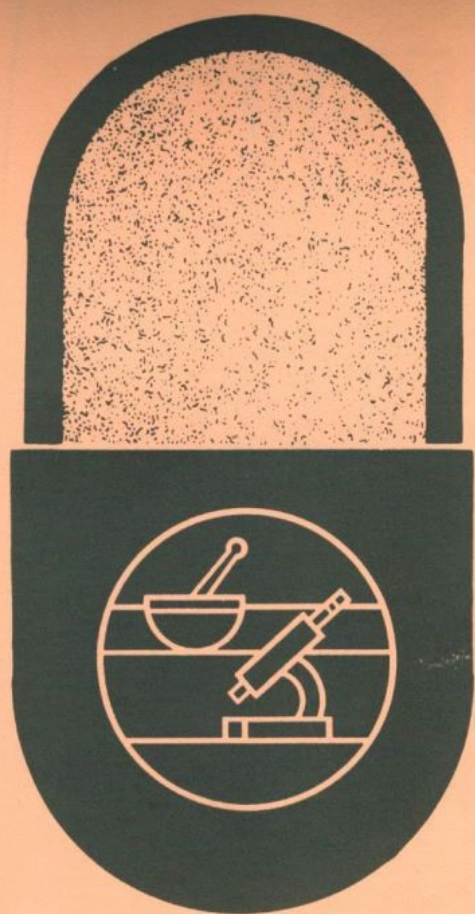


**CUMULATIVE
SUPPLEMENT 11
JAN'90-NOV'90**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

10TH 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 11th Edition



APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

**11th EDITION
1991**

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS
10TH EDITION
CUMULATIVE SUPPLEMENT 11
NOVEMBER 1990

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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, 10th 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Division of Blood and Blood Products and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 effective date for the approved drug product (the earliest date a product may be marketed) appears, when appropriate, to the left of the approval date.

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, Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products 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, Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products 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 will remain in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Drug Products with Approval under Section 505 of the Act Administered by the Division of Blood and Blood Products List and the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness 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 10th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 11th 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)
Tranlylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.3 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>
BOOTS COMPANY USA INC	BOOTS PHARMS INC	BOOTS PHARM
MERRELL DOW PHARMACEUTICALS INC SUB DOW CHEMCIAL CO	MERRRELL DOW PHARMS INC SUB MARION MERRELL DOW INC	MERRELL DOW PHARMS
MARION LABORATORIES INC	MARION MERRELL DOW INC	MARION MERRELL DOW
NORDISK INSULIN LABORATORIUM	NOVO NORDISK PHARMS INC	NOVO NORDISK PHARMS
NORDISK USA	NOVO NORDISK PHARMS INC	NOVO NORDISK PHARMS

<u>FORMER APPLICANT (NAME)</u>	<u>APPLICANT (NAME) CHANGES</u>	<u>NEW APPLICANT (NAME)</u>	<u>ABBREVIATED NAME</u>
PACO RESEARCH & DEVELOPMENT		PACO RESEARCH CORP	PACO RES
SQUIBB NOVO INC		NOVO NORDISK PHARMS INC	NOVO NORDISK PHARMS
TAKEDA-ABBOTT RESEARCH & DEVELOPMENT		TAP PHARMS INC	TAP PHARMS

1.4 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 1989) 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 1989	MAR 1990	JUN 1990	SEP 1990
DRUG PRODUCTS LISTED	10123	10095	10083	10047
SINGLE SOURCE	2030 (20.1%)	2039 (20.2%)	2064 (20.5%)	2058 (20.5%)
MULTISOURCE	8093 (79.9%)	8056 (79.8%)	8019 (79.5%)	7989 (79.5%)
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7213 (71.5%)	7183 (71.2%)	7147 (71.1%)
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	723 (7.1%)	713 (7.1%)	711 (7.1%)
EXCEPTIONS ¹	119 (1.2%)	120 (1.2%)	123 (1.2%)	131 (1.3%)
NEW MOLECULAR ENTITIES APPROVED	--	3	4	3
NUMBER OF APPLICANTS	400	406	414	416

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

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PRESCRIPTION DRUG PRODUCT LIST
10TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 11 / JAN '90 - NOV '90

ACETAMINOPHEN; ASPIRIN; CODEINE PHOSPHATE

CAPSULE; ORAL		
ACETAMINOPHEN, ASPIRIN, AND CODEINE PHOSPHATE		
MIKART	150MG;180MG;15MG	N81095 001
		OCT 26, 1990
	150MG;180MG;30MG	N81096 001
		OCT 26, 1990
	150MG;180MG;60MG	N81097 001
		OCT 26, 1990

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL		
CONTEN		
AB GRAHAM LABS	650MG;50MG	N89405 001
		MAY 15, 1990
TABLET; ORAL		
SEDAPAP		
MAYRAND	650MG;50MG	N88944 001
		OCT 17, 1985
/SEDAPAP-16/ /MAYRAND/	/650MG;50MG/	/N88944/001/ /OCT 17, 1985/

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL		
ACETAMINOPHEN AND CODEINE PHOSPHATE #3		
/AA/ /SUPERPHARM/	/300MG;30MG/	/N89253/001/ /MAY 19, 1986/
3 SUPERPHARM	300MG;30MG	N89253 001
		MAY 19, 1986
ACETAMINOPHEN AND CODEINE PHOSPHATE #4		
/AA/ /SUPERPHARM/	/300MG;60MG/	/N89254/001/ /MAY 19, 1986/
3 SUPERPHARM	300MG;60MG	N89254 001
		MAY 19, 1986
/EMPRACET W/ CODEINE PHOSPHATE #3/ /BURROUGHS WELLCOME/	/300MG;30MG/	/N83951/001/ /MAY 19, 1986/
3 BURROUGHS WELLCOME	300MG;30MG	N83951 001
/EMPRACET W/ CODEINE PHOSPHATE #4/ /BURROUGHS WELLCOME/	/300MG;60MG/	/N83951/002/ /MAY 19, 1986/
3 BURROUGHS WELLCOME	300MG;60MG	N83951 002

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL		
HYDROCODONE BITARTRATE AND ACETAMINOPHEN		
/AA/ /PHARM/BASICS/	/500MG;5MG/	/N89290/001/ /MAY 29, 1987/
3 PHARM BASICS	500MG;5MG	N89290 001
		MAY 29, 1987
MORCET		
AA ABANA	500MG;5MG	N88871 001
		MAY 15, 1986
/AA/ /HOLLAND/	/500MG;5MG/	/N88871/001/ /MAY 15, 1986/

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC		
ACETIC ACID		
> DLT > /AT/	/KV/	/22/
> ADD >	3 KV	2%
		/N85493/001/ N85493 001

ACETIC ACID, GLACIAL; HYDROCORTISONE

SOLUTION/DROPS; OTIC		
ACETIC ACID W/ HYDROCORTISONE		
> DLT > /AT/	/KV/	/22;12/
> ADD >	3 KV	2%;1%
		/N85492/001/ N85492 001

ACETYLCYSTEINE

SOLUTION; INHALATION		
ACETYLCYSTEINE		
/AN/ /QUAD/	/102/	/N71740/001/ /AUG 11, 1987/
/AN/	/202/	/N71741/001/ /AUG 11, 1987/
/AN/ /MUCOSOL-10/	/102/	/N70575/001/ /OCT 14, 1986/
/AN/ /DEF/	/202/	/N70576/001/ /OCT 14, 1986/
SOLUTION; INHALATION, ORAL		
ACETYLCYSTEINE		
AN QUAD	10%	N71740 001
		AUG 11, 1987
AN	20%	N71741 001
		AUG 11, 1987

[illegible]

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

AA	MYLAN	0.025MG;2.5MG	N85762 001
AA	PARKER/DAVIS	0.025MG;2.5MG	N87131 001
AA	DIPHENOXYLATE HCL W/ ATROPINE SULFATE	0.025MG;2.5MG	N85762/001

ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

AA	STERLING	0.4MG/ML;50MG/ML	N87853/001
AA	STERLING	0.4MG/ML;75MG/ML	N87847 001
AA	STERLING	0.4MG/ML;100MG/ML	N87848 001

MEPERIDINE AND ATROPINE SULFATE

AA	MYETH/AYERST	0.4MG/ML;50MG/ML	N85121/001
AA	MYETH/AYERST	0.4MG/ML;75MG/ML	N85121/002
AA	MYETH/AYERST	0.4MG/ML;100MG/ML	N85121 003

BACLOFEN

TABLET; ORAL

AA	BACLOFEN	10MG	N71901 001
AA	BACLOFEN	20MG	N71902 001

BUTABARBITAL SODIUM

TABLET; ORAL

AA	BUTABARBITAL SODIUM	15MG	N85938/001
----	---------------------	------	------------

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM

CHLORIDE; SODIUM LACTATE

AA	INJECTABLE; INJECTION	DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER	N18499 001
AA	CUTTER	20MG/100ML; 50MG/100ML; 30MG/100ML	N18499/001
AA	CUTTER	20MG/100ML; 50MG/100ML; 30MG/100ML	N18499/001

LACTATED RINGER'S AND DEXTROSE 5% IN PLASTIC CONTAINER

AA	BAXTER	20MG/100ML; 50MG/100ML; 30MG/100ML	N18499 001
AA	BAXTER	20MG/100ML; 50MG/100ML; 30MG/100ML	N18499 001

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;

SODIUM ACETATE; SODIUM CHLORIDE

AA	INJECTABLE; INJECTION	TPN ELECTROLYTES IN PLASTIC CONTAINER	N18499/001
AA	ABBOTT	16.5MG/ML; 25.4MG/ML; 74.6MG/ML	N18499/001
AA	ABBOTT	121MG/ML; 16.1MG/ML	N18499/001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM

AA	BAXTER	20MG/100ML; 50MG/100ML; 30MG/100ML	N18499 001
----	--------	------------------------------------	------------

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

AB	CLAY PARK	EQ 0.05% BASEM	N72536 001
----	-----------	----------------	------------

LOTION; TOPICAL

AB	CLAY PARK	EQ 0.05% BASEM	N72538 001
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BROMPHENIRAMINE MALEATE

INJECTABLE; INJECTION

AA	BROMPHENIRAMINE MALEATE	100MG/ML	N83820 001
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ELIXIR; ORAL

AA	PHARM BASICS	4MG/5ML; 25MG/5ML	N88687 001
AA	PHARM BASICS	4MG/5ML; 25MG/5ML	N88687 001

BUTABARBITAL SODIUM

TABLET; ORAL

AA	REID ROWELL	16.4MG	N83606 001
AA	REID ROWELL	16.4MG	N83606 001

CARTICOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

AA	BURROUGHS WELLCOME	12M	N19972 001
----	--------------------	-----	------------

CEFDROXIL

CAPSULE; ORAL

AA	CEFDROXIL	250MG BASE	N83606 001
AA	CEFDROXIL	250MG BASE	N83606 001

PUREPAC

500MG BASE

AA	PUREPAC	500MG BASE	N62766 001
----	---------	------------	------------

BIOCRRAFT

500MG BASE

AA	BIOCRRAFT	500MG BASE	N62698 001
----	-----------	------------	------------

DURICEF

500MG BASE/5ML

AA	DURICEF	500MG BASE/5ML	N50527 002
----	---------	----------------	------------

CEFADROXIL

POWDER FOR RECONSTITUTION; ORAL

ULTRACEF

AB	BRISTOL	EQ 125MG BASE/5ML	N62334 001
AB		EQ 125MG BASE/5ML	N62376 001
			MAR 16, 1982
AB		EQ 250MG BASE/5ML	N62334 002
AB		EQ 250MG BASE/5ML	N62376 002
			MAR 16, 1982
		/EQ/125MG/BASE/5ML/	/N62334/001/
		/EQ/125MG/BASE/5ML/	/N62376/001/
			/MAR/16,/1982/
		/EQ/250MG/BASE/5ML/	/N62334/002/
		/EQ/250MG/BASE/5ML/	/N62376/002/
			/MAR/16,/1982/

TABLET; ORAL

/AB/	/CEFADROXIL/	/EQ 1GM BASE/	/N62774/001/
	/ZENITH/		/APR/08,/1987/
			N62774 001
			APR 08, 1987

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP	LEMMON	EQ 5GM BASE/VIALM	N63018 001
			MAR 05, 1990
AP		EQ 10GM BASE/VIALM	N63018 002
			MAR 05, 1990

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

CEFOBID

PFIZER

EQ 1GM BASE/VIAL	N50551 001
	NOV 18, 1982
EQ 2GM BASE/VIAL	N50551 002
	NOV 18, 1982
EQ 10GM BASE/VIALM	N50551 003
	MAR 05, 1990
/EQ/1GM/BASE/VIAL/	/N50551/001/
/EQ/2GM/BASE/VIAL/	/NOV/18,/1982/
	/N50551/002/
	/NOV/18,/1982/

/ROERIS/

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

CEFOBID IN PLASTIC CONTAINER

PFIZER

EQ 20MG BASE/ML

N50613 002

JUL 31, 1987

EQ 40MG BASE/ML

N50613 001

JUL 23, 1986

/ROERIS/

/EQ/20MG/BASE/ML/

/N50613/002/

/JUL/31,/1987/

/EQ/40MG/BASE/ML/

/N50613/001/

/JUL/23,/1986/

CEFTAZIDIME

INJECTABLE; INJECTION

CEPTAZ

GLAXO

500MG/VIALM

N50646 001

SEP 27, 1990

1GM/VIALM

N50646 002

SEP 27, 1990

2GM/VIALM

N50646 003

SEP 27, 1990

10GM/VIALM

N50646 004

SEP 27, 1990

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN MONOHYDRATE

/BX/ /VITARINE/

/EQ/250MG/BASE/

/N62159/001/

/BX/

/EQ/500MG/BASE/

/N62159/002/

a VITARINE

EQ 250MG BASE

N62159 001

a

EQ 500MG BASE

N62159 002

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

/BX/ /VITARINE/

/EQ/125MG/BASE/5ML/

/N62779/001/

/BX/

/EQ/250MG/BASE/5ML/

/DEC/22,/1987/

a VITARINE

EQ 125MG BASE/5ML

N62779 001

a

EQ 250MG BASE/5ML

DEC 22, 1987

N62781 001

DEC 22, 1987

CEPHALEXIN

TABLET; ORAL

CEPHALEXIN

/BX/	/VITARINE/	/EQ/250MG/BASE/	/N62863/001/
			/AUG/11,/1988/
/BX/		/EQ/500MG/BASE/	/N62863/002/
			/AUG/11,/1988/
/BX/		/EQ/1GM/BASE/	/N62863/003/
			/AUG/11,/1988/
	a VITARINE	EQ 250MG BASE	N62863 001
			AUG 11, 1988
	a	EQ 500MG BASE	N62863 002
			AUG 11, 1988
	a	EQ 1GM BASE	N62863 003
			AUG 11, 1988

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION

CEPHAPIRIN SODIUM

/AB/	/LYPHOMED/	/EQ 20GM BASE/VIAL/	/N62723/005/
			/NOV/17,/1986/
			N62723 005
			NOV 17, 1986

CEPHRADINE

CAPSULE; ORAL

CEPHRADINE

/BX/	/VITARINE/	/250MG/	/N62813/001/
			/FEB/25,/1988/
/BX/		/500MG/	/N62813/002/
			/FEB/25,/1988/
	a VITARINE	250MG	N62813 001
			FEB 25, 1988
	a	500MG	N62813 002
			FEB 25, 1988

CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED

/TABLET;/ORAL/

/MENRIUM/10-4/

/10MG;0.4MG/

/N14740/006/

/ROCHE/

/MENRIUM/5-2/

/5MG;0.2MG/

/N14740/002/

/ROCHE/

/MENRIUM/5-4/

/5MG;0.4MG/

/N14740/004/

/ROCHE/

CHLORDIAZEPOXIDE; ESTROGENS, ESTERIFIED

TABLET; ORAL

MENRIUM 10-4

ROCHE

10MG;0.4MG

N14740 006

MENRIUM 5-2

ROCHE

5MG;0.2MG

N14740 002

MENRIUM 5-4

ROCHE

5MG;0.4MG

N14740 004

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/AA/ /PUREPAC/

/4MG/

/N86306/001/

/AA/

/ROXANE/

/4MG/

/N86306/001/

a ROXANE

4MG

N80626 001

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

AA

MUTUAL PHARM

500MG

N89970 001

SEP 27, 1990

CHROMIC PHOSPHATE, P-32

> DLT >

/INJECTABLE;/INJECTION/

> DLT >

/PHOSPHOCOL/P/32/

> DLT >

/MALLINCKRODT/

/5MCI/ML/

/N17084/001/

> ADD >

INJECTABLE; INJECTION

> ADD >

PHOSPHOCOL P32

> ADD >

MALLINCKRODT

5MCI/ML

N17084 001

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

TAGAMET HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

SKF

EQ 6MG BASE/ML

N19434 001

OCT 31, 1985

/TAGAMET/IN/SODIUM/CHLORIDE/0.9%/IN/PLASTIC/CONTAINER/

/SKF/

/EQ/6MG/BASE/ML/

/N19434/001/

/OCT/31,/1985/

[illegible]

DESOXIMETASONECREAM; TOPICAL
DESOXIMETASONE

> ADD > AB TARO 0.05% N73210 001
> ADD > AB TARO 0.05% NOV 30, 1990
> ADD > AB TARO 0.25% N73193 001
> ADD > AB TARO 0.25% NOV 30, 1990

> ADD > AB TOPICORT HOECHST ROUSSEL 0.25% N17856 001
> ADD > AB TOPICORT LP HOECHST ROUSSEL 0.05% N18309 001

DEXAMETHASONETABLET; ORAL
DEXAMETHASONE
2 BARR

0.5MG N84766 001

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

/AA/ /INTL/MEDICATION/ /EQ 20MG PHOSPHATE/ML/ /N88522/001/
/FEB/17/1984/
2 INTL MEDICATION EQ 20MG PHOSPHATE/ML N88522 001
FEB 17, 1984
AP KENDALL MCGAW EQ 4MG PHOSPHATE/MLM N81125 001
AUG 31, 1990
AP EQ 10MG PHOSPHATE/MLM N81126 001
AUG 31, 1990

OINTMENT; OPHTHALMIC

MAXIDEX

AT ALCON EQ 0.05% PHOSPHATE N83342 001
/OINTMENT; OPHTHALMIC; OTIC/
/MAXIDEX/
/AT/ /ALCON/ /EQ 0.05% PHOSPHATE/ /N83342/001/

/SOLUTION/DROPS; OPHTHALMIC/

DEXAMETHASONE SODIUM PHOSPHATE

/AT/ /STERIS/ /EQ 0.1% PHOSPHATE/ /N88771/001/
/JAN/16/1985/

SOLUTION/DROPS; OPHTHALMIC, OTIC

DEXAMETHASONE SODIUM PHOSPHATE

AT STERIS EQ 0.1% PHOSPHATE N88771 001
JAN 16, 1985

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC
CONTAINER

KENDALL MCGAW 3.3GM/100ML; 300MG/100MLM N19631 016
JAN 19, 1990

DEZOCINE

INJECTABLE; INJECTION

DALGAN

ASTRA

5MG/ML N19082 001

10MG/ML DEC 29, 1989

15MG/ML N19082 002

DEC 29, 1989

N19082 003

DEC 29, 1989

/WYETH/STERIS/ /5MG/ML/ /N19082/001/

/DEC/29/1989/ /N19082/002/

/N19082/003/

/DEC/29/1989/ /N19082/004/

/DEC/29/1989/

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/HYPAQUE-M/

/STERLING/

/50%;25%/

/N10220/003/

/2/

/60%;30%/

/N10220/002/

HYPAQUE-M, 75%

STERLING

50%;25%

N10220 003

HYPAQUE-M, 90%

STERLING

60%;30%

N10220 002

DIAZEPAM

TABLET; ORAL

DIAZEPAM

/BX/ /SUPERPHARM/ /10MG/

/N70644/001/

/DEC/11/1985/

N70644 001

DEC 11, 1985

2 SUPERPHARM

10MG

DICLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

DYNAPEN

/AA/ /BRISTOL/ /EQ 62.5MG BASE/5ML/ /N50337/002/
2 BRISTOL EQ 62.5MG BASE/5ML N50337 002

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

TENUATE

/AA/ /MERRELL/DOW/ /25MG/ /N17668/001/
2 MERRELL DOW 25MG N17668 001

TABLET, EXTENDED RELEASE; ORAL

TENUATE

/BC/ /MERRELL/DOW/ /75MG/ /N17669/001/
2 MERRELL DOW 75MG N17669 001

DIGOXIN

INJECTABLE; INJECTION

DIGOXIN

> DLT > /AA/ /LYPHOMED/ /0.25MG/ML/ /N83217/001/
> ADD > 2 LYPHOMED 0.25MG/ML N83217 001

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE
HYDROCHLORIDE

/INJECTABLE; INJECTION/

/EMBOLEX/

/SANDOZ/

/0.5MG/0.7ML;5,000 UNITS/0.7ML;/

/7.46MG/0.7ML/

/N18885/002/

/NOV/30/1984/

2 SANDOZ 0.5MG/0.7ML;5,000 UNITS/0.7ML;

7.46MG/0.7ML

N18885 002

NOV 30, 1984

DIMENHYDRINATE

TABLET; ORAL

DIMENHYDRINATE

/AA/ /ANABOLIC/ /50MG/ /N85985/001/
2 ANABOLIC 50MG N85985 001

DINOPROST TROMETHAMINE

/INJECTABLE; INJECTION/

/PROSTIN/F2/ALPHA/

/UPJOHN/

/EQ 5MG BASE/ML/

/N17434/001/

2 UPJOHN

EQ 5MG BASE/ML

N17434 001

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/AA/ /ANABOLIC/ /25MG/ /N83634/001/

2 ANABOLIC 25MG N83634 001

/AA/ /HEATHER/ /25MG/ /N84524/001/

2 HEATHER 25MG N84524 001

/AA/ /HEATHER/ /50MG/ /N83953/001/

2 HEATHER 50MG N83953 001

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

BARR

25MG

N87184 001

OCT 03, 1990

N87716 001

OCT 03, 1990

N87717 001

OCT 03, 1990

N89425 001

JUL 12, 1990

N89426 001

JUL 12, 1990

N89427 001

JUL 12, 1990

PERSANTINE

BOEHRINGER INGELHEIM 25MG

N12836 003

DEC 22, 1986

N12836 004

FEB 06, 1987

N12836 005

FEB 06, 1987

AB

25MG

AB

50MG

AB

75MG

DISOPYRAMIDE PHOSPHATE	CAPSULE; ORAL	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB	AB
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[illegible]

HALCINONIDEointment; topical

HALOG	/0.1%/ 0.1%	/N17824/001/ N17824 001
/SQIBB/ WESTWOOD		

solution; topical

HALOG	/0.1%/ 0.1%	/N17823/001/ N17823 001
/SQIBB/ WESTWOOD		

HEPARIN SODIUMinjectable; injectionHEPARIN LOCK FLUSH

/AP/ /LYPHOMED/	/100 UNITS/ML/ 100 UNITS/ML	/N17651/010/ N17651 010
3 LYPHOMED		
/AP/ /SOLOPAK/	/10 UNITS/ML/ 10 UNITS/ML	/N87958/001/ N87958 001
3 SOLOPAK		APR 20, 1983

HEPARIN SODIUM

/AP/ /CHAMBERLIN/	/1,000 UNITS/ML/ 1,000 UNITS/ML	/N17130/001/ N17130 001
/AP/ /CHAMBERLIN/	/5,000 UNITS/ML/ 5,000 UNITS/ML	/N17130/002/ N17130 002
/AP/ /CHAMBERLIN/	/10,000 UNITS/ML/ 10,000 UNITS/ML	/N17130/003/ N17130 003
/AP/ /CHAMBERLIN/	/20,000 UNITS/ML/ 20,000 UNITS/ML	/N17130/004/ N17130 004
3 CHAMBERLIN		
3		
3		
3		
/AP/ /LYPHOMED/	/1,000 UNITS/ML/ 1,000 UNITS/ML	/N17651/005/ N17651 005
/AP/ /LYPHOMED/	/1,000 UNITS/ML/ 1,000 UNITS/ML	/N17651/005/ N17651 005
/AP/ /LYPHOMED/	/10,000 UNITS/ML/ 10,000 UNITS/ML	/N17651/003/ N17651 003
/AP/ /LYPHOMED/	/20,000 UNITS/ML/ 20,000 UNITS/ML	/N17651/008/ N17651 008
3 LYPHOMED		
3		
3		
3		
/WYETH/AYERST/	/15,000 UNITS/ML/ 15,000 UNITS/ML	/N17007/005/ N17007 005
3 WYETH AYERST		

HOMATROPINE METHYLBROMIDEtablets; chewable; oral

/EQUIP/		
/MISSION PHARMA/	/3MG/ 3MG	/N86310/001/ N86310 001
3 MISSION PHARMA		

HYDRALAZINE HYDROCHLORIDEtablet; oralHYDRALAZINE HCL

/AA/ /SUPERPHARM/	/10MG/ 10MG	/N88787/001/ N88787 001
/AA/ /SUPERPHARM/	/25MG/ 25MG	/N88788/001/ N88788 001
/AA/ /SUPERPHARM/	/50MG/ 50MG	/N88789/001/ N88789 001
3 SUPERPHARM		AUG 28, 1984
3		AUG 28, 1984
3		AUG 28, 1984

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDEcapsule; oralHYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/AA/ /SUPERPHARM/	/25MG;25MG/ 25MG;25MG	/N89200/001/ N89200 001
3 SUPERPHARM		FEB 09, 1987

tablet; oralHYDRALAZINE AND HYDROCHLOROTHIAZIDE

/BP/ /CHELSEA/	/25MG;15MG/ 25MG;15MG	/N85827/001/ N85827 001
3 CHELSEA		

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINEtablet; oralUNIPRES

/BP/ /REID ROWELL/	/25MG;15MG;0.1MG/ 25MG;15MG;0.1MG	/N85893/001/ N85893 001
3 REID ROWELL		

HYDROCHLOROTHIAZIDEtablet; oralHYDROCHLOROTHIAZIDE

/AA/ /REID ROWELL/	/25MG/ 25MG	/N85323/001/ N85323 001
3 REID ROWELL		

HYDROCHLOROTHIAZIDE; LISINAPRILtablet; oralPRINZIDE 12.5

AB /MSD	/12.5MG;20MG/ 12.5MG;20MG	/N19778/001/ N19778 001
		FEB 16, 1989

ZESTORETIC 20/12.5

AB /IMPERIAL CHEM	/12.5MG;20MG/ 12.5MG;20MG	/N19888/001/ N19888 001
		SEP 20, 1990

HYDROCHLOROTHIAZIDE; TRIAMTERENEcapsule; oralDYAZIDE

/AB/ /SKF/	/25MG;50MG/ 25MG;50MG	/N16042/002/ N16042 002
/BX/ /BOLAR/	/25MG;50MG/ 25MG;50MG	/N171845/001/ N171845 001
		AUG 21, 1987

tablet; oralTRIAMTERENE AND HYDROCHLOROTHIAZIDE

/BX/ /VITARINE/	/50MG;75MG/ 50MG;75MG	/N71360/001/ N71360 001
3 VITARINE		DEC 08, 1987

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDEsyrup; oralHYCOMINEDUPONT

5MG/5ML;25MG/5MLM	N19410 001
	AUG 17, 1990

HYCOMINE PEDIATRICDUPONT

2.5MG/5ML;12.5MG/5MLM	N19411 001
	AUG 17, 1990

HYDROCORTISONEcream; topicalHYDROCORTISONE

/AT/ /PHARM/BASICS/	/1%/ 1%	/N88027/001/ N88027 001
/AT/ /PHARM/BASICS/	/2.5%/ 2.5%	/N88029/001/ N88029 001
3 PHARM BASICS		SEP 27, 1983
3		SEP 27, 1983

HYDROCORTISONEcream; topicalHYDROCORTISONE

/AT/ /SYOSSET/	/1%/ 1%	/N87427/001/ N87427 001
		APR 04, 1988

NOGENIC HC

AT /SYOSSET		
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ointment; topicalHYDROCORTISONE

/AT/ /PHARM/BASICS/	/1%/ 1%	/N88061/001/ N88061 001
/AT/ /PHARM/BASICS/	/2.5%/ 2.5%	/N88039/001/ N88039 001
3 PHARM BASICS		SEP 27, 1983
3		SEP 27, 1983

tablet; oralHYDROCORTISONE

/BP/ /VITARINE/	/20MG/ 20MG	/N80642/002/ N80642 002
3 VITARINE		
/BP/ /ANABOLIC/	/20MG/ 20MG	/N83140/001/ N83140 001
3 ANABOLIC		

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATEsuspension; oticPEDIOTIC

AT /BURROUGHS WELLCOME	/1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62822 001
		SEP 29, 1987

PEDIOTIC CORTISPORIN

/AT/ /BURROUGHS WELLCOME/	/1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62822/001/ N62822 001
		SEP 29, 1987

HYDROXYZINE HYDROCHLORIDEinjectable; injectionHYDROXYZINE HCL

/AP/ /SOLOPAK/	/25MG/ML/ 25MG/ML	/N87592/001/ N87592 001
3 SOLOPAK		

IBUPROFEN

TABLET; ORAL			
<u>IBUPROFEN</u>			
/AB/	/MCNEIL/	/400MG/	/N70081/001/
/AB/		/600MG/	/JUN/16./1986/
	a MCNEIL	400MG	/N70476/001/
	a	600MG	/JUN/16./1986/
/AB/	/SUPERPHARM/	/400MG/	/N70708/001/
BX	SUPERPHARM	400MG	/APR/25./1986/

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION			
<u>IDAMYCIN</u>			
	ADRIA	5MG/VIALM	N50661 002
		10MG/VIALM	SEP 27, 1990
			N50661 001
			SEP 27, 1990

IFOSFAMIDE

INJECTABLE; INJECTION			
<u>IFEX</u>			
	/BRISTOL MYERS SQUIBB/3GM/VIAL/		/N19763/002/
	a BRISTOL MYERS SQUIBB 3GM/VIAL		/DEC/30./1988/
			N19763 002
			DEC 30, 1988

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL			
<u>IMIPRAMINE HCL</u>			
AB	MUTUAL PHARM	10MG	N81048 001
			JUN 05, 1990
AB		25MG	N81049 001
			JUN 05, 1990
AB		50MG	N81050 001
			JUN 05, 1990

INDOMETHACIN

CAPSULE; ORAL			
<u>INDOMETHACIN</u>			
/BX/	/VITARINE/	/25MG/	/N71711/001/
/BX/		/50MG/	/JUL/05./1988/
	a VITARINE	25MG	/N71712/001/
	a	50MG	/JUL/05./1988/
/AB/	/ZENITH/	/25MG/	N71711 001
/AB/		/50MG/	JUL 05, 1988
	a ZENITH	25MG	N71712 001
	a	50MG	JUL 05, 1988

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL			
<u>INDOMETHACIN</u>			
/BX/	/VITARINE/	/75MG/	/N71531/001/
	a VITARINE	75MG	/JUL/21./1987/
			N71531 001
			JUL 21, 1987

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION			
<u>IODOHIPPURATE SODIUM I 131</u>			
	CIS	0.2MCI/ML	N17313 001
	/SORIN/	/0.2MCI/ML/	/N17313/001/

IOTHALAMATE SODIUM

INJECTABLE; INJECTION			
<u>CONRAY 325</u>			
	MALLINCKRODT	54.3%	N17685 001
	CONRAY 400		N14295 001
	MALLINCKRODT	66.8%	
	/CONRAY-325/		/N17685/001/
	/MALLINCKRODT/	/54.3%/	
	/CONRAY-400/		/N14295/001/
	/MALLINCKRODT/	/66.8%/	

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION			
<u>ISOETHARINE HCL</u>			
AN	DEY LABS	0.08%	N88187 001
		/0.08%/	DEC 03, 1982
			/N88187/001/
			/DEC/03./1982/
AN	INTL MEDTN SYS	0.08%	N86651 002
		/0.0833%/	/N86651/002/
<u>ISOETHARINE HCL S/F</u>			
AN	DEY LABS	0.08%	N39817 001
		/0.08%/	NOV 22, 1988
			/N89817/001/
			/NOV/22./1988/

ISONIAZID

TABLET; ORAL			
<u>ISONIAZID</u>			
/AB/	/ANABOLIC/	/100MG/	/N84050/001/
	a ANABOLIC	100MG	N84050 001
/AB/	/PUREPAC PHARM/	/50MG/	/N80132/003/
/AB/		/100MG/	/JUL/14./1982/
	a PUREPAC PHARM	50MG	/N80132/004/
	a	100MG	/JUL/14./1982/
			N80132 003
			JUL 14, 1982
			N80132 004
			JUL 14, 1982

ISOPROTERENOL HYDROCHLORIDE

INJECTABLE; INJECTION			
<u>ISOPROTERENOL HCL</u>			
> DLT >/AB/	/LYPHOMED/	/0.2MG/ML/	/N83431/001/
> ADD >	a LYPHOMED	0.2MG/ML	N83431 001

ISOSORBIDE DINITRATE

TABLET; ORAL			
<u>ISOSORBIDE DINITRATE</u>			
/AB/	/SUPERPHARM/	/5MG/	/N89190/001/
/AB/		/10MG/	/FEB/17./1987/
/AB/		/20MG/	/N89191/001/
	a SUPERPHARM	5MG	/FEB/17./1987/
	a	10MG	N89190 001
	a	20MG	FEB 17, 1987
			N89191 001
			FEB 17, 1987
			N89192 001
			FEB 17, 1987

KANAMYCIN SULFATE

INJECTABLE; INJECTION			
<u>KANAMYCIN SULFATE</u>			
/AB/	/WARNER/CHILCOTT/	/EQ 1GM BASE/3ML/	/N63092/001/
	a WARNER CHILCOTT	EQ 1GM BASE/3ML	/OCT/11./1989/
			N63092 001
			OCT 11, 1989

KETOCONAZOLE

SHAMPOO; TOPICAL			
<u>NIZORAL</u>			
	JANSSEN RES	2%M	N19927 001
			AUG 31, 1990

LEUPROLIDE ACETATE

INJECTABLE; INJECTION			
<u>LUPRON DEPOT</u>			
	/TAKEDA/ABBOTT/	/7.5MG/VIAL/	/N20011/001/
	LUPRON DEPOT	3.75MG/VIALM	/JAN/26./1989/
	TAP PHARMS	7.5MG/VIAL	N20011 001
			OCT 22, 1990
			N19732 001
			JAN 26, 1989

[illegible][illegible]

METHARBITAL

1910/11

100 2280N
/N00322/001/

1944, 1945, 1946, 1947, 1948, 1949, 1950, 1951, 1952, 1953, 1954, 1955, 1956, 1957, 1958, 1959, 1960, 1961, 1962, 1963, 1964, 1965, 1966, 1967, 1968, 1969, 1970, 1971, 1972, 1973, 1974, 1975, 1976, 1977, 1978, 1979, 1980, 1981, 1982, 1983, 1984, 1985, 1986, 1987, 1988, 1989, 1990, 1991, 1992, 1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 26

/Ed. 500MG BASE/VIAL

(5842568-063-63)

FOI b7E - 1

a EQ 500MG BASE/VIAL

3 EQ 1GM BASE/VIAL

TABLET; ORAL

10/10/10

25MG a WEST WARD

ETHYLBROMIDE

SOLUTION/DROPS; OPHTHALMIC

1957/1958 1958/1959

BAUSCH AND LOMB 0.3%

INJECTABLE: INJECTION

/ROBINS/
/EQ/IDMS/BASE/ML/

ORAL

ONT
ECONOMY
JUN 1

100

SULFATE

LINE SULFATE

NTIN

ACCEPTED

738

HYDROCHLORIDE

NI

SODIUM

708

\$/\$

Product Name	Strength	Form	Manufacturer	Lot Number	Expiration Date	Batch Number	Quantity	Unit	Price	Total
NITROGLYCERIN	10MG/ML	INJECTION	MARION MERRELL	N7159 001	FEB 28, 1990		10MG/ML	10MG/ML		
NITROGLYCERIN IN DEXTROSE 5%	10MG/100ML		ABBOTT LABS	N71846 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71847 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71848 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71849 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71850 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71851 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71852 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71853 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71854 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71855 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71856 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71857 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71858 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71859 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71860 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71861 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71862 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71863 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71864 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71865 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71866 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71867 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71868 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71869 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71870 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71871 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71872 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71873 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71874 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71875 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71876 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71877 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71878 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/100ML			N71879 001	AUG 31, 1990		10MG/100ML	10MG/100ML		
BAXTER	10MG/10									

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

IONAMIN-15

FISONS

/PENNYALT/

IONAMIN-30

FISONS

/PENNYALT/

EQ 15MG BASE
/EQ 15MG BASE/EQ 30MG BASE
/EQ 30MG BASE/N11613 004
/N11613/004/N11613 002
/N11613/002/PHENYTOIN SODIUM

INJECTABLE; INJECTION

PHENYTOIN SODIUM

/AP/ /WARNER/CHILCOTT/

/50MG/ML/

a WARNER CHILCOTT

50MG/ML

/N89441/001/
/MAR/30/1990/
N89900 001
MAR 30, 1990PHENYTOIN SODIUM, EXTENDED

CAPSULE; ORAL

EXTENDED PHENYTOIN SODIUM

/AB/ /SIDMAK/

/100MG/

a SIDMAK

100MG

/N89441/001/
/DEC/18/1986/
N89441 001
DEC 18, 1986

PHENYTEX

/BX/ /BOLAR/

/100MG/

a BOLAR

100MG

/N88711/001/
/DEC/21/1984/
N88711 001
DEC 21, 1984PHYTONADIONE

INJECTABLE; INJECTION

VITAMIN K1

/BP/ /ABBOTT/

/10MG/ML/

a ABBOTT

10MG/ML

/N87956/001/
/JUL/25/1983/
N87956 001
JUL 25, 1983PIPECURONIUM BROMIDE

INJECTABLE; INJECTION

ARDUAN

ORGANON

1MG/ML

N19638 001
JUN 26, 1990PIPERAZINE CITRATE

SYRUP; ORAL

/AA/ /BYTEL/

/STERLING/

a STERLING

/EQ 500MG BASE/5ML/
EQ 500MG BASE/5ML/N17796/001/
N17796 001POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM
BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

AA GLYCOPREP

SUPERPHARM

236GM/BOT; 2.97GM/BOT; 6.74GM/BOT;
5.86GM/BOT; 22.74GM/BOT

N72319 001

DEC 23, 1988

/AA/ /TOSA/MEDCL/

/236GM/BOT; 2.97GM/BOT; 6.74GM/BOT;
5.86GM/BOT; 22.74GM/BOT/ /N72319/001/
/DEC/23/1988/POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

AB K-LEASE

ADRIA

10 MEQ

N72427 001

MAR 28, 1990

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

/BX/ /LYPHOMED/

> DLT > /AP/

> ADD >

a LYPHOMED

/2MEQ/ML/
2MEQ/ML/N80204/001/
N80204 001PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

/BX/ /SUPERPHARM/

/5MG/

a SUPERPHARM

5MG

/N88892/001/
/FEB/26/1985/
N88892 001

FEB 26, 1985

/BX/ /UDL/

/5MG/

a UDL

5MG

/N87987/001/
/JAN/18/1983/
N87987 001

JAN 18, 1983

PREDNISOLONE ACETATE

INJECTABLE; INJECTION

PREDNISOLONE ACETATE

/BP/ /AKORN/

a AKORN

/25MG/ML/
25MG/ML/N83032/001/
N83032 001PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

/METRETON/

/SCHERING/

a SCHERING

/EQ 0.5% PHOSPHATE/
EQ 0.5% PHOSPHATE/N83834/001/
N83834 001PREDNISONE

TABLET; ORAL

PREDNISONE

/AB/ /PRIVATE/FMLTNS/

a PRIVATE FMLTNS

/20MG/
20MG/N85151/001/
N85151 001

/BX/ /UDL/LABS/

/5MG/

/N87984/001/
/JAN/18/1983/
N87984 001

/BX/

/10MG/

/N87985/001/
/JAN/18/1983/
N87985 001

/BX/

/20MG/

/N87986/001/
/JAN/18/1983/
N87986 001

a UDL LABS

5MG

JAN 18, 1983

a

10MG

N87985 001

a

20MG

JAN 18, 1983

N87986 001

JAN 18, 1983

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HCL

> DLT > /AA/

> DLT > /AA/

> ADD >

> ADD >

/KV/PHARM/

a KV PHARM

a

/6.25MG/5ML/
/25MG/5ML/

6.25MG/5ML

25MG/5ML

/N85388/001/
/N85385/001/
N85388 001

N85385 001

TABLET; ORAL

PROMETHAZINE HCL

> DLT > /BP/

> ADD >

/PRIVATE/FMLTNS/

a PRIVATE FMLTNS

/12.5MG/

12.5MG

/N83214/001/
N83214 001PROPANTHELINE BROMIDE

TABLET; ORAL

PROPANTHELINE BROMIDE

/AA/ /PRIVATE/FMLTNS/

a PRIVATE FMLTNS

/15MG/
15MG/N80977/001/
N80977 001PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

/AA/ /ANABOLIC/

a ANABOLIC

/65MG/
65MG/N83185/001/
N83185 001

/AA/ /PRIVATE/FMLTNS/

a PRIVATE FMLTNS

/32MG/
32MG/N83464/001/
N83464 001

a

65MG

N83113 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

THDERAL

/AB/ /WYETH/AYERST/LABS/

a WYETH AYERST LABS

/90MG/

/N16418/010/
/OCT/18/1982/
N16418 010

OCT 18, 1982

/AB/ /PRIVAT/PHARM/

/10MG/

/N70211/001/
/NOV/19/1985/
N70211 001

/AB/

/20MG/

/N70212/001/
/NOV/19/1985/
N70212 001

/AB/

/40MG/

/N70213/001/
/NOV/19/1985/
N70213 001

/AB/

/60MG/

/N70214/001/
/NOV/19/1985/
N70214 001

PROPRANOLOL HCL

/AB/ /DANBURY/PHARMA/

a DANBURY PHARMA

/90MG/

90MG

/N71183/001/
/OCT/06/1986/
N71183 001

OCT 06, 1986

[illegible][illegible]

[illegible]

CLOTRIMAZOLE

> ADD >	CREAM; VAGINAL		
> ADD >	GYNE-LOTIMIN		
> ADD >	SCHERING	1% M	N18052 002
> ADD >			NOV 30, 1990
> ADD >	TABLET; VAGINAL		
> ADD >	GYNE-LOTIMIN		
> ADD >	SCHERING	100MG M	N17717 002
> ADD >			NOV 30, 1990

DIPHENHYDRAMINE HYDROCHLORIDE

	SYRUP; ORAL		
	<u>DIPHENHYDRAMINE HCL</u>		
AA	HI TECH	<u>12.5MG/5MLM</u>	N72416 001
			SEP 28, 1990

PERMETHRIN

	LOTION; TOPICAL		
	NIX		
	BURROUGHS WELLCOME	1% M	N19918 001
			MAY 02, 1990

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: ANTI-CYTOMEGALOVIRUS MONOCLONAL ANTIBODIES TRADE: NOT ESTABLISHED	PREVENTION OF HUMAN CYTOMEGALOVIRUS INFECTION IN BONE MARROW AND ORGAN TRANSPLANT PATIENTS. TREATMENT OF HUMAN CYTOMEGALOVIRUS INFECTION IN BONE MARROW AND ORGAN TRANSPLANT PATIENTS. PREVENTION OF HUMAN CYTOMEGALOVIRUS INFECTION IN PATIENTS DIAGNOSED WITH AIDS. TREATMENT OF HUMAN CYTOMEGALOVIRUS INFECTION IN PATIENTS DIAGNOSED WITH AIDS.	MEDIMORPHICS
GENERIC: BOTULINUM TOXIN TYPE A TRADE: OCULINUM*/**	TREATMENT OF STRABISMUS ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE). TREATMENT OF BLEPHAROSPASM ASSOCIATED WITH DYSTONIA IN ADULTS (PATIENTS 12 YEARS OF AGE AND ABOVE).*/** [DEC 29, 1996]	ALAN B. SCOTT, M.D.
GENERIC: BOVINE COLOSTRUM TRADE: NOT ESTABLISHED	TREATMENT OF AIDS-RELATED DIARRHEA.	DONALD H. HASTINGS, D.V.M.
GENERIC: COAGULATION FACTOR IX (HUMAN) TRADE: ALPHANINE	FOR USE AS REPLACEMENT THERAPY IN PATIENTS WITH HEMOPHILIA B FOR THE PREVENTION AND CONTROL OF BLEEDING EPISODES, AND DURING SURGERY TO CORRECT DEFECTIVE HEMOSTASIS.	ALPHA THERPTCS
GENERIC: CYTOMEGALOVIRUS IMMUNE GLOBULIN (HUMAN) TRADE: NOT ESTABLISHED*/**	PREVENTION OR ATTENUATION OF PRIMARY CYTOMEGALOVIRUS DISEASE IN IMMUNOSUPPRESSED RECIPIENTS OF ORGAN TRANSPLANTS. [APR 17, 1997]	MASSACHUSETTS PUBLIC HEALTH BIOLOGIC LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: C1-INHIBITOR TRADE: C1-INHIBITOR (HUMAN) VAPOR HEATED, IMMUNO	PREVENTION OF ACUTE ATTACKS OF ANGIOEDEMA, INCLUDING SHORT-TERM PROPHYLAXIS FOR PATIENTS REQUIRING DENTAL OR OTHER SURGICAL PROCEDURES. TREATMENT OF ACUTE ATTACKS OF ANGIOEDEMA.	IMMUNO CLIN RES
GENERIC: CD4 IMMUNOGLOBULIN G (RECOMBINANT HUMAN) TRADE: NOT ESTABLISHED	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) RESULTING FROM INFECTION WITH THE HUMAN IMMUNODEFICIENCY VIRUS (HIV-1).	GENETECH
GENERIC: CD-45 MONOCLONAL ANTIBODIES TRADE: NOT ESTABLISHED	PREVENTION OF ACUTE GRAFT REJECTION OF HUMAN ORGAN TRANSPLANTS.	NJC ENTERPRISES
GENERIC: DISACCHARIDE TRIPEPTIDE GLYCEROL DIPALMITOYL (DTP-GDP) TRADE: IMMOTHER	TREATMENT OF PULMONARY AND HEPATIC METASTASES IN COLORECTAL ADENOCARCINOMA PATIENTS.	IMMUNOTHERAPEUTICS
GENERIC: GRANULOCYTE-COLONY STIMULATING FACTOR (RECOMBINANT-METHIONYL HUMAN) TRADE: NEUPOGEN	TREATMENT OF MYELODYSPLASTIC SYNDROME. TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANTS. TREATMENT OF PATIENTS WITH SEVERE CHRONIC NEUTROPENIA (ABSOLUTE NEUTROPHIL COUNT LESS THAN 500 PER CUBIC MILLIMETER).	AMGEN
GENERIC: GRANULOCYTE MACROPHAGE-COLONY STIMULATING FACTOR TRADE: NOT ESTABLISHED	TREATMENT OF NEUTROPENIA DUE TO HAIRY CELL LEUKEMIA. TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA TO INCREASE GRANULOCYTE COUNTS.	SCHERING PLOUGH

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: GROUP B STREPTOCOCCUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF NEONATES WITH DISSEMINATED GROUP B STREPTOCOCCAL INFECTION.	UNIVAX
GENERIC: [INDIUM 111 MURINE ANTI-CEA MONOCLONAL ANTIBODY TYPE ZCE 025] TRADE: CEAKER	FOR THE DETECTION OF SUSPECTED AND PREVIOUSLY UNIDENTIFIED TUMOR FOCI OF RECURRENT COLORECTAL CARCINOMA.	HYBRITECH
GENERIC: INTERFERON ALPHA-2A (RECOMBINANT) TRADE: ROFERON-A	TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN COMBINATION WITH TECELEUKIN. TREATMENT OF METASTATIC MALIGNANT MELANOMA IN COMBINATION WITH TECELEUKIN. CONCOMITANT ADMINISTRATION WITH FLUOROURACIL FOR THE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.	ROCHE
GENERIC: INTERFERON ALPHA-2B (RECOMBINANT) TRADE: INTRON A	TREATMENT OF PATIENTS WITH CHRONIC DELTA HEPATITIS.	SCHERING PLOUGH
GENERIC: INTERLEUKIN-2 POLYETHYLENE CONJUGATE; RECOMBINANT E. COLI TRADE: NOT ESTABLISHED	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.	CETUS
GENERIC: LACTOBIN TRADE: LACTOBIN	TREATMENT OF AIDS ASSOCIATED DIARRHEA UNRESPONSIVE TO INITIAL ANTIDIARRHEAL THERAPY.	ROXANE LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: LEUKOPOIETIN TRADE: LEUKINE	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.	IMMUNEX
GENERIC: MONOCLONAL ANTIBODIES PM-81 AND AML 2-23 TRADE: NOT ESTABLISHED	FOR EXOGENOUS DEPLETION OF CD14 AND CD15 POSITIVE ACUTE MYELOID LEUKEMIC BONE MARROW CELLS FROM PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION.	MEDAREX
GENERIC: MUCOID EXOPOLYSACCHARIDE PSEUDOMONAS HYPERIMMUNE GLOBULIN TRADE: MEPIG	PREVENTION OF PULMONARY INFECTIONS DUE TO PSEUDOMONAS AERUGINOSA IN PATIENTS WITH CYSTIC FIBROSIS.	UNIVAX BIOLOGICS
GENERIC: ONCORAD OV103 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CARCINOMA.	CYTOGEN
GENERIC: RESPIRATORY SYNCYTIAL VIRUS IMMUNE GLOBULIN (HUMAN) TRADE: HYPERMUNE RSV	PROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS LOWER RESPIRATORY INFECTIONS IN INFANTS AND YOUNG CHILDREN AT HIGH RISK OF SERIOUS DISEASE. TREATMENT OF RESPIRATORY SYNCYTIAL VIRUS LOWER RESPIRATORY INFECTIONS IN HOSPITALIZED INFANTS AND YOUNG CHILDREN.	MOLECULAR VACCINES
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY ⁹) TO MYELOID CELLS (CD-33) TRADE: NOT ESTABLISHED	FOR USE IN THE EX VIVO TREATMENT OF AUTOLOGOUS BONE MARROW AND SUBSEQUENT REINFUSION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.	IMMUNOGEN

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: TECELEUKIN TRADE: NOT ESTABLISHED	TREATMENT OF METASTATIC MALIGNANT MELANOMA. TREATMENT OF METASTATIC RENAL CELL CARCINOMA. TREATMENT OF METASTATIC MALIGNANT MELANOMA IN COMBINATION WITH ROFERON-A. TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN COMBINATION WITH ROFERON-A (INTERFERON ALPHA-2A, RECOMBINANT/ROCHE).	ROCHE

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ALL-TRANS RETINOIC ACID TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE PROMYELOCYTIC LEUKEMIA.	ROCHE
GENERIC: ALPHA-GALACTOSIDASE A TRADE: FABRISE	TREATMENT OF FABRY'S DISEASE.	ROBERT J. DESNICK, M.D., PH.D. MOUNT SINAI SCHOOL OF MEDICINE
GENERIC: AMILORIDE HCL SOLUTION FOR INHALATION TRADE: NOT ESTABLISHED	TREATMENT OF CYSTIC FIBROSIS.	GLAXO
GENERIC: BMY-45622 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CANCER.	BRISTOL SQUIBB
GENERIC: CALCITONIN SALMON NASAL SPRAY TRADE: MIACALCIN	TREATMENT OF SYMPTOMATIC PAGET'S DISEASE OF BONE (OSTEITIS DEFORMANS).	SANDOZ
GENERIC: CALCIUM CARBONATE TRADE: R & D CALCIUM CARBONATE/600	TREATMENT OF HYPERPHOSPHATEMIA IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD).	R AND D LABS
GENERIC: CALCIUM GLUCONATE GEL 2.5% TRADE: NOT ESTABLISHED	EMERGENCY TOPICAL TREATMENT OF HYDROGEN FLUORIDE (HYDROFLUORIC ACID) BURNS.	PADDOCK LABS
GENERIC: COLFOSCERIL PALMITATE TRADE: EXOSURF NEONATAL */**	PREVENTION OF HYALINE MEMBRANE DISEASE (HMD), ALSO KNOWN AS RESPIRATORY DISTRESS SYNDROME (RDS), IN INFANTS BORN AT 32 WEEKS GESTATION OR LESS. */** [AUG 02, 1997] TREATMENT OF ESTABLISHED HMD AT ALL GESTATIONAL AGES. */** [AUG 02, 1997]	BURROUGHS WELLC

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: CROMOLYN SODIUM TRADE: GASTROCROM */**	MASTOCYTOSIS. [DEC 22, 1996]	FISONS
GENERIC: DEHYDREX TRADE: NOT ESTABLISHED	TREATMENT OF RECURRENT CORNEAL EROSION UNRESPONSIVE TO CONVENTIONAL THERAPY.	HOLLES LABS
GENERIC: DEXTRAN SULFATE (INHALED, AEROSOLIZED) TRADE: UENDEX	ADJUNCT TO THE TREATMENT OF CYSTIC FIBROSIS.	THOMAS P. KENNEDY, M.D. J. HOIDAL, M.D. DUKE UNIVERSITY MEDICAL CENTER
GENERIC: DISODIUM CLODRONATE TETRAHYDRATE TRADE: BONEFOS	TREATMENT OF INCREASED BONE RESORPTION DUE TO MALIGNANCY.	LEIRAS PHARMS
GENERIC: DYNAMINE TRADE: NOT ESTABLISHED	TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME.	MAYO CLINIC AND FOUNDATION
GENERIC: FLUOROURACIL	CONCOMITANT ADMINISTRATION WITH ROFERON-A FOR THE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.	ROCHE
GENERIC: GENTAMICIN LIPOSOME INJECTION TRADE: NOT ESTABLISHED	TREATMENT OF DISSEMINATED MYCOBACTERIUM AVIUM-INTRACELLULARE INFECTION.	LIPOSOME
GENERIC: GONADORELIN ACETATE TRADE: LUTREPULSE */**	TREATMENT OF PRIMARY HYPOTHALAMIC AMENORRHEA. [OCT 10, 1996]	RW JOHNSON

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: GOSSYPOL TRADE: NOT ESTABLISHED	TREATMENT OF CANCER OF THE ADRENAL CORTEX.	MARCUS M. REIDENBERG, M.D. CORNELL UNIVERSITY MEDICAL COLLEGE
GENERIC: HYDROXYUREA TRADE: HYDREA	TREATMENT OF SICKLE CELL ANEMIA AS SHOWN BY THE PRESENCE OF HEMOGLOBIN S.	BRISTOL SQUIBB
GENERIC: IDARUBICIN HYDROCHLORIDE TRADE: IDAMYCIN*/**	TREATMENT OF ACUTE MYELOGENOUS LEUKEMIA (AML), ALSO REFERRED TO AS ACUTE NONLYMPHOCYTIC LEUKEMIA (ANLL). [SEP 27, 1990]	ADRIA LABS
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF HEPARIN-ASSOCIATED THROMBOCYTOPENIA.	BERLEX LABS
GENERIC: L-BACLOFEN TRADE: NOT ESTABLISHED	TREATMENT OF TRIGEMINAL NEURALGIA.	GERHARD H. FROMM, M.D. UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE
GENERIC: LEUPEPTIN TRADE: NOT ESTABLISHED	ADJUNCT TO MICROSURGICAL PERIPHERAL NERVE REPAIR.	LAWRENCE C. HURST, M.D. STATE UNIVERSITY OF NEW YORK
GENERIC: LIOTHYRONINE INJECTION TRADE: NOT ESTABLISHED	TREATMENT OF MYXEDEMA COMA/PRE-COMA.	SMITHKLINE BEECHAM
GENERIC: MAFENIDE ACETATE SOLUTION TRADE: SULFAMYLON	FOR USE IN THE PREVENTION OF GRAFT LOSS OF MESHED AUTOGRAFTS ON EXCISED BURN WOUNDS.	STERLING DRUG

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: MEFLOQUINE HCL TRADE: LARIAM*/**	TREATMENT OF ACUTE MALARIA DUE TO PLASMODIUM FAL- CIPARUM AND PLASMODIUM VIVAX.*/** [MAY 02, 1996] PROPHYLAXIS OF PLASMODIUM FALCIPARUM MALARIA WHICH IS RESISTANT TO OTHER AVAILABLE DRUGS.*/** [MAY 02, 1996]	ROCHE
GENERIC: METHOTREXATE USP WITH LAUROCAPRAM TRADE: NOT ESTABLISHED	TOPICAL TREATMENT OF MYCOSIS FUNGOIDES.	WHITBY RES
GENERIC: MICROBUBBLE CONTRAST AGENT TRADE: FILMIX (NEUROSONOGRAPHIC CONTRAST AGENT)	INTRAOPERATIVE AID IN THE IDENTIFICATION AND LOCALIZATION OF INTRACRANIAL TUMORS.	CAV-CON
GENERIC: MORPHINE SULFATE CONCENTRATE TRADE: INFUMORPH	FOR USE IN MICROINFUSION DEVICES FOR INTRASPINAL ADMINISTRATION IN THE TREATMENT OF INTRACTABLE CHRONIC PAIN.	ELKINS SINN
GENERIC: N-ACETYL PROCAINAMIDE TRADE: NAPA	TO LOWER THE DEFIBRILLATION ENERGY REQUIREMENT SUFFICIENTLY TO ALLOW AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) THERAPY IN THOSE PATIENTS WHO COULD OTHERWISE NOT USE THE DEVICE.	MEDCO RES
GENERIC: OXANDROLONE TRADE: NOT ESTABLISHED	TREATMENT OF CONSTITUTIONAL DELAY OF GROWTH AND PUBERTY. TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	GYNEX

ORPHAN DRUG PRODUCT DESIGNATIONS
DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: PEGADEMASE BOVINE TRADE: ADAGEN*/**	USE AS ENZYME REPLACEMENT THERAPY FOR ADENOSINE DEAMINASE (ADA) DEFICIENCY IN PATIENTS WITH SEVERE COMBINED IMMUNODEFICIENCY (SCID) WHO ARE NOT SUITABLE CANDIDATES FOR (OR WHO HAVE FAILED) BONE MARROW TRANSPLANTATION. [MAR 21, 1997]	ENZON
GENERIC: PILOCARPINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF XEROSTOMIA INDUCED BY RADIATION THERAPY FOR HEAD AND NECK CANCER.	MGI PHARMA
GENERIC: POLOXAMER 188 TRADE: RHEOTHRX COPOLYMER	TREATMENT OF SEVERE BURNS REQUIRING HOSPITALIZATION.	CYTRX
GENERIC: PR-122 (REDOX-PHENYTOIN) TRADE: NOT ESTABLISHED	FOR THE EMERGENCY RESCUE TREATMENT OF STATUS EPILEPTICUS, GRAND MAL TYPE.	PHARMATEC
GENERIC: PR-225 (REDOX ACYCLOVIR) TRADE: NOT ESTABLISHED	TREATMENT OF HERPES SIMPLEX ENCEPHALITIS IN INDIVIDUALS AFFLICTED WITH AIDS.	PHARMATEC
GENERIC: PR-239 (REDOX PENICILLIN G) TRADE: NOT ESTABLISHED	TREATMENT OF AIDS ASSOCIATED NEUROSYPHILIS.	PHARMATEC
GENERIC: PR-320 (MOLECUSOL-CARBAMAZEPINE) TRADE: NOT ESTABLISHED	FOR THE EMERGENCY RESCUE TREATMENT OF STATUS EPILEPTICUS, GRAND MAL TYPE.	PHARMATEC
GENERIC: RHEOTHRX TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE BURNS IN HOSPITALIZED PATIENTS.	CYTRX

ORPHAN DRUG PRODUCT DESIGNATIONS
DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: SERMORELIN ACETATE TRADE: GEREF	AS AN ADJUNCT TO GONADOTROPIN THERAPY IN THE INDUCTION OF OVULATION IN WOMEN WITH ANOVULATORY OR OLIGO-OVULATORY INFERTILITY WHO FAIL TO OVULATE IN RESPONSE TO ADEQUATE TREATMENT WITH CLOMIPHENE CITRATE ALONE AND GONADOTROPIN THERAPY ALONE.	SERONO LABS
GENERIC: SHORT CHAIN FATTY ACID SOLUTION TRADE: NOT ESTABLISHED	TREATMENT OF THE ACTIVE PHASE OF ULCERATIVE COLITIS WITH INVOLVEMENT RESTRICTED TO THE LEFT SIDE OF THE COLON.	RICHARD I. BREUER EVANSTON HOSP
GENERIC: SK&F 110679 TRADE: NOT ESTABLISHED	LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	SK&F LABS
GENERIC: SODIUM DICHLOROACETATE TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL LACTIC ACIDOSIS. TREATMENT OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.	PETER STACPOOLE, M.D., PH.D. UNIVERSITY OF FLORIDA
GENERIC: SOMATROPIN TRADE: HUMATROPE	TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	LILLY
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL COMPLICATIONS OF CHEMOTHERAPY IN BONE MARROW TRANSPLANT RECIPIENTS.	NASKA PHARMA
GENERIC: SULFAPYRIDINE TRADE: NOT ESTABLISHED	TREATMENT OF DERMATITIS HERPETIFORMIS.	JACOBUS PHARM

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: THALIDOMIDE TRADE: NOT ESTABLISHED	TREATMENT OF GRAFT VERSUS HOST DISEASE (GVHD) IN PATIENTS RECEIVING BONE MARROW TRANSPLANTATION (BMT). PREVENTION OF GVHD IN PATIENTS RECEIVING BMT.	ANDRULIS RES
GENERIC: TRIPTORELIN PAMOATE TRADE: DECAPEPTYL INJECTION	FOR USE IN THE PALLIATIVE TREATMENT OF ADVANCED OVARIAN CARCINOMA OF EPITHELIAL ORIGIN.	ORGANON
GENERIC: 2-CHLORODEOXYADENOSINE TRADE: NOT ESTABLISHED	TREATMENT OF HAIRY CELL LEUKEMIA.	RW JOHNSON
GENERIC: 2-CHLORO-2'-DEOXYADENOSINE TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE MYELOID LEUKEMIA.	ST JUDE CHILDRENS
GENERIC: 2,3-DIMERCAPTOSUCCINIC ACID TRADE: CHEMET	PREVENTION OF CYSTINE KIDNEY STONE FORMATION IN PATIENTS WITH HOMOZYGOUS CYSTINURIA WHO ARE PRONE TO STONE DEVELOPMENT.	MCNEIL CONSUMER
GENERIC: 566C80 TRADE: NOT ESTABLISHED	TREATMENT OF AIDS ASSOCIATED PNEUMOCYSTIS CARINII PNEUMONIA (PCP).	BURROUGHS WELLC

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

NO NOVEMBER 1990 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, ROOM 17B-06, 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, 10TH 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
THEOPHYLLINE (CAPSULE AND TABLET)	SEP 01/1984	
THEOPHYLLINE (CAPSULE/ EXTENDED RELEASE AND TABLET/ EXTENDED RELEASE)	SEP 01/1984	
ONCE A DAY DOSING++SINGLE DOSE STUDY		
TWICE A DAY DOSING++SINGLE DOSE STUDY		
ONCE A DAY DOSING++MULTIPLE DOSE STUDY		
TWICE A DAY DOSING++MULTIPLE DOSE STUDY		

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, 10TH 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
ALBUTEROL SULFATE SOLUTION; ORAL	2MG/5ML	89 P-0447/CP	BIOCRAFT LABS	NEW DOSAGE FORM	APPROVED MAR 15, 1990
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 7.5MG	90 P-0050/CP	MASON PHARMS	NEW STRENGTH	APPROVED JUN 01, 1990
CHLORZOXAZONE CAPSULE; ORAL	250MG	90 P-0084/ CP0001	MIKART	NEW DOSAGE FORM	APPROVED MAY 24, 1990
HYDROCORTISONE SOLUTION; TOPICAL	2.5%	89 P-0175/CP	GENDERM	NEW STRENGTH	APPROVED JAN 11, 1990
HYDROCORTISONE ACETATE CREAM; TOPICAL	2.5%	90 P-0049/CP	FERNDALE LABS	NEW STRENGTH	APPROVED JUN 22, 1990
HYDROCORTISONE ACETATE LOTION; TOPICAL	1%	90 P-0049/CP	FERNDALE LABS	NEW DOSAGE FORM	APPROVED JUN 22, 1990

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HYDROCORTISONE ACETATE LOTION; TOPICAL	2.5%	90 P-0049/CP	FERNDAL LABS	NEW DOSAGE FORM	APPROVED JUN 22, 1990
ISOSORBIDE DINITRATE TABLET, EXTENDED RELEASE; ORAL	60MG	89 P-0485/CP	ADRIA LABS	NEW STRENGTH	APPROVED JUN 01, 1990
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	0.05MG/ML (500ML/CONTAINER)	89 P-0422/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 20, 1990
NITROGLYCERIN IN DEXTROSE 5% INJECTABLE; INJECTION	0.2MG/ML (500ML/CONTAINER)	89 P-0422/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 20, 1990
PENTAMIDINE ISETHIONATE INJECTABLE; INJECTION	100MG/ML (3ML/VIAL)	89 P-0435/CP	ASTRA PHARM PRODS	NEW DOSAGE FORM	APPROVED JAN 18, 1990
THEOPHYLLINE TABLET; ORAL	150MG	89 P-0499/CP	SCI CONSULTING	NEW STRENGTH	APPROVED MAY 03, 1990
TOLMETIN SODIUM TABLET; ORAL	EQ 400MG BASE	90 P-0011/CP	QUANTUM PHARMCS	NEW STRENGTH	APPROVED MAY 03, 1990
VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED RELEASE; ORAL	120MG	89 P-0220/CP	LEDERLE LABS	NEW STRENGTH	APPROVED JAN 11, 1990

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CLONIDINE HYDROCHLORIDE CAPSULE, EXTENDED RELEASE; ORAL	0.2MG	88 P-0365/CP	BOEHR INGEL	NEW DOSAGE FORM	DENIED JAN 11, 1990

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, 10TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

I-41	MIGRAINE HEADACHE PROPHYLAXIS
I-42	HERPES ZOSTER
I-43	HERPES SIMPLEX ENCEPHALITIS
I-44	MAINTENANCE THERAPY IN HEALED DUODENAL ULCER PATIENTS AT DOSE OF 1 GRAM TWICE DAILY
I-45	ACUTE TREATMENT OF VARICELLA ZOSTER VIRUS
I-46	USE IN PEDIATRIC COMPUTED TOMOGRAPHIC HEAD AND BODY IMAGING
I-47	TREATMENT OF PEDIATRIC PATIENTS WITH SYMPTOMATIC HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
I-48	PEDIATRIC ANGIOCARDIOGRAPHY
I-49	TREATMENT OF TRAVELERS' DIARRHEA DUE TO SUSCEPTIBLE STRAINS OF ENTEROTOXIGENIC ESCHERICHIA COLI
I-50	FOR USE IN WOMEN WITH AXILLARY NODE-NEGATIVE BREAST CANCER
I-51	TREATMENT OF PRIMARY DYSMENORRHEA AND FOR THE TREATMENT OF IDIOPATHIC HEAVY MENSTRUAL BLOOD LOSS
I-52	PEDIATRIC EXCRETORY UROGRAPHY
I-53	TREATMENT OF PANIC DISORDER, WITH OR WITHOUT AGORAPHOBIA

REFERENCES
PATENT USE CODE

U-42	ADJUVANT TREATMENT IN COMBINATION WITH FLUOROURACIL AFTER SURGICAL RESECTION IN PATIENTS WITH DUKES' STAGE C COLON CANCER
U-43	MANAGEMENT OF CHRONIC PAIN IN PATIENTS REQUIRING OPIOID ANALGESIA

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
18828 001	ACYCLOVIR; ZOVIRAX				I-45	APR 20, 1993
19909 001	ACYCLOVIR; ZOVIRAX				I-45	APR 26, 1993
18603 001	ACYCLOVIR SODIUM; ZOVIRAX				I-43	FEB 09, 1993
>ADD>	18276 001 ALPRAZOLAM; XANAX	3980789	SEP 14, 1993		I-42	FEB 09, 1993
>ADD>	18276 002 ALPRAZOLAM; XANAX	3980789	SEP 14, 1993		I-53	NOV 06, 1993
>ADD>	18276 003 ALPRAZOLAM; XANAX	3980789	SEP 14, 1993		I-53	NOV 06, 1993
>ADD>	18276 004 ALPRAZOLAM; XANAX	3987052	OCT 19, 1993		I-53	NOV 06, 1993
	19155 001 AMMONIUM LACTATE; LAC-HYDRIN	4105783	OCT 26, 1995			
>ADD>	19429 003 ASPIRIN; FIORINAL W/CODEINE NO 3				NC	OCT 26, 1993
	18240 004 ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-3		
		3836671	SEP 17, 1991	U-39	I-39	SEP 13, 1992
		3836671	SEP 17, 1991	U-8		
72303 001	ATENOLOL; ATENOLOL	3934032	JAN 20, 1993	U-3	I-39	SEP 13, 1992
		3836671	SEP 17, 1991	U-39		
		3836671	SEP 17, 1991	U-8		
72304 001	ATENOLOL; ATENOLOL	3934032	JAN 20, 1993	U-3	I-39	SEP 13, 1992
		3836671	SEP 17, 1991	U-39		
		3836671	SEP 17, 1991	U-8		
19845 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC S	4311708	JAN 19, 1999		NDF	DEC 29, 1992
19880 001	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
19880 002	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
19880 003	CARBOPLATIN; PARAPLATIN	4140707	AUG 25, 1998			
19972 001	CARTEOLOL HYDROCHLORIDE; OPTIPRESS	4309432	JAN 05, 1999		NDF	MAY 23, 1993
		3910924	OCT 07, 1994		NCE	DEC 28, 1993
19481 001	CITRIC ACID; RENACIDIN				ODE	OCT 02, 1997
19966 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NP	FEB 22, 1993
					NCE	DEC 27, 1990
20044 001	COLFOSCERIL PALMITATE; EXOSURF NEONATAL	4826821	MAY 02, 2006		ODE	AUG 02, 1997
		4312860	JAN 26, 1999		NCE	AUG 02, 1995
>ADD>	19668 001 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
>ADD>	19668 002 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
>ADD>	19668 003 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
>ADD>	19668 004 DOXAZOSIN MESYLATE; CARDURA				NCE	NOV 02, 1995
>ADD>	19879 002 EFLORNITHINE HYDROCHLORIDE; ORNIDYL	4413141	NOV 01, 2000		ODE	NOV 28, 1997
>ADD>		4339151	AUG 16, 2000		NCE	NOV 28, 1995
>ADD>	19653 001 ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
>DLT>	19653 001 ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1996		NC	DEC 29, 1992
>ADD>	19653 002 ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996		NC	DEC 29, 1992
>DLT>	19653 002 ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1996		NC	DEC 29, 1992

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19813 001	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43	NDF	AUG 07, 1993
19813 002	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43	NDF	AUG 07, 1993
19813 003	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43	NDF	AUG 07, 1993
19813 004	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
		4144317	SEP 09, 1992			
		4060084	JUN 28, 1994	U-43	NDF	AUG 07, 1993
19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
		4404216	SEP 13, 2000		NCE	JAN 29, 1995
20001 001	FLUOCINOLONE ACETONIDE; FS SHAMPOO				NDF	AUG 27, 1993
18554 001	FLUTAMIDE; EULEXIN	4329364	MAY 11, 2001	U-23		
19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4963344	MAR 03, 2004		I-38	AUG 10, 1992
		4957939	MAR 03, 2004		I-31	APR 28, 1992
		4355032	MAR 16, 2003	U-33	NCE	JUN 23, 1994
>ADD> 19661 001	GANCICLOVIR SODIUM; CYTOVENE	4355032	MAR 16, 2003	U-33	NCE	JUN 23, 1994
>DLT> 19661 001	GANCICLOVIR SODIUM; CYTOVENE	4355032	MAR 16, 2003	U-33	NCE	JUN 23, 1994
19032 001	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
19032 002	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
19032 003	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
17556 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
17818 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
17824 001	HALCINONIDE; HALOG	3892856	JUL 01, 1992			
18234 001	HALCINONIDE; HALOG-E	4048310	SEP 13, 1994			
50661 001	IDARUBICIN HYDROCHLORIDE; IDAMYCIN				ODE	SEP 27, 1997
50661 002	IDARUBICIN HYDROCHLORIDE; IDAMYCIN				ODE	SEP 27, 1997
19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			

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
18956 002	IOHEXOL; OMNIPAQUE 240	4021481	MAY 03, 1994			
18735 002	IOPAMIDOL; ISOVUE-300				I-46	MAY 30, 1993
					I-52	SEP 21, 1993
18735 003	IOPAMIDOL; ISOVUE-370				I-48	OCT 04, 1992
19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 1999		NCE	DEC 07, 1994
19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 1999		NCE	DEC 07, 1994
19927 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		NDF	AUG 31, 1993
20011 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NP	OCT 22, 1993
20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL	4584305	APR 22, 2003	U-42	NCE	JUN 18, 1995
18006 001	MECLOFENAMATE SODIUM; MECLOMEN				I-51	JUL 23, 1993
18006 002	MECLOFENAMATE SODIUM; MECLOMEN				I-51	JUL 23, 1993
19591 001	MEFLOQUINE HYDROCHLORIDE; LARIAM				ODE	MAY 02, 1996
19907 001	METIPRANLOL HYDROCHLORIDE; OPTIPRANLOL				NCE	DEC 29, 1994
19786 001	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19786 002	METOPROLOL FUMARATE; LOPRESSOR	3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19786 003	METOPROLOL FUMARATE; LOPRESSOR	4892739	JAN 09, 2007			
		3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19786 004	METOPROLOL FUMARATE; LOPRESSOR	4892739	JAN 09, 2007			
		3916899	NOV 04, 1992			
		3845770	NOV 05, 1991			
19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
		3740395	JUN 19, 1990		NCE	JUN 19, 1995
19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
		3740395	JUN 19, 1990		NCE	JUN 19, 1995
19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
		3740395	JUN 19, 1990		NCE	JUN 19, 1995
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		NCE	FEB 13, 1995
19356 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	MAR 01, 1993
					NDF	JUN 18, 1993
19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN				D-1	JUL 05, 1993
72409 001	NIFEDIPINE; NIFEDIPINE				PC	MAR 02, 1991
19715 001	OLSALAZINE SODIUM; DIPENTUM				NCE	JUL 31, 1995
>ADD> 19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2002			
>DLT> 19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2002			

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19818 001	PEGADEMASE BOVINE; ADAGEN	4179337	DEC 18, 1996		ODE	MAR 21, 1997
19918 001	PERMETHRIN; NIX	4024163	MAY 17, 1996		NCE	MAR 21, 1995
19638 001	PIPECURONIUM BROMIDE; ARDUAN				NCE	MAR 31, 1991
87361 001	PROCAINAMIDE HYDROCHLORIDE; PRONESTYL-SR	4252786	FEB 24, 1998		NCE	JUN 26, 1995
>ADD> >DLT> 19627 001	PROPOFOL; DIPRIVAN	4056635	NOV 01, 1998			
10929 001	SODIUM IODIDE, I-131; IODOTOPE	4056635 4349529	NOV 01, 1998 SEP 14, 1999			
10929 002	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
10929 003	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
18333 001	SUCRALFATE; CARAFATE				I-44	MAY 11, 1993
17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-49	JUN 15, 1993
17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-49	JUN 15, 1993
17377 001	SULFAMETHOXAZOLE; BACTRIM				I-49	JUN 15, 1993
17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-49	JUN 15, 1993
17560 001	SULFAMETHOXAZOLE; BACTRIM				I-49	JUN 15, 1993
17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-49	JUN 15, 1993
17598 001	SULFAMETHOXAZOLE; SEPTRA				I-49	JUN 15, 1993
17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-49	JUN 15, 1993
17970 001	TAMOXIFEN CITRATE; NOLVADEX	4536516	AUG 20, 2002		I-50	JUN 21, 1993
18107 001	TECHNETIUM TC-99M MEDRONATE KIT; MDP-SQUIBB	4115541	SEP 19, 1995			
19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3				NCE	JUN 15, 1995
17339 001	TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR; MINITEC	4041317	AUG 09, 1994			
		3920995	NOV 18, 1992			
18017 001	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
18017 002	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
18017 004	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
19614 001	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
		4833130	FEB 02, 2005		I-47	MAY 02, 1993
		4828838	FEB 02, 2005		ODE	MAR 19, 1994
		4724232	FEB 02, 2005		NCE	MAR 19, 1992
19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
		4833130	FEB 02, 2005		ODE	MAR 19, 1994
		4818538	FEB 02, 2005		I-47	MAY 02, 1993
		4724232	FEB 02, 2005		NCE	MAR 19, 1992
19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
		4833130	FEB 02, 2005		NCE	MAR 19, 1992
		4818538	FEB 02, 2005			
		4724232	FEB 02, 2005		ODE	MAR 19, 1994

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