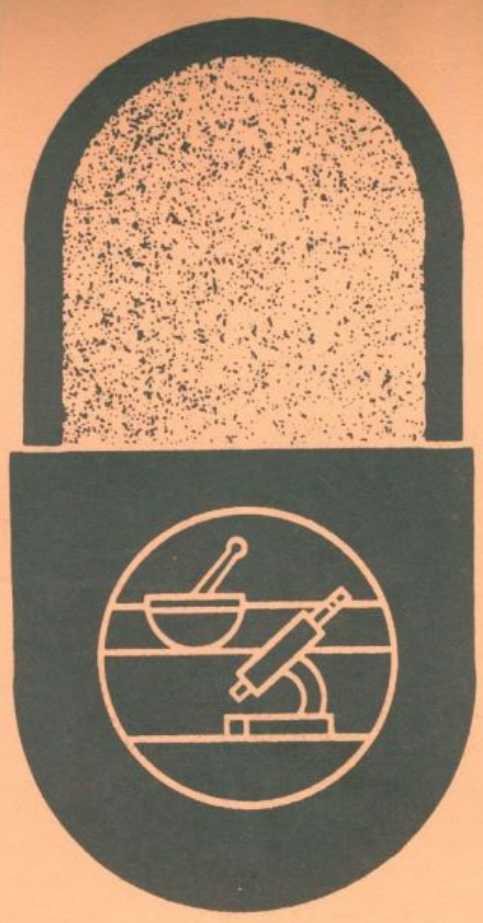
CUMULATIVE
SUPPLEMENT 11
JAN'89-NOV'89



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 11

NOVEMBER 1989

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CUMULATIVE SUPPLEMENT 11

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 9th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product, along with the application number and product number (FDA's internal file number). All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to place an asterisk (*) to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement.

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.] The effective date for the approved drug product (the earliest date a product may be marketed) appears, when appropriate, to the left of the approval date.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Additions new to the Prescription Drug Product List, OTC Drug Product List, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (⧫) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

Deletions new to the Prescription Drug Product List, OTC Drug Product List, Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data are indicated by the symbol >DLT> (DELETE) to the left of the line containing overstruck print. The >DLT> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print will remain in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List and the Patent and Exclusivity Data will be dropped in subsequent Cumulative Supplements.

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the " ə " symbol to designate their non-marketed status. All products having a " ə " symbol in the 12th Cumulative Supplement of the 9th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 9th Edition.

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the appropriate Drug Product List.

Products	Federal Register Reference
Nitroglycerin (capsule, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;oral)	SEP 7, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 5, 1985 (50 FR 27688)
Tranylcypromine Sulfate	MAR 22, 1984 (49 FR 10708)

1.3 APPLICANT (NAME) CHANGES

Because it is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

APPLICANT (NAME) CHANGES

FORMER APPLICANT (NAME)	NEW APPLICANT (NAME)	NEW ABBREVIATED NAME
DUPONT CRITICAL CARE SUB EI DUPONT DE NEMOURS & COMPANY INC	DUPONT PHARMACEUTICALS DIV EI DUPONT DE NEMOURS & CO INC	DUPONT PHARMS
INTERNATIONAL PHARMACEUTICAL PRODUCTS INC	NORBROOK AMERICA INC	NORBROOK AM
MAURRY BIOLOGICAL CO INC	NORBROOK AMERICA INC	NORBROOK AM
NORBROOK AMERICA INC	AKORN INC	AKORN

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	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091	10157	10137	10153
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)	1982 (19.6%)	1978 (19.5%)
MULTISOURCE	8108 (80.3%)	8164 (80.4%)	8155 (80.4%)	8175 (80.5%)
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)	7341 (72.4%)	7350 (72.4%)
NOT THERAPEUTICALLY EQUIVALENT	748 (7.4%)	726 (7.1%)	701 (6.9%)	709 (7.0%)
EXCEPTIONS[1]	118 (1.1%)	117 (1.2%)	113 (1.1%)	116 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	--	3	4	2
NUMBER OF APPLICANTS	374	393	394	397

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

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

/AA/	/DURAMED/PHARMS/	/300MG;15MG/	/N88353/001/ /FEB/06,/1984/	
/AA/		/300MG;30MG/	/N88354/001/ /FEB/06,/1984/	> ADD >
/AA/		/300MG;60MG/	/N88355/001/ /FEB/06,/1984/	> ADD >
	ə DURAMED PHARMS	300MG;15MG	N88353 001 FEB 06, 1984	> ADD >
	ə	300MG;30MG	N88354 001 FEB 06, 1984	> ADD >
	ə	300MG;60MG	N88355 001 FEB 06, 1984	> ADD >
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
/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/

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/
	ə DUPONT PHARMS	500MG;2.5MG	N85910 001

/OXYCODONE 5/APAP 500/

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL
ROXICET 5/500

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

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

CAPSULE; ORAL
TYLOX

∂ 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

	∂ VANGARD LABS	250MG	N87654 001 FEB 05, 1982

ACETRIZOATE SODIUM

SOLUTION; INTRAUTERINE
SALPIX

	∂ 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

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL
MUCOMYST

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

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
∂	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

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

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

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

ALLOPURINOL

TABLET; ORAL

LOPURIN

~~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 11 3.5% IN PLASTIC CONTAINER~~

~~ABBOTT LABS~~	~~3.5%~~	~~N19491 001~~
		~~OCT 10, 1986~~
∂ ABBOTT LABS	3.5%	N19491 001
		OCT 10, 1986

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

~~AMINOSYN 3.5% W/ DEXTROSE 25% IN PLASTIC CONTAINER~~

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

~~AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER~~

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

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

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

ə ABBOTT LABS	3.5%;32MG/100ML;128MG/100ML; 222MG/100ML;49MG/100ML	N19493 001 OCT 16, 1986

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL
AMITRIPTYLINE HCL

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

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

AMOXICILLIN

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL
PERPHENAZINE AND AMITRIPTYLINE HCL

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

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN

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

AMOXAPINE

TABLET; ORAL
AMOXAPINE

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

ASENDIN

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

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

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

AMOXICILLIN

CAPSULE; ORAL
AMOXICILLIN

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

POWDER FOR RECONSTITUTION; ORAL
AMOXICILLIN

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

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL
AMPICILLIN

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

/TABLET;/CHEWABLE;/ORAL/
/POLYCILLIN/

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

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL
BUTALBITAL W/ ASPIRIN & CAFFEINE

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

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
NORGESIC

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

NORGESIC FORTE

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

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE COMPOUND

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

ORPHENADRINE COMPOUND DOUBLE STRENGTH

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

ORPHENGESIC

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

ORPHENGESIC FORTE

AB	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

ASPIRIN; CARISOPRODOL

TABLET; ORAL

CARISOPRODOL AND ASPIRIN

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

ATENOLOL

INJECTABLE; INJECTION

TENORMIN

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

ATENOLOL

TABLET; ORAL

TENORMIN

AB	ICI PHARM	50MG	N18240 001
AB		100MG	N18240 002
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

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

BACLOFEN

TABLET; ORAL
BACLOFEN

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

BENDROFLUMETHIAZIDE

TABLET; ORAL
NATURETIN-2.5
SQUIBB 2.5MG N12164 001
a SQUIBB 2.5MG N12164 001

BENZONATATE

CAPSULE; ORAL
TESSALON
DUPONT PHARMS 100MG N11210 001
FOREST LABS 100MG N11210 001

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE

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

BETAMETHASONE DIPROPIONATE

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

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

BETAMETHASONE DIPROPIONATE

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

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

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

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

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

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

BETAXOLOL HYDROCHLORIDE

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
	a CHELSEA LABS	5MG	N85841 001
	a	10MG	N85842 001
	a	25MG	N85839 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

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

/BRETYLIUM TOSYLATE IN DEXTROSE 5%/

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

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

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

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL

BROMPHENIRAMINE MALEATE

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

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/	/CHELSEA/LABS/	/4MG/	/N85769/001/	
	∂ CHELSEA LABS	4MG	N85769 001	
/AA/	/CORD/LABS/	/4MG/	/N83215/001/	
	∂ CORD LABS	4MG	N83215 001	

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

/BIPHETANE DC/

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

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-AT/

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

BROMFED-DM

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

BUPROPION HYDROCHLORIDE

/TABLET;ORAL/

/WELLBUTRIN/

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

TABLET; ORAL

WELLBUTRIN

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

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM

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

CALCITONIN, SALMON

INJECTABLE; INJECTION
CALCIMAR

/RORER/PHARM/	/400/IU/VIAL/	/N17497/001/
ə 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

>DLT>	/KENDALL/MCGAW/	/34MG/100ML;5GM/100ML;30MG/100ML;/	
>DLT>		/74MG/100ML;640MG/100ML;500MG/100ML;/	
>DLT>		/74MG/100ML/	/N18269/002/
>DLT>			/JAN/17,/1983/
>ADD>	KENDALL MCGAW	35MG/100ML;5GM/100ML;30MG/100ML;	
>ADD>		74MG/100ML;640MG/100ML;500MG/100ML;	
>ADD>		74MG/100ML	N18269 002
>ADD>			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/
	ə 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/
	ə 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

/dddddddddst/

/INJECTABLE;/INJECTION/
/PROSTIN/15M/
/UPJOHN/ /EQ/0.25MG/BASE/ML/ /N17989/001/

CARBOPROST TROMETHAMINE

INJECTABLE; INJECTION
HEBAMATE
UPJOHN EQ 0.25MG BASE/ML N17989 001

CARISOPRODOL

TABLET; ORAL
CARISOPRODOL
AA CORD LABS 350MG¤ N81025 001
APR 13, 1989

CARTEOLOL HYDROCHLORIDE

TABLET; ORAL
CARTROL
/ABBOTT/LABS/ /10MG/ /N19204/003/
/DEC/28,/1988/
∂ ABBOTT LABS 10MG N19204 003
DEC 28, 1988

CEFADROXIL

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

POWDER FOR RECONSTITUTION; ORAL
CEFADROXIL
AB BIOCRAFT LABS EQ 125MG BASE/5ML¤ N62698 001
MAR 01, 1989
AB EQ 250MG BASE/5ML¤ N62698 002
MAR 01, 1989
AB EQ 500MG BASE/5ML¤ N62698 003
MAR 01, 1989

CEFADROXIL

POWDER FOR RECONSTITUTION; ORAL
ULTRACEF
AB BRISTOL LABS EQ 125MG BASE/5ML N62334 001
AB EQ 125MG BASE/5ML N62376 001
MAR 16, 1982
AB EQ 250MG BASE/5ML N62334 002
AB EQ 250MG BASE/5ML N62376 002
MAR 16, 1982

CEFAZOLIN SODIUM

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

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/ /TAG/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/ /TAG/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

CERULETIDE DIETHYLAMINE

INJECTABLE; INJECTION

	ADRIA LABS	0.02MG/ML	N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

	ABBOTT LABS	5MG	N85447 001	
		5MG	N85517 001	
		10MG	N85447 002	
		10MG	N85518 001	
		25MG	N85447 003	
		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	

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
AB	MK LABS	5MG	N85118 001	
AB		10MG	N85119 001	
AB		25MG	N85120 001	
AB	ROXANE LABS	5MG	N84706 001	
AB		10MG	N84700 001	
AB		25MG	N84705 001	
AB	VANGARD LABS	5MG	N88129 001	MAR 28, 1983
AB		10MG	N88010 001	MAR 28, 1983
AB		25MG	N88130 001	MAR 28, 1983

CHLOROQUINE HYDROCHLORIDE

INJECTABLE; INJECTION

ARALEN

	STERLING DRUG	EQ 40MG BASE/ML	N06002 002

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

/3/	/BOOTS/PHARMS/	/4MG/	/N83753/001/
/AA/	/CHELSEA/LABS/	/4MG/	/N85139/001/
	∂ CHELSEA LABS	4MG	N85139 001
/AA/	/LEDERLE/LABS/	/4MG/	/N86941/001/
	∂ LEDERLE LABS	4MG	N86941 001
	∂ PHARMAFAIR	4MG	N83753 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

/BC/	/CHELSEA/LABS/	/12MG;75MG/	/N88681/001/ /SEP/29,/1987/
	∂ 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

/3/	/BOOTS/PHARMS/	/10MG/	/N84414/001/
/3/		/25MG/	/N84415/001/
/3/		/50MG/	/N84411/001/
/3/		/100MG/	/N84412/001/
/3/		/200MG/	/N84413/001/
	∂ BOOTS USA	10MG	N84414 001
	∂	25MG	N84415 001
	∂	50MG	N84411 001
	∂	100MG	N84412 001
	∂	200MG	N84413 001

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL
CHLORPROMAZINE HCL

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

CHLORPROPAMIDE

TABLET; ORAL
CHLORPROPAMIDE

/AB/	/CHELSEA/LABS/	/250MG/	/N86866/001/
	∂ 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/
	∂ VANGARD LABS	25MG	N88012 001 JUL 14, 1982
	∂	50MG	N88073 001 MAR 25, 1983
AB	MARNER CHILCOTT	25MG	N87515 001 JAN 24, 1983
AB		50MG	N87516 001 FEB 09, 1983

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

/AA/	/AM THERPTCS/	/500MG/	/N89911/001/ †† /JUN/23,/1989/
/AA/	/CHELSEA LABS/	/250MG/	/N86948/001/ /AUG/09,/1982/
∂ 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

CHYMOPAPAIN

INJECTABLE; INJECTION

CHYMODIACTIN

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

CLINDAMYCIN 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

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

/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

	UPJOHN	EQ 6MG BASE/ML	N50639 001 AUG 30, 1989
		EQ 12MG BASE/ML	N50639 002 AUG 30, 1989

CLINDAMYCIN PHOSPHATE

AP	ASTRA PHARM	EQ 150MG BASE/ML	N62928 001 FEB 13, 1989
AP	DUPONT CRI CARE	EQ 150MG BASE/ML	N62908 001 FEB 01, 1989
AP	LEDERLE PARNTLS	EQ 150MG BASE/ML	N63068 001 AUG 28, 1989

LOTION; TOPICAL

CLEOCIN T

	UPJOHN	EQ 1% BASE	N50600 001 MAY 31, 1989

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

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

†† SEE SECTION 1.5 OF INTRODUCTION

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL
CLORAZEPATE DIPOTASSIUM

/AB/	/CHELSEA/LABS/	/3.75MG/	/N71878/001/	
			/MAR/15,/1988/	
/AB/		/7.5MG/	/N71879/001/	
			/MAR/15,/1988/	
/AB/		/15MG/	/N71860/001/	
			/MAR/15,/1988/	
	ə CHELSEA LABS	3.75MG	N71878 001	
			MAR 15, 1988	
	ə	7.5MG	N71879 001	
			MAR 15, 1988	
	ə	15MG	N71860 001	
			MAR 15, 1988	
>DLT >/AB/	/QUANTUM/PHARMCS/	/3.75MG/	/N71549/001/	
>DLT >			/SEP/12,/1988/	
>DLT >/AB/		/7.5MG/	/N71550/001/	
>DLT >			/SEP/12,/1988/	
>DLT >/AB/		/15MG/	/N71522/001/	
>DLT >			/SEP/12,/1988/	
>ADD > BX	QUANTUM PHARMCS	3.75MG	N71549 001	
>ADD >			SEP 12, 1988	
>ADD > BX		7.5MG	N71550 001	
>ADD >			SEP 12, 1988	
>ADD > BX		15MG	N71522 001	
>ADD >			SEP 12, 1988	

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

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

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM

>DLT >/AB/	/QUANTUM/PHARMCS/	/3.75MG/	/N71730/001/	
>DLT >			/OCT/26,/1987/	
>DLT >/AB/		/7.5MG/	/N71731/001/	
>DLT >			/OCT/26,/1987/	
>DLT >/AB/		/15MG/	/N71702/001/	
>DLT >			/OCT/26,/1987/	
>ADD > BX	QUANTUM PHARMCS	3.75MG	N71730 001	
>ADD >			OCT 26, 1987	
>ADD > BX		7.5MG	N71731 001	
>ADD >			OCT 26, 1987	
>ADD > BX		15MG	N71702 001	
>ADD >			OCT 26, 1987	

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

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE

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

CRYPTENAMINE ACETATES

/INJECTABLE;/INJECTION/
/UNITENSEN/
/WALLACE/LABS/ /260/CSR/UNITS/ML/ /N08814/001/
∂ WALLACE LABS 260 CSR UNITS/ML N08814 001

CYANOCOBALAMIN

INJECTABLE; INJECTION
/REDISOL/
/AP/ /MS&D/ /1MG/ML/ /N06668/010/
∂ MS&D 1MG/ML N06668 010
/VI-TWEL/
/AP/ /BERLEX/LABS/ /1MG/ML/ /N07012/002/
∂ 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/
∂ 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/
∂ 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/
∂ 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/ /N85816/001/
/BP/ /1.5MG/ /N85840/001/
∂ CHELSEA LABS 0.75MG N85816 001
∂ 1.5MG N85840 001

DEXAMETHASONE

TABLET; ORAL
DEXAMETHASONE

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

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

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

DEXTROSE; POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/
/10MEQ IN PLASTIC CONTAINER/

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

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

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

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

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

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

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

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

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

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

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

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

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

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

/CARDIOGRAFIN/

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

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

HYPAQUE-M

/STERLING/DRUG/	/60%;30%/	/N10220/002/
∂ 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
>DLT >/AB/	/SUPERPHARM/		/2MG/	/N70642/001/ /DEC/11,/1985/
>DLT >/AB/			/5MG/	/N70643/001/ /DEC/11,/1985/
>DLT >/AB/			/10MG/	/N70644/001/ /DEC/11,/1985/
>ADD >	BX	SUPERPHARM	2MG	N70642 001 DEC 11, 1985
>ADD >	BX		5MG	N70643 001 DEC 11, 1985
>ADD >	BX		10MG	N70644 001 DEC 11, 1985

INJECTABLE; INJECTION

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

DIAZEPAM

TABLET; ORAL

Q-PAM

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

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

VOLTAREN

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

DICYCLOMINE HYDROCHLORIDE

CAPSULE; ORAL

DICYCLOMINE HCL

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

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL

HETRAZAN

/S/LEDERLE/LABS/	/50MG/	/N06459/001/	
LEDERLE LABS	50MG	N06459 001	

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

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

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

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

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

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

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL

/AA/	/DIPHEN/ /PBI/ ∂ PBI	/12.5MG/5ML/ 12.5MG/5ML	/N84640/001/ N84640 001	
AA	DIPHENHYDRAMINE HCL CENCI LABS	12.5MG/5ML	N87941 001 DEC 17, 1982	
/AA/	/LEDERLE/LABS/ ∂ LEDERLE LABS	/12.5MG/5ML/ 12.5MG/5ML	/N86937/001/ N86937 001	
/AA/	/LIFE/LABS/	/12.5MG/5ML/	/N87941/001/ /DEC/17,/1982/	
/AA/	/PRIVATE/FMLTNS/ ∂ PRIVATE FMLTNS	/12.5MG/5ML/ 12.5MG/5ML	/N85287/001/ N85287 001	

DISULFIRAM

TABLET; ORAL

DISULFIRAM

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

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

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
AP		100MG/VIAL*	N62926 003	APR 13, 1989

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

	DOXYCYCLINE HYCLATE			
/AA/	/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

TABLET; ORAL

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

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

	FENTANYL CITRATE AND DROPERIDOL			
AP	ASTRA PHARM	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/	
∂	CHASE CHEM	50,000 IU	N80747 001	

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

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

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

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

ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL

SUSPENSION; ORAL
ILOSONE SULFA
/LILLY/ /EQ 125MG BASE/5ML;/ /EQ 600MG BASE/5ML¤/ /N50599/001/ /SEP 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 VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION

>DLT>	/DELADUMONE OB/		
>DLT>/AO/	/SQUIBB/	/8MG/ML;180MG/ML/	/N09545/002/
>ADD>	∂ SQUIBB	8MG/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/

ESTROGENS, CONJUGATED

TABLET; ORAL
CONJUGATED ESTROGENS

BP	DURAMED PHARMS	0.3MG	N86492 001
BP		0.625MG	N83272 001
BP		1.25MG	N83294 001
BP		2.5MG	N83295 001
/BS/		/0.3MG/	/N86492/001/
/BS/		/0.625MG/	/N83272/001/
/BS/		/1.25MG/	/N83294/001/
/BS/		/2.5MG/	/N83295/001/
BP	ZENITH LABS	0.3MG	N88569 001 NOV 29, 1984
BP		0.625MG	N83373 001
BP		1.25MG	N83601 001
BP		2.5MG	N83602 001
/BS/		/0.3MG/	/N88569/001/ /NOV 29, 1984/
/BS/		/0.625MG/	/N83373/001/
/BS/		/1.25MG/	/N83601/001/
/BS/		/2.5MG/	/N83602/001/

PREMARIN

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

ETHINYL ESTRADIOL; NORETHINDRONE

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

FENOPROFEN CALCIUM

CAPSULE; ORAL
FENOPROFEN CALCIUM
> DLT >/AB/ /QUANTUM PHARMCS/ /EQ 200MG BASE/ /N72214/001/ /APR/14,/1988/
> DLT >
> DLT >/AB/ /EQ 300MG BASE/ /N71738/001/ /APR/14,/1988/
> DLT >
> ADD > BX QUANTUM PHARMCS EQ 200MG BASE N72214 001 APR 14, 1988
> ADD >
> ADD > BX EQ 300MG BASE N71738 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%/ /N72494/001/ /JAN/19,/1989/

FLUOCINONIDE

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

SOLUTION; TOPICAL
FLUOCINONIDE
AT LEMMON 0.05% N72511 001 FEB 07, 1989
AT THAMES PHARMA 0.05% N72857 001 AUG 02, 1989

FLUOROMETHOLONE; SULFACETAMIDE SODIUM

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

FLUOROMETHOLONE ACETATE; TOBRAMYCIN

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

FLUOXYMESTERONE

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

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL
FLURAZEPAM HCL

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

FLUTAMIDE

CAPSULE; ORAL
EULEXIN

	SCHERING	125MG¤	N18554 001 JAN 27, 1989

FOLIC ACID

TABLET; ORAL
FOLIC ACID

/AA/	/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

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

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

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

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

>DLT>	/HALDOL/DECANOATE/			
>DLT>	/MCNEIL/PHARM/	/EQ/50MG/BASE/ML/	/N18701/001/	
>DLT>			/JAN/14,/1986/	
>ADD>	HALDOL DECANOATE 50			
>ADD>	RW JOHNSON	EQ 50MG BASE/ML	N18701 001	
>ADD>			JAN 14, 1986	

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

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

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

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

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

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

HEPARIN SODIUM 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/500/UNITS/AND/SODIUM/CHLORIDE/0.9%/IN/ /PLASTIC/CONTAINER/

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

HEXOCYCLIUM METHYLSULFATE

/TABLET;/ORAL/ /TRAL/

	/ABBOTT/LABS/	/25MG/	/N10599/001/
	∂ 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/
	∂ PBI	25MG	N87780 001
			MAR 29, 1982
	∂	50MG	N87751 001
			MAR 29, 1982
/AA/	/VANGARD/LABS/	/50MG/	/N87908/001/
			/MAY/07,/1982/
	∂ 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/
	∂ CHELSEA LABS	25MG;15MG;0.1MG	N85771 001

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/BOOTS/LABS/	/25MG/	/N84325/001/
/AB/		/50MG/	/N84324/001/

HYDROCHLOROTHIAZIDE

TABLET; ORAL

	HYDROCHLOROTHIAZIDE		
/AB/	/CHELSEA/LABS/	/25MG/	/N85232/002/
/AB/		/50MG/	/N85233/001/
/AB/		/50MG/	/N86087/001/
/AB/		/50MG/	/N86594/001/
/AB/		/100MG/	/N87002/001/
	∂ CHELSEA LABS	25MG	N85232 002
	∂	50MG	N85233 001
	∂	50MG	N86087 001
	∂	50MG	N86594 001
	∂	100MG	N87002 001
/AB/	/PBI/	/25MG/	/N87827/001/ /APR 19, 1982/
/AB/		/50MG/	/N87752/001/ /APR 19, 1982/
	∂ PBI	25MG	N87827 001 APR 19, 1982
	∂	50MG	N87752 001 APR 19, 1982
AB	PHARMAFAIR	25MG	N84325 001
AB		50MG	N84324 001
/AB/	/VANGARD/LABS/	/25MG/	/N87638/001/
/AB/		/50MG/	/N87610/001/
	∂ VANGARD LABS	25MG	N87638 001
	∂	50MG	N87610 001
/AB/	/WHITE/TN/PAULSN/	/25MG/	/N83809/002/
/AB/		/50MG/	/N83809/001/
/AB/		/100MG/	/N85347/001/
	∂ WHITE TN PAULSN	25MG	N83809 002
	∂	50MG	N83809 001
	∂	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.P.-50/		
/BP/	/WHITE/TN/PAULSN/	/50MG;0.125MG/	/N85338/001/
	∂ WHITE TN PAULSN	50MG;0.125MG	N85338 001
	HYDROCHLOROTHIAZIDE W/ RESERPINE		
	/∂/BOOTS/PHARMS/	/50MG;0.125MG/	/N85420/001/
/BP/	/CHELSEA/LABS/	/25MG;0.125MG/	/N86330/002/
/BP/		/50MG;0.125MG/	/N86331/001/
	∂ CHELSEA LABS	25MG;0.125MG	N86330 002
	∂	50MG;0.125MG	N86331 001
	∂ PHARMAFAIR	50MG;0.125MG	N85420 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

	SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE		
/AB/	/CHELSEA/LABS/	/25MG;25MG/	/N86026/001/
	∂ CHELSEA LABS	25MG;25MG	N86026 001
/AB/	/PBI/	/25MG;25MG/	/N87651/001/
	∂ PBI	25MG;25MG	N87651 001
/AB/	/VANGARD/LABS/	/25MG;25MG/	/N87655/001/
	∂ 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
/A/	/VITARINE/	/25MG;50MG/	/N71337/001/	/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 > /AB/	/QUANTUM/PHARMCS/	/50MG;75MG/	/N71980/001/	/FEB/01,/1988/
>ADD > BX	QUANTUM PHARMCS	50MG;75MG	N71980 001	FEB 01, 1988
/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

/BP/	/WHITE/TN/PAULSN/	/10MG/	/N80344/001/	
/BP/		/20MG/	/N80344/002/	
∂	WHITE TN PAULSN	10MG	N80344 001	
∂		20MG	N80344 002	

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE

AT	PARKE DAVIS	1%	N89914 001	JAN 03, 1989

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

>DLT >	/AEROSOL;/RECTAL/			
>DLT >	/PROCTOFOAM/HC/			
>DLT >	/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
>ADD >	PROCTOFOAM HC			
>ADD > 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	N86662/001 FEB 14, 1986
AP		25MG/ML	N89106/001 FEB 14, 1986
AP		50MG/ML	N89107/001 FEB 14, 1986
∂	PHARMAFAIR	25MG/ML	N88862 001 FEB 14, 1986
∂		25MG/ML	N89106 001 FEB 14, 1986
∂		50MG/ML	N89107 001 FEB 14, 1986

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

AA	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

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

PEDIA PROFEN

AA	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
			N71264/001 JUL 25, 1986

IBUPROFEN

TABLET; ORAL

IBUPROFEN

AB	BOOTS USA	400MG	N70083 001 FEB 22, 1985
AB		600MG	N70556 001 JUN 14, 1985
∂		800MG	N71264 001 JUL 25, 1986
AA	CHELSEA LABS	300MG	N71338/001 DEC 01, 1986
∂	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
∂		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
∂	CHELSEA LABS	10MG	N85875 001
∂		25MG	N85878 001
∂		50MG	N85877 001
AB	PBI	25MG	N87776/001 FEB 10, 1982
∂	PBI	25MG	N87776 001 FEB 10, 1982

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

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

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

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/

IOHEXOL

/INJECTABLE;/INJECTION/ /OMNIPAQUE/300/ /STERLING/DRUG/	/64.7%/		/N18956/003/ /DEC/26,/1985/
/OMNIPAQUE/350/ /STERLING/DRUG/	/75.5%/		/N18956/004/ /DEC/26,/1985/

SOLUTION; INJECTION, ORAL

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

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

/AN/	/BAXTER/	/0.08%/		/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

> ADD > **KETOROLAC TROMETHAMINE**

> ADD > INJECTABLE; INJECTION
> ADD > TORADOL

> ADD >	SYNTEX LABS	15MG/ML¤	N19698 001	NOV 30, 1989
> ADD >		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 R&D	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; METHYLPARABEN/

/TABLET;ORAL/

/EUTHROID-0.5/			
/PARKE/DAVIS/	/0.03MG;0.0075MG/	/N16686/001/	
/EUTHROID-1/			
/PARKE/DAVIS/	/0.06MG;0.015MG/	/N16686/002/	
/EUTHROID-2/			
/PARKE/DAVIS/	/0.12MG;0.03MG/	/N16686/003/	
/EUTHROID-3/			
/PARKE/DAVIS/	/0.18MG;0.045MG/	/N16686/004/	
/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/

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

LIDOCAINE HYDROCHLORIDE

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

LIDOCAINE HCL
AT PACO RES 4%¤ N89688 001
JUN 30, 1989

LIOTRIX (T4;T3)

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

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

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

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

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

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

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

MALATHION

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

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

MANNITOL

SOLUTION; IRRIGATION
/RESECTISOL/
/KENDALL/MCGAW/ /5GM/100ML/ /N16764/002/

MANNITOL

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

MEBENDAZOLE

TABLET, CHEWABLE; ORAL
VERMOX
/JANSSEN PHARMA/
JANSSEN RES — /100MG/ 100MG — /N17481/001/ 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/
	∂ VANGARD LABS	12.5MG	N87877 001 APR 20, 1982
	∂	25MG	N87620 001 JAN 04, 1982

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLODIUM
/QUANTUM PHARMCS/

>DLT >/AB/		/EQ 50MG BASE/	/N71380/001/ /JUL 14, 1987/
>DLT >		/EQ 100MG BASE/	/N71381/001/ /JUL 14, 1987/
>DLT >/AB/			
>DLT >			
>ADD > BX	QUANTUM PHARMCS	EQ 50MG BASE	N71380 001 JUL 14, 1987
>ADD >		EQ 100MG BASE	N71381 001 JUL 14, 1987
>ADD > BX			
>ADD >			
	MECLOFENAMATE SODIUM		
AB	BARR LABS	EQ 50MG BASE*	N72848 001 MAR 20, 1989
AB		EQ 100MG BASE*	N72809 001 MAR 20, 1989

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM
/VITARINE/

/AB/		/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
/VITARINE/

/AB/		/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
∂ WALTER REED — 250MG* — N19578 001 MAY 02, 1989

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

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

MEPROBAMATE

TABLET; ORAL

	MEPROBAMATE			
/AA/	/BOOTS/PHARMS/	/400MG/	/N84153/001/	
/AA/	/CHELSEA/LABS/	/600MG/	/N85719/001/	
	ə CHELSEA LABS	600MG	N85719 001	
/AA/	/LEDERLE/LABS/	/400MG/	/N86299/001/	
	ə LEDERLE LABS	400MG	N86299 001	
	ə PHARMAFAIR	400MG	N84153 001	
/AA/	/VANGARD/LABS/	/400MG/	/N88011/001/	JUL 14, 1982
	ə VANGARD LABS	400MG	N88011 001	JUL 14, 1982
/AA/	/WHITE/TN/PAULSN/	/200MG/	/N83830/001/	
/AA/		/400MG/	/N83442/001/	
	ə WHITE TN PAULSN	200MG	N83830 001	
	ə	400MG	N83442 001	

MESNA

INJECTABLE; INJECTION

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

METAPROTERENOL SULFATE

SOLUTION; INHALATION

/AN/	/DEY-DOSE/	/5%/	/N70005/001/	/AUG/17,/1987/
	/DEY/LABS/			
/AN/	/DEY-LUTE/	/0.4%/	/N71786/001/	/AUG/05,/1988/
	/DEY/LABS/	/0.6%/	/N70804/001/	/AUG/17,/1987/
/AN/		/0.63%/	/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			
	/3/DORSEY/LABS/	/1MG/	/N13420/001/	
	ə SANDOZ PHARMS	1MG	N13420 001	

METHOCARBAMOL

TABLET; ORAL

	METHOCARBAMOL			
	/3/BOOTS/PHARMS/	/500MG/	/N84231/002/	
	/3/	/750MG/	/N84471/001/	
	ə PHARMAFAIR	500MG	N84231 002	
	ə	750MG	N84471 001	

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM

/AP/	/LYPHOMED/	/EQ 20MG BASE/VIAL/	/N88935/001/ /OCT/11,/1985/
/AP/		/EQ 50MG BASE/VIAL/	/N88936/001/ /OCT/11,/1985/
/AP/		/EQ 100MG BASE/VIAL/	/N88937/001/ /OCT/11,/1985/
∂	LYPHOMED	EQ 20MG BASE/VIAL	N88935 001 OCT 11, 1985
∂		EQ 50MG BASE/VIAL	N88936 001 OCT 11, 1985
∂		EQ 100MG BASE/VIAL	N88937 001 OCT 11, 1985

MEXATE-AQ

/AP/	/BRISTOL/CARIB/	/EQ 25MG BASE/ML/	/N88760/001/ /FEB/14,/1985/
AP	BRISTOL MYERS	EQ 25MG BASE/ML	N88760 001 FEB 14, 1985

MEXATE-AQ PRESERVED

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

METHYCLOTHIAZIDE

TABLET; ORAL

METHYCLOTHIAZIDE

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

METHYLDOPA

TABLET; ORAL

METHYLDOPA

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

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

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

METHYLPREDNISOLONE ACETATE

/ENEMA;/RECTAL/

/MEDROL/

/UPJOHN/		/40MG/BOT/	/N18102/001/
∂	UPJOHN	40MG/BOT	N18102 001

METHYLTESTOSTERONE

TABLET; BUCCAL

ANDROID 5

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

TABLET; ORAL

ANDROID 10

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

ANDROID 25

/AB/	/BROWN/PHARM/	/25MG/	/N87147/001/
AB	ICN PHARMS	25MG	N87147 001

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

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

METOCLOPRAMIDE HYDROCHLORIDE

MINOXIDIL

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL
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	

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

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

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

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	
AB		20MG	N18482 002	
			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 SEP 06, 1989
		60MG	N19684 002 SEP 06, 1989
		90MG	N19684 003 SEP 06, 1989

NITROFURANTOIN

TABLET; ORAL

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

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

	NITROFURANTOIN MACROCRYSTALLINE		
AB	BOLAR PHARM	50MG	N70248 001 JUN 24, 1988
AB		100MG	N70249 001 JUN 24, 1988
BX	BOLAR PHARM	50MG	N70248 001 JUN 24, 1988
BX		100MG	N70249 001 JUN 24, 1988

NITROGLYCERIN

	OINTMENT; TOPICAL		> DLT >	
	NITROGLYCERIN		> DLT >	
	ALTANA	2%	> DLT >	N87355 001 JUL 08, 1988
			> DLT >	
	OINTMENT; TRANSDERMAL		> ADD >	
	NITROGLYCERIN		> ADD >	
	ALTANA	2%	> ADD >	N87355 001 JUL 08, 1988

NYSTATIN

POWDER; ORAL

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

TABLET; VAGINAL

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

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

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

† DELAYED EFFECTIVE DATE PENDING COURT DECISION

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/
∂ SEARLE	2.5MG	N13718 001

OXAZEPAM

CAPSULE; ORAL
ZAXOPAM

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

OXYBUTYNIN CHLORIDE

TABLET; ORAL
OXYBUTYNIN CHLORIDE

AB	BOLAR PHARM	5MG	N72485 001 APR 19, 1989

OXYTOCIN

INJECTABLE; INJECTION

/OXYTOCIN/10/USP/UNITS/IN/DEXTROSE/5%/			
/ABBOTT/LABS/		/1/USP/UNIT/100ML/	/N19185/004/ /MAR/29,/1985/
		/2/USP/UNITS/100ML/	/N19185/003/ /MAR/29,/1985/
∂ ABBOTT LABS		1 USP UNIT/100ML	N19185 004 MAR 29, 1985
∂		2 USP UNITS/100ML	N19185 003 MAR 29, 1985
/OXYTOCIN/20/USP/UNITS/IN/DEXTROSE/5%/			
/ABBOTT/LABS/		/2/USP/UNITS/100ML/	/N19185/002/ /MAR/29,/1985/
∂ 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/TN/PAULSN/ /100MG/ /N83338/001/
∂ WHITE TN PAULSN 100MG N83338 001

PERMETHRIN

CREAM; TOPICAL
ELIMITE
BURROUGHS WELLC 5%* N19855 001
AUG 25, 1989

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
/DI-METREX/
/AA/ /PRIVATE/FMLTNS/ /35MG/ /N85698/001/
∂ PRIVATE FMLTNS 35MG N85698 001
PHENDIMETRAZINE TARTRATE
/AA/ /CHELSEA/LABS/ /35MG/ /N85767/001/
/AA/ /35MG/ /N85768/001/
/AA/ /35MG/ /N85770/001/
/AA/ /35MG/ /N85773/001/
∂ CHELSEA LABS 35MG N85767 001
∂ 35MG N85768 001
∂ 35MG N85770 001
∂ 35MG N85773 001
/AA/ /PRIVATE/FMLTNS/ /35MG/ /N85199/001/
∂ PRIVATE FMLTNS 35MG N85199 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL
/AA/ /CHELSEA/LABS/ /30MG/ /N86740/001/
/MAR/21,/1985/
∂ CHELSEA LABS 30MG N86740 001
MAR 21, 1985

TABLET; ORAL
PHENTERMINE HCL
/AA/ /CHELSEA/LABS/ /8MG/ /N85739/001/
∂ CHELSEA LABS 8MG N85739 001

PHENYL AMINOSALICYLATE

/POWDER;/ORAL/
/PHENY-PAS-TEBAMIN/
/PURDUE/FRDRK/ /50%/ /N11695/002/
∂ PURDUE FRDRK 50% N11695 002

/TABLET;/ORAL/
/PHENY-PAS-TEBAMIN/
/PURDUE/FRDRK/ /500MG/ /N11695/003/
∂ PURDUE FRDRK 500MG N11695 003

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

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

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
PREFRIN-A
ALLERGAN PHARMS 0.12%;0.1% N07953 001

PHENYTOIN SODIUM, PROMPT

CAPSULE; ORAL
PHENYTOIN SODIUM
/3/BOOTS/PHARMS/ /100MG/ /N85435/001/
@ PHARMAFAIR 100MG N85435 001

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

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

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

POWDER FOR RECONSTITUTION; ORAL
COLYTE
AA REED & CARNRICK 240GM/BOT;2.98GM/BOT;6.72GM/BOT;
5.84GM/BOT;22.72GM/BOT N18983 007
JUN 12, 1987
>DLT > /REED/&/CARNRICK/ /120GM/PACKET;1.49GM/PACKET;/
>DLT > /3.36GM/PACKET;2.92GM/PACKET;/
>DLT > /11.36GM/PACKET/ /N18983/005/
>DLT > /OCT/26,/1984/
>ADD > @ REED & CARNRICK 120GM/PACKET;1.49GM/PACKET;
>ADD > 3.36GM/PACKET;2.92GM/PACKET;
>ADD > 11.36GM/PACKET N18983 005
>ADD > OCT 26, 1984
/REED/&/CARNRICK/ /240GM/BOT;2.98GM/BOT;6.72GM/BOT;/
/5.84GM/BOT;22.72GM/BOT/ /N18983/007/
/JUN/12,/1987/
>DLT > /REED/&/CARNRICK/ /360GM/PACKET;4.47GM/PACKET;/
>DLT > /10.08GM/PACKET;8.76GM/PACKET;/
>DLT > /34.08GM/PACKET/ /N18983/006/
>DLT > /OCT/26,/1984/
>ADD > @ REED & CARNRICK 360GM/PACKET;4.47GM/PACKET;
>ADD > 10.08GM/PACKET;8.76GM/PACKET;
>ADD > 34.08GM/PACKET N18983 006
>ADD > OCT 26, 1984

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

POWDER FOR RECONSTITUTION; ORAL
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
>DLT >/AP/ /LYPHOMED/ /2MEQ/ML/ /N86713/001/
>DLT >/AP/ /2MEQ/ML/ /N86714/001/
>ADD > @ LYPHOMED 2MEQ/ML N86713 001
>ADD > @ 2MEQ/ML N86714 001

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; SODIUM CHLORIDE

PRAZOSIN HYDROCHLORIDE

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
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
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
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 MAY 16, 1989 : SEP 12, 1988
AB		EQ 2MG BASE	N71995 001 MAY 16, 1989 : SEP 12, 1988
AB		EQ 5MG BASE	N71745 001 MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

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

TABLET; ORAL
PREDNISOLONE
/BX/ /CHELSEA/LABS/ /5MG/ /N85415/001/
/BX/ /5MG/ /N85416/001/
∂ CHELSEA LABS 5MG N85415 001
∂ 5MG N85416 001
/BX/ /WHITE/TN/PAULSN/ /5MG/ /N80342/001/
∂ WHITE TN PAULSN 5MG N80342 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

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

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
/PREDNISOLONE SODIUM PHOSPHATE/
/∂/MAURRY/BIDL/ /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/

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

PREDNISONE

TABLET; ORAL
PREDNISONE
AB CORD LABS 10MG¤ N89983 001
JAN 12, 1989
AB 50MG¤ N89984 001
JAN 12, 1989
AB HALSEY DRUG 5MG N80300 001
/BX/ /5MG/ /N80300/001/
/ROXANE/LABS/ /25MG/ /N87833/001/
/MAY/04,/1982/
∂ 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
/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

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION
PROCAINAMIDE HCL

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

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL

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

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE

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

PROGESTERONE

INJECTABLE; INJECTION
PROGESTERONE

	/LILLY/	/25MG/ML/	/N09238/002/	
	ə LILLY	25MG/ML	N09238 002	

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
/ZIPAN-25/

/AP/	/ALTANA/	/25MG/ML/	/N83997/001/	
	ə ALTANA	25MG/ML	N83997 001	
	/ZIPAN-50/			
/AP/	/ALTANA/	/50MG/ML/	/N83997/002/	
	ə ALTANA	50MG/ML	N83997 002	

TABLET; ORAL
PROMETHAZINE HCL

	/ə/BOOTS/PHARMS/	/12.5MG/	/N84160/001/	
	/ə/	/25MG/	/N84166/001/	
	/ə/	/50MG/	/N84539/001/	
	ə BOOTS USA	12.5MG	N84160 001	
	ə	25MG	N84166 001	
	ə	50MG	N84539 001	

PROMETHAZINE HYDROCHLORIDE

TABLET; ORAL
PROMETHAZINE HCL

/BP/	/CHELSEA/LABS/	/12.5MG/	/N85986/001/	
/BP/		/25MG/	/N85684/001/	
/BP/		/50MG/	/N85664/001/	
	ə CHELSEA LABS	12.5MG	N85986 001	
	ə	25MG	N85684 001	
	ə	50MG	N85664 001	

> ADD > ## PROPAFENONE HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > RYTHMOL

> ADD >	KNOLL PHARM	150MG¤	N19151 001	
> ADD >			NOV 27, 1989	
> ADD >		300MG¤	N19151 002	
> ADD >			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/	
	ə 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 HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

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

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

>DLT>/AB/	/MARTEC PHARM/	/10MG/	/N70120/001/	/AUG 06, 1985/
>DLT>				
>DLT>/AB/		/20MG/	/N70121/001/	/AUG 06, 1985/
>DLT>				
>DLT>/AB/		/40MG/	/N70122/001/	/AUG 06, 1985/
>DLT>				
>DLT>/AB/		/60MG/	/N70123/001/	/OCT 29, 1986/
>DLT>				
>DLT>/AB/		/80MG/	/N70124/001/	/AUG 06, 1985/
>DLT>				
>ADD>	∂ MARTEC PHARM	10MG	N70120 001	AUG 06, 1985
>ADD>				
>ADD>	∂	20MG	N70121 001	AUG 06, 1985
>ADD>				
>ADD>	∂	40MG	N70122 001	AUG 06, 1985
>ADD>				
>ADD>	∂	60MG	N70123 001	OCT 29, 1986
>ADD>				
>ADD>	∂	80MG	N70124 001	AUG 06, 1985
>ADD>				
AB	MYLAN PHARMS	60MG*	N72275 001	JUN 09, 1989

PROPYLIODONE

SUSPENSION; INTRATRACHEAL

/DIONOSIL/AQUEOUS/

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

PROPYLTHIOURACIL

TABLET; ORAL

PROPYLTHIOURACIL

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

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

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

PYRIDOSTIGMINE BROMIDE

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

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

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

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIDINE GLUCONATE
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
AB	WHITE TN PAULSN	200MG	N85444 001

RESERPINE

TABLET; ORAL
RESERPINE

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

RIFAMPIN

CAPSULE; ORAL
RIFADIN

AB	DOW PHARMS	300MG	N50420 001
		150MG	N62303 001
AB	MERRELL DOW	300MG	N50420 001
		150MG	N62303 001

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

SAFFLOWER OIL

INJECTABLE; INJECTION
LIPOSYN/10%
ABBOTT LABS — 10% — N18203 001

LIPOSYN/20%
ABBOTT LABS — 20% — N18614 001

SCOPOLAMINE

FILM, EXTENDED RELEASE; PERCUTANEOUS
TRANSDERM-SCOP
CIBA PHARM — 0.5MG/24HR — N17874 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM
WHITE TN PAULSN — 100MG — N85798 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
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

>ADD> DRESSING; TOPICAL
>ADD> SILDIMAC
>ADD> MARION LABS 1%¤ N19608 001
>ADD> 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

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

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
/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 PYROPHOSPHATE KIT

INJECTABLE; INJECTION
> DLT > /AN-PYROTEC/
> DLT > /AP/ /CIS/US/ /N/A/ /N19039/001/
> DLT > /JUN/30,/1987/
> ADD > ∂ CIS US N/A N19039 001
> ADD > 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/

SOLUTION; INJECTION, ORAL
AN-SULFUR COLLOID

CIS US	N/A	N17858 001

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL
TETRACYCLINE HCL

/A/	/BOOTS/PHARMS/	/250MG/	/N61802/001/
/A/		/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
/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

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

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR

/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/

a 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

TABLET; ORAL

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

>DLT >/AB/ /QUANTUM/PHARMCS/ /5MG/ /N72466/001/ /MAY/19,/1989/

>DLT >/AB/ /10MG/ /N72467/001/ /MAY/19,/1989/

>DLT >/AB/ /20MG/ /N72468/001/ /MAY/19,/1989/

>ADD > BX QUANTUM PHARMCS 5MG N72466 001 MAY 19, 1989

>ADD > BX 10MG N72467 001 MAY 19, 1989

>ADD > BX 20MG N72468 001 MAY 19, 1989

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

NEBCIN

AP LILLY EQ 10MG BASE/ML N50477 005

AP EQ 10MG BASE/ML N62008 004

AP EQ 10MG BASE/ML N62707 001 APR 29, 1987

AP EQ 40MG BASE/ML N62008 001

TOBRAMYCIN SULFATE

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

TRIALODINE

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

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE

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

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
TRIAMCINOLONE ACETONIDE

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

TRICHLORMETHIAZIDE

TABLET; ORAL
TRICHLORMETHIAZIDE

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

TRIHEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL
ARTANE

AA	LEDERLE LABS	2MG/5ML	N06773 009

TRIHEXYPHENIDYL HCL

AA	LIQUIPHARM	2MG/5ML¤	N89514 001 APR 07, 1989

TABLET; ORAL
TRIHEXYPHENIDYL HCL

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

TRIMIPRAMINE MALEATE

CAPSULE; ORAL
TRIMIPRAMINE MALEATE

/AB/	/VITARINE/	/EQ 25MG BASE/	/N71832/001/ /SEP/10,/1987/
/AB/		/EQ 50MG BASE/	/N71833/001/ /SEP/10,/1987/
/AB/		/EQ 100MG BASE/	/N71834/001/ /SEP/10,/1987/
BX	VITARINE	EQ 25MG BASE	N71832 001 SEP 10, 1987
BX		EQ 50MG BASE	N71833 001 SEP 10, 1987
BX		EQ 100MG BASE	N71834 001 SEP 10, 1987

TRIPELENNAMINE HYDROCHLORIDE

TABLET; ORAL
TRIPELENNAMINE HCL

/AA/	/CHELSEA/LABS/	/50MG/	/N085188/001/	
	∂ CHELSEA LABS	50MG	N85188 001	

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL
TRIPROLIDINE HCL

/AA/	/BARRE/NATL/	/1.25MG/5ML/	/N085940/001/	
	∂ BARRE NATL	1.25MG/5ML	N85940 001	
/AA/	/HALSEY/DRUG/	/1.25MG/5ML/	/N088735/001/ /JAN/17,/1985/	
	HALSEY DRUG	1.25MG/5ML	N88735 001 JAN 17, 1985	

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL
VERAPAMIL HCL

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

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE

>DLT >/AP/	/LYPHOMED/	/10MG/VIAL/	/N089011/001/ /NOV/18,/1985/	
>DLT > >ADD > >ADD >	∂ LYPHOMED	10MG/VIAL	N89011 001 NOV 18, 1985	

VITAMIN A

CAPSULE; ORAL
VITAMIN A

>DLT >/AA/	/CHASE/CHEM/	/50,000 IU/	/N083351/001/	
>ADD >	∂ CHASE CHEM	50,000 IU	N83351 001	

VITAMIN A PALMITATE

CAPSULE; ORAL
VITAMIN A

>DLT >/AA/	/CHASE/CHEM/	/EQ 50,000 UNITS BASE/	/N080746/001/	
>DLT >/AA/		/EQ 50,000 UNITS BASE/	/N083207/001/	
>ADD >	∂ CHASE CHEM	EQ 50,000 UNITS BASE	N80746 001	
>ADD >	∂	EQ 50,000 UNITS BASE	N83207 001	

WATER FOR IRRIGATION, STERILE

LIQUID; IRRIGATION
STERILE WATER IN PLASTIC CONTAINER

/AT/	/CUTTER/BIOL/	/100%/	/N018246/001/	
	∂ CUTTER BIOL	100%	N18246 001	

ZIDOVUDINE

SYRUP; ORAL
RETROVIR

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

ACETAMINOPHEN

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

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

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

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
BIOSCRUB
KW GRIFFEN 4%¤ N19822 001 MAR 31, 1989
E-Z SCRUB 107
DESERET MED 4%¤ N72525 001 OCT 24, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
/PSEUDO-CHLOR/
/KV/PHARM/ /12MG;120MG/ /N71455/001/ /MAR/01,/1989/
PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE
KV PHARM 12MG;120MG N71455 001 MAR 01, 1989
PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE
/GRAHAM/LABS/ /8MG;120MG/ /N18844/001/ /MAR/20,/1985/
@ GRAHAM LABS 8MG;120MG N18844 001 MAR 20, 1985

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

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

CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX

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

CLOTRIMAZOLE

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

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

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

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

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

DIPHENHYDRAMINE HYDROCHLORIDE

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

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

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

IBUPROFEN

TABLET; ORAL
IBUPROFEN

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

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL
COADVIL

WHITEHALL LABS	200MG;30MG¤	N19771 001 SEP 19, 1989

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 70/30

LILLY	30 UNITS/ML; 70 UNITS/ML¤	N19717 001 APR 25, 1989

LOPERAMIDE HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > IMODIUM A-D

> ADD > MCNEIL CONSUMER	2MG¤	> ADD > N19860 001 NOV 22, 1989

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

/VISINE/11/ /PFIZER/	/0.025%/	/N19407 001 MAR 31, 1989/
VISINE L.R. PFIZER	0.025%¤	N19407 001 MAR 31, 1989

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

/SYRUP; ORAL/
/PHENERGAN/VC/

/A/WYETH/AYERST/LABS/	/10MG/5ML;6.25MG/5ML/	/N88604 004 AUG 11, 1988/

POVIDONE-IODINE

SOLUTION; TOPICAL
E-Z PREP

BECTON DICKINSN	10%¤	N19382 001 JUL 25, 1989

POVIDONE IODINE

BAXTER	1%¤	N19522 001 MAR 31, 1989

SPONGE; TOPICAL
E-Z PREP

BECTON DICKINSN	5%¤	N19382 002 JUL 25, 1989

E-Z PREP 220

BECTON DICKINSN	5%¤	N19382 003 JUL 25, 1989

E-Z SCRUB 201

BECTON DICKINSN	20%	N19240 001 NOV 29, 1985

E-Z SCRUB 241

BECTON DICKINSN	10%	N19476 001 JAN 07, 1987
/DESERET/MED/	/10%/	/N19476 001 JAN 07, 1987/

/POVIDONE-IODINE/

/DESERET/MED/	/10%/	/N19240 001 NOV 29, 1985/

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
TRIPROLIDINE AND PSEUDOEPHRINE HCL

KV PHARM	120MG;5MG¤	N71798 001 MAR 16, 1989

SYRUP; ORAL
/HYFED/

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

PSEUDOEPHEDRINE POLISTIREX

SUSPENION, EXTENDED RELEASE; ORAL

PSEUDO-12		
FISONS	EQ 60MG HCL/5ML	N19401 001
		JUN 19, 1987
/PENWALT/	/EQ/60MG/HCL/5ML/	/N19401/001/
		/JUN/19/1987/

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT LIST
CUMULATIVE SUPPLEMENT NUMBER 11 / JAN '89 - NOV '89

NO NOVEMBER 1989 APPROVALS

ORPHAN DRUG DESIGNATIONS

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

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

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

REFER BACK TO THE ADDENDUM TO APPROVED DRUG PRODUCTS, 9TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS INCLUDES DESIGNATIONS THROUGH MARCH 31, 1989. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

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

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ANCROD TRADE: ARVIN	FOR USE AS AN ANTITHROMBOTIC IN PATIENTS WITH HEPARIN-INDUCED THROMBOCYTOPENIA OR THROMBOSIS, WHO REQUIRE IMMEDIATE AND CONTINUED ANTICOAGULATION.	KNOLL PHARMACEUTICALS 30 NO. JEFFERSON RD WHIPPANY, NJ 07981
GENERIC: ANTIHEMOPHILIC FACTOR (RECOMBINANT) TRADE: NOT ESTABLISHED	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. CUTTER BIOLOGICAL ELKHART, IN 46515
GENERIC: 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.	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: 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

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: IODINE I 131 MURINE MONOCLONAL ANTIBODY IGG2A TO B CELL TRADE: IMMURAIT, LL-2-I-131	TREATMENT OF B-CELL LEUKEMIA AND B-CELL LYMPHOMA.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060
GENERIC: MONOCLONAL FACTOR IX TRADE: NOT ESTABLISHED	REPLACEMENT TREATMENT AND PROPHYLAXIS OF HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B.	ARMOUR PHARMACEUTICAL COMPANY 920A HARVEST DRIVE SUITE 200 BLUE BELL, PA 19422
GENERIC: PEG-L-ASPARAGINASE TRADE: NOT ESTABLISHED	TREATMENT OF ACUTE LYMPHOCYTIC LEUKEMIA (ALL).	ENZON, INC. 300-C CORPORATE COURT SOUTH PLAINFIELD, NJ 07080
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY^9) TO MYELOID CELLS (CD-33) TRADE: ANTI-MY^9-BR	TREATMENT OF MYELOID LEUKEMIAS.	IMMUNOGEN, INC. 148 SIDNEY STREET CAMBRIDGE, MA 02139
GENERIC: TECHNETIUM TC 99M MURINE MONOCLONAL ANTIBODY TO HUMAN ALPHA-FETOPROTEIN TRADE: IMMURAID, AFP-TC99M	DETECTION HEPATOCELLULAR CARCINOMA AND HEPATOBLASTOMA. DETECTION OF ALPHA-FETOPROTEIN (AFP) PRODUCING GERM CELL TUMORS.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
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: CITRIC ACID, GLUCONO-DELTA-LACTONE, AND MAGNESIUM CARBONATE TRADE: RENACIDIN	TREATMENT OF RENAL AND BLADDER CALCULI OF THE APATITE OR STRUVITE VARIETY.	UNITED GUARDIAN, INC. 230 MARCUS BLVD. HAUPPUAGE, NY 11788
GENERIC: DIHEMATOPORPHYRIN ETHERS TRADE: PHOTOFRIN	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

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: DIHEMATOPORPHYRIN ETHERS TRADE: PHOTOFRIN II	USE FOR THE PHOTODYNAMIC THERAPY OF PATIENTS WITH PRIMARY OR RECURRENT OBSTRUCTING (EITHER PARTIALLY OR COMPLETELY) ESOPHAGEAL CARCINOMA.	QLT PHOTOTHERAPEUTICS, INC. NORTH MIDDLETOWN ROAD PEARL RIVER, NY 10965
GENERIC: ENISOPROST TRADE: NOT ESTABLISHED	FOR CO-ADMINISTRATION WITH CYCLOSPORINE IN ORGAN TRANSPLANT RECIPIENTS TO REDUCE ACUTE TRANSPLANT REJECTION. FOR CO-ADMINISTRATION WITH CYCLOSPORINE IN ORGAN TRANSPLANT RECIPIENTS TO DIMINISH THE NEPHROTOXICITY INDUCED BY CYCLOSPORINE.	G.D. SEARLE & CO. 4901 SEARLE PARKWAY SKOKIE, IL 60077
GENERIC: ETHIOFOS TRADE: ETHYOL	USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN AND CYCLOPHOSPHAMIDE IN THE TREATMENT OF OVARIAN CARCINOMA. USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN IN THE TREATMENT OF METASTATIC MELANOMA.	U.S. BIOSCIENCE, INC 920-B HARVEST DRIVE P.O. BOX 220 BLUE BELL, PA 19422
GENERIC: FLUDARABINE PHOSPHATE TRADE: NOT ESTABLISHED	TREATMENT OF NON-HODGKIN'S LYMPHOMA (NHL).	TRITON BIOSCIENCES 1501 HARBOR BAY PARKWAY ALAMEDA, CA 94501
GENERIC: FLUOROURACIL TRADE: NOT APPLICABLE	FOR USE IN COMBINATION WITH INTERFERON ALFA-2A RECOMBINANT FOR THE TREATMENT OF ESOPHAGEAL CARCINOMA.	HOFFMAN-LA ROCHE INC 340 KINGSLAND STREET NUTLEY, NJ 07110
GENERIC: GANCICLOVIR (DHPG) TRADE: CYTOVENE*/**	TREATMENT OF CYTOMEGALOVIRUS (CMV) RETINITIS IN IMMUNOCOMPROMISED INDIVIDUALS, INCLUDING PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)*/**. [JUN 23, 1996]	SYNTEX (U.S.A.), INC. 3401 HILLVIEW AVENUE PALO ALTO, CA 94304

GENERIC: GANCICLOVIR (DHPG) TRADE: CYTOVENE*/**	TREATMENT OF CYTOMEGALOVIRUS (CMV) RETINITIS IN IMMUNOCOMPROMISED INDIVIDUALS, INCLUDING PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)*/**. [JUN 23, 1996]	SYNTEX (U.S.A.), INC. 3401 HILLVIEW AVENUE PALO ALTO, CA 94304

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-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: LEVOCARNITINE TRADE: VITACARN	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: 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

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: SELEGILINE HCL TRADE: ELDEPRYL*/** (FORMERLY DEPRENYL)	ADJUNCT IN THE MANAGEMENT OF PARKINSONIAN PATIENTS BEING TREATED WITH LEVODOPA/CARBIDOPA WHO EXHIBIT DETERIORATION IN THE QUALITY OF THEIR RESPONSE TO THIS THERAPY*/**. [JUNE 05, 1996]	SOMERSET PHARMACEUTICALS ONE OLDE TOWNE COURT BERNARDSVILLE, NJ 07924

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: SOMATROPIN TRADE: SAIZEN	ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES 100 LONGWATER CIRCLE NORWELL, MA 02061
GENERIC: SYNTHETIC SURFACTANT TRADE: EXOSURF	PREVENTION OF HYALINE MEMBRANE DISEASE (HMD), ALSO KNOWN AS RESPIRATORY DISTRESS SYNDROME (RDS), IN INFANTS BORN AT 32 WEEKS GESTATION OR LESS. TREATMENT OF ESTABLISHED HMD AT ALL GESTATIONAL AGES.	BURROUGHS WELLCOME 3030 CORNWALLIS RD RESEARCH TRIANGLE PK, NC 27709
GENERIC: T4 ENDONUCLEASE V, LIPOSOME ENCAPSULATED TRADE: T4N5	TO PREVENT CUTANEOUS NEOPLASMS AND OTHER SKIN ABNORMALITIES ASSOCIATED WITH PATIENTS DIAGNOSED WITH XERODERMA PIGMENTOSUM (XP).	APPLIED GENETICS, INC. 205 BUFFALO AVENUE FREEPORT, NY 11520
GENERIC: TROLEANDOMYCIN TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE STEROID-REQUIRING ASTHMA	STANLEY SZEFLER, MD NATIONAL JEWISH CENTER FOR IMMUNOLOGY AND RESPIRATORY MEDICINE 1400 JACKSON STREET DENVER, CO 80206
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 PRODUCTS WHICH MUST DEMONSTRATE IN VIVO BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

NO NOVEMBER 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	89P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989

HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HALOPERIDOL DECANOATE INJECTABLE; INJECTION	EQ 50MG BASE/ML (2ML/CONTAINER)	88 P-0411/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
HYDROCORTISONE VALERATE LOTION; TOPICAL	0.2%	89 P-0028/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
HYDROCORTISONE VALERATE SOLUTION; TOPICAL	0.2%	89 P-0029/CP	MCKENNA, CONNER & CUNEO	NEW DOSAGE FORM	APPROVED MAY 10, 1989
MORPHINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	30MG	89 P-0071/CP	OXFORD RES INTL	NEW DOSAGE FORM	APPROVED MAY 10, 1989
PENTETATE PENTASODIUM; STANNOUS CHLORIDE (TECHNETIUM TC-99M PENTETATE KIT) INJECTABLE; INJECTION	10MG 0.55MG	89 P-0113/CP	CADEMA MED PRODS	NEW STRENGTH	APPROVED JUL 14, 1989
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE IN PLASTIC CONTAINER POWDER FOR RECONSTITUTION; ORAL	59GM/PACKET 0.7425GM/PACKET 1.685GM/PACKET 1.465M/PACKET 5.685GM/PACKET	88 P-0419/CP	GUIDELINES	NEW STRENGTH	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
PREDNISONE CAPSULE; ORAL	1MG 2.5MG 5MG 10MG 20MG 25MG 50MG	88 P-0391/CP	ASCHER	NEW DOSAGE FORM	APPROVED MAR 01, 1989
THIOTEPA, STERILE INJECTABLE; INJECTION	30MG/VIAL 60MG/VIAL	88 P-0412/CP	QUAD PHARMS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ALLOPURINOL SODIUM INJECTABLE; INJECTION	500MG (30ML/VIAL)	89 P-0103/CP	BURROUGHS WELLC	NEW DOSAGE FORM NEW INGREDIENT (NEW SALT) NEW ROUTE OF ADMINISTRATION	DENIED JUL 14, 1989
PHENYLPROPANOLAMINE HYDROCHLORIDE FILM, EXTENDED RELEASE; PERCUTANEOUS	150MG	88 P-0265/CP	BIO AMERICAN	NEW DOSAGE FORM NEW STRENGTH NEW INDICATION	DENIED OCT 07, 1988

EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

REFERENCES
NEW 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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	19937 002	ADENOSINE; ADENOCARD	4673563	JUN 16, 2004	U-56	NCE	OCT 30, 1994
>ADD>	19729 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
	18240 001	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
>ADD>			3836671	SEP 17, 1991	U-57		
>DLT>			3836671	SEP 17, 1991	U-56		
>ADD>			3836671	SEP 17, 1991	U-58		
>DLT>			3836671	SEP 17, 1991	U-57		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
	18240 002	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
>ADD>			3836671	SEP 17, 1991	U-57		
>DLT>			3836671	SEP 17, 1991	U-56		
>ADD>			3836671	SEP 17, 1991	U-58		
>DLT>			3836671	SEP 17, 1991	U-57		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
>ADD>	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 08, 1999		NDF	OCT 27, 1992
	19507 002	BETAXOLOL HYDROCHLORIDE; KERLONE	4311708	JAN 19, 1999	U-5	NCE	AUG 30, 1990
			4252984	AUG 08, 1999		NDF	OCT 27, 1992
	18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18469 001	CALCIUM CHLORIDE; BSS PLUS	4550022	OCT 29, 2002			
			4443432	APR 17, 2001			
	19880 001	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 002	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 003	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	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
>ADD>	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
	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
	71611 001	CYCLOBENZAPRINE HYDROCHLORIDE; CYCLOBENZAPRINE HCL				PC	NOV 15, 1989

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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APPL/PROD NUMBER INGREDIENT NAME; TRADE NAME PATENT NUMBER PATENT EXPIRES USE CODE EXCLUS CODE EXCLUS EXPIRES

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
						I-97	NOV 28, 1992
>ADD>	17922 001	DESMOPRESSIN ACETATE; DDAVP				NCE	JUL 28, 1993
	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	NOV 05, 1992
	19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NP	JAN 23, 1992
						NCE	NOV 05, 1992
	19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NP	JAN 23, 1992
						NCE	NOV 05, 1992
	19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NP	JAN 23, 1992
						NCE	NOV 05, 1992
	19471 004	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NP	JAN 23, 1992
	19386 003	ESMOLOL HYDROCHLORIDE; BREVIBLOC	4387103	JUN 07, 2000	U-16	NCE	DEC 31, 1991
	18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
>ADD>			4472382	JAN 27, 2003	U-42		
>DLT>			~~4472382~~	~~SEP 18, 2001~~	~~U-42~~		
>ADD>			4329364	MAY 11, 2002	U-41		
>DLT>			~~4329364~~	~~MAY 11, 1999~~	~~U-41~~		
						I-88	APR 28, 1992
	19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST				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
	19778 001	HYDROCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
	19778 002	HYDROCHLOROTHIAZIDE; PRINZIDE 25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
			4374829	DEC 30, 2001		NC	FEB 16, 1992
	19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20/25	4472380	SEP 18, 2001			
			4374829	DEC 30, 2001		NCE	DEC 29, 1992
						NC	SEP 19, 1992
	19771 001	IBUPROFEN; COADVIL	4788220	NOV 29, 2005		NDF	SEP 19, 1992
	19833 002	IBUPROFEN; CHILDREN'S ADVIL				NDF	SEP 19, 1992
	19842 001	IBUPROFEN; PEDIA PROFEN				ODE	DEC 30, 1995
	19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
	19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992			

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	18956 001	IOHEXOL; OMNIPAQUE 180				I-89	JUN 30, 1992
	18956 002	IOHEXOL; OMNIPAQUE 240				I-90	JUN 30, 1992
						NR	JUN 30, 1992
						I-92	JUL 28, 1992
						I-93	JUL 28, 1992
	18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-85	MAR 31, 1992
						I-90	JUN 30, 1992
						NR	JUN 30, 1992
						I-94	JUL 28, 1992
						I-92	JUL 28, 1992
	18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-85	MAR 31, 1992
						NR	JUN 30, 1992
						I-90	JUN 30, 1992
						I-91	JUN 30, 1992
	18956 006	IOHEXOL; OMNIPAQUE 210	4396597	JUL 14, 1998			
			4250113	DEC 26, 1999		I-93	JUL 28, 1992
			4021481	MAY 03, 1994		NS	JUN 30, 1992
	18735 003	IOPAMIDOL; ISOVUE-370				I-55	OCT 04, 1992
	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
>ADD>	19698 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
>ADD>	19698 002	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
>ADD>	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
>ADD>	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
	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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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
>ADD>	19488 002	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993
>ADD>	19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
>ADD>			4765989	SEP 16, 2003			
>ADD>			4612008	SEP 16, 2003		NDF	SEP 06, 1992
>ADD>			4327725	MAY 04, 1997			
>ADD>			3916899	NOV 05, 1991			
>ADD>			3845770	NOV 05, 1991			
>ADD>	19684 002	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
>ADD>			4765989	SEP 16, 2003			
>ADD>			4612008	SEP 16, 2003		NDF	SEP 06, 1992
>ADD>			4327725	MAY 04, 1997			
>ADD>			3916899	NOV 05, 1991			
>ADD>			3845770	NOV 05, 1991			
>ADD>	19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
>ADD>			4765989	SEP 16, 2003			
>ADD>			4612008	SEP 16, 2003		NDF	SEP 06, 1992
>ADD>			4327725	MAY 04, 1997			
>ADD>			3916899	NOV 05, 1991			
>ADD>			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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS	4271143	JUN 02, 1998			
						NCE	NOV 27, 1994
>ADD>	19151 001	PROPAFENONE HYDROCHLORIDE; RYTHMOL				NCE	NOV 27, 1994
>ADD>	19151 002	PROPAFENONE HYDROCHLORIDE; RYTHMOL					
>ADD>	19627 001	PROPOFOL; DIPRIVAN	4798846	NOV 01, 1994			
			4056635	NOV 01, 1994		NCE	OCT 02, 1994
						NCE	JUN 05, 1994
	19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL				ODE	JUN 05, 1996
>ADD>	19608 001	SILVER SULFADIAZINE; SILDIMAC	4563184	JAN 07, 2003		NP	NOV 30, 1992
	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			
	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		
	19910 001	ZIDOVUDINE; RETROVIR				NCE	MAR 19, 1992