APPROVED DRUG PRODUCTS
With Therapeutic Equivalence Evaluations

The "Orange Book"

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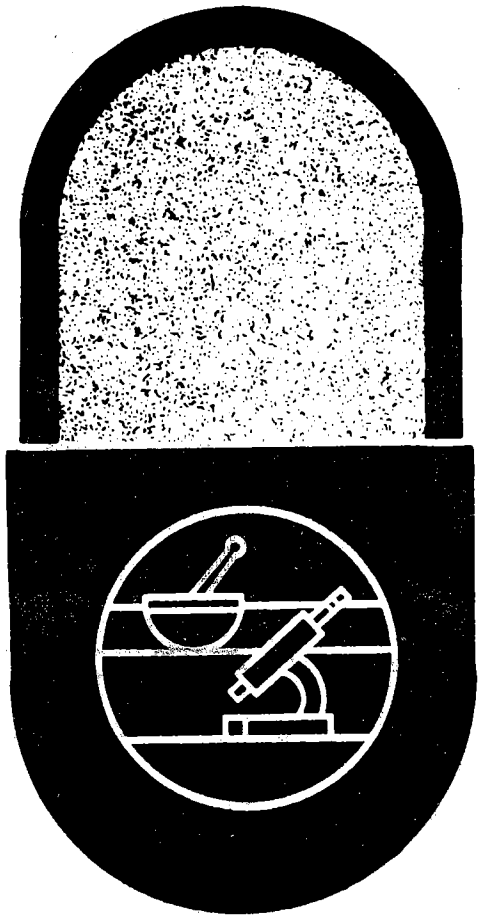
CUMULATIVE SUPPLEMENT 12

JAN'89-DEC'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

CUMULATIVE SUPPLEMENT 12

DECEMBER 1989

CONTENTS

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9th EDITION

CUMULATIVE SUPPLEMENT 12

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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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 Produ List, Drug Products in the Division of Blood and Blood Products Approv Under Section 505 of the Act List and the Patent and Exclusivity Data a indicated by the symbol >DLT< (DELETE) to the left of the l containing overstruck print. The >DLT< symbol is dropped in subsequ Cumulative Supplements for that item. The overstruck print will remain the Prescription Drug Product List and OTC Drug Product Lists in Cumulative Supplements for this edition. However, the overstruck print the Drug Products in the Division of Blood and Blood Products Appr Under Section 505 of the Act List and the Patent and Exclusivity Data be dropped in subsequent Cumulative Supplements.

Products discontinued from marketing or products which have had approval withdrawn for other than safety or effectiveness reasons, wi flagged in this Cumulative Supplement with the " ∂ " symbol to desi their non-marketed status. All products having a " ∂ " symbol in the Cumulative Supplement of the 9th Edition List will then be added t "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
NORBROOK AMERICA INC	AKORN INC	AKORN
3M RIKER	3M PHARMACEUTICALS	3M PHARMS

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
MCNEIL PHARMACEUTICAL DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON PHARM RESEARCH INST DIV MCNEILAB INC	RW JOHNSON
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 Index Listed by Applicant" were not printed within the List.

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

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

1.5 RESCISSION OF APPROVAL LETTERS

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

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

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1988) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product, provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1988	JUN 1989	SEP 1989	DEC 1989
DRUG PRODUCTS LISTED	10091	10137	10153	10123
SINGLE SOURCE	1983 (19.7%)	1982 (19.6%)	1978 (19.5%)	2030 (20.1%)
MULTISOURCE	8108 (80.3%)	8155 (80.4%)	8175 (80.5%)	8093 (79.9%)
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7341 (72.4%)	7350 (72.4%)	7222 (71.3%)
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	701 (6.9%)	709 (7.0%)	752 (7.4%)
EXCEPTIONS[1]	118 (1.1%)	113 (1.1%)	116 (1.1%)	119 (1.2%)
NEW MOLECULAR ENTITIES APPROVED	--	4	2	13
NUMBER OF APPLICANTS	374	394	397	400

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

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

> ADD >		**ACETAMINOPHEN, BUTALBITAL AND CAFFEINE**		
> ADD >	AB	GILBERT LABS	325MG;50MG;40MG	N88825 001
> ADD >				DEC 05, 1984
> DLT >		/ESGIC/		
> DLT >	/AB/	/GILBERT/LABS/	/325MG;50MG;40MG/	/N88825/001/
> DLT >				/DEC/05,/1984/

TABLET; ORAL

> ADD >		**ACETAMINOPHEN, BUTALBITAL AND CAFFEINE**		
> ADD >	AB	GILBERT LABS	325MG;50MG;40MG	N87629 001
> ADD >				NOV 13, 1984
> DLT >		/ESGIC/		
> DLT >	/AB/	/GILBERT/LABS/	/325MG;50MG;40MG/	/N87629/001/
> DLT >				/NOV/13,/1984/

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/
	ə DURAMED PHARMS	300MG;15MG	N88353 001 FEB 06, 1984
	ə	300MG;30MG	N88354 001 FEB 06, 1984
	ə	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/
	ə PBI	300MG;30MG	N87919 001 JUN 22, 1982
	ə	300MG;60MG	N87920 001 JUN 22, 1982

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE

/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/
	ə WHITE TN PAULSN	300MG;30MG	N84360 001
	ə	300MG;60MG	N85607 001

CODEINE PHOSPHATE AND ACETAMINOPHEN

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

PAPA-DEINE #3

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

PAPA-DEINE #4

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ALLAY

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

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	MIKART	500MG;5MG¤	N81067 001 NOV 30, 1989
AA		500MG;5MG¤	N81068 001 NOV 30, 1989
AA		500MG;5MG¤	N81069 001 NOV 30, 1989
AA		500MG;5MG¤	N81070 001 NOV 30, 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

ANEXSIA-D

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

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

	/@/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

ACYCLOVIR

> ADD >

> ADD > SUSPENSION; ORAL

> ADD > ZOVIRAX

> ADD > BURROUGHS WELLC 200MG/5ML¤ N19909 001 DEC 22, 1989

ADENOSINE

INJECTABLE; INJECTION

ADENOCARD

	MEDCO RES	3MG/ML¤	N19937 002 OCT 30, 1989

ALBUMIN, CHROMATED CR-51 SERUM

INJECTABLE; INJECTION

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

ALBUMIN, IODINATED I-125 SERUM

INJECTABLE; INJECTION

ALBUMOTOPE 125 I		
∂ ISO TEX DIAGS	5-50 UCI/AMP	N17836 001
/∂/SQUIBB/	/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
/∂/SQUIBB/	/5/UCI/AMP/	/N17837/004/
/∂/	/20/UCI/AMP/	/N17837/005/
	/0.5MCI/VIAL/	/N17837/001/
	/1MCI/VIAL/	/N17837/002/
/∂/	/2MCI/VIAL/	/N17837/003/

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	AM THERPTCS	EQ 2MG BASE¤		N72449 001
		DEC 05, 1989 : FEB 01, 1989		
AB		EQ 4MG BASE¤		N72450 001
		DEC 05, 1989 : FEB 01, 1989		
AB	BIOCRAFT LABS	EQ 2MG BASE¤		N72619 001
		DEC 05, 1989 : APR 07, 1989		
AB		EQ 4MG BASE¤		N72620 001
		DEC 05, 1989 : APR 07, 1989		
AB	CORD LABS	EQ 2MG BASE¤		N72151 001
		DEC 05, 1989 : MAR 23, 1989		
AB		EQ 4MG BASE¤		N72152 001
		DEC 05, 1989 : MAR 23, 1989		

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

AB	LEDERLE LABS	EQ 2MG BASE¤		N72859 001
				DEC 20, 1989
AB		EQ 4MG BASE¤		N72860 001
				DEC 20, 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	BOOTS USA	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 II 3.5%/IN PLASTIC CONTAINER/		
/ABBOTT LABS/	/3.5%/	/N19401/001/
		/OCT 16, 1986/

AMINO ACIDS

INJECTABLE; INJECTION
/AMINOSYN/II/3.5%/IN/PLASTIC/CONTAINER/

@ ABBOTT LABS	3.5%	N19491 001
		OCT 10, 1986

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION
/AMINOSYN/3.5%/W/DEXTROSE/25%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /3.5%;25GM/100ML/ /N19118/001/
/OCT/11,/1984/

@ ABBOTT LABS	3.5%;25GM/100ML	N19118 001
		OCT 11, 1984

/AMINOSYN/3.5%/W/DEXTROSE/5%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /3.5%;5GM/100ML/ /N19120/001/
/OCT/11,/1984/

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

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

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

@ 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/

@ CORD LABS	100MG	N85261 003

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

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

AMMONIUM LACTATE

LOTION; TOPICAL

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

AMOXAPINE

TABLET; ORAL

	AMOXAPINE		
AB	WATSON LABS	25MG¤	N72418 001 MAY 11, 1989
AB		50MG¤	N72419 001 MAY 11, 1989
AB		100MG¤	N72420 001 MAY 11, 1989
AB		150MG¤	N72421 001 MAY 11, 1989
	ASENDIN		
AB	LEDERLE LABS	25MG	N18021 001
AB		50MG	N18021 002
AB		100MG	N18021 003
AB		150MG	N18021 004

AMOXICILLIN

CAPSULE; ORAL

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

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

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

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

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

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

AMPICILLIN

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

/TABLET,/CHEWABLE;/ORAL/

/POLYCILLIN/

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

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL ASPIRIN AND CAFFEINE

>DLT >/AB/	/QUANTUM/PHARMCS/	/325MG;50MG;40MG/	/N88972/001/	/JUN/18,/1985/
>DLT >				
>ADD >	ə QUANTUM PHARMCS	325MG;50MG;40MG	N88972 001 JUN 18, 1985	
>ADD >				

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

NORGESIC

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

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

NORGESIC FORTE

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

ORPHENADRINE COMPOUND

/AB/	/VITARINE/	/385MG;30MG;25MG/	/N71564/001/	/JUN/23,/1988/
BX	VITARINE	385MG;30MG;25MG	N71564 001 JUN 23, 1988	

ORPHENADRINE COMPOUND DOUBLE STRENGTH

/AB/	/VITARINE/	/770MG;60MG;50MG/	/N71565/001/	/JUN/23,/1988/
BX	VITARINE	770MG;60MG;50MG	N71565 001 JUN 23, 1988	

ORPHENGESIC

/AB/	/PAR/PHARM/	/385MG;30MG;25MG/	/N71642/001/	/JUN/23,/1987/
BX	PAR PHARM	385MG;30MG;25MG	N71642 001 JUN 23, 1987	

ORPHENGESIC FORTE

/AB/	/PAR/PHARM/	/770MG;60MG;50MG/	/N71643/001/	/JUN/23,/1987/
BX	PAR PHARM	770MG;60MG;50MG	N71643 001 JUN 23, 1987	

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

ASPIRIN; MEPROBAMATE

TABLET; ORAL

> DLT >	/G-GESIC/			
> DLT > /AB/	/QUANTUM/PHARMCS/	/325MG;200MG/	/N88740/001/ /JUN/01,/1984/	
> DLT >				
> ADD >	@ QUANTUM PHARMCS	325MG;200MG	N88740 001	
> ADD >			JUN 01, 1984	

ATENOLOL

INJECTABLE; INJECTION

TENORMIN

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

TABLET; ORAL

TENORMIN

AB	ICI PHARM	50MG	N18240 001
AB		100MG	N18240 002
/AB/	/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/
	@ 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/	/N85876/001/
/AA/	/PBI/	/0.025MG;2.5MG/	/N87842/001/ /MAR/29,/1982/
	@ 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/
	@ 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

BACLOFEN

TABLET; ORAL

BACLOFEN

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

BENDROFLUMETHIAZIDE

TABLET; ORAL

/NATURETIN-2.5/

/SQUIBB/	/2.5MG/	/N12164/001/
@ SQUIBB	2.5MG	N12164 001

BENZONATATE

CAPSULE; ORAL

TESSALON

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

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

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

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

>DLT >/AA/	/QUANTUM/PHARMCS/	/0.5MG/	/N88514/001/ /JAN/31,/1984/
>DLT >			
>DLT >/AA/		/1MG/	/N88510/001/ /JAN/31,/1984/
>DLT >			
>DLT >/AA/		/2MG/	/N88511/001/ /JAN/31,/1984/
>DLT >			
>ADD >	∂ QUANTUM PHARMCS	0.5MG	N88514 001
>ADD >			JAN 31, 1984
>ADD >	∂	1MG	N88510 001
>ADD >			JAN 31, 1984
>ADD >	∂	2MG	N88511 001
>ADD >			JAN 31, 1984

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL
/DIPROLENE/

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

/DIPROLENE/AF/

/BX/	/SCHERING/	/EQ/0.05%/BASE/	/N19555/001/ /APR/27,/1987/

CREAM, AUGMENTED; TOPICAL
DIPROLENE
SCHERING EQ 0.05% BASE N19408 001
JAN 31, 1986

DIPROLENE AF
SCHERING EQ 0.05% BASE N19555 001
APR 27, 1987

LOTION; TOPICAL
/DIPROLENE/

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

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

OINTMENT; TOPICAL
/DIPROLENE/

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

BETAMETHASONE DIPROPIONATE

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

BETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETOPTIC S
ALCON LABS EQ 0.25% BASE‡ N19845 001
DEC 29, 1989

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

BETHANECHOL CHLORIDE

TABLET; ORAL
BETHANECHOL CHLORIDE

/AA/	/CHELSEA/LABS/	/5MG/	/N85841/001/
/AA/		/10MG/	/N85842/001/
/AA/		/25MG/	/N85839/001/
	∂ CHELSEA LABS	5MG	N85841 001
	∂	10MG	N85842 001
	∂	25MG	N85839 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE

	/LYPHOMED/	/100MG/ML/	/N71298/001/ /FEB/13,/1987/
	∂ LYPHOMED	100MG/ML	N71298 001
			FEB 13, 1987

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/
	ə ABBOTT LABS	200MG/100ML	N19005 002 APR 16, 1986
	ə	400MG/100ML	N19005 003 APR 16, 1986
	ə	800MG/100ML	N19005 001 APR 16, 1986
BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER			
AP	BAXTER	200MG/100ML*	N19837 002 APR 12, 1989
AP		400MG/100ML*	N19837 001 APR 12, 1989

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL

BROMPHENIRAMINE MALEATE			
/AA/	/BARRE/NATL/	/2MG/5ML/	/N86936/001/
	ə BARRE NATL	2MG/5ML	N86936 001
/AA/	/PBI/	/2MG/5ML/	/N87964/001/ /JAN 25, 1983/
	ə PBI	2MG/5ML	N87964 001 JAN 25, 1983

TABLET; ORAL

BROMPHENIRAMINE MALEATE			
/AA/	/CHELSEA/LABS/	/4MG/	/N85769/001/
	ə CHELSEA LABS	4MG	N85769 001
/AA/	/CORD/LABS/	/4MG/	/N83215/001/
	ə CORD LABS	4MG	N83215 001

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

DIPHETANE DC			
/AA/	/PBI/	/2MG/5ML;10MG/5ML;/ /12.5MG/5ML/	/N88964/001/ /FEB 21, 1985/

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

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

BUPROPION HYDROCHLORIDE

TABLET; ORAL

/TABLET;ORAL/			
WELLBUTRIN			
/ə/	/BURROUGHS WELLC/	/50MG/	/N18644/001/ /DEC 30, 1985/
/ə/		/75MG/	/N18644/002/ /DEC 30, 1985/
/ə/		/100MG/	/N18644/003/ /DEC 30, 1985/
	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/
	ə CHELSEA LABS	15MG	N85764 001
	ə	30MG	N85772 001

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

/AA/	/WHITE/IN/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; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION
ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER

/KENDALL/MCGAW/	/35MG/100ML;5GM/100ML;30MG/100ML;/ /74MG/100ML;640MG/100ML;500MG/100ML;/ /74MG/100ML/	/N18269/002/ /JAN/17,/1983/
KENDALL MCGAW	35MG/100ML;5GM/100ML;30MG/100ML; 74MG/100ML;640MG/100ML;500MG/100ML; 74MG/100ML	N18269 002 JAN 17, 1983

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/	/N19264/003/ /DEC/28,/1988/
	∂ ABBOTT LABS	10MG	N19204 003 DEC 28, 1988

CEFADROXIL

CAPSULE; ORAL

CEFADROXIL

AB	BIOCRAFT LABS	EQ 500MG BASE¤	N62695 001 FEB 10, 1989
AB	PUREPAC PHARM	EQ 500MG BASE¤	N63017 001 JAN 05, 1989

POWDER FOR RECONSTITUTION; ORAL

CEFADROXIL

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

ULTRACEF

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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

AP	LEMMON	EQ 250MG BASE/VIAL¤	N63016 001 MAR 14, 1989
AP		EQ 500MG BASE/VIAL¤	N63016 002 MAR 14, 1989
AP		EQ 1GM BASE/VIAL¤	N63016 003 MAR 14, 1989
> ADD > AP	MARSAM PHARMS	EQ 250MG BASE/VIAL¤	N62988 001 DEC 29, 1989
> ADD > AP		EQ 500MG BASE/VIAL¤	N62988 002 DEC 29, 1989
> ADD > AP		EQ 1GM BASE/VIAL¤	N62988 003 DEC 29, 1989
> ADD > AP		EQ 5GM BASE/VIAL¤	N62989 001 DEC 29, 1989
> ADD > AP		EQ 10GM BASE/VIAL¤	N62989 002 DEC 29, 1989
> ADD > AP		EQ 20GM BASE/VIAL¤	N62989 003 DEC 29, 1989
> ADD >	/TAG/PHARMS/	/EQ/250MG/BASE/VIAL¤/	/N63016/001/ /MAR/14,/1989/
		/EQ/500MG/BASE/VIAL¤/	/N63016/002/ /MAR/14,/1989/
		/EQ/1GM/BASE/VIAL¤/	/N63016/003/ /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

> ADD > CEFMETAZOLE SODIUM

> ADD > INJECTABLE; INJECTION

> ADD > ZEFAZONE

> ADD > UPJOHN	EQ 1GM BASE/VIAL¤	N50637 001 DEC 11, 1989
> ADD >	EQ 2GM BASE/VIAL¤	N50637 002 DEC 11, 1989

CEFPIRAMIDE SODIUM

INJECTABLE; INJECTION
CEFPIRAMIDE SODIUM

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

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
FORTAZ IN PLASTIC CONTAINER

GLAXO	EQ 10MG BASE/ML¤	N50634 001	APR 28, 1989
	EQ 20MG BASE/ML¤	N50634 002	APR 28, 1989
	EQ 40MG BASE/ML¤	N50634 003	APR 28, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION
ZINACEF IN PLASTIC CONTAINER

GLAXO	EQ 15MG BASE/ML¤	N50643 001	APR 28, 1989
	EQ 30MG BASE/ML¤	N50643 002	APR 28, 1989

CEPHALEXIN

CAPSULE; ORAL
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/	/IAS/PHARMS/	/EQ 250MG BASE/	/N62821/001/	/FEB/05,/1988/
/AB/		/EQ 500MG BASE/	/N62823/001/	/FEB/05,/1988/

CEPHALEXIN

CAPSULE; ORAL
CEPHALEXIN MONOHYDRATE

/AB/	/VITARINE/	/EQ 250MG BASE/	/N62159/001/	
/AB/		/EQ 500MG BASE/	/N62159/002/	
BX	VITARINE	EQ 250MG BASE	N62159 001	
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/	/IAS/PHARMS/	/EQ 125MG BASE/5ML/	/N62873/001/	/MAY/23,/1988/
/AB/		/EQ 250MG BASE/5ML/	/N62867/001/	/APR/15,/1988/
/AB/	/VITARINE/	/EQ 125MG BASE/5ML/	/N62779/001/	/DEC/22,/1987/
/AB/		/EQ 250MG BASE/5ML/	/N62781/001/	/DEC/22,/1987/
BX	VITARINE	EQ 125MG BASE/5ML	N62779 001	DEC 22, 1987
BX		EQ 250MG BASE/5ML	N62781 001	DEC 22, 1987

TABLET; ORAL
CEPHALEXIN

AB	BIOCRAFT LABS	EQ 250MG BASE¤	N63023 001	JAN 12, 1989
AB		EQ 500MG BASE¤	N63024 001	JAN 12, 1989
/AB/	/VITARINE/	/EQ 250MG BASE/	/N62863/001/	/AUG/11,/1988/
/AB/		/EQ 500MG BASE/	/N62863/002/	/AUG/11,/1988/
/AB/		/EQ 1GM BASE/	/N62863/003/	/AUG/11,/1988/
BX	VITARINE	EQ 250MG BASE	N62863 001	AUG 11, 1988
BX		EQ 500MG BASE	N62863 002	AUG 11, 1988
BX		EQ 1GM BASE	N62863 003	AUG 11, 1988

CEPHRADINE

CAPSULE; ORAL

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

CERULETIDE DIETHYLAMINE

/INJECTABLE;/INJECTION/

	/TYMTRAN/		
	/ADRIA/LABS/	/0.02MG/ML/	/N18296/001/
	a ADRIA LABS	0.02MG/ML	N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	/A-POXIDE/		
/AB/	/ABBOTT/LABS/	/5MG/	/N85447/001/
/AB/		/5MG/	/N85517/001/
/AB/		/10MG/	/N85447/002/
/AB/		/10MG/	/N85518/001/
/AB/		/25MG/	/N85447/003/
/AB/		/25MG/	/N85513/001/
	a ABBOTT LABS	5MG	N85447 001
	a	5MG	N85517 001
	a	10MG	N85447 002
	a	10MG	N85518 001
	a	25MG	N85447 003
	a	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/
	a LEDERLE LABS	5MG	N87234 001
	a	10MG	N87037 001
	a	25MG	N87231 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	CHLORDIAZEPOXIDE HCL		
/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/
	a LEMMON	5MG	N88705 001 JAN 18, 1985
	a	10MG	N88706 001 JAN 18, 1985
	a	25MG	N86494 001
	a	25MG	N88707 001 JAN 18, 1985
/AB/	/MK/LABS/	/5MG/	/N85116/001/
/AB/		/10MG/	/N85119/001/
/AB/		/25MG/	/N85120/001/
/AB/	/ROXANE/LABS/	/5MG/	/N84706/001/
/AB/		/10MG/	/N84700/001/
/AB/		/25MG/	/N84705/001/
	a ROXANE LABS	5MG	N84706 001
	a	10MG	N84700 001
	a	25MG	N84705 001
/AB/	/VANGARD/LABS/	/5MG/	/N88129/001/ /MAR/28,/1983/
/AB/		/10MG/	/N88010/001/ /MAR/28,/1983/
/AB/		/25MG/	/N88130/001/ /MAR/28,/1983/
	a VANGARD LABS	5MG	N88129 001 MAR 28, 1983
	a	10MG	N88010 001 MAR 28, 1983
	a	25MG	N88130 001 MAR 28, 1983

CHLOROQUINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/

/ARALEN/		
/a/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/
/AA/	/CHELSEA/LABS/	/4MG/	/N85139/001/
	ə CHELSEA LABS	4MG	N85139 001
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/
	ə LEDERLE LABS	4MG	N86941 001
	ə PHARMAFAIR	4MG	N83753 001
>_DLT_>/AA/	/QUANTUM/PHARMCS/	/4MG/	/N80938/001/
>_ADD_>	ə QUANTUM PHARMCS	4MG	N80938 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

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

/ə/BOOTS/PHARMS/	/10MG/	/N84414/001/
/ə/	/25MG/	/N84415/001/
/ə/	/50MG/	/N84411/001/
/ə/	/100MG/	/N84412/001/
/ə/	/200MG/	/N84413/001/

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL

CHLORPROMAZINE HCL

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

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

/AB/	/CHELSEA/LABS/	/250MG/	/N86866/001/
	ə 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/
	ə VANGARD LABS	25MG	N88012 001 JUL 14, 1982
	ə	50MG	N88073 001 MAR 25, 1983

CHLORTHALIDONE

TABLET; ORAL
CHLORTHALIDONE

AB	WARNER CHILCOTT	25MG	N87515 001 JAN 24, 1983
AB		50MG	N87516 001 FEB 09, 1983

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE

/AA/	/AM/THERPTCS/	/500MG¤/	/N89911/001/ ††	> ADD >
			/JUN/23,/1989/	> ADD >
/AA/	/CHELSEA/LABS/	/250MG/	/N86948/001/	> ADD >
			/AUG/09,/1982/	> ADD >
	ə CHELSEA LABS	250MG	N86948 001 AUG 09, 1982	
/AA/	/PAR/PHARM/	/500MG¤/	/N89898/001/ ††	
			/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	

CHOLESTYRAMINE

POWDER; ORAL
QUESTRAN

> DLT >	/BRISTOL/MYERS/	/EQ/4GM/RESIN/PACKET/	/N16019/001/	

CHYMOPAPAIN

INJECTABLE; INJECTION
CHYMODIACTIN

	/BAXTER/	/4,000/UNITS/VIAL/	/N18663/002/	> ADD >
			/AUG/21,/1984/	> ADD >
		/10,000/UNITS/VIAL/	/N18663/001/	> ADD >
			/NOV/10,/1982/	> ADD >
	BOOTS USA	4,000 UNITS/VIAL	N18663 002 AUG 21, 1984	
		10,000 UNITS/VIAL	N18663 001 NOV 10, 1982	

CHYMOPAPAIN

INJECTABLE; INJECTION
/DISEASE/

	/BOOTS/PHARMS/	/12,500/UNITS/VIAL/	/N18625/001/ /JAN/18,/1984/
	ə BOOTS USA	12,500 UNITS/VIAL	N18625 001 JAN 18, 1984

CLAVULANATE POTASSIUM; TICARCILLIN DISODIUM

INJECTABLE; INJECTION
TIMENTIN IN PLASTIC CONTAINER

	BEECHAM LABS	EQ 100MG ACID/100ML; EQ 3GM BASE/100ML¤	N50658 001 DEC 15, 1989

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

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION
CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	UPJOHN	EQ 6MG BASE/ML	N50639 001 AUG 30, 1989
AP		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
> ADD > AP	KENDALL MCGAW	EQ 150MG BASE/ML¤	N63041 001 DEC 29, 1989

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

AP	LEDERLE PARNTLS	EQ 150MG BASE/ML	N63068 001	AUG 28, 1989
> ADD >	**CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%**			
> ADD > AP	LYPHOMED	EQ 900MG BASE/100ML	N50635 001	DEC 22, 1989
> ADD > AP		EQ 12MG BASE/ML	N50636 001	DEC 22, 1989
> ADD >	**CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER**			
> ADD > AP	BAXTER	EQ 6MG BASE/ML	N50648 001	DEC 29, 1989
> ADD > AP		EQ 900MG BASE/100ML	N50648 003	DEC 29, 1989
> ADD > AP		EQ 12MG BASE/ML	N50648 002	DEC 29, 1989

LOTION; TOPICAL

CLEOCIN T

UPJOHN	EQ 1% BASE	N50600 001	MAY 31, 1989

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

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

> ADD > CLOMIPRAMINE HYDROCHLORIDE

> ADD > CAPSULE; ORAL

ANAFRANIL

CIBA PHARM	25MG	N19906 001	DEC 29, 1989
	50MG	N19906 002	DEC 29, 1989
	75MG	N19906 003	DEC 29, 1989

CLONIDINE

> DLT > /FILM;/EXTENDED/RELEASE;/PERCUTANEOUS/

/CATAPRES-TTS-1/

/BOEHR/INGEL/	/0.1MG/24HR/	/N18891/001/	/OCT/10,/1984/

/CATAPRES-TTS-2/

/BOEHR/INGEL/	/0.2MG/24HR/	/N18891/002/	/OCT/10,/1984/

> DLT > /FILM;/EXTENDED/RELEASE;/PERCUTANEOUS/

/CATAPRES-TTS-3/

/BOEHR/INGEL/	/0.3MG/24HR/	/N18891/003/	/OCT/10,/1984/

> ADD > FILM, EXTENDED RELEASE; TRANSDERMAL

CATAPRES-TTS-1

BOEHR INGEL	0.1MG/24HR	N18891 001 OCT 10, 1984

CATAPRES-TTS-2

BOEHR INGEL	0.2MG/24HR	N18891 002 OCT 10, 1984

CATAPRES-TTS-3

BOEHR INGEL	0.3MG/24HR	N18891 003 OCT 10, 1984

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

> DLT > /AB/ /AM/THERPTCS/ /0.1MG/ /N70881/001/ /MAY/27,/1986/

> DLT > /AB/ /0.2MG/ /N70882/001/ /MAY/27,/1986/

> DLT > /AB/ /0.3MG/ /N70883/001/ /MAY/27,/1986/

> ADD > BX	AM THERPTCS	0.1MG	N70881 001	MAY 27, 1986
> ADD > BX		0.2MG	N70882 001	MAY 27, 1986
> ADD > BX		0.3MG	N70883 001	MAY 27, 1986

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/

a	CHELSEA LABS	3.75MG	N71878 001 MAR 15, 1988
a		7.5MG	N71879 001 MAR 15, 1988
a		15MG	N71860 001 MAR 15, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

>DLT >/BX/	/QUANTUM/PHARMCS/	/3.75MG/	/N71549/001/	/SEP/12,/1988/	
>DLT >					
>DLT >/BX/		/7.5MG/	/N71550/001/	/SEP/12,/1988/	
>DLT >					
>DLT >/BX/		/15MG/	/N71522/001/	/SEP/12,/1988/	
>DLT >					
>ADD >	a QUANTUM PHARMCS	3.75MG	N71549 001	SEP 12, 1988	
>ADD >					
>ADD >	a	7.5MG	N71550 001	SEP 12, 1988	
>ADD >					
>ADD >	a	15MG	N71522 001	SEP 12, 1988	
>ADD >					

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/	
	a LEDERLE LABS	3.75MG	N72013 001	DEC 15, 1987	
	a	7.5MG	N72014 001	DEC 15, 1987	
	a	15MG	N72015 001	DEC 15, 1987	
>DLT >/BX/	/QUANTUM/PHARMCS/	/3.75MG/	/N71730/001/	/OCT/26,/1987/	
>DLT >					
>DLT >/BX/		/7.5MG/	/N71731/001/	/OCT/26,/1987/	
>DLT >					
>DLT >/BX/		/15MG/	/N71702/001/	/OCT/26,/1987/	
>DLT >					
>ADD >	a QUANTUM PHARMCS	3.75MG	N71730 001	OCT 26, 1987	
>ADD >					
>ADD >	a	7.5MG	N71731 001	OCT 26, 1987	
>ADD >					
>ADD >	a	15MG	N71702 001	OCT 26, 1987	
>ADD >					

CLOXACILLIN SODIUM

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

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

>DLT > /BP/	/QUANTUM/PHARMCS/	/25MG/	/N80836/001/	
>ADD >	a QUANTUM PHARMCS	25MG	N80836 001	
/BP/	/WHITE/TN/PAULSN/	/25MG/	/N80341/001/	
	a WHITE TN PAULSN	25MG	N80341 001	

CROMOLYN SODIUM

CAPSULE; ORAL
GASTROCROM

FISONS	100MG	N19188 001	DEC 22, 1989

CRYPTENAMINE ACETATES

/INJECTABLE;/INJECTION/
/UNITENSEN/

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

CYANOCOBALAMIN

INJECTABLE; INJECTION
/REDISOL/

/AP/	/MS&D/	/1MG/ML/	/N06668/010/
	a MS&D	1MG/ML	N06668 010

CYANOCOBALAMIN

INJECTABLE; INJECTION

/AP/	/VI-TWEL/ /BERLEX/LABS/	/1MG/ML/	/N07012/002/	
	ə BERLEX LABS	1MG/ML	N07012 002	

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

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

CYSTEINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/

	/CYSTEINE/HCL/ /KABIVITRUM/	/7.25%/	/N19523/001/ /OCT/22,/1986/	
	ə KABIVITRUM	7.25%	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/	/75MG/5ML/	/N50257/001/	
	ə LEDERLE LABS	75MG/5ML	N50257 001	

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL

	DESIPRAMINE HCL			
/AB/	/VITARINE/	/10MG/	/N72167/001/ /FEB/03,/1988/	
/AB/		/25MG/	/N71601/001/ /JUN/05,/1987/	
/AB/		/50MG/	/N71588/001/ /JUN/05,/1987/	
/AB/		/75MG/	/N71602/001/ /OCT/05,/1987/	
/AB/		/100MG/	/N71766/001/ /OCT/05,/1987/	
/AB/		/150MG/	/N72254/001/ /FEB/03,/1988/	
BX	VITARINE	10MG	N72167 001 FEB 03, 1988	
BX		25MG	N71601 001 JUN 05, 1987	
BX		50MG	N71588 001 JUN 05, 1987	
BX		75MG	N71602 001 OCT 05, 1987	
BX		100MG	N71766 001 OCT 05, 1987	
BX		150MG	N72254 001 FEB 03, 1988	

DESOXYCORTICOSTERONE ACETATE

/INJECTABLE;/INJECTION/

	/DOCA/ /ORGANON/	/5MG/ML/	/N01104/001/	
	ə 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/	
	ə CHELSEA LABS	0.75MG	N85818 001	
	ə	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
/ø/		/0.25MG/	/N85455/001/
/ø/		/0.5MG/	/N85458/001/
/ø/		/0.75MG/	/N80968/001/
/ø/		/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

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHENERGAN W/ DEXTROMETHORPHAN

> ADD >				
> ADD >	AA	WYETH AYERST LABS	15MG/5ML;6.25MG/5ML¤	N11265 002
> ADD >				APR 02, 1984

DEXTROSE

INJECTABLE; INJECTION
DEXTROSE 50% IN PLASTIC CONTAINER

> ADD >	AP	ABBOTT LABS	50GM/100ML¤	N19894 001
> ADD >				DEC 26, 1989

DEXTROSE 70% IN PLASTIC CONTAINER

> ADD >	AP	ABBOTT LABS	70GM/100ML¤	N19893 001
> ADD >				DEC 26, 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

DEXTROSE; POTASSIUM CHLORIDE

INJECTABLE; INJECTION
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

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; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

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

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

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

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

/AP/ /BAXTER/ /5GM/100ML;75MG/100ML;/ /N18008/002/
/450MG/100ML/

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

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

> ADD > DEZOCINE

> ADD > INJECTABLE; INJECTION
> ADD > DALGAN

> ADD >	WYETH AYERST LABS	5MG/ML¤	N19082 001 DEC 29, 1989
> ADD >		10MG/ML¤	N19082 002 DEC 29, 1989
> ADD >		15MG/ML¤	N19082 003 DEC 29, 1989

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

	/CARDIOGRAFIN/		
	/SQUIBB/	/85%/	/N11620/002/
	@ SQUIBB	85%	N11620 002

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

	HYPAQUE-M		
	/STERLING/DRUG/	/60%;30%/	/N10220/002/
	@ STERLING DRUG	60%;30%	N10220 002
	MD-76		
AP	MALLINCKRODT	66%;10%¤	N19292 001 SEP 29, 1989

DIAZEPAM

TABLET; ORAL

	DIAZEPAM			
/AB/	/MARTEC/PHARM/	/10MG¤/		/N72402/001/ /APR 25, 1989/
	@ MARTEC PHARM	10MG¤		N72402 001 APR 25, 1989

DIAZEPAM

TABLET; ORAL

DIAZEPAM

/AB/	/SUPERPHARM/	/2MG/	/N70642/001/ /DEC/11,/1985/
/AB/		/5MG/	/N70643/001/ /DEC/11,/1985/
/AB/		/10MG/	/N70644/001/ /DEC/11,/1985/
BX	SUPERPHARM	2MG	N70642 001 DEC 11, 1985
BX		5MG	N70643 001 DEC 11, 1985
BX		10MG	N70644 001 DEC 11, 1985

Q-PAM

>DLT >/BX/	/QUANTUM/PHARMCS/	/2MG/	/N70423/001/ /DEC/12,/1985/
>DLT >/BX/		/2MG/	/N72431/001/ /APR/29,/1988/
>DLT >/BX/		/5MG/	/N70424/001/ /DEC/12,/1985/
>DLT >/BX/		/5MG/	/N72432/001/ /APR/29,/1988/
>DLT >/BX/		/10MG/	/N70425/001/ /DEC/12,/1985/
>DLT >/BX/		/10MG/	/N72433/001/ /APR/29,/1988/
>ADD >	ə QUANTUM PHARMCS	2MG	N70423 001 DEC 12, 1985
>ADD >	ə	2MG	N72431 001 APR 29, 1988
>ADD >	ə	5MG	N70424 001 DEC 12, 1985
>ADD >	ə	5MG	N72432 001 APR 29, 1988
>ADD >	ə	10MG	N70425 001 DEC 12, 1985
>ADD >	ə	10MG	N72433 001 APR 29, 1988

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

VOLTAREN

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

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/

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HCL

AB	PIONEER PHARMS	10MG	N89361 001 JAN 10, 1989

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL

HETRAZAN

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

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

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

DIETHYLSTILBESTROL

SUPPOSITORY; VAGINAL

>DLT >	/DIETHYLSTILBESTROL/		
>DLT >/AT/	/LILLY/	/0.1MG/	/N04040/001/
>DLT >/AT/		/0.5MG/	/N04040/002/
>ADD >	DIETHYLSTILBESTROL		
>ADD >	ə LILLY	0.1MG	N04040 001
>ADD >	ə	0.5MG	N04040 002
	STILBESTROL		
>DLT >/AT/	/SQUIBB/	/0.1MG/	/N04056/001/
>DLT >/AT/		/0.5MG/	/N04056/002/
>ADD >	SQUIBB	0.1MG	N04056 001
>ADD >		0.5MG	N04056 002

DIETHYLSTILBESTROL

TABLET; ORAL
DIETHYLSTILBESTROL

> DLT >	/BP/	/LILLY/	/0.1MG/	/N04041/002/
> DLT >	/BP/		/0.5MG/	/N04041/003/
> ADD >	BP	LILLY	5MG	N04041 005
> ADD >		ə	0.1MG	N04041 002
> ADD >		ə	0.5MG	N04041 003

TABLET, DELAYED RELEASE; ORAL
DIETHYLSTILBESTROL

> DLT >	/BE/	/LILLY/	/0.5MG/	/N04039/003/
> ADD >		ə LILLY	0.5MG	N04039 003

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CARDIZEM SR

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

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

	/AA/	/CHELSEA/LABS/	/25MG/	/N85138/001/
	ə CHELSEA LABS		25MG	N85138 001
> DLT >	/AA/	/QUANTUM/PHARMCS/	/25MG/	/N85701/001/
> DLT >	/AA/		/50MG/	/N85701/002/
> ADD >	ə QUANTUM PHARMCS		25MG	N85701 001
> ADD >	ə		50MG	N85701 002
	/AA/	/VANGARD/LABS/	/25MG/	/N88034/001/ /OCT/27,/1982/
	/AA/		/50MG/	/N87630/001/
	ə VANGARD LABS		25MG	N88034 001 OCT 27, 1982
	ə		50MG	N87630 001
	/AA/	/WHITE/TN/PAULSN/	/50MG/	/N80800/001/
	ə WHITE TN PAULSN		50MG	N80800 001

ELIXIR; ORAL
/DIPHEN/

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

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL
DIPHENHYDRAMINE HCL

	AA	CENCI LABS	12.5MG/5ML	N87941 001 DEC 17, 1982
	/AA/	/LEDERLE/LABS/	/12.5MG/5ML/	/N86937/001/
	ə 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/
	ə 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
AP	WARNER CHILCOTT	40MG/ML	N18138 001
AP		40MG/ML	N70558 001 SEP 20, 1985
ə		80MG/ML	N70559 001 SEP 20, 1985

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

	/DOPASTAT/			
/AP/	/PARKE/DAVIS/	/40MG/ML/	/N18138/001/	
/AP/		/40MG/ML/	/N70558/001/ /SEP/20,/1985/	
/AP/		/80MG/ML/	/N70559/001/ /SEP/20,/1985/	

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

>DLT >/BX/	/QUANTUM/PHARMCS/	/EQ 10MG BASE/	/N70972/001/ /SEP/29,/1987/	
>DLT >/BX/		/EQ 25MG BASE/	/N70973/001/ /SEP/29,/1987/	
>DLT >/BX/		/EQ 50MG BASE/	/N70931/001/ /SEP/29,/1987/	
>DLT >/BX/		/EQ 75MG BASE/	/N70932/001/ /SEP/29,/1987/	
>DLT >/BX/		/EQ 100MG BASE¤/	/N72375/001/ /MAR/15,/1989/	
>DLT >/BX/		/EQ 150MG BASE¤/	/N72376/001/ /MAR/15,/1989/	
>ADD >	ə QUANTUM PHARMCS	EQ 10MG BASE	N70972 001 SEP 29, 1987	
>ADD >	ə	EQ 25MG BASE	N70973 001 SEP 29, 1987	
>ADD >	ə	EQ 50MG BASE	N70931 001 SEP 29, 1987	
>ADD >	ə	EQ 75MG BASE	N70932 001 SEP 29, 1987	
>ADD >	ə	EQ 100MG BASE¤	N72375 001 MAR 15, 1989	
>ADD >	ə	EQ 150MG BASE¤	N72376 001 MAR 15, 1989	

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN RDF

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

DOXORUBICIN HCL

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

RUBEX

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

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE MONOHYDRATE

>ADD >	MEDICOPHARMA	EQ 100MG BASE¤	N50641 001 DEC 29, 1989

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

/AB/	/VITARINE/	/EQ 50MG BASE/	/N62780/001/ /APR/12,/1988/
/AB/		/EQ 100MG BASE/	/N62227/001/
BX	VITARINE	EQ 50MG BASE	N62780 001 APR 12, 1988
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/ /MAR/31,/1983/
ə CHELSEA LABS	EQ 50MG BASE	N62392 001 MAR 31, 1983

DOXYLAMINE SUCCINATE

TABLET; ORAL
DOXYLAMINE SUCCINATE

> DLT > /AA/	/COPLEY/PHARM/	/25MG/	/N88900/001/ /OCT/08,/1985/
> DLT >			
> ADD >	COPLEY PHARM	25MG	N88900 001 OCT 08, 1985
> ADD >			
> DLT > /AA/	/QUANTUM/PHARMCS/	/25MG/	/N88603/001/ /AUG/07,/1984/
> DLT >			
> ADD >	ə QUANTUM PHARMCS	25MG	N88603 001 AUG 07, 1984
> ADD >			

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

/AA/	/CHASE/CHEM/	/50,000 IU/	/N80747/001/
	ə CHASE CHEM	50,000 IU	N80747 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

/AA/	/LEDERLE/LABS/	/0.5MG/	/N86984/001/
/AA/		/1MG/	/N86985/001/
	ə LEDERLE LABS	0.5MG	N86984 001
	ə	1MG	N86985 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL
ERGOLOID MESYLATES

/AA/	/VANGARD/LABS/	/0.5MG/	/N88013/001/ /SEP/20,/1982/
/AA/		/1MG/	/N88014/001/ /SEP/20,/1982/
	ə VANGARD LABS	0.5MG	N88013 001 SEP 20, 1982
	ə	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/16,/1988/
	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

ESTRADIOL

>DLT> /FILM;/EXTENDED/RELEASE;/PERCUTANEOUS/
>DLT> /ESTRADERM/
>DLT> /CIBA/PHARM/ /0.05MG/24HR/ /N19081/002/
>DLT> /SEP/10,/1986/
>DLT> /0.1MG/24HR/ /N19081/003/
>DLT> /SEP/10,/1986/

>ADD> FILM, EXTENDED RELEASE; TRANSDERMAL
>ADD> ESTRADERM
>ADD> CIBA PHARM 0.05MG/24HR N19081 002
>ADD> SEP 10, 1986
>ADD> 0.1MG/24HR N19081 003
>ADD> SEP 10, 1986

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
/DELANDRONE DB/
/AO/ /SQUIBB/ /5MG/ML;180MG/ML/ /N09545/002/
@ SQUIBB 5MG/ML;180MG/ML N09545 002

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS
BP CHELSEA LABS 0.625MG N85800 001
BP 1.25MG N85801 001
BP 2.5MG N85826 001
/BS/ /0.625MG/ /N85800/001/
/BS/ /1.25MG/ /N85801/001/
/BS/ /2.5MG/ /N85826/001/
BP DURAMED PHARMS 0.3MG N86492 001
BP 0.625MG N83272 001
BP 1.25MG N83294 001
BP 2.5MG N83295 001
/BS/ /0.3MG/ /N86492/001/
/BS/ /0.625MG/ /N83272/001/
/BS/ /1.25MG/ /N83294/001/
/BS/ /2.5MG/ /N83295/001/
BP ZENITH LABS 0.3MG N88569 001
NOV 29, 1984
BP 0.625MG N83373 001
BP 1.25MG N83601 001
BP 2.5MG N83602 001
/BS/ /0.3MG/ /N88569/001/
/NOV/29,/1984/
/BS/ /0.625MG/ /N83373/001/
/BS/ /1.25MG/ /N83601/001/
/BS/ /2.5MG/ /N83602/001/

ESTROGENS, CONJUGATED

TABLET; ORAL
PREMARIN
BP WYETH AYERST LABS 0.3MG N04782 003
BP 0.625MG N04782 004
BP 1.25MG N04782 001
BP 2.5MG N04782 002
/BS/ /0.3MG/ /N04782/003/
/BS/ /0.625MG/ /N04782/004/
/BS/ /0.9MG/ /N04782/005/
/JAN/26,/1984/
/BS/ /1.25MG/ /N04782/001/
/BS/ /2.5MG/ /N04782/002/
SQUIBB 0.9MG N04782 005
JAN 26, 1984

ESTROGENS, ESTERIFIED

TABLET; ORAL
FEMOGEN
/BS/ /PRIVATE/FMLTNS/ /2.5MG/ /N85007/001/
@ PRIVATE FMLTNS 2.5MG N85007 001

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
NORCEPT-E 1/35 21
AB GYNOPHARMA 0.035MG;1MG N71545 001
FEB 09, 1989

TABLET; ORAL-28
NORCEPT-E 1/35 28
AB GYNOPHARMA 0.035MG;1MG N71546 001
FEB 09, 1989

>ADD> ETHINYL ESTRADIOL; NORGESTIMATE

>ADD> TABLET; ORAL-21
>ADD> ORTHO CYCLEN-21
>ADD> RW JOHNSON 0.035MG;0.25MG N19653 001
>ADD> DEC 29, 1989

>ADD> TABLET; ORAL-28
>ADD> ORTHO CYCLEN-28
>ADD> RW JOHNSON 0.035MG;0.25MG N19653 002
>ADD> DEC 29, 1989

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM

> DLT >	/BX/	/QUANTUM/PHARMCS/	/EQ/200MG/BASE/	/N72214/001/ /APR/14,/1988/
> DLT >				
> DLT >	/BX/		/EQ/300MG/BASE/	/N71738/001/ /APR/14,/1988/
> DLT >				
> ADD >		@ QUANTUM PHARMCS	EQ 200MG BASE	N72214 001 APR 14, 1988
> ADD >				
> ADD >		@	EQ 300MG BASE	N71738 001 APR 14, 1988
> ADD >				

TABLET; ORAL
FENOPROFEN CALCIUM

> DLT >	/AB/	/QUANTUM/PHARMCS/	/EQ 600MG BASE/	/N72194/001/ /APR/14,/1988/
> DLT >				
> ADD >		@ QUANTUM PHARMCS	EQ 600MG BASE	N72194 001 APR 14, 1988
> ADD >				

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
	VASODERM E		
AB	TICAN PHARM	0.05%¤	N72494 001 JAN 19, 1989
/AB/	/TJ/ROACO/	/0.05%¤/	/N72464/001/ /JAN/13

FLUOCINONIDE

GEL; TOPICAL
FLUOCINOHIDE

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

SOLUTION; TOPICAL
FLUOCINOHIDE

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/
BP	ICN PHARMS	10MG	N87196 001
	FLUOXYMESTERONE		
/BP/	/BROWN/PHARM/	/10MG/	/N88221/001/ /MAY/05,/1983/
BP	ICN PHARMS	10MG	N88221 001 MAY 05, 1983

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

AB	CHELSEA LABS	15MG¤	N72368 001 MAR 30, 1989
AB		30MG¤	N72369 001 MAR 30, 1989

FLUTAMIDE

> ADD >
> ADD >
> ADD >
> ADD >

CAPSULE; ORAL
EULEXIN

SCHERING	125MG¤	N18554 001 JAN 27, 1989

FOLIC ACID

TABLET; ORAL
FOLIC ACID

	/BOOTS/PHARMS/	/1MG/	/N84158/001/
	@ BOOTS USA	1MG	N84158 001
/AA/	/CHELSEA/LABS/	/1MG/	/N85141/002/
	@ CHELSEA LABS	1MG	N85141 002
/AA/	/PBI/	/1MG/	/N87828/001/ /MAY/13,/1982/
	@ PBI	1MG	N87828 001 MAY 13, 1982
/AA/	/VANGARD/LABS/	/1MG/	/N88730/001/ /MAR/23,/1984/
	@ VANGARD LABS	1MG	N88730 001 MAR 23, 1984
/AA/	/WHITE/TN/PAULSN/	/1MG/	/N80691/002/
	@ WHITE TN PAULSN	1MG	N80691 002

GANCICLOVIR SODIUM

INJECTABLE; INJECTION
CYTOVENE

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

GEMFIBROZIL

> ADD >
> ADD >
> ADD >
> ADD >

CAPSULE; ORAL
LOPID

/PARKE/DAVIS/	/200MG/	/N18422/001/
@ PARKE DAVIS	200MG	N18422 001

GEMFIBROZIL

TABLET; ORAL
LOPID

PARKE DAVIS	600MG	N18422 003 NOV 20, 1986

GENTAMICIN SULFATE; PREDNISOLONE ACETATE

> ADD >
> ADD >
> ADD >
> ADD >

OINTMENT; OPHTHALMIC
PRED-G

ALLERGAN PHARMS	EQ 0.3% BASE;0.6%¤	N50612 001 DEC 01, 1989

GLYCOPYRROLATE

TABLET; ORAL
GLYCOPYRROLATE

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

GONADORELIN ACETATE

INJECTABLE; INJECTION
LUTREPULSE PUMP KIT

RW JOHNSON	0.8MG/VIAL¤	N19687 001 OCT 10, 1989
	3.2MG/VIAL¤	N19687 002 OCT 10, 1989

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION
CHORIONIC GONADOTROPIN

/STERIS/LABS/	/2,000/UNITS/VIAL/	/N17016/009/ /DEC/27,/1984/
@ STERIS LABS	2,000 UNITS/VIAL	N17016 009 DEC 27, 1984

> ADD > GOSERELIN ACETATE

> ADD >
> ADD >
> ADD >
> ADD >

IMPLANT; IMPLANTATION
ZOLADEX

IMPERIAL CHEM	EQ 3.6MG BASE¤	N19726 001 DEC 29, 1989

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
>DLT >/AB/	/QUANTUM/PHARMCS/	/0.5MG/	/N71255/001/ /FEB/17,/1987/
>DLT >			
>DLT >/AB/		/1MG/	/N71269/001/ /FEB/17,/1987/
>DLT >			
>DLT >/AB/		/2MG/	/N71256/001/ /FEB/17,/1987/
>DLT >			
>DLT >/AB/		/5MG/	/N71257/001/ /FEB/17,/1987/
>DLT >			
>ADD >	ə QUANTUM PHARMCS	0.5MG	N71255 001 FEB 17, 1987
>ADD >			
>ADD >	ə	1MG	N71269 001 FEB 17, 1987
>ADD >			
>ADD >	ə	2MG	N71256 001 FEB 17, 1987
>ADD >			
>ADD >	ə	5MG	N71257 001 FEB 17, 1987
>ADD >			

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

/HALDOL/DECANOATE/ /MCNEIL/PHARM/ /EQ/50MG/BASE/ML/ /N18701/001/ /JAN/14,/1986/

HALDOL DECANOATE 50		
RW JOHNSON	EQ 50MG BASE/ML	N18701 001 JAN 14, 1986

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

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

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER

AP	BAXTER	4,000 UNITS/100ML	N18814 001 OCT 31, 1983

HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	ABBOTT LABS	4,000 UNITS/100ML¤	N19805 001 JAN 25, 1989

HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

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

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

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

/BAXTER/	/500/UNITS/100ML/	/N18609/003/ /APR/28,/1982/
ə 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/
ə KENDALL MCGAW	1,000 UNITS/100ML	N19042 004 MAR 29, 1985

HEXOCYCLIUM METHYLSULFATE

/TABLET;/ORAL/ /TRAL/

/ABBOTT/LABS/	/25MG/	/N10599/001/
ə 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
/AA/	/PBI/	/25MG/	/N87780/001/ /MAR/29,/1982/
/AA/		/50MG/	/N87751/001/ /MAR/29,/1982/
	a PBI	25MG	N87780 001 MAR 29, 1982
	a	50MG	N87751 001 MAR 29, 1982
>_DLT_>/AA/	/QUANTUM/PHARMCS/	/10MG/	/N88671/001/ /MAY/01,/1984/
>_DLT_>			
>_DLT_>/AA/		/25MG/	/N88657/001/ /JUN/15,/1984/
>_DLT_>			
>_DLT_>/AA/		/50MG/	/N88652/001/ /MAY/08,/1984/
>_DLT_>			
>_DLT_>/AA/		/100MG/	/N88686/001/ /MAY/01,/1984/
>_DLT_>			
>_ADD_>	a QUANTUM PHARMCS	10MG	N88671 001 MAY 01, 1984
>_ADD_>			
>_ADD_>	a	25MG	N88657 001 JUN 15, 1984
>_ADD_>			
>_ADD_>	a	50MG	N88652 001 MAY 08, 1984
>_ADD_>			
>_ADD_>	a	100MG	N88686 001 MAY 01, 1984
>_ADD_>			
/AA/	/VANGARD/LABS/	/50MG/	/N87908/001/ /MAY/07,/1982/
	a VANGARD LABS	50MG	N87908 001 MAY 07, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

/HYDRALAZINE;/HYDROCHLOROTHIAZIDE/W//RESERPINE/

/BP/	/CHELSEA/LABS/	/25MG;15MG;0.1MG/	/N85771/001/
	a CHELSEA LABS	25MG;15MG;0.1MG	N85771 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/BOOTS/LABS/	/25MG/	/N84325/001/
/AB/		/50MG/	/N84324/001/
/AB/	/CHELSEA/LABS/	/25MG/	/N85232/002/
/AB/		/50MG/	/N85233/001/
/AB/		/50MG/	/N86087/001/
/AB/		/50MG/	/N86594/001/
/AB/		/100MG/	/N87002/001/
	a CHELSEA LABS	25MG	N85232 002
	a	50MG	N85233 001
	a	50MG	N86087 001
	a	50MG	N86594 001
	a	100MG	N87002 001
/AB/	/PBI/	/25MG/	/N87827/001/ /APR/19,/1982/
/AB/		/50MG/	/N87752/001/ /APR/19,/1982/
	a PBI	25MG	N87827 001 APR 19, 1982
	a	50MG	N87752 001 APR 19, 1982
AB	PHARMAFAIR	25MG	N84325 001
AB		50MG	N84324 001
>_DLT_>/AB/	/QUANTUM/PHARMCS/	/50MG/	/N85152/002/
>_ADD_>	a QUANTUM PHARMCS	50MG	N85152 002
/AB/	/VANGARD/LABS/	/25MG/	/N87638/001/
/AB/		/50MG/	/N87610/001/
	a VANGARD LABS	25MG	N87638 001
	a	50MG	N87610 001
/AB/	/WHITE/TN/PAULSN/	/25MG/	/N83809/002/
/AB/		/50MG/	/N83809/001/
/AB/		/100MG/	/N85347/001/
	a WHITE TN PAULSN	25MG	N83809 002
	a	50MG	N83809 001
	a	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

/H.R.-50/

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

HYDROCHLOROTHIAZIDE W/ RESERPINE

/ə/	/BOOTS/PHARMS/	/50MG;0.125MG/	/N85426/001/
/BP/	/CHELSEA/LABS/	/25MG;0.125MG/	/N86330/002/
/BP/		/50MG;0.125MG/	/N86331/001/
	ə CHELSEA LABS	25MG;0.125MG	N86330 002
	ə	50MG;0.125MG	N86331 001
	ə PHARMAFAIR	50MG;0.125MG	N85420 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

/AB/	/CHELSEA/LABS/	/25MG;25MG/	/N86026/001/
	ə CHELSEA LABS	25MG;25MG	N86026 001
/AB/	/PBI/	/25MG;25MG/	/N87651/001/
	ə PBI	25MG;25MG	N87651 001
/AB/	/VANGARD/LABS/	/25MG;25MG/	/N87655/001/
	ə VANGARD LABS	25MG;25MG	N87655 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

/AB/	/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

	/AB/	/PAR/PHARM/	/50MG;75MG/	/N72337/001/ /MAY/11,/1988/
	BX	PAR PHARM	50MG;75MG	N72337 001 MAY 11, 1988
>DLT>	/BX/	/QUANTUM/PHARMCS/	/50MG;75MG/	/N71980/001/ /FEB/01,/1988/
>DLT>				
>ADD>		ə QUANTUM PHARMCS	50MG;75MG	N71980 001 FEB 01, 1988
>ADD>				
	/AB/	/VITARINE/	/50MG;75MG/	/N71360/001/ /DEC/08,/1987/
	BX	VITARINE	50MG;75MG	N71360 001 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

>DLT>	/BP/	/QUANTUM/PHARMCS/	/20MG/	/N80624/001/
>ADD>		ə QUANTUM PHARMCS	20MG	N80624 001
	/BP/	/WHITE/TN/PAULSN/	/10MG/	/N80344/001/
	/BP/		/20MG/	/N80344/002/
		ə WHITE TN PAULSN	10MG	N80344 001
		ə	20MG	N80344 002

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

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

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

/AEROSOL;/RECTAL/
/PROCTOFOAM/HC/
/REED/&/CARNRICK/ /1%;1%/ /N86195/001/

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

PROCTOFOAM HC

BX	REED & CARNRICK	1%;1%	N86195 001

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

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

HYDROFLUMETHIAZIDE

TABLET; ORAL
HYDROFLUMETHIAZIDE

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

HYDROXOCOBALAMIN

INJECTABLE; INJECTION
HYDROXOCOBALAMIN

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

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL

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

TABLET; ORAL
HYDROXYZINE HCL

>DLT >/AB/ >DLT >	/QUANTUM/PHARMCS/	/10MG/	/N88540/001/ /OCT/22,/1985/
>DLT >/AB/ >DLT >		/25MG/	/N88551/001/ /OCT/22,/1985/
>DLT >/AB/ >DLT >		/50MG/	/N88529/001/ /OCT/22,/1985/
>ADD > >ADD >	∂ QUANTUM PHARMCS	10MG	N88540 001 OCT 22, 1985
>ADD > >ADD >	∂	25MG	N88551 001 OCT 22, 1985
>ADD > >ADD >	∂	50MG	N88529 001 OCT 22, 1985

HYDROXYZINE PAMOATE

CAPSULE; ORAL
HYDROXYZINE PAMOATE

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

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S ADVIL

/AB/	/WHITEHALL/LABS/	/100MG/5ML¤/	/N19833/002/ /SEP/19,/1989/
BX	WHITEHALL LABS	100MG/5ML¤	N19833 002 SEP 19, 1989

IBUPROFEN

SUSPENSION; ORAL

PEDIA PROFEN

/AB/	/MCNEIL/CONSUMER/	/100MG/5ML¤/	/N19842/001/ /SEP/19,/1989/
BX	MCNEIL CONSUMER	100MG/5ML¤	N19842 001 SEP 19, 1989

TABLET; ORAL

IBUPROFEN

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

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

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

>_ADD_> ## INDECAINIDE HYDROCHLORIDE

>_ADD_> TABLET, EXTENDED RELEASE; ORAL

>_ADD_> **DECABID**

>_ADD_>	ELI LILLY	EQ 50MG BASE¤
>_ADD_>		N19693 001 DEC 29, 1989
>_ADD_>		EQ 75MG BASE¤
>_ADD_>		N19693 002 DEC 29, 1989
>_ADD_>		EQ 100MG BASE¤
>_ADD_>		N19693 003 DEC 29, 1989

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

/AB/	/VITARINE/	/25MG/	/N71711/001/ /JUL/05,/1988/
/AB/		/50MG/	/N71712/001/ /JUL/05,/1988/
BX	VITARINE	25MG	N71711 001 JUL 05, 1988
BX		50MG	N71712 001 JUL 05, 1988

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

	INDOMETHACIN		
AB	INWOOD LABS	75MG¤	N72410 001 MAR 15, 1989
/AB/	/VITARINE/	/75MG/	/N71531/001/ /JUL/21,/1987/
BX	VITARINE	75MG	N71531 001 JUL 21, 1987

IOHEXOL

INJECTABLE; INJECTION

OMNIPAQUE 210		
STERLING DRUG	45.3%¤	N18956 006 JUN 30, 1989
/INJECTABLE;/INJECTION/ /OMNIPAQUE/240/		
/STERLING/DRUG/	/51.8%/	/N18956/002/ /DEC/26,/1985/
/OMNIPAQUE/300/		
/STERLING/DRUG/	/64.7%/	/N18956/003/ /DEC/26,/1985/
/OMNIPAQUE/350/		
/STERLING/DRUG/	/75.5%/	/N18956/004/ /DEC/26,/1985/

SOLUTION; INJECTION, ORAL

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

> ADD > IOTROLAN

> ADD > INJECTABLE; INTRATHECAL

> ADD > OSMOVIST		
> ADD > BERLEX LABS	EQ 190MG IODINE/ML¤	N19580 001 DEC 07, 1989
> ADD >	EQ 240MG IODINE/ML¤	N19580 002 DEC 07, 1989

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

	ISOETHARINE HCL		
/AN/	/BAXTER/	/0.08%/	/N88144/001/ /JUL/29,/1983/
/AN/		/0.25%/	/N88146/001/ /AUG/01,/1983/
	ə BAXTER	0.08%	N88144 001 JUL 29, 1983
		/0.14%/	/N88145/001/ /MAR/26,/1984/
	ə	0.14%	N88145 001 MAR 26, 1984
	ə	0.25%	N88146 001 AUG 01, 1983

ISONIAZID

TABLET; ORAL

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

KANAMYCIN SULFATE

INJECTABLE; INJECTION

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

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

TORADOL		
SYNTEX LABS	15MG/ML¤	N19698 001 NOV 30, 1989
	30MG/ML¤	N19698 002 NOV 30, 1989

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/
@ 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 7.5MG/VIAL¤ N19732 001 JAN 26, 1989
/TAP/PHARMS/ /7.5MG/VIAL/ /N19732/001/

LEVOBUNOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
BETAGAN
ALLERGAN PHARMS 0.25%¤ N19814 001 JUN 28, 1989

/LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM/

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

/LEVOTHYROXINE SODIUM; LIOTHYRONINE SODIUM/

/TABLET;ORAL/
/EUTHROID-1/
/PARKE/DAVIS/ /0.06MG;0.015MG/ /N16680/002/
/EUTHROID-2/
/PARKE/DAVIS/ /0.12MG;0.03MG/ /N16680/003/
/EUTHROID-3/
/PARKE/DAVIS/ /0.18MG;0.045MG/ /N16680/004/
/THYROLAR-5/
/@/ARMOUR/PHARM/ /0.25MG;0.0625MG/ /N16807/006/

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
/AP/ /INTL/MEDTN/SYS/ /4%/ /N17702/002/
@ 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
/LIDOCAINE HCL W/ DEXTROSE/
/AP/ /ABBOTT/LABS/ /5%/ /N83914/001/

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

LIOTRIX (T4;T3)

TABLET; ORAL

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

LISINOPRIL

TABLET; ORAL

PRINIVIL

AB	MS&D RES LABS	40MG	N19558 004 OCT 25, 1988

ZESTRIL

AB	IMPERIAL CHEM	40MG	N19777 004 MAY 19, 1988

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

AB	PBI	300MG¤	N72542 001 FEB 01, 1989

LORAZEPAM

TABLET; ORAL

/LORAZ/

>DLT> /AB/	/QUANTUM/PHARMCS/	/0.5MG/	/N70200/001/ /AUG/09,/1985/
>DLT> /AB/		/1MG/	/N70201/001/ /AUG/09,/1985/
>DLT> /AB/		/2MG/	/N70202/001/ /AUG/09,/1985/
>ADD>	∂ QUANTUM PHARMCS	0.5MG	N70200 001 AUG 09, 1985
>ADD>	∂	1MG	N70201 001 AUG 09, 1985
>ADD>	∂	2MG	N70202 001 AUG 09, 1985

LORAZEPAM

TABLET; ORAL

LORAZEPAM

>DLT> /AB/	/AM/THERPTCS/	/0.5MG/		/N70727/001/ /MAR/07,/1986/
>DLT> /AB/		/1MG/		/N70728/001/ /MAR/07,/1986/
>DLT> /AB/		/2MG/		/N70729/001/ /MAR/07,/1986/
>ADD> BX	AM THERPTCS	0.5MG	N70727 001	MAR 07, 1986
>ADD> BX		1MG	N70728 001	MAR 07, 1986
>ADD> BX		2MG	N70729 001	MAR 07, 1986

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/
/ə/PURDUE/FREDRK/ /0.5%/ /N18613/001/
/AUG/02,/1982/

MANNITOL

SOLUTION; IRRIGATION
/RESECTISOL/
/KENDALL/MCGAW/ /5GM/100ML/ /N16704/002/
ə 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
AA CORD LABS 12.5MG¤ N84843 002
MAY 22, 1989
AA 25MG¤ N84092 003
MAY 22, 1989
/AA/ /VANGARD/LABS/ /12.5MG/ /N87877/001/
/APR/20,/1982/
/AA/ /25MG/ /N87620/001/
/JAN/04,/1982/
ə VANGARD LABS 12.5MG N87877 001
APR 20, 1982
ə 25MG N87620 001
JAN 04, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLODIUM
>DLT >/BX/ /QUANTUM/PHARMCS/ /EQ/50MG/BASE/ /N71380/001/
>DLT > /JUL/14,/1987/
>DLT >/BX/ /EQ/100MG/BASE/ /N71381/001/
>DLT > /JUL/14,/1987/
>ADD > ə QUANTUM PHARMCS EQ 50MG BASE N71380 001
>ADD > JUL 14, 1987
>ADD > ə EQ 100MG BASE N71381 001
>ADD > JUL 14, 1987

MECLOFENAMATE SODIUM
AB BARR LABS EQ 50MG BASE¤ N72848 001
MAR 20, 1989
AB EQ 100MG BASE¤ N72809 001
MAR 20, 1989
/AB/ /VITARINE/ /EQ 50MG BASE/ /N71710/001/
/JUN/15,/1988/
/AB/ /EQ 100MG BASE/ /N71684/001/
/JUN/15,/1988/
BX VITARINE EQ 50MG BASE N71710 001
JUN 15, 1988
BX EQ 100MG BASE N71684 001
JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL
MEFENAMIC ACID
/AB/ /VITARINE/ /250MG/ /N72179/001/
/APR/21,/1988/
BX VITARINE 250MG N72179 001
APR 21, 1988

MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL
LARIAM
ROCHE 250MG¤ N19591 001
MAY 02, 1989
MEFLOQUINE HCL
ə 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

	/∂/BOOTS/PHARMS/	/400MG/	/N84153/001/
/AA/	/CHELSEA/LABS/	/600MG/	/N85719/001/
	∂ CHELSEA LABS	600MG	N85719 001
/AA/	/LEDERLE/LABS/	/400MG/	/N86299/001/
	∂ LEDERLE LABS	400MG	N86299 001
	∂ PHARMAFAIR	400MG	N84153 001
>DLT>/AA/	/QUANTUM/PHARMCS/	/200MG/	/N15426/002/
>DLT>/AA/		/400MG/	/N15426/001/
>ADD>	∂ QUANTUM PHARMCS	200MG	N15426 002
>ADD>	∂	400MG	N15426 001
/AA/	/VANGARD/LABS/	/400MG/	/N88011/001/ /JUL/14,/1982/
	∂ VANGARD LABS	400MG	N88011 001 JUL 14, 1982
/AA/	/WHITE/TN/PAULSN/	/200MG/	/N83830/001/
/AA/		/400MG/	/N83442/001/
	∂ WHITE TN PAULSN	200MG	N83830 001
	∂	400MG	N83442 001

MESNA

INJECTABLE; INJECTION
MESNEX

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

MESNA

INJECTABLE; INJECTION
MESNEX

	/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

/∂/DORSEY/LABS/	/1MG/	/N13420/001/
∂ SANDOZ PHARMS	1MG	N13420 001

METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL

/∂/BOOTS/PHARMS/	/500MG/	/N84231/002/
/∂/	/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/	
	ə LYPHOMED	EQ 20MG BASE/VIAL	N88935 001 OCT 11, 1985	
	ə	EQ 50MG BASE/VIAL	N88936 001 OCT 11, 1985	
	ə	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¤	N89887 001 APR 14, 1989	

METHYCLOTHIAZIDE

TABLET; ORAL

	METHYCLOTHIAZIDE			
/AB/	/CHELSEA/LABS/	/2.5MG/	/N88750/001/ /SEP/06,/1984/	
	ə 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; NEOMYCIN SULFATE

>DLT>	/OINTMENT;/OPHTHALMIC/			
>DLT>	/NEO-MEDROL/			
>DLT>	/UPJOHN/	/0.1%;EQ 3.5MG BASE/GM/		/N60645/001/
>ADD>	ə UPJOHN	0.1%;EQ 3.5MG BASE/GM		N60645 001

METHYLPREDNISOLONE ACETATE

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

METHYLTESTOSTERONE

TABLET; BUCCAL

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

TABLET; ORAL

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

>ADD> METIPRANOLOL HYDROCHLOIDE

>ADD> SOLUTION/DROPS; OPHTHALMIC

>ADD>	METIPRANOLOL HCL			
>ADD>	BAUSCH & LOMB	0.3%¤		N19907 001 DEC 29, 1989
>ADD>				

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
/CLOPRA/

/AB/	/QUANTUM/PHARMCS/	/EQ 5MG BASE/	/N72384/001/ /JUN/02,/1988/
/AB/		/EQ 10MG BASE/	/N70294/001/ /JUL/29,/1985/
> ADD >	∂ QUANTUM PHARMCS	EQ 5MG BASE	N72384 001 JUN 02, 1988
> ADD >	∂	EQ 10MG BASE	N70294 001 JUL 29, 1985

/CLOPRA-YELLOW/

/AB/	/QUANTUM/PHARMCS/	/EQ 10MG BASE/	/N70632/001/ /OCT/28,/1985/
> ADD >	∂ QUANTUM PHARMCS	EQ 10MG BASE	N70632 001 OCT 28, 1985

METOCLOPRAMIDE HCL

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

> ADD > METOPROLOL FUMARATE

> ADD > TABLET, EXTENDED RELEASE; ORAL
> ADD > LOPRESSOR

GEIGY PHARMS	EQ 100MG TARTRATE¤	N19786 001 DEC 27, 1989
	EQ 200MG TARTRATE¤	N19786 002 DEC 27, 1989
	EQ 300MG TARTRATE¤	N19786 003 DEC 27, 1989
	EQ 400MG TARTRATE¤	N19786 004 DEC 27, 1989

METOPROLOL TARTRATE

TABLET; ORAL
LOPRESSOR

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

METRIZAMIDE

INJECTABLE; INJECTION
AMIPAQUE

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

MICONAZOLE NITRATE

TAMPON; VAGINAL
MONISTAT 5

RW JOHNSON	100MG¤	N18592 001 OCT 27, 1989

MINOXIDIL

TABLET; ORAL
MINODYL

/BX/	/QUANTUM/PHARMCS/	/2.5MG/	/N72153/001/ /JUL/13,/1988/
/BX/		/10MG/	/N71534/001/ /MAR/19,/1987/
> ADD >	∂ QUANTUM PHARMCS	2.5MG	N72153 001 JUL 13, 1988
> ADD >	∂	10MG	N71534 001 MAR 19, 1987

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
NALLPEN IN PLASTIC CONTAINER
BAXTER EQ 20MG BASE/ML¤ N50655 001 OCT 31, 1989
EQ 40MG BASE/ML¤ N50655 002 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
/AP/	/INTL/MEDTN/SYS/	/0.4MG/ML/	/N70417/001/ /NOV/06,/1985/
/AP/		/1MG/ML/	/N72115/001/ /APR/27,/1988/
> DLT >			
> ADD >	a INTL MEDTN SYS	0.4MG/ML	N70417 001 NOV 06, 1985
> ADD >	a	1MG/ML	N72115 001 APR 27, 1988

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
MURO'S OPCON

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

OPCON

AT	BAUSCH & LOMB	0.1%	N87506 001

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

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

NIACIN

TABLET; ORAL

NIACIN

/AA/	/CHELSEA/LABS/	/500MG/	/N85172/001/		
	@ CHELSEA LABS	500MG	N85172 001		

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE

AB	CHASE LABS	10MG¤	N72409 001		
			JUL 04, 1990 : 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	> ADD >	
AB		20MG	N18482 002	> ADD >	
			JUL 24, 1986	> ADD >	
/AB/	/PFIZER/LABS/	/10MG/	/N18482/001/	> ADD >	
/AB/		/20MG/	/N18482/002/	> ADD >	
			/JUL/24,/1986/	> ADD >	

TABLET, EXTENDED RELEASE; ORAL

PROCARDIA XL

	PFIZER	30MG¤	N19684 001	> ADD >	
			SEP 06, 1989	> ADD >	
		60MG¤	N19684 002	> ADD >	
			SEP 06, 1989	> ADD >	
		90MG¤	N19684 003	> ADD >	
			SEP 06, 1989	> ADD >	

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN

/AB/	/CHELSEA/LABS/	/50MG/	/N85797/001/	> DLT >	/AB/	/QUANTUM/PHARMCS/	/50MG/	/N80003/001/
/AB/		/100MG/	/N85796/001/	> DLT >	/AB/		/100MG/	/N80003/002/
	@ CHELSEA LABS	50MG	N85797 001	> ADD >		@ QUANTUM PHARMCS	50MG	N80003 001
	@	100MG	N85796 001	> ADD >		@	100MG	N80003 002

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN MACROCRYSTALLINE

				> DLT >	/BX/	/BOLAR/PHARM/	/50MG/	/N70248/001/
				> DLT >				/JUN/24,/1988/
				> DLT >	/BX/		/100MG/	/N70249/001/
				> DLT >				/JUN/24,/1988/
				> ADD >		@ BOLAR PHARM	50MG	N70248 001
				> ADD >				JUN 24, 1988
				> ADD >		@	100MG	N70249 001
				> ADD >				JUN 24, 1988

NITROGLYCERIN

INJECTABLE; INJECTION

				> ADD >	NITROGLYCERIN 100MG IN DEXTROSE 5%
				> ADD >	BAXTER 40MG/100ML¤ N19970 003
				> ADD >	DEC 29, 1989
				> ADD >	NITROGLYCERIN 25MG IN DEXTROSE 5%
				> ADD >	BAXTER 10MG/100ML¤ N19970 001
				> ADD >	DEC 29, 1989
				> ADD >	NITROGLYCERIN 50MG IN DEXTROSE 5%
				> ADD >	BAXTER 20MG/100ML¤ N19970 002
				> ADD >	DEC 29, 1989

/OINTMENT;TOPICAL/

/NITROGLYCERIN/

/ALTANA/	/2%/	/N87355/001/
		/JUL/08,/1988/

OINTMENT; TRANSDERMAL

NITROGLYCERIN

ALTANA	2%	N87355 001
		JUL 08, 1988

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

NYSTATIN

POWDER; ORAL
BARSTATIN 100

AA	BARLAN PHARMA	100%	N62489 001 APR 27, 1988

TABLET; ORAL
NYSTATIN

> DLT >	/AA/	/QUANTUM/PHARMCS/	/500,000 UNITS/	/N62525/001/ /OCT/29,/1984/
> DLT >				
> ADD >		ə QUANTUM PHARMCS	500,000 UNITS	N62525 001 OCT 29, 1984
> ADD >				

TABLET; VAGINAL
NYSTATIN

	/AT/	/CHELSEA/LABS/	/100,000 UNITS/	/N62176/001/
		ə CHELSEA LABS	100,000 UNITS	N62176 001
> DLT >	/AT/	/QUANTUM/PHARMCS/	/100,000 UNITS/	/N62509/001/ /APR/03,/1984/
> DLT >				
> ADD >		ə QUANTUM PHARMCS	100,000 UNITS	N62509 001 APR 03, 1984
> ADD >				

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¤	N50640 001 OCT 26, 1989
		EQ 40MG BASE/ML¤	N50640 002 OCT 26, 1989

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

OXAZEPAM

CAPSULE; ORAL
ZAXOPAM

> DLT >	/BX/	/QUANTUM/PHARMCS/	/10MG/	/N70650/001/ /MAR/01,/1988/
> DLT >				
> DLT >	/BX/		/15MG/	/N70640/001/ /MAR/01,/1988/
> DLT >				
> DLT >	/BX/		/30MG/	/N70641/001/ /MAR/01,/1988/
> DLT >				
> ADD >		ə QUANTUM PHARMCS	10MG	N70650 001 MAR 01, 1988
> ADD >				
> ADD >		ə	15MG	N70640 001 MAR 01, 1988
> ADD >				
> ADD >		ə	30MG	N70641 001 MAR 01, 1988
> ADD >				

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE

	AB	BOLAR PHARM	5MG¤	N72485 001 APR 19, 1989
> DLT >	/AB/	/QUANTUM/PHARMCS/	/5MG/	/N72296/001/ /DEC/08,/1988/
> DLT >				
> ADD >		ə QUANTUM PHARMCS	5MG	N72296 001 DEC 08, 1988
> ADD >				

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

INJECTABLE; INJECTION

/OXYTOCIN/20/USP/UNITS/IN/DEXTROSE/5%/		
/ABBOTT/LABS/	/2/USP/UNITS/100ML/	/N19185/002/
		/MAR/29,/1985/
@ ABBOTT LABS	2 USP UNITS/100ML	N19185 002
		MAR 29, 1985
/OXYTOCIN/5/USP/UNITS/IN/DEXTROSE/5%/		
/ABBOTT/LABS/	/1/USP/UNIT/100ML/	/N19185/001/
		/MAR/29,/1985/
@ 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/
@ 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/
@ 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/IN/PAULSN/	/100MG/	/N83338/001/
	@ WHITE TN PAULSN	100MG	N83338 001

SODIUM PENTOBARBITAL

>DLT >/AA/	/QUANTUM/PHARMCS/	/100MG/	/N83368/001/
>ADD >	@ QUANTUM PHARMCS	100MG	N83368 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

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
PHENDIMETRAZINE TARTRATE

AA	PRIVATE FMLTNS	35MG		N85199 001
ə	PRIVATE FMLTNS	35MG		N85199 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL

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

TABLET; ORAL
PHENTERMINE HCL

AA	CHELSEA LABS	8MG		N85739 001
ə	CHELSEA LABS	8MG		N85739 001

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL
IONAMIN-30

DLT	AB	PENNWALT	EQ 30MG BASE	N11613 002
ADD		PENNWALT PHARM	EQ 30MG BASE	N11613 002
DLT		PHENTERMINE RESIN 30		
DLT	AB	QUANTUM PHARMCS	EQ 30MG BASE	N89120 001
DLT				
ADD		ə QUANTUM PHARMCS	EQ 30MG BASE	N89120 001
ADD				FEB 04, 1988

PHENYL AMINOSALICYLATE

POWDER; ORAL
PHENY-PAS-TEBAMIN

PURDUE FRDRK	50%		N11695 002
ə PURDUE FRDRK	50%		N11695 002

TABLET; ORAL
PHENY-PAS-TEBAMIN

PURDUE FRDRK	500MG		N11695 003
ə PURDUE FRDRK	500MG		N11695 003

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL
PHENERGAN VC

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

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
PREFRIN-A

ALLERGAN PHARMS	0.12%;0.1%		N07953 001

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
PHENYTOIN SODIUM

ə PHARMAFAIR	100MG		N85435 001

PINACIDIL

CAPSULE, EXTENDED RELEASE; ORAL
PINDAC

ELI LILLY	12.5MG*		N19456 001 DEC 28, 1989
	25MG*		N19456 002 DEC 28, 1989

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

/REED/&/CARNRICK/ /120GM/PACKET;1.49GM/PACKET;/ /3.36GM/PACKET;2.92GM/PACKET;/ /11.36GM/PACKET/ /N18983/005/ /OCT/26,/1984/

@ REED & CARNRICK 120GM/PACKET;1.49GM/PACKET; 3.36GM/PACKET;2.92GM/PACKET; 11.36GM/PACKET N18983 005 OCT 26, 1984

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

/REED/&/CARNRICK/ /360GM/PACKET;4.47GM/PACKET;/ /10.08GM/PACKET;8.76GM/PACKET;/ /34.08GM/PACKET/ /N18983/006/ /OCT/26,/1984/

@ REED & CARNRICK 360GM/PACKET;4.47GM/PACKET; 10.08GM/PACKET;8.76GM/PACKET; 34.08GM/PACKET N18983 006 OCT 26, 1984

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

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

/AP/ /LYPHOMED/ /2MEQ/ML/ /N86713/001/

/AP/ /2MEQ/ML/ /N86714/001/

@ LYPHOMED 2MEQ/ML N86713 001

@ 2MEQ/ML N86714 001

>ADD> POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER

>ADD> BAXTER 14.9MG/ML¤ N19904 001 DEC 26, 1989

>ADD> POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER

>ADD> BAXTER 29.8MG/ML¤ N19904 002 DEC 26, 1989

>ADD> POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER

>ADD> BAXTER 2.24GM/100ML¤ N19904 003 DEC 26, 1989

>ADD> POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER

>ADD> BAXTER 2.98GM/100ML¤ N19904 004 DEC 26, 1989

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 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

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

/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

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

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

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

PRALIDOXIME CHLORIDE

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

∂ WYETH AYERST LABS — 500MG — N14122 002

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

AB	AM THERPTCS	EQ 1MG BASE¤	N72782 001
		MAY 16, 1989 : APR 11, 1989	
AB		EQ 2MG BASE¤	N72783 001
		MAY 16, 1989 : APR 11, 1989	
AB		EQ 5MG BASE¤	N72784 001
		MAY 16, 1989 : APR 11, 1989	

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL

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	
AB	MYLAN PHARMS	EQ 1MG BASE¤	N72573 001
		MAY 16, 1989 : FEB 28, 1989	
AB		EQ 2MG BASE¤	N72574 001
		MAY 16, 1989 : FEB 28, 1989	
AB		EQ 5MG BASE¤	N72575 001
		MAY 16, 1989 : FEB 28, 1989	
AB	PUREPAC PHARM	EQ 1MG BASE¤	N72991 001
		MAY 16, 1989 : APR 26, 1989	
AB		EQ 2MG BASE¤	N72921 001
		MAY 16, 1989 : APR 26, 1989	
AB		EQ 5MG BASE¤	N72992 001
		MAY 16, 1989 : APR 26, 1989	
/AB/	/ZENITH LABS/	/EQ 1MG BASE/	/N71994/001/ /SEP/12,/1988/
AB	ZENITH LABS	EQ 1MG BASE	N71994 001
		MAY 16, 1989 : SEP 12, 1988	
/AB/		/EQ 2MG BASE/	/N71995/001/ /SEP/12,/1988/
AB		EQ 2MG BASE	N71995 001
		MAY 16, 1989 : SEP 12, 1988	
/AB/		/EQ 5MG BASE/	/N71745/001/ /SEP/12,/1988/
AB		EQ 5MG BASE	N71745 001
		MAY 16, 1989 : SEP 12, 1988	

PREDNISOLONE

SYRUP; ORAL
PRELONE
MURO PHARM 5MG/5ML¤ N89654 001
JAN 17, 1989

TABLET; ORAL
PREDNISOLONE
/BX/ /CHELSEA/LABS/ /5MG/ /N85415/001/
/BX/ /5MG/ /N85416/001/
∂ CHELSEA LABS 5MG N85415 001
∂ 5MG N85416 001
> DLT > /BX/ /QUANTUM/PHARMCS/ /5MG/ /N80625/001/
> ADD > ∂ QUANTUM PHARMCS 5MG N80625 001
/BX/ /WHITE/TN/PAULSN/ /5MG/ /N80342/001/
∂ WHITE TN PAULSN 5MG N80342 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

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

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
/PREDNISOLONE SODIUM PHOSPHATE/
/∂/MAURRY/BIOL/ /EQ/0.9%/PHOSPHATE/ /N83358/002/
PREDNISOLONE SODIUM PHOSPHATE
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/

PREDNISONE

TABLET; ORAL
DELTASONE
AB UPJOHN 50MG N09986 008
/BX/ /50MG/ /N09986/008/

PREDNISONE
> DLT >/AB/ /AM/THERPTCS/ /5MG/ /N89387/001/
> DLT > /NOV/06,/1986/
> DLT >/AB/ /10MG/ /N89388/001/
> DLT > /NOV/06,/1986/
> DLT >/AB/ /20MG/ /N89389/001/
> DLT > /NOV/06,/1986/
> ADD > BX AM THERPTCS 5MG N89387 001
> ADD > NOV 06, 1986
> ADD > BX 10MG N89388 001
> ADD > NOV 06, 1986
> ADD > BX 20MG N89389 001
> ADD > NOV 06, 1986
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/
> DLT > /BX/ /QUANTUM/PHARMCS/ /5MG/ /N80491/001/
> DLT > /BX/ /20MG/ /N85811/001/
> ADD > ∂ QUANTUM PHARMCS 5MG N80491 001
> ADD > ∂ 20MG N85811 001
/ROXANE/LABS/ /25MG/ /N87833/001/
/MAY/04,/1982/
∂ ROXANE LABS 25MG N87833 001
MAY 04, 1982
/BX/ /VANGARD/LABS/ /5MG/ /N87682/001/
/JAN/15,/1982/
/BX/ /20MG/ /N87701/001/
/JAN/15,/1982/
∂ VANGARD LABS 5MG N87682 001
JAN 15, 1982
∂ 20MG N87701 001
JAN 15, 1982
/AB/ /WHITE/TN/PAULSN/ /10MG/ /N89028/001/
/JUL/24,/1986/
/BX/ /2.5MG/ /N84913/001/
/BX/ /5MG/ /N80343/001/
/BX/ /20MG/ /N84913/002/
∂ WHITE TN PAULSN 2.5MG N84913 001
∂ 5MG N80343 001
∂ 10MG N89028 001
JUL 24, 1986
20MG N84913 002

PREDNISONE

TABLET; ORAL

	SERVISONE		
BX	LEDERLE LABS	5MG	N80223 001
	∂ LEDERLE LABS	5MG	N80223 001

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

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

INJECTABLE; INJECTION

PROCAINAMIDE HCL

AP	PHARMAFAIR	100MG/ML	N88824 001 NOV 20, 1985
AP		500MG/ML	N88830 001 NOV 20, 1985
	∂ PHARMAFAIR	100MG/ML	N88824 001 NOV 20, 1985
	∂	500MG/ML	N88830 001 NOV 20, 1985

TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

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

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

	PHENERGAN-25		
AP	ALTANA	25MG/ML	N83997 001
	PHENERGAN-50		
AP	ALTANA	50MG/ML	N83997 002
	∂ ALTANA	25MG/ML	N83997 001
	∂ ALTANA	50MG/ML	N83997 002

TABLET; ORAL

PROMETHAZINE HCL

	∂/BOOTS/PHARMS	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
	∂ BOOTS USA	12.5MG	N84160 001
	∂	25MG	N84166 001
	∂	50MG	N84539 001
	∂ CHELSEA LABS	12.5MG	N85986 001
	∂	25MG	N85684 001
	∂	50MG	N85664 001

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL

	RYTHMOL		
	KNOLL PHARM	150MG¤	N19151 001 NOV 27, 1989
		300MG¤	N19151 002 NOV 27, 1989

PROPOFOL

INJECTABLE; INJECTION

	DIPRIVAN		
	ICI AMERICAS	10MG/ML¤	N19627 001 OCT 02, 1989

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

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/
	ə LEDERLE LABS	10MG	N72117 001 JUN 23, 1988
	ə	20MG	N72118 001 JUN 23, 1988
	ə	40MG	N72119 001 JUN 23, 1988
	ə	80MG	N72120 001 JUN 23, 1988

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

	PROPRANOLOL HCL		
/AB/	/MARTEC/PHARM/	/10MG/	/N70120/001/ /AUG/06,/1985/
/AB/		/20MG/	/N70121/001/ /AUG/06,/1985/
/AB/		/40MG/	/N70122/001/ /AUG/06,/1985/
/AB/		/60MG/	/N70123/001/ /OCT/29,/1986/
/AB/		/80MG/	/N70124/001/ /AUG/06,/1985/
	ə MARTEC PHARM	10MG	N70120 001 AUG 06, 1985
	ə	20MG	N70121 001 AUG 06, 1985
	ə	40MG	N70122 001 AUG 06, 1985
	ə	60MG	N70123 001 OCT 29, 1986
	ə	80MG	N70124 001 AUG 06, 1985
AB	MYLAN PHARMS	60MG¤	N72275 001 JUN 09, 1989

PROPYLIODONE

SUSPENSION; INTRATRACHEAL

	/DIONOSIL/AQUEOUS/		
	/GLAXO/	/50%/	/N09309/001/
	ə GLAXO	50%	N09309 001

PROPYLTHIOURACIL

TABLET; ORAL

	PROPYLTHIOURACIL		
	/ə/BOOTS/PHARMS/	/50MG/	/N84075/001/
	ə BOOTS USA	50MG	N84075 001
/BD/	/CHELSEA/LABS/	/50MG/	/N85201/001/
	ə CHELSEA LABS	50MG	N85201 001

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

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

PYRIDOSTIGMINE BROMIDE

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

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

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

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIDINE GLUCONATE
/LILLY/ /80MG/ML/ /N07529/001/
LILLY 80MG/ML¤ N07529 002
FEB 10, 1989

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE
AB MUTUAL PHARM 100MG¤ N81029 001
APR 14, 1989
AB 200MG¤ N81030 001
APR 14, 1989
AB 300MG¤ N81031 001
APR 14, 1989
/AB/ /PBI/ /200MG/ /N87837/001/
/APR/14,/1982/
∂ PBI 200MG N87837 001
APR 14, 1982
>DLT >/AB/ /QUANTUM/PHARMCS/ /200MG/ /N83622/001/
>ADD > ∂ QUANTUM PHARMCS 200MG N83622 001
/AB/ /WHITE/IN/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

RESERPINE

TABLET; ORAL
RESERPINE
/BP/ /ZENITH/LABS/ /0.1MG/ /N11185/001/
/BP/ /0.25MG/ /N11185/002/
∂ ZENITH LABS 0.1MG N11185 001
∂ 0.25MG N11185 002

RIFAMPIN

CAPSULE; ORAL
RIFADIN
/AB/ /DOW/PHARMS/ /300MG/ /N50420/001/
/150MG/ /N62303/001/
AB MERRELL DOW 300MG N50420 001
150MG N62303 001

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

>ADD > RUBIDIUM CHLORIDE RB-82

>ADD > INJECTABLE; INJECTION
>ADD > CARDIOGEN-82
>ADD > SQUIBB DIAGS N/A¤ N19414 001
>ADD > DEC 29, 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

>DLT > /FILM;/EXTENDED/RELEASE;/PERCUTANEOUS/
>DLT > /TRANSDERM-SCOP/
>DLT > /CIBA/PHARM/ /0.5MG/24HR¤/ /N17874/001/

SCOPOLAMINE

> ADD > FILM, EXTENDED RELEASE; TRANSDERMAL
> ADD > TRANSDERM-SCOP
> ADD > CIBA PHARM 0.5MG/24HR¤ 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-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/FLINT/ /1%/ /N18578/001/
/FEB/25,/1982/
AB BOOTS USA 1% N18578 001
FEB 25, 1982

SILVER SULFADIAZINE

DRESSING; TOPICAL
SILDIMAC
MARION LABS 1%¤ N19608 001
NOV 30, 1989

SINCALIDE

INJECTABLE; INJECTION
KINEVAC
/SQUIBB/ /0.005MG/VIAL/ /N17697/001/
SQUIBB DIAGS 0.005MG/VIAL N17697 001

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
/AP/ /CUTTER/BIOL/ /450MG/100ML/ /N18503/001/
@ CUTTER BIOL 450MG/100ML N18503 001
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
/AP/ /CUTTER/BIOL/ /900MG/100ML/ /N18502/001/
@ CUTTER BIOL 900MG/100ML N18502 001

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

SODIUM IODIDE, I-123

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

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL
/PHOSPHOTOPE/
/SQUIBB/ /1-8MCI/VIAL/ /N10927/001/
@ SQUIBB 1-8MCI/VIAL N10927 001

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE

AA	CAROLINA MED	454GM/BOT¤	N89910 001 JAN 19, 1989

SOMATREM

INJECTABLE; INJECTION
PROTROPIN

GENENTECH	10MG/VIAL¤	N19107 002 OCT 24, 1989

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
HUMATROPE

/LILLY/	/2MG/VIAL/	/N19640/001/ /JUN/23,/1987/
@ LILLY	2MG/VIAL	N19640 001 JUN 23, 1987

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE

/AB/	/VANGARD/LABS/	/25MG/	/N87648/001/ /FEB/01,/1982/
	@ VANGARD LABS	25MG	N87648 001 FEB 01, 1982

SULCONAZOLE NITRATE

CREAM; TOPICAL
SULCOSYN

/SYNTEX/LABS/	/1%/	/N18737/001/ /FEB/28,/1989/
WESTWOOD PHARMS	1%¤	N18737 001 FEB 28, 1989

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULTEN-10

AT	BAUSCH & LOMB	10%	N87818 001 FEB 03, 1983

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULTEN-10

/AT/	/MURO/PHARM/	/10%/	/N87818/001/ /FEB/03,/1983/

SULFINPYRAZONE

CAPSULE; ORAL
SULFINPYRAZONE

/AB/	/VANGARD/LABS/	/200MG/	/N88666/001/ /FEB/17,/1984/
	@ VANGARD LABS	200MG	N88666 001 FEB 17, 1984

SULFISOXAZOLE

TABLET; ORAL
SULFISOXAZOLE

/S/BOOTS/PHARMS/		/500MG/	/N84385/001/
@ PHARMAFAIR		500MG	N84385 001

SUTILAINS

OINTMENT; TOPICAL
TRAVASE

/BAXTER/	/82,000/UNITS/GM/	/N12828/001/
BOOTS USA	82,000 UNITS/GM	N12828 001

TECHNETIUM TC-99M FERPENTETATE KIT

/INJECTABLE;/INJECTION/
/RENOTEC/

/SQUIBB/	/N/A/	/N17045/001/
@ SQUIBB	N/A	N17045 001

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
TECHNESCAN DTPA KIT

> ADD >				
> ADD >	AP	MS&D RES LABS	N/A¤	N18511 001 DEC 29, 1989
> ADD >				

TECHNETIUM TC-99M PYROPHOSPHATE KIT

INJECTABLE; INJECTION
/AN-PYROTEC/

/AP/	/CIS/US/	/N/A/	/N19039/001/ /JUN/30,/1987/
	ə CIS US	N/A	N19039 001 JUN 30, 1987

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL
SODIUM PERTECHNETATE TC 99M

/AP/	/CIS/US/	/12MCI/ML/	/N17321/001/
/AP/		/24MCI/ML/	/N17321/002/
/AP/		/48MCI/ML/	/N17321/003/
	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/
CIS US	N/A	N17858 001

TEMAZEPAM

CAPSULE; ORAL
/TEMAZ/

>DLT> /AB/	/QUANTUM/PHARMCS/	/15MG/	/N70564/001/ /OCT/15,/1985/
>DLT> /AB/		/30MG/	/N70547/001/ /OCT/15,/1985/

TEMAZEPAM

CAPSULE; ORAL
/TEMAZ/

>DLT> >ADD>	ə QUANTUM PHARMCS	15MG	N70564 001 OCT 15, 1985
>ADD>	ə	30MG	N70547 001 OCT 15, 1985

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/	/QUANTUM/PHARMCS/	/250MG/	/N60059/001/
>ADD>	ə QUANTUM PHARMCS	250MG	N60059 001
/AB/	/VITARINE/	/250MG/	/N61471/001/
BX	VITARINE	250MG	N61471 001
BX		500MG	N61471 002 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

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SLO-BID

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

THEO-DUR SPRINKLE

BC	KEY PHARMS	75MG	N88015 001 SEP 10, 1985

ELIXIR; ORAL

ELIXOPHYLLIN

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

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
	/MEAD/JOHNSON/	/300MG/	/N88656/001/ /AUG/22,/1985/

TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR

BC	BRISTOL MYERS	300MG	N87563 001 JUN 21, 1983
/BC/	/MEAD/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

/AB/	/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

INJECTABLE; INJECTION

NAVANE

	/ROERIG/	/EQ/5MG/BASE/ML/	/N16964/002/
	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

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

> DLT >	/BX/ /QUANTUM/PHARMCS/	/5MG¤/	/N72466/001/ /MAY/19,/1989/	
> DLT >				
> ADD >	ə QUANTUM PHARMCS	5MG¤	N72466 001 MAY 19, 1989	
> ADD >				
> DLT >	/BX/ /QUANTUM/PHARMCS/	/10MG¤/	/N72467/001/ /MAY/19,/1989/	
> DLT >				
> ADD >	ə QUANTUM PHARMCS	10MG¤	N72467 001 MAY 19, 1989	
> ADD >				
> DLT >	/BX/ /QUANTUM/PHARMCS/	/20MG¤/	/N72468/001/ /MAY/19,/1989/	
> DLT >				
> ADD >	ə QUANTUM PHARMCS	20MG¤	N72468 001 MAY 19, 1989	
> ADD >				

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

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

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

> DLT >	/BX/ /QUANTUM/PHARMCS/	/100MG/	/N70921/001/ /DEC/01,/1986/
> DLT >			
> ADD >	ə QUANTUM PHARMCS	100MG	N70921 001 DEC 01, 1986
> ADD >			

TRIALODINE

> DLT >	/BX/ /QUANTUM/PHARMCS/	/50MG/	/N70942/001/ /DEC/01,/1986/
> DLT >			
> ADD >	ə QUANTUM PHARMCS	50MG	N70942 001 DEC 01, 1986
> ADD >			

TRIAMCINOLONE

TABLET; ORAL

TRIAMCINOLONE

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

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE

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

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE

/BP/	/CHELSEA/LABS/	/2MG/	/N86458/001/
	ə CHELSEA LABS	2MG	N86458 001

TRIHEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL

ARTANE

AA	LEDERLE LABS	2MG/5ML	N06773 009

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/

SODIUM MONOFLUOROPHOSPHATE

>_DLT_>	/PASTE;/DENTAL/		
>_DLT_>	/EXTRA-STRENGTH/AIM/		
>_DLT_>	/CHESEBROUGH/	/1.2%/	/N19518/001/ /JUN/03,/1987/
>_DLT_>			
>_ADD_>	@ CHESEBROUGH	1.2%	N19518 001 JUN 03, 1987
>_ADD_>			

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND
BLOOD PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT LIST

PERFLUORODECALIN; PERFLUOROTRI-N-PROPYLAMINE

INJECTABLE; INJECTION

FLUOSOL			
ALPHA THERPTC	17.5GM/100ML;7.5GM/100ML	N 860909	DEC 26, 1989

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: ANTITHROMBIN III (HUMAN) TRADE: ATNATIV*/**	HEREDITARY AT-III DEFICIENCY IN CONNECTION WITH SURGICAL OR OBSTETRICAL PROCEDURES OR WHEN THEY SUFFER FROM THROMBOEMBOLISM. [DEC 13, 1996]	KABI VITRUM, INC. 160 INDUSTRIAL DR. FRANKLIN, CA 45005
GENERIC: CD4, HUMAN RECOMBINANT SOLUBLE TRADE: RECEPTIN	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BIOGEN, INCORPORATED 14 CAMBRIDGE CENTER CAMBRIDGE, MA 02142
GENERIC: CD4, HUMAN TRUNCATED-369 AA POLYPEPTIDE (RECOMBINANT CHO CELLS) TRADE: SOLUBLE T4	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	SMITH KLINE & FRENCH LABORATORIES 1500 SPRING GARDEN STREET PHILADELPHIA, PA 19101
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. TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT (BMT).	SCHERING CORPORATION 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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: HUMAN IMMUNODEFICIENCY VIRUS (HIV-1) IMMUNE GLOBULIN (HUMAN) I.V. TRADE: NOT ESTABLISHED	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)	ABBOTT LABORATORIES DIAGNOSTICS DIVISION ABBOTT PARK, IL 60064
GENERIC: HUMAN T-LYMPHOTROPIC VIRUS TYPE III gp160 ANTIGENS, RECOMBINANT VACCINE, ALUM ABSORBED TRADE: VAXSYN HIV-1	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	MICROGENESYS, INC. 400 FRONTAGE ROAD WEST HAVEN, CT 06516
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
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: MELANOMA VACCINE TRADE: MELACCINE™	TREATMENT OF STAGE III-IV MELANOMA.	RIBI IMMUNOCHEM RESEARCH, INC. 553 OLD CORVALLIS RD. HAMILTON, MT 59840

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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: BETHANIDINE SULFATE TRADE: NOT ESTABLISHED	FOR THE PREVENTION OF THE RECURRENCE OF PRIMARY VENTRICULAR FIBRILLATION.	MEDCO RESEARCH, 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: (-) CARBOVIR TRADE: NOT ESTABLISHED	TREATMENT OF PERSONS WITH AIDS AND IN THE TREATMENT OF PERSONS WITH SYMPTOMATIC HIV INFECTION AND A CD4 COUNT OF LESS THAN 200/MM^3.	GLAXO INC. 5 MOORE DRIVE RESEARCH TRIANGLE PARK, NC 27709
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

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: DIHEMATOPORPHYRIN ETHERS TRADE: PHOTOFRIN	USE FOR THE PHOTODYNAMIC THERAPY OF PATIENTS WITH PRIMARY OR RECURRENT OBSTRUCTING (EITHER PARTIALLY OR COMPLETELY) ESOPHAGEAL CARCINOMA. USE IN THE PHOTODYNAMIC THERAPY OF PATIENTS WITH TRANSITIONAL CELL CARCINOMA IN SITU OF THE URINARY BLADDER.	QLT PHOTOTHERAPEUTICS, INC NORTH MIDDLETOWN RD. 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
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 PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME. (AIDS)*/**. [JUN 23, 1996]	SYNTEX (U.S.A.), INC. 3401 HILLVIEW AVENUE PALO ALTO, CA 94304

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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
GENERIC: L-CARNITINE TRADE: VITA CARN	PREVENTION OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY. TREATMENT OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY.	KENDALL MCGAW LABORATORIES, INC 2525 MCGAW AVENUE IRVINE, CA 92714-5898
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: MULTI-VITAMIN INFUSION-NEONATAL FORMULA TRADE: NOT ESTABLISHED	FOR THE ESTABLISHMENT AND MAINTENANCE OF TOTAL PARENTERAL NUTRITION IN VERY LOW BIRTH WEIGHT INFANTS (LESS THAN 1500 GRAMS).	ARMOUR PHARMACEUTICAL 920 A HARVEST DRIVE SUITE 200 BLUE BELL, PA 19422

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: 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: OVINE CORTICOTROPIN RELEASING HORMONE (oCRH) TRADE: NOT ESTABLISHED	USE IN DIFFERENTIATING PITUITARY AND ECTOPIC PRODUCTION OF ACTH IN PATIENTS WITH ACTH-DEPENDENT CUSHING'S SYNDROME.	FERRING LABORATORIES INCORPORATED 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: POLYMER IMPLANT CONTAINING CARMUSTINE TRADE: BIODEL™ CONTAINING BCNU	FOR THE LOCALIZED PLACEMENT IN THE BRAIN FOR THE TREATMENT OF RECURRENT MALIGNANT GLIOMA.	NOVA PHARMACEUTICAL CORPORATION 6200 FREEPORT CENTER BALTIMORE, MD 21224-2788
GENERIC: RIFABUTIN TRADE: NOT ESTABLISHED	FOR THE PREVENTION OF MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE IN PATIENTS WITH AIDS AND IN PATIENTS WITH CD4 COUNTS LESS THAN 200/MM^3. FOR THE TREATMENT OF DISSEMINATED MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE.	ADRIA LABORATORIES P.O. BOX 16529 COLUMBUS, OH 43216
GENERIC: RIFAMPIN TRADE: RIFADIN I.V.*/**	ANTITUBERCULOSIS TREATMENT WHERE USE OF THE ORAL FORM OF THE DRUG IS NOT FEASIBLE. [MAY 25, 1996]	MERRELL DOW RESEARCH INST. 2110 E. GALBRAITH CINCINNATI, OH 45215

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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: 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: 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
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: 3'AZIDO-2', 3'DIDEOXYURIDINE TRADE: NOT ESTABLISHED	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	TRITON BIOSCIENCES INCORPORATED 1501 HARBOR BAY PKWY ALAMEDA, CA 94501

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: 4-AMINOSALICYLIC ACID TRADE: NOT ESTABLISHED	FOR USE IN PATIENTS WITH MILD TO MODERATE ULCERATIVE COLITIS WHO ARE INTOLERANT TO SULFASALAZINE.	WARREN L. BEEKEN, M.D. GIVEN C-317 UNIVERSITY OF VERMONT BURLINGTON, VT 05405
GENERIC: 4-HYDROPEROXYCYCLOPHOSPHAMIDE (4-HC) TRADE: NOT ESTABLISHED	FOR USE IN THE EX VIVO TREATMENT OF AUTOLOGOUS BONE MARROW AND SUBSEQUENT REINFUSION IN PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA (AML), ALSO REFERRED TO AS ACUTE NONLYMPHOCYTIC LEUKEMIA (ANLL).	NOVA PHARMACEUTICAL CORPORATION 6200 FREEPORT CENTRE BALTIMORE, MD 21224

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

NO DECEMBER 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
HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89 P-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 1.465GM/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 INDICATION NEW STRENGTH	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 DOSING SCHEDULE

D-16 CONTINUOUS INTRAVENOUS INFUSION

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
I-97 PRIMARY NOCTURNAL ENURESIS

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~~
U-57	ANGINA PECTORIS
U-58	ACUTE MYOCARDIAL INFARCTION
U-59	METHOD OF TREATMENT OF BURNS
U-60	METHOD OF TREATING CARDIAC ARRHYTHMIAS

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	19909 001	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997		NCE	MAR 29, 1992
	19937 002	ADENOSINE; ADENOCARD	4673563	JUN 16, 2004	U-56	NCE	OCT 30, 1994
	19729 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
>DLT>	18207 007	AMILORIDE HYDROCHLORIDE; MODURETIC 5-50	3787430	DEC 15, 1990			
	18240 001	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
			3836671	SEP 17, 1991	U-57		
			3836671	SEP 17, 1991	U-58		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
	18240 002	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
			3836671	SEP 17, 1991	U-57		
			3836671	SEP 17, 1991	U-58		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
	19058 001	ATENOLOL; TENORMIN	3836671	SEP 17, 1991		NDF	SEP 13, 1992
	19459 001	AVOBENZONE; PHOTOPLEX	4387089	JUN 07, 2002		NCE	SEP 30, 1993
	19716 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4775529	OCT 04, 2005		NP	AUG 01, 1991
	19270 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC	4252984	AUG 30, 1999		NCE	AUG 30, 1990
	19507 001	BETAXOLOL HYDROCHLORIDE; KERLONE	4311708	JAN 19, 1999	U-5	NCE	AUG 30, 1990
			4252984	AUG 30, 1999		NDF	OCT 27, 1992
	19507 002	BETAXOLOL HYDROCHLORIDE; KERLONE	4311708	JAN 19, 1999	U-5	NCE	AUG 30, 1990
			4252984	AUG 30, 1999		NDF	OCT 27, 1992
>ADD>	19845 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC S	4342783	AUG 03, 1999			
>ADD>			4311708	JAN 19, 1999			
>ADD>			4252984	AUG 30, 1999		NCE	AUG 30, 1990
	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
	19204 001	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
	19204 002	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
	19204 003	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
	17939 002	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		D-16	NOV 13, 1992
	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>	19906 001	CLOMIPRAMINE HYDROCHLORIDE; ANAFRANIL				NCE	DEC 29, 1994
>ADD>	19906 002	CLOMIPRAMINE HYDROCHLORIDE; ANAFRANIL				NCE	DEC 29, 1994
>ADD>	19906 003	CLOMIPRAMINE HYDROCHLORIDE; ANAFRANIL				NCE	DEC 29, 1994

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	17613 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
	17619 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
	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
>ADD>	19188 001	CROMOLYN SODIUM; GASTROCROM	4395421	JUL 26, 2000			
>DLT>	17827 001	CYCLOBENZAPRINE HYDROCHLORIDE; FLEXERIL	3882246	MAY 06, 1992			
>DLT>	17827 002	CYCLOBENZAPRINE HYDROCHLORIDE; FLEXERIL	3882246	MAY 06, 1992			
	71611 001	CYCLOBENZAPRINE HYDROCHLORIDE; CYCLOBENZAPRINE HCL				PC	NOV 15, 1989
	17922 001	DESMOPRESSIN ACETATE; DDAVP				I-97	NOV 28, 1992
>ADD>	19082 001	DEZOCINE; DALGAN				NCE	DEC 29, 1994
>ADD>	19082 002	DEZOCINE; DALGAN				NCE	DEC 29, 1994
>ADD>	19082 003	DEZOCINE; DALGAN				NCE	DEC 29, 1994
	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	NCE	DEC 31, 1991
>ADD>	19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1994		NC	DEC 29, 1992
>ADD>	19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1994		NC	DEC 29, 1992
	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
			4472382	JAN 27, 2003	U-42		
			4329364	MAY 11, 2002	U-41		
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST				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
	19687 001	GONADORELIN ACETATE; LUTREPULSE PUMP KIT				NE	OCT 10, 1992
	19687 002	GONADORELIN ACETATE; LUTREPULSE PUMP KIT				NE	OCT 10, 1992
>ADD>	19726 001	GOSERELIN ACETATE; ZOLADEX	4100274	JUL 10, 1995		NCE	DEC 29, 1994

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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
	19771 001	IBUPROFEN; COADVIL				NC	SEP 19, 1992
	19833 002	IBUPROFEN; CHILDREN'S ADVIL	4788220	NOV 29, 2005		NDF	SEP 19, 1992
	19842 001	IBUPROFEN; PEDIA PROFEN				NDF	SEP 19, 1992
	19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
	19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
>ADD>	19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2001		NCE	DEC 29, 1994
>ADD>			4389393	JUN 21, 2000			
>ADD>			4197313	APR 08, 1997	U-60		
>ADD>	19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2001		NCE	DEC 29, 1994
>ADD>			4389393	JUN 21, 2000			
>ADD>			4197313	APR 08, 1997	U-60		
>ADD>	19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2001		NCE	DEC 29, 1994
>ADD>			4389393	JUN 21, 2000			
>ADD>			4197313	APR 08, 1997	U-60		
	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
	18735 003	IOPAMIDOL; ISOVUE-370				I-55	OCT 04, 1992
>ADD>	19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 1997		NCE	DEC 07, 1994
>ADD>	19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 1997		NCE	DEC 07, 1994

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19710 001	IOVERSOL; OPTIRAY 320	4396598	OCT 26, 2002	U-46	NCE	DEC 30, 1993
			4396598	OCT 26, 2002	U-47		
	19710 002	IOVERSOL; OPTIRAY 240	4396598	OCT 26, 2002	U-48	NCE	DEC 30, 1993
	19710 003	IOVERSOL; OPTIRAY 160	4396598	OCT 26, 2002	U-49	NCE	DEC 30, 1993
	19698 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
	19698 002	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
	19698 003	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
	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
	19860 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D	3714159	JAN 30, 1990			
	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
	19884 001	MESNA; MESNEX	4220660	DEC 02, 1999	U-38	ODE	DEC 30, 1995
>ADD>	19786 001	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993			
>ADD>			3876802	APR 08, 1992		NP	DEC 27, 1992
>ADD>	19786 002	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993			
>ADD>			3876802	APR 08, 1992		NP	DEC 27, 1992
>ADD>	19786 003	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993			
>ADD>			3876802	APR 08, 1992		NP	DEC 27, 1992
>ADD>	19786 004	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993			
>ADD>			3876802	APR 08, 1992		NP	DEC 27, 1992
	18592 001	MICONAZOLE NITRATE; MONISTAT 5	3717655	FEB 20, 1990		NDF	OCT 27, 1992
	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
	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
	19488 001	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993
	19488 002	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
			4765989	SEP 16, 2003			
			4612008	SEP 16, 2003		NDF	SEP 06, 1992
			4327725	MAY 04, 1997			
			3916899	NOV 05, 1991			
			3845770	NOV 05, 1991			
	19684 002	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
			4765989	SEP 16, 2003			
			4612008	SEP 16, 2003		NDF	SEP 06, 1992
			4327725	MAY 04, 1997			
			3916899	NOV 05, 1991			
			3845770	NOV 05, 1991			
	19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
			4765989	SEP 16, 2003			
			4612008	SEP 16, 2003		NDF	SEP 06, 1992
			4327725	MAY 04, 1997			
			3916899	NOV 05, 1991			
			3845770	NOV 05, 1991			
	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
	19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
	19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
	19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
	19810 001	OMEPRAZOLE; LOSEC	4786505	NOV 22, 2005	U-55	NCE	SEP 14, 1994
			4255431	MAR 10, 1998			
	19407 001	OXYMETAZOLINE HYDROCHLORIDE; VISINE L.R.				NDF	MAY 30, 1989
	19887 001	PENTAMIDINE ISETHIONATE; NEBUPENT				ODE	JUN 15, 1996
						NDF	JUN 15, 1992
	19385 001	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
	19385 002	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
	19385 003	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
	19855 001	PERMETHRIN; ELIMITE	4024163	MAY 17, 1996		NCE	MAR 31, 1991
						NDF	AUG 25, 1992
	18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS	4271143	JUN 02, 1998			
>ADD>	19456 001	PINACIDIL; PINDAC	RE31244	NOV 08, 1994	U-5	NCE	DEC 28, 1994
>ADD>	19456 002	PINACIDIL; PINDAC	RE31244	NOV 08, 1994	U-5	NCE	DEC 28, 1994
	19151 001	PROPAFENONE HYDROCHLORIDE; RYTHMOL				NCE	NOV 27, 1994
	19151 002	PROPAFENONE HYDROCHLORIDE; RYTHMOL				NCE	NOV 27, 1994
	19627 001	PROPOFOL; DIPRIVAN	4798846	NOV 01, 1994			
			4056635	NOV 01, 1994		NCE	OCT 02, 1994

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	50627 001	RIFAMPIN; RIFADIN				ODE	MAY 25, 1996
>ADD>	19414 001	RUBIDIUM CHLORIDE RB-82; CARDIOGEN-82	4400358	AUG 23, 2000		NCE	DEC 29, 1994
	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL				NCE	JUN 05, 1994
						ODE	JUN 05, 1996
	19608 001	SILVER SULFADIAZINE; SILDIMAC	4563184	JAN 07, 2003		NP	NOV 30, 1992
>ADD>			3761590	SEP 25, 1990	U-59		
	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			
>ADD>	18511 001	TECHNETIUM TC-99M PENTETATE KIT; TECHNESCAN DTPA KIT	3725295	APR 03, 1990			
	17628 002	TOLMETIN SODIUM; TOLECTIN 600	3752826	AUG 14, 1990			
	19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
			RE30910	JAN 07, 1994	U-44		
			RE30910	JAN 07, 1994	U-45		
	19594 002	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
			RE30910	JAN 07, 1994	U-44		
			RE30910	JAN 07, 1994	U-45		
>ADD>	19152 002	VERAPAMIL HYDROCHLORIDE; ISOPTIN SR				NS	DEC 15, 1992
	19910 001	ZIDOVUDINE; RETROVIR				NCE	MAR 19, 1992

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
841207 001	PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%; PENTASPAN				ODE	MAY 19, 1994
860909 001	PERFLUORODECALIN; FLUOSOL	3911138	OCT 07, 1992		NCE	DEC 26, 1994
		4252827	FEB 24, 1998			

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