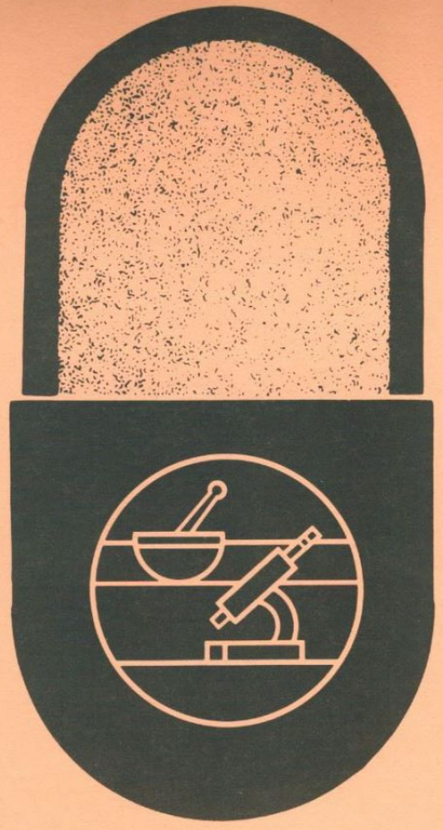
CUMULATIVE SUPPLEMENT 6
JAN'90-JUN'90



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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JUNE 1990

CONTENTS

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CUMULATIVE SUPPLEMENT 6

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of Blood and Blood Products and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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

@ PBI 500MG;5MG N89290 001 MAY 29, 1987

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

ACETYLCYSTEINE

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

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

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

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

ACETYLCYSTEINE

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

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

ALBUTEROL SULFATE

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

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
AMILORIDE HCL AND HYDROCHLOROTHIAZIDE
/AB/ /BARR/LABS/ /5MG;50MG/ /N71111/001/ /DEC/25,/1990/;/MAY/10,/1988/
AB BARR LABS 5MG;50MG N71111 001 MAY 10, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL
/AB/ /CHELSEA/LABS/ /50MG;4MG/ /N71558/001/ /MAR/02,/1987/
BX CHELSEA LABS 50MG;4MG N71558 001 MAR 02, 1987

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
BIPHETAMINE 12.5
FISONS EQ 6.25MG BASE; EQ 6.25MG BASE N10093 007
/PENNWALT/ /EQ/6.25MG/BASE;/ /EQ/6.25MG/BASE/ /N10093/007/

AMPHETAMINE RESIN COMPLEX; DEXTROAMPHETAMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

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/	
ə VITARINE	385MG;30MG;25MG	N71564 001 JUN 23, 1988	
/ORPHENADRINE/COMPOUND/DOUBLE/STRENGTH/			
/BX/ /VITARINE/	/770MG;60MG;50MG/	/N71565/001/ /JUN/23,/1988/	
ə VITARINE	770MG;60MG;50MG	N71565 001 JUN 23, 1988	

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

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

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	

BACLOFEN

TABLET; ORAL

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

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

	BETAMETHASONE DIPROPIONATE			
AB	CLAY PARK LABS	EQ 0.05% BASE¤	N72536 001 JAN 31, 1990	

LOTION; TOPICAL

	BETAMETHASONE DIPROPIONATE			
AB	CLAY PARK LABS	EQ 0.05% BASE¤	N72538 001 JAN 31, 1990	

BETAMETHASONE DIPROPIONATE

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

/BROMANATE/

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

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

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

INJECTABLE; INJECTION
TPN ELECTROLYTES IN PLASTIC CONTAINER

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

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

POWDER FOR RECONSTITUTION; ORAL
CEPHALEXIN

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

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/
@	VITARINE	EQ 250MG BASE	N62863 001 AUG 11, 1988
@		EQ 500MG BASE	N62863 002 AUG 11, 1988
@		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/
@	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/
@	VITARINE	250MG	N62813 001 FEB 25, 1988
@		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/
@	PUREPAC PHARM	4MG	N86306 001
/AA/	/ROXANE/LABS/	/4MG/	/N80626/001/
@	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

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
/TAGAMET/IN/SODIUM/CHLORIDE/0.9%/IN/PLASTIC/CONTAINER/
/SKAF/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

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

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
> ADD > BULL LABS 20MG/ML¤ N71868 001 JUN 04, 1990
> ADD >

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

DEXTROSE; SODIUM CHLORIDE

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

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

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

DIAZEPAM

TABLET; ORAL
DIAZEPAM
/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

TABLET; ORAL
DEXAMETHASONE
∂ BARR LABS 0.5MG N84766 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

DINOPROST TROMETHAMINE

/INJECTABLE;/INJECTION/
/PROSTIN/F2/ALPHA/
/UPJOHN/ /EQ/5MG/BASE/ML/ /N17434/001/
∂ UPJOHN EQ 5MG BASE/ML N17434 001

DISOPYRAMIDE PHOSPHATE

CAPSULE; ORAL
DISOPYRAMIDE PHOSPHATE
/AB/ /CHELSEA/LABS/ /EQ 100MG BASE/ /N71020/001/ /DEC/01,/1986/
/AB/ /EQ 150MG BASE/ /N71021/001/ /DEC/01,/1986/
BX CHELSEA LABS EQ 100MG BASE N71020 001 DEC 01, 1986
BX EQ 150MG BASE N71021 001 DEC 01, 1986

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
ADAPIN
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

ERGOLOID MESYLATES

TABLET; ORAL
/GERIMAL/
/AB/ /CHELSEA/LABS/ /1MG/ /N88207/001/ /MAR/22,/1984/
∂ CHELSEA LABS 1MG N88207 001 MAR 22, 1984

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

>DLT >	/AA/	/SUPERPHARM/	/0.5MG/	/N89233/001/ /SEP/23,/1986/
>DLT >				
>DLT >	/AA/		/1MG/	/N89234/001/ /SEP/23,/1986/
>DLT >				
>ADD >		ə SUPERPHARM	0.5MG	N89233 001 SEP 23, 1986
>ADD >				
>ADD >		ə	1MG	N89234 001 SEP 23, 1986
>ADD >				

ERYTHROMYCIN

SOLUTION; TOPICAL
ERYTHROMYCIN

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

TABLET, DELAYED RELEASE; ORAL
E-BASE

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

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
TESTOSTERONE ENANTHATE-ESTRADIOL VALERATE

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

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

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

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN

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

ETHYLESTRENOL

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

FENTANYL CITRATE

INJECTABLE; INJECTION
FENTANYL CITRATE

AP		ABBOTT LABS	EQ 0.05MG BASE/ML¤	N70636 001 APR 30, 1990
AP			EQ 0.05MG BASE/ML¤	N70637 001 APR 30, 1990

FLUCONAZOLE

INJECTABLE; INJECTION
DIFLUCAN

		PFIZER CTL RES	2MG/ML¤	N19950 001 JAN 29, 1990

FLUCONAZOLE

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

FLUNISOLIDE

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

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

FLUOCINOLONE ACETONIDE

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

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

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN
/AP/ /LYPHOMED/ /15,000 UNITS/VIAL/ /N17067/004/
@ LYPHOMED 15,000 UNITS/VIAL N17067 004

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN
/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/ /SOLOPAK/LABS/ /10 UNITS/ML/ /N87958/001/ /APR/20,/1983/
@ SOLOPAK LABS 10 UNITS/ML N87958 001 APR 20, 1983

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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL
>DLT >/AA/ /SUPERPHARM/ /10MG/ /N88787/001/ /AUG/28,/1984/
>DLT >/AA/ /25MG/ /N88788/001/ /AUG/28,/1984/
>DLT >/AA/ /50MG/ /N88789/001/ /AUG/28,/1984/
>ADD > @ SUPERPHARM 10MG N88787 001 AUG 28, 1984
>ADD > @ 25MG N88788 001 AUG 28, 1984
>ADD > @ 50MG N88789 001 AUG 28, 1984

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE
>DLT >/AB/ /SUPERPHARM/ /25MG;25MG/ /N89200/001/ /FEB/09,/1987/
>ADD > @ SUPERPHARM 25MG;25MG N89200 001 FEB 09, 1987

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL
HYDRALAZINE AND HYDROCHLORTHIAZIDE

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

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL
DYAZIDE

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

/TRIAMTERENE/AND/HYDROCHLOROTHIAZIDE/

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

TABLET; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE

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

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/	

HOGENIC HC

AT	SYOSSET LABS	1%	N87427 001 APR 04, 1988	

HYDROCORTISONE

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	

IBUPROFEN

TABLET; ORAL
IBUPROFEN

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

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL
IMIPRAMINE HCL

> ADD > > ADD >	AB	MUTUAL PHARM	10MG	N81048 001 JUN 05, 1990
> ADD > > ADD >	AB		25MG	N81049 001 JUN 05, 1990
> ADD > > ADD >	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	

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

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

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

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

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION

IODOHIPPURATE SODIUM I 131

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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

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

ISOETHARINE HCL S/F

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

ISONIAZID

TABLET; ORAL

ISONIAZID

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

ISOSORBIDE DINITRATE

TABLET; ORAL

ISOSORBIDE DINITRATE

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

>ADD> LEVAMISOLE HYDROCHLORIDE

>ADD> TABLET; ORAL

>ADD> ERGAMISOL

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

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL

>DLT >	/AA/	/SUPERPHARM/	/12.5MG/	/N89113/001/ /AUG/20,/1985/
>DLT >				
>DLT >	/AA/		/25MG/	/N89114/001/ /AUG/20,/1985/
>DLT >				
>ADD >		@ SUPERPHARM	12.5MG	N89113 001 AUG 20, 1985
>ADD >				
>ADD >		@	25MG	N89114 001 AUG 20, 1985
>ADD >				

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

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

MEFENAMIC ACID

CAPSULE; ORAL

/MEFENAMIC/ACID/

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

PONSTEL

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

MEGESTROL ACETATE

TABLET; ORAL

MEGESTROL ACETATE

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

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/AA/	/REID/ROWELL/	/200MG/	/N84435/001/
	@ REID ROWELL	200MG	N84435 001

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

/NORINYL/1+80/21-DAY/

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

TABLET; ORAL-28

/NORINYL/1+80/28-DAY/

	/SYNTEX/(FP)/	/0.08MG;1MG/	/N16725/001/
	@ SYNTEX (FP)	0.08MG;1MG	N16725 001

METAPROTERENOL SULFATE

TABLET; ORAL

METAPROTERENOL SULFATE

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

METHICILLIN SODIUM

INJECTABLE; INJECTION

STAPHCILLIN

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

METHYLTESTOSTERONE

TABLET; ORAL

METHYLTESTOSTERONE

>DLT >	/BP/	/WEST/WARD/PHARM/	/25MG/	/N84642/001/
>ADD >		@ WEST WARD PHARM	25MG	N84642 001

METOCLOPRAMIDE HYDROCHLORIDE

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

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

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCIN
> DLT > /LEDERLE/LABS/ /EQ/50MG/BASE/ /N50315/002/
> ADD > ∂ LEDERLE LABS EQ 50MG BASE N50315 002
> ADD > EQ 50MG BASE¤ N50649 001
> ADD > MAY 31, 1990
> DLT > /EQ/100MG/BASE/ /N50315/001/
> ADD > ∂ EQ 100MG BASE N50315 001
> ADD > EQ 100MG BASE¤ N50649 002
> ADD > MAY 31, 1990

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

> ADD > MORICIZINE HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > ETHMOZINE
> ADD > DUPONT PHARMS 200MG¤ N19753 001 JUN 19, 1990
> ADD > 250MG¤ N19753 002 JUN 19, 1990
> ADD > 300MG¤ N19753 003 JUN 19, 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

> ADD > GEL; TOPICAL
> ADD > NAFTIN
> ADD > 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/	/PUREPAC/PHARM/	/20MG/		/N72556/001/ /APR/28,/1989/
AB	PUREPAC PHARM	20MG		N72556 001 SEP 20, 1990 : APR 28, 1989

NITROGLYCERIN

INJECTABLE; INJECTION

NITRO-BID

AP	MARION MERRELL DOW	10MG/ML¤		N71159 001 FEB 28, 1990

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

SANDOSTATIN

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

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

>DLT >/AB/	/CHELSEA/LABS/	/10MG/		/N71661/001/ /MAR/02,/1988/
>DLT > >DLT >/AB/		/15MG/		/N71662/001/ /MAR/02,/1988/
>DLT > /AB/		/30MG/		/N71663/001/ /MAR/02,/1988/
>ADD > BX	CHELSEA LABS	10MG		N71661 001 MAR 02, 1988
>ADD > >ADD > BX		15MG		N71662 001 MAR 02, 1988
>ADD > BX		30MG		N71663 001 MAR 02, 1988

PEGADEMASE BOVINE

INJECTABLE; INJECTION

ADAGEN

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

PENBUTOLOL SULFATE

TABLET; ORAL

LEVATOL

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

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM IN PLASTIC CONTAINER

BAXTER	20,000 UNITS/ML¤	>ADD >	N50638 001 JUN 25, 1990
	40,000 UNITS/ML¤	>ADD >	N50638 002 JUN 25, 1990
	60,000 UNITS/ML¤	>ADD >	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

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

IONAMIN-15

FISONS /PENNWALT/	EQ 15MG BASE /EQ/15MG/BASE/		N11613 004 /N11613/004/

IONAMIN-30

FISONS /PENNWALT/	EQ 30MG BASE /EQ/30MG/BASE/		N11613 002 /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	
>DLT>	/PHENYTEX/			
>DLT> /BX/	/BOLAR/PHARM/	/100MG¤/	/N88711/001/ /DEC/21,/1984/	
>DLT>				
>ADD>	@ BOLAR PHARM	100MG¤	N88711 001 DEC 21, 1984	
>ADD>				

>ADD> PIPECURONIUM BROMIDE

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

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

>DLT> /BX/	/SUPERPHARM/	/5MG/	/N88892/001/ /FEB/26,/1985/	
>DLT>				
>ADD>	@ SUPERPHARM	5MG	N88892 001 FEB 26, 1985	
>ADD>				
/BX/	/UDL/LABS/	/5MG/	/N87987/001/ /JAN/18,/1983/	
	@ UDL LABS	5MG	N87987 001 JAN 18, 1983	

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/	
	@ UDL LABS	5MG	N87984 001 JAN 18, 1983	
	@	10MG	N87985 001 JAN 18, 1983	
	@	20MG	N87986 001 JAN 18, 1983	

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 HYDROCHLORIDE

TABLET; ORAL

	/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	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		
/BP/	/ANABOLIC/	/50MG/	/N80285/001/
	∂ ANABOLIC	50MG	N80285 001

PROTEIN HYDROLYSATE

INJECTABLE; INJECTION

	AMINOSOL 5%		
/AP/	/ABBOTT/LABS/	/5%/	/N05932/012/ /JAN/31,/1985/
	ABBOTT LABS	5%	N05932 012 JAN 31, 1985
	/HYPROTIGEN 5%/		
/AP/	/KENDALL/MCGAW/	/5%/	/N06170/003/ /JAN/10,/1984/
	∂ KENDALL MCGAW	5%	N06170 003 JAN 10, 1984

QUAZEPAM

TABLET; ORAL

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

QUINIDINE SULFATE

TABLET; ORAL

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

RAUWOLFIA SERPENTINA

TABLET; ORAL

	/WOLFINA/		
/BP/	/FOREST/PHARMS/	/100MG/	/N09255/006/
	∂ FOREST PHARMS	100MG	N09255 006

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

INJECTABLE; INJECTION

SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

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

SODIUM CHLORIDE 5% IN PLASTIC CONTAINER

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

SULFASALAZINE

TABLET; ORAL

/S.A.S.-500/

/AB/	/REID/ROWELL/	/500MG/	/N83450/001/
	@ REID ROWELL	500MG	N83450 001

SULINDAC

TABLET; ORAL

SULINDAC

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

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION

AN-MAA

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

> ADD > TECHNETIUM TC-99M MERTIATIDE KIT

> ADD > INJECTABLE; INJECTION
> ADD > TECHNESCAN MAG3

> ADD >	MALLINCKRODT	N/A	N19882 001
> ADD >			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

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

TABLET, EXTENDED RELEASE; ORAL

/THEOPHYLLINE/

/AB/	/INWOOD LABS/	/100MG/	/N88326/001/ /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

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

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

	/AB/	/SUPERPHARM/	/250MG/	/N70763/001/ /JUN/16,/1986/
>DLT>/AB/			/500MG/	/N70764/001/ /JUN/16,/1986/
>DLT>				
		@ SUPERPHARM	250MG	N70763 001 JUN 16, 1986
>ADD>		@	500MG	N70764 001 JUN 16, 1986
>ADD>				

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

/SK&F/CO/

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

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

>DLT>	/BP/	/CHELSEA LABS/	/4MG/	/N85962/001/
>ADD>		@ CHELSEA LABS	4MG	N85962 001

TRIENTINE HYDROCHLORIDE

CAPSULE; ORAL

/CUPRID/

/MSD/		/250MG/	/N19194/001/ /NOV/08,/1985/

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

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

TABLET; ORAL
VERAPAMIL HCL

/AB/	/CHELSEA/LABS/	/80MG/	/N70421/001/ /SEP/17,/1986/
>DLT >/AB/		/120MG/	/N70422/001/ /SEP/17,/1986/
>DLT >	BX CHELSEA LABS	80MG	N70421 001 SEP 17, 1986
>ADD > >ADD >	BX	120MG	N70422 001 SEP 17, 1986

WARFARIN SODIUM

/INJECTABLE;/INJECTION/
/COUMADIN/

/DUPONT/PHARMS/	/50MG/VIAL/ /75MG/VIAL/	/N09218/020/ /N09218/012/
ə DUPONT PHARMS	50MG/VIAL	N09218 020
ə	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 6 / JAN '90 - JUN '90

NO JUNE 1990 APPROVALS

ORPHAN DRUG PRODUCT DESIGNATIONS

SECTION 526 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT CONTAINS PROVISIONS WHEREBY FDA MAY DESIGNATE A SPONSOR'S DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT AS A "DESIGNATED ORPHAN DRUG." SECTION 527 OF THE ACT ESTABLISHES A PROCESS WHEREBY A SPONSOR MAY RECEIVE SEVEN YEARS OF EXCLUSIVE APPROVAL STATUS IF THAT SPONSOR IS THE FIRST TO ACHIEVE NEW DRUG, ANTIBIOTIC, OR BIOLOGICAL PRODUCT APPROVAL FOR A DESIGNATED ORPHAN DRUG FOR THE DESIGNATED INDICATION(S). THE EXCLUSIVE APPROVAL MAY BE REVOKED BY WRITTEN CONSENT OF THE SPONSOR OR BY FDA ACTION AFTER FINDING THAT THE SPONSOR HOLDING EXCLUSIVE APPROVAL CANNOT ASSURE THE AVAILABILITY OF SUFFICIENT QUANTITIES OF THE DRUG TO MEET THE NEEDS OF PATIENTS WITH THE DESIGNATED ORPHAN INDICATION(S).

WHEN A PRODUCT IS GRANTED ORPHAN DRUG DESIGNATION, IT WILL APPEAR IN THIS SECTION. ONCE A BIOLOGICAL OR DRUG PRODUCT IS LICENSED/APPROVED FOR MARKETING, IT WILL BE LISTED IN THIS SECTION AND ASTERISKED, AS APPROPRIATE, TO DENOTE MARKETING/EXCLUSIVE APPROVAL STATUS. IN ADDITION, THE EXCLUSIVITY EXPIRATION DATE WILL BE DISPLAYED FOLLOWING THE APPROVED DESIGNATED INDICATION(S).

THE FOLLOWING DRUGS AND BIOLOGICALS HAVE BEEN GRANTED ORPHAN DRUG DESIGNATION PURSUANT TO SECTION 526 OF THE FOOD, DRUG, AND COSMETIC ACT AS AMENDED BY THE ORPHAN DRUG ACT [PUBLIC LAW 97-414].

ORPHAN DRUG PRODUCT DESIGNATIONS

BIOLOGICAL DESIGNATIONS

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ONCORAD OV103 TRADE: NOT ESTABLISHED	TREATMENT OF OVARIAN CARCINOMA.	CYTOGEN CORP. 600 COLLEGE RD. EAST PRINCETON, NJ 08540
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY^9) TO MYELOID CELLS (CD-33) TRADE: ANTI-MY^9-BR	FOR USE IN THE EX VIVO TREATMENT OF AUTOLOGOUS BONE MARROW AND SUBSEQUENT REINFUSION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA.	IMMUNOGEN, INC. 148 SIDNEY ST. CAMBRIDGE, MA 02139
GENERIC: TECELEUKIN TRADE: NOT ESTABLISHED	TREATMENT OF METASTATIC MALIGNANT MELANOMA. TREATMENT OF METASTATIC RENAL CELL CARCINOMA. TREATMENT OF METASTATIC MALIGNANT MELANOMA IN COMBINATION WITH ROFERON-A. TREATMENT OF METASTATIC RENAL CELL CARCINOMA IN COMBINATION WITH ROFERON-A (INTERFERON ALPHA-2A, RECOMBINANT/ROCHE).	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: CALCIUM CARBONATE TRADE: R & D CALCIUM CARBONATE/600	TREATMENT OF HYPERPHOSPHATEMIA IN PATIENTS WITH END STAGE RENAL DISEASE (ESRD).	R AND D LABORATORIES, INC. 4204 GLENCOE AVE. MARINA DEL REY, CA 90292
GENERIC: CROMOLYN SODIUM TRADE: GASTROCROM*/**	MASTOCYTOSIS. [DECEMBER 22, 1996]	FISONS CORP. 2 PRESTON CT. BEDFORD, MA 01730
GENERIC: DEHYDREX TRADE: NOT ESTABLISHED	TREATMENT OF RECURRENT CORNEAL EROSION UNRESPONSIVE TO CONVENTIONAL THERAPY.	HOLLES LABS, INC. 30 FOREST NOTCH COHASSET, MA 02025
GENERIC: DISACCHARIDE TRIPEPTIDE GLYCEROL DIPALMITOYL (DTP-GDP) TRADE: IMMTHER	TREATMENT OF PULMONARY AND HEPATIC METASTASES IN COLORECTAL ADENOCARCINOMA PATIENTS.	IMMUNOTHERAPEUTICS, INC. 509 25TH AVE. NORTH FARGO, ND 58102
GENERIC: DISODIUM CLODRONATE TETRAHYDRATE TRADE: BONEFOS	TREATMENT OF INCREASED BONE RESORPTION DUE TO MALIGNANCY.	LEIRAS PHARMACEUTICALS, INC. 2345 WAUKEGAN RD. SUITE N-135 BANNOCKBURN, IL 60015
GENERIC: DYNAMINE TRADE: NOT ESTABLISHED	TREATMENT OF LAMBERT-EATON MYASTHENIC SYNDROME.	MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH MAYO CLINIC AND FOUNDATION 200 S.W. 1ST AVE. ROCHESTER, MN 55905

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ETHIOFOS TRADE: ETHYOL	USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN IN THE TREATMENT OF ADVANCED OVARIAN CARCINOMA. USE AS A CHEMOPROTECTIVE AGENT FOR CYCLOPHOSPHAMIDE IN THE TREATMENT OF ADVANCED OVARIAN CARCINOMA.	U.S. BIOSCIENCE, INC. 920-B HARVEST DR. SUITE 200 BLUE BELL, PA 19422
GENERIC: FLUOROURACIL	CONCOMITANT ADMINISTRATION WITH ROFERON-A FOR THE TREATMENT OF PATIENTS WITH ADVANCED COLORECTAL CANCER.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: GLYCEROL, 10% TRADE: NOT ESTABLISHED	TO DECREASE INTRACRANIAL HYPERTENSION AND/OR ALLEVIATE CEREBRAL EDEMA IN PATIENTS WHO MAY BENEFIT FROM OSMOTHERAPY.	CHUGAI PHARMACEUTICAL CO., LTD. 1-9, KYOBASHI 2-CHOME CHUO-KU, TOKYO 104, JAPAN
GENERIC: GONADORELIN ACETATE TRADE: LUTREPULSE*/**	TREATMENT OF PRIMARY HYPOTHALAMIC AMENORRHEA. [OCT 10, 1996]	R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE ROUTE 202, P.O. BOX 300 RARITAN, NJ 08869
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF HEPARIN-ASSOCIATED THROMBOCYTOPENIA.	BERLEX LABS. 300 FAIRFIELD RD. WAYNE, NJ 07470
GENERIC: MEFLOQUINE HCL TRADE: LARIAM*/**	TREATMENT OF ACUTE MALARIA DUE TO PLASMODIUM FALCIPARUM AND PLASMODIUM VIVAX. [MAY 02, 1996] PROPHYLAXIS OF PLASMODIUM FALCIPARUM MALARIA WHICH IS RESISTANT TO OTHER AVAILABLE DRUGS. [MAY 02, 1996]	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: N-ACETYL PROCAINAMIDE TRADE: NAPA	TO LOWER THE DEFIBRILLATION ENERGY REQUIREMENT SUFFICIENTLY TO ALLOW AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (AICD) THERAPY IN THOSE PATIENTS WHO COULD OTHERWISE NOT USE THE DEVICE.	MEDCO RESEARCH, INC. 8733 BEVERLY BLVD., SUITE 404 LOS ANGELES, CA 90048
GENERIC: PEGADEMASE BOVINE TRADE: ADAGEN*/**	USE AS ENZYME REPLACEMENT THERAPY FOR ADENOSINE DEAMINASE (ADA) DEFICIENCY IN PATIENTS WITH SEVERE COMBINED IMMUNODEFICIENCY (SCID) WHO ARE NOT SUITABLE CANDIDATES FOR (OR WHO HAVE FAILED) BONE MARROW TRANSPLANTATION. [MAR 21, 1997]	ENZON, INC. 40 CRAGWOOD RD. SOUTH PLAINFIELD, NJ 07080
GENERIC: PR-225 (REDOX ACYCLOVIR) TRADE: NOT ESTABLISHED	TREATMENT OF HERPES SIMPLEX ENCEPHALITIS IN INDIVIDUALS AFFLICTED WITH AIDS.	PHARMATEC, INC. P.O. BOX 730 ALACHUA, FL 32615
GENERIC: PR-239 (REDOX PENICILLIN G) TRADE: NOT ESTABLISHED	TREATMENT OF AIDS ASSOCIATED NEUROSYPHILIS.	PHARMATEC, INC. P.O. BOX 730 ALACHUA, FL 32615
GENERIC: RHEOTHRX TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE BURNS IN HOSPITALIZED PATIENTS.	CYTRX CORP. 150 TECHNOLOGY PKWY. TECHNOLOGY PARK/ ATLANTA NORCROSS, GA 30092
GENERIC: SERMORELIN ACETATE [GRF(1-29)NH2] TRADE: GEREF	AS AN ADJUNCT TO GONADOTROPIN THERAPY IN THE INDUCTION OF OVULATION IN WOMEN WITH ANOVULATORY OR OLIGO-OVULATORY INFERTILITY WHO FAIL TO OVULATE IN RESPONSE TO ADEQUATE TREATMENT WITH CLOMIPHENE CITRATE ALONE AND GONADOTROPIN THERAPY ALONE.	SERONO LABS. 100 LONGWATER CIRCLE NORWELL, MA 02061

ORPHAN DRUG PRODUCT DESIGNATIONS

DRUG DESIGNATIONS

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: SHORT CHAIN FATTY ACID SOLUTION TRADE: NOT ESTABLISHED	TREATMENT OF THE ACTIVE PHASE OF ULCERATIVE COLITIS WITH INVOLVEMENT RESTRICTED TO THE LEFT SIDE OF THE COLON.	RICHARD I. BREUER EVANSTON HOSPITAL 2650 RIDGE AVE. EVANSTON, IL 60201
GENERIC: SK&F 110679 TRADE: NOT ESTABLISHED	LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	SMITH KLINE & FRENCH LABS. P.O. BOX 1539, L231 KING OF PRUSSIA, PA 19406
GENERIC: SODIUM DICHLOROACETATE TRADE: NOT ESTABLISHED	TREATMENT OF CONGENITAL LACTIC ACIDOSIS. TREATMENT OF HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA.	PETER STACPOOLE, M.D., PH.D. UNIVERSITY OF FLORIDA BOX J-226 GAINESVILLE, FL 32610
GENERIC: SOMATROPIN TRADE: HUMATROPE	TREATMENT OF SHORT STATURE ASSOCIATED WITH TURNER'S SYNDROME.	ELI LILLY AND CO. LILLY CORPORATE CENTER INDIANAPOLIS, IN 46285
GENERIC: SUCRALFATE TRADE: NOT ESTABLISHED	TREATMENT OF ORAL COMPLICATIONS OF CHEMOTHERAPY IN BONE MARROW TRANSPLANT RECIPIENTS.	NASKA PHARMACAL CO., INC. 55 PLANT AVE. HAUPPAUGE, NY 11788
GENERIC: THALIDOMIDE TRADE: NOT ESTABLISHED	TREATMENT OF GRAFT VERSUS HOST DISEASE (GVHD) IN PATIENTS RECEIVING BONE MARROW TRANSPLANTATION (BMT). PREVENTION OF GVHD IN PATIENTS RECEIVING BMT.	ANDRULIS RESEARCH CORP. 4600 EAST-WEST HIGHWAY SUITE 900 BETHESDA, MD 20814

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

NO JUNE 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 LOTION; TOPICAL	2.5%	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
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

	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
	18240 004	ATENOLOL; TENORMIN				I-42	FEB 09, 1993
			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	3910924	OCT 07, 1994		NCE	DEC 28, 1993
						NDF	MAY 23, 1993
	19966 001	CLOBETASOL PROPIONATE; TEMOVATE	3721687	MAR 20, 1992		NP	FEB 22, 1993
						NCE	DEC 27, 1990
	19949 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	19949 002	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	19949 003	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	19950 001	FLUCONAZOLE; DIFLUCAN	4416682	NOV 22, 2000			
			4404216	SEP 13, 2000		NCE	JAN 29, 1995
	18554 001	FLUTAMIDE; EULEXIN	4329364	MAY 11, 2001	U-23		
	17556 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
	17818 001	HALCINONIDE; HALOG	3892857	JUL 01, 1992			
	17824 001	HALCINONIDE; HALOG	3892856	JUL 01, 1992			
	18234 001	HALCINONIDE; HALOG-E	4048310	SEP 13, 1994			
	19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4382093	MAY 03, 2000			
	18956 002	IOHEXOL; OMNIPAQUE 240	4021481	MAY 03, 1994			
	18735 002	IOPAMIDOL; ISOVUE-300				I-46	MAY 30, 1993
	18735 003	IOPAMIDOL; ISOVUE-370				I-48	OCT 04, 1992
>ADD>	20035 001	LEVAMISOLE HYDROCHLORIDE; ERGAMISOL				NCE	JUN 18, 1995

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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	3740395	JUN 19, 1990		NCE	JUN 19, 1995
>ADD>	19753 002	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3740395	JUN 19, 1990		NCE	JUN 19, 1995
>ADD>	19753 003	MORICIZINE HYDROCHLORIDE; ETHMOZINE	3740395	JUN 19, 1990		NCE	JUN 19, 1995
	19886 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1997		NCE	FEB 13, 1995
>ADD>	19356 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	MAR 01, 1993
>ADD>						NDF	JUN 18, 1993
	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
>ADD>	19638 001	PIPECURONIUM BROMIDE; ARDUAN				NCE	JUN 26, 1995
	87361 001	PROCAINAMIDE HYDROCHLORIDE; PRONESTYL-SR	4252786	FEB 24, 1998			
	10929 001	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	10929 002	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	10929 003	SODIUM IODIDE, I-131; IODOTOPE	4349529	SEP 14, 1999			
	18333 001	SUCRALFATE; CARAFATE				I-44	MAY 11, 1993
>ADD>	17376 001	SULFAMETHOXAZOLE; SEPTRA	4209513	JUN 24, 1997		I-49	JUN 15, 1993
>ADD>	17376 002	SULFAMETHOXAZOLE; SEPTRA DS	4209513	JUN 24, 1997		I-49	JUN 15, 1993
>ADD>	17377 001	SULFAMETHOXAZOLE; BACTRIM				I-49	JUN 15, 1993
>ADD>	17377 002	SULFAMETHOXAZOLE; BACTRIM DS				I-49	JUN 15, 1993
>ADD>	17560 001	SULFAMETHOXAZOLE; BACTRIM				I-49	JUN 15, 1993
>ADD>	17560 002	SULFAMETHOXAZOLE; BACTRIM PEDIATRIC				I-49	JUN 15, 1993
>ADD>	17598 001	SULFAMETHOXAZOLE; SEPTRA				I-49	JUN 15, 1993
>ADD>	17598 002	SULFAMETHOXAZOLE; SEPTRA GRAPE				I-49	JUN 15, 1993
>ADD>	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			
>ADD>	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			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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
	18017 001	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
	18017 002	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
	18017 004	TIMOLOL MALEATE; BLOCADREN				I-41	MAR 03, 1993
>ADD>	19614 001	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006		NDF	MAY 29, 1993
>ADD>	19614 002	VERAPAMIL HYDROCHLORIDE; VERELAN	4863742	SEP 05, 2006		NDF	MAY 29, 1993
	19655 001	ZIDOVUDINE; RETROVIR	4833130	MAY 23, 2006		I-47	MAY 02, 1993
			4724232	FEB 09, 2005		NCE	MAR 19, 1992
	19910 001	ZIDOVUDINE; RETROVIR	4833130	MAY 23, 2006		ODE	MAR 19, 1994
			4724232	FEB 09, 2005		NCE	MAR 19, 1992
						I-47	MAY 02, 1993
	19951 001	ZIDOVUDINE; RETROVIR	4833130	MAY 23, 2006		NCE	MAR 19, 1992
						ODE	MAR 19, 1994