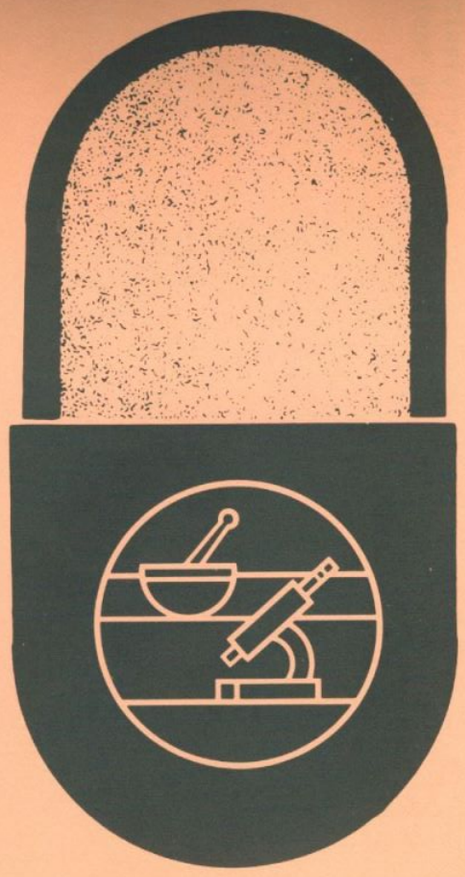
CUMULATIVE SUPPLEMENT 8
JAN'90-AUG'90



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

10TH EDITION

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

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

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AUGUST 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Division of Blood and Blood Products and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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	
SINGLE SOURCE	2030 (20.1%)	2039 (20.2%)	2064 (20.5%)	
MULTISOURCE	8093 (79.9%)	8056 (79.8%)	8019 (79.5%)	
THERAPEUTICALLY EQUIVALENT	7222 (71.3%)	7213 (71.5%)	7183 (71.2%)	
NOT THERAPEUTICALLY EQUIVALENT	752 (7.4%)	723 (7.1%)	713 (7.1%)	
EXCEPTIONS[1]	119 (1.2%)	120 (1.2%)	123 (1.2%)	
NEW MOLECULAR ENTITIES APPROVED	--	3	4	
NUMBER OF APPLICANTS	400	406	414	

[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; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
/AA/ /PBI/ /500MG;5MG/ /N89290/001/ /MAY/29,/1987/
ə PBI 500MG;5MG N89290 001 MAY 29, 1987

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

ACETYLCYSTEINE

/SOLUTION;/INHALATION/
/ACETYLCYSTEINE/
/AN/ /QUAD/PHARMS/ /10%/ /N71740/001/ /AUG/11,/1987/
/AN/ /20%/ /N71741/001/ /AUG/11,/1987/

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

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

SOLUTION; INHALATION, ORAL
ACETYLCYSTEINE
AN QUAD PHARMS 10% N71740 001 AUG 11, 1987
AN 20% N71741 001 AUG 11, 1987

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL
MUCOSOL-10
AN DEY LABS 10% N70575 001 OCT 14, 1986

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

ACETYLDIGITOXIN

>DLT> /TABLET;/ORAL/
>DLT> /ACYLANID/
>DLT> /SANDOZ/PHARMS/ /0.1MG/ /N09436/001/
>ADD> ə 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

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
ə 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

>DLT<	/AMMONIUM/CHLORIDE/0.9%/IN/NORMAL/SALINE/			
>DLT<	/KENDALL/MCGAW/	/900MG/100ML/		/N06580/001/
>ADD<	@ 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
/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/

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

/ORPHENADRINE/COMPOUND/				
@ 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

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

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

>ADD<	DIPHENOXYLATE HCL AND ATROPINE SULFATE			
>ADD< AA	MYLAN PHARMS	0.025MG;2.5MG		N85762 001

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

		DIPHENOXYLATE HCL AND ATROPINE SULFATE	
> DLT >/AA/	/PARKE/DAVIS/	/0.025MG;2.5MG/	/N87131/001/
> ADD >	@ PARKE DAVIS	0.025MG;2.5MG	N87131 001
> DLT >	/DIPHENOXYLATE HCL W/ ATROPINE SULFATE/		
> DLT >/AA/	/MYLAN/PHARMS/	/0.025MG;2.5MG/	/N85762/001/

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; 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

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR; ORAL

	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		
> DLT >/AA/	/REID/ROWELL/	/16.2MG/	/N83606/001/
> DLT >/AA/		/32.4MG/	/N83898/001/
> ADD >	@ REID ROWELL	16.2MG	N83606 001
> ADD >	@	32.4MG	N83898 001
> DLT >		/48.6MG/	/N83897/001/
> ADD >	@	48.6MG	N83897 001
> DLT >		/97.2MG/	/N83896/001/
> ADD >	@	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

>_DLT_>	/MEAD/JOHNSON/	/EQ/250MG/BASE/	/N50512/002/	
>_ADD_>	@ MEAD JOHNSON	EQ 250MG BASE	N50512 002	

CEFADROXIL

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

DURICEF

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

ULTRACEF

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

TABLET; ORAL
/CEFADROXIL/

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

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

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

CEPHALEXIN

TABLET; ORAL
CEPHALEXIN
/BX/ /VITARINE/ — /EQ/250MG/BASE/ — /N62863/001/ /AUG/11,/1988/
/BX/ — /EQ/500MG/BASE/ — /N62863/002/ /AUG/11,/1988/
/BX/ — /EQ/1GM/BASE/ — /N62863/003/ /AUG/11,/1988/
ə VITARINE — EQ 250MG BASE — N62863 001 AUG 11, 1988
ə — EQ 500MG BASE — N62863 002 AUG 11, 1988
ə — EQ 1GM BASE — N62863 003 AUG 11, 1988

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION
CEPHAPIRIN SODIUM
/AP/ /LYPHOMED/ — /EQ 20GM BASE/VIAL/ — /N62723/005/ /NOV/17,/1986/
ə LYPHOMED — EQ 20GM BASE/VIAL — N62723 005 NOV 17, 1986

CEPHRADINE

CAPSULE; ORAL
CEPHRADINE
/BX/ /VITARINE/ — /250MG/ — /N62813/001/ /FEB/25,/1988/
/BX/ — /500MG/ — /N62813/002/ /FEB/25,/1988/
ə VITARINE — 250MG — N62813 001 FEB 25, 1988
ə — 500MG — N62813 002 FEB 25, 1988

CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED

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

CHLORDIAZEPOXIDE; ESTROGENS, ESTERIFIED

TABLET; ORAL

MENRIUM 10-4			
ROCHE	10MG;0.4MG	N14740 006	
MENRIUM 5-2			
ROCHE	5MG;0.2MG	N14740 002	
MENRIUM 5-4			
ROCHE	5MG;0.4MG	N14740 004	

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

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

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

TAGAMET HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

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

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

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

CLOBETASOL PROPIONATE

SOLUTION; TOPICAL

TEMOVATE			
GLAXO	0.05%¤		N19966 001
			FEB 22, 1990

CLOCORTOLONE PIVALATE

CREAM; TOPICAL

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

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

>DLT>	/AB/	/INTERPHARM/	/0.1MG/		/N71252/001/
>DLT>					/OCT/01,/1986/
>DLT>	/AB/		/0.2MG/		/N71253/001/
>DLT>					/OCT/01,/1986/
>DLT>	/AB/		/0.3MG/		/N71254/001/
>DLT>					/OCT/01,/1986/
>ADD>	BX	INTERPHARM	0.1MG		N71252 001
>ADD>					OCT 01, 1986
>ADD>	BX		0.2MG		N71253 001
>ADD>					OCT 01, 1986
>ADD>	BX		0.3MG		N71254 001
>ADD>					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/
ə WARNER CHILCOTT		3.75MG		N71774 001
				MAR 01, 1988
ə		7.5MG		N71775 001
				MAR 01, 1988
ə		15MG		N71776 001
				MAR 01, 1988

CLORAZEPATE DIPOTASSIUM

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/

TRIPROLIDINE HCL, PSEUDOEPHEDRINE HCL AND CODEINE PHOSPHATE

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

> ADD > COLFOSCERIL PALMITATE

> ADD > POWDER FOR RECONSTITUTION; INTRATRACHEAL
> ADD > EXOSURF NEONATAL

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

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

ə BARR LABS	0.5MG	N84766 001	

DYDROGESTERONE

TABLET; ORAL
GYNOREST

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

ERGOLOID MESYLATES

TABLET; ORAL
GERINAL

/AB/ /CHELSEA/LABS/	/1MG/	/N88207/001/ /MAR/22,/1984/	
ə 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/	
ə SUPERPHARM	0.5MG	N89233 001 SEP 23, 1986	
ə	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/	
ə BARRE NATL	2%	N62327 001 APR 19, 1982	
ə	2%	N62342 001 FEB 25, 1982	

ERYTHROMYCIN

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

>DLT >/AO/ /SAVAGE/LABS/	/8MG/ML;180MG/ML/	/N86423/001/	
>ADD > SAVAGE LABS	8MG/ML;180MG/ML	N86423 001	
>ADD > TESTOSTERONE ENANTHATE AND ESTRADIOL VALERATE			
>ADD > AO STERIS LABS	4MG/ML;90MG/ML	N85865 001	
>ADD > ə	8MG/ML;180MG/ML	N85860 001	
>DLT > /TESTOSTERONE ENANTHATE-ESTRADIOL VALERATE/			
>DLT >/AO/ /STERIS/LABS/	/4MG/ML;90MG/ML/	/N85865/001/	
/AO/	/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	

TABLET; ORAL
CONJUGATED ESTROGENS
/BP/ /CHELSEA/LABS/ /0.625MG/ /N85800/001/
@ CHELSEA LABS 0.625MG N85800 001

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN
/BS/ /PRIVATE/FMLTNS/ /1.25MG/ /N85008/001/
@ PRIVATE FMLTNS 1.25MG N85008 001

ETHANOLAMINE OLEATE

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

ETHINYL ESTRADIOL; NORETHINDRONE

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

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

ETHYLESTRENOL

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

>ADD> FENTANYL

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

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/
ə PBI		0.01%	N88757 001 FEB 11, 1985
ə		0.025%	N88756 001 MAR 28, 1985

OINTMENT; TOPICAL

FLUOCINOLONE ACETONIDE			
/AT/	/PBI/	/0.025%/	/N88742/001/ FEB/08,/1985/
ə PBI		0.025%	N88742 001 FEB 08, 1985

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

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN			
/AP/	/LYPHOMED/	/15,000 UNITS/VIAL/	/N17067/004/
ə LYPHOMED		15,000 UNITS/VIAL	N17067 004
/AP/	/STERIS/LABS/	/15,000 UNITS/VIAL/	/N17016/010/ FEB/15,/1985/
STERIS LABS		2,000 UNITS/VIAL¤	N17016 011 FEB 16, 1990
		15,000 UNITS/VIAL	N17016 010 FEB 15, 1985

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH			
/AP/	/LYPHOMED/	/100 UNITS/ML/	/N17651/010/
ə LYPHOMED		100 UNITS/ML	N17651 010
/AP/	/SOLOPAK/LABS/	/10 UNITS/ML/	/N87958/001/ APR/20,/1983/
ə SOLOPAK LABS		10 UNITS/ML	N87958 001 APR 20, 1983

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM			
> DLT > /AP/	/CHAMBERLIN/	/1,000 UNITS/ML/	/N17130/001/
> DLT > /AP/		/5,000 UNITS/ML/	/N17130/002/
> DLT > /AP/		/10,000 UNITS/ML/	/N17130/003/
> DLT > /AP/		/20,000 UNITS/ML/	/N17130/004/
> ADD > ə CHAMBERLIN		1,000 UNITS/ML	N17130 001
> ADD > ə		5,000 UNITS/ML	N17130 002
> ADD > ə		10,000 UNITS/ML	N17130 003
> ADD > ə		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/
ə LYPHOMED		1,000 UNITS/ML	N17033 001
ə		1,000 UNITS/ML	N17651 005
ə		10,000 UNITS/ML	N17651 003
ə		20,000 UNITS/ML	N17651 008
/WYETH/AYERST/LABS/		/15,000/UNITS/ML/	/N17007/005/
ə WYETH AYERST LABS		15,000 UNITS/ML	N17007 005

HOMATROPINE METHYLBROMIDE

/TABLET;/CHEWABLE;/ORAL/		
/EQUIPIN/		
/MISSION/PHARMA/	/3MG/	/N86310/001/
ə MISSION PHARMA	3MG	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/
ə SUPERPHARM		10MG	N88787 001 AUG 28, 1984
ə		25MG	N88788 001 AUG 28, 1984
ə		50MG	N88789 001 AUG 28, 1984

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE

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

TABLET; ORAL
HYDRALAZINE AND HYDROCHLORTHIAZIDE

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

HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDROCHLOROTHIAZIDE

>DLT >/AB/	/REID/ROWELL/	/25MG/	/N85323/001/	
>ADD >	ə REID ROWELL	25MG	N85323 001	

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE

/AB/	/SK&F/LABS/	/25MG;50MG/	/N16042/002/	
	SK&F LABS	25MG;50MG	N16042 002	
	/TRIAMTERENE/AND/HYDROCHLOROTHIAZIDE/			
/BX/	/BOLAR/PHARM/	/25MG;50MG/	/N71845/001/	/AUG/21,/1987/

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

>ADD > HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

>ADD > SYRUP; ORAL
>ADD > HYCOMINE
>ADD > EI DUPONT 5MG/5ML;25MG/5ML¤ N19410 001
>ADD > AUG 17, 1990
>ADD > HYCOMINE PEDIATRIC
>ADD > EI DUPONT 2.5MG/5ML;12.5MG/5ML¤ N19411 001
>ADD > 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

/HYDROTEX/

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

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION; OTIC
>ADD > PEDIOTIC
>ADD > AT BURROUGHS WELLC 1%;EQ 3.5MG BASE/ML; N62822 001
>ADD > 10,000 UNITS/ML SEP 29, 1987
>DLT > /PEDIOTIC CORTISPORIN/
>DLT >/AT/ /BURROUGHS/WELLC/ /1%;EQ 3.5MG BASE/ML;/ /N62822/001/
>DLT > /10,000 UNITS/ML/ /SEP/29,/1987/
>DLT >

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

>DLT >/AP/	/SOLOPAK/LABS/	/25MG/ML/	/N87592/001/	
>ADD >	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/
	@ MCNEIL CONSUMER	400MG	N70081 001 JUN 16, 1986
	@	600MG	N70476 001 JUN 16, 1986
/AB/	/SUPERPHARM/	/400MG/	/N70708/001/ /APR/25,/1986/
BX	SUPERPHARM	400MG	N70708 001 APR 25, 1986

IFOSFAMIDE

INJECTABLE; INJECTION
IFEX

	/BRISTOL/SQUIBB/	/3GM/VIAL/	/N19763/002/ /DEC/30,/1988/
	@ 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/
	@ VITARINE	25MG	N71711 001 JUL 05, 1988
	@	50MG	N71712 001 JUL 05, 1988

INDOMETHACIN

CAPSULE; ORAL
INDOMETHACIN

/AB/	/ZENITH/LABS/	/25MG/	/N18730/001/ /MAY/04,/1984/
/AB/		/50MG/	/N18730/002/ /MAY/04,/1984/
	@ ZENITH LABS	25MG	N18730 001 MAY 04, 1984
	@	50MG	N18730 002 MAY 04, 1984

CAPSULE, EXTENDED RELEASE; ORAL
INDOMETHACIN

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

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION
IODOHIPPURATE SODIUM I 131

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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION
ISOETHARINE HCL

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

ISOETHARINE HCL S/F

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

ISONIAZID

TABLET; ORAL

ISONIAZID

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

> ADD > SHAMPOO; TOPICAL
> ADD > NIZORAL
> ADD > JANSSEN RES 2%¤ N19927 001
> ADD > AUG 31, 1990

LEVAMISOLE HYDROCHLORIDE

TABLET; ORAL

ERGAMISOL

JANSSEN RES EQ 50MG BASE¤ N20035 001 JUN 18, 1990

MEBUTAMATE

> DLT > /TABLET;ORAL/
> DLT > /DORMATE/

> DLT >	/WALLACE/PHARMS/	/600MG/	/N17374/001/
> ADD >	ə WALLACE PHARMS	600MG	N17374 001

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

> DLT >	/AA/	/CAMALL/	/12.5MG/	/N84464/001/
	/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

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

> DLT >	/AB/	/BOLAR/PHARM/	/EQ 50MG BASE/	/N70400/001/ /NOV/25,/1986/
> DLT >	/AB/		/EQ 100MG BASE/	/N70401/001/ /NOV/25,/1986/
> ADD >	BX	BOLAR PHARM	EQ 50MG BASE	N70400 001 NOV 25, 1986
> ADD >	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/	
	@ 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/	
@ INTL MEDTN SYS	10MG/ML	N86332 001	

MEPROBAMATE

TABLET; ORAL

	MEPROBAMATE			
>DLT >/AA/	/PRIVATE/FMLTNS/	/400MG/	/N14601/001/	
>ADD >	@ PRIVATE FMLTNS	400MG	N14601 001	
/AA/	/REID/ROWELL/	/200MG/	/N84435/001/	
	@ REID ROWELL	200MG	N84435 001	

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

	NORETHIN 1/50M-21			
>ADD > AB	SCHIAPPARELLI SEARLE	0.05MG;1MG	N71539 001	
>ADD >			APR 12, 1988	
>DLT >/AB/	/SEARLE/	/0.05MG;1MG/	/N71539/001/	
>DLT >			/APR/12,/1988/	

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

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

TABLET; ORAL-28

	NORETHIN 1/50M-28			
>ADD > AB	SCHIAPPARELLI SEARLE	0.05MG;1MG	N71540 001	
>ADD >			APR 12, 1988	
>DLT >/AB/	/SEARLE/	/0.05MG;1MG/	/N71540/001/	
>DLT >			/APR/12,/1988/	
	/NORINYL/1+80/28-DAY/			
	/SYNTEX/(FP)/	/0.08MG;1MG/	/N16725/001/	
	@ SYNTEX (FP)	0.08MG;1MG	N16725 001	

METAPROTERENOL SULFATE

TABLET; ORAL

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

METHARBITAL

>DLT >	/TABLET;/ORAL/			
>DLT >	/GEMONIL/			
>DLT >	/ABBOTT/LABS/	/100MG/	/N08322/001/	
>ADD >	@ ABBOTT LABS	100MG	N08322 001	

METHICILLIN SODIUM

INJECTABLE; INJECTION

	STAPHCILLIN		
	/BRISTOL/LABS/	/EQ/900MG/BASE/VIAL/	/N50117/001/
	@ BRISTOL LABS	EQ 900MG BASE/VIAL	N50117 001
		/EQ/3.6GM/BASE/VIAL/	/N50117/002/
	@	EQ 3.6GM BASE/VIAL	N50117 002
		/EQ/5.4GM/BASE/VIAL/	/N50117/003/
	@	EQ 5.4GM BASE/VIAL	N50117 003

METHYLPREDNISOLONE SODIUM SUCCINATE

INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE

/AP/	/INTL/MEDTN/SYS/	/EQ 40MG BASE/VIAL/	/N87812/001/ /FEB/09,/1983/	> ADD >	AB	
/AP/		/EQ 125MG BASE/VIAL/	/N87813/001/ /FEB/09,/1983/	> ADD >	AB	
/AP/		/EQ 500MG BASE/VIAL/	/N87851/001/ /FEB/09,/1983/	> ADD >		
/AP/		/EQ 1GM BASE/VIAL/	/N87852/001/ /FEB/09,/1983/	> DLT >		
	ə INTL MEDTN SYS	EQ 40MG BASE/VIAL	N87812 001 FEB 09, 1983	> ADD >	AB	
	ə	EQ 125MG BASE/VIAL	N87813 001 FEB 09, 1983	> ADD >	AB	
	ə	EQ 500MG BASE/VIAL	N87851 001 FEB 09, 1983	> ADD >		
	ə	EQ 1GM BASE/VIAL	N87852 001 FEB 09, 1983	> DLT >		

METHYLTESTOSTERONE

TABLET; ORAL
METHYLTESTOSTERONE

/BP/	/WEST/WARD/PHARM/	/25MG/	/N84642/001/	
	ə WEST WARD PHARM	25MG	N84642 001	

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
METOCLOPRAMIDE HCL

AB	CORD LABS	EQ 10MG BASE¤	N72215 001 JAN 30, 1990	
AB	MARTEC PHARM	EQ 10MG BASE	N70598 001 FEB 02, 1987	
	/ə/	/EQ/10MG/BASE/	/N70598/001/ /FEB/02,/1987/	

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCIN

	LEDERLE LABS	EQ 50MG BASE¤	N50649 001 MAY 31, 1990	
		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

	WARNER CHILCOTT	EQ 50MG BASE¤	N63066 001 AUG 14, 1990	
		EQ 100MG BASE¤	N63067 001 JUL 31, 1990	

/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	

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

MORPHINE SULFATE

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

NAFARELIN ACETATE

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

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
> DLT >/AB/ /CHASE/LABS/ /10MG/ /N72409/001/
> DLT > /JUL/06,/1990/:/JUL/10,/1989/
> ADD > AB CHASE LABS 10MG N72409 001
> ADD > SEP 04, 1990 : JUL 10, 1989
> DLT >/AB/ /PUREPAC/PHARM/ /10MG/ /N72579/001/
> DLT > /APR/28,/1989/¶
> ADD > AB PUREPAC PHARM 10MG N72579 001
> ADD > APR 28, 1989
> DLT >/AB/ /20MG¤/ /N72556/001/N
> DLT > /SEP/20,/1990/:/APR/28,/1989/
> ADD > AB 20MG¤ N72556 001
> ADD > SEP 20, 1990 : APR 28, 1989

NITROGLYCERIN

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

> ADD > NITROGLYCERIN IN DEXTROSE 5%
> ADD > AP ABBOTT LABS 10MG/100ML¤ N71846 001
> ADD > AUG 31, 1990
> ADD > AP 20MG/100ML¤ N71847 001
> ADD > AUG 31, 1990
> ADD > AP 40MG/100ML¤ N71848 001
> ADD > AUG 31, 1990
> ADD > AP BAXTER 10MG/100ML N19970 001
> ADD > DEC 29, 1989
> ADD > AP 20MG/100ML N19970 002
> ADD > DEC 29, 1989
> ADD > AP 40MG/100ML N19970 003
> ADD > DEC 29, 1989
> DLT > /NITROGLYCERIN/100MG/IN/DEXTROSE/5%/
> DLT > /BAXTER/ /40MG/100ML/ /N19970/003/
> DLT > /DEC/29,/1989/
> DLT > /NITROGLYCERIN/25MG/IN/DEXTROSE/5%/
> DLT > /BAXTER/ /10MG/100ML/ /N19970/001/
> DLT > /DEC/29,/1989/
> DLT > /NITROGLYCERIN/50MG/IN/DEXTROSE/5%/
> DLT > /BAXTER/ /20MG/100ML/ /N19970/002/
> DLT > /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/0.1MG/BASE/ML/ /N19667/002/
/OCT/21,/1988/
EQ 100UGM BASE/ML N19667 002
OCT 21, 1988
/EQ/0.5MG/BASE/ML/ /N19667/003/
/OCT/21,/1988/
EQ 500UGM BASE/ML N19667 003
OCT 21, 1988

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/
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

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

PERPHENAZINE

TABLET; ORAL

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

>ADD> PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

>ADD> TABLET; ORAL
>ADD> AZO GANTRISIN
>ADD> ROCHE 50MG;500MG N19358 001
>ADD> 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

>DLT> /BP/ /ABBOTT/LABS/ /10MG/ML/ /N87956/001/ /JUL/25,/1983/
>DLT>
>ADD> @ ABBOTT LABS 10MG/ML N87956 001 JUL 25, 1983
>ADD>

PIPECURONIUM BROMIDE

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

PIPERAZINE CITRATE

SYRUP; ORAL
BRYREL

/AA/ /STERLING/DRUG/ /EQ 500MG BASE/5ML/ /N17796/001/

@ STERLING DRUG EQ 500MG BASE/5ML N17796 001

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

POWDER 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/

@ SUPERPHARM 5MG N88892 001 FEB 26, 1985

/BX/ /UDL/LABS/ /5MG/ /N87987/001/ /JAN/18,/1983/

@ UDL LABS 5MG N87987 001 JAN 18, 1983

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
PREDNISOLONE ACETATE

>DLT> /BP/ /AKORN/ /25MG/ML/ /N83032/001/
>ADD> @ AKORN 25MG/ML N83032 001

PREDNISONE

TABLET; ORAL
PREDNISONE

>DLT> /AB/ /PRIVATE/FMLTNS/ /20MG/ /N85151/001/
>ADD> @ PRIVATE FMLTNS 20MG N85151 001

PREDNISONE

TABLET; ORAL

PREDNISONE

/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

>DLT >/AA/	/PRIVATE/FMLTNS/	/15MG/	/N80977/001/	
>ADD >	ə PRIVATE FMLTNS	15MG	N80977 001	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

>DLT >/AA/	/PRIVATE/FMLTNS/	/32MG/	/N83464/001/	
>DLT >/AA/		/65MG/	/N83113/001/	
>ADD >	ə PRIVATE FMLTNS	32MG	N83464 001	
>ADD >	ə	65MG	N83113 001	

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERAL

/AB/	/WYETH/AYERST/LABS/	/20MG/	/N16418/010/ /OCT/18,/1982/	
	ə 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 HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

>DLT >/AB/	/DANBURY/PHARMA/	/90MG/	/N71183/001/ /OCT/06,/1986/	
>DLT > >ADD >	ə 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	
	/ə/	/10MG/	/N70120/001/ /AUG/06,/1985/	
	/ə/	/20MG/	/N70121/001/ /AUG/06,/1985/	
	/ə/	/40MG/	/N70122/001/ /AUG/06,/1985/	
	/ə/	/60MG/	/N70123/001/ /OCT/29,/1986/	
	/ə/	/80MG/	/N70124/001/ /AUG/06,/1985/	
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/
	ə ANABOLIC	50MG	N80285 001

PROTEIN HYDROLYSATE

/INJECTABLE;/INJECTION/

/AMINOSOL/5%/

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

PROTEIN HYDROLYSATE

/INJECTABLE;/INJECTION/
/HYPROTIGEN 5%/
/AP/ /KENDALL/MCGAW/ /5%/ /N06170/003/
/JAN/10,/1984/
@ KENDALL MCGAW 5% N06170 003
JAN 10, 1984

QUAZEPAM

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

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
/AB/ /LEDERLE/LABS/ /200MG/ /N86176/001/
@ LEDERLE LABS 200MG N86176 001

RAUWOLFIA SERPENTINA

TABLET; ORAL
/WOLFINA/
/BP/ /FOREST/PHARMS/ /100MG/ /N09255/006/
@ FOREST PHARMS 100MG N09255 006

SARALASIN ACETATE

>DLT> /INJECTABLE;/INJECTION/
>DLT> /SARENIN/
>DLT> /NORWICH/EATON/ /EQ/0.6MG/BASE/ML/ /N18009/001/
>ADD> @ NORWICH EATON EQ 0.6MG BASE/ML N18009 001

SODIUM CHLORIDE

INJECTABLE; INJECTION
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/
@ KENDALL MCGAW 3GM/100ML N19635 003
MAR 09, 1988
SODIUM CHLORIDE 5% IN PLASTIC CONTAINER
/AP/ /BAXTER/ /5GM/100ML/ /N19022/002/
/NOV/01,/1983/
BAXTER 5GM/100ML N19022 002
NOV 01, 1983
/AP/ /KENDALL/MCGAW/ /5GM/100ML/ /N19635/004/
/MAR/09,/1988/
@ KENDALL MCGAW 5GM/100ML N19635 004
MAR 09, 1988

SOYBEAN OIL

INJECTABLE; INJECTION
>DLT> /TRAVAMULSION 20%/
>DLT> /AP/ /BAXTER/ /20%/ /N18758/001/
>DLT> /FEB/15,/1983/
>DLT>
>ADD> @ BAXTER 20% N18758 001
>ADD> FEB 15, 1983

SULFAMETHIZOLE

TABLET; ORAL
>DLT> /MICROSUL/
>DLT> /FOREST/PHARMS/ /1GM/ /N86012/001/
>ADD> @ FOREST PHARMS 1GM N86012 001

SULFASALAZINE

TABLET; ORAL
/S.A.S.-500/
/AB/ /REID/ROWELL/ /500MG/ /N83450/001/
@ REID ROWELL 500MG N83450 001

SULFISOXAZOLE

TABLET; ORAL

>DLT>	/SULFOXIN/			
>DLT>/AB/	/REID/ROWELL/	/500MG/	/N80040/001/	
>ADD>	@ REID ROWELL	500MG	N80040 001	

SULINDAC

TABLET; ORAL

SULINDAC

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

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

AN-MAA

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

TECHNETIUM TC-99M 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/	/SYNCOR/INTL/	/N/A/	/N17714/001/	

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

>DLT> /BC/	/RW/JOHNSON/	/250MG/	/N86471/001/	
>DLT>			/FEB/08,/1985/	
>ADD>	@ RW JOHNSON	250MG	N86471 001	
>ADD>			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

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	

TIMOLOL MALEATE

TABLET; ORAL
TIMOLOL MALEATE

/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 HYDROCHLORIDE

TABLET; ORAL
TRAZODONE HCL

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

TRIAMCINOLONE ACETONIDE

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

TRIAMTERENE

CAPSULE; ORAL
DYRENIUM

/SKAF/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/
	ə CHELSEA LABS	4MG	N85962 001

TRIENTINE HYDROCHLORIDE

CAPSULE; ORAL
/CUPRID/

/MSD/	/250MG/	/N19164/001/ /NOV/08,/1985/

TRIENTINE HYDROCHLORIDE

VERAPAMIL HYDROCHLORIDE

TRIENTINE HYDROCHLORIDE

CAPSULE; ORAL
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/
ə 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/
ə VITARINE		EQ 25MG BASE	N71832 001 SEP 10, 1987
ə		EQ 50MG BASE	N71833 001 SEP 10, 1987
ə		EQ 100MG BASE	N71834 001 SEP 10, 1987

TRISULFAPYRIMIDINES

SUSPENSION; ORAL
/TRIPLE SULFA/

/AB/	/BARRE/NATL/	/500MG/5ML/	/N80280/001/
ə BARRE NATL		500MG/5ML	N80280 001

UREA

INJECTABLE; INJECTION
/STERILE UREA/

/AP/	/ABBOTT/LABS/	/40GM/VIAL/	/N17698/001/
ə 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/
ə SEARLE		2.5MG/ML	N19038 001 MAR 30, 1984

VERAPAMIL HCL

/AP/	/LYPHOMED/	/2.5MG/ML/	/N70348/001/ /MAY/01,/1986/
ə 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

>DLT >/AA/	/SQUIBB/	/EQ 50,000 UNITS BASE/	/N80860/001/
>ADD >	ə 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

PERMETHRIN

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

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE DIVISION OF BLOOD AND BLOOD PRODUCTS LIST
CUMULATIVE SUPPLEMENT NUMBER 8 / JAN '90 - AUG '90

NO AUGUST 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: 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: [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

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: LEUKOPOIETIN TRADE: LEUKINE	TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT, FOR THE PROMOTION OF EARLY ENGRAFTMENT, AND FOR THE TREATMENT OF GRAFT FAILURE AND DELAY OF ENGRAFTMENT.	IMMUNEX
GENERIC: MONOCLONAL ANTIBODIES PM-81 AND AML 2-23 TRADE: NOT ESTABLISHED	FOR EXOGENOUS DEPLETION OF CD14 AND CD15 POSITIVE ACUTE MYELOID LEUKEMIC BONE MARROW CELLS FROM PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION.	MEDAREX
GENERIC: ONCORAD OV103 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CARCINOMA.	CYTOGEN

GENERIC: ONCORAD OV103 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CARCINOMA.	CYTOGEN

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
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: 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

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF HEPARIN-ASSOCIATED THROMBOCYTOPENIA.	BERLEX LABS
GENERIC: L-BACLOFEN TRADE: NOT ESTABLISHED	TREATMENT OF TRIGEMINAL NEURALGIA.	GERHARD H. FROMM, M.D. UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE
GENERIC: 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: 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

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: 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

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

NO AUGUST 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

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
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.

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
>ADD>	20044 001	COLFOSCERIL PALMITATE; EXOSURF NEONATAL				NCE	AUG 02, 1995
>ADD>						ODE	AUG 02, 1997
>ADD>	19813 001	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
>ADD>			4144317	SEP 09, 1992			
>ADD>			4060084	JUN 28, 1994	U-43		
>ADD>	19813 002	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
>ADD>			4144317	SEP 09, 1992			
>ADD>			4060084	JUN 28, 1994	U-43		
>ADD>	19813 003	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
>ADD>			4144317	SEP 09, 1992			
>ADD>			4060084	JUN 28, 1994	U-43		
>ADD>	19813 004	FENTANYL; DURAGESIC	4588580	MAY 13, 2003	U-43		
>ADD>			4144317	SEP 09, 1992			
>ADD>			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
>ADD>	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
	17556 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
	17818 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
	17824 001	HALCINONIDE; HALOG	3892856	JUL 01, 1992			
	18234 001	HALCINONIDE; HALOG-E	4048310	SEP 13, 1994			
	19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	18956 002	IOHEXOL; OMNIPAQUE 240	4021481	MAY 03, 1994			
	18735 002	IOPAMIDOL; ISOVUE-300				I-46	MAY 30, 1993
	18735 003	IOPAMIDOL; ISOVUE-370				I-48	OCT 04, 1992
>ADD>	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; METIPRANOLOL HCL				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			
>ADD>	19753 001	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
			3740395	JUN 19, 1990		NCE	JUN 19, 1995
>ADD>	19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
			3740395	JUN 19, 1990		NCE	JUN 19, 1995
>ADD>	19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3864487	FEB 04, 1992			
			3740395	JUN 19, 1990		NCE	JUN 19, 1995
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		NCE	FEB 13, 1995
	19356 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	MAR 01, 1993
						NDF	JUN 18, 1993
>ADD>	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN				D-1	JUL 05, 1993
>ADD>	72409 001	NIFEDIPINE; NIFEDIPINE				PC	MAR 02, 1991
	19715 001	OLSALAZINE SODIUM; DIPENTUM				NCE	JUL 31, 1995
>ADD>	19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 2000			
>DLT>	19810 001	OMEPRAZOLE; PRILOSEC	4255431	MAR 10, 1998			

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
	19818 001	PEGADEMASE BOVINE; ADAGEN	4179337	DEC 18, 1996			
						NCE	MAR 21, 1995
	19918 001	PERMETHRIN; NIX	4024163	MAY 17, 1996		NCE	MAR 31, 1991
	19638 001	PIPECURONIUM BROMIDE; ARDUAN				NCE	JUN 26, 1995
	87361 001	PROCAINAMIDE HYDROCHLORIDE; PRONESTYL-SR	4252786	FEB 24, 1998			
>ADD>	19627 001	PROPOFOL; DIPRIVAN	4056635	NOV 01, 1996		NCE	OCT 02, 1994
>DLT>	19627 001	PROPOFOL; DIPRIVAN	4056635	NOV 01, 1994			
	10929 001	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	10929 002	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	10929 003	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	18333 001	SUCRALFATE; CARAFATE				I-44	MAY 11, 1993
>ADD>	18738 001	SULCONAZOLE NITRATE; EXELDERM	4055652	OCT 25, 1996			
>DLT>	18738 001	SULCONAZOLE NITRATE; EXELDERM	4055652	OCT 25, 1996			
	17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-49	JUN 15, 1993
	17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-49	JUN 15, 1993
	17598 001	SULFAMETHOXAZOLE; SEPTRA				I-49	JUN 15, 1993
	17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-49	JUN 15, 1993
	17970 001	TAMOXIFEN CITRATE; NOLVADEX	4536516	AUG 20, 2002		I-50	JUN 21, 1993
	18107 001	TECHNETIUM TC-99M MEDRONATE KIT; MDP-SQUIBB	4115541	SEP 19, 1995			
	19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3				NCE	JUN 15, 1995
	17339 001	TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR; MINITEC	4041317	AUG 09, 1994			
			3920995	NOV 18, 1992			
	18017 001	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
	18017 002	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
	18017 004	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
	19614 001	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
	19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006	U-3	NDF	MAY 29, 1993
	19655 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
			4833130	FEB 02, 2005		I-47	MAY 02, 1993
			4828838	FEB 02, 2005		ODE	MAR 19, 1994
			4724232	FEB 02, 2005		NCE	MAR 19, 1992
	19910 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
			4833130	FEB 02, 2005		ODE	MAR 19, 1994
			4818538	FEB 02, 2005		I-47	MAY 02, 1993
			4724232	FEB 02, 2005		NCE	MAR 19, 1992
	19951 001	ZIDOVUDINE; RETROVIR	4837208	FEB 02, 2005			
			4833130	FEB 02, 2005		NCE	MAR 19, 1992
			4818538	FEB 02, 2005			
			4724232	FEB 02, 2005		ODE	MAR 19, 1994