

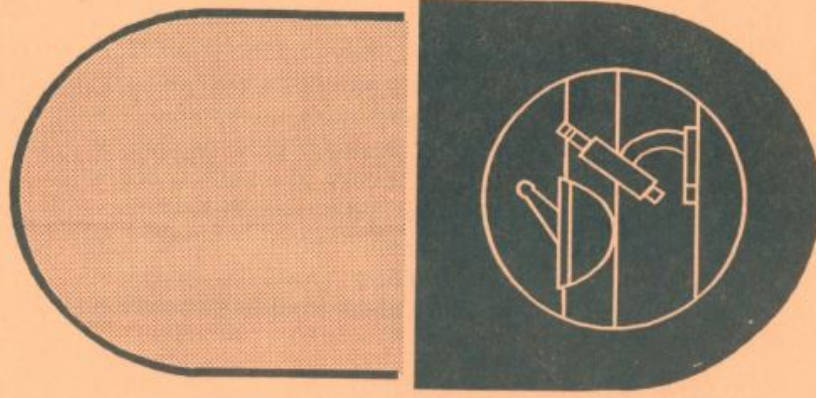
**CUMULATIVE
SUPPLEMENT 12**

JAN'91-DEC'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

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

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New 12th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**12TH EDITION
1992**

CONTENTS

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

11TH EDITION

Cumulative Supplement

December 1991

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

11TH EDITION

CUMULATIVE SUPPLEMENT 12

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

1.3 CHANGE OF A THERAPEUTIC EQUIVALENCY CODE FOR A DRUG ENTITY

Methylphenidate Hydrochloride:

In Cumulative Supplement 4 of the Approved Drug Products with Therapeutic Equivalence Evaluations, 11th Edition, the Agency proposed to change the therapeutic equivalence code for methylphenidate hydrochloride oral tablets from a drug product not presenting a bioequivalence problem **AA** to a drug product with a potential bioequivalence problem **BP**.

The Agency solicited comments from interested persons to be received no later than 60 days from the first day in Cumulative Supplement 4 or April 1, 1991. The proposal did not elicit any comments from the readers.

The therapeutic equivalence code for the drug entity in this dosage form will be changed to reflect it has a potential for a bioequivalence problem. An acceptable bioequivalence study, among other things, will be required before an approval is granted for a methylphenidate tablet application.

As mentioned in the 4th Cumulative Supplement proposal for a change in the code for methylphenidate hydrochloride oral tablets, the Agency commissioned a bioequivalence study under its extramural contract research program to study the two approved methylphenidate oral immediate-release tablets. The study demonstrated that the two drug products were bioequivalent. This supplement will reflect that finding by coding the two products as **AB**.

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 or B 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
FOREST LABORATORIES INC	FOREST LABORATORIES INC	FOREST LABS
FOREST PHARMACEUTICALS INC	FOREST PHARMACEUTICALS INC	FOREST PHARMS
GIST BROCADES	BROCADES PHARMA bv	BROCADES PHARMA
ICI PHARMACEUTICALS PR INC	IPR PHARMACEUTICALS INC	IPR
KENDALL MCGAW PHARMACEUTICALS	GENSIA PHARMACEUTICALS INC	GENSIA

APPLICANT (NAME) CHANGES

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>ABBREVIATED NAME</u>
PHARMACIA LABORATORIES DIV PHARMACIA INC	KABI PHARMACIA	KABI
REID ROWELL INC	SOLVAY PHARMACEUTICALS	SOLVAY

1.6 REVISED TRADE NAME SELECTION CRITERIA

The following is a revision to the main volume of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 11th Edition's Section 1.4, Practitioner's Responsibilities.

To relate trade name (proprietary name) information on a product label to that on the List, the following should be noted: if the applicant is the marketer, its name appears on the List and on the label; if the Agency is aware of a corporate relationship between the applicant and the marketer, the trade name (proprietary name) of the drug product (established drug name if no trade name exists) appears on the List. If a corporate relationship exists between an application holder and a marketer and both firms are distributing the drug product, the FDA reserves the right to select the trade name of either the marketer or the application holder to appear on the List. If there is no known corporate relationship between the applicant and the marketer, the established drug name appears on the List.

1.7 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

CATEGORIES COUNTED	DEC 1990	JUN 1991	SEP 1991	DEC 1991
DRUG PRODUCTS LISTED	10123	9900	9869	9584
SINGLE SOURCE	2030 (20.1%)	2110 (21.3%)	2103 (21.4%)	2187 (22.8%)
MULTISOURCE	8093 (79.9%)	7790 (78.7%)	7766 (78.6%)	7397 (77.2%)
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	6937 (70.1%)	6914 (70.0%)	6580 (68.7%)
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	702 (7.1%)	706 (7.2%)	664 (6.9%)
EXCEPTIONS ¹	119 (1.2%)	151 (1.5%)	146 (1.4%)	153 (1.6%)
NEW MOLECULAR ENTITIES APPROVED	--	4	3	17
NUMBER OF APPLICANTS	400	417	418	430

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

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

/AB/ /BOLAR/ /N70398/001/ /DEC 18, 1986/

/AB/ /BOLAR/ /N70399/001/ /DEC 18, 1986/

3 BOLAR 325MG;50MG

3 650MG;100MG

> DLT > /B* /CHELSEA/

> DLT > /B* /

> DLT > /B* /

/650MG;100MG/

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE

/AB/ /PHARM BASICS/ /N70753/001/ /NOV 03, 1986/

/AB/ /PHARM BASICS/ /N70754/001/ /NOV 03, 1986/

B* 250MG

B* 500MG

ACETOPHENAZINE MALEATE

/TABLET; ORAL/

/TINDAL/

/BP/ /SCHERING/

3 SCHERING

/20MG/

20MG

/N12254/002/

N12254 002

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

250MG

/250MG/

/250MG/

250MG

N83320 001

/N83320/001/

/N84498/002/

N84498 002

/AB/ /ALRA/

/AB/ /BOLAR/

3 BOLAR

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

/ORLEX/

/NORMICH/EATON/

3 NORMICH EATON

/N86845/001/

N86845 001

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC

/ORLEX/Hc/

/NORMICH/EATON/

3 NORMICH EATON

/N86844/001/

N86844 001

ACYCLOVIR

TABLET; ORAL

ZOVIRAX

BURROUGHS WELLCOME

400MG

800MG

N20089 001

APR 30, 1991

N20089 002

APR 30, 1991

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN COPLEY

EQ 0.5% BASE

N73307 001

NOV 27, 1991

AMILORIDE, HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

AMINOHIPPURATE SODIUM

TABLET; ORAL

ANTILORIDE HCL AND HYDROCHLOROTHIAZIDE

> DLT > /AB/	/BIORAFIT/	/5MG; 50MG/	/N70795/001/	/AP/	/MSD/	/20% /	/N05619/001/
> DLT >			/JUL/15/1987/		MSD	20% /	N05619 001
> ADD > AB	BIORAFIT	EQ 5MG ANHYDROUS; 50MG	N70795 001	/AP/	/MSD/	/20% /	/N05619/001/
> ADD >			JUL 15, 1987				/N05619/001/
> DLT > /AB/	/GENEVA/	/5MG; 50MG/	/N73357/001/		/QUAD/		/N05619/001/
> DLT >			/NOV/27/1991/				/N05619/001/
> ADD > AB	GENEVA	EQ 5MG ANHYDROUS; 50MG	N73357 001		@ QUAD	20% /	NB9821 001
> ADD >			NOV 27, 1991				JUL 14, 1988
> DLT > /AB/	/MYLAN/	/5MG; 50MG/	/N73334/001/				
> DLT >			/OCT/31/1991/				
> ADD > AB	MYLAN	EQ 5MG ANHYDROUS; 50MG	N73209 001				
> ADD >			OCT 31, 1991				
> DLT > /AB/	/ROYCE/	/5MG; 50MG/	/N73334/001/				
> DLT >			/JUL/19/1991/				
> ADD > AB	ROYCE	EQ 5MG ANHYDROUS; 50MG	N73334 001				
> ADD >			JUL 19, 1991				

HYDRO-RIDE

> DLT > /AB/	/PAR/	/5MG; 50MG/	/N70347/001/				N81142 001
> DLT >			/AUG/05/1985/				SEP 25, 1991
> ADD > AB	PAR	EQ 5MG ANHYDROUS; 50MG	N70347 001				/N87867/001/
> ADD >			AUG 06, 1986				/N05619/001/

MODURETIC 5-50

> DLT > /AB/	/MSD/	/5MG; 50MG/	/N18201/001/				/N05619/001/
> ADD > AB	MSD	EQ 5MG ANHYDROUS; 50MG	N18201 001				/N05619/001/

AMINO ACIDS

INJECTABLE; INJECTION

AMINOSYN II 10% IN PLASTIC CONTAINER

ABBOTT 10%
N20015 001
DEC 19, 1991

AMINOSYN II 15% IN PLASTIC CONTAINER

ABBOTT 15%
N20041 001
DEC 19, 1991

AMINOCAPROIC ACID

INJECTABLE; INJECTION

AMINOCAPROIC ACID

> DLT > /AB/	/QUAD/	/250MG/ML/	/N70694/001/				/N70694/001/
> DLT >			/MAR/04/1986/				/N70694/001/
> ADD > AB	QUAD	250MG/ML	N70694 001				/N70694/001/
> ADD >			MAR 04, 1986				/N70694/001/

INJECTABLE; INJECTION

AMINOPHYLLINE

AP GENSA
25MG/ML

INJECTABLE; INJECTION

AMINOPHYLLINE

AP GENSA
25MG/ML

INJECTABLE; INJECTION

AMINOPHYLLINE

AP GENSA
25MG/ML

INJECTABLE; INJECTION

AMINOPHYLLINE

AP GENSA
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INJECTABLE; INJECTION

AMINOPHYLLINE

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INJECTABLE; INJECTION

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INJECTABLE; INJECTION

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INJECTABLE; INJECTION

AMINOPHYLLINE

AP GENSA
25MG/ML

INJECTABLE; INJECTION

AMINOPHYLLINE

AP GENSA
25MG/ML

INJECTABLE; INJECTION

AMOXAPINE

TABLET; ORAL

AMOXAPINE

GENEVA

25MG

N72943 001

JUN 28, 1991

50MG

N72944 001

JUN 28, 1991

100MG

N72878 001

JUN 28, 1991

150MG

N72879 001

JUN 28, 1991

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

/INTL/NEPACATION/

/EQ 1GM BASE/VIAL/

/N62634/002/

/JAN 09, 1987/

/EQ 2GM BASE/VIAL/

/N62634/003/

/JAN 09, 1987/

/EQ 1GM BASE/VIAL/

/N62634 002

JAN 09, 1987

/EQ 2GM BASE/VIAL/

/N62634 003

JAN 09, 1987

/EQ 10GM BASE/VIAL/

/N61395 006

JAN 09, 1987

/EQ 250MG BASE/

/N60908 001

JAN 09, 1987

/EQ 500MG BASE

/N60908 002

JAN 09, 1987

/EQ 10GM BASE/VIAL/

/N61395 006

JAN 09, 1987

/EQ 250MG BASE/

/N60908 001

JAN 09, 1987

/EQ 500MG BASE

/N60908 002

JAN 09, 1987

/EQ 10GM BASE/VIAL/

/N61395 006

JAN 09, 1987

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

INJECTABLE; INJECTION

M.V.I.-12 LYOPHILIZED

ASTRA

AP

100MG/VIAL; 0.06MG/VIAL;

0.005MG/VIAL; 15MG/VIAL; 5UGM/VIAL;

0.4MG/VIAL; 40MG/VIAL; 4MG/VIAL;

3.6MG/VIAL; 3MG/VIAL; 1MG/VIAL;

10MG/VIAL

N18933 002

AUG 08, 1985

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

INJECTABLE; INJECTION/

BEROCCA/PN/

ROCHE/

AP

150MG/VIAL; 0.03MG/VIAL; 0.0025MG/VIAL;

7.5MG/VIAL; 100 IU/VIAL; 0.2MG/VIAL;

20MG/VIAL; 2MG/VIAL; 1.8MG/VIAL; 1.5MG/VIAL;

1.650 IU/VIAL; 5 IU/VIAL

N06071 003

OCT 10, 1985

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

INJECTABLE; INJECTION

M.V.I.-12

ASTRA

AP

10MG/VIAL; 0.006MG/VIAL; 0.5UGM/VIAL;

1.5MG/VIAL; 20 IU/VIAL; 0.04MG/VIAL; 4MG/VIAL;

0.4MG/VIAL; 0.3MG/VIAL; 0.3MG/VIAL;

330 UNITS /VIAL; 1 IU/VIAL

N08609 004

AUG 08, 1985

10MG/VIAL; 0.006MG/VIAL; 0.5UGM/VIAL;

1.5MG/VIAL; 20 IU/VIAL; 0.04MG/VIAL; 4MG/VIAL;

0.4MG/VIAL; 0.3MG/VIAL; 0.3MG/VIAL;

330 UNITS /VIAL; 1 IU/VIAL

N08609 004

AUG 08, 1985

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

INJECTABLE; INJECTION

MVC PLUS

/AB/ /ASCOT/

/10MG/ML; 0.006MG/ML; 0.5U/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/

AP STERIS

10MG/ML; 0.006MG/ML; 0.5U/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/
 /AB/ /CHELSEA/

/N86231/002/
 /FEB/12, 1985/

BUTALBITAL, ASPIRIN AND CAFFEINE
 CHELSEA 325MG; 50MG; 40MG

AB N86231 002
 FEB 12, 1985

TABLET; ORAL

/BUTALBITAL, W/ ASPIRIN AND CAFFEINE/
 /AB/ /CHELSEA/

/N86231/002/
 /MAR/23, 1984/

BUTALBITAL, ASPIRIN AND CAFFEINE
 CHELSEA 325MG; 50MG; 40MG

AB N86237 002
 MAR 23, 1984

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

MORGESIC

> DLT > /AB/ /34/ /385MG; 30MG; 25MG/

> DLT > /AB/ /34/ /385MG; 30MG; 25MG/

> ADD > /AB/ /34/ /385MG; 30MG; 25MG/

> ADD > /AB/ /34/ /385MG; 30MG; 25MG/

MORGESIC FORTE

> DLT > /AB/ /34/ /770MG; 60MG; 50MG/

> DLT > /AB/ /34/ /770MG; 60MG; 50MG/

> ADD > /AB/ /34/ /770MG; 60MG; 50MG/

> ADD > /AB/ /34/ /770MG; 60MG; 50MG/

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

> DLT > /AB/ /PAR/ /385MG; 30MG; 25MG/

> DLT > /AB/ /PAR/ /385MG; 30MG; 25MG/

> DLT > /AB/ /PAR/ /385MG; 30MG; 25MG/

> DLT > /AB/ /PAR/ /385MG; 30MG; 25MG/

> DLT > /AB/ /PAR/ /385MG; 30MG; 25MG/

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND 65
 389MG; 32.4MG; 65MG

389MG; 32.4MG; 65MG

389MG; 32.4MG; 65MG

389MG; 32.4MG; 65MG

389MG; 32.4MG; 65MG

ASPIRIN; CARISOPRODOL

TABLET; ORAL

> DLT > /AB/ /BOLAR/ /325MG; 200MG/

> DLT > /AB/ /BOLAR/ /325MG; 200MG/

> ADD > /AB/ /BOLAR/ /325MG; 200MG/

> ADD > /AB/ /BOLAR/ /325MG; 200MG/

ASPIRIN; MEPROBAMATE

TABLET; ORAL

> DLT > /AB/ /PAR/ /325MG; 200MG/

> DLT > /AB/ /PAR/ /325MG; 200MG/

> ADD > /AB/ /PAR/ /325MG; 200MG/

> ADD > /AB/ /PAR/ /325MG; 200MG/

ATENOLOL

TABLET; ORAL

> DLT > /AB/ /DANBURY/ /50MG/

> DLT > /AB/ /DANBURY/ /50MG/

> ADD > /AB/ /DANBURY/ /50MG/

> ADD > /AB/ /DANBURY/ /50MG/

N73352 001
 DEC 27, 1991

N73353 001
 DEC 27, 1991

/N71644/001/
 /JUN/23, 1987/

/N71643/001/
 /JUN/23, 1987/

N84553 002
 AUG 17, 1983
 /N84553/002/
 /AUG/17, 1983/

/N88809/001/
 /OCT/03, 1985/
 N88809 001
 OCT 03, 1985

/N89126/001/
 /AUG/19, 1986/
 N89126 001
 AUG 19, 1986

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

/AA/ /PHARM/BASICS/ /0.5MG/

/AA/ /1MG/

/AA/ /2MG/

B* PHARM BASICS

0.5MG

B* 1MG

B* 2MG

/N89211/001/

/JUN 14, 1988/

/N89212/001/

/JUN 14, 1988/

/N89213/001/

/JUN 14, 1988/

/N89211 001

JUN 14, 1988

N89212 001

JUN 14, 1988

N89213 001

JUN 14, 1988

BERACTANT

SUSPENSION; INTRATRACHEAL

SURVANTA

ROSS

25MG/ML

N20032 001

JUL 01, 1991

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

/BETHANECHOL CHLORIDE/

/AP/ /QUAD/ /5MG/ML/

QUAD 5MG/ML

URECHOLINE

/AP/ /MSD/ /5MG/ML/

5MG/ML

/N86536/001/

N86536 001

/N89815/001/

/APR 12, 1988/

N89815 001

APR 12, 1988

TABLET; ORAL

BETHANECHOL CHLORIDE

/AA/ /BOLAR/ /5MG/

/AA/ /10MG/

/AA/ /25MG/

/AA/ /50MG/

BOLAR

5MG

10MG

25MG

50MG

N85230 002

N85228 001

N85229 001

N87397 001

N85230 002

N85228 001

N85229 001

N87397 001

N85230 002

N85228 001

N85229 001

N87397 001

N85230 002

N85228 001

N85229 001

N87397 001

N85230 002

BETHANECHOL CHLORIDE

TABLET; ORAL

DUVOID

ROBERTS

AA

AA

AA

10MG

25MG

50MG

N86262 001

N86263 001

N85882 003

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

/AP/ /QUAD/ /50MG/ML/

50MG/ML

QUAD

50MG/ML

/N71181/001/

/FEB 16, 1988/

N71181 001

FEB 16, 1988

FEB 16, 1988

FEB 16, 1988

FEB 16, 1988

FEB 16, 1988

FEB 16, 1988

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/ /PAR/ /4MG/

4MG

PAR

4MG

/N87669/001/

N87669 001

N87669 001

N87669 001

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

/ELIXIR; ORAL/

/BIPHEN/

/PHARM/BASICS/

PHARM BASICS

4MG/5ML; 25MG/5ML

/N86687/001/

/SEP 26, 1984/

N86687 001

SEP 26, 1984

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENEX

/NORWICH/EATON/

R AND C

EQ 0.3MG BASE/ML

/N18401/001/

N18401 001

N18401 001

N18401 001

BUPROPION HYDROCHLORIDE

TABLET; ORAL

WELLBUTRIN

/BURROUGHS/ WELLCOME/ /50MG/

a BURROUGHS WELLCOME 50MG

/N18644/001/
DEC 30, 1985/DEC 30, 1985/
N18644 001

DEC 30, 1985

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

/AA/ /CORD/ /15MG/

/AA/ a CORD 15MG

/N84292/003/
FEB 09, 1982/FEB 09, 1982/
N84292 003

FEB 09, 1982

/AA/ a WHITE TONNE PAULSEN/ /15MG/

a WHITE TONNE PAULSEN 15MG

/N84272/002/
FEB 09, 1982/FEB 09, 1982/
N84272 002

FEB 09, 1982

BUTORPHANOL TARTRATE

SPRAY, METERED; NASAL

STADOL

BRISTOL MYERS SQUIBB 1MG/INH

/N19890/001/
DEC 12, 1991

DEC 12, 1991

CALCITONIN, SALMON

INJECTABLE; INJECTION

CALCTHAR

AP RHONE POULENC RORER 200 IU/ML

N17769 001

MTCALCITH

AP SANDOZ 200 IU/ML

N17808 002

MAR 29, 1991

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM
CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM
CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

BSS PLUS

ALCON

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;

0.2MG/ML; 0.38MG/ML; 2.1MG/ML;

7.14MG/ML; 0.42MG/ML N18469 001

N19856 001

MAY 30, 1991

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM
CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM
CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

ENDOSOL PLUS

AT ENTRAVISION

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;

0.2MG/ML; 0.38MG/ML; 2.1MG/ML;

7.14MG/ML; 0.42MG/ML N20079 001

NOV 27, 1991

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM
CHLORIDE/INJECTABLE; INJECTION/
/ACETATED RINGER'S/ IN PLASTIC CONTAINER/
/MCGAM/

a MCGAM

20MG/100ML; 30MG/100ML; 380MG/100ML;

600MG/100ML

N18725 001

NOV 29, 1982

CALCIUM GLUCEPATE

INJECTABLE; INJECTION

CALCIUM GLUCEPATE

/AB/ /ABBOTT/

a ABBOTT

/EQ 90MG CALCIUM/5ML/

N83159 001

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

/AB/ /PHARM BASICS/

/200MG/

B* PHARM BASICS

200MG

N70300 001

MAY 15, 1986

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL

SINEMET CR

MSD

50MG; 200MG

N19856 001

MAY 30, 1991

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

/AA/ BOLAR
350MG
AA MUTUAL PHARM

/EQ 350MG/
350MG

/N63214/001
N85433 001
N89346 001
OCT 17, 1991

CEFADROXIL

CAPSULE; ORAL

ULTRACEF

/AB/ BRISTOL

/EQ 500MG BASE/

/N63214/001
MAR 16, 1982
MAR 16, 1982

POWDER FOR RECONSTITUTION; ORAL

ULTRACEF

/AB/ BRISTOL

/EQ 125MG BASE/5ML

/EQ 250MG BASE/5ML

/EQ 500MG BASE/5ML

/N63214/001
MAR 16, 1982
MAR 16, 1982
MAR 16, 1982
MAR 16, 1982

3 BRISTOL

3

3

TABLET; ORAL

ULTRACEF

/AB/ BRISTOL

/EQ 1GM BASE/

EQ 1GM BASE

/N63214/001
AUG 31, 1982
AUG 31, 1982

3 BRISTOL

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

HANFORD

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

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

N63214 001
DEC 27, 1991
N63216 001
DEC 27, 1991
N63207 001
DEC 27, 1991
N63208 001
DEC 27, 1991
N63209 001
DEC 27, 1991

CEFPROZIL

POWDER FOR RECONSTITUTION; ORAL

CEFZIL

BRISTOL MYERS SQUIBB

125MG/5ML

250MG/5ML

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

TABLET; ORAL

CEFZIL

BRISTOL MYERS SQUIBB

250MG

500MG

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

N50664 001
DEC 23, 1991
N50664 002
DEC 23, 1991

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN MONOHYDRATE

/EQ 250MG BASE/

/EQ 500MG BASE/

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

CEPHALEXIN MONOHYDRATE
VITARINE

EQ 250MG BASE

EQ 500MG BASE

N62159 001
N62159 002

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

ANCEF IN PLASTIC CONTAINER

BAXTER

EQ 10MG BASE/ML

EQ 20MG BASE/ML

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

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

SQUIBB MARK

EQ 125MG BASE/5ML

N62986 001
APR 18, 1991

CHLORPHENIRAMINE MALEATEINJECTABLE; INJECTION

/AP/ CHLORPHENIRAMINE MALEATE /10MG/ML/
AP STERIS 10MG/ML

TABLET; ORAL

/AA/ /ANTAGONATE/
/MILES/
3 MILES

CHLORPHENIRAMINE MALEATE

& ELKINS SINN 4MG
/3/QUANTUM/PHARMACE/ 4MG
/4MG/
/4MG/
3 VITARINE 4MG
/PHENETRON/
/LANNETT/
3 LANNETT 4MG

> ADD >
> DLT >

CHLORPROMAZINE HYDROCHLORIDEINJECTABLE; INJECTION

/AP/ CHLORPROMAZINE HCL /25MG/ML/
AP LEMMON/ 25MG/ML
STERIS

CHLORPROPAMIDETABLET; ORAL

/AB/ CHLORPROPAMIDE /100MG/
/BOLAR/ 250MG
/AB/ /250MG/
100MG

3 BOLAR

3

/DURAMED/

> DLT > /AB/ /100MG/
> DLT > /AB/ /250MG/
> DLT > 100MG
> ADD > 250MG
> ADD >
> ADD >

CHLORPROPAMIDETABLET; ORAL

/AB/ CHLORPROPAMIDE /100MG/
/PHARM/BASICS/ /250MG/
/AB/

B* PHARM BASICS 100MG

B* 250MG

CHLORTHALIDONETABLET; ORAL

/AB/ CHLORTHALIDONE /25MG/
/BOLAR/ /50MG/
3 BOLAR 25MG

3 /SUPERPHARM/ 50MG

/AB/ /25MG/

3 SUPERPHARM 25MG

CHLORZOXAZONETABLET; ORAL

/AA/ CHLORZOXAZONE 500MG
DANBURY

N81019 001
JUL 29, 1991

CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATESOLUTION; IRRIGATIONRENACIDIN

GUARDIAN LABS

6.602GM/100ML; 0.198GM/100ML;
3.177GM/100ML N19481 001

/UNITED/GUARDIAN/

/6.602GM/100ML; 0.198GM/100ML;
/3.177GM/100ML/ OCT 02, 1990
N19481 001
/OCT/02/1990/

/N83708/001/
/AUG/30/1984/
/N83709/001/
/AUG/30/1984/
/N83708/001/
/AUG/30/1984/
/N83709/001/
/AUG/30/1984/

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

N81019 001
JUL 29, 1991

6.602GM/100ML; 0.198GM/100ML;
3.177GM/100ML N19481 001

/6.602GM/100ML; 0.198GM/100ML;
/3.177GM/100ML/ OCT 02, 1990
N19481 001
/OCT/02/1990/

CLARITHROMYCIN

TABLET; ORAL
BIAKIN
ABBOTT

250MG
N50662 001
OCT 31, 1991
500MG
N50662 002
OCT 31, 1991

CLIOQUINOL; HYDROCORTISONE

CREAM; TOPICAL
VIOFORM-HYDROCORTISONE
CIBA

3%; 0.5%
N10412 002
3%; 1%
N10412 001

OINTMENT; TOPICAL
VIOFORM-HYDROCORTISONE
CIBA

3%; 0.5%
N10412 004
3%; 1%
N10412 003

CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

TAVIST D
/PULSE/

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

CLOFIBRATE

CAPSULE; ORAL

CLOFIBRATE

AB NOVOPHARM

500MG

N72600 001
JUL 25, 1991

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

AB DANBURY

EQ 75MG BASE

N63082 001
JUL 31, 1991

EQ 150MG BASE

N63083 001
JUL 31, 1991

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

AB /LEMON/

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

EQ 150MG BASE/ML

N62877 001
MAR 15, 1988

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

AB /POLAR/

0.1MG

N70395 001
MAR 23, 1987

0.2MG

N70396 001
MAR 23, 1987

0.3MG

N70397 001
MAR 23, 1987

3 BOLAR

3

3

3

3

3

3

3

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3

CYTARABINE

INJECTABLE; INJECTION

CYTARABINE

/AP/ /QUAD/ /100MG/VIAL/ /N71248/001/

/AP/ /QUAD/ /500MG/VIAL/ /DEC 30, 1987/

3 QUAD 100MG/VIAL /N71248 001

3 500MG/VIAL /DEC 30, 1987

DACARBAZINE

INJECTABLE; INJECTION

DACARBAZINE

/AP/ /QUAD/ /100MG/VIAL/ /N70821/001/

/AP/ /QUAD/ /200MG/VIAL/ /OCT 09, 1986/

3 QUAD 100MG/VIAL /N70821 001

3 200MG/VIAL /OCT 09, 1986

3 500MG/VIAL /N71563/001/

3 500MG/VIAL /MAY 06, 1988

DANAZOL

CAPSULE; ORAL

DANAZOL

> DLT > /AP/ /AN/THERAP/ /200MG/ /N71563/001/

> DLT > /AP/ /AN/THERAP/ /200MG/ /DEC 30, 1987/

> ADD > 3 AM THERAP 200MG /N71569 001

> ADD > 3 AM THERAP 200MG /DEC 30, 1987

> DLT > /AP/ /STERLING/ /200MG/ /N71557/002/

> ADD > /AP/ /STERLING/ /200MG/ /N71557 002

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

CERUBIDINE

> DLT > /AP/ /RHONE/POULENC/ /EQ 20MG BASE/VIAL/ /N61876/001/

> ADD > /AP/ /RHONE/POULENC RORER /EQ 20MG BASE/VIAL/ /N61876 001

DESERPIDINE; METHYLCLOTHIAZIDE

TABLET; ORAL

ENDURONYL

/BP/ /ABBOTT/ /0.25MG;5MG/ /N12775/001/

/BP/ /ABBOTT/ /0.25MG;5MG/ /N12775 001

ENDURONYL FORTE

/BP/ /ABBOTT/ /0.5MG;5MG/ /N12775/002/

/BP/ /ABBOTT/ /0.5MG;5MG/ /N12775 002

/BP/ /BOLAR/ /0.5MG;5MG/ /N88486/001/

/BP/ /BOLAR/ /0.5MG;5MG/ /AUG 10, 1984

3 BOLAR 0.25MG;5MG /N88486 001

3 0.5MG;5MG /AUG 10, 1984

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

/AB/ /PHARM/BASICS/ /25MG/ /N71864/001/

/AB/ /PHARM/BASICS/ /25MG/ /SEP 09, 1987

/AB/ /PHARM/BASICS/ /25MG/ /N71865/001/

/AB/ /PHARM/BASICS/ /25MG/ /SEP 09, 1987

/AB/ /PHARM/BASICS/ /25MG/ /N71866/001/

/AB/ /PHARM/BASICS/ /25MG/ /SEP 09, 1987

B* PHARM BASICS 25MG /N71864 001

B* PHARM BASICS 25MG /SEP 09, 1987

B* PHARM BASICS 25MG /N71865 001

B* PHARM BASICS 25MG /SEP 09, 1987

B* PHARM BASICS 25MG /N71866 001

B* PHARM BASICS 25MG /SEP 09, 1987

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

VITTARINE

> ADD > AB	25MG	N71601 001	/AB/	/EQ 4MG PHOSPHATE/ML/	/N84355 001/
> ADD >		JUN 05, 1987			/MAR 18, 1987/
> ADD > AB	50MG	N71588 001	/AB/	/EQ 10MG PHOSPHATE/ML/	/N84355 001/
> ADD >		JUN 05, 1987			/MAR 18, 1987/
> ADD > AB	75MG	N71602 001	/AB/	/EQ 20MG PHOSPHATE/ML/	/N84355 001/
> ADD >		OCT 05, 1987			/MAR 18, 1987/
> ADD > AB	100MG	N71766 001	/AB/	/EQ 40MG PHOSPHATE/ML/	/N84355 001/
> ADD >		OCT 05, 1987			/MAR 18, 1987/
> DLT >	/25MG/	/N71601 001/			
> DLT >	/50MG/	/N71588 001/			
> DLT >	/75MG/	/N71602 001/			
> DLT >	/100MG/	/N71766 001/			

DESMOPRESSIN ACETATE

SOLUTION; NASAL

CONCENTRAID

FERRING

BX	0.01%	N19776 001	AT	EQ 0.1% PHOSPHATE	N88433 001
		DEC 26, 1990			DEC 15, 1983
	/0.01%/	/N19776 001/			/N88433 001/
		/DEC 26, 1990/			/DEC 15, 1983/
BX	0.01%	N17922 001	AT	EQ 0.1% PHOSPHATE	N84173 001
	/0.01%/	/N17922 001/			/N84173 001/

DDAVP

RHONE POULENC RORER

0.01%
/0.01%/

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

/BP/	/BPOLAR/	/0.75MG/			/N84457 001/
		0.75MG			N84457 001
/BP/	/CORD/	/0.75MG/			/N80399 001/
		0.75MG			

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE

CENTRAL PHARMS

PHARMS

DEXAMETHASONE SODIUM PHOSPHATE

LEMMON

/BP/	/EQ 4MG PHOSPHATE/ML/	/N84342 001/			/N84342 001/
		N84342 001			
/BP/	/EQ 4MG PHOSPHATE/ML/	/N84355 001/			/N84355 001/

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

/BP/	/QUAD/	/EQ 4MG PHOSPHATE/ML/	/N84355 001/
			/MAR 18, 1987/
/BP/		/EQ 10MG PHOSPHATE/ML/	/N84355 001/
			/MAR 18, 1987/
/BP/		/EQ 20MG PHOSPHATE/ML/	/N84355 001/
			/MAR 18, 1987/
/BP/		/EQ 40MG PHOSPHATE/ML/	/N84355 001/
			/MAR 18, 1987/
	3 QUAD	EQ 4MG PHOSPHATE/ML	N89280 001
			MAR 18, 1987
	3	EQ 10MG PHOSPHATE/ML	N89281 001
			MAR 18, 1987
	3	EQ 20MG PHOSPHATE/ML	N89282 001
			MAR 18, 1987
	3	EQ 40MG PHOSPHATE/ML	N89372 001
			MAR 18, 1987
AP	STERIS	EQ 4MG PHOSPHATE/ML	N84355 001
	HEXADROL		
/BP/	/ORGANON/	/EQ 20MG PHOSPHATE/ML/	/N14694 004/
	ORGANON	EQ 20MG PHOSPHATE/ML	N14694 004

SOLUTION/DROPS; OPHTHALMIC

DEXAIR

BAUSCH AND LOMB

EQ 0.1% PHOSPHATE

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

/EQ 0.1% PHOSPHATE/

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

MARION MERRELL DOM

180MG

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

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

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

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

3 ELKINS SINN

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

N85701 001
N85701 002
/N85701/001/
/N85701/002/

INJECTABLE; INJECTION

CARDIZEM

MARION MERRELL DOM

25MG/VIAL

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

3 KV

/14.5MG/5ML/
12.5MG/5ML

/N85621/001/
N85621 001

DIMENHYDRINATE

INJECTABLE; INJECTION

DIMENHYDRINATE

/AP/

AP

/50MG/ML/
50MG/ML

/N83531/001/
N83531 001

LIQUID; ORAL

DIMENHYDRINATE

3 ALRA

12.5MG/4ML

N80715 001

AB

TABLET; ORAL

DIPYRIDAMOLE

3 GENEVA

25MG

N86944 002

AB

LEDERLE

25MG

APR 16, 1991

AB

LEDERLE

25MG

FEB 05, 1991

AB

LEDERLE

50MG

N89000 001

AB

LEDERLE

75MG

FEB 05, 1991

AB

LEDERLE

75MG

N89001 001

AB

LEDERLE

75MG

FEB 05, 1991

TABLET; ORAL

DIMENHYDRINATE

3 HEATHER

50MG

N80841 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

3 ALRA

25MG

50MG

N80519 004

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 100MG BASE

FEB 02, 1986

AB

3 BOLAR

EQ 150MG BASE

FEB 02, 1986

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '91 - DEC '91

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

B* CHELSEA EQ 100MG BASE

B* EQ 150MG BASE

/BX/ /EQ/100MG/BASE/

/BX/ /EQ/150MG/BASE/

/AB/ /MYLAN/ /EQ/100MG/BASE/

/AB/ /EQ/150MG/BASE/

a MYLAN

a

DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTREX

LILLY

EQ 12.5MG BASE/ML
/EQ/250MG/BASE/VIAL/N17820 002
/N17820/002/DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

GENSIA

40MG/MLM

AP

AP

80MG/MLM

/AP/ /SOLOPAK/

/40MG/ML/

a SOLOPAK

40MG/ML

N72999 001
OCT 23, 1991
N73000 001
OCT 23, 1991
/N73000/001/
/AUG/29/1985/
N70011 001
AUG 29, 1985DOXACURIUM CHLORIDE

INJECTABLE; INJECTION

NUROMAX

BURROUGHS WELLCOME

EQ 1MG BASE/MLM

N19946 001
MAR 07, 1991DOXEPTIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPTIN HCL

/AB/ /BARR/

/AB/

/AB/

/AB/

a BARR

a

a

a

/BX/ /CHELSEA/

/BX/

/BX/

/BX/

/BX/

/BX/

a CHELSEA

a

a

a

a

a

/AB/ /PUREPAC/

/AB/

a PUREPAC

a

/EQ/25MG/BASE/
/FEB/18/1988/
/N71502/001/
/EQ/50MG/BASE/
/FEB/18/1988/
/N71653/001/
/EQ/75MG/BASE/
/FEB/18/1988/
/N71654/001/
/EQ/100MG/BASE/
/FEB/18/1988/
/N71521/001/
EQ 25MG BASE
N71502 001
FEB 18, 1988
EQ 50MG BASE
N71653 001
FEB 18, 1988
EQ 75MG BASE
N71654 001
FEB 18, 1988
EQ 100MG BASE
N71521 001
FEB 18, 1988
/EQ/10MG/BASE/
/N70952/001/
/MAR/04/1987/
/EQ/25MG/BASE/
/N70953/001/
/MAY/15/1986/
/EQ/50MG/BASE/
/N70954/001/
/MAY/15/1986/
EQ 75MG BASE
N71763 001
FEB 09, 1988
EQ 100MG BASE
N70955 001
MAY 15, 1986
EQ 150MG BASE
N71764 001
FEB 09, 1988
/EQ/75MG/BASE/
/N72386/001/
/SEP/08/1988/
/EQ/150MG/BASE/
/N72387/001/
/SEP/08/1988/
EQ 75MG BASE
N72386 001
SEP 08, 1988
EQ 150MG BASE
N72387 001
SEP 08, 1988

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS: ORAL

IRYU SPRINKLES

184356/001
184356 001

1546

$$\begin{array}{r} > \frac{DLT}{DLT} > \\ > \frac{DLT}{DLT} > \\ > \frac{DLT}{DLT} > \\ > \frac{ADD}{ADD} > \\ > \frac{ADD}{ADD} > \end{array}$$

1.25MG

GEL; TOPICAL
E/GEL
/FULTON/

 $\frac{2}{\sqrt{2}}$

ERYGEL

1001 0035463 N85463

 $\frac{2}{3}$

SOLUTION; TOPICAL

ERYTHROMYCIN
CLAY PARK

22/22

72

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE
/NASKA/
/Ed 400MG BASE/5ML/

185446/663/
N85020 002

184936/661/
185177/661/

0.5MG / 50077 /

1/24/94

/GNT/

0.5MG



ESTROGENS, ESTERIFIED

TABLET; ORAL

BS/ FEVEX/
BS/ SYNTEX/
BS/ SYNTEX
BS/ FEHODEN/
BS/ PRIVATE/FORM/
BS/ PRIVATE FORM

0.625MG/
1.25MG/
0.625MG
1.25MG
0.625MG/
0.625MG

N83220 001
N83220 002
N89567 001
FEB 27, 1991
N89582 001
JUL 17, 1991

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

TABLET; ORAL-28

DEJULEN 1/35-28
SEARLE
ETHYNODIOL DIACETATE AND ETHYNYL ESTRADIOL 1/35-28
WATSON
ETHYNODIOL DIACETATE AND ETHYNYL ESTRADIOL 1/50-28
WATSON

0.05MG; 1MG
0.035MG; 1MG
0.05MG; 1MG
0.05MG; 1MG

N16936 001
N72721 001
DEC 30, 1991
N72723 001
DEC 30, 1991

ESTROPIPATE

TABLET; ORAL

OGEN
ABBOTT
ORTHO-EST
JOHNSON RM

0.75MG
1.5MG
0.75MG
1.5MG

N83220 001
N83220 002
N89567 001
FEB 27, 1991
N89582 001
JUL 17, 1991

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

ETHYNYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHINDRONE AND ETHYNYL ESTRADIOL (10/11)
WATSON
NORETHINDRONE AND ETHYNYL ESTRADIOL (7/14)
WATSON

0.035MG; 0.5MG AND 1MG
0.035MG; 0.5MG AND 1MG
0.035MG; 0.5MG AND 1MG
0.035MG; 0.5MG AND 1MG

N71043 001
APR 01, 1988
N71041 001
SEP 24, 1991

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHANOLIN
BLOCK/PLUGS/

50MG/ML
50MG/ML

N19357 001
DEC 22, 1988

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

TABLET; ORAL-28

NORETHINDRONE AND ETHYNYL ESTRADIOL (10/11)
WATSON
NORETHINDRONE AND ETHYNYL ESTRADIOL (7/14)
WATSON

0.035MG; 0.5MG AND 1MG
0.035MG; 0.5MG AND 1MG
0.035MG; 0.5MG AND 1MG
0.035MG; 0.5MG AND 1MG

N71044 001
APR 01, 1988
N71042 001
SEP 24, 1991

ETHYNYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET; ORAL-21

DEJULEN 1/35-21
SEARLE

DEJULEN 1/50-21
SEARLE

ETHYNODIOL DIACETATE AND ETHYNYL ESTRADIOL 1/35-21
WATSON

ETHYNODIOL DIACETATE AND ETHYNYL ESTRADIOL 1/50-21
WATSON

0.035MG; 1MG
0.05MG; 1MG
0.035MG; 1MG
0.05MG; 1MG

N18168 001
N16927 001
N72720 001
DEC 30, 1991
N72722 001
DEC 30, 1991

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

TABLET; ORAL-28

DEJULEN 1/35-28
SEARLE

0.035MG; 1MG

N18160 001

> ADD > AB

ETHYNYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-28

NORLESTRIN 28 1/50
PARKE/DAVIS

0.05MG; 1MG

N16723 001

ETODOLAC

CAPSULE; ORAL

LODINE

MYETH AVERST

200MG

N18922 002

JAN 31, 1991

300MG

N18922 003

JAN 31, 1991

EQ 0.05MG BASE/ML

N72786 001
SEP 24, 1991

FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

PLENDIL

MSD

5MG

N19834 001

JUL 26, 1991

10MG

N19834 002

JUL 26, 1991

/N18799/001/
N17879 001

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

/AM/THERAP/

/EQ 200MG BASE/

/N72307/001/
AUG 22, 1988

/EQ 300MG BASE/

/N72308/001/
AUG 22, 1988

EQ 200MG BASE

/N72981/001/
AUG 19, 1991

EQ 300MG BASE

/N72982/001/
AUG 19, 1991

EQ 200MG BASE

/N72946/001/
APR 30, 1991

EQ 300MG BASE

/N72472/001/
APR 30, 1991

EQ 200MG BASE

/N72307/001/
AUG 22, 1988

EQ 300MG BASE

/N72308/001/
AUG 22, 1988

EQ 200MG BASE

/N72981/001/
AUG 19, 1991

EQ 300MG BASE

/N72982/001/
AUG 19, 1991

EQ 200MG BASE

/N72946/001/
APR 30, 1991

EQ 300MG BASE

/N72472/001/
APR 30, 1991

WARNER CHILCOTT

AB

AB

AB

AB

TABLET; ORAL

FENOPROFEN CALCIUM

/AM/THERAP/

/EQ 600MG BASE/

/N72309/001/
JUN 16, 1988

EQ 600MG BASE

/N72309/001/
JUN 16, 1988

/EQ 600MG BASE/

/N72362/001/
JUN 16, 1988

EQ 600MG BASE

/N72362/001/
JUN 16, 1988

PHARM BASICS

AB

AB

AB

AB

FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE

AP

STERLING

EQ 0.05MG BASE/ML

N72786 001
SEP 24, 1991

FIBRINOGEN, I-125

INJECTABLE; INJECTION

/IBRI/

/AMERSHAM/

@ AMERSHAM

/154/UCI/VIAL/
154 UCI/VIAL

/N18799/001/
N17879 001

FLOXURIDINE

INJECTABLE; INJECTION

/FLOXURIDINE/

/AP/

/QUAD/

/500MG/VIAL/
500MG/VIAL

/N71055/001/
AUG 24, 1987

@ QUAD

FUDR

/ROCHE/

ROCHE

/500MG/VIAL/
500MG/VIAL

/N16929/001/
N16929 001

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

FLUDARA

BERLEX

50MG/VIAL

N20038 001
APR 18, 1991

FLUMAZENIL

INJECTABLE; INJECTION

MAZICON

ROCHE

0.1MG/ML

N20073 001
DEC 20, 1991

FLUCINOLONE ACETONIDE

CREAM; TOPICAL

/FLUCET/

/NAC/

/0.052/

/N88361/001/
JAN 16, 1984

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '91 - DEC '91

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

FLUOCINOLONE ACETONIDE

AT NMC 0.01%

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB TARO 0.05%

AB TIGAN 0.05%

/AB/ /VASODERM/ 0.05%
/TARO/

/AB/ /VASODERM 'E/ 0.05%
/TIGAN/

ointment; topical

FLUOCINONIDE

> ADD >
> ADD > AB LEMON 0.05%
> ADD >

> ADD > AB LDEX 0.05%
> ADD > AB SYNTEX

FLUOROURACIL

INJECTABLE; INJECTION

ADRUCEL

AP ADRIA 50MG/ML

AP 50MG/ML

AP 50MG/ML

FLUOROURACIL

> ADD > AP ABIC 50MG/ML
> ADD >
> DLT > /AB/ /ANDAN/ 50MG/ML
> DLT >

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

/AB/ /QUAD/ 50MG/ML
/AB/ 50MG/ML

3 QUAD 50MG/ML

3 50MG/ML

/AB/ /SOLOPAK/ 50MG/ML

3 SOLOPAK 50MG/ML

FLUOXETINE HYDROCHLORIDE

SOLUTION; ORAL

PROZAC

LILLY

EQ 20MG BASE/5ML

FLUOXYMESTERONE

TABLET; ORAL

FLUOXYMESTERONE

/BP/ /BOLAR/ 2MG
/BP/ 5MG
/BP/ 10MG

3 BOLAR 2MG

3 5MG

3 10MG

> DLT > /ORAL-TESTERYL/ 2MG
> DLT > /SQUIBB/ 5MG
> DLT > /BP/ 10MG
> ADD > 3 SQUIBB 2MG
> ADD > 3 5MG

/N89368/001
/FEB/03/1987
/N89455/001
/FEB/03/1987
/N89368/001
FEB 03, 1987
N89455 001
FEB 03, 1987
/N89368/001
/DEC/28/1984
N88766 001
DEC 28, 1984

N20101 001
APR 24, 1991

/N88265/001
/DEC/06/1983
/N88265/001
/DEC/06/1983
/N88265/001
/DEC/06/1983
N88260 001
DEC 06, 1983
N88265 001
DEC 06, 1983
N88309 001
DEC 06, 1983
/N11359/001
/N11359/002
N11359 001
N11359 002

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION

FLUPHENAZINE

/AB/ /QJAD/

3 QUAD

/2.5MG/ML/

25MG/ML

/N70762/001/
/FEB/20, 1986/
N70762 001
FEB 20, 1986

FLUPHENAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
FLUPHENAZINE HCL

AA COPLE

5MG/ML

N73058 001
AUG 30, 1991

INJECTABLE; INJECTION

FLUPHENAZINE HCL

/AB/ /QJAD/

/2.5MG/ML/

2.5MG/ML

/N89800/001/
/JUN/08, 1988/
N89800 001
JUN 08, 1988

TABLET; ORAL

FLUPHENAZINE HCL

/AB/ /BOLAR/

/1MG/

/2.5MG/

/5MG/

/10MG/

3 BOLAR

1MG

3

2.5MG

3

5MG

3

10MG

/N88555/001/
/DEC/18, 1987/
N88555 001
DEC 18, 1987
/N88544/001/
/DEC/18, 1987/
N88544 001
DEC 18, 1987
/N88527/001/
/DEC/18, 1987/
N88527 001
DEC 18, 1987
/N88550/001/
/DEC/18, 1987/
N88550 001
DEC 18, 1987

> DLT >
> ADD >

> DLT >
> ADD >

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

AB GENEVA

15MG

AB

30MG

N71716 001
JUL 31, 1991
N71717 001
JUL 31, 1991

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL
/PHARM/BASICS/

/15MG/

/30MG/

B* PHARM BASICS

15MG

B* PHARM BASICS

30MG

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

FOSCARNET SODIUM

INJECTABLE; INJECTION

FOSCAVIR

ASTRA

24MG/ML

N20068 001
SEP 27, 1991

FOSINOPRIL SODIUM

TABLET; ORAL

MONOPRIL

BRISTOL MYERS SQUIBB

10MG

20MG

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

FURAZOLIDONE

SUSPENSION; ORAL

FUROXONE

/NORWICH/EATON/
ROBERTS

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

/N11323/002/
N11323 002

TABLET; ORAL

FUROXONE

/NORWICH/EATON/
ROBERTS

/100MG/
100MG

/N11270/002/
N11270 002

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

/AB/ /SOLOPAK/

/10MG/ML/

3 SOLOPAK

10MG/ML

/N70023/001/
/FEB/05, 1986/
N70023 001
FEB 05, 1986

FUROSEMIDE

INJECTABLE; INJECTION

AP
FUROSEMIDE
STERLING

10MG/MLM

N72080 001
AUG 13, 1991

SOLUTION; ORAL

AA
FUROSEMIDE
PHARM BASICS

10MG/ML

N70655 001
OCT 02, 1987

/AA/
MYROSEMIDE
/PHARM/BASICS/

10MG/ML

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

GALLIUM NITRATE

INJECTABLE; INJECTION

GANITE
FUJISAWA

25MG/MLM

N19961 002
JAN 17, 1991

GENTAMICIN SULFATE

INJECTABLE; INJECTION

AP
GENTAMICIN SULFATE
GENSIA

EQ 10MG BASE/MLM

N63149 001
NOV 21, 1991

EQ 40MG BASE/MLM

N63106 002
NOV 21, 1991

SOLUTION/DROPS; OPHTHALMIC

/AT/
GENTAMICIN SULFATE
/PACO/

EQ 3MG BASE/ML

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

EQ 3MG BASE/ML

N62932 001
NOV 07, 1988

GENTIAN VIOLET

/TAMPON/ /VAGINAL/
/GENAPAX/
/KEY/PHARMS/
3 KEY PHARMS

5MG/
5MG

/N85017/001/
N85017 001

GLUCAGON HYDROCHLORIDE

INJECTABLE; INJECTION

AA/
GLUCAGON
/LILLY/
LILLY

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

/N12122/002/
N12122 002

/AA/
GLUCAGON
/QUAD/

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

3 QUAD

N71023 001
MAR 04, 1987

GLUTETHIMIDE

TABLET; ORAL

/AA/
GLUTETHIMIDE
/Rhone-Poulenc/RORER/

250MG

/N09519/002/
N09519 002

500MG

/N09519/005/
N09519 005

GLUTETHIMIDE

/AA/
GLUTETHIMIDE
/CHELSEA/

500MG

/N85763/001/
N85763 001

GLYCOPYRROLATE

INJECTABLE; INJECTION

AP
GLYCOPYRROLATE
GENSIA

0.2MG/MLM

N81169 001
SEP 10, 1991

/AA/
GLYCOPYRROLATE
/QUAD/

/N89397/001/
N89397 001

0.2MG/ML

DEC 09, 1986

TABLET; ORAL

/AA/
GLYCOPYRROLATE
/BOLAR/

1MG/
1MG

/N85562/001/
N85562 001

GONADOTROPIN, CHORIONICINJECTABLE; INJECTIONCHORIONIC GONADOTROPIN

/AP/	/QUAD/	/5,000 UNITS/VIAL/	/N89312/001/ DEC 04, 1986
/AP/		/5,000 UNITS/VIAL/	/N89313/001/ DEC 04, 1986
/AP/		/10,000 UNITS/VIAL/	/N89314/001/ DEC 04, 1986
/AP/		/10,000 UNITS/VIAL/	/N89315/001/ DEC 04, 1986
/AP/		/20,000 UNITS/VIAL/	/N89316/001/ DEC 04, 1986
3	QUAD	5,000 UNITS/VIAL	N89312 001 DEC 04, 1986
3		5,000 UNITS/VIAL	N89313 001 DEC 04, 1986
3		10,000 UNITS/VIAL	N89314 001 DEC 04, 1986
3		10,000 UNITS/VIAL	N89315 001 DEC 04, 1986
3		20,000 UNITS/VIAL	N89316 001 DEC 04, 1986

GUANETHIDINE MONOSULFATETABLET; ORAL

/AB/ /BOLAR/ GUANETHIDINE MONOSULFATE/
EQ 10MG SULFATE/

/AB/ /EQ 25MG SULFATE/

3 BOLAR EQ 10MG SULFATE

3 EQ 25MG SULFATE

/AB/ /CIBA/ ISMELIN

/AB/ /EQ 10MG SULFATE/

/AB/ /EQ 25MG SULFATE/

3 EQ 10MG SULFATE

3 EQ 25MG SULFATE

HALOBETASOL PROPIONATECREAM; TOPICALULTRAVATE

/PRISTOL/ MYERS/ SQUIBB/ 0.05% /

WESTWOOD SQUIBB 0.05%

/N19967/001/
DEC 27, 1990

HALOBETASOL PROPIONATEointment; topicalULTRAVATE

/PRISTOL/ MYERS/ SQUIBB/ 0.05% /

WESTWOOD SQUIBB 0.05%

/N19968/001/
DEC 27, 1990

HALOPERIDOLTABLET; ORALHALOPERIDOL

/AB/ /BOLAR/ 0.5MG

/AB/ 1MG

/AB/ 2MG

/AB/ 5MG

/AB/ 10MG

/AB/ 20MG

3 BOLAR

3

3

3

3

3

3

AB DANBURY

AB

/N71571/001/
JUN 03, 1988
N71571 001
JUN 03, 1988
N71572 001
JUN 03, 1988
N71573 001
JUN 03, 1988
N71374 001
JUN 03, 1988
N71375 001
JUN 03, 1988
N71376 001
JUN 03, 1988
N72113 001
AUG 27, 1991
N72353 001
AUG 27, 1991

HALOPERIDOLTABLET; ORAL
HALOPERIDOL
/DURAMED/

> DLT > /AB/	/N71216/001/	/0.5MG/
> DLT >	/DEC 04, 1986/	
> DLT > /AB/	/N71217/001/	/1MG/
> DLT >	/DEC 04, 1986/	
> DLT > /AB/	/N71218/001/	/2MG/
> DLT >	/DEC 04, 1986/	
> DLT > /AB/	/N71219/001/	/5MG/
> DLT >	/DEC 04, 1986/	
> DLT > /AB/	/N71220/001/	/10MG/
> DLT >	/JUL 07, 1987/	
> DLT > /AB/	/N71221/001/	/20MG/
> DLT >	/JUL 07, 1987/	
> ADD >	N71216 001	0.5MG
> ADD >	DEC 04, 1986	
> ADD >	N71217 001	1MG
> ADD >	DEC 04, 1986	
> ADD >	N71218 001	2MG
> ADD >	DEC 04, 1986	
> ADD >	N71219 001	5MG
> ADD >	DEC 04, 1986	
> ADD >	N71220 001	10MG
> ADD >	JUL 07, 1987	
> ADD >	N71221 001	20MG
> ADD >	JUL 07, 1987	
> DLT > /AB/	/N71328/001/	/40MG/
> DLT >	/JUL 20, 1987/	
> ADD >	N71328 001	20MG
> ADD >	JUL 20, 1987	
> ADD > AB	N70720 001	
> ADD >	JUN 10, 1986	
> ADD > AB	N70721 001	1MG
> ADD >	JUN 10, 1986	
> ADD > AB	N70722 001	2MG
> ADD >	JUN 10, 1986	
> ADD > AB	N70723 001	5MG
> ADD >	JUN 10, 1986	
> ADD > AB	N70724 001	10MG
> ADD >	JUN 10, 1986	
> ADD > AB	N70725 001	20MG
> ADD >	JUN 10, 1986	

HALOPERIDOLTABLET; ORAL
HALOPERIDOL
/SEARLE/

> DLT > /AB/	/N70726/001/	/0.5MG/
> DLT >	/JUN 10, 1986/	
> DLT > /AB/	/N70727/001/	/1MG/
> DLT >	/JUN 10, 1986/	
> DLT > /AB/	/N70728/001/	/2MG/
> DLT >	/JUN 10, 1986/	
> DLT > /AB/	/N70729/001/	/5MG/
> DLT >	/JUN 10, 1986/	
> DLT > /AB/	/N70730/001/	/10MG/
> DLT >	/JUN 10, 1986/	
> DLT > /AB/	/N70731/001/	/20MG/
> DLT >	/JUN 10, 1986/	

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL

> ADD > AA	SCHIAPPARELLI SEARLE EQ 2MG BASE/ML	N70726 001
> ADD >		JUN 10, 1986
> DLT > /AB/	/SEARLE/	/N70726/001/
> DLT >		/JUN 10, 1986/

INJECTABLE; INJECTION

HALOPERIDOL
/LEHMAN/

/AB/	/ED '5MG' BASE/ML/	/N70713/001/
/AB/	/ED '5MG' BASE/ML/	/MAY 17, 1988/
/AB/	/ED '5MG' BASE/ML/	/N70714/001/
/AB/	/ED '5MG' BASE/ML/	/MAY 17, 1988/
/AB/	/ED '5MG' BASE/ML/	/N70744/001/
/AB/	/ED '5MG' BASE/ML/	/MAY 17, 1988/
/AB/	/ED '5MG' BASE/ML/	/N71002/001/
/AB/	/ED '5MG' BASE/ML/	/JAN 02, 1987/
/AB/	EQ 5MG BASE/ML	N71082 001
/AB/	/ED '5MG' BASE/ML/	JAN 02, 1987
/AB/	/ED '5MG' BASE/ML/	/N70802/001/
/AB/	EQ 5MG BASE/ML	N70802 001
/AB/	EQ 5MG BASE/ML	DEC 14, 1987
/AB/	EQ 5MG BASE/ML	N70713 001
/AB/	EQ 5MG BASE/ML	MAY 17, 1988
/AB/	EQ 5MG BASE/ML	N70714 001
/AB/	EQ 5MG BASE/ML	MAY 17, 1988
/AB/	EQ 5MG BASE/ML	N70744 001
/AB/	EQ 5MG BASE/ML	MAY 17, 1988

HEPARIN SODIUMINJECTABLE; INJECTION

HEPARIN LOCK FLUSH
/INTL/MEDICATION/
a INTL MEDICATION

/10 UNITS/ML/

10 UNITS/ML

/500 UNITS/ML/

500 UNITS/ML

/100 UNITS/ML/

100 UNITS/ML

a SOLOPAK

HEPARIN SODIUM

/LYPHOMED/

a LYPHOMED

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

/10,000 UNITS/100ML/

10,000 UNITS/100ML

a ABBOTT

/HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.9% IN
/PLASTIC CONTAINER/
/MCGAM/

/5,000 UNITS/100ML/

5,000 UNITS/100ML

a MCGAM

> ADD > HISTRELIN ACETATE> ADD > INJECTABLE; INJECTION

SUPPRELIN

JOHNSON RW

EQ 0.2MG BASE/MLM

EQ 0.5MG BASE/MLM

EQ 1MG BASE/MLM

a SOLOPAK

a

HYDRALAZINE HYDROCHLORIDEINJECTABLE; INJECTIONHYDRALAZINE HCL

/SOLOPAK/

/100MG/ML/

100MG/ML

/20MG/ML/

20MG/ML

a SOLOPAK

a

HYDRALAZINE HYDROCHLORIDETABLET; ORALHYDRALAZINE HCL

/CHELSEA/

/45MG/

/50MG/

a CHELSEA

a

25MG

50MG

a

a

a

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/N85532/002/
/MAR/24/1982/
/N85533/002/
/MAR/25/1982/
/N85532 002
MAY 24, 1982
/N85533 002
MAY 25, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDECAPSULE; ORALHYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/BOLAR/

/25MG;25MG/

/50MG;50MG/

/100MG;50MG/

25MG;25MG

50MG;50MG

100MG;50MG

a BOLAR

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TABLET; ORALAPRESOLINE-ESIDROX

/CIBA/

/25MG;15MG/

/25MG;15MG/

/HYDRALAZINE/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

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/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/25MG;15MG/

/N12826/002/
/N12026 002
/N85373/001/
/N85373 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINETABLET; ORALHYDRALAZINE AND HYDRALAZINE

/BOLAR/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/25MG;15MG;0.1MG/

/N83770/001/
/N83770 001

/N86357/001/
/N86357 001
/N86357/002/
/N86357 002
/N86357/003/
/N86357 003
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/N86357/142/
/N8

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

/AT/ /LIFE/LABS/ /12/

/N86416/001/
/JAN/25/1982/

INJECTABLE; INJECTION

HYDROCORTISONE ACETATE

/BP/ /LEMON/ /25MG/ML/

/BP/ /50MG/ML/

BP 25MG/ML

BP 50MG/ML

/N83759/001/
/N83759/002/
N83759 001
N83759 002HYDROCORTISONE BUTYRATE

CREAM; TOPICAL

HYDROCORTISONE BUTYRATE

/AT/ /SIST/ /0.12/

/N18514/001/
/MAR/31/1982/

/LOCOD/ /OMEN/GALDERMA/ /0.12/

/N18795/001/
/JAN/07/1983/LOCOD

BROCADES PHARMA

0.12

3 OMEN GALDERMA

0.12

N18514 001
MAR 31, 1982
N18795 001
JAN 07, 1983

SOLUTION; TOPICAL

HYDROCORTISONE BUTYRATE

/AT/ /SIST/ /0.12/

/N19116/001/
/FEB/25/1987/

/LOCOD/ /OMEN/GALDERMA/ /0.12/

/N19819/001/
/SEP/15/1988/LOCOD

BROCADES PHARMA

0.12

3 OMEN GALDERMA

0.12

N19116 001
FEB 25, 1987
N19819 001
SEP 15, 1988HYDROCORTISONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

HYDROCORTISONE SODIUM PHOSPHATE

/AP/ /QUAD/ /EQ 50MG BASE/ML/

3 QUAD

EQ 50MG BASE/ML

/N89581/001/
/MAY/28/1987/
N89581 001
MAY 28, 1987HYDROCORTONE

/AP/ /MSD/ /EQ 50MG BASE/ML/

EQ 50MG BASE/ML

/N12052/001/
N12052 001HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION

HYDROCORTISONE SODIUM SUCCINATE

/AP/ /LYPHOMED/ /EQ 100MG BASE/ML/

/AP/ /EQ 100MG BASE/ML/

/AP/ /EQ 250MG BASE/ML/

/AP/ /EQ 500MG BASE/ML/

/AP/ /EQ 1GM BASE/ML/

/N88667/001/
/JUN/08/1984/
N88667 001
JUN 08, 1984
/N88712/001/
/JUN/08/1984/
N88712 001
JUN 08, 1984
/N88668/001/
/JUN/08/1984/
N88668 001
JUN 08, 1984
/N88669/001/
/JUN/08/1984/
N88669 001
JUN 08, 1984
/N88670/001/
/JUN/08/1984/
N88670 001
JUN 08, 1984HYDROFLUMETHIAZIDE; RESERPINE

TABLET; ORAL

HYDROFLUMETHIAZIDE AND RESERPINE

B* PHARM BASICS

50MG;0.125MG

/BP/ /50MG;0.125MG/

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

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'91 - DEC'91

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HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

DURAMED

/EQ '25MG HCL/

/EQ '50MG HCL/

/EQ '100MG HCL/

EQ 25MG HCL

EQ 50MG HCL

EQ 100MG HCL

EQ 25MG HCL

EQ 50MG HCL

EQ 100MG HCL

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EQ 50MG HCL

EQ 100MG HCL

/N85593/001/

/FEB/29/1984/

/N85594/001/

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/N89032/001/

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/JAN/02/1987/

/N89035/001/

/JAN/02/1987/

/N89036/001/

/JAN/02/1987/

/N89037/001/

/JAN/02/1987/

/N89038/001/

/JAN/02/1987/

/N89039/001/

/JAN/02/1987/

/N89040/001/

/JAN/02/1987/

/N89041/001/

/JAN/02/1987/

/N89042/001/

/JAN/02/1987/

/N89043/001/

/JAN/02/1987/

/N89044/001/

/JAN/02/1987/

/N89045/001/

/JAN/02/1987/

/N89046/001/

/JAN/02/1987/

/N89047/001/

/JAN/02/1987/

/N89048/001/

/JAN/02/1987/

/N89049/001/

/JAN/02/1987/

/N89050/001/

/JAN/02/1987/

/N89051/001/

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/JAN/02/1987/

/N89032/001/

/JAN/02/1987/

/N89033/001/

/JAN/02/1987/

/N89034/001/

/JAN/02/1987/

/N89035/001/

/JAN/02/1987/

/N89036/001/

/JAN/02/1987/

/N89037/001/

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

/AB/ /AB/ /AB/ /10MG/ /25MG/ /50MG/ /10MG/ /25MG/ /50MG/ 3 BOLAR 3 3 PRAMINE 3 ALRA 3 /3/BANMAX/ /3/ /3/

/N85220/001/ /N85221/001/ /N85220 001 /N84252 002 /N85221 001 /N83827 001 /N83827 002 /N83827 003 /N83827/001/ /N83827/002/ /N83827/003/

/AB/ /AB/ /25MG/ /50MG/ 25MG 50MG 3 SUPERPHARM 3 CAPSULE, EXTENDED RELEASE; ORAL

/N76487/001/ /OCT 10, 1986/ /N76488/001/ /OCT 10, 1986/ /N70487 001 /N70488 001 /OCT 10, 1986

> ADD > > DLT > > DLT >

N71531 001 /JUL 21, 1987 /N71531/001/ /JUL 21, 1987/

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

/AB/ /AB/ /25MG/ /50MG/ 25MG 50MG 25MG 50MG 3 BOLAR 3 DANBURY AB

/N76784/001/ /AUG 20, 1986 /N70785 001 /AUG 20, 1986 /N72996 001 /JUL 31, 1991 /N72997 001 /JUL 31, 1991 /N76784/001/ /OCT 18, 1985 /N76784/001/ /OCT 18, 1985 /N70326 001 /OCT 18, 1985 /N70327 001 /OCT 18, 1985 /N76784/001/ /JUN 18, 1985 /N70354 001 /JUN 18, 1985

/AB/ /AB/ /25MG/ /50MG/ 25MG 50MG 3 SUPERPHARM 3 CAPSULE, EXTENDED RELEASE; ORAL

/N76784/001/ /OCT 18, 1985 /N76784/001/ /OCT 18, 1985 /N70326 001 /OCT 18, 1985 /N70327 001 /OCT 18, 1985 /N76784/001/ /JUN 18, 1985 /N70354 001 /JUN 18, 1985

ISOETHARINE HCL

ISOETHARINE HCL

> DLT > /AB/ /AB/ /25MG/ /50MG/ 25MG 50MG 3 DURAMED 3 /3/ROXANE/ /3/ROXANE/ 25MG 50MG 3 ROXANE 3

/N76784/001/ /AUG 20, 1986 /N70785 001 /AUG 20, 1986 /N72996 001 /JUL 31, 1991 /N72997 001 /JUL 31, 1991 /N76784/001/ /OCT 18, 1985 /N76784/001/ /OCT 18, 1985 /N70326 001 /OCT 18, 1985 /N70327 001 /OCT 18, 1985 /N76784/001/ /JUN 18, 1985 /N70354 001 /JUN 18, 1985

/AB/ /AB/ /25MG/ /50MG/ 25MG 50MG 3 SUPERPHARM 3 CAPSULE, EXTENDED RELEASE; ORAL

/N76784/001/ /OCT 18, 1985 /N76784/001/ /OCT 18, 1985 /N70326 001 /OCT 18, 1985 /N70327 001 /OCT 18, 1985 /N76784/001/ /JUN 18, 1985 /N70354 001 /JUN 18, 1985

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

/AB/ /AB/ /25MG/ /50MG/ 25MG 50MG 3 SUPERPHARM 3 CAPSULE, EXTENDED RELEASE; ORAL

/N76784/001/ /OCT 18, 1985 /N76784/001/ /OCT 18, 1985 /N70326 001 /OCT 18, 1985 /N70327 001 /OCT 18, 1985 /N76784/001/ /JUN 18, 1985 /N70354 001 /JUN 18, 1985

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'91 - DEC'91

ISOETHARTINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARTINE HCL

AN ASTRA

0.125/M

N89615 001
JUN 13, 1991

AN

0.167/M

N89616 001
JUN 13, 1991

AN

0.2/M

N89617 001
JUN 13, 1991

AN

0.25/M

N89618 001
JUN 13, 1991

0.062/M

N89614 001
JUN 13, 1991

ISOETHARTINE MESYLATE

AEROSOL, METERED; INHALATION
BRONCHOMETER

/BN/ /STERLING/
BN STERLING

/0.34MG/BASE/INH/
0.34MG/INH

/N12339/001/
N12339 007

ISONIAZID

INJECTABLE; INJECTION
ISONIAZID

/AP/ /QUAD/

/100MG/ML/

/N08662/001/
/08662/001/
N89816 001
OCT 28, 1988

QUAD

100MG/ML

HYDRAZID
/SQUIBB/
SQUIBB

/100MG/ML/

/N08662/001/
N08662 001

SYRUP; ORAL
/ROCHE/
ROCHE

/50MG/5ML/

/N08420/001/
N08420 001

TABLET; ORAL
ISONIAZID

/AA/ /BOLAR/
/AA/ /BOLAR/

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

/N08401/001/
/N08378/001/
N80401 001
N83178 001
N83610 001

AA BOLAR
AA ZENITH

> ADD > ISOSORBIDE MONONITRATE

> ADD > TABLET; ORAL
> ADD > ISMO
> ADD > WYETH

20MG

N19091 001
DEC 30, 1991

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE
/INTL/MEDICATION/

/AP/ /AP/

/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

3 INTL MEDICATION
3

/EQ 75MG BASE/2ML/
/EQ 500MG BASE/2ML/
EQ 75MG BASE/2ML
EQ 500MG BASE/2ML
EQ 1GM BASE/3ML

/N62642/001/
/FEB/03/1986/
/N62642/002/
/FEB/03/1986/
/N62642/003/
/FEB/03/1986/
N62642 001
FEB 03, 1986
N62642 002
FEB 03, 1986
N62642 003
FEB 03, 1986

> DLT > /AP/ /QUAD/
> DLT > /AP/ /QUAD/

> DLT > /AP/ /QUAD/
> DLT > /AP/ /QUAD/

> DLT > /AP/ /QUAD/
> DLT > /AP/ /QUAD/

> ADD > /AP/ /QUAD/
> ADD > /AP/ /QUAD/

> ADD > /AP/ /QUAD/
> ADD > /AP/ /QUAD/

> ADD > /AP/ /QUAD/
> ADD > /AP/ /QUAD/

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
KETALAR
/PARKE/DAVIS/

/AP/ /AP/ /AP/

/EQ 10MG BASE/ML/
/EQ 50MG BASE/ML/
/EQ 100MG BASE/ML/
EQ 10MG BASE/ML
EQ 50MG BASE/ML
EQ 100MG BASE/ML

/N16812/001/
/N16812/002/
/N16812/003/
N16812 001
N16812 002
N16812 003

PARKE DAVIS

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '91 - DEC '91

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

KETAMINE HCL

/AP/ /QUAD/ /N71949/001/ /EQ 10MG BASE/ML/

/AP/ /QUAD/ /N71950/001/ /EQ 50MG BASE/ML/

/AP/ /QUAD/ /N71951/001/ /EQ 100MG BASE/ML/

3 QUAD

EQ 10MG BASE/ML

3

EQ 50MG BASE/ML

3

EQ 100MG BASE/ML

KETOCONAZOLESUSPENSION; ORALNIZORALJANSSEN

/100MG/5ML/

3 JANSSEN

100MG/5ML

KETOROLAC TROMETHAMINE

TABLET; ORAL

TORADOLSYNTEX

> ADD >

> ADD >

> ADD >

> ADD >

10MG

N19645 001

DEC 20, 1991

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUMABIC

EQ 3MG BASE/ML

N89352 001

JUN 01, 1988

EQ 50MG BASE/VIAL

N89353 001

JUN 01, 1988

/EQ 5MG BASE/ML/

N16913 001

JUN 01, 1988

/EQ 50MG BASE/VIAL/

N16913 001

JUN 01, 1988

LEVODOPA

CAPSULE; ORAL

DOPARNORMICH/EATON

/100MG/

/250MG/

/500MG/

100MG

250MG

500MG

N16913 001

N16913 002

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM/QUAD/

/EQ 5MG BASE/ML/

N89503 001

OCT 05, 1987

/AP/

/EQ 5MG BASE/ML/

N89504 001

DEC 22, 1987

/AP/

/EQ 50MG BASE/VIAL/

N89496 001

MAR 05, 1987

/AP/

/EQ 100MG BASE/VIAL/

N89636 001

DEC 24, 1987

3 QUAD

EQ 5MG BASE/ML

N89503 001

OCT 05, 1987

3

EQ 5MG BASE/ML

N89504 001

DEC 22, 1987

3

EQ 50MG BASE/VIAL

N89496 001

MAR 05, 1987

3

EQ 100MG BASE/VIAL

N89636 001

DEC 24, 1987

MELCOVORINBURROUGHS WELLCOME

/EQ 5MG BASE/ML/

N87439 001

OCT 19, 1982

EQ 5MG BASE/ML

N87439 001

OCT 19, 1982

TABLET; ORAL

LEUCOVORIN CALCIUM/PAR/

/EQ 5MG BASE/

N71600 001

OCT 14, 1987

/AP/

/EQ 25MG BASE

N71598 001

OCT 14, 1987

3 PAR

EQ 5MG BASE

N71600 001

OCT 14, 1987

3

EQ 25MG BASE

N71598 001

OCT 14, 1987

METHANTHIELINE BROMIDE

TABLET; ORAL

BANTHINE

/AA/ /SEARLE/

/50MG/

/N07390/001/

METHOCARBAMOL

INJECTABLE; INJECTION

METHOCARBAMOL

MARSAM

100MG/ML

N89849 001
DEC 27, 1991

TABLET; ORAL

METHOCARBAMOL

/AM/ /THERAP/

/50MG/

/N89417/001/

/750MG/

/FEB 11, 1987

/500MG/

/FEB 11, 1987

/750MG/

/FEB 11, 1987

/500MG/

/FEB 11, 1987

/750MG/

/FEB 11, 1987

/500MG/

/FEB 11, 1987

/750MG/

/FEB 11, 1987

/500MG/

/FEB 11, 1987

/750MG/

/FEB 11, 1987

/500MG/

/FEB 11, 1987

/750MG/

/FEB 11, 1987

METHOTREXATE SODIUM

INJECTABLE; INJECTION

ABITREXATE

ABIC

EQ 25MG BASE/ML

N89161 001

EQ 50MG BASE/VIAL

MAR 10, 1987

EQ 100MG BASE/VIAL

N89354 001

EQ 250MG BASE/VIAL

JUL 17, 1987

EQ 25MG BASE/ML

N89356 001

EQ 50MG BASE/VIAL

JUL 17, 1987

EQ 100MG BASE/VIAL

JUL 17, 1987

EQ 250MG BASE/VIAL

JUL 17, 1987

EQ 25MG BASE/ML

JUL 17, 1987

EQ 50MG BASE/VIAL

JUL 17, 1987

EQ 100MG BASE/VIAL

JUL 17, 1987

EQ 250MG BASE/VIAL

JUL 17, 1987

EQ 25MG BASE/ML

JUL 17, 1987

EQ 50MG BASE/VIAL

JUL 17, 1987

EQ 100MG BASE/VIAL

JUL 17, 1987

EQ 250MG BASE/VIAL

JUL 17, 1987

FOLEX PFS

ADRIA

EQ 25MG BASE/ML

N81242 001

AUG 23, 1991

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE

LEDERLE

/LPHOMED/

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EQ 2.5MG BASE/ML

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N11719/004/

2.5MG

5MG

2.5MG

5MG

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5MG

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5MG

N11719/004/

N11719 004

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N11719/004/

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5MG

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5MG

2.5MG

METHYLDOPA

TABLET; ORAL
METHYLDOPA
/ROXANE/

/N88745/661/
 /MAR/21, 1985/
 N88745 001
 MAR 21, 1985

AB/	MEYLILOPA /ROXANE/	/125MG/
AB/		/250MG/
AB/		/500MG/

/N70192 001
 APR 25, 1986
 /N70193 001
 APR 25, 1986
 /N70194 001
 APR 25, 1986
 N70192 001
 APR 25, 1986
 N70193 001
 APR 25, 1986
 N70194 001
 APR 25, 1986

2 ROXANE

② ②

AB/	125M6/
AB/	250M6/
AB/	500M6/

/N70245/001/
 /FEB/25, 1986/
 /N70246/001/
 /FEB/25, 1986/
 /N70247/001/
 /FEB/25, 1986/

500MG

METHYLDOPATE HYDROCHLORIDE

2 BOLAR

INJECTABLE; INJECTION
METHYLDOPATE HCl

50MG/MLM

N72974 001
NOV 22, 1991
/N71024/001/
SEP 18, 1986
N71024 001
SEP 18, 1986

CHÉL'SÉA/

AP/	QJAD/	50MG/MIL/
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50MG/ML/

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

FEB 25, 1988
/N70260/001/
JUN/24, 1985/
/N70261/001/
JUN/24, 1985/
/N70262/001/
JUN/24, 1985/

125MG
/50005/
/50057/
/50577/

2 QUAD 50MG/ML

METHYLPHENIDATE HYDROCHLORIDE

3 CHelsea

TABLET; ORAL
METHYLPHENIDATE
/MO/ PHARM/

250MG
500MG
/566057/
/566057/

JUN 24, 1985
N70261 001
JUN 24, 1985
N70262 001
JUN 24, 1985

	DLT > AA/	MD/PHARM/	5MG/
	DLT > AA/		10MG/
	DLT > AA/		20MG/
	ADD > AB	MD PHARM	5MG
	ADD > AB		10MG
	ADD > AB		20MG

N85426 001
 N85426 001
 N85426 001
 N86429 001
 N85799 001
 N86428 001
 N10187 003
 N10187 006
 N10187 010
 N10187 003
 N10187 006
 N10187 010

/dúrahánéd/

560MG / 450MG

JUN 24, 1985
/N71066/001/
DEC 16, 1985/
/N71066/001/
DEC 16, 1986/

MD PHARM

RTTALIN
127661

	> DLT >	/AA/		/SMG/
RITALIN	> DLT >	/AA/		/TOMG/
/CIBA/	> DLT >	/AA/		/ZOMG/
	> ADD >	AB	CIBA	SMG
	> ADD >	AB		TOMG
	> ADD >	AB		ZOMG

3 DURAMED

250MG
500MG

N71006 001
DEC 16, 1986
N71009 001
DEC 16, 1986

CIBA

9

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE ACETATE
/A/ LENTON/
/A/ 20MG/ML/
/A/ 40MG/ML/
/A/ 80MG/ML/
20MG/ML
40MG/ML
80MG/ML
3
3
3

/N87248/001
/N85374/001
/N86507/001
N87248 001
N85374 001
N86507 001

/AP/ /QUAD/ /EQ 40MG BASE/VIAL/ /N89264/001/
/AP/ /EQ 125MG BASE/VIAL/ /N89265/001/
/AP/ /EQ 500MG BASE/VIAL/ /N89266/001/
/AP/ /EQ 1GM BASE/VIAL/ /N89267/001/
3 QUAD EQ 40MG BASE/VIAL N89264 001
3 EQ 125MG BASE/VIAL N89265 001
3 EQ 500MG BASE/VIAL N89266 001
3 EQ 1GM BASE/VIAL N89267 001
JAN 22, 1986
JAN 22, 1986
JAN 22, 1986
JAN 22, 1986

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION

A-METHAPRED
ABBOTT
AP EQ 40MG BASE/VIALM
AP EQ 125MG BASE/VIALM
AP EQ 500MG BASE/VIALM
AP EQ 1GM BASE/VIALM

N89573 001
FEB 22, 1991
N89574 001
FEB 22, 1991
N89575 001
FEB 22, 1991
N89576 001
FEB 22, 1991

METHYLPREDNISOLONE SODIUM SUCCINATE

/AP/ /LYPHONED/ /EQ 40MG BASE/VIAL/
/AP/ /EQ 125MG BASE/VIAL/
/AP/ /EQ 500MG BASE/VIAL/
/AP/ /EQ 500MG BASE/VIAL/
/AP/ /EQ 1GM BASE/VIAL/
/AP/ /EQ 1GM BASE/VIAL/

/N88676/001/
/JUN 08, 1984/
/N88677/001/
/JUN 08, 1984/
/N88678/001/
/JUN 08, 1984/
/N89186/001/
/MAR 28, 1986/
/N88679/001/
/JUN 08, 1984/
/N89188/001/
/MAR 28, 1986/
N88676 001
JUN 08, 1984
N88677 001
JUN 08, 1984
N88678 001
JUN 08, 1984
N89186 001
MAR 28, 1986
N88679 001
JUN 08, 1984
N89188 001
MAR 28, 1986

3 LYPHONED

EQ 40MG BASE/VIAL
EQ 125MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 500MG BASE/VIAL
EQ 1GM BASE/VIAL
EQ 1GM BASE/VIAL

/N83240/001/
/N83240/001/
N03240 001
N03240 003

METHYPRYLON

TABLET; ORAL

NOLUDAR
/ROCHE/
3 ROCHE

/N89660/002/
N09660 002

METHYLTESTOSTERONE

TABLET; BUCCAL/SUBLINGUAL

/AB/ /METANDREN/
/AB/ /CIBA/
3 CIBA
3

/N83240/004/
/N03240/004/
N03240 004
N03240 005

METHYLTESTOSTERONE

/BP/ /PHARM/BASICS/
3 PHARM BASICS

/N80271/001/
N80271 001

TABLET; ORAL

/AB/ /METANDREN/
/AB/ /CIBA/
3 CIBA
3

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

METRONIDAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

FLAGYL I.V.

> ADD > AB
> DLT > AB

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

N18353 001
/N18353/001/

INJECTABLE; INJECTION
INFUMORPH
ELKINS SINN

10MG/MLM
25MG/MLM

N18565 003
JUL 19, 1991
N18565 004
JUL 19, 1991

MICONAZOLE NITRATE

CREAM; VAGINAL

MONISTAT 7

> ADD >

2%

JOHNSON RM

N17450 001

MORPHINE SULFATE

STERIS

AP

0.5MG/MLM

N73373 001
SEP 30, 1991

AP

0.5MG/MLM

N73375 001
SEP 30, 1991

AP

1MG/MLM

N73374 001
SEP 30, 1991

AP

1MG/MLM

N73376 001
SEP 30, 1991

SUPPOSITORY; VAGINAL

MONISTAT 7

> ADD >
> ADD >

100MG

N18520 001
MAR 15, 1982

TABLET, EXTENDED RELEASE; ORAL

MS CONTIN

BC

PURDUE FREDERICK

30MG

N19516 001
MAY 29, 1987

BC

60MG

N19516 002
APR 08, 1988

BC

100MG

N19516 004
JAN 16, 1990

ORAMORPH SR

BC

ROXANE LABS

30MG

N19977 001
AUG 15, 1991

BC

60MG

N19977 002
AUG 15, 1991

BC

100MG

N19977 003
AUG 15, 1991

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCYCLINE HCL

DANBURY

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

EQ 50MG BASEM

N63181 001
DEC 30, 1991

EQ 100MG BASEM

N63065 001
DEC 30, 1991

NABUMETONE

> ADD >

TABLET; ORAL

RELAFEN

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

SMITHKLINE BEECHAM

500MG

N19583 001
DEC 24, 1991

750MG

N19583 002
DEC 24, 1991

MINOXIDIL

TABLET; ORAL

MINOXIDIL

/AB/ /PHARM/BASICS/

/4.5MG/

/N71537/001/
/DEC/16/1988/

B* PHARM BASICS

2.5MG

N71537 001
DEC 16, 1988

NAFARELIN ACETATE

SPRAY, METERED; NASAL

SYNAREL

/SYNTEX/

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

/EQ/2MG/BASE/ML/

/N19886/001/
/FEB/13/1990/

EQ 0.2MG BASE/INH

N19886 001
FEB 13, 1990

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE

/AD/ /QUAD/

/10MG/ML/

/N70692/001/

/AD/

INJECTABLE; INJECTION

NANDROLONE DECANOATE

/AD/ /QUAD/

/50MG/ML/

/N89248/001/

/AD/

/20MG/ML/

/N70693/001/

/AD/

/100MG/ML/

/N89249/001/

3 QUAD

10MG/ML

/N70692/001/

/AD/

/200MG/ML/

/N89250/001/

3

20MG/ML

/N70693/001/

/AD/

/50MG/ML

/N89248/001/

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE

/AD/ /ELKINS/SINN/

/0.4MG/ML/

/N70496/001/

/AD/

INJECTABLE; INJECTION

NANDROLONE PHENPROPIONATE

/AD/ /QUAD/

/25MG/ML/

/N89254/001/

3

0.4MG/ML

/N70496/001/

/AD/

/50MG/ML

/N89254/001/

3 ELKINS SINN

0.4MG/ML

/N70496/001/

/AD/

/100MG/ML

/N89254/001/

NALOXONE HCL

/AD/ /LYPHOMED/

/1MG/ML/

/N71604/001/

/AD/

INJECTABLE; INJECTION

NANDROLONE PHENPROPIONATE

/AD/ /QUAD/

/25MG/ML/

/N89254/001/

3

1MG/ML

/N71604/001/

/AD/

/50MG/ML

/N89254/001/

3

0.02MG/ML

/N70678/001/

/AD/

/25MG/ML

/N89254/001/

3

0.4MG/ML

/N70679/001/

/AD/

/50MG/ML

/N89254/001/

3

1MG/ML

/N70680/001/

/AD/

/25MG/ML

/N89254/001/

NANDROLONE DECANOATE

INJECTABLE; INJECTION

NANDROLONE DECANOATE

/AD/ /LEMON/

/50MG/ML/

/N89254/001/

/AD/

TABLET; ORAL

NEOMYCIN SULFATE

/AD/ /ROXANE/

/EQ 350MG BASE/

/N89254/001/

3

50MG/ML

/N89254/001/

/AD/

/EQ 350MG BASE

/N89254/001/

/AD/

50MG/ML

/N89254/001/

/AD/

/EQ 350MG BASE

/N89254/001/

/AD/

50MG/ML

/N89254/001/

/AD/

/EQ 350MG BASE

/N89254/001/

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50MG/ML

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/EQ 350MG BASE

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50MG/ML

/N89254/001/

/AD/

/EQ 350MG BASE

/N89254/001/

/AD/

50MG/ML

/N89254/001/

/AD/

/EQ 350MG BASE

/N89254/001/

PANIDRONATE DISODIUMINJECTABLE; INJECTION
ARELIA

CIBA GEIGY

30MG/VIAL

N20036 001
OCT 31, 1991PANCURONIUM BROMIDEINJECTABLE; INJECTION
PANCURONIUM BROMIDE

/AA/ /QUAD/

/1MG/ML/

/N72209/001/
JUN 03, 1988

/AA/

/2MG/ML/

/N72208/001/
JUN 03, 1988

a QUAD

1MG/ML

N72209 001

a

2MG/ML

N72208 001
JUN 03, 1988PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

/AA/ /CHELSEA/

/100MG/

/N85791/001/
N85791 001

> ADD >

> DLT >

a CHELSEA
a ELKINS SINN
/a/ QUANTUM PHARMICS/

100MG

N83368 001

/AA/ /MYETH AYERST/

/100MG/

/N83239/001/
N83239 001

a MYETH AYERST

100MG

PENTOSTATININJECTABLE; INJECTION
NIPENT

PARKE DAVIS

10MG/VIAL

N20122 001
OCT 11, 1991PERPHENAZINETABLET; ORAL
PERPHENAZINE

B* CHELSEA

8MG

N89700 001
DEC 23, 1987

/BX/

/8MG/

/N89700/001/
DEC 23, 1987PHENDIMETRAZINE TARTRATECAPSULE, EXTENDED RELEASE; ORAL
PHENDIMETRAZINE TARTRATE

BC VITARINE

105MG

N18074 001
/N18074/001/

/a/ /SOLVAY/

/105MG/

/N88024/001/
DEC 22, 1982

/a/ /SOLVAY/

/105MG/

/N88024/001/
DEC 22, 1982

a SOLVAY

105MG

TABLET; ORAL

BONTREL PDM

35MG

N85272 001

CARNICK

35MG

/N85272/001/
/N85272/001/

/PHENDIMETRAZINE TARTRATE/

/35MG/

/N85272/001/
/N85272/001/

/CORD/

/35MG/

/N85272/001/
/N85272/001/

PHENDIMETRAZINE TARTRATE

35MG

N86365 001
N89452 001

a CORD

35MG

OCT 30, 1991

a MIKART

35MG

OCT 30, 1991

PENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PENTERMINE HCL

/30MG/

/N88948/001/
/APR 25, 1986/

> DLT >

> DLT >

> ADD >

> ADD >

/AA/ /PIRAMED/

/30MG/

/N88948/001/
/APR 25, 1986/

a DURAMED

30MG

N88948 001
APR 25, 1986PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

/50MG/ML/

/N88521/001/
/DEC 18, 1984/

/a/ /SOLVAY/

/50MG/ML/

/N88521/001/
/DEC 18, 1984/

a SOLOPAK

50MG/ML

N88521 001
DEC 18, 1984PINACIDILCAPSULE, EXTENDED RELEASE; ORAL
PINDAC
LEO

12.5MG

N19456 001
DEC 28, 1989

25MG

N19456 002
DEC 28, 1989

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

/AB/ /BOLAR/

/250MG/

/N83795/001/

250MG

/N84357/001/

2

N83795 001

2

N84357 001

INJECTABLE; INJECTION

PROCAINAMIDE HCL

/AP/ /QUAD/

/100MG/ML/

/N89256/001/

2

MAY 30, 1986

2

N89257 001

2

MAY 30, 1986

2

MAY 30, 1986

2

MAY 30, 1986

2

MAY 30, 1986

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MAY 30, 1986

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MAY 30, 1986

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MAY 30, 1986

PROCHLORPERAZINE EDISYLATE

/CONCENTRATE; ORAL/

PROCHLORPERAZINE EDISYLATE/

/PHARM/BASICS/

/N89598/001/

EQ 10MG BASE/ML

/OCT 25, 1984/

2

N89598 001

2

OCT 25, 1984

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

/AP/ /QUAD/

/EQ 5MG BASE/ML/

/N89637/001/

2

FEB 01, 1988

2

N89638 001

2

FEB 01, 1988

2

FEB 01, 1988

2

FEB 01, 1988

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FEB 01, 1988

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FEB 01, 1988

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FEB 01, 1988

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FEB 01, 1988

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE

/AB/ /BOLAR/

/EQ 5MG BASE/

/N85580/001/

2

N85580 001

2

N85178 001

2

N85579 001

2

N85580 001

2

N85178 001

2

N85579 001

TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

/AB/ /BOLAR/

/1GM/

/N89520/001/

2

JAN 15, 1987

2

N89520 001

2

JAN 15, 1987

2

JAN 15, 1987

2

JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

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JAN 15, 1987

2

JAN 15, 1987

PROCHLORPERAZINE MALEATE

TABLET; ORAL

/AB/ PROCHLORPERAZINE MALEATE /ED 5MG BASE/
/DURANED/
/AB/ /ED 10MG BASE/
/AB/ /ED 25MG BASE/

B* DURANED EQ 5MG BASE
B* EQ 10MG BASE
B* EQ 25MG BASE

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

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

SOLUTION/DROPS; OPHTHALMIC

/PROPARGOLINE HCL/
/BARNES/HIND/
3 SOLA BARNES HIND
3

/0.5%/
/0.5%/
0.5%
0.5%

/N84144/001/
/N84151/001/
N84144 001
N84151 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL
3 ALRA
/3/BARNES/

65MG
/65MG/

N83184 001
/N83184/001/

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HCL

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

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

/AB/ /1MG/ML/
/AB/ /1MG/ML/
3 SOLOPAK
1MG/ML

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

SUPPOSITORY; RECTAL

PROMETHAZINE HCL

/BR/ /50MG/
PROMETHEGAN
G AND M
50MG

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

SOLUTION; ORAL

/AB/ PROPRANOLOL HCL
/AB/ /PHARM/BASICS/
3 PHARM BASICS
3

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

/N71984/001/
/MAR 03, 1989/
/N71985/001/
/MAR 03, 1989/
/N71984 001
MAR 03, 1989

PROPANTHELINE BROMIDE

TABLET; ORAL

PRO-BANTHINE

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

N08732 003
N08732 002
/N08732/003/
/N08732/002/

/AB/ /ROXANE/
/AB/ /ROXANE/
ROXANE
20MG/5ML
40MG/5ML

/N70979 001
MAY 15, 1987
N70979 001
MAY 15, 1987

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

/AB/ /SUPERPHARM/

/40MG/

/N71517/001/

/AB/

/80MG/

/N71518/001/

3 SUPERPHARM

40MG

N71517 001

3

80MG

N71518 001

JUN 08, 1988

PROTAHINE SULFATE

INJECTABLE; INJECTION

PROTAHINE SULFATE

/QJAB/

/50MG/VIAL/

/N89307/001/

3 QUAD

50MG/VIAL

N89307 001

MAY 30, 1986

PSEUDOEPHEDRINE HYDROCHLORIDE; TERFENADINE

TABLET, EXTENDED RELEASE; ORAL

SELDANE-D

MERRELL DOW

120MG;60MG

N19664 001

AUG 19, 1991

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL

PYRIDOSTIGMINE BROMIDE

KALI DUPHAR

30MG

N89572 001

NOV 27, 1990

/N89572/001/

/NOV/27,1990/

/PUREPAC/

/30MG/

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION

PYRIDOXINE HCL

/LEHMON/

AP STERIS

/100MG/ML/

100MG/ML

/N83760/001/

N83760 001

PYRILAMINE MALEATE

TABLET; ORAL

PYRILAMINE MALEATE

/AB/ /CHELSEA/

/45MG/

/N85231/001/

3 CHELSEA

25MG

N85231 001

/AB/ /RICHLYN/

/45MG/

/N86666/001/

RICHLYN

25MG

N86666 001

QUAZEPAM

TABLET; ORAL

DORAL

BAKER CUMMINS

7.5MG

N18708 003

FEB 26, 1987

N18708 001

DEC 27, 1985

/DORALIN/

/7.5MG/

/N18708/003/

/BAKER/CUMMINS/

/15MG/

/FEB/26,1987/

/N18708/001/

/DEC/27,1985/

QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

ACCUPRIL

PARKE DAVIS

EQ 5MG BASEM

N19885 001

NOV 19, 1991

EQ 10MG BASEM

N19885 002

NOV 19, 1991

EQ 20MG BASEM

N19885 003

NOV 19, 1991

EQ 40MG BASEM

N19885 004

NOV 19, 1991

GUINESTROL

TABLET; ORAL

ESTROVIS

PARKE DAVIS

0.1MG

N16768 002

QUINIDINE GLUCONATE

/TABLET; DORAL/

/QUINACT/

/BERLEX/

/25MG/

/40MG/

/N85376/001/

/N85376/001/

SECOBARBITAL SODIUM

TABLET; ORAL
SECOBARBITAL SODIUM
/AYERST/
@ WYETH AYERST

/100MG/
100MG

/N86396/001/
N86390 001

TABLET; ORAL
SPIRONOLACTONE
/BOLAR/
@ BOLAR

/25MG/
25MG

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

SELENIUM SULFIDE

LOTION/SHAMPOO; TOPICAL
SELENIUM SULFIDE
AT CLAY PARK

2.52M

N8996 001
JAN 10, 1991

SUCCIMER

CAPSULE; ORAL
CHEMET
MCNEIL

100MG

N1998 002
JAN 30, 1991

> ADD > SERTRALINE HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > ZOLOFT
> ADD > PFIZER

EQ 50MG BASEM

N19839 001
DEC 30, 1991

EQ 100MG BASEM

N19839 002
DEC 30, 1991

EQ 150MG BASEM

N19839 003
DEC 30, 1991

EQ 200MG BASEM

N19839 004
DEC 30, 1991

> ADD > TABLET; ORAL
> DLT > CARAFATE
> DLT > BLUE RIDGE
> DLT > /MARION/MERRELL/POW /1GM/
1GM

N18333 001
/N18333/001/

> ADD > SIMVASTATIN

> ADD > TABLET; ORAL
> ADD > ZOCOR
> ADD > MSD

5MG

N19766 001
DEC 23, 1991

10MG

N19766 002
DEC 23, 1991

20MG

N19766 003
DEC 23, 1991

40MG

N19766 004
DEC 23, 1991

> ADD > CREAM; VAGINAL
> ADD > SULTRIN
> ADD > JOHNSON RW

N05794 001

SULFABENZAMIDE; SULFACETAMIDE; SULFATHIAZOLE; UREA

> DLT > CREAM; VAGINAL
> DLT > /SULTRIN/
> DLT > /AT/ JOHNSON/RW

/3.72; 2.86; 3.42; 0.64/
/N05794/001/

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
SODIUM NITROPRUSSIDE
/LYPHOMED/
@ LYPHOMED

/50MG/VIAL/
50MG/VIAL

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

SULFASALAZINE

TABLET, DELAYED RELEASE; ORAL

AZULFIDINE EN-TABS

KABI

500MG

/AB/ /PHARMACIA/

500MG

/AB/ /SULFASALAZINE/

500MG

/AB/ /BOLAR/

500MG

3 BOLAR

500MG

N07073 002

APR 06, 1983

/N07073/002/

/APR/06,1983/

/N08052/001/

/MAY/24,1983/

N80052 001

MAY 24, 1983

SULFISOXAZOLE

TABLET; ORAL

SOXAZOLE

3 ALRA

/3/BANNA/

500MG

500MG

N80366 001

/N80366/001/

SULINDAC

TABLET; ORAL

SULINDAC

GENEVA

150MG

200MG

150MG

200MG

150MG

200MG

150MG

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/A

N19981 001

JUN 10, 1991

TEMASEPAM

CAPSULE; ORAL

RESTORIL

SANDOZ

7.5MG

/AB/ /TEMASEPAM/

15MG

/AB/ /BOLAR/

30MG

/AB/ /BOLAR/

15MG

3 BOLAR

15MG

3

30MG

> DLT > /AB/ /DURAMED/

15MG

> DLT > /AB/ /DURAMED/

30MG

> DLT > /AB/ /DURAMED/

15MG

> ADD > /AB/ /DURAMED/

30MG

> ADD > /AB/ /DURAMED/

15MG

> ADD > /AB/ /DURAMED/

30MG

> ADD > /AB/ /PHARM/BASICS/

15MG

> ADD > /AB/ /PHARM/BASICS/

30MG

B* PHARM BASICS

15MG

B* PHARM BASICS

30MG

TERCONAZOLE

CREAM; VAGINAL

TERAZOL 3

JOHNSON RW

0.8%^m

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

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

LENNON

100MG/mL

200MG/mL

/AB/ /LENNON/

100MG/mL

/AB/ /LENNON/

200MG/mL

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

/N71708/001/

/SEP/29,1988/

/N71709/001/

/SEP/29,1988/

N71708 001

SEP 29, 1988

N71709 001

SEP 29, 1988

/N70449/001/

/JUL/07,1986/

/N70450/001/

/JUL/07,1986/

N70449 001

JUL 07, 1986

N70450 001

JUL 07, 1986

N19964 001

FEB 21, 1991

/N84461/001/

/N84461/002/

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

/AD/ /QUAD/ /100MG/ML/

/AD/ /QUAD/ /200MG/ML/

2 QUAD 100MG/ML

2 200MG/ML

STERIS 100MG/ML

AO 200MG/ML

/N89326/001/

/OCT 28, 1988/

/N89327/001/

/OCT 28, 1988/

/N84401/001/

/N84401/002/

POWDER FOR RECONSTITUTION; TOPICAL

TETRAHYDROXYCORTICOLINE HCL

> ADD > 250MG

> DLT > /2.5MG/ML/

> ADD > AB 250MG

> DLT > /2.5MG/ML/

POWDER FOR RECONSTITUTION; TOPICAL

TOPICYCLINE

/P/AND/6/

ROBERTS

N80059 001

/N80059/001/

N81471 001

/N81471/001/

N854493 001

/N854493/001/

N50493 001

TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

TESTOSTERONE ENANTHATE

> DLT > /DELAESTRIL/

> DLT > /3QUAD/

> ADD > 200MG/ML

/AD/ /QUAD/ /100MG/ML/

/AD/ /QUAD/ /200MG/ML/

/AD/ /QUAD/ /100MG/ML/

/AD/ /QUAD/ /200MG/ML/

2 QUAD 100MG/ML

2 200MG/ML

STERIS 100MG/ML

AO 200MG/ML

/N89326/001/

/N89327/001/

/N89327/002/

/N89327/003/

/SEP 16, 1986/

/N89325/001/

/SEP 16, 1986/

/N89324/001/

SEP 16, 1986

N89325 001

SEP 16, 1986

N83667 001

N83667 002

THEOPHYLLINE

POWDER FOR RECONSTITUTION; TOPICAL

THEOPHYLLINE HCL

> ADD > 100MG

> DLT > /2.5MG/ML/

> ADD > AB 200MG

> DLT > /2.5MG/ML/

POWDER FOR RECONSTITUTION; TOPICAL

TOPICYCLINE

/P/AND/6/

ROBERTS

N87155 001

/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

THEOPHYLLINE

> ADD > 100MG

> DLT > /2.5MG/ML/

> ADD > AB 200MG

> DLT > /2.5MG/ML/

POWDER FOR RECONSTITUTION; TOPICAL

TOPICYCLINE

/P/AND/6/

ROBERTS

N87155 001

/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

TESTOSTERONE PROPIONATE

INJECTABLE; INJECTION

TESTOSTERONE PROPIONATE

/AD/ /QUAD/ /100MG/ML/

/AD/ /QUAD/ /200MG/ML/

/AD/ /QUAD/ /100MG/ML/

/AD/ /QUAD/ /200MG/ML/

2 QUAD 100MG/ML

2 200MG/ML

STERIS 100MG/ML

AO 200MG/ML

/N85490/001/

/N85490/002/

/N85490/003/

/N85490/004/

/NOV 03, 1986/

/N85490/001/

/NOV 03, 1986/

/N85490/002/

/N85490/003/

> ADD > 100MG

> DLT > /2.5MG/ML/

> ADD > AB 200MG

> DLT > /2.5MG/ML/

POWDER FOR RECONSTITUTION; TOPICAL

TOPICYCLINE

/P/AND/6/

ROBERTS

N84731 001

/N84731/001/

/NOV 07, 1986/

/N84731/002/

/NOV 07, 1986/

/N84731/003/

/NOV 07, 1986/

N84731 001

NOV 07, 1986

N84731 002

NOV 07, 1986

N84731 003

NOV 07, 1986

> ADD > 100MG

> DLT > /2.5MG/ML/

> ADD > AB 200MG

> DLT > /2.5MG/ML/

POWDER FOR RECONSTITUTION; TOPICAL

TOPICYCLINE

/P/AND/6/

ROBERTS

N84731 001

/N84731/001/

/NOV 07, 1986/

/N84731/002/

/NOV 07, 1986/

/N84731/003/

/NOV 07, 1986/

N84731 001

NOV 07, 1986

N84731 002

NOV 07, 1986

N84731 003

NOV 07, 1986

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

/BC/ /CENTRAL PHARMS/ /125MG/ /N88654/001/
/FEB/12/1985/
/BC/ /CENTRAL PHARMS/ /250MG/ /N88689/001/
/FEB/12/1985/
3 CENTRAL PHARMS 125MG N88654 001
FEB 12, 1985
3 CENTRAL PHARMS 250MG N88689 001
FEB 12, 1985

THEOPHYLLINE-SR

/BC/ /SCHERER/ /300MG/ /N88255/001/
/JUN/12/1986/
3 SCHERER 300MG N88255 001
JUN 12, 1986

TABLET; ORAL

/BP/ /THEOCLEAR-100/ /100MG/ /N85353/002/
3 CENTRAL PHARMS 100MG N85353 002
/BP/ /THEOCLEAR-200/ /200MG/ /N85353/001/
3 CENTRAL PHARMS 200MG N85353 001

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

/AP/ /THIAMINE HCL/ /100MG/ML/ /N83534/001/
/AP/ /LENNON/ /200MG/ML/ /N83534/002/
/AP/ /LYPHOMED/ /100MG/ML/ /N80509/001/
3 LYPHOMED 100MG/ML N80509 001
/AP/ /STERIS/ /100MG/ML/ /N83534/001/
/AP/ /STERIS/ /200MG/ML/ /N83534/002/

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

/AP/ /THIORIDAZINE HCL/ /30MG/ML/ /N87766/001/
/APR/26/1983/
3 BARRE 30MG/ML N87766 001
APR 26, 1983

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

/AB/ /THIORIDAZINE HCL/ /10MG/ /N88412/001/
/BOLAR/ /SEP/12/1983/
/AB/ /BOLAR/ /15MG/ /N88345/001/
/JUL/28/1983/
/AB/ /BOLAR/ /25MG/ /N88296/001/
/JUL/28/1983/
/AB/ /BOLAR/ /50MG/ /N88323/001/
/JUL/28/1983/
/AB/ /BOLAR/ /100MG/ /N88284/001/
/AUG/25/1983/
/AB/ /BOLAR/ /150MG/ /N88410/001/
/MAR/05/1984/
/AB/ /BOLAR/ /200MG/ /N88381/001/
/MAR/14/1984/
/AB/ /ROXANE/ /10MG/ /N88663/001/
/MAR/15/1984/
/AB/ /ROXANE/ /25MG/ /N88664/001/
/MAR/15/1984/
/AB/ /ROXANE/ /50MG/ /N88665/001/
/MAR/15/1984/
/AB/ /ROXANE/ /100MG/ /N89048/001/
/FEB/26/1985/
3 ROXANE 10MG N88663 001
MAR 15, 1984
3 ROXANE 25MG N88664 001
MAR 15, 1984
3 ROXANE 50MG N88665 001
MAR 15, 1984
3 ROXANE 100MG N89048 001
FEB 26, 1985

THIOTHIXENE

CAPSULE; ORAL

THIOTHIXENE
/AM/THERAP/

/1MG/

/2MG/

/5MG/

/10MG/

/20MG/

3 AM THERAP

1MG

3

2MG

3

5MG

3

10MG

3

20MG

/CHELSEA/

/2MG/

3

/5MG/

3

/10MG/

3 CHELSEA

2MG

3

5MG

3

10MG

/N71884/001/
/AUG/12, 1987//N71885/001/
/AUG/12, 1987//N71886/001/
/AUG/12, 1987//N71887/001/
/AUG/12, 1987//N72000/001/
/DEC/13, 1987//N71884/001/
AUG 12, 1987/N71885/001/
AUG 12, 1987/N71886/001/
AUG 12, 1987/N71887/001/
AUG 12, 1987/N72000/001/
DEC 17, 1987/N71884/001/
/JUN/25, 1987//N71885/001/
/JUN/25, 1987//N71886/001/
/JUN/25, 1987//N71887/001/
/JUN/25, 1987//N71888/001/
/JUN/25, 1987//N71889/001/
JUN 25, 1987/N71890/001/
JUN 25, 1987/N71891/001/
JUN 25, 1987/N71892/001/
JUN 25, 1987/N71893/001/
JUN 25, 1987/N71894/001/
JUN 25, 1987/N71895/001/
JUN 25, 1987/N71896/001/
JUN 25, 1987/N71897/001/
JUN 25, 1987THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL
/PACO/

/EQ 5MG BASE/ML/

/EQ 1MG BASE/ML/

EQ 5MG BASE/ML

EQ 1MG BASE/ML

3 PACO

3

/N71898/001/
/DEC/16, 1988//N71899/001/
/SEP/26, 1989//N71900/001/
DEC 16, 1988/N71901/001/
SEP 20, 1989/N71902/001/
SEP 20, 1989/N71903/001/
SEP 20, 1989/N71904/001/
SEP 20, 1989/N71905/001/
SEP 20, 1989/N71906/001/
SEP 20, 1989/N71907/001/
SEP 20, 1989/N71908/001/
SEP 20, 1989/N71909/001/
SEP 20, 1989/N71910/001/
SEP 20, 1989/N71911/001/
SEP 20, 1989/N71912/001/
SEP 20, 1989/N71913/001/
SEP 20, 1989TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLID
SYNTEX

250MG

N19979 002
OCT 31, 1991TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE
/BOLAR/

/5MG/

/10MG/

/20MG/

3 BOLAR

5MG

3

10MG

3

20MG

AB DANBURY

5MG

AB

10MG

AB

20MG

/PHARM/BASICS/

/5MG/

/AB/

/10MG/

/AB/

/20MG/

B* PHARM BASICS

5MG

B*

10MG

B*

20MG

JAN 10, 1989
N72001 001
JAN 10, 1989
N72002 001
JAN 10, 1989
N72003 001
JAN 10, 1989TIOCONAZOLE

OINTMENT; VAGINAL

/VAGISTAT/

/2/FUSISANA/

VAGISTAT-1

BRISTOL MYERS

6.5%

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

/N19355/001/
/DEC/30, 1986/N19355 001
DEC 30, 1986

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP	ABBOTT	EQ 10MG BASE/MLM	N63080 001	> DLT > /AB/
AP		EQ 10MG BASE/MLM	APR 30, 1991	> DLT >
AP		EQ 40MG BASE/MLM	N63112 001	> DLT > /AB/
AP		EQ 40MG BASE/MLM	APR 30, 1991	> DLT >
AP		EQ 40MG BASE/MLM	N63111 001	> DLT > /AB/
AP		EQ 40MG BASE/MLM	APR 30, 1991	> DLT >
AP	ELKINS SINN	EQ 10MG BASE/MLM	N63161 001	> ADD >
AP		EQ 10MG BASE/MLM	MAY 29, 1991	> ADD >
AP		EQ 40MG BASE/MLM	N63128 001	> ADD >
AP		EQ 40MG BASE/MLM	NOV 27, 1991	> ADD >
AP		EQ 40MG BASE/MLM	N63127 001	> ADD >
AP	LEDERLE	EQ 10MG BASE/MLM	NOV 27, 1991	> ADD >
AP		EQ 40MG BASE/MLM	N63113 001	/AB/ /PHARM/BASICS/
AP		EQ 40MG BASE/MLM	APR 26, 1991	/AB/
AP		EQ 40MG BASE/MLM	N63117 001	/AB/
AP		EQ 40MG BASE/MLM	APR 26, 1991	/AB/
AP		EQ 40MG BASE/MLM	N63118 001	/AB/
AP		EQ 40MG BASE/MLM	JUL 29, 1991	

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

/AB/	/BOLAR/	/100MG/	/N70242/001/	> DLT >
/AB/		/250MG/	AUG 01, 1986	> DLT >
/AB/		/500MG/	N70243 001	> DLT >
	a BOLAR	100MG	AUG 01, 1986	> DLT >
	a	250MG	N70244 001	> DLT >
	a	500MG	AUG 01, 1986	> DLT >
	/CHELSEA/	/100MG/	/N70245/001/	> DLT >
		/250MG/	JAN 09, 1986	> DLT >
		/500MG/	/N70246/001/	> DLT >
			JAN 09, 1986	> DLT >
			/N70247/001/	> DLT >
			JAN 09, 1986	> DLT >

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

> DLT > /AB/	/100MG/	/N70165/001/
> DLT >		JAN 10, 1986
> DLT > /AB/	/250MG/	/N70166/001/
> DLT >		JAN 10, 1986
> DLT > /AB/	/500MG/	/N70167/001/
> DLT >		JAN 10, 1986
> ADD >	100MG	N70165 001
> ADD >		JAN 10, 1986
> ADD >	250MG	N70166 001
> ADD >		JAN 10, 1986
> ADD >	500MG	N70167 001
> ADD >		JAN 10, 1986
/AB/ /PHARM/BASICS/	/100MG/	/N71355/001/
/AB/	/250MG/	JAN 11, 1988
/AB/	/500MG/	/N71356/001/
		APR 02, 1986
		/N71357/001/
		APR 02, 1986
B* PHARM BASICS	100MG	N71355 001
B*	250MG	JAN 11, 1988
B*	500MG	N70168 001
		APR 02, 1986
		N70169 001
		APR 02, 1986

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

/AB/	/500MG/	N86141 001
/AB/	/500MG/	/N86142/001/
	/250MG/	JAN 10, 1986
	/500MG/	/N86143/001/
		MAY 29, 1987
		/N86144/001/
		MAY 29, 1987
a BOLAR	250MG	N89110 001
a	500MG	MAY 29, 1987
		N89111 001
		MAY 29, 1987

TOLMETIN SODIUM

CAPSULE; ORAL
TOLECTIN DS
AB JOHNSON RW

EQ 400MG BASE

N18084 001

TOLMETIN SODIUM

CAPSULE; ORAL

TOLMETIN SODIUM

AB MUTUAL PHARM

AB NOVOPHARM

TABLET; ORAL

TOLECTIN

AB JOHNSON RM

TOLMETIN SODIUM

AB MUTUAL PHARM

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL/AN/THERAP/

> DLT > /AB/

> DLT >

> DLT > /AB/

> DLT >

> ADD >

> ADD >

> ADD >

3 AM THERAP

3

/AB/ /BOLAR/

/AB/

3 BOLAR

3

/B* /CHELSEA/

> DLT >

> DLT >

> DLT >

> DLT >

AB MYLAN

AB

/AB/ /PHARM/BASICS/

/AB/

B* PHARM BASICS

B*

EQ 400MG BASEM

EQ 400MG BASEM

EQ 200MG BASE

EQ 200MG BASEM

/50MG/

/100MG/

50MG

100MG

/50MG/

/100MG/

50MG

100MG

/50MG/

/100MG/

50MG

100MG

/50MG/

/100MG/

50MG

100MG

N73311 001

NOV 27, 1991

N73290 001

NOV 27, 1991

N17628 001

N73310 001

NOV 27, 1991

/N71139/001/

/OCT/29/1986/

/N71140/001/

/OCT/29/1986/

N71139 001

OCT 29, 1986

N71140 001

OCT 29, 1986

/N71112/001/

/NOV/17/1986/

/N71113/001/

/NOV/17/1986/

N71112 001

NOV 17, 1986

N71113 001

NOV 17, 1986

/N70556/001/

/OCT/10/1986/

/N70557/001/

/OCT/10/1986/

N71405 001

FEB 27, 1991

N71406 001

FEB 27, 1991

/N70449/001/

/APR/29/1987/

/N70450/001/

/APR/29/1987/

N70491 001

APR 29, 1987

N70492 001

APR 29, 1987

TRETINOLIN

GEL; TOPICAL

RETIN-A

/AT/ /JOHNSON/RM/

/0.012/

/N17576/001/

TRIAMCINOLONE ACETONIDE

AEROSOL, METERED; NASAL

NASACORT

RHONE POULENC RORER

N19798 001

JUL 11, 1991

CREAM; TOPICAL

/KENAC//NMC/

/N87797/001/

/JUN/07/1982/

/N87798/001/

/JUN/04/1982/

TRIAMCINOLONE ACETONIDE

G AND W

AT 0.0252M

AT 0.12M

AT 0.0252M

AT 0.12M

/AT/ /PHARM/BASICS/

/AT/ /0.012/

/AT/ /0.0252/

3 PHARM BASICS

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

3 0.12M

3 0.52M

3 0.0252M

TRIAMCINOLONE ACETONIDE

ointment; topical

/AT/ /KENAC/ /0.1%/
/NMC/

TRIAMCINOLONE ACETONIDE

AT NMC 0.1%
/AT/ /PHARM/BASIC/ /0.025%/
/AT/ /0.1%/
/AT/ /0.5%/
3 PHARM BASICS 0.025%
3 0.1%
3 0.5%

TRIAMCINOLONE DIACETATE

injectable; injection

TRIAMCINOLONE DIACETATE
/BP/ /LENNON/ /40MG/ML/
BP STERIS 40MG/ML

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

/BP/ /BOLAR/ /4MG/
3 BOLAR 4MG

TRIFLUOPERAZINE HYDROCHLORIDE

injectable; injection

STELAZINE

/AP/ /SKF/ /EQ 2MG BASE/ML/
SKF

/AP/ /TRIFLUOPERAZINE HCL/ /EQ 2MG BASE/ML/
/QUAD/

3 QUAD

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

/AB/ /BOLAR/ /EQ 1MG BASE/
/AB/ /EQ 2MG BASE/
/AB/ /EQ 5MG BASE/
/AB/ /EQ 10MG BASE/
3 BOLAR EQ 1MG BASE
3 EQ 2MG BASE
3 EQ 5MG BASE
3 EQ 10MG BASE

> DLT > /B* / /DURAMED/
> DLT >
> DLT > /B* /
> DLT > /B* /
> DLT > /B* /
> DLT > /B* /
> DLT > /B* /
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >

TRIHENXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHENXYPHENIDYL HCL

/AB/ /BOLAR/ /EQ 2MG/
/AB/ /EQ 5MG/
3 BOLAR 2MG
3 5MG

/N85975 001/
JUN 23, 1988
/N85976 001/
JUN 23, 1988
/N85973 001/
JUN 23, 1988
/N85970 001/
JUN 23, 1988
/N85975 001/
JUN 23, 1988

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

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N85268 001

TRIMEPAZINE TARTRATE

SYRUP; ORAL

TEMARIL

/AB/ /HERBERT/

HERBERT

/TRIMEPAZINE TARTRATE/

/PHARM/BASICS/

3 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

/N88285/001/

/APR 11, 1985/

N88285 001

APR 11, 1985

SUSPENSION; ORAL

SULFOS

/AB/ /MYETH AYERST/

3 MYETH AYERST

TABLET; ORAL

SULFOS

/AB/ /MYETH AYERST/

3 MYETH AYERST

/500MG/5ML/

500MG/5ML

/500MG/

500MG

/N80013/002/

N80013 002

/N30013/001/

N30013 001

TRIMETHOBENZAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

TRIMETHOBENZAMIDE HCL

/AB/ /SOLOPAK/

3 SOLOPAK

/100MG/ML/

100MG/ML

/N89043/001/

/APR 04, 1986/

N89043 001

APR 04, 1986

SYRUP; ORALDEPAKENE

/AB/ /ABBOTT/

MYPROIC ACID

/PHARM/BASICS/

> DLT >

> DLT >

> DLT >

> DLT >

> DLT >

/N18082/001/

/EQ 250MG BASE/5ML/

/N18082/001/

/JUL 01, 1986/

TRIMPRAMINE MALEATE

CAPSULE; ORAL

TRIMPRAMINE MALEATE

/AB/ /PHARM/BASICS/

/AB/ /PHARM/BASICS/

/AB/ /PHARM/BASICS/

B* PHARM BASICS

B* PHARM BASICS

B* PHARM BASICS

/EQ 25MG BASE/

/EQ 50MG BASE/

/EQ 100MG BASE/

EQ 25MG BASE

EQ 50MG BASE

EQ 100MG BASE

/N71283/001/

/DEC 08, 1987/

/N71284/001/

/DEC 08, 1987/

/N71285/001/

/DEC 08, 1987/

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DEC 08, 1987

N71284 001

DEC 08, 1987

N71285 001

DEC 08, 1987

VALPROIC ACID

CAPSULE; ORAL

VALPROIC ACID

AB SCHERER

SYRUP; ORAL

DEPAKENE

ABBOTT

MYPROIC ACID

PHARM BASICS

> ADD >

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> ADD >

> ADD >

> ADD >

250MG

250MG/5ML

250MG/5ML

N73229 001

OCT 29, 1991

N18082 001

N70868 001

JUL 01, 1986

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOMYCIN HCL

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> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

/EQ 500MG BASE/VIAL/

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EQ 500MG BASE/VIAL

EQ 1GM BASE/VIAL

/N62845/001/

/JUL 15, 1988/

/N62845/002/

/JUL 15, 1988/

N62845 001

JUL 15, 1988

N62845 002

JUL 15, 1988

TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

TRIPROLIDINE HCL

/AB/ /DANBURY/

/AB/ /VITARINE/

3 VITARINE

/2.5MG/

2.5MG

/2.5MG/

2.5MG

/N85094/001/

/N85610/001/

N85094 001

N85610 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '91 - DEC '91

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

/CALAN/
/AP/ /SEARLE/

/4.5MG/ML/

3 SEARLE

2.5MG/ML

/N76925/001/
/MAR/30/1984/
N18925 001
MAR 30, 1984VERAPAMIL HCL

/QUAD/

/4.5MG/ML/

3 QUAD

2.5MG/ML

/N76672/001/
/MAR/07/1986/
N70672 001
MAR 07, 1986

/AP/ /SOLOPAK/

/4.5MG/ML/

3 SOLOPAK

2.5MG/ML

/N76697/001/
/JUL/31/1987/
N70697 001
JUL 31, 1987

TABLET; ORAL

VERAPAMIL HCL

/CHELSEA/

/40MG/

/N72799/001/
/APR/28/1989/
N70421 001
SEP 17, 1986
N70422 001
SEP 17, 1986> DLT >
> DLT >

B*

CHELSEA

80MG

B*

CHELSEA

120MG

/BX/

/80MG/

/N70421/001/
/SEP/17/1986/
/N70422/001/
/SEP/17/1986/
N72799 001
APR 28, 1989

/BX/

/120MG/

> ADD >
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3

40MG

TABLET, EXTENDED RELEASE; ORAL

ISOPTIN SR

KNOLL

120MG

N19152 003
MAR 06, 1991VINBLASTINE SULFATE

INJECTABLE; INJECTION

VINBLASTINE SULFATE

/LYPHOMED/

/1MG/ML/

/N89515/001/
/APR/29/1987/
N89515 001
APR 29, 1987

LYPHOMED

1MG/ML

VINBLASTINE SULFATE

INJECTABLE; INJECTION

VINBLASTINE SULFATE

/1MG/ML/

/N89511/001/
/MAR/23/1987/
/N89515/001/
/AUG/07/1986/
N89311 001
MAR 23, 1987
N89365 001
AUG 07, 1986

/10MG/VIAL/

1MG/ML

10MG/VIAL

3 QUAD

3

VINCRISTINE SULFATE

INJECTABLE; INJECTION

VINCRISTINE SULFATE

/1MG/ML/

/N70873/001/
FEB 19, 1987
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/N71560/001/
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APR 11, 1988
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APR 11, 1988

ABIC

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APR 11, 1988

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APR 11, 1988

BULL

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APR 11, 1988

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1MG/ML

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1MG/VIAL

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APR 11, 1988

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2MG/VIAL

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APR 11, 1988

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5MG/VIAL

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N71560 001
APR 11, 1988

VITAMIN A

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> DLT > /AQUASOL A/
> DLT > /ARMOUR/

/50,000 UNITS/ML/

/N06023/001/

> DLT > GAS; INHALATION
> DLT > /XENON A/ 133-0.5.5./
> ADD > /MEDI/ PHYSICS/
 @ MEDI PHYSICS

/10001 VIAL/
10MCI/VIAL/N17605/001/
N17605 001

VITAMIN A PALMITATE

CAPSULE; ORAL
/VITAMIN A/
/MILES/
@ MILES

/EQ 50,000 UNITS BASE/

/N80972/001/
N80972 001

POWDER; ORAL
XYLO-PFAN
AA

25GM/BOT
/25GM/BOT/N17605 001
/N17605/001/

> ADD > AP INJECTABLE; INJECTION
> ADD > ARMOUR PHARM
VITAMIN A PALMITATE
BEL MAR LABS
> DLT > /BEL/MAR/LABS/

EQ 50,000 UNITS BASE/ML

N06823 001

XYLOSE
AA

25GM/BOT

N18856 001

/3/

MAR 26, 1987
/N18856/001/
/MAR/26, 1987/

MARFARIN SODIUM

TABLET; ORAL

MARFARIN SODIUM
/BX/ /BOLAR/

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/N86123/001/
AUG 17, 1982

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/N86120/001/
AUG 17, 1982

/5MG/

/N86119/001/
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/7.5MG/

/N86118/001/
AUG 17, 1982

/10MG/

/N86122/001/
AUG 17, 1982

@ BOLAR

N86123 001

2MG

AUG 17, 1982

2.5MG

N86120 001

5MG

AUG 17, 1982

7.5MG

N86118 001

10MG

AUG 17, 1982

/2MG/

AUG 17, 1982

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JUN 27, 1985

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AUG 06, 1985

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/N86121/001/
JUL 02, 1985

2MG

N86122 001

2.5MG

N86120 001

5MG

N86121 001

JUL 02, 1985

JUN 27, 1985

AUG 06, 1985

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AUG 06, 1985

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AUG 06, 1985

N86121 001

JUL 02, 1985

JUN 27, 1985

AUG 06, 1985

N86121 001

JUL 02, 1985

JUN 27, 1985

AUG 06, 1985

N86121 001

JUL 02, 1985

JUN 27, 1985

AUG 06, 1985

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JUL 02, 1985

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AUG 06, 1985

N86121 001

JUL 02, 1985

JUN 27, 1985

AUG 06, 1985

N86121 001

JUL 02, 1985

JUN 27, 1985

AUG

ACETAMINOPHEN

SUPPOSITORY; RECTAL

TYLENOL
/MCNEIL

120MG
650MG
120MG
650MG

3 MCNEIL
3

N17756/002
N17756/001
N17756 002
N17756 001

N18181 002
APR 01, 1991

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL

EXIDINE
/3X/120MG

120MG
650MG

XTTRIUM

N19444/001
N19444/002
N19444 001
N19444 002

N70770 001
SEP 30, 1991

MICRODERM
JOHNSON AND JOHNSON

42M

Sponge; Topical

MICRODERM
JOHNSON AND JOHNSON

42M

N72295 001
N72295 002

FEB 28, 1991

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

Capsule, Extended Release; Oral

PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE
/3/120MG

N18844/001
N18844/002
N18844 001
N18844 002

MAR 20, 1985

GRAHAM LABS

8MG;120MG

N18844/001
N18844/002
N18844 001
N18844 002

MAR 20, 1985

CLOTIRIMAZOLE

CREAM; TOPICAL

MYCELEX
MILES

12M

N18183 002
N18183 001

APR 01, 1991

CREAM; VAGINAL

MYCELEX-7
MILES

12M

N18230 002
N18230 001

DEC 26, 1991

CLOTIRIMAZOLE

SOLUTION; TOPICAL

MYCELEX
MILES

12M

N18181 002
APR 01, 1991

TABLET; VAGINAL

MYCELEX-7
MILES

100MG

N18182 002
DEC 26, 1991

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

DISOBROM
GENEVA

6MG;120MG

N70770 001
SEP 30, 1991

DOXYLAMINE SUCCINATE

TABLET; ORAL

/DOXY-SLEEP-AID
/PAR

25MG

N70156 001
JUL 02, 1987

DOXYLAMINE SUCCINATE

COPLEY

25MG

N88900 002
FEB 12, 1988

HYDROCORTISONE

/DANTHENT; TOPICAL
/HC/ (HYDROCORTISONE)
/C/ AND/ M
3 C AND M

0.5%

N80481 001

IBUPROFEN

TABLET; ORAL

IBUPROFEN
LUCHEN

200MG

N72901 001
DEC 19, 1991

200MG

N72903 001
DEC 19, 1991

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL
ADUIL COLD AND SINUS
WHITEHALL
200MG;30MG
N19771 001
SEP 19, 1989
/NOVOTEST/WHITEHALL/
/200MG;30MG/
/N19771/001/
/SEP 19, 1989/

N19965 001
JUN 25, 1991

100UNITS/MLM

INJECTABLE; INJECTION
NOVOLIN L
NOVO NORDISK

MICONAZOLE NITRATE

CREAM; VAGINAL
MONISTAT 7
JOHNSON RM
2/M

N17450 002
FEB 15, 1991

SUPPOSITORY; VAGINAL

MONISTAT 7
JOHNSON RM

N18520 002
FEB 15, 1991

100MG

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN 70/30
NOVO NORDISK

N19938 001
JUN 25, 1991

30UNITS/ML;70UNITS/MLM

TABLET, EXTENDED RELEASE; ORAL
SUDAFED 12 HOUR
BURROUGHS WELLCOME

N73585 001
OCT 31, 1991

120MG

INSULIN PORK

INJECTABLE; INJECTION
INSULIN
/NOVO/NORDISK/
a NOVO NORDISK

/N17926/001/
N17926 001

TABLET, EXTENDED RELEASE; ORAL
TRIPROLIDINE AND PSEUDOEPHEDRINE HCL
KV
120MG;5MG

N72758 001
NOV 25, 1991

INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
NOVOLIN N
NOVO NORDISK

N19959 001
JUL 01, 1991

100UNITS/MLM

INSULIN ZINC SUSP BEEF

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

/N17998/001/
N17998 001

/40 UNITS/ML/
40 UNITS/ML

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 12 / JAN '91 - DEC '91

CDP BLOOD BAG UNIT

INJECTABLE; INJECTION
CDP BLOOD BAG UNIT IN PLASTIC CONTAINER
BAXTER HLTHCARE

N900224
DEC 27, 1991

PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
PENTASPER IN PLASTIC CONTAINER
DUPONT MERCK
PHARM

10GM/100ML; 0.9GM/100ML
N890104
APR 04, 1991

HETASTARCH 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
HESPER IN PLASTIC CONTAINER
DUPONT MERCK
PHARM

6GM/100ML; 0.9GM/100ML

N890105
APR 04, 1991

RED CELL PRESERVATION SOLUTION SYSTEM

INJECTABLE; INJECTION
ADSOL IN PLASTIC CONTAINER
BAXTER HLTHCARE

N900223
DEC 27, 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. TREATMENT OF DYNAMIC MUSCLE CONTRACTURE IN PEDIATRIC CEREBRAL PALSY PATIENTS.	ALLERGAN
GENERIC: CHIMERIC M-T412 (HUMAN-MURINE) TRADE: IGG MONOCLONAL ANTI-CD4 ANTIBODY NOT ESTABLISHED	TREATMENT OF MULTIPLE SCLEROSIS.	CENTOCOR, INC

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. TREATMENT OF ESSENTIAL BLEPHAROSPASM.	PORTON PRODUCTS LIMITED
GENERIC: CRYPTOSPORIDIUM HYPERIMMUNE BOVINE COLOSTRUM IGG TRADE: NOT ESTABLISHED	TREATMENT OF DIARRHEA IN AIDS PATIENTS CAUSED BY INFECTION WITH CRYPTOSPORIDIUM PARVUM.	IMMUCELL CORPORATION
GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN INTRAVERNOUS (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 AFFLICTED 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 HUMAN, 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. TREATMENT OF MULTIPLE SCLEROSIS.	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: LIPOSOME ENCAPSULATED RECOMBINANT INTERLEUKIN-2 TRADE: NOT ESTABLISHED	TREATMENT OF BRAIN AND CNS TUMORS.	ONCOTHERAPEUTICS, INC
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 (RHONASE) TRADE: NOT ESTABLISHED	TO REDUCE MUCOUS VISCOSITY AND ENABLE CLEARANCE OF AIRWAY SECRETIONS IN PATIENTS WITH CYSTIC FIBROSIS.	GENENTECH, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: RECOMBINANT SECRETORY LEUCOCYTE PROTEASE INHIBITOR TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL ALPHA-1 ANTITRYPSIN DEFICIENCY. TREATMENT OF CYSTIC FIBROSIS.	SYNERGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MCA (ANTI-B4) TRADE: NOT ESTABLISHED	FOR THE EX-VIVO PURGING OF LEUKEMIC CELLS FROM THE BONE MARROW OF NON-T CELL ACUTE LYMPHOCYTIC LEUKEMIA PATIENTS WHO ARE IN COMPLETE REMISSION.	IMMUNOGEN, INC
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MCA (N901) 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. TREATMENT OF CYTOMEGALOVIRUS RETINITIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME.	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: AMPHOTERICIN B LIPID COMPLEX TRADE: NOT ESTABLISHED	TREATMENT OF CRYPTOCOCCAL MENINGITIS.	BRISTOL MYERS SQUIBB COMPANY
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: BACLOFEN TRADE: NOT ESTABLISHED	TREATMENT OF INTRACTABLE SPASTICITY DUE TO MULTIPLE SCLEROSIS OR SPINAL CORD INJURY.	INFUSAID, INC
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: DAPSONE TRADE: DAPSONE	PROPHYLAXIS OF PNEUMOCYSTIS CARINII PNEUMONIA.	JACOBUS PHARMACEUTICAL 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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: DEXRAZOXONE TRADE: ZINECARD	PREVENTION OF CARDIOMYOPATHY ASSOCIATED WITH DOXORUBICIN ADMINISTRATION.	ADRIA LABORATORIES
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
GENERIC: FLUDARABINE PHOSPHATE TRADE: FLUDARA*/**	TREATMENT OF REFRACTORY B-CELL CHRONIC LYMPHOCYTIC 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
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: GM 6001 TRADE: NOT ESTABLISHED	TREATMENT OF CORNEAL ULCERS.	GLYCOMED, INC
GENERIC: HALOFANTRINE TRADE: HALFAN	TREATMENT OF MILD TO MODERATE ACUTE MALARIA CAUSED BY SUSCEPTIBLE STRAINS OF P. FACIPARUM AND P. VIVAX.	SMITHKLINE BEECHAM PHARMACEUTICALS
GENERIC: HISTRELIN TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE INTERMITTENT PORPHYRIA, HEREDITARY COPROPORPHYRIA, AND VARIEGATE PORPHYRIA.	KARL E. ANDERSON, M.D. UNIVERSITY OF TEXAS

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: HISTRELIN ACETATE TRADE: SUPPRELIN*/**	TREATMENT OF CENTRAL PRECOCIOUS PUBERTY. [DEC 24, 1998]	RW JOHNSON
GENERIC: IDARUBICIN HCL TRADE: IDAMYCIN	TREATMENT OF ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) IN PEDIATRIC PATIENTS.	ADRIA
GENERIC: KETOCONAZOLE TRADE: NIZORAL	FOR USE WITH CYCLOPORIN A TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORIN IN ORGAN TRANSPLANTATION.	PHARMEDIC COMPANY
GENERIC: LEUCOVORIN CALCIUM TRADE: LEUCOVORIN CALCIUM*/**	FOR USE IN COMBINATION WITH 5-FLUOROURACIL FOR THE TREATMENT OF METASTATIC COLORECTAL CANCER. (USE IN COMBINATION WITH 5-FLUOROURACIL TO PROLONG SURVIVAL IN THE PALLIATIVE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.*/** [DEC 12, 1998])	LEDERLE
GENERIC: L-BACLOFEN TRADE: NEURALGON	TREATMENT OF INTRACTABLE SPASTICITY ASSOCIATED WITH SPINAL CORD INJURY OR MULTIPLE SCLEROSIS.	MERICON INDUSTRIES, INC
GENERIC: L-LEUCOVORIN CALCIUM TRADE: ISOVORIN	USE IN CONJUNCTION WITH HIGH-DOSE METHOTREXATE IN THE TREATMENT OF OSTEOSARCOMA.	LEDERLE LABORATORIES
GENERIC: LODOXAMIDE TROMETHAMINE TRADE: ALOWIDE	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.	MEDICAL CENTER JONATHAN FLEISCHMANN, M.D. CLEVELAND METROHEALTH
GENERIC: OFLOXACIN TRADE: NOT ESTABLISHED	TREATMENT OF BACTERIAL CORNEAL ULCERS.	ALLERGAN, INC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 TOXOPLASMOSIS IN PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BURROUGHS WELLCOME COMPANY
GENERIC: PRAMIRACETAM SULFATE TRADE: NOT ESTABLISHED	FOR THE MANAGEMENT OF COGNITIVE DYSFUNCTION AND ENHANCEMENT OF ANTIDEPRESSANT ACTIVITY ASSOCIATED WITH ELECTROCONVULSIVE THERAPY.	CAMBRIDGE NEUROSCIENCE, INC
GENERIC: RECOMBINANT BETA-GLUCOCEREBROSIDASE TRADE: NOT ESTABLISHED	FOR REPLACEMENT THERAPY IN PATIENTS WITH TYPES I, II, AND III GAUCHER'S DISEASE.	GENZYME CORPORATION
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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SERMORELIN ACETATE TRADE: GERE	TREATMENT OF AIDS-ASSOCIATED CATABOLISM/WEIGHT LOSS.	SERONO
GENERIC: SOMATROPIN TRADE: SAIZEN	TREATMENT OF AIDS-ASSOCIATED CATABOLISM/WEIGHT LOSS.	SERONO LABORATORIES, 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 PHARMACEUTICALS, INC
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
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-DIAMINOPYRIDINE TRADE: DYNAMINE	TREATMENT OF HEREDITARY MOTOR AND SENSORY NEUROPATHY TYPE I (CHARCOT-MARIE-TOOTH DISEASE).	MAYO CLINIC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

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

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

NO DECEMBER 1991 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFD-650, MPN-2 ROOM 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
ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE CAPSULE; ORAL	325MG 50MG 40MG 30MG	91 P-069/ CP2	KING & SPAULDING	NEW COMBINATION	APPROVED DEC 10, 1991
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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
DOPAMINE HYDROCHLORIDE INJECTABLE; INJECTION	5MG/ML	90 P-0137/ CPI	ABBOTT	NEW STRENGTH	APPROVED APR 10, 1991
ESTRADIOL FILM, EXTENDED RELEASE; TRANSDERMAL	0.067MG/24HR	90 P-0125/ CPI	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
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (25ML/VIAL)	91 P-0041/ CPI	ADRIA	NEW STRENGTH	APPROVED MAY 22, 1991
LEUCOVORIN CALCIUM INJECTABLE; INJECTION	EQ 200MG BASE/VIAL	91 P-0235/ CPI	CETUS	NEW STRENGTH	APPROVED DEC 10, 1991
NIFEDIPINE CAPSULE, EXTENDED RELEASE; ORAL	30MG 60MG 90MG	90 P-0436/ CPI	KV	NEW DOSAGE FORM	APPROVED OCT 23, 1991
PANCURONIUM BROMIDE INJECTABLE; INJECTION	0.1MG/ML	91 P-0006/ CPI	LYPHOMED	NEW STRENGTH	APPROVED OCT 28, 1991
TECHNETIUM TC99 MEDRONATE KIT INJECTABLE; INJECTION	N/A	91 P-0040/ CPI	ABARTS	NEW STRENGTH	APPROVED OCT 28, 1991
TERFENADINE CAPSULE; ORAL	60MG	91 P-0087 CPI	ARTHUR A. CHECCHI	NEW DOSAGE FORM	APPROVED OCT 28, 1991
THEOPHYLLINE TABLET, EXTENDED RELEASE; ORAL	800MG	91 P-0209/ CPI	PURDUE FREDERICK	NEW STRENGTH	APPROVED DEC 10, 1991

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ALBUTEROL SULFATE CAPSULE, EXTENDED RELEASE; ORAL	EQ 4MG BASE	89 P-0207/CP	PARTICLE DYNAMICS	NEW DOSAGE FORM	DENIED DEC 13, 1991
FUROSEMIDE INJECTABLE; INJECTION	1MG/ML	90 P-0313/ CP1	LYPHOMED	NEW STRENGTH	DENIED OCT 28, 1991

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 DOSING SCHEDULE
D-17 400MG EVERY 12 HOURS FOR THREE DAYS FOR UNCOMPLICATED URINARY TRACT INFECTIONS

REFERENCES
NEW INDICATION

1-55 HYPERTENSION
1-56 EROSIIVE 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 EROSIIVE 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
1-65 PREVENTION OF UPPER GASTROINTESTINAL BLEEDING IN CRITICALLY ILL PATIENTS
1-66 UNCOMPLICATED GONORRHEA

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

EXCLUSIVITY TERMS

REFERENCES

PATENT USE CODE

U-49
U-50
U-51
U-52
U-53
U-54
U-55
U-56

SYMPTOMATIC CANCER-RELATED HYPERCALCEMIA
USE IN TREATING INFLAMMATORY DERMATOSES
BLOOD POOL IMAGING, INCLUDING FIRST PASS AND GATED EQUILIBRIUM IMAGING AND FOR DETECTION OF SITES OF GASTROINTESTINAL BLEEDING
TREATMENT OF ADULT AND PEDIATRIC PATIENTS (OVER SIX MONTHS OF AGE) WITH ADVANCED HIV INFECTION
HYPERCALCEMIA OF MALIGNANCY
REVERSAL AGENT OR ANTAGONIST OF NONDEPOLARIZING NEUROMUSCULAR BLOCKING AGENTS
TREATMENT OF PAIN
AID TO SMOKING CESSATION

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		I-45	APR 26, 1993
20089 002	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997		I-45	APR 26, 1993
20057 003	ALGLUCERASE; CEREDASE				NCE	APR 05, 1996
18276 001	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46	ODE	APR 05, 1998
18276 002	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
18276 003	ALPRAZOLAM; XANAX	4508726	APR 02, 2002	U-46		
18276 004	ALPRAZOLAM; XANAX	3980789	SEP 14, 1993			
19926 001	ALTRETAINE; HEXALEN	4105783	OCT 26, 1995		ODE	DEC 26, 1997
19155 001	AMMONIUM LACTATE; LAC-HYDRIN	4072746	APR 23, 1998	U-7	NCE	JUL 31, 1994
18700 001	AMINONE LACTATE; INOCOR	4952586	AUG 28, 2007	U-54	NC	NOV 06, 1994
19677 001	ATROPINE SULFATE; ENLON-PLUS	4952586	AUG 28, 2007	U-54	NC	NOV 06, 1994
19678 001	ATROPINE SULFATE; ENLON-PLUS	4410520	OCT 18, 2000		NCE	JUN 25, 1996
19851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN	4410520	OCT 18, 2000		NCE	JUN 25, 1996
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
19845 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC S	4911920	MAR 27, 2007		NDF	DEC 12, 1994
19890 001	BUTORPHANOL TARTRATE; STADOL				I-63	OCT 24, 1994
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
17939 002	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		I-65	NOV 13, 1994

> ADD >
> ADD >
> ADD >

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>						
>ADD>						
>ADD>						
>ADD>						
>ADD>						
>ADD>						
19616 004	ENOXACIN; PENETREX	4442101	APR 10, 2001			
		4359578	NOV 16, 1999		NCE	DEC 31, 1996
		4352803	OCT 05, 1999	U-36		
19616 005	ENOXACIN; PENETREX	4442101	APR 10, 2001			
		4359578	NOV 16, 1999		NCE	DEC 31, 1996
		4352803	OCT 05, 1999	U-36		
		3987052	OCT 19, 1995			
		3987052	OCT 19, 1995			
19080 001	ESTAZOLAM; PROSOM					
19080 002	ESTAZOLAM; PROSOM					
19081 002	ESTRADIOL; ESTRADERM					
19081 003	ESTRADIOL; ESTRADERM					
19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		I-62	OCT 24, 1994
19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		I-62	OCT 24, 1994
18922 002	ETODOLAC; LODINE	4076831	FEB 28, 1997		NC	DEC 29, 1992
		3939178	FEB 17, 1993	U-45	NC	DEC 29, 1992
18922 003	ETODOLAC; LODINE	4076831	FEB 28, 1997		NCE	JAN 31, 1996
		3939178	FEB 17, 1993	U-45		
		3939178	FEB 17, 1993		NCE	JAN 31, 1996
		4264611	APR 28, 1998		NCE	JUL 26, 1996
		4262611	APR 28, 1998		NCE	JUL 26, 1996
19834 001	FELODIPINE; PLENDIL					
19834 002	FELODIPINE; PLENDIL					
18830 001	FLECAINIDE ACETATE; TAMBOCOR					
18830 003	FLECAINIDE ACETATE; TAMBOCOR					
18830 004	FLECAINIDE ACETATE; TAMBOCOR					
19949 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		I-64	OCT 23, 1994
19949 002	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		I-64	OCT 23, 1994
19949 003	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
19950 001	FLUCONAZOLE; DIFLUCAN	4404216	OCT 16, 2003		NCE	JAN 29, 1995
20038 001	FLUDARABINE PHOSPHATE; FLUDARA	4357324	NOV 02, 1999		NCE	APR 18, 1996
					ODE	APR 18, 1998
20073 001	FLUMAZENIL; MAZICON	4316839	FEB 23, 1999		NCE	DEC 20, 1996
20101 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001		NCE	DEC 29, 1992
19957 001	FLUTICASONE PROPIONATE; CUTIVATE	4335121	MAR 16, 2002			
19958 001	FLUTICASONE PROPIONATE; CUTIVATE	4335121	MAR 16, 2002			
20068 001	FOSCARNET SODIUM; FOSCAVIR					
19915 002	FOSINOPRIL SODIUM; MONOPRIL	4384123	MAY 17, 2000		NCE	SEP 27, 1996
19915 003	FOSINOPRIL SODIUM; MONOPRIL	4337201	JUN 29, 1999		NCE	MAY 16, 1996
19961 002	GALLIUM NITRATE; GANITE	4384123	MAY 17, 2000			
		4337201	JUN 29, 1999		NCE	MAY 16, 1996
		4529593	JAN 17, 2005	U-49	ODE	JAN 17, 1998

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19967 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	DEC 17, 2004		NCE	DEC 17, 1995
19968 001	HALOBETASOL PROPIONATE; ULTRAVATE	4619921	DEC 17, 2004		NCE	DEC 17, 1995
19836 001	HISTRELIN; SUPPRELIN	4244946	JAN 13, 1998		NCE	DEC 24, 1996
>ADD>					ODE	DEC 24, 1998
19836 002	HISTRELIN; SUPPRELIN	4244946	JAN 13, 1998		NCE	DEC 24, 1996
>ADD>					ODE	DEC 24, 1998
19836 003	HISTRELIN; SUPPRELIN	4244946	JAN 13, 1998		NCE	DEC 24, 1996
>ADD>					ODE	DEC 24, 1998
19784 001	IBUPROFEN; RUFEN				ODE	DEC 24, 1998
19580 001	IOTROLAN; OSMOVIET	4239747	DEC 16, 1999		NCE	DEC 07, 1994
19580 002	IOTROLAN; OSMOVIET	4239747	DEC 16, 1999		NCE	DEC 07, 1994
19091 001	ISOSORBIDE MONONITRATE; ISMO				NDF	SEP 19, 1992
19546 001	ISRADIPINE; DYNACIRC				NCE	DEC 07, 1994
>ADD>					NCE	DEC 07, 1994
19546 002	ISRADIPINE; DYNACIRC				NCE	DEC 07, 1994
>ADD>					NCE	DEC 07, 1994
19546 003	ISRADIPINE; DYNACIRC				NCE	DEC 07, 1994
>ADD>					NCE	DEC 07, 1994
19546 004	ISRADIPINE; DYNACIRC				NCE	DEC 07, 1994
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19546 005	ISRADIPINE; DYNACIRC				NCE	DEC 07, 1994
>ADD>					NCE	DEC 07, 1994
19546 006	ISRADIPINE; DYNACIRC				NCE	DEC 07, 1994
>ADD>					NCE	DEC 07, 1994
19645 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55		
19698 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55		
19698 002	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1997	U-55		
>ADD>					U-55	
18686 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 001	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 002	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 003	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18687 004	LABETALOL HYDROCHLORIDE; NORMODYNE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 002	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 003	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
18716 004	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
19425 001	LABETALOL HYDROCHLORIDE; TRANDATE	4012444	AUG 02, 1998		NCE	AUG 01, 1994
>ADD>					ODE	DEC 12, 1998
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				ODE	DEC 12, 1998
>ADD>					ODE	DEC 12, 1998
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				ODE	DEC 12, 1998
>ADD>					ODE	DEC 12, 1998
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				ODE	DEC 12, 1998
>ADD>					ODE	DEC 12, 1998
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				ODE	DEC 12, 1998
20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL				NCE	JUN 18, 1995
20088 001	LEVONORGESTREL; NORPLANT SYSTEM				NP	DEC 10, 1993
20105 001	LIOTHYRONINE SODIUM; TRIOSTAT				NDF	DEC 31, 1994
19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE				NCE	JUN 19, 1995
19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE				NCE	JUN 19, 1995
19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE				NCE	JUN 19, 1995
>ADD>					NCE	JUN 19, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999		NCE	FEB 13, 1995
>ADD>		4597961	JUL 01, 2003	U-56		
>ADD>		4597961	JUL 01, 2003	U-56		
>ADD>		4597961	JUL 01, 2003	U-56		
18612 001	NICOTINE POLACRILEX; NICORETTE	3901248	AUG 26, 1992		NCE	JAN 13, 1994
19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
19684 002	NIFEDIPINE; PROCARDIA XL	4765989	SEP 16, 2003		D-2	SEP 06, 1992
19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
		4783337	SEP 16, 2003		I-55	SEP 06, 1992
		4765989	SEP 16, 2003		D-2	SEP 06, 1992
20064 001	NITROFURANTOIN; MACROBID	4382090	MAY 03, 2000	U-18	NDF	DEC 24, 1994
19508 001	NIZATIDINE; AXID	4382090	MAY 03, 2000	U-18	I-59	JUL 26, 1994
19508 002	NIZATIDINE; AXID	4639458	JAN 27, 2004		I-59	JUL 26, 1994
19384 002	NORFLOXACIN; NOROXIN				I-66	NOV 26, 1994
19757 001	NORFLOXACIN; CHIBROXIN	4551456	NOV 05, 2002		D-17	NOV 26, 1994
19735 001	OFLOXACIN; FLOXIN	4146719	MAR 27, 1998		NDF	JUN 17, 1994
19735 002	OFLOXACIN; FLOXIN	4382892	MAY 10, 2002			
19735 003	OFLOXACIN; FLOXIN	4382892	MAY 10, 2002			
19715 001	OLSAZINE SODIUM; DIPENTUM	4382892	MAY 10, 2002			
19810 001	OMEPRazole; PRILOSEC	4559330	AUG 04, 2004		NCE	JUL 31, 1995
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFRAN	4255431	MAR 10, 2000	U-44	I-57	JUN 12, 1994
		4753789	JUN 28, 2005		NCE	JAN 04, 1996
20036 001	PAMIDRONATE DISODIUM; AREDIA	4695578	JAN 03, 2005		NCE	OCT 31, 1996
		4711880	DEC 08, 2004	U-53		
20122 001	PENTOSTATIN; NIPENT	3962432	JUN 08, 1993			
		3923785	DEC 02, 1992			
18631 001	PENTOXIFYLLINE; TRENTAL	3737433	APR 03, 1997		ODE	OCT 11, 1998
19456 001	PINACIDIL; PINDAC	RE31244	NOV 08, 1996		NCE	OCT 11, 1996
19456 002	PINACIDIL; PINDAC	RE31244	NOV 08, 1996	U-3	NCE	AUG 30, 1994
19797 001	POLYETHYLENE GLYCOL 3350; NULYTELY	RE31244	NOV 08, 1996	U-3	NCE	DEC 28, 1994
19898 002	PRAVASTATIN SODIUM; PRAVACHOL				NCE	DEC 28, 1994
19898 003	PRAVASTATIN SODIUM; PRAVACHOL	4346227	AUG 24, 1999		NP	APR 22, 1994
19568 001	PREDNICARBATE; DERMATOP	4346227	AUG 24, 1999		NCE	OCT 31, 1996
19627 001	PROPOFOL; DIPRIVAN	4242334	DEC 30, 1997	U-50	NCE	OCT 31, 1996
19664 001	PSEUDOEPHEDRINE HYDROCHLORIDE; SELDANE-D	4056635	NOV 01, 1996		NE	SEP 23, 1994
		3878217	APR 15, 1994		NCE	OCT 02, 1994
					NC	AUG 19, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
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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
19885 001	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005	U-3	NCE	NOV 19, 1996
		4344949	AUG 17, 1999			
19885 002	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005	U-3	NCE	NOV 19, 1996
		4344949	AUG 17, 1999			
19885 003	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005	U-3	NCE	NOV 19, 1996
		4344949	AUG 17, 1999			
19885 004	QUINAPRIL HYDROCHLORIDE; ACCUPRIL	4743450	MAY 10, 2005	U-3	NCE	NOV 19, 1996
		4344949	AUG 17, 1999			
19901 001	RAMIPRIL; ALTACE	4587258	JAN 29, 2005		NCE	NOV 19, 1996
>ADD>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>DLT>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>DLT>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>DLT>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 002	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>DLT>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 003	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>DLT>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19901 004	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>ADD>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
>DLT>	RAMIPRIL; ALTACE	4587258	MAY 06, 2003		NCE	JAN 28, 1996
19863 001	SERMORELIN ACETATE; GEREFF	4703035	DEC 28, 2004	U-47	NCE	DEC 28, 1995
		4517181	MAY 14, 2002		NCE	DEC 28, 1995
19839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	AUG 20, 2002		NCE	DEC 30, 1996
>ADD>	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	AUG 20, 2002		NCE	DEC 30, 1996
>DLT>	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	AUG 20, 2002		NCE	DEC 30, 1996
>ADD>	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	AUG 20, 2002		NCE	DEC 30, 1996
>DLT>	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	AUG 20, 2002		NCE	DEC 30, 1996
19765 001	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001		NCE	DEC 23, 1997
>ADD>	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001		NCE	DEC 23, 1997
>DLT>	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001		NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001		NCE	DEC 23, 1997
>ADD>	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001		NCE	DEC 23, 1997
>DLT>	SIMVASTATIN; ZOCOR	4444784	APR 24, 2001		NCE	DEC 23, 1997
19998 002	SUCCIMER; CHEMET	4444784	APR 24, 2001		NCE	DEC 23, 1997
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
19785 002	TECHNETIUM TC-99M SESTAMIBI KIT; CARDIOLITE	4452774	SEP 09, 2004		NCE	DEC 21, 1995
18163 001	TEMAZEPAM; RESTORIL				D-17	OCT 25, 1994
18163 002	TEMAZEPAM; RESTORIL				NS	OCT 25, 1994
18163 003	TEMAZEPAM; RESTORIL				D-17	OCT 25, 1994
19979 001	TICLOPIDINE HYDROCHLORIDE; TICLID				NS	OCT 25, 1994
19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID				D-17	OCT 25, 1994
19798 001	TRIAMCINOLONE ACETONIDE; NASACORT				NS	OCT 25, 1994
		4591592	MAY 27, 2003		NCE	OCT 31, 1996
		4051141	SEP 27, 1994		NCE	OCT 31, 1996
		4591592	MAY 27, 2003		NCE	OCT 31, 1996
		4051141	SEP 27, 1994		NR	JUL 11, 1994

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