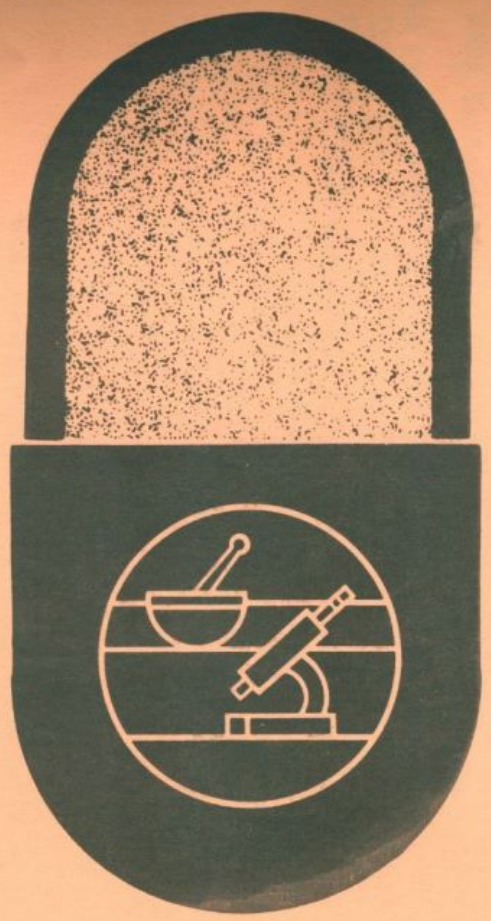
CUMULATIVE
SUPPLEMENT 10
JAN'89-OCT'89



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

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

APPROVED DRUG PRODUCTS

with

THERAPEUTIC EQUIVALENCE EVALUATIONS

9TH EDITION

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OCTOBER 1989

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CUMULATIVE SUPPLEMENT 10

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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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 & CO INC	DUPONT PHARMS
INTERNATIONAL PHARMACEUTICAL PRODUCTS INC	NORBROOK AMERICA INC	NORBROOK AM
MAURRY BIOLOGICAL CO INC	NORBROOK AMERICA INC	NORBROOK AM
MCNEIL PHARMACEUTICAL DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON PHARM RESEARCH INST DIV MCNEILAB INC	RW JOHNSON

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
ORTHO PHARMACEUTICAL CORP	RW JOHNSON PHARM RESEARCH INST DIV ORTHO PHARM 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 Inde Listed by Applicant" were not printed within the List.

b. The locator tabs for the "Drug Products Which Must Demonstrate in viv Bioavailability Only If Product Fails to Achieve Adequate Dissolution," "ANDA Suitability Petitions," "Product Name Index," and "Product Name Index Listed b 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 an American Therapeutics, Inc. (ATI), rescinded the approval letters of June 5 an June 23, 1989, respectively, for chlorzoxazone 500mg tablets. The approval were rescinded because of substantial deficiencies in manufacturing practice 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 an 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	10153
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)	1982 (19.6%)	1978 (19.5%)
MULTISOURCE	8108 (80.3%)	8164 (80.4%)	8155 (80.4%)	8175 (80.5%)
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)	7341 (72.4%)	7350 (72.4%)
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	726 (7.1%)	701 (6.9%)	709 (7.0%)
EXCEPTIONS[1]	118 (1.1%)	117 (1.2%)	113 (1.1%)	116 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	--	3	4	2
NUMBER OF APPLICANTS	374	393	394	397

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

[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/	
/AA/		/300MG;30MG/	/N88354/001/ /FEB/06,/1984/	
/AA/		/300MG;60MG/	/N88355/001/ /FEB/06,/1984/	
	∂ DURAMED PHARMS	300MG;15MG	N88353 001 FEB 06, 1984	
	∂	300MG;30MG	N88354 001 FEB 06, 1984	
	∂	300MG;60MG	N88355 001 FEB 06, 1984	
AA	PUREPAC PHARM	300MG;30MG	N86681 001	
AA		300MG;60MG	N86683 001	
	ROXANE LABS	500MG;15MG㊎	N89511 001 APR 25, 1989	
		500MG;30MG㊎	N89512 001 APR 25, 1989	
		500MG;60MG㊎	N89513 001 APR 25, 1989	

ACETAMINOPHEN W/ CODEINE PHOSPHATE

/AA/	/PBI/	/300MG;30MG/	/N87919/001/ /JUN/22,/1982/	
/AA/		/300MG;60MG/	/N87920/001/ /JUN/22,/1982/	
	∂ PBI	300MG;30MG	N87919 001 JUN 22, 1982	
	∂	300MG;60MG	N87920 001 JUN 22, 1982	
/AA/	/PUREPAC/PHARM/	/300MG;30MG/	/N86681/001/	
/AA/		/300MG;60MG/	/N86683/001/	
/AA/	/WHITE/TN/PAULSN/	/300MG;30MG/	/N84360/001/	
/AA/		/300MG;60MG/	/N85607/001/	
	∂ WHITE TN PAULSN	300MG;30MG	N84360 001	
	∂	300MG;60MG	N85607 001	

CODEINE PHOSPHATE AND ACETAMINOPHEN

/AA/	/ICN/PHARMS/	/300MG;30MG/	/N85896/001/	
	∂ ICN PHARMS	300MG;30MG	N85896 001	

PAPA-DEINE #3

/AA/	/VANGARD/LABS/	/300MG;30MG/	/N88037/001/ /MAR/20,/1984/	
	∂ VANGARD LABS	300MG;30MG	N88037 001 MAR 20, 1984	

PAPA-DEINE #4

/AA/	/VANGARD/LABS/	/300MG;60MG/	/N88715/001/ /MAR/20,/1984/	
	∂ 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

TABLET; ORAL

ANEXSIA

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

ANEXSIA 7.5/650

AA	BEECHAM LABS	650MG;7.5MG	N89725 001 SEP 30, 1987

> ADD >
> ADD >
> ADD >

/ANEXSIA-D/

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

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

> DLT >/AA/	/BEECHAM/LABS/	/650MG;7.5MG/	/N89725/001/ /SEP/30,/1987/	
> DLT >	MIKART	500MG;2.5MG㊎	N89698 001 AUG 25, 1989	
		500MG;7.5MG㊎	N89699 001 AUG 25, 1989	

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/2.5/APAP/500/

	/DUPONT/PHARMS/	/500MG;2.5MG/	/N85910/001/	
	∂ DUPONT PHARMS	500MG;2.5MG	N85910 001	

/OXYCODONE/5/APAP/500/

/AA/	/DUPONT/PHARMS/	/500MG;5MG/	/N85911/001/	
	∂ DUPONT PHARMS	500MG;5MG	N85911 001	

ROXICET 5/500

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

CAPSULE; ORAL
TYLOX
/S/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
AA CORD LABS 650MG;65MG N89959 001
JUL 18, 1989

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

>ADD> ADENOSINE

>ADD> INJECTABLE; INJECTION
>ADD> ADENOCARD
>ADD> MEDCO RES 3MG/ML N19937 002
>ADD> OCT 30, 1989

ALBUMIN, CHROMATED CR-51 SERUM

INJECTABLE; INJECTION
CHROMALBIN
ISO TEX DIAGS 100 UCI/VIAL N17835 001
@ 250 UCI/VIAL N17835 002
@ 500 UCI/VIAL N17835 003
/S/ISO/TEX/DIAGS/ /100/UCI/VIAL/ /N17835/001/
/S/ /250/UCI/VIAL/ /N17835/002/
/S/ /500/UCI/VIAL/ /N17835/003/

ALBUMIN, IODINATED I-125 SERUM

INJECTABLE; INJECTION
ALBUMOTOPE 125 I
@ ISO TEX DIAGS 5-50 UCI/AMP N17836 001
/S/ISO/TEX/ /5-50/UCI/AMP/ /N17836/001/

ALBUMIN, IODINATED I-131 SERUM

INJECTABLE; INJECTION
ALBUMOTOPE 131 I
@ ISO TEX DIAGS 5 UCI/AMP N17837 004
@ 20 UCI/AMP N17837 005
0.5MCI/VIAL N17837 001
1MCI/VIAL N17837 002
@ 2MCI/VIAL N17837 003
/S/ISO/TEX/ /5/UCI/AMP/ /N17837/004/
/S/ /20/UCI/AMP/ /N17837/005/
/0.5MCI/VIAL/ /N17837/001/
/1MCI/VIAL/ /N17837/002/
/S/ /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

ALBUTEROL SULFATE

AMINO ACIDS

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

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

AB	BOOTS/PHARMS	100MG	N71586/001
			APR 02, 1987
AB		300MG	N71587/001
			APR 02, 1987
AB	BOOTS USA	100MG	N18297/001
AB		100MG	N71586 001
			APR 02, 1987
AB		300MG	N18297/002
AB		300MG	N71587 001
			APR 02, 1987
∂		100MG	N18297 001
∂		300MG	N18297 002

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

AB	BARR LABS	5MG;50MG	N71111/001
			MAY 10, 1988
AB	BARR LABS	5MG;50MG	N71111 001
		DEC 25, 1990 : MAY 10, 1988	

AMINO ACIDS

INJECTABLE; INJECTION

	AMINOSYN 11 3.5% IN PLASTIC CONTAINER		
	ABBOTT LABS	3.5%	N19491/001
			OCT 10, 1986
∂	ABBOTT LABS	3.5%	N19491 001
			OCT 10, 1986

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

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

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

/INJECTABLE;/INJECTION/
/AMINOSYN/II/3.5%/N/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

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

AMOXICILLIN

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

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

AMMONIUM LACTATE

LOTION; TOPICAL

LAC-HYDRIN

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

AMOXAPINE

TABLET; ORAL

AMOXAPINE

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

ASENDIN

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

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

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

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

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

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

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

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

AMPICILLIN

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

/TABLET;/CHEWABLE;/ORAL/

/POLYCILLIN/

/BRISTOL/LABS/		/EQ/125MG/BASE/	/N50093/001/
∂	BRISTOL LABS	EQ 125MG BASE	N50093 001

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL W/ ASPIRIN & CAFFEINE

/AB/	/BOOTS/LABS/	/325MG;50MG;40MG/	/N87048/002/DEC/09,/1983/
AB	PHARMAFAIR	325MG;50MG;40MG	N87048 002 DEC 09, 1983

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

MORGESIC

>DLT>/AB/	/3M/RIKER/	/385MG;30MG;25MG/	/N13416/003/OCT/27,/1982/
>DLT> >ADD>	3M RIKER	385MG;30MG;25MG	N13416 003 OCT 27, 1982

MORGESIC FORTE

>DLT>/AB/	/3M/RIKER/	/770MG;60MG;50MG/	/N13416/004/OCT/27,/1982/
>DLT> >ADD>	3M RIKER	770MG;60MG;50MG	N13416 004 OCT 27, 1982

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

	ORPHENADRINE COMPOUND			
> DLT >	/AA/	/VITARINE/	/385MG;30MG;25MG/	/N71564/001/ /JUN/23,/1988/
> DLT >				
> ADD >	BX	VITARINE	385MG;30MG;25MG	N71564 001 JUN 23, 1988
> ADD >				
	ORPHENADRINE COMPOUND DOUBLE STRENGTH			
> DLT >	/AA/	/VITARINE/	/770MG;60MG;50MG/	/N71565/001/ /JUN/23,/1988/
> DLT >				
> ADD >	BX	VITARINE	770MG;60MG;50MG	N71565 001 JUN 23, 1988
> ADD >				
	ORPHENGESIC			
> DLT >	/AA/	/PAR/PHARM/	/385MG;30MG;25MG/	/N71642/001/ /JUN/23,/1987/
> DLT >				
> ADD >	BX	PAR PHARM	385MG;30MG;25MG	N71642 001 JUN 23, 1987
> ADD >				
	ORPHENGESIC FORTE			
> DLT >	/AA/	/PAR/PHARM/	/770MG;60MG;50MG/	/N71643/001/ /JUN/23,/1987/
> DLT >				
> ADD >	BX	PAR PHARM	770MG;60MG;50MG	N71643 001 JUN 23, 1987
> ADD >				

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

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

ATENOLOL

INJECTABLE; INJECTION

	TENORMIN			
	ICI PHARM	0.5MG/ML		N19058 001 SEP 13, 1989

ATENOLOL

TABLET; ORAL

	TENORMIN			
AB	ICI PHARM	50MG		N18240 001
AB		100MG		N18240 002
/AA/	/STUART/PHARMS/	/50MG/		/N18240/001/
/AB/		/100MG/		/N18240/002/

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

	DIPHENOXYLATE HCL AND ATROPINE SULFATE			
AA	CHELSEA LABS	0.025MG;2.5MG		N85876 001
/AA/	/LEDERLE/LABS/	/0.025MG;2.5MG/		/N86950/001/
	ə LEDERLE LABS	0.025MG;2.5MG		N86950 001
AA	PHARMAFAIR	0.025MG;2.5MG		N85035 001
	DIPHENOXYLATE HCL W/ ATROPINE SULFATE			
/AA/	/CHELSEA/LABS/	/0.025MG;2.5MG/		/N85676/001/
/AA/	/PBI/	/0.025MG;2.5MG/		/N87842/001/ /MAR/29,/1982/
	ə PBI	0.025MG;2.5MG		N87842 001 MAR 29, 1982
	DIPHENOXYLATE W/ ATROPINE SULFATE			
/AA/	/BOOTS/LABS/	/0.025MG;2.5MG/		/N85035/001/
	LO-TROL			
/AA/	/VANGARD/LABS/	/0.025MG;2.5MG/		/N88009/001/ /MAR/25,/1983/
	ə 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

ATENOLOL

INJECTABLE; INJECTION
TENORMIN
ICI PHARM — 0.5MG/ML — N19058 001 SEP 13, 1989

BACLOFEN

TABLET; ORAL
BACLOFEN
>DLT >/AA/ /VITARINE/ /10MG/ /N71901/001/
>DLT >
>DLT >/AA/ /20MG/ /N71902/001/
>DLT >
>ADD > BX VITARINE 10MG N71901 001 APR 13, 1988
>ADD >
>ADD > BX 20MG N71902 001 APR 13, 1988
>ADD >

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

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

LOTION, AUGMENTED; TOPICAL
DIPROLENE
SCHERING — EQ 0.05% BASE — N19716 001 AUG 01, 1988

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

OINTMENT, AUGMENTED; TOPICAL
DIPROLENE
SCHERING — EQ 0.05% BASE — N18741 001 JUL 27, 1983

BETAXOLOL HYDROCHLORIDE

>ADD > TABLET; ORAL
>ADD > KERLONE
>ADD > LOREX PHARMS 10MG N19507 001 OCT 27, 1989
>ADD >
>ADD > 20MG N19507 002 OCT 27, 1989
>ADD >

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
∂	ABBOTT LABS	200MG/100ML	N19005 002	APR 16, 1986
∂		400MG/100ML	N19005 003	APR 16, 1986
∂		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	BARRE NATL	2MG/5ML	N86936 001	
AA	PBI	2MG/5ML	N87964 001	JAN 25, 1983
∂	BARRE NATL	2MG/5ML	N86936 001	
∂	PBI	2MG/5ML	N87964 001	JAN 25, 1983

TABLET; ORAL

	BROMPHENIRAMINE MALEATE			
AA	CHELSEA LABS	4MG	N85769 001	
AA	CORD LABS	4MG	N83215 001	
∂	CHELSEA LABS	4MG	N85769 001	
∂	CORD LABS	4MG	N83215 001	

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

	BYNETANE DC			
AA	PBI	2MG/5ML;10MG/5ML; 12.5MG/5ML	N88904 001	FEB 21, 1985

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

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

BUPROPION HYDROCHLORIDE

TABLET; ORAL

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

BUTABARBITAL SODIUM

TABLET; ORAL

	BUTABARBITAL SODIUM			
AA	CHELSEA LABS	15MG	N85764 001	
AA		30MG	N85772 001	
∂	CHELSEA LABS	15MG	N85764 001	
∂		30MG	N85772 001	

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

/AA/	/WHITE/TN/PAULSN/	/30MG/	/N83337/001/
	∂ WHITE TN PAULSN	30MG	N83337 001

CALCITONIN, SALMON

INJECTABLE; INJECTION
CALCIMAR

	/RORER/PHARM/	/400/IU/VIAL/	/N17497/001/
	∂ RORER PHARM	400 IU/VIAL	N17497 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; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION
ISOLYTE E IN PLASTIC CONTAINER

KENDALL MCGAW	35MG/100ML;30MG/100ML;74MG/100ML; 640MG/100ML;500MG/100ML; 74MG/100ML‡	N19718 001 SEP 29, 1989

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; IRRIGATION
RINGER'S IN PLASTIC CONTAINER

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

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER

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

SOLUTION; IRRIGATION
LACTATED RINGER'S IN PLASTIC CONTAINER

AT	BAXTER	20MG/100ML;30MG/100ML;600MG/100ML; 310MG/100ML‡	N19933 001 AUG 29, 1989

CARBOPLATIN

INJECTABLE; INJECTION
PARAPLATIN

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

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

CEPHALEXIN

CEPHALEXIN

CAPSULE; ORAL

	CEFANEX			
AB	BRISTOL MYERS	EQ 250MG BASE*	N63063 001	SEP 29, 1989
AB		EQ 500MG BASE*	N63063 002	SEP 29, 1989
	CEPHALEXIN			
AB	LEMMON	EQ 250MG BASE	N62821 001	FEB 05, 1988
AB		EQ 500MG BASE	N62823 001	FEB 05, 1988
/AB/	/IAG/PHARMS/	/EQ 250MG BASE/	/N62821/001/	/FEB/05,/1988/
/AB/		/EQ 500MG BASE/	/N62823/001/	/FEB/05,/1988/
	CEPHALEXIN MONOHYDRATE			
>DLT >/AB/	/VITARINE/	/EQ 250MG BASE/	/N62159/001/	
>DLT >/AB/		/EQ 500MG BASE/	/N62159/002/	
>ADD > BX	VITARINE	EQ 250MG BASE	N62159 001	
>ADD > BX		EQ 500MG BASE	N62159 002	

POWDER FOR RECONSTITUTION; ORAL

	CEPHALEXIN			
AB	LEMMON	EQ 125MG BASE/5ML	N62873 001	MAY 23, 1988
AB		EQ 250MG BASE/5ML	N62867 001	APR 15, 1988
AB	SQUIBB MARK	EQ 250MG BASE/5ML*	N62987 001	JUL 25, 1989
/AB/	/IAG/PHARMS/	/EQ 125MG BASE/5ML/	/N62873/001/	/MAY/23,/1988/
/AB/		/EQ 250MG BASE/5ML/	/N62867/001/	/APR/15,/1988/
>DLT >/AB/	/VITARINE/	/EQ 125MG BASE/5ML/	/N62779/001/	/DEC/22,/1987/
>DLT >				
>DLT >/AB/		/EQ 250MG BASE/5ML/	/N62781/001/	/DEC/22,/1987/
>DLT >				
>ADD > BX	VITARINE	EQ 125MG BASE/5ML	N62779 001	DEC 22, 1987
>ADD >				
>ADD > BX		EQ 250MG BASE/5ML	N62781 001	DEC 22, 1987
>ADD >				

TABLET; ORAL

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

CEPHALEXIN

TABLET; ORAL

	CEPHALEXIN			
>DLT >/AB/	/VITARINE/	/EQ 250MG BASE/	/N62863/001/	/AUG/11,/1988/
>DLT >				
>DLT >/AB/		/EQ 500MG BASE/	/N62863/002/	/AUG/11,/1988/
>DLT >				
>DLT >/AB/		/EQ 1GM BASE/	/N62863/003/	/AUG/11,/1988/
>DLT >				
>ADD > BX	VITARINE	EQ 250MG BASE	N62863 001	AUG 11, 1988
>ADD >				
>ADD > BX		EQ 500MG BASE	N62863 002	AUG 11, 1988
>ADD >				
>ADD > BX		EQ 1GM BASE	N62863 003	AUG 11, 1988
>ADD >				

CEPHRADINE

CAPSULE; ORAL

	CEPHRADINE			
>DLT >/AB/	/VITARINE/	/250MG/	/N62813/001/	/FEB/25,/1988/
>DLT >				
>DLT >/AB/		/500MG/	/N62813/002/	/FEB/25,/1988/
>DLT >				
>ADD > BX	VITARINE	250MG	N62813 001	FEB 25, 1988
>ADD >				
>ADD > BX		500MG	N62813 002	FEB 25, 1988
>ADD >				

CERULETIDE DIETHYLAMINE

/INJECTABLE;/INJECTION/

/IMTRAN/

/ADRIA/LABS/	/0.02MG/ML/	/N18296/001/
@ ADRIA LABS	0.02MG/ML	N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

/A-POXIDE/

/ABBOTT/LABS/	/5MG/	/N85441/001/	
	/5MG/	/N85517/001/	
	/10MG/	/N85441/002/	
	/10MG/	/N85518/001/	
	/25MG/	/N85441/003/	
	/25MG/	/N85513/001/	

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	A-POXIDE		
	ə ABBOTT LABS	5MG	N85447 001
	ə	5MG	N85517 001
	ə	10MG	N85447 002
	ə	10MG	N85518 001
	ə	25MG	N85447 003
	ə	25MG	N85513 001
	CHLORDIAZEPOXIDE HCL		
AB	FERRANTE	5MG	N85118 001
AB		10MG	N85119 001
AB		25MG	N85120 001
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
AB	/LEMMON/	/5MG/	/N88705/001/ JAN/18,/1985/
AB		/10MG/	/N88706/001/ JAN/18,/1985/
AB		/25MG/	/N86494/001/
AB		/25MG/	/N88707/001/ JAN/18,/1985/
	ə LEMMON	5MG	N88705 001 JAN 18, 1985
	ə	10MG	N88706 001 JAN 18, 1985
	ə	25MG	N86494 001
	ə	25MG	N88707 001 JAN 18, 1985
AB	/MK/LABS/	/5MG/	/N85118/001/
AB		/10MG/	/N85119/001/
AB		/25MG/	/N85120/001/
AB	/ROXANE/LABS/	/5MG/	/N84706/001/
AB		/10MG/	/N84700/001/
AB		/25MG/	/N84705/001/
	ə ROXANE LABS	5MG	N84706 001
	ə	10MG	N84700 001
	ə	25MG	N84705 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		
	/ə/BOOTS/PHARMS/	/4MG/	/N83753/001/
AB	/CHELSEA/LABS/	/4MG/	/N85139/001/
	ə CHELSEA LABS	4MG	N85139 001
AB	/LEDERLE/LABS/	/4MG/	/N86941/001/
	ə LEDERLE LABS	4MG	N86941 001
	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

CHLORPROPAMIDE

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

/A/	/BOOTS/PHARMS/	/10MG/	/N84414/001/
/A/		/25MG/	/N84415/001/
/A/		/50MG/	/N84411/001/
/A/		/100MG/	/N84412/001/
/A/		/200MG/	/N84413/001/
A	BOOTS USA	10MG	N84414 001
A		25MG	N84415 001
A		50MG	N84411 001
A		100MG	N84412 001
A		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/
A	CHELSEA LABS	10MG	N85959 001
A		25MG	N85956 001
A		50MG	N85960 001
A		100MG	N85957 001
A		200MG	N85958 001
/BP/	/VANGARD/LABS/	/10MG/	/N88038/001/ /AUG/16,/1982/
/BP/		/25MG/	/N87645/001/
/BP/		/50MG/	/N87646/001/
A	VANGARD LABS	10MG	N88038 001 AUG 16, 1982
A		25MG	N87645 001
A		50MG	N87646 001

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

/AA/	/CHELSEA/LABS/	/250MG/	/N86866/001/
A	CHELSEA LABS	250MG	N86866 001

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

/AB/	/PARKE/DAVIS/	/25MG/	/N87515/001/ /JAN/24,/1983/
/AB/		/50MG/	/N87516/001/ /FEB/09,/1983/
/AB/	/VANGARD/LABS/	/25MG/	/N88012/001/ /JUL/14,/1982/
/AB/		/50MG/	/N88073/001/ /MAR/25,/1983/
A	VANGARD LABS	25MG	N88012 001 JUL 14, 1982
A		50MG	N88073 001 MAR 25, 1983
AB	WARNER CHILCOTT	25MG	N87515 001 JAN 24, 1983
AB		50MG	N87516 001 FEB 09, 1983

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

/AA/	/AM/THERPICS/	/500MG=/	/N89911/001/ †† /JUN/23,/1989/
/AA/	/CHELSEA/LABS/	/250MG/	/N86948/001/ /AUG/09,/1982/
A	CHELSEA LABS	250MG	N86948 001 AUG 09, 1982
/AA/	/PAR/PHARM/	/500MG=/	/N89896/001/ †† /JUN/05,/1989/
AA	PIONEER PHARMS	250MG=	N89592 001 JAN 06, 1989
AA		500MG=	N89948 001 JAN 06, 1989
AA	ROYCE LABS	500MG=	N81040 001 AUG 22, 1989

†† SEE SECTION 1.5 OF INTRODUCTION

CHYMOPAPAIN

INJECTABLE; INJECTION

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

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

		CLINDAMYCIN HCL		
AB		BIOCRAFT LABS	EQ 75MG BASE‡	N63027 001 SEP 20, 1989
AB			EQ 150MG BASE‡	N63029 001 SEP 20, 1989
> DLT >	/AB/	/VITARINE/	/EQ 75MG BASE/	/N62910/001/ /JUL/05,/1988/
> DLT >	/AB/		/EQ 150MG BASE/	/N62910/002/ /JUL/05,/1988/
> ADD >	BX	VITARINE	EQ 75MG BASE	N62910 001 JUL 05, 1988
> ADD >	BX		EQ 150MG BASE	N62910 002 JUL 05, 1988

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER

	UPJOHN	EQ 6MG BASE/ML‡	N50639 001 AUG 30, 1989
		EQ 12MG BASE/ML‡	N50639 002 AUG 30, 1989
	CLINDAMYCIN PHOSPHATE		
AP	ASTRA PHARM	EQ 150MG BASE/ML‡	N62928 001 FEB 13, 1989
AP	DUPONT CRI CARE	EQ 150MG BASE/ML‡	N62908 001 FEB 01, 1989
AP	LEDERLE PARNTLS	EQ 150MG BASE/ML‡	N63068 001 AUG 28, 1989

CLINDAMYCIN PHOSPHATE

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

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

CYCLOPHOSPHAMIDE

CLOXACILLIN SODIUM

PONDER FOR RECONSTITUTION; ORAL
CLOXACILLIN SODIUM

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

CLOZAPINE

TABLET; ORAL
CLOZARIL

	SANDOZ	25MG*	N19758 001 SEP 26, 1989
		100MG*	N19758 002 SEP 26, 1989

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

/N/A;/N/A/
/RUBRATOPE-60/KIT/
/SQUIBB/

	a SQUIBB	N/A;N/A;N/A;N/A N/A;N/A;N/A;N/A	/N16090/001/ N16090 001

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

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

CRYPTENAMINE ACETATES

/INJECTABLE;/INJECTION/
/UNITENSEN/
/WALLACE/LABS/

a WALLACE LABS	260 CSR UNITS/ML	N08814 001

CYANOCOBALAMIN

INJECTABLE; INJECTION
/REDISOL/

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

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION
NEOSAR

AP	ADRIA LABS	2GM/VIAL*	N87442 005 MAR 30, 1989

CYSTEINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/
/CYSTEINE/HCL/
/KABIVITRUM/

a KABIVITRUM	7.25%	/N19523/001/ /OCT/22,/1986/ N19523 001 OCT 22, 1986

CYTARABINE

INJECTABLE; INJECTION
CYTARABINE

AP	CETUS BEN VENUE	100MG/VIAL*	N71471 001 AUG 02, 1989
AP		500MG/VIAL*	N71472 001 AUG 02, 1989

DEMECLOCYCLINE HYDROCHLORIDE

/SYRUP;/ORAL/
/DECLOMYCIN/
/LEDERLE/LABS/

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

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

DESIPRAMINE HCL

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

DESOXYCORTICOSTERONE ACETATE

/INJECTABLE;/INJECTION/

/DOCA/

/ORGANON/	/5MG/ML/	/N01104/001/
@ ORGANON	5MG/ML	N01104 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/
@ CHELSEA LABS		0.75MG	N85818 001
@		1.5MG	N85840 001

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

BP	DANBURY PHARMA	0.25MG	N85455 001
BP		0.5MG	N85458 001
BP		0.75MG	N80968 001
BP		1.5MG	N85456 001
/@/		/0.25MG/	/N85455/001/
/@/		/0.5MG/	/N85458/001/
/@/		/0.75MG/	/N80968/001/
/@/		/1.5MG/	/N85456/001/

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

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

DEXTROSE; POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER

	KENDALL MCGAW	5GM/100ML;37MG/100ML	N19699 001 SEP 29, 1989

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;75MG/100ML	N19699 002 SEP 29, 1989

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% IN PLASTIC CONTAINER

	KENDALL MCGAW	5GM/100ML;110MG/100ML	N19699 003 SEP 29, 1989

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;150MG/100ML	N19699 004 SEP 29, 1989

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER

	KENDALL MCGAW	5GM/100ML;220MG/100ML	N19699 005 SEP 29, 1989

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML;300MG/100ML	N19699 006 SEP 29, 1989

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/10MEQ IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;75MG/100ML; 450MG/100ML/	/N18008/005/
			/APR/28,/1982/
/AP/		/5GM/100ML;150MG/100ML; 450MG/100ML/	/N18008/006/
			/APR/28,/1982/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/15MEQ IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;224MG/100ML; 450MG/100ML/	/N18008/003/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/20MEQ (K) IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;300MG/100ML; 450MG/100ML/	/N18008/001/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/20MEQ IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;150MG/100ML; 450MG/100ML/	/N18008/007/
			/APR/28,/1982/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/30MEQ IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;224MG/100ML; 450MG/100ML/	/N18008/008/
			/APR/28,/1982/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/40MEQ IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;300MG/100ML; 450MG/100ML/	/N18008/009/
			/APR/28,/1982/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/5MEQ (K) IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;150MG/100ML; 450MG/100ML/	/N18008/004/

/DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/5MEQ IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML;75MG/100ML; 450MG/100ML/	/N18008/002/
	ə BAXTER	5GM/100ML;224MG/100ML; 450MG/100ML	N18008 003
	ə BAXTER	5GM/100ML;300MG/100ML; 450MG/100ML	N18008 001
	ə BAXTER	5GM/100ML;75MG/100ML; 450MG/100ML	N18008 002

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	5GM/100ML;75MG/100ML; 450MG/100ML	N18008 005 APR 28, 1982
AP		5GM/100ML;150MG/100ML; 450MG/100ML	N18008 006 APR 28, 1982

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	5GM/100ML;150MG/100ML; 450MG/100ML	N18008 007 APR 28, 1982

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	5GM/100ML;224MG/100ML; 450MG/100ML	N18008 008 APR 28, 1982

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	5GM/100ML;300MG/100ML; 450MG/100ML	N18008 009 APR 28, 1982

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	BAXTER	5GM/100ML;150MG/100ML; 450MG/100ML	N18008 004

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/AP/	/CUTTER/BIOL/	/5GM/100ML;900MG/100ML/	/N18500/001/
	ə CUTTER BIOL	5GM/100ML;900MG/100ML	N18500 001

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/
	∂ STERLING DRUG	60%;30%	N10220 002

MD-76

AP	MALLINCKRODT	66%;10%Ⓜ	N19292 001 SEP 29, 1989

DIAZEPAM

TABLET; ORAL

DIAZEPAM

/AA/	/MARTEC/PHARM/	/10MG/	/N72402/001/ /APR/25,/1989/
	∂ MARTEC PHARM	10MGⓂ	N72402 001 APR 25, 1989

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

VOLTAREN

	/CIBA/PHARM/	/25MG/	/N19201/001/ /JUL/28,/1988/
		/50MG/	/N19201/002/ /JUL/28,/1988/
		/75MG/	/N19201/003/ /JUL/28,/1988/
	GEIGY PHARMS	25MG	N19201 001 JUL 28, 1988
		50MG	N19201 002 JUL 28, 1988
		75MG	N19201 003 JUL 28, 1988

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HCL

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

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL

HETRAZAN

	/∂/LEDERLE/LABS/	/50MG/	/N06459/001/
	LEDERLE LABS	50MG	N06459 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

/AA/	/CHELSEA/LABS/	/25MG/	/N85741/001/
	∂ CHELSEA LABS	25MG	N85741 001

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

	MARION LABS	60MGⓂ	N19471 001 JAN 23, 1989
		90MGⓂ	N19471 002 JAN 23, 1989
		120MGⓂ	N19471 003 JAN 23, 1989
	∂	180MGⓂ	N19471 004 JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/AA/	/CHELSEA/LABS/	/25MG/	/N85138/001/
	∂ CHELSEA LABS	25MG	N85138 001
/AA/	/VANGARD/LABS/	/25MG/	/N86614/001/ /OCT/27,/1982/
/AA/		/50MG/	/N87630/001/
	∂ VANGARD LABS	25MG	N88034 001 OCT 27, 1982
	∂	50MG	N87630 001
/AA/	/WHITE/TN/PAULSN/	/50MG/	/N80800/001/
	∂ WHITE TN PAULSN	50MG	N80800 001

ELIXIR; ORAL

/DIPHEN/

/AA/	/PBI/	/12.5MG/5ML/	/N84640/001/
	∂ PBI	12.5MG/5ML	N84640 001

DIPHENHYDRAMINE HCL

AA	CENCI LABS	12.5MG/5ML	N87941 001 DEC 17, 1982
/AA/	/LEDERLE/LABS/	/12.5MG/5ML/	/N86937/001/
	∂ LEDERLE LABS	12.5MG/5ML	N86937 001
/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/
	ə CHELSEA LABS	250MG	N87973 001	AUG 05, 1983
	ə	500MG	N87974 001	AUG 05, 1983

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL
DEPAKOTE

	ABBOTT LABS	EQ 125MG BASE*	N19680 001 SEP 12, 1989

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION
DOPAMINE HCL

AP	ABBOTT LABS	40MG/ML*	N70656 001 JAN 24, 1989
AP		80MG/ML*	N70657 001 JAN 24, 1989
>ADD>	DOPAMINE HCL		
>ADD> AP	MARNER CHILCOTT	40MG/ML	N18138 001
>ADD> AP		40MG/ML	N70558 001 SEP 20, 1985
>ADD>	ə	80MG/ML	N70559 001 SEP 20, 1985
>ADD>			
>DLT>	/DOPASTAT/		
>DLT> /AP/	/PARKE/DAVIS/	/40MG/ML/	/N18138/001/
>DLT> /AP/		/40MG/ML/	/N70558/001/ /SEP/20,/1985/
>DLT> /AP/		/80MG/ML/	/N70559/001/ /SEP/20,/1985/

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL

AB	QUANTUM PHARMCS	EQ 100MG BASE*	N72375 001 MAR 15, 1989
AB		EQ 150MG BASE*	N72376 001 MAR 15, 1989

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
ADRIAMYCIN PFS

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

CAPSULE; ORAL
DOXYCYCLINE HYCLATE

>DLT> /AB/	/VITARINE/	/EQ 50MG BASE/	/N62780/001/	/APR/12,/1988/
>DLT> /AB/		/EQ 100MG BASE/	/N62227/001/	/APR/12,/1988/
>ADD> BX	VITARINE	EQ 50MG BASE	N62780 001	APR 12, 1988
>ADD> BX		EQ 100MG BASE	N62227 001	

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

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE			
/CHELSEA/LABS/	/EQ/50MG/BASE/	/N62392/001/	
@ CHELSEA LABS	EQ 50MG BASE	N62392 001 MAR 31, 1983	

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE AND DROPERIDOL

AP	ASTRA PHARM	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

ERGOCALCIFEROL

CAPSULE; ORAL

VITAMIN D

> DLT > /AA/	/CHASE/CHEM/	/50,000 IU/	/N80747/001/
> ADD >	@ CHASE CHEM	50,000 IU	N80747 001

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 ESTOLATE; SULFISOXAZOLE ACETYL

SUSPENSION; ORAL

ILOSONE SULFA			
/LILLY/	/EQ/125MG/BASE/5ML;/ /EQ/600MG/BASE/5ML/	/N50599/001/ /SEP/29,/1989/	
LILLY	EQ 125MG BASE/5ML; EQ 600MG BASE/5ML	N50599 001 SEP 29, 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			
EI DUPONT	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/

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

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

/BP/	/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

ETHINYL ESTRADIOL; NORETHINDRONE

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

FLUOCINOLONE ACETONIDE

/GEL;/TOPICAL/
/FLUONID/

/HERBERT/LABS/	/0.025%/	/N87300/001/ /MAY 27, 1982/
∂ HERBERT LABS	0.025%	N87300 001 MAY 27, 1982

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE

AB	LEMMON	0.05%	N72488 001 FEB 06, 1989
AB		0.05%	N72490 001 FEB 07, 1989

VANODERM E

AB	TICAN PHARM	0.05%	N72494 001 JAN 19, 1989
/AB/	/TJ/ROACO/	/0.05%/	/N72494/001/ /JAN 19, 1989/

GEL; TOPICAL
FLUOCINONIDE

AB	LEMMON	0.05%	N72537 001 FEB 07, 1989

LIDEX

AB	SYNTEX LABS	0.05%	N17373 001

SOLUTION; TOPICAL
FLUOCINONIDE

AT	LEMMON	0.05%	N72511 001 FEB 07, 1989
AT	THAMES PHARMA	0.05%	N72857 001 AUG 02, 1989

FLUOROMETHOLONE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC
FML-S
ALLERGAN PHARMS — 0.1%;10%Ⓜ — N19525 001 SEP 29, 1989

FLUOROMETHOLONE ACETATE; TOBRAMYCIN

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

FLUOXYMESTERONE

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

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
/AA/ /CHELSEA LABS/ /1MG/ — /N85141/002/ N85141 002
a CHELSEA LABS 1MG
/AA/ /PBI/ /1MG/ — /N87828/001/ /MAY 13, 1982/ N87828 001 MAY 13, 1982
a PBI 1MG
/AA/ /VANGARD LABS/ /1MG/ — /N88730/001/ /MAR 23, 1984/ N88730 001 MAR 23, 1984
a VANGARD LABS 1MG
/AA/ /WHITE TN PAULSN/ /1MG/ — /N80691/002/ N80691 002
a WHITE TN PAULSN 1MG

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/ N18422 001
a PARKE DAVIS 200MG

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

GLYCOPYRROLATE

TABLET; ORAL
GLYCOPYRROLATE
/AA/ /CHELSEA LABS/ /2MG/ — /N86178/001/ N86178 001
a CHELSEA LABS 2MG

FLUTAMIDE

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

FOLIC ACID

TABLET; ORAL
FOLIC ACID
/BOOTS/PHARMS/ — /1MG/ — /N84158/001/
a BOOTS USA — 1MG — N84158 001

GLYCOPYRROLATE

TABLET; ORAL
GLYCOPYRROLATE
/AA/ — /CHELSEA/LABS/ — /2MG/ — /N86178/001/
a CHELSEA LABS — 2MG — N86178 001

>ADD> GONADORELIN ACETATE

>ADD> INJECTABLE; INJECTION
>ADD> LUTREPULSE PUMP KIT
>ADD> RW JOHNSON — 0.8MG/VIAL — N19687 001 OCT 10, 1989
>ADD> — 3.2MG/VIAL — N19687 002 OCT 10, 1989

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN
/STERIS/LABS/ — /2,000/UNITS/VIAL/ — /N17016/000/ /DEC/27,/1984/
a STERIS LABS — 2,000 UNITS/VIAL — N17016 009 DEC 27, 1984

HALOPERIDOL

TABLET; ORAL
HALOPERIDOL
AB LEDERLE LABS — 0.5MG — N72727 001 SEP 19, 1989
AB — 1MG — N72728 001 SEP 19, 1989
AB — 2MG — N72729 001 SEP 19, 1989
AB — 5MG — N72730 001 SEP 19, 1989
AB — 10MG — N72731 001 SEP 19, 1989
AB — 20MG — N72732 001 SEP 19, 1989

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM
AP STERIS LABS — 40,000 UNITS/ML — N17064 006
/A/ — /40,000/UNITS/ML/ — /N17064/006/

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

INJECTABLE; INJECTION
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/AND/SODIUM/CHLORIDE/0.9%/IN/ /PLASTIC/CONTAINER/
/BAXTER/ — /500/UNITS/100ML/ — /N18609/003/ /APR/28,/1982/
a BAXTER — 500 UNITS/100ML — N18609 003 APR 28, 1982

/HEPARIN/SODIUM/5000/UNITS/IN/SODIUM/CHLORIDE/0.9%/IN/ /PLASTIC/CONTAINER/
/AP/ /KENDALL/MCGAW/ — /1,000/UNITS/100ML/ — /N19042/004/ /MAR/29,/1985/
a KENDALL MCGAW — 1,000 UNITS/100ML — N19042 004 MAR 29, 1985

HEXOCYCLIUM METHYLSULFATE

/TABLET;/ORAL/ /TRAL/
/ABBOTT/LABS/ — /25MG/ — /N10599/001/
a ABBOTT LABS — 25MG — N10599 001

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

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

	HYDRALAZINE HCL			
/AA/	/PBI/	/10MG/	/N87780/001/	
			/MAR/29,/1982/	
/AA/		/50MG/	/N87751/001/	
			/MAR/29,/1982/	
	ə PBI	25MG	N87780 001	
			MAR 29, 1982	
	ə	50MG	N87751 001	
			MAR 29, 1982	
/AA/	/VANGARD/LABS/	/50MG/	/N87908/001/	
			/MAY/07,/1982/	
	ə VANGARD LABS	50MG	N87908 001	
			MAY 07, 1982	

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

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

HYDROCHLOROTHIAZIDE

TABLET; ORAL

	HYDROCHLOROTHIAZIDE			
/AA/	/BOOTS/LABS/	/25MG/	/N64325/001/	
/AB/		/50MG/	/N64324/001/	
/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	
/AA/	/PBI/	/25MG/	/N87827/001/	
			/APR/19,/1982/	
/AA/		/50MG/	/N87752/001/	
			/APR/19,/1982/	
	ə PBI	25MG	N87827 001	
			APR 19, 1982	
	ə	50MG	N87752 001	
			APR 19, 1982	
AB	PHARMAFAIR	25MG	N84325 001	
AB		50MG	N84324 001	

HYDROCHLOROTHIAZIDE

TABLET; ORAL

	HYDROCHLOROTHIAZIDE			
/AA/	/VANGARD/LABS/	/25MG/	/N87638/001/	
/AB/		/50MG/	/N87610/001/	
	ə VANGARD LABS	25MG	N87638 001	
	ə	50MG	N87610 001	
/AA/	/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		
AB	MS&D RES LABS	25MG;20MG	N19778 002
			FEB 16, 1989
	ZESTORETIC 20/25		
AB	IMPERIAL CHEM	25MG;20MG	N19888 002
			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

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

HYDROCHLOROTHIAZIDE W/ RESERPINE

/@/	/BOOTS/PHARMS/	/50MG;0.125MG/	/N85426/001/
/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
	@ PHARMAFAIR	50MG;0.125MG	N85420 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

/AA/	/CHELSEA/LABS/	/25MG;25MG/	/N86026/001/
	@ CHELSEA LABS	25MG;25MG	N86026 001
/AA/	/PBI/	/25MG;25MG/	/N87651/001/
	@ PBI	25MG;25MG	N87651 001
/AA/	/VANGARD/LABS/	/25MG;25MG/	/N87655/001/
	@ VANGARD LABS	25MG;25MG	N87655 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

/AA/	/BOLAR/PHARM/	/25MG;50MG/	/N71845/001/
			/AUG/21,/1987/
BX	BOLAR PHARM	25MG;50MG	N71845 001
			AUG 21, 1987
/@/	/VITARINE/	/25MG;50MG/	/N71737/001/
			/FEB/12,/1988/

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

>DLT>	/AA/	/PAR/PHARM/	/50MG;75MG/	/N72337/001/
>DLT>				/MAY/11,/1988/
>ADD>	BX	PAR PHARM	50MG;75MG	N72337 001
>ADD>				MAY 11, 1988
>DLT>	/AA/	/VITARINE/	/50MG;75MG/	/N71360/001/
>DLT>				/DEC/08,/1987/
>ADD>	BX	VITARINE	50MG;75MG	N71360 001
>ADD>				DEC 08, 1987

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 ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL

EPIFOAM

/AT/	/REED/&/CARNRICK/	/1%;1%/	/N86457/001/
BX	REED & CARNRICK	1%;1%	N86457 001

HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%

/AT/	/COPLEY/PHARM/	/1%;1%/	/N89440/001/
			/MAY/17,/1988/
BX	COPLEY PHARM	1%;1%	N89440 001 MAY 17, 1988

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/	>DLT> >DLT> >ADD> >ADD>	BX	WHITEHALL LABS	100MG/5ML
	ə CHELSEA LABS	50MG	N88528 001 AUG 15, 1984				

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

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

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

	HYDROXYZINE HCL						
/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/				
	ə PHARMAFAIR	25MG/ML	N88862 001 FEB 14, 1986				
	ə	25MG/ML	N89106 001 FEB 14, 1986				
	ə	50MG/ML	N89107 001 FEB 14, 1986				

HYDROXYZINE PAMOATE

CAPSULE; ORAL

	HYDROXYZINE PAMOATE						
/AB/	/CHELSEA/LABS/	/EQ 100MG HCL/	/N86728/001/ /OCT/05,/1982/				
	ə CHELSEA LABS	EQ 100MG HCL	N86728 001 OCT 05, 1982				

IBUPROFEN

SUSPENSION; ORAL

	CHILDREN'S ADVIL						
/AA/	/WHITEHALL/LABS/	/100MG/5ML/	/N19833/002/ /SEP/19,/1989/	>DLT> >DLT> >ADD> >ADD>	BX	WHITEHALL LABS	100MG/5ML
			N19833 002 SEP 19, 1989				
	PEDIA PROFEN						
/AA/	/MCNEIL/CONSUMER/	/100MG/5ML/	/N19842/001/ /SEP/19,/1989/	>DLT> >DLT> >ADD> >ADD>	BX	MCNEIL CONSUMER	100MG/5ML
			N19842 001 SEP 19, 1989				

TABLET; ORAL

	IBUPROFEN						
/AB/	/BOOTS/LABS/	/400MG/	/N70556/001/ /JUN/14,/1985/				
/A/		/600MG/	/N71264/001/ /JUL/25,/1986/				
AB		BOOTS USA	400MG				
AB			600MG				
	ə		800MG				
			N70556 001 JUN 14, 1985				
			N71264 001 JUL 25, 1986				
/AB/	/CHELSEA/LABS/	/300MG/	/N71338/001/ /DEC/01,/1986/				
	ə CHELSEA LABS	300MG	N71338 001 DEC 01, 1986				
	RUFEN						
/AB/	/BOOTS/PHARMS/	/400MG/	/N18197/001/				
/AB/		/400MG/	/N70083/001/ /FEB/22,/1985/				
/AB/		/600MG/	/N18197/002/ /MAR/05,/1984/				
/AB/		/600MG/	/N70088/001/ /FEB/08,/1985/				
/AB/		/600MG/	/N70099/001/ /MAR/29,/1985/				
/AB/		/800MG/	/N70745/001/ /JUL/23,/1986/				
AB		BOOTS USA	400MG				
AB			600MG				
AB			600MG				
AB			800MG				
	ə		600MG				
			N18197 001				
			N70088 001 FEB 08, 1985				
			N70099 001 MAR 29, 1985				
			N70745 001 JUL 23, 1986				
			N18197 002 MAR 05, 1984				

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

/AB/	/CHELSEA/LABS/	/10MG/	/A85875/001/
/AB/		/25MG/	/A85878/001/
/AB/		/50MG/	/A85877/001/
	ə CHELSEA LABS	10MG	A85875 001
	ə	25MG	A85878 001
	ə	50MG	A85877 001
/AB/	/PBI/	/25MG/	/A87776/001/ /FEB/10,/1982/
	ə PBI	25MG	A87776 001 FEB 10, 1982
/AB/	/VANGARD/LABS/	/10MG/	/A88036/001/ /NOV/03,/1982/
/AB/		/25MG/	/A87619/001/ /FEB/09,/1982/
/AB/		/50MG/	/A87631/001/ /JAN/04,/1982/
	ə VANGARD LABS	10MG	A88036 001 NOV 03, 1982
	ə	25MG	A87619 001 FEB 09, 1982
	ə	50MG	A87631 001 JAN 04, 1982

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

>DLT>	/AB/	/VITARINE/	/25MG/	/A71711/001/ /JUL/05,/1988/
>DLT>	/AB/		/50MG/	/A71712/001/ /JUL/05,/1988/
>ADD>	BX	VITARINE	25MG	A71711 001 JUL 05, 1988
>ADD>	BX		50MG	A71712 001 JUL 05, 1988

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

	AB	INWOOD LABS	75MG(M)	A72410 001 MAR 15, 1989
>DLT>	/AB/	/VITARINE/	/75MG/	/A71531/001/ /JUL/21,/1987/
>ADD>	BX	VITARINE	75MG	A71531 001 JUL 21, 1987

IOHEXOL

INJECTABLE; INJECTION

OMNIPAQUE 210

STERLING DRUG	45.3%(M)	N18956 006 JUN 30, 1989

/INJECTABLE;/INJECTION/

/OMNIPAQUE/240/ /STERLING/DRUG/	/51.6%/	/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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

/AN/	/BAXTER/	/0.08%/	/A88144/001/ /JUL/29,/1983/
/AN/		/0.125%/	/A88146/001/ /AUG/01,/1983/
	ə BAXTER	0.08%	A88144 001 JUL 29, 1983
		/0.14%/	/A88145/001/ /MAR/26,/1984/
	ə	0.14%	A88145 001 MAR 26, 1984
	ə	0.25%	A88146 001 AUG 01, 1983

ISONIAZID

TABLET; ORAL

ISONIAZID			
AA	CHELSEA LABS	100MG	N85790 001
AA	CHELSEA LABS	300MG	N85784 001
AA	WHITE TN PAULSN	100MG	N80120 002

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE			
> ADD > AP	WARNER CHILCOTT	EQ 1GM BASE/3ML*	N63092 001 OCT 11, 1989
> ADD >			

LACTULOSE

SYRUP; ORAL

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

SYRUP; ORAL, RECTAL

LACTULOSE			
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

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

BETAGAN			
	ALLERGAN PHARMS	0.25%*	N19814 001 JUN 28, 1989

LEVOTHYROXINE SODIUM, LIOTHYRONINE SODIUM, LIOTRIX

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-5			
	ARMOUR PHARM	0.25MG;0.0625MG	N16807 006

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL			
AP	INTL MEDTN SYS	4%	N17702 002
XYLOCAINE			
AP	ASTRA PHARM	1%	N16801 005 JAN 19, 1988

INJECTABLE; SPINAL

LIDOCAINE HCL AND DEXTROSE 7.5%			
AP	ABBOTT LABS	5%	N83914 001

SOLUTION; TOPICAL

LARYNGOTRACHEAL ANESTHESIA KIT			
AA	KENDALL	4%	N87931 001 JAN 10, 1983

LIDOCAINE HYDROCHLORIDE

SOLUTION; TOPICAL
/LARYNGOTRACHEAL ANESTHESIA KIT/
∂ KENDALL 4% N87931 001 JUN 10, 1983

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 >DLT>
THYROLAR-0.5
RORER PHARM 0.025MG;0.00625MG N16807 005 >DLT>
THYROLAR-1
RORER PHARM 0.05MG;0.0125MG N16807 004 >DLT>
THYROLAR-2
RORER PHARM 0.1MG;0.025MG N16807 002 >ADD>
THYROLAR-3
RORER PHARM 0.15MG;0.0375MG N16807 003 >ADD>
THYROLAR-5
∂ RORER PHARM 0.25MG;0.0625MG N16807 006 >ADD>

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

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC

INJECTABLE; INJECTION
ISOLYTE S PH 7.4 IN PLASTIC CONTAINER
KENDALL MCGAW 30MG/100ML;37MG/100ML;0.82MG/100ML; 370MG/100ML;530MG/100ML; 500MG/100ML;12MG/100ML¤ N19696 001 SEP 29, 1989

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION
ISOLYTE S IN PLASTIC CONTAINER
AP KENDALL MCGAW 30MG/100ML;37MG/100ML;370MG/100ML; 530MG/100ML; 500MG/100ML¤ N19711 001 SEP 29, 1989

SOLUTION; IRRIGATION
/PHYSIOSOL/IN/PLASTIC/CONTAINER/
/∂/ABBOTT/LABS/ /30MG/100ML;37MG/100ML;222MG/100ML; /526MG/100ML; /502MG/100ML/ /N18406/002/ /JUL/08,/1982/

PHYSIOSOL PH 7.4 IN PLASTIC CONTAINER
ABBOTT LABS 30MG/100ML;37MG/100ML;222MG/100ML; 526MG/100ML; 502MG/100ML N18406 002 JUL 08, 1982

MALATHION

LOTION; TOPICAL
OVIDE
GENDERM 0.5% N18613 001 AUG 02, 1982

/LOTION;/TOPICAL/
/PRIODERM/
/∂/PURDUE/FRDRK/ /0.5%/ /N18613/001/ /AUG/02,/1982/

MANNITOL

SOLUTION; IRRIGATION
/RESECTISOL/
/KENDALL/MCGAW/ /5GM/100ML/ /N16704/002/

MANNITOL

SOLUTION; IRRIGATION
/RESECTISOL/
@ KENDALL MCGAW — 5GM/100ML — N16704 002

MEBENDAZOLE

TABLET, CHEWABLE; ORAL
VERMOX
/JANSSEN/PHARMA/ — /100MG/ — /N17481/001/
JANSSEN RES — 100MG — N17481 001

MECLIZINE HYDROCHLORIDE

TABLET; ORAL
MECLIZINE HCL
>ADD > AA CORD LABS — 12.5MG — N84843 002 MAY 22, 1989
>ADD > AA — 25MG — N84092 003 MAY 22, 1989
/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
>DLT >/AA/ /VITARINE/ — /EQ 50MG BASE/ — /N71716/001/ /JUN 15, 1988/
>DLT > >DLT >/AA/ — /EQ 100MG BASE/ — /N71684/001/ /JUN 15, 1988/
>ADD > BX VITARINE — EQ 50MG BASE — N71710 001 JUN 15, 1988
>ADD > >ADD > BX — EQ 100MG BASE — N71684 001 JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL
MEFENAMIC ACID
>DLT >/AA/ /VITARINE/ — /250MG/ — /N72179/001/ /APR 21, 1988/
>DLT >
>ADD > BX VITARINE — 250MG — N72179 001 APR 21, 1988
>ADD >

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 — 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
/AA/ /CHELSEA/LABS/ — /600MG/ — /N85719/001/
@ CHELSEA LABS — 600MG — N85719 001
/AA/ /LEDERLE/LABS/ — /400MG/ — /N86299/001/
@ LEDERLE LABS — 400MG — N86299 001
@ PHARMAFAIR — 400MG — N84153 001

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/AA/ /VANGARD/LABS/ /400MG/ /N88011/001/ >DLT >

@ VANGARD LABS 400MG /JUL/14,/1982/ >ADD >

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/SQUIBB/ /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

METHIXENE HYDROCHLORIDE

TABLET; ORAL

TREST

/A/DORSEY/LABS/ /1MG/ /N13420/001/

@ SANDOZ PHARMS 1MG N13420 001

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

/A/BOOTS/PHARMS/ /500MG/ /N84231/002/

/A/ /750MG/ /N84471/001/

@ PHARMAFAIR 500MG N84231 002

@ 750MG N84471 001

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM

/AP/ /LYPHOMED/ /EQ 20MG BASE/VIAL/ /N88935/001/

/OCT/11,/1985/

/AP/ /EQ 50MG BASE/VIAL/ /N88936/001/

/OCT/11,/1985/

/AP/ /EQ 100MG BASE/VIAL/ /N88937/001/

/OCT/11,/1985/

@ LYPHOMED EQ 20MG BASE/VIAL N88935 001

OCT 11, 1985

@ EQ 50MG BASE/VIAL N88936 001

OCT 11, 1985

@ EQ 100MG BASE/VIAL N88937 001

OCT 11, 1985

MEXATE-AQ

/AP/ /BRISTOL/CARIB/ /EQ 25MG BASE/ML/ /N88760/001/

/FEB/14,/1985/

AP BRISTOL MYERS EQ 25MG BASE/ML N88760 001

FEB 14, 1985

MEXATE-AQ PRESERVED

AP BRISTOL MYERS EQ 25MG BASE/ML[M] N89887 001

APR 14, 1989

METHYCLOTHIAZIDE

TABLET; ORAL

METHYCLOTHIAZIDE

/AA/ /CHELSEA/LABS/ /2.5MG/ /N88750/001/

/SEP/06,/1984/

@ 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/
	ə	16MG	N86159 001 FEB 09, 1982

METHYLPREDNISOLONE ACETATE

/ENEMA;/RECTAL/
/MEDROL/

	/UPJOHN/	/40MG/BOT/	/N18102/001/
	ə UPJOHN	40MG/BOT	N18102 001

METHYLTESTOSTERONE

TABLET; BUCCAL
ANDROID 5

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

TABLET; ORAL
ANDROID 10

/AA/	/BROWN/PHARM/	/10MG/	/N86450/001/
AB	ICN PHARMS	10MG	N86450 001

ANDROID 25

/AA/	/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

TABLET; ORAL
METOCLOPRAMIDE HCL

AB	INVAMED	EQ 5MG BASE	N72436 001 JUN 22, 1989
/AA/	/MARTEC/PHARM/	/EQ 10MG BASE/	/N70598/001/ /FEB/02,/1987/
	ə MARTEC PHARM	EQ 10MG BASE	N70598 001 FEB 02, 1987

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

MICONAZOLE NITRATE

>ADD>	TAMPON; VAGINAL			
>ADD>	MONISTAT 5			
>ADD>		RH JOHNSON	100MG	*N18592 001 OCT 27, 1989*
>ADD>				

> ADD > TAMPON; VAGINAL
> ADD > MONISTAT 5
> ADD > RH JOHNSON 100MG¤ N18592 001
> ADD > OCT 27, 1989

MOMETASONE FUROATE

LOTION; TOPICAL
ELOCON
SCHERING 0.1%¤ N19796 001
MAR 30, 1989

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MS CONTIN
PURDUE FRDRK 15MG¤ N19516 003
SEP 12, 1989

NAFCILLIN SODIUM

INJECTABLE; INJECTION
> ADD > NALLPEN IN PLASTIC CONTAINER
> ADD > BAXTER EQ 20MG BASE/ML¤ N50655 001
> ADD > OCT 31, 1989
> ADD > EQ 40MG BASE/ML¤ N50655 002
> ADD > OCT 31, 1989

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

AP	ABBOTT LABS	10MG/ML¤	N70914 001 FEB 03, 1989
AP		10MG/ML¤	N70915 001 FEB 03, 1989
AP		20MG/ML¤	N70916 001 FEB 03, 1989
AP		20MG/ML¤	N70917 001 FEB 03, 1989
AP		20MG/ML¤	N70918 001 FEB 03, 1989
AP	ASTRA PHARM	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	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/
	ə 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

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

PROCARDIA

AB	PFIZER	10MG		N18482 001
AB		20MG		N18482 002 JUL 24, 1986
~~AA~~	~~PFIZER LABS~~	~~10MG~~		~~N18482 001~~
~~AB~~		~~20MG~~		~~N18482 002~~ ~~JUL 24, 1986~~

TABLET, EXTENDED RELEASE; ORAL

PROCARDIA XL

PFIZER	30MG‡		N19684 001 SEP 06, 1989
	60MG‡		N19684 002 SEP 06, 1989
	90MG‡		N19684 003 SEP 06, 1989

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

~~AA~~	~~CHELSEA LABS~~	~~50MG~~		~~N85797 001~~
~~AB~~		~~100MG~~		~~N85796 001~~
∂	CHELSEA LABS	50MG		N85797 001
∂		100MG		N85796 001

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN MACROCRYSTALLINE

~~AA~~	~~BOLAR PHARM~~	~~50MG~~	~~N70248 001~~
~~AB~~		~~100MG~~	~~N70249 001~~
BX	BOLAR PHARM	50MG	N70248 001 JUN 24, 1988
BX		100MG	N70249 001 JUN 24, 1988

NYSTATIN

POWDER; ORAL

BARSTATIN 100

AA	BARLAN PHARMA	100%	N62489 001 APR 27, 1988

TABLET; VAGINAL

NYSTATIN

~~AT~~	~~CHELSEA LABS~~	~~100,000 UNITS~~	~~N62176 001~~
∂	CHELSEA LABS	100,000 UNITS	N62176 001

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

LOSEC

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

OXACILLIN SODIUM

INJECTABLE; INJECTION

BACTOCILL IN PLASTIC CONTAINER

BAXTER	EQ 20MG BASE/ML‡	>ADD>	N50640 001 OCT 26, 1989
	EQ 40MG BASE/ML‡	>ADD>	N50640 002 OCT 26, 1989

1 DELAYED EFFECTIVE DATE PENDING COURT DECISION

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

OXANDROLONE

/TABLET;ORAL/
/ANAVAR/

/SEARLE/	/2.5MG/	/N13718/001/
ə SEARLE	2.5MG	N13718 001

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE

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

OXYTOCIN

INJECTABLE; INJECTION
/OXYTOCIN/10/USP/UNITS/IN/DEXTROSE/5%/

/ABBOTT/LABS/	/1/USP/UNIT/100ML/	/N19185/004/ /MAR/29,/1985/
	/2/USP/UNITS/100ML/	/N19185/003/ /MAR/29,/1985/
ə ABBOTT LABS	1 USP UNIT/100ML	N19185 004 MAR 29, 1985
ə	2 USP UNITS/100ML	N19185 003 MAR 29, 1985

/OXYTOCIN/20/USP/UNITS/IN/DEXTROSE/5%/

/ABBOTT/LABS/	/2/USP/UNITS/100ML/	/N19185/002/ /MAR/29,/1985/
ə ABBOTT LABS	2 USP UNITS/100ML	N19185 002 MAR 29, 1985

OXYTOCIN

INJECTABLE; INJECTION
/OXYTOCIN/5/USP/UNITS/IN/DEXTROSE/5%/

/ABBOTT/LABS/	/1/USP/UNIT/100ML/	/N19185/001/ /MAR/29,/1985/
ə ABBOTT LABS	1 USP UNIT/100ML	N19185 001 MAR 29, 1985

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

/SOLUTION;ORAL/
/PARADIONE/

/ABBOTT/LABS/	/300MG/ML/	/N06800/002/
ə ABBOTT LABS	300MG/ML	N06800 002

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/	
	@ WHITE TN PAULSN	100MG	N83338 001	

PERMETHRIN

CREAM; TOPICAL
ELIMITE

BURROUGHS WELLC	5%*	N19855 001	AUG 25, 1989

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
DI-METREX

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

PHENDIMETRAZINE TARTRATE

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

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL

/AA/	/CHELSEA/LABS/	/30MG/	/N86740/001/	
	@ CHELSEA LABS	30MG	N86740 001	MAR 21, 1985

TABLET; ORAL
PHENTERMINE HCL

/AA/	/CHELSEA/LABS/	/8MG/	/N85739/001/	
	@ CHELSEA LABS	8MG	N85739 001	

PHENYL AMINOSALICYLATE

POWDER;ORAL
PHENY-PAS-TEBANIN

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

TABLET;ORAL
PHENY-PAS-TEBANIN

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

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHENERGAN VC

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

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
PREFRIN-A

ALLERGAN PHARMS	0.12%;0.1%	N07953 001	

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
PHENYTOIN SODIUM

/S/BOOTS/PHARMS/	/100MG/	/N85435/001/	
@ PHARMAFAIR	100MG	N85435 001	

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

POWDER FOR RECONSTITUTION; ORAL

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

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

POWDER FOR RECONSTITUTION; ORAL

COLYTE

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

/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

TABLET, EXTENDED RELEASE; ORAL

K-DUR 10

/BC/ /KEY PHARMS/ /10MEQ/ /N19439 002/
/JUN 13, 1986/

BC SCHERING 10MEQ N19439 002 JUN 13, 1986

K-DUR 20

/KEY PHARMS/ /20MEQ/ /N19439 001/
/JUN 13, 1986/

SCHERING 20MEQ N19439 001 JUN 13, 1986

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.037% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 37MG/100ML;900MG/100ML‡ N19708 001 SEP 29, 1989

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

KENDALL MCGAW 75MG/100ML;900MG/100ML‡ N19708 002 SEP 29, 1989

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 110MG/100ML; 900MG/100ML‡ N19708 003 SEP 29, 1989

POTASSIUM CHLORIDE 0.15% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 150MG/100ML; 900MG/100ML‡ N19708 004 SEP 29, 1989

POTASSIUM CHLORIDE 0.22% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAW 220MG/100ML; 900MG/100ML‡ N19708 005 SEP 29, 1989

POTASSIUM CHLORIDE 0.3% IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 300MG/100ML; 900MG/100ML‡ N19708 006 SEP 29, 1989

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

/AP/ /BAXTER/ /75MG/100ML;900MG/100ML/ /N17648 004/

∂ BAXTER 75MG/100ML;900MG/100ML N17648 004

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

∂ KENDALL MCGAW 75MG/100ML;900MG/100ML N18722 001 NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER

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

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

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER

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

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

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN
PLASTIC CONTAINER

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

PRALIDOXIME CHLORIDE

	∂ 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
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

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
PRAZOSIN HCL

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	MAY 16, 1989 : SEP 12, 1988
AB		EQ 2MG BASE	N71995 001	MAY 16, 1989 : 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

TABLET; ORAL
PREDNISOLONE

BX	CHELSEA LABS	5MG	N85415 001
BX		5MG	N85416 001
BX	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

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC

		SULPHRIN		
/BT/	/MURO/PHARM/	/10%;10%/	/N60060/001/ DEC/28,/1982/	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

>DLT>		/PREDNISOLONE SODIUM PHOSPHATE/		
>DLT>	/3/MAURRY/BIOL/	/EQ 0.9%/PHOSPHATE/	/N83358/002/	
>ADD>		PREDNISOLONE SODIUM PHOSPHATE		
>ADD> AT	NORBROOK AM	EQ 0.9% PHOSPHATE	N83358 002	

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/	
	/ROXANE/LABS/	/25MG/	/N87833/001/ /MAY/04,/1982/	
	ə ROXANE LABS	25MG	N87833 001 MAY 04, 1982	
/BX/	/VANGARD/LABS/	/5MG/	/N87682/001/ /JAN/15,/1982/	
/BX/		/20MG/	/N87701/001/ /JAN/15,/1982/	
	ə VANGARD LABS	5MG	N87682 001 JAN 15, 1982	
	ə	20MG	N87701 001 JAN 15, 1982	

PREDNISONE

TABLET; ORAL

	PREDNISONE			
/AB/	/WHITE/TN/PAULSN/	/10MG/	/N89028/001/ /JUL/24,/1986/	
/BX/		/2.5MG/	/N84913/001/	
/BX/		/5MG/	/N80343/001/	
/BX/		/20MG/	/N84913/002/	
	ə WHITE TN PAULSN	2.5MG	N84913 001	
	ə	5MG	N80343 001	
	ə	10MG	N89028 001 JUL 24, 1986	
		20MG	N84913 002	
	/SERVISONE/			
/BX/	/LEDERLE/LABS/	/5MG/	/N80223/001/	
	ə LEDERLE LABS	5MG	N80223 001	

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

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

INJECTABLE; INJECTION

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

TABLET, EXTENDED RELEASE; ORAL

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

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE

AP	ELKINS SINN	EQ 5MG BASE/ML		N89903 001 AUG 29, 1989

PROGESTERONE

INJECTABLE; INJECTION
PROGESTERONE

	~~LILLY~~	~~25MG/ML~~	~~N09238 002~~	
	∂ LILLY	25MG/ML	N09238 002	

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
~~ZIPAN-25~~

~~AP~~	~~ALTANA~~	~~25MG/ML~~	~~N83997 001~~	
	∂ ALTANA	25MG/ML	N83997 001	

~~ZIPAN-50~~

~~AP~~	~~ALTANA~~	~~50MG/ML~~	~~N83997 002~~	
	∂ ALTANA	50MG/ML	N83997 002	

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	

> ADD > PROPOFOL

> ADD > INJECTABLE; INJECTION
> ADD > DIPRIVAN

> ADD >	ICI AMERICAS	10MG/ML		N19627 001 OCT 02, 1989
> ADD >				

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

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

> ADD > PROPOFOL

> ADD > INJECTABLE; INJECTION
> ADD > DIPRIVAN
> ADD > ICI AMERICAS 10MG/ML‡ N19627 001
> ADD > OCT 02, 1989

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL

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

PROPYLIODONE

SUSPENSION; INTRATRACHEAL
/DIONOSIL/AQUEOUS/

	/GLAXO/	/50%/	/N09309 001/
	∂ GLAXO	50%	N09309 001

PROPYLTHIOURACIL

TABLET; ORAL
PROPYLTHIOURACIL

	/S/BOOTS/PHARMS/	/50MG/	/N84075 001/
	∂ BOOTS USA	50MG	N84075 001
/BP/	/CHELSEA LABS/	/50MG/	/N85201 001/
	∂ CHELSEA LABS	50MG	N85201 001

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION
MESTINON

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

SYRUP; ORAL
MESTINON

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

PYRIDOSTIGMINE BROMIDE

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
/AB/	/PBI/	/200MG/	/N87837 001/ /APR 14, 1982/
	∂ PBI	200MG	N87837 001 APR 14, 1982
/AB/	/WHITE TN PAULSN/	/200MG/	/N85444 001/
	∂ WHITE TN PAULSN	200MG	N85444 001

RESERPINE

TABLET; ORAL
RESERPINE

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

RIFAMPIN

CAPSULE; ORAL
RIFADIN

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 10%

	ABBOTT LABS	10%	N18203 001
@	ABBOTT LABS	10%	N18203 001

LIPOSYN 20%

	ABBOTT LABS	20%	N18614 001
@	ABBOTT LABS	20%	N18614 001

SCOPOLAMINE

FILM, EXTENDED RELEASE; PERCUTANEOUS
TRANSDERM-SCOP

>ADD<	CIBA PHARM	0.5MG/24HR	N17874 001
>DLT<		1.5MG	N17874 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

INJECTABLE; INJECTION
SECRETIN-KABI

	PHARMACIA LABS	75CU/VIAL	N18290 001

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
ELDEPRYL

	SOMERSET PHARMS	5MG*	N19334 001 JUN 05, 1989

SELENOMETHIONINE, SE-75

INJECTABLE; INJECTION
SELENOMETHIONINE SE 75

	MALLINCKRODT	100 UCI/ML	N17098 001
@	MALLINCKRODT	100 UCI/ML	N17098 001
	MEDI PHYSICS	250 UCI/ML	N17257 001
@	MEDI PHYSICS	250 UCI/ML	N17257 001

SILVER SULFADIAZINE

CREAM; TOPICAL
SSD

AB	BOOTS USA	1%	N18578 001 FEB 25, 1982

SINCALIDE

INJECTABLE; INJECTION
KINEVAC

	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

SODIUM CHLORIDE

SPIRONOLACTONE

SODIUM CHLORIDE

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

SODIUM IODIDE, I-123

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

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL
PHOSPHORUS P 32
/SQUIBB/ 1-8MCI/VIAL N10927 001
∂ SQUIBB 1-8MCI/VIAL

SODIUM POLYSTYRENE SULFONATE

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

SOMATREM

INJECTABLE; INJECTION
PROTROPIN
> ADD > GENENTECH 10MG/VIAL* N19107 002 OCT 24, 1989
> ADD >

SOMATROPIN, BIOSYNTHETIC

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

SPIRONOLACTONE

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

SULCONAZOLE NITRATE

CREAM; TOPICAL
SULCOSYN
/SYNTEX LABS/ 1% N18737 001 FEB 28, 1989
WESTWOOD PHARMS 1%*

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULTEN-10
AT BAUSCH & LOMB 10% N87818 001 FEB 03, 1983
/AT/ MIRO PHARM 10% N87818 001 FEB 03, 1983

SULFINPYRAZONE

CAPSULE; ORAL
SULFINPYRAZONE
/AB/ VANGARD LABS 200MG N88666 001 FEB 17, 1984
∂ VANGARD LABS 200MG

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE
/A/ BOOTS PHARMS 500MG N84385 001
∂ PHARMAFAIR 500MG

SUTILAINS

OINTMENT; TOPICAL
TRAVASE
/BAXTER/ 62,000 UNITS/GM N12828 001

SUTILAINS

OINTMENT; TOPICAL

TRAVASE		
BOOTS USA	82,000 UNITS/GM	N12828 001

TECHNETIUM TC-99M FERPENTETATE KIT

/INJECTABLE;/INJECTION/

/RENOTEC/		
/SQUIBB/	/N/A/	/N17045/001/
ə SQUIBB	N/A	N17045 001

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL

SODIUM PERTECHNETATE TC 99M		
/CIS/US/	/12MCI/ML/	/N17321/001/
	/24MCI/ML/	/N17321/002/
	/48MCI/ML/	/N17321/003/
ə CIS US	12MCI/ML	N17321 001
ə	24MCI/ML	N17321 002
ə	48MCI/ML	N17321 003
/GAMMA/DIAG/LABS/	/10-60MCI/ML/	/N17725/001/
MALLINCKRODT	10-60MCI/ML	N17725 001

TECHNETIUM TC-99M SULFUR COLLOID

SOLUTION; INJECTION, ORAL

TECHNETIUM TC 99M SULFUR COLLOID		
/GAMMA/DIAG/LABS/	/3MCI/ML/	/N17724/001/
MALLINCKRODT	3MCI/ML	N17724 001

TECHNETIUM TC-99M SULFUR COLLOID KIT

/INJECTABLE;/INJECTION/

/AN-SULFUR/COLLOID/		
/CIS/US/	/N/A/	/N17858/001/

SOLUTION; INJECTION, ORAL

AN-SULFUR COLLOID		
CIS US	N/A	N17858 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL			
/ə/BOOTS/PHARMS/		/250MG/	/N61802/001/
/ə/		/500MG/	/N61802/002/
ə BOOTS USA		250MG	N61802 001
ə		500MG	N61802 002
/AB/ /CHELSEA/LABS/		/250MG/	/N62103/001/
/AB/		/500MG/	/N62103/002/
ə CHELSEA LABS		250MG	N62103 001
ə		500MG	N62103 002
>_DLT_>/AB/ /VITARINE/		/250MG/	/N61471/001/
>_ADD_>	BX VITARINE	250MG	N61471 001
>_ADD_>	BX	500MG	N61471 002
>_ADD_>			SEP 06, 1988

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION

THALLOUS CHLORIDE TL 201			
AP	SQUIBB DIAGS	1MCI/ML	N18548 001
			DEC 30, 1982

THEOPHYLLINE

CAPSULE; ORAL

ELIXOPHYLLIN			
/BX/ /BERLEX/LABS/		/100MG/	/N85545/001/
			/JUL/31,/1984/
/BX/		/200MG/	/N83921/001/
			/JUL/31,/1984/
BX	FOREST LABS	100MG	N85545 001
			JUL 31, 1984
BX		200MG	N83921 001
			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

ELIXIR; ORAL

ELIXOPHYLLIN			
/AA/ /BERLEX/LABS/		/80MG/15ML/	/N85186/001/
AA	FOREST LABS	80MG/15ML	N85186 001

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

THEOPHYLLINE

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

TABLET; ORAL
QUIBRON-T
BRISTOL MYERS 300MG N88656 001
AUG 22, 1985
/HEAD/JOHNSON/ /300MG/ /N88656/001/
/AUG/22,/1985/

TABLET, EXTENDED RELEASE; ORAL
QUIBRON-T/SR
BC BRISTOL MYERS 300MG N87563 001
JUN 21, 1983
/BC/ /HEAD/JOHNSON/ /300MG/ /N87563/001/
/JUN/21,/1983/

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

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOTHIXENE HCL
PACO RES EQ 1MG BASE/ML‡ N71917 001
SEP 20, 1989

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

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
NEBCIN
AP LILLY EQ 10MG BASE/ML N50477 005
AP EQ 10MG BASE/ML N62008 004
AP EQ 10MG BASE/ML N62707 001
APR 29, 1987
AP EQ 40MG BASE/ML N62008 001

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION
TOBRAMYCIN SULFATE

AP	MARSAM PHARMS	EQ 10MG BASE/ML	N62945 001 AUG 09, 1989
AP		EQ 40MG BASE/ML	N62945 002 AUG 09, 1989

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

[illegible]	[illegible]	[illegible]	[illegible]
	∂ 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	

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	

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

[illegible]	[illegible]	[illegible]	[illegible]
	∂ VANGARD LABS	2MG	N88035 001 JUL 30, 1982

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE

> DLT >	[illegible]	[illegible]	[illegible]	[illegible]
> DLT >				
> DLT >	[illegible]	[illegible]	[illegible]	[illegible]
> DLT >				
> DLT >	[illegible]	[illegible]	[illegible]	[illegible]
> DLT >				
> ADD >	BX	VITARINE	EQ 25MG BASE	N71832 001 SEP 10, 1987
> ADD >				
> ADD >	BX		EQ 50MG BASE	N71833 001 SEP 10, 1987
> ADD >				
> ADD >	BX		EQ 100MG BASE	N71834 001 SEP 10, 1987
> ADD >				

TRIPELENNAMINE HYDROCHLORIDE

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL

TRIPELENNAMINE HCL

AA	CHELSEA LABS	50MG	N85188 001
	∂ CHELSEA LABS	50MG	N85188 001

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIPROLIDINE HCL

AA	BARRE NATL	1.25MG/5ML	N85940 001
	∂ BARRE NATL	1.25MG/5ML	N85940 001
AA	HALSEY DRUG	1.25MG/5ML	N88735 001 JAN 17, 1985
	HALSEY DRUG	1.25MG/5ML	N88735 001 JAN 17, 1985

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

ZIDOVUDINE

SYRUP; ORAL

RETROVIR

BURROUGHS WELLC	50MG/5ML	N19910 001 SEP 28, 1989

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G&M 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
> ADD > E-Z SCRUB 107
> ADD > DESERET MED 4%¤ N72525 001 OCT 24, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
/PSEUDO-CHLOR/ /KV/PHARM/ /12MG;120MG/ /N71455/001/
PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE
KV PHARM 12MG;120MG N71455 001 MAR 01, 1989

PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE
/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/

> ADD > CLOTRIMAZOLE

> ADD > CREAM; TOPICAL
> ADD > LOTRIMIN AF
> ADD > SCHERING 1%¤ N17619 002 OCT 27, 1989

> ADD > LOTION; TOPICAL
> ADD > LOTRIMIN AF
> ADD > SCHERING 1%¤ N18813 002 OCT 27, 1989

> ADD > SOLUTION; TOPICAL
> ADD > LOTRIMIN AF
> ADD > SCHERING 1%¤ N17613 002 OCT 27, 1989

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

/SYRUP;/ORAL/
/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

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL
COADVIL

WHITEHALL LABS	200MG;30MG¤	N19771 001 SEP 19, 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

>DLT>	/VISINE/II/		
>DLT>	/PFIZER/	/0.025%/	/N19407/001/ /MAR/31,/1989/
>DLT>			
>ADD>	VISINE L.R.		
>ADD>	PFIZER	0.025%¤	N19407 001 MAR 31, 1989
>ADD>			

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

/SYRUP;/ORAL/		
/PHENERGAN/VC/		
/∂/WYETH/AYERST/LABS/	/10MG/5ML;6.25MG/5ML/	/N88604/004/ /AUG/11,/1988/

POVIDONE-IODINE

SOLUTION; TOPICAL
E-Z PREP

BECTON DICKINSN	10%¤	N19382 001 JUL 25, 1989

POVIDONE IODINE

BAXTER	1%¤	N19522 001 MAR 31, 1989

SPONGE; TOPICAL
E-Z PREP

BECTON DICKINSN	5%¤	N19382 002 JUL 25, 1989

E-Z PREP 220

BECTON DICKINSN	5%¤	N19382 003 JUL 25, 1989

E-Z SCRUB 201

BECTON DICKINSN	20%	N19240 001 NOV 29, 1985

E-Z SCRUB 241

BECTON DICKINSN	10%	N19476 001 JAN 07, 1987
/DESERET/MED/	/10%/	/N19476/001/ /JAN/07,/1987/
/POVIDONE-IODINE/		
/DESERET/MED/	/20%/	/N19240/001/ /NOV/29,/1985/

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 10 / JAN '89 - OCT '89

NO OCTOBER 1989 APPROVALS

ORPHAN DRUG 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 INCLUDES DESIGNATIONS THROUGH MARCH 31, 1989. 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 BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ANCROD TRADE: ARVIN	FOR USE AS AN ANTITHROMBOTIC IN PATIENTS WITH HEPARIN-INDUCED THROMBOCYTOPENIA OR THROMBOSIS, WHO REQUIRE IMMEDIATE AND CONTINUED ANTICOAGULATION.	KNOLL PHARMACEUTICALS 30 NO. JEFFERSON RD WHIPPANY, NJ 07981
GENERIC: ANTIHEMOPHILIC FACTOR (RECOMBINANT) TRADE: NOT ESTABLISHED	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. CUTTER BIOLOGICAL ELKHART, IN 46515
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. TREATMENT OF PATIENTS WITH MYELODYSPLASTIC SYNDROME. TREATMENT OF APLASTIC ANEMIA.	SCHERING CORPORATION 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033
GENERIC: HUMAN IGM MONOCLONAL ANTIBODY (C-58) TO CYTOMEGALOVIRUS (CMV) TRADE: CENTOVIR	TREATMENT OF CYTOMEGALOVIRUS (CMV) INFECTIONS IN BONE MARROW TRANSPLANT PATIENTS. PROPHYLAXIS OF CMV INFECTIONS IN BONE MARROW TRANSPLANT PATIENTS.	CENTOCOR, INC. 244 GREAT VALLEY PKWY MALVERN, PA 19355
GENERIC: INDIUM IN 111 MURINE MONOCLONAL ANTIBODY B72.3 TRADE: ONCOSCINT OV103	DETECTION OF OVARIAN CANCER.	CYTOGEN CORPORATION 201 COLLEGE RD. EAST PRINCETON, NJ 08540

GENERIC: INDIUM IN 111 MURINE MONOCLONAL ANTIBODY B72.3 TRADE: ONCOSCINT OV103	DETECTION OF OVARIAN CANCER.	CYTOGEN CORPORATION 201 COLLEGE RD. EAST PRINCETON, NJ 08540
GENERIC: INDIUM IN 111 MURINE MONOCLONAL ANTIBODY FAB TO MYOSIN TRADE: MYOSCINT	DIAGNOSING MYOCARDITIS.	CENTOCOR, INC 244 GREAT VALLEY PKWY MALVERN, PA 19355

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: INTERFERON ALFA-2A (RECOMBINANT) TRADE: ROFERON-A	TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA (CML). FOR USE IN COMBINATION WITH FLUOROURACIL FOR THE TREATMENT OF ESOPHAGEAL CARCINOMA.	HOFFMAN-LA ROCHE 340 KINGSLAND STREET NUTLEY, NJ 07110
GENERIC: IODINE I 131 MURINE MONOCLONAL ANTIBODY IGG2A TO B CELL TRADE: IMMURAIT, LL-2-I-131	TREATMENT OF B-CELL LEUKEMIA AND B-CELL LYMPHOMA.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060
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
GENERIC: PEG-L-ASPARAGINASE TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL).	ENZON, INC. 300-C CORPORATE COURT SOUTH PLAINFIELD, NJ 07080
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY^9) TO MYELOID CELLS (CD-33) TRADE: ANTI-MY^9-BR	TREATMENT OF MYELOID LEUKEMIAS.	IMMUNOGEN, INC. 148 SIDNEY STREET CAMBRIDGE, MA 02139
GENERIC: TECHNETIUM TC 99M MURINE MONOCLONAL ANTIBODY TO HUMAN ALPHA-FETOPROTEIN TRADE: IMMURAID, AFP-TC99M	DETECTION HEPATOCELLULAR CARCINOMA AND HEPATOBLASTOMA. DETECTION OF ALPHA-FETOPROTEIN (AFP) PRODUCING GERM CELL TUMORS.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060
GENERIC: TECHNETIUM TC 99M MURINE MONOCLONAL ANTIBODY TO HUMAN CHORIONIC GONADOTROPIN (HCG) TRADE: IMMURAID, HCG-TC99M	DETECTION OF HCG PRODUCING TUMORS SUCH AS GERM CELL TUMORS AND TROPHOBLASTIC CELL TUMORS.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ADENOSINE TRADE: NOT ESTABLISHED	FOR USE IN CONJUNCTION WITH BCNU IN THE TREATMENT OF BRAIN TUMORS.	MEDCO RES INC. 8733 BEVERLY BLVD. SUITE 404 LOS ANGELES, CA 90048
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: CITRIC ACID, GLUCONO-DELTA-LACTONE, AND MAGNESIUM CARBONATE TRADE: RENACIDIN	TREATMENT OF RENAL AND BLADDER CALCULI OF THE APATITE OR STRUVITE VARIETY.	UNITED GUARDIAN, INC. 230 MARCUS BLVD. HAUPPUAGE, NY 11788
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: ENISOPROST TRADE: NOT ESTABLISHED	FOR CO-ADMINISTRATION WITH CYCLOSPORINE IN ORGAN TRANSPLANT RECIPIENTS TO REDUCE ACUTE TRANSPLANT REJECTION. FOR CO-ADMINISTRATION WITH CYCLOSPORINE IN ORGAN TRANSPLANT RECIPIENTS TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORINE.	G.D. SEARLE & CO. 4901 SEARLE PARKWAY SKOKIE, IL 60077

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ETHIOFOS TRADE: ETHYOL	USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN AND CYCLOPHOSPHAMIDE IN THE TREATMENT OF OVARIAN CARCINOMA. USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN IN THE TREATMENT OF METASTATIC MELANOMA.	U.S. BIOSCIENCE, INC 920-B HARVEST DRIVE P.O. BOX 220 BLUE BELL, PA 19422
GENERIC: FLUDARABINE PHOSPHATE TRADE: NOT ESTABLISHED	TREATMENT OF NON-HODGKIN'S LYMPHOMA (NHL).	TRITON BIOSCIENCES 1501 HARBOR BAY PARKWAY ALAMEDA, CA 94501
GENERIC: FLUOROURACIL TRADE: NOT APPLICABLE	FOR USE IN COMBINATION WITH INTERFERON ALFA-2A RECOMBINANT FOR THE TREATMENT OF ESOPHAGEAL CARCINOMA.	HOFFMAN-LA ROCHE INC 340 KINGSLAND STREET NUTLEY, NJ 07110
GENERIC: GANCICLOVIR (DHPG) TRADE: CYTOVENE*/**	TREATMENT OF CYTOMEGALOVIRUS (CMV) RETINITIS IN IMMUNOCOMPROMISED INDIVIDUALS, INCLUDING PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)*/**. [JUN 23, 1996]	SYNTEX (U.S.A.), INC. 3401 HILLVIEW AVENUE PALO ALTO, CA 94304
GENERIC: HUMAN GROWTH HORMONE, RECOMBINANT TRADE: NOT ESTABLISHED	TREATMENT OF CHILDREN OF SHORT STATURE ASSOCIATED WITH CHRONIC RENAL FAILURE.	GENETECH, INC. 460 PT SAN BRUNO BLVD. SOUTH SAN FRANCISCO, CA 94080
GENERIC: HUMAN GROWTH HORMONE RELEASING FACTOR TRADE: NOT ESTABLISHED	FOR THE LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	HOFFMAN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF RAYNAUD'S PHENOMENON SECONDARY TO SYSTEMIC SCLEROSIS.	BERLEX LABORATORIES 110 EAST HANOVER AVE CEDAR KNOLLS, NJ 07927

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: L-CYCLOSERINE TRADE: NOT ESTABLISHED	TREATMENT OF GAUCHER'S DISEASE.	THE CITY COLLEGE CITY UNIVERSITY OF N.Y. MEDICAL SCHOOL CONVENT AVE. @ 138 ST. N.Y., NY 10031
GENERIC: LYSINE ACETYLSALICYLATE TRADE: ASPEGIC	TREATMENT OF PAIN AND FEVER SECONDARY TO SICKLE CELL DISEASE CRISIS.	G.D. SEARLE & CO. 4901 SEARLE PKWY SKOKIE, IL 60077
GENERIC: NG-29 TRADE: NOT ESTABLISHED	FOR THE ASSESSMENT OF THE CAPACITY OF THE PITUITARY GLAND TO RELEASE GH IN CHILDREN OF SHORT STATURE POSSIBLY DUE TO GH DEFICIENCY.	FERRING LABORATORIES MONTEBELLO PARK 75 MONTEBELLO RD. SUFFERN, NY 10901
GENERIC: PENTAMIDINE ISETHIONATE (INHALATION) TRADE: NEBUPENT*/** (FORMERLY PENTAM 300)	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN PATIENTS AT HIGH RISK OF DEVELOPING THIS DISEASE. [JUN 15, 1996]	LYPHOMED, INC. 2020 RUBY STREET MELROSE PARK, IL 60160
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 05, 1996]	SOMERSET PHARMACEUTICALS ONE OLDE TOWNE COURT BERNARDSVILLE, NJ 07924

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 05, 1996]	SOMERSET PHARMACEUTICALS ONE OLDE TOWNE COURT BERNARDSVILLE, NJ 07924

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: SOMATROPIN TRADE: SAIZEN	ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES 100 LONGWATER CIRCLE NORWELL, MA 02061
GENERIC: SYNTHETIC SURFACTANT TRADE: EXOSURF	PREVENTION OF HYALINE MEMBRANE DISEASE (HMD), ALSO KNOWN AS RESPIRATORY DISTRESS SYNDROME (RDS), IN INFANTS BORN AT 32 WEEKS GESTATION OR LESS. TREATMENT OF ESTABLISHED HMD AT ALL GESTATIONAL AGES.	BURROUGHS WELLCOME 3030 CORNWALLIS RD RESEARCH TRIANGLE PK, NC 27709
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
GENERIC: TROLEANDOMYCIN TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE STEROID-REQUIRING ASTHMA	STANLEY SZEFLER, MD NATIONAL JEWISH CENTER FOR IMMUNOLOGY AND RESPIRATORY MEDICINE 1400 JACKSON STREET DENVER, CO 80206

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

NO OCTOBER 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 VITRO)	AUG 25, 1988	JUN 27, 1989
ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER - IN VIVO)	AUG 25, 1988	FEB 09, 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; BUTALBITAL; CAFFEINE CAPSULE; ORAL	500MG 50MG 40MG	89 P-0345/CP	MALLARD	NEW DOSAGE FORM	APPROVED OCT 27, 1989
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

CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989
HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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%	89 P-0028/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
HYDROCORTISONE VALERATE SOLUTION; TOPICAL	0.2%	89 P-0029/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	30MG	89 P-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
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	88 P-0419/CP	GUIDELINES	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
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
PHENYLPROPANOLAMINE HYDROCHLORIDE FILM, EXTENDED RELEASE; PERCUTANEOUS	150MG	88 P-0265/CP	BIO AMERICAN	NEW DOSAGE FORM NEW STRENGTH NEW INDICATION	DENIED OCT 07, 1988

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-73	FOLLICULAR STIMULATION IN IN VITRO FERTILIZATION
I-73	STIMULATE THE DEVELOPMENT OF MULTIPLE FOLLICLES/OOCYTES IN OVULATORY PATIENTS PARTICIPATING IN AN IN VITRO FERTILIZATION PROGRAM
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
I-95	CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS OF THE CENTRAL NERVOUS SYSTEM IN CHILDREN (2 YEARS OF AGE AND OLDER)
I-96	TREATMENT OF ACUTE MYOCARDIAL INFARCTION

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
U-54	METHODS OF TREATING BACTERIAL ILLNESSES
U-55	METHOD OF TREATING GASTROINTESTINAL DISEASE
U-56	TREATMENT OF PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA
U-57	ANGINA MYOCARDIAL INFARCTION

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19937 002	ADENOSINE; ADENOCARD	4673563	JUN 16, 2004	U-56	NCE	OCT 30, 1994
	18240 001	ATENOLOL; TENORMIN	3663607	MAY 16, 1989		I-96	SEP 13, 1992
>ADD>			3934032	JAN 20, 1993	U-5		
>ADD>			3836671	SEP 17, 1991	U-56		
>ADD>			3836671	SEP 17, 1991	U-57		
>ADD>	18240 002	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
>ADD>			3836671	SEP 17, 1991	U-56		
>ADD>			3836671	SEP 17, 1991	U-57		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
						NDF	SEP 13, 1992
	19058 001	ATENOLOL; TENORMIN	4387089	JUN 07, 2002		NCE	SEP 30, 1993
	19459 001	AVOBENZONE; PHOTOPLEX	4775529	OCT 04, 2005		NP	AUG 01, 1991
	19716 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4252984	AUG 30, 1999		NCE	AUG 30, 1990
	19270 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC	4311708	JAN 19, 1999	U-5	NCE	AUG 30, 1990
>ADD>	19507 001	BETAXOLOL HYDROCHLORIDE; KERLONE	4252984	AUG 08, 1999		NDF	OCT 27, 1992
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>ADD>			4252984	AUG 08, 1999		NDF	OCT 27, 1992
	18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	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
>ADD>	19204 001	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
>DLT>	19204 001	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		NCE	DEC 28, 1993
>ADD>	19204 002	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
>DLT>	19204 002	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		NCE	DEC 28, 1993
>ADD>	19204 003	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
>DLT>	19204 003	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		NCE	DEC 28, 1993
	19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
	19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
	19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
>ADD>	17613 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
>ADD>	17619 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
>ADD>	18813 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
	19758 001	CLOZAPINE; CLOZARIL				NCE	SEP 26, 1994
	19758 002	CLOZAPINE; CLOZARIL				NCE	SEP 26, 1994
	71611 001	CYCLOBENZAPRINE HYDROCHLORIDE; CYCLOBENZAPRINE HCL				PC	NOV 15, 1989

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	19201 001	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
	19201 002	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
	19201 003	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
	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		
	18554 001	FLUTAMIDE; EULEXIN				NCE	DEC 31, 1991
			4474813	NOV 30, 1993		NCE	JAN 27, 1994
			4472382	SEP 18, 2001	U-42		
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4329364	MAY 11, 1999	U-41		
						I-88	APR 28, 1992
						I-95	AUG 10, 1992
	19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-53		
			4423050	OCT 19, 1999	U-52		
						ODE	JUN 23, 1996
			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
>ADD>	19687 001	GONADORELIN ACETATE; LUTREPULSE PUMP KIT				NE	OCT 10, 1992
>ADD>	19687 002	GONADORELIN ACETATE; LUTREPULSE PUMP KIT				NE	OCT 10, 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
	19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20/25	4472380	SEP 18, 2001			
			4374829	DEC 30, 2001		NCE	DEC 29, 1992
						NC	SEP 19, 1992
	19771 001	IBUPROFEN; COADVIL	4788220	NOV 29, 2005		NDF	SEP 19, 1992
	19833 002	IBUPROFEN; CHILDREN'S ADVIL				NDF	SEP 19, 1992
	19842 001	IBUPROFEN; PEDIA PROFEN					
>ADD>	19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
>DLT>	19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
>ADD>	19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
>DLT>	19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995

	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
						I-92	JUL 28, 1992
						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
						I-94	JUL 28, 1992
						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
	18956 006	IOHEXOL; OMNIPAQUE 210	4396597	JUL 14, 1998			
			4250113	DEC 26, 1999		I-93	JUL 28, 1992
			4021481	MAY 03, 1994		NS	JUN 30, 1992
						I-55	OCT 04, 1992
>ADD>	18735 003	IOPAMIDOL; ISOVUE-370	4396598	OCT 26, 2002	U-46	NCE	DEC 30, 1993
>ADD>	19710 001	IOVERSOL; OPTIRAY 320	4396598	AUG 02, 2000	U-46	NCE	DEC 30, 1993
>DLT>	19710 001	IOVERSOL; OPTIRAY 320	4396598	OCT 26, 2002	U-47		
>ADD>			4396598	AUG 02, 2000	U-47		
>DLT>							
>ADD>	19710 002	IOVERSOL; OPTIRAY 240	4396598	OCT 26, 2002	U-48	NCE	DEC 30, 1993
>DLT>	19710 002	IOVERSOL; OPTIRAY 240	4396598	AUG 02, 2000	U-48	NCE	DEC 30, 1993
>ADD>	19710 003	IOVERSOL; OPTIRAY 160	4396598	OCT 26, 2002	U-49	NCE	DEC 30, 1993
>DLT>	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
	19219 002	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN	3649691	MAR 14, 1991			
	19814 001	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN	3649691	MAR 14, 1991		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
	17646 001	MENOTROPINS; PERGONAL				I-73	AUG 23, 1992
	17646 002	MENOTROPINS; PERGONAL				I-73	AUG 23, 1992
>ADD>	19884 001	MESNA; MESNEX	4220660	DEC 02, 1999	U-38	ODE	DEC 30, 1995
>DLT>	19884 001	MESNA; MESNEX	4220660	SEP 02, 1997	U-38	ODE	DEC 30, 1995
>ADD>	18592 001	MICONAZOLE NITRATE; MONISTAT 5	3717655	FEB 20, 1990		NDF	OCT 27, 1992

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19268 001	MISOPROSTOL; CYTOTEC	3965143	JUN 22, 1995		NCE	DEC 27, 1993
>DLT>	19268 001	MISOPROSTOL; CYTOTEC	3965143	JUN 22, 1995		NCE	DEC 27, 1993
	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
>ADD>	19516 003	MORPHINE SULFATE; MS CONTIN				NDF	MAY 29, 1990
	19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
						I-87	APR 05, 1992
>ADD>	19488 001	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993
>DLT>	19488 001	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993
	19684 001	NIFEDIPINE; PROCARDIA XL				NDF	SEP 06, 1992
	19684 002	NIFEDIPINE; PROCARDIA XL				NDF	SEP 06, 1992
	19684 003	NIFEDIPINE; PROCARDIA XL				NDF	SEP 06, 1992
>ADD>	18869 001	NIMODIPINE; NIMOTOP	4406906	SEP 27, 2002	U-39		
>DLT>	18869 001	NIMODIPINE; NIMOTOP	4406906	SEP 27, 2002	U-39		
	19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
	19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
>ADD>	19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
>DLT>	19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
>ADD>	19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
>DLT>	19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
>ADD>	19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4786505	NOV 22, 2005	U-55	NCE	SEP 14, 1994
>DLT>	19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4255431	MAR 10, 1998			
	19810 001	OMEPRAZOLE; LOSEC				NDF	MAY 30, 1989
						ODE	JUN 15, 1996
	19407 001	OXYMETAZOLINE HYDROCHLORIDE; VISINE L.R.				NDF	JUN 15, 1992
	19887 001	PENTAMIDINE ISETHIONATE; NEBUPENT	4166182	AUG 28, 1998		NCE	DEC 30, 1993
			4166182	AUG 28, 1998		NCE	DEC 30, 1993
>ADD>	19385 001	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
>DLT>	19385 001	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
>ADD>	19385 002	PERGOLIDE MESYLATE; PERMAX	4024163	MAY 17, 1996		NCE	MAR 31, 1991
>DLT>	19385 002	PERGOLIDE MESYLATE; PERMAX				NDF	AUG 25, 1992
>ADD>	19385 003	PERGOLIDE MESYLATE; PERMAX	4271143	JUN 02, 1998			
>DLT>	19385 003	PERGOLIDE MESYLATE; PERMAX	4056635	NOV 01, 1994		NCE	OCT 02, 1994
	19855 001	PERMETHRIN; ELIMITE				NCE	JUN 05, 1994
						ODE	JUN 05, 1996
	18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS					
>ADD>	19627 001	PROPOFOL; DIPRIVAN					
	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL					

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19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				NR	MAY 10, 1992
19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				NR	MAY 10, 1992
18737 001	SULCONAZOLE NITRATE; SULCOSYN	4055652	OCT 25, 1996		NCE	AUG 30, 1990
					NDF	FEB 28, 1992
17970 001	TAMOXIFEN CITRATE; NOLVADEX				I-86	MAR 16, 1992
19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC	4789736	DEC 06, 2005		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			
		3752826	AUG 14, 1990			
17628 002	TOLMETIN SODIUM; TOLECTIN 600	RE30910	JAN 07, 1994	U-43		
19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		
19594 002	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		
19910 001	ZIDOVUDINE; RETROVIR				NCE	MAR 19, 1992

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