CUMULATIVE
SUPPLEMENT 9
JAN'90-SEP'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
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Office of Management
Center for Drug Evaluation and Research, FDA

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SEPTEMBER 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Division of Blood and Blood Products and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 "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	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

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

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

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-10/			
	/MAYRAND/	/650MG;50MG/	/N88944/001/	/OCT/17,/1985/

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

>DLT>	/ENDRACET-#3 W/ CODEINE PHOSPHATE #3/			
>DLT>/AA/	/BURROUGHS/WELLC/	/300MG;30MG/	/N83951/001/	
>ADD>	∂ BURROUGHS WELLC	300MG;30MG	N83951 001	
>DLT>	/ENDRACET-#4 W/ CODEINE PHOSPHATE #4/			
>DLT>/AA/	/BURROUGHS/WELLC/	/300MG;60MG/	/N83951/002/	
>ADD>	∂ BURROUGHS WELLC	300MG;60MG	N83951 002	

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/

ACETYLCYSTEINE

/SOLUTION;/INHALATION/

	/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
	MUCOSOL-10			
AN	DEY LABS	10%	N70575 001	OCT 14, 1986
	MUCOSOL-20			
AN	DEY LABS	20%	N70576 001	OCT 14, 1986

ACETYLDIGITOXIN

/TABLET;/ORAL/

/ACYLANID/			
/SANDOZ/PHARMS/	/0.1MG/	/N09436/001/	
∂ SANDOZ PHARMS	0.1MG	N09436 001	

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

ALLOPURINOL

TABLET; ORAL

	ALLOPURINOL			
>DLT>/AB/	/SUPERPHARM/	/100MG/	/N70950/001/	/SEP/04,/1986/
>DLT>				
>ADD>	∂ SUPERPHARM	100MG	N70950 001	SEP 04, 1986
>ADD>				

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

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

	@ PAL PAK	100MG	N84533 001
/BD/	/VALE/CHEM/	/100MG/	/N84533/001/

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

AMMONIUM CHLORIDE

INJECTABLE; INJECTION
/AMMONIUM/CHLORIDE/0.9%/IN/NORMAL/SALINE/

/KENDALL/MCGAW/	/900MG/100ML/	/N06580/001/
@ KENDALL MCGAW	900MG/100ML	N06580 001

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
BIPHETAMINE 12.5

FISONS	EQ 6.25MG BASE;	
	EQ 6.25MG BASE	N10093 007
/PENNWALT/	/EQ/6.25MG/BASE;/	
	/EQ/6.25MG/BASE/	/N10093/007/

BIPHETAMINE 20

FISONS	EQ 10MG BASE;	
	EQ 10MG BASE	N10093 003
/PENNWALT/	/EQ/10MG/BASE;/	
	/EQ/10MG/BASE/	/N10093/003/

BIPHETAMINE 7.5

FISONS	EQ 3.75MG BASE;	
	EQ 3.75MG BASE	N10093 009

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
BIPHETAMINE 7.5

/PENNWALT/	/EQ/3.75MG/BASE;/	
	/EQ/3.75MG/BASE/	/N10093/009/

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

/ORPHENADRINE/COMPOUND/DOUBLE/STRENGTH/

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

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL
OXYCODONE AND ASPIRIN

AA	BARR LABS	325MG;4.5MG;0.38MG	N87794 001
			MAY 26, 1982
	/OXYCODONE W/ ASPIRIN/		
/AA/	/BARR/LABS/	/325MG;4.5MG;0.38MG/	/N87794/001/
			/MAY/26,/1982/

ATENOLOL

TABLET; ORAL
TENORMIN

ICI PHARM	25MG¤	N18240 004
		APR 09, 1990

ATENOLOL; CHLORTHALIDONE

ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL
ATENOLOL AND CHLORTHALIDONE

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

TENORETIC 100

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

TENORETIC 50

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

> ADD > ATROPINE SULFATE

> ADD > AEROSOL, METERED; INHALATION
> ADD > ATROPINE SULFATE

> ADD >	DEPT ARMY	EQ 0.36MG BASE/INH	N20056 001	SEP 19, 1990

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

AA	MYLAN PHARMS	0.025MG;2.5MG	N85762 001	
/AA/	/PARKE/DAVIS/	/0.025MG;2.5MG/	/N87131/001/	
	@ PARKE DAVIS	0.025MG;2.5MG	N87131 001	

/DIPHENOXYLATE HCL AND ATROPINE SULFATE/

/AA/	/MYLAN PHARMS/	/0.025MG;2.5MG/	/N85762/001/	

ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
ATROPINE AND DEMEROL

> DLT >/AP/	/STERLING/DRUG/	/0.4MG/ML;50MG/ML/	/N87853/001/	/NOV/26,/1982/
> DLT >				
> DLT >/AP/		/0.4MG/ML;75MG/ML/	/N87847/001/	/NOV/26,/1982/
> DLT >				
> DLT >/AP/		/0.4MG/ML;100MG/ML/	/N87848/001/	/NOV/26,/1982/
> DLT >				
> ADD >	STERLING DRUG	0.4MG/ML;50MG/ML	N87853 001	NOV 26, 1982
> ADD >				
> ADD >		0.4MG/ML;75MG/ML	N87847 001	NOV 26, 1982
> ADD >				
> ADD >		0.4MG/ML;100MG/ML	N87848 001	NOV 26, 1982
> ADD >				

ATROPINE SULFATE; MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
MEPERIDINE AND ATROPINE SULFATE

> DLT >/AP/	/WYETH/AYERST/LABS/	/0.4MG/ML;50MG/ML/	/N85121/001/	
> DLT >/AP/		/0.4MG/ML;75MG/ML/	/N85121/002/	
> DLT >/AP/		/0.4MG/ML;100MG/ML/	/N85121/003/	
> ADD >	@ WYETH AYERST LABS	0.4MG/ML;50MG/ML	N85121 001	
> ADD >	@	0.4MG/ML;75MG/ML	N85121 002	
> ADD >	@	0.4MG/ML;100MG/ML	N85121 003	

BACLOFEN

TABLET; ORAL
BACLOFEN

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

INJECTABLE; INJECTION
BROMPHENIRAMINE MALEATE

> DLT >	/STERIS/LABS/	/100MG/ML/	/N83820/001/	
> ADD >	@ STERIS LABS	100MG/ML	N83820 001	

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

BIPHETAP

/AA/	/PBI/	/4MG/5ML;25MG/5ML/	/N88687/001/ /SEP/26,/1984/
	PBI	4MG/5ML;25MG/5ML	N88687 001 SEP 26, 1984

BROMANATE

/AA/	/BARRE/NATL/	/4MG/5ML;25MG/5ML/	/N88688/001/ /FEB/06,/1985/
	∂ BARRE NATL	4MG/5ML;25MG/5ML	N88688 001 FEB 06, 1985

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

/AA/	/REID/ROWELL/	/16.2MG/	/N83606/001/
/AA/		/32.4MG/	/N83898/001/
	∂ REID ROWELL	16.2MG	N83606 001
	∂	32.4MG	N83898 001
		/48.6MG/	/N83897/001/
	∂	48.6MG	N83897 001
		/97.2MG/	/N83896/001/
	∂	97.2MG	N83896 001

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

LACTATED RINGER'S AND DEXTROSE 5% IN PLASTIC CONTAINER

AP	BAXTER	20MG/100ML;5GM/100ML;30MG/100ML; 600MG/100ML; 310MG/100ML	N16679 001

LACTATED RINGER'S W/ DEXTROSE 5% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/20MG/100ML;5GM/100ML;30MG/100ML; 600MG/100ML; 310MG/100ML/	/N16679/001/

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

TPN ELECTROLYTES IN PLASTIC CONTAINER

	/ABBOTT/LABS/	/16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML/	/N19399/001/ /JUN/16,/1986/
	∂ ABBOTT LABS	16.5MG/ML;25.4MG/ML;74.6MG/ML; 121MG/ML;16.1MG/ML	N19399 001 JUN 16, 1986

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

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

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OPTIPRESS

	BURROUGHS WELLC	1%	N19972 001 MAY 23, 1990

CEFADROXIL

CAPSULE; ORAL

	/CEFADROXIL/		
/AB/	/BIOCRAFT/LABS/	/EQ 500MG BASE/	/N62695/001/ /FEB/10,/1989/
/AB/	/PUREPAC/PHARM/	/EQ 500MG BASE/	/N63017/001/ /JAN/05,/1989/
/AB/	/ZENITH/LABS/	/EQ 500MG BASE/	/N62766/001/ /MAR/03,/1987/
	∂ BIOCRAFT LABS	EQ 500MG BASE	N62695 001 FEB 10, 1989
	∂ PUREPAC PHARM	EQ 500MG BASE	N63017 001 JAN 05, 1989
	∂ ZENITH LABS	EQ 500MG BASE	N62766 001 MAR 03, 1987

DURICEF

	/MEAD/JOHNSON/	/EQ/250MG/BASE/	/N50512/002/
	∂ MEAD JOHNSON	EQ 250MG BASE	N50512 002

CEFADROXIL

PONDER FOR RECONSTITUTION; ORAL

/CEFADROXIL/
/AB/ /BIOCRAFT/LABS/ /EQ 125MG BASE/5ML/ /N62698/001/ /MAR/01,/1989/
/AB/ /EQ 250MG BASE/5ML/ /N62698/002/ /MAR/01,/1989/
/AB/ /EQ 500MG BASE/5ML/ /N62698/003/ /MAR/01,/1989/

ə BIOCRAFT LABS	EQ 125MG BASE/5ML	N62698 001	MAR 01, 1989
ə	EQ 250MG BASE/5ML	N62698 002	MAR 01, 1989
ə	EQ 500MG BASE/5ML	N62698 003	MAR 01, 1989

DURICEF

AB MEAD JOHNSON	EQ 125MG BASE/5ML	N50527 002	
AB	EQ 250MG BASE/5ML	N50527 003	

ULTRACEF

AB BRISTOL LABS	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

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

ə ZENITH LABS	EQ 1GM BASE	N62774 001	APR 08, 1987

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP LEMMON	EQ 5GM BASE/VIAL¤	N63018 001	MAR 05, 1990
AP	EQ 10GM BASE/VIAL¤	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/VIAL¤	N50551 003	MAR 05, 1990

/ROERIG/ /EQ/1GM/BASE/VIAL/ /N50551/001/ /NOV/18,/1982/
/EQ/2GM/BASE/VIAL/ /N50551/002/ /NOV/18,/1982/

CEFOBID IN PLASTIC CONTAINER

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

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

CEFTAZIDIME

INJECTABLE; INJECTION

CEPTAZ

GLAXO	500MG/VIAL¤	N50646 001	SEP 27, 1990
	1GM/VIAL¤	N50646 002	SEP 27, 1990
	2GM/VIAL¤	N50646 003	SEP 27, 1990
	10GM/VIAL¤	N50646 004	SEP 27, 1990

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN MONOHYDRATE

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

ə VITARINE	EQ 250MG BASE	N62159 001	
ə	EQ 500MG BASE	N62159 002	

CEPHALEXIN

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/	
	ə VITARINE	EQ 125MG BASE/5ML	N62779 001 DEC 22, 1987	
	ə	EQ 250MG BASE/5ML	N62781 001 DEC 22, 1987	

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

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

>ADD>	AA	MUTUAL PHARM	500MG¤	N89970 001 SEP 27, 1990

>ADD>

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/
	∂ VITARINE	EQ 75MG BASE	N62910 001 JUL 05, 1988
	∂	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

CLOCORTOLONE PIVALATE

CREAM; TOPICAL
CLODERM

HERMAL PHARM	0.1%	N17765 001
/RW/JOHNSON/	/0.1%/	/N17765/001/

CLONIDINE HYDROCHLORIDE

TABLET; ORAL
CLONIDINE HCL

/AB/	/INTERPHARM/	/0.1MG/	/N71252/001/ /OCT/01,/1986/
/AB/		/0.2MG/	/N71253/001/ /OCT/01,/1986/
/AB/		/0.3MG/	/N71254/001/ /OCT/01,/1986/
BX	INTERPHARM	0.1MG	N71252 001 OCT 01, 1986
BX		0.2MG	N71253 001 OCT 01, 1986
BX		0.3MG	N71254 001 OCT 01, 1986

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

/AB/	/WARNER/CHILCOTT/	/3.75MG/	/N71774/001/ /MAR/01,/1988/
/AB/		/7.5MG/	/N71775/001/ /MAR/01,/1988/
/AB/		/15MG/	/N71776/001/ /MAR/01,/1988/
	∂ WARNER CHILCOTT	3.75MG	N71774 001 MAR 01, 1988
	∂	7.5MG	N71775 001 MAR 01, 1988
	∂	15MG	N71776 001 MAR 01, 1988

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

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

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL
/PSEUDODINE-C/

/AA/	/PBI/	/10MG/5ML;30MG/5ML;/ /1.25MG/5ML/	/N88833/001/ /NOV/16,/1984/

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL
TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE PHOSPHATE

AA	PBI	10MG/5ML;30MG/5ML; 1.25MG/5ML	N88833 001 NOV 16, 1984	

COLFOSCERIL PALMITATE

POWDER FOR RECONSTITUTION; INTRATRACHEAL
EXOSURF NEONATAL

	BURROUGHS WELLC	108MG/VIAL¤	N20044 001 AUG 02, 1990

CYANOCOBALAMIN; TANNIC ACID; ZINC ACETATE

/INJECTABLE;/INJECTION/
/DEPINAR/

	/ARMOUR/PHARM/	/0.5MG/ML;2.3MG/ML;/ /1MG/ML/	/N11208/001/
	∂ 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

CYTARABINE

INJECTABLE; INJECTION
CYTARABINE

	BULL LABS	20MG/ML¤	N71868 001 JUN 04, 1990
		20MG/ML¤	N72168 001 AUG 31, 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/
	∂ VITARINE	10MG		N72167 001 FEB 03, 1988
	∂	25MG		N71601 001 JUN 05, 1987
	∂	50MG		N71588 001 JUN 05, 1987
	∂	75MG		N71602 001 OCT 05, 1987
	∂	100MG		N71766 001 OCT 05, 1987
	∂	150MG		N72254 001 FEB 03, 1988

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

	∂ BARR LABS	0.5MG	N84766 001

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
DEXAMETHASONE SODIUM PHOSPHATE

/AP/	/INTL/MEDTN/SYS/	/EQ 20MG PHOSPHATE/ML/		/N88522/001/ /FEB/17,/1984/
	∂ INTL MEDTN SYS	EQ 20MG PHOSPHATE/ML		N88522 001 FEB 17, 1984
AP	KENDALL MCGAW	EQ 4MG PHOSPHATE/ML¤		N81125 001 AUG 31, 1990
AP		EQ 10MG PHOSPHATE/ML¤		N81126 001 AUG 31, 1990

>ADD> OINTMENT; OPHTHALMIC
>ADD> MAXIDEX
>ADD> AT ALCON LABS EQ 0.05% PHOSPHATE N83342 001

>ADD > OINTMENT; OPHTHALMIC
>ADD > MAXIDEX
>ADD > AT ALCON LABS EQ 0.05% PHOSPHATE N83342 001

DEXAMETHASONE SODIUM PHOSPHATE

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

>DLT > /SOLUTION/DROPS;/OPHTHALMIC/
>DLT > /DEXAMETHASONE SODIUM PHOSPHATE/
>DLT >/AT/ /STERIS/LABS/ /EQ 0.1% PHOSPHATE/ /N88771/001/
>DLT > /JAN/16,/1985/

>ADD > SOLUTION/DROPS; OPHTHALMIC, OTIC
>ADD > DEXAMETHASONE SODIUM PHOSPHATE
>ADD > AT STERIS LABS EQ 0.1% PHOSPHATE N88771 001
>ADD > 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/100ML N19631 016 JAN 19, 1990

DEZOCINE

INJECTABLE; INJECTION
DALGAN
ASTRA PHARM 5MG/ML N19082 001 DEC 29, 1989
10MG/ML N19082 002 DEC 29, 1989
15MG/ML N19082 003 DEC 29, 1989
/WYETH/AYERST/LABS/ /5MG/ML/ /N19082/001/ /DEC/29,/1989/
/10MG/ML/ /N19082/002/ /DEC/29,/1989/
/15MG/ML/ /N19082/003/ /DEC/29,/1989/

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
/HYPAQUE-M/
/STERLING/DRUG/ /50%;25%/ /N10220/003/
/3/ /60%;30%/ /N10220/002/
HYPAQUE-M,75%
STERLING DRUG 50%;25% N10220 003

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
HYPAQUE-M,90%
STERLING DRUG 60%;30% N10220 002

DIAZEPAM

TABLET; ORAL
DIAZEPAM
/BX/ /SUPERPHARM/ /10MG/ /N70644/001/ /DEC/11,/1985/
@ 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
/AA/ /MERRELL/DOW/PHARMS/ /25MG/ /N17668/001/
@ MERRELL DOW PHARMS 25MG N17668 001

TABLET, EXTENDED RELEASE; ORAL
/TENUATE/
/BC/ /MERRELL/DOW/PHARMS/ /75MG/ /N17669/001/
@ MERRELL DOW PHARMS 75MG N17669 001

DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/
/EMBOLEX/
/SANDOZ/PHARMS/ /0.5MG/0.7ML;5,000/UNITS/0.7ML;/ /7.46MG/0.7ML/ /N18885/002/ /NOV/30,/1984/
@ SANDOZ PHARMS 0.5MG/0.7ML;5,000 UNITS/0.7ML; 7.46MG/0.7ML N18885 002 NOV 30, 1984

DIMENHYDRINATE

TABLET; ORAL

DIMENHYDRINATE

>_DLT_>/AA/	/ANABOLIC/	/50MG/	/N85985/001/	
>_ADD_>	ə ANABOLIC	50MG	N85985 001	

DINOPROST TROMETHAMINE

/INJECTABLE;/INJECTION/

/PROSTIN/F2/ALPHA/

/UPJOHN/	/EQ/5MG/BASE/ML/	/N17434/001/	
ə UPJOHN	EQ 5MG BASE/ML	N17434 001	

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

>_DLT_>/AA/	/ANABOLIC/	/25MG/	/N83634/001/	
>_ADD_>	ə ANABOLIC	25MG	N83634 001	
>_DLT_>/AA/	/HEATHER/DRUG/	/50MG/	/N83953/001/	
>_ADD_>	ə HEATHER DRUG	50MG	N83953 001	

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

AB	PUREPAC PHARM	25MG¤	N89425 001 JUL 12, 1990
AB		50MG¤	N89426 001 JUL 12, 1990
AB		75MG¤	N89427 001 JUL 12, 1990

PERSANTINE

AB	BOEHR INGEL	25MG	N12836 003 DEC 22, 1986
AB		50MG	N12836 004 FEB 06, 1987
AB		75MG	N12836 005 FEB 06, 1987

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
>_DLT_>/AB/	/SUPERPHARM/	/EQ 150MG BASE/	/N70941/001/ /FEB/09,/1987/
>_DLT_> >_ADD_> >_ADD_>	ə SUPERPHARM	EQ 150MG BASE	N70941 001 FEB 09, 1987

DIVALPROEX SODIUM

TABLET, DELAYED RELEASE; ORAL

DEPAKOTE CP

ABBOTT LABS	EQ 250MG BASE¤	N19794 001 JUL 11, 1990
	EQ 500MG BASE¤	N19794 002 JUL 11, 1990

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

ADAPIN

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INTRAVENOUS

DOXORUBICIN HCL

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

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

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

INJECTABLE; INJECTION

VIBRAMYCIN

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

DYDROGESTERONE

TABLET; ORAL

GYNOREST

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

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

>ADD>	AP	ELKINS SINN	0.01MG/ML;1%	N80406 001
>ADD>	AP		0.01MG/ML;2%	N80406 002
>DLT>		/LIDOCAINE HCL W/ EPINEPHRINE/		
>DLT>	/AP/	/ELKINS/SINN/	/0.01MG/ML;1%/	/N80406/001/
>DLT>	/AP/		/0.01MG/ML;2%/	/N80406/002/

ERGOLOID MESYLATES

TABLET; ORAL

/GERIMAL/

/AB/	/CHELSEA/LABS/	/1MG/	/N88207/001/ /MAR/22,/1984/
∂	CHELSEA LABS	1MG	N88207 001 MAR 22, 1984

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/	/SUPERPHARM/	/0.5MG/	/N89233/001/ /SEP/23,/1986/
/AA/		/1MG/	/N89234/001/ /SEP/23,/1986/
∂	SUPERPHARM	0.5MG	N89233 001 SEP 23, 1986
∂		1MG	N89234 001 SEP 23, 1986

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYC

AB	FAULDING	250MG	N50536 001

SOLUTION; TOPICAL

ERYTHROMYCIN

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

TABLET, DELAYED RELEASE; ORAL

E-BASE

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

E-MYCIN

AB	BOOTS USA	250MG	N60272 001
AB		333MG	N60272 002
/AB/	/UPJOHN/	/250MG/	/N60272/001/
/AB/		/333MG/	/N60272/002/

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
AB BARR LABS EQ 500MG BASE¤ N63179 001 MAY 15, 1990

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
DITATE-DS
/AD/ /SAVAGE/LABS/ /8MG/ML;180MG/ML/ /N86423/001/
SAVAGE LABS 8MG/ML;180MG/ML N86423 001
TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE
AQ STERIS LABS 4MG/ML;90MG/ML N85865 001
ə 8MG/ML;180MG/ML N85860 001
/TESTOSTERONE ENANTHATE-ESTRADIOL VALERATE/
/AD/ /STERIS/LABS/ /4MG/ML;90MG/ML/ /N85865/001/
/AQ/ /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

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
BLOCK DRUG 50MG/ML N19357 001 DEC 22, 1988

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
/GLAXO/ /50MG/ML/ /N19357/001/ /DEC/22/1988/

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/35E-21
AB SCHIAPPARELLI SEARLE 0.035MG;1MG N71480 001 APR 12, 1988
/AB/ /SEARLE/ /0.035MG;1MG/ /N71480/001/ /APR/12/1988/

TABLET; ORAL-28
NORETHIN 1/35E-28
AB SCHIAPPARELLI SEARLE 0.035MG;1MG N71481 001 APR 12, 1988
/AB/ /SEARLE/ /0.035MG;1MG/ /N71481/001/ /APR/12/1988/

ETHYLESTRENOL

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

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL
DURAGESIC
ALZA 0.6MG/24HR¤ N19813 004 AUG 07, 1990
1.2MG/24HR¤ N19813 003 AUG 07, 1990
1.8MG/24HR¤ N19813 002 AUG 07, 1990
2.4MG/24HR¤ N19813 001 AUG 07, 1990

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN
BLOCK DRUG 50MG/ML N19357 001
DEC 22, 1988

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

FLUOCINOLONE ACETONIDE

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

SHAMPOO; TOPICAL
FS SHAMPOO
HILL DERM 0.01%¤ N20001 001
AUG 27, 1990

FLUOCINONIDE

SOLUTION; TOPICAL
FLUOCINONIDE
>ADD > AT COPLEY PHARM 0.05%¤ N72522 001
>ADD > SEP 28, 1990

FOLIC ACID

TABLET; ORAL
FOLIC ACID
>DLT >/AA/ /ANABOLIC/ /1MG/ /N84915/001/
>ADD > ∂ ANABOLIC 1MG N84915 001

FUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
>ADD > AP LEDERLE PARNTLS 10MG/ML¤ N71439 001
>ADD > SEP 14, 1990

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

HALCINONIDE

CREAM; TOPICAL

HALOG

>DLT >/AT/	/SQUIBB/	/0.1%/	/N17556/001/	
>DLT >		/0.025%/	/N17818/001/	
>ADD >	WESTWOOD PHARMS	0.025%	N17818 001	
>ADD >		0.1%	N17556 001	

HALOG-E

>DLT >/AT/	/SQUIBB/	/0.1%/	/N18234/001/	
>ADD >	WESTWOOD PHARMS	0.1%	N18234 001	

OINTMENT; TOPICAL

HALOG

>DLT >	/SQUIBB/	/0.1%/	/N17824/001/	
>ADD >	WESTWOOD PHARMS	0.1%	N17824 001	

SOLUTION; TOPICAL

HALOG

>DLT >	/SQUIBB/	/0.1%/	/N17823/001/	
>ADD >	WESTWOOD PHARMS	0.1%	N17823 001	

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH

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

HEPARIN SODIUM

/AP/	/CHAMBERLIN/	/1,000 UNITS/ML/	/N17130/001/	
/AP/		/5,000 UNITS/ML/	/N17130/002/	
/AP/		/10,000 UNITS/ML/	/N17130/003/	
/AP/		/20,000 UNITS/ML/	/N17130/004/	
	@ CHAMBERLIN	1,000 UNITS/ML	N17130 001	
	@	5,000 UNITS/ML	N17130 002	
	@	10,000 UNITS/ML	N17130 003	
	@	20,000 UNITS/ML	N17130 004	
/AP/	/LYPHOMED/	/1,000 UNITS/ML/	/N17033/001/	
/AP/		/1,000 UNITS/ML/	/N17651/005/	
/AP/		/10,000 UNITS/ML/	/N17651/003/	
/AP/		/20,000 UNITS/ML/	/N17651/008/	
	@ LYPHOMED	1,000 UNITS/ML	N17033 001	
	@	1,000 UNITS/ML	N17651 005	
	@	10,000 UNITS/ML	N17651 003	
	@	20,000 UNITS/ML	N17651 008	
	/WYETH/AYERST/LABS/	/15,000 UNITS/ML/	/N17007/005/	
	@ WYETH AYERST LABS	15,000 UNITS/ML	N17007 005	

HOMATROPINE METHYLBROMIDE

/TABLET;/CHEWABLE;/ORAL/

/EQUIPIN/

/MISSION/PHARMA/	/5MG/		/N86310/001/
@ MISSION PHARMA	5MG		N86310 001

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

/AB/	/SUPERPHARM/	/25MG;25MG/	/N89200/001/ /FEB/09,/1987/	
	@ SUPERPHARM	25MG;25MG	N89200 001 FEB 09, 1987	

TABLET; ORAL

HYDRALAZINE AND HYDROCHLORTHIAZIDE

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

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/REID/ROWELL/	/25MG/	/N85323/001/	
	@ REID ROWELL	25MG	N85323 001	

HYDROCHLOROTHIAZIDE; LISINOPRIL

HYDROCORTISONE

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL

PRINZIDE 12,5

> ADD > AB MS&D RES LABS 12.5MG;20MG N19778 001 FEB 16, 1989

ZESTORETIC 20/12,5

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

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

HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

HYCOMINE

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

HYCOMINE PEDIATRIC

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

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

/AT/ /PBI/ /1%/ /N88027/001/ /SEP/27,/1983/

/AT/ /2.5%/ /N88029/001/ /SEP/27,/1983/

ə PBI 1% N88027 001 SEP 27, 1983

ə 2.5% N88029 001 SEP 27, 1983

HYDROCORTISONE

CREAM; TOPICAL

/HYDROTEX/

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

HOGENIC HC

AT SYOSSET LABS 1% N87427 001 APR 04, 1988

OINTMENT; TOPICAL

HYDROCORTISONE

/AT/ /PBI/ /1%/ /N88061/001/ /SEP/27,/1983/

/AT/ /2.5%/ /N88039/001/ /SEP/27,/1983/

ə PBI 1% N88061 001 SEP 27, 1983

ə 2.5% N88039 001 SEP 27, 1983

TABLET; ORAL

HYDROCORTISONE

> DLT > /BP/ /ANABOLIC/ /20MG/ /N83140/001/

> ADD > ə ANABOLIC 20MG N83140 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC

PEDIOTIC

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

/PEDIOTIC CORTISPORIN/

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

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

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

ə SOLOPAK LABS 25MG/ML N87592 001

IBUPROFEN

TABLET; ORAL
IBUPROFEN

/AB/	/MCNEIL/CONSUMER/	/400MG/	/N70081/001/ /JUN/16,/1986/
/AB/		/600MG/	/N70476/001/ /JUN/16,/1986/
	ə MCNEIL CONSUMER	400MG	N70081 001 JUN 16, 1986
	ə	600MG	N70476 001 JUN 16, 1986
/AB/	/SUPERPHARM/	/400MG/	/N70708/001/ /APR/25,/1986/
BX	SUPERPHARM	400MG	N70708 001 APR 25, 1986

> ADD > IDARUBICIN HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > IDAMYCIN

> ADD >	ADRIA LABS	5MG/VIAL¤	N50661 002 SEP 27, 1990
> ADD >		10MG/VIAL¤	N50661 001 SEP 27, 1990

IFOSFAMIDE

INJECTABLE; INJECTION
IFEX

	/BRISTOL/SQUIBB/	/3GM/VIAL/	/N19763/002/ /DEC/30,/1988/
	ə BRISTOL SQUIBB	3GM/VIAL	N19763 002 DEC 30, 1988

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

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
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

>DLT >/AA/	/ANABOLIC/	/100MG/	/N84050/001/	
>ADD >	ə ANABOLIC	100MG	N84050 001	
/AA/	/PUREPAC/PHARM/	/50MG/	/N80132/003/	
			/JUL/14,/1982/	
/AA/		/100MG/	/N80132/004/	
			/JUL/14,/1982/	
	ə PUREPAC PHARM	50MG	N80132 003	
			JUL 14, 1982	
	ə	100MG	N80132 004	
			JUL 14, 1982	

ISOSORBIDE DINITRATE

TABLET; ORAL
ISOSORBIDE DINITRATE

/AB/	/SUPERPHARM/	/5MG/	/N89190/001/	
			/FEB/17,/1987/	
/AB/		/10MG/	/N89191/001/	
			/FEB/17,/1987/	
/AB/		/20MG/	/N89192/001/	
			/FEB/17,/1987/	
	ə SUPERPHARM	5MG	N89190 001	
			FEB 17, 1987	
	ə	10MG	N89191 001	
			FEB 17, 1987	
	ə	20MG	N89192 001	
			FEB 17, 1987	

KANAMYCIN SULFATE

INJECTABLE; INJECTION
KANAMYCIN SULFATE

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

KETOCONAZOLE

SHAMPOO; TOPICAL
NIZORAL

JANSSEN RES	2%N		N19927 001	
			AUG 31, 1990	

LEVAMISOLE HYDROCHLORIDE

TABLET; ORAL
ERGAMISOL

JANSSEN RES	EQ 50MG BASEN		N20035 001	
			JUN 18, 1990	

LINDANE

LOTION; TOPICAL

>DLT >	/GAMENE/			
>DLT >/AT/	/BARNES/HIND/	/1%/	/N84989/001/	
>ADD >	ə BARNES HIND	1%	N84989 001	

SHAMPOO; TOPICAL

>DLT >	/GAMENE/			
>DLT >/AT/	/BARNES/HIND/	/1%/	/N84988/001/	
>ADD >	ə BARNES HIND	1%	N84988 001	

MEBUTAMATE

/TABLET;/ORAL/				
/DORMATE/				
	/WALLACE/PHARMS/	/600MG/	/N17374/001/	
	ə WALLACE PHARMS	600MG	N17374 001	

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HCL

>DLT >/AA/	/ANABOLIC/	/25MG/	/N85891/001/	
>ADD >	ə ANABOLIC	25MG	N85891 001	
/AA/	/CAMALL/	/12.5MG/	/N84464/001/	
>DLT >/AA/		/25MG/	/N84713/001/	
/AA/	/SUPERPHARM/	/12.5MG/	/N89113/001/	
			/AUG/20,/1985/	
/AA/		/25MG/	/N89114/001/	
			/AUG/20,/1985/	
	ə SUPERPHARM	12.5MG	N89113 001	
			AUG 20, 1985	
	ə	25MG	N89114 001	
			AUG 20, 1985	

TABLET, CHEWABLE; ORAL
MECLIZINE HCL

>DLT >/AA/	/ANABOLIC/	/25MG/	/N86392/001/	
>ADD >	ə ANABOLIC	25MG	N86392 001	

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

/AB/	/BOLAR/PHARM/	/EQ 50MG BASE/	/N70400/001/ /NOV/25,/1986/	
/AB/		/EQ 100MG BASE/	/N70401/001/ /NOV/25,/1986/	
BX	BOLAR PHARM	EQ 50MG BASE	N70400 001 NOV 25, 1986	
BX		EQ 100MG BASE	N70401 001 NOV 25, 1986	
/BX/	/VITARINE/	/EQ/50MG/BASE/	/N71710/001/ /JUN/15,/1988/	
/BX/		/EQ/100MG/BASE/	/N71684/001/ /JUN/15,/1988/	
	ə VITARINE	EQ 50MG BASE	N71710 001 JUN 15, 1988	
	ə	EQ 100MG BASE	N71684 001 JUN 15, 1988	

MEFENAMIC ACID

CAPSULE; ORAL

/MEFENAMIC/ACID/

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

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

/AP/	/INTL/MEDTN/SYS/	/10MG/ML/	/N86332/001/
	ə INTL MEDTN SYS	10MG/ML	N86332 001

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

>DLT>	/AA/	/ANABOLIC/	/200MG/	/N84220/001/
>DLT>	/AA/		/400MG/	/N84589/002/
>ADD>		ə ANABOLIC	200MG	N84220 001
>ADD>		ə	400MG	N84589 002
	/AA/	/PRIVATE/FMLTNS/	/400MG/	/N14601/001/
		ə PRIVATE FMLTNS	400MG	N14601 001
	/AA/	/REID/ROWELL/	/200MG/	/N84435/001/
		ə REID ROWELL	200MG	N84435 001

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

NORETHIN 1/50M-21

AB	SCHIAPPARELLI SEARLE	0.05MG;1MG	N71539 001 APR 12, 1988
/AB/	/SEARLE/	/0.05MG;1MG/	/N71539/001/ /APR/12,/1988/

/NORINYL/1+80/21-DAY/

/SYNTEX/(FP)/	/0.08MG;1MG/	/N16724/001/
ə SYNTEX (FP)	0.08MG;1MG	N16724 001

TABLET; ORAL-28

NORETHIN 1/50M-28

AB	SCHIAPPARELLI SEARLE	0.05MG;1MG	N71540 001 APR 12, 1988
/AB/	/SEARLE/	/0.05MG;1MG/	/N71540/001/ /APR/12,/1988/

/NORINYL/1+80/28-DAY/

/SYNTEX/(FP)/	/0.08MG;1MG/	/N16725/001/
ə 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*

METHARBITAL

METIPRANOLOL HYDROCHLOIDE

METHARBITAL

/TABLET;ORAL/
/GEMONIL/
/ABBOTT/LABS/ /100MG/ /N08322/001/
ə ABBOTT LABS 100MG N08322 001

METHICILLIN SODIUM

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

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE
/AP/ /INTL/MEDTN/SYS/ /EQ 40MG BASE/VIAL/ /N87812/001/ /FEB/09,/1983/
/AP/ /EQ 125MG BASE/VIAL/ /N87813/001/ /FEB/09,/1983/
/AP/ /EQ 500MG BASE/VIAL/ /N87851/001/ /FEB/09,/1983/
/AP/ /EQ 1GM BASE/VIAL/ /N87852/001/ /FEB/09,/1983/
ə INTL MEDTN SYS EQ 40MG BASE/VIAL N87812 001 FEB 09, 1983
ə EQ 125MG BASE/VIAL N87813 001 FEB 09, 1983
ə EQ 500MG BASE/VIAL N87851 001 FEB 09, 1983
ə EQ 1GM BASE/VIAL N87852 001 FEB 09, 1983

METHYLTESTOSTERONE

TABLET; ORAL
METHYLTESTOSTERONE
/BP/ /WEST/WARD/PHARM/ /25MG/ /N84642/001/
ə WEST WARD PHARM 25MG N84642 001

METIPRANOLOL HYDROCHLOIDE

SOLUTION/DROPS; OPHTHALMIC
/METIPRANOLOL/HCL/
/BAUSCH/&/LOMB/ /0.3%/ /N19907/001/ /DEC/29,/1989/
OPTIPRANOLOL
BAUSCH & LOMB 0.3% N19907 001 DEC 29, 1989

METOCLOPRAMIDE HYDROCHLORIDE

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

TABLET; ORAL
METOCLOFRAMIDE HCL
AB CORD LABS EQ 10MG BASE* N72215 001 JAN 30, 1990
AB MARTEC PHARM EQ 10MG BASE N70598 001 FEB 02, 1987
/3/ /EQ/10MG/BASE/ /N70598/001/ /FEB/02,/1987/

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCIN
AB LEDERLE LABS EQ 50MG BASE* N50649 001 MAY 31, 1990
AB EQ 100MG BASE* N50649 002 MAY 31, 1990
/EQ/50MG/BASE/ /N50315/002/
ə EQ 50MG BASE N50315 002
/EQ/50MG/BASE*/ /N50649/001/ /MAY/31,/1990/
/EQ/100MG/BASE/ /N50315/001/
ə EQ 100MG BASE N50315 001
/EQ/100MG/BASE*/ /N50649/002/ /MAY/31,/1990/
MINOCYCLINE HCL
AB WARNER CHILCOTT EQ 50MG BASE* N63066 001 AUG 14, 1990
AB EQ 100MG BASE* N63067 001 JUL 31, 1990

MINOCYCLINE HYDROCHLORIDE

/TABLET;/ORAL/
/MINOCIN/
/LEDERLE/LABS/ /EQ/50MG/BASE/ /N50451/003/ /AUG/10,/1982/
/EQ/100MG/BASE/ /N50451/002/ /AUG/10,/1982/

ə LEDERLE LABS	EQ 50MG BASE	N50451 003	AUG 10, 1982
ə	EQ 100MG BASE	N50451 002	AUG 10, 1982

MISOPROSTOL

TABLET; ORAL
CYTOTEC

>ADD<	SEARLE	0.1MG¤	N19268 003	SEP 21, 1990
>ADD<				

MORICIZINE HYDROCHLORIDE

TABLET; ORAL
ETHMOZINE

DUPONT PHARMS	200MG¤	N19753 001	JUN 19, 1990
	250MG¤	N19753 002	JUN 19, 1990
	300MG¤	N19753 003	JUN 19, 1990

MORPHINE SULFATE

INJECTABLE; INJECTION
MORPHINE SULFATE

SURVIVAL TECH	15MG/ML¤	N19999 001	JUL 12, 1990

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

NAFTIFINE HYDROCHLORIDE

GEL; TOPICAL
NAFTIN

ALLERGAN PHARMS	1%¤	N19356 001	JUN 18, 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/ /CHASE/LABS/ /10MG/ /N72409/001/ /JUL/04,/1990/;/JUL/10,/1989/

AB	CHASE LABS	10MG	N72409 001	SEP 04, 1990 : JUL 10, 1989
/AB/	/PUREPAC/PHARM/	/10MG/	/N72579/001/ /APR/28,/1989/	
AB	PUREPAC PHARM	10MG	N72579 001	APR 28, 1989
/AB/		/20MG¤/	/N72556/001/ /SEP/20,/1990/;/APR/28,/1989/	
AB		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

NITROGLYCERIN IN DEXTROSE 5%

AP	ABBOTT LABS	10MG/100ML¤	N71846 001	AUG 31, 1990
AP		20MG/100ML¤	N71847 001	AUG 31, 1990
AP		40MG/100ML¤	N71848 001	AUG 31, 1990

NITROGLYCERIN

INJECTABLE; INJECTION
NITROGLYCERIN IN DEXTROSE 5%

AP	BAXTER	10MG/100ML	N19970 001 DEC 29, 1989
AP		20MG/100ML	N19970 002 DEC 29, 1989
AP		40MG/100ML	N19970 003 DEC 29, 1989

/NITROGLYCERIN/100MG/IN/DEXTROSE/5%/ /BAXTER/ /40MG/100ML/ /N19970/003/ /DEC/29,/1989/

/NITROGLYCERIN/25MG/IN/DEXTROSE/5%/ /BAXTER/ /10MG/100ML/ /N19970/001/ /DEC/29,/1989/

/NITROGLYCERIN/50MG/IN/DEXTROSE/5%/ /BAXTER/ /20MG/100ML/ /N19970/002/ /DEC/29,/1989/

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 100UGM BASE/ML	N19667 002 OCT 21, 1988
	EQ 500UGM BASE/ML	N19667 003 OCT 21, 1988

/EQ/0.1MG/BASE/ML/ /N19667/002/ /OCT/21,/1988/

/EQ/0.5MG/BASE/ML/ /N19667/003/ /OCT/21,/1988/

OLSALAZINE SODIUM

CAPSULE; ORAL
DIPENTUM

	PHARMACIA	250MG¤	N19715 001 JUL 31, 1990

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
/LOSEC/ /MS&D/RES/LABS/ /20MG/ /N19810/001/ /SEP/14,/1989/

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
PRILOSEC

	MS&D RES LABS	20MG	N19810 001 SEP 14, 1989

OXAZEPAM

CAPSULE; ORAL
OXAZEPAM

/AB/ /CHELSEA/LABS/ /10MG/ /N71661/001/ /MAR/02,/1988/

/AB/ /15MG/ /N71662/001/ /MAR/02,/1988/

/AB/ /30MG/ /N71663/001/ /MAR/02,/1988/

BX	CHELSEA LABS	10MG	N71661 001 MAR 02, 1988
BX		15MG	N71662 001 MAR 02, 1988
BX		30MG	N71663 001 MAR 02, 1988
> ADD > AB	DANBURY PHARMA	10MG¤	N72952 001 SEP 28, 1990
> ADD > AB		15MG¤	N72953 001 SEP 28, 1990
> ADD > AB		30MG¤	N72954 001 SEP 28, 1990

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

AP	KENDALL MCGAW	1MG/ML¤	N72759 001 JUL 31, 1990
AP		2MG/ML¤	N72760 001 JUL 31, 1990

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

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION
PENICILLIN G POTASSIUM IN PLASTIC CONTAINER
BAXTER
20,000 UNITS/ML¤ N50638 001 JUN 25, 1990
40,000 UNITS/ML¤ N50638 002 JUN 25, 1990
60,000 UNITS/ML¤ N50638 003 JUN 25, 1990

PENTOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM PENTOBARBITAL
>DLT>/AA/ /ANABOLIC/ /100MG/ /N84590/001/
>ADD> ∂ ANABOLIC 100MG N84590 001

>DLT> /TABLET;/ORAL/
>DLT> /SODIUM/PENTOBARBITAL/
>DLT> /ANABOLIC/ /100MG/ /N84238/001/
>ADD> ∂ ANABOLIC 100MG N84238 001

PERPHENAZINE

TABLET; ORAL
PERPHENAZINE
/AB/ /CHELSEA/LABS/ /8MG/ /N89700/001/ /DEC/23,/1987/
BX CHELSEA LABS 8MG N89700 001 DEC 23, 1987

PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

TABLET; ORAL
AZO GANTRISIN
ROCHE 50MG;500MG N19358 001 AUG 31, 1990

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
IONAMIN-15
FISONS EQ 15MG BASE N11613 004
/PENNWALT/ /EQ/15MG/BASE/ /N11613/004/
IONAMIN-30
FISONS EQ 30MG BASE N11613 002
/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
/BX/ /BOLAR/PHARM/ /100MG¤/ /N88711/001/ /DEC/21,/1984/
∂ BOLAR PHARM 100MG¤ N88711 001 DEC 21, 1984

PHYTONADIONE

INJECTABLE; INJECTION
VITAMIN K1
/BP/ /ABBOTT/LABS/ /10MG/ML/ /N87956/001/ /JUL/25,/1983/
∂ ABBOTT LABS 10MG/ML N87956 001 JUL 25, 1983

PIPECURONIUM BROMIDE

INJECTABLE; INJECTION
ARDUAN
ORGANON 1MG/ML¤ N19638 001 JUN 26, 1990

PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

TABLET; ORAL
AZO GANTRISIN
ROCHE — 50MG;500MG — N19358 001 AUG 31, 1990

PIPECURONIUM BROMIDE

INJECTABLE; INJECTION
ARDUAN
ORGANON — 1MG/ML — N19638 001 JUN 26, 1990

PIPERAZINE CITRATE

SYRUP; ORAL
/BRYBEL/
/AA/ /STERLING/DRUG/ /EQ 500MG BASE/5ML/ /N17796/001/
ə STERLING DRUG — EQ 500MG BASE/5ML — N17796 001

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

PONDER FOR RECONSTITUTION; ORAL
GLYCOPREP
AA SUPERPHARM — 236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT — N72319 001 DEC 23, 1988
/AA/ /TOSA/MED/PRODS/ /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
K-LEASE
AB ADRIA LABS — 10 MEQ — N72427 001 MAR 28, 1990

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE
/BX/ /SUPERPHARM/ /5MG/ /N88892/001/ /FEB/26,/1985/
ə SUPERPHARM — 5MG — N88892 001 FEB 26, 1985
/BX/ /UDL/LABS/ /5MG/ /N87987/001/ /JAN/18,/1983/
ə UDL LABS — 5MG — N87987 001 JAN 18, 1983

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE
/BP/ /AKORN/ /25MG/ML/ /N83032/001/
ə AKORN — 25MG/ML — N83032 001

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
/METRETON/
>DLT> /SCHERING/ /EQ/0.5%/PHOSPHATE/ /N83834/001/
>ADD> ə SCHERING — EQ 0.5% PHOSPHATE — N83834 001

PREDNISONE

TABLET; ORAL
PREDNISONE
/AB/ /PRIVATE/FMLTNS/ /20MG/ /N85151/001/
ə PRIVATE FMLTNS — 20MG — N85151 001
/BX/ /UDL/LABS/ /5MG/ /N87984/001/ /JAN/18,/1983/
/BX/ /10MG/ /N87985/001/ /JAN/18,/1983/
/BX/ /20MG/ /N87986/001/ /JAN/18,/1983/
ə UDL LABS — 5MG — N87984 001 JAN 18, 1983
ə — 10MG — N87985 001 JAN 18, 1983
ə — 20MG — N87986 001 JAN 18, 1983

PROPANTHELINE BROMIDE

TABLET; ORAL
PROPANTHELINE BROMIDE
/AA/ /PRIVATE/FMLTNS/ /15MG/ /N80977/001/
ə PRIVATE FMLTNS — 15MG — N80977 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL
>DLT>/AA/ /ANABOLIC/ /65MG/ /N83185/001/
>ADD> ə ANABOLIC — 65MG — N83185 001
/AA/ /PRIVATE/FMLTNS/ /32MG/ /N83464/001/
/AA/ /65MG/ /N83113/001/
ə PRIVATE FMLTNS — 32MG — N83464 001
ə — 65MG — N83113 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERAL

/AB/ /WYETH/AYERST/LABS/ /90MG/ /N16418/010/ /OCT/18,/1982/

∂ WYETH AYERST LABS 90MG N16418 010 OCT 18, 1982

/PROPRANOLOL/

/AB/ /MYLAN/PHARMS/ /10MG/ /N70211/001/ /NOV/19,/1985/

/AB/ /20MG/ /N70212/001/ /NOV/19,/1985/

/AB/ /40MG/ /N70213/001/ /NOV/19,/1985/

/AB/ /80MG/ /N70214/001/ /NOV/19,/1985/

PROPRANOLOL HCL

/AB/ /DANBURY/PHARMA/ /90MG/ /N71183/001/ /OCT/06,/1986/

∂ DANBURY PHARMA 90MG N71183 001 OCT 06, 1986

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

/∂/ /10MG/ /N70120/001/ /AUG/06,/1985/

/∂/ /20MG/ /N70121/001/ /AUG/06,/1985/

/∂/ /40MG/ /N70122/001/ /AUG/06,/1985/

/∂/ /60MG/ /N70123/001/ /OCT/29,/1986/

/∂/ /80MG/ /N70124/001/ /AUG/06,/1985/

AB MYLAN PHARMS 10MG N70211 001 NOV 19, 1985

AB 20MG N70212 001 NOV 19, 1985

AB 40MG N70213 001 NOV 19, 1985

AB 80MG N70214 001 NOV 19, 1985

PROPYLTHIOURACIL

TABLET; ORAL

PROPYLTHIOURACIL

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

∂ ANABOLIC 50MG N80285 001

PROTEIN HYDROLYSATE

/INJECTABLE;/INJECTION/

/AMINOSOL/5%/

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

∂ ABBOTT LABS 5%¤ N05932 012 JAN 31, 1985

/INJECTABLE;/INJECTION/

/HYDROTIGEN 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 GLUCONATE

TABLET, EXTENDED RELEASE; ORAL

QUINIDINE GLUCONATE

>DLT >/AB/ /SUPERPHARM/ /324MG/ /N89164/001/ /NOV/21,/1985/

>DLT >

>ADD > ∂ SUPERPHARM 324MG N89164 001 NOV 21, 1985

>ADD >

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

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

RAUWOLFIA SERPENTINA

TABLET; ORAL

/WOLFINA/

/BP/	/FOREST/PHARMS/	/100MG/	/N09255/006/	
	ə FOREST PHARMS	100MG	N09255 006	

SARALASIN ACETATE

/INJECTABLE;/INJECTION/

/SARENIN/

	/NORWICH/EATON/	/EQ/0.6MG/BASE/ML/	/N18009/001/	
	ə NORWICH EATON	EQ 0.6MG BASE/ML	N18009 001	

SECOBARBITAL SODIUM

INJECTABLE; INJECTION

>DLT>		/SECONAL SODIUM/			
>DLT>/AP/		/LILLY/	/50MG/ML/	/N07392/002/	
>ADD>		ə LILLY	50MG/ML	N07392 002	

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE

>DLT>/AP/		/ABBOTT/LABS/	/20GM/100ML/	/N17013/001/	
>ADD>		ə ABBOTT LABS	20GM/100ML	N17013 001	

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP		BAXTER	450MG/100ML		N18016 001
		/SODIUM CHLORIDE 0.45% IN WATER IN PLASTIC CONTAINER/			
/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/	
		ə KENDALL MCGAW	3GM/100ML	N19635 003	
				MAR 09, 1988	

SODIUM CHLORIDE

INJECTABLE; INJECTION

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/	
		ə KENDALL MCGAW	5GM/100ML	N19635 004	
				MAR 09, 1988	

SOYBEAN OIL

INJECTABLE; INJECTION

>ADD>		LIPOSYN III 10%			
>ADD>	AP	ABBOTT LABS	10%		N18969 001
>ADD>					SEP 24, 1984
>DLT>		/ə/	/10%/		/N18969/001/
>DLT>					/SEP/24,/1984/
>ADD>		LIPOSYN III 20%			
>ADD>	AP	ABBOTT LABS	20%		N18970 001
>ADD>					SEP 25, 1984
>DLT>		/ə/	/20%/		/N18970/001/
>DLT>					/SEP/25,/1984/
		/TRAVAMULSION 20%/			
/AP/		/BAXTER/	/20%/		/N18758/001/
					/FEB/15,/1983/
		ə BAXTER	20%		N18758 001
					FEB 15, 1983

SULFAMETHIZOLE

TABLET; ORAL

/MICROSUL/

	/FOREST/PHARMS/	/1GM/		/N86012/001/
	ə FOREST PHARMS	1GM		N86012 001

SULFASALAZINE

TABLET; ORAL

/S.A.S.-500/

/AB/	/REID/ROWELL/	/500MG/		/N83456/001/
	ə REID ROWELL	500MG		N83456 001

SULFISOXAZOLE

TABLET; ORAL
/SULSOXIN/
/AB/ /REID/ROWELL/ /500MG/ /N80040/001/
@ REID ROWELL 500MG N80040 001

SULINDAC

TABLET; ORAL
SULINDAC
/AB/ /AM/THERAPTICS/ /150MG/ /N72171/001/
/APR/03,/1990/:/MAY/23,/1990/
/AB/ /200MG/ /N72172/001/
/APR/03,/1990/:/MAY/23,/1990/

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 MERTIATIDE KIT

INJECTABLE; INJECTION
TECHNESCAN MAG3
MALLINCKRODT N/A# N19882 001
JUN 15, 1990

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
AN-DTPA
AP CIS US N/A N17714 001
/AP/ /SINCOR/INTL/ /N/A/ /N17714/001/

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL
SODIUM PERTECHNETATE TC 99M
>DLT> /MEDI/PHYSICS/ /2-100MCI/ML/ /N17471/001/
>ADD> @ MEDI PHYSICS 2-100MCI/ML N17471 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
/BX/ /VITARINE/ /250MG/ /N61471/001/
/BX/ /500MG/ /N61471/002/
/SEP/06,/1988/
@ VITARINE 250MG N61471 001
@ 500MG N61471 002
SEP 06, 1988

TETRACYCLINE PHOSPHATE COMPLEX

CAPSULE; ORAL
TETREX
/BRISTOL/LABS/ /EQ/250MG/HCL/ /N50212/002/
@ BRISTOL LABS EQ 250MG HCL N50212 002
/EQ/500MG/HCL/ /N50212/003/
@ EQ 500MG HCL N50212 003

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
THEOPHYL-SR
/BC/ /RW/JOHNSON/ /250MG/ /N86471/001/
/FEB/08,/1985/
@ RW JOHNSON 250MG N86471 001
FEB 08, 1985

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
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

TRAZODONE HYDROCHLORIDE

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

AB	MYLAN PHARMS	5MG	N72666 001 JUN 08, 1990
AB		10MG	N72667 001 JUN 08, 1990
AB		20MG	N72668 001 JUN 08, 1990
/BX/	/QUANTUM/PHARMCS/	/10MG/	/N72467/001/ /MAY/19,/1989/
/BX/		/20MG/	/N72468/001/ /MAY/19,/1989/
	ə QUANTUM PHARMCS	10MG	N72467 001 MAY 19, 1989
	ə	20MG	N72468 001 MAY 19, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

ABBOTT LABS	EQ 80MG BASE/100ML	N63081 001 JUL 31, 1990
	EQ 1.2MG BASE/ML	N63081 003 JUL 31, 1990

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE

/AB/	/SUPERPHARM/	/250MG/	/N70763/001/ /JUN/16,/1986/
/AB/		/500MG/	/N70764/001/ /JUN/16,/1986/
	ə SUPERPHARM	250MG	N70763 001 JUN 16, 1986
	ə	500MG	N70764 001 JUN 16, 1986

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
DESYREL

AB	BRISTOL MYERS	50MG	N18207 001
AB		100MG	N18207 002
AB		150MG	N18207 003 MAR 25, 1985
		300MG	N18207 004 NOV 07, 1988
/AB/	/MEAD/JOHNSON/	/50MG/	/N18207/001/
/AB/		/100MG/	/N18207/002/
/AB/		/150MG/	/N18207/003/ /MAR/25,/1985/

TRAZODONE HCL

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

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
/FLUTEX/

/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/

KENALOG

> DLT >	/AT/	/SQUIBB/	/0.025%/	/N11601/003/
> DLT >	/AT/		/0.1%/	/N11601/006/
> ADD >	AT	WESTWOOD PHARMS	0.025%	N11601 003
> ADD >	AT		0.1%	N11601 006

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

OINTMENT; TOPICAL
KENALOG

> DLT >	/AT/	/SQUIBB/	/0.025%/	/N11600/003/
> DLT >	/AT/		/0.1%/	/N11600/001/
> ADD >	AT	WESTWOOD PHARMS	0.025%	N11600 003
> ADD >	AT		0.1%	N11600 001

TRIAMTERENE

CAPSULE; ORAL

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

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE			
/BP/ /CHELSEA/LABS/	/4MG/	/N85962/001/	
@ CHELSEA LABS	4MG	N85962 001	

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/			
/AB/ /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

CAPSULE, EXTENDED RELEASE; ORAL

VERELAN		
ELAN PHARM	120MG*	N19614 001
		MAY 29, 1990
	240MG*	N19614 002
		MAY 29, 1990

INJECTABLE; INJECTION

CALAN			
/AP/ /SEARLE/	/2.5MG/ML/	/N19038/001/	
		/MAR/30,/1984/	
@ SEARLE	2.5MG/ML	N19038 001	
		MAR 30, 1984	

INJECTABLE; INJECTION

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

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

	VERAPAMIL HCL			
/AP/	/LYPHOMED/	/2.5MG/ML/	/N70348/001/	
			/MAY/01,/1986/	
	∂ LYPHOMED	2.5MG/ML	N70348 001	
			MAY 01, 1986	

TABLET; ORAL

	VERAPAMIL HCL			
/AB/	/CHELSEA/LABS/	/80MG/	/N70421/001/	
			/SEP/17,/1986/	
/AB/		/120MG/	/N70422/001/	
			/SEP/17,/1986/	
BX	CHELSEA LABS	80MG	N70421 001	
			SEP 17, 1986	
BX		120MG	N70422 001	
			SEP 17, 1986	

VINBLASTINE SULFATE

INJECTABLE; INJECTION

	VELSAR			
/AP/	/ADRIA/LABS/	/10MG/VIAL/	/N89565/001/	
			/AUG/18,/1987/	
AP	BULL LABS	10MG/VIAL	N89565 001	
			AUG 18, 1987	

VITAMIN A PALMITATE

CAPSULE; ORAL

	VITAMIN A			
/AA/	/SQUIBB/	/EQ 50,000 UNITS BASE/	/N80860/001/	
	∂ SQUIBB	EQ 50,000 UNITS BASE	N80860 001	

WARFARIN SODIUM

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

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
> ADD > HI TECH PHARMA 12.5MG/5ML¤ N72416 001
> ADD > SEP 28, 1990

PERMETHRIN

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

NO SEPTEMBER 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
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: 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: IMMTHER	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.	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
GENERIC: GROUP B STREPTOCOCCUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF NEONATES WITH DISSEMINATED GROUP B STREPTOCOCCAL INFECTION.	UNIVAX

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
GENERIC: GROUP B STREPTOCOCCUS IMMUNE GLOBULIN TRADE: NOT ESTABLISHED	TREATMENT OF NEONATES WITH DISSEMINATED GROUP B STREPTOCOCCAL INFECTION.	UNIVAX

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 BEN VENUE
GENERIC: LACTOBIN TRADE: LACTOBIN	TREATMENT OF AIDS ASSOCIATED DIARRHEA UNRESPONSIVE TO INITIAL ANTIDIARRHEAL THERAPY.	ROXANE LABS
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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: 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 SEROUS 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
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: ALPHA-GALACTOSIDASE A TRADE: FABRASE	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: 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
GENERIC: CROMOLYN SODIUM TRADE: GASTROCROM*/**	MASTOCYTOSIS. [DECEMBER 22, 1996]	FISONS
GENERIC: DEHYDREX TRADE: NOT ESTABLISHED	TREATMENT OF RECURRENT CORNEAL EROSION UNRESPONSIVE TO CONVENTIONAL THERAPY.	HOLLES LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF HEPARIN-ASSOCIATED THROMBOCYTOPENIA.	BERLEX LABS

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 SODIUM INJECTION TRADE: NOT ESTABLISHED	TREATMENT OF MYXEDEMA COMA.	SK&F LABS
GENERIC: MAFENIDE ACETATE SOLUTION TRADE: SULFAMYLON	FOR USE IN THE PREVENTION OF GRAFT LOSS OF MESHED AUTOGRAFTS ON EXCISED BURN WOUNDS.	STERLING DRUG
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]	ROCHE
GENERIC: MORPHINE SULFATE CONCENTRATE TRADE: INFUMORPH	FOR USE IN MICROINFUSION DEVICES FOR INTRASPINAL ADMINISTRATION IN THE TREATMENT OF INTRACTABLE CHRONIC PAIN.	ELKINS SINN

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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 SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	GYNEX
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-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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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
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-CHLORO-2'-DEOXYADENOSINE TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE MYELOID LEUKEMIA.	ST JUDE CHILDRENS
GENERIC: 566C80 TRADE: NOT ESTABLISHED	TREATMENT OF AIDS ASSOCIATED PNEUMOCYSTIS CARINII PNEUMONIA (PCP).	BURROUGHS WELLC

GENERIC: 2-CHLORO-2'-DEOXYADENOSINE TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE MYELOID LEUKEMIA.	ST JUDE CHILDRENS
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 SEPTEMBER 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 07, 1984	
THEOPHYLLINE (CAPSULE, EXTENDED RELEASE AND TABLET, EXTENDED RELEASE)	SEP 07, 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	FERNDALE 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

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
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

REFERENCES
PATENT USE CODE

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
						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			
	19972 001	CARTEOLOL HYDROCHLORIDE; OPTIPRESS	4309432	JAN 05, 1999		NDF	MAY 23, 1993
			3910924	OCT 07, 1994		NCE	DEC 28, 1993
	19966 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NP	FEB 22, 1993
						NCE	DEC 27, 1990
	20044 001	COLFOSCERIL PALMITATE; EXOSURF NEONATAL				NCE	AUG 02, 1995
						ODE	AUG 02, 1997
>ADD>	19813 001	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43	NDF	AUG 07, 1993
			4144317	SEP 09, 1992			
			4060084	JUN 28, 1994	U-43		
>ADD>	19813 002	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43	NDF	AUG 07, 1993
			4144317	SEP 09, 1992			
			4060084	JUN 28, 1994	U-43		
>ADD>	19813 003	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43	NDF	AUG 07, 1993
			4144317	SEP 09, 1992			
			4060084	JUN 28, 1994	U-43		
>ADD>	19813 004	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43	NDF	AUG 07, 1993
			4144317	SEP 09, 1992			
			4060084	JUN 28, 1994	U-43		
	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		

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>	19032 001	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
>DLT>	19032 001	GUANFACINE HYDROCHLORIDE; TENEX	3632645	JAN 04, 1991			
>ADD>	19032 002	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
>DLT>	19032 002	GUANFACINE HYDROCHLORIDE; TENEX	3632645	JAN 04, 1991			
>ADD>	19032 003	GUANFACINE HYDROCHLORIDE; TENEX	3632645	OCT 26, 1990		NCE	OCT 27, 1991
>DLT>	19032 003	GUANFACINE HYDROCHLORIDE; TENEX	3632645	JAN 04, 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			
>ADD>	50661 001	IDARUBICIN; IDAMYCIN				ODE	SEP 27, 1997
>ADD>	50661 002	IDARUBICIN; 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			
	18956 002	IOHEXOL; OMNIPAQUE 240	4021481	MAY 03, 1994			
	18735 002	IOPAMIDOL; ISOVUE-300				I-46	MAY 30, 1993
>ADD>						I-52	SEP 21, 1993
	18735 003	IOPAMIDOL; ISOVUE-370				I-48	OCT 04, 1992
	19927 001	KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999		NDF	AUG 31, 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	METIPRANOLOL HYDROCHLOIDE; OPTIPRANOLOL				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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 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
19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2000			
19818 001	PEGADEMASE BOVINE; ADAGEN	4179337	DEC 18, 1996			
19918 001	PERMETHRIN; NIX				NCE	MAR 21, 1995
19638 001	PIPECURONIUM BROMIDE; ARDUAN	4024163	MAY 17, 1996		NCE	MAR 31, 1991
87361 001	PROCAINAMIDE HYDROCHLORIDE; PRONESTYL-SR				NCE	JUN 26, 1995
19627 001	PROPOFOL; DIPRIVAN	4252786	FEB 24, 1998			
10929 001	SODIUM IODIDE, I-131; IODOTOPE	4056635	NOV 01, 1996		NCE	OCT 02, 1994
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	4349529	SEP 14, 1999			
17376 001	SULFAMETHOXAZOLE; SEPTRA				I-44	MAY 11, 1993
17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-49	JUN 15, 1993
17377 001	SULFAMETHOXAZOLE; BACTRIM	4209513	JUN 24, 1997		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				I-49	JUN 15, 1993
18107 001	TECHNETIUM TC-99M MEDRONATE KIT; MDP-SQUIBB	4536516	AUG 20, 2002		I-50	JUN 21, 1993
19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3	4115541	SEP 19, 1995			
17339 001	TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR; MINITEC				NCE	JUN 15, 1995
18017 001	TIMOLOL MALEATE; BLOCADREN	4041317	AUG 09, 1994			
18017 002	TIMOLOL MALEATE; BLOCADREN	3920995	NOV 18, 1992			
18017 004	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
19614 001	VERAPAMIL HYDROCHLORIDE; VERELAN				I-41	MAR 03, 1993
19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN				I-41	MAR 03, 1993
		4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
		4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993

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
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