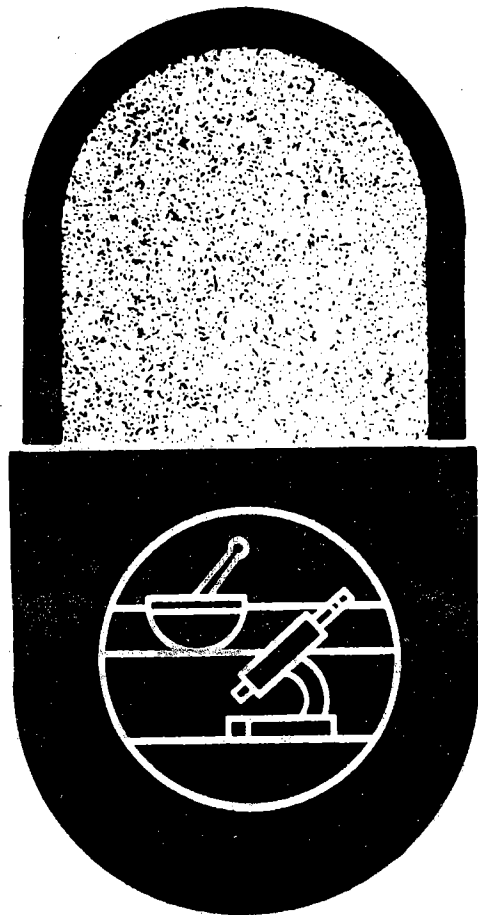


**CUMULATIVE
SUPPLEMENT 12
JAN'89-DEC'89**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

9TH EDITION

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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
9TH EDITION

CUMULATIVE SUPPLEMENT 12

DECEMBER 1989

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
9th EDITION
CUMULATIVE SUPPLEMENT 12
DECEMBER 1989

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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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 remain 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 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 approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the "Ⓢ" symbol to designate their non-marketed status. All products having a "Ⓢ" symbol in the 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.

<u>Products</u>	<u>Federal Register Reference</u>
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

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>NEW ABBREVIATED NAME</u>
DUPONT CRITICAL CARE SUB EI DUPONT DE NEMOURS & COMPANY INC	DUPONT PHARMACEUTICALS DIV EI DUPONT DE NEMOURS & CO INC	DUPONT PHARMS
INTERNATIONAL PHARMACEUTICAL PRODUCTS INC	NORBROOK AMERICA INC	NORBROOK AM
MAURRY BIOLOGICAL CO INC	NORBROOK AMERICA INC	NORBROOK AM
NORBROOK AMERICA INC	AKORN INC	AKORN
3M RIKER	3M PHARMACEUTICALS	3M PHARMS

APPLICANT (NAME) CHANGES

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>NEW ABBREVIATED NAME</u>
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

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

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

PRESCRIPTION DRUG PRODUCT LIST
9TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'89 - DEC'89

1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

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

TABLET; ORAL

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

/AA/	<u>ACETAMINOPHEN AND CODEINE PHOSPHATE</u>			
/AA/	/DURAMED/PHARMS/	/300MG;15MG/		/N88353/001/
				/FEB/06,1984/
/AA/		/300MG;30MG/		/N88354/001/
				/FEB/06,1984/
/AA/		/300MG;60MG/		/N88355/001/
				/FEB/06,1984/
	3	DURAMED PHARMS	300MG;15MG	N88353 001
				FEB 06, 1984
	3		300MG;30MG	N88354 001
				FEB 06, 1984
	3		300MG;60MG	N88355 001
				FEB 06, 1984
AA	PUREPAC PHARM	300MG;30MG		N86681 001
AA		300MG;60MG		N86683 001
	ROXANE LABS	500MG;15MG		N89511 001
				APR 25, 1989
		500MG;30MG		N89512 001
				APR 25, 1989
		500MG;60MG		N89513 001
				APR 25, 1989
/AA/	<u>ACETAMINOPHEN W/ CODEINE PHOSPHATE</u>			
/AA/	/PBI/	/300MG;30MG/		/N87919/001/
				/JUN/22,1982/
/AA/		/300MG;60MG/		/N87920/001/
				/JUN/22,1982/
	3	PBI	300MG;30MG	N87919 001
				JUN 22, 1982
	3		300MG;60MG	N87920 001
				JUN 22, 1982

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

/AA/	<u>ACETAMINOPHEN W/ CODEINE PHOSPHATE</u>			
/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/
	3	WHITE TN PAULSN	300MG;30MG	N84360 001
	3		300MG;60MG	N85607 001
/AA/	<u>CODEINE PHOSPHATE AND ACETAMINOPHEN</u>			
/AA/	/ICN/PHARMS/	/300MG;30MG/		/N85696/001/
	3	ICN PHARMS	300MG;30MG	N85696 001
/AA/	/PAPA-DEINE #3/			
/AA/	/VANGARD/LABS/	/300MG;30MG/		/N88037/001/
	3	VANGARD LABS	300MG;30MG	N88037 001
				MAR 20, 1984
/AA/	/PAPA-DEINE #4/			
/AA/	/VANGARD/LABS/	/300MG;60MG/		/N88715/001/
	3	VANGARD LABS	300MG;60MG	N88715 001
				MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

AA	<u>ALLAY</u>			
AA	LUCHER PHARMS	500MG;5MG		N89907 001
				JAN 13, 1989
AA	<u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u>			
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

AA	<u>ANEXSTIA</u>			
AA	BEECHAM LABS	500MG;5MG		N89160 001
				APR 23, 1987
AA	<u>ANEXSTIA 7.5/650</u>			
AA	BEECHAM LABS	650MG;7.5MG		N89725 001
				SEP 30, 1987
/AA/	/ANEXSTIA-D/			
/AA/	/BEECHAM/LABS/	/500MG;5MG/		/N89160/001/
				/APR/23,1987/

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
 /AA/ /BEECHAM/LABS/ /650MG;7.5MG/ /N89725/001/
 /SEP/30/1989/ N89698 001
 MIKART 500MG;2.5MG 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
 AA TYLOX
 MCNEIL PHARM 500MG;5MG N88790 001
 DEC 12, 1984

TABLET; ORAL
OXYCODONE/2.5/APAP/500
 /DUPONT/PHARMS/ /500MG;2.5MG/ /N85910/001/
 @ DUPONT PHARMS 500MG;2.5MG N85910 001
 /AA/ OXYCODONE 5/APAP 500
 /DUPONT/PHARMS/ /500MG;5MG/ /N85911/001/
 @ DUPONT PHARMS 500MG;5MG N85911 001
ROXICET 5/500
 /AA/ /ROXANE/LABS/ /500MG;5MG/ /N89775/001/
 /JAN/12/1989/ N89775 001
 ROXANE LABS 500MG;5MG JAN 12, 1989

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

CAPSULE; ORAL
 TYLOX
 /@/MCNEIL/LABS/ /500MG;4.5MG;0.38MG/ /N85375/001/
 @ RW JOHNSON 500MG;4.5MG;0.38MG N85375 001

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL
PROPOXYPHENE HCL AND ACETAMINOPHEN
 AA CORD LABS 650MG;65MG N89959 001
 JUL 18, 1989

ACETAZOLAMIDE

TABLET; ORAL
ACETAZOLAMIDE
 /AB/ /VANGARD/LABS/ /250MG/ /N87654/001/
 /FEB/05/1982/ N87654 001
 @ VANGARD LABS 250MG FEB 05, 1982

ACETRIZOATE SODIUM

/SOLUTION; INTRAUTERINE/
 /SALPIX/
 /ORTHO/PHARM/ /53%/ /N89008/001/
 @ RW JOHNSON 53% N09008 001

ACETYLCYSTEINE

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

ACYCLOVIR

> ADD > SUSPENSION; ORAL
 > ADD > ZOVIRAX
 > ADD > BURROUGHS WELLC 200MG/5ML N19909 001
 > ADD > DEC 22, 1989

ADENOSINE

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

ALBUMIN, CHROMATED CR-51 SERUMINJECTABLE; INJECTION
CHROMALBIN

ISO TEX DIAGS	100 UCI/VIAL	N17835 001
2	250 UCI/VIAL	N17835 002
2	500 UCI/VIAL	N17835 003
/SQUIBB/DIAGS/	/100 UCI/VIAL/	/N17835/001/
/2/	/250 UCI/VIAL/	/N17835/002/
/2/	/500 UCI/VIAL/	/N17835/003/

ALBUMIN, IODINATED I-125 SERUM

INJECTABLE; INJECTION

ALBUMOTOPE 125 I		
2 ISO TEX DIAGS	5-50 UCI/AMP	N17836 001
/SQUIBB/	/5-50 UCI/AMP/	/N17836/001/

ALBUMIN, IODINATED I-131 SERUM

INJECTABLE; INJECTION

ALBUMOTOPE 131 I		
2 ISO TEX DIAGS	5 UCI/AMP	N17837 004
2	20 UCI/AMP	N17837 005
	0.5MCI/VIAL	N17837 001
	1MCI/VIAL	N17837 002
2	2MCI/VIAL	N17837 003
/SQUIBB/	/5 UCI/AMP/	/N17837/004/
/2/	/20 UCI/AMP/	/N17837/005/
	/0.5MCI/VIAL/	/N17837/001/
	/1MCI/VIAL/	/N17837/002/
/2/	/2MCI/VIAL/	/N17837/003/

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

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

ALBUTEROL SULFATE

TABLET; ORAL

ALBUTEROL SULFATE

> ADD >	AB	LEDERLE LABS	EQ 2MG BASEM	N72859 001
> ADD >				DEC 20, 1989
> ADD >	AB		EQ 4MG BASEM	N72860 001
> ADD >				DEC 20, 1989
	AB	MUTUAL PHARM	EQ 2MG BASEM	N72636 001
			DEC 05, 1989 : FEB 01, 1989	
	AB		EQ 4MG BASEM	N72637 001
			DEC 05, 1989 : FEB 01, 1989	
	AB	SIDMAK LABS	EQ 2MG BASEM	N72316 001
			DEC 05, 1989 : JAN 30, 1989	
	AB		EQ 4MG BASEM	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
	2	100MG	N18297 001
	2	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%/	/N10401/001/
		/OCT/10/1986/

AMINO ACIDSINJECTABLE; INJECTION

/AMINOSYN/11/3.5%/IN/PLASTIC/CONTAINER/
 @ ABBOTT LABS 3.5%

N19491 001
 OCT 10, 1986

AMINO ACIDS; DEXTROSEINJECTABLE; 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/11/3.5%/M/IN/PLASTIC/CONTAINER/
 /ABBOTT/LABS/ /3.5%;32MG/100ML;128MG/100ML;/
 /222MG/100ML;49MG/100ML/ /N19493/001/
 /OCT/16./1986/

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

AMINOPHYLLINETABLET; ORALAMINOPHYLLINE

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

AMITRIPTYLINE HYDROCHLORIDETABLET; ORALAMITRIPTYLINE HCL

/AB/ /CHELSEA/LABS/ /150MG/ /N85821/001/
 @ CHELSEA LABS 150MG N85821 001

/AB/ /LEDERLE/LABS/ /10MG/ /N87366/001/
 /JAN/04./1982/

/AB/ /25MG/ /N87367/001/
 /MAY/03./1982/

/AB/ /50MG/ /N87181/001/
 /JAN/04./1982/

/AB/ /75MG/ /N87369/001/
 /JAN/04./1982/

/AB/ /100MG/ /N87368/001/
 /MAY/03./1982/

/AB/ /150MG/ /N87370/001/
 /JAN/04./1982/

@ LEDERLE LABS 10MG N87366 001
 JAN 04, 1982

@ 25MG N87367 001
 MAY 03, 1982

@ 50MG N87181 001
 JAN 04, 1982

@ 75MG N87369 001
 JAN 04, 1982

@ 100MG N87368 001
 MAY 03, 1982

@ 150MG N87370 001
 JAN 04, 1982

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTYLINE HCL

/AB/	/PBI/	/25MG/
Q	PBI	25MG
/AB/	/ROXANE LABS/	/10MG/
/AB/		/25MG/
/AB/		/50MG/
/AB/		/75MG/
/AB/		/100MG/
/AB/		/150MG/
Q	ROXANE LABS	10MG
Q		25MG
Q		50MG
Q		75MG
Q		100MG
Q		150MG
/AB/	/VANGARD LABS/	/10MG/
/AB/		/25MG/
/AB/		/50MG/
/AB/		/75MG/
/AB/		/100MG/
Q	VANGARD LABS	10MG
Q		25MG
Q		50MG
Q		75MG
Q		100MG

/N87775/001/
 /FEB/10,1982/
 N87775 001
 FEB 10, 1982
 /N86144/001/
 /N86145/001/
 /N86143/001/
 /N86147/001/
 /N86146/001/
 /N86148/001/
 N86144 001
 N86145 001
 N86143 001
 N86147 001
 N86146 001
 N86148 001
 /N87632/001/
 /FEB/01,1982/
 /N87570/001/
 /FEB/08,1982/
 /N87616/001/
 /FEB/08,1982/
 /N87617/001/
 /FEB/05,1982/
 /N87639/001/
 /FEB/08,1982/
 N87632 001
 FEB 01, 1982
 N87570 001
 FEB 08, 1982
 N87616 001
 FEB 08, 1982
 N87617 001
 FEB 05, 1982
 N87639 001
 FEB 08, 1982

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

AB	DANBURY PHARMA	10MG;2MG
AB		10MG;4MG
AB		25MG;2MG
AB		25MG;4MG
AB		50MG;4MG

N72539 001
 FEB 15, 1989
 N72540 001
 FEB 15, 1989
 N72541 001
 FEB 15, 1989
 N72134 001
 FEB 15, 1989
 N72135 001
 FEB 15, 1989

AMMONIUM LACTATE

LOTION; TOPICAL

LAC-HYDRIN

/BRISTOL MYERS/

WESTWOOD PHARMS

/EQ/12%/ACID/

EQ 12% ACID

/N19155/001/
 /APR/24,1985/
 N19155 001
 APR 24, 1985

AMOXAPINE

TABLET; ORAL

AMOXAPINE

AB	WATSON LABS	25MG
AB		50MG
AB		100MG
AB		150MG

N72418 001
 MAY 11, 1989
 N72419 001
 MAY 11, 1989
 N72420 001
 MAY 11, 1989
 N72421 001
 MAY 11, 1989

ASENDIN

AB	LEDERLE LABS	25MG
AB		50MG
AB		100MG
AB		150MG

N18021 001
 N18021 002
 N18021 003
 N18021 004

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

AB	LEMMON	250MG
AB		500MG

N63030 001
 FEB 28, 1989
 N63031 001
 FEB 28, 1989

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

/TAG/PHARMS/

/250MG/

/N63030/001/

/FEB/28/1989/

/500MG/

/N63031/001/

/FEB/28/1989/

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

AB NOVOPHARM

250MG/5ML

N63001 001

JAN 06, 1989

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

AMPICILLIN

AB CLONMEL CHEMS

EQ 125MG BASE/5ML

N62982 001

FEB 10, 1989

AB

EQ 250MG BASE/5ML

N62982 002

FEB 10, 1989

/TABLET;/CHEWABLE;/ORAL/

/POLYICILLIN/

/BRISTOL/LABS/

/EQ/125MG/BASE/

/N50093/001/

a BRISTOL LABS

EQ 125MG BASE

N50093 001

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL ASPIRIN AND CAFFEINE

> DLT > /AB/ /QUANTUM/PHARMCS/ /325MG;50MG;40MG/

> DLT >

> ADD >

> ADD >

a QUANTUM PHARMCS

325MG;50MG;40MG

/N88972/001/

/JUN/18/1985/

N88972 001

JUN 18, 1985

BUTALBITAL W/ ASPIRIN & CAFFEINE

/AB/ /BOOTS/LABS/

/325MG;50MG;40MG/

/N87048/002/

/DEC/09/1983/

AB PHARMAFAIR

325MG;50MG;40MG

N87048 002

DEC 09, 1983

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

MORGESIC

AB 3M RIKER

385MG;30MG;25MG

N13416 003

OCT 27, 1982

/3M/RIKER/

/385MG;30MG;25MG/

/N13416/003/

/OCT/27/1982/

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

MORGESIC FORTE

AB 3M RIKER

770MG;60MG;50MG

N13416 004

OCT 27, 1982

/3M/RIKER/

/770MG;60MG;50MG/

/N13416/004/

/OCT/27/1982/

ORPHENADRINE COMPOUND

/AB/ /VITARINE/

/385MG;30MG;25MG/

/N71564/001/

/JUN/23/1988/

BX VITARINE

385MG;30MG;25MG

N71564 001

JUN 23, 1988

ORPHENADRINE COMPOUND DOUBLE STRENGTH

/AB/ /VITARINE/

/770MG;60MG;50MG/

/N71565/001/

/JUN/23/1988/

BX VITARINE

770MG;60MG;50MG

N71565 001

JUN 23, 1988

ORPHENGESIC

/AB/ /PAR/PHARM/

/385MG;30MG;25MG/

/N71642/001/

/JUN/23/1987/

BX PAR PHARM

385MG;30MG;25MG

N71642 001

JUN 23, 1987

ORPHENGESIC FORTE

/AB/ /PAR/PHARM/

/770MG;60MG;50MG/

/N71643/001/

/JUN/23/1987/

BX PAR PHARM

770MG;60MG;50MG

N71643 001

JUN 23, 1987

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE/

/AA/ /CHELSEA/LABS/

/389MG;32.4MG;65MG/

/N85732/002/

/SEP/03/1984/

a CHELSEA LABS

389MG;32.4MG;65MG

N85732 002

SEP 03, 1984

ASPIRIN; CARISOPRODOL

TABLET; ORAL

CARISOPRODOL AND ASPIRIN

AB PAR PHARM

325MG;200MG

N89594 001

MAR 31, 1989

ASPIRIN; MEPROBAMATE

TABLET; ORAL
 > DLT > /Q-GENIC/
 > DLT > /AB/ /QUANTUM/PHARMCS/ /325MG;200MG/ /N88740/001/
 > DLT > /JUN/01/1984/
 > ADD > @ QUANTUM PHARMCS 325MG;200MG N88740 001
 > ADD > JUN 01, 1984

ATENOLOL

INJECTABLE; INJECTION

TENORMIN

ICI PHARM

0.5MG/MLM

N19058 001
SEP 13, 1989

TABLET; ORAL

TENORMIN

AB ICI PHARM

50MG

N18240 001

AB 100MG

N18240 002

/AB/ /STUART/PHARMS/ /50MG/ /N18240/001/

/AB/ /100MG/ /N18240/002/

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

AA CHELSEA LABS 0.025MG;2.5MG N85876 001

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

@ LEDERLE LABS 0.025MG;2.5MG N86950 001

AA PHARMAFAIR 0.025MG;2.5MG N85035 001

DIPHENOXYLATE HCL W/ ATROPINE SULFATE

/AA/ /CHELSEA/LABS/ /0.025MG;2.5MG/ /N85876/001/

/AA/ /PBI/ /0.025MG;2.5MG/ /N87842/001/

@ PBI 0.025MG;2.5MG N87842 001

/MAR/29/1982/

N87842 001

MAR 29, 1982

/DIPHENOXYLATE W/ ATROPINE SULFATE/

/AA/ /BOOTS/LABS/ /0.025MG;2.5MG/ /N85035/001/

/AA/ /LO-TROL/ /0.025MG;2.5MG/ /N88009/001/

@ VANGARD LABS 0.025MG;2.5MG N88009 001

/MAR/25/1983/

N88009 001

MAR 25, 1983

AZTREONAM

INJECTABLE; INJECTION

AZACTAM IN PLASTIC CONTAINER

SQUIBB

10MG/MLM

N50632 003

MAY 24, 1989

20MG/MLM

N50632 002

MAY 24, 1989

40MG/MLM

N50632 001

MAY 24, 1989

BACLOFEN

TABLET; ORAL

BACLOFEN

/AB/ /VITARINE/

/10MG/

/N71901/001/

/APR/13/1988/

/AB/

/20MG/

/N71902/001/

/APR/13/1988/

BX VITARINE

10MG

N71901 001

APR 13, 1988

BX

20MG

N71902 001

APR 13, 1988

BENDROFLUMETHIAZIDE

TABLET; ORAL

/NATURETIN-2.5/

/SQUIBB/

/2.5MG/

/N12164/001/

@ SQUIBB

2.5MG

N12164 001

BENZONATATE

CAPSULE; ORAL

TESSALON

/DUPONT/PHARMS/

/100MG/

/N11210/001/

FOREST LABS

100MG

N11210 001

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA INVAMED

0.5MG

N72264 001

FEB 27, 1989

AA

1MG

N72265 001

FEB 27, 1989

AA

2MG

N72266 001

FEB 27, 1989

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

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

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

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

CREAM, AUGMENTED; TOPICAL

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

LOTION; TOPICAL

/BX/	/DIPROLENE/		
	/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

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

BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL

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

BETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC

> ADD >	BETOPTIC S		
> ADD >	ALCON LABS	EQ 0.25% BASEM	N19845 001
> ADD >			DEC 29, 1989

TABLET; ORAL

KERLONE			
LOREX PHARMS	10MGm	N19507 001	
		OCT 27, 1989	
	20MGm	N19507 002	
		OCT 27, 1989	

BETHANECHOL CHLORIDE

TABLET; ORAL

/AA/	/BETHANECHOL CHLORIDE	/5MG/	/N85841/001/
/AA/	/CHELSEA/LABS/	/10MG/	/N85842/001/
/AA/		/25MG/	/N85839/001/
@	CHELSEA LABS	5MG	N85841 001
@		10MG	N85842 001
@		25MG	N85839 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE			
/LYPHOMED/	/100MG/ML/	/N71298/001/	
@ LYPHOMED	100MG/ML	/FEB/13/1987/	
		N71298 001	
		FEB 13, 1987	

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

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

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL

<u>AA/</u>	<u>BROMPHENIRAMINE MALEATE</u> /BARRE NATL/	<u>/2MG/5ML/</u>	<u>/N86936/001/ N86936 001</u>
<u>AA/</u>	/PBI/	<u>/2MG/5ML/</u>	<u>/N87964/001/ /JAN/25./1983/ N87964 001 JAN 25, 1983</u>
	ABBOTT LABS	2MG/5ML	

TABLET; ORAL

<u>AA/</u>	<u>BROMPHENIRAMINE MALEATE</u> /CHELSEA LABS/	<u>/4MG/</u>	<u>/N85769/001/ N85769 001</u>
<u>AA/</u>	/CORD LABS/	<u>/4MG/</u>	<u>/N83215/001/ N83215 001</u>
	CHELSEA LABS	4MG	
	CORD LABS	4MG	

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE;
PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

<u>AA/</u>	<u>BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; /PBI/</u>	<u>/2MG/5ML; 10MG/5ML; /12.5MG/5ML/</u>	<u>/N88904/001/ /FEB/21./1985/</u>
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BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE;
PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

<u>AA</u>	<u>MYPHETANE DC</u> PBI	<u>2MG/5ML; 10MG/5ML; 12.5MG/5ML</u>	N88904 001 FEB 21, 1985
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BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE;
PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

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

BUPROPION HYDROCHLORIDE

/TABLET; ORAL/

<u>AA/</u>	<u>WELLBUTRIN/</u> /BURROUGHS WELLC/	<u>/50MG/</u>	<u>/N18644/001/ /DEC/30./1985/</u>
<u>AA/</u>		<u>/75MG/</u>	<u>/N18644/002/ /DEC/30./1985/</u>
<u>AA/</u>		<u>/100MG/</u>	<u>/N18644/003/ /DEC/30./1985/</u>

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

<u>AA/</u>	<u>BUTABARBITAL SODIUM</u> /CHELSEA LABS/	<u>/15MG/ /30MG/</u>	<u>/N85764/001/ /N85772/001/</u>
<u>AA/</u>		<u>15MG</u>	N85764 001
<u>AA/</u>		<u>30MG</u>	N85772 001

BUTABARBITAL SODIUM

TABLET; ORAL

BUTABARBITAL SODIUM

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

CALCITONIN, SALMON

INJECTABLE; INJECTION

CALCIMAR

/RORER/PHARM/

2 RORER PHARM

/400 IU/VIAL/

400 IU/VIAL

/N17497/001/

N17497 001

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION

ISOLYTE E W/ DEXTROSE 5% IN PLASTIC CONTAINER

/KENDALL/MCGAW/

/35MG/100ML; 5GM/100ML; 30MG/100ML; /

/74MG/100ML; 640MG/100ML; 500MG/100ML; /

/74MG/100ML/

/N18269/002/

/JAN 17, 1983/

KENDALL MCGAW

35MG/100ML; 5GM/100ML; 30MG/100ML;

74MG/100ML; 640MG/100ML; 500MG/100ML;

74MG/100ML

N18269 002

JAN 17, 1983

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

SOLUTION; INTRAPERITONEAL

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

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

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

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION

ISOLYTE E IN PLASTIC CONTAINER

KENDALL MCGAW

35MG/100ML; 30MG/100ML; 74MG/100ML;

640MG/100ML; 500MG/100ML;

74MG/100ML

N19718 001

SEP 29, 1989

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; IRRIGATION

RINGER'S IN PLASTIC CONTAINER

/AT/	/ABBOTT/LABS/	/33MG/100ML; 30MG/100ML; /	
		/860MG/100ML/	/N18462/001/
	2 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/
	2 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

/0000000000/

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

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

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

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

> ADD > CEFMETAZOLE SODIUM

> ADD > INJECTABLE; INJECTION

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

CEFTIRAMIDE SODIUM

INJECTABLE; INJECTION
CEFTIRAMIDE SODIUM
WYETH AYERST LABS

EQ 1GM BASE/VIALM N50633 002
JAN 31, 1989
EQ 2GM BASE/VIALM N50633 003
JAN 31, 1989
EQ 10GM BASE/VIALM N50633 005
JAN 31, 1989

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
FORTAZ IN PLASTIC CONTAINER
GLAXO

EQ 10MG BASE/MLM N50634 001
APR 28, 1989
EQ 20MG BASE/MLM N50634 002
APR 28, 1989
EQ 40MG BASE/MLM N50634 003
APR 28, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION
ZINACEF IN PLASTIC CONTAINER
GLAXO

EQ 15MG BASE/MLM N50643 001
APR 28, 1989
EQ 30MG BASE/MLM N50643 002
APR 28, 1989

CEPHALEXIN

CAPSULE; ORAL

CEFALEX

AB BRISTOL MYERS

EQ 250MG BASEM N63063 001
SEP 29, 1989
EQ 500MG BASEM N63063 002
SEP 29, 1989

CEPHALEXIN

AB LEMMON

EQ 250MG BASE N62821 001
FEB 05, 1988
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/

/AB/

BX VITARINE

BX

/EQ '250MG' BASE/

/EQ '500MG' BASE/

EQ 250MG BASE

EQ 500MG BASE

/N62159/001/

/N62159/002/

N62159 001

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/5MLM

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 BIOCRRAFT LABS

EQ 250MG BASEM

N63023 001

JAN 12, 1989

AB

EQ 500MG BASEM

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

CERULETIDE DIETHYLAMINE

/INJECTABLE; INJECTION/	
/TYMITRAN/	
/ADRIA/LABS/	/0.02MG/ML/
Q ADRIA LABS	0.02MG/ML

/N18296/001/
N18296 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL			
<u>A-POXIDE</u>			
/AB/	/ABBOTT/LABS/	/5MG/	/N85447/001/
/AB/		/5MG/	/N85517/001/
/AB/		/10MG/	/N85447/002/
/AB/		/10MG/	/N85518/001/
/AB/		/25MG/	/N85447/003/
/AB/		/25MG/	/N85513/001/
Q	ABBOTT LABS	5MG	N85447 001
Q		5MG	N85517 001
Q		10MG	N85447 002
Q		10MG	N85518 001
Q		25MG	N85447 003
Q		25MG	N85513 001
<u>CHLORDIAZEPOXIDE HCL</u>			
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/
Q	LEDERLE LABS	5MG	N87234 001
Q		10MG	N87037 001
Q		25MG	N87231 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL			
<u>CHLORDIAZEPOXIDE HCL</u>			
/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/
Q	LEMMON	5MG	N88705 001
Q		10MG	N88706 001
Q		25MG	N86494 001
Q		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/
Q	ROXANE LABS	5MG	N84706 001
Q		10MG	N84700 001
Q		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/
Q	VANGARD LABS	5MG	N88129 001
Q		10MG	N88010 001
Q		25MG	N88130 001
			MAR 28, 1983

CHLOROQUINE HYDROCHLORIDE

/INJECTABLE; INJECTION/			
/ARALEN/			
/STERLING/	/EQ/40MG/BASE/ML/		/N06002/002/
INJECTABLE; INJECTION			
ARALEN HCL			
STERLING DRUG	EQ 40MG BASE/ML		N06002 002

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/AA/	/3/	BOOTS/PHARMS/	/4MG/	/N83753/001/
/AA/	/3/	CHELSEA/LABS/	/4MG/	/N85139/001/
		3 CHELSEA LABS	4MG	N85139 001
/AA/	/3/	LEDERLE/LABS/	/4MG/	/N86941/001/
		3 LEDERLE LABS	4MG	N86941 001
		3 PHARMAFAIR	4MG	N83753 001
> DLT >/AA/	/3/	QUANTUM/PHARMS/	/4MG/	/N80938/001/
> ADD >		3 QUANTUM PHARMS	4MG	N80938 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

/BC/	/3/	CHELSEA/LABS/	/12MG;75MG/	/N88681/001/
		3 CHELSEA LABS	12MG;75MG	/SEP/29,1987/
				N88681 001
AB		CORD LABS	12MG;75MG	SEP 29, 1987
				N88940 001
				JAN 26, 1989

ORNADE

AB		SK&F LABS	12MG;75MG	N12152 004
/BC/	/3/		/12MG;75MG/	/N12152/004/

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, 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/

CHLORPROMAZINE HYDROCHLORIDE

TABLET; ORAL

CHLORPROMAZINE HCL

	3	BOOTS USA	10MG	N84414 001
	3		25MG	N84415 001
	3		50MG	N84411 001
	3		100MG	N84412 001
	3		200MG	N84413 001
/BP/	/3/	CHELSEA/LABS/	/10MG/	/N85959/001/
/BP/	/3/		/25MG/	/N85956/001/
/BP/	/3/		/50MG/	/N85960/001/
/BP/	/3/		/100MG/	/N85957/001/
/BP/	/3/		/200MG/	/N85958/001/
	3	CHELSEA LABS	10MG	N85959 001
	3		25MG	N85956 001
	3		50MG	N85960 001
	3		100MG	N85957 001
	3		200MG	N85958 001
/BP/	/3/	VANGARD/LABS/	/10MG/	/N88038/001/
/BP/	/3/		/25MG/	/AUG/16,1982/
/BP/	/3/		/50MG/	/N87645/001/
	3	VANGARD LABS	10MG	/N87646/001/
				N88038 001
				AUG 16, 1982
	3		25MG	N87645 001
	3		50MG	N87646 001

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

/AB/	/3/	CHELSEA/LABS/	/250MG/	/N86866/001/
		3 CHELSEA LABS	250MG	N86866 001

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

/AB/	/3/	PARKE/DAVIS/	/25MG/	/N87515/001/
				/JAN/24,1983/
/AB/	/3/		/50MG/	/N87516/001/
				/FEB/09,1983/
/AB/	/3/	VANGARD/LABS/	/25MG/	/N88012/001/
				/JUL/14,1982/
/AB/	/3/		/50MG/	/N88073/001/
				/MAR/25,1983/
	3	VANGARD LABS	25MG	N88012 001
				JUL 14, 1982
	3		50MG	N88073 001
				MAR 25, 1983

CHLORTHALIDONE

TABLET; ORAL

CHLORTHALIDONE

AB WARNER CHILCOTT 25MG
AB 50MG

N87515 001
JAN 24, 1983
N87516 001
FEB 09, 1983

CHLORZOXAZONE

TABLET; ORAL

CHLORZOXAZONE

/AA/ /AM/THERPTCS/ /500MG/†
/AA/ /CHELSEA/LABS/ /250MG/†
a CHELSEA LABS 250MG
/AA/ /PAR/PHARM/ /500MG/†
AA PIONEER PHARMS 250MG
AA 500MG
AA ROYCE LABS 500MG

/N86911/001/†
/JUN/23/1989/
/N86948/001/†
/AUG/09/1982/
N86948 001
AUG 09, 1982
/N86948/001/†
/JUN/05/1989/
N89592 001
JAN 06, 1989
N89948 001
JAN 06, 1989
N81040 001
AUG 22, 1989

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

CHOLESTYRAMINE

POWDER; ORAL

QUESTRAN

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

CHYMOPAPAIN

INJECTABLE; INJECTION

CHYMODIACTIN

/BAXTER/

/4,000/UNITS/VIAL/

/10,000/UNITS/VIAL/

BOOTS USA

4,000 UNITS/VIAL

10,000 UNITS/VIAL

/N18663/002/
/AUG/21/1984/
/N18663/001/
/NOV/10/1982/
N18663 002
AUG 21, 1984
N18663 001
NOV 10, 1982

> ADD > AP
> ADD >
> ADD > AP
> ADD >

CHYMOPAPAIN

INJECTABLE; INJECTION

/DISCISE/

/BOOTS/PHARMS/

/12,500/UNITS/VIAL/

/N18625/001/
/JAN/18/1984/
N18625 001
JAN 18, 1984

a BOOTS USA

12,500 UNITS/VIAL

CLAVULANATE POTASSIUM; TICARCILLIN DISODIUM

INJECTABLE; INJECTION

TIMENTIN IN PLASTIC CONTAINER

BEECHAM LABS

EQ 100MG ACID/100ML;

EQ 3GM BASE/100ML

N50658 001
DEC 15, 1989

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HCL

AB BIOCRRAFT LABS

EQ 75MG BASE

N63027 001
SEP 20, 1989
N63029 001
SEP 20, 1989

AB

EQ 150MG BASE

/AB/ /VITARINE/

/EQ 75MG BASE/

/N62910/001/
/JUL/05/1988/
/N62910/002/
/JUL/05/1988/

/AB/

/EQ 150MG BASE/

BX VITARINE

EQ 75MG BASE

N62910 001
JUL 05, 1988
N62910 002
JUL 05, 1988

BX

EQ 150MG BASE

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER

UPJOHN

EQ 6MG BASE/ML

N50639 001
AUG 30, 1989
N50639 002
AUG 30, 1989

EQ 12MG BASE/ML

CLINDAMYCIN PHOSPHATE

AP ASTRA PHARM

EQ 150MG BASE/ML

N62928 001
FEB 13, 1989
N62908 001
FEB 01, 1989

AP DUPONT CRI CARE

EQ 150MG BASE/ML

N63041 001
DEC 29, 1989

KENDALL MCGAW

EQ 150MG BASE/ML

> ADD > AP
> ADD >

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

AP LEDERLE PARNTLS EQ 150MG BASE/MLM N63068 001
AUG 28, 1989

> ADD > CLINDAMYCIN PHOSPHATE IN DEXTROSE 5%
> ADD > AP LYPHOMED EQ 900MG BASE/100MLM N50635 001
> ADD > DEC 22, 1989
> ADD > AP EQ 12MG BASE/MLM N50636 001
> ADD > DEC 22, 1989
> ADD > CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER
> ADD > AP BAXTER EQ 6MG BASE/MLM N50648 001
> ADD > DEC 29, 1989
> ADD > AP EQ 900MG BASE/100MLM N50648 003
> ADD > DEC 29, 1989
> ADD > AP EQ 12MG BASE/MLM N50648 002
> ADD > DEC 29, 1989

LOTION; TOPICAL

CLEOCIN T

UPJOHN

EQ 1% BASEM N50600 001
MAY 31, 1989

SOLUTION; TOPICAL

CLINDAMYCIN PHOSPHATE

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

> ADD > CLOMIPRAMINE HYDROCHLORIDE

> ADD > CAPSULE; ORAL

ANAFRANIL

CIBA PHARM

25MGM N19906 001
DEC 29, 1989
50MGM N19906 002
DEC 29, 1989
75MGM N19906 003
DEC 29, 1989

CLONIDINE

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

> DLT > /CATAPRES-TTS-1/

> DLT > /BOEHR/INGEL/ /0.1MG/24HR/

> DLT > /CATAPRES-TTS-2/

> DLT > /BOEHR/INGEL/ /0.2MG/24HR/

> DLT > /CATAPRES-TTS-3/

> DLT > /BOEHR/INGEL/ /0.3MG/24HR/

/N18891/001/
/OCT/10,1984/

/N18891/002/
/OCT/10,1984/

CLONIDINE

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

> DLT > /CATAPRES-TTS-3/

> DLT > /BOEHR/INGEL/ /0.3MG/24HR/

> DLT > /N18891/003/
/OCT/10,1984/

> ADD > FILM, EXTENDED RELEASE; TRANSDERMAL

> ADD > CATAPRES-TTS-1

> ADD > BOEHR INGEL 0.1MG/24HR

> ADD > N18891 001
OCT 10, 1984

> ADD > CATAPRES-TTS-2

> ADD > BOEHR INGEL 0.2MG/24HR

> ADD > N18891 002
OCT 10, 1984

> ADD > CATAPRES-TTS-3

> ADD > BOEHR INGEL 0.3MG/24HR

> ADD > N18891 003
OCT 10, 1984

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

> DLT > /AB/ /AM/THERPTCS/ /0.1MG/

> DLT > /AB/ /0.2MG/

> DLT > /AB/ /0.3MG/

> DLT > /AB/ /0.3MG/

> DLT > /AB/ /0.3MG/

> ADD > BX AM THERPTCS 0.1MG

> ADD > 0.2MG

> ADD > 0.3MG

> ADD > 0.3MG

> ADD > 0.3MG

> ADD > 0.3MG

> ADD > 0.3MG

/N70881/001/
/MAY/27,1986/

/N70882/001/
/MAY/27,1986/

/N70883/001/
/MAY/27,1986/

N70881 001
MAY 27, 1986

N70882 001
MAY 27, 1986

N70883 001
MAY 27, 1986

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

/AB/ /CHELSEA/LABS/ /3.75MG/

/AB/ /7.5MG/

/AB/ /15MG/

/AB/ /15MG/

3 CHELSEA LABS 3.75MG

3 7.5MG

3 15MG

/N71878/001/
/MAR/15,1988/

/N71879/001/
/MAR/15,1988/

/N71860/001/
/MAR/15,1988/

N71878 001
MAR 15, 1988

N71879 001
MAR 15, 1988

N71860 001
MAR 15, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

> DLT >	/BX/	/QUANTUM/PHARMCS/	/3.75MG/	/N71544/001/
> DLT >				/SEP/12,1988/
> DLT >	/BX/		/7.5MG/	/N71550/001/
> DLT >				/SEP/12,1988/
> DLT >	/BX/		/15MG/	/N71522/001/
> DLT >				/SEP/12,1988/
> ADD >	@	QUANTUM PHARMCS	3.75MG	N71549 001
> ADD >				SEP 12, 1988
> ADD >	@		7.5MG	N71550 001
> ADD >				SEP 12, 1988
> ADD >	@		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/
	@	LEDERLE LABS	3.75MG
			N72013 001
	@		7.5MG
			N72014 001
	@		15MG
			N72015 001
			DEC 15, 1987
> DLT >	/BX/	/QUANTUM/PHARMCS/	/3.75MG/
> DLT >			
> DLT >	/BX/		/7.5MG/
> DLT >			
> DLT >	/BX/		/15MG/
> DLT >			
> ADD >	@	QUANTUM PHARMCS	3.75MG
> ADD >			
> ADD >	@		7.5MG
> ADD >			
> ADD >	@		15MG
> ADD >			

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

CLOXACILLIN SODIUM

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

CLOZAPINE

TABLET; ORAL

CLOZARIL

SANDOZ

25MG

N19758 001

SEP 26, 1989

100MG

N19758 002

SEP 26, 1989

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

/N/A;/N/A/

/RUBRATOPE-60/KIT/

/SQUIBB/

@ SQUIBB

/N/A;N/A;N/A;N/A/

N/A;N/A;N/A;N/A

/N16090/001/

N16090 001

CORTISONE ACETATE

TABLET; ORAL

CORTISONE ACETATE

> DLT > /BP/ /QUANTUM/PHARMCS/

/25MG/

/N80836/001/

> ADD > @ QUANTUM PHARMCS

25MG

N80836 001

> DLT > /BP/ /WHITE/TN/PAULSN/

/25MG/

/N80341/001/

@ WHITE TN PAULSN

25MG

N80341 001

CROMOLYN SODIUM

> ADD > CAPSULE; ORAL

GASTROCROM

> ADD > FISONS

100MG

N19188 001

> ADD >

DEC 22, 1989

CRYPTENAMINE ACETATES

/INJECTABLE;/INJECTION/

/UNITENSEN/

/WALLACE/LABS/

@ WALLACE LABS

/260/CSR/UNITS/ML/

260 CSR UNITS/ML

/N08814/001/

N08814 001

CYANOCOBALAMIN

INJECTABLE; INJECTION

/REBISOL/

/AB/ /MS&D/

@ MS&D

/1MG/ML/

1MG/ML

/N06668/010/

N06668 010

CYANOCOBALAMIN

INJECTABLE; INJECTION

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

CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

NEOSAR
 AP ADRIA LABS 2GM/VIALM 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/VIALM N71471 001
 AUG 02, 1989
 AP 500MG/VIALM N71472 001
 AUG 02, 1989

DEMECLOCYCLINE HYDROCHLORIDE

/SYRUP; ORAL/
/DECELOMYCIN/

/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%M N89170 001
 MAY 09, 1989
 AT MAXIDEX
ALCON LABS 0.1% N13422 001

TABLET; ORAL

DEXAMETHASONE

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

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

BP	DANBURY PHARMA	0.25MG	N85455 001
BP		0.5MG	N85458 001
BP		0.75MG	N80968 001
BP		1.5MG	N85456 001
/2/		/0.25MG/	/N85455/001/
/2/		/0.5MG/	/N85458/001/
/2/		/0.75MG/	/N80968/001/
/2/		/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
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DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN W/ DEXTROMETHORPHAN

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

INJECTABLE; INJECTION

DEXTROSE 50% IN PLASTIC CONTAINER

> ADD >	AP	ABBOTT LABS	50GM/100ML	N19894 001 DEC 26, 1989
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DEXTROSE 70% IN PLASTIC CONTAINER

> ADD >	AP	ABBOTT LABS	70GM/100ML	N19893 001 DEC 26, 1989
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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
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POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% IN PLASTIC CONTAINER

	KENDALL MCGAW	5GM/100ML; 110MG/100ML	N19699 003 SEP 29, 1989
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POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% IN PLASTIC CONTAINER

AP	KENDALL MCGAW	5GM/100ML; 150MG/100ML	N19699 004 SEP 29, 1989
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POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% IN PLASTIC CONTAINER

	KENDALL MCGAW	5GM/100ML; 220MG/100ML	N19699 005 SEP 29, 1989
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POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% IN PLASTIC CONTAINER

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

INJECTABLE; INJECTION

/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/ 10MG IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML; 15MG/100ML;/	/N18008/001/
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/AP/		/450MG/100ML/	/APR 28, 1982/
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/AP/		/5GM/100ML; 150MG/100ML;/	/N18008/001/
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/AP/		/450MG/100ML/	/APR 28, 1982/
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/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/ 15MG IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML; 224MG/100ML;/	/N18008/001/
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/AP/		/450MG/100ML/	/APR 28, 1982/
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/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/ 20MG (K) IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML; 300MG/100ML;/	/N18008/001/
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/AP/		/450MG/100ML/	/APR 28, 1982/
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/DEXTROSE 5%; SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/ 30MG IN PLASTIC CONTAINER/

/AP/	/BAXTER/	/5GM/100ML; 224MG/100ML;/	/N18008/001/
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/AP/		/450MG/100ML/	/APR 28, 1982/
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DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER
 /AP/ /BAXTER/ /5GM/100ML;300MG/100ML;/ /N18008/003/
 /450MG/100ML/ /APR/28/1982/

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 5MEQ (K) IN PLASTIC CONTAINER
 /AP/ /BAXTER/ /5GM/100ML;150MG/100ML;/ /N18008/004/
 /450MG/100ML/

DEXTROSE 5%, SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER
 /AP/ /BAXTER/ /5GM/100ML;75MG/100ML;/ /N18008/002/
 /450MG/100ML/

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

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

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

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 AP BAXTER 5GM/100ML;75MG/100ML; N18008 005
 450MG/100ML APR 28, 1982

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

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 AP BAXTER 5GM/100ML;150MG/100ML; N18008 007
 450MG/100ML APR 28, 1982

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 AP BAXTER 5GM/100ML;224MG/100ML; N18008 008
 450MG/100ML APR 28, 1982

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 AP BAXTER 5GM/100ML;300MG/100ML; N18008 009
 450MG/100ML APR 28, 1982

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 AP BAXTER 5GM/100ML;150MG/100ML; N18008 004
 450MG/100ML

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 /AP/ /CUTTER/BIOL/ /5GM/100ML;900MG/100ML/ /N18500/001/
 @ CUTTER BIOL 5GM/100ML;900MG/100ML N18500 001

> ADD > DEZOCINE

> ADD > INJECTABLE; INJECTION

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

DIATRIZOATE MEGLUMINE

INJECTABLE; INJECTION

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

DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

HYPAQUE-M
 /STERLING/DRUG/ /66%;36%/ /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/
 @ MARTEC PHARM 10MGx N72402 001
 APR 25, 1989

DIAZEPAM

TABLET; ORAL

DIAZEPAM

/AB/	/SUPERPHARM/	/2MG/
/AB/		/5MG/
/AB/		/10MG/
BX	SUPERPHARM	2MG
BX		5MG
BX		10MG

Q-PAM

> DLT >	/BX/	/QUANTUM/PHARMCS/	/2MG/
> DLT >			
> DLT >	/BX/		/2MG/
> DLT >			
> DLT >	/BX/		/5MG/
> DLT >			
> DLT >	/BX/		/5MG/
> DLT >			
> DLT >	/BX/		/10MG/
> DLT >			
> DLT >	/BX/		/10MG/
> DLT >			
> ADD >	a	QUANTUM PHARMCS	2MG
> ADD >			
> ADD >	a		2MG
> ADD >			
> ADD >	a		5MG
> ADD >			
> ADD >	a		5MG
> ADD >			
> ADD >	a		10MG
> ADD >			
> ADD >	a		10MG
> ADD >			

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

VOLTAREN

GEIGY PHARMS

25MG

50MG

75MG

/N70642/001/
/DEC/11./1985/
/N70643/001/
/DEC/11./1985/
/N70644/001/
/DEC/11./1985/
N70642 001
DEC 11, 1985
N70643 001
DEC 11, 1985
N70644 001
DEC 11, 1985

/N70423/001/
/DEC/12./1985/
/N72431/001/
/APR/29./1988/
/N70424/001/
/DEC/12./1985/
/N72432/001/
/APR/29./1988/
/N70425/001/
/DEC/12./1985/
/N72433/001/
/APR/29./1988/
N70423 001
DEC 12, 1985
N72431 001
APR 29, 1988
N70424 001
DEC 12, 1985
N72432 001
APR 29, 1988
N70425 001
DEC 12, 1985
N72433 001
APR 29, 1988

N19201 001
JUL 28, 1988
N19201 002
JUL 28, 1988
N19201 003
JUL 28, 1988

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL

VOLTAREN

CIBA/PHARM/

/25MG/

/50MG/

/75MG/

/N19201/001/
/JUL/28./1988/
/N19201/002/
/JUL/28./1988/
/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

/2/LEDERLE/LABS/

/50MG/

LEDERLE LABS

50MG

/N06459/001/
N06459 001

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

/AB/ /CHELSEA/LABS/

/25MG/

a CHELSEA LABS

25MG

/N05741/001/
N85741 001

DIETHYLSTILBESTROL

SUPPOSITORY; VAGINAL

DIETHYLSTILBESTROL/

> DLT >	/AT/	/LILLY/	/0.1MG/
> DLT >	/AT/		/0.5MG/
> ADD >			

/N04040/001/
/N04040/002/

DIETHYLSTILBESTROL

> ADD >	a	LILLY	0.1MG
> ADD >	a		0.5MG

N04040 001
N04040 002

STILBESTROL

> DLT >	/AT/	/SQUIBB/	/0.1MG/
> DLT >	/AT/		/0.5MG/
> ADD >			
> ADD >		SQUIBB	0.1MG
> ADD >			0.5MG

/N04056/001/
/N04056/002/
N04056 001
N04056 002

DIETHYLSTILBESTROLTABLET; ORAL
DIETHYLSTILBESTROL

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

TABLET, DELAYED RELEASE; ORAL
DIETHYLSTILBESTROL

> DLT >	/BP/	/LILLY/	/0.5MG/	/N04039/003/
> ADD >	a	LILLY	0.5MG	N04039 003

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

MARION LABS

60MG

N19471 001

JAN 23, 1989

90MG

N19471 002

JAN 23, 1989

120MG

N19471 003

JAN 23, 1989

a

180MG

N19471 004

JAN 23, 1989

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

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

ELIXIR; ORAL

DIPHEN/

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

DIPHENHYDRAMINE HYDROCHLORIDE

ELIXIR; ORAL

DIPHENHYDRAMINE HCL

AA	CENCI LABS	12.5MG/5ML	N87941 001
			DEC 17, 1982
/AA/	/LEDERLE/LABS/	/12.5MG/5ML/	/N86937/001/
a	LEDERLE LABS	12.5MG/5ML	N86937 001
/AA/	/LIFE/LABS/	/12.5MG/5ML/	/N87941/001/
/AA/	/PRIVATE/FMLTNS/	/12.5MG/5ML/	/DEC 17, 1982/
a	PRIVATE FMLTNS	12.5MG/5ML	/N85287/001/
			N85287 001

DISULFIRAM

TABLET; ORAL

DISULFIRAM

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

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL

DEPAKOTE

ABBOTT LABS

EQ 125MG BASEM

N19680 001

SEP 12, 1989

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

AP	ABBOTT LABS	40MG/ML	N70656 001
AP		80MG/ML	JAN 24, 1989
AP	WARNER CHILCOTT	40MG/ML	N70657 001
AP		40MG/ML	JAN 24, 1989
			N18138 001
			N70558 001
a		80MG/ML	SEP 20, 1985
			N70559 001
			SEP 20, 1985

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

<u>AP</u>	<u>DOASSTAT</u>	<u>/40MG/ML/</u>	<u>/N18138/001/</u>
<u>AP</u>	<u>/PARKE/DAVIS/</u>	<u>/40MG/ML/</u>	<u>/N70558/001/</u>
			<u>/SEP/20,1985/</u>
<u>AP</u>		<u>/80MG/ML/</u>	<u>/N70559/001/</u>
			<u>/SEP/20,1985/</u>

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIN HCL

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

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

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN RDE

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

DOXORUBICIN HCL

<u>AP</u>	<u>CETUS BEN VENUE</u>	<u>2MG/MLH</u>	<u>N62975 001</u>
			<u>MAR 17, 1989</u>
<u>AP</u>		<u>10MG/VIALH</u>	<u>N62921 001</u>
			<u>MAR 17, 1989</u>
<u>AP</u>		<u>20MG/VIALH</u>	<u>N62921 002</u>
			<u>MAR 17, 1989</u>
<u>AP</u>		<u>50MG/VIALH</u>	<u>N62921 003</u>
			<u>MAR 17, 1989</u>

RUBEX

<u>AP</u>	<u>BRISTOL MYERS</u>	<u>10MG/VIALH</u>	<u>N62926 001</u>
			<u>APR 13, 1989</u>
<u>AP</u>		<u>50MG/VIALH</u>	<u>N62926 002</u>
			<u>APR 13, 1989</u>
		<u>100MG/VIALH</u>	<u>N62926 003</u>
			<u>APR 13, 1989</u>

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE MONOHYDRATE

<u>> ADD ></u>	<u>MEDICOPHARMA</u>	<u>EQ 100MG BASEH</u>	<u>N50641 001</u>
<u>> ADD ></u>			<u>DEC 29, 1989</u>

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

<u>/AB/</u>	<u>/VITARINE/</u>	<u>/EQ '50MG' BASE/</u>	<u>/N62780/001/</u>
			<u>/APR/12,1988/</u>
<u>/AB/</u>		<u>/EQ '100MG' BASE/</u>	<u>/N62227/001/</u>
<u>BX</u>	<u>VITARINE</u>	<u>EQ 50MG BASE</u>	<u>N62780 001</u>
			<u>APR 12, 1988</u>
<u>BX</u>		<u>EQ 100MG BASE</u>	<u>N62227 001</u>

INJECTABLE; INJECTION

DOXYCYCLINE HYCLATE

<u>AP</u>	<u>LEDERLE PARNTLS</u>	<u>EQ 100MG BASE/VIALH</u>	<u>N62992 001</u>
			<u>FEB 16, 1989</u>
<u>AP</u>		<u>EQ 200MG BASE/VIALH</u>	<u>N62992 002</u>
			<u>FEB 16, 1989</u>

DOXYCYCLINE HYCLATE

TABLET; ORAL

DOXYCYCLINE HYCLATE

/CHELSEA/LABS/

/EQ/50MG/BASE/

/N62392/001/

/MAR/31/1983/

N62392 001

MAR 31, 1983

a CHELSEA LABS

EQ 50MG BASE

DOXYLAMINE SUCCINATE

TABLET; ORAL

DOXYLAMINE SUCCINATE

/COPLY/PHARM/

/25MG/

/N88900/001/

/OCT/08/1985/

N88900 001

OCT 08, 1985

/N88603/001/

/AUG/07/1984/

N88603 001

AUG 07, 1984

COPLY PHARM

25MG

/QUANTUM/PHARMCS/

/25MG/

a QUANTUM PHARMCS

25MG

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/

N80747 001

a CHASE CHEM

50,000 IU

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/ /LEDERLE/LABS/

/0.5MG/

/N86984/001/

/N86985/001/

N86984 001

N86985 001

a LEDERLE LABS

0.5MG

a

1MG

ERGOLOID MESYLATES

TABLET; SUBLINGUAL

ERGOLOID MESYLATES

/AA/ /VANGARD/LABS/

/0.5MG/

/N88613/001/

/SEP/20/1982/

/N88614/001/

/SEP/20/1982/

N88013 001

SEP 20, 1982

N88014 001

SEP 20, 1982

a VANGARD LABS

0.5MG

a

1MG

ERYTHROMYCIN

CAPSULE, DELAYED REL PELLETS; ORAL

ERYTHROMYCIN

AB BARR LABS

250MG

N63098 001

MAY 04, 1989

ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL

SUSPENSION; ORAL

ILOSONE SULFA

/LILLY/

/EQ/125MG/BASE/5ML/

/EQ/600MG/BASE/5ML/

/N50599/001/

/SEP/29/1989/

LILLY

EQ 125MG BASE/5ML;

EQ 600MG BASE/5ML

N50599 001

SEP 29, 1989

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROMYCIN LACTOBIONATE

AP LEDERLE PARNTLS

EQ 500MG BASE/VIAL

N62993 001

MAY 09, 1989

AP

EQ 1GM BASE/VIAL

N62993 002

MAY 09, 1989

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC

EI DUPONT

100MG/ML

N19386 003

DEC 31, 1986

ESTRADIOL

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

ESTRADIOL VALERATE; TESTOSTERONE ENANTHATE

INJECTABLE; INJECTION
 /60/ /DELAUDONE DB/
 /60/ /SQUIBB/ 8MG/ML;180MG/ML/ /N09545/002/
 @ 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/
 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/
 /BS/ /0.625MG/ /N83373/001/
 /BS/ /1.25MG/ /N83601/001/
 /BS/ /2.5MG/ /N83602/001/

ESTROGENS, CONJUGATED

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

ESTROGENS, ESTERIFIED

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

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
 NORCEPT-E 1/35 21
 AB GYNOPHARMA 0.035MG;1MG N71545 001
 FEB 09, 1989
 TABLET; ORAL-28
 NORCEPT-E 1/35 28
 AB GYNOPHARMA 0.035MG;1MG N71546 001
 FEB 09, 1989

> ADD > ETHINYL ESTRADIOL; NORGESTIMATE

> ADD > TABLET; ORAL-21
 > ADD > ORTHO CYCLEN-21
 > ADD > RW JOHNSON 0.035MG;0.25MG N19653 001
 > ADD > DEC 29, 1989
 > ADD > TABLET; ORAL-28
 > ADD > ORTHO CYCLEN-28
 > ADD > RW JOHNSON 0.035MG;0.25MG N19653 002
 > ADD > DEC 29, 1989

FENOPROFEN CALCIUM

CAPSULE; ORAL

FENOPROFEN CALCIUM

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

TABLET; ORAL

FENOPROFEN CALCIUM

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

FERROUS CITRATE, FE-59

/INJECTABLES/INJECTION/			
/FERROUS/CITRATE/FE/59/			
/MALLINCKRODT/	/25/UCI/ML/		/N16729/001/
Q MALLINCKRODT	25 UCI/ML		N16729 001

FLUOCINOLONE ACETONIDE

/GEL;/TOPICAL/			
/FLUONID/			
/HERBERT/LABS/	/0.025%/		/N87300/001/
Q HERBERT LABS	0.025%		/MAY/27, 1982/
			N87300 001
			MAY 27, 1982

FLUOCINONIDE

CREAM; TOPICAL

FLUOCINONIDE

AB	LEMMON	0.05%M	N72488 001
			FEB 06, 1989
AB		0.05%M	N72490 001
			FEB 07, 1989
AB	<u>VASODERM E</u>	0.05%M	N72494 001
	TICAN PHARM		JAN 19, 1989
/AB/	/TJ/ROACO/	/0.05%/	/N72494/001/
			/JAN/20, 1989/

FLUOCINONIDE

GEL; TOPICAL

FLUOCINONIDE

AB	LEMMON	0.05%M	N72537 001
			FEB 07, 1989

LIDEX

AB	SYNTEX LABS	0.05%	N17373 001
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SOLUTION; TOPICAL

FLUOCINONIDE

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

FLUOROMETHOLONE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC

FML-S

ALLERGAN PHARMS	0.1%;10%M	N19525 001
		SEP 29, 1989

FLUOROMETHOLONE ACETATE; TOBRAMYCIN

SUSPENSION/DROPS; OPHTHALMIC

TOBRASONE

ALCON LABS	0.1%;0.3%M	N50628 001
		JUL 21, 1989

FLUOXYMESTERONE

TABLET; ORAL

ANDROID-F

/BP/	/BROWN/PHARM/	/10MG/	/N87196/001/
BP	ICN PHARMS	10MG	N87196 001
/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
 /2/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/
 @ PBI 1MG N87828 001
 MAY 13, 1982
 /AA/ /VANGARD/LABS/ /1MG/ /N88730/001/
 @ 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

GENTAMICIN SULFATE; PREDNISOLONE ACETATE

> ADD > OINTMENT; OPHTHALMIC
 > ADD > PRED-G
 > ADD > ALLERGAN PHARMS EQ 0.3% BASE;0.6%# N50612 001
 > ADD > DEC 01, 1989

GLYCOPYRROLATE

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

GONADORELIN ACETATE

INJECTABLE; INJECTION
 LUTREPULSE PUMP KIT
 RM 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/
 @ STERIS LABS 2,000 UNITS/VIAL N17016 009
 DEC 27, 1984

> ADD > GOSERELIN ACETATE

> ADD > IMPLANT; IMPLANTATION
 > ADD > ZOLADEX
 > ADD > IMPERIAL CHEM EQ 3.6MG BASE# N19726 001
 > ADD > DEC 29, 1989

HALOPERIDOL

TABLET; ORAL

HALOPERIDOL

AB	LEDERLE LABS	0.5MG	N72727 001
			SEP 19, 1989
AB		1MG	N72728 001
			SEP 19, 1989
AB		2MG	N72729 001
			SEP 19, 1989
AB		5MG	N72730 001
			SEP 19, 1989
AB		10MG	N72731 001
			SEP 19, 1989
AB		20MG	N72732 001
			SEP 19, 1989
> DLT > /AB/	/QUANTUM/PHARMCS/	/0.5MG/	/N71255/001/
> DLT >			/FEB/17./1987/
> DLT > /AB/		/1MG/	/N71269/001/
> DLT >			/FEB/17./1987/
> DLT > /AB/		/2MG/	/N71255/001/
> DLT >			/FEB/17./1987/
> DLT > /AB/		/5MG/	/N71257/001/
> DLT >			/FEB/17./1987/
> ADD >	@ QUANTUM PHARMCS	0.5MG	N71255 001
> ADD >	@	1MG	FEB 17, 1987
> ADD >	@		N71269 001
> ADD >	@	2MG	FEB 17, 1987
> ADD >	@		N71256 001
> ADD >	@	5MG	FEB 17, 1987
> ADD >	@		N71257 001
> ADD >	@		FEB 17, 1987

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALDOL/DECANOATE/
MCKEIL/PHARM/HALDOL DECANOATE 50
RW JOHNSON

/EQ/50MG/BASE/ML/	/N18701/001/
	/JAN/14./1986/
EQ 50MG BASE/ML	N18701 001
	JAN 14, 1986

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM

AP	STERIS LABS	40,000 UNITS/ML	N17064 006
/2/		/40,000/UNITS/ML/	/N17064/006/

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% INPLASTIC CONTAINER

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

HEPARIN SODIUM 20,000 UNITS AND DEXTROSE 5% IN PLASTICCONTAINER

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

HEPARIN SODIUM 20,000 UNITS IN DEXTROSE 5% IN PLASTICCONTAINER

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

HEPARIN SODIUM 2000 UNITS IN SODIUM CHLORIDE 0.9% INPLASTIC CONTAINER

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

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTICCONTAINER

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

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

/BAXTER/	/500/UNITS/100ML/	/N18609/003/
		/APR/28./1982/

@ BAXTER	500 UNITS/100ML	N18609 003
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		APR 28, 1982
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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

HEXOCYCLUM METHYLSULFATETABLET; ORAL/TRAL/

/ABBOTT/LABS/	/25MG/	/N10599/001/
@ ABBOTT LABS	25MG	N10599 001

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

/AA/	/CHELSEA/LABS/	/25MG/
/AA/		/50MG/
	CHELSEA LABS	25MG
		50MG
/AA/	/PBI/	/25MG/
/AA/		/50MG/
	@ PBI	25MG
	@	50MG
> DLT >	/AA/ /QUANTUM/PHARMCS/	/10MG/
> DLT >		
> DLT >	/AA/	/25MG/
> DLT >		
> DLT >	/AA/	/50MG/
> DLT >		
> DLT >	/AA/	/100MG/
> DLT >		
> ADD >	@ QUANTUM PHARMCS	10MG
> ADD >	@	25MG
> ADD >	@	50MG
> ADD >	@	100MG
> ADD >	/AA/ /VANGARD/LABS/	/50MG/
	@ VANGARD LABS	50MG

/N85532/002/
/MAY/24,/1982/
/N85533/002/
/MAY/25,/1982/
N85532 002
MAY 24, 1982
N85533 002
MAY 25, 1982
/N87780/001/
/MAR/29,/1982/
/N87751/001/
/MAR/29,/1982/
N87780 001
MAR 29, 1982
N87751 001
MAR 29, 1982
/N88671/001/
/MAY/01,/1984/
/N88657/001/
/JUN/15,/1984/
/N88652/001/
/MAY/08,/1984/
/N88686/001/
/MAY/01,/1984/
N88671 001
MAY 01, 1984
N88657 001
JUN 15, 1984
N88652 001
MAY 08, 1984
N88686 001
MAY 01, 1984
/N87908/001/
/MAY/07,/1982/
N87908 001
MAY 07, 1982

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/BOOTS/LABS/	/25MG/	/N84325/001/
/AB/		/50MG/	/N84324/001/
/AB/	/CHELSEA/LABS/	/25MG/	/N85232/002/
/AB/		/50MG/	/N85233/001/
/AB/		/50MG/	/N86087/001/
/AB/		/50MG/	/N86594/001/
/AB/		/100MG/	/N87002/001/
	@ CHELSEA LABS	25MG	N85232 002
	@	50MG	N85233 001
	@	50MG	N86087 001
	@	50MG	N86594 001
	@	100MG	N87002 001
/AB/	/PBI/	/25MG/	/N87827/001/
/AB/		/50MG/	/APR/19,/1982/
	@ PBI	25MG	/N87752/001/
	@	50MG	/APR/19,/1982/
			N87827 001
			APR 19, 1982
			N87752 001
			APR 19, 1982
AB	PHARMAFAIR	25MG	N84325 001
AB		50MG	N84324 001
> DLT >	/AB/ /QUANTUM/PHARMCS/	/50MG/	/N85152/002/
> ADD >	@ QUANTUM PHARMCS	50MG	N85152 002
/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; LISINAPRIL

TABLET; ORAL

PRINZIDE 12.5

MS&D RES LABS

12.5MG;20MG

N19778 001
FEB 16, 1989PRINZIDE 25

MS&D RES LABS

25MG;20MG

N19778 002
FEB 16, 1989ZESTORETIC 20/25

IMPERIAL CHEM

25MG;20MG

N19888 002
JUL 20, 1989HYDRALAZINE 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; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

/AB/ /POLAR/PHARM/ /25MG:50MG/

/N71845/001/
/AUG/21./1987/
N71845 001
AUG 21, 1987
/N71737/001/
/FEB/12./1988/

/VITARINE/ 25MG;50MG/

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

/AB/	/PAR/PHARM/	/50MG;75MG/
------	-------------	-------------

BX	PAR PHARM	50MG;75MG
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```
> DLT > /BX/ /QUANTUM/PHARMCS/ /50MG;75MG/
> DLT >
> ADD >          @ QUANTUM PHARMCS          50MG;75MG
> ADD >
```

/AB/ /VITARINE/ /50MG:75MG/

12/22/2011 12:22:21 PM

BX	VITARINE	50MG; 75MG
----	----------	------------

/N72337/001/
 /MAY/11,/1988/
 N72337 001
 MAY 11, 1988
 /N71980/001/
 /FEB/01,/1988/
 N71980 001
 FEB 01, 1988
 /N71360/001/
 /DEC/08,/1987/
 N71360 001
 DEC 08, 1987

HYDROCORTISONE

/N85338/001/
N85338 001

CREAM; TOPICAL

/N85426/001/

/N86330/002/

/N86331/001/

N86330 002

N86331 001

N85420 001

TABLET; ORAL

HYDROCORTISONE

/QUANTUM/PHARMS/

/N86026/001/

N86026 001

/N87651/001/

N87651 001

/N87655/001/

N87655 001

> <u>DLT</u> >	/BP/	/QUANTUM/PHARMCS/	/20MG/
> <u>ADD</u> >		@ QUANTUM PHARMCS	20MG
	/BP/	/WHITE/TN/PAULSN/	/10MG/
	/BP/		/20MG/
		@ WHITE TN PAULSN	10MG
			20MG

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

AT PARKE DAVIS 171

N89914 001
JAN 03, 1989

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDEHYDROXYZINE HYDROCHLORIDE

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

AEROSOL; TOPICAL
EPIFOAM
/AT/ /REED & CARNRICK/ 1%;1% /N86457/001/
BX REED & CARNRICK 1%;1% N86457 001

/AT/ /HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%
/COPLY PHARM/ 1%;1% /N89440/001/
BX COPLEY PHARM 1%;1% N89440 001
MAY 17, 1988

PROCTOFOAM HC
BX REED & CARNRICK 1%;1% N86195 001

INJECTABLE; INJECTION
HYDROXYZINE HCL
/AP/ /PHARMAFAIR/ /25MG/ML/ /N88862/001/
/FEB/14,/1986/
/AP/ /25MG/ML/ /N89106/001/
/FEB/14,/1986/
/AP/ /50MG/ML/ /N89107/001/
/FEB/14,/1986/

3 PHARMAFAIR 25MG/ML N88862 001
FEB 14, 1986
3 25MG/ML N89106 001
FEB 14, 1986
3 50MG/ML N89107 001
FEB 14, 1986

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT
AP ABBOTT LABS EQ 100MG BASE/VIALM N89577 001
APR 11, 1989

AP EQ 250MG BASE/VIALM N89578 001
APR 11, 1989

AP EQ 500MG BASE/VIALM N89579 001
APR 11, 1989

AP EQ 1GM BASE/VIALM N89580 001
APR 11, 1989

TABLET; ORAL
HYDROXYZINE HCL
> DLT > /AB/ /QUANTUM/PHARMCS/ /10MG/ /N88540/001/
> DLT > /OCT/22,/1985/
> DLT > /AB/ /25MG/ /N88551/001/
> DLT > /OCT/22,/1985/
> DLT > /AB/ /50MG/ /N88529/001/
> DLT > /OCT/22,/1985/

> ADD > 3 QUANTUM PHARMCS 10MG N88540 001
> ADD > 3 25MG N88551 001
> ADD > 3 50MG N88529 001
> ADD > OCT 22, 1985

HYDROFLUMETHIAZIDEHYDROXYZINE PAMOATE

TABLET; ORAL
HYDROFLUMETHIAZIDE
/AB/ /CHELSEA/LABS/ /50MG/ /N88528/001/
/AUG/15,/1984/
3 CHELSEA LABS 50MG N88528 001
AUG 15, 1984

CAPSULE; ORAL
HYDROXYZINE PAMOATE
/AB/ /CHELSEA/LABS/ /EQ 100MG HCL/ /N86728/001/
/OCT/05,/1982/
3 CHELSEA LABS EQ 100MG HCL N86728 001
OCT 05, 1982

HYDROXOCOBALAMINIBUPROFEN

INJECTABLE; INJECTION
HYDROXOCOBALAMIN
/AP/ /LYPHOMED/ /1MG/ML/ /N84921/001/
3 LYPHOMED 1MG/ML N84921 001

SUSPENSION; ORAL
CHILDREN'S ADVIL
/AB/ /WHITEHALL/LABS/ /100MG/5MLM/ /N19833/002/
/SEP/19,/1989/
BX WHITEHALL LABS 100MG/5MLM N19833 002
SEP 19, 1989

IBUPROFEN

SUSPENSION; ORAL

PEDIA PROFEN

/AB/ /MCNEIL/CONSUMER/ /100MG/5ML/

BX MCNEIL CONSUMER 100MG/5ML

TABLET; ORAL

IBUPROFEN

/AB/ /BOOTS/LABS/ /600MG/

/2/ /600MG/

AB BOOTS USA 400MG

AB 600MG

2 800MG

/AB/ /CHELSEA/LABS/ /300MG/

2 CHELSEA LABS 300MG

RUFEN

/AB/ /BOOTS/PHARMS/ /400MG/

/AB/ /400MG/

/AB/ /600MG/

/AB/ /600MG/

/AB/ /600MG/

/AB/ /600MG/

AB BOOTS USA 400MG

AB 600MG

AB 600MG

AB 800MG

2 600MG

/N19842/001/
/SEP/19/1989/
N19842 001
SEP 19, 1989

/N70556/001/
/JUN/14/1985/
/N71264/001/
/JUL/25/1986/
N70083 001
FEB 22, 1985
N70556 001
JUN 14, 1985
N71264 001
JUL 25, 1986
/N71338/001/
/DEC/01/1986/
N71338 001
DEC 01, 1986

/N18197/001/
/N70088/001/
/FEB/22/1985/
/N18197/002/
/MAR/05/1984/
/N70088/001/
/FEB/08/1985/
/N70099/001/
/MAR/29/1985/
/N70745/001/
/JUL/23/1986/
N18197 001
N70088 001
FEB 08, 1985
N70099 001
MAR 29, 1985
N70745 001
JUL 23, 1986
N18197 002
MAR 05, 1984

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

/AB/ /CHELSEA/LABS/ /10MG/

/AB/ /25MG/

/AB/ /50MG/

2 CHELSEA LABS 10MG

2 25MG

2 50MG

/AB/ /PBI/ /25MG/

2 PBI 25MG

/AB/ /VANGARD/LABS/ /10MG/

/AB/ /25MG/

/AB/ /50MG/

2 VANGARD LABS 10MG

2 25MG

2 50MG

/N85875/001/
/N85878/001/
/N85877/001/
N85875 001
N85878 001
N85877 001
/N87776/001/
/FEB/10/1982/
N87776 001
FEB 10, 1982
/N88036/001/
/NOV/03/1982/
/N87619/001/
/FEB/09/1982/
/N87631/001/
/JAN/04/1982/
N88036 001
NOV 03, 1982
N87619 001
FEB 09, 1982
N87631 001
JAN 04, 1982

> ADD > INDECAINIDE HYDROCHLORIDE

> ADD > TABLET, EXTENDED RELEASE; ORAL

> ADD > DECABID

> ADD > ELI LILLY

> ADD > EQ 50MG BASEM N19693 001

> ADD > EQ 75MG BASEM N19693 002

> ADD > EQ 100MG BASEM N19693 003

> ADD > DEC 29, 1989

> ADD > DEC 29, 1989

> ADD > DEC 29, 1989

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

/AB/ /VITARINE/ /25MG/

/AB/ /50MG/

BX VITARINE 25MG

BX 50MG

/N71711/001/
/JUL/05/1988/
/N71712/001/
/JUL/05/1988/
N71711 001
JUL 05, 1988
N71712 001
JUL 05, 1988

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

AB	INWOOD LABS	75MG	N72410 001
			MAR 15, 1989
/AA/	/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%/
/OMNIPAQUE/300/	
/STERLING/DRUG/	/64.7%/
/OMNIPAQUE/350/	
/STERLING/DRUG/	/75.5%/

/N18956/002/
/DEC/26, 1985/
/N18956/003/
/DEC/26, 1985/
/N18956/004/
/DEC/26, 1985/

SOLUTION; INJECTION, ORAL

OMNIPAQUE 240	
STERLING DRUG	51.8%
OMNIPAQUE 300	
STERLING DRUG	64.7%
OMNIPAQUE 350	
STERLING DRUG	75.5%

N18956 002
DEC 26, 1985
N18956 003
DEC 26, 1985
N18956 004
DEC 26, 1985

> ADD > IOTROLAN> ADD > INJECTABLE; INTRATHECAL> ADD > OSMOVIST> ADD > BERLEX LABS EQ 190MG IODINE/ML> ADD > N19580 001> ADD > DEC 07, 1989> ADD > EQ 240MG IODINE/ML> ADD > N19580 002> ADD > DEC 07, 1989ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

/AA/	/BAXTER/	/0.082/	/N88144/001/
			/JUL/29, 1983/
/AA/		/0.252/	/N88146/001/
			/AUG/01, 1983/
	@ BAXTER	0.08%	N88144 001
			JUL 29, 1983
		/0.142/	/N88145/001/
			/MAR/26, 1984/
	@	0.14%	N88145 001
			MAR 26, 1984
	@	0.25%	N88146 001
			AUG 01, 1983

ISONIAZID

TABLET; ORAL

ISONIAZID

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

KANAMYCIN SULFATE

INJECTABLE; INJECTION

KANAMYCIN SULFATE

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

KETOROLAC TROMETHAMINE

INJECTABLE; INJECTION

TORADOL

SYNTEX LABS

15MG/ML

N19698 001

NOV 30, 1989

30MG/ML

N19698 002

NOV 30, 1989

LACTULOSE

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

SYRUP; ORAL, RECTAL
LACTULOSE
 /AA/ /REID/ROWELL/ /10GM/15ML/ /N17906/001/
 3 REID ROWELL 10GM/15ML N17906 001

PORTALAC
 AA REID ROWELL 10GM/15ML N72374 001
 MAR 22, 1989

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
 LEUCOVORIN CALCIUM
 LEDERLE LABS EQ 350MG BASE/VIAL N08107 005
 APR 05, 1989

WELLCOVORIN
 AP BURROUGHS WELLC EQ 50MG BASE/VIAL N89465 001
 JAN 23, 1989

AP EQ 100MG BASE/VIAL N89834 001
 JAN 23, 1989

EQ 25MG BASE/VIAL N89833 001
 JAN 23, 1989

LEUPROLIDE ACETATE

INJECTABLE; INJECTION
 LUPRON DEPOT
 TAKEDA ABBOTT 7.5MG/VIAL N19732 001
 JAN 26, 1989

/TAP/PHARMS/ /7.5MG/VIAL/ /N19732/001/

LEVOBUNOLOL HYDROCHLORIDE

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

/LEVOBUNOLOL HYDROCHLORIDE SOLUTION/

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

/LEVOBUNOLOL HYDROCHLORIDE SOLUTION/

/TABLETS/ ORAL/
 /EUTHROID-1/
 /PARKE/DAVIS/ /0.06MG;0.015MG/ /N16680/002/
 /EUTHROID-2/
 /PARKE/DAVIS/ /0.12MG;0.03MG/ /N16680/003/
 /EUTHROID-3/
 /PARKE/DAVIS/ /0.18MG;0.045MG/ /N16680/004/
 /THYROLAR-0.25/
 /2/ ARMOUR/PHARM/ /0.0125MG;0.0031MG/ /N16807/001/

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
LIDOCAINE HCL
 /AP/ /INTL/MEDTN/SYS/ /42/ /N17702/002/
 3 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

/AP/ /LIDOCAINE HCL W/ DEXTROSE/ /52/ /N83914/001/
 /ABBOTT/LABS/

SOLUTION; TOPICAL
/LARYNGOTRACHEAL ANESTHESIA KIT/
 /AT/ /KENDALL/ /42/ /N87931/001/
 3 KENDALL 4% N87931 001
 JUN 10, 1983

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

LIOTRIX (T4;T3)

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

EUTHROID-1
 PARKE DAVIS 0.06MG;0.015MG N16680 002

EUTHROID-2
 PARKE DAVIS 0.12MG;0.03MG N16680 003

EUTHROID-3
 PARKE DAVIS 0.18MG;0.045MG N16680 004

THYROLAR-0.25
 RORER PHARM 0.0125MG;0.0031MG N16807 001

LIOTRIX (T4;T3)

TABLET; ORAL

THYROLAR-0.5

RORER PHARM

0.025MG;0.00625MG

N16807 005

THYROLAR-1

RORER PHARM

0.05MG;0.0125MG

N16807 004

THYROLAR-2

RORER PHARM

0.1MG;0.025MG

N16807 002

THYROLAR-3

RORER PHARM

0.15MG;0.0375MG

N16807 003

THYROLAR-5

2 RORER PHARM

0.25MG;0.0625MG

N16807 006

LISINAPRIL

TABLET; ORAL

PRINIVIL

AB MS&D RES LABS

40MG

N19558 004

OCT 25, 1988

ZESTRIL

AB IMPERIAL CHEM

40MG

N19777 004

MAY 19, 1988

LITHIUM CARBONATE

CAPSULE; ORAL

LITHIUM CARBONATE

AB PBI

300MG

N72542 001

FEB 01, 1989

LORAZEPAM

TABLET; ORAL

> DLT > /LORAZ/

> DLT > /AB/ /QUANTUM/PHARMCS/ /0.5MG/

> DLT > /AB/ /1MG/

> DLT > /AB/ /2MG/

> DLT > /AB/ /2MG/

> ADD > 2 QUANTUM PHARMCS 0.5MG

> ADD > 2 1MG

> ADD > 2 2MG

> ADD >

/N70200/001/

/AUG/09/1985/

/N70201/001/

/AUG/09/1985/

/N70202/001/

/AUG/09/1985/

N70200 001

AUG 09, 1985

N70201 001

AUG 09, 1985

N70202 001

AUG 09, 1985

LORAZEPAM

TABLET; ORAL

LORAZEPAM

/AM/THERPTCS/

/0.5MG/

/N70727/001/

/MAR/07/1986/

> DLT >

> DLT >

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

> ADD >

BX AM THERPTCS

0.5MG

N70727 001

MAR 07, 1986

BX

1MG

N70728 001

MAR 07, 1986

BX

2MG

N70729 001

MAR 07, 1986

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE,

MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE;

SODIUM PHOSPHATE, DIBASIC

INJECTABLE; INJECTION

ISOLYTE S PH 7.4 IN PLASTIC CONTAINER

KENDALL MCGAW

30MG/100ML;37MG/100ML;0.82MG/100ML;

370MG/100ML;530MG/100ML;

500MG/100ML;12MG/100ML N19696 001

SEP 29, 1989

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE;

SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION

ISOLYTE S IN PLASTIC CONTAINER

AP

KENDALL MCGAW

30MG/100ML;37MG/100ML;370MG/100ML;

530MG/100ML;

500MG/100ML N19711 001

SEP 29, 1989

SOLUTION; IRRIGATION

PHYSIOSOL IN PLASTIC CONTAINER

/2/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

MALATHIONLOTION; TOPICAL
OVIDE

GENDERM

0.5%

N18613 001
AUG 02, 1982/LOTION; TOPICAL/
/PRIDERM/
/2/PURDUE/FDRK/

/0.5%/

/N18613/001/
/AUG/02./1982/MANNITOL

SOLUTION; IRRIGATION

/RESECTISOL/

/KENDALL/MCGAW/

2 KENDALL MCGAW

/56M/100ML/
56M/100ML/N16704/002/
N16704 002MEBENDAZOLETABLET; CHEWABLE; ORAL
VERMOX/JANSSEN/PHARMA/
JANSSEN RES/100MG/
100MG/N17481/001/
N17481 001MECLIZINE 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/

2 VANGARD LABS

12.5MG

N87877 001
APR 20, 1982

2

25MG

N87620 001
JAN 04, 1982MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLODIUM

> DLT > /BX/ /QUANTUM/PHARMCS/

/EQ/50MG/BASE/

/N71380/001/

> DLT >

/JUL/14./1987/

> DLT > /BX/

/EQ/100MG/BASE/

/N71381/001/

> DLT >

/JUL/14./1987/

> ADD >

2 QUANTUM PHARMCS

EQ 50MG BASE

N71380 001

> ADD >

JUL 14, 1987

> ADD >

2

EQ 100MG BASE

N71381 001

> ADD >

JUL 14, 1987

MECLOFENAMATE SODIUM

AB

BARR LABS

EQ 50MG BASE

N72848 001

AB

EQ 100MG BASE

MAR 20, 1989

/AB/

/VITARINE/

/EQ/50MG/BASE/

/N71710/001/

/AB/

/EQ/100MG/BASE/

/JUN/15./1988/

BX

VITARINE

EQ 50MG BASE

N71710 001

BX

EQ 100MG BASE

JUN 15, 1988

N71684 001

JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL

MEFENAMIC ACID

/AB/

/VITARINE/

/250MG/

/N72179/001/

BX

VITARINE

250MG

/APR/21./1988/

N72179 001

APR 21, 1988

MEFLOQUINE HYDROCHLORIDE

TABLET; ORAL

LARIAM

ROCHE

250MG

N19591 001

MAY 02, 1989

MEFLOQUINE HCL

2 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/	/2/BOOTS/PHARMS/	/400MG/	/N84153/001/
/AA/	/CHELSEA/LABS/	/600MG/	/N85719/001/
	2 CHELSEA LABS	600MG	N85719 001
/AA/	/LEDERLE/LABS/	/400MG/	/N86299/001/
	2 LEDERLE LABS	400MG	N86299 001
	2 PHARMAFAIR	400MG	N84153 001
> DLT > /AA/	/QUANTUM/PHARMCS/	/200MG/	/N15426/002/
> DLT > /AA/		/400MG/	/N15426/001/
> ADD >	2 QUANTUM PHARMCS	200MG	N15426 002
> ADD >	2	400MG	N15426 001
/AA/	/VANGARD/LABS/	/400MG/	/N88011/001/
			/JUL 14, 1982/
	2 VANGARD LABS	400MG	N88011 001
			JUL 14, 1982
/AA/	/WHITE/TN/PAULSN/	/200MG/	/N83830/001/
/AA/		/400MG/	/N83442/001/
	2 WHITE TN PAULSN	200MG	N83830 001
	2	400MG	N83442 001

MESNA

INJECTABLE; INJECTION

MESNEX

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

MESNA

INJECTABLE; INJECTION

MESNEX

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

METAPROTERENOL SULFATE

SOLUTION; INHALATION

DEY-DOSE/

/AN/	/DEY/LABS/	/52/	/N70805/001/
			/AUG 17, 1987/
/AN/	/DEY-LUTE/	/0.42/	/N71786/001/
	/DEY/LABS/		/AUG 05, 1988/
/AN/		/0.62/	/N70804/001/
			/AUG 17, 1987/
		/0.332/	/N71806/001/
			/AUG 05, 1988/
		/0.52/	/N71805/001/
			/AUG 05, 1988/

METAPROTERENOL SULFATE

AN	DEY LABS	0.42	N71786 001
			AUG 05, 1988
AN		0.62	N70804 001
			AUG 17, 1987
AN		52	N70805 001
			AUG 17, 1987
		0.332	N71806 001
			AUG 05, 1988
		0.52	N71805 001
			AUG 05, 1988

METHIXENE HYDROCHLORIDE

TABLET; ORAL

TREST

/2/DORSEY/LABS/	/1MG/	/N13420/001/
2 SANDOZ PHARMS	1MG	N13420 001

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

/2/BOOTS/PHARMS/	/500MG/	/N84231/002/
/2/	/750MG/	/N84471/001/
2 PHARMAFAIR	500MG	N84231 002
2	750MG	N84471 001

METHOTREXATE SODIUMINJECTABLE; INJECTION
METHOTREXATE SODIUM

/AB/	/LYPHOMED/	/EQ '20MG BASE/VIAL/	/N88935/001/
			/OCT/11./1985/
/AB/		/EQ '50MG BASE/VIAL/	/N88936/001/
			/OCT/11./1985/
/AB/		/EQ '100MG BASE/VIAL/	/N88937/001/
			/OCT/11./1985/
Q	LYPHOMED	EQ 20MG BASE/VIAL	N88935 001
Q		EQ 50MG BASE/VIAL	OCT 11, 1985
Q		EQ 100MG BASE/VIAL	N88936 001
			OCT 11, 1985
			N88937 001
			OCT 11, 1985
/AB/	<u>MEXATE-AQ</u> /BRISTOL/CARIB/	/EQ '25MG BASE/ML/	/N88760/001/
			/FEB/14./1985/
AP	BRISTOL MYERS	EQ 25MG BASE/ML	N88760 001
			FEB 14, 1985
AP	<u>MEXATE-AQ PRESERVED</u> 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/
Q	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/
Q		16MG	N86159 001
			FEB 09, 1982

METHYLPREDNISOLONE; NEOMYCIN SULFATE

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

METHYLPREDNISOLONE ACETATE

/ENEMA; RECTAL/

/MEDROL/

/UPJOHN/

Q UPJOHN

/40MG/BOT/

40MG/BOT

/N18102/001/

N18102 001

METHYLTESTOSTERONE

TABLET; BUCCAL

ANDROID 5

/BROWN/PHARM/

ICN PHARMS

/5MG/

5MG

/N87222/001/

N87222 001

TABLET; ORAL

ANDROID 10

/AB/ /BROWN/PHARM/

AB ICN PHARMS

/10MG/

10MG

/N86450/001/

N86450 001

ANDROID 25

/AB/ /BROWN/PHARM/

AB ICN PHARMS

/25MG/

25MG

/N87147/001/

N87147 001

> ADD > METIPRANOLOL HYDROCHLORIDE

> ADD > SOLUTION/DROPS; OPHTHALMIC

> ADD > METIPRANOLOL HCL

> ADD > BAUSCH & LOMB

0.3%

N19907 001

DEC 29, 1989

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

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

TABLET; ORAL

> DLT >	/CLOPRA/		
> DLT >/AB/	/QUANTUM/PHARMCS/	/EQ 5MG BASE/	/N72384/001/
> DLT >			/JUN/02,/1988/
> DLT >/AB/		/EQ 10MG BASE/	/N70294/001/
> DLT >			/JUL/29,/1985/
> ADD >	@ QUANTUM PHARMCS	EQ 5MG BASE	N72384 001
> ADD >			JUN 02, 1988
> ADD >	@	EQ 10MG BASE	N70294 001
> ADD >			JUL 29, 1985
> DLT >	/CLOPRA-YELLOW/		
> DLT >/AB/	/QUANTUM/PHARMCS/	/EQ 10MG BASE/	/N70632/001/
> DLT >			/OCT/28,/1985/
> ADD >	@ QUANTUM PHARMCS	EQ 10MG BASE	N70632 001
> ADD >			OCT 28, 1985
	<u>METOCLOPRAMIDE HCL</u>		
AB	INVAMED	EQ 5MG BASEM	N72436 001
			JUN 22, 1989
/AB/	/MARTEC/PHARM/	/EQ 10MG BASE/	/N70598/001/
			/FEB/02,/1987/
	@ MARTEC PHARM	EQ 10MG BASE	N70598 001
			FEB 02, 1987

> ADD > METOPROLOL FUMARATE

> ADD >	TABLET, EXTENDED RELEASE; ORAL		
> ADD >	LOPRESSOR		
> ADD >	GEIGY PHARMS	EQ 100MG TARTRATEM	N19786 001
> ADD >			DEC 27, 1989
> ADD >		EQ 200MG TARTRATEM	N19786 002
> ADD >			DEC 27, 1989
> ADD >		EQ 300MG TARTRATEM	N19786 003
> ADD >			DEC 27, 1989
> ADD >		EQ 400MG TARTRATEM	N19786 004
> ADD >			DEC 27, 1989

METOPROLOL TARTRATE

TABLET; ORAL

LOPRESSOR

AB	GEIGY PHARMS	50MG	N17963 001
AB		100MG	N17963 002
	<u>METOPROLOL TARTRATE</u>		
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/
@ 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 >/BX/	/QUANTUM/PHARMCS/	/2.5MG/	/N72153/001/
> DLT >			/JUL/13,/1988/
> DLT >/BX/		/10MG/	/N71534/001/
> DLT >			/MAR/19,/1987/
> ADD >	@ QUANTUM PHARMCS	2.5MG	N72153 001
> ADD >			JUL 13, 1988
> ADD >	@	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

EQ 40MG BASE/ML

N50655 001
OCT 31, 1989
N50655 002
OCT 31, 1989

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL

AP ABBOTT LABS 10MG/ML

AP 10MG/ML

AP 20MG/ML

AP 20MG/ML

AP 20MG/ML

AP ASTRA PHARM 10MG/ML

AP 10MG/ML

AP 10MG/ML

AP 20MG/ML

AP 20MG/ML

AP 20MG/ML

N70914 001
FEB 03, 1989
N70915 001
FEB 03, 1989
N70916 001
FEB 03, 1989
N70917 001
FEB 03, 1989
N70918 001
FEB 03, 1989
N72070 001
APR 10, 1989
N72071 001
APR 10, 1989
N72072 001
APR 10, 1989
N72073 001
APR 10, 1989
N72074 001
APR 10, 1989
N72075 001
APR 10, 1989

> DLT > /AP/

> DLT >

> DLT > /AP/

> DLT >

> ADD >

> ADD >

> ADD >

> ADD >

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

AP ASTRA PHARM

0.02MG/ML

AP

0.02MG/ML

AP

0.02MG/ML

AP

0.02MG/ML

AP

0.02MG/ML

AP

0.4MG/ML

AP

0.4MG/ML

AP

0.4MG/ML

AP

0.4MG/ML

AP

0.4MG/ML

AP

1MG/ML

AP

1MG/ML

AP

1MG/ML

0.4MG/ML

1MG/ML

0.4MG/ML

1MG/ML

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

MURO'S OPCON

/AT/ /MURO/PHARM/

OPCON

AT BAUSCH & LOMB

/0.12/

0.1%

N72081 001
APR 11, 1989
N72082 001
APR 11, 1989
N72083 001
APR 11, 1989
N72084 001
APR 11, 1989
N72085 001
APR 11, 1989
N72086 001
APR 11, 1989
N72087 001
APR 11, 1989
N72088 001
APR 11, 1989
N72089 001
APR 11, 1989
N72090 001
APR 11, 1989
N72091 001
APR 11, 1989
N72092 001
APR 11, 1989
N72093 001
APR 11, 1989
/N70417/001/
/NOV/06/1985/
/N72115/001/
/APR/27/1988/
N70417 001
NOV 06, 1985
N72115 001
APR 27, 1988

/N87506/001/

N87506 001

NYSTATIN

POWDER; ORAL

BARSTATIN 100

AA BARLAN PHARMA

100%N62489 001
APR 27, 1988

TABLET; ORAL

NYSTATIN

> DLT > /AA/ /QUANTUM/PHARMCS/ /500,000 UNITS/

> DLT > /OCT/29./1984/

> ADD > @ QUANTUM PHARMCS 500,000 UNITS

> ADD > N62525 001

OCT 29, 1984

TABLET; VAGINAL

NYSTATIN

/AT/ /CHELSEA/LABS/ /100,000 UNITS/

@ CHELSEA LABS 100,000 UNITS

> DLT > /AT/ /QUANTUM/PHARMCS/ /100,000 UNITS/

> DLT > /APR/03./1984/

> ADD > @ QUANTUM PHARMCS 100,000 UNITS

> ADD > N62509 001

APR 03, 1984

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

LOSEC

MS&D RES LABS

20MG

N19810 001
SEP 14, 1989OXACILLIN 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, 1989OXACILLIN 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, 1989OXANDROLONE

/TABLETS/ORAL/

/ANAVAR/

/SEARLE/

@ SEARLE

/2.5MG/

2.5MG

/N13718/001/

N13718 001

OXAZEPAM

CAPSULE; ORAL

ZAXOPAM

> DLT > /BX/ /QUANTUM/PHARMCS/ /10MG/

> DLT > /MAR/01./1988/

> DLT > /BX/ /15MG/

> DLT > /MAR/01./1988/

> DLT > /BX/ /30MG/

> DLT > /MAR/01./1988/

> ADD > @ QUANTUM PHARMCS 10MG

> ADD > N70650 001

> ADD > @ 15MG

> ADD > N70640 001

> ADD > @ 30MG

> ADD > N70641 001

MAR 01, 1988

OXYBUTYNIN CHLORIDE

TABLET; ORAL

OXYBUTYNIN CHLORIDE

AB

BOLAR PHARM

5MG

N72485 001

APR 19, 1989

> DLT > /AB/ /QUANTUM/PHARMCS/ /5MG/

> DLT > /N72296/001/

> ADD > @ QUANTUM PHARMCS 5MG

> ADD > /DEC/08./1988/

N72296 001

DEC 08, 1988

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

INJECTABLE; INJECTION

/OXYTOCIN/20/USP/UNITS/IN/DEXTROSE/5%/
/ABBOTT/LABS/ 1/2/USP/UNITS/100ML/

a ABBOTT LABS 2 USP UNITS/100ML

/N19185/002/
/MAR/29/1985/
N19185 002
MAR 29, 1985/OXYTOCIN/5/USP/UNITS/IN/DEXTROSE/5%/
/ABBOTT/LABS/ 1/1/USP/UNIT/100ML/

a ABBOTT LABS 1 USP UNIT/100ML

/N19185/001/
/MAR/29/1985/
N19185 001
MAR 29, 1985PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

AP ABBOTT LABS 1MG/ML

N72320 001
JAN 19, 1989

AP 2MG/ML

N72321 001
JAN 19, 1989PARAMETHADIONE/SOLUTION;/ORAL/
/PARAMETHADIONE//ABBOTT/LABS/ 1/300MG/ML/
a ABBOTT LABS 300MG/ML/N06600/002/
N06600 002PENBUTOLOL SULFATE

TABLET; ORAL

LEVATOL
/LILLY/ 1/10MG/

REED & CARNRICK 10MG

/N18976/001/
/DEC/30/1987/
N18976 001
DEC 30, 1987PENICILLIN G BENZATHINE/SUSPENSION;/ORAL/
/BICILLIN//WYETH/AYERST/LABS/ 1/300,000/UNITS/5ML/
a WYETH AYERST LABS 300,000 UNITS/5ML/N50126/002/
N50126 002PENICILLIN 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, 1989PENTAMIDINE ISETHIONATE

POWDER FOR RECONSTITUTION; INHALATION

NEBUPENT

LYPHOMED

300MG/VIAL

N19887 001
JUN 15, 1989PENTOBARBITAL SODIUM

CAPSULE; ORAL

PENTOBARBITAL SODIUM/AA/ /WHITE/TN/PAULSN/ 1/100MG/
a WHITE TN PAULSN 100MG/N83338/001/
N83338 001SODIUM PENTOBARBITAL> DLT > /AA/ /QUANTUM/PHARMCS/ 1/100MG/
> ADD > a QUANTUM PHARMCS 100MG/N83368/001/
N83368 001PERMETHRIN

CREAM; TOPICAL

ELIMITE

BURROUGHS WELLC

5%
N19855 001
AUG 25, 1989PHENDIMETRAZINE TARTRATE

TABLET; ORAL

DI-METREX/AA/ /PRIVATE/FMLTNS/ 1/35MG/
a PRIVATE FMLTNS 35MG/N85698/001/
N85698 001PHENDIMETRAZINE TARTRATE/AA/ /CHELSEA/LABS/ 1/35MG/
/AA/ 35MG/
/AA/ 35MG/
/AA/ 35MG/
/AA/ 35MG//N85767/001/
/N85768/001/
/N85770/001/
/N85773/001/

a CHELSEA LABS 35MG

N85767 001

a 35MG

N85768 001

a 35MG

N85770 001

a 35MG

N85773 001

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

<u>PHENDIMETRAZINE TARTRATE</u>		
/AA/ /PRIVATE/FMLTNS/	/35MG/	/N85199/001/
Q PRIVATE FMLTNS	35MG	N85199 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

<u>PHENTERMINE HCL</u>		
/AA/ /CHELSEA/LABS/	/30MG/	/N86740/001/
Q CHELSEA LABS	30MG	MAR/21/1985/
		N86740 001
		MAR 21, 1985

TABLET; ORAL

<u>PHENTERMINE HCL</u>		
/AA/ /CHELSEA/LABS/	/8MG/	/N85739/001/
Q CHELSEA LABS	8MG	N85739 001

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

<u>IONAMIN-30</u>		
> DLT > /AA/ /PENNWALT/	/EQ 30MG BASE/	/N11613/002/
> ADD >	PENNWALT PHARM	EQ 30MG BASE
> DLT >		N11613 002
> DLT > /AA/ /PHENTERMINE RESIN 30/	/EQ 30MG BASE/	/N89120/001/
> DLT > /AA/ /QUANTUM/PHARMCS/		FEB/04/1988/
> ADD >	Q QUANTUM PHARMCS	N89120 001
> ADD >		FEB 04, 1988

PHENYL AMINOSALICYLATE

/POWDER;/ORAL/

/PHENY-PAS-TEBAMIN/		
/PURDUE/FDRK/	/50%/	/N11695/002/
Q PURDUE FDRK	50%	N11695 002

/TABLET;/ORAL/

/PHENY-PAS-TEBAMIN/		
/PURDUE/FDRK/	/500MG/	/N11695/003/
Q PURDUE FDRK	500MG	N11695 003

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

<u>PHENERGAN VC</u>		
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		
/Q/BOOTS/PHARMS/	/100MG/	/N85435/001/
Q PHARMAFAIR	100MG	N85435 001

> ADD > PINACIDIL

> ADD >

CAPSULE, EXTENDED RELEASE; ORAL

> ADD >

PINDAC

> ADD >

ELI LILLY

12.5MG

N19456 001

> ADD >

> ADD >

25MG

DEC 28, 1989

> ADD >

N19456 002

DEC 28, 1989

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

POWDER FOR RECONSTITUTION; ORAL

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

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

POWDER FOR RECONSTITUTION; ORAL

COLYTE

AA REED & CARNRICK 240GM/BOT;2.98GM/BOT;6.72GM/BOT;
5.84GM/BOT;22.72GM/BOT N18983 007
JUN 12, 1987
/REED/A/CARNRICK/ /120GM/PACKET;1.49GM/PACKET;/
/3.36GM/PACKET;2.92GM/PACKET;/
/11.36GM/PACKET/ /N18983/005/
/OCT/26./1984/
a REED & CARNRICK 120GM/PACKET;1.49GM/PACKET;
3.36GM/PACKET;2.92GM/PACKET;
11.36GM/PACKET N18983 005
OCT 26, 1984
/REED/A/CARNRICK/ /240GM/BOT;2.98GM/BOT;6.72GM/BOT;/
/5.84GM/BOT;22.72GM/BOT/ /N18983/007/
/JUN/12./1987/
/REED/A/CARNRICK/ /360GM/PACKET;4.47GM/PACKET;/
/10.08GM/PACKET;8.76GM/PACKET;/
/34.08GM/PACKET/ /N18983/006/
/OCT/26./1984/
a REED & CARNRICK 360GM/PACKET;4.47GM/PACKET;
10.08GM/PACKET;8.76GM/PACKET;
34.08GM/PACKET N18983 006
OCT 26, 1984
GOLYTELY
AA BRAINTREE LABS 236GM/BOT;2.97GM/BOT;6.74GM/BOT;
5.86GM/BOT;22.74GM/BOT N19011 001
JUL 13, 1984

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

/AP/ /LYPHOMED/ /2MEQ/ML/ /N86713/001/
/AP/ /2MEQ/ML/ /N86714/001/
a LYPHOMED 2MEQ/ML N86713 001
a 2MEQ/ML N86714 001
> ADD > POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER
> ADD > BAXTER 14.9MG/ML N19904 001
> ADD > DEC 26, 1989
> ADD > POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER
> ADD > BAXTER 29.8MG/ML N19904 002
> ADD > DEC 26, 1989
> ADD > POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER
> ADD > BAXTER 2.24GM/100ML N19904 003
> ADD > DEC 26, 1989
> ADD > POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER
> ADD > BAXTER 2.98GM/100ML N19904 004
> ADD > DEC 26, 1989

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE; ORAL

K-DUR 10
/BC/ /KET/PHARMS/ /10MEQ/ /N19439/002/
/JUN/13./1986/
BC SCHERING 10MEQ N19439 002
JUN 13, 1986
K-DUR 20
/KET/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% INPLASTIC CONTAINER

AP KENDALL MCGAW 150MG/100ML;
900MG/100ML N19708 004
SEP 29, 1989
POTASSIUM CHLORIDE 0.22% IN SODIUM CHLORIDE 0.9% IN
PLASTIC CONTAINER
KENDALL MCGAW 220MG/100ML;
900MG/100ML N19708 005
SEP 29, 1989

POTASSIUM CHLORIDE 0.3% IN SODIUM CHLORIDE 0.9% IN PLASTICCONTAINER

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

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% INPLASTIC CONTAINER

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

POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTIONSODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN

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

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

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% INPLASTIC CONTAINER

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

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

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% INPLASTIC CONTAINER

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

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

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% INPLASTIC CONTAINER

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

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

PRALIDOXIME CHLORIDE/TABLET;/ORAL//PROTOPAM/CHLORIDE//WYETH/AYERST/LABS/

Q WYETH AYERST LABS

/500MG/
500MG

/N14122/002/
N14122 002

PRAZOSIN HYDROCHLORIDECAPSULE; ORALPRAZOSIN HCL

AB AM THERPTCS

EQ IMG BASEM N72782 001
MAY 16, 1989 : APR 11, 1989

AB

EQ 2MG BASEM N72783 001
MAY 16, 1989 : APR 11, 1989

AB

EQ 5MG BASEM N72784 001
MAY 16, 1989 : APR 11, 1989

PRAZOSIN HYDROCHLORIDECAPSULE; ORALPRAZOSIN HCL

CORD LABS

AB

EQ IMG BASEM N72576 001

MAY 16, 1989 : APR 10, 1989

AB

EQ 2MG BASEM N72577 001

MAY 16, 1989 : APR 10, 1989

AB

EQ 5MG BASEM N72578 001

MAY 16, 1989 : APR 10, 1989

AB

DANBURY PHARMA

EQ IMG BASEM N72352 001

MAY 16, 1989 : JAN 11, 1989

AB

EQ 2MG BASEM N72333 001

MAY 16, 1989 : JAN 11, 1989

AB

EQ 5MG BASEM N72609 001

MAY 16, 1989 : JAN 11, 1989

AB

LEDERLE LABS

EQ IMG BASEM N72705 001

MAY 16, 1989 : MAR 15, 1989

AB

EQ 2MG BASEM N72706 001

MAY 16, 1989 : MAR 15, 1989

AB

EQ 5MG BASEM N72707 001

MAY 16, 1989 : MAR 15, 1989

AB

MYLAN PHARMS

EQ IMG BASEM N72573 001

MAY 16, 1989 : FEB 28, 1989

AB

EQ 2MG BASEM N72574 001

MAY 16, 1989 : FEB 28, 1989

AB

EQ 5MG BASEM N72575 001

MAY 16, 1989 : FEB 28, 1989

AB

PUREPAC PHARM

EQ IMG BASEM N72991 001

MAY 16, 1989 : APR 26, 1989

AB

EQ 2MG BASEM N72921 001

MAY 16, 1989 : APR 26, 1989

AB

EQ 5MG BASEM N72992 001

MAY 16, 1989 : APR 26, 1989

/AB/

/ZENITH/LABS/

/EQ IMG BASE/ /N71994/001/

/SEP/12/1988/

AB

ZENITH LABS

EQ IMG BASE N71994 001

MAY 16, 1989 : SEP 12, 1988

/AB/

/EQ 2MG BASE/ /N71995/001/

/SEP/12/1988/

AB

EQ 2MG BASE N71995 001

MAY 16, 1989 : SEP 12, 1988

/AB/

/EQ 5MG BASE/ /N71745/001/

/SEP/12/1988/

AB

EQ 5MG BASE N71745 001

MAY 16, 1989 : SEP 12, 1988

PREDNISOLONESYRUP; ORAL
PRELONE

MURO PHARM

5MG/5ML

N89654 001
JAN 17, 1989

TABLET; ORAL

PREDNISOLONE

/BX/ /CHELSEA/LABS/

/5MG/

/N85415/001/

/BX/ /5MG/

/N85416/001/

a CHELSEA LABS

5MG

N85415 001

a

5MG

N85416 001

> DLT > /BX/ /QUANTUM/PHARMS/

/5MG/

/N80625/001/

> ADD > a QUANTUM PHARMS

5MG

N80625 001

/BX/ /WHITE/TN/PAULSN/

/5MG/

/N80342/001/

a 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/ /MURD/PHARM/

/0.5%;10%/

/N88089/001/
/DEC/28/1982/PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC

PREDNISOLONE SODIUM PHOSPHATE

/a/MAURRY/BIOL/

/EQ/0.9%/PHOSPHATE/

/N83358/002/

AT PREDNISOLONE SODIUM PHOSPHATE

NORBROOK AM

EQ 0.9% PHOSPHATE

N83358 002

PREDNISONE

SOLUTION; ORAL

PREDNISONE INTENSOL

ROXANE LABS

5MG/ML

N88810 001
FEB 20, 1985

/SYRUP; ORAL/

/PREDNISONE/INTENSOL/

/ROXANE/LABS/

/5MG/ML/

/N88810/001/
/FEB/20/1985/PREDNISONE

TABLET; ORAL

DELTASONE

UPJOHN

50MG

N09986 008

/BX/

/50MG/

/N09986/008/

PREDNISONE

/AM/THERPTCS/

/5MG/

/N89387/001/

> DLT > /AB/

> DLT >

> DLT > /AB/

> DLT >

> DLT > /AB/

> DLT >

> ADD > BX

AM THERPTCS

5MG

N89387 001

> ADD >

> ADD > BX

10MG

N89388 001

> ADD >

> ADD > BX

20MG

NOV 06, 1986

> ADD >

AB

CORD LABS

10MG

N89389 001

AB

50MG

NOV 06, 1986

AB

HALSEY DRUG

5MG

N89383 001

/BX/

/5MG/

JAN 12, 1989

> DLT > /BX/

/QUANTUM/PHARMS/

/5MG/

N89984 001

> DLT > /BX/

a QUANTUM PHARMS

/20MG/

JAN 12, 1989

> ADD >

a

5MG

N80300 001

> ADD >

a

20MG

/N80491/001/

/ROXANE/LABS/

/25MG/

/N85811/001/

a ROXANE LABS

25MG

/N87833/001/

/BX/

/VANGARD/LABS/

/5MG/

/MAY/04/1982/

/BX/

/20MG/

/N87682/001/

a VANGARD LABS

5MG

/N87682/001/

a

20MG

/N87701/001/

/AB/

/WHITE/TN/PAULSN/

/10MG/

JAN 15, 1982

/BX/

/2.5MG/

/N89028/001/

/BX/

/5MG/

/JUL/24/1986/

/BX/

/20MG/

/N84913/001/

a WHITE TN PAULSN

2.5MG

/N84913/002/

a

5MG

N84913 001

a

10MG

N80343 001

20MG

N89028 001

JUL 24, 1986

N84913 002

PREDNISONE

TABLET; ORAL		
<u>/SERVISON/</u>		
<u>/BX/</u>	<u>/LEDERLE/LABS/</u>	<u>/5MG/</u>
	Q LEADERLE LABS	5MG
		<u>/N80223/001/</u>
		N80223 001

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL		
<u>PROCAINAMIDE HCL</u>		
<u>/AB/</u>	<u>/VANGARD/LABS/</u>	<u>/250MG/</u>
		<u>/N87643/001/</u>
		<u>/JUN/01/1982/</u>
<u>/AB/</u>		<u>/500MG/</u>
		<u>/N87875/001/</u>
		<u>/JUN/01/1982/</u>
	Q VANGARD LABS	250MG
		N87643 001
		JUN 01, 1982
	Q	500MG
		N87875 001
		JUN 01, 1982

INJECTABLE; INJECTION		
<u>PROCAINAMIDE HCL</u>		
<u>/AB/</u>	<u>/PHARMAFAIR/</u>	<u>/100MG/ML/</u>
		<u>/N88824/001/</u>
		<u>/NOV/20/1985/</u>
<u>/AB/</u>		<u>/500MG/ML/</u>
		<u>/N88830/001/</u>
		<u>/NOV/20/1985/</u>
	Q PHARMAFAIR	100MG/ML
		N88824 001
		NOV 20, 1985
	Q	500MG/ML
		N88830 001
		NOV 20, 1985

TABLET, EXTENDED RELEASE; ORAL		
<u>PROCAINAMIDE HCL</u>		
<u>AB</u>	<u>INWOOD LABS</u>	<u>500MG</u>
		<u>/N89840 001</u>
		MAR 06, 1989

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION		
<u>PROCHLORPERAZINE EDISYLATE</u>		
<u>AP</u>	<u>ELKINS SINN</u>	<u>EQ 5MG BASE/ML</u>
		<u>/N89903 001</u>
		AUG 29, 1989

PROGESTERONE

INJECTABLE; INJECTION		
<u>PROGESTERONE</u>		
	<u>/LILLY/</u>	<u>/25MG/ML/</u>
	Q LILLY	25MG/ML
		<u>/N09238/002/</u>
		N09238 002

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION		
<u>/ZIPAH-25/</u>		
<u>/AP/</u>	<u>/ALTANA/</u>	<u>/25MG/ML/</u>
	Q ALTANA	25MG/ML
		<u>/N83997/001/</u>
		N83997 001
<u>/ZIPAH-50/</u>		
<u>/AP/</u>	<u>/ALTANA/</u>	<u>/50MG/ML/</u>
	Q ALTANA	50MG/ML
		<u>/N83997/002/</u>
		N83997 002

TABLET; ORAL		
<u>PROMETHAZINE HCL</u>		
<u>/A/</u>	<u>/BOOTS/PHARMS/</u>	<u>/12.5MG/</u>
		<u>/N84160/001/</u>
		<u>/JUN/01/1982/</u>
<u>/A/</u>		<u>/25MG/</u>
		<u>/N84166/001/</u>
		<u>/JUN/01/1982/</u>
	Q BOOTS USA	12.5MG
		N84160 001
	Q	25MG
		N84166 001
		50MG
		N84539 001
<u>/BP/</u>	<u>/CHELSEA/LABS/</u>	<u>/12.5MG/</u>
		<u>/N85986/001/</u>
<u>/BP/</u>		<u>/25MG/</u>
		<u>/N85684/001/</u>
<u>/BP/</u>		<u>/50MG/</u>
		<u>/N85664/001/</u>
	Q CHELSEA LABS	12.5MG
		N85986 001
	Q	25MG
		N85684 001
	Q	50MG
		N85664 001

PROPAFENONE HYDROCHLORIDE

TABLET; ORAL		
<u>RYTHMOL</u>		
	<u>KNOLL PHARM</u>	<u>150MG</u>
		<u>/N19151 001</u>
		NOV 27, 1989
		<u>/N19151 002</u>
		NOV 27, 1989
		<u>300MG</u>

PROPOFOL

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

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL		
<u>PROPOXYPHENE HCL</u>		
<u>/AA/</u>	<u>/CHELSEA/LABS/</u>	<u>/65MG/</u>
	Q CHELSEA LABS	65MG
		<u>/N85190/001/</u>
		N85190 001

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

IMDERAL 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
<u>PROPRANOLOL HCL</u>			
AB	INWOOD LABS	60MG x	N72499 001
			APR 11, 1989
AB		80MG x	N72500 001
			APR 11, 1989
AB		120MG x	N72501 001
			APR 11, 1989
AB		160MG x	N72502 001
			APR 11, 1989

SOLUTION; ORAL

PROPRANOLOL HCL

AA	PBI	20MG/5ML x	N71984 001
			MAR 03, 1989
AA		40MG/5ML x	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

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

PROPYLIODONE

SUSPENSION; INTRATRACHEAL

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

PROPYLTHIOURACIL

TABLET; ORAL

PROPYLTHIOURACIL

/AB/	/BOOTS/PHARMS/	/50MG/	/N84075/001/
	@ BOOTS USA	50MG	N84075 001
/BP/	/CHELSEA/LABS/	/50MG/	/N85201/001/
	@ CHELSEA LABS	50MG	N85201 001

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

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

PYRIDOSTIGMINE BROMIDE

SYRUP; ORAL
MESTINON
ICN PHARMS
/ROCHE/

60MG/5ML
/60MG/5ML/

N15193 001
/N15193/001/

TABLET; ORAL
MESTINON
ICN PHARMS
/ROCHE/

60MG
/60MG/

N09829 002
/N09829/002/

TABLET, EXTENDED RELEASE; ORAL
MESTINON
ICN PHARMS
/ROCHE/

180MG
/180MG/

N11665 001
/N11665/001/

QUINIDINE GLUCONATE

INJECTABLE; INJECTION
QUINIDINE GLUCONATE
/LILLY/
LILLY

/80MG/ML/
80MG/ML

/N07529/001/
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/

/N07837/001/
/APR/14/1982/

@ PBI 200MG

N87837 001
APR 14, 1982

> DLT > /AB/ /QUANTUM/PHARMS/ /200MG/

/N03622/001/
N83622 001

> ADD > @ QUANTUM PHARMS 200MG

/AB/ /WHITE/TN/PAULSN/ /200MG/

/N05444/001/
N85444 001

@ WHITE TN PAULSN 200MG

RESERPINE

TABLET; ORAL
RESERPINE
/BP/ /ROXANE/LABS/
@ ROXANE LABS

/0.25MG/
0.25MG

/N09859/002/
N09859 002

RESERPINE

TABLET; ORAL
RESERPINE
/BP/ /ZENITH/LABS/
/BP/

/0.1MG/
/0.25MG/

/N11185/001/
/N11185/002/

@ ZENITH LABS
@

0.1MG
0.25MG

N11185 001
N11185 002

RIFAMPIN

CAPSULE; ORAL
RIFADIN
/AB/ /DOW/PHARMS/

/300MG/
/150MG/

/N50420/001/
/N50420/001/

AB MERRELL DOW

300MG
150MG

N50420 001
N62303 001

INJECTABLE; INJECTION
RIFADIN
MERRELL DOW

600MG/VIAL

N50627 001
MAY 25, 1989

> ADD > RUBIDIUM CHLORIDE RB-82

> ADD > INJECTABLE; INJECTION
> ADD > CARDIOGEN-82
> ADD > SQUIBB DIAGS
> ADD >

N/A

N19414 001
DEC 29, 1989

SAFFLOWER OIL

/INJECTABLE; INJECTION/

/LIPOSYN/10%/

/ABBOTT/LABS/

/10%/

/N18203/001/

@ ABBOTT LABS

10%

N18203 001

/LIPOSYN/20%/

/ABBOTT/LABS/

/20%/

/N18614/001/

@ ABBOTT LABS

20%

N18614 001

SCOPOLAMINE

> DLT > /FILM; EXTENDED RELEASE; PERCUTANEOUS/
> DLT > /TRANSDERM-SCOP/
> DLT > /CIBA/PHARM/

/0.5MG/24HR/

/N11874/001/

SCOPOLAMINE

> ADD > FILM, EXTENDED RELEASE; TRANSDERMAL
 > ADD > TRANSDERM-SCOP
 > ADD > CIBA PHARM 0.5MG/24HRM N17874 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
SECOBARBITAL SODIUM
 /AA/ /WHITE/TN/PAULSN/ /100MG/ /N85798/001/
 @ WHITE TN PAULSN 100MG N85798 001
SODIUM SECOBARBITAL
 /AA/ /CHELSEA/LABS/ /100MG/ /N85792/001/
 @ CHELSEA LABS 100MG N85792 001

SECRETIN

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

SELEGILINE HYDROCHLORIDE

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

SELENOMETHIONINE, SE-75

INJECTABLE; INJECTION
 SELENOMETHIONINE SE 75
 /MALLINCKRODT/ /100UCI/ML/ /N17098/001/
 @ MALLINCKRODT 100 UCI/ML N17098 001
 /MEDI/PHYSICS/ /250UCI/ML/ /N17257/001/
 @ MEDI PHYSICS 250 UCI/ML N17257 001

SILVER SULFADIAZINE

CREAM; TOPICAL
SSD
 /AB/ /BOOTS/FLINT/ /1Z/ /N18578/001/
 /FEB/25/1982/
 AB BOOTS USA 1Z N18578 001
 FEB 25, 1982

SILVER SULFADIAZINE

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

SINCALIDE

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

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 /AB/ /CUTTER/BIOL/ /450MG/100ML/ /N18503/001/
 @ CUTTER BIOL 450MG/100ML N18503 001
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 /AB/ /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 UCIM N71909 001
 FEB 28, 1989
 AA 200 UCIM N71910 001
 FEB 28, 1989

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL
 /PHOSPHOTOPÉ/
 /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/BOTM

N89910 001
 JAN 19, 1989

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULTEN-10
 /AT/ /MURDO/PHARM/ /10Z/

/N87818/001/
 /FEB/03/1983/

SOMATREM

INJECTABLE; INJECTION
 PROTROPIN
 GENENTECH 10MG/VIALM

N19107 002
 OCT 24, 1989

SULFINPYRAZONE

CAPSULE; ORAL
SULFINPYRAZONE
 /AB/ /VANGARD/LABS/ /200MG/
 @ VANGARD LABS 200MG

/N88666/001/
 /FEB/17/1984/
 N88666 001
 FEB 17, 1984

SOMATROPIN, BIOSYNTHETIC

INJECTABLE; INJECTION
 HUMATROPE
 /LILLY/ /2MG/VIAL/
 @ LILLY 2MG/VIAL

/N19640/001/
 /JUN/23/1987/
 N19640 001
 JUN 23, 1987

SULFISOXAZOLE

TABLET; ORAL
 SULFISOXAZOLE
 /@/BOOTS/PHARMS/ /500MG/
 @ PHARMAFAIR 500MG

/N84385/001/
 N84385 001

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
 /AB/ /VANGARD/LABS/ /25MG/
 @ VANGARD LABS 25MG

/N87648/001/
 /FEB/01/1982/
 N87648 001
 FEB 01, 1982

SUTILAINS

OINTMENT; TOPICAL
 TRAVASE
 /BAXTER/ /82,000/UNITS/GM/
 BOOTS USA 82,000 UNITS/GM

/N12828/001/
 N12828 001

SULCONAZOLE NITRATE

CREAM; TOPICAL
 SULCOSYN
 /SANTEX/LABS/ /1ZM/
 WESTWOOD PHARMS 1ZM

/N18737/001/
 /FEB/28/1989/
 N18737 001
 FEB 28, 1989

TECHNETIUM TC-99M FERMENTETATE KIT

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

/N17045/001/
 N17045 001

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
TECHNESCAN DTPA KIT
 MS&D RES LABS N/A

N18511 001
 DEC 29, 1989

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULTEN-10
 AT BAUSCH & LOMB 10Z

N87818 001
 FEB 03, 1983

> ADD >
 > ADD > AP
 > ADD >

TECHNETIUM TC-99M PYROPHOSPHATE KIT

INJECTABLE; INJECTION

/AP/ /AN-PYROTEC/
/CIS/US/ /N/A/
@ CIS US N/A

/N19039/001/
/JUN/30./1987/
N19039 001
JUN 30, 1987

> DLT >
> ADD >
> ADD >
> ADD >
> ADD >

TEMAZEPAM

CAPSULE; ORAL

/TEMAZ/
@ QUANTUM PHARMCS 15MG
@ 30MG

N70564 001
OCT 15, 1985
N70547 001
OCT 15, 1985

TECHNETIUM TC-99M SODIUM PERTECHNETATE

SOLUTION; INJECTION, ORAL

SODIUM PERTECHNETATE TC 99M

/AP/ /CIS/US/ /12MCI/ML/
/AP/ /24MCI/ML/
/AP/ /48MCI/ML/
@ CIS US 12MCI/ML
@ 24MCI/ML
@ 48MCI/ML
/SAMMA/DIAG/LABS/ /10-60MCI/ML/
MALLINCKRODT 10-60MCI/ML

/N17321/001/
/N17321/002/
/N17321/003/
N17321 001
N17321 002
N17321 003
/N17725/001/
N17725 001

> DLT >
> ADD >

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

/2/BOOTS/PHARMS/ /250MG/
/2/ /500MG/
@ BOOTS USA 250MG
@ 500MG
/AB/ /CHELSEA/LABS/ /250MG/
/AB/ /500MG/
@ CHELSEA LABS 250MG
@ 500MG
/AB/ /QUANTUM/PHARMCS/ /250MG/
/AB/ /QUANTUM PHARMCS /250MG/
/AB/ /VITARINE/ /250MG/
BX VITARINE 250MG
BX 500MG

/N61802/001/
/N61802/002/
N61802 001
N61802 002
/N62103/001/
/N62103/002/
N62103 001
N62103 002
/N60059/001/
N60059 001
/N61471/001/
N61471 001
N61471 002
SEP 06, 1988

TECHNETIUM TC-99M SULFUR COLLOID

SOLUTION; INJECTION, ORAL

TECHNETIUM TC 99M SULFUR COLLOID

/SAMMA/DIAG/LABS/ /3MCI/ML/
MALLINCKRODT 3MCI/ML

/N17724/001/
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

TEMAZEPAM

CAPSULE; ORAL

/TEMAZ/
> DLT > /AB/ /QUANTUM/PHARMCS/ /15MG/
> DLT > /AB/ /30MG/
> DLT >
> DLT >

/N70564/001/
/OCT/15./1985/
/N70547/001/
/OCT/15./1985/

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/
/BX/ /200MG/
BX FOREST LABS 100MG
BX 200MG

/N85545/001/
/JUL/31./1984/
/N83921/001/
/JUL/31./1984/
N85545 001
JUL 31, 1984
N83921 001
JUL 31, 1984

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL			
SLO-BID			
BC	RORER PHARM	75MG	N89539 001 MAY 10, 1989
BC		125MG	N89540 001 MAY 10, 1989
THEO-DUR SPRINKLE			
BC	KEY PHARMS	75MG	N88015 001 SEP 10, 1985
ELIXIR; ORAL			
<u>ELIXOPHYLLIN</u>			
/AA/	/BERLEX/LABS/	/80MG/15ML/	/N85186/001/
AA	FOREST LABS	80MG/15ML	N85186 001
SUSPENSION; ORAL			
ELIXICON			
	/BERLEX/LABS/	/100MG/5ML/	/N85502/001/
	FOREST LABS	100MG/5ML	N85502 001
TABLET; ORAL			
QUIBRON-T			
	BRISTOL MYERS	300MG	N88656 001 AUG 22, 1985
	/MEAD/JOHNSON/	/300MG/	/N88656/001/
			/AUG/22/1985/
TABLET, EXTENDED RELEASE; ORAL			
QUIBRON-T/SR			
BC	BRISTOL MYERS	300MG	N87563 001 JUN 21, 1983
/BC/	/MEAD/JOHNSON/	/300MG/	/N87563/001/
			/JUN/21/1983/
<u>THEO-DUR</u>			
AB	KEY PHARMS	100MG	N85328 001
AB		200MG	N86998 001
/BC/		/100MG/	/N85328/001/
/BC/		/200MG/	/N86998/001/
<u>THEOPHYLLINE</u>			
AB	INWOOD LABS	100MG	N88320 001 FEB 21, 1985
AB		200MG	N88321 001 FEB 21, 1985
/BC/		/100MG/	/N88320/001/
/BC/		/200MG/	/FEB/21/1985/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL			
<u>THIORIDAZINE HCL</u>			
/AB/	/CHELSEA/LABS/	/15MG/	/N88562/001/
	3 CHELSEA LABS	15MG	/MAY/11/1984/
			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/	/N16904/002/
	ROERIG	EQ 10MG BASE/VIAL	N16904 002

TIMOLOL MALEATE

TABLET; ORAL			
<u>BLOCADREN</u>			
AB	MS&D	5MG	N18017 001
AB		10MG	N18017 002
AB		20MG	N18017 004
<u>TIMOLOL MALEATE</u>			
AB	BOLAR PHARM	5MG	N72269 001
			APR 11, 1989 : MAR 14, 1989
AB		10MG	N72270 001
			APR 11, 1989 : MAR 14, 1989
AB		20MG	N72271 001
			APR 11, 1989 : MAR 14, 1989
AB	CORD LABS	5MG	N72550 001
			APR 13, 1989
AB		10MG	N72551 001
			APR 13, 1989
AB		20MG	N72552 001
			APR 13, 1989
AB	PBI	5MG	N72001 001
			APR 11, 1989 : JAN 10, 1989
AB		10MG	N72002 001
			APR 11, 1989 : JAN 10, 1989
AB		20MG	N72003 001
			APR 11, 1989 : JAN 10, 1989

TIMOLOL MALEATE

TABLET; ORAL

TIMOLOL MALEATE

> DLT >	/BX/	/QUANTUM/PHARMCS/	/5MG/	/N72466/001/
> DLT >				/MAY/19./1989/
> ADD >		Q QUANTUM PHARMCS	5MG	N72466 001
> ADD >				MAY 19, 1989
> DLT >	/BX/	/QUANTUM/PHARMCS/	/10MG/	/N72466/001/
> DLT >				/MAY/19./1989/
> ADD >		Q QUANTUM PHARMCS	10MG	N72467 001
> ADD >				MAY 19, 1989
> DLT >	/BX/	/QUANTUM/PHARMCS/	/20MG/	/N72466/001/
> DLT >				/MAY/19./1989/
> ADD >		Q QUANTUM PHARMCS	20MG	N72468 001
> ADD >				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
	<u>TOBRAMYCIN SULFATE</u>		
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/
	Q VANGARD LABS	500MG	N87876 001
			APR 20, 1982

TOLMETIN SODIUM

TABLET; ORAL

TOLECTIN 600

MCNEIL PHARM

EQ 600MG BASE	N17628 002
	MAR 08, 1989

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL

AB	LEMMON	50MG	N72192 001
			FEB 02, 1989
AB		100MG	N72193 001
			FEB 02, 1989
> DLT >	/BX/	/QUANTUM/PHARMCS/	/100MG/
> DLT >			
> ADD >		Q QUANTUM PHARMCS	100MG
> ADD >			
	TRIALODINE		
> DLT >	/BX/	/QUANTUM/PHARMCS/	/50MG/
> DLT >			
> ADD >		Q QUANTUM PHARMCS	50MG
> ADD >			

TRIAMCINOLONE

TABLET; ORAL

TRIAMCINOLONE

/BP/	/CHELSEA/LABS/	/4MG/	/N85834/001/
	Q 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/
	Q CHELSEA LABS	2MG	N86458 001

TRIHENXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL

ARTANE

AA	LEDERLE LABS	2MG/5ML	N06773 009
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PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
 TRIPROLIDINE AND PSEUDOEPHEDRINE HCL
 KV PHARM 120MG;5MGx

N71798 001
 MAR 16, 1989

SYRUP; ORAL

/MYFED/
 /PBI/

/30MG/5ML;1.25MG/5ML/

/N88116/001/
 /MAR/04/1983/

Q PBI

30MG/5ML;1.25MG/5ML

N88116 001
 MAR 04, 1983

PSEUDOEPHEDRINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

PSEUDO-12

FISONS

EQ 60MG HCL/5ML

N19401 001

JUN 19, 1987

/PENNYALT/

/EQ/60MG/HCL/5ML/

/N19401/001/
 /JUN/19/1987/

SODIUM MONOFLUOROPHOSPHATE

> DLT >

/PASTE;DENTAL/

> DLT >

/EXTRA-STRENGTH/AM/

> DLT >

/CHESEBROUGH/

/1.2%/

/N19518/001/
 /JUN/03/1987/

> DLT >

> ADD >

Q CHESEBROUGH

1.2%

N19518 001
 JUN 03, 1987

> ADD >

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

PERFLUORODECALIN; PERFLUOROTRI-N-PROPYLAMINE

INJECTABLE; INJECTION

FLUOSOL

ALPHA THERPTC

17.5GM/100ML; 7.5GM/100ML

N 860909
DEC 26, 1989

ORPHAN DRUG DESIGNATIONS

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

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

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

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

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

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ANCROD TRADE: ARVIN	FOR USE AS AN ANTITHROMBOTIC IN PATIENTS WITH HEPARIN-INDUCED THROMBOCYTOPENIA OR THROMBOSIS, WHO REQUIRE IMMEDIATE AND CONTINUED ANTICOAGULATION.	KNOLL PHARMACEUTICALS 30 NO. JEFFERSON RD WHIPPANY, NJ 07981
GENERIC: ANTIHEMOPHILIC FACTOR (RECOMBINANT) TRADE: NOT ESTABLISHED	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. CUTTER BIOLOGICAL ELKHART, IN 46515
GENERIC: ANTITHROMBIN III (HUMAN) TRADE: ATNATIV*/**	HEREDITARY AT-III DEFICIENCY IN CONNECTION WITH SURGICAL OR OBSTETRICAL PROCEDURES OR WHEN THEY SUFFER FROM THROMBOEMBOLISM. [DEC 13, 1996]	KABI VITRUM, INC. 160 INDUSTRIAL DR. FRANKLIN, CA 45005
GENERIC: CD4, HUMAN RECOMBINANT SOLUBLE TRADE: RECEPTIN	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	BIOGEN, INCORPORATED 14 CAMBRIDGE CENTER CAMBRIDGE, MA 02142
GENERIC: CD4, HUMAN TRUNCATED-369 AA POLYPEPTIDE (RECOMBINANT CHO CELLS) TRADE: SOLUBLE T4	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	SMITH KLINE & FRENCH LABORATORIES 1500 SPRING GARDEN STREET PHILADELPHIA, PA 19101
GENERIC: GRANULOCYTE MACROPHAGE-COLONY STIMULATING FACTOR, RECOMBINANT E. COLI [RGM-CSF] TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE THERMAL INJURIES IN PATIENTS WITH GREATER THAN 40% FULL OR PARTIAL THICKNESS BURNS. TREATMENT OF PATIENTS WITH MYELODYSPLASTIC SYNDROME. TREATMENT OF APLASTIC ANEMIA. TREATMENT OF NEUTROPENIA ASSOCIATED WITH BONE MARROW TRANSPLANT (BMT).	SCHERING CORPORATION 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: HUMAN IGM MONOCLONAL ANTIBODY (C-58) TO CYTOMEGALOVIRUS (CMV) TRADE: CENTOVIR	TREATMENT OF CYTOMEGALOVIRUS (CMV) INFECTIONS IN BONE MARROW TRANSPLANT PATIENTS. PROPHYLAXIS OF CMV INFECTIONS IN BONE MARROW TRANSPLANT PATIENTS.	CENTOCOR, INC. 244 GREAT VALLEY PKWY MALVERN, PA 19355
GENERIC: HUMAN IMMUNODEFICIENCY VIRUS (HIV-1) IMMUNE GLOBULIN (HUMAN) I.V. TRADE: NOT ESTABLISHED	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)	ABBOTT LABORATORIES DIAGNOSTICS DIVISION ABBOTT PARK, IL 60064
GENERIC: HUMAN T-LYMPHOTROPIC VIRUS TYPE III gp160 ANTIGENS, RECOMBINANT VACCINE, ALUM ABSORBED TRADE: VAXSYN HIV-1	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	MICROGENESYS, INC. 400 FRONTAGE ROAD WEST HAVEN, CT 06516
GENERIC: INDIUM IN 111 MURINE MONOCLONAL ANTIBODY B72.3 TRADE: ONCOSCINT OV103	DETECTION OF OVARIAN CANCER.	CYTOGEN CORPORATION 201 COLLEGE RD. EAST PRINCETON, NJ 08540
GENERIC: INDIUM IN 111 MURINE MONOCLONAL ANTIBODY FAB TO MYOSIN TRADE: MYOSCINT	DIAGNOSING MYOCARDITIS.	CENTOCOR, INC 244 GREAT VALLEY PKWY MALVERN, PA 19355
GENERIC: INTERFERON ALFA-2A (RECOMBINANT) TRADE: ROFERON-A	TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA (CML). FOR USE IN COMBINATION WITH FLUOROURACIL FOR THE TREATMENT OF ESOPHAGEAL CARCINOMA.	HOFFMAN-LA ROCHE 340 KINGSLAND STREET NUTLEY, NJ 07110
GENERIC: IODINE I 131 MURINE MONOCLONAL ANTIBODY IGG2A TO B CELL TRADE: IMMURAIT, LL-2-I-131	TREATMENT OF B-CELL LEUKEMIA AND B-CELL LYMPHOMA.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060
GENERIC: MELANOMA VACCINE TRADE: MELACCINE TM	TREATMENT OF STAGE III-IV MELANOMA.	RIBI IMMUNOCHEM RESEARCH, INC. 553 OLD CORVALLIS RD. HAMILTON, MT 59840

BIOLOGICAL DRUG DESIGNATIONS

[Approved for Marketing*]

[Exclusive Approval**]

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

<u>NAME OF DRUG</u>	<u>DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]</u>	<u>SPONSOR NAME AND ADDRESS</u>
GENERIC: ADENOSINE TRADE: NOT ESTABLISHED	FOR USE IN CONJUNCTION WITH BCNU IN THE TREATMENT OF BRAIN TUMORS.	MEDCO RES INC. 8733 BEVERLY BLVD. SUITE 404 LOS ANGELES, CA 90048
GENERIC: BETHANIDINE SULFATE TRADE: NOT ESTABLISHED	FOR THE PREVENTION OF THE RECURRENCE OF PRIMARY VENTRICULAR FIBRILLATION.	MEDCO RESEARCH, INC 8733 BEVERLY BLVD. SUITE 404 LOS ANGELES, CA 90048
GENERIC: BROMHEXINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF MILD TO MODERATE KERATOCONJUNCTIVITIS SICCA IN PATIENTS WITH SJOGREN'S SYNDROME.	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. 90 EAST RIDGE P.O. BOX 368 RIDGEFIELD, CT 06877
GENERIC: CALCIUM ACETATE TRADE: NOT ESTABLISHED	TREATMENT OF HYPERPHOSPHATEMIA IN END STAGE RENAL DISEASE (ESRD).	PHARMEDIC COMPANY 130 EXMOOR COURT DEERFIELD, IL 60015
GENERIC: (-) CARBOVIR TRADE: NOT ESTABLISHED	TREATMENT OF PERSONS WITH AIDS AND IN THE TREATMENT OF PERSONS WITH SYMPTOMATIC HIV INFECTION AND A CD4 COUNT OF LESS THAN 200/MM ³ .	GLAXO INC. 5 MOORE DRIVE RESEARCH TRIANGLE PARK, NC 27709
GENERIC: CITRIC ACID, GLUCONO-DELTA-LACTONE, AND MAGNESIUM CARBONATE TRADE: RENACIDIN	TREATMENT OF RENAL AND BLADDER CALCULI OF THE APATITE OR STRUVITE VARIETY.	UNITED GUARDIAN, INC. 230 MARCUS BLVD. HAUPPUGA, NY 11788

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

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

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: HUMAN GROWTH HORMONE, RECOMBINANT TRADE: NOT ESTABLISHED	TREATMENT OF CHILDREN OF SHORT STATURE ASSOCIATED WITH CHRONIC RENAL FAILURE.	GENETECH, INC. 460 PT SAN BRUNO BLVD. SOUTH SAN FRANCISCO, CA 94080
GENERIC: HUMAN GROWTH HORMONE RELEASING FACTOR TRADE: NOT ESTABLISHED	FOR THE LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	HOFFMAN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF RAYNAUD'S PHENOMENON SECONDARY TO SYSTEMIC SCLEROSIS.	BERLEX LABORATORIES 110 EAST HANOVER AVE CEDAR KNOLLS, NJ 07927
GENERIC: L-CARNITINE TRADE: VITA CARN	PREVENTION OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY. TREATMENT OF SECONDARY CARNITINE DEFICIENCY IN VALPROIC ACID TOXICITY.	KENDALL MCGAW LABORATORIES, INC 2525 MCGAW AVENUE IRVINE, CA 92714-5898
GENERIC: L-CYCLOSERINE TRADE: NOT ESTABLISHED	TREATMENT OF GAUCHER'S DISEASE.	THE CITY COLLEGE CITY UNIVERSITY OF N.Y. MEDICAL SCHOOL CONVENT AVE. @ 138 ST. N.Y., NY 10031
GENERIC: LYSINE ACETYLSALICYLATE TRADE: ASPEGIC	TREATMENT OF PAIN AND FEVER SECONDARY TO SICKLE CELL DISEASE CRISIS.	G.D. SEARLE & CO. 4901 SEARLE PKWY SKOKIE, IL 60077
GENERIC: MULTI-VITAMIN INFUSION-NEONATAL FORMULA TRADE: NOT ESTABLISHED	FOR THE ESTABLISHMENT AND MAINTENANCE OF TOTAL PARENTERAL NUTRITION IN VERY LOW BIRTH WEIGHT INFANTS (LESS THAN 1500 GRAMS).	ARMOUR PHARMACEUTICAL 920 A HARVEST DRIVE SUITE 200 BLUE BELL, PA 19422

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: NG-29 TRADE: NOT ESTABLISHED	FOR THE ASSESSMENT OF THE CAPACITY OF THE PITUITARY GLAND TO RELEASE GH IN CHILDREN OF SHORT STATURE POSSIBLY DUE TO GH DEFICIENCY.	FERRING LABORATORIES MONTEBELLO PARK 75 MONTEBELLO RD. SUFFERN, NY 10901
GENERIC: OVINE CORTICOTROPIN RELEASING HORMONE (oCRH) TRADE: NOT ESTABLISHED	USE IN DIFFERENTIATING PITUITARY AND ECTOPIC PRODUCTION OF ACTH IN PATIENTS WITH ACTH-DEPENDENT CUSHING'S SYNDROME.	FERRING LABORATORIES INCORPORATED MONTEBELLO PARK 75 MONTEBELLO RD. SUFFERN, NY 10901
GENERIC: PENTAMIDINE ISETHIONATE (INHALATION) TRADE: NEBUPENT*/** (FORMERLY PENTAM 300)	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN PATIENTS AT HIGH RISK OF DEVELOPING THIS DISEASE. [JUN 15, 1996]	LYPHOMED, INC. 2020 RUBY STREET MELROSE PARK, IL 60160
GENERIC: POLOXAMER 188, N.F. TRADE: RHEOTHRX COPOLYMER	TREATMENT OF SICKLE CELL CRISIS.	CYTRX CORPORATION 150 TECHNOLOGY PARKWAY TECHNOLOGY PARK/ATLANTA NORCROSS, GA 30092
GENERIC: POLYMER IMPLANT CONTAINING CARMUSTINE TRADE: BIODEL™ CONTAINING BCNU	FOR THE LOCALIZED PLACEMENT IN THE BRAIN FOR THE TREATMENT OF RECURRENT MALIGNANT GLIOMA.	NOVA PHARMACEUTICAL CORPORATION 6200 FREEPORT CENTER BALTIMORE, MD 21224-2788
GENERIC: RIFABUTIN TRADE: NOT ESTABLISHED	FOR THE PREVENTION OF MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE IN PATIENTS WITH AIDS AND IN PATIENTS WITH CD4 COUNTS LESS THAN 200/MM ³ . FOR THE TREATMENT OF DISSEMINATED MYCOBACTERIUM AVIUM COMPLEX (MAC) DISEASE.	ADRIA LABORATORIES P.O. BOX 16529 COLUMBUS, OH 43216
GENERIC: RIFAMPIN TRADE: RIFADIN I.V.*/**	ANTITUBERCULOSIS TREATMENT WHERE USE OF THE ORAL FORM OF THE DRUG IS NOT FEASIBLE. [MAY 25, 1996]	MERRELL DOW RESEARCH INST. 2110 E. GALBRAITH CINCINNATI, OH 45215

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: SELEGILINE HCL TRADE: ELDEPRYL*/** (FORMERLY DEPRENYL)	ADJUNCT IN THE MANAGEMENT OF PARKINSONIAN PATIENTS BEING TREATED WITH LEVODOPA/CARBIDOPA WHO EXHIBIT DETERIORATION IN THE QUALITY OF THEIR RESPONSE TO THIS THERAPY*/**. [JUNE 05, 1996]	SOMERSET PHARMACEUTICALS ONE OLDE TOWNE COURT BERNARDSVILLE, NJ 07924
GENERIC: SOMATROPIN TRADE: SAIZEN	ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES 100 LONGWATER CIRCLE NORWELL, MA 02061
GENERIC: SYNTHETIC SURFACTANT TRADE: EXOSURF	PREVENTION OF HYALINE MEMBRANE DISEASE (HMD), ALSO KNOWN AS RESPIRATORY DISTRESS SYNDROME (RDS), IN INFANTS BORN AT 32 WEEKS GESTATION OR LESS. TREATMENT OF ESTABLISHED HMD AT ALL GESTATIONAL AGES.	BURROUGHS WELLCOME 3030 CORNWALLIS RD RESEARCH TRIANGLE PK, NC 27709
GENERIC: TROLEANDOMYCIN TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE STEROID-REQUIRING ASTHMA	STANLEY SZEFLER, MD NATIONAL JEWISH CENTER FOR IMMUNOLOGY AND RESPIRATORY MEDICINE 1400 JACKSON STREET DENVER, CO 80206
GENERIC: T4 ENDONUCLEASE V, LIPOSOME ENCAPSULATED TRADE: T4N5	TO PREVENT CUTANEOUS NEOPLASMS AND OTHER SKIN ABNORMALITIES ASSOCIATED WITH PATIENTS DIAGNOSED WITH XERODERMA PIGMENTOSUM (XP).	APPLIED GENETICS, INC. 205 BUFFALO AVENUE FREEPORT, NY 11520
GENERIC: 3'AZIDO-2', 3'DIDEOXYURIDINE TRADE: NOT ESTABLISHED	TREATMENT OF ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS).	TRITON BIOSCIENCES INCORPORATED 1501 HARBOR BAY PKWY ALAMEDA, CA 94501

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

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

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

NO DECEMBER 1989 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR IN VIVO BIOEQUIVALENCE STUDIES AND IN VITRO DISSOLUTION TESTING AVAILABLE FROM THE DIVISION OF BIOEQUIVALENCE, HFN-250, ROOM 17B-06, 5600 FISHERS LANE, ROCKVILLE, MD 20857. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER - <u>IN VITRO</u>)	AUG 25, 1988	JUN 27, 1989
ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER - <u>IN VIVO</u>)	AUG 25, 1988	FEB 09, 1989
GEMFIBROZIL (CAPSULE)	JUN 23, 1989	
TOLMETIN SODIUM (CAPSULE AND TABLET)	APR 20, 1989	

ANDA SUITABILITY PETITIONS

THE FOLLOWING ARE TWO LISTS OF PETITIONS FILED UNDER SECTION 505(j)(2)(C) OF THE ACT WHERE THE AGENCY HAS DETERMINED THAT THE REFERENCED PRODUCT: (1) IS SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS APPROVED) OR (2) IS NOT SUITABLE FOR SUBMISSION AS AN ANDA (PETITIONS DENIED). THE DETERMINATION THAT AN ANDA WILL BE APPROVED IS NOT MADE UNTIL THE ANDA ITSELF IS SUBMITTED AND REVIEWED BY THE AGENCY. A COPY OF EACH PETITION IS LISTED BY DOCKET NUMBER ON PUBLIC DISPLAY IN FDA'S DOCKETS MANAGEMENT BRANCH, HFA-305, ROOM 4-62, 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 9TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
ACETAMINOPHEN; BUTALBITAL; CAFFEINE CAPSULE; ORAL	500MG 50MG 40MG	89 P-0345/CP	MALLARD	NEW DOSAGE FORM	APPROVED OCT 27, 1989
ACETAMINOPHEN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 10MG	88 P-0416/CP	MORAVEC	NEW STRENGTH	APPROVED MAR 01, 1989
CARMUSTINE, STERILE INJECTABLE; INJECTION	200MG/VIAL	88 P-0410/CP	QUAD PHARMS	NEW STRENGTH	APPROVED FEB 13, 1989
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989
HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89 P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

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

EXCLUSIVITY TERMS

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

REFERENCES
NEW DOSING SCHEDULE

D-16 CONTINUOUS INTRAVENOUS INFUSION

NEW INDICATION

~~I-73 FOLLICULAR STIMULATION IN IN VITRO FERTILIZATION~~
I-73 STIMULATE THE DEVELOPMENT OF MULTIPLE FOLLICLES/OOCYTES IN OVULATORY PATIENTS PARTICIPATING IN AN IN VITRO FERTILIZATION PROGRAM
I-84 ADJUNCTIVE THERAPY TO DIET TO REDUCE THE RISK OF CORONARY ARTERY DISEASE
I-85 SELECTIVE ADULT VISCERAL ARTERIOGRAPHY
I-86 METASTATIC BREAST CANCER IN PREMENOPAUSAL WOMEN AS AN ALTERNATIVE TO OOPHORECTOMY OR OVARIAN IRRADIATION
I-87 TREATMENT OF TINEA PEDIS
I-88 CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS IN THE SPINE AND ASSOCIATED TISSUES
I-89 PEDIATRIC MYELOGRAPHY
I-90 ORAL USE OF DILUTED OMNIPAQUE INJECTION IN ADULTS FOR CONTRAST ENHANCED COMPUTED TOMOGRAPHY OF THE ABDOMEN
I-91 ORAL USE IN ADULTS FOR PASS-THROUGH EXAMINATION OF THE GASTROINTESTINAL TRACT
I-92 PEDIATRIC CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC HEAD IMAGING
I-93 ARTHROGRAPHY OF THE SHOULDER JOINTS IN ADULTS
I-94 RADIOGRAPHY OF THE TEMPOROMANDIBULAR JOINT IN ADULTS
I-95 CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS OF THE CENTRAL NERVOUS SYSTEM IN CHILDREN (2 YEARS OF AGE AND OLDER)
I-96 TREATMENT OF ACUTE MYOCARDIAL INFARCTION
I-97 PRIMARY NOCTURNAL ENURESIS

EXCLUSIVITY TERMS

REFERENCES
PATENT USE CODE

U-41 METHOD FOR TREATING PROSTATIC CARCINOMA COMPRISING ADMINISTERING FLUTAMIDE
U-42 METHOD FOR TREATING PROSTATE ADENOCARCINOMA COMPRISING ADMINISTERING AN ANTIANDROGEN INCLUDING
FLUTAMIDE AND AN LHRH AGONIST
U-43 REDUCING CHOLESTEROL IN CHOLELITHIASIS PATIENTS
U-44 REDUCING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-45 DISSOLVING CHOLESTEROL GALLSTONES AND/OR FRAGMENTS THEREOF
U-46 CEREBRAL, CORONARY, PERIPHERAL, VISCERAL AND RENAL ARTERIOGRAPHY, AORTOGRAPHY AND
LEFT VENTRICULOGRAPHY
U-47 CT IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY
U-48 CEREBRAL ANGIOGRAPHY, AND VENOGRAPHY
U-49 INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY
U-50 PALLIATIVE TREATMENT OF PATIENTS WITH OVARIAN CARCINOMA RECURRENT AFTER PRIOR CHEMOTHERAPY,
INCLUDING PATIENTS WHO HAVE BEEN PREVIOUSLY TREATED WITH CISPLATIN
U-51 TREATING VIRAL INFECTIONS IN A MAMMAL
U-52 TREATING VIRAL INFECTIONS IN A WARM BLOODED ANIMAL
U-53 TREATING CYTOMEGALOVIRUS IN A HUMAN WITH AN INJECTABLE COMPOSITION
U-54 METHODS OF TREATING BACTERIAL ILLNESSES
U-55 METHOD OF TREATING GASTROINTESTINAL DISEASE
U-56 TREATMENT OF PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA
~~U-57~~ ~~ANGINA/MYOCARDIAL/INFARCTION~~
U-57 ANGINA PECTORIS
U-58 ACUTE MYOCARDIAL INFARCTION
U-59 METHOD OF TREATMENT OF BURNS
U-60 METHOD OF TREATING CARDIAC ARRHYTHMIAS

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
>ADD>	19909 001	ACYCLOVIR; ZOVIRAX	4199574	APR 22, 1997		NCE	MAR 29, 1992
	19937 002	ADENOSINE; ADENOCARD	4673563	JUN 16, 2004	U-56	NCE	OCT 30, 1994
	19729 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
>DLT>	18207 001	AMLODIPINE HYDROCHLORIDE; MORTUARIUM 3-30	3787430	DEC 23, 1990			
	18240 001	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
			3836671	SEP 17, 1991	U-57		
			3836671	SEP 17, 1991	U-58		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
	18240 002	ATENOLOL; TENORMIN	3934032	JAN 20, 1993	U-5		
			3836671	SEP 17, 1991	U-57		
			3836671	SEP 17, 1991	U-58		
			3663607	MAY 16, 1989		I-96	SEP 13, 1992
	19058 001	ATENOLOL; TENORMIN	3836671	SEP 17, 1991		NDF	SEP 13, 1992
	19459 001	AVOBENZONE; PHOTOPLEX	4387089	JUN 07, 2002		NCE	SEP 30, 1993
	19716 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4775529	OCT 04, 2005		NP	AUG 01, 1991
	19270 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC	4252984	AUG 30, 1999		NCE	AUG 30, 1990
	19507 001	BETAXOLOL HYDROCHLORIDE; KERLONE	4311708	JAN 19, 1999	U-5	NCE	AUG 30, 1990
			4252984	AUG 30, 1999		NDF	OCT 27, 1992
	19507 002	BETAXOLOL HYDROCHLORIDE; KERLONE	4311708	JAN 19, 1999	U-5	NCE	AUG 30, 1990
			4252984	AUG 30, 1999		NDF	OCT 27, 1992
>ADD>	19845 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC S	4342783	AUG 03, 1999			
>ADD>			4311708	JAN 19, 1999			
>ADD>			4252984	AUG 30, 1999		NCE	AUG 30, 1990
	18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18469 001	CALCIUM CHLORIDE; BSS PLUS	4550022	OCT 29, 2002			
			4443432	APR 17, 2001			
	19880 001	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 002	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 003	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19204 001	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
	19204 002	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
	19204 003	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1994		NCE	DEC 28, 1993
	17939 002	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993		D-16	NOV 13, 1992
	19537 002	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
	19537 003	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
	19537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
>ADD>	19906 001	CLOMIPRAMINE HYDROCHLORIDE; ANAFRANIL				NCE	DEC 29, 1994
>ADD>	19906 002	CLOMIPRAMINE HYDROCHLORIDE; ANAFRANIL				NCE	DEC 29, 1994
>ADD>	19906 003	CLOMIPRAMINE HYDROCHLORIDE; ANAFRANIL				NCE	DEC 29, 1994

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
17613 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
17619 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
18813 002	CLOTRIMAZOLE; LOTRIMIN AF	3705172	DEC 05, 1989			
19758 001	CLOZAPINE; CLOZARIL				NCE	SEP 26, 1994
19758 002	CLOZAPINE; CLOZARIL				NCE	SEP 26, 1994
>ADD> 19188 001	CROMOLYN SODIUM; GASTROCROM	4395421	JUL 26, 2000			
>DLT> 17827 001	CYCLOBENZAPRINE HYDROCHLORIDE; FLEXERYL	3882246	MAY 06, 1992			
>DLT> 17827 002	CYCLOBENZAPRINE HYDROCHLORIDE; FLEXERYL	3882246	MAY 06, 1992			
71611 001	CYCLOBENZAPRINE HYDROCHLORIDE; CYCLOBENZAPRINE HCL				PC	NOV 15, 1989
17922 001	DESMOPRESSIN ACETATE; DDAVP				I-97	NOV 28, 1992
>ADD> 19082 001	DEZOCINE; DALGAN				NCE	DEC 29, 1994
>ADD> 19082 002	DEZOCINE; DALGAN				NCE	DEC 29, 1994
>ADD> 19082 003	DEZOCINE; DALGAN				NCE	DEC 29, 1994
19201 001	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
19201 002	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
19201 003	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
19471 001	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
19471 002	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NP	JAN 23, 1992
19471 003	DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		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
>ADD> 19653 001	ETHINYL ESTRADIOL; ORTHO CYCLEN-21	4027019	MAY 31, 1994		NC	DEC 29, 1992
>ADD> 19653 002	ETHINYL ESTRADIOL; ORTHO CYCLEN-28	4027019	MAY 31, 1994		NC	DEC 29, 1992
18554 001	FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993		NCE	JAN 27, 1994
		4472382	JAN 27, 2003	U-42		
19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4329364	MAY 11, 2002	U-41		
19661 001	GANCICLOVIR SODIUM; CYTOVENE	4507305	OCT 19, 1999	U-53	I-88	APR 28, 1992
		4423050	OCT 19, 1999	U-52	I-95	AUG 10, 1992
18422 001	GEMFIBROZIL; LOPID	4355032	OCT 19, 1999	U-51	ODE	JUN 23, 1996
18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		NCE	JUN 23, 1994
18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
19687 001	GONADORELIN ACETATE; LUTREPULSE PUMP KIT	3674836	JAN 04, 1993		I-84	JAN 17, 1992
19687 002	GONADORELIN ACETATE; LUTREPULSE PUMP KIT				NE	OCT 10, 1992
>ADD> 19726 001	GOSERELIN ACETATE; ZOLADEX	4100274	JUL 10, 1995		NE	OCT 10, 1992
					NCE	DEC 29, 1994

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19778 001	HYDROCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NCE	DEC 29, 1992
		4374829	DEC 30, 2001		NC	FEB 16, 1992
19778 002	HYDROCHLOROTHIAZIDE; PRINZIDE 25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
		4374829	DEC 30, 2001		NC	FEB 16, 1992
19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20/25	4472380	SEP 18, 2001			
		4374829	DEC 30, 2001		NCE	DEC 29, 1992
19771 001	IBUPROFEN; COADVIL				NC	SEP 19, 1992
19833 002	IBUPROFEN; CHILDREN'S ADVIL	4788220	NOV 29, 2005		NDF	SEP 19, 1992
19842 001	IBUPROFEN; PEDIA PROFEN				NDF	SEP 19, 1992
19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1992		ODE	DEC 30, 1995
>ADD> 19693 001	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2001		NCE	DEC 29, 1994
>ADD>		4389393	JUN 21, 2000			
>ADD>		4197313	APR 08, 1997	U-60		
>ADD> 19693 002	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2001		NCE	DEC 29, 1994
>ADD>		4389393	JUN 21, 2000			
>ADD>		4197313	APR 08, 1997	U-60		
>ADD> 19693 003	INDECAINIDE HYDROCHLORIDE; DECABID	4452745	JUN 05, 2001		NCE	DEC 29, 1994
>ADD>		4389393	JUN 21, 2000			
>ADD>		4197313	APR 08, 1997	U-60		
18956 001	IOHEXOL; OMNIPAQUE 180				I-89	JUN 30, 1992
18956 002	IOHEXOL; OMNIPAQUE 240				I-90	JUN 30, 1992
					NR	JUN 30, 1992
					I-92	JUL 28, 1992
18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-93	JUL 28, 1992
					I-85	MAR 31, 1992
					I-90	JUN 30, 1992
					NR	JUN 30, 1992
					I-94	JUL 28, 1992
18956 004	IOHEXOL; OMNIPAQUE 350	4021481	MAY 03, 1994		I-92	JUL 28, 1992
					I-85	MAR 31, 1992
					NR	JUN 30, 1992
					I-90	JUN 30, 1992
18956 006	IOHEXOL; OMNIPAQUE 210	4396597	JUL 14, 1998		I-91	JUN 30, 1992
		4250113	DEC 26, 1999		I-93	JUL 28, 1992
		4021481	MAY 03, 1994		NS	JUN 30, 1992
>ADD> 18735 003	IOPAMIDOL; ISOVUE-370				I-55	OCT 04, 1992
>ADD> 19580 001	IOTROLAN; OSMOVIST	4239747	DEC 16, 1997		NCE	DEC 07, 1994
>ADD> 19580 002	IOTROLAN; OSMOVIST	4239747	DEC 16, 1997		NCE	DEC 07, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19710 001	IOVERSOL; OPTIRAY 320	4396598	OCT 26, 2002	U-46	NCE	DEC 30, 1993
19710 002	IOVERSOL; OPTIRAY 240	4396598	OCT 26, 2002	U-47		
19710 003	IOVERSOL; OPTIRAY 160	4396598	OCT 26, 2002	U-48	NCE	DEC 30, 1993
19698 001	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995	U-49	NCE	DEC 30, 1993
19698 002	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
19698 003	KETOROLAC TROMETHAMINE; TORADOL	4089969	MAY 16, 1995		NCE	NOV 30, 1994
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NCE	NOV 30, 1994
					ODE	AUG 31, 1995
					I-79	AUG 31, 1995
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NCE	APR 09, 1990
					NP	JAN 26, 1992
19219 002	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN	3649691	MAR 14, 1991			
19814 001	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN	3649691	MAR 14, 1991		NS	JUN 28, 1992
19777 004	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
19860 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D	3714159	JAN 30, 1990			
19578 001	MEFLOQUINE HYDROCHLORIDE; MEFLOQUINE HCL				NCE	MAY 02, 1994
19591 001	MEFLOQUINE HYDROCHLORIDE; LARIAM				NCE	MAY 02, 1994
17646 001	MENOTROPINS; PERGONAL				I-73	AUG 23, 1992
17646 002	MENOTROPINS; PERGONAL				I-73	AUG 23, 1992
19884 001	MESNA; MESNEX	4220660	DEC 02, 1999	U-38	ODE	DEC 30, 1995
>ADD>	19786 001	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993		
>ADD>			3876802	APR 08, 1992	NP	DEC 27, 1992
>ADD>	19786 002	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993		
>ADD>			3876802	APR 08, 1992	NP	DEC 27, 1992
>ADD>	19786 003	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993		
>ADD>			3876802	APR 08, 1992	NP	DEC 27, 1992
>ADD>	19786 004	METOPROLOL FUMARATE; LOPRESSOR	3998790	DEC 21, 1993		
>ADD>			3876802	APR 08, 1992	NP	DEC 27, 1992
18592 001	MICONAZOLE NITRATE; MONISTAT 5	3717655	FEB 20, 1990		NDF	OCT 27, 1992
19268 001	MISOPROSTOL; CYTOTEC	3965143	JUN 22, 1995		NCE	DEC 27, 1993
19625 001	MOMETASONE FUROATE; ELOCON	4808610	FEB 28, 2006			
19796 001	MOMETASONE FUROATE; ELOCON	4775529	OCT 04, 2005		NCE	APR 30, 1992
		4472393	SEP 18, 2001		NDF	MAR 30, 1992
19516 003	MORPHINE SULFATE; MS CONTIN				NDF	MAY 29, 1990
19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
					I-87	APR 05, 1992
19488 001	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993
19488 002	NICARDIPINE HYDROCHLORIDE; CARDENE	3985758	OCT 12, 1995		NCE	DEC 21, 1993

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19684 001	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003		NDF	SEP 06, 1992
		4327725	MAY 04, 1997			
		3916899	NOV 05, 1991			
19684 002	NIFEDIPINE; PROCARDIA XL	3845770	NOV 05, 1991			
		4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003		NDF	SEP 06, 1992
		4327725	MAY 04, 1997			
		3916899	NOV 05, 1991			
		3845770	NOV 05, 1991			
19684 003	NIFEDIPINE; PROCARDIA XL	4783337	SEP 16, 2003			
		4765989	SEP 16, 2003			
		4612008	SEP 16, 2003		NDF	SEP 06, 1992
		4327725	MAY 04, 1997			
		3916899	NOV 05, 1991			
		3845770	NOV 05, 1991			
18869 001	NIMODIPINE; NIMOTOP	4406906	SEP 27, 2002	U-39		
19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2002		NCE	OCT 21, 1993
19810 001	OMEPRazole; LOSEC	4786505	NOV 22, 2005	U-55	NCE	SEP 14, 1994
		4255431	MAR 10, 1998			
19407 001	OXYMETAZOLINE HYDROCHLORIDE; VISINE L.R.				NDF	MAY 30, 1989
19887 001	PENTAMIDINE ISETHIONATE; NEBUPENT				ODE	JUN 15, 1996
					NDF	JUN 15, 1992
19385 001	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
19385 002	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
19385 003	PERGOLIDE MESYLATE; PERMAX	4166182	AUG 28, 1998		NCE	DEC 30, 1993
19855 001	PERMETHRIN; ELIMITE	4024163	MAY 17, 1996		NCE	MAR 31, 1991
					NDF	AUG 25, 1992
18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS	4271143	JUN 02, 1998			
>ADD> 19456 001	PINACIDIL; PINDAC	RE31244	NOV 08, 1994	U-5	NCE	DEC 28, 1994
>ADD> 19456 002	PINACIDIL; PINDAC	RE31244	NOV 08, 1994	U-5	NCE	DEC 28, 1994
19151 001	PROPAFENONE HYDROCHLORIDE; RYTHMOL				NCE	NOV 27, 1994
19151 002	PROPAFENONE HYDROCHLORIDE; RYTHMOL				NCE	NOV 27, 1994
19627 001	PROPOFOL; DIPRIVAN	4798846	NOV 01, 1994			
		4056635	NOV 01, 1994		NCE	OCT 02, 1994

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
>ADD> 50627 001	RIFAMPIN; RIFADIN				ODE	MAY 25, 1996
>ADD> 19414 001	RUBIDIUM CHLORIDE RB-82; CARDIOGEN-82	4400358	AUG 23, 2000		NCE	DEC 29, 1994
19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL				NCE	JUN 05, 1994
					ODE	JUN 05, 1996
19608 001	SILVER SULFADIAZINE; SILDIMAC	4563184	JAN 07, 2003		NP	NOV 30, 1992
>ADD> 19640 001	SOMATROPIN; BIOSYNTHETIC; HUMATROPE	3761590	SEP 25, 1990	U-59		
19640 004	SOMATROPIN; BIOSYNTHETIC; HUMATROPE				NR	MAY 10, 1992
18737 001	SULCONAZOLE NITRATE; SULCOSYN	4055652	OCT 25, 1996		NR	MAY 10, 1992
					NCE	AUG 30, 1990
					NDF	FEB 28, 1992
17970 001	TAMOXIFEN CITRATE; NOLVADEX				I-86	MAR 16, 1992
19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC	4789736	DEC 06, 2005		NCE	DEC 30, 1993
18321 001	TECHNETIUM TC-99M OXIDRONATE KIT; OSTEOSCAN-HDP	4497744	FEB 05, 2002			
		4432963	FEB 21, 2001			
		4247534	JAN 27, 1998			
		4233284	NOV 11, 1997			
>ADD> 18511 001	TECHNETIUM TC-99M PENTETATE KIT; TECHNESCAN DTPA KIT	3725295	APR 03, 1990			
17628 002	TOLMETIN SODIUM; TOLECTIN 600	3752826	AUG 14, 1990			
19594 001	URSODIOL; ACTIGALL	RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		
		RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		
>ADD> 19152 002	VERAPAMIL HYDROCHLORIDE; ISOPTIN SR				NS	DEC 15, 1992
19910 001	ZIDOVUDINE; RETROVIR				NCE	MAR 19, 1992

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

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