

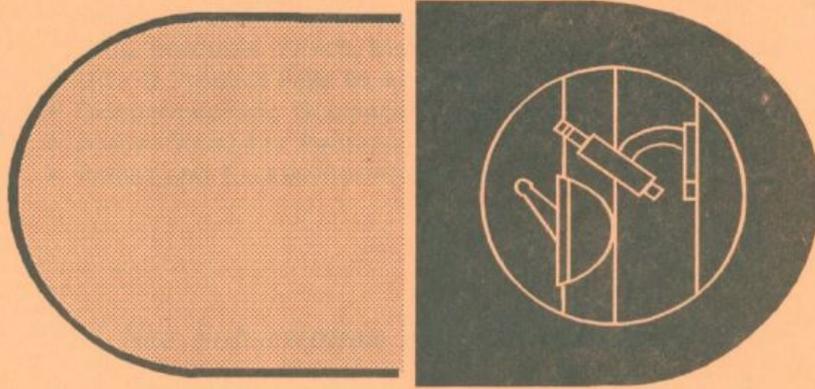
**CUMULATIVE
SUPPLEMENT 10**

JAN'91-OCT'91

APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

11TH EDITION



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

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Prepared By
Division of Drug Information Resources
Office of Management
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**APPROVED
DRUG PRODUCTS**

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1992

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

Cumulative Supplement

October 1991

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

CUMULATIVE SUPPLEMENT 10

OCTOBER 1991

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, 11th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, along with the application number and product number (FDA's internal file number). 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 11th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 12th Edition.

1.2 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)

1.3 CHANGE OF A THERAPEUTIC EQUIVALENCY CODE FOR A DRUG ENTITY

Methylphenidate Hydrochloride:

In its initial considerations, the Agency did not classify methylphenidate hydrochloride (MPD) as having an actual or potential bioequivalence problem (42 FR 1624, January 7, 1977). MPD in oral tablet form (Ritalin™, manufactured by Ciba Pharmaceuticals) is a DESI drug product that was raised to the effective status on October 7, 1970 (35 FR 15771). MPD in tablet form remained single source until December 23, 1977 when it became available from MD Pharmaceutical. In the first and subsequent editions of the "Orange Book" this drug product has been coded coded **AA**.

Recently, FDA's Therapeutic Inequivalence Action Coordination Committee (TIACC) investigated a report from the Kaiser Permanente Medical Care Program in Oakland, California, suggesting therapeutic inequivalence regarding duration of action in a marketed lot of MD Pharmaceutical MPD tablets. Samples from MD Pharmaceutical and Ciba were tested in accordance with USP dissolution test procedures by an FDA field laboratory. Although both products met the single point USP criteria of not less than 75% of the labeled amount of MPD dissolved within 45 minutes, the dissolution profile of the MD Pharmaceutical product was much faster than that of the Ciba product.

Based on these in vitro dissolution data, FDA commissioned an in- vivo bioequivalence study under its extramural contract research program. The bioequivalence study indicated that at one-half and three-fourths hours after administration of a single 20 mg dose, somewhat more of MD Pharmaceutical's product had been absorbed compared to Ciba's Ritalin. However, the MD Pharmaceutical MPD 20 mg tablets met FDA's criteria for rate and extent of absorption, and were considered to be bioequivalent to Ciba's Ritalin 20 mg tablets.

Because of the in vitro dissolution data coupled with new information discovered during the course of this evaluation, the FDA has proposed a change in the therapeutic equivalence code from AA to BP for listed MPD tablets. This change requires that firms submitting an ANDA for MPD tablets submit an acceptable in vivo bioequivalence study to gain approval in addition to submission of all previously required information.

Agency reasons for considering this change in the equivalence code is as follows:

- 1) Although early work suggested that MPD tablets are completely absorbed recent studies utilizing more specific techniques calculated the relative bioavailability to be 11 to 53%. (Chan et al: Pediatrics, 72, 56-59, 1983). This raised concerns regarding possible approval of a superbioavailable drug product.
- 2) The current dl-MPD pharmacological activity derives primarily from the d isomer which may exhibit non-linear kinetics. (Srinivas et al: Journal of Pharmacology and Experimental Therapeutics, 241, 300-306, 1987).
- 3) The previously cited in vitro dissolution data suggesting that substantial differences in in vitro dissolution may exist between different formulations of MPD.

The Agency invites written comments and scientific data regarding the Agency's proposal to change the therapeutic equivalence code for listed MPD oral tablets from AA to BP. The comment period will be 60 days from the first day in the monthly Supplement.

1.4 THE B* THERAPEUTIC EQUIVALENCE CODE

Drug products requiring further FDA investigation and review to determine therapeutic equivalence.

The code **B*** is assigned to products that were previously assigned an **A** code if FDA receives new information that raises a significant question regarding therapeutic equivalence that can be resolved only through further Agency investigation and/or review of data and information submitted by the applicant. The **B*** code signifies that the Agency will take no position regarding the therapeutic equivalence of the product until the Agency completes its investigation and review.

1.5 APPLICANT (NAME) CHANGES

Because 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, 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

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>ABBREVIATED NAME</u>
CORD LABORATORIES INC	GENEVA PHARMACEUTICALS INC	GENEVA
GIST BROCADES	BROCADES PHARMA bv	BROCADES PHARMA
ICI PHARMACEUTICALS PR INC	IPR PHARMACEUTICALS INC	IPR
KENDALL MCGAW PHARMACEUTICALS	GENSIA PHARMACEUTICALS INC	GENSIA
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI
REID ROWELL INC	SOLVAY PHARMACEUTICALS	SOLVAY

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

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

The baseline column (Dec 1990) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

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

New Molecular Entity

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

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 1990</u>	<u>MAR 1991</u>	<u>JUN 1991</u>	<u>SEP 1991</u>
DRUG PRODUCTS LISTED	10123	9953	9900	9869
SINGLE SOURCE	2030 (20.1%)	2090 (21.0%)	2110 (21.3%)	2103 (21.4%)
MULTISOURCE	8093 (79.9%)	7863 (79.0%)	7790 (78.7%)	7766 (78.6%)
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7061 (71.0%)	6937 (70.1%)	6914 (70.0%)
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	660 (6.6%)	702 (7.1%)	706 (7.2%)
EXCEPTIONS ¹	119 (1.2%)	142 (1.4%)	151 (1.5%)	146 (1.4%)
NEW MOLECULAR ENTITIES APPROVED	--	5	4	3
NUMBER OF APPLICANTS	400	408	417	418

¹Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

ACETAZOLAMIDE

TABLET; ORAL
ACETAZOLAMIDE

> DLT > /AB/
> ADD >
ALRA
/BAMAX/
/BOLAR/
@ BOLAR

N83320 001
/N83320/001/
/N84498/002/
N84498 002

ACYCLOVIR
TABLET; ORAL
ZOVIRAX
BURROUGHS WELLCOME

400MG
800MG

N20089 001
APR 30, 1991
N20089 002
APR 30, 1991

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

/DLX/
/NORMICH/EATON/
@ NORMICH EATON

/22/
2%

/N86845/001/
N86845 001

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
DANBURY

AB
EQ 2MG BASEM

AB
EQ 4MG BASEM

AB
EQ 2MG BASEM

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE
/PHARM/BASICS/

/AB/
/250MG/

/AB/
/500MG/

B* PHARM BASICS

250MG

B* PHARM BASICS

500MG

/N70753/001/
/NOV/03/1986/
/N70754/001/
/NOV/03/1986/
/N70753/001/
NOV 03, 1986
/N70754/001/
NOV 03, 1986

ALCOHOL

INJECTABLE; INJECTION

/ALCOHOL, 5% IN DEXTROSE, 5%/
/AB/
/CUTTER/
@ CUTTER

/N83483/001/
N83483 001

ALGLUCERASE

INJECTABLE; INJECTION
CEREDASE
GENZYME

80 UNITS/MLM

N20057 003
APR 05, 1991

ACETOPHENAZINE MALEATE

TABLET; ORAL

/TINDAL/
/SCHERING/
@ SCHERING

/20MG/
20MG

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL
/BOLAR/

/AB/
/300MG/

300MG

/N18241/002/
/NOV/16/1984/
N18241 002
NOV 16, 1984

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL
/AB/ /PUREPAC/

/100MG/

/N70579/001/

/APR 14, 1986/

/250MG/ML/

/AB/

INJECTABLE; INJECTION

AMINOPHYLLINE

/AB/ /ANTI-MEDICATION/

/250MG/ML/

/N87867/001/

/NOV 10, 1983/

/N87868/001/

/NOV 10, 1983/

25MG/ML

N87867 001

25MG/ML

NOV 10, 1983

25MG/ML

NOV 10, 1983

25MG/ML

N87868 001

25MG/ML

NOV 10, 1983

25MG/ML

N87867 001

ALPRAZOLAM

TABLET; ORAL

XANAX
/3/UP/JOHN/

/2MG/

/N18276/004/

/NOV 27, 1985/

N18276 004

NOV 27, 1985

100MG

200MG

1.00MG/

2.00MG/

> ADD >

> ADD >

> DLT >

> DLT >

TABLET; ORAL

AMINOPHYLLINE

LANNETT

/3/

/3/

100MG

200MG

1.00MG/

2.00MG/

N84588 001

N84588 002

N84588/001/

N84588/002/

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

AMANTADINE HCL
AA COPLE

50MG/5MLM

N73115 001

AUG 23, 1991

100MG

200MG

1.00MG/

2.00MG/

N84588 001

N84588 002

N84588/001/

N84588/002/

AMTLORID HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMTLORID HCL AND HYDROCHLOROTHIAZIDE
MYLAN

5MG;50MGM

N73209 001

OCT 31, 1991

N73334 001

JUL 19, 1991

10MG

25MG

50MG

75MG

100MG

N86454 001

N86454 002

N86454 003

N86454 004

N86454 005

> ADD >

> ADD >

3 SQUIBB

3

3

3

3

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE
AP GENSA

25MG/MLM

N81142 001

SEP 25, 1991

10MG

25MG

50MG

75MG

100MG

N86454 001

N86454 002

N86454 003

N86454 004

N86454 005

AP

AMOXAPINE

TABLET; ORAL
AMOXAPINE
GENEVA

AB 25MG# N72943 001 JUN 28, 1991
AB 50MG# N72944 001 JUN 28, 1991
AB 100MG# N72878 001 JUN 28, 1991
AB 150MG# N72879 001 JUN 28, 1991

AMPICILLIN SODIUM

INJECTABLE; INJECTION
AMPICILLIN SODIUM
ANTI-MEDICATION

/AP/ /EQ 1GM BASE/VIAL/ /N62634/002/ JAN 09, 1987/
/AP/ /EQ 2GM BASE/VIAL/ /N62634/003/ JAN 09, 1987/
@ INTL MEDICATION EQ 1GM BASE/VIAL N62634 002 JAN 09, 1987
@ POLYCYCLIN-H EQ 2GM BASE/VIAL N62634 003 JAN 09, 1987

AP BRISTOL

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL
PENICILLIN
MYETH AYERST

> DLT > /AB/ /EQ 250MG BASE/ /N60908/001/
> DLT > /AB/ /EQ 500MG BASE/ /N60908/002/
> ADD > @ MYETH AYERST EQ 250MG BASE N60908 001
> ADD > @ EQ 500MG BASE N60908 002

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
ERGOALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;
RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION
M.V.I.-12 LYOPHILIZED
/ARMOUR/

/AP/ /100MG/VIAL; 0.06MG/VIAL; /N86231/002/ FEB 12, 1985/
/0.005MG/VIAL; 15MG/VIAL; 5UGM/VIAL; /N86231/002/ FEB 12, 1985/
/0.4MG/VIAL; 50MG/VIAL; 5MG/VIAL; /N86231/002/ FEB 12, 1985/
/3.6MG/VIAL; 3MG/VIAL; 1MG/VIAL; /N86231/002/ FEB 12, 1985/
/10MG/VIAL/ /N86231/002/ FEB 12, 1985/

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
ERGOALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE;
RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION
M.V.I.-12 LYOPHILIZED

AP ASTRA
100MG/VIAL; 0.06MG/VIAL; N18933 002
0.005MG/VIAL; 15MG/VIAL; 5UGM/VIAL; AUG 08, 1985
0.4MG/VIAL; 50MG/VIAL; 5MG/VIAL;
3.6MG/VIAL; 3MG/VIAL; 1MG/VIAL;

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
ERGOALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE
HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE
HYDROCHLORIDE; VITAMIN A; VITAMIN E

INJECTABLE; INJECTION

MVC PLUS
/ASCOT/

/AP/ /10MG/ML; 0.006MG/ML; 0.5UGM/ML; /N18439/002/ AUG 08, 1985/
/1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML;
/0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
/330 UNITS/ML; 1 IU/ML/ /N18439/002/ AUG 08, 1985/
AP STERIS
10MG/ML; 0.006MG/ML; 0.5UGM/ML;
1.5MG/ML; 20 IU/ML; 0.04MG/ML; 4MG/ML;
0.4MG/ML; 0.36MG/ML; 0.3MG/ML;
330 UNITS/ML; 1 IU/ML N18439 002 AUG 08, 1985

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL
BUTALBITAL W/ ASPIRIN AND CAFFEINE
/CHELSEA/

/AB/ /325MG; 50MG; 40MG/ /N86231/002/ FEB 12, 1985/

BUTALBITAL, ASPIRIN AND CAFFEINE

AB CHELSEA 325MG; 50MG; 40MG

N86231 002
FEB 12, 1985

TABLET; ORAL
BUTALBITAL W/ ASPIRIN AND CAFFEINE
/CHELSEA/

/AB/ /325MG; 50MG; 40MG/ /N86231/002/ FEB 12, 1985/

BUTALBITAL, ASPIRIN AND CAFFEINE

AB CHELSEA 325MG; 50MG; 40MG

N86231 002
MAR 23, 1984

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENGESIC
PAR
B*
/BX/
385MG;30MG;25MG
/385MG;30MG;25MG/
/385MG;30MG;25MG/
N71642 001
JUN 23, 1987
/N71642/001/
/JUN/23, 1987/
ORPHENGESIC FORTE
PAR
B*
/BX/
770MG;60MG;50MG
/770MG;60MG;50MG/
/770MG;60MG;50MG/
N71643 001
JUN 23, 1987
/N71643/001/
/JUN/23, 1987/

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
COMPOUND 65
a ALRA
/a/BANMAX/
389MG;32.4MG;65MG
/389MG;32.4MG;65MG/
/389MG;32.4MG;65MG/
N84553 002
AUG 17, 1983
/N84553/002/
/AUG/17, 1983/

ASPIRIN; CARTISOPRODOL

TABLET; ORAL
/CARTISOPRODOL COMPOUND/
/BOLAR/
a BOLAR
325MG;200MG
/325MG;200MG/
/325MG;200MG/
N86809 001
OCT 03, 1985
/N86809/001/
/OCT/03, 1985/

ATENOLOL

TABLET; ORAL
ATENOLOL
COPLEY
AB
AB
50MG
100MG

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
/HEATHER/
a HEATHER
/LONSATE/
/CORD/
/AA/
/AB/
0.025MG;2.5MG
0.025MG;2.5MG
/0.025MG;2.5MG/
/0.025MG;2.5MG/
/0.025MG;2.5MG/
N73025 001
SEP 17, 1991
N73026 001
SEP 17, 1991
/N86798/001/
N86798 001
/N85311/001/
N85311 001

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
LONOX
CORD
AA
0.025MG;2.5MG
N85311 002
BACLOFEN
TABLET; ORAL
BACLOFEN
DANBURY
AB
AB
/AB/
/AB/
/PHARM/BASICS/
/AB/
B*
B*
10MG
20MG
10MG
20MG
/10MG/
/20MG/
10MG
20MG
N72824 001
SEP 18, 1991
N72825 001
SEP 18, 1991
/N72824/001/
/MAY/06, 1988/
/N72825/001/
/MAY/06, 1988/
/N72824/001/
/MAY/06, 1988/
N71260 001
MAY 06, 1988
N71261 001
MAY 06, 1988

BENAZEPRIL HYDROCHLORIDE

TABLET; ORAL
LOTENSIN
CIBA
EQ 5MG BASEM
EQ 10MG BASEM
EQ 20MG BASEM
EQ 40MG BASEM
N19851 001
JUN 25, 1991
N19851 002
JUN 25, 1991
N19851 003
JUN 25, 1991
N19851 004
JUN 25, 1991

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

/AA/ /CORD/ /15MG/

/N84292/003/
/FEB/09/1982/
/N84272/002/
N84292 003

/AA/ @ CORD /30MG/ 15MG

/AA/ @ /WHITE/TONNE/PAULSEN/ /15MG/ 30MG

/N83325/002/
N83325 002

@ WHITE TONNE PAULSEN 15MG

CALCITONIN, SALMON

INJECTABLE; INJECTION

CALCTHAR

AP RHONE POULENC RORER 200 IU/ML

N17769 001

MEACALCTH

AP SANDOZ 200 IU/MLM

N17808 002
MAR 29, 1991

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

/INJECTABLE; INJECTION/
/ACETATED/RINGER'S/IN/PLASTIC/CONTAINER/
/MCGAW/ /20MG/100ML; 30MG/100ML; 100ML; 300MG/100ML;
/NOV/29/1982/
N18725 001

@ MCGAW

20MG/100ML; 30MG/100ML; 600MG/100ML

N18725 001
NOV 29, 1982

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

CALCIUM GLUCEPTATE

/AB/ /ABBOTT/ /EQ 90MG CALCIUM/5ML/ /N83159/001/

N83159 001

@ ABBOTT

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/AB/ /PHARM/BASICS/ /200MG/

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

B* PHARM BASICS 200MG

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
SINEMET CR

MSD 50MG; 200MG

N19856 001
MAY 30, 1991

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

/AA/ /BOLAR/ /350MG/ /N85433/001/

N85433 001
N89346 001
OCT 17, 1991

@ BOLAR MUTUAL PHARM

>_ADD > AA
>_ADD >

CEFADROXIL

CAPSULE; ORAL

ULTRACEF

/AB/ /BRISTOL/ /EQ 500MG BASE/

/N62378/001/
/MAR/16/1982/
N62378 001
MAR 16, 1982

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

/INJECTABLE; INJECTION/
/ACETATED/RINGER'S/IN/PLASTIC/CONTAINER/
/MCGAW/ /20MG/100ML; 30MG/100ML; 100ML; 300MG/100ML;
/NOV/29/1982/
N18725 001

@ MCGAW

20MG/100ML; 30MG/100ML; 600MG/100ML

N18725 001
NOV 29, 1982

CALCIUM GLUCEPTATE

INJECTABLE; INJECTION

CALCIUM GLUCEPTATE

/AB/ /ABBOTT/ /EQ 90MG CALCIUM/5ML/ /N83159/001/

N83159 001

@ ABBOTT

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/AB/ /PHARM/BASICS/ /200MG/

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

B* PHARM BASICS 200MG

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL
SINEMET CR

MSD 50MG; 200MG

N19856 001
MAY 30, 1991

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

/AA/ /BOLAR/ /350MG/ /N85433/001/

N85433 001
N89346 001
OCT 17, 1991

@ BOLAR MUTUAL PHARM

>_ADD > AA
>_ADD >

CEFADROXIL

CAPSULE; ORAL

ULTRACEF

/AB/ /BRISTOL/ /EQ 500MG BASE/

/N62378/001/
/MAR/16/1982/
N62378 001
MAR 16, 1982

POWDER FOR RECONSTITUTION; ORAL

ULTRACEF

/AB/ /BRISTOL/ /EQ 125MG BASE/5ML/

/N62376/001/
/MAR/16/1982/

/AB/ /BRISTOL/ /EQ 250MG BASE/5ML/

/N62376/002/
/MAR/16/1982/

/AB/ /BRISTOL/ /EQ 500MG BASE/5ML/

/N62376/003/
/MAR/16/1982/

@ BRISTOL EQ 125MG BASE/5ML

N62376 001
MAR 16, 1982

@ EQ 250MG BASE/5ML

N62376 002
MAR 16, 1982

@ EQ 500MG BASE/5ML

N62376 003
MAR 16, 1982

TABLET; ORAL

ULTRACEF

/AB/ /BRISTOL/ /EQ 1GM BASE/

/N62408/001/
/AUG/31/1982/
N62408 001
AUG 31, 1982

@ BRISTOL EQ 1GM BASE

CEFZOLIN SODIUM

INJECTABLE; INJECTION
ANCEF IN PLASTIC CONTAINER
BAXTER

EQ 10MG BASE/MLM
EQ 20MG BASE/MLM

N63002 001
MAR 28, 1991
N63002 002
MAR 28, 1991

/N50548/002/
N50548 002

CEPHRADINE

CAPSULE; ORAL
VELDSEF 500
/ERSANA/
a ERSANA

/500MG/
500MG

CHLORDIAZEPOXIDE HYDROCHLORIDE

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN
SQUIBB MARK

EQ 125MG BASE/5MLM

N62986 001
APR 18, 1991

/N88987/001/
APR 25, 1985
/N88986/001/
APR 25, 1985
/N88988/001/
APR 25, 1985
/N88987 001
APR 25, 1985
N88986 001
APR 25, 1985
N88988 001
APR 25, 1985

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL
/SUPERPHARM/
/5MG/
/10MG/
/25MG/
5MG
10MG
25MG

CEPHALOTHIN SODIUM

INJECTABLE; INJECTION
CEPHALOTHIN
/INTL MEDICATION/

EQ 1GM BASE/VIAL/
EQ 2GM BASE/VIAL/
EQ 4GM BASE/VIAL/
EQ 500MG BASE/VIAL/
EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 4GM BASE/VIAL
EQ 500MG BASE/VIAL

/N62426/001/
MAY 03, 1985
/N62426/003/
MAY 03, 1985
/N62426/004/
MAY 03, 1985
/N62426/001/
MAY 03, 1985
N62426 001
MAY 03, 1985
N62426 002
MAY 03, 1985
N62426 003
MAY 03, 1985
N62426 004
MAY 03, 1985

N85107 001
N85009 001
N85108 001
/N85107/001/
/N85108/001/
/N85108/001/

EQ 1GM BASE/VIAL/
EQ 2GM BASE/VIAL/
EQ 4GM BASE/VIAL/
EQ 500MG BASE/VIAL/
EQ 1GM BASE/VIAL
EQ 2GM BASE/VIAL
EQ 4GM BASE/VIAL
EQ 500MG BASE/VIAL

LYGEN
a ALRA
a
/a/BANMAX/
/a/
/a/

5MG
10MG
25MG
5MG
10MG
25MG
5MG
10MG
25MG

CHLOROTHIAZIDE

TABLET; ORAL
CHLOROTHIAZIDE
/BOLAR/

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

/N85165/001/
/N84026/001/
/SEP 01, 1982/
N85165 001
N84026 001
SEP 01, 1982
/N85196/001/
/AUG 15, 1983/
N86796 001
AUG 15, 1983

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

a BOLAR
a

/a/
/CHELSEA/
a CHELSEA

250MG
500MG
250MG
500MG
500MG

CEPHRADINE

CAPSULE; ORAL
VELDSEF 250
/ERSANA/
a ERSANA

/N50548/001/
N50548 001

/250MG/
250MG

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

CHLOROTHIAZIDE; RESERPINE

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

TABLET; ORAL
 /CHLOROTHIAZIDE/M/RESERPINE/
 /BOLAR/
 @ BOLAR
 /500MG;0.125MG/
 500MG;0.125MG

/N88151/001/
 /JUN/09,1983/
 N88151 001
 JUN 09, 1983

CHLORPHENIRAMINE MALEATE

INJECTABLE; INJECTION
 CHLORPHENIRAMINE MALEATE
 /LEMMON/
 AP AP STERIS
 /10MG/ML/
 10MG/ML

TABLET; ORAL

/ANTAGONATE/
 /MILES/
 @ MILES
 CHLORPHENIRAMINE MALEATE
 /VITARINE/
 @ VITARINE
 /PHENETRON/
 /LANNETT/
 @ LANNETT

/4MG/
 4MG
 /4MG/
 4MG
 /4MG/
 4MG

/N83381/001/
 N83381 001
 /N85837/001/
 N85837 001
 /N88846/001/
 N88846 001

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
 CHLORPROMAZINE HCL
 /LEMMON/
 AP AP STERIS
 /25MG/ML/
 25MG/ML

CHLORPROPAMIDE

TABLET; ORAL
 CHLORPROPAMIDE
 /BOLAR/
 @ BOLAR
 @

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

/N88608/001/
 /APR/12,1984/
 N88608 001
 APR 12, 1984
 /N88568/001/
 /APR/12,1984/
 N88568 001
 APR 12, 1984

CHLORPROPAMIDE

TABLET; ORAL
 CHLORPROPAMIDE
 /PHARM/BASICS/
 /AB/
 /AB/
 B* PHARM BASICS
 B*

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

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

CHLORTHALIDONE

TABLET; ORAL
 CHLORTHALIDONE
 /BOLAR/
 @ BOLAR
 @
 /SUPERPHARM/
 @ SUPERPHARM

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

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

/N87050/001/
 /N87029/001/
 N87050 001
 N87029 001
 /N87473/001/
 /FEB/09,1983/
 N87473 001
 FEB 09, 1983

CHLORZOXAZONE

TABLET; ORAL
 CHLORZOXAZONE
 DANBURY
 AA

/N85591/001/
 N85591 001

CLARITHROMYCIN

TABLET; ORAL
 BIAIXIN
 ABBOTT

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

250MG
 500MG

/N88662/001/
 /OCT/31,1991/
 N88662 001
 OCT 31, 1991

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 TAVIST D
 /BORGES/
 /ED/IMS/BASE;75MG/
 /N18298/001/
 /DEC/15,1982/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST D
SANDOZ
EQ 1MG BASE; 75MG
N18298 001
DEC 15, 1982

> ADD >
> ADD >

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

> DLT > /AB/ /0.1MG/
> DLT > /POLAR/ /0.2MG/
> DLT > /AB/ /0.3MG/
> DLT > /AB/ /0.1MG/
> DLT > /AB/ /0.2MG/
> DLT > /AB/ /0.3MG/
> ADD > @ BOLAR 0.1MG
> ADD > @ 0.2MG
> ADD > @ 0.3MG

/N70395/001/
/MAR/23, 1987/
/N70395/001/
/MAR/23, 1987/
/N70397/001/
/MAR/23, 1987/
/N70395/001/
/MAR/23, 1987/
/N70397/001/
/MAR/23, 1987/
N70395 001
MAR 23, 1987
N70396 001
MAR 23, 1987
N70397 001
MAR 23, 1987

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

AB DANBURY
EQ 75MG BASEM
N63082 001
JUL 31, 1991

EQ 150MG BASEM

N63083 001
JUL 31, 1991

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

/AB/ /LEMON/ /EQ 150MG BASE/ML/
/AB/ /LEMON/ /EQ 150MG BASE/ML/
AP STERIS
EQ 150MG BASE/ML
N62900 001
JUN 08, 1988
AP EQ 150MG BASE/ML
N63079 001
MAR 05, 1990

/N62900/001/
/JUN/08, 1988/
/N63079/001/
/MAR/05, 1990/
N62900 001
JUN 08, 1988
N63079 001
MAR 05, 1990

> DLT > /AB/ /0.1MG/
> DLT > /AB/ /0.2MG/
> DLT > /AB/ /0.3MG/
> ADD > @ DURAMED 0.1MG
> ADD > @ 0.2MG
> ADD > @ 0.3MG

/N71103/001/
/AUG/14, 1986/
/N71102/001/
/AUG/14, 1986/
/N71101/001/
/AUG/14, 1986/
/N71103/001/
/AUG/14, 1986/
/N71102/001/
/AUG/14, 1986/
/N71101/001/
/AUG/14, 1986/
N71103 001
AUG 14, 1986
N71102 001
AUG 14, 1986
N71101 001
AUG 14, 1986

CLIOQUINOL; HYDROCORTISONE

CREAM; TOPICAL

VIOFORM-HYDROCORTISONE

CIBA
3%; 0.5%
3%; 1%

N10412 002
N10412 001

OINTMENT; TOPICAL

VIOFORM-HYDROCORTISONE

@ CIBA
3%; 0.5%
3%; 1%

N10412 004
N10412 003

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

AB NOVOPHARM
500MG

N72600 001
JUL 25, 1991

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/ /PHARM/BASICS/ /3.75MG/
/AB/ /PHARM/BASICS/ /7.5MG/
/AB/ /PHARM/BASICS/ /15MG/
B* PHARM BASICS 3.75MG
B* 7.5MG
B* 15MG
/AB/ /PUREPAC/ /3.75MG/
@ PUREPAC 3.75MG

> ADD >
> ADD >

/N71242/001/
/MAY/20, 1987/
/N71243/001/
/MAY/20, 1987/
/N71244/001/
/MAY/20, 1987/
/N71242/001/
/MAY/20, 1987/
/N71243/001/
/MAY/20, 1987/
/N71244/001/
/MAY/20, 1987/
N71242 001
MAY 20, 1987
N71243 001
MAY 20, 1987
N71244 001
MAY 20, 1987
/N71924/001/
/APR/25, 1988/
N71924 001
APR 25, 1988

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

AP STERIS EQ 4MG PHOSPHATE/ML N84355 001

SOLUTION/DROPS; OPHTHALMIC

DEXAIR

AT BAUSCH AND LOMB EQ 0.1% PHOSPHATE N88433 001

/AT/ /PHARMAFAIR/ /EQ 0.1% PHOSPHATE/ N88433 001

DEC 15, 1983

/DEC/15/1983/

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

/AP/ /CUTTER/ /10GM/100ML/ N18504 001

3 CUTTER 10GM/100ML

DEXTROSE 50% IN PLASTIC CONTAINER

AP BAXTER 50GM/100MLM N20047 001

DEXTROSE 60% IN PLASTIC CONTAINER

AP BAXTER 60GM/100MLM JUL 02, 1991

DEXTROSE 70% IN PLASTIC CONTAINER

AP BAXTER 70GM/100MLM N20047 002

JUL 02, 1991

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE

/AP/ /MCSAM/ /5GM/100ML; 220MG/100ML; N18268 002

/5GM/100ML; 450MG/100ML/

450MG/100ML; N18268 002

JUL 02, 1991

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

/AP/ /CUTTER/ /5GM/100ML; 20MG/100ML/ N18399 001

3 CUTTER 5GM/100ML; 20MG/100ML N18399 001

DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

/AP/ /ABBOTT/ /5GM/100ML; 30MG/100ML/ N17799 001

ABBOTT 5GM/100ML; 30MG/100ML N17799 001

/AP/ /CUTTER/ /5GM/100ML; 30MG/100ML/ N18501 001

3 CUTTER 5GM/100ML; 30MG/100ML N18501 001

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/AP/ /CUTTER/ /5GM/100ML; 450MG/100ML/ N18400 001

3 CUTTER 5GM/100ML; 450MG/100ML N18400 001

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/AP/ /DIATRIZOATE-60/ /5.2%:8%/ N88166 001

3 INTL MEDICATION 5.2%:8% N88166 001

JUN 17, 1983

/JUN/17/1983/

DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/AP/ /MALLINCKRODT/ /50%:50% N87075 001

3 MALLINCKRODT 50%:50% N87075 001

JUN 17, 1983

DIAZEPAM

INJECTABLE; INJECTION

/AP/ /LEMMON/ /5MG/ML/ N70911 001

3 LEMMON 5MG/ML N70911 001

AUG 28, 1986

/AUG/28/1986/

/AUG/28/1986/

/AUG/28/1986/

/DEC/01/1986/

N70911 001

AUG 28, 1986

/AUG/28/1986/

AUG 28, 1986

/AUG/28/1986/

N70930 001

DEC 01, 1986

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

/DEC/01/1986/

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
VOLTAREN
CIBA

0.1%
N20037 001
MAR 28, 1991

DIETHYLSTILBESTROL

TABLET; ORAL
STILBESTROL

/6.5MG/
0.5MG
/N83004/001

/6.5MG/
1MG
/N84056/006/
/N84056/009/
/N84056/010/
/N84056/007/
/N84056/017/
/N84056/007
/N84056/017
/N84056/008
/N84056/009
/N84056/010

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HCL
/BOLAR/
3 BOLAR
N83179 001
FEB 12, 1986

/10MG/
10MG

3 SQUIBB
3
3
3
3

TABLET; ORAL

DICYCLOMINE HCL

/BOLAR/
3 BOLAR
N84361 001
FEB 06, 1986

/20MG/
20MG

DILTIAZEM HYDROCHLORIDE

INJECTABLE; INJECTION
CARDIZEM
MARION MERRELL DOM

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

25MG/VIAL
50MG/VIAL
N20027 001
OCT 24, 1991
N20027 002
OCT 24, 1991

DIDANOSINE

POWDER FOR RECONSTITUTION; ORAL
VIDEX

BRISTOL MYERS SQUIBB 10MG/ML
N20156 001
OCT 09, 1991
N20155 003
OCT 09, 1991
N20155 004
OCT 09, 1991
N20155 005
OCT 09, 1991
N20155 006
OCT 09, 1991

100MG/PACKET
167MG/PACKET
250MG/PACKET
375MG/PACKET

DIMENHYDRINATE

INJECTABLE; INJECTION

DIMENHYDRINATE
/LEMON/
STERIS

/50MG/ML/
50MG/ML
/N83531/001/
N83531 001

LIQUID; ORAL

DIMENHYDRINATE
3 ALRA
/3/BANMAX/

12.5MG/4ML
/12.5MG/4ML/
N80715 001
/N80715/001/

TABLET, CHEMABLE; ORAL

VIDEX

BRISTOL MYERS SQUIBB 25MG
N20154 002
OCT 09, 1991
N20154 003
OCT 09, 1991
N20154 004
OCT 09, 1991
N20154 005
OCT 09, 1991

25MG
50MG
100MG
150MG

TABLET; ORAL/
DIMENHYDRINATE/
/CHELSEA/
3 CHELSEA

/50MG/
50MG
/N85166/001/
N85166 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL
3 ALRA
3

25MG
50MG
N80519 004
N80519 003

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
/S/ BANNA/

/50MG/

/N80519/003/

ELIXIR; ORAL
DIPHENHYDRAMINE HCL
/KV/
@ KV

/12.5MG/5ML/
12.5MG/5ML

/N85621/001/
N85621 001

INJECTABLE; INJECTION
DIPHENHYDRAMINE HCL
@ ELKINS/SINN/
@ ELKINS SINN
/LEMON/
AP STERIS

/50MG/ML/
50MG/ML
/10MG/ML/
10MG/ML

/N83183/001/
N83183 001
/N83533/001/
N83533 001

DIPYRIDAMOLE

TABLET; ORAL
DIPYRIDAMOLE
GENEVA

> ADD > AB
> ADD >

25MGH

N86944 002
APR 16, 1991

AB LEDELER

25MGH

N88999 001
FEB 05, 1991

AB

50MGH

N89000 001
FEB 05, 1991

AB

75MGH

N89001 001
FEB 05, 1991

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE
/BOLAR/

> DLT > /AB/

> DLT >

> DLT > /AB/

> DLT >

> ADD >

> ADD >

> ADD >

/EQ 100MG BASE/

/EQ 150MG BASE/

EQ 100MG BASE

EQ 150MG BASE

EQ 100MG BASE

EQ 150MG BASE

/EQ 100MG BASE/

/EQ 150MG BASE/

@ BOLAR

@

B* CHELSEA

B*

/BX/

/BX/

/N70240/001/
FEB 02, 1986
/N70241/001/
FEB 02, 1986
/N71020/001/
DEC 01, 1986
/N71021/001/
DEC 01, 1986
/N71022/001/
DEC 01, 1986
/N71023/001/
DEC 01, 1986

N70240 001

N70241 001

N71020 001

N71021 001

N71022 001

N71023 001

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE
/MYLAN/

/EQ 100MG BASE/

/EQ 150MG BASE/

EQ 100MG BASE

EQ 150MG BASE

@ MYLAN

@

/N70138/001/
JUN 14, 1985

/N70139/001/
JUN 14, 1985

N70138 001

N70139 001

JUN 14, 1985

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOBUTREX
LILLY

EQ 12.5MG BASE/ML

/EQ 25MG BASE/ML/

N17820 002

/N17820/002/

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL
GENSIA

> ADD > AP

> ADD >

> ADD > AP

> ADD >

/AP/

40MG/ML

80MG/ML

40MG/ML

40MG/ML

@ SOLOPAK

N72999 001

OCT 23, 1991

N73000 001

OCT 23, 1991

/N70011/001/
AUG 29, 1985

N70011 001

AUG 29, 1985

DOXACURIUM CHLORIDE

INJECTABLE; INJECTION
NUROMAX
BURROUGHS WELLCOME

EQ 1MG BASE/ML

N19946 001

MAR 07, 1991

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL
/BARR/

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

/EQ 25MG BASE/
/EQ 50MG BASE/
/EQ 75MG BASE/
/EQ 100MG BASE/
EQ 25MG BASE
EQ 50MG BASE
EQ 75MG BASE
EQ 100MG BASE

/N71502/001/
/FEB/18/1988/
/N71653/001/
/FEB/18/1988/
/N71654/001/
/FEB/18/1988/
/N71521/001/
/FEB/18/1988/
N71502 001
FEB 18, 1988
N71653 001
FEB 18, 1988
N71654 001
FEB 18, 1988
N71521 001
FEB 18, 1988

CAPSULE; ORAL
DOXEPIN HCL
ROYCE

AB
AB
AB

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

N72985 001
MAR 29, 1991
N72986 001
MAR 29, 1991
N72987 001
MAR 29, 1991

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS
ADRIA

AP
AP
AP
AP

2MG/ML
200MG/100ML
2MG/ML
200MG/100ML
/4MG/ML/
2MG/ML

N50629 001
DEC 23, 1987
N50629 002
MAY 03, 1988
N63165 001
JAN 30, 1991
N63165 002
JAN 30, 1991
/N50629/002/
/MAY/03/1988/
N62975 001
MAR 17, 1989

DOXORUBICIN HCL
CETUS BEN VENUE

AP

2MG/ML

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
/SUPERPHARM/

AB/
AB/

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

/N52469/001/
/OCT/31/1984/
/N52469/002/
/OCT/31/1984/
N62469 001
OCT 31, 1984
N62469 002
OCT 31, 1984

TABLET; ORAL
DOXYCYCLINE HYCLATE
/CHELSEA/

AB/
a

/EQ 100MG BASE/
EQ 100MG BASE

/N62392/002/
/MAR/31/1988/
N62392 002
MAR 31, 1988

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL
/BARR/

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

/EQ 25MG BASE/
/EQ 50MG BASE/
/EQ 75MG BASE/
/EQ 100MG BASE/
EQ 25MG BASE
EQ 50MG BASE
EQ 75MG BASE
EQ 100MG BASE

/N71502/001/
/FEB/18/1988/
/N71653/001/
/FEB/18/1988/
/N71654/001/
/FEB/18/1988/
/N71521/001/
/FEB/18/1988/
N71502 001
FEB 18, 1988
N71653 001
FEB 18, 1988
N71654 001
FEB 18, 1988
N71521 001
FEB 18, 1988

CAPSULE; ORAL
DOXEPIN HCL
ROYCE

AB
AB
AB

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

N72985 001
MAR 29, 1991
N72986 001
MAR 29, 1991
N72987 001
MAR 29, 1991

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS
ADRIA

AP
AP
AP
AP

2MG/ML
200MG/100ML
2MG/ML
200MG/100ML
/4MG/ML/
2MG/ML

N50629 001
DEC 23, 1987
N50629 002
MAY 03, 1988
N63165 001
JAN 30, 1991
N63165 002
JAN 30, 1991
/N50629/002/
/MAY/03/1988/
N62975 001
MAR 17, 1989

DOXORUBICIN HCL
CETUS BEN VENUE

AP

2MG/ML

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE
/SUPERPHARM/

AB/
AB/

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

/N52469/001/
/OCT/31/1984/
/N52469/002/
/OCT/31/1984/
N62469 001
OCT 31, 1984
N62469 002
OCT 31, 1984

TABLET; ORAL
DOXYCYCLINE HYCLATE
/CHELSEA/

AB/
a

/EQ 100MG BASE/
EQ 100MG BASE

/N62392/002/
/MAR/31/1988/
N62392 002
MAR 31, 1988

AMERICAN LABORATORIES

DOXYLAMINE SUCCINATE

/TABLET/06A1/
/DOXYLAMINE SUCCINATE/
/AA/ /POPLEY/

/2.5MG/

/N88906/061/
/DEC/08/1985/

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

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ERGOLOID MESYLATES
/POLAR/

/0.5MG/
/1MG/

/N34930/061/
/N85177/061/
N84930 001

DROPERIDOL

INJECTABLE; INJECTION
DROPERIDOL
/ASTRA/

/2.5MG/ML/
2.5MG/ML

/N72020/061/
/DEC/19/1988/
N72020 001
OCT 19, 1988

/AA/
/AA/

@ BOLAR
@
/KV/
@ KV
@

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

N85177 001
/N86265/061/
/N86264/061/
N86265 001
N36264 001

EDETATE DISODIUM

INJECTABLE; INJECTION
DISODIUM EDETATE
/LEMON/
AP STERIS

/150MG/ML/
150MG/ML

/N84356/061/
N84356 001

/2%/
2%
2%

/N63107/061/
/AUG/23/1991/
N63107 001
AUG 23, 1991

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL W/ EPINEPHRINE
/LEMON/
@ STERIS

/0.01MG/ML;1%/
0.01MG/ML;1%

/N85463/061/
N85463 001

SOLUTION; TOPICAL
ERYTHROMYCIN
CLAY PARK

2%
2%
2%

N50617 001
OCT 21, 1987
N63038 001
JAN 11, 1991
/N50532/061/
N50532 001

ERGOLOID MESYLATES

TABLET; ORAL
ERGOLOID MESYLATES
/POLAR/

/1MG/
1MG
1MG

/N86433/061/
/MAY/27/1982/
N86433 001
MAY 27, 1982
N81113 001
OCT 31, 1991

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL
ERYTHROMYCIN ETHYLSUCCINATE
/NASKA/

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

/N82674/061/
/MAR/10/1987/
N82674 001
MAR 10, 1987

TABLET; SUBLINGUAL

/DEASTIN-54/
/BRISTOL MYERS/SQUIBB/1MG/
@ BRISTOL MYERS SQUIBB 1MG

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

/100MG/ML/
100MG/ML

/N19386/063/
/DEC/31/1986/
N19386 003
DEC 31, 1986

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28
NORETHINDRONE AND ETHINYL ESTRADIOL (10/11)
 0.035MG;0.5MG AND 1MG
 WATSON
 N71044 001
 APR 01, 1988

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
 0.035MG;0.5MG AND 1MG
 WATSON
 N71042 001
 SEP 24, 1991

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-28
 NORLESTRIN 28 1/50
 3 PARKE DAVIS
 N16723 001

TABLET; ORAL-28
 NORLESTRIN 28 1/50
 3 PARKE DAVIS
 N16723 001

ETODOLAC

CAPSULE; ORAL
 LODINE
 WYETH AYERST
 200MG
 300MG
 N18922 002
 JAN 31, 1991
 N18922 003
 JAN 31, 1991

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL
 PLENDIL
 MSD
 5MG
 10MG
 N19834 001
 JUL 26, 1991
 N19834 002
 JUL 26, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM
 DANBURY
 EQ 200MG BASE
 EQ 300MG BASE
 N72981 001
 AUG 19, 1991
 N72982 001
 AUG 19, 1991

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM
 WARNER CHILCOTT
 EQ 200MG BASE
 EQ 300MG BASE
 N72946 001
 APR 30, 1991
 N72472 001
 APR 30, 1991

TABLET; ORAL
FENOPROFEN CALCIUM
 PHARM BASICS
 EQ 600MG BASE
 N72362 001
 JUN 16, 1988

FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE
 STERLING
 EQ 0.05MG BASE/ML
 N72786 001
 SEP 24, 1991

FIBRINOGEN, I-125

INJECTABLE; INJECTION
 BERLIN
 AMERSHAM
 EQ 154 UCI/VIAL
 N17879 001
 SEP 24, 1991

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION
 FLUDARA
 BERLEX
 50MG/VIAL
 N20038 001
 APR 18, 1991

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
 FLUCET
 NMC
 EQ 0.01%
 N88361 001
 JAN 16, 1984

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB

TARO

0.05%

N19117 001
JUN 26, 1984

TABLET; ORAL

FLUOXYMESTERONE

/2MG/

/N88266/001/
/DEC/06, 1983/

AB

TICAN

0.05%

N72494 001
JAN 19, 1989

/βp/

/5MG/

/N88265/001/
/DEC/06, 1983/

/AB/
/VASOFORM/

/0.05%

/N19117/001/
/JUN/26, 1984/

/βp/

/10MG/

/N88309/001/
/DEC/06, 1983/

/AB/
/VASOFORM E/

/0.05%

/N19117/001/
/JAN/19, 1989/

3 BOLAR

2MG

N88260 001
DEC 06, 1983

3

5MG

N88265 001
DEC 06, 1983

3

10MG

N88309 001
DEC 06, 1983

> ADD >

FLUOROURACIL

INJECTABLE; INJECTION

ADRUCIL

> ADD >

AP

ADRIA

50MG/MLM

N40023 001
OCT 18, 1991

CONCENTRATE; ORAL

FLUPHENAZINE HCL

5MG/MLM

N73058 001
AUG 30, 1991

> ADD >

AP

ADRIA

50MG/MLM

N81222 001
JUN 28, 1991

AA

5MG/MLM

N73058 001
AUG 30, 1991

AP

ADRIA

50MG/MLM

N81225 001
AUG 28, 1991

TABLET; ORAL

FLUPHENAZINE HCL

5MG/MLM

N73058 001
AUG 30, 1991

FLUOROURACIL
/SOLOPAK/

/50MG/ML/

/N88766/001/
/DEC/28, 1984/

TABLET; ORAL

FLUPHENAZINE HCL

/10MG/

/N88555/001/
/DEC/18, 1987/

/AP/

3 SOLOPAK

50MG/ML

/N88766/001/
/DEC/28, 1984/

/βp/

/2.5MG/

/N88554/001/
/DEC/18, 1987/

3

SOLOPAK

50MG/ML

/N88766/001/
/DEC/28, 1984/

/βp/

/5MG/

/N88557/001/
/DEC/18, 1987/

3

SOLOPAK

50MG/ML

/N88766/001/
/DEC/28, 1984/

/βp/

/10MG/

/N88550/001/
/DEC/18, 1987/

3

SOLOPAK

50MG/ML

/N88766/001/
/DEC/28, 1984/

3 BOLAR

1MG

N88555 001
DEC 18, 1987

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

PROZAC

LILLY

EQ 20MG BASE/5MLM

N20101 001
APR 24, 1991

2.5MG

N88544 001
DEC 18, 1987

3

PROZAC

EQ 20MG BASE/5MLM

N20101 001
APR 24, 1991

5MG

N88527 001
DEC 18, 1987

3

PROZAC

EQ 20MG BASE/5MLM

N20101 001
APR 24, 1991

10MG

N88550 001
DEC 18, 1987

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

15MGM

N71716 001
JUL 31, 1991

AB

GENEVA

15MGM

N71716 001
JUL 31, 1991

AB

GENEVA

30MGM

N71717 001
JUL 31, 1991

LIBRARY

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

FLURAZEPAM HYDROCHLORIDE

capsule; oral

FLURAZEPAM HCL
/ AA / PHARM/BASICS /

/ 15MG /

/ 30MG /

B* PHARM BASICS

15MG

B* PHARM BASICS

30MG

/N70562/001/
/JUL/09/1987/
/N70563/001/
/JUL/09/1987/
N70562 001
JUL 09, 1987
N70563 001
JUL 09, 1987

25MG/MLM

N19961 002
JAN 17, 1991

FOSCARNET SODIUM

INJECTABLE; INJECTION
FOSCAVIR
ASTRA

24MG/MLM

N20068 001
SEP 27, 1991

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

/N62932/001/
/NOV/07/1988/
N62932 001
NOV 07, 1988

FOSINOPRIL SODIUM

TABLET; ORAL
MONOPRIL
BRISTOL MYERS SQUIBB 10MGX
20MGX

N19915 002
MAY 16, 1991
N19915 003
MAY 16, 1991

/N85017/001/
N85017 001

GENTIAN VIOLET

/TAMPON; VAGINAL/
/PENAPAK/
/KEY PHARMS/
@ KEY PHARMS

/ 5MG /
5MG

GLUTETHIMIDE

TABLET; ORAL
/DORIDEN/
/RHONE/POULENC/RORER// 500MG/
/ 500MG /
@ RHONE POULENC RORER 250MG
@ 500MG
GLUTETHIMIDE
/CHELSEA/
@ CHELSEA

/N09519/002/
/N09519/005/
N09519 002
N09519 005
/N85763/001/
N85763 001

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
/ AA / SOLOPAK /

/ 10MG/ML /

10MG/ML

10MG/MLM

/N70023/001/
/FEB/05/1986/
N70023 001
FEB 05, 1986
N72080 001
AUG 13, 1991

SOLUTION; ORAL
FUROSEMIDE
PHARM BASICS

10MG/ML

N70655 001
OCT 02, 1987

AP

0.2MG/MLM

N81169 001
SEP 10, 1991

/ AA / MYROSEMIDE /
/ AA / PHARM/BASICS /

/ 10MG/ML /

/N70655/001/
/OCT/02/1987/

> DLT > / AA /
> ADD >

/ 1MG /
1MG

/N85562/001/
N85562 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

STERIS

EQ 5MG BASE/ML

N70713 001

MAY 17, 1988

EQ 5MG BASE/ML

N70714 001

MAY 17, 1988

EQ 5MG BASE/ML

N70744 001

MAY 17, 1988

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

/INTL/MEDICATION/

@ INTL MEDICATION

/10 UNITS/ML/

10 UNITS/ML

/N86357/001/

N86357 001

/500 UNITS/ML/

500 UNITS/ML

/N86357/002/

N86357 002

/100 UNITS/ML/

100 UNITS/ML

/N87959/001/

N87959 001

@ SOLOPAK

APR 20, 1983

@ SOLOPAK

/5,000 UNITS/ML/

5,000 UNITS/ML

/N17029/002/

N17029 002

/HEPARIN SODIUM 10,000 UNITS IN 100ML/

10,000 UNITS/100ML

/N16911/005/

JAN 30, 1985

@ ABBOTT

/10,000 UNITS/100ML

N18911 006

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

25,000 UNITS/100ML

JAN 30, 1985

/MCCAM

/5,000 UNITS/100ML/

5,000 UNITS/100ML

/N19135/001/

MAR 29, 1985

@ MCCAM

5,000 UNITS/100ML

N19135 001

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

/SOLOPAK/

/20MG/ML/

/N88517/001/

AUG 22, 1985

/20MG/ML/

20MG/ML

/N88518/001/

APR 20, 1984

@ SOLOPAK

20MG/ML

N88517 001

@

20MG/ML

N88518 001

APR 20, 1984

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

/CHELSEA/

/25MG/

25MG

/N85532/002/

MAY 24, 1982

/50MG/

50MG

/N85533/002/

MAY 25, 1982

@ CHELSEA

25MG

N85532 002

@

50MG

N85533 002

MAY 25, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/BOLAR/

/25MG; 25MG/

25MG; 25MG

/N85457/001/

MAR 04, 1982

/50MG; 50MG/

50MG; 50MG

/N85458/001/

MAR 04, 1982

/100MG; 50MG/

100MG; 50MG

/N85460/001/

MAR 04, 1982

@ BOLAR

25MG; 25MG

N85457 001

@

50MG; 50MG

MAR 04, 1982

@

100MG; 50MG

N85440 001

MAR 04, 1982

TABLET; ORAL

APRESOLINE-ESTRODOL

/CIBA/

/25MG; 15MG/

25MG; 15MG

/N12026/002/

MAR 04, 1982

/HYDROCHLOROTHIAZIDE/W/ HYDRALAZINE/

/25MG; 15MG/

25MG; 15MG

/N85373/001/

MAR 04, 1982

@ BOLAR

25MG; 15MG

N85373 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDROCHLOROTHIAZIDE/W/ RESERPINE AND HYDRALAZINE/

/25MG; 15MG; 0.1MG/

25MG; 15MG; 0.1MG

/N83770/001/

MAR 30, 1981

@ BOLAR

25MG; 15MG; 0.1MG

N83770 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

HYDROXYZINE HYDROCHLORIDE

HYDROXYZINE PAMOATE

TABLET; ORAL
HYDROXYZINE HCL
/BARR/

CAPSULE; ORAL
HYDROXYZINE PAMOATE
/SUPERPHARM/

> DLT >	/AB/	/10MG/	/NOV/15, 1983/	/AB/	/ED 25MG HCL/	/N89031 001/	JAN 02, 1987
> DLT >	/AB/	/25MG/	/NOV/15, 1983/	/AB/	/ED 50MG HCL/	/N89032 001/	JAN 02, 1987
> DLT >	/AB/	/50MG/	/APR/18, 1983/	/AB/	/ED 100MG HCL/	/N89033 001/	JAN 02, 1987
> DLT >	/AB/	/100MG/	/APR/18, 1983/	/AB/	/ED 25MG HCL/	/N89031 001/	JAN 02, 1987
> ADD >	3	10MG	N88409 001	3	EQ 25MG HCL	N89031 001	JAN 02, 1987
> ADD >	3	25MG	N87857 001	3	EQ 50MG HCL	N89032 001	JAN 02, 1987
> ADD >	3	50MG	N87860 001	3	EQ 100MG HCL	N89033 001	JAN 02, 1987
> ADD >	3	100MG	N87862 001	3	EQ 25MG HCL	N89031 001	JAN 02, 1987
> ADD >	/AB/	/PHARM/BASICS/	APR 18, 1983	/AB/	/VANGARD/	N88392 001	SEP 19, 1983
> ADD >	/AB/	/10MG/	APR 18, 1983				
> ADD >	/AB/	/25MG/	/N89121 001/				
> ADD >	/AB/	/50MG/	/MAR/20, 1986/				
B*		10MG	N89121 001				
B*		25MG	MAR 20, 1986				
B*		50MG	N89122 001				
			MAR 20, 1986				
			N89123 001				
			MAR 20, 1986				

IBUPROFEN
SUSPENSION; ORAL
RUFEN
BOOTS

TABLET; ORAL
IBUPROFEN
/CHELSEA/

> DLT >	/AB/	/400MG/	/SEP/06, 1985/	/AB/	/400MG/	/N70038 001/	SEP 06, 1985
> DLT >	/AB/	/600MG/	/SEP/06, 1985/	/AB/	/600MG/	/N70041 001/	SEP 06, 1985
> DLT >	/AB/	/800MG/	/SEP/06, 1985/	/AB/	/800MG/	/N71911 001/	SEP 06, 1985
> ADD >	3	400MG	N70038 001	3	400MG	N70038 001	SEP 06, 1985
> ADD >	3	600MG	N70041 001	3	600MG	N70041 001	SEP 06, 1985
> ADD >	3	800MG	N71911 001	3	800MG	N71911 001	SEP 06, 1985
> ADD >	3	400MG	SEP 06, 1985	3	400MG	N70038 001	SEP 06, 1985
> ADD >	3	600MG	SEP 06, 1985	3	600MG	N70041 001	SEP 06, 1985
> ADD >	3	800MG	N71911 001	3	800MG	N71911 001	SEP 06, 1985

HYDROXYZINE PAMOATE
CAPSULE; ORAL
/BOLAR/

TABLET; ORAL
IBUPROFEN
/CHELSEA/

> DLT >	/AB/	/ED 25MG HCL/	/NOV/15, 1983/	/AB/	/ED 25MG HCL/	/N86698 001/	JUL 31, 1991
> DLT >	/AB/	/EQ 50MG HCL/	/NOV/15, 1983/	/AB/	/ED 50MG HCL/	/N86695 001/	JUN 28, 1991
> DLT >	/AB/	/EQ 100MG HCL/	/APR/18, 1983/	/AB/	/ED 100MG HCL/	/N81165 001/	JUN 28, 1991
> ADD >	3	EQ 25MG HCL	N86698 001	3	EQ 25MG HCL	N81165 001	JUN 28, 1991
> ADD >	3	EQ 50MG HCL	N86695 001	3	EQ 50MG HCL	N81127 001	JUN 28, 1991
> ADD >	3	EQ 100MG HCL	N86697 001	3	EQ 100MG HCL	N81128 001	JUN 28, 1991
> ADD >	3	EQ 25MG HCL	N81165 001	3	EQ 25MG HCL	N81129 001	JUN 28, 1991
> ADD >	3	EQ 50MG HCL	JUL 31, 1991	3	EQ 50MG HCL	N81127 001	JUN 28, 1991
> ADD >	3	EQ 100MG HCL	JUN 28, 1991	3	EQ 100MG HCL	N81128 001	JUN 28, 1991
> ADD >	3	EQ 25MG HCL	N81165 001	3	EQ 25MG HCL	N81129 001	JUN 28, 1991
> ADD >	3	EQ 50MG HCL	JUN 28, 1991	3	EQ 50MG HCL	N81127 001	JUN 28, 1991
> ADD >	3	EQ 100MG HCL	JUN 28, 1991	3	EQ 100MG HCL	N81128 001	JUN 28, 1991

ISONIAZID

TABLET; ORAL

ISONIAZID

> DLT > /AA/
> DLT > /BA/
> ADD > @ BOLAR
> ADD > @ ZENITH

/100MG/
/300MG/
100MG
300MG
300MG

/N80401 /001/
/N83178 /001/
N80401 001
N83178 001
N83610 001

/1%/
/2%/
1%
2%
/0.5%/
/2%/
0.5%
4%
/1%/
/2%/
1%
2%

/N80414 /001/
/N80414 /002/
N80414 001
N80414 002
/N85131 /001/
/N84626 /001/
N85131 001
N84626 001
/N83627 /001/
/N83627 /002/
N83627 001
N83627 002

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

/INTL/MEDICATION/

> DLT > /AP/
> DLT > /BP/
> DLT > /BP/
> ADD > @ INTL MEDICATION
> ADD > @
> ADD >
> ADD >

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

/N62466 /001/
/SEP 30, 1983/
/N62466 /002/
/SEP 30, 1983/
N62466 001
SEP 30, 1983
N62466 002
SEP 30, 1983

SOLUTION; TOPICAL

LIDOCAINE HCL

/AI/
/PACO/
@ PACO

/4%/
4%

/N69688 /001/
/JUN 30, 1989/
N89688 001
JUN 30, 1989

KETOCONAZOLE

/SUSPENSION; ORAL/

NIZORAL

/JANSSEN/

@ JANSSEN

/100MG/5ML/
100MG/5ML

/N70767 /001/
/NOV 07, 1986/
N70767 001
NOV 07, 1986

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

LINCOMYCIN HCL

AP
STERIS

EQ 300MG BASE/MLM

N63180 001
APR 16, 1991

LEVONORGESTREL

IMPLANT; IMPLANTATION

LEVONORGESTREL SYSTEM

/WYETH AYERST/

NORPLANT SYSTEM

WYETH AYERST

/36MG/IMPLANT/
36MG/IMPLANT

/N20088 /001/
/DEC 10, 1990/
N20088 001
DEC 10, 1990

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

TABLET; ORAL

CYTOMEL

/SKF/
SKF

/LIDOTHYRONINE SODIUM/
/BOLAR/
@ BOLAR

/EQ 0.025MG BASE/
EQ 0.025MG BASE
/EQ 0.025MG BASE/
EQ 0.025MG BASE

/N10379 /001/
N10379 002
/N85755 /001/
/JAN 25, 1982/
N85755 001
JAN 25, 1982

LITHIUM CARBONATE

TABLET; ORAL

LITHIUM CARBONATE

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

/ 300MG/
300MG
/ 300MG/
300MG

/N70407/001/
/MAR/19/1987/
N70407 001
MAR 19, 1987
/N72542/001/
/FEB/01/1989/
N72542 001
FEB 01, 1989

/PHARM/BASICS/

B* PHARM BASICS

LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL

MODIUM

JANSSEN

AB
AB
AB
AB

LOPERAMIDE HCL

MYLAN

NOVOPHARM

2MG
2MG
2MG
2MG

N17690 001
N17694 001
N72741 001
SEP 18, 1991
N73122 001
AUG 30, 1991

> ADD > AB
> ADD >
> ADD > AB
> ADD >
> ADD > AB
> ADD >

B* PHARM BASICS

1MG
2MG
0.5MG
1MG
2MG

N70539 001
DEC 22, 1986
N70540 001
DEC 22, 1986
N72926 001
OCT 31, 1991
N72927 001
OCT 31, 1991
N72928 001
OCT 31, 1991

LORAZEPAM

CONCENTRATE; ORAL

LORAZEPAM INTENSOL

ROXANE

2MG/ML

N72755 001
JUN 28, 1991

TABLET; ORAL

MEVACOR

MSD

10MG

N19643 002
MAR 28, 1991

TABLET; ORAL

LORAZEPAM

/AM/THERAP/

/BX/ / 0.5MG/
/BX/ / 1MG/
/BX/ / 2MG/
a AM THERAP 0.5MG
a 1MG
a 2MG

/N70727/001/
/MAR/07/1986/
N70727 001
MAR 07, 1986
N70728 001
MAR 07, 1986
N70729 001
MAR 07, 1986

MANNITOL

INJECTABLE; INJECTION

MANNITOL 10%

/AP/ /CUTTER/
a CUTTER

/ 10GM/100ML/
10GM/100ML

/N16472/002/
N16472 002

MANNITOL 15%

/AP/ /CUTTER/
a CUTTER

/ 15GM/100ML/
15GM/100ML

/N16472/005/
N16472 005

MANNITOL 20%

/AP/ /CUTTER/
a CUTTER

/ 20GM/100ML/
20GM/100ML

/N16472/004/
N16472 004

LORAZEPAM

TABLET; ORAL

LORAZEPAM

MUTUAL PHARM

0.5MG

N72553 001
MAR 29, 1991
N72554 001
MAR 29, 1991
N72555 001
MAR 29, 1991
/N70539/001/
/DEC/22/1986/
/N70540/001/
/DEC/22/1986/
N70539 001
DEC 22, 1986
N70540 001
DEC 22, 1986
N72926 001
OCT 31, 1991
N72927 001
OCT 31, 1991
N72928 001
OCT 31, 1991

AB
AB
AB
/AB/
/AB/

/PHARM/BASICS/

B* PHARM BASICS

1MG
2MG
0.5MG
1MG
2MG

N70539 001
DEC 22, 1986
N70540 001
DEC 22, 1986
N72926 001
OCT 31, 1991
N72927 001
OCT 31, 1991
N72928 001
OCT 31, 1991

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'91 - OCT'91

MAPROTILINE HYDROCHLORIDE

TABLET; ORAL
MAPROTILINE HCL
/BOLAR/

> DLT > /AB/	/25MG/	/N71943/001/	/AP/	INJECTABLE; INJECTION	/25MG/ML/	/N88274/001/
> DLT > /AD/	/50MG/	/DEC/30/1987/	/AP/	<u>MEPERIDINE HCL</u>	/50MG/ML/	/JUN/15/1984/
> DLT > /AB/	/15MG/	/N71944/001/	/AP/	/ELKINS/SINN/	/75MG/ML/	/N88280/001/
> DLT > /AD/	25MG	/DEC/30/1987/	/AP/		/100MG/ML/	/JUN/15/1984/
> ADD >		N71943 001				/N88283/001/
> ADD >		DEC 30, 1987				/JUN/15/1984/
> ADD >		N71944 001				N88279 001
> ADD >		DEC 30, 1987				JUN 15, 1984
> ADD >		N71945 001				N88280 001
> ADD >		DEC 30, 1987				JUN 15, 1984
> ADD >						N88281 001
> ADD >						JUN 15, 1984
> ADD >						N88282 001
> ADD >						JUN 15, 1984

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM
/PHARM/BASICS/

/AB/	/EQ_50MG_BASE/	/N71007/001/		<u>MEPROBAMATE</u>		N80380 001
/AD/	/EQ_100MG_BASE/	/MAR/25/1988/		TABLET; ORAL		N80380 002
B*	EQ 50MG BASE	/N71008/001/		BAMATE		/N80380/001/
B*	EQ 100MG BASE	/MAR/25/1988/		@ ALRA		/N80380/002/
		N71007 001		@		
		MAR 25, 1988		/@/PANNAX/		
		N71008 001		/@/		
		MAR 25, 1988				

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE
PHARM BASICS

B*	20MG	N70646 001		<u>MESTRANOL; NORETHYNODREL</u>		N80380 001
B*	40MG	OCT 02, 1987				N80380 002
/BX/	/20MG/	N70647 001				/N80380/001/
/BX/	/40MG/	OCT 02, 1987				/N80380/002/
		N70646/001/				
		/OCT/02/1987/				
		N70647/001/				
		/OCT/02/1987/				

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE HCL
/ELKINS/SINN/

/AB/	/25MG/ML/					/N88274/001/
/AD/	/50MG/ML/					/JUN/15/1984/
/AP/	/75MG/ML/					/N88280/001/
/AP/	/100MG/ML/					/JUN/15/1984/
						/N88283/001/
						/JUN/15/1984/
						N88279 001
						JUN 15, 1984
						N88280 001
						JUN 15, 1984
						N88281 001
						JUN 15, 1984
						N88282 001
						JUN 15, 1984

/0.1MG;2.5MG/
0.1MG;2.5MG

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE
GENEVA

N73034 001
AUG 30, 1991

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE / 10MG /
 /AB/ /AM/ THERAP /
 /AB/ / 40MG /
 @ AM THERAP 10MG
 @ 20MG
 @ DANBURY 10MG
 @ 20MG
 /AB/ /PHARM/BASICS/ 10MG /
 /AB/ / 40MG /
 B* PHARM BASICS 10MG
 B* 20MG

/N72054/001
 /JUN/23/1988
 /N72055/001
 /JUN/23/1988
 N72054 001
 JUN 23, 1988
 N72055 001
 JUN 23, 1988
 N73013 001
 JAN 31, 1991
 N72795 001
 JAN 31, 1991
 /N71013/001
 /JAN/25/1988
 /N71014/001
 /JAN/25/1988
 N71013 001
 JAN 25, 1988
 N71014 001
 JAN 25, 1988

TABLET; ORAL

BANTHINE
 /SEARLE/

> DLT > /AA/ / 50MG /
 > ADD >

/N67390/001/

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL
 /BOLAR/

> DLT > /AA/ / 500MG /
 > DLT > /AB/ / 750MG /
 > ADD > @ BOLAR
 > ADD > @

/N83605/001/
 /N83605/002/
 N83605 001
 N83605 002

METHOTREXATE SODIUM

INJECTABLE; INJECTION
FOLEX PFS
 ADRIA

AP

N81242 001
 AUG 23, 1991

METHOTREXATE
 /LEDERLE/
 LEDERLE

/AB/

/EQ 2.5MG BASE/ML/
 EQ 2.5MG BASE/ML

/N11719/004/
 N11719 004

METHOTREXATE SODIUM
 /LYPHOMED/

/AB/ / 3 LYPHOMED
 @
 /AB/

/N89323/001/
 /JUN/13/1986/
 /N89323/001/
 /JUN/13/1986/
 N89323 001
 JUN 13, 1986
 N89322 001
 JUN 13, 1986

METHADONE HYDROCHLORIDE

/TABLET; EFFERVESCENT;/ ORAL/
 /MESTADONE/
 /VITARINE/

@ VITARINE 1.5MG
 @ 5MG
 @ 10MG
 @ 40MG
 @ VITARINE 2.5MG
 @ 5MG
 @ 10MG
 @ 40MG

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

METHYLCLOTHIAZIDE

TABLET; ORAL
METHYLCLOTHIAZIDE
 /BOLAR/

> DLT > /AB/ / 2.5MG /
 > DLT > /AB/ / 5MG /
 > DLT > /AB/ / 2.5MG
 > ADD > @ BOLAR
 > ADD > @
 > ADD > @

/N85487/001/
 /MAR/11/1982/
 /N85487/001/
 /MAR/11/1982/
 N85487 001
 MAR 11, 1982
 N85476 001
 MAR 11, 1982
 /N88745/001/
 /MAR/21/1985/
 N88745 001
 MAR 21, 1985

METHANTHELIN BROMIDE

TABLET; ORAL
BANTHINE
 SCHIAPPARELLI SEARLE

50MG

N07390 001

> ADD > AA

APR 1991

METHYLDOPA

TABLET; ORAL

METHYLDOPA

> DLT > /AB/ /125MG/ /N70245/001/ /FEB/25/1986/

> DLT > /AB/ /150MG/ /N70246/001/ /FEB/25/1986/

> DLT > /AB/ /500MG/ /N70247/001/ /FEB/25/1986/

> ADD > 3 BOLAR 125MG N70245 001 FEB 25, 1986

> ADD > 3 250MG N70246 001 FEB 25, 1986

> ADD > 3 500MG N70247 001 FEB 25, 1986

> ADD > /AB/ /ROXANE/ /125MG/ /N70192/001/ /APR/25/1986/

> ADD > /AB/ /250MG/ /N70193/001/ /APR/25/1986/

> ADD > /AB/ /500MG/ /N70194/001/ /APR/25/1986/

3 ROXANE 125MG N70192 001 APR 25, 1986

3 250MG N70193 001 APR 25, 1986

3 500MG N70194 001 APR 25, 1986

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE ACETATE

/3/ LENTON/ /20MG/ML/ /N7248/001/

/3/ /40MG/ML/ /N85374/001/

/3/ /80MG/ML/ /N86507/001/

3 STERIS 20MG/ML N87248 001

3 40MG/ML N85374 001

3 80MG/ML N86507 001

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED

ABBOTT

AP EQ 40MG BASE/VIALM /N89573/001/ /FEB/22/1991/

AP EQ 125MG BASE/VIALM /N89574/001/ /FEB/22/1991/

AP EQ 500MG BASE/VIALM /N89575/001/ /FEB/22/1991/

AP EQ 1GM BASE/VIALM /N89576/001/ /FEB/22/1991/

METHYLPREDNISOLONE SODIUM SUCCINATE

L-PHOMED

/AP/ /EQ 40MG BASE/VIAL/ /N86676/001/ /JUN/08/1984/

/AP/ /EQ 125MG BASE/VIAL/ /N86677/001/ /JUN/08/1984/

/AP/ /EQ 500MG BASE/VIAL/ /N86678/001/ /JUN/08/1984/

/AP/ /EQ 500MG BASE/VIAL/ /N89186/001/ /MAR/28/1986/

/AP/ /EQ 1GM BASE/VIAL/ /N86679/001/ /JUN/08/1984/

/AP/ /EQ 1GM BASE/VIAL/ /N89188/001/ /MAR/28/1986/

3 LYPHOMED EQ 40MG BASE/VIAL N88676 001 JUN 08, 1984

3 EQ 125MG BASE/VIAL N88677 001 JUN 08, 1984

3 EQ 500MG BASE/VIAL N88678 001 JUN 08, 1984

3 EQ 500MG BASE/VIAL N89186 001 MAR 28, 1986

3 EQ 1GM BASE/VIAL N88679 001 JUN 08, 1984

3 EQ 1GM BASE/VIAL N89188 001 MAR 28, 1986

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

METANDREN

CIBA

/AB/ /AB/ /5MG/ /N83240/004/ /FEB/22/1986/

/AB/ /AB/ /10MG/ /N83240/005/ /FEB/22/1986/

3 CIBA 5MG N03240 004

3 10MG N03240 005

/BP/ /PHARM/BASICS/ /10MG/ /N86671/001/ /FEB/22/1986/

3 PHARM BASICS 10MG N80271 001

/N83240/004/ /FEB/22/1986/

/N83240/005/ /FEB/22/1986/

N03240 004

N03240 005

/N86671/001/ /FEB/22/1986/

N80271 001

METHYLTESTOSTERONE

TABLET; ORAL
/MÉTANDRÉN/
/CIBA/
@ CIBA
@

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

/N03240/001/
/N03240/003/
N03240 001
N03240 003

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

/N70558/001/
/FEB/02/1987/
/N70558/001/
/JUL/29/1985/
N70339 001
JUL 29, 1985
N70598 001
FEB 02, 1987

METHYPRYLON

TABLET; ORAL
NOLUDAR
/ROCHE/
@ ROCHE

/50MG/
50MG

/N09660/001/
N09660 002

/EQ 10MG BASE/
EQ 10MG BASE

/N70558/001/
/FEB/02/1987/
/N70558/001/
/JUL/29/1985/
N70339 001
JUL 29, 1985
N70598 001
FEB 02, 1987

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
METOCLOPRAMIDE HCL
ABBOTT

EQ 10MG BASE/2MLM

N73117 001
JAN 17, 1991

EQ 10MG BASE/2MLM

N73118 001
JAN 17, 1991

/EQ 10MG BASE/2ML/
EQ 10MG BASE/2ML

/N70622/001/
/MAR/02/1987/
N70622 001
MAR 02, 1987

/500MG/100ML
500MG/100ML
500MG/100ML
500MG/100ML

/N70004/001/
MAY 08, 1985
N70042 001
DEC 20, 1984

SYRUP; ORAL

METOCLOPRAMIDE HCL
/PACO/
@ PACO
AA PHARMS ASSOC

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

/N71665/001/
/DEC/05/1988/
N71665 001
DEC 05, 1988
N72744 001
MAY 28, 1991

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

/N70008 001
DEC 11, 1984
N70009 001
DEC 11, 1984

TABLET; ORAL

METOCLOPRAMIDE HCL
/BARR/
@ BARR
/BOLAR/
@ BOLAR
AB LEDERLE

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

/N70660/001/
/FEB/10/1987/
N70660 001
FEB 10, 1987
/N70363/001/
/MAR/02/1987/
N70363 001
MAR 02, 1987
N72639 001
MAY 09, 1991

/25/
/100MG/
/25/
/100MG/

/N70558/001/
/MAR/15/1982/
/N70558/001/
/MAR/15/1982/

MICONAZOLE NITRATE

/CREAM; VAGINAL/
/MONSTAT/
/AT/
/JOHNSON/RW/
/SUPPOSITORY; VAGINAL/
/MONSTAT/
/AT/
/JOHNSON/RW/

/25/
/100MG/

/N70558/001/
/MAR/15/1982/
/N70558/001/
/MAR/15/1982/

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

<u>MILTIRINONE LACTATE</u>									
/INJECTABLE; INJECTION/ /MILTIRINONE LACTATE/ /STERLING/									
⊗ STERLING	/EQ/1MG/BASE/ML/ EQ 1MG BASE/ML	/N19436/001/ /DEC/16, 1988/ N19436 001 DEC 31, 1987	/AP/ ⊗ ELKINS SINN	<u>NALOXONE HYDROCHLORIDE</u> INJECTABLE; INJECTION NALOXONE /ELKINS/SINN/	/0.4MG/ML/ 0.4MG/ML				/N70496/001/ /DEC/22, 1985/ N70496 001 OCT 22, 1985
<u>MINOXIDIL</u>									
TABLET; ORAL MINOXIDIL /AB/ /PHARM/BASICS/	/4.5MG/	/N71537/001/ /DEC/16, 1988/ N71537 001 DEC 16, 1988	> DLT > > DLT > > ADD > > ADD >	<u>NALOXONE HCL</u> /LYPHOMED/ ⊗ LYPHOMED	/1MG/ML/ 1MG/ML				/N71604/001/ /DEC/16, 1988/ N71604 001 DEC 16, 1988
B* PHARM BASICS	2.5MG			<u>NANDROLONE DECANOATE</u> INJECTABLE; INJECTION NANDROLONE DECANOATE /LEMON/	/50MG/ML/ 50MG/ML 100MG/ML				
<u>MORPHINE SULFATE</u>									
INJECTABLE; INJECTION INFUMORPH ELKINS SINN	10MG/ML 25MG/ML		/AD/ /AD/ /AD/ AO AO AO	<u>NEOMYCIN SULFATE</u> TABLET; ORAL NEOMYCIN SULFATE /ROXANE/ ⊗ ROXANE	/50MG/ML/ 50MG/ML 100MG/ML				/N87598/001/ /OCT/06, 1983/ N87598 001 OCT 06, 1983 /N88554/001/ /FEB/10, 1986/ N88554 001 FEB 10, 1986 /N87599/001/ /OCT/06, 1983/ N87599 001 OCT 06, 1983
<u>MORPHINE SULFATE</u> STERIS	0.5MG/ML	N18565 003 JUL 19, 1991							
AP	0.5MG/ML	N18565 004 JUL 19, 1991							
AP	1MG/ML	N73373 001 SEP 30, 1991							
AP	1MG/ML	N73375 001 SEP 30, 1991							
AP	1MG/ML	N73374 001 SEP 30, 1991							
AP	1MG/ML	N73376 001 SEP 30, 1991							
BC	30MG	N19516 001 MAY 29, 1987	> DLT >/AD/ > ADD >	<u>NIACIN</u> TABLET; ORAL NIACIN /WEST/WARD/ ⊗ WEST WARD	/EQ 350MG BASE/ EQ 350MG BASE				/N62173/001/ N62173 001
BC	60MG	N19516 002 APR 08, 1988							
BC	100MG	N19516 004 JAN 16, 1990							
BC	30MG	N19977 001 AUG 15, 1991							
BC	60MG	N19977 002 AUG 15, 1991							
BC	100MG	N19977 003 AUG 15, 1991							

NIFEDIPINE

CAPSULE; ORAL
NIFEDIPINE

AB

CHASE

20MG

N73421 001

> ADD >

AB

SCHERER

10MG

N73250 001

> ADD >

/AD/ /CAMER/ /NILES/ 2 MILES /100,000 UNITS/GM/ 100,000 UNITS/GM/

/N61616/001/ N61810 001

NITROFURAZONE

CREAM; TOPICAL

FURACIN

/NORMICH/EATON/ ROBERTS

/0.2%/ 0.2%

/N83766/001/ N83789 001

INJECTABLE; INJECTION

ZOFRAN

GLAXO

EQ 2MG BASE/MLM

N20007 001
JAN 04, 1991

POWDER; TOPICAL

FURACIN

/NORMICH/EATON/ ROBERTS

/0.2%/ 0.2%

/N83791/001/ N83791 001

TABLET, EXTENDED RELEASE; ORAL

NORELEX

/3M/

/100MG/ 100MG

/N12157/001/ N12157 001

NITROGLYCERIN

INJECTABLE; INJECTION

NITROGLYCERIN

/LYPHOMED/

/5MG/ML/ 5MG/ML

/N71203/001/ N71203 001

/3M/

/100MG/ 100MG

/N12157/001/ N12157 001

NITROGLYCERIN

3 LYPHOMED

/5MG/ML/ 5MG/ML

/N71203/001/ N71203 001

/3M/

/100MG/ 100MG

/N12157/001/ N12157 001

NITROGLYCERIN

3 SOLOPAK

/5MG/ML/ 5MG/ML

/N70634/001/ N70634 001

/3M/

/100MG/ 100MG

/N84303/001/ N84303 001

NITROGLYCERIN

3 RORER

/0.8MG/ML/ 0.8MG/ML

/N18774/001/ N18774 001

/3M/

/100MG/ 100MG

/N84303/001/ N84303 001

NITROSTAT

/PARKE/DAVIS/ PARKE DAVIS

/0.8MG/ML/ 0.8MG/ML

/N18588/001/ N18588 001

/3M/

/100MG/ 100MG

/N84303/001/ N84303 001

NORFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

CHIBROXIN

MSD

0.3%/

N19757 001

JUN 17, 1991

RECEIVED
JUN 17 1991

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

/AB/ /ELKINS/SINN/

/EQ 250MG BASE/VIAL/

/N62711/001/
/FEB/03/1989/

/EQ 500MG BASE/VIAL/

/N62711/002/
/FEB/03/1989/

/EQ 1GM BASE/VIAL/

/N62711/003/
/FEB/03/1989/

/EQ 2GM BASE/VIAL/

/N62711/004/
/FEB/03/1989/

/EQ 4GM BASE/VIAL/

/N62711/005/
/FEB/03/1989/

/EQ 10GM BASE/VIAL/

/N62711/006/
/FEB/03/1989/

3 ELKINS SINN

EQ 250MG BASE/VIAL

N62711 001

3

EQ 500MG BASE/VIAL

FEB 03, 1989

3

EQ 1GM BASE/VIAL

FEB 03, 1989

3

EQ 2GM BASE/VIAL

FEB 03, 1989

3

EQ 4GM BASE/VIAL

FEB 03, 1989

3

EQ 10GM BASE/VIAL

FEB 03, 1989

OXANDROLONE

/TABLET; ORAL/

/ANAVAR/

/3/SEARLE/

TABLET; ORAL

OXANDRIN

GYNEX

2.5MG

N13718 001

/N13718/001/

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

B* CHELSEA

10MG

N71661 001

B* CHELSEA

15MG

MAR 02, 1988

B* CHELSEA

30MG

MAR 02, 1988

/BX/

/10MG/

MAR 02, 1988

/BX/

/15MG/

MAR 02, 1988

/BX/

/30MG/

MAR 02, 1988

OXTRIPHYLLINE

TABLET, DELAYED RELEASE; ORAL

CHOLEDYL

/PARKE/DAVIS/

/100MG/

/N09268/003/

/ADD/

/200MG/

/N09268/007/

/ADD/

100MG

N09268 007

/DLT/

/100MG/

N09268 003

/DLT/

/200MG/

N09268 007

/DLT/

/100MG/

N09268 003

/DLT/

/200MG/

N09268 007

3 BOLAR

100MG

N87866 001

3

200MG

N87835 001

/ADD/

200MG

AUG 25, 1983

OXYBUTYRIN CHLORIDE

TABLET; ORAL

OXYBUTYRIN CHLORIDE

/BOLAR/

/5MG/

/N72485/001/

3 BOLAR

5MG

N72485 001

/ADD/

5MG

APR 19, 1989

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

ARELIA

CIBA GEIGY

30MG/VIALM

N20036 001

OCT 31, 1991

>_ADD_> PAMIDRONATE DISODIUM

>_ADD_> INJECTABLE; INJECTION

>_ADD_> ARELIA

>_ADD_> CIBA GEIGY

30MG/VIALM

N20036 001

OCT 31, 1991

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

/100MG/

/100MG/

100MG

/100MG/

100MG

/N85791/001/

N85791 001

/N83239/001/

N83239 001

/AP/

/SOLOPAK/

@ SOLOPAK

50MG/ML

/50MG/ML/

/N80521/001/

/PEC/18,1984/

N88521 001

DEC 18, 1984

/AA/

/CHELSEA/

@ CHELSEA

/MYETH/AYERST/

@ MYETH AYERST

/AA/

>_DLT_>

>_ADD_>

>_ADD_> PENTOSTATIN

>_ADD_> INJECTABLE; INJECTION

>_ADD_> NIPENT

>_ADD_> PARKE DAVIS

10MG/VIALM

N20122 001

OCT 11, 1991

PINACIDIL

CAPSULE, EXTENDED RELEASE; ORAL

PINDAC

LEO

12.5MG

25MG

N19456 001

DEC 28, 1989

N19456 002

DEC 28, 1989

/N19456/001/

/PEC/18,1989/

N19456 001

/PEC/18,1989/

/LILLY/

/12.5MG/

N19456 001

DEC 28, 1989

N19456 002

DEC 28, 1989

/N19456/001/

/PEC/18,1989/

N19456 001

/PEC/18,1989/

PIPERAZINE CITRATE

SYRUP; ORAL

PIPERAZINE CITRATE

/BARRE/

@ BARRE

/EQ 500MG BASE/5ML

/N80774/001/

N80774 001

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM

BICARBONATE; SODIUM CHLORIDE

POWDER FOR RECONSTITUTION; ORAL

NULYTELY

BRAINTREE

420GM/BOT; 1.48GM/BOT; 5.72GM/BOT;

11.2GM/BOTM

N19797 001

APR 22, 1991

N18074 001

/N18074/001/

N19797 001

APR 22, 1991

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

/CORD/

@ CORD

MIKART

35MG

35MG

/N86365/001/

N86365 001

N89452 001

OCT 30, 1991

N86365 001

DEC 23, 1988

N72319 001

DEC 23, 1988

/N72319/001/

/PEC/18,1988/

N72319 001

/PEC/18,1988/

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

/AP/ /CUTTER/ /1MEQ/ML/ /N80195/002/
/AP/ /CUTTER/ /2MEQ/ML/ /N80195/001/
/AP/ /CUTTER/ /3MEQ/ML/ /N80195/003/
@ CUTTER /N80195/002/
@ /N80195/001/
/AP/ /ELKINS/SINN/ /2MEQ/ML/ /N80203/001/
@ ELKINS SINN /N80203/001/
/AP/ /LEMON/ /2MEQ/ML/ /N86208/001/
/AP/ /LILLY/ /2MEQ/ML/ /N86210/001/
@ LILLY /N86210/001/
AP STERIS /N86210/001/
AP /N86210/001/

/1MEQ/ML/ /N80195/002/
/2MEQ/ML/ /N80195/001/
/3MEQ/ML/ /N80195/003/
N80195 002
N80195 001
N80195 003
/N80203/001/
N80203 001
/N86208/001/
/N86210/001/
/N86210/001/
N86210 002
N86208 001
N86210 001

/AP/ /CENTRAL/PHARMS/ /25MG/ML/
/AP/ @ CENTRAL PHARMS /25MG/ML/
/AP/ /LEMON/ /50MG/ML/
BP STERIS /25MG/ML/
BP /50MG/ML

/N84717/001/
N84717 001
/N83654/001/
/N83654/001/
/N83654/001/
N83654 001
N85781 001
N85781 001

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE

>_ADD> AT /N81043/001/
>_ADD> AT /N81044/001/
>_ADD> AT /N81044/001/
>_ADD> AT /N81044/001/

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

>_ADD> PRAVASTATIN SODIUM

TABLET; ORAL
PRAVACHOL
BRISTOL MYERS SQUIBB 10MG#
20MG#

N19898 002
OCT 31, 1991
N19898 003
OCT 31, 1991

PRAZEPAM

CAPSULE; ORAL
PRAZEPAM
/PHARM/BASICS/

/AD/ /PHARM/BASICS/ /5MG/
/AD/ /PHARM/BASICS/ /10MG/
B* PHARM BASICS 5MG
B* PHARM BASICS 10MG

/N70427/001/
/NOV/86/1987/
/N70428/001/
/NOV/86/1987/
N70427 001
NOV 06, 1987
N70428 001
NOV 06, 1987

PREDNICARBATE

OINTMENT; TOPICAL
DERMATOP
HOECHST ROUSSEL 0.1%#

N19568 001
SEP 23, 1991

PREDNISONE

TABLET; ORAL
DELTA-DOME/
MILES/
MILES

/BX/ /MILES/ /5MG/
/BX/ @ MILES /5MG/
/BX/ /MILES/ /5MG/
/BX/ /MILES/ /10MG/
/BX/ /MILES/ /20MG/

/N80293/001/
N80293 001

AB /BX/ /MILES/ /5MG/
/BX/ /MILES/ /5MG/
/BX/ /MILES/ /5MG/
/BX/ /MILES/ /10MG/
/BX/ /MILES/ /20MG/

N84655 001
/N84655/001/

PREDNICEN-M
CENTRAL PHARMS

/BX/ /AM/THERAP/ /5MG/
/BX/ /AM/THERAP/ /10MG/
/BX/ /AM/THERAP/ /20MG/

/N89387/001/
/NOV/86/1986/
/N89388/001/
/NOV/86/1986/
/N89389/001/
/NOV/86/1986/
/N89387/001/
N89387 001
NOV 06, 1986
N89388 001
NOV 06, 1986
N89389 001
NOV 06, 1986
/N86596/001/
N86596 001

@ AM THERAP 5MG
@ AM THERAP 10MG
@ AM THERAP 20MG

/DLT/ /BARR/ /50MG/
/ADD/ @ BARR 50MG

PREDNISON

TABLET; ORAL
PREDNISON
ROXANE

AB	> DLT > /AB/	N87800 001	1MG
AB	> DLT >	APR 22, 1982	
AB	> ADD >	N87801 001	2.5MG
AB	> ADD >	APR 22, 1982	
AB	> DLT > /AB/	N84122 001	10MG
AB	> DLT >	N87342 001	20MG
AB	> ADD >	N84283 001	50MG
AB	> ADD >	/N17109/001/	/20MG/
AB	> ADD >	/N87800/001/	/1MG/
AB	> ADD >	/APR/22, 1982/	
AB	> ADD >	/N87801/001/	/2.5MG/
AB	> ADD >	/APR/22, 1982/	
AB	> ADD >	/N84122/001/	/10MG/
AB	> ADD >	N17109 001	20MG
AB	> ADD >	/N87342/001/	/20MG/
AB	> ADD >	/N84283/001/	/50MG/

PRIMIDONE

TABLET; ORAL
PRIMIDONE
/BOLAR/
a BOLAR

> DLT > /AB/	/N85052/001/	250MG
> ADD >	N85052 001	

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL
PROCAINAMIDE HCL
/BOLAR/

> DLT > /AB/	/N83795/001/	250MG
> DLT >	/N84357/001/	500MG
> ADD >	N83795 001	250MG
> ADD >	N84357 001	500MG

INJECTABLE; INJECTION
PROCAINAMIDE HCL
/WARNER/CHILCOTT/

> DLT > /AB/	/N89528/001/	100MG/ML
> DLT >	/MAY/03, 1988/	
> DLT > /AB/	/N89529/001/	500MG/ML
> DLT >	/MAY/03, 1988/	
> ADD >	N89528 001	100MG/ML
> ADD >	N89529 001	500MG/ML
> ADD >	MAY 03, 1988	
> ADD >	MAY 03, 1988	

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL
/BOLAR/

> DLT > /AB/	/N89520/001/	1GM
> DLT >	/JAN/15, 1987/	
> ADD >	N89520 001	1GM
> ADD >	JAN 15, 1987	
> DLT > /AB/	/N86489/001/	1GM
> DLT >	/JAN/16, 1985/	
> ADD >	N88489 001	1GM
> ADD >	JAN 16, 1985	

PROCAN SR
/PARKE/DAVIS/

PARKE DAVIS

PROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINE HCL
/CUTTER/

/AP/	/N80415/001/	1/2
/AP/	/N80415/002/	1/2
> ADD >	N80415 001	1/2
> ADD >	N80415 002	1/2
> ADD >	/N83535/001/	1/2
> ADD >	/N83535/002/	1/2
> ADD >	N83535 001	1/2
> ADD >	N83535 002	1/2

PROCHLORPERAZINE EDISYLATE

/CONCENTRATE; ORAL/
/PROCHLORPERAZINE/EDISYLATE/
/PHARM/BASICS/
a PHARM BASICS

> DLT > /AB/	/N88598/001/	EQ 10MG BASE/ML
> DLT >	/OCT/25, 1984/	
> ADD >	N88598 001	EQ 10MG BASE/ML
> ADD >	OCT 25, 1984	

SYRUP; ORAL
COMPAZINE
/SKF/

/AA/	/N11188/001/	EQ 5MG BASE/5ML
/AA/	/N11188/001/	EQ 5MG BASE/5ML
> DLT > /AB/	/N88597/001/	EQ 5MG BASE/5ML
> DLT >	/OCT/25, 1984/	
> ADD >	N88597 001	EQ 5MG BASE/5ML
> ADD >	OCT 25, 1984	

PROCHLORPERAZINE MALEATE

TABLET; ORAL
/PROCHLORPERAZINE/
/BOLAR/

> DLT > /AB/ /EQ 5MG BASE/
> DLT > /AB/ /EQ 10MG BASE/
> DLT > /AB/ /EQ 25MG BASE/
> ADD > @ BOLAR
> ADD > @
> ADD > @

/N85560/001/
/N85578/001/
/N85579/001/
N85580 001
N85178 001
N85579 001

/1MG/ML/
1MG/ML

/N70135/001/
/APR/15,1986/
N70135 001
APR 15, 1986

PROCHLORPERAZINE MALEATE
/DURAMED/

/AB/ /EQ 5MG BASE/
/AB/ /EQ 10MG BASE/
/AB/ /EQ 25MG BASE/
B* DURAMED
B*
B*

/N89484/001/
/JAN/20,1987/
/N89485/001/
/JAN/20,1987/
/N89486/001/
/JAN/20,1987/
N89484 001
JAN 20, 1987
N89485 001
JAN 20, 1987
N89486 001
JAN 20, 1987

/20MG/5ML/
/40MG/5ML/
20MG/5ML
40MG/5ML

/N71985/001/
/MAR/03,1989/
/N71985/001/
/MAR/03,1989/
N71984 001
MAR 03, 1989
N71985 001
MAR 03, 1989
/N76979/001/
/MAY/15,1987/
/N76980/001/
/MAY/15,1987/
N70979 001
MAY 15, 1987
N70690 001
MAY 15, 1987

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
PROMETHAZINE HCL
/LEMMON/
STERIS
AP
AP

/AB/ /25MG/ML/
/AP/ /25MG/ML/
/AP/ /50MG/ML/
AP

/N83531/001/
/N83532/001/
N83532 001
N83532 002

TABLET; ORAL
PROPRANOLOL HCL
/BOLAR/

> DLT > /AB/ /10MG/
> DLT > /AB/ /20MG/
> DLT > /AB/ /40MG/
> DLT > /AB/ /60MG/
> DLT > /AB/ /80MG/
> ADD > @ BOLAR
> ADD > @
> ADD > @

/N70378/001/
/MAR/19,1987/
/N70379/001/
/MAR/19,1987/
/N70380/001/
/MAR/19,1987/
/N70381/001/
/MAR/19,1987/
/N70382/001/
/MAR/19,1987/
N70378 001
MAR 19, 1987
N70379 001
MAR 19, 1987
N70380 001
MAR 19, 1987
N70381 001
MAR 19, 1987
N70382 001
MAR 19, 1987

SUPPOSITORY; RECTAL
PROMETHAZINE HCL
/S/AND/W/
G AND W

> DLT > /BR/ /50MG/
> DLT > /BR/ /50MG
> ADD > @

/N87165/001/
/AUG/14,1987/
N87165 001
AUG 14, 1987

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL
@ ALRA
/BANNAX/

65MG
/55MG/

N83184 001
/N83184/001/

10MG
20MG
40MG
60MG
80MG

N70378 001
MAR 19, 1987
N70379 001
MAR 19, 1987
N70380 001
MAR 19, 1987
N70381 001
MAR 19, 1987
N70382 001
MAR 19, 1987

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL
 /AB/ /PURANED/

/AB/ /40MG/ /N76368/001/
 /SEP/09/1985/
 /AB/ /60MG/ /N76369/001/
 /OCT/01/1986/
 /AB/ /80MG/ /N76370/001/
 /SEP/09/1985/

B* DURAMED

40MG

N70308 001

B* DURAMED

60MG

SEP 09, 1985

B* DURAMED

80MG

OCT 01, 1986

/AB/ /MARTEC/

/AB/ /10MG/ /N76126/001/
 /AB/ /20MG/ /N76127/001/
 /AB/ /40MG/ /N76128/001/
 /AB/ /60MG/ /N76129/001/
 /AB/ /80MG/ /N76130/001/
 /AUG/06/1985/

SEP 09, 1985

/AB/ /SCHERING

10MG

AUG 06, 1985

/AB/ /SCHERING

20MG

AUG 06, 1985

/AB/ /SCHERING

40MG

AUG 06, 1985

/AB/ /SCHERING

60MG

OCT 29, 1986

/AB/ /SUPERPHARM/

80MG

AUG 06, 1985

/AB/ /SUPERPHARM

40MG

JUN 08, 1988

/AB/ /SUPERPHARM

80MG

JUN 08, 1988

3 SUPERPHARM

40MG

JUN 08, 1988

3 SUPERPHARM

80MG

JUN 08, 1988

/AB/ /SUPERPHARM/

/AB/ /40MG/ /N71517/001/
 /JUN/08/1988/
 /AB/ /80MG/ /N71518/001/
 /JUN/08/1988/

AUG 06, 1985

3 SUPERPHARM

40MG

JUN 08, 1988

3 SUPERPHARM

80MG

JUN 08, 1988

PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE

TABLET, EXTENDED RELEASE; ORAL

SELDANE-D

MERRELL DOM

120MG; 60MG

N19664 001

AUG 19, 1991

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL
PYRIDOSTIGMINE BROMIDE
 KALI DUPHAR

/AB/ /PUPREPAC/ /30MG/ /N89572 001/
 NOV 27, 1990
 /NOV/27/1990/

N89572 001
 NOV 27, 1990
 /NOV/27/1990/

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

PYRIDOXINE HCL
 /AB/ /LEMON/ /100MG/ML/
 AP STERIS

/AB/ /100MG/ML/ /N83760 001/
 100MG/ML

/N83760/001/
 N83760 001

PYRILAMINE MALEATE

TABLET; ORAL

PYRILAMINE MALEATE
 /AB/ /CHELSEA/ /25MG/ /N85231 001/
 CHELSEA
 /AB/ /RICHLIN/ /25MG/ /N80808 001/
 RICHLIN

/AB/ /25MG/ /N85231/001/
 25MG
 /AB/ /25MG/ /N80808/001/
 25MG

/N85231/001/
 N85231 001
 /N80808/001/
 N80808 001

QUAZEPAM

TABLET; ORAL

DORAL
 BAKER CUMMINS

7.5MG
 15MG

N18708 003
 FEB 26, 1987
 N18708 001
 DEC 27, 1985

/AB/ /DORALIN/ /7.5MG/ /N18708/003/
 /BAKER/CUMMINS/

/AB/ /7.5MG/ /N18708/003/
 /FEB/26/1987/
 /N18708/001/
 /DEC/27/1985/

N18708 003
 FEB 26, 1987
 N18708 001
 DEC 27, 1985

QUINESTROL

TABLET; ORAL

ESTROVIS
 PARKE DAVIS

0.1MG

N16768 002

QUINIDINE GLUCONATE

/TABLET; ORAL/
/QUINACT/
/BERLEX/

/266MG/
/400MG/
266MG
400MG

/N85978/001/
/N86099/001/
N85978 001
N86099 001

TABLET, EXTENDED RELEASE; ORAL

/QUINATIME/
/BOLAR/
3 BOLAR

/324MG/
324MG

/N87448/001/
N87448 001

QUINIDINE GLUCONATE

/ROXANE/

/324MG/
324MG

/N88431/001/
/JAN/96, 1984/
N88431 001
JAN 06, 1984

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

/VANSARD/

/200MG/
200MG

/N87909/001/
/JUL/13, 1982/
N87909 001
JUL 13, 1982

QUINORA

/KEY/PHARMS/
3 KEY PHARMS

/200MG/
200MG

/N83576/001/
N83576 001

RANIPRIL

CAPSULE; ORAL

ALTACE

HOECHST ROUSSEL

1.25MGH

2.5MGH

5MGH

10MGH

N19901 001

JAN 28, 1991

N19901 002

JAN 28, 1991

N19901 003

JAN 28, 1991

N19901 004

JAN 28, 1991

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

ZANTAC IN PLASTIC CONTAINER

/DILAXO/

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

3 GLAXO

EQ 1MG BASE/MLM

/N19593/001/
/DEC/17, 1986/
N19593 001
DEC 17, 1986
N19593 002
SEP 27, 1991

RAUNOLFIA SERPENTINA

TABLET; ORAL

RAUNOLFIA SERPENTINA

BP DANBURY

50MG
/50MG/

N80907 001
/N80907/001/

RESERPINE

TABLET; ORAL

RESERPINE

/BP/

/WHITE/TONNE/PAULSEN/0.1MG/
/BP/

3 WHITE TONNE PAULSEN

3 0.25MG
/1MG/
1MG

/N80723/001/
/N80723/002/
N80723 001
N80723 002
/N80723/003/
N80723 003

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HCL

AP ABBOTT

10MG/MLM

N71618 001

FEB 28, 1991

AP ABBOTT

15MG/MLM

N71619 001

FEB 28, 1991

RITODRINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT

30MG/100MLM

N71438 001

JAN 22, 1991

SECOBARBITAL SODIUM

CAPSULE; ORAL

SECOBARBITAL SODIUM

/MYETH/AYERST/

100MG/
100MG

/N86390/001/
N86390 001

SECOBARBITAL SODIUM
/MYETH/AYERST/
3 MYETH AYERST

/100MG/
100MG

/N86396/001/
N86390 001

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE

2.5%
50MG/VIAL

N89996 001
JAN 10, 1991

AP
80MG/ML; 16MG/ML

N71556 001
DEC 17, 1987

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
SULFAMETHOXAZOLE AND TRIMETHOPRIM

200MG/5ML; 40MG/5ML

N70028 001
OCT 29, 1985

SUSPENSION; ORAL
COTRIM PEDZATRIC

200MG/5ML; 40MG/5ML

N70028 001
OCT 29, 1985

/SULFAMETHOXAZOLE AND TRIMETHOPRIM/
/PIANTEX/
200MG/5ML; 40MG/5ML

/N70028/001/
/OCT/29/1985/

/N70031/001/
/JAN/17/1985/
N70031 001
JAN 17, 1985

50MG/VIAL
50MG/VIAL

TABLET; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM
/PHARM/BASICS/
400MG; 80MG

/N70203/001/
/NOV/08/1985/
/N70204/001/
/NOV/08/1985/
N70203 001
NOV 08, 1985
N70204 001
NOV 08, 1985
N72768 001
AUG 30, 1991

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

25MG
25MG

/N86898/002/
/MAR/02/1982/
N86898 002
MAR 02, 1982

400MG; 80MG
800MG; 160MG
400MG; 80MG

N70203 001
NOV 08, 1985
N70204 001
NOV 08, 1985
N72768 001
AUG 30, 1991

SUCCIMER

CAPSULE; ORAL
CHEMET
MCNEIL

100MG

N19998 002
JAN 30, 1991

SULFANILAMIDE

CREAM; VAGINAL
SULFANILAMIDE

15%
15%

N88718 001
SEP 19, 1985

TABLET; ORAL

SULFAMETHOXAZOLE

500MG
500MG

/N85053/001/
N85053 001

/VAGITROL/
/LEMMON/
15%

/N88718/001/
/SEP/19/1985/

SULFAMETHOXAZOLE; TRIMETHOPRIM

INJECTABLE; INJECTION
COTRIM

80MG/ML; 16MG/ML

/N71556/001/
/DEC/17/1987/

500MG

N07073 002
APR 06, 1983

SULFAMETHOXAZOLE AND TRIMETHOPRIM

80MG/ML; 16MG/ML

N73303 001
OCT 31, 1991

GENSIA

500MG

/N07073/002/
/APR/06/1983/

TABLET, DELAYED RELEASE; ORAL

AZULFEDINE EM-TABS

500MG

N07073 002
APR 06, 1983

/PHARMACIA/

500MG

/N07073/002/
/APR/06/1983/

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

> ADD >
> ADD >

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

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

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

SULFASALAZINE

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

TABLET, DELAYED RELEASE; ORAL
SULFASALAZINE
 /BE/ /BOLAR/
 500MG
 500MG

/N88852/001/
 /MAY/24, 1983/
 N88052 001
 MAY 24, 1983

SULFISOXAZOLE

TABLET; ORAL
 SOXAZOLE
 3 ALRA
 /3/BANMAX/
 500MG
 /500MG/

N80366 001
 /N88366/001/

SULINDAC

TABLET; ORAL
SULINDAC
 GENEVA
 AB 150MG
 AB 200MG
 AB 150MG
 AB 200MG
 AB 150MG
 AB 200MG
 AB 150MG
 AB 200MG

N72712 001
 AUG 30, 1991
 N72713 001
 AUG 30, 1991
 N73261 001
 SEP 06, 1991
 N73262 001
 SEP 06, 1991
 N72050 001
 APR 17, 1991
 N72051 001
 APR 17, 1991
 N72710 001
 MAR 25, 1991
 N72711 001
 MAR 25, 1991

TECHNETIUM TC-99M RED BLOOD CELL KIT

INJECTABLE; INJECTION
 ULTRATAG
 MALLINCKRODT N/AH

N19981 001
 JUN 10, 1991

TEMAZEPAM

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

CAPSULE; ORAL
 RESTORIL
 SANDOZ
TEMAZEPAM
 /BOLAR/
 7.5MG
 /15MG/
 /30MG/
 15MG
 30MG
 /15MG/
 /30MG/
 15MG
 30MG

N18163 003
 OCT 25, 1991
 /N70383/001/
 /MAR/23, 1987/
 /N70384/001/
 /MAR/23, 1987/
 N70383 001
 MAR 23, 1987
 N70384 001
 MAR 23, 1987
 /N70489/001/
 /JUL/07, 1986/
 /N70490/001/
 /JUL/07, 1986/
 N70489 001
 JUL 07, 1986
 N70490 001
 JUL 07, 1986

TERCONAZOLE

CREAM; VAGINAL
 TERAZOL 3
 JOHNSON RM

0.8%
 0.8%
 0.8%

N19964 001
 FEB 21, 1991

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION
TESTOSTERONE CYPIONATE
 /LEMMON/
 100MG/ML
 200MG/ML
 100MG/ML
 200MG/ML

/N84401/001/
 /N84401/002/
 N84401 001
 N84401 002

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
 /LEMMON/
 100MG/ML
 200MG/ML
 100MG/ML
 200MG/ML

/N83667/001/
 /N83667/002/
 N83667 001
 N83667 002

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION

TESTOSTERONE PROPIONATE

/AD/ /25MG/ML/
 /AD/ /50MG/ML/
 /AD/ /100MG/ML/
 STERIS
 AO 25MG/ML
 AO 50MG/ML
 AO 100MG/ML

/N85490/001
 /N85490/002
 /N85490/003
 N85490 001
 N85490 002
 N83595 003

THEOPHYLLINE

CAPSULE; ORAL

SCHERER

/BX/ /SCHERER/
 /BX/ /SCHERER/
 /BX/ /SCHERER/
 3 FISON
 3
 3
 THEOPHYLLINE
 /BX/ /SCHERER/
 /BX/ /SCHERER/
 /BX/ /SCHERER/
 3 SCHERER
 3
 3
 CAPSULE, EXTENDED RELEASE; ORAL
 /BC/ /JOHNSON/RW/
 3 JOHNSON RW
 125MG

/N87155/001
 /FEB/25/1985
 /N87155/002
 /FEB/25/1985
 /N87155/003
 /FEB/25/1985
 N87155 001
 FEB 25, 1985
 N87155 002
 FEB 25, 1985
 N87155 003
 FEB 25, 1985
 /N84731/002
 /NOV/07/1986
 /N84731/001
 /NOV/07/1986
 /N84731/003
 /NOV/07/1986
 N84731 002
 NOV 07, 1986
 N84731 001
 NOV 07, 1986
 N84731 003
 NOV 07, 1986
 /N86480/001
 /FEB/08/1985
 N86480 001
 FEB 08, 1985

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

THEOPHYLLINE

/BC/ /CENTRAL/PHARMS/
 /BC/ /CENTRAL/PHARMS/
 3 CENTRAL PHARMS
 3
 THEOPHYLLINE-SR
 /BC/ /SCHERER/
 3 SCHERER

/N88654/001
 /FEB/12/1985
 /N88654/002
 /FEB/12/1985
 N88654 001
 FEB 12, 1985
 N88654 002
 FEB 12, 1985
 /N88655/001
 /JUN/12/1986
 N88255 001
 JUN 12, 1986

/BC/ /CENTRAL/PHARMS/
 /BC/ /CENTRAL/PHARMS/
 3 CENTRAL PHARMS
 3
 THEOPHYLLINE-SR
 /BC/ /SCHERER/
 3 SCHERER

TABLET; ORAL
 THEOCLEAR-100
 /BP/ /CENTRAL/PHARMS/
 3 CENTRAL PHARMS
 /BP/ /THEOCLEAR-200/
 3 CENTRAL PHARMS

/N85353/002
 N85353 002
 /N85353/001
 N85353 001

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

THIAMINE HCL

/AP/ /LEMON/
 /AP/ /LEMON/
 /BP/ /LYPHOMED/
 3 LYPHOMED
 AP STERIS
 AP

/N83534/001
 /N83534/002
 /N83534/003
 N80509 001
 N80509 001
 N83534 001
 N83534 002

/AP/ /LEMON/
 /AP/ /LEMON/
 /BP/ /LYPHOMED/
 3 LYPHOMED
 AP STERIS
 AP

/100MG/ML/
 /200MG/ML/
 /100MG/ML/
 100MG/ML
 100MG/ML
 200MG/ML

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

/BOLAR/

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

/5MG/
/10MG/
/20MG/

a BOLAR

a

a

AB DANBURY

AB

AB

AB

AB

/AB/ /PHARM/BASICS/

/AB/

/AB/

B* PHARM BASICS

B*

B*

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

ABBOTT

EQ 10MG BASE/MLM

EQ 10MG BASE/MLM

EQ 40MG BASE/MLM

EQ 40MG BASE/MLM

N63080 001

APR 30, 1991

N63112 001

APR 30, 1991

N63111 001

APR 30, 1991

N63161 001

MAY 29, 1991

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

TOBRAMYCIN SULFATE

LEDERLE

AP

AP

AP

EQ 10MG BASE/MLM

EQ 40MG BASE/MLM

EQ 40MG BASE/MLM

N63113 001

APR 26, 1991

N63117 001

APR 26, 1991

N63118 001

JUL 29, 1991

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

/BOLAR/

> DLT > /AB/

> ADD >

/AB/ /CHELSEA/

/AB/

/AB/

/AB/

B* CHELSEA

B*

B*

/AB/ /PHARM/BASICS/

/AB/

/AB/

/AB/

B* PHARM BASICS

B*

B*

/N70244/001

/AUG/01/1986/

/N70243/001

/AUG/01/1986/

/N70244/001

/AUG/01/1986/

/N70244/001

/AUG/01/1986/

N70242 001

AUG 01, 1986

N70243 001

AUG 01, 1986

N70244 001

AUG 01, 1986

/N70285/001

/JAN/09/1986/

/N70286/001

/JAN/09/1986/

/N70287/001

/JAN/09/1986/

N70285 001

JAN 09, 1986

N70286 001

JAN 09, 1986

N70287 001

JAN 09, 1986

/N71355/001

/JAN/11/1988/

/N70169/001

/APR/02/1985/

/N70169/001

/APR/02/1986/

N71355 001

JAN 11, 1988

N70168 001

APR 02, 1986

N70169 001

APR 02, 1986

/100MG/

/250MG/

/500MG/

100MG

250MG

500MG

100MG

250MG

500MG

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

/AT/ /VENAC/ /NMC/ /0.1% /

TRIAMCINOLONE ACETONIDE

AT NMC 0.1% /

/AT/ /PHARM/BASICS/ /0.025% /

/AT/ /0.1% /

/AT/ /0.5% /

3 PHARM BASICS 0.025% /

3 0.1% /

3 0.5% /

TRIAMCINOLONE DIACETATE

INJECTABLE; INJECTION

/BP/ /LEMION/ /STERIS /40MG/ML /40MG/ML

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

> DLT > /BP/ /BOLAR/ /4MG/ /4MG/

> ADD > 3 BOLAR

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

> DLT > /AB/ /BOLAR/ /EQ 1MG BASE/

> DLT > /AB/ /BOLAR/ /EQ 2MG BASE/

> DLT > /AB/ /BOLAR/ /EQ 5MG BASE/

> DLT > /AB/ /BOLAR/ /EQ 10MG BASE/

> ADD > 3 BOLAR

> ADD > 3

> ADD > 3

> ADD > 3

> ADD > /AB/ /BOLAR/ /EQ 1MG BASE/

> ADD > /AB/ /BOLAR/ /EQ 2MG BASE/

> ADD > /AB/ /BOLAR/ /EQ 5MG BASE/

> ADD > /AB/ /BOLAR/ /EQ 10MG BASE/

> ADD > B* DURAMED

> ADD > B*

> ADD > B*

> ADD > B*

/N85975/001/ JUN/23, 1988 /

/N85976/001/ JUN/23, 1988 /

/N85973/001/ JUN/23, 1988 /

/N88710/001/ JUN/23, 1988 /

/N88967/001/ APR/23, 1985 /

/N88968/001/ APR/23, 1985 /

/N88969/001/ APR/23, 1985 /

/N88970/001/ APR/23, 1985 /

N88967 001

APR 23, 1985

N88968 001

APR 23, 1985

N88969 001

APR 23, 1985

N88970 001

APR 23, 1985

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHEXYPHENIDYL HCL

> DLT > /AA/ /BOLAR/ /2MG/

> DLT > /AA/ /BOLAR/ /5MG/

> ADD > 3 BOLAR

> ADD > 3

/N85117/001/ /N85105/001/ N85117 001 N85105 001

APR 23 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

TRIMEPRAZINE TARTRATE

SYRUP; ORAL

TENARIL

/AB/ /HERBERT/
HERBERT

/AB/ /TRIMEPRAZINE TARTRATE/
/PHARM/BASICS/

/EQ 2.5MG BASE/5ML/
EQ 2.5MG BASE/5ML

/EQ 2.5MG BASE/5ML/
EQ 2.5MG BASE/5ML

/N11316/003/
N11316 003

/N86285/001/
/APR/11./1985/
N86285 001
APR 11, 1985

IRISULFAPYRIMIDINES

SUSPENSION; ORAL

/AB/ /SULFONE/
/MYETH/AYERST/
@ MYETH AYERST

/500MG/5ML/
500MG/5ML

/N80013/002/
N80013 002

TABLET; ORAL

/AB/ /SULFONE/
/MYETH/AYERST/
@ MYETH AYERST

/500MG/
500MG

/N80013/001/
N80013 001

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

/AB/ /SOLOPAK/

@ SOLOPAK

/100MG/ML/
100MG/ML

/N89043/001/
/APR/04./1986/
N89043 001
APR 04, 1986

VALPROIC ACID

CAPSULE; ORAL

VALPROIC ACID
SCHERER

> -ADD > AB
> -ADD >

250MG

N73229 001
OCT 29, 1991

TRIMIPRAMINE MALEATE

CAPSULE; ORAL

TRIMIPRAMINE MALEATE

/AB/ /PHARM/BASICS/

/AB/ /PHARM/BASICS/

/AB/ /PHARM/BASICS/

B* PHARM BASICS

B* PHARM BASICS

B* PHARM BASICS

/EQ 25MG BASE/
EQ 25MG BASE

/EQ 50MG BASE/
EQ 50MG BASE

/EQ 100MG BASE/
EQ 100MG BASE

/N71283/001/
/DEC/08./1987/
N71283 001
DEC 08, 1987

/N71284/001/
/DEC/08./1987/
N71284 001
DEC 08, 1987

/N85510/001/
N85510 001
N85510/001/
N85510 001

TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

TRIPROLIDINE HCL

/AB/ /DANBURY/
DANBURY

/AB/ /VITARINE/
@ VITARINE

/2.5MG/
2.5MG
/2.5MG/
2.5MG

/N70421/001/
N70421 001
SEP 17, 1986

/N70422/001/
N70422 001
SEP 17, 1986

N19152 003
MAR 06, 1991

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

/AB/ /CALAB/
/SEARLE/

@ SEARLE

/2.5MG/ML/
2.5MG/ML

/N18925/001/
/MAR/30./1984/
N18925 001
MAR 30, 1984

VERAPAMIL HCL

/AB/ /SOLOPAK/

@ SOLOPAK

/2.5MG/ML/
2.5MG/ML

/N70697/001/
/JUL/31./1987/
N70697 001
JUL 31, 1987

TABLET; ORAL

VERAPAMIL HCL
CHELSEA

B*

80MG

B*

120MG

/BX/

/2.5MG/

N70421 001
SEP 17, 1986

N70422 001
SEP 17, 1986

/N70421/001/
/SEP/17./1986/

/N70422/001/
/SEP/17./1986/

VITAMIN A PALMITATE

capsule; oral

VI-000-A/
/MILES/
3 MILES

EQ 50,000 UNITS BASE/
EQ 50,000 UNITS BASE N80972 001/
N80972 001

MARFARIN SODIUM

TABLET; ORAL
MARFARIN SODIUM

DLT > /BX/ /BOLAR/
> DLT > /BX/
> ADD > 3 BOLAR
> ADD >
> ADD >

/2MG/
/2.5MG/
/5MG/
/7.5MG/
/10MG/
2MG
2.5MG
5MG
7.5MG
10MG
N86123 001
AUG 17, 1982
N86120 001
AUG 17, 1982
N86119 001
AUG 17, 1982
N86118 001
AUG 17, 1982
N86122 001
AUG 17, 1982
N86123 001
AUG 17, 1982
N86120 001
AUG 17, 1982
N86119 001
AUG 17, 1982
N86118 001
AUG 17, 1982
N86122 001
AUG 17, 1982
N86123 001
AUG 17, 1982
N86120 001
AUG 17, 1982
N86119 001
AUG 17, 1982
N86118 001
AUG 17, 1982
N86122 001
AUG 17, 1982

XYLOSE

POWDER; ORAL
XYLO-PEFAN

AA ADRIA
AA XYLOSE
LYNE
/3/

25GM/BOT
/25GM/BOT/
25GM/BOT
/25GM/BOT/
N17605 001
/N17605/001/
N18856 001
MAR 26, 1987
/N18856/001/
/MAR/26/1987/

ADRIA LIBRARY

ACETAMINOPHEN

SUPPOSITORY; RECTAL

*/TYLONDY/
/MCNEIL/
a MCNEIL
a*
*/120MG/
/650MG/
120MG
650MG*

*/N17756/002/
/N17756/001/
N17756 002
N17756 001*

25MG#

N88900 002
FEB 12, 1988

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
EXIDINE

*/a/XITRIUM/
/2%/
2%*

XTRTRIUM

MICRODERM

JOHNSON AND JOHNSON 4/2#

*/N19422/001/
/DEC/17,1985/
N19422 001
DEC 17, 1985*

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL

ADVIL COLD AND SINUS
WHITEHALL

200MG;30MG

N19771 001
SEP 19, 1989

Sponge; TOPICAL
MICRODERM

JOHNSON AND JOHNSON 4/2#

*/COADVYL/
/WHITEHALL/
/200MG;30MG/
N72295 001
FEB 28, 1991*

*/N19771/001/
/SEP/19,1989/*

CLOTRIMAZOLE

CREAM; TOPICAL
MYCELEX

MILES 1/2#

*N18183 002
APR 01, 1991*

100UNITS/ML#

N19938 001
JUN 25, 1991

SOLUTION; TOPICAL
MYCELEX

MILES 1/2#

*N18181 002
APR 01, 1991*

INSULIN BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION

NOVOLIN R
NOVO NORDISK

100UNITS/ML#

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION

NOVOLIN 70/30
NOVO NORDISK

30UNITS/ML;70UNITS/ML#

N19991 001
JUN 25, 1991

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
DISOBROM
GENEVA

6MG;120MG#

*N70770 001
SEP 30, 1991*

INJECTABLE; INJECTION
INSULIN

*/NOVO/NORDISK/
a NOVO NORDISK*

*/40 UNITS/ML/
40 UNITS/ML*

*/N17926/001/
N17926 001*

INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN N
NOVO NORDISK

100UNITS/MLM

N19959 001
JUL 01, 1991

INSULIN ZINC SUSP BEEF

INJECTABLE; INJECTION
LENTE INSULIN
/Novo/Nordisk/
a NOVO NORDISK

/40 UNITS/ML/
40 UNITS/ML

/N17998/001/
N17998 001

INSULIN ZINC SUSP BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN L
NOVO NORDISK

100UNITS/MLM

N19965 001
JUN 25, 1991

MICONAZOLE NITRATE

CREAM; VAGINAL
MONISTAT 7
JOHNSON RM

2/m

N17450 002
FEB 15, 1991

SUPPOSITORY; VAGINAL
MONISTAT 7
JOHNSON RM

100MGm

N18520 002
FEB 15, 1991

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR
BURROUGHS WELLCOME

120MGm

N73585 001
OCT 31, 1991

>_ADD_>
>_ADD_>
>_ADD_>
>_ADD_>

NOV 1991

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '91 - OCT '91

HETASTARCH 6% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

INJECTABLE; INJECTION
HESPAN
DUPONT MERCK
PHARM
6GM/100ML; 0.9GM/100ML
N890105
APR 04, 1991

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

INJECTABLE; INJECTION
PENTASPAN
DUPONT MERCK
PHARM
10GM/100ML; 0.9GM/100ML
N890104
APR 04, 1991

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALPHA-GALACTOSIDASE A TRADE: CC-GALACTOSIDASE	TREATMENT OF ALPHA-GALACTOSIDASE A DEFICIENCY. (FABRY'S DISEASE).	DAVID H. CALHOUN, PH.D. CITY COLLEGE OF NEW YORK
GENERIC: ANTIVENOM (CROTALIDAE) PURIFIED (AVIAN) TRADE: NOT ESTABLISHED	TREATMENT OF ENVENOMATION BY POISONOUS SNAKES BELONGING TO THE CROTALIDAE FAMILY.	OPHIDIAN PHARMA
GENERIC: BOTULINUM TOXIN TYPE A TRADE: OCULINUM*/**	TREATMENT OF STRABISMUS ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE). */** [DEC 29, 1996] TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE). */** [DEC 29, 1996] TREATMENT OF CERVICAL DYSTONIA.	ALLERGAN

APPROVED

ORPHAN DRUG PRODUCT DESIGNATIONS
BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CLOSTRIDIUM BOTULINUM TYPE F NEUROTOXIN TRADE: NOT ESTABLISHED	TREATMENT OF SPASMODIC TORTICOLLIS.	PORTON PRODUCTS LIMITED
GENERIC: CHIMERIC M-T412 (HUMAN-MURINE) IGG MONOCLONAL ANTI-CD4 ANTIBODY TRADE: NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.	CENTOCOR, INC
GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TRADE: NOT ESTABLISHED	USE IN CONJUNCTION WITH GANCICLOVIR SODIUM FOR THE TREATMENT OF CYTOMEGALOVIRUS PNEUMONIA IN BONE MARROW TRANSPLANT PATIENTS.	MILES, INC
GENERIC: EPOETIN ALPHA (RECOMBINANT-HUMAN) TRADE: EPOGEN**/**	TREATMENT OF ANEMIA ASSOCIATED WITH HIV INFECTION OR HIV TREATMENT. [TREATMENT OF AZT-INDUCED ANEMIA IN HIV INFECTED PATIENTS.*/**] [DEC 31, 1997]	AMGEN
GENERIC: FILGRASTIM TRADE: NEUPOGEN	TREATMENT OF PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) WHO, IN ADDITION, ARE AFFECTED WITH CYTOMEGALOVIRUS RETINITIS (CMV RETINITIS) AND ARE BEING TREATED WITH GANCICLOVIR.	AMGEN, INC
GENERIC: HUMAN MONOCLONAL ANTIBODY AGAINST HEPATITIS B VIRUS TRADE: NOT ESTABLISHED	PROPHYLAXIS OF HEPATITIS B REINFECTION IN PATIENTS UNDERGOING LIVER TRANSPLANTATION SECONDARY TO END-STAGE CHRONIC HEPATITIS B INFECTION.	SANDOZ PHARMACEUTICALS CORPORATION
GENERIC: INSULIN-LIKE GROWTH FACTOR-1 TRADE: MYOTROPHIN	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	CEPHALON, INC
GENERIC: INTERFERON (RECOMBINANT, BETA) TRADE: R-IFN-BETA	SYSTEMIC TREATMENT OF METASTATIC RENAL CELL CARCINOMA. SYSTEMIC TREATMENT OF CUTANEOUS T-CELL LYMPHOMA. SYSTEMIC TREATMENT OF CUTANEOUS MALIGNANT MELANOMA. INTRALESIONAL AND/OR SYSTEMIC TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA.	BIOGEN

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: INTERLEUKIN-1 ALPHA, HUMAN RECOMBINANT TRADE: NOT ESTABLISHED	FOR THE PROMOTION OF EARLY ENGRAFTMENT IN BONE MARROW TRANSPLANTATION. FOR HEMATOPOIETIC POTENTIATION IN APLASTIC ANEMIA.	IMMUNEX CORPORATION
GENERIC: INTERLEUKIN-1 RECEPTOR ANTAGONIST, HUMAN RECOMBINANT TRADE: ANTRIL	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	SYNERGEN, INC
GENERIC: INTERLEUKIN-3, RECOMBINANT HUMAN TRADE: NOT ESTABLISHED	PROMOTION OF ERYTHROPOIESIS IN DIAMOND-BLACKFAN ANEMIA (CONGENITAL PURE CELL RED APLASIA).	IMMUNEX CORPORATION
GENERIC: MONOCLONAL ANTIBODY PM-81 TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA.	MEDAREX, INC
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	TREATMENT OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS, INC
GENERIC: MYELIN TRADE: NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.	AUTOIMMUNE, INC
GENERIC: POLY I: POLY C ₁₂ U TRADE: AMPLIGEN	TREATMENT OF RENAL CELL CARCINOMA.	HEM RESEARCH, INC
GENERIC: RECOMBINANT HUMAN DEOXYRIBONUCLEASE (RDNASE) TRADE: NOT ESTABLISHED	TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.	GENENTECH, INC
GENERIC: RECOMBINANT SECRETORY LEUCOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL ALPHA-1 ANTITRYPSIN DEFICIENCY. TREATMENT OF CYSTIC FIBROSIS.	SYNERGEN, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-B4) TO B CELL (CD 19) TRADE: NOT ESTABLISHED	FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.	IMMUNOGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (N901) TO CD56 POSITIVE CELLS TRADE: NOT ESTABLISHED	TREATMENT OF SMALL CELL LUNG CANCER.	IMMUNOGEN, INC
GENERIC: SARGRAMOSTIM TRADE: LEUKINE*/**	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS IN PATIENTS WITH NON-HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE AND ACUTE LYMPHOBLASTIC LEUKEMIA. [MAR 5, 1998]	IMMUNEX
GENERIC: SDZ MSL-109 TRADE: NOT ESTABLISHED	PROPHYLAXIS OF CYTOMEGALOVIRUS DISEASE IN PATIENTS UNDERGOING SOLID ORGAN TRANSPLANTATION.	SANDOZ PHARMACEUTICALS CORP
GENERIC: THYMOSIN ALPHA-1 TRADE: NOT ESTABLISHED	ADJUNCTIVE TREATMENT OF CHRONIC ACTIVE HEPATITIS B.	ALPHA 1 BIOMEDICALS, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALGLUCERASE TRADE: CEREDASE*/**	REPLACEMENT THERAPY IN PATIENTS WITH GAUCHER'S DISEASE TYPE 1. [APR 5, 1998]	GENZYME
GENERIC: BERACTANT TRADE: SURVANTA*/**	PREVENTION OF NEONATAL RESPIRATORY DISTRESS SYNDROME (RDS).*/** [JUL 1, 1998] TREATMENT OF NEONATAL RESPIRATORY DISTRESS SYNDROME (RDS).*/** [JUL 1, 1998]	ROSS
GENERIC: CALCIUM GLUCONATE GEL TRADE: H-F GEL	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	LTR PHARMACEUTICALS, INC
GENERIC: CYCLOSPORINE 2% OPHTHALMIC OINTMENT TRADE: SANDIMMUNE	TREATMENT OF PATIENTS AT HIGH RISK OF GRAFT REJECTION FOLLOWING PENETRATING KERATOPLASTY. USE IN CORNEAL MELTING SYNDROMES OF KNOWN OR PRESUMED IMMUNOLOGIC ETIOPATHOGENESIS INCLUDING MOOREN'S ULCER.	SANDOZ PHARMACEUTICALS CORP
GENERIC: CYSTEAMINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF NEPHROPATHIC CYSTINOSIS.	WARNER-LAMBERT COMPANY
GENERIC: DEFEROXAMINE AND DEXTRAN TRADE: BIO-RESCUE	TREATMENT OF ACUTE IRON POISONING.	BIOMEDICAL FRONTIERS, INC
GENERIC: DESMOPRESSIN ACETATE TRADE: DDAVP HIGH CONCENTRATION	TREATMENT OF MILD HEMOPHILIA A AND VON WILLEBRAND'S DISEASE.	RORER PHARMACEUTICAL CORP
GENERIC: DRONABINOL TRADE: MARINOL	STIMULATION OF APPETITE AND PREVENTION OF WEIGHT LOSS IN PATIENTS WITH A CONFIRMED DIAGNOSIS OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	UNIMED, INC
GENERIC: ETIDRONATE DISODIUM TRADE: DIDRONEL	PREVENTION OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION. TREATMENT OF DEGENERATIVE METABOLIC BONE DISEASE OCCURRING IN PATIENTS WHO REQUIRE LONG TERM (6 MONTHS OR GREATER) TOTAL PARENTERAL NUTRITION.	MGI PHARMA, INC

ORPHAN DRUG PRODUCT DESIGNATIONS
DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: FLUDARABINE PHOSPHATE TRADE: FLUDARA*/**	TREATMENT OF REFRACTORY B-CELL CHRONIC LYMPHOCYTTIC LEUKEMIA. [APR 18, 1998]	BERLEX
GENERIC: FOSPHENYTOIN TRADE: NOT ESTABLISHED	ACUTE TREATMENT OF PATIENTS WITH STATUS EPILEPTICUS OF THE GRAND MAL TYPE.	WARNER-LAMBERT COMPANY
GENERIC: GALLIUM NITRATE TRADE: GANITE*/**	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY. [JAN 17, 1998]	FUJISAWA PHARM
GENERIC: GENTAMICIN IMPREGNATED PMMA BEADS ON SURGICAL WIRE TRADE: SEPTOPAL	TREATMENT OF CHRONIC OSTEOMYELITIS OF POST-TRAUMATIC, POSTOPERATIVE OR HEMATOGENOUS ORIGIN.	E. MERCK, DARMSTADT
GENERIC: HISTRELIN TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE INTERMITTENT PORPHYRIA, HEREDITARY COPROPORPHYRIA, AND VARIEGATE PORPHYRIA.	KARL E. ANDERSON, M.D. UNIVERSITY OF TEXAS
GENERIC: IDARUBICIN HCL TRADE: IDAMYCIN	TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PEDIATRIC PATIENTS.	ADRIA
GENERIC: KETOCONAZOLE TRADE: NOT ESTABLISHED	FOR USE WITH CYCLOPORIN A TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORIN IN ORGAN TRANSPLANTATION.	PHARMEDIC COMPANY
GENERIC: L-LEUCOVORIN CALCIUM TRADE: ISOVORIN	USE IN CONJUNCTION WITH HIGH-DOSE METHOTREXATE IN THE TREATMENT OF OSTEOSARCOMA.	LEDERLE LABORATORIES
GENERIC: LODOXAMIDE TROMETHAMINE TRADE: ALOMIDE	TREATMENT OF VERNAL KERATOCONJUNCTIVITIS.	ALCON LABORATORIES, INC
GENERIC: METRONIDAZOLE TRADE: METROGEL	TREATMENT OF PERIORAL DERMATITIS.	CURATEK PHARMACEUTICALS
GENERIC: NIFEDIPINE TRADE: NOT ESTABLISHED	TREATMENT OF INTERSTITIAL CYSTITIS.	JONATHAN FLEISCHMANN, M.D. CLEVELAND METROHEALTH MEDICAL CENTER

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: OFLOXACIN TRADE: NOT ESTABLISHED	TREATMENT OF BACTERIAL CORNEAL ULCERS.	ALLERGAN, INC
GENERIC: OM 401 TRADE: DREPANOL	PROPHYLACTIC TREATMENT OF SICKLE CELL DISEASE.	OMEX INTERNATIONAL, INC
GENERIC: OXANDROLONE TRADE: OXANDRIN	ADJUNCTIVE THERAPY FOR AIDS PATIENTS SUFFERING FROM HIV-WASTING SYNDROME.	GYNEX, INC
GENERIC: PENTOSTATIN TRADE: NIPENT*/**	TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA. TREATMENT OF HAIRY CELL LEUKEMIA. (SINGLE AGENT TREATMENT FOR ADULT PATIENTS WITH ALPHA-INTERFERON-REFRACTORY HAIRY CELL LEUKEMIA.*/** [OCT 11, 1998])	PARKE-DAVIS
GENERIC: POLOXAMER 331 TRADE: PROTOX	INITIAL THERAPY OF TOXOPLASMOSES IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BURROUGHS WELLCOME COMPANY
GENERIC: RECOMBINANT HUMAN SUPEROXIDE DISMUTASE TRADE: NOT ESTABLISHED	PREVENTION OF BRONCHOPULMONARY DYSPLASIA IN PREMATURE NEONATES WEIGHING LESS THAN 1500 GMS.	BIO TECHNOLOGY GENERAL CORP
GENERIC: RIBAVIRIN TRADE: VIRAZOLE	TREATMENT OF HEMORRHAGIC FEVER WITH RENAL SYNDROME.	ICN PHARMACEUTICALS, INC
GENERIC: SUCCIMER TRADE: CHEMET*/**	TREATMENT OF LEAD POISONING IN CHILDREN.*/** [JAN 30, 1998] TREATMENT OF MERCURY INTOXICATION.	MCNEIL
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL ULCERATIONS AND DYSPHAGIA IN PATIENTS WITH EPIDERMOLYSIS BULLOSA.	NASKA PHARMCAL CO
GENERIC: TESTOSTERONE PROPIONATE TRADE: NOT ESTABLISHED	TREATMENT OF VULVAR DYSTROPHIES.	STAR PHARMACEUTICALS, INC
GENERIC: TESTOSTERONE SUBLINGUAL TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY IN BOYS.	GYNEX, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: TIRATRICOL TRADE: TRIACANA	USE IN COMBINATION WITH LEVO-THYROXINE TO SUPPRESS THYROID STIMULATING HORMONE (TSH) IN PATIENTS WITH WELL-DIFFERENTIATED THYROID CANCER WHO ARE INTOLERANT TO ADEQUATE DOSES OF LEVO-THYROXINE ALONE.	MEDGENIX GROUP
GENERIC: TOREMIFENE TRADE: NOT ESTABLISHED	HORMONAL THERAPY OF METASTATIC CARCINOMA OF THE BREAST.	ADRIA LABORATORIES, INC
GENERIC: URSODEOXYCHOLIC ACID TRADE: ACTIGALL	MANAGEMENT OF THE CLINICAL SIGNS AND SYMPTOMS ASSOCIATED WITH PRIMARY BILIARY CIRRHOSIS.	CIBA GEIGY
GENERIC: URSODEOXYCHOLIC ACID TRADE: URSOFALK	TREATMENT OF PATIENTS WITH PRIMARY BILIARY CIRRHOSIS.	INTERFALK U.S., INC
GENERIC: 3,4 DIAMINOPYRADINE TRADE: DYNAMINE	TREATMENT OF HEREDITARY MOTOR AND SENSORY NEUROPATHY TYPE I (CHARCOT-MARIE-TOOTH DISEASE).	MAYO CLINIC
GENERIC: 6-METHYLENANDROSTA-1,4-DIENE-3,17-DIONE TRADE: NOT ESTABLISHED	HORMONAL THERAPY OF METASTATIC CARCINOMA OF THE BREAST.	ADRIA LABORATORIES, INC
GENERIC: 566C80 TRADE: NOT ESTABLISHED	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN HIGH-RISK, HIV-INFECTED PATIENTS DEFINED BY ONE OR BOTH OF THE FOLLOWING CRITERIA: (1) A HISTORY OF ONE OR MORE EPISODES OF PCP, (2) A PERIPHERAL CD4+ (T4 HELPER/INDUCER) LYMPHOCYTE COUNT LESS THAN OR EQUAL TO 200/MM ³ .	BURROUGHS WELLCOME COMPANY

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 278, 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, 11TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)

DATE

REVISED DATE

ESTROGENS, CONJUGATED (TABLET)

AUG 21, 1991

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, 11TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED					
DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CARBAMAZEPINE SUSPENSION; ORAL	200MG/5ML	89 P-0399/CP	GUIDELINES	NEW DOSAGE FORM	APPROVED MAY 16, 1991
CLOBETASOL PROPIONATE LOTION; TOPICAL	0.05%	90 P-0198/ CP1	KROSS	NEW DOSAGE FORM	APPROVED MAR 14, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/VIAL	90 P-0250/ CP1	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	200MG/VIAL	90 P-0250/ CP2	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/VIAL	90 P-0250/ CP3	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	1GM/VIAL	90 P-0250/ CP4	PHARMACHEMIE	NEW DOSAGE FORM	APPROVED MAY 07, 1991
CYTARABINE INJECTABLE; INJECTION	20MG/ML (100ML/CONTAINER)	86 P-0428/ CP005	ADRIA	NEW DOSAGE FORM	APPROVED OCT 28, 1991
DOPAMINE HYDROCHLORIDE INJECTABLE; INJECTION	5MG/ML	90 P-0137/ CP1	ABBOTT	NEW STRENGTH	APPROVED APR 10, 1991

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (25ML/VIAL)	91 P-0041/ CP1	ADRIA	NEW STRENGTH	APPROVED MAY 22, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.067MG/24HR	90 P-0125/ CP1	NOVEN PHARMS	NEW STRENGTH	APPROVED MAR 14, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.084MG/24HR	90 P-0125/ CP2	NOVEN PHARMS	NEW STRENGTH	APPROVED MAR 14, 1991
NIFEDIPINE CAPSULE, EXTENDED RELEASE; ORAL	30MG 50MG 90MG	90 P-0436/ CP1	KV	NEW DOSAGE FORM	APPROVED OCT 23, 1991
PANCURONIUM BROMIDE INJECTABLE; INJECTION	0.1MG/ML	91 P-0006/ CP1	LYPHOMED	NEW STRENGTH	APPROVED OCT 28, 1991
TECHNETIUM Tc99 MEDRONATE KIT INJECTABLE; INJECTION	N/A	91 P-0040/ CP1	ABARIS	NEW STRENGTH	APPROVED OCT 28, 1991
TERFENADINE CAPSULE; ORAL	60MG	91 P-0087 CP1	ARTHUR A. CHECCHI	NEW DOSAGE FORM	APPROVED OCT 28, 1991

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
FUROSEMIDE INJECTABLE; INJECTION	1MG/ML	90 P-0313/ CPI	LYPHOMED	NEW STRENGTH	DENIED OCT 28, 1991

APPROVED 10/28/91

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, 11TH 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

1-55	HYPERTENSION
1-56	EROSIVE GASTROESOPHAGEAL REFLUX DISEASE
1-57	SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER
1-58	INITIAL TREATMENT OF ADVANCED OVARIAN CARCINOMA IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC AGENTS
1-59	ENDOSCOPICALLY DIAGNOSED ESOPHAGITIS, INCLUDING EROSIVE AND ULCERATIVE ESOPHAGITIS, AND ASSOCIATED HEARTBURN DUE TO GASTROESOPHAGEAL REFLUX DISEASE
1-60	SINGLE APPLICATION TREATMENT OF HEAD LICE IN CHILDREN TWO MONTHS TO TWO YEARS IN AGE
1-61	FEMALE ANDROGENETIC ALOPECIA
1-62	PREVENTION AND TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS.
1-63	ONCE DAILY TREATMENT AS INITIAL THERAPY IN THE TREATMENT OF HYPERTENSION.
1-64	PREVENTION OF SUPRAVENTRICULAR ARRHYTHMIAS.

REFERENCES
PATENT USE CODE

U-44	RELIEF OF NAUSEA AND VOMITING
U-45	TREATMENT OF INFLAMMATION AND ANALGESIA
U-46	TREATMENT OF PANIC DISORDER
U-47	STIMULATION OF THE RELEASE OF GROWTH HORMONE
U-48	ANALGESIA
U-49	SYMPTOMATIC CANCER-RELATED HYPERCALCEMIA
U-50	USE IN TREATING INFLAMMATORY DERMATOSES
U-51	BLOOD POOL IMAGING, INCLUDING FIRST PASS AND GATED EQUILIBRIUM IMAGING AND FOR DETECTION OF SITES OF GASTROINTESTINAL BLEEDING
U-52	TREATMENT OF ADULT AND PEDIATRIC PATIENTS (OVER SIX MONTHS OF AGE) WITH ADVANCED HIV INFECTION
U-53	HYPERCALCEMIA OF MALIGNANCY

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
20089 001	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997			
20089 002	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997		NCE	APR 05, 1996
20057 003	ALGLUCERASE; CEREDASE				ODE	APR 05, 1998
18276 001	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
18276 002	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
18276 003	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
18276 004	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
		3980789	SEP 14, 1993			
19926 001	ALTRETAMINE; HEXALEN				ODE	DEC 26, 1997
19155 001	AMMONIUM LACTATE; LAC-HYDRIN	4105783	OCT 26, 1995			
18700 001	AMRINONE LACTATE; INOCOR	4072746	APR 23, 1998			
19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000	U-7	NCE	JUL 31, 1994
19851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
19851 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
19851 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
20032 001	BERACTANT; SURVANTA	4397839	AUG 10, 2000		NCE	JUL 01, 1996
18709 001	CAPTOPRIL; CAPOZIDE 25/15				I-63	OCT 24, 1994
18709 002	CAPTOPRIL; CAPOZIDE 25/25				I-63	OCT 24, 1994
18709 003	CAPTOPRIL; CAPOZIDE 50/25				I-63	OCT 24, 1994
18709 004	CAPTOPRIL; CAPOZIDE 50/15				I-63	OCT 24, 1994
19856 001	CARBIDOPA; SINEMET CR	4900755	MAY 23, 2006			
		4832957	MAY 23, 2006			
		3830827	AUG 20, 1991			
19880 001	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		NDF	MAY 30, 1994
19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		I-58	JUL 05, 1994
19880 003	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998		I-58	JUL 05, 1994
20044 001	CETYL ALCOHOL; EXOSURF NEONATAL	4312860	NOV 23, 2001		NC	AUG 02, 1993
17920 002	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
17920 004	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
17920 005	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		I-56	MAR 07, 1994
19849 001	DAPIPRAZOLE HYDROCHLORIDE; REV-EYES	4605671	FEB 24, 1998		I-56	MAR 07, 1994
19082 001	DEZOCINE; DALGAN	4001331	AUG 12, 2003		NCE	DEC 31, 1995
		3836670	JAN 04, 1996			
			SEP 09, 1991	U-48		

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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
19082 002	DEZOCINE; DALGAN	4605671	AUG 12, 2003		NCE	DEC 29, 1994
		4001331	JAN 04, 1996	U-48		
		3836670	SEP 09, 1991			
19082 003	DEZOCINE; DALGAN	4605671	AUG 12, 2003		NCE	DEC 29, 1994
		4001331	JAN 04, 1996	U-48		
		3836670	SEP 09, 1991			
20037 001	DICLOFENAC SODIUM; VOLTAREN	4960779	OCT 02, 2007			
		3652762	MAR 28, 1991		NDF	MAR 28, 1994
20154 002	DIDANOSINE; VIDEX	4861759	AUG 29, 2006	U-52	NCE	OCT 09, 1996
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20027 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM	4988731	JAN 29, 2008		NDF	OCT 24, 1994
20027 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM	4988731	JAN 29, 2008		NDF	OCT 24, 1994
18723 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
18723 002	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
18723 003	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
19680 001	DIVALPROEX SODIUM; DEPAKOTE	4988731	JAN 29, 2008			
19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	4988731	JAN 29, 2008			
19946 001	DOXACURIUM CHLORIDE; NUROMAX	4701460	OCT 20, 2004		NCE	MAR 07, 1996
19668 001	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1999		NCE	NOV 02, 1995
19668 002	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1999		NCE	NOV 02, 1995
19668 003	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1999		NCE	NOV 02, 1995
19668 004	DOXAZOSIN MESYLATE; CARDURA	4188390	FEB 12, 1999		NCE	NOV 02, 1995
19080 001	ESTAZOLAM; PROSOM	3987052	OCT 19, 1995			
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19081 002	ESTRADIOL; ESTRADERM	4027019	MAY 31, 1996		I-62	OCT 24, 1994
19081 003	ESTRADIOL; ESTRADERM	4027019	MAY 31, 1996		I-62	DEC 24, 1994
19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996		NC	DEC 29, 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
18922 002	ET000LAC; L00INE	4076831	FEB 28, 1995	U-45	NCE	JAN 31, 1996
18922 003	ET000LAC; L00INE	3939178	FEB 17, 1993			
		4076831	FEB 28, 1995	U-45		
19834 001	FELODIPINE; PLENDIL	3939178	FEB 17, 1993			
19834 002	FELODIPINE; PLENDIL	4264611	APR 28, 1998			
18830 001	FLECAINIDE ACETATE; TAMBOCOR	4262611	APR 28, 1998			
18830 003	FLECAINIDE ACETATE; TAMBOCOR					
18830 004	FLECAINIDE ACETATE; TAMBOCOR					
19949 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003			
19949 002	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003			
19949 003	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003			
19950 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003			
20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 1999			
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001			
19957 001	FLUTICASON PROPIONATE; CUITIVATE	4335121	MAR 16, 2002			
19957 002	FLUTICASON PROPIONATE; CUITIVATE	4335121	MAR 16, 2002			
19958 001	FLUTICASON PROPIONATE; CUITIVATE	4335121	MAR 16, 2002			
19958 002	FLUTICASON PROPIONATE; CUITIVATE	4335121	MAR 16, 2002			
20068 001	FOSCARNET SODIUM; FOSCAVIR	4384123	MAY 17, 2000			
19915 002	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 1999			
19915 003	FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000			
19961 002	GALLIUM NITRATE; GANITE	4337201	JUN 29, 1999	U-49		
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	DEC 17, 2004			
19967 002	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	DEC 17, 2004			
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	DEC 17, 2004			
19968 002	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	DEC 17, 2004			
19784 001	IBUPROFEN; RUFEN	4239747	DEC 16, 1999			
19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 1999			
19580 002	IOTROLAN; OSMOVIST	4466972	AUG 21, 2001	U-3		
19546 001	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3		
19546 002	ISRADIPINE; DYNACIRC	4466972	AUG 21, 2001	U-3		

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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
18631 001	PENTOXIFYLLINE; TRENTAL	3737433	APR 03, 1997		NCE	AUG 30, 1994
19456 001	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19456 002	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19797 001	POLYETHYLENE GLYCOL 3350; NULYTELY				NP	APR 22, 1994
19898 002	PRAVASTATIN SODIUM; PRACHOL	4346227	AUG 24, 1999		NCE	OCT 31, 1996
19898 003	PRAVASTATIN SODIUM; PRACHOL	4346227	AUG 24, 1999		NCE	OCT 31, 1996
19568 001	PREDNICARBATE; DERMATOP	4242334	DEC 30, 1997	U-50	NE	SEP 23, 1994
19627 001	PROPOFOL; DIPRIVAN	4056635	NOV 01, 1996		NCE	OCT 02, 1994
19664 001	PSEUDOEPHEDRINE HYDROCHLORIDE; SELDANE-D	3878217	APR 15, 1994		NC	AUG 19, 1994
19901 001	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 002	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 003	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 004	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19863 001	SERMORELIN ACETATE; GEREFF	4703035	MAY 14, 2002	U-47	NCE	DEC 28, 1995
19998 002	SUCCIMER; CHEMET	4517181	MAY 14, 2002		NCE	DEC 28, 1995
19981 001	TECHNETIUM TC-99M RED BLOOD CELL KIT; ULTRATAG	4755375	JUL 05, 2005	U-51	NC	JUN 10, 1994
19785 001	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	SEP 09, 2004		NCE	DEC 21, 1995
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19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4051141	SEP 27, 1994		NCE	OCT 31, 1996
19798 001	TRIAMCINOLONE ACETONIDE; NASACORT	4051141	SEP 27, 1994		NR	JUL 11, 1994

