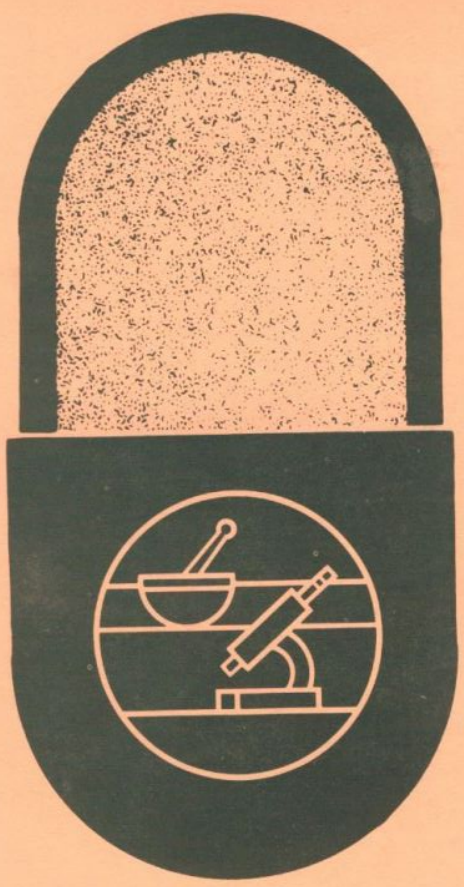
CUMULATIVE SUPPLEMENT 7

JAN'89-JUL'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
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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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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
DUPONT CRITICAL CARE SUB EI DUPONT DE NEMOURS & COMPANY INC	DUPONT PHARMACEUTICALS DIV EI DUPONT DE NEMOURS & COMPANY INC	DUPONT PHARMS
MCNEIL PHARMACEUTICAL DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
ORTHO PHARMACEUTICAL CORP	RW JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE DIVISION OF ORTHO PHARMACEUTICAL CORP	RW JOHNSON
SCHERING CORP	SCHERING CORP SUB SCHERING PLOUGH CORP	SCHERING

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 RESCISSION OF APPROVAL LETTERS

On August 3, 1989, the Agency, in separate letters to Par Pharmaceutical and American Therapeutics, Inc. (ATI), rescinded the approval letters of June 5 and June 23, 1989, respectively, for chlorzoxazone 500mg tablets. The approvals were rescinded because of substantial deficiencies in manufacturing practices discovered by the Agency at each firm at the time of each approval. These products are considered unapproved new drugs that cannot be marketed.

The Agency is assessing all current information available to make a fair and final determination concerning the adequacy of Par's and ATI's manufacturing practices with regard to these ANDAs. An opportunity for hearing, as required by Section 505(c)(1), will be provided should the Agency determine it cannot approve these applications.

1.6 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

AA	DURAMED PHARMS	300MG;15MG	N88353 001	FEB 06, 1984
		300MG;30MG	N88354 001	FEB 06, 1984
		300MG;60MG	N88355 001	FEB 06, 1984
	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
		300MG;60MG	N87920 001	JUN 22, 1982
AA	WHITE TN PAULSN	300MG;30MG	N84360 001	
AA		300MG;60MG	N85607 001	
AA	VANGARD LABS	300MG;30MG	N88037 001	MAR 20, 1984
AA	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

AA	BEECHAM LABS	500MG;5MG	N89160 001	APR 23, 1987

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

AA	MCNEIL LABS	500MG;4.5MG;0.38MG	N85375 001	
	RW JOHNSON	500MG;4.5MG;0.38MG	N85375 001	

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL

PROPOXYPHENE HCL AND ACETAMINOPHEN

> ADD >					
> ADD >	AA	CORD LABS	650MG;65MG‡	N89959 001	JUL 18, 1989
> ADD >					

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

AB	VANGARD LABS	250MG	N87654 001	FEB 05, 1982
∂	VANGARD LABS	250MG	N87654 001	FEB 05, 1982

ACETRIZOATE SODIUM

SOLUTION; INTRAUTERINE

SALPIX

	ORTHO PHARM	53%	N09008 001
∂	RW JOHNSON	53%	N09008 001

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

ACETYLCYSTEINE

AN	DUPONT CRI CARE	10%¤	N71364 001	MAY 01, 1989
AN		20%¤	N71365 001	MAY 01, 1989

MUCOMYST

AN	MEAD JOHNSON	10%	N13601 002
AN		20%	N13601 001

ALBUMIN, CHROMATED CR-51 SERUM

INJECTABLE; INJECTION

CHROMALBIN

>ADD>	ISO TEX DIAGS	100 UCI/VIAL	N17835 001	
>ADD>	∂	250 UCI/VIAL	N17835 002	
>ADD>	∂	500 UCI/VIAL	N17835 003	
>DLT>	SQUIBB/DIAGS	100 UCI/VIAL	N17835 001	
>DLT>	∂	250 UCI/VIAL	N17835 002	
>DLT>	∂	500 UCI/VIAL	N17835 003	

ALBUMIN, IODINATED I-125 SERUM

INJECTABLE; INJECTION

ALBUMOTOPE 125 I

>ADD>	∂ ISO TEX DIAGS	5-50 UCI/AMP	N17836 001	
>DLT>	∂/SQUIBB	5-50 UCI/AMP	N17836 001	

ALBUMIN, IODINATED I-131 SERUM

INJECTABLE; INJECTION

ALBUMOTOPE 131 I

>ADD>	∂ ISO TEX DIAGS	5 UCI/AMP	N17837 004	
>ADD>	∂	20 UCI/AMP	N17837 005	
>ADD>		0.5MCI/VIAL	N17837 001	
>ADD>		1MCI/VIAL	N17837 002	
>ADD>	∂	2MCI/VIAL	N17837 003	
>DLT>	∂/SQUIBB	5/UCI/AMP	N17837 004	
>DLT>	∂	20/UCI/AMP	N17837 005	
>DLT>		0.5MCI/VIAL	N17837 001	
>DLT>		1MCI/VIAL	N17837 002	
>DLT>	∂	2MCI/VIAL	N17837 003	

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

ALLOPURINOL

TABLET; ORAL

LOPURIN

>DLT>/AB/	BOOTS/LABS	100MG	N18297 001	
>DLT>/AB/		300MG	N18297 002	
>DLT>/AB/	BOOTS/PHARMS	100MG	N71586 001	APR 02, 1987
>DLT>/AB/		300MG	N71587 001	APR 02, 1987

ALLOPURINOL

TABLET; ORAL
LOPURIN

> ADD > AB	BOOTS USA	100MG	N18297 001	
> ADD > AB		100MG	N71586 001	
			APR 02, 1987	
> ADD >				
> ADD > AB		300MG	N18297 002	
> ADD > AB		300MG	N71587 001	
			APR 02, 1987	
> ADD >				

AMINO ACIDS

INJECTABLE; INJECTION

/AMINOSYN/11/3.5%/IN/PLASTIC/CONTAINER/			
/ABBOTT/LABS/	/3.5%/		/N19491/001/
			/OCT/16,/1986/
ə 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/
ə 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/
ə 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

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

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

INJECTABLE;/INJECTION/

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

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

/BP/ /CHELSEA/LABS/	/150MG/		/N85821/001/
ə CHELSEA LABS	150MG		N85821 001

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

/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/
	∂ LEDERLE LABS	10MG	N87366 001	JAN 04, 1982
	∂	25MG	N87367 001	MAY 03, 1982
	∂	50MG	N87181 001	JAN 04, 1982
	∂	75MG	N87369 001	JAN 04, 1982
	∂	100MG	N87368 001	MAY 03, 1982
	∂	150MG	N87370 001	JAN 04, 1982
/AB/	/PBI/	/25MG/	/N87775/001/	/FEB/10,/1982/
	∂ 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/	
	∂ ROXANE LABS	10MG	N86144 001	
	∂	25MG	N86145 001	
	∂	50MG	N86143 001	
	∂	75MG	N86147 001	
	∂	100MG	N86146 001	
	∂	150MG	N86148 001	

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

/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/
	∂ VANGARD LABS	10MG	N87632 001	FEB 01, 1982
	∂	25MG	N87570 001	FEB 08, 1982
	∂	50MG	N87616 001	FEB 08, 1982
	∂	75MG	N87617 001	FEB 05, 1982
	∂	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
	/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

/AA/	/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/

/AA/	/CHELSEA/LABS/	/389MG;32.4MG;65MG/	/N85732/002/ /SEP/03,/1984/
	@ CHELSEA LABS	389MG;32.4MG;65MG	N85732 002 SEP 03, 1984

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

>ADD>	AA	CHELSEA LABS	0.025MG;2.5MG	N85876 001
	/AA/	/LEDERLE/LABS/	/0.025MG;2.5MG/	/N86950/001/
		@ LEDERLE LABS	0.025MG;2.5MG	N86950 001
>ADD>		DIPHENOXYLATE HCL AND ATROPINE SULFATE		
>ADD>	AA	PHARMAFAIR	0.025MG;2.5MG	N85035 001
		DIPHENOXYLATE HCL W/ ATROPINE SULFATE		
>DLT>	/AA/	/CHELSEA/LABS/	/0.025MG;2.5MG/	/N85876/001/
	/AA/	/PBI/	/0.025MG;2.5MG/	/N87842/001/ /MAR/29,/1982/
		@ PBI	0.025MG;2.5MG	N87842 001 MAR 29, 1982
>DLT>		/DIPHENOXYLATE W/ ATROPINE SULFATE/		
>DLT>	/AA/	/BOOTS/LABS/	/0.025MG;2.5MG/	/N85035/001/
		/LO-TROL/		
	/AA/	/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
	ə 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

BETAMETHASONE DIPROPIONATE

CREAM, AUGMENTED; TOPICAL
DIPROLENE

BX	SCHERING	EQ 0.05% BASE	N19408 001 JAN 31, 1986

LOTION; TOPICAL

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

LOTION, AUGMENTED; TOPICAL
DIPROLENE

BX	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

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

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE

AA	CHELSEA LABS	5MG	N85841 001
AA		10MG	N85842 001
AA		25MG	N85839 001
	ə CHELSEA LABS	5MG	N85841 001
	ə	10MG	N85842 001
	ə	25MG	N85839 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE IN DEXTROSE 5%

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

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

~~BRETYLIUM TOSYLATE IN DEXTROSE 5%~~

	ə ABBOTT LABS	200MG/100ML	N19005 002 APR 16, 1986
	ə	400MG/100ML	N19005 003 APR 16, 1986
	ə	800MG/100ML	N19005 001 APR 16, 1986

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~~
	ə PBI	2MG/5ML	N87964 001 JAN 25, 1983

TABLET; ORAL

BROMPHENIRAMINE MALEATE

~~AA~~	~~CHELSEA LABS~~	~~4MG~~	~~N85769 001~~
	ə CHELSEA LABS	4MG	N85769 001

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

~~BROMFED-AT~~

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

BROMFED-DM

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

BUPROPION HYDROCHLORIDE

~~TABLET; ORAL~~

~~WELLBUTRIN~~

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

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

~~AA~~	~~CHELSEA LABS~~	~~15MG~~	~~N85764 001~~
~~AA~~	~~CHELSEA LABS~~	~~30MG~~	~~N85772 001~~
	ə CHELSEA LABS	15MG	N85764 001
	ə	30MG	N85772 001
~~AA~~	~~WHITE TN PAULSN~~	~~30MG~~	~~N83337 001~~
	ə WHITE TN PAULSN	30MG	N83337 001

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;/ /86OMG/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
> ADD > AB	SQUIBB MARK	EQ 250MG BASE/5ML¤		N62987 001 JUL 25, 1989
> ADD > /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

/AB/ /LEDERLE/LABS/	/5MG/	/N87234/001/
/AB/	/10MG/	/N87037/001/
/AB/	/25MG/	/N87231/001/
ə LEDERLE LABS	5MG	N87234 001
ə	10MG	N87037 001
ə	25MG	N87231 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/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

/INJECTABLE;/INJECTION/

ARALEN

/ə/STERLING/DRUG/ /EQ/40MG/BASE/ML/ /N06002/002/

INJECTABLE; INJECTION

ARALEN HCL

STERLING DRUG	EQ 40MG BASE/ML	N06002 002

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

>DLT>	/ə/BOOTS/PHARMS/	/4MG/	/N83753/001/
/AA/	/CHELSEA/LABS/	/4MG/	/N85139/001/
	ə CHELSEA LABS	4MG	N85139 001
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/
	ə LEDERLE LABS	4MG	N86941 001
>ADD>	ə PHARMAFAIR	4MG	N83753 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

/BC/	/CHELSEA/LABS/	/12MG;75MG/	/N88681/001/ /SEP/29,/1987/
	ə CHELSEA LABS	12MG;75MG	N88681 001 SEP 29, 1987
AB	CORD LABS	12MG;75MG	N88940 001 JAN 26, 1989

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

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>	/ə/BOOTS/PHARMS/	/10MG/	/N84414/001/
>DLT>	/ə/	/25MG/	/N84415/001/
>DLT>	/ə/	/50MG/	/N84411/001/
>DLT>	/ə/	/100MG/	/N84412/001/
>DLT>	/ə/	/200MG/	/N84413/001/
>ADD>	ə BOOTS USA	10MG	N84414 001
>ADD>	ə	25MG	N84415 001
>ADD>	ə	50MG	N84411 001
>ADD>	ə	100MG	N84412 001
>ADD>	ə	200MG	N84413 001
/BP/	/CHELSEA/LABS/	/10MG/	/N85959/001/
/BP/		/25MG/	/N85956/001/
/BP/		/50MG/	/N85960/001/
/BP/		/100MG/	/N85957/001/
/BP/		/200MG/	/N85958/001/
	ə CHELSEA LABS	10MG	N85959 001
	ə	25MG	N85956 001
	ə	50MG	N85960 001
	ə	100MG	N85957 001
	ə	200MG	N85958 001

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL

/BP/	/VANGARD LABS/	/10MG/	/N88038/001/ /AUG 16, 1982/
/BP/		/25MG/	/N87645/001/
/BP/		/50MG/	/N87646/001/
∂ VANGARD LABS		10MG	N88038 001 AUG 16, 1982
∂		25MG	N87645 001
∂		50MG	N87646 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

/AB/	/VANGARD LABS/	/25MG/	/N88012/001/ /JUL 14, 1982/
/AB/		/50MG/	/N88073/001/ /MAR 25, 1983/
∂ VANGARD LABS		25MG	N88012 001 JUL 14, 1982
∂		50MG	N88073 001 MAR 25, 1983

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

> DLT >	/AA/	/AM THERPTCS/	/500MG✠/	/N89911/001/ †† /JUN 23, 1989/
> DLT >	/AA/	/CHELSEA LABS/	/250MG/	/N86948/001/ /AUG 09, 1982/
∂ CHELSEA LABS			250MG	N86948 001 AUG 09, 1982
> DLT >	/AA/	/PAR PHARM/	/500MG✠/	/N89958/001/ †† /JUN 05, 1989/
> DLT >	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
/DISCASE/			
/BOOTS PHARMS/		/12,500/UNITS/VIAL/	/N18625/001/ /JAN 18, 1984/
∂ BOOTS USA		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
AT	LEMMON	EQ 1% BASE✠	N62930 001 JUN 28, 1989

†† SEE SECTION 1.5 OF INTRODUCTION

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/	/CHELSEA/LABS/	/3.75MG/	/N71878/001/ /MAR/15,/1988/	
/AB/		/7.5MG/	/N71879/001/ /MAR/15,/1988/	
/AB/		/15MG/	/N71860/001/ /MAR/15,/1988/	
	ə CHELSEA LABS	3.75MG	N71878 001 MAR 15, 1988	
	ə	7.5MG	N71879 001 MAR 15, 1988	
	ə	15MG	N71860 001 MAR 15, 1988	

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/	/LEDERLE/LABS/	/3.75MG/	/N72013/001/ /DEC/15,/1987/	
/AB/		/7.5MG/	/N72014/001/ /DEC/15,/1987/	
/AB/		/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

/INJECTABLE;/INJECTION/ /UNITENSEN/

/WALLACE/LABS/	/260/CSR/UNITS/ML/	/N08814/001/
ə WALLACE LABS	260 CSR UNITS/ML	N08814 001

CYANOCOBALAMIN

INJECTABLE; INJECTION

/REDISOL/

/AP/	/MSD/	/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

/BP/	/CHELSEA/LABS/	/0.75MG/	/N85818/001/
/BP/		/1.5MG/	/N85840/001/
	ə CHELSEA LABS	0.75MG	N85818 001
	ə	1.5MG	N85840 001

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

>ADD>	BP	DANBURY PHARMA	0.25MG		N85455 001
>ADD>	BP		0.5MG		N85458 001
>ADD>	BP		0.75MG		N80968 001
>ADD>	BP		1.5MG		N85456 001
>DLT>		/ə/	/0.25MG/		/N85455/001/
>DLT>		/ə/	/0.5MG/		/N85458/001/
>DLT>		/ə/	/0.75MG/		/N80968/001/
>DLT>		/ə/	/1.5MG/		/N85456/001/

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

>ADD>					
>ADD>	AT	FOUGERA	0.1%;EQ 3.5MG BASE/GM; 10,000 UNITS/GM		N62938 001 JUL 31, 1989
>ADD>					
>ADD>					

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

	/CARDIOGRAFIN/			
	/SQUIBB/	/85%/		/N11620/002/
	ə 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

	/ə/LEDERLE/LABS/	/50MG/		/N06459/001/
	LEDERLE LABS	50MG		N06459 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
DIETHYLPROPION HCL

/AA/	/CHELSEA/LABS/	/25MG/		/N85741/001/
	ə 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
	ə	180MG*		N19471 004 JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

/AA/	/CHELSEA/LABS/	/25MG/		/N85138/001/
	ə CHELSEA LABS	25MG		N85138 001
/AA/	/VANGARD/LABS/	/25MG/		/N88034/001/ /OCT 27, 1982/
/AA/		/50MG/		/N87630/001/
	ə VANGARD LABS	25MG		N88034 001 OCT 27, 1982
	ə	50MG		N87630 001
/AA/	/WHITE/TN/PAULSN/	/50MG/		/N80800/001/
	ə WHITE TN PAULSN	50MG		N80800 001

ELIXIR; ORAL
/DIPHEN/

/AA/	/PBI/	/12.5MG/5ML/		/N84640/001/
	ə PBI	12.5MG/5ML		N84640 001
	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	N85287 001

DISULFIRAM

TABLET; ORAL
DISULFIRAM

/BX/	/CHELSEA/LABS/	/250MG/	/N87973/001/ /AUG/05,/1983/
/BX/		/500MG/	/N87974/001/ /AUG/05,/1983/
∂	CHELSEA LABS	250MG	N87973 001 AUG 05, 1983
∂		500MG	N87974 001 AUG 05, 1983

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 002 MAY 03, 1988
AP		2MG/ML	N50629 001 DEC 23, 1987

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

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

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	
/BP/		/0.625MG/	/N85800 001/	
/BP/		/1.25MG/	/N85801 001/	
/BP/		/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	
/BP/		/0.3MG/	/N86492 001/	
/BP/		/0.625MG/	/N83272 001/	
/BP/		/1.25MG/	/N83294 001/	
/BP/		/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	
/BP/		/0.3MG/	/N88569 001/	/NOV 29, 1984/
/BP/		/0.625MG/	/N83373 001/	
/BP/		/1.25MG/	/N83601 001/	
/BP/		/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	
/BP/		/0.3MG/	/N04782 003/	
/BP/		/0.625MG/	/N04782 004/	
/BP/		/0.9MG/	/N04782 005/	/JAN 26, 1984/
/BP/		/1.25MG/	/N04782 001/	
/BP/		/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
>ADD > AB TICAN PHARM 0.05% N72494 001 JAN 19, 1989
>ADD >
>DLT >/AB/ /TJ/ROACO/ /0.05%/ /N72494/001/ /JAN/19,/1989/
>DLT >

GEL; TOPICAL
FLUOCINONIDE
AB LEMMON 0.05% N72537 001 FEB 07, 1989
LIDEX
AB SYNTEX LABS 0.05% N17373 001

FLUOCINONIDE

SOLUTION; TOPICAL
FLUOCINONIDE
AT LEMMON 0.05% N72511 001 FEB 07, 1989

>ADD > FLUOROMETHOLONE ACETATE; TOBRAMYCIN

>ADD > SUSPENSION/DROPS; OPHTHALMIC
>ADD > TOBRASONE
>ADD > ALCON LABS 0.1%;0.3% N50628 001 JUL 21, 1989
>ADD >

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 > /∂/BOOTS/PHARMS/ /1MG/ /N84158/001/
>ADD > ∂ BOOTS USA 1MG N84158 001

FOLIC ACID

TABLET; ORAL
FOLIC ACID

/AA/	/CHELSEA/LABS/	/1MG/	/N85141/002/
	∂ 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

GANCICLOVIR SODIUM

INJECTABLE; INJECTION
CYTOVENE

	SYNTEX LABS	EQ 500MG BASE/VIAL¤	N19661 001 JUN 23, 1989

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

/AA/	/CHELSEA/LABS/	/2MG/	/N86178/001/
	∂ CHELSEA LABS	2MG	N86178 001

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM

AP	STERIS LABS	40,000 UNITS/ML	N17064 006
/S/		/40,000 UNITS/ML/	/N17064/006/

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP	ABBOTT LABS	200 UNITS/100ML¤	N18916 010 JUN 23, 1989

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

AP	ABBOTT LABS	200 UNITS/100ML¤	N18916 011 JUN 23, 1989

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

AP	ABBOTT LABS	5,000 UNITS/100ML¤	N19805 002 JAN 25, 1989

/HEPARIN SODIUM 5000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER/

/AP/	/KENDALL/MCGAW/	/1,000 UNITS/100ML/	/N19042/004/ /MAR/29,/1985/
	∂ KENDALL MCGAW	1,000 UNITS/100ML	N19042 004 MAR 29, 1985

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL
HYDRALAZINE HCL

/AA/	/CHELSEA/LABS/	/25MG/	/N85532/002/ /MAY/24,/1982/
/AA/		/50MG/	/N85533/002/ /MAY/25,/1982/
	CHELSEA LABS	25MG	N85532 002 MAY 24, 1982
		50MG	N85533 002 MAY 25, 1982
/AA/	/PBI/	/25MG/	/N87780/001/ /MAR/29,/1982/
/AA/		/50MG/	/N87751/001/ /MAR/29,/1982/
	∂ PBI	25MG	N87780 001 MAR 29, 1982
	∂	50MG	N87751 001 MAR 29, 1982

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

	HYDRALAZINE HCL			
/AA/	/VANGARD LABS/	/50MG/	/N87908/001/	
			/MAY 07, 1982/	
	ə VANGARD LABS	50MG	N87908 001	
			MAY 07, 1982	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

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

HYDROCHLOROTHIAZIDE

TABLET; ORAL

	HYDROCHLOROTHIAZIDE				
DLT >/AB/	/BOOTS/LABS/	/25MG/	/N84325/001/		
DLT >/AB/		/50MG/	/N84324/001/		
/AB/	/CHELSEA/LABS/	/25MG/	/N85232/002/		
/AB/		/50MG/	/N85233/001/		
/AB/		/50MG/	/N86087/001/		
/AB/		/50MG/	/N86594/001/		
/AB/		/100MG/	/N87002/001/		
	ə CHELSEA LABS	25MG	N85232 002		
	ə	50MG	N85233 001		
	ə	50MG	N86087 001		
	ə	50MG	N86594 001		
	ə	100MG	N87002 001		
/AB/	/PBI/	/25MG/	/N87827/001/		
			/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		
>ADD > AB	PHARMAFAIR	25MG	N84325 001		
>ADD > AB		50MG	N84324 001		
/AB/	/VANGARD LABS/	/25MG/	/N87638/001/		
/AB/		/50MG/	/N87610/001/		
	ə VANGARD LABS	25MG	N87638 001		
	ə	50MG	N87610 001		

HYDROCHLOROTHIAZIDE

TABLET; ORAL

	HYDROCHLOROTHIAZIDE			
/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			
>ADD > AB	MS&D RES LABS	25MG;20MG	N19778 002	
>ADD >			FEB 16, 1989	
>ADD >	ZESTORETIC 20/25			
>ADD > AB	IMPERIAL CHEM	25MG;20MG¤	N19888 002	
>ADD >			JUL 20, 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	
AB	LEDERLE LABS	15MG;250MG¤	N72507 001	
			JUN 02, 1989	
AB		25MG;250MG¤	N72508 001	
			JUN 02, 1989	
AB		30MG;500MG¤	N72509 001	
			JUN 02, 1989	
AB		50MG;500MG¤	N72510 001	
			JUN 02, 1989	

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

	/H.R.-50/			
/BP/	/WHITE/TN/PAULSN/	/50MG;0.125MG/	/N85338/001/	

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

	H.R.-50		
	∂ WHITE TN PAULSN	50MG;0.125MG	N85338 001
	HYDROCHLOROTHIAZIDE W/ RESERPINE		
> DLT >	∂/BOOTS/PHARMS/	50MG;0.125MG	N85420 001
BP	/CHELSEA/LABS/	25MG;0.125MG	N86330 002
BP		50MG;0.125MG	N86331 001
	∂ CHELSEA LABS	25MG;0.125MG	N86330 002
	∂	50MG;0.125MG	N86331 001
> ADD >	∂ PHARMAFAIR	50MG;0.125MG	N85420 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

> DLT > AB	/VITARINE/	25MG;50MG	N71737 001
> DLT >			FEB 12, 1988
> ADD >	∂ VITARINE	25MG;50MG	
> ADD >			

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

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

TABLET; ORAL

HYDROCORTISONE

BP	/WHITE/TN/PAULSN/	10MG	N80344 001
BP		20MG	N80344 002
	∂ WHITE TN PAULSN	10MG	N80344 001
	∂	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
	∂ CHELSEA LABS	50MG	N88528 001 AUG 15, 1984

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

HYDROXOCOBALAMIN

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

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL

/AP/	/PHARMAFAIR/	/25MG/ML/	/N88862/001/	/FEB/14,/1986/
/AP/		/25MG/ML/	/N89106/001/	/FEB/14,/1986/
/AP/		/50MG/ML/	/N89107/001/	/FEB/14,/1986/
	∂ PHARMAFAIR	25MG/ML	N88862 001	FEB 14, 1986
	∂	25MG/ML	N89106 001	FEB 14, 1986
	∂	50MG/ML	N89107 001	FEB 14, 1986

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

/AB/	/CHELSEA/LABS/	/EQ 100MG HCL/	/N86728/001/	/OCT/05,/1982/
	∂ CHELSEA LABS	EQ 100MG HCL	N86728 001	OCT 05, 1982

IBUPROFEN

TABLET; ORAL

IBUPROFEN

> DLT >/AB/	/BOOTS/LABS/	/600MG/	/N70556/001/	/JUN/14,/1985/
> DLT >				
> DLT >	/∂/	/800MG/	/N71264/001/	/JUL/25,/1986/
> DLT >				
> ADD > AB	BOOTS USA	400MG	N70083 001	FEB 22, 1985
> ADD >				
> ADD > AB		600MG	N70556 001	JUN 14, 1985
> ADD >				
> ADD >	∂	800MG	N71264 001	JUL 25, 1986
> ADD >				
/AB/	/CHELSEA/LABS/	/300MG/	/N71338/001/	/DEC/01,/1986/
	∂ CHELSEA LABS	300MG	N71338 001	DEC 01, 1986

IBUPROFEN

TABLET; ORAL

RUFEN

> DLT >/AB/	/BOOTS/PHARMS/	/400MG/	/N18197/001/	/FEB/22,/1985/
> DLT >/AB/		/400MG/	/N70083/001/	/FEB/22,/1985/
> DLT >				
> DLT >/AB/		/600MG/	/N18197/002/	/MAR/05,/1984/
> DLT >				
> DLT >/AB/		/600MG/	/N70088/001/	/FEB/08,/1985/
> DLT >				
> DLT >/AB/		/600MG/	/N70099/001/	/MAR/29,/1985/
> DLT >				
> DLT >/AB/		/800MG/	/N70745/001/	/JUL/23,/1986/
> DLT >				
> ADD > AB	BOOTS USA	400MG	N18197 001	FEB 08, 1985
> ADD > AB		600MG	N70088 001	MAR 05, 1984
> ADD >				
> ADD > AB		600MG	N70099 001	MAR 29, 1985
> ADD >				
> ADD > AB		800MG	N70745 001	JUL 23, 1986
> ADD >				
> ADD >	∂	600MG	N18197 002	MAR 05, 1984
> ADD >				

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

/AB/	/CHELSEA/LABS/	/10MG/	/N85875/001/	/NOV/03,/1982/
/AB/		/25MG/	/N85878/001/	/NOV/03,/1982/
/AB/		/50MG/	/N85877/001/	/NOV/03,/1982/
	∂ CHELSEA LABS	10MG	N85875 001	NOV 03, 1982
	∂	25MG	N85878 001	NOV 03, 1982
	∂	50MG	N85877 001	NOV 03, 1982
/AB/	/PBI/	/25MG/	/N87776/001/	/FEB/10,/1982/
	∂ PBI	25MG	N87776 001	FEB 10, 1982
/AB/	/VANGARD/LABS/	/10MG/	/N88036/001/	/NOV/03,/1982/
/AB/		/25MG/	/N87619/001/	/FEB/09,/1982/
/AB/		/50MG/	/N87631/001/	/JAN/04,/1982/
	∂ VANGARD LABS	10MG	N88036 001	NOV 03, 1982
	∂	25MG	N87619 001	FEB 09, 1982
	∂	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

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

SOLUTION; INJECTION, ORAL

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

ISONIAZID

TABLET; ORAL

ISONIAZID

>DLT >	/AA/	/CHELSEA LABS/	/100MG/	/N85790 001/
>DLT >	/AA/		/300MG/	/N85784 001/
>ADD >		@ CHELSEA LABS	100MG	N85790 001
>ADD >		@	300MG	N85784 001
>DLT >	/AA/	/WHITE TN PAULSN/	/100MG/	/N80120 002/
>ADD >		@ WHITE TN PAULSN	100MG	N80120 002

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/

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAGAN

	ALLERGAN	0.25%	N19814 001 JUN 28, 1989

/LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM/

/TABLET; ORAL/

/EUTHROID-0.5/

	/PARKE DAVIS/	/0.03MG;0.0075MG/	/N16680 001/

/LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM/

/TABLET;/ORAL/
/EUTHROID-1/
/PARKE/DAVIS/ /0.06MG;0.015MG/ /N16680/002/
/EUTHROID-2/
/PARKE/DAVIS/ /0.12MG;0.03MG/ /N16680/003/
/EUTHROID-3/
/PARKE/DAVIS/ /0.18MG;0.045MG/ /N16680/004/
/THYROLAR-5/
/@/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
AT PACO RES 4%¤ N89688 001 JUN 30, 1989

LIOTRIX (T4;T3)

TABLET; ORAL
EUTHROID-0.5
PARKE DAVIS 0.03MG;0.0075MG N16680 001
EUTHROID-1
PARKE DAVIS 0.06MG;0.015MG N16680 002
EUTHROID-2
PARKE DAVIS 0.12MG;0.03MG N16680 003
EUTHROID-3
PARKE DAVIS 0.18MG;0.045MG N16680 004
THYROLAR-0.25
RORER PHARM 0.0125MG;0.0031MG N16807 001
THYROLAR-0.5
RORER PHARM 0.025MG;0.00625MG N16807 005
THYROLAR-1
RORER PHARM 0.05MG;0.0125MG N16807 004
THYROLAR-2
RORER PHARM 0.1MG;0.025MG N16807 002
THYROLAR-3
RORER PHARM 0.15MG;0.0375MG N16807 003

LIOTRIX (T4;T3)

TABLET; ORAL
THYROLAR-5
@ 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

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/	/BOOTS/PHARMS/	/400MG/	/N84153/001/
/AA/	/CHELSEA/LABS/	/600MG/	/N85719/001/
	∂ CHELSEA LABS	600MG	N85719 001
/AA/	/LEDERLE/LABS/	/400MG/	/N86299/001/
	∂ LEDERLE LABS	400MG	N86299 001
>ADD>	∂ PHARMAFAIR	400MG	N84153 001

MEPROBAMATE

TABLET; ORAL

	MEPROBAMATE		
/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

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

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

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

>DLT>		/3/BOOTS/PHARMS/	/500MG/	/N84231/002/
>DLT>		/3/	/750MG/	/N84471/001/
>ADD>		3 PHARMAFAIR	500MG	N84231 002
>ADD>		3	750MG	N84471 001

METHOTREXATE SODIUM

INJECTABLE; INJECTION
METHOTREXATE SODIUM

>DLT>	/AP/	/LYPHOMED/	/EQ 20MG BASE/VIAL/	/N88935/001/ OCT 11, 1985
>DLT>	/AP/		/EQ 50MG BASE/VIAL/	/N88936/001/ OCT 11, 1985
>DLT>	/AP/		/EQ 100MG BASE/VIAL/	/N88937/001/ OCT 11, 1985
>ADD>		3 LYPHOMED	EQ 20MG BASE/VIAL	N88935 001 OCT 11, 1985
>ADD>		3	EQ 50MG BASE/VIAL	N88936 001 OCT 11, 1985
>ADD>		3	EQ 100MG BASE/VIAL	N88937 001 OCT 11, 1985

MEXATE-AQ PRESERVED

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

METHYCLOTHIAZIDE

TABLET; ORAL
METHYCLOTHIAZIDE

/AB/	/CHELSEA/LABS/	/2.5MG/	/N88750/001/ SEP 06, 1984
	3 CHELSEA LABS	2.5MG	N88750 001 SEP 06, 1984

METHYLDOPA

TABLET; ORAL
METHYLDOPA

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

METHYLPREDNISOLONE

TABLET; ORAL
METHYLPREDNISOLONE

AB	CHELSEA LABS	4MG	N86161 001 FEB 09, 1982
/BP/		/4MG/	/N86161/001/ /FEB/09,/1982/
/BP/		/16MG/	/N86159/001/ /FEB/09,/1982/
	3	16MG	N86159 001 FEB 09, 1982

METHYLPREDNISOLONE ACETATE

/ENEMA;/RECTAL/
/MEDROL/

	/UPJOHN/	/40MG/BOT/	/N18102/001/
	3 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

AP	ABBOTT LABS	EQ 10MG BASE/2ML¤	N70505 001 JUN 23, 1989
AP		EQ 10MG BASE/2ML¤	N70506 001 JUN 22, 1989
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

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
METOCLOPRAMIDE HCL

AB	INVAMED	EQ 5MG BASE¤	N72436 001	JUN 22, 1989

METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR

AB	GEIGY PHARMS	50MG	N17963 001	
AB		100MG	N17963 002	

METOPROLOL TARTRATE

AB	HENRY SCHEIN	50MG¤	N71690 001	DEC 21, 1993 : FEB 08, 1989
AB		100MG¤	N71691 001	DEC 21, 1993 : FEB 08, 1989

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE

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

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

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				
/AA/	/SQUIBB/	/EQ 350MG BASE/			/N60365/001/
	∂ SQUIBB	EQ 350MG BASE			N60365 001

NIACIN

TABLET; ORAL

	NIACIN				
/AA/	/CHELSEA/LABS/	/500MG/			/N85172/001/
	∂ CHELSEA LABS	500MG			N85172 001

NIFEDIPINE

CAPSULE; ORAL

	NIFEDIPINE				
>ADD> AB	CHASE LABS	10MG¤		JUL 04, 1990 : JUL 10, 1989	N72409 001
>ADD> AB	PUREPAC PHARM	10MG¤			N72579 001 † APR 28, 1989
AB		20MG¤			N72556 001 † APR 28, 1989

NITROFURANTOIN

TABLET; ORAL

	NITROFURANTOIN				
/AB/	/CHELSEA/LABS/	/50MG/			/N85797/001/
/AB/		/100MG/			/N85796/001/
	∂ CHELSEA LABS	50MG			N85797 001
	∂	100MG			N85796 001

NYSTATIN

POWDER; ORAL

>ADD>	BARSTATIN 100				
>ADD> AA	BARLAN PHARMA	100%			N62489 001 APR 27, 1988
>ADD>					

NYSTATIN

TABLET; VAGINAL

	NYSTATIN				
/AT/	/CHELSEA/LABS/	/100,000 UNITS/			/N62176/001/
	∂ 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

PARAMETHADIONE

>DLT>	/SOLUTION;ORAL/				
>DLT>	/PARADIONE/				
>DLT>	/ABBOTT/LABS/	/300MG/ML/			/N06800/002/
>ADD>	∂ ABBOTT LABS	300MG/ML			N06800 002

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

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

NEBUPENT		
LYPHOMED	300MG/VIAL*	N19887 001
		JUN 15, 1989

PENTOBARBITAL SODIUM

CAPSULE; ORAL

PENTOBARBITAL SODIUM			
/AA/ /WHITE/TN/PAULSN/	/100MG/		/N83338/001/
ə WHITE TN PAULSN	100MG		N83338 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

/DI-METREX/			
/AA/ /PRIVATE/FMLTNS/	/35MG/		/N85698/001/
ə PRIVATE FMLTNS	35MG		N85698 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE			
/AA/ /CHELSEA/LABS/	/35MG/		/N85767/001/
/AA/	/35MG/		/N85768/001/
/AA/	/35MG/		/N85770/001/
/AA/	/35MG/		/N85773/001/
ə CHELSEA LABS	35MG		N85767 001
ə	35MG		N85768 001
ə	35MG		N85770 001
ə	35MG		N85773 001
/AA/ /PRIVATE/FMLTNS/	/35MG/		/N85199/001/
ə PRIVATE FMLTNS	35MG		N85199 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL			
/AA/ /CHELSEA/LABS/	/30MG/		/N86740/001/
			/MAR/21,/1985/
ə CHELSEA LABS	30MG		N86740 001
			MAR 21, 1985

TABLET; ORAL

PHENTERMINE HCL			
/AA/ /CHELSEA/LABS/	/8MG/		/N85739/001/
ə CHELSEA LABS	8MG		N85739 001

PHENYL AMINOSALICYLATE

/POWDER;/ORAL/			
/PHENY-PAS-TEBAMIN/			
/PURDUE/FRDRK/	/50%/		/N11695/002/
ə PURDUE FRDRK	50%		N11695 002
/TABLET;/ORAL/			
/PHENY-PAS-TEBAMIN/			
/PURDUE/FRDRK/	/500MG/		/N11695/003/
ə 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

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
PHENYTOIN SODIUM
>DLT< /A/BOOTS/PHARMS/ /100MG/ /N85435/001/
>ADD< a PHARMAFAIR 100MG N85435 001

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

POWDER FOR RECONSTITUTION; ORAL
/SOLYTELY/
/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
/240GM/BOT;2.98GM/BOT;6.72GM/BOT;/
/5.84GM/BOT;22.72GM/BOT/ /N18983/001/
/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/
a BAXTER 75MG/100ML;900MG/100ML N17648 004
/AP/ /KENDALL/MCGAW/ /75MG/100ML;900MG/100ML/ /N18722/001/
/NOV/09,/1982/
a 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/
a 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/
a 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/
a KENDALL MCGAW 300MG/100ML;
900MG/100ML N18722 004
NOV 09, 1982

PRALIDOXIME CHLORIDE

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

/BX/	/CHELSEA/LABS/	/5MG/	/N85415/001/
/BX/		/5MG/	/N85416/001/
	∂ CHELSEA LABS	5MG	N85415 001
	∂	5MG	N85416 001
/BX/	/WHITE/TN/PAULSN/	/5MG/	/N80342/001/
	∂ 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
AB	HALSEY DRUG	5MG	N80300 001
/BX/		/5MG/	/N80300/001/
/BX/	/VANGARD/LABS/	/5MG/	/N87682/001/
			/JAN/15,/1982/
/BX/		/20MG/	/N87701/001/
			/JAN/15,/1982/
	∂ VANGARD LABS	5MG	N87682 001
			JAN 15, 1982
	∂	20MG	N87701 001
			JAN 15, 1982

PREDNISONE

TABLET; ORAL

	PREDNISONE			
/AB/	/WHITE/TN/PAULSN/	/10MG/	/N89028/001/	> DLT >
			/JUL/24,/1986/	> DLT >
/BX/		/2.5MG/	/N84913/001/	> DLT >
/BX/		/5MG/	/N80343/001/	> ADD >
/BX/		/20MG/	/N84913/002/	> ADD >
	@ WHITE TN PAULSN	2.5MG	N84913 001	> ADD >
	@	5MG	N80343 001	
	@	10MG	N89028 001	
			JUL 24, 1986	
		20MG	N84913 002	

	SERVISONE		
/BX/	/LEDERLE/LABS/	/5MG/	/N80223/001/
	@ 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/
	@ VANGARD LABS	250MG	N87643 001
			JUN 01, 1982
	@	500MG	N87875 001
			JUN 01, 1982

INJECTABLE; INJECTION

	PROCAINAMIDE HCL		
/AP/	/PHARMAFAIR/	/100MG/ML/	/N88824/001/
			/NOV/20,/1985/
/AP/		/500MG/ML/	/N88830/001/
			/NOV/20,/1985/
	@ PHARMAFAIR	100MG/ML	N88824 001
			NOV 20, 1985
	@	500MG/ML	N88830 001
			NOV 20, 1985

TABLET, EXTENDED RELEASE; ORAL

	PROCAINAMIDE HCL		
AB	INWOOD LABS	500MG‡	N89840 001
			MAR 06, 1989

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL

	PROMETHAZINE HCL		
	/@/BOOTS/PHARMS/	/12.5MG/	/N84160/001/
	/@/	/25MG/	/N84166/001/
	/@/	/50MG/	/N84539/001/
	@ BOOTS USA	12.5MG	N84160 001
	@	25MG	N84166 001
	@	50MG	N84539 001
/BP/	/CHELSEA/LABS/	/12.5MG/	/N85986/001/
/BP/		/25MG/	/N85684/001/
/BP/		/50MG/	/N85664/001/
	@ CHELSEA LABS	12.5MG	N85986 001
	@	25MG	N85684 001
	@	50MG	N85664 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

	PROPOXYPHENE HCL		
/AA/	/CHELSEA/LABS/	/65MG/	/N85190/001/
	@ 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

PROPRANOLOL HYDROCHLORIDE

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

TABLET; ORAL
PROPRANOLOL HCL

/AA/	/LEDERLE/LABS/	/10MG/	/N72117/001/ /JUN/23,/1988/
/AA/		/20MG/	/N72118/001/ /JUN/23,/1988/
/AA/		/40MG/	/N72119/001/ /JUN/23,/1988/
/AA/		/80MG/	/N72120/001/ /JUN/23,/1988/
	ə LEDERLE LABS	10MG	N72117 001 JUN 23, 1988
	ə	20MG	N72118 001 JUN 23, 1988
	ə	40MG	N72119 001 JUN 23, 1988
	ə	80MG	N72120 001 JUN 23, 1988
AB	MYLAN PHARMS	60MG*	N72275 001 JUN 09, 1989

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

>_DLT_>	/ə/BOOTS/PHARMS/	/50MG/	/N84075/001/
>_ADD_>	ə BOOTS USA	50MG	N84075 001
/BD/	/CHELSEA/LABS/	/50MG/	/N85201/001/
	ə CHELSEA LABS	50MG	N85201 001

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION
MESTINON

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

PYRIDOSTIGMINE BROMIDE

SYRUP; ORAL
MESTINON

	ICN PHARMS	60MG/5ML	N15193 001
	/ROCHE/	/60MG/5ML/	/N15193/001/

TABLET; ORAL
MESTINON

	ICN PHARMS	60MG	N09829 002
	/ROCHE/	/60MG/	/N09829/002/

TABLET, EXTENDED RELEASE; ORAL
MESTINON

	ICN PHARMS	180MG	N11665 001
	/ROCHE/	/180MG/	/N11665/001/

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
/AA/	/PBI/	/200MG/	/N87837/001/ /APR/14,/1982/
	ə PBI	200MG	N87837 001 APR 14, 1982
/AA/	/WHITE/TN/PAULSN/	/200MG/	/N85444/001/
	ə WHITE TN PAULSN	200MG	N85444 001

RESERPINE

TABLET; ORAL
RESERPINE

/BP/	/ROXANE/LABS/	/0.25MG/	/N09859/002/
	ə ROXANE LABS	0.25MG	N09859 002

RESERPINE

TABLET; ORAL
RESERPINE
/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
/AB/ /DOW/PHARMS/ /300MG/ /N50420/001/
/150MG/ /N62303/001/
AB MERRELL DOW 300MG N50420 001
150MG N62303 001

INJECTABLE; INJECTION
RIFADIN
MERRELL DOW 600MG/VIAL‡ N50627 001
MAY 25, 1989

SAFFLOWER OIL

INJECTABLE; INJECTION
/LIPOSYN/20%/
/ABBOTT/LABS/ /20%/ /N18614/001/
∂ 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/ /N18296/001/

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
ELDEPRYL
SOMERSET PHARMS 5MG‡ N19334 001
JUN 05, 1989

SILVER SULFADIAZINE

CREAM; TOPICAL
SSD
>ADD> AB BOOTS (USA) 1% N18578 001
>ADD> FEB 25, 1982
>DLT> /AB/ /BOOTS/FLINT/ /1%/ /N18578/001/
>DLT> /FEB/25,/1982/

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

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

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 N10927 001

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 N19640 001
JUN 23, 1987

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AB/ /VANGARD/LABS/ /25MG/ /N87648/001/
/FEB/01,/1982/
@ VANGARD LABS 25MG N87648 001
FEB 01, 1982

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 N88666 001
FEB 17, 1984

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE
>DLT> /3/BOOTS/PHARMS/ /500MG/ /N84385/001/
>ADD> @ PHARMAFAIR 500MG N84385 001

SUTILAINS

OINTMENT; TOPICAL
TRAVASE
>DLT> /BAXTER/ /82,000/UNITS/GM/ /N12828/001/
>ADD> BOOTS (USA) 82,000 UNITS/GM N12828 001

TECHNETIUM TC-99M FERPENTETATE KIT

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

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
/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/

TECHNETIUM TC-99M SULFUR COLLOID

SOLUTION; INJECTION, ORAL
TECHNETIUM TC 99M SULFUR COLLOID
MALLINCKRODT 3MCI/ML N17724 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL
> DLT > /∂/BOOTS/PHARMS/ /250MG/ /N61802/001/
> DLT > /∂/ /500MG/ /N61802/002/
> ADD > ∂ BOOTS USA 250MG N61802 001
> ADD > ∂ 500MG N61802 002
/AB/ /CHELSEA/LABS/ /250MG/ /N62103/001/
/AB/ /500MG/ /N62103/002/
∂ CHELSEA LABS 250MG N62103 001
∂ 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; ORAL
ELIXOPHYLLIN
> DLT > /BX/ /BERLEX/LABS/ /100MG/ /N85545/001/
> DLT > /JUL/31,/1984/
> DLT > /BX/ /200MG/ /N83921/001/
> DLT > /JUL/31,/1984/
> ADD > BX FOREST LABS 100MG N85545 001
> ADD > JUL 31, 1984
> ADD > BX 200MG N83921 001
> ADD > JUL 31, 1984

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

ELIXIR; ORAL
ELIXOPHYLLIN
> DLT >/AA/ /BERLEX/LABS/ /80MG/15ML/ /N85186/001/
> ADD > AA FOREST LABS 80MG/15ML N85186 001

SUSPENSION; ORAL
ELIXICON
> DLT > /BERLEX/LABS/ /100MG/5ML/ /N85502/001/
> ADD > FOREST LABS 100MG/5ML N85502 001

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

/BP/	/CHELSEA/LABS/	/4MG/		/N85834/001/
	∂ CHELSEA LABS	4MG		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

/BP/	/CHELSEA/LABS/	/2MG/		/N86458/001/
	∂ CHELSEA LABS	2MG		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/	/2MG/		/N88035/001/
				/JUL/30,/1982/
	∂ VANGARD LABS	2MG		N88035 001
				JUL 30, 1982

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL
TRIPELENNAMINE HCL

/AA/	/CHELSEA LABS/	/50MG/	/N85188/001/
	@ CHELSEA LABS	50MG	N85188 001

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

/AT/	/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

FOAMICON		
INVAMED	80MG;20MG¤	N72687 001 JUN 28, 1989

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL

BIOSCRUB		
KW GRIFFEN	4%¤	N19822 001 MAR 31, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE		
> ADD >	KV PHARM	12MG;120MG	N71455 001 MAR 01, 1989
> ADD >	/PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE/		
> ADD >	/KV/PHARM/	/12MG;120MG¤/	/N71455/001/ /MAR/01,/1989/
> DLT >			
> DLT >	PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE		
> DLT >	/GRAHAM/LABS/	/8MG;120MG/	/N18844/001/ /MAR/20,/1985/
	∂ 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

/PHENERGAN/DM/		
/WYETH/AYERST/LABS/	/15MG/5ML;6.25MG/5ML/	/N11265/003/ /AUG/11,/1988/
PHENERGAN W/ DEXTROMETHORPHAN		
WYETH AYERST LABS	15MG/5ML;6.25MG/5ML	N11265 003 AUG 11, 1988

DIPHENHYDRAMINE HYDROCHLORIDE

SYRUP; ORAL

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

IBUPROFEN

TABLET; ORAL

IBUPROFEN		
/CHELSEA/LABS/	/200MG/	/N71765/001/ /SEP/04,/1987/
∂ CHELSEA LABS	200MG	N71765 001 SEP 04, 1987
MUTUAL PHARM	200MG¤	N72249 001 JAN 10, 1989

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

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

∂ WYETH AYERST LABS 10MG/5ML;6.25MG/5ML N08604 004
AUG 11, 1988

POVIDONE-IODINE

SOLUTION; TOPICAL
>ADD< E-Z PREP
>ADD< BECTON DICKINSN 10% N19382 001
>ADD< JUL 25, 1989
POVIDONE IODINE
BAXTER 1% N19522 001
MAR 31, 1989

SPONGE; TOPICAL
>ADD< E-Z PREP
>ADD< BECTON DICKINSN 5% N19382 002
>ADD< JUL 25, 1989
>ADD< E-Z PREP 220
>ADD< BECTON DICKINSN 5% N19382 003
>ADD< JUL 25, 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/

∂ 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 APPROVED UNDER SECTION 505 OF THE ACT LIST
CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '89 - JUL '89

NO JULY 1989 APPROVALS

ORPHAN DRUG PRODUCT DESIGNATIONS

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

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
GENERIC: PENTAMIDINE ISETHIONATE (INHALATION) TRADE: NEBUPENT*/** (FORMERLY PENTAM 300)	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN PATIENTS AT HIGH RISK OF DEVELOPING THIS DISEASE. [JUNE 15, 1996]	LYPHOMED, INC. 2020 RUBY STREET MELROSE PARK, IL 60160

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: SELEGILINE HCL TRADE: ELDEPRYL*/** (FORMERLY DEPRENYL)	ADJUNCT IN THE MANAGEMENT OF PARKINSONIAN PATIENTS BEING TREATED WITH LEVODOPA/CARBIDOPA WHO EXHIBIT DETERIORATION IN THE QUALITY OF THEIR RESPONSE TO THIS THERAPY*/**. [JUNE 5, 1996]	SOMERSET PHARMACEUTICALS ONE OLDE TOWNE COURT BERNARDSVILLE, NJ 07924
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 JULY 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
PENTETATE PENTASODIUM; STANNOUS CHLORIDE (TECHNETIUM TC-99M PENTETATE KIT) INJECTABLE; INJECTION	10MG 0.55MG	89 P-0113/CP	CADEMA MED PRODS	NEW STRENGTH	APPROVED JUL 14, 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
THIOTEPA, STERILE INJECTABLE; INJECTION	30MG/VIAL 60MG/VIAL	88 P-0412/CP	QUAD PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ALLOPURINOL SODIUM INJECTABLE; INJECTION	500MG (30ML/VIAL)	89 P-0103/CP	BURROUGHS WELLC	NEW DOSAGE FORM NEW INGREDIENT (NEW SALT) NEW ROUTE OF ADMINISTRATION	DENIED JUL 14, 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
I-92	PEDIATRIC CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC HEAD IMAGING
I-93	ARTHROGRAPHY OF THE SHOULDER JOINTS IN ADULTS
I-94	RADIOGRAPHY OF THE TEMPOROMANDIBULAR JOINT IN ADULTS

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
>ADD>	19716 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4775529	OCT 04, 2005		NP	AUG 01, 1991
	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
	19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-53		
			4423050	OCT 19, 1999	U-52		
			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>	19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20/25	4472380	SEP 18, 2001			
>ADD>			4374829	DEC 30, 2001		NCE	DEC 29, 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
	18956 001	IOHEXOL; OMNIPAQUE 180				I-89	JUN 30, 1992
	18956 002	IOHEXOL; OMNIPAQUE 240				I-90	JUN 30, 1992
						NR	JUN 30, 1992
>ADD>						I-92	JUL 28, 1992
>ADD>						I-93	JUL 28, 1992
	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-85	MAR 31, 1992
						I-90	JUN 30, 1992
						NR	JUN 30, 1992
>ADD>						I-94	JUL 28, 1992
>ADD>						I-92	JUL 28, 1992
	18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-85	MAR 31, 1992
						NR	JUN 30, 1992
						I-90	JUN 30, 1992
						I-91	JUN 30, 1992
>ADD>	18956 006	IOHEXOL; OMNIPAQUE 210	4396597	JUL 14, 1998			
>ADD>			4250113	DEC 26, 1999		I-93	JUL 28, 1992
>ADD>			4021481	MAY 03, 1994		NS	JUN 30, 1992
	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
	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

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
	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
	19887 001	PENTAMIDINE ISETHIONATE; NEBUPENT				ODE	JUN 15, 1996
						NDF	JUN 15, 1992
>ADD>	18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS	4271143	JUN 02, 1998			
	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL				NCE	JUN 05, 1994
						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
>ADD>	19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC	4789736	DEC 06, 2005		NCE	DEC 30, 1993
	18321 001	TECHNETIUM TC-99M OXIDRONATE KIT; OSTEOSCAN-HDP	4497744	FEB 05, 2002			
			4432963	FEB 21, 2001			
			4247534	JAN 27, 1998			
			4233284	NOV 11, 1997			
	17628 002	TOLMETIN SODIUM; TOLECTIN 600	3752826	AUG 14, 1990			
	19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
			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		

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