

/AB/ SULFAMETHOXAZOLE AND TRIMETHOPRIM
CETUS BEN VENUE
80MG/ML; 16MG/ML/N72383/001/
APR 29, 1992

TABLET; ORAL

SULFASALAZINE
@ EON LABS
/500MG/
/500MG//N86184/001/
/N86184/001/

TABLET; ORAL

> ADD > /AB/ SULFAMETHOXAZOLE AND TRIMETHOPRIM
> ADD > @ EON LABS
/400MG;80MG//N18598/001/
MAY 19, 1982

TABLET; ORAL

SULFASALAZINE
/AB/ SULFASALAZINE
@ PARKE DAVIS/
/500MG/
/500MG//N84955/001/
N84955 001/AB/ INTERPHARM/400MG;80MG/
/800MG;160MG//N71299/001/
MAY 19, 1982

TABLET; ORAL

SULFISOXAZOLE
/AB/ SULFISOXAZOLE
@ WEST WARD/
/500MG/
/500MG//N80379/001/
N80379 001B* INTERPHARM

400MG;80MG

/N71299/001/
MAY 19, 1982B* INTERPHARM

800MG;160MG

/N71300/001/
OCT 27, 1987

TABLET; ORAL

SULINDAC/AB/ MARTEC

/400MG;80MG/

/N72408/001/
OCT 27, 1987

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992/B* PHARM/BASICS

/400MG;80MG/

/N72408/001/
OCT 27, 1987

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992/B* PHARM/BASICS

/400MG;80MG/

/N72408/001/
OCT 27, 1987

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992/B* PHARM/BASICS

/400MG;80MG/

/N72408/001/
OCT 27, 1987

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

400MG;80MG

/N70203/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992@ PHARM BASICS

800MG;160MG

/N70204/001/
NOV 08, 1985

TABLET; ORAL

SULINDAC
LEMMON/N72972/001/
FEB 28, 1992

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

THEOPHYLLINECAPSULE, EXTENDED RELEASE; ORAL
SOMOPHYLLIN-CRT

/BC/ /FISONS/

/50MG/

/N87763/001/
/FEB/27, 1985/

/BC/ /FISONS/

/100MG/

/N87194/001/
/FEB/27, 1985/

/BC/ /FISONS/

/200MG/

/N88382/001/
/FEB/27, 1985/

/BC/ /FISONS/

/250MG/

/N87193/001/
/FEB/27, 1985/

/BC/ /FISONS/

/300MG/

/N88383/001/
/FEB/27, 1985/

BC GRAHAM LABS

50MG

/N87763/001/
/FEB/27, 1985/

BC

100MG

/N87194/001/
/FEB/27, 1985/

BC

200MG

/N88382/001/
/FEB/27, 1985/

BC

250MG

/N87193/001/
/FEB/27, 1985/

BC

300MG

/N88383/001/
/FEB/27, 1985/

THEO-24

/BC/ /SEARLE/

/100MG/

/N87942/001/
/AUG/22, 1983/

/BC/ /SEARLE/

/200MG/

/N87943/001/
/AUG/22, 1983/

/BC/ /SEARLE/

/300MG/

/N87944/001/
/AUG/22, 1983/

/BC/ /SEARLE/

/400MG/

/N87945/001/
/AUG/22, 1983/

BC WHITBY PHARMS

100MG

/N87942/001/
/AUG/22, 1983/

BC

200MG

/N87943/001/
/AUG/22, 1983/

BC

300MG

/N87944/001/
/AUG/22, 1983/

BC

400MG

/N81034/001/
/FEB/28, 1992/

THEOPHYLLINE

© EON LABS

260MG

/N87462/001/
/MAY/11, 1982/

/BC/ /FISONS/

/260MG/

/N87462/001/
/MAY/11, 1982/

TABLET, EXTENDED RELEASE; ORAL

T-PHYL

200MG

/N88253/001/
/AUG/17, 1983/

BC PURDUE FREDERICK

200MG

/N88253/001/
/AUG/17, 1983/

/BC/ /PURDUE FREDERICK/

/200MG/

/N88253/001/
/AUG/17, 1983/THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

/AP/ /LUITPOLD/

/100MG/ML/

/N80667/001/
/FEB/09, 1988/

/AP/ /LUITPOLD/

/100MG/ML/

/N80667/001/
/FEB/09, 1988/

/AP/ /PARKE/DAVIS/

/100MG/ML/

/N80770/001/
/FEB/09, 1988/

/AP/ /PARKE DAVIS

/100MG/ML/

/N80770/001/
/FEB/09, 1988/THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

/AB/ /PAR/

/150MG/

/N89764/001/
/FEB/09, 1988/

/AB/ /PAR/

/200MG/

/N89765/001/
/FEB/09, 1988/

/AB/ /PAR/

/150MG/

/N89764/001/
/FEB/09, 1988/

/AB/ /PAR/

/200MG/

/N89765/001/
/FEB/09, 1988/

/AB/ /PAR/

/150MG/

/N89764/001/
/FEB/09, 1988/

/AB/ /PAR/

/200MG/

/N89765/001/
/FEB/09, 1988/THIOXIPERINE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOXIPERINE HCL INTENSOL

/AA/ /ROXANE

/EQ 5MG BASE/MLM

/N73494/001/
/JUN 30, 1992/TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

/BC/ /PHARM/BASICS/

/5MG/

/N72001/001/
/JAN 10, 1989/

/BC/ /PHARM/BASICS/

/10MG/

/N72002/001/
/JAN 10, 1989/

/BC/ /PHARM/BASICS/

/20MG/

/N72003/001/
/JAN 10, 1989/

/BC/ /PHARM/BASICS/

/5MG/

/N72001/001/
/JAN 10, 1989/

/BC/ /PHARM/BASICS/

/10MG/

/N72002/001/
/JAN 10, 1989/

/BC/ /PHARM/BASICS/

/20MG/

/N72003/001/
/JAN 10, 1989/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'92 - JUL'92

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP	ABBOTT	EQ 40MG BASE/MLM	N63116 001 MAY 18, 1992	AB	<u>TOLMETIN SODIUM</u> GENEVA	EQ 400MG BASEM	N73462 001 APR 30, 1992
AP	GENSIA	EQ 40MG BASE/MLM	N63100 001 JAN 30, 1992	AB	LEMMON	EQ 400MG BASEM	N73519 001 MAY 29, 1992
				AB	PUREPAC	EQ 400MG BASEM	N73308 001 JAN 24, 1992

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

AB	INTERPHARM	/250MG/	/N71270/001/ SEP 23, 1986	AB	<u>TOLECTIN 600</u> JOHNSON RM	EQ 600MG BASE	N17628 002 MAR 08, 1989
AB		/500MG/	/N71271/001/ SEP 23, 1986				
B*	INTERPHARM	250MG	N71270 001 SEP 23, 1986	> ADD > AB	<u>TOLMETIN SODIUM</u> GENEVA	EQ 200MG BASEM	N73588 001 JUL 31, 1992
B*		500MG	N71271 001 SEP 23, 1986	> ADD > AB	PUREPAC	EQ 600MG BASEM	N73527 001 JUN 30, 1992
/B*/	/PHARM/BASICS/	/100MG/	/N71355/001/ JAN 11, 1988				
/B*/		/250MG/	/N70168/001/ APR 02, 1986				
/B*/		/500MG/	/N70169/001/ APR 02, 1986				
	PHARM BASICS	100MG	N71355 001 JAN 11, 1988		<u>TRAZODONE HYDROCHLORIDE</u>	/50MG/	/N70491/001/ APR 29, 1987
		250MG	N70168 001 APR 02, 1986		TRAZODONE HCL	/100MG/	/N70492/001/ APR 29, 1987
		500MG	N70169 001 APR 02, 1986		PHARM BASICS	50MG	N70491 001 APR 29, 1987
						100MG	N70492 001 APR 29, 1987

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

> ADD > AB	EON LABS	500MG	N12678 001 JAN 18, 1992		<u>TRICHLORMETHIAZIDE</u>	/4MG/	/N86171/001/ N86171 001
/AB/	PARKE DAVIS	/500MG/	/N86047/001/ N86047 001		TRICHLORMETHIAZIDE		
> DLT > /AB/	PARKE DAVIS	500MG	N86047 001 JAN 18, 1992		VITARINE		
	VITARINE	/500MG/	/N12678/001/ JAN 24, 1992				

TOLMETIN SODIUM

CAPSULE; ORAL
TOLMETIN SODIUM

AB	BAKER CUMMINS	EQ 400MG BASEM	N73392 001 JAN 24, 1992				
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TRIMIPRAMINE MALEATE

CAPSULE; ORAL

SURMONTIL
/AB/ /WYETH/AYERST/
/AB/ /WYETH/AYERST/
/AB/ /WYETH/AYERST/
/AB/ /WYETH/AYERST/

+ WYETH AYERST

EQ 100MG BASE

EQ 25MG BASE

EQ 50MG BASE

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

/AB/

/AB/

EQ 100MG BASE

TRIMIPRAMINE MALEATE

a EON LABS

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

N71832 001

SEP 10, 1987

N71833 001

SEP 10, 1987

N71834 001

SEP 10, 1987

a PHARM BASICS

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

N71283 001

DEC 08, 1987

N71284 001

DEC 08, 1987

N71285 001

DEC 08, 1987

TRIMIPRAMINE MALEATE

/a/ /WYETH/AYERST/

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

N71832 001

SEP 10, 1987

N71833 001

SEP 10, 1987

N71834 001

SEP 10, 1987

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL

GYN-SULF

G AND M

3.7%;2.86%;3.42%

N88607 001

JUN 09, 1986

SULTRIN

JOHNSON RW

3.7%;2.86%;3.42%

N05794 001

TRIPLE SULFA (SULFABENZAMIDE;SULFACETAMIDE;SULFATHIAZOLE)

CREAM; VAGINAL

TRIPLE SULFA

AT

CLAY PARK

3.7%;2.86%;3.42%

N87285 001

NOV 15, 1982

AT

FOUGERA

3.7%;2.86%;3.42%

N86424 001

AT

NMC

3.7%;2.86%;3.42%

N87864 001

SEP 01, 1982

TRYUL

AT

SAVAGE

3.7%;2.86%;3.42%

N87887 001

JUL 23, 1982

VAGILIA

a LENNON

3.7%;2.86%;3.42%

N88821 001

NOV 09, 1987

TABLET; VAGINAL

SULTRIN

JOHNSON RW

TRIPLE SULFA

a FOUGERA

a PHARMADERM

184MG;143.75MG;172.5MG

N05794 002

184MG;143.75MG;172.5MG

N88463 001

JAN 03, 1985

184MG;143.75MG;172.5MG

N88462 001

JAN 03, 1985

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

/SULFALID/

/FOREST PHARMS/

a FOREST PHARMS

/500MG/5ML/

500MG/5ML

/N86100/001/

N80100 001

VECURONIUM BROMIDE

INJECTABLE; INJECTION

NORCURON

ORGANON

20MG/VIALM

N18776 003

JAN 03, 1992

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN

+ ELAN

180MGH

N19614 003

JAN 09, 1992

WARFARIN SODIUM

TABLET: ORAL

/WÄRFÄRIN/SÖÖTUM/

PHARM/BASICS/

12.5m/s

/ ५५५ /

PHARM BASICS

2 EMC

5MG

TABLET; ORAL

HIVID

0.75MGH

0.375MG/M

N83080 001

N83080 002

1999/999999

1200/0000

N85479 001

185479/001/

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G AND W

120MG

N72218 001

MAR 27, 1992

325MG

N72344 001

MAR 27, 1992

650MG

N72237 001

MAR 27, 1992

SODIUM MONOFLUOROPHOSPHATE

PASTE; DENTAL

EXTRA-STRENGTH AIM

/3/CHESBROUGH/PODS/ 1.2%

CHESEBROUGH PONDS 1.2%

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

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
MICROCOL
JOHNSON AND JOHNSON 0.5%

N72292 001

JAN 28, 1992

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
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
PERRIGO

1MG/5ML

N73243 001

JAN 21, 1992

1MG/5ML

N73079 001

APR 30, 1992

ROXANE

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '92 - JUL '92

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

INJECTABLE; INJECTION

6% GENTRAN 75 AND 10% TRAVERS
TRAVENOL LABS

6GM/100ML; 0.9GM/100ML
0.9GM/100ML

N08788

UROKINASE

INJECTABLE; INJECTION

BREOKINASE

STERLING DRUG

250,000 IU/VIAL

N17873

ORPHAN DRUG PRODUCT DESIGNATIONS

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

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

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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALDESLEUKIN TRADE: PROLEUKIN*/**	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS. */** [MAY 05, 1999]	CETUS CORPORATION
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 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
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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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
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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL

GENERIC: SECRETORY LEUKOCYTE PROTEASE INHIBITOR
TRADE: NOT ESTABLISHED

GENERIC: TECHNETIUM TC99M MURINE MONOCLONAL
ANTIBODY (IGG2A) TO BCE
TRADE: IMMURATD-LL-2[99mTc]

DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]

TREATMENT OF BRONCHOPULMONARY DYSPLASIA.

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
LYMPHOCYTIC LEUKEMIA.

SPONSOR NAME

SYNERGEN, INC

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.	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.	PHARMAVENE, INC
GENERIC: DAPSONE TRADE: DAPSONE	FOR THE COMBINATION TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA IN CONJUNCTION WITH TRIMETHOPRIM.	JACOBUS PHARMACEUTICAL COMPANY
GENERIC: DIANEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS TRADE: NUTRINEAL PD-2 PERITONEAL DIALYSIS SOLN WITH 1.1% AMINO ACIDS	FOR 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: 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 PHENYLBUTYRATE TRADE: NOT ESTABLISHED	TREATMENT OF SICKLING DISORDERS, WHICH INCLUDE S-S HEMOGLOBINOPATHY, S-C HEMOGLOBINOPATHY, AND S-THALASSEMIA HEMOGLOBINOPATHY.	JOHNS HOPKINS MEDICAL INSTITUTIONS
GENERIC: SODIUM MONOMERCAPTOUNDECAHYDRO-CLOSODODECABORATE TRADE: BOROCELL	FOR USE IN BORON NEUTRON CAPTURE THERAPY IN THE TREATMENT OF GLIOBLASTOMA MULTIFORME.	NEUTRON TECHNOLOGY CORPORATION
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 JULY 1992 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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.

REVISED DATE

DATE

DRUG NAME (DOSAGE FORM)

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 CROSSOVER DESIGN	JUN 15, 1992
TERFENADINE (TABLET)	JUL 01, 1992
	JUN 12, 1992

JUN 15, 1992

ANDA SUITABILITY PETITIONS

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

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

DRUG NAME DOSAGE FORM; ROUTE	PETITIONS APPROVED			REASON FOR STATUS
	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	
ACETAMINOPHEN; CODEINE PHOSPHATE TABLET; ORAL	500MG 7.5MG	91 P-0514/ CPI	SOFTAN	APPROVED JUN 03, 1992
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	91 P-0348/ CPI	HAMER	APPROVED MAR 17, 1992
CHLORZOXAZONE TABLET; ORAL	750MG	91 P0153/ CPI	MIKART	APPROVED JUN 03, 1992
HYDROCORTISONE ACETATE AEROSOL; TOPICAL	2.5%	92 P-0101/ CPI	HOGAN & HARTSON	APPROVED JUL 08, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	5MG/ML (50ML/CONTAINER)	91 P-0387/ CPI	ABBOTT	APPROVED FEB 18, 1992
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	10MG/ML (100ML/CONTAINER)	91 P-0387/ CPI	ABBOTT	APPROVED FEB 18, 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

- | | |
|------|---|
| 1-67 | TREATMENT OF ACUTE ASTHMATIC ATTACKS IN CHILDREN SIX YEARS OF AGE AND OLDER |
| 1-68 | CENTRAL PRECOCIOUS PUBERTY |
| 1-69 | 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 |
| 1-70 | USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER |
| 1-71 | VARICELLA INFECTIONS (CHICKENPOX) |
| 1-72 | PREVENTION OF CMV DISEASE IN TRANSPLANT PATIENTS AT RISK FOR CMV DISEASE |
| 1-73 | INITIATE AND MAINTAIN MONITORED ANESTHESIA CARE (MAC) SEDATION DURING DIAGNOSTIC PROCEDURES |
| 1-74 | INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY |
| 1-75 | TREATMENT OF ENDOSCOPICALLY DIAGNOSED EROSIVE ESOPHAGITIS |

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 |

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
>ADD>	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
>ADD>	19787 001 AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
>ADD>	19787 002 AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		NCE	JUL 31, 1997
>ADD>	19787 003 AMLODIPINE BESYLATE; NORVASC	4572909	FEB 25, 2003		ODE	JUN 17, 1999
	20075 001 BACLOFEN; LIORESAL				NDF	JUN 17, 1995
>ADD>	20075 002 BACLOFEN; LIORESAL				ODE	JUN 17, 1999
					NDF	JUN 17, 1995
>ADD>	19851 001 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	19851 002 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	19851 003 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	19851 004 BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2002		NCE	JUN 25, 1996
	20033 001 BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NC	MAY 19, 1995
	20033 002 BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
					NC	MAY 19, 1995
	20033 003 BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
					NC	MAY 19, 1995
	20033 004 BENAZEPRIL HYDROCHLORIDE; LOTENSIN HCT	4410520	OCT 18, 2002		NCE	JUN 25, 1996
					NC	MAY 19, 1995
	19001 001 BEPRIDIL HYDROCHLORIDE; BEPADIN	RE30577	JUN 08, 1995		NCE	DEC 28, 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
>ADD>	19982 001 BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998		NCE	JUL 31, 1997
>ADD>		4171370	OCT 16, 1996			
>ADD>	19982 002 BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 1998		NCE	JUL 31, 1997
>ADD>		4171370	OCT 16, 1996			
>ADD>	19548 001 BITOLTEROL MESYLATE; TORNALATE	4336400	JUN 22, 1999	U-5		
		4138581	FEB 06, 1998		NDF	FEB 19, 1995
	19890 001 BUTORPHANOL TARTRATE; STADOL	4464378	AUG 07, 2001	U-60	NDF	DEC 12, 1994

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
19847 001	CIPROFLOXACIN; CIPRO	4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002		NCE	OCT 22, 1992
19857 001	CIPROFLOXACIN; CIPRO IN DEXTROSE 5%	4957922	SEP 18, 2007			
		4808583	FEB 28, 2006			
		4705789	NOV 10, 2004			
		4670444	OCT 01, 2002			
		4957922	SEP 18, 2007			
19858 001	CIPROFLOXACIN; CIPRO IN SODIUM CHLORIDE 0.9%	4808583	FEB 28, 2006			
		4705789	NOV 10, 2004		NCE	OCT 22, 1992
		4670444	OCT 01, 2002			
		4670444	OCT 01, 2002			
		4670444	OCT 01, 2002			
		4670444	OCT 01, 2002			
		4670444	OCT 01, 2002			
		4960799	OCT 02, 2007			
19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO			U-36		OCT 22, 1992
19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO			U-36		OCT 22, 1992
19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO			U-36		OCT 22, 1992
19992 001	CIPROFLOXACIN HYDROCHLORIDE; CILLOXAN				NCE	OCT 22, 1992
20037 001	DICLOFENAC SODIUM; VOLTAREN				NDF	DEC 31, 1993
20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NDF	MAR 28, 1994
20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM				NCE	NOV 05, 1992
20062 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD				NCE	NOV 05, 1992
					NCE	NOV 05, 1992
20062 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	5002776	MAR 26, 2008			
		4894240	JAN 16, 2007		NP	DEC 27, 1994
		5002776	MAR 26, 2008		NCE	NOV 05, 1992
20062 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM CD	4894240	JAN 16, 2007		NP	DEC 27, 1994
		5002776	MAR 26, 2008		NCE	NOV 05, 1992
20092 001	DILTIAZEM HYDROCHLORIDE; DILACOR XR	4894240	JAN 16, 2007		NP	DEC 27, 1994
					NP	DEC 27, 1994
20092 002	DILTIAZEM HYDROCHLORIDE; DILACOR XR				NCE	NOV 05, 1992
					NP	DEC 27, 1994
20092 003	DILTIAZEM HYDROCHLORIDE; DILACOR XR				NCE	NOV 05, 1992
					NP	DEC 27, 1994
19946 001	DOXACURIUM CHLORIDE; NUROMAX				NCE	NOV 05, 1992
19697 001	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN				NCE	MAR 07, 1996
19697 002	ETHINYL ESTRADIOL; ORTHO TRI-CYCLEN				NP	JUL 03, 1995
19462 001	FAMOTIDINE; PEPCID				NP	JUL 03, 1995
19462 002	FAMOTIDINE; PEPCID				I-69	DEC 10, 1994
19527 001	FAMOTIDINE; PEPCID				I-69	DEC 10, 1994
					I-69	DEC 10, 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
19834 001	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998		NCE	JUL 25, 1996
20180 001	FINASTERIDE; PROSCAR	4760071	JUL 26, 2005			
20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4377584	MAR 22, 2000		NCE	JUN 19, 1997
20068 001	FOSCARNET SODIUM; FOSCAVIR	4357324	NOV 02, 2001		NCE	APR 18, 1996
		4771041	JUL 29, 1997			
		4665062	JUL 29, 1997			
		4339445	JUL 29, 1997	U-64		
		4215113	JUL 29, 1997	U-64	NCE	SEP 27, 1996
19915 002	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	MAY 16, 1996
19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 2001		NCE	MAY 16, 1996
19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-35	I-72	MAY 15, 1995
20051 001	GLYBURIDE; GLYNASE	4916163	APR 10, 2007		NCE	MAY 01, 1994
		4735805	APR 05, 2005		NP	MAR 04, 1995
		3507961	APR 21, 1992			
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
		3426067	APR 21, 1992			
20051 002	GLYBURIDE; GLYNASE	4916163	APR 10, 2007		NCE	MAY 01, 1994
		4735805	APR 05, 2005		NP	MAR 04, 1995
		3507961	APR 21, 1992			
		3507954	APR 21, 1992			
		3454635	APR 21, 1992			
		3426067	APR 21, 1992			
20055 001	GLYBURIDE; GLUBATE	4012444	MAR 15, 1994		NP	MAR 04, 1995
20055 002	GLYBURIDE; GLUBATE	4012444	MAR 15, 1994		NCE	MAY 01, 1994
		4012444	MAR 15, 1994		NP	MAR 04, 1995
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE				NCE	MAY 01, 1994
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE				D-1	DEC 31, 1994
20250 001	HALOFANTRINE HYDROCHLORIDE; HALFAN				D-1	DEC 31, 1994
19046 001	HYDROCHLOROTHIAZIDE; NORMOZIDE				NCE	JUL 24, 1997
19046 002	HYDROCHLOROTHIAZIDE; NORMOZIDE				NCE	AUG 01, 1994
19046 003	HYDROCHLOROTHIAZIDE; NORMOZIDE				NCE	AUG 01, 1994
19046 004	HYDROCHLOROTHIAZIDE; NORMOZIDE				NCE	AUG 01, 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
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	4396598	OCT 26, 2002	U-61	NP	APR 29, 1995
19710 004	TOVERSOL; OPTIRAY 300	4396598	OCT 26, 2002	U-62	NS	JAN 22, 1995
19710 005	TOVERSOL; OPTIRAY 350				NS	JAN 22, 1995
19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55	I-74	JAN 22, 1995
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NDF	DEC 20, 1994
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NCE	NOV 30, 1994
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-70	DEC 12, 1994
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT				I-70	DEC 12, 1994
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4917893	MAR 24, 2004			
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
		4917893	MAR 24, 2004			
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				ODE	DEC 31, 1998
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN				NCE	FEB 21, 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				NE	JAN 10, 1995
19962 003	METOPROLOL SUCCINATE; TOPROL XL				NE	JAN 10, 1995
		3998790	APR 08, 1992			
		3876802	APR 08, 1992			
		3998790	APR 08, 1992			
		3876802	APR 08, 1992			
		3998790	APR 08, 1992			
		3876802	APR 08, 1992			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20098 001	MIVACURIUM CHLORIDE; MIVACRON	4761418	AUG 02, 2005		NCE	JAN 22, 1997
20098 002	MIVACURIUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	AUG 02, 2005		NCE	JAN 22, 1997
19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2000		NCE	DEC 24, 1996
19583 002	NABUMETONE; RELAFEN	4061779	DEC 06, 1994	U-19		
19886 001	NAFARELIN ACETATE; SYNAREL	4420639	DEC 13, 2000		NCE	DEC 24, 1996
20109 001	NAFARELIN ACETATE; SYNAREL	4061779	DEC 06, 1994	U-19		
19734 001	NICARDIPINE HYDROCHLORIDE; CARDENE	4234571	NOV 18, 1997		I-68	FEB 26, 1995
20005 001	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NCE	FEB 13, 1995
20005 002	NICARDIPINE HYDROCHLORIDE; CARDENE SR				I-68	FEB 26, 1995
20005 003	NICARDIPINE HYDROCHLORIDE; CARDENE SR				NDF	JAN 30, 1995
19983 001	NICOTINE; PROSTEP				NCE	DEC 21, 1993
19983 002	NICOTINE; PROSTEP				NDF	FEB 21, 1995
20076 001	NICOTINE; HABITROL	4946853	AUG 07, 2007	U-56	NDF	FEB 21, 1995
20076 002	NICOTINE; HABITROL	4946853	AUG 07, 2007	U-56	NS	JAN 28, 1995
20076 003	NICOTINE; HABITROL	5016652	MAY 21, 2008		NS	JAN 28, 1995
20150 001	NICOTINE; NICOTROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20150 002	NICOTINE; NICOTROL	5016652	MAY 21, 2008		NDF	NOV 07, 1994
20150 003	NICOTINE; NICOTROL				NP	APR 22, 1995
20165 001	NICOTINE; NICODERM				NP	APR 22, 1995
20165 002	NICOTINE; NICODERM	5004610	APR 02, 2008		NP	APR 22, 1995
20165 003	NICOTINE; NICODERM	4144317	SEP 09, 1992		NDF	NOV 07, 1994
20064 001	NITROFURANTOIN; MACROBID	5004610	APR 02, 2008		NDF	NOV 07, 1994
19757 001	NORFLOXACIN; CHIBROXIN	4144317	SEP 09, 1992		NDF	NOV 07, 1994
20087 001	OFLOXACIN; FLOXIN IN DEXTROSE 5%	5004610	APR 02, 2008		NDF	NOV 07, 1994
20087 002	OFLOXACIN; FLOXIN	5004610	APR 02, 2008		NDF	NOV 07, 1994
20087 003	OFLOXACIN; FLOXIN	4144317	SEP 09, 1992		NDF	NOV 07, 1994
20087 004	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4798725	JAN 17, 2006		NDF	NOV 07, 1994
20087 005	OFLOXACIN; FLOXIN IN DEXTROSE 5%	4772473	SEP 20, 2005		NDF	DEC 24, 1994
19715 001	OLSAZINE SODIUM; DIPENTUM	4551456	NOV 05, 2002	U-57	NCE	DEC 28, 1995
		4382892	MAY 10, 2000		NCE	DEC 28, 1995
		4382892	MAY 10, 2000		NCE	DEC 28, 1995
		4382892	MAY 10, 2000		NCE	DEC 28, 1995
		4382892	MAY 10, 2000		NCE	DEC 28, 1995
		4382892	MAY 10, 2000		NCE	DEC 28, 1995
		4559330	AUG 04, 2004	U-58	NCE	JUL 31, 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
19775 001	PRazosin Hydrochloride; MINIPRESS XL	5082668 4783337 4765989 4612008 4327725 4092315 5082668 4783337 4765989 4612008 4327725 4092315 4448774 4798846 4521431 4521431 4128658 4444784 4444784 4444784 4730000 4730000 4863742	SEP 16, 2003 SEP 16, 2003 SEP 16, 2003 SEP 16, 2003 MAY 04, 1999 MAY 30, 1995 SEP 16, 2003 SEP 16, 2003 SEP 16, 2003 SEP 16, 2003 MAY 04, 1999 MAY 30, 1995 MAY 15, 2001 NOV 01, 1996 JUN 04, 2002 JUN 04, 2002 DEC 05, 1995 APR 24, 2001 APR 24, 2001 APR 24, 2001 APR 24, 2001 MAR 08, 2005 MAR 08, 2005 SEP 05, 2006			
19775 002	PRazosin Hydrochloride; MINIPRESS XL				NDF	JAN 29, 1995
19157 001	PREDNISOLONE Sodium Phosphate; PEDIAPRED				NDF	JAN 29, 1995
19627 001	PROPOFOL; DIPRIVAN				I-73	DEC 31, 1994
18703 001	RANITIDINE Hydrochloride; ZANTAC 150				I-75	MAY 19, 1995
18703 002	RANITIDINE Hydrochloride; ZANTAC 300				I-75	MAY 19, 1995
19675 001	RANITIDINE Hydrochloride; ZANTAC				I-75	MAY 19, 1995
19766 001	SIMVASTATIN; ZOCOR			U-59	NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR			U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR			U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR			U-59	NCE	DEC 23, 1997
20166 001	SODIUM THIOSULFATE				NCE	DEC 23, 1997
20063 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; RBC-SCAN				NP	JUN 14, 1997
20043 003	TEMAFLOXACIN Hydrochloride; OMNIFLOX			U-36	NCE	JUN 11, 1995
20043 004	TEMAFLOXACIN Hydrochloride; OMNIFLOX			U-36	NCE	JAN 30, 1997
20119 001	TENIPOSIDE; VUMON				NCE	JAN 30, 1997
19614 003	VERAPAMIL Hydrochloride; VERELAN				NCE	JUL 14, 1997
20199 001	ZALCITABINE; HIVID				NDF	MAY 29, 1993
20199 002	ZALCITABINE; HIVID				NCE	JUN 19, 1997
19655 001	ZIDOVUDINE; RETROVIR				ODE	JUN 19, 1999
		4837208 4833130 4828838 4724232	FEB 09, 2005 FEB 09, 2005 FEB 09, 2005 FEB 09, 2005		I-47 ODE NCE ODE	MAY 02, 1993 MAR 19, 1994 MAR 19, 1992

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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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