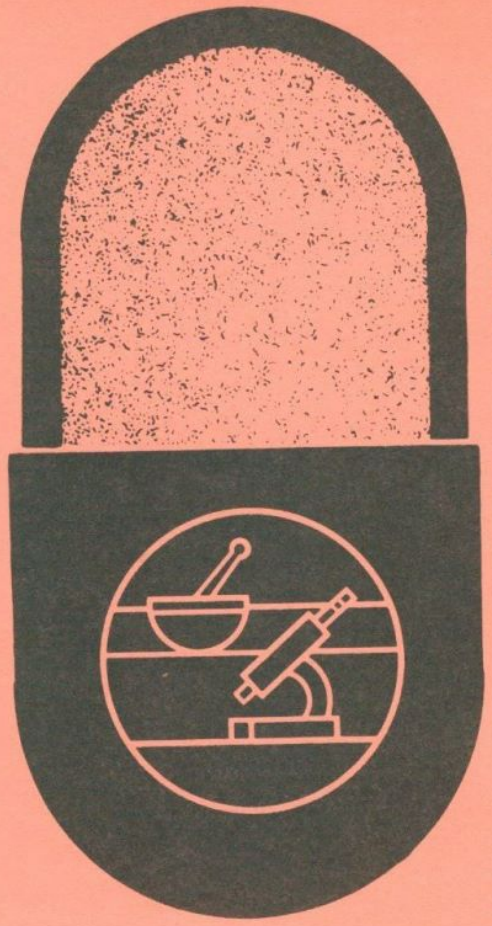
SUPPLEMENT 6

JAN'89-JUN'89



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT

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

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CUMULATIVE SUPPLEMENT 6

JUNE 1989

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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, 9th 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 in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 in the Division of Blood and Blood Products Approved Under Section 505 of the Act 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 9th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 9th 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)	NEW ABBREVIATED NAME
SCHERING CORP	SCHERING CORP SUB SCHERING PLOUGH CORP	SCHERING
MCNEIL PHARMACEUTICAL DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON
ORTHO PHARMACEUTICAL CORP	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIVISION OF ORTHO PHARMACEUTICAL CORP	RW JOHNSON

1.4 CORRECTIONS TO THE 9TH EDITION

a. The locator tabs for the "OTC Drug Product List" and the "Product Name Index Listed by Applicant" were not printed within the List.

b. The locator tabs for the "Drug Products Which Must Demonstrate *in vivo* Bioavailability Only If Product Fails to Achieve Adequate Dissolution," "ANDA Suitability Petitions," "Product Name Index," and "Product Name Index Listed by Applicant" were placed incorrectly within the List.

c. On page 3-374, "ANDA Suitability Petitions," the heading "Petitions Approved" should read "Petitions Denied."

1.5 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 1988) 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 1988	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091	10157	10137	
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)	1982 (19.6%)	
MULTISOURCE	8108 (80.3%)	8164 (80.4%)	8155 (80.4%)	
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)	7341 (72.4%)	
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	726 (7.1%)	701 (6.9%)	
EXCEPTIONS[1]	118 (1.1%)	117 (1.2%)	113 (1.1%)	
NEW MOLECULAR ENTITIES APPROVED	--	3	4	
NUMBER OF APPLICANTS	374	393	394	

[1] Amino acid-containing products of varying composition (see Introduction, page 1-7 of the List).

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

> DLT >	/AA/	/DURAMED/PHARMS/	/300MG;15MG/	/N88353/001/ /FEB/06,/1984/
> DLT >				
> DLT >	/AA/		/300MG;30MG/	/N88354/001/ /FEB/06,/1984/
> DLT >				
> DLT >	/AA/		/300MG;60MG/	/N88355/001/ /FEB/06,/1984/
> DLT >				
> ADD >		ə DURAMED PHARMS	300MG;15MG	N88353 001 FEB 06, 1984
> ADD >				
> ADD >		ə	300MG;30MG	N88354 001 FEB 06, 1984
> ADD >				
> ADD >		ə	300MG;60MG	N88355 001 FEB 06, 1984
> ADD >				
		ROXANE LABS	500MG;15MG‡	N89511 001 APR 25, 1989
			500MG;30MG‡	N89512 001 APR 25, 1989
			500MG;60MG‡	N89513 001 APR 25, 1989

ACETAMINOPHEN W/ CODEINE PHOSPHATE

/AA/	/PBI/		/300MG;30MG/	/N87919/001/ /JUN/22,/1982/
/AA/			/300MG;60MG/	/N87920/001/ /JUN/22,/1982/
		ə PBI	300MG;30MG	N87919 001 JUN 22, 1982
		ə	300MG;60MG	N87920 001 JUN 22, 1982
/AA/	/WHITE/TN/PAULSN/		/300MG;30MG/	/N84360/001/
/AA/			/300MG;60MG/	/N85607/001/
		ə WHITE TN PAULSN	300MG;30MG	N84360 001
		ə	300MG;60MG	N85607 001
	/PAPA-DEINE #3/			
/AA/	/VANGARD/LABS/		/300MG;30MG/	/N88037/001/ /MAR/20,/1984/
		ə VANGARD LABS	300MG;30MG	N88037 001 MAR 20, 1984
	/PAPA-DEINE #4/			
/AA/	/VANGARD/LABS/		/300MG;60MG/	/N88715/001/ /MAR/20,/1984/
		ə VANGARD LABS	300MG;60MG	N88715 001 MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

AA		LUCHEM PHARMS	500MG;5MG‡	N89907 001 JAN 13, 1989

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

ANEXSIA

> ADD >				
> ADD >	AA	BEECHAM LABS	500MG;5MG	N89160 001 APR 23, 1987
> ADD >				
> DLT >		/ANEXSIA-D/		
> DLT >	/AA/	/BEECHAM/LABS/	/500MG;5MG/	/N89160/001/ /APR/23,/1987/
> DLT >				

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL

OXYCODONE AND ACETAMINOPHEN

AA	HALSEY DRUG	500MG;5MG‡	N89994 001 MAY 04, 1989

TYLOX

AA	MCNEIL PHARM	500MG;5MG	N88790 001 DEC 12, 1984

TABLET; ORAL

OXYCODONE 5/APAP 500

AA	DUPONT PHARMS	500MG;5MG	N85911 001

ROXICET 5/500

AA	ROXANE LABS	500MG;5MG‡	N89775 001 JAN 12, 1989

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

CAPSULE; ORAL

TYLOX

> DLT >	/ə/MCNEIL/LABS/	/500MG;4.5MG;0.38MG/	/N85375/001/
> ADD >	ə RW JOHNSON	500MG;4.5MG;0.38MG	N85375 001

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

/AB/	/VANGARD/LABS/		/250MG/	/N87654/001/ /FEB/05,/1982/
		ə VANGARD LABS	250MG	N87654 001 FEB 05, 1982

ACETRIZOATE SODIUM

/SOLUTION;/INTRAUTERINE/

/SALPIX/

/ORTHO/PHARM/ /53%/ /N09008/001/

ACETRIZOATE SODIUM

/SOLUTION;/INTRAUTERINE/
/SALPIX/
> DLT >
> ADD >
> ADD >
∂ ORTHO PHARM 53% N09008 001

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL
ACETYLCYSTEINE
AN DUPONT CRI CARE 10%¤ N71364 001 > DLT >
MAY 01, 1989 > DLT >
AN 20%¤ N71365 001 > DLT >
MAY 01, 1989 > ADD >
> ADD >
MUCOMYST
AN MEAD JOHNSON 10% N13601 002 > DLT >
AN 20% N13601 001 > DLT >
> DLT >
> ADD >
> ADD >

ALBUTEROL SULFATE

TABLET; ORAL
ALBUTEROL SULFATE
AB AM THERPTCS EQ 2MG BASE¤ N72449 001
DEC 05, 1989 : FEB 01, 1989
AB EQ 4MG BASE¤ N72450 001
DEC 05, 1989 : FEB 01, 1989
AB BIOCRAFT LABS EQ 2MG BASE¤ N72619 001
DEC 05, 1989 : APR 07, 1989
AB EQ 4MG BASE¤ N72620 001
DEC 05, 1989 : APR 07, 1989
AB CORD LABS EQ 2MG BASE¤ N72151 001
DEC 05, 1989 : MAR 23, 1989
AB EQ 4MG BASE¤ N72152 001
DEC 05, 1989 : MAR 23, 1989
AB MUTUAL PHARM EQ 2MG BASE¤ N72636 001
DEC 05, 1989 : FEB 01, 1989
AB EQ 4MG BASE¤ N72637 001
DEC 05, 1989 : FEB 01, 1989
AB SIDMAK LABS EQ 2MG BASE¤ N72316 001
DEC 05, 1989 : JAN 30, 1989
AB EQ 4MG BASE¤ N72317 001
DEC 05, 1989 : JAN 30, 1989

AMINO ACIDS

INJECTABLE; INJECTION
> DLT > /AMINOSYN/II/3.5%/IN/PLASTIC/CONTAINER/
> DLT > /ABBOTT/LABS/ /3.5%/ /N19491/001/
> DLT > /OCT/10,/1986/

AMINO ACIDS

INJECTABLE; INJECTION
/AMINOSYN/II/3.5%/IN/PLASTIC/CONTAINER/
∂ ABBOTT LABS 3.5% N19491 001
OCT 10, 1986

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION
/AMINOSYN/3.5%/W//DEXTROSE/25%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /3.5%;25GM/100ML/ /N19118/001/
/OCT/11,/1984/
∂ ABBOTT LABS 3.5%;25GM/100ML N19118 001
OCT 11, 1984
/AMINOSYN/3.5%/W//DEXTROSE/5%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /3.5%;5GM/100ML/ /N19120/001/
/OCT/11,/1984/
∂ ABBOTT LABS 3.5%;5GM/100ML N19120 001
OCT 11, 1984
TRAVASOL 2.75% IN DEXTROSE 10% IN PLASTIC CONTAINER
BAXTER 2.75%;10GM/100ML N19520 002
SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 15% IN PLASTIC CONTAINER
BAXTER 2.75%;15GM/100ML N19520 003
SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 20% IN PLASTIC CONTAINER
BAXTER 2.75%;20GM/100ML N19520 004
SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 25% IN PLASTIC CONTAINER
BAXTER 2.75%;25GM/100ML N19520 005
SEP 23, 1988
TRAVASOL 2.75% IN DEXTROSE 5% IN PLASTIC CONTAINER
BAXTER 2.75%;5GM/100ML N19520 001
SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 10% IN PLASTIC CONTAINER
BAXTER 4.25%;10GM/100ML N19520 007
SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 15% IN PLASTIC CONTAINER
BAXTER 4.25%;15GM/100ML N19520 008
SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 20% IN PLASTIC CONTAINER
BAXTER 4.25%;20GM/100ML N19520 009
SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER
BAXTER 4.25%;25GM/100ML N19520 010
SEP 23, 1988
TRAVASOL 4.25% IN DEXTROSE 5% IN PLASTIC CONTAINER
BAXTER 4.25%;5GM/100ML N19520 006
SEP 23, 1988

AMINO ACIDS; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC

>DLT>	/INJECTABLE;/INJECTION/			
>DLT>	/AMINOSYN/11/3.5%/M/IN/PLASTIC/CONTAINER/			
>DLT>	/ABBOTT/LABS/	/3.5%;32MG/100ML;128MG/100ML;/		
>DLT>		/222MG/100ML;49MG/100ML/	/N19493/001/	
>DLT>			/OCT/16,/1986/	
>ADD>	ə ABBOTT LABS	3.5%;32MG/100ML;128MG/100ML;		
>ADD>		222MG/100ML;49MG/100ML	N19493 001	
>ADD>			OCT 16, 1986	

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

/BD/	/CORD/LABS/	/100MG/	/N85261/003/	
	ə CORD LABS	100MG	N85261 003	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

>DLT>/AB/	/CHELSEA/LABS/	/150MG/	/N85821/001/	
>ADD>	ə CHELSEA LABS	150MG	N85821 001	
/AB/	/LEDERLE/LABS/	/10MG/	/N87366/001/	
			/JAN/04,/1982/	
/AB/		/25MG/	/N87367/001/	
			/MAY/03,/1982/	
/AB/		/50MG/	/N87181/001/	
			/JAN/04,/1982/	
/AB/		/75MG/	/N87369/001/	
			/JAN/04,/1982/	
/AB/		/100MG/	/N87368/001/	
			/MAY/03,/1982/	
/AB/		/150MG/	/N87370/001/	
			/JAN/04,/1982/	
	ə LEDERLE LABS	10MG	N87366 001	
			JAN 04, 1982	
	ə	25MG	N87367 001	
			MAY 03, 1982	
	ə	50MG	N87181 001	
			JAN 04, 1982	
	ə	75MG	N87369 001	
			JAN 04, 1982	
	ə	100MG	N87368 001	
			MAY 03, 1982	
	ə	150MG	N87370 001	
			JAN 04, 1982	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

/AB/	/PBI/	/25MG/	/N87775/001/	
			/FEB/10,/1982/	
	ə PBI	25MG	N87775 001	
			FEB 10, 1982	
/AB/	/ROXANE/LABS/	/10MG/	/N86144/001/	
/AB/		/25MG/	/N86145/001/	
/AB/		/50MG/	/N86143/001/	
/AB/		/75MG/	/N86147/001/	
/AB/		/100MG/	/N86146/001/	
/AB/		/150MG/	/N86148/001/	
	ə ROXANE LABS	10MG	N86144 001	
	ə	25MG	N86145 001	
	ə	50MG	N86143 001	
	ə	75MG	N86147 001	
	ə	100MG	N86146 001	
	ə	150MG	N86148 001	
/AB/	/VANGARD/LABS/	/10MG/	/N87632/001/	
			/FEB/01,/1982/	
/AB/		/25MG/	/N87570/001/	
			/FEB/08,/1982/	
/AB/		/50MG/	/N87616/001/	
			/FEB/08,/1982/	
/AB/		/75MG/	/N87617/001/	
			/FEB/05,/1982/	
/AB/		/100MG/	/N87639/001/	
			/FEB/08,/1982/	
	ə VANGARD LABS	10MG	N87632 001	
			FEB 01, 1982	
	ə	25MG	N87570 001	
			FEB 08, 1982	
	ə	50MG	N87616 001	
			FEB 08, 1982	
	ə	75MG	N87617 001	
			FEB 05, 1982	
	ə	100MG	N87639 001	
			FEB 08, 1982	

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

	PERPHENAZINE AND AMITRIPTYLINE HCL		
AB	DANBURY PHARMA	10MG;2MG*	N72539 001 FEB 15, 1989
AB		10MG;4MG*	N72540 001 FEB 15, 1989
AB		25MG;2MG*	N72541 001 FEB 15, 1989
AB		25MG;4MG*	N72134 001 FEB 15, 1989
AB		50MG;4MG*	N72135 001 FEB 15, 1989

AMMONIUM LACTATE

LOTION; TOPICAL

	LAC-HYDRIN		
	/BRISTOL/MYERS/	/EQ/12%/ACID/	/N19155/001/ /APR/24,/1985/
	WESTWOOD PHARMS	EQ 12% ACID	N19155 001 APR 24, 1985

AMOXAPINE

TABLET; ORAL

	AMOXAPINE		
AB	WATSON LABS	25MG*	N72418 001 MAY 11, 1989
AB		50MG*	N72419 001 MAY 11, 1989
AB		100MG*	N72420 001 MAY 11, 1989
AB		150MG*	N72421 001 MAY 11, 1989

	ASENDIN		
AB	LEDERLE LABS	25MG	N18021 001
AB		50MG	N18021 002
AB		100MG	N18021 003
AB		150MG	N18021 004

AMOXICILLIN

CAPSULE; ORAL

	AMOXICILLIN		
AB	LEMMON	250MG*	N63030 001 FEB 28, 1989
AB		500MG*	N63031 001 FEB 28, 1989

AMOXICILLIN

CAPSULE; ORAL

	AMOXICILLIN		
	/TAG/PHARMS/	/250MG/	/N63030/001/ /FEB/28,/1989/
		/500MG/	/N63031/001/ /FEB/28,/1989/

POWDER FOR RECONSTITUTION; ORAL

	AMOXICILLIN		
AB	NOVOPHARM	250MG/5ML*	N63001 001 JAN 06, 1989

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

	AMPICILLIN		
AB	CLONMEL CHEMS	EQ 125MG BASE/5ML*	N62982 001 FEB 10, 1989
AB		EQ 250MG BASE/5ML*	N62982 002 FEB 10, 1989

/TABLET;/CHEWABLE;/ORAL/

	POLYCILLIN		
	/BRISTOL/LABS/	/EQ/125MG/BASE/	/N50093/001/
	@ BRISTOL LABS	EQ 125MG BASE	N50093 001

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

	BUTALBITAL W/ ASPIRIN & CAFFEINE		
/AB/	/BOOTS/LABS/	/325MG;50MG;40MG/	/N87048/002/ /DEC/09,/1983/
AB	PHARMAFAIR	325MG;50MG;40MG	N87048 002 DEC 09, 1983

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

	PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE		
>DLT> /AA/	/CHELSEA/LABS/	/389MG;32.4MG;65MG/	/N85732/002/ /SEP/03,/1984/
>DLT> >DLT> >ADD> >ADD>	@ CHELSEA LABS	389MG;32.4MG;65MG	N85732 002 SEP 03, 1984

ASPIRIN; CARISOPRODOL

BENZTROPINE MESYLATE

ASPIRIN; CARISOPRODOL

TABLET; ORAL
CARISOPRODOL AND ASPIRIN

AB	PAR PHARM	325MG;200MG¤	N89594 001	MAR 31, 1989

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE

/AA/	/LEDERLE/LABS/	/0.025MG;2.5MG/	/N86950/001/	
	∂ LEDERLE LABS	0.025MG;2.5MG	N86950 001	

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

/AA/	/PBI/	/0.025MG;2.5MG/	/N87842/001/	/MAR/29,/1982/
	∂ PBI	0.025MG;2.5MG	N87842 001	MAR 29, 1982
/AA/	/LO-TROL/ /VANGARD/LABS/	/0.025MG;2.5MG/	/N88009/001/	/MAR/25,/1983/
	∂ VANGARD LABS	0.025MG;2.5MG	N88009 001	MAR 25, 1983

AZTREONAM

INJECTABLE; INJECTION
AZACTAM IN PLASTIC CONTAINER

SQUIBB	10MG/ML¤	N50632 003	MAY 24, 1989
	20MG/ML¤	N50632 002	MAY 24, 1989
	40MG/ML¤	N50632 001	MAY 24, 1989

BENDROFLUMETHIAZIDE

TABLET; ORAL

/NATURETIN-2.5/ /SQUIBB/	/2.5MG/	/N12164/001/	
∂ SQUIBB	2.5MG	N12164 001	

BENZONATATE

CAPSULE; ORAL
TESSALON

/DUPONT/PHARMS/	/100MG/	/N11210/001/	
FOREST LABS	100MG	N11210 001	

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

AA	INVAMED	0.5MG¤	N72264 001	FEB 27, 1989
AA		1MG¤	N72265 001	FEB 27, 1989
AA		2MG¤	N72266 001	FEB 27, 1989

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

		/DIPROLENE/			
/BX/	/SCHERING/	/EQ/0.05%/BASE/	/N19408/001/	/JAN/31,/1986/	
		/DIPROLENE/AF/			
/BX/	/SCHERING/	/EQ/0.05%/BASE/	/N19555/001/	/APR/27,/1987/	

CREAM, AUGMENTED; TOPICAL
DIPROLENE

SCHERING	EQ 0.05% BASE	N19408 001	JAN 31, 1986

DIPROLENE AF

SCHERING	EQ 0.05% BASE	N19555 001	APR 27, 1987

LOTION; TOPICAL

		/DIPROLENE/			
/BX/	/SCHERING/	/EQ/0.05%/BASE/	/N19716/001/	/AUG/01,/1988/	

LOTION, AUGMENTED; TOPICAL
DIPROLENE

SCHERING	EQ 0.05% BASE	N19716 001	AUG 01, 1988

OINTMENT; TOPICAL

		/DIPROLENE/			
/BX/	/SCHERING/	/EQ/0.05%/BASE/	/N18741/001/	/JUL/27,/1983/	

OINTMENT, AUGMENTED; TOPICAL
DIPROLENE

SCHERING	EQ 0.05% BASE	N18741 001	JUL 27, 1983

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

> DLT >	AA	CHELSEA LABS	5MG	N85841 001
> DLT >	AA		10MG	N85842 001
			25MG	N85839 001
> ADD >		∂	5MG	
> ADD >		∂	10MG	
			25MG	

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE IN DEXTROSE 5%

> DLT >	AP	ABBOTT LABS	200MG/100ML	N19005 002 APR 16, 1986
> DLT >	AP		400MG/100ML	N19005 003 APR 16, 1986
> DLT >	AP		800MG/100ML	N19005 001 APR 16, 1986
> ADD >		∂	200MG/100ML	
> ADD >		∂	400MG/100ML	
> ADD >		∂	800MG/100ML	

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	BAXTER	200MG/100ML*		N19837 002 APR 12, 1989
AP		400MG/100ML*		N19837 001 APR 12, 1989

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL

BROMPHENIRAMINE MALEATE

AA	PBI	2MG/5ML		N87964 001 JAN 25, 1983
	∂ PBI	2MG/5ML		

TABLET; ORAL

BROMPHENIRAMINE MALEATE

AA	CHELSEA LABS	4MG		N85769 001
	∂ CHELSEA LABS	4MG		

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

BROMFED-AT

> DLT >	AA	MURO PHARM	2MG/5ML;10MG/5ML; 30MG/5ML	N89681 001 DEC 22, 1988
> DLT >				
> DLT >				
> ADD >				
> ADD >	AA	MURO PHARM	2MG/5ML;10MG/5ML; 30MG/5ML	N89681 001 DEC 22, 1988
> ADD >				
> ADD >				

BUPROPION HYDROCHLORIDE

TABLET; ORAL

WELLBUTRIN

		BURROUGHS WELLC	50MG	N18644 001 DEC 30, 1985
			75MG	N18644 002 DEC 30, 1985
			100MG	N18644 003 DEC 30, 1985

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

> DLT >	AA	CHELSEA LABS	15MG	N85764 001
> DLT >	AA		30MG	N85772 001
> ADD >		∂ CHELSEA LABS	15MG	
> ADD >		∂	30MG	
	AA	WHITE TN PAULSN	30MG	N83337 001
		∂ WHITE TN PAULSN	30MG	

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

SOLUTION; INTRAPERITONEAL
DIANEAL PD-2 W/ DEXTROSE 1.5% IN PLASTIC CONTAINER

AT	BAXTER	18.3MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N17512 004
/AT/		/25.7MG/100ML;1.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML/	/N17512/004/

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; IRRIGATION
RINGER'S IN PLASTIC CONTAINER

/AT/	/ABBOTT/LABS/	/33MG/100ML;30MG/100ML; 860MG/100ML/	/N18462/001/
	∂ ABBOTT LABS	33MG/100ML;30MG/100ML; 860MG/100ML	N18462 001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER

/AP/	/CUTTER/BIOL/	/20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML/	/N18417/001/
	∂ CUTTER BIOL	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML	N18417 001

CARBOPLATIN

INJECTABLE; INJECTION
PARAPLATIN

	BRISTOL MYERS	50MG/VIAL*	N19880 001 MAR 03, 1989
		150MG/VIAL*	N19880 002 MAR 03, 1989
		450MG/VIAL*	N19880 003 MAR 03, 1989

/CARBOPROST/

/INJECTABLE;/INJECTION/
/PROSTIN/15M/

	/UPJOHN/	/EQ/0.25MG/BASE/ML/	/N17989/001/

CARBOPROST TROMETHAMINE

INJECTABLE; INJECTION
HEBAMATE

	UPJOHN	EQ 0.25MG BASE/ML	N17989 001

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL

AA	CORD LABS	350MG*	N81025 001 APR 13, 1989

CARTEOLOL HYDROCHLORIDE

TABLET; ORAL
CARTROL

	/ABBOTT/LABS/	/10MG/	/N19204/003/ /DEC/28,/1988/
	∂ ABBOTT LABS	10MG	N19204 003 DEC 28, 1988

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

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

ULTRACEF

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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

	CEFAZOLIN SODIUM			
AP	LEMMON	EQ 250MG BASE/VIAL*		N63016 001 MAR 14, 1989
AP		EQ 500MG BASE/VIAL*		N63016 002 MAR 14, 1989
AP		EQ 1GM BASE/VIAL*		N63016 003 MAR 14, 1989
	/TAG/PHARMS/	/EQ/1MG/BASE/VIAL/		/N63016/003/ /MAR/14,/1989/
		/EQ/250MG/BASE/VIAL/		/N63016/001/ /MAR/14,/1989/
		/EQ/500/BASE/VIAL/		/N63016/002/ /MAR/14,/1989/

CEFIXIME

POWDER FOR RECONSTITUTION; ORAL

SUPRAX			
LEDERLE LABS	100MG/5ML*		N50622 001 APR 28, 1989

TABLET; ORAL

SUPRAX			
LEDERLE LABS	200MG*		N50621 001 APR 28, 1989
	400MG*		N50621 002 APR 28, 1989

CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION

CEFPIRAMIDE SODIUM			
WYETH AYERST LABS	EQ 1GM BASE/VIAL*		N50633 002 JAN 31, 1989
	EQ 2GM BASE/VIAL*		N50633 003 JAN 31, 1989
	EQ 10GM BASE/VIAL*		N50633 005 JAN 31, 1989

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION

FORTAZ IN PLASTIC CONTAINER			
GLAXO	EQ 10MG BASE/ML*		N50634 001 APR 28, 1989
	EQ 20MG BASE/ML*		N50634 002 APR 28, 1989
	EQ 40MG BASE/ML*		N50634 003 APR 28, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION

ZINACEF IN PLASTIC CONTAINER			
GLAXO	EQ 15MG BASE/ML*		N50643 001 APR 28, 1989
	EQ 30MG BASE/ML*		N50643 002 APR 28, 1989

CEPHALEXIN

CAPSULE; ORAL

	CEPHALEXIN			
AB	LEMMON	EQ 250MG BASE		N62821 001 FEB 05, 1988
AB		EQ 500MG BASE		N62823 001 FEB 05, 1988
/AB/	/TAG/PHARMS/	/EQ/250MG/BASE/		/N62821/001/ /FEB/05,/1988/
/AB/		/EQ/500MG/BASE/		/N62823/001/ /FEB/05,/1988/

POWDER FOR RECONSTITUTION; ORAL

	CEPHALEXIN			
AB	LEMMON	EQ 125MG BASE/5ML		N62873 001 MAY 23, 1988
AB		EQ 250MG BASE/5ML		N62867 001 APR 15, 1988
/AB/	/TAG/PHARMS/	/EQ/125MG/BASE/5ML/		/N62873/001/ /MAY/23,/1988/
/AB/		/EQ/250MG/BASE/5ML/		/N62867/001/ /APR/15,/1988/

TABLET; ORAL

	CEPHALEXIN			
AB	BIOCRAFT LABS	EQ 250MG BASE*		N63023 001 JAN 12, 1989
AB		EQ 500MG BASE*		N63024 001 JAN 12, 1989

CERULETIDE DIETHYLAMINE

/INJECTABLE;/INJECTION/
/TYMTRAN/
/ADRIA/LABS/ /0.02MG/ML/ /N18296/001/
ə ADRIA LABS 0.02MG/ML N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

>DLT >	/AB/	/LEDERLE/LABS/	/5MG/	/N87234/001/
>DLT >	/AB/		/10MG/	/N87037/001/
>DLT >	/AB/		/25MG/	/N87231/001/
>ADD >		ə LEDERLE LABS	5MG	N87234 001
>ADD >		ə	10MG	N87037 001
>ADD >		ə	25MG	N87231 001
	/AB/	/VANGARD/LABS/	/5MG/	/N88129/001/ /MAR/28,/1983/
	/AB/		/10MG/	/N88010/001/ /MAR/28,/1983/
	/AB/		/25MG/	/N88130/001/ /MAR/28,/1983/
		ə VANGARD LABS	5MG	N88129 001 MAR 28, 1983
		ə	10MG	N88010 001 MAR 28, 1983
		ə	25MG	N88130 001 MAR 28, 1983

CHLOROQUINE HYDROCHLORIDE

>DLT >	/INJECTABLE;/INJECTION/		
>DLT >	/ARALEN/		
>DLT >	/ə/STERLING/DRUG/	/EQ/40MG/BASE/ML/	/N06002/002/
>ADD >	INJECTABLE; INJECTION		
>ADD >	ARALEN HCL		
>ADD >	STERLING DRUG	EQ 40MG BASE/ML	N06002 002

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

/AA/	/CHELSEA/LABS/	/4MG/	/N85139/001/
	ə CHELSEA LABS	4MG	N85139 001
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/
	ə LEDERLE LABS	4MG	N86941 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

>DLT >	/BC/	/CHELSEA/LABS/	/12MG;75MG/	/N88681/001/ /SEP/29,/1987/
>ADD >		ə CHELSEA LABS	12MG;75MG	N88681 001 SEP 29, 1987
	AB	CORD LABS	12MG;75MG	N88940 001 JAN 26, 1989
		ORNADE		
	AB	SK&F LABS	12MG;75MG	N12152 004
	/BC/		/12MG;75MG/	/N12152/004/

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
TUSSIONEX
FISONS EQ 8MG MALEATE/5ML; EQ 10MG BITARTRATE/5ML N19111 001 DEC 31, 1987
/PENNWALT/ /EQ/8MG/MALEATE/5ML;/ /EQ/10MG/BITARTRATE/5ML/ /N19111/001/ /DEC/31,/1987/

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL

>DLT >	/BP/	/CHELSEA/LABS/	/10MG/	/N85959/001/
>DLT >	/BP/		/25MG/	/N85956/001/
>DLT >	/BP/		/50MG/	/N85960/001/
>DLT >	/BP/		/100MG/	/N85957/001/
>DLT >	/BP/		/200MG/	/N85958/001/
>ADD >		ə CHELSEA LABS	10MG	N85959 001
>ADD >		ə	25MG	N85956 001
>ADD >		ə	50MG	N85960 001
>ADD >		ə	100MG	N85957 001
>ADD >		ə	200MG	N85958 001
	/BP/	/VANGARD/LABS/	/10MG/	/N88038/001/ /AUG/16,/1982/
	/BP/		/25MG/	/N87645/001/
	/BP/		/50MG/	/N87646/001/
		ə VANGARD LABS	10MG	N88038 001 AUG 16, 1982
		ə	25MG	N87645 001
		ə	50MG	N87646 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

/AA/	/VANGARD/LABS/	/25MG/	/N88012/001/	/JUL/14,/1982/
/AA/		/50MG/	/N88073/001/	/MAR/25,/1983/
	ə VANGARD LABS	25MG	N88012 001	JUL 14, 1982
	ə	50MG	N88073 001	MAR 25, 1983

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

>ADD > AA	AM THERPTCS	500MG¤	N89911 001	JUN 23, 1989	
>ADD > /AA/	/CHELSEA/LABS/	/250MG/	/N86948/001/	/AUG/09,/1982/	
	ə CHELSEA LABS	250MG	N86948 001	AUG 09, 1982	
>ADD > AA	PAR PHARM	500MG¤	N89898 001	JUN 05, 1989	
>ADD > AA	PIONEER PHARMS	250MG¤	N89592 001	JAN 06, 1989	
AA		500MG¤	N89948 001	JAN 06, 1989	

CHYMOPAPAIN

INJECTABLE; INJECTION
CHYMODIACTIN

/BAXTER/	/4,000/UNITS/VIAL/	/N18663/002/	/AUG/21,/1984/	
	/10,000/UNITS/VIAL/	/N18663/001/	/NOV/10,/1982/	
BOOTS (USA)	4,000 UNITS/VIAL	N18663 002	AUG 21, 1984	
	10,000 UNITS/VIAL	N18663 001	NOV 10, 1982	
/DISEASE/ /BOOTS/PHARMS/	/12,500/UNITS/VIAL/	/N18625/001/	/JAN/18,/1984/	
ə BOOTS PHARMS	12,500 UNITS/VIAL	N18625 001	JAN 18, 1984	

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLINDAMYCIN PHOSPHATE

AP	ASTRA PHARM PRODS	EQ 150MG BASE/ML¤	N62928 001	FEB 13, 1989
AP	DUPONT CRI CARE	EQ 150MG BASE/ML¤	N62908 001	FEB 01, 1989

LOTION; TOPICAL
CLEOCIN T

UPJOHN	EQ 1% BASE¤	N50600 001	MAY 31, 1989

SOLUTION; TOPICAL
CLINDAMYCIN PHOSPHATE

AT	COPLEY PHARM	EQ 1% BASE¤	N62944 001	JAN 11, 1989
>ADD > AT	LEMMON	EQ 1% BASE¤	N62930 001	JUN 28, 1989

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

>DLT >/AA/	/CHELSEA/LABS/	/3.75MG/	/N71878/001/	/MAR/15,/1988/
>DLT > >DLT >/AA/		/7.5MG/	/N71879/001/	/MAR/15,/1988/
>DLT > >DLT >/AA/		/15MG/	/N71860/001/	/MAR/15,/1988/
>ADD >	ə CHELSEA LABS	3.75MG	N71878 001	MAR 15, 1988
>ADD > >ADD >	ə	7.5MG	N71879 001	MAR 15, 1988
>ADD > >ADD >	ə	15MG	N71860 001	MAR 15, 1988

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

/AA/	/LEDERLE/LABS/	/3.75MG/	/N72013/001/	/DEC/15,/1987/
/AA/		/7.5MG/	/N72014/001/	/DEC/15,/1987/
/AA/		/15MG/	/N72015/001/	/DEC/15,/1987/
	ə LEDERLE LABS	3.75MG	N72013 001	DEC 15, 1987
	ə	7.5MG	N72014 001	DEC 15, 1987
	ə	15MG	N72015 001	DEC 15, 1987

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM

AA	NOVOPHARM	EQ 125MG BASE/5ML*	N62978 001	APR 06, 1989

COBALT CHLORIDE, CO-60; CYANOCOBALAMIN; CYANOCOBALAMIN, CO-60; INTRINSIC FACTOR

/N/A:/N/A/
/RUBRATOPE-60/KIT/

/SQUIBB/	/N/A;N/A;N/A;N/A/	/N16090/001/	
ə SQUIBB	N/A;N/A;N/A;N/A	N16090 001	

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

/BP/	/WHITE/TN/PAULSN/	/25MG/	/N80341/001/	
	ə WHITE TN PAULSN	25MG	N80341 001	

CRYPTENAMINE ACETATES

>DLT>	/INJECTABLE;/INJECTION/			
>DLT>	/UNITENSEN/			
>DLT>	/WALLACE/LABS/	/260/CSR/UNITS/ML/	/N08814/001/	
>ADD>	ə WALLACE LABS	260 CSR UNITS/ML	N08814 001	

CYANOCOBALAMIN

INJECTABLE; INJECTION
/REDISOL/

/AP/	/MS&D/	/1MG/ML/	/N06668/010/	
	ə MS&D	1MG/ML	N06668 010	
	/VI-TWEL/			
/AP/	/BERLEX/LABS/	/1MG/ML/	/N07012/002/	
	ə BERLEX LABS	1MG/ML	N07012 002	

DEMECLOCYCLINE HYDROCHLORIDE

/SYRUP;/ORAL/
/DECLOMYCIN/

/LEDERLE/LABS/	/75MG/5ML/	/N50257/001/	
ə LEDERLE LABS	75MG/5ML	N50257 001	

DEXAMETHASONE

SUSPENSION/DROPS; OPHTHALMIC
DEXAMETHASONE

AT	STERIS LABS	0.1%*	N89170 001	MAY 09, 1989

MAXIDEX

AT	ALCON LABS	0.1%	N13422 001	

TABLET; ORAL
DEXAMETHASONE

>DLT>	/BP/	/CHELSEA/LABS/	/0.75MG/	/N85818/001/
	/BP/		/1.5MG/	/N85840/001/
>ADD>	ə CHELSEA LABS		0.75MG	N85818 001
	ə		1.5MG	N85840 001

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION
/CARDIOGRAFIN/

/SQUIBB/	/85%/	/N11620/002/	
SQUIBB	85%	N11620 002	

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION
HYPAQUE-M

/STERLING/DRUG/	/60%;30%/	/N10220/002/	
ə STERLING DRUG	60%;30%	N10220 002	

DIAZEPAM

TABLET; ORAL
DIAZEPAM

AB	MARTEC PHARM	10MG*	N72402 001	APR 25, 1989

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL
DICYCLOMINE HCL

AB	PIONEER PHARMS	10MG*	N89361 001	JAN 10, 1989

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL
HETRAZAN
/S/ LEDERLE LABS — 50MG — N06459 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL
> DLT > > ADD > /AA/ CHELSEA LABS — 25MG — N85741 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM SR
MARION LABS — 60MG¤ — N19471 001 JAN 23, 1989
90MG¤ — N19471 002 JAN 23, 1989
120MG¤ — N19471 003 JAN 23, 1989
∂ 180MG¤ — N19471 004 JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL
> DLT > > ADD > /AA/ CHELSEA LABS — 25MG — N85138 001
/AA/ VANGARD LABS — 25MG — N88034 001 OCT 27, 1982
/AA/ — 50MG — N87630 001
∂ VANGARD LABS — 25MG
∂ — 50MG
/AA/ WHITE TN PAULSN — 50MG — N80800 001

ELIXIR; ORAL
/DIPHEN/
/AA/ PBI — 12.5MG/5ML — N84640 001
∂ PBI
DIPHENHYDRAMINE HCL
AA CENCI LABS — 12.5MG/5ML — N87941 001 DEC 17, 1982

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIPHENHYDRAMINE HCL
/AA/ LIFE LABS — 12.5MG/5ML — N87941 001 DEC 17, 1982
/AA/ PRIVATE FMLTNS — 12.5MG/5ML — N85287 001
∂ PRIVATE FMLTNS — 12.5MG/5ML

DISULFIRAM

TABLET; ORAL
DISULFIRAM
> DLT > /BX/ CHELSEA LABS — 250MG — N87973 001 AUG 05, 1983
> DLT > > DLT > /BX/ — 500MG — N87974 001 AUG 05, 1983
> DLT > > DLT > > ADD > > ADD > > ADD > > ADD > ∂ CHELSEA LABS — 250MG
∂ — 500MG

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL
AP ABBOTT LABS — 40MG/ML¤ — N70656 001 JAN 24, 1989
AP — 80MG/ML¤ — N70657 001 JAN 24, 1989

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL
AB QUANTUM PHARMCS — EQ 100MG BASE¤ — N72375 001 MAR 15, 1989
AB — EQ 150MG BASE¤ — N72376 001 MAR 15, 1989

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS
AP ADRIA LABS — 2MG/ML — N50629 001 DEC 23, 1987
AP — 2MG/ML — N50629 002 MAY 03, 1988

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN RDF

AP	ADRIA LABS	10MG/VIAL	N50467 001
AP		20MG/VIAL	N50467 003 MAY 20, 1985
AP		50MG/VIAL	N50467 002

DOXORUBICIN HCL

AP	CETUS BEN VENUE	2MG/ML*	N62975 001 MAR 17, 1989
AP		10MG/VIAL*	N62921 001 MAR 17, 1989
AP		20MG/VIAL*	N62921 002 MAR 17, 1989
AP		50MG/VIAL*	N62921 003 MAR 17, 1989

RUBEX

AP	BRISTOL MYERS	10MG/VIAL*	N62926 001 APR 13, 1989
AP		50MG/VIAL*	N62926 002 APR 13, 1989
		100MG/VIAL*	N62926 003 APR 13, 1989

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

DOXYCYCLINE HYCLATE

AP	LEDERLE PARNTLS	EQ 100MG BASE/VIAL*	N62992 001 FEB 16, 1989
AP		EQ 200MG BASE/VIAL*	N62992 002 FEB 16, 1989

TABLET; ORAL

DOXYCYCLINE HYCLATE

>DLT>	/CHELSEA/LABS/	/EQ/50MG/BASE/	/N62392/001/ /MAR/31,/1983/
>DLT>			
>ADD>	∂ CHELSEA LABS	EQ 50MG BASE	N62392 001 MAR 31, 1983
>ADD>			

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE AND DROPERIDOL

AP	ASTRA PHARM PRODS	2.5MG/ML; EQ 0.05MG BASE/ML*	N72026 001 APR 13, 1989
AP		2.5MG/ML; EQ 0.05MG BASE/ML*	N72027 001 APR 13, 1989
AP		2.5MG/ML; EQ 0.05MG BASE/ML*	N72028 001 APR 13, 1989

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/	/LEDERLE/LABS/	/0.5MG/	/N86984/001/
/AA/		/1MG/	/N86985/001/
	∂ LEDERLE LABS	0.5MG	N86984 001
	∂	1MG	N86985 001
/AA/	/VANGARD/LABS/	/0.5MG/	/N88013/001/ /SEP/20,/1982/
/AA/		/1MG/	/N88014/001/ /SEP/20,/1982/
	∂ VANGARD LABS	0.5MG	N88013 001 SEP 20, 1982
	∂	1MG	N88014 001 SEP 20, 1982

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYTHROMYCIN

AB	BARR LABS	250MG*	N63098 001 MAY 04, 1989

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROMYCIN LACTOBIONATE

AP	LEDERLE PARNTLS	EQ 500MG BASE/VIAL*	N62993 001 MAY 09, 1989
AP		EQ 1GM BASE/VIAL*	N62993 002 MAY 09, 1989

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION
BREVIBLOC
DUPONT PHARMS — 100MG/ML — N19386 003 DEC 31, 1986

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

BP	CHELSEA LABS	0.625MG	N85800 001
BP		1.25MG	N85801 001
BP		2.5MG	N85826 001
/BS/		/0.625MG/	/N85800/001/
/BS/		/1.25MG/	/N85801/001/
/BS/		/2.5MG/	/N85826/001/
BP	DURAMED PHARMS	0.3MG	N86492 001
BP		0.625MG	N83272 001
BP		1.25MG	N83294 001
BP		2.5MG	N83295 001
/BS/		/0.3MG/	/N86492/001/
/BS/		/0.625MG/	/N83272/001/
/BS/		/1.25MG/	/N83294/001/
/BS/		/2.5MG/	/N83295/001/
BP	ZENITH LABS	0.3MG	N88569 001 NOV 29, 1984
BP		0.625MG	N83373 001
BP		1.25MG	N83601 001
BP		2.5MG	N83602 001
/BS/		/0.3MG/	/N88569/001/ /NOV 29, 1984/
/BS/		/0.625MG/	/N83373/001/
/BS/		/1.25MG/	/N83601/001/
/BS/		/2.5MG/	/N83602/001/
	PREMARIN		
BP	WYETH AYERST LABS	0.3MG	N04782 003
BP		0.625MG	N04782 004
BP		1.25MG	N04782 001
BP		2.5MG	N04782 002
/BS/		/0.3MG/	/N04782/003/
/BS/		/0.625MG/	/N04782/004/
/BS/		/0.9MG/	/N04782/005/ /JAN 26, 1984/
/BS/		/1.25MG/	/N04782/001/
/BS/		/2.5MG/	/N04782/002/
		0.9MG	N04782 005 JAN 26, 1984

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN

/BS/	/PRIVATE/FMLTNS/	/2.5MG/	/N85007/001/
	@ PRIVATE FMLTNS	2.5MG	N85007 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORCEPT-E 1/35 21

AB	GYNOPHARMA	0.035MG;1MG	N71545 001 FEB 09, 1989

TABLET; ORAL-28
NORCEPT-E 1/35 28

AB	GYNOPHARMA	0.035MG;1MG	N71546 001 FEB 09, 1989

FERROUS CITRATE, FE-59

/INJECTABLE;/INJECTION/
/FERROUS/CITRATE/FE/59/
/MALLINCKRODT/ — /25/UCI/ML/ — /N16729/001/
@ MALLINCKRODT — 25 UCI/ML — N16729 001

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB	LEMMON	0.05%	N72488 001 FEB 06, 1989
AB		0.05%	N72490 001 FEB 07, 1989
	VASODERM E		
AB	TJ ROACO	0.05%	N72494 001 JAN 19, 1989

GEL; TOPICAL
FLUOCINONIDE

AB	LEMMON	0.05%	N72537 001 FEB 07, 1989
	LIDEX		
AB	SYNTEX LABS	0.05%	N17373 001

SOLUTION; TOPICAL
FLUOCINONIDE

AT	LEMMON	0.05%	N72511 001 FEB 07, 1989

FLUOXYMESTERONE

TABLET; ORAL
ANDROID-F
/BP/ /BROWN/PHARM/ /10MG/ /N87196/001/
BP ICN PHARMS 10MG N87196 001
FLUOXYMESTERONE
/BP/ /BROWN/PHARM/ /10MG/ /N88221/001/ /MAY/05,/1983/
BP ICN PHARMS 10MG N88221 001 MAY 05, 1983

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL
AB CHELSEA LABS 15MG¤ N72368 001 MAR 30, 1989
AB 30MG¤ N72369 001 MAR 30, 1989

FLUTAMIDE

CAPSULE; ORAL
EULEXIN
SCHERING 125MG¤ N18554 001 JAN 27, 1989

FOLIC ACID

TABLET; ORAL
FOLIC ACID
>DLT >/AA/ /CHELSEA/LABS/ /1MG/ /N85141/002/
>ADD > @ CHELSEA LABS 1MG N85141 002
/AA/ /PBI/ /1MG/ /N87828/001/ /MAY/13,/1982/
@ PBI 1MG N87828 001 MAY 13, 1982
/AA/ /VANGARD/LABS/ /1MG/ /N88730/001/ /MAR/23,/1984/
@ VANGARD LABS 1MG N88730 001 MAR 23, 1984
/AA/ /WHITE/TN/PAULSN/ /1MG/ /N80691/002/
@ WHITE TN PAULSN 1MG N80691 002

>ADD > **GANCICLOVIR SODIUM**

>ADD > INJECTABLE; INJECTION
>ADD > CYTOVENE
>ADD > SYNTEX LABS EQ 500MG BASE/VIAL¤ N19661 001 JUN 23, 1989
>ADD >

GEMFIBROZIL

CAPSULE; ORAL
LOPID
/PARKE/DAVIS/ /200MG/ /N18422/001/
@ PARKE DAVIS 200MG N18422 001

TABLET; ORAL
LOPID
PARKE DAVIS 600MG N18422 003 NOV 20, 1986

GLYCOPYRROLATE

TABLET; ORAL
GLYCOPYRROLATE
>DLT >/AA/ /CHELSEA/LABS/ /2MG/ /N86178/001/
>ADD > @ CHELSEA LABS 2MG N86178 001

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM
AP STERIS LABS 40,000 UNITS/ML N17064 006
/3/ /40,000/UNITS/ML/ /N17064/006/
HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0,9% IN PLASTIC CONTAINER
>ADD > AP ABBOTT LABS 200 UNITS/100ML¤ N18916 010 JUN 23, 1989
>ADD >
HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER
AP BAXTER 4,000 UNITS/100ML N18814 001 OCT 31, 1983
HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER
AP ABBOTT LABS 4,000 UNITS/100ML¤ N19805 001 JAN 25, 1989
HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0,9% IN PLASTIC CONTAINER
>ADD > AP ABBOTT LABS 200 UNITS/100ML¤ N18916 011 JUN 23, 1989
>ADD >

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	ABBOTT LABS	5,000 UNITS/100ML¤	N19805 002 JAN 25, 1989	
> DLT >	/HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN/			
> DLT >	/PLASTIC CONTAINER/			
> DLT >/AP/	/KENDALL/MCGAW/	/1,000 UNITS/100ML/	/N19042/004/ /MAR/29,/1985/	
> DLT >			N19042 004	
> ADD >	ə KENDALL MCGAW	1,000 UNITS/100ML	MAR 29, 1985	
> ADD >				

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

> DLT >/AA/	/CHELSEA/LABS/	/25MG/	/N85532/002/ /MAY/24,/1982/	
> DLT >		/50MG/	/N85533/002/ /MAY/25,/1982/	
> DLT >/AA/	CHELSEA LABS	25MG	N85532 002 MAY 24, 1982	
> DLT >		50MG	N85533 002 MAY 25, 1982	
> ADD >				
> ADD >				
> ADD >				
/AA/	/PBI/	/25MG/	/N87780/001/ /MAR/29,/1982/	
/AA/		/50MG/	/N87751/001/ /MAR/29,/1982/	
	ə PBI	25MG	N87780 001 MAR 29, 1982	
	ə	50MG	N87751 001 MAR 29, 1982	
/AA/	/VANGARD/LABS/	/50MG/	/N87908/001/ /MAY/07,/1982/	
	ə VANGARD LABS	50MG	N87908 001 MAY 07, 1982	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

> DLT >	/HYDRALAZINE;/HYDROCHLOROTHIAZIDE/W//RESERPINE/		
> DLT > /BP/	/CHELSEA/LABS/	/25MG;15MG;0.1MG/	/N85771/001/
> ADD >	ə CHELSEA LABS	25MG;15MG;0.1MG	N85771 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

> DLT >/AB/	/CHELSEA/LABS/	/25MG/	/N85232/002/
> DLT >/AB/		/50MG/	/N85233/001/
> DLT >/AB/		/50MG/	/N86087/001/
> DLT >/AB/		/50MG/	/N86594/001/
> DLT >/AB/		/100MG/	/N87002/001/
> DLT >			N85232 002
> ADD >	ə CHELSEA LABS	25MG	N85233 001
> ADD >	ə	50MG	N86087 001
> ADD >	ə	50MG	N86594 001
> ADD >	ə	100MG	N87002 001
> ADD >			/N87827/001/
/AB/	/PBI/	/25MG/	/APR/19,/1982/
/AB/		/50MG/	/N87752/001/ /APR/19,/1982/
	ə PBI	25MG	N87827 001 APR 19, 1982
	ə	50MG	N87752 001 APR 19, 1982
/AB/	/VANGARD/LABS/	/25MG/	/N87638/001/
/AB/		/50MG/	/N87610/001/
	ə VANGARD LABS	25MG	N87638 001
	ə	50MG	N87610 001
/AB/	/WHITE/TN/PAULSN/	/25MG/	/N83809/002/
/AB/		/50MG/	/N83809/001/
/AB/		/100MG/	/N85347/001/
	ə WHITE TN PAULSN	25MG	N83809 002
	ə	50MG	N83809 001
	ə	100MG	N85347 001

HYDROCHLOROTHIAZIDE; LISINOPRIL

TABLET; ORAL

PRINZIDE 12.5		
MS&D RES LABS	12.5MG;20MG¤	N19778 001 FEB 16, 1989
PRINZIDE 25		
MS&D RES LABS	25MG;20MG¤	N19778 002 FEB 16, 1989

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL
METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	DANBURY PHARMA	15MG;250MG¤	N70958 001	FEB 06, 1989
AB		25MG;250MG¤	N70959 001	JAN 19, 1989
AB		30MG;500MG¤	N71069 001	JAN 19, 1989
AB		50MG;500MG¤	N70960 001	FEB 06, 1989
> ADD > AB	LEDERLE LABS	15MG;250MG¤	N72507 001	JUN 02, 1989
> ADD > AB		25MG;250MG¤	N72508 001	JUN 02, 1989
> ADD > AB		30MG;500MG¤	N72509 001	JUN 02, 1989
> ADD > AB		50MG;500MG¤	N72510 001	JUN 02, 1989

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL
H.R.-50

/BP/	/WHITE/TN/PAULSN/	/50MG;0.125MG/	/N85338/001/
	ə WHITE TN PAULSN	50MG;0.125MG	N85338 001

HYDROCHLOROTHIAZIDE W/ RESERPINE

> DLT > /BP/	/CHELSEA/LABS/	/25MG;0.125MG/	/N86330/002/
> DLT > /BP/		/50MG;0.125MG/	/N86331/001/
> ADD >	ə CHELSEA LABS	25MG;0.125MG	N86330 002
> ADD >	ə	50MG;0.125MG	N86331 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

/AB/	/PBI/	/25MG;25MG/	/N87651/001/
	ə PBI	25MG;25MG	N87651 001
/AB/	/VANGARD/LABS/	/25MG;25MG/	/N87655/001/
	ə VANGARD LABS	25MG;25MG	N87655 001

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

AT	NMC LABS	2.5%¤	N89754 001	FEB 01, 1989
AT	TOPIDERM	1%¤	N89273 001	FEB 17, 1989

HYDROCORTISONE

TABLET; ORAL
HYDROCORTISONE

> DLT > /BP/	/WHITE/TN/PAULSN/	/10MG/	/N80344/001/
> DLT > /BP/		/20MG/	/N80344/002/
> ADD >	ə WHITE TN PAULSN	10MG	N80344 001
> ADD >	ə	20MG	N80344 002

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

AT	PARKE DAVIS	1%¤	N89914 001	JAN 03, 1989

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

AP	ABBOTT LABS	EQ 100MG BASE/VIAL¤	N89577 001	APR 11, 1989
AP		EQ 250MG BASE/VIAL¤	N89578 001	APR 11, 1989
AP		EQ 500MG BASE/VIAL¤	N89579 001	APR 11, 1989
AP		EQ 1GM BASE/VIAL¤	N89580 001	APR 11, 1989

HYDROFLUMETHIAZIDE

TABLET; ORAL
HYDROFLUMETHIAZIDE

/AB/	/CHELSEA/LABS/	/50MG/	/N88528/001/	/AUG/15,/1984/
	ə CHELSEA LABS	50MG	N88528 001	AUG 15, 1984

HYDROXOCOBALAMIN

INJECTABLE; INJECTION
HYDROXOCOBALAMIN

/AP/	/LYPHOMED/	/1MG/ML/	/N84921/001/
	ə LYPHOMED	1MG/ML	N84921 001

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

	HYDROXYZINE HCL				
>DLT >/AP/	/PHARMAFAIR/	/25MG/ML/	/N88862/001/		
>DLT >			/FEB/14,/1986/		
>DLT >/AP/		/25MG/ML/	/N89106/001/		
>DLT >			/FEB/14,/1986/		
>DLT >/AP/		/50MG/ML/	/N89107/001/		
>DLT >			/FEB/14,/1986/		
>ADD >	a PHARMAFAIR	25MG/ML	N88862 001		
>ADD >			FEB 14, 1986		
>ADD >	a	25MG/ML	N89106 001		
>ADD >			FEB 14, 1986		
>ADD >	a	50MG/ML	N89107 001		
>ADD >			FEB 14, 1986		

HYDROXYZINE PAMOATE

CAPSULE; ORAL

	HYDROXYZINE PAMOATE				
>DLT >/AB/	/CHELSEA LABS/	/EQ 100MG HCL/	/N86728/001/		
>DLT >			/OCT/05,/1982/		
>ADD >	a CHELSEA LABS	EQ 100MG HCL	N86728 001		
>ADD >			OCT 05, 1982		

IBUPROFEN

TABLET; ORAL

	IBUPROFEN				
>DLT >/AB/	/CHELSEA LABS/	/300MG/	/N71338/001/		
>DLT >			/DEC/01,/1986/		
>ADD >	a CHELSEA LABS	300MG	N71338 001		
>ADD >			DEC 01, 1986		

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	IMIPRAMINE HCL				
>DLT >/AB/	/CHELSEA LABS/	/10MG/	/N85875/001/		
>DLT >/AB/		/25MG/	/N85878/001/		
>DLT >/AB/		/50MG/	/N85877/001/		
>ADD >	a CHELSEA LABS	10MG	N85875 001		
>ADD >	a	25MG	N85878 001		
>ADD >	a	50MG	N85877 001		
	/AB/ /PBI/	/25MG/	/N87776/001/		
			/FEB/10,/1982/		
	a PBI	25MG	N87776 001		
			FEB 10, 1982		

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	IMIPRAMINE HCL				
/AB/	/VANGARD LABS/	/10MG/	/N88036/001/		
			/NOV/03,/1982/		
/AB/		/25MG/	/N87619/001/		
			/FEB/09,/1982/		
/AB/		/50MG/	/N87631/001/		
			/JAN/04,/1982/		
	a VANGARD LABS	10MG	N88036 001		
			NOV 03, 1982		
	a	25MG	N87619 001		
			FEB 09, 1982		
	a	50MG	N87631 001		
			JAN 04, 1982		

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

	INDOMETHACIN				
AB	INWOOD LABS	75MG*	N72410 001		
			MAR 15, 1989		

IOHEXOL

INJECTABLE; INJECTION

	OMNIPAQUE 210				
>ADD >	STERLING DRUG	45.3%*	N18956 006		
>ADD >			JUN 30, 1989		
>ADD >					
>DLT >	/OMNIPAQUE/240/		/N18956/002/		
>DLT >	/STERLING/DRUG/	/51.8%/	/DEC/26,/1985/		
>DLT >					
>DLT >	/OMNIPAQUE/300/		/N18956/003/		
>DLT >	/STERLING/DRUG/	/64.7%/	/DEC/26,/1985/		
>DLT >					
>DLT >	/OMNIPAQUE/350/		/N18956/004/		
>DLT >	/STERLING/DRUG/	/75.5%/	/DEC/26,/1985/		
>DLT >					

SOLUTION; INJECTION, ORAL

>ADD >	OMNIPAQUE 240				
>ADD >	STERLING DRUG	51.8%	N18956 002		
>ADD >			DEC 26, 1985		
>ADD >					
>ADD >	OMNIPAQUE 300				
>ADD >	STERLING DRUG	64.7%	N18956 003		
>ADD >			DEC 26, 1985		
>ADD >					
>ADD >	OMNIPAQUE 350				
>ADD >	STERLING DRUG	75.5%	N18956 004		
>ADD >			DEC 26, 1985		

LACTULOSE

SYRUP; ORAL
DUPHALAC
AA REID ROWELL 10GM/15ML* N72372 001 MAR 22, 1989

SYRUP; ORAL, RECTAL
LACTULOSE
/AA/ /KALI/DUPHAR/ /10GM/15ML/ /N17906/001/
AA REID ROWELL 10GM/15ML N17906 001
PORTALAC
AA REID ROWELL 10GM/15ML* N72374 001 MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM
LEDERLE LABS EQ 350MG BASE/VIAL* N08107 005 APR 05, 1989
WELLCOVORIN
AP BURROUGHS WELLC EQ 50MG BASE/VIAL* N89465 001 JAN 23, 1989
AP EQ 100MG BASE/VIAL* N89834 001 JAN 23, 1989
EQ 25MG BASE/VIAL* N89833 001 JAN 23, 1989

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
LUPRON DEPOT
TAKEDA ABBOTT R&D 7.5MG/VIAL N19732 001 JAN 26, 1989
/TAP/PHARMS/ /7.5MG/VIAL/ /N19732/001/ /JAN/26,/1989/

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
BETAGAN
>ADD> ALLERGAN 0.25%* N19814 001 JUN 28, 1989
>ADD>

>DLT> /LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM/

>DLT> /TABLET;/ORAL/
>DLT> /EUTHROID-0.5/
>DLT> /PARKE/DAVIS/ /0.03MG;0.0075MG/ /N16680/001/

>DLT> /LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM/

>DLT> /TABLET;/ORAL/
>DLT> /EUTHROID-1/
>DLT> /PARKE/DAVIS/ /0.06MG;0.015MG/ /N16680/002/
>DLT> /EUTHROID-2/
>DLT> /PARKE/DAVIS/ /0.12MG;0.03MG/ /N16680/003/
>DLT> /EUTHROID-3/
>DLT> /PARKE/DAVIS/ /0.18MG;0.045MG/ /N16680/004/
>DLT> /THYROLAR-0.25/
>DLT> /ARMOUR/PHARM/ /0.0125MG;0.0031MG/ /N16807/001/
>DLT> /THYROLAR-0.5/
>DLT> /ARMOUR/PHARM/ /0.025MG;0.00625MG/ /N16807/005/
>DLT> /THYROLAR-1/
>DLT> /ARMOUR/PHARM/ /0.05MG;0.0125MG/ /N16807/004/
>DLT> /THYROLAR-2/
>DLT> /ARMOUR/PHARM/ /0.1MG;0.025MG/ /N16807/002/
>DLT> /THYROLAR-3/
>DLT> /ARMOUR/PHARM/ /0.15MG;0.0375MG/ /N16807/003/
>DLT> /THYROLAR-5/
>DLT> /3/ARMOUR/PHARM/ /0.25MG;0.0625MG/ /N16807/006/

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
XYLOCAINE
AP ASTRA PHARM PRODS 1% N16801 005 JAN 19, 1988

INJECTABLE; SPINAL
LIDOCAINE HCL AND DEXTROSE 7.5%
AP ABBOTT LABS 5% N83914 001
/LIDOCAINE HCL W/ DEXTROSE/
/AP/ /ABBOTT/LABS/ /5%/ /N83914/001/

SOLUTION; TOPICAL
LIDOCAINE HCL
>ADD> AT PACO RES 4%* N89688 001 JUN 30, 1989
>ADD>

>ADD> LIOTRIX (T4;T3)

>ADD> TABLET; ORAL
>ADD> EUTHROID-0.5
>ADD> PARKE DAVIS 0.03MG;0.0075MG N16680 001
>ADD> EUTHROID-1
>ADD> PARKE DAVIS 0.06MG;0.015MG N16680 002

> ADD > LIOTRIX (T4;T3)

> ADD > TABLET; ORAL

> ADD >	EUTHROID-2		
> ADD >	PARKE DAVIS	0.12MG;0.03MG	N16680 003
> ADD >	EUTHROID-3		
> ADD >	PARKE DAVIS	0.18MG;0.045MG	N16680 004
> ADD >	THYROLAR-0.25		
> ADD >	RORER PHARM	0.0125MG;0.0031MG	N16807 001
> ADD >	THYROLAR-0.5		
> ADD >	RORER PHARM	0.025MG;0.00625MG	N16807 005
> ADD >	THYROLAR-1		
> ADD >	RORER PHARM	0.05MG;0.0125MG	N16807 004
> ADD >	THYROLAR-2		
> ADD >	RORER PHARM	0.1MG;0.025MG	N16807 002
> ADD >	THYROLAR-3		
> ADD >	RORER PHARM	0.15MG;0.0375MG	N16807 003
> ADD >	THYROLAR-5		
> ADD >	@ RORER PHARM	0.25MG;0.0625MG	N16807 006

LISINOPRIL

TABLET; ORAL

	PRINIVIL		
AB	MS&D RES LABS	40MG	N19558 004 OCT 25, 1988
	ZESTRIL		
AB	IMPERIAL CHEM	40MG	N19777 004 MAY 19, 1988

LITHIUM CARBONATE

CAPSULE; ORAL

	LITHIUM CARBONATE		
AB	PBI	300MG‡	N72542 001 FEB 01, 1989

MANNITOL

SOLUTION; IRRIGATION

	/RESECTISOL/ /KENDALL/MCGAW/	/5GM/100ML/	/N16704/002/
	@ KENDALL MCGAW	5GM/100ML	N16704 002

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

	MECLIZINE HCL		
/AA/	/VANGARD/LABS/	/12.5MG/	/N87877/001/ /APR/20,/1982/
/AA/		/25MG/	/N87620/001/ /JAN/04,/1982/
	@ VANGARD LABS	12.5MG	N87877 001 APR 20, 1982
	@	25MG	N87620 001 JAN 04, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL

	MECLOFENAMATE SODIUM		
AB	BARR LABS	EQ 50MG BASE‡	N72848 001 MAR 20, 1989
AB		EQ 100MG BASE‡	N72809 001 MAR 20, 1989

MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL

	LARIAM		
	ROCHE	250MG‡	N19591 001 MAY 02, 1989
	MEFLOQUINE HCL		
	@ WALTER REED	250MG‡	N19578 001 MAY 02, 1989

MEPERIDINE HYDROCHLORIDE

METAPROTERENOL SULFATE

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

AP	ASTRA PHARM PRODS	25MG/ML¤	N89781 001 MAR 31, 1989
AP		50MG/ML¤	N89782 001 MAR 31, 1989
AP		50MG/ML¤	N89783 001 MAR 31, 1989
AP		50MG/ML¤	N89784 001 MAR 31, 1989
AP		75MG/ML¤	N89785 001 MAR 31, 1989
AP		100MG/ML¤	N89786 001 MAR 31, 1989
AP		100MG/ML¤	N89787 001 MAR 31, 1989
AP		100MG/ML¤	N89788 001 MAR 31, 1989

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

>DLT >/AA/	/CHELSEA/LABS/	/600MG/	/N85719/001/
>ADD >	∂ CHELSEA LABS	600MG	N85719 001
/AA/	/LEDERLE/LABS/	/400MG/	/N86299/001/
	∂ LEDERLE LABS	400MG	N86299 001
/AA/	/VANGARD/LABS/	/400MG/	/N88011/001/ /JUL/14,/1982/
	∂ VANGARD LABS	400MG	N88011 001 JUL 14, 1982
/AA/	/WHITE/TN/PAULSN/	/200MG/	/N83830/001/
/AA/		/400MG/	/N83442/001/
	∂ WHITE TN PAULSN	200MG	N83830 001
	∂	400MG	N83442 001

MESNA

INJECTABLE; INJECTION

MESNEX

ASTA PHARMA	100MG/ML	N19884 001 DEC 30, 1988
/BRISTOL/MYERS/	/100MG/ML/	/N19884/001/ /DEC/30,/1988/

METAPROTERENOL SULFATE

SOLUTION; INHALATION

>DLT >		/DEY-DOSE/		
>DLT >/AN/		/DEY/LABS/	/5%/	/N70805/001/ /AUG/17,/1987/
>DLT >		/DEY-LUTE/		
>DLT >/AN/		/DEY/LABS/	/0.4%/	/N71786/001/ /AUG/05,/1988/
>DLT >/AN/			/0.6%/	/N70804/001/ /AUG/17,/1987/
>DLT >			/0.33%/	/N71806/001/ /AUG/05,/1988/
>DLT >			/0.5%/	/N71805/001/ /AUG/05,/1988/

METAPROTERENOL SULFATE

>ADD > AN	DEY LABS	0.4%	N71786 001 AUG 05, 1988
>ADD > AN		0.6%	N70804 001 AUG 17, 1987
>ADD > AN		5%	N70805 001 AUG 17, 1987
>ADD >		0.33%	N71806 001 AUG 05, 1988
>ADD >		0.5%	N71805 001 AUG 05, 1988

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE-AQ PRESERVED

AP	BRISTOL MYERS	EQ 25MG BASE/ML¤	N89887 001 APR 14, 1989

METHYCLOTHIAZIDE

TABLET; ORAL

METHYCLOTHIAZIDE

>DLT >/AA/	/CHELSEA/LABS/	/2.5MG/	/N88750/001/ /SEP/06,/1984/
>DLT >			
>ADD >	∂ CHELSEA LABS	2.5MG	N88750 001 SEP 06, 1984
>ADD >			

METHYLDOPA

TABLET; ORAL

		METHYLDOPA				
> ADD >	AB	SUPERPHARM	250MG¤	N70669 001 JUN 23, 1989		
> ADD >						
> ADD >			500MG¤	N70670 001 JUN 23, 1989		
> ADD >	AB					
> ADD >						

METHYLPREDNISOLONE

TABLET; ORAL

	METHYLPREDNISOLONE			
AB	CHELSEA LABS	4MG	N86161 001 FEB 09, 1982	
/BP/		/4MG/	/N86161/001/ /FEB/09,/1982/	
> DLT > /BP/		/16MG/	/N86159/001/ /FEB/09,/1982/	
> DLT >				
> ADD >	ə	16MG	N86159 001 FEB 09, 1982	
> ADD >				

METHYLPREDNISOLONE ACETATE

/ENEMA;/RECTAL/ /MEDROL/ /UPJOHN/	/40MG/BOT/	/N18102/001/	
ə UPJOHN	40MG/BOT	N18102 001	

METHYLTESTOSTERONE

TABLET; BUCCAL

ANDROID 5			
/BROWN/PHARM/	/5MG/	/N87222/001/	
ICN PHARMS	5MG	N87222 001	

TABLET; ORAL

ANDROID 10			
/AB/ /BROWN/PHARM/	/10MG/	/N86450/001/	
AB ICN PHARMS	10MG	N86450 001	
ANDROID 25			
/AB/ /BROWN/PHARM/	/25MG/	/N87147/001/	
AB ICN PHARMS	25MG	N87147 001	

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

		METOCLOPRAMIDE HCL			
> ADD >	AP	ABBOTT LABS	EQ 10MG BASE/2ML¤	N70505 001 JUN 23, 1989	
> ADD >					
> ADD >	AP		EQ 10MG BASE/2ML¤	N70506 001 JUN 22, 1989	
> ADD >					
	AP	BULL LABS	EQ 10MG BASE/2ML¤	N71990 001 JAN 18, 1989	
	AP	DUPONT CRI CARE	EQ 10MG BASE/2ML¤	N71291 001 MAR 03, 1989	

TABLET; ORAL

	METOCLOPRAMIDE HCL			
> ADD >	AB	INVAMED	EQ 5MG BASE¤	N72436 001 JUN 22, 1989
> ADD >				

METOPROLOL TARTRATE

TABLET; ORAL

	LOPRESSOR			
AB	GEIGY PHARMS	50MG		N17963 001
AB		100MG		N17963 002
	METOPROLOL TARTRATE			
AB	HENRY SCHEIN	50MG¤	DEC 21, 1993 : FEB 08, 1989	N71690 001
AB		100MG¤	DEC 21, 1993 : FEB 08, 1989	N71691 001

METRIZAMIDE

INJECTABLE; INJECTION

AMIPAQUE			
/STERLING/DRUG/	/2.5GM/VIAL/	/N17982/003/ /SEP/12,/1983/	
ə STERLING DRUG	2.5GM/VIAL	N17982 003 SEP 12, 1983	

MOMETASONE FUROATE

LOTION; TOPICAL

ELOCON			
SCHERING	0.1%		N19796 001 MAR 30, 1989

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

AP	ABBOTT LABS	10MG/ML¤	N70914 001 FEB 03, 1989
AP		10MG/ML¤	N70915 001 FEB 03, 1989
AP		20MG/ML¤	N70916 001 FEB 03, 1989
AP		20MG/ML¤	N70917 001 FEB 03, 1989
AP		20MG/ML¤	N70918 001 FEB 03, 1989
AP	ASTRA PHARM PRODS	10MG/ML¤	N72070 001 APR 10, 1989
AP		10MG/ML¤	N72071 001 APR 10, 1989
AP		10MG/ML¤	N72072 001 APR 10, 1989
AP		20MG/ML¤	N72073 001 APR 10, 1989
AP		20MG/ML¤	N72074 001 APR 10, 1989
AP		20MG/ML¤	N72075 001 APR 10, 1989

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL

AP	ASTRA PHARM PRODS	0.02MG/ML¤	N72081 001 APR 11, 1989
AP		0.02MG/ML¤	N72082 001 APR 11, 1989
AP		0.02MG/ML¤	N72083 001 APR 11, 1989
AP		0.02MG/ML¤	N72084 001 APR 11, 1989
AP		0.02MG/ML¤	N72085 001 APR 11, 1989
AP		0.4MG/ML¤	N72086 001 APR 11, 1989
AP		0.4MG/ML¤	N72087 001 APR 11, 1989
AP		0.4MG/ML¤	N72088 001 APR 11, 1989
AP		0.4MG/ML¤	N72089 001 APR 11, 1989
AP		0.4MG/ML¤	N72090 001 APR 11, 1989
AP		1MG/ML¤	N72091 001 APR 11, 1989
AP		1MG/ML¤	N72092 001 APR 11, 1989
AP		1MG/ML¤	N72093 001 APR 11, 1989

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
MURO'S OPCON

/AT/	/MURO/PHARM/	/0.1%/	/N87506/001/

OPCON

AT	BAUSCH & LOMB	0.1%	N87506 001

NEOMYCIN SULFATE

TABLET; ORAL
NEOMYCIN SULFATE

>_DLT_>/AA/	/SQUIBB/	/EQ 350MG BASE/	/N60365/001/
>_ADD_>	@ SQUIBB	EQ 350MG BASE	N60365 001

NIACIN

TABLET; ORAL

NIACIN

~~AA~~	~~CHELSEA LABS~~	~~500MG~~	~~N85172 001~~	
	ə CHELSEA LABS	500MG	N85172 001	

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

AB	PUREPAC PHARM	10MG¤	N72579 001 †	APR 28, 1989
AB		20MG¤	N72556 001 †	APR 28, 1989

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

> DLT > ~~AB~~	~~CHELSEA LABS~~	~~50MG~~	~~N85797 001~~	
> DLT > ~~AB~~	~~CHELSEA LABS~~	~~100MG~~	~~N85796 001~~	
> ADD >	ə CHELSEA LABS	50MG	N85797 001	
> ADD >	ə	100MG	N85796 001	

NYSTATIN

TABLET; VAGINAL

NYSTATIN

> DLT > ~~AA~~	~~CHELSEA LABS~~	~~100,000 UNITS~~	~~N62176 001~~	
> ADD >	ə CHELSEA LABS	100,000 UNITS	N62176 001	

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

AP	ELKINS SINN	EQ 250MG BASE/VIAL¤	N62711 001	FEB 03, 1989
AP		EQ 500MG BASE/VIAL¤	N62711 002	FEB 03, 1989
AP		EQ 1GM BASE/VIAL¤	N62711 003	FEB 03, 1989
AP		EQ 2GM BASE/VIAL¤	N62711 004	FEB 03, 1989
AP		EQ 4GM BASE/VIAL¤	N62711 005	FEB 03, 1989
AP		EQ 10GM BASE/VIAL¤	N62711 006	FEB 03, 1989

OXYBUTYNIN CHLORIDE

TABLET; ORAL

OXYBUTYNIN CHLORIDE

AB	BOLAR PHARM	5MG¤	N72485 001	APR 19, 1989

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

AP	ABBOTT LABS	1MG/ML¤	N72320 001	JAN 19, 1989
AP		2MG/ML¤	N72321 001	JAN 19, 1989

PENBUTOLOL SULFATE

TABLET; ORAL

LEVATOL

~~LILLY~~	~~10MG~~	~~N18976 001~~	~~DEC 30, 1987~~
REED & CARNRICK	10MG	N18976 001	DEC 30, 1987

PENICILLIN G BENZATHINE

~~SUSPENSION; ORAL~~

~~BICILLIN~~

~~WYETH AYERST LABS~~	~~300,000 UNITS/5ML~~	~~N50126 002~~	
ə WYETH AYERST LABS	300,000 UNITS/5ML	N50126 002	

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

AA	CLONMEL CHEMS	EQ 125MG BASE/5ML¤	N62981 001	FEB 10, 1989
AA		EQ 250MG BASE/5ML¤	N62981 002	FEB 10, 1989

PENTAMIDINE ISETHIONATE

POWDER FOR RECONSTITUTION; INHALATION

> ADD >	NEBUPENT			
> ADD >	LYPHOMED	300MG/VIAL¤	N19887 001	JUN 15, 1989

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

PENTOBARBITAL SODIUM

CAPSULE; ORAL

PENTOBARBITAL SODIUM

/AA/	/WHITE/TN/PAULSN/	/100MG/	/N83338/001/			
	@ WHITE TN PAULSN	100MG	N83338 001			

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

/DI-METREX/

/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85698/001/			
	@ PRIVATE FMLTNS	35MG	N85698 001			

PHENDIMETRAZINE TARTRATE

>DLT >/AA/	/CHELSEA/LABS/	/35MG/	/N85767/001/			
>DLT >/AA/		/35MG/	/N85768/001/			
>DLT >/AA/		/35MG/	/N85770/001/			
>DLT >/AA/		/35MG/	/N85773/001/			
>ADD >	@ CHELSEA LABS	35MG	N85767 001	>DLT >		
>ADD >	@	35MG	N85768 001	>DLT >		
>ADD >	@	35MG	N85770 001	>DLT >		
>ADD >	@	35MG	N85773 001	>DLT >		
/AA/	/PRIVATE/FMLTNS/	/35MG/	/N85199/001/			
	@ PRIVATE FMLTNS	35MG	N85199 001			

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

>DLT >/AA/	/CHELSEA/LABS/	/30MG/	/N86740/001/	>ADD >	AA	REED & CARNRICK
>DLT >			/MAR/21,/1985/	>ADD >		
>ADD >	@ CHELSEA LABS	30MG	N86740 001	>ADD >		
>ADD >			MAR 21, 1985	>DLT >		
				>DLT >		
				>DLT >		

240GM/BOT;2.98GM/BOT;6.72GM/BOT;
5.84GM/BOT;22.72GM/BOT N18983 007
JUN 12, 1987

/240GM/BOT;2.98GM/BOT;6.72GM/BOT;/
/5.84GM/BOT;22.72GM/BOT/ /N18983/001/
/JUN/12,/1987/

TABLET; ORAL

PHENTERMINE HCL

>DLT >/AA/	/CHELSEA/LABS/	/8MG/	/N85739/001/	>ADD >	AA	BRAINTREE LABS
>ADD >	@ CHELSEA LABS	8MG	N85739 001	>ADD >		
				>ADD >		

236GM/BOT;2.97GM/BOT;6.74GM/BOT;
5.86GM/BOT;22.74GM/BOT N19011 001
JUL 13, 1984

PHENYL AMINOSALICYLATE

/POWDER;/ORAL/

/PHENY-PAS-TEBAMIN/

/PURDUE/FRDRK/	/50%/	/N11695/002/	
@ PURDUE FRDRK	50%	N11695 002	

/TABLET;/ORAL/

/PHENY-PAS-TEBAMIN/

/PURDUE/FRDRK/	/500MG/	/N11695/003/	
@ PURDUE FRDRK	500MG	N11695 003	

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN VC

AA	WYETH AYERST LABS	5MG/5ML;6.25MG/5ML*	N08604 003	APR 02, 1984

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC

PREFRIN-A

ALLERGAN	0.12%;0.1%	N07953 001	

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

POWDER FOR RECONSTITUTION; ORAL

/GOLYTELY/

/BRAINTREE/LABS/ /236GM/BOT;2.97GM/BOT;6.74GM/BOT;/
/5.86GM/BOT;22.74GM/BOT/ /N19011/001/
/JUL/13,/1984/

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

POWDER FOR RECONSTITUTION; ORAL

COLYTE

AA	REED & CARNRICK	240GM/BOT;2.98GM/BOT;6.72GM/BOT; 5.84GM/BOT;22.72GM/BOT	N18983 007	JUN 12, 1987

GOLYTELY

AA	BRAINTREE LABS	236GM/BOT;2.97GM/BOT;6.74GM/BOT; 5.86GM/BOT;22.74GM/BOT	N19011 001	JUL 13, 1984

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER

/AP/	/BAXTER/	/75MG/100ML;900MG/100ML/	/N17648/004/	
@ BAXTER		75MG/100ML;900MG/100ML	N17648 004	
/AP/	/KENDALL/MCGAW/	/75MG/100ML;900MG/100ML/	/N18722/001/	/NOV/09,/1982/
@ KENDALL MCGAW		75MG/100ML;900MG/100ML	N18722 001	NOV 09, 1982

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0,9% AND POTASSIUM CHLORIDE 0,15% IN PLASTIC CONTAINER

/AP/ /KENDALL/MCGAW/ /150MG/100ML;/ /900MG/100ML/ /N18722/002/ /NOV/09,/1982/

∂ KENDALL MCGAW 150MG/100ML; 900MG/100ML N18722 002 NOV 09, 1982

SODIUM CHLORIDE 0,9% AND POTASSIUM CHLORIDE 0,22% IN PLASTIC CONTAINER

/AP/ /KENDALL/MCGAW/ /220MG/100ML;/ /900MG/100ML/ /N18722/003/ /NOV/09,/1982/

∂ KENDALL MCGAW 220MG/100ML; 900MG/100ML N18722 003 NOV 09, 1982

SODIUM CHLORIDE 0,9% AND POTASSIUM CHLORIDE 0,3% IN PLASTIC CONTAINER

/AP/ /KENDALL/MCGAW/ /300MG/100ML;/ /900MG/100ML/ /N18722/004/ /NOV/09,/1982/

∂ KENDALL MCGAW 300MG/100ML; 900MG/100ML N18722 004 NOV 09, 1982

PRALIDOXIME CHLORIDE

/TABLET;/ORAL/ /PROTOPAM/CHLORIDE/ /WYETH/AYERST/LABS/ /500MG/ /N14122/002/

∂ WYETH AYERST LABS 500MG N14122 002

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

AB	AM THERPTCS	EQ 1MG BASE¤	N72782 001 MAY 16, 1989 : APR 11, 1989
AB		EQ 2MG BASE¤	N72783 001 MAY 16, 1989 : APR 11, 1989
AB		EQ 5MG BASE¤	N72784 001 MAY 16, 1989 : APR 11, 1989
AB	CORD LABS	EQ 1MG BASE¤	N72576 001 MAY 16, 1989 : APR 10, 1989
AB		EQ 2MG BASE¤	N72577 001 MAY 16, 1989 : APR 10, 1989
AB		EQ 5MG BASE¤	N72578 001 MAY 16, 1989 : APR 10, 1989

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

AB	DANBURY PHARMA	EQ 1MG BASE¤	N72352 001 MAY 16, 1989 : JAN 11, 1989
AB		EQ 2MG BASE¤	N72333 001 MAY 16, 1989 : JAN 11, 1989
AB		EQ 5MG BASE¤	N72609 001 MAY 16, 1989 : JAN 11, 1989
AB	LEDERLE LABS	EQ 1MG BASE¤	N72705 001 MAY 16, 1989 : MAR 15, 1989
AB		EQ 2MG BASE¤	N72706 001 MAY 16, 1989 : MAR 15, 1989
AB		EQ 5MG BASE¤	N72707 001 MAY 16, 1989 : MAR 15, 1989
AB	MYLAN PHARMS	EQ 1MG BASE¤	N72573 001 MAY 16, 1989 : FEB 28, 1989
AB		EQ 2MG BASE¤	N72574 001 MAY 16, 1989 : FEB 28, 1989
AB		EQ 5MG BASE¤	N72575 001 MAY 16, 1989 : FEB 28, 1989
AB	PUREPAC PHARM	EQ 1MG BASE¤	N72991 001 MAY 16, 1989 : APR 26, 1989
AB		EQ 2MG BASE¤	N72921 001 MAY 16, 1989 : APR 26, 1989
AB		EQ 5MG BASE¤	N72992 001 MAY 16, 1989 : APR 26, 1989
/AB/	/ZENITH/LABS/	/EQ 1MG BASE/	/N71994/001/ /SEP/12,/1988/
AB	ZENITH LABS	EQ 1MG BASE	N71994 001 MAY 16, 1989 : SEP 12, 1988
/AB/		/EQ 2MG BASE/	/N71995/001/ /SEP/12,/1988/
AB		EQ 2MG BASE	N71995 001 MAY 16, 1989 : SEP 12, 1988
/AB/		/EQ 5MG BASE/	/N71745/001/ /SEP/12,/1988/
AB		EQ 5MG BASE	N71745 001 MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

SYRUP; ORAL

PRELONE

MURO PHARM 5MG/5ML¤ N89654 001 JAN 17, 1989

PREDNISOLONE

TABLET; ORAL
PREDNISOLONE

>_DLT_>	/BX/	/CHELSEA/LABS/	/5MG/	/N85415/001/	
>_DLT_>	/BX/		/5MG/	/N85416/001/	
>_ADD_>		ə CHELSEA LABS	5MG	N85415 001	
>_ADD_>		ə	5MG	N85416 001	
	/BX/	/WHITE/TN/PAULSN/	/5MG/	/N80342/001/	
		ə WHITE TN PAULSN	5MG	N80342 001	

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC
SULPHRIN

AT	BAUSCH & LOMB	0.5%;10%	N88089 001	
			DEC 28, 1982	
/AT/	/MURO/PHARM/	/0.5%;10%/	/N88089/001/	
			/DEC/28,/1982/	

PREDNISONE

SOLUTION; ORAL
PREDNISONE INTENSOL

	ROXANE LABS	5MG/ML	N88810 001	
			FEB 20, 1985	
	/SYRUP;/ORAL/			
	/PREDNISONE/INTENSOL/			
	/ROXANE/LABS/	/5MG/ML/	/N88810/001/	
			/FEB/20,/1985/	

TABLET; ORAL
DELTASONE

AB	UPJOHN	50MG	N09986 008	
/BX/		/50MG/	/N09986/008/	

PREDNISONE

AB	CORD LABS	10MG*	N89983 001	
			JAN 12, 1989	
AB		50MG*	N89984 001	
			JAN 12, 1989	
>_ADD_> AB	HALSEY DRUG	5MG	N80300 001	
>_DLT_> /BX/		/5MG/	/N80300/001/	
/BX/	/VANGARD/LABS/	/5MG/	/N87682/001/	
			/JAN/15,/1982/	
/BX/		/20MG/	/N87701/001/	
			/JAN/15,/1982/	
	ə VANGARD LABS	5MG	N87682 001	
			JAN 15, 1982	
	ə	20MG	N87701 001	
			JAN 15, 1982	

PREDNISONE

TABLET; ORAL
PREDNISONE

/AB/	/WHITE/TN/PAULSN/	/10MG/	/N89028/001/	
			/JUL/24,/1986/	
/BX/		/2.5MG/	/N84913/001/	
/BX/		/5MG/	/N80343/001/	
/BX/		/20MG/	/N84913/002/	
	ə WHITE TN PAULSN	2.5MG	N84913 001	
	ə	5MG	N80343 001	
	ə	10MG	N89028 001	
			JUL 24, 1986	
		20MG	N84913 002	

/SERVISONE/

/BX/	/LEDERLE/LABS/	/5MG/	/N80223/001/	
	ə LEDERLE LABS	5MG	N80223 001	

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL
PROCAINAMIDE HCL

/AB/	/VANGARD/LABS/	/250MG/	/N87643/001/	
			/JUN/01,/1982/	
/AB/		/500MG/	/N87875/001/	
			/JUN/01,/1982/	
	ə VANGARD LABS	250MG	N87643 001	
			JUN 01, 1982	
	ə	500MG	N87875 001	
			JUN 01, 1982	

INJECTABLE; INJECTION
PROCAINAMIDE HCL

>_DLT_>/AP/	/PHARMAFAIR/	/100MG/ML/	/N88824/001/	
>_DLT_>			/NOV/20,/1985/	
>_DLT_>/AP/		/500MG/ML/	/N88830/001/	
>_DLT_>			/NOV/20,/1985/	
>_ADD_>	ə PHARMAFAIR	100MG/ML	N88824 001	
>_ADD_>			NOV 20, 1985	
>_ADD_>	ə	500MG/ML	N88830 001	
>_ADD_>			NOV 20, 1985	

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL

AB	INWOOD LABS	500MG*	N89840 001	
			MAR 06, 1989	

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

	/BP/	/CHELSEA/LABS/	/12.5MG/	/N85986/001/	
>DLT>	/BP/		/25MG/	/N85684/001/	
	/BP/		/50MG/	/N85664/001/	
		@ CHELSEA LABS	12.5MG	N85986 001	
>ADD>		@	25MG	N85684 001	
		@	50MG	N85664 001	

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
PROPOXYPHENE HCL

>DLT>	/AA/	/CHELSEA/LABS/	/65MG/	/N85190/001/	
>ADD>		@ CHELSEA LABS	65MG	N85190 001	

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
INDERAL LA

AB	WYETH AYERST LABS	60MG	N18553 004	MAR 18, 1987
AB		80MG	N18553 002	APR 19, 1983
AB		120MG	N18553 003	APR 19, 1983
AB		160MG	N18553 001	APR 19, 1983

PROPRANOLOL HCL

AB	INWOOD LABS	60MG‡	N72499 001	APR 11, 1989
AB		80MG‡	N72500 001	APR 11, 1989
AB		120MG‡	N72501 001	APR 11, 1989
AB		160MG‡	N72502 001	APR 11, 1989

SOLUTION; ORAL
PROPRANOLOL HCL

AA	PBI	20MG/5ML‡	N71984 001	MAR 03, 1989
AA		40MG/5ML‡	N71985 001	MAR 03, 1989
AA	ROXANE LABS	20MG/5ML	N70979 001	MAY 15, 1987
AA		40MG/5ML	N70690 001	MAY 15, 1987

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

	/AB/	/LEDERLE/LABS/	/10MG/	/N72117/001/	/JUN/23,/1988/
	/AB/		/20MG/	/N72118/001/	/JUN/23,/1988/
	/AB/		/40MG/	/N72119/001/	/JUN/23,/1988/
	/AB/		/80MG/	/N72120/001/	/JUN/23,/1988/
		@ LEDERLE LABS	10MG	N72117 001	JUN 23, 1988
		@	20MG	N72118 001	JUN 23, 1988
		@	40MG	N72119 001	JUN 23, 1988
		@	80MG	N72120 001	JUN 23, 1988
>ADD>	AB	MYLAN PHARMS	60MG‡	N72275 001	JUN 09, 1989
>ADD>					

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

>DLT>	/BD/	/CHELSEA/LABS/	/50MG/	/N85201/001/	
>ADD>		@ CHELSEA LABS	50MG	N85201 001	

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION
MESTINON

AP	ICN PHARMS	5MG/ML		N09830 001	
/AP/	/ROCHE/	/5MG/ML/		/N09830/001/	

SYRUP; ORAL
MESTINON
ICN PHARMS /ROCHE/ — 60MG/5ML /60MG/5ML/ — N15193 001 /N15193/001/

TABLET; ORAL
MESTINON
ICN PHARMS /ROCHE/ — 60MG /60MG/ — N09829 002 /N09829/002/

TABLET, EXTENDED RELEASE; ORAL
MESTINON
ICN PHARMS /ROCHE/ — 180MG /180MG/ — N11665 001 /N11665/001/

QUINIDINE GLUCONATE

SAFFLOWER OIL

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIDINE GLUCONATE

/LILLY/	/80MG/ML/	/N07529/001/		
LILLY	80MG/ML	N07529 002		
		FEB 10, 1989		

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

AB	MUTUAL PHARM	100MG	N81029 001	
			APR 14, 1989	
AB		200MG	N81030 001	
			APR 14, 1989	
AB		300MG	N81031 001	
			APR 14, 1989	
/AB/	/PBI/	/200MG/	/N87837/001/	
			/APR/14,/1982/	
	∂ PBI	200MG	N87837 001	
			APR 14, 1982	
/AB/	/WHITE/TN/PAULSN/	/200MG/	/N85444/001/	
	∂ WHITE TN PAULSN	200MG	N85444 001	

RESERPINE

TABLET; ORAL
RESERPINE

>DLT >	/BP/	/ROXANE/LABS/	/0.25MG/	/N09859/002/	
>ADD >		∂ ROXANE LABS	0.25MG	N09859 002	
	/BP/	/ZENITH/LABS/	/0.1MG/	/N11185/001/	
	/BP/		/0.25MG/	/N11185/002/	
		∂ ZENITH LABS	0.1MG	N11185 001	
		∂	0.25MG	N11185 002	

RIFAMPIN

CAPSULE; ORAL
RIFADIN

>DLT >	/AB/	/DOW/PHARMS/	/300MG/	/N50420/001/	
>DLT >			/150MG/	/N62303/001/	
>ADD >	AB	MERRELL DOW	300MG	N50420 001	
>ADD >			150MG	N62303 001	

INJECTABLE; INJECTION
RIFADIN

MERRELL DOW	600MG/VIAL	N50627 001		
		MAY 25, 1989		

SAFFLOWER OIL

INJECTABLE; INJECTION

>DLT >		/LIPOSYN/20%/			
>DLT >		/ABBOTT/LABS/	/20%/	/N18614/001/	
>ADD >		∂ ABBOTT LABS	20%	N18614 001	

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM

/AA/	/WHITE/TN/PAULSN/	/100MG/	/N85798/001/	
	∂ WHITE TN PAULSN	100MG	N85798 001	
	SODIUM SECOBARBITAL			
/AA/	/CHELSEA/LABS/	/100MG/	/N85792/001/	
	∂ CHELSEA LABS	100MG	N85792 001	

SECRETIN

INJECTABLE; INJECTION
SECRETIN-FERRING

FERRING LABS	75CU/VIAL	N18290 001	
/SECRETIN-KABI/			
/PHARMACIA/LABS/	/75CU/VIAL/	/N18290/001/	

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
ELDEPRYL

>ADD >	SOMERSET PHARMS	5MG	N19334 001
>ADD >			JUN 05, 1989

SINCALIDE

INJECTABLE; INJECTION
KINEVAC

/SQUIBB/	/0.005MG/VIAL/	/N17697/001/	
SQUIBB DIAGS	0.005MG/VIAL	N17697 001	

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/BP/	/CUTTER/BIOL/	/450MG/100ML/	/N18503/001/	
	∂ CUTTER BIOL	450MG/100ML	N18503 001	
	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER			
/BP/	/CUTTER/BIOL/	/900MG/100ML/	/N18502/001/	
	∂ CUTTER BIOL	900MG/100ML	N18502 001	

SODIUM CHLORIDE

SOLUTION; IRRIGATION

	SODIUM CHLORIDE IN PLASTIC CONTAINER			
AT	CUTTER BIOL	900MG/100ML	N18247 001	
	∂ CUTTER BIOL	900MG/100ML		

SODIUM IODIDE, I-123

CAPSULE; ORAL

	SODIUM IODIDE I 123			
AA	BENEDICT NUCLR	200 UCI	N18671 002	MAY 27, 1982
AA	MALLINCKRODT	100 UCI*	N71909 001	FEB 28, 1989
AA		200 UCI*	N71910 001	FEB 28, 1989

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL

	PHOSPHOTOPE			
	SQUIBB	1-8MCI/VIAL	N10927 001	
	∂ SQUIBB	1-8MCI/VIAL		

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL

	SODIUM POLYSTYRENE SULFONATE			
AA	CAROLINA MED	454GM/BOT*	N89910 001	JAN 19, 1989

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION

	HUMATROPE			
	LILLY	2MG/VIAL	N19640 001	JUN 23, 1987
	∂ LILLY	2MG/VIAL		

SPIRONOLACTONE

TABLET; ORAL

	SPIRONOLACTONE			
AB	VANGARD LABS	25MG	N87648 001	FEB 01, 1982
	∂ VANGARD LABS	25MG		

SULCONAZOLE NITRATE

CREAM; TOPICAL

	SULCOSYN			
	SYNTEX LABS	1%	N18737 001	FEB 28, 1989

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

	SULTEN-10			
AT	BAUSCH & LOMB	10%	N87818 001	FEB 03, 1983
AT	MURO PHARM	10%	N87818 001	FEB 03, 1983

SULFINPYRAZONE

CAPSULE; ORAL

	SULFINPYRAZONE			
AB	VANGARD LABS	200MG	N88666 001	FEB 17, 1984
	∂ VANGARD LABS	200MG		

TECHNETIUM TC-99M FERPENTETATE KIT

	INJECTABLE; INJECTION			
	RENOTEC			
	SQUIBB	N/A	N17045 001	
	∂ SQUIBB	N/A		

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL

	SODIUM PERTECHNETATE TC 99M			
AP	CIS US	12MCI/ML	N17321 001	
AP		24MCI/ML	N17321 002	
AP		48MCI/ML	N17321 003	

SOLUTION; INJECTION, ORAL

SODIUM PERTECHNETATE TC 99M

AP	CIS US	12MCI/ML	N17321 001
AP		24MCI/ML	N17321 002
AP		48MCI/ML	N17321 003

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL

SODIUM PERTECHNETATE TC 99M

	/GAMMA/DIAG/LABS/	/10-60MCI/ML/	/N17725/001/
	MALLINCKRODT	10-60MCI/ML	N17725 001
/AP/	/SYNCOR/INTL/	/12MCI/ML/	/N17321/001/
/AP/		/24MCI/ML/	/N17321/002/
/AP/		/48MCI/ML/	/N17321/003/

TECHNETIUM TC-99M SULFUR COLLOID

SOLUTION; INJECTION, ORAL

TECHNETIUM TC 99M SULFUR COLLOID

/GAMMA/DIAG/LABS/	/3MCI/ML/	/N17724/001/	
MALLINCKRODT	3MCI/ML	N17724 001	

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

>DLT >/AB/	/CHELSEA/LABS/	/250MG/	/N62103/001/	
>DLT >/AB/		/500MG/	/N62103/002/	
>ADD >	∂ CHELSEA LABS	250MG	N62103 001	
>ADD >	∂	500MG	N62103 002	

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION

THALLOUS CHLORIDE TL 201

AP	SQUIBB DIAGS	1MCI/ML	N18548 001
			DEC 30, 1982

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SLO-BID

BC	RORER PHARM	75MG∝	N89539 001
			MAY 10, 1989
BC		125MG∝	N89540 001
			MAY 10, 1989

THEO-DUR SPRINKLE

BC	KEY PHARMS	75MG	N88015 001
			SEP 10, 1985

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

THEO-DUR

AB	KEY PHARMS	100MG	N85328 001
AB		200MG	N86998 001
/BC/		/100MG/	/N85328/001/
/BC/		/200MG/	/N86998/001/

THEOPHYLLINE

AB	INWOOD LABS	100MG	N88320 001
			FEB 21, 1985
AB		200MG	N88321 001
			FEB 21, 1985
/BC/		/100MG/	/N88320/001/
			/FEB/21,/1985/
/BC/		/200MG/	/N88321/001/
			/FEB/21,/1985/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

>DLT >/AB/	/CHELSEA/LABS/	/15MG/	/N88562/001/	
>DLT >			/MAY/11,/1984/	
>ADD >	∂ CHELSEA LABS	15MG	N88562 001	
>ADD >			MAY 11, 1984	

THIOTHIXENE HYDROCHLORIDE

INJECTABLE; INJECTION

NAVANE

/ROERIG/	/EQ/5MG/BASE/ML/	/N16904/002/	
ROERIG	EQ 10MG BASE/VIAL	N16904 002	

TIMOLOL MALEATE

TABLET; ORAL

BLOCADREN

AB	MS&D	5MG	N18017 001
AB		10MG	N18017 002
AB		20MG	N18017 004

TIMOLOL MALEATE

AB	BOLAR PHARM	5MG∝	N72269 001
			APR 11, 1989 : MAR 14, 1989
AB		10MG∝	N72270 001
			APR 11, 1989 : MAR 14, 1989
AB		20MG∝	N72271 001
			APR 11, 1989 : MAR 14, 1989

TIMOLOL MALEATE

TABLET; ORAL

	TIMOLOL MALEATE			
AB	CORD LABS	5MG¤	N72550 001	APR 13, 1989
AB		10MG¤	N72551 001	APR 13, 1989
AB		20MG¤	N72552 001	APR 13, 1989
AB	PBI	5MG¤	N72001 001	APR 11, 1989 : JAN 10, 1989
AB		10MG¤	N72002 001	APR 11, 1989 : JAN 10, 1989
AB		20MG¤	N72003 001	APR 11, 1989 : JAN 10, 1989
AB	QUANTUM PHARMCS	5MG¤	N72466 001	MAY 19, 1989
AB		10MG¤	N72467 001	MAY 19, 1989
AB		20MG¤	N72468 001	MAY 19, 1989

TOLBUTAMIDE

TABLET; ORAL

	TOLBUTAMIDE		
/AB/	/VANGARD LABS/	/500MG/	/N87876/001/ /APR 20, 1982/
	∂ VANGARD LABS	500MG	N87876 001 APR 20, 1982

TOLMETIN SODIUM

TABLET; ORAL

	TOLECTIN 600		
	MCNEIL PHARM	EQ 600MG BASE¤	N17628 002 MAR 08, 1989

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

	TRAZODONE HCL		
AB	LEMMON	50MG¤	N72192 001 FEB 02, 1989
AB		100MG¤	N72193 001 FEB 02, 1989

TRIAMCINOLONE

TABLET; ORAL

		TRIAMCINOLONE			
>DLT> >ADD>	/BP/	/CHELSEA/LABS/ ∂ CHELSEA LABS	/4MG/ 4MG	/N85834/001/ N85834 001

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

	TRIAMCINOLONE ACETONIDE		
AT	TOPIDERM	0.025%¤	N89274 001 FEB 21, 1989
AT		0.1%¤	N89275 001 FEB 21, 1989
AT		0.5%¤	N89276 001 FEB 21, 1989

TRICHLORMETHIAZIDE

TABLET; ORAL

		TRICHLORMETHIAZIDE		
>DLT> >ADD>	/BP/	/CHELSEA/LABS/ ∂ CHELSEA LABS	/2MG/ 2MG	/N86458/001/ N86458 001

TRIHEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL

	ARTANE		
AA	LEDERLE LABS	2MG/5ML	N06773 009
	TRIHEXYPHENIDYL HCL		
AA	LIQUIPHARM	2MG/5ML¤	N89514 001 APR 07, 1989

TABLET; ORAL

		TRIHEXYPHENIDYL HCL		
/AA/		/VANGARD LABS/ ∂ VANGARD LABS	/2MG/ 2MG	/N88035/001/ /JUL 30, 1982/ N88035 001 JUL 30, 1982

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL

		TRIPELENNAMINE HCL		
>DLT> >ADD>	/AA/	/CHELSEA/LABS/ ∂ CHELSEA LABS	/50MG/ 50MG	/N85188/001/ N85188 001

VERAPAMIL HYDROCHLORIDE

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

AB	CHELSEA LABS	40MG	N72799 001 APR 28, 1989
AB	MYLAN PHARMS	80MG	N71482 001 FEB 15, 1989
AB		120MG	N71483 001 FEB 15, 1989
AB	SIDMAK LABS	80MG	N72124 001 JAN 26, 1989
AB		120MG	N72125 001 JAN 26, 1989

WATER FOR IRRIGATION, STERILE

LIQUID; IRRIGATION
STERILE WATER IN PLASTIC CONTAINER

/AI/	/CUTTER/BIOL/	/100%/	/N18246/001/
	@ CUTTER BIOL	100%	N18246 001

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G&W LABS — 325MG — N18060 003 DEC 18, 1986

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
> ADD > FOAMICON
> ADD > INVAMED — 80MG;20MG¤ — N72687 001 JUN 28, 1989
> ADD >

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
BIOSCRUB
KW GRIFFEN — 4%¤ — N19822 001 MAR 31, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
PSEUDO-CHLOR
KV PHARM — 12MG;120MG¤ — N71455 001 MAR 01, 1989

PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE — /8MG;120MG/ — /N18844/001/ /MAR/20,/1985/
/GRAHAM/LABS/
∂ GRAHAM LABS — 8MG;120MG — N18844 001 MAR 20, 1985

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PENNTUSS
FISONS — EQ 4MG MALEATE/5ML; EQ 10MG BASE/5ML — N18928 001 AUG 14, 1985

/PENNWALT/ — /EQ/4MG/MALEATE/5ML;/ /EQ/10MG/BASE/5ML/ — /N18928/001/ /AUG/14,/1985/

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
CORSYM
FISONS — EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML — N18050 001 JAN 04, 1984

/PENNWALT/ — /EQ/4MG/MALEATE/5ML;/ /EQ/37.5MG/HCL/5ML/ — /N18050/001/ /JAN/04,/1984/

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
> DLT > /PHENERGAN/DM/
> DLT > /WYETH/AYERST/LABS/ — /15MG/5ML;6.25MG/5ML/ — /N11265/003/ /AUG/11,/1988/
> DLT >
> ADD > PHENERGAN W/ DEXTROMETHORPHAN
> ADD > WYETH AYERST LABS — 15MG/5ML;6.25MG/5ML — N11265 003 AUG 11, 1988
> ADD >

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL
DIPHENHYDRAMINE HCL
NASKA PHARMA — 12.5MG/5ML¤ — N70497 001 APR 25, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN
> DLT > /CHELSEA/LABS/ — /200MG/ — /N71765/001/ /SEP/04,/1987/
> DLT > ∂ CHELSEA LABS — 200MG — N71765 001 SEP 04, 1987
> ADD > MUTUAL PHARM — 200MG¤ — N72249 001 JAN 10, 1989
> ADD >

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 70/30
LILLY — 30 UNITS/ML; 70 UNITS/ML¤ — N19717 001 APR 25, 1989

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VISINE II
PFIZER 0.025% N19407 001
MAR 31, 1989

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

>DLT > /SYRUP;/ORAL/
>DLT > /PHENERGAN/VC/
>DLT > /WYETH/AYERST/LABS/ /10MG/5ML;6.25MG/5ML/ /N08604/004/
>DLT > /AUG/11,/1988/
>ADD > ə WYETH AYERST LABS 10MG/5ML;6.25MG/5ML N08604 004
>ADD > AUG 11, 1988

POVIDONE-IODINE

SOLUTION; TOPICAL
POVIDONE IODINE
BAXTER 1% N19522 001
MAR 31, 1989

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
TRIPROLIDINE AND PSEUDOEPHRINE HCL
KV PHARM 120MG;5MG N71798 001
MAR 16, 1989

SYRUP; ORAL
/MYFED/
/PBI/ /30MG/5ML;1.25MG/5ML/ /N88116/001/
/MAR/04,/1983/
ə PBI 30MG/5ML;1.25MG/5ML N88116 001
MAR 04, 1983

PSEUDOEPHEDRINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL
PSEUDO-12
FISONS EQ 60MG HCL/5ML N19401 001
JUN 19, 1987
/PENNWALT/ /EQ/60MG/HCL/5ML/ /N19401/001/
/JUN/19,/1987/

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'89- JUN'89
APPROVED UNDER SECTION 505 OF THE ACT LIST

NO JUNE 1989 APPROVALS

ORPHAN DRUG PRODUCT DESIGNATIONS

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).

THE "CUMULATIVE LIST OF ORPHAN DRUG PRODUCT DESIGNATIONS," ISSUED AS AN ADDENDUM TO THE 9TH EDITION OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, IS CURRENT THROUGH MARCH 31, 1989. THIS SECTION OF THE CUMULATIVE SUPPLEMENT WILL SERVE AS AN UPDATE TO THAT ADDENDUM AND WILL REPLACE THE FORMER SECTION ENTITLED "ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL." THE NDA NUMBER/LICENSE NUMBER, APPROVAL DATE, DOSAGE FORM, ROUTE OF ADMINISTRATION, AND STRENGTH THAT APPEARED IN THE FORMER SECTION MAY BE FOUND ELSEWHERE IN THIS PUBLICATION FOR APPROVED DRUGS; FOR LICENSED BIOLOGICALS, THIS INFORMATION WILL NO LONGER BE DISPLAYED.

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).

REFER BACK TO THE ADDENDUM TO APPROVED DRUG PRODUCTS, 9TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS DESIGNATIONS. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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].

BIOLOGICAL DRUG DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: GRANULOCYTE MACROPHAGE-COLONY STIMULATING FACTOR, RECOMBINANT E. COLI [RGM-CSF] TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE THERMAL INJURIES IN PATIENTS WITH GREATER THAN 40% FULL OR PARTIAL THICKNESS BURNS.	SCHERING CORPORATION 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033
GENERIC: INTERFERON ALFA-2A (RECOMBINANT) TRADE: ROFERON-A	TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA (CML).	HOFFMAN-LA ROCHE 340 KINGSLAND STREET NUTLEY, NJ 07110
GENERIC: MONOCLONAL FACTOR IX TRADE: NOT ESTABLISHED	REPLACEMENT TREATMENT AND PROPHYLAXIS OF HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B.	ARMOUR PHARMACEUTICAL COMPANY 920A HARVEST DRIVE SUITE 200 BLUE BELL, PA 19422

DRUG DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: BROMHEXINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF MILD TO MODERATE KERATOCONJUNCTIVITIS SICCA IN PATIENTS WITH SJOGREN'S SYNDROME.	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. 90 EAST RIDGE P.O. BOX 368 RIDGEFIELD, CT 06877
GENERIC: CALCIUM ACETATE TRADE: NOT ESTABLISHED	TREATMENT OF HYPERPHOSPHATEMIA IN END STAGE RENAL DISEASE (ESRD).	PHARMEDIC COMPANY 130 EXMOOR COURT DEERFIELD, IL 60015
GENERIC: DIHEMATOPORPHYRIN ETHERS TRADE: PHOTOFRIN II	USE FOR THE PHOTODYNAMIC THERAPY OF PATIENTS WITH PRIMARY OR RECURRENT OBSTRUCTING (EITHER PARTIALLY OR COMPLETELY) ESOPHAGEAL CARCINOMA.	QLT PHOTOTHERAPEUTICS, INC. NORTH MIDDLETOWN ROAD PEARL RIVER, NY 10965
GENERIC: FLUDARABINE PHOSPHATE TRADE: NOT ESTABLISHED	TREATMENT OF NON-HODGKIN'S LYMPHOMA (NHL).	TRITON BIOSCIENCES 1501 HARBOR BAY PARKWAY ALAMEDA, CA 94501

DRUG DESIGNATIONS
[Approved for Marketing*]
[Exclusive Approval**]

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: POLOXAMER 188, N.F. TRADE: RHEOTHRX COPOLYMER	TREATMENT OF SICKLE CELL CRISIS.	CYTRX CORPORATION 150 TECHNOLOGY PARKWAY TECHNOLOGY PARK/ATLANTA NORCROSS, GA 30092
GENERIC: SOMATROPIN TRADE: SAIZEN	ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES 100 LONGWATER CIRCLE NORWELL, MA 02061
GENERIC: T4 ENDONUCLEASE V, LIPOSOME ENCAPSULATED TRADE: T4N5	TO PREVENT CUTANEOUS NEOPLASMS AND OTHER SKIN ABNORMALITIES ASSOCIATED WITH PATIENTS DIAGNOSED WITH XERODERMA PIGMENTOSUM (XP).	APPLIED GENETICS, INC. 205 BUFFALO AVENUE FREEPORT, NY 11520

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

NO JUNE 1989 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, HFN-250, 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, 9TH 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
ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER - IN VIVO)	AUG 25, 1988	FEB 09, 1989
ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER - IN VITRO)	AUG 25, 1988	JUN 27, 1989
GEMFIBROZIL (CAPSULE)	JUN 23, 1989	
TOLMETIN SODIUM (CAPSULE AND TABLET)	APR 20, 1989	

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, 9TH 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
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 10MG	88 P-0416/CP	MORAVEC	NEW STRENGTH	APPROVED MAR 01, 1989
CARMUSTINE, STERILE INJECTABLE; INJECTION	200MG/VIAL	88 P-0410/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989
HALOPERIDOL DECANOATE INJECTABLE; INJECTION	EQ 50MG BASE/ML (2ML/CONTAINER)	88 P-0411/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
HYDROCORTISONE VALERATE LOTION; TOPICAL	0.2%	89P-0028/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
HYDROCORTISONE VALERATE SOLUTION; TOPICAL	0.2%	89P-0029/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	30MG	89P-0071/CP	OXFORD RES INTL	NEW DOSAGE FORM	APPROVED MAY 10, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE IN PLASTIC CONTAINER POWDER FOR RECONSTITUTION; ORAL	59GM/PACKET 0.7425GM/PACKET 1.685GM/PACKET 1.465M/PACKET 5.685GM/PACKET	88P-0419/CP	GUIDELINES	NEW STRENGTH	APPROVED MAR 01, 1989
PREDNISONE CAPSULE; ORAL	1MG 2.5MG 5MG 10MG 20MG 25MG 50MG	88 P-0391/CP	ASCHER	NEW DOSAGE FORM	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
THIOTEPA, STERILE INJECTABLE; INJECTION	30MG/VIAL 60MG/VIAL	88 P-0412/CP	QUAD PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

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, 9TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW INDICATION

I-84 ADJUNCTIVE THERAPY TO DIET TO REDUCE THE RISK OF CORONARY ARTERY DISEASE

I-85 SELECTIVE ADULT VISCERAL ARTERIOGRAPHY

I-86 METASTATIC BREAST CANCER IN PREMENOPAUSAL WOMEN AS AN ALTERNATIVE TO OOPHORECTOMY OR OVARIAN IRRADIATION

I-87 TREATMENT OF TINEA PEDIS

I-88 CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS IN THE SPINE AND ASSOCIATED TISSUES

I-89 PEDIATRIC MYELOGRAPHY

I-90 ORAL USE OF DILUTED OMNIPAQUE INJECTION IN ADULTS FOR CONTRAST ENHANCED COMPUTED TOMOGRAPHY OF THE ABDOMEN

I-91 ORAL USE IN ADULTS FOR PASS-THROUGH EXAMINATION OF THE GASTROINTESTINAL TRACT

EXCLUSIVITY TERMS

REFERENCES
PATENT USE CODE

U-41	METHOD FOR TREATING PROSTATIC CARCINOMA COMPRISING ADMINISTERING FLUTAMIDE
U-42	METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING FLUTAMIDE AND AN LHRH AGONIST
U-43	REDUCING CHOLESTEROL IN CHOLELITHIASIS PATIENTS
U-44	REDUCING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-45	DISSOLVING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-46	CEREBRAL, CORONARY, PERIPHERAL, VISCERAL AND RENAL ARTERIOGRAPHY, AORTOGRAPHY AND LEFT VENTRICULOGRAPHY
U-47	CT IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY
U-48	CEREBRAL ANGIOGRAPHY, AND VENOGRAPHY
U-49	INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
U-50	PALLIATIVE TREATMENT OF PATIENTS WITH OVARIAN CARCINOMA RECURRENT AFTER PRIOR CHEMOTHERAPY, INCLUDING PATIENTS WHO HAVE BEEN PREVIOUSLY TREATED WITH CISPLATIN
U-51	TREATING VIRAL INFECTIONS IN A MAMMAL
U-52	TREATING VIRAL INFECTIONS IN A WARM BLOODED ANIMAL
U-53	TREATING CYTOMEGALOVIRUS IN A HUMAN WITH AN INJECTABLE COMPOSITION

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
	19270 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC	4252984	AUG 30, 1999		NCE	AUG 30, 1990
	18469 001	CALCIUM CHLORIDE; BSS PLUS	4550022	OCT 29, 2002			
			4443432	APR 17, 2001			
	19880 001	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 002	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 003	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19471 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
						NP	JAN 23, 1992
	19386 003	ESMOLOL HYDROCHLORIDE; BREVIBLOC	4387103	JUN 07, 2000	U-16		
						NCE	DEC 31, 1991
	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
			4472382	SEP 18, 2001	U-42		
			4329364	MAY 11, 1999	U-41		
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST				I-88	APR 28, 1992
>ADD>	19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-53		
>ADD>			4423050	OCT 19, 1999	U-52		
>ADD>			4355032	OCT 19, 1999	U-51	NCE	JUN 23, 1994
	18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
	19778 001	HYDROCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
	19778 002	HYDROCHLOROTHIAZIDE; PRINZIDE 25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
>ADD>	18956 001	IOHEXOL; OMNIPAQUE 180				I-89	JUN 30, 1992
>ADD>	18956 002	IOHEXOL; OMNIPAQUE 240				I-90	JUN 30, 1992
>ADD>						NR	JUN 30, 1992
	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-85	MAR 31, 1992
>ADD>						I-90	JUN 30, 1992
>ADD>						NR	JUN 30, 1992
	18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-85	MAR 31, 1992
>ADD>						NR	JUN 30, 1992
>ADD>						I-90	JUN 30, 1992
>ADD>						I-91	JUN 30, 1992
>ADD>	18956 006	IOHEXOL; OMNIPAQUE 210				NS	JUN 30, 1992

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19710 001	IOVERSOL; OPTIRAY-320	4396598	AUG 02, 2000	U-46	NCE	DEC 30, 1993
			4396598	AUG 02, 2000	U-47		
	19710 002	IOVERSOL; OPTIRAY-240	4396598	AUG 02, 2000	U-48	NCE	DEC 30, 1993
	19710 003	IOVERSOL; OPTIRAY-160	4396598	AUG 02, 2000	U-49	NCE	DEC 30, 1993
	08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				ODE	AUG 31, 1995
						I-79	AUG 31, 1995
	19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NCE	APR 09, 1990
						NP	JAN 26, 1992
>ADD>	19814 001	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN				NS	JUN 28, 1992
	19777 004	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
	19578 001	MEFLOQUINE HYDROCHLORIDE; MEFLOQUINE HCL				NCE	MAY 02, 1994
	19591 001	MEFLOQUINE HYDROCHLORIDE; LARIAM				NCE	MAY 02, 1994
	19625 001	MOMETASONE FUROATE; ELOCON	4808610	FEB 28, 2006			
	19796 001	MOMETASONE FUROATE; ELOCON	4775529	OCT 04, 2005		NCE	APR 30, 1992
			4472393	SEP 18, 2001		NDF	MAR 30, 1992
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
						I-87	APR 05, 1992
	19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
	19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
	19407 001	OXYMETAZOLINE HYDROCHLORIDE; VISINE II				NDF	MAY 30, 1989
>ADD>	19887 001	PENTAMIDINE ISETHIONATE; NEBUPENT				ODE	JUN 15, 1996
	18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS	4271143	JUN 02, 1998			
>ADD>	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL				NCE	JUN 05, 1994
>ADD>						ODE	JUN 05, 1996
	19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				NR	MAY 10, 1992
	19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				NR	MAY 10, 1992
	18737 001	SULCONAZOLE NITRATE; SULCOSYN	4055652	OCT 25, 1996		NCE	AUG 30, 1990
						NDF	FEB 28, 1992
	17970 001	TAMOXIFEN CITRATE; NOLVADEX				I-86	MAR 16, 1992
	19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC	4789736	DEC 06, 2005			
>ADD>	18321 001	TECHNETIUM TC-99M OXIDRONATE KIT; OSTEOSCAN-HDP	4497744	FEB 05, 2002			
>ADD>			4432963	FEB 21, 2001			
>ADD>			4247534	JAN 27, 1998			
>ADD>			4233284	NOV 11, 1997			
			3752826	AUG 14, 1990			
	17628 002	TOLMETIN SODIUM; TOLECTIN 600	RE30910	JAN 07, 1994	U-43		
	19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-44		
			RE30910	JAN 07, 1994	U-45		
	19594 002	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
			RE30910	JAN 07, 1994	U-44		
			RE30910	JAN 07, 1994	U-45		