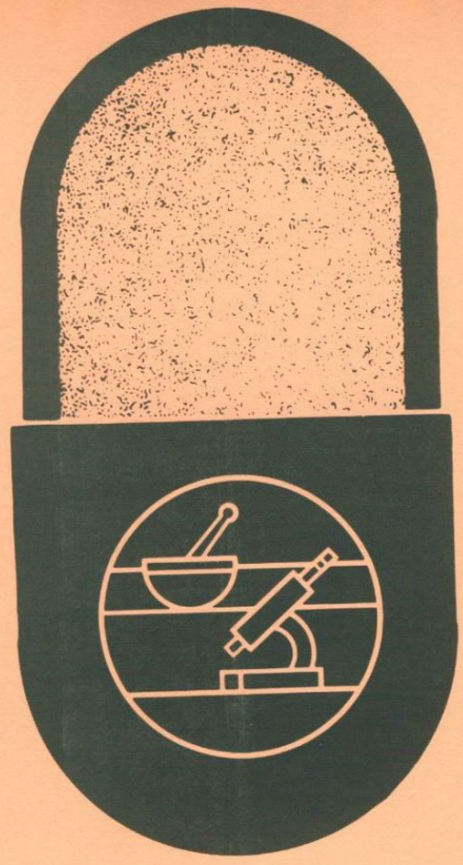
CUMULATIVE
SUPPLEMENT 5
JAN'90-MAY'90



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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MAY 1990

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CUMULATIVE SUPPLEMENT 5

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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Division of Blood and Blood Products and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 "ə" symbol to designate their non-marketed status. All products having a "ə" 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.

Products	Federal Register Reference
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 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

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	ABBREVIATED NAME
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

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	ABBREVIATED NAME
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		
SINGLE SOURCE	2030 (20.1%)	2039 (20.2%)		
MULTISOURCE	8093 (79.9%)	8056 (79.8%)		
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7213 (71.5%)		
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	723 (7.1%)		
EXCEPTIONS[1]	119 (1.2%)	120 (1.2%)		
NEW MOLECULAR ENTITIES APPROVED	--	3		
NUMBER OF APPLICANTS	400	406		

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

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL

CONTEN

>ADD> AB	GRAHAM LABS	650MG;50MG¤	N89405 001	
>ADD>			MAY 15, 1990	

TABLET; ORAL

SEDAPAP

>ADD>	MAYRAND	650MG;50MG	N88944 001	
>ADD>			OCT 17, 1985	
>DLT>	/SEDAPAP-10/			
>DLT>	/MAYRAND/	/650MG;50MG/	/N88944/001/	
>DLT>			/OCT/17,/1985/	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

/AA/	/PBI/	/500MG;5MG/	/N89290/001/	
			/MAY/29,/1987/	
	∂ PBI	500MG;5MG	N89290 001	
			MAY 29, 1987	

NORCET

AA	ABANA PHARMS	500MG;5MG	N88871 001	
			MAY 15, 1986	
/AA/	/HOLLOWAY/PHARMS/	/500MG;5MG/	/N88871/001/	
			/MAY/15,/1986/	

ACETYLCYSTEINE

/SOLUTION;/INHALATION/

/ACETYLCYSTEINE/

/AN/	/QUAD/PHARMS/	/10%/	/N71740/001/	
			/AUG/11,/1987/	
/AN/		/20%/	/N71741/001/	
			/AUG/11,/1987/	
	/MUCOSOL-10/			
/AN/	/DEY/LABS/	/10%/	/N70575/001/	
			/OCT/14,/1986/	
	/MUCOSOL-20/			
/AN/	/DEY/LABS/	/20%/	/N70576/001/	
			/OCT/14,/1986/	

SOLUTION; INHALATION, ORAL

ACETYLCYSTEINE

AN	QUAD PHARMS	10%	N71740 001	
			AUG 11, 1987	
AN		20%	N71741 001	
			AUG 11, 1987	

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

MUCOSOL-10

AN	DEY LABS	10%	N70575 001	
			OCT 14, 1986	

MUCOSOL-20

AN	DEY LABS	20%	N70576 001	
			OCT 14, 1986	

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	LEMMON	EQ 2MG BASE¤	N72938 001	
			MAR 30, 1990	
AB		EQ 4MG BASE¤	N72939 001	
			MAR 30, 1990	
AB	WARNER CHILCOTT	EQ 2MG BASE¤	N72817 001	
			JAN 09, 1990	
AB		EQ 4MG BASE¤	N72818 001	
			JAN 09, 1990	

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

/AB/	/BARR/LABS/	/5MG;50MG/	/N71111/001/	
			/DEC/25,/1990/;/MAY/10,/1988/	
AB	BARR LABS	5MG;50MG	N71111 001	
			MAY 10, 1988	

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

/AB/	/CHELSEA/LABS/	/50MG;4MG/	/N71558/001/	
			/MAR/02,/1987/	
BX	CHELSEA LABS	50MG;4MG	N71558 001	
			MAR 02, 1987	

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

BIPHETAMINE 12.5

>ADD>	FISONS	EQ 6.25MG BASE;		
>ADD>		EQ 6.25MG BASE	N10093 007	
>DLT>	/PENNWALT/	/EQ/6.25MG/BASE;/		
>DLT>		/EQ/6.25MG/BASE/	/N10093/007/	

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

BIPHETAMINE 20

>ADD>	FISONS	EQ 10MG BASE; EQ 10MG BASE	N10093 003	
>ADD>	/PENNWALT/	/EQ 10MG BASE;/ /EQ 10MG BASE/	/N10093 003/	
>DLT>				
>DLT>				

BIPHETAMINE 7.5

>ADD>	FISONS	EQ 3.75MG BASE; EQ 3.75MG BASE	N10093 009	
>ADD>	/PENNWALT/	/EQ 3.75MG BASE;/ /EQ 3.75MG BASE/	/N10093 009/	
>DLT>				
>DLT>				

ANTAZOLINE PHOSPHATE; NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

VASOCON-A

IOLAB PHARM	0.5%;0.05%Ⓡ	N18746 001	APR 30, 1990

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

/ORPHENADRINE/COMPOUND/

/BX/	/VITARINE/	/385MG;30MG;25MG/	/N71564/001/	/JUN/23,/1988/
ə VITARINE		385MG;30MG;25MG	N71564 001	JUN 23, 1988

/ORPHENADRINE/COMPOUND/DOUBLE/STRENGTH/

/BX/	/VITARINE/	/770MG;60MG;50MG/	/N71565/001/	/JUN/23,/1988/
ə VITARINE		770MG;60MG;50MG	N71565 001	JUN 23, 1988

ATENOLOL

TABLET; ORAL

TENORMIN

ICI PHARM	25MGⓇ		N18240 004	APR 09, 1990

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

>ADD> AB	ICI PHARMS	50MG;25MGⓇ	N72301 001	MAY 31, 1990
>ADD> AB		100MG;25MGⓇ	N72302 001	MAY 31, 1990

TENORETIC 100

>ADD> AB	STUART PHARMS	100MG;25MG	N18760 001	JUN 08, 1984

TENORETIC 50

>ADD> AB	STUART PHARMS	50MG;25MG	N18760 002	JUN 08, 1984

BACLOFEN

TABLET; ORAL

BACLOFEN

/BX/	/VITARINE/	/10MG/	/N71901/001/	/APR/13,/1988/
/BX/		/20MG/	/N71902/001/	/APR/13,/1988/
ə VITARINE		10MG	N71901 001	APR 13, 1988
ə		20MG	N71902 001	APR 13, 1988

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASEⓇ	N72536 001	JAN 31, 1990

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASEⓇ	N72538 001	JAN 31, 1990

OINTMENT; TOPICAL

BETAMETHASONE DIPROPIONATE

AB	CLAY PARK LABS	EQ 0.05% BASEⓇ	N72526 001	JAN 31, 1990

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

BIPHETAP

>DLT >/AA/	/PBI/	/4MG/5ML;25MG/5ML/	/N88687/001/ /SEP/26,/1984/	>ADD >	
>DLT >				>ADD >	
>ADD >	PBI	4MG/5ML;25MG/5ML	N88687 001 SEP 26, 1984	>ADD >	
>ADD >				>ADD >	
>DLT >	/BROMANATE/			>ADD >	
>DLT >/AA/	/BARRE/NATL/	/4MG/5ML;25MG/5ML/	/N88688/001/ /FEB/06,/1985/	>ADD >	
>DLT >				>DLT >	
>ADD >	∂ BARRE NATL	4MG/5ML;25MG/5ML	N88688 001 FEB 06, 1985	>DLT >	
>ADD >				>DLT >	

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

/AP/	/CUTTER/BIOL/	/20MG/100ML;5GM/100ML;30MG/100ML;/ /600MG/100ML;/ /310MG/100ML/	/N18499/001/	>ADD >	
	∂ CUTTER BIOL	20MG/100ML;5GM/100ML;30MG/100ML; 600MG/100ML; 310MG/100ML	N18499 001	>ADD >	
				>ADD >	
				>ADD >	
				>DLT >	
				>DLT >	
				>DLT >	
				>DLT >	

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

>ADD > AP	BAXTER	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML	N16682 001	>ADD >	
>ADD >				>ADD >	

CARTEOLOL HYDROCHLORIDE

>ADD >	SOLUTION/DROPS; OPHTHALMIC			>ADD >	
>ADD >	OPTIPRESS			>ADD >	
>ADD >	BURROUGHS WELLC	1%	N19972 001 MAY 23, 1990	>ADD >	
>ADD >				>ADD >	

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP	LEMMON	EQ 5GM BASE/VIAL*	N63018 001 MAR 05, 1990	>ADD >	
AP		EQ 10GM BASE/VIAL*	N63018 002 MAR 05, 1990	>ADD >	

CEFOPERAZONE SODIUM

INJECTABLE; INJECTION

CEFOBID

	PFIZER	EQ 1GM BASE/VIAL	N50551 001 NOV 18, 1982	>ADD >	
		EQ 2GM BASE/VIAL	N50551 002 NOV 18, 1982	>ADD >	
		EQ 10GM BASE/VIAL*	N50551 003 MAR 05, 1990	>ADD >	
	/ROERIG/	/EQ/1GM/BASE/VIAL/	/N50551/001/ /NOV/18,/1982/	>ADD >	
		/EQ/2GM/BASE/VIAL/	/N50551/002/ /NOV/18,/1982/	>DLT >	
				>DLT >	
				>DLT >	

CEFOBID IN PLASTIC CONTAINER

	PFIZER	EQ 20MG BASE/ML	N50613 002 JUL 31, 1987	>ADD >	
		EQ 40MG BASE/ML	N50613 001 JUL 23, 1986	>ADD >	
	/ROERIG/	/EQ/20MG/BASE/ML/	/N50613/002/ /JUL/31,/1987/	>ADD >	
		/EQ/40MG/BASE/ML/	/N50613/001/ /JUL/23,/1986/	>ADD >	
				>DLT >	
				>DLT >	
				>DLT >	
				>DLT >	

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN MONOHYDRATE

/BX/	/VITARINE/	/EQ/250MG/BASE/	/N62159/001/
/BX/		/EQ/500MG/BASE/	/N62159/002/
	∂ VITARINE	EQ 250MG BASE	N62159 001
	∂	EQ 500MG BASE	N62159 002

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

/BX/	/VITARINE/	/EQ/125MG/BASE/5ML/	/N62779/001/ /DEC/22,/1987/
/BX/		/EQ/250MG/BASE/5ML/	/N62781/001/ /DEC/22,/1987/
	∂ VITARINE	EQ 125MG BASE/5ML	N62779 001 DEC 22, 1987
	∂	EQ 250MG BASE/5ML	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/
	ə VITARINE	EQ 250MG BASE	N62863 001 AUG 11, 1988
	ə	EQ 500MG BASE	N62863 002 AUG 11, 1988
	ə	EQ 1GM BASE	N62863 003 AUG 11, 1988

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION
CEPHAPIRIN SODIUM

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

CEPHRADINE

CAPSULE; ORAL
CEPHRADINE

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

CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED

/TABLET; ORAL/			
/MENRIUM 10-4/ /ROCHE/		/10MG;0.4MG/	/N14746 006/
/MENRIUM 5-2/ /ROCHE/		/5MG;0.2MG/	/N14746 002/
/MENRIUM 5-4/ /ROCHE/		/5MG;0.4MG/	/N14746 004/

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 PHARM/	/4MG/	/N86306 001/
	ə PUREPAC PHARM	4MG	N86306 001
/AA/	/ROXANE LABS/	/4MG/	/N80626 001/
	ə ROXANE LABS	4MG	N80626 001

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
TAGAMET HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

SK&F LABS	EQ 6MG BASE/ML	N19434 001 OCT 31, 1985
/TAGAMET IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER/ /SK&F LABS/	/EQ 6MG BASE/ML/	/N19434 001/ /OCT 31, 1985/

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL
CLINDAMYCIN HCL

/BX/	/VITARINE/	/EQ 75MG BASE/	/N62910 001/ /JUL 05, 1988/
/BX/		/EQ 150MG BASE/	/N62910 002/ /JUL 05, 1988/
	ə VITARINE	EQ 75MG BASE	N62910 001 JUL 05, 1988
	ə	EQ 150MG BASE	N62910 002 JUL 05, 1988

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	LEMMON	EQ 150MG BASE/ML	N63079 001 MAR 05, 1990

CLOBETASOL PROPIONATE

SOLUTION; TOPICAL

TEMOVATE			
GLAXO	0.05%	N19966 001	FEB 22, 1990

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

> DLT >	/AB/	/WARNER/CHILCOTT/	/3.75MG/	/N71774/001/ /MAR/01,/1988/
> DLT >	/AB/		/7.5MG/	/N71775/001/ /MAR/01,/1988/
> DLT >	/AB/		/15MG/	/N71776/001/ /MAR/01,/1988/
> ADD >	a	WARNER CHILCOTT	3.75MG	N71774 001 MAR 01, 1988
> ADD >	a		7.5MG	N71775 001 MAR 01, 1988
> ADD >	a		15MG	N71776 001 MAR 01, 1988

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

> ADD >	AB	CORD LABS	3.75MG	N72512 001 MAY 11, 1990
> ADD >	AB		7.5MG	N72513 001 MAY 11, 1990
> ADD >	AB		15MG	N72514 001 MAY 11, 1990

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

> DLT >		/PSEUDODINE C/		
> DLT >	/AA/	/PBI/	/10MG/5ML;30MG/5ML;/ /1.25MG/5ML/	/N88833/001/ /NOV/16,/1984/
> ADD >		TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE PHOSPHATE		
> ADD >	AA	PBI	10MG/5ML;30MG/5ML; 1.25MG/5ML	N88833 001 NOV 16, 1984

CYANOCOBALAMIN; TANNIC ACID; ZINC ACETATE

> DLT >		/INJECTABLE;/INJECTION/		
> DLT >		/DEPINAR/		
> DLT >		/ARMOUR/PHARM/	/0.5MG/ML;2.3MG/ML;/ /1MG/ML/	/N11208/001/
> ADD >	a	ARMOUR PHARM	0.5MG/ML;2.3MG/ML; 1MG/ML	N11208 001

CYCLOSPORINE

CAPSULE; ORAL

SANDIMMUNE			
SANDOZ PHARMS	25MG	N50625 001	MAR 02, 1990
	100MG	N50625 002	MAR 02, 1990

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

/BX/	/VITARINE/	/10MG/	/N72167/001/ /FEB/03,/1988/
/BX/		/25MG/	/N71601/001/ /JUN/05,/1987/
/BX/		/50MG/	/N71588/001/ /JUN/05,/1987/
/BX/		/75MG/	/N71602/001/ /OCT/05,/1987/
/BX/		/100MG/	/N71766/001/ /OCT/05,/1987/
/BX/		/150MG/	/N72254/001/ /FEB/03,/1988/
a	VITARINE	10MG	N72167 001 FEB 03, 1988
a		25MG	N71601 001 JUN 05, 1987
a		50MG	N71588 001 JUN 05, 1987
a		75MG	N71602 001 OCT 05, 1987
a		100MG	N71766 001 OCT 05, 1987
a		150MG	N72254 001 FEB 03, 1988

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE		
@ BARR LABS	0.5MG	N84766 001

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER		
KENDALL MCGAW	3.3GM/100ML; 300MG/100ML	N19631 016 JAN 19, 1990

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

/HYPAQUE-M/ /STERLING/DRUG/	/50%;25%/	/N10220/003/
HYPAQUE-M,75%		
STERLING DRUG	50%;25%	N10220 003

DIAZEPAM

TABLET; ORAL

DIAZEPAM			
> DLT > /BX/ /SUPERPHARM/	/10MG/	/N70644/001/ /DEC/11,/1985/	
> ADD > @ SUPERPHARM	10MG	N70644 001 DEC 11, 1985	

DICLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

DYNAPEN

/AB/ /BRISTOL/LABS/	/EQ 62.5MG BASE/5ML/	/N50337/002/	
@ BRISTOL LABS	EQ 62.5MG BASE/5ML	N50337 002	

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

TENUATE

> DLT > /AA/ /MERRELL/DOW/PHARMS/	/25MG/	/N17668/001/	
> ADD > @ MERRELL DOW PHARMS	25MG	N17668 001	

DIETHYLPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

> DLT > /TENUATE/			
> DLT > /BC/ /MERRELL/DOW/PHARMS/	/75MG/	/N17669/001/	
> ADD > @ MERRELL DOW PHARMS	75MG	N17669 001	

DINOPROST TROMETHAMINE

> DLT > /INJECTABLE;/INJECTION/			
> DLT > /PROSTIN/F2/ALPHA/			
> DLT > /UPJOHN/	/EQ/5MG/BASE/ML/	/N17434/001/	
> ADD > @ UPJOHN	EQ 5MG BASE/ML	N17434 001	

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL

DISOPYRAMIDE PHOSPHATE

/AB/	/CHELSEA/LABS/	/EQ 100MG BASE/	/N71020/001/ /DEC/01,/1986/	
/AB/		/EQ 150MG BASE/	/N71021/001/ /DEC/01,/1986/	
BX	CHELSEA LABS	EQ 100MG BASE	N71020 001 DEC 01, 1986	
BX		EQ 150MG BASE	N71021 001 DEC 01, 1986	

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

ADAPIN

> ADD > AB FISONS	EQ 10MG BASE	N16987 001	
> ADD > AB	EQ 25MG BASE	N16987 002	
> ADD > AB	EQ 50MG BASE	N16987 003	
> ADD > AB	EQ 75MG BASE	N16987 006	
> ADD > AB	EQ 100MG BASE	N16987 004	
> ADD > AB	EQ 150MG BASE	N16987 007	
> ADD >		APR 13, 1987	
> DLT > /AB/ /PENNWALT/	/EQ 10MG BASE/	/N16987/001/	
> DLT > /AB/	/EQ 25MG BASE/	/N16987/002/	
> DLT > /AB/	/EQ 50MG BASE/	/N16987/003/	
> DLT > /AB/	/EQ 75MG BASE/	/N16987/006/	
> DLT > /AB/	/EQ 100MG BASE/	/N16987/004/	
> DLT > /AB/	/EQ 150MG BASE/	/N16987/007/ /APR/13,/1987/	

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INTRAVENOUS
DOXORUBICIN HCL

> ADD >	AP	PHARMACHEMIE BV	10MG/VIAL*	N63097 001 MAY 21, 1990
> ADD >				
> ADD >	AP		20MG/VIAL*	N63097 002 MAY 21, 1990
> ADD >				
> ADD >	AP		50MG/VIAL*	N63097 003 MAY 21, 1990
> ADD >				

DOXYCYCLINE HYCLATE

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

/BX/	/VITARINE/	/EQ 50MG BASE/	/N62780 001 APR 12, 1988/
/BX/		/EQ 100MG BASE/	/N62227 001/
	ə VITARINE	EQ 50MG BASE	N62780 001 APR 12, 1988
	ə	EQ 100MG BASE	N62227 001

INJECTABLE; INJECTION
VIBRAMYCIN

AP	PFIZER LABS	EQ 100MG BASE/VIAL	N50442 002
AP		EQ 200MG BASE/VIAL	N50442 001
/ə/		/EQ 100MG BASE/VIAL/	/N50442 002/
/ə/		/EQ 200MG BASE/VIAL/	/N50442 001/

DYDROGESTERONE

TABLET; ORAL
GYNOREST

/ə/KALI/DUPHAR/		/5MG/	/N17388 001/
/ə/		/10MG/	/N17388 002/
	ə REID ROWELL	5MG	N17388 001
	ə	10MG	N17388 002

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

/AT/	/BARRE/NATL/	/2%/	/N62327 001 APR 19, 1982/
/AT/		/2%/	/N62342 001 FEB 25, 1982/
	ə BARRE NATL	2%	N62327 001 APR 19, 1982
	ə	2%	N62342 001 FEB 25, 1982

ERYTHROMYCIN

TABLET, DELAYED RELEASE; ORAL
E-BASE

> ADD >	AB	BARR LABS	333MG*	N63028 001 MAY 15, 1990
> ADD >				
> ADD >	AB		333MG*	N63086 001 MAY 15, 1990
> ADD >				

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL
ERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL

AB	BARR LABS	EQ 200MG BASE/5ML; EQ 600MG BASE/5ML	N62759 001 MAY 20, 1988

ERYTHROMYCIN STEARATE

TABLET; ORAL
ERYTHROMYCIN STEARATE

> ADD >	AB	BARR LABS	EQ 500MG BASE*	N63179 001 MAY 15, 1990
> ADD >				

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE-ESTRADIOL VALERATE

/AQ/	/STERIS/LABS/	/8MG/ML;180MG/ML/	/N85860 001/
	ə STERIS LABS	8MG/ML;180MG/ML	N85860 001

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

/BP/	/CHELSEA/LABS/	/0.625MG/	/N85800 001/
	ə CHELSEA LABS	0.625MG	N85800 001

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN

/BS/	/PRIVATE/FMLTNS/	/1.25MG/	/N85008 001/
	ə PRIVATE FMLTNS	1.25MG	N85008 001

ETHYLESTRENOL

/ELIXIR;ORAL/
/MAXIBOLIN/
/ORGANON/ /2MG/5ML/ /N14006/002/
∂ ORGANON 2MG/5ML N14006 002

FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE
AP ABBOTT LABS EQ 0.05MG BASE/ML N70636 001 APR 30, 1990
AP EQ 0.05MG BASE/ML N70637 001 APR 30, 1990

FLUCONAZOLE

INJECTABLE; INJECTION
DIFLUCAN
PFIZER CTL RES 2MG/ML N19950 001 JAN 29, 1990

TABLET; ORAL
DIFLUCAN
PFIZER CTL RES 50MG N19949 001 JAN 29, 1990
100MG N19949 002 JAN 29, 1990
200MG N19949 003 JAN 29, 1990

FLUNISOLIDE

/SPRAY;INHALATION/NASAL/
/NASALIDE/
/SYNTEX/LABS/ /0.025MG/INH/ /N18148/001/

SPRAY, METERED; NASAL
NASALIDE
SYNTEX LABS 0.025MG/INH N18148 001

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL
FLUOCINOLONE ACETONIDE
/AT/ /PBI/ /0.01%/ /N88757/001/ FEB 11, 1985
/AT/ /0.025%/ /N88756/001/ MAR 28, 1985
∂ PBI 0.01% N88757 001 FEB 11, 1985
∂ 0.025% N88756 001 MAR 28, 1985

OINTMENT; TOPICAL
FLUOCINOLONE ACETONIDE
/AT/ /PBI/ /0.025%/ /N88742/001/ FEB 08, 1985
∂ PBI 0.025% N88742 001 FEB 08, 1985

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN
/AP/ /LYPHOMED/ /15,000 UNITS/VIAL/ /N17067/004/
∂ LYPHOMED 15,000 UNITS/VIAL N17067 004
/AP/ /STERIS/LABS/ /15,000 UNITS/VIAL/ /N17016/010/ FEB 15, 1985
STERIS LABS 2,000 UNITS/VIAL N17016 011 FEB 16, 1990
15,000 UNITS/VIAL N17016 010 FEB 15, 1985

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH
>DLT >/AP/ /SOLOPAK/LABS/ /10 UNITS/ML/ /N87956/001/ APR 20, 1983
>DLT >
>ADD >
>ADD > ∂ SOLOPAK LABS 10 UNITS/ML N87956 001 APR 20, 1983

HEPARIN SODIUM
/AP/ /LYPHOMED/ /1,000 UNITS/ML/ /N17033/001/
∂ LYPHOMED 1,000 UNITS/ML N17033 001

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDRALAZINE AND HYDROCHLORTHIAZIDE

/BP/	/CHELSEA/LABS/	/25MG;15MG/	/N85827/001/	
	ə CHELSEA LABS	25MG;15MG	N85827 001	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE

/AB/	/SK&F/LABS/	/25MG;50MG/	/N16042/002/	
	SK&F LABS	25MG;50MG	N16042 002	

/TRIAMTERENE/AND/HYDROCHLOROTHIAZIDE/

/BX/	/BOLAR/PHARM/	/25MG;50MG/	/N71845/001/ /AUG/21,/1987/	

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

>DLT>	/AT/	/PBI/	/1%/	/N88027/001/ /SEP/27,/1983/
>DLT>	/AT/		/2.5%/	/N88029/001/ /SEP/27,/1983/
>ADD>		ə PBI	1%	N88027 001 SEP 27, 1983
>ADD>		ə	2.5%	N88029 001 SEP 27, 1983

>DLT>	/HYDROTEX/			
>DLT>	/AT/	/SYOSSET/LABS/	/1%/	/N87427/001/ /APR/04,/1988/
>DLT>				
>ADD>		NOGENIC HC		
>ADD>	AT	SYOSSET LABS	1%	N87427 001 APR 04, 1988
>ADD>				

HYDROCORTISONE

OINTMENT; TOPICAL
HYDROCORTISONE

>DLT>	/AT/	/PBI/	/1%/	/N88061/001/ /SEP/27,/1983/
>DLT>				
>DLT>	/AT/		/2.5%/	/N88039/001/ /SEP/27,/1983/
>DLT>				
>ADD>		ə PBI	1%	N88061 001 SEP 27, 1983
>ADD>				
>ADD>		ə	2.5%	N88039 001 SEP 27, 1983
>ADD>				

IBUPROFEN

TABLET; ORAL
IBUPROFEN

/AB/	/MCNEIL/CONSUMER/	/600MG/	/N70476/001/ /JUN/16,/1986/	
	ə MCNEIL CONSUMER	600MG	N70476 001 JUN 16, 1986	

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

/BX/	/VITARINE/	/25MG/	/N71711/001/ /JUL/05,/1988/	
/BX/		/50MG/	/N71712/001/ /JUL/05,/1988/	
	ə VITARINE	25MG	N71711 001 JUL 05, 1988	
	ə	50MG	N71712 001 JUL 05, 1988	
/AB/	/ZENITH/LABS/	/25MG/	/N18730/001/ /MAY/04,/1984/	
/AB/		/50MG/	/N18730/002/ /MAY/04,/1984/	
	ə ZENITH LABS	25MG	N18730 001 MAY 04, 1984	
	ə	50MG	N18730 002 MAY 04, 1984	

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

/BX/	/VITARINE/	/75MG/	/N71531/001/ /JUL/21,/1987/	
	ə VITARINE	75MG	N71531 001 JUL 21, 1987	

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION
IODOHIPPURATE SODIUM I 131

CIS US	0.2MCI/ML	N17313 001
/SORIN/	/0.2MCI/ML/	/N17313/001/

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

/AN/	/DEY/LABS/	/0.08%/	/N88187/001/ /DEC/03,/1982/
	DEY LABS	0.08%	N88187 001 DEC 03, 1982

ISOETHARINE HCL S/F

/AN/	/DEY/LABS/	/0.08%/	/N89817/001/ /NOV/22,/1988/
	DEY LABS	0.08%	N89817 001 NOV 22, 1988

ISONIAZID

TABLET; ORAL
ISONIAZID

/AA/	/PUREPAC/PHARM/	/50MG/	/N80132/003/ /JUL/14,/1982/
/AA/		/100MG/	/N80132/004/ /JUL/14,/1982/
	∂ PUREPAC PHARM	50MG	N80132 003 JUL 14, 1982
	∂	100MG	N80132 004 JUL 14, 1982

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE

/AP/	/WARNER/CHILCOTT/	/EQ 1GM BASE/3ML/	/N63092/001/ /OCT/11,/1989/
	∂ WARNER CHILCOTT	EQ 1GM BASE/3ML	N63092 001 OCT 11, 1989

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM

/BX/	/VITARINE/	/EQ/50MG/BASE/	/N71710/001/ /JUN/15,/1988/
/BX/		/EQ/100MG/BASE/	/N71684/001/ /JUN/15,/1988/
	∂ VITARINE	EQ 50MG BASE	N71710 001 JUN 15, 1988
	∂	EQ 100MG BASE	N71684 001 JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL
MEFENAMIC ACID

/BX/	/VITARINE/	/250MG/	/N72179/001/ /APR/21,/1988/
	∂ VITARINE	250MG	N72179 001 APR 21, 1988

PONSTEL

/AB/	/PARKE/DAVIS/PR/	/250MG/	/N15034/003/
AB	PARKE DAVIS PR	250MG	N15034 003

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

/AB/	/PBI/	/20MG/	/N70646/001/ /OCT/02,/1987/
/AB/		/40MG/	/N70647/001/ /OCT/02,/1987/
BX	PBI	20MG	N70646 001 OCT 02, 1987
BX		40MG	N70647 001 OCT 02, 1987

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE

>DLT>	/AA/	/REID/ROWELL/	/200MG/	/N84435/001/
>ADD>		∂ REID ROWELL	200MG	N84435 001

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21
/NORINYL/1+80/21-DAY/
/SYNTEX/(FP)/ /0.08MG;1MG/ /N16724/001/
∂ SYNTEX (FP) 0.08MG;1MG N16724 001

TABLET; ORAL-28
/NORINYL/1+80/28-DAY/
/SYNTEX/(FP)/ /0.08MG;1MG/ /N16725/001/
∂ SYNTEX (FP) 0.08MG;1MG N16725 001

METAPROTERENOL SULFATE

TABLET; ORAL
METAPROTERENOL SULFATE
AB BIOCRAFT LABS 10MG¤ N72519 001
MAR 30, 1990
AB 20MG¤ N72520 001
MAR 30, 1990

METHICILLIN SODIUM

INJECTABLE; INJECTION
STAPHCILLIN
/BRISTOL LABS/ /EQ/900MG/BASE/VIAL/ /N50117/001/
∂ BRISTOL LABS EQ 900MG BASE/VIAL N50117 001
/EQ/3.6GM/BASE/VIAL/ /N50117/002/
∂ EQ 3.6GM BASE/VIAL N50117 002
/EQ/5.4GM/BASE/VIAL/ /N50117/003/
∂ EQ 5.4GM BASE/VIAL N50117 003

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
REGLAN
/AH/ROBINS/ /EQ/10MG/BASE/ML/ /N17862/004/
/MAY/28,/1987/
∂ AH ROBINS EQ 10MG BASE/ML N17862 004
MAY 28, 1987

TABLET; ORAL
METOCLOPRAMIDE HCL
AB CORD LABS EQ 10MG BASE¤ N72215 001
JAN 30, 1990
AB MARTEC PHARM EQ 10MG BASE N70598 001
FEB 02, 1987
/∂/ /EQ/10MG/BASE/ /N70598/001/
/FEB/02,/1987/

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MS CONTIN
PURDUE FRDRK 100MG¤ N19516 004
JAN 16, 1990

NAFARELIN ACETATE

SPRAY, METERED; NASAL
SYNAREL
SYNTEX LABS EQ 2MG BASE/ML¤ N19886 001
FEB 13, 1990

NAPROXEN SODIUM

TABLET; ORAL
/ANAPROX/
/SYNTEX/PR/ /550MG/ /N18164/003/
/SEP/30,/1987/
ANAPROX DS
SYNTEX PR 550MG N18164 003
SEP 30, 1987

NIFEDIPINE

CAPSULE; ORAL
NIFEDIPINE
/AB/ /PUREPAC/PHARM/ /20MG/ /N72556/001/
/APR/28,/1989/
AB PUREPAC PHARM 20MG N72556 001
SEP 20, 1990 : APR 28, 1989

NITROGLYCERIN

INJECTABLE; INJECTION
NITRO-BID
AP MARION MERRELL DOW 10MG/ML¤ N71159 001
FEB 28, 1990

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN

/SANDOZ/PHARMS/	/EQ/0.05MG/BASE/ML/	/N19667/001/ /OCT/21,/1988/
SANDOZ PHARMS	EQ 50UGM BASE/ML	N19667 001 OCT 21, 1988
	/EQ/0.1MG/BASE/ML/	/N19667/002/ /OCT/21,/1988/
	EQ 100UGM BASE/ML	N19667 002 OCT 21, 1988
	/EQ/0.5MG/BASE/ML/	/N19667/003/ /OCT/21,/1988/
	EQ 500UGM BASE/ML	N19667 003 OCT 21, 1988

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

/AB/	/CHELSEA/LABS/	/30MG/	/N71663/001/ /MAR/02,/1988/
BX	CHELSEA LABS	30MG	N71663 001 MAR 02, 1988

PEGADEMASE BOVINE

INJECTABLE; INJECTION
ADAGEN

ENZON	250 UNITS/ML¤	N19818 001 MAR 21, 1990

PENBUTOLOL SULFATE

TABLET; ORAL
LEVATOL

/REED/&/CARNRICK/	/10MG/	/N18976/001/ /DEC/30,/1987/
∂ REED & CARNRICK	10MG	N18976 001 DEC 30, 1987
	20MG	N18976 004 JAN 05, 1989

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE

/AB/	/CHELSEA/LABS/	/8MG/	/N89700/001/ /DEC/23,/1987/
BX	CHELSEA LABS	8MG	N89700 001 DEC 23, 1987

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
IONAMIN-15

>ADD>	FISONS	EQ 15MG BASE	N11613 004
>DLT>	/PENNWALT/	/EQ/15MG/BASE/	/N11613/004/

IONAMIN-30

>ADD>	FISONS	EQ 30MG BASE	N11613 002
>DLT>	/PENNWALT/	/EQ/30MG/BASE/	/N11613/002/

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM

/AP/	/WARNER/CHILCOTT/	/50MG/ML¤/	/N89900/001/ /MAR/30,/1990/
	∂ WARNER CHILCOTT	50MG/ML¤	N89900 001 MAR 30, 1990

PHENYTOIN SODIUM, EXTENDED

CAPSULE; ORAL
EXTENDED PHENYTOIN SODIUM

/AB/	/SIDMAK/LABS/	/100MG/	/N89441/001/ /DEC/18,/1986/
	∂ SIDMAK LABS	100MG	N89441 001 DEC 18, 1986

PHENYTEX

/AB/	/BOLAR/PHARM/	/100MG/	/N88711/001/ /DEC/21,/1984/
BX	BOLAR PHARM	100MG	N88711 001 DEC 21, 1984

PIPERAZINE CITRATE

SYRUP; ORAL
/BRYREL/

/AA/	/STERLING/DRUG/	/EQ 500MG BASE/5ML/
	∂ STERLING DRUG	EQ 500MG BASE/5ML

/N17796/001/
N17796 001

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUS

POWDER FOR RECONSTITUTION; ORAL

GLYCOPREP

> ADD >	AA	SUPERPHARM	236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT	N72319 001 DEC 23, 1988
> ADD >				
> ADD >				
> DLT >	/AA/	/TOSA/MED/PRODS/	/236GM/BOT;2.97GM/BOT;6.74GM/BOT; /5.86GM/BOT;22.74GM/BOT/	/N72319/001/ /DEC/23,/1988/
> DLT >				
> DLT >				

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

K-LEASE

AB	ADRIA LABS	10 MEQ	N72427 001 MAR 28, 1990

PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

> DLT >	/BX/	/UDL/LABS/	/5MG/	/N87987/001/ /JAN/18,/1983/
> DLT >				
> ADD >		ə UDL LABS	5MG	N87987 001 JAN 18, 1983
> ADD >				

PREDNISONE

TABLET; ORAL

PREDNISONE

> DLT >	/BX/	/UDL/LABS/	/5MG/	/N87984/001/ /JAN/18,/1983/
> DLT >				
> DLT >	/BX/		/10MG/	/N87985/001/ /JAN/18,/1983/
> DLT >				
> DLT >	/BX/		/20MG/	/N87986/001/ /JAN/18,/1983/
> DLT >				
> ADD >		ə UDL LABS	5MG	N87984 001 JAN 18, 1983
> ADD >				
> ADD >		ə	10MG	N87985 001 JAN 18, 1983
> ADD >				
> ADD >		ə	20MG	N87986 001 JAN 18, 1983
> ADD >				

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERAL

	/AB/	/WYETH/AYERST/LABS/	/40MG/	/N16418/010/ /OCT/18,/1982/
		ə WYETH AYERST LABS	90MG	N16418 010 OCT 18, 1982
> DLT >		/PROPRANOLOL/		
> DLT >	/AB/	/MYLAN/PHARMS/	/10MG/	/N70211/001/ /NOV/19,/1985/
> DLT >				
> DLT >	/AB/		/20MG/	/N70212/001/ /NOV/19,/1985/
> DLT >				
> DLT >	/AB/		/40MG/	/N70213/001/ /NOV/19,/1985/
> DLT >				
> DLT >	/AB/		/80MG/	/N70214/001/ /NOV/19,/1985/
> DLT >				

PROPRANOLOL HCL

AB	MARTEC PHARM	10MG	N70120 001 AUG 06, 1985
AB		20MG	N70121 001 AUG 06, 1985
AB		40MG	N70122 001 AUG 06, 1985
AB		60MG	N70123 001 OCT 29, 1986
AB		80MG	N70124 001 AUG 06, 1985
/ə/		/10MG/	/N70120/001/ /AUG/06,/1985/
/ə/		/20MG/	/N70121/001/ /AUG/06,/1985/
/ə/		/40MG/	/N70122/001/ /AUG/06,/1985/
/ə/		/60MG/	/N70123/001/ /OCT/29,/1986/
/ə/		/80MG/	/N70124/001/ /AUG/06,/1985/

PROPRANOLOL HCL

> ADD >				
> ADD >	AB	MYLAN PHARMS	10MG	N70211 001 NOV 19, 1985
> ADD >				
> ADD >	AB		20MG	N70212 001 NOV 19, 1985
> ADD >				
> ADD >	AB		40MG	N70213 001 NOV 19, 1985
> ADD >				
> ADD >	AB		80MG	N70214 001 NOV 19, 1985
> ADD >				

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

/BD/	/ANABOLIC/	/50MG/	/N80285/001/	
	∂ ANABOLIC	50MG	N80285 001	

PROTEIN HYDROLYSATE

INJECTABLE; INJECTION
AMINOSOL 5%

/AP/	/ABBOTT/LABS/	/5%/	/N05932/012/ /JAN/31,/1985/	
	ABBOTT LABS	5%	N05932 012 JAN 31, 1985	

HYPROTIGEN 5%

/AP/	/KENDALL/MCGAW/	/5%/	/N06170/003/ /JAN/10,/1984/	
	∂ KENDALL MCGAW	5%	N06170 003 JAN 10, 1984	

QUAZEPAM

TABLET; ORAL
DORMALIN

BAKER CUMMINS	7.5MG	N18708 003 FEB 26, 1987	
	15MG	N18708 001 DEC 27, 1985	
/SCHERING/	/7.5MG/	/N18708/003/ /FEB/26,/1987/	
	/15MG/	/N18708/001/ /DEC/27,/1985/	

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

/AB/	/LEDERLE/LABS/	/200MG/	/N86176/001/	
	∂ LEDERLE LABS	200MG	N86176 001	

RAUWOLFIA SERPENTINA

TABLET; ORAL
/WOLFINA/

>DLT> >DLT> >ADD>	/BP/ /FOREST/PHARMS/ ∂ FOREST PHARMS	/100MG/ 100MG	/N09255/006/ N09255 006	

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	450MG/100ML		N18016 001
/AP/	/BAXTER/	/450MG/100ML/		/N18016/001/

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/3GM/100ML/		/N19022/001/ /NOV/01,/1983/
	BAXTER	3GM/100ML		N19022 001 NOV 01, 1983
/AP/	/KENDALL/MCGAW/	/3GM/100ML/		/N19635/003/ /MAR/09,/1988/
	∂ KENDALL MCGAW	3GM/100ML		N19635 003 MAR 09, 1988

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/5GM/100ML/		/N19022/002/ /NOV/01,/1983/
	BAXTER	5GM/100ML		N19022 002 NOV 01, 1983
/AP/	/KENDALL/MCGAW/	/5GM/100ML/		/N19635/004/ /MAR/09,/1988/
	∂ KENDALL MCGAW	5GM/100ML		N19635 004 MAR 09, 1988

SULFASALAZINE

TABLET; ORAL
/S,A,S,-500/

>DLT> >DLT> >ADD>	/AB/ /REID/ROWELL/ ∂ REID ROWELL	/500MG/ 500MG		/N83450/001/ N83450 001

SULINDAC

TABLET; ORAL
SULINDAC

/AB/	/AM/THERPTCS/	/150MG/		/N72171/001/ /APR/03,/1990/;/MAY/23,/1988/
/AB/		/200MG/		/N72172/001/ /APR/03,/1990/;/MAY/23,/1988/

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
AN-MAA

BS	CIS US	N/A		N17792 001
/BS/	/SORIN/	/N/A/		/N17792/001/

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
AN-DTPA

AP	CIS US	N/A	N17714 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL

BX	VITARINE	250MG	N61471 001
BX		500MG	N61471 002
			SEP 06, 1988
	ə VITARINE	250MG	N61471 001
	ə	500MG	N61471 002
			SEP 06, 1988

TETRACYCLINE PHOSPHATE COMPLEX

CAPSULE; ORAL
TETREX

BRISTOL LABS	EQ 250MG HCL	N50212 002
ə BRISTOL LABS	EQ 250MG HCL	N50212 002
	EQ 500MG HCL	N50212 003
ə	EQ 500MG HCL	N50212 003

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL
THEOCHRON

AB	INWOOD LABS	100MG	N88320 001
			FEB 21, 1985
AB		200MG	N88321 001
			FEB 21, 1985
AB		300MG	N87400 002
			JAN 11, 1983
	THEOPHYLLINE		
AB	INWOOD LABS	100MG	N88320 001
			FEB 21, 1985
AB		200MG	N88321 001
			FEB 21, 1985
AB		300MG	N87400 002
			JAN 11, 1983

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL
THEOPHYLLINE

AB	SIDMAK LABS	100MG	N89807 001
			APR 30, 1990
AB		200MG	N89808 001
			APR 30, 1990
AB		300MG	N89763 001
			APR 30, 1990

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

> DLT >	BX	QUANTUM PHARMCS	10MG	N72467 001
> DLT >				MAY 19, 1989
> DLT >	BX		20MG	N72468 001
> DLT >				MAY 19, 1989
> ADD >		ə QUANTUM PHARMCS	10MG	N72467 001
> ADD >				MAY 19, 1989
> ADD >		ə	20MG	N72468 001
> ADD >				MAY 19, 1989

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

> DLT >	AB	SUPERPHARM	250MG	N70763 001
> DLT >				JUN 16, 1986
> ADD >		ə SUPERPHARM	250MG	N70763 001
> ADD >				JUN 16, 1986

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

AB	CORD LABS	50MG	N72484 001
			APR 30, 1990
AB		100MG	N72483 001
			APR 30, 1990

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

	TRIATEX			
AT	SYOSSET LABS	0.025%	N87430 001	NOV 01, 1988
AT		0.1%	N87429 001	NOV 01, 1988
AT		0.5%	N87428 001	NOV 01, 1988

TRIAMTERENE

CAPSULE; ORAL

	DYRENIUM		
	SK&F LABS	50MG	N13174 001
		100MG	N13174 002

TRIENTINE HYDROCHLORIDE

CAPSULE; ORAL

	CUPRID			
	MS&D	250MG	N19194 001	NOV 08, 1985
	SYPRINE			
	MS&D	250MG	N19194 001	NOV 08, 1985

TRIMEPRAZINE TARTRATE

SYRUP; ORAL

	TRIMEPRAZINE TARTRATE			
AA	BARRE/NATL	EQ 2.5MG BASE/5ML	N85015 001	FEB 18, 1982
	∂ BARRE NATL	EQ 2.5MG BASE/5ML	N85015 001	FEB 18, 1982

TRIMIPRAMINE MALEATE

CAPSULE; ORAL

	TRIMIPRAMINE MALEATE			
BX	VITARINE	EQ 25MG BASE	N71832 001	SEP 10, 1987
BX		EQ 50MG BASE	N71833 001	SEP 10, 1987
BX		EQ 100MG BASE	N71834 001	SEP 10, 1987
	∂ VITARINE	EQ 25MG BASE	N71832 001	SEP 10, 1987
	∂	EQ 50MG BASE	N71833 001	SEP 10, 1987
	∂	EQ 100MG BASE	N71834 001	SEP 10, 1987

TRISULFAPYRIMIDINES

SUSPENSION; ORAL

	TRIPLE SULFA			
AA	BARRE/NATL	500MG/5ML	N80280 001	
	∂ BARRE NATL	500MG/5ML	N80280 001	

UREA

INJECTABLE; INJECTION

	STERILE UREA			
AP	ABBOTT/LABS	40GM/VIAL	N17698 001	
	∂ ABBOTT LABS	40GM/VIAL	N17698 001	
	UREAPHIL			
AP	ABBOTT/LABS	40GM/VIAL	N12154 001	
	ABBOTT LABS	40GM/VIAL	N12154 001	

VERAPAMIL HYDROCHLORIDE

> ADD > CAPSULE, EXTENDED RELEASE; ORAL

> ADD >	VERELAN			
> ADD >	ELAN PHARM	120MG¤	N19614 001	MAY 29, 1990
> ADD >		240MG¤	N19614 002	MAY 29, 1990

> ADD >

INJECTABLE; INJECTION

	CALAN			
> DLT > AP	SEARLE	2.5MG/ML	N19038 001	MAR 30, 1984
> DLT >				
> ADD >	∂ SEARLE	2.5MG/ML	N19038 001	MAR 30, 1984

> ADD >

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

/AB/	/CHELSEA LABS/	/80MG/	/N70421 001/ /SEP 17, 1986/
BX	CHELSEA LABS	80MG	N70421 001 SEP 17, 1986

WARFARIN SODIUM

>DLT>	/INJECTABLE;INJECTION/		
>DLT>	/COUMADIN/		
>DLT>	/DUPONT PHARMS/	/50MG/VIAL/	/N09218 020/
>DLT>		/75MG/VIAL/	/N09218 012/
>ADD>	∂ DUPONT PHARMS	50MG/VIAL	N09218 020
>ADD>	∂	75MG/VIAL	N09218 012

TABLET; ORAL
COUMADIN

DUPONT PHARMS	1MG¤	N09218 022 MAR 01, 1990

ZIDOVUDINE

INJECTABLE; INJECTION
RETROVIR

BURROUGHS WELLC	10MG/ML¤	N19951 001 FEB 02, 1990

PERMETHRIN

> ADD >	LOTION; TOPICAL			
> ADD >	NIX			
> ADD >	BURROUGHS WELLC	1%	N19918 001	
> ADD >			MAY 02, 1990	

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 5 / JAN '90 - MAY '90

NO MAY 1990 APPROVALS

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 AND ADDRESS
GENERIC: ANTI-CMV 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, INC. SUITE 600 1120 VERMONT AVE. WASHINGTON, D.C. 20005
GENERIC: BOTULINUM A TOXIN 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. 2232 WEBSTER ST. SAN FRANCISCO, CA 94115
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 375 SOUTH ST., JAMAICA PLAIN BOSTON, MA 02130
GENERIC: GRANULOCYTE MACROPHAGE-COLONY STIMULATING FACTOR, RECOMBINANT E. COLI [RGM-CSF] TRADE: NOT ESTABLISHED	TREATMENT OF NEUTROPENIA DUE TO HAIRY CELL LEUKEMIA. TREATMENT OF PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA TO INCREASE GRANULOCYTE COUNTS.	SCHERING CORP. 2000 GALLOPING HILL RD. KENILWORTH, NJ 07033
GENERIC: GROUP B STREPTOCOCCUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF NEONATES WITH DISSEMINATED GROUP B STREPTOCOCCAL INFECTION.	UNIVAX CORP. 12111 PARKLAWN DR. ROCKVILLE, MD 20852

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: [INDIUM 111 MURINE ANTI-CEA MONOCLONAL ANTIBODY TYPE ZCE 025 (IN 111 MUROMONAB-CEA)] TRADE: CEAKER	FOR THE DETECTION OF SUSPECTED AND PREVIOUSLY UNIDENTIFIED TUMOR FOCI OF RECURRENT COLORECTAL CARCINOMA.	HYBRITECH, INC. 11095 TORREYANNA RD. SAN DIEGO, CA 92121
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.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: INTERFERON ALPHA-2B (RECOMBINANT) TRADE: INTRON A	TREATMENT OF PATIENTS WITH CHRONIC DELTA HEPATITIS.	SCHERING CORP. 2000 GALLOPING HILL RD. KENILWORTH, NJ 07033
GENERIC: INTERLEUKIN-2 POLYETHYLENE CONJUGATE; RECOMBINANT E. COLI TRADE: PEG-IL2	TREATMENT OF PRIMARY IMMUNODEFICIENCY DISEASE ASSOCIATED WITH T-CELL DEFECTS.	CETUS CORP. 1400 FIFTY-THIRD ST. EMERYVILLE, CA 94608
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 CORP. 51 UNIVERSITY ST. SEATTLE, WA 98101
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, INC. 12 WEST COMMERCE AVE. WEST LEBANON, NH 03784

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ONCORAD OV103 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CARCINOMA.	CYTOGEN CORP. 600 COLLEGE RD. EAST PRINCETON, NJ 08540
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY^9) TO MYELOID CELLS (CD-33) TRADE: ANTI-MY^9-BR	FOR USE IN THE EX VIVO TREATMENT OF AUTOLOGOUS BONE MARROW AND SUBSEQUENT REINFUSION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.	IMMUNOGEN, INC. 148 SIDNEY ST. CAMBRIDGE, MA 02139
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).	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: CROMOLYN SODIUM TRADE: GASTROCROM*/**	MASTOCYTOSIS. [DECEMBER 22, 1996]	FISONS CORP. 2 PRESTON CT. BEDFORD, MA 01730
GENERIC: DEHYDREX TRADE: NOT ESTABLISHED	TREATMENT OF RECURRENT CORNEAL EROSION UNRESPONSIVE TO CONVENTIONAL THERAPY.	HOLLES LABS, INC. 30 FOREST NOTCH COHASSET, MA 02025
GENERIC: DISACCHARIDE TRIPEPTIDE GLYCEROL DIPALMITOYL (DTP-GDP) TRADE: IMMTHER	TREATMENT OF PULMONARY AND HEPATIC METASTASES IN COLORECTAL ADENOCARCINOMA PATIENTS.	IMMUNOTHERAPEUTICS, INC. 509 25TH AVE. NORTH FARGO, ND 58102
GENERIC: DISODIUM CLODRONATE TETRAHYDRATE TRADE: BONEFOS	TREATMENT OF INCREASED BONE RESORPTION DUE TO MALIGNANCY.	LEIRAS PHARMACEUTICALS, INC. 2345 WAUKEGAN RD. SUITE N-135 BANNOCKBURN, IL 60015
GENERIC: DYNAMINE TRADE: NOT ESTABLISHED	TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME.	MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH MAYO CLINIC AND FOUNDATION 200 S.W. 1ST AVE. ROCHESTER, MN 55905
GENERIC: ETHIOFOS TRADE: ETHYOL	USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN IN THE TREATMENT OF ADVANCED OVARIAN CARCINOMA. USE AS A CHEMOPROTECTIVE AGENT FOR CYCLOPHOSPHAMIDE IN THE TREATMENT OF ADVANCED OVARIAN CARCINOMA.	U.S. BIOSCIENCE, INC. 920-B HARVEST DR. SUITE 200 BLUE BELL, PA 19422

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: FLUOROURACIL	CONCOMITANT ADMINISTRATION WITH ROFERON-A FOR THE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: GLYCEROL, 10% TRADE: NOT ESTABLISHED	TO DECREASE INTRACRANIAL HYPERTENSION AND/OR ALLEVIATE CEREBRAL EDEMA IN PATIENTS WHO MAY BENEFIT FROM OSMOTHERAPY.	CHUGAI PHARMACEUTICAL CO., LTD. 1-9, KYOBASHI 2-CHOME CHUO-KU, TOKYO 104, JAPAN
GENERIC: GONADORELIN ACETATE TRADE: LUTREPULSE*/**	TREATMENT OF PRIMARY HYPOTHALAMIC AMENORRHEA. [OCT 10, 1996]	R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE ROUTE 202, P.O. BOX 300 RARITAN, NJ 08869
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF HEPARIN-ASSOCIATED THROMBOCYTOPENIA.	BERLEX LABS. 300 FAIRFIELD RD. WAYNE, NJ 07470
GENERIC: MEFLOQUINE HCL TRADE: LARIAM*/**	TREATMENT OF ACUTE MALARIA DUE TO PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX. [MAY 02, 1996] PROPHYLAXIS OF PLASMODIUM FALCIPARUM MALARIA WHICH IS RESISTANT TO OTHER AVAILABLE DRUGS. [MAY 02, 1996]	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
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 RESEARCH, INC. 8733 BEVERLY BLVD., SUITE 404 LOS ANGELES, CA 90048

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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, INC. 40 CRAGWOOD RD. SOUTH PLAINFIELD, NJ 07080
GENERIC: PR-225 (REDOX ACYCLOVIR) TRADE: NOT ESTABLISHED	TREATMENT OF HERPES SIMPLEX ENCEPHALITIS IN INDIVIDUALS AFFLICTED WITH AIDS.	PHARMATEC, INC. P.O. BOX 730 ALACHUA, FL 32615
GENERIC: PR-239 (REDOX PENICILLIN G) TRADE: NOT ESTABLISHED	TREATMENT OF AIDS ASSOCIATED NEUROSYPHILIS.	PHARMATEC, INC. P.O. BOX 730 ALACHUA, FL 32615
GENERIC: RHEOTHRX TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE BURNS IN HOSPITALIZED PATIENTS.	CYTRX CORP. 150 TECHNOLOGY PKWY. TECHNOLOGY PARK/ ATLANTA NORCROSS, GA 30092
GENERIC: SERMORELIN ACETATE [GRF(1-29)NH2] 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. 100 LONGWATER CIRCLE NORWELL, MA 02061
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 HOSPITAL 2650 RIDGE AVE. EVANSTON, IL 60201

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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.	SMITH KLINE & FRENCH LABS. P.O. BOX 1539, L231 KING OF PRUSSIA, PA 19406
GENERIC: SOMATROPIN TRADE: HUMATROPE	TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	ELI LILLY AND CO. LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL COMPLICATIONS OF CHEMOTHERAPY IN BONE MARROW TRANSPLANT RECIPIENTS.	NASKA PHARMACAL CO., INC. 55 PLANT AVE. HAUPPAUGE, NY 11788
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 RESEARCH CORP. 4600 EAST-WEST HIGHWAY SUITE 900 BETHESDA, MD 20814

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

NO MAY 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
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
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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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 SCHEUDLE, 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

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>	18828 001	ACYCLOVIR; ZOVIRAX				I-45	APR 20, 1993
>ADD>	19909 001	ACYCLOVIR; ZOVIRAX				I-45	APR 26, 1993
>ADD>	18603 001	ACYCLOVIR SODIUM; ZOVIRAX				I-43	FEB 09, 1993
>ADD>						I-42	FEB 09, 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		
	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			
>ADD>	19972 001	CARTEOLOL HYDROCHLORIDE; OPTIPRESS	3910924	OCT 07, 1994		NCE	DEC 28, 1993
>ADD>						NDF	MAY 23, 1993
	19966 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NP	FEB 22, 1993
						NCE	DEC 27, 1990
	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
	18554 001	FLUTAMIDE; EULEXIN	4329364	MAY 11, 2001	U-23		
	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			
	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			
	18956 002	IOHEXOL; OMNIPAQUE 240	4021481	MAY 03, 1994			
>ADD>	18735 002	IOPAMIDOL; ISOVUE-300				I-46	MAY 30, 1993
>ADD>	18735 003	IOPAMIDOL; ISOVUE-370				I-48	OCT 04, 1992
>DLT>	18735 003	IOPAMIDOL; ISOVUE-370				I-48	OCT 04, 1992
>ADD>	19591 001	MEFLOQUINE HYDROCHLORIDE; LARIAM				ODE	MAY 02, 1996

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

*U.S. G.P.O. 1990-261-208:00012

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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			
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		NCE	FEB 13, 1995
	19818 001	PEGADEMASE BOVINE; ADAGEN	4179337	DEC 18, 1996			
	19818 001	PEGADEMASE BOVINE; ADAGEN				NCE	MAR 21, 1995
>ADD>	19918 001	PERMETHRIN; NIX	4024163	MAY 17, 1996		NCE	MAR 31, 1991
	87361 001	PROCAINAMIDE HYDROCHLORIDE; PRONESTYL-SR	4252786	FEB 24, 1998			
	10929 001	SODIUM IODIDE, I-131; IODOTOPE	4349529	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			
>ADD>	18333 001	SUCRALFATE; CARAFATE				I-44	MAY 11, 1993
	18107 001	TECHNETIUM TC-99M MEDRONATE KIT; MDP-SQUIBB	4115541	SEP 19, 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
>ADD>	19614 001	VERAPAMIL HYDROCHLORIDE; VERELAN				NDF	MAY 29, 1993
>ADD>	19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN				NDF	MAY 29, 1993
>ADD>	19655 001	ZIDOVUDINE; RETROVIR	4833130	MAY 23, 2006		I-47	MAY 02, 1993
>ADD>			4724232	FEB 09, 2005		NCE	MAR 19, 1992
>ADD>	19910 001	ZIDOVUDINE; RETROVIR	4833130	MAY 23, 2006		ODE	MAR 19, 1994
>ADD>			4724232	FEB 09, 2005		NCE	MAR 19, 1992
>ADD>						I-47	MAY 02, 1993
>ADD>	19951 001	ZIDOVUDINE; RETROVIR	4833130	MAY 23, 2006		NCE	MAR 19, 1992
						ODE	MAR 19, 1994