

APPROVED DRUG PRODUCTS

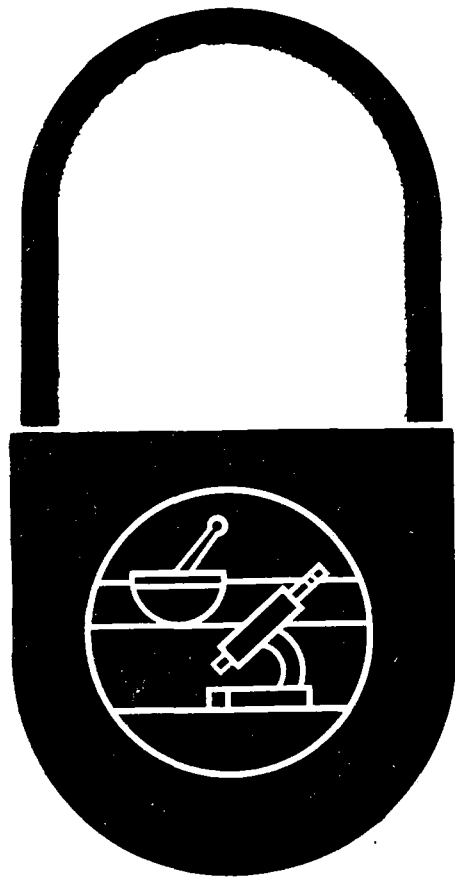
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 12
JAN'88-DEC'88**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

8TH EDITION

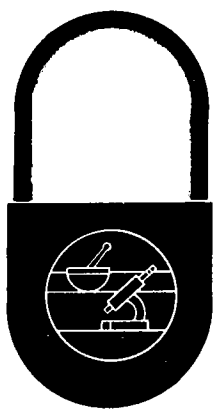
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**9TH EDITION
1989**

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
8TH EDITION

CUMULATIVE SUPPLEMENT 12
DECEMBER 1988

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APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
8th EDITION
CUMULATIVE SUPPLEMENT 12
DECEMBER 1988

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, 8th 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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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, List of Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act and the Patent and Exclusivity Data are indicated by the symbol >ADD> to the left of the line on which new information exists. The >ADD> symbol is then dropped in subsequent Cumulative Supplements for that item. A newly approved product is also identified by a lozenge (■) to the right of its strength which remains throughout all Cumulative Supplements for this edition.

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

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the "•" symbol to designate their non-marketed status. All products having a "•" symbol in the 12th Cumulative Supplement of the 8th 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>
AYERST LABORATORIES INC DIV AMERICAN HOME PRODUCTS CORP	WYETH AYERST LABORATORIES INC	WYETH AYERST LABS
HOECHST CELANESE	HOECHST ROUSSEL PHARMACEUTICAL INC	HOECHST
MY K LABORATORIES INC	PHARMACEUTICAL BASICS INC	PBI
NOVOCOL CHEMICAL MANUFACTURING COMPANY INC	NOVOCOL PHARMACEUTICAL INC	NOVOCOL PHARM

APPLICANT (NAME) CHANGES

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>NEW ABBREVIATED NAME</u>
SEARLE PHARMACEUTICALS INC	GD SEARLE CO	SEARLE
TRAVENOL LABORATORIES INC	BAXTER HEALTHCARE CORP	BAXTER
WYETH INC	WYETH AYERST LABORATORIES INC	WYETH AYERST LABS
WYETH LABORATORIES INC	WYETH AYERST LABORATORIES INC	WYETH AYERST LABS

1.4 TRAZODONE HYDROCHLORIDE

Generic Trazodone HCl 150mg tablet entries, marked with a (+), are rated as therapeutically equivalent (AB) to Mead Johnson's Desyrel (Trazodone HCl) Dividose 150mg tablets. The therapeutic equivalence determination, among other things, was made on the basis of an acceptable bioequivalence study and acceptable in vitro dissolution testing. A patent that exists on the Desyrel 150mg tablet scoring design, which enables the patient to break Desyrel into three 50mg segments, prevents a generic firm from copying this feature. Therefore, a patient will not be able to obtain three 50mg segments from the generic tablet. Prescribers and dispensers should be aware of this difference and take it into account when writing a prescription or practicing drug product selection.

1.5 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 1987) 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.

COUNTS CUMULATIVE BY QUARTER¹

<u>CATEGORIES COUNTED</u>	<u>DEC 1987</u>	<u>JUN 1988</u>	<u>JUN 1988</u>	<u>DEC 1988</u>
DRUG PRODUCTS LISTED	9709	9769	9993	10091*
SINGLE SOURCE	2096 (21.6%)	1975 (20.2%)	1973 (19.7%)	1983 (19.7%)
MULTISOURCE	7613 (78.4%)	7794 (79.8%)	8020 (80.3%)	8108 (80.3%)
THERAPEUTICALLY EQUIVALENT	6691 (68.9%)	6937 (71.0%)	7161 (71.7%)	7242 (71.8%)
NOT THERAPEUTICALLY EQUIVALENT	848 (8.7%)	757 (7.8%)	749 (7.5%)	748 (7.4%)
EXCEPTIONS ²	74 (0.8%)	100 (1.0%)	110 (1.1%)	118 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	--	2	3	17
NUMBER OF APPLICANTS	349	378	387	374

*This number is inclusive of products discontinued since December 1987, and any products approved or discontinued through December 1988.

¹Cumulative counts are calculated from January 1, 1988 to, and including, the month indicated.

²Amino acid-containing products of varying composition (see Introduction, page 1-8 of the List).

PRESCRIPTION DRUG PRODUCT LIST
8TH EDITION
CUMULATIVE SUPPLEMENT NUMBER 12 / JAN'88 - DEC'88

1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL

BUTALBITAL AND ACETAMINOPHEN

AB	HALSEY DRUG	325MG;50MG	N89568 001
			OCT 05, 1988

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE
MIKART

N89451 001
MAY 23, 1988

BUTALBITAL, APAP, AND CAFFEINE

AB	HALSEY DRUG	325MG;50MG;40MG	N89536 001
			FEB 16, 1988

ESGIC

> ADD >	AB	FOREST PHARMS	325MG;50MG;40MG	N89660 001
> ADD >				DEC 23, 1988

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL

HYAPAP AND CODEINE

AA	HY K LABS	120MG/5ML;12MG/5ML	N87006 001
AA	HYAPAP W/ CODEINE		
/AA/	HY K LABS	120MG/5ML;12MG/5ML	N87006/001/
AA	TYLENOL W/ CODEINE		
/AA/	MCNEIL LABS	120MG/5ML;12MG/5ML	N85057/001/
AA	MCNEIL PHARM	120MG/5ML;12MG/5ML	N85057 001

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA	BARR LABS	300MG;30MG	N85794 001
/AA/	BARR LABS	300MG;30MG	N87762/001/
			DEC 10, 1982
AA	CHARLOTTE PHARM	300MG;15MG	N89990 001
			SEP 30, 1988
AA		300MG;30MG	N89805 001
			SEP 30, 1988
AA		300MG;60MG	N89828 001
			SEP 30, 1988
AA	HALSEY DRUG	300MG;60MG	N86549 001
AA	MUTUAL PHARM	300MG;15MG	N89671 001
			FEB 10, 1988
AA		300MG;30MG	N89672 001
			FEB 10, 1988
AA		300MG;60MG	N89673 001
			FEB 10, 1988
AA	PHARMAFAIR	300MG;30MG	N87762 001
			DEC 10, 1982

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE

/AA/	BARR LABS	300MG;30MG	N85794/001/
/AA/	HALSEY DRUG	300MG;30MG	N85794/001/
/AA/	TYLENOL W/ CODEINE		
/AA/	MCNEIL LABS	325MG;7.5MG	N85056/001/
/AA/		325MG;15MG	N85056/002/
/AA/		325MG;30MG	N85056/003/
/AA/		325MG;60MG	N85056/004/
AA	MCNEIL PHARM	325MG;7.5MG	N85056 001
AA		325MG;15MG	N85056 002
AA		325MG;30MG	N85056 003
AA		325MG;60MG	N85056 004
/AA/	TYLENOL W/ CODEINE NO. 1	300MG;7.5MG	N85055/001/
AA	MCNEIL PHARM	300MG;7.5MG	N85055 001
/AA/	TYLENOL W/ CODEINE NO. 2	300MG;15MG	N85055/002/
AA	MCNEIL PHARM	300MG;15MG	N85055 002
/AA/	TYLENOL W/ CODEINE NO. 3	300MG;30MG	N85055/003/
AA	MCNEIL PHARM	300MG;30MG	N85055 003
/AA/	TYLENOL W/ CODEINE NO. 4	300MG;60MG	N85055/004/
AA	MCNEIL PHARM	300MG;60MG	N85055 004

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

AA	GRAHAM LABS	500MG;5MG	N87336 001
			JUL 08, 1982
AA	CO-GENIC		
AA	CENTRAL PHARMS	500MG;5MG	N89360 001
			MAR 02, 1988
/AA/	GRAHAM LABS	500MG;5MG	N87336/001/
			JUL 08, 1982

TABLET; ORAL

HYCOPAP

> ADD >	AA	CHARLOTTE PHARM	500MG;5MG	N89971 001
> ADD >				DEC 02, 1988

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	BEECHAM LABS	650MG;7.5MG	N89725 001
			SEP 30, 1987
AA	CHARLOTTE PHARM	500MG;5MG	N89831 001
			SEP 07, 1988

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA	LUCHER PHARMS	<u>500MG; 5MG</u>	N89696 001 APR 21, 1988
AA	MIKART	<u>650MG; 7.5MG</u>	N89689 001 JUN 29, 1988
> ADD >	WATSON LABS	<u>500MG; 5MG</u>	N89883 001 DEC 01, 1988
> ADD >	VICODIN ES		
> ADD >	KNOLL PHARM	<u>750MG; 7.5MG</u>	N89736 001 DEC 09, 1988
> ADD >			

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

AB	HALSEY DRUG	<u>325MG; 50MG</u>	N72105 001 MAY 13, 1988
AB		<u>650MG; 100MG</u>	N72106 001 MAY 13, 1988
AB	MYLAN PHARMS	<u>650MG; 100MG</u>	N72195 001 FEB 16, 1988

ACETAZOLAMIDE

TABLET; ORAL

ACETAZOLAMIDE

AB	MUTUAL PHARM	<u>125MG</u>	N89752 001 JUN 22, 1988
AB		<u>250MG</u>	N89753 001 JUN 22, 1988
AB	<u>DIAMOX</u> LEDERLE LABS	<u>125MG</u>	N08943 001

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

AP	QUAD PHARMS	<u>500MG/VIAL</u>	N89619 001 JAN 13, 1988
AP	<u>DIAMOX</u> LEDERLE LABS	<u>500MG/VIAL</u>	N09388 001

ACETOHYDROXAMIC ACID

TABLET; ORAL

LITHOSTAT

MISSION PHARMA

250MG

/W/O/RES//250MG/

N18749 001
MAY 31, 1983
/N18749/001/
/MAY/31/1983/

ALBUTEROL SULFATE

CAPSULE; INHALATION

VENTOLIN ROTACAPS

GLAXO

EQ 0.2MG BASEM

N19489 001
MAY 04, 1988

ALSEROXYLON

TABLET; ORAL

/RAUTENSIN//BP/ /DORSEY/LABS//2MG/

/N09215/001/
N09215 001

/BP/ /RAUWILLOID//RIKER/LABS//2MG/

/N08867/001/
N08867 001

RAUWILLOID

RIKER LABS

2MG

N08867 001

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL

/AMANTADINE HCL//AB/ /REID/ROWELL//100MG/

/N71000/001/
/SEP/04/1986/

/REID/ROWELL//SYNADINEAB REID ROWELL100MG

N71000 001
SEP 04, 1986

AMCINONIDE

LOTION; TOPICAL

CYCLOCORT

LEDERLE LABS

0.1%M

N19729 001
JUN 13, 1988

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AB AMILORIDE HCL AND HYDROCHLOROTHIAZIDE
BARR LABS 5MG;50MG

N71111 001
MAY 10, 1988

AMINO ACIDS

INJECTABLE; INJECTION

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

3 ABBOTT LABS 3.5%

/N18875/001/
/AUG/08/1984/
N18875 001
AUG 08, 1984

/NEOPHAN/6.4%/
/KABIVITRUM/ 6.4%

3 KABIVITRUM 6.4%

/N18792/001/
/JAN/17/1984/
N18792 001
JAN 17, 1984

TRAVASOL 10% IN PLASTIC CONTAINER
BAXTER 10%

N18931 004
APR 27, 1988

TROPHAMINE 10%
KENDALL MCGAW 10%

N19018 003
SEP 07, 1988

AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE;
POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM
CHLORIDE

INJECTABLE; INJECTION

AMINOSYN II 3.5% W/ ELECTROLYTES IN DEXTROSE 25% W/
CALCIUM IN PLASTIC CONTAINER

ABBOTT LABS 3.5%;36.8MG/100ML;25GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19683 001

NOV 07, 1988

3.5%;36.8MG/100ML;25GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19714 001

SEP 12, 1988

AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE;
POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM
CHLORIDE

INJECTABLE; INJECTION

AMINOSYN II 4.25% W/ ELECTROLYTES IN DEXTROSE 20% W/
CALCIUM IN PLASTIC CONTAINER

ABBOTT LABS 4.25%;36.8MG/100ML;20GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19683 002

NOV 07, 1988

4.25%;36.8MG/100ML;20GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19714 002

SEP 12, 1988

AMINOSYN II 4.25% W/ ELECTROLYTES IN DEXTROSE 25% W/
CALCIUM IN PLASTIC CONTAINER

ABBOTT LABS 4.25%;36.8MG/100ML;25GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19683 003

NOV 07, 1988

4.25%;36.8MG/100ML;25GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19714 004

SEP 12, 1988

AMINOSYN II 5% W/ ELECTROLYTES IN DEXTROSE 25% W/ CALCIUM
IN PLASTIC CONTAINER

ABBOTT LABS 5%;36.8MG/100ML;25GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19683 004

NOV 07, 1988

5%;36.8MG/100ML;25GM/100ML;
51MG/100ML;22.4MG/100ML;261MG/100ML
205MG/100ML N19714 003

SEP 12, 1988

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

AMINOSYN II 3.5% IN DEXTROSE 25% IN PLASTIC CONTAINER

ABBOTT LABS 3.5%;25GM/100ML N19681 001
NOV 01, 1988
3.5%;25GM/100ML N19713 006

SEP 09, 1988

AMINOSYN II 3.5% IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABS 3.5%;5GM/100ML N19681 002
NOV 01, 1988
3.5%;5GM/100ML N19713 002

SEP 09, 1988

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

AMINOSYN II 4.25% IN DEXTROSE 10% IN PLASTIC CONTAINER			
ABBOTT LABS	4.25%;10GM/100MLM	N19681 004	
		NOV 01, 1988	
	4.25%;10GM/100MLM	N19713 001	
		SEP 09, 1988	
AMINOSYN II 4.25% IN DEXTROSE 20% IN PLASTIC CONTAINER			
ABBOTT LABS	4.25%;20GM/100MLM	N19681 005	
		NOV 01, 1988	
	4.25%;20GM/100MLM	N19713 004	
		SEP 09, 1988	
AMINOSYN II 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER			
ABBOTT LABS	4.25%;25GM/100MLM	N19681 003	
		NOV 01, 1988	
	4.25%;25GM/100MLM	N19713 005	
		SEP 09, 1988	
AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER			
ABBOTT LABS	5%;25GM/100MLM	N19681 006	
		NOV 01, 1988	
	5%;25GM/100MLM	N19713 003	
		SEP 09, 1988	

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

INJECTABLE; INJECTION

AMINOSYN II 4.25% W/ ELECT AND ADJUSTED PHOSPHATE IN DEXTROSE 10% IN PLASTIC CONTAINER			
ABBOTT LABS	4.25%;10GM/100ML;51MG/100ML;		
	176.5MG/100ML;22.4MG/100ML;		
	104.5MG/100ML;		
	205MG/100MLM	N19682 003	
		NOV 01, 1988	
	4.25%;10GM/100ML;51MG/100ML;		
	176.5MG/100ML;22.4MG/100ML;		
	104.5MG/100ML;		
	205MG/100MLM	N19712 002	
		SEP 08, 1988	

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

INJECTABLE; INJECTION

AMINOSYN II 3.5% M IN DEXTROSE 5% IN PLASTIC CONTAINER			
ABBOTT LABS	3.5%;5GM/100ML;30MG/100ML;		
	97MG/100ML;120MG/100ML;		
	49.3MG/100MLM	N19682 001	
		NOV 01, 1988	
	3.5%;5GM/100ML;30MG/100ML;		
	97MG/100ML;120MG/100ML;		
	49.3MG/100MLM	N19712 001	
		SEP 08, 1988	
AMINOSYN II 4.25% M IN DEXTROSE 10% IN PLASTIC CONTAINER			
ABBOTT LABS	4.25%;10GM/100ML;30MG/100ML;		
	97MG/100ML;120MG/100ML;		
	49.3MG/100MLM	N19682 002	
		NOV 01, 1988	

AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE

INJECTABLE; INJECTION

FREAMINE III 8.5% W/ ELECTROLYTES			
KENDALL MCGAW	8.5%;110MG/100ML;230MG/100ML;		
	10MG/100ML;440MG/100ML;		
	690MG/100MLM	N16822 007	
		JUL 01, 1988	

AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

AMINOSYN II 3.5% M IN PLASTIC CONTAINER			
ABBOTT LABS	3.5%;21MG/100ML;40MG/100ML;		
	128MG/100ML;		
	234MG/100ML	N18875 002	
		AUG 08, 1984	
2 ABBOTT LABS			
	3.5%;21MG/100ML;40MG/100ML;		
	128MG/100ML;		
	234MG/100ML	N18875 002	
		AUG 08, 1984	

AMINOCAPROIC ACID

INJECTABLE; INJECTION

AMICAR

> ADD > AP	LEDERLE LABS	250MG/ML	N15229 002
> DLT > AP	LEDERLE/PARNTIS	250MG/ML	N15229 002

AMINOCAPROIC ACID

INJECTABLE; INJECTION

AMINOCAPROIC ACID

AP	ABBOTT LABS	250MG/ML	N70888 001
			JUN 16, 1988

AMINOHIPPURATE SODIUM

INJECTABLE; INJECTION

AMINOHIPPURATE SODIUM

AP	MS&D	20%	N05619 001
AP	QUAD PHARMS	20%	N89821 001
			JUL 14, 1988

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

/BP/	/BARR/LABS/	/100MG/	/N86297/001/
			/AUG/19/1983/
/BP/		/200MG/	/N86298/001/
			/AUG/19/1983/
	3 BARR LABS	100MG	N88297 001
			AUG 19, 1983
	3	200MG	N88298 001
			AUG 19, 1983
BD	HALSEY DRUG	100MG	N84674 001
/2/		/100MG/	/N84674/001/
BD	3 RICHLYN LABS	100MG	N84574 001
BD	3	200MG	N84576 001
/2/		/100MG/	/N84574/001/
/2/		/200MG/	/N84576/001/
BD	VALE CHEM	100MG	N84533 001
/2/		/100MG/	/N84533/001/

AMINOSALICYLATE SODIUM

TABLET; ORAL

TEEBACIN

/BP/	/CNSOL/MIDLAND/	/500MG/	/N07320/002/
	3 CNSOL MIDLAND	500MG	N07320 002

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRIPTIL

/AB/	/PARKE/DAYIS/	/10MG/	/N81030/001/
/AB/		/25MG/	/N83937/001/
/AB/		/50MG/	/N81030/002/
/AB/		/75MG/	/N84957/001/
/AB/		/100MG/	/N85093/001/
/AB/		/150MG/	/N86295/001/
AB	WARNER CHILCOTT	10MG	N83939 001
AB		25MG	N83937 001
AB		50MG	N83938 002
AB		75MG	N84957 001
AB		100MG	N85093 001
AB		150MG	N86295 001

AMITRIPTYLINE HCL

/AB/	/LEDERLE/LABS/	/10MG/	/N86744/001/
/AB/		/25MG/	/N86746/001/
/AB/		/50MG/	/N86743/001/
/AB/		/75MG/	/N86745/001/
/AB/		/100MG/	/N86747/001/
3	LEDERLE LABS	10MG	N86744 001
3		25MG	N86746 001
3		50MG	N86743 001
3		75MG	N86745 001
3		100MG	N86747 001

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

> ADD >	AB	DANBURY PHARMA	EQ 12.5MG BASE;5MG	N72052 001
> ADD >	AB			DEC 16, 1988
> ADD >	AB		EQ 25MG BASE;10MG	N72053 001
> ADD >	AB			DEC 16, 1988
	AB	PAR PHARM	EQ 12.5MG BASE;5MG	N72277 001
	AB			MAY 09, 1988
	AB		EQ 25MG BASE;10MG	N72278 001
	AB	PHARM BASICS	EQ 12.5MG BASE;5MG	MAY 09, 1988
	AB		EQ 25MG BASE;10MG	N70477 001
				JAN 12, 1988
				N70478 001
				JAN 12, 1988

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

AB	MYLAN PHARMS	<u>10MG;2MG</u>	N70336 001 NOV 10, 1988
AB		<u>10MG;4MG</u>	N71442 001 NOV 10, 1988
AB		<u>25MG;2MG</u>	N70337 001 NOV 10, 1988
AB		<u>25MG;4MG</u>	N70338 001 NOV 10, 1988
AB		<u>50MG;4MG</u>	N71443 001 NOV 10, 1988

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

AB	CLONNEL CHEMS	<u>250MG</u>	N62884 001 FEB 25, 1988
AB		<u>500MG</u>	N62881 001 FEB 25, 1988

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

AB	CLONNEL CHEMS	<u>125MG/5ML</u>	N62927 001 NOV 25, 1988
AB		<u>250MG/5ML</u>	N62927 002 NOV 25, 1988
AB	NOVOPHARM	<u>125MG/5ML</u>	N62946 001 NOV 01, 1988
AB	<u>POLYMOX</u>		
AB	BRSTL MYRS IND	<u>125MG/5ML</u>	N62885 001 MAR 08, 1988
AB		<u>250MG/5ML</u>	N62885 002 MAR 08, 1988

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

AP	MARSAM PHARMS	<u>EQ 125MG BASE/VIAL</u>	N62816 001 OCT 24, 1988
AP		<u>EQ 250MG BASE/VIAL</u>	N62816 002 OCT 24, 1988
AP		<u>EQ 500MG BASE/VIAL</u>	N62816 003 OCT 24, 1988
AP		<u>EQ 1GM BASE/VIAL</u>	N62816 004 OCT 24, 1988
AP		<u>EQ 2GM BASE/VIAL</u>	N62816 005 OCT 24, 1988
AP		<u>EQ 10GM BASE/VIAL</u>	N62994 001 SEP 15, 1988

AMPICILLIN SODIUM; SULBACTAM SODIUM

INJECTABLE; INJECTION

UNASYN

PFIZER LABS

EQ 1GM BASE/VIAL;
EQ 500MG BASE/VIAL

N62901 001
NOV 23, 1988

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMPICILLIN

AB	CLONNEL CHEMS	<u>EQ 250MG BASEM</u>	N62883 001 FEB 25, 1988
AB		<u>EQ 500MG BASEM</u>	N62882 001 FEB 25, 1988
/AB/	/LEDERLE LABS/	/EQ 250MG BASE/	/N62208 001/
/AB/		/EQ 500MG BASE/	/N62208 002/
	2 LEDERLE LABS	EQ 250MG BASE	N62208 001
	2	EQ 500MG BASE	N62208 002
	<u>POLYCYLLIN</u>		
AB	BRSTL MYRS IND	<u>EQ 250MG BASEM</u>	N62888 001 MAR 04, 1988
AB		<u>EQ 500MG BASEM</u>	N62888 002 MAR 04, 1988

POWDER FOR RECONSTITUTION; ORAL

AMPICILLIN

/AB/	/AYERST LABS/	/EQ 125MG BASE/5ML/	/N50019 002/
/AB/		/EQ 250MG BASE/5ML/	/N50019 003/
/AB/		/EQ 100MG BASE/ML/	/N50019 001/
	2 AYERST LABS	EQ 125MG BASE/5ML	N50019 002
	2	EQ 250MG BASE/5ML	N50019 003
	2	EQ 100MG BASE/ML	N50019 001

ANILERIDINE HYDROCHLORIDE

/TABLET;/ORAL/
/LERITINE;/
/MS&D/

/EQ/25MG/BASE/
EQ 25MG BASE

/N10585/002/
N10585 002

ANILERIDINE PHOSPHATE

/INJECTABLE;/INJECTION/
/LERITINE;/
/MS&D/

/EQ/25MG/BASE/ML/
EQ 25MG BASE/ML

/N10520/003/
N10520 003

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENADRINE COMPOUND

AB VITARINE 385MG;30MG;25MG

N71564 001
JUN 23, 1988

ORPHENADRINE COMPOUND DOUBLE STRENGTH

AB VITARINE 770MG;60MG;50MG

N71565 001
JUN 23, 1988

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL
COMPOUND 65

/AA/ /BANMAX/PHARMS/

/389MG;32.4MG;65MG/

3 BANMAX PHARMS 389MG;32.4MG;65MG

/N84553/002/
/AUG/17/1983/
N84553 002
AUG 17, 1983

ASPIRIN; HYDROCODONE BITARTRATE

TABLET; ORAL
AZDONE

CENTRAL PHARMS 500MG;5MG

N89420 001
JAN 25, 1988

ASPIRIN; MEPROBAMATE

TABLET; ORAL
MEPRO-ASPIRIN

AB VITARINE 325MG;200MG

N89127 001
MAR 02, 1987

ASPIRIN; MEPROBAMATE

TABLET; ORAL
MEPRO-ASPIRIN
/AA/ /VITARINE/

/325MG;200MG/

/N89127/001/
/MAR/02/1987/

ASPIRIN; METHOCARBAMOL

TABLET; ORAL
METHOCARBAMOL AND ASPIRIN

AB PAR PHARM 325MG;400MG

N89657 001
NOV 04, 1988

> ADD > ASTEMIZOLE

> ADD > TABLET; ORAL
> ADD > HISMANAL

> ADD > JANSSEN PHARMA 10MG

N19402 001
DEC 29, 1988

ATENOLOL

TABLET; ORAL
ATENOLOL

AB ICI PHARMS 50MG

N72303 001
JUL 15, 1988

AB 100MG

N72304 001
JUL 15, 1988

TENORMIN

AB STUART PHARMS 50MG
AB 100MG

N18240 001
N18240 002

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL
MOTOFEN

/3/CARNRICK/LABS/
MOTOFEN

/0.025MG;1MG/

CARNRICK LABS 0.025MG;1MG

/N17744/002/
N17744 002

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

AZATHIOPRINE

AP QUAD PHARMS EQ 100MG BASE/VIAL

N71056 001
JUN 08, 1988

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

IMURAN

AP BURROUGHS WELLC EQ 100MG BASE/VIAL N17391 001

BACLOFEN

TABLET; ORAL

BACLOFEN

AB PHARM BASICS 10MG N71260 001

MAY 06, 1988

AB 20MG N71261 001

MAY 06, 1988

AB VITARINE 10MG N71901 001

APR 13, 1988

AB 20MG N71902 001

APR 13, 1988

AB ZENITH LABS 10MG N72234 001

JUL 21, 1988

AB 20MG N72235 001

JUL 21, 1988

LTORISAL

AB GEIGY PHARMS 10MG N17851 001

LTORISAL DS

AB GEIGY PHARMS 20MG N17851 003

JAN 20, 1982

BENZTHIAZIDE

TABLET; ORAL

/BENZTHIAZIDE/

/BP/ /PRIVATE/FMLTNS/ /50MG/ /N83206/001/

3 PRIVATE FMLTNS

50MG

N83206 001

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA PAR PHARM 0.5MG N88877 001

APR 11, 1985

AA 1MG N88894 001

APR 11, 1985

AA 2MG N88895 001

APR 11, 1985

/BP/ /0.5MG/ /N88877/001/

/APR/11/1985/

/BP/ /1MG/ /N88894/001/

/APR/11/1985/

/BP/ /2MG/ /N88895/001/

/APR/11/1985/

AA PHARM BASICS 0.5MG N89211 001

JUN 14, 1988

AA 1MG N89212 001

JUN 14, 1988

AA 2MG N89213 001

JUN 14, 1988

AA QUANTUM PHARMCS 0.5MG N88514 001

JAN 31, 1984

AA 1MG N88510 001

JAN 31, 1984

AA 2MG N88511 001

JAN 31, 1984

/BP/ /0.5MG/ /N88514/001/

/JAN/31/1984/

/BP/ /1MG/ /N88510/001/

/JAN/31/1984/

/BP/ /2MG/ /N88511/001/

/JAN/31/1984/

AA SIDMAK LABS 0.5MG N89058 001

AUG 10, 1988

AA 1MG N89059 001

AUG 10, 1988

AA 2MG N89060 001

AUG 10, 1988

COGENTIN

MS&D

AA 0.5MG N09193 004

N09193 003

AA 1MG N09193 002

N09193 002

/BP/ /0.5MG/ /N09193/001/

/N09193/001/

/BP/ /1MG/ /N09193/002/

/N09193/002/

/BP/ /2MG/ /N09193/002/

/N09193/002/

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL
BETAMETHASONE DIPROPIONATE
 AB COPLEY PHARM EQ 0.05% BASEM N71882 001
 JUN 06, 1988
 AB THAMES PHARMA EQ 0.05% BASEM N72276 001
 AUG 24, 1988
 DIPROLENE
 BX SCHERING EQ 0.05% BASEM N19716 001
 AUG 01, 1988

BETAMETHASONE VALERATE

CREAM; TOPICAL
DERMABET
 AB TARO PHARMS EQ 0.1% BASEM N72041 001
 JAN 06, 1988

LOTION; TOPICAL
BETAMETHASONE VALERATE
 AB COPLEY PHARM EQ 0.1% BASEM N71883 001
 APR 22, 1988

BETAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION
 /HISTALOGS/
 /LILLY/
 2 LILLY /50MG/ML/ 50MG/ML /N09344/001/
 N09344 001

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION
BETHANECHOL CHLORIDE
 AP QUAD PHARMS 5MG/MLM N89815 001
 APR 12, 1988
URECHOLINE
 AP MS&D 5MG/ML N06536 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
 AP LUITPOLD PHARMS 50MG/MLM N70891 001
 JUL 26, 1988
 AP QUAD PHARMS 50MG/MLM N71181 001
 FEB 16, 1988

BROMPHENIRAMINE MALEATE

TABLET; ORAL
BROMPHENIRAMINE MALEATE
 /AA/ /BARR/LABS/ /4MG/ /N84468/001/
 2 BARR LABS 4MG N84468 001

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE;
PSEUDOPHEDRINE HYDROCHLORIDE

SYRUP; ORAL
 > ADD > BROMFED-AT
 > ADD > AA MURO PHARM 2MG/5ML; 10MG/5ML;
 > ADD > 30MG/5ML N89681 001
 > ADD > DEC 22, 1988

BUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
 > DLT > /BUPIVACAINE/SPINAL/
 > DLT > /ABBOTT/LABS/ /0.75%/
 > DLT > /N71810/001/
 /DEC/11/1987/

SENSORCAINE
 > DLT > /AA/ /ASTRA/PHARM/PRODS/ /0.75%/
 > DLT > /N71202/001/
 /APR/15/1987/

> ADD > INJECTABLE; SPINAL
 > ADD > BUPIVACAINE
 > ADD > AP ABBOTT LABS 0.75% N71810 001
 > ADD > DEC 11, 1987
 > ADD > MARCAINE
 > ADD > AP STERLING DRUG 0.75% N18692 001
 > ADD > MAY 04, 1984
 > ADD > SENSORCAINE
 > ADD > AP ASTRA PHARM PRODS 0.75% N71202 001
 > ADD > APR 15, 1987

> DLT > /BUPIVACAINE/HYDROCHLORIDE; DEXTROSE/
 > DLT > /INJECTABLE; INJECTION/
 > DLT > /MARCAINE/SPINAL/
 > DLT > /2/STERLING/DRUG/ /0.75%; 0.25%/
 /N18692/001/
 /MAY/04/1984/

BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE

INJECTABLE; INJECTION

BUPIVACAINE HCL AND EPINEPHRINE

ABBOTT LABS	0.25%;0.005MG/MLM	N71165 001
		JUN 16, 1988
	0.25%;0.005MG/MLM	N71166 001
		JUN 16, 1988
	0.25%;0.005MG/MLM	N71167 001
		JUN 16, 1988
	0.5%;0.005MG/MLM	N71168 001
		JUN 16, 1988
	0.5%;0.005MG/MLM	N71169 001
		JUN 16, 1988
	0.5%;0.005MG/MLM	N71170 001
		JUN 16, 1988
	0.75%;0.005MG/MLM	N71171 001
		JUN 16, 1988

CALCIUM; MEGLUMINE; METRIZOIC ACID

> DLT > //INJECTABLE//INJECTION/
 > DLT > //ISOPAGUE/286//
 > DLT > //STERLING/DRUG/
 > DLT > //STERLING/DRUG/
 > ADD > 2 STERLING DRUG
 > ADD > 461.8MG/ML

0.35MG/ML;140.1MG/ML;
 461.8MG/ML

N17506 001

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

SOLUTION; INTRAPERITONEAL

DIAHEAL PD-1 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AI BAXTER 25.7MG/100ML;3.5GM/100ML;
 15.2MG/100ML;567MG/100ML;
 392MG/100ML N17512 010
 NOV 18, 1985

DIAHEAL PD-2 W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AI BAXTER 25.7MG/100ML;3.5GM/100ML;
 5.08MG/100ML;538MG/100ML;
 448MG/100ML N17512 011
 NOV 18, 1985

IMPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AI ABBOTT LABS 25.7MG/100ML;3.5GM/100ML;
 15.2MG/100ML;567MG/100ML;
 392MG/100ML N18379 007
 JUN 24, 1988

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

SOLUTION; INTRAPERITONEAL

IMPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

AI ABBOTT LABS 25.7MG/100ML;3.5GM/100ML;
 5.08MG/100ML;538MG/100ML;
 448MG/100ML N18379 008
 JUN 24, 1988

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

DEXTROSE 2.5% IN HALF-STRENGTH LACTATED RINGER'S IN PLASTIC CONTAINER

KENDALL MCGAW 10MG/100ML;2.5GM/100ML;15MG/100ML;
 300MG/100ML;
 160MG/100ML N19634 001
 FEB 24, 1988

DEXTROSE 4% IN MODIFIED LACTATED RINGER'S IN PLASTIC CONTAINER

KENDALL MCGAW 4MG/100ML;4GM/100ML;6MG/100ML;
 120MG/100ML;62MG/100ML N19634 002
 FEB 24, 1988

DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

AP KENDALL MCGAW 20MG/100ML;5GM/100ML;30MG/100ML;
 600MG/100ML;
 310MG/100ML N19634 003
 FEB 24, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

AP ABBOTT LABS 20MG/100ML;5GM/100ML;104MG/100ML;
 600MG/100ML;
 310MG/100ML N19685 005
 OCT 17, 1988

AP 20MG/100ML;5GM/100ML;179MG/100ML;
 600MG/100ML;
 310MG/100ML N19685 006
 OCT 17, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND LACTATED RINGER'S IN PLASTIC CONTAINER

AP ABBOTT LABS 20MG/100ML;5GM/100ML;254MG/100ML;
 600MG/100ML;
 310MG/100ML N19685 007
 OCT 17, 1988

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND LACTATEDRINGER'S IN PLASTIC CONTAINER

AP ABBOTT LABS 20MG/100ML; 5GM/100ML; 179MG/100ML;
600MG/100ML;
310MG/100ML N19685 002
OCT 17, 1988

AP 20MG/100ML; 5GM/100ML; 328MG/100ML;
600MG/100ML;
310MG/100ML N19685 008
OCT 17, 1988

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATEDRINGER'S IN PLASTIC CONTAINER

AP ABBOTT LABS 20MG/100ML; 5GM/100ML; 254MG/100ML;
600MG/100ML;
310MG/100ML N19685 003
OCT 17, 1988

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND LACTATEDRINGER'S IN PLASTIC CONTAINER

AP ABBOTT LABS 20MG/100ML; 5GM/100ML; 328MG/100ML;
600MG/100ML;
310MG/100ML N19685 004
OCT 17, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND LACTATEDRINGER'S IN PLASTIC CONTAINER

AP ABBOTT LABS 20MG/100ML; 5GM/100ML; 104MG/100ML;
600MG/100ML;
310MG/100ML N19685 001
OCT 17, 1988

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

AP KENDALL MCGAM 20MG/100ML; 30MG/100ML; 600MG/100ML;
310MG/100ML N19632 001
FEB 29, 1988

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

AB WARNER CHILCOTT 100MG N71940 001
FEB 01, 1988

TEGRETOL

AB GEIGY PHARMS 100MG N18281 001

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

AA PIONEER PHARMS 350MG N89390 001

AA VITARINE 350MG N89566 001

OCT 13, 1988
AUG 30, 1988

CARPENAZINE MALEATE

/TABLET;/ORAL/

/PROKETAZINE/

/WYETH/AYERST/LABS/

2 25MG/ 25MG
2 50MG/ 50MG

/N12768/002/
/N12768/004/
N12768 002
N12768 004

CARPROFEN

/TABLET;/ORAL/

/RINADYL/

/ROCHE/

100MG/ 100MG
150MG/ 150MG
2 ROCHE 100MG
2 150MG

/N18550/002/
/DEC/31/1987/
/N18550/003/
/DEC/31/1987/
N18550 002
DEC 31, 1987
N18550 003
DEC 31, 1987

> ADD > CARTEOLOL HYDROCHLORIDE

> ADD >

TABLET; ORAL

> ADD >

CARTROL

> ADD >

ABBOTT LABS

2.5MG

> ADD >

> ADD >

5MG

> ADD >

> ADD >

10MG

> ADD >

N19204 001
DEC 28, 1988
N19204 002
DEC 28, 1988
N19204 003
DEC 28, 1988

CEFACTOR

POWDER FOR RECONSTITUTION; ORAL

CECLOR
LILLY

EQ 187MG BASE/5MLM N62206 003
APR 20, 1988
EQ 375MG BASE/5MLM N62206 004
APR 20, 1988

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

ANCEF

AP SK&F LABS

EQ 5GM BASE/VIAL N50461 004

CEFAZOLIN SODIUM

AP BEN VENUE LABS

EQ 250MG BASE/VIALM N62894 001
JUL 21, 1988AP EQ 500MG BASE/VIALM N62894 002
JUL 21, 1988AP EQ 1GM BASE/VIALM N62894 003
JUL 21, 1988AP EQ 5GM BASE/VIALM N62894 004
JUL 21, 1988AP EQ 10GM BASE/VIALM N62894 005
JUL 21, 1988AP ELKINS SINN EQ 250MG BASE/VIALM N62807 001
JAN 12, 1988AP EQ 500MG BASE/VIALM N62807 002
JAN 12, 1988AP EQ 1GM BASE/VIALM N62807 003
JAN 12, 1988AP EQ 5GM BASE/VIALM N62807 004
JAN 12, 1988AP EQ 10GM BASE/VIALM N62807 005
JAN 12, 1988AP EQ 20GM BASE/VIALM N62807 006
JAN 12, 1988> ADD > ZOLICEF

> ADD > AP BRISTOL MYERS

EQ 500MG BASE/VIALM N62831 001
DEC 09, 1988> ADD > AP EQ 1GM BASE/VIALM N62831 002
DEC 09, 1988CEFOTETAN DISODIUM

INJECTABLE; INJECTION

CEFOTAN

STUART PHARMS

EQ 10GM BASE/VIALM N50588 003
APR 25, 1988> ADD > CEFOTIAM HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION

> ADD > CERADON

> ADD > TAKEDA CHEM

EQ 1GM BASE/VIALM

N50601 001
DEC 30, 1988CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

AB JEROME STEVENS

EQ 250MG BASEM

N62870 001
MAR 17, 1988AB EQ 500MG BASEM N62869 001
MAR 17, 1988AB LABROS ATRAL EQ 250MG BASEM N62713 001
JUL 15, 1988AB EQ 500MG BASEM N62713 002
JUL 15, 1988AB SQUIBB MARK EQ 250MG BASEM N62973 001
NOV 08, 1988AB EQ 500MG BASEM N62974 001
NOV 23, 1988AB TAG PHARMS EQ 250MG BASEM N62821 001
FEB 05, 1988AB EQ 500MG BASEM N62823 001
FEB 05, 1988AB YOSHITOMI PHARM EQ 250MG BASEM N62872 001
JUN 20, 1988AB EQ 500MG BASEM N62871 001
JUL 05, 1988

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

AB TAG PHARMS

EQ 125MG BASE/5MLM

N62873 001
MAY 23, 1988AB EQ 250MG BASE/5MLM N62867 001
APR 15, 1988

TABLET; ORAL

CEPHALEXIN

AB VITARINE

EQ 250MG BASEM

N62863 001
AUG 11, 1988AB EQ 500MG BASEM N62863 002
AUG 11, 1988AB EQ 1GM BASEM N62863 003
AUG 11, 1988KEFLET

AB LILLY

EQ 1GM BASE

N50440 002

CEPHALEXIN HYDROCHLORIDE

TABLET; ORAL
KEFTAB
LILLY

EQ 333MG BASEM

N50614 003
MAY 16, 1988

CEPHAPIRIN SODIUM

INJECTABLE; INJECTION
CEFADYL

AP BRSTL MYRS IND

EQ 500MG BASE/VIALM

N62961 001
SEP 20, 1988

AP

EQ 1GM BASE/VIALM

N62961 002
SEP 20, 1988

AP

EQ 2GM BASE/VIALM

N62961 003
SEP 20, 1988

AP

EQ 4GM BASE/VIALM

N62961 004
SEP 20, 1988

CEPHRADINE

CAPSULE; ORAL
CEPHRADINE

AB BARR LABS

250MG

N62850 001
APR 22, 1988

AB

500MG

N62851 001
APR 22, 1988

AB

VITARINE

250MG

N62813 001
FEB 25, 1988

AB

500MG

N62813 002
FEB 25, 1988

POWDER FOR RECONSTITUTION; ORAL

CEPHRADINE

AB BARR LABS

125MG/5MLM

N62858 001
MAY 19, 1988

AB

250MG/5MLM

N62859 001
MAY 19, 1988

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

/AB/ /LEDERLE/LABS/

/5MG/

/N86892/001/

/AB/ /10MG/

/N86876/001/

/AB/ /25MG/

/N86893/001/

2 LEADERLE LABS

5MG

N86892 001

2

10MG

N86876 001

2

25MG

N86893 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

AB PIONEER PHARMS

10MG

N89533 001

AB

25MG

JUL 15, 1988

N89558 001

JUL 15, 1988

/AB/ /PUREPAC/PHARM/

/5MG/

/N85155/001/

/AB/ /10MG/

/10MG/

/N84939/002/

/AB/ /25MG/

/25MG/

/N85144/001/

2 PUREPAC PHARM

5MG

N85155 001

2

10MG

N84939 002

2

25MG

N85144 001

/AB/ /LYSEN/

/5MG/

/N85107/002/

/AB/ /BANMAX/PHARMS/

/10MG/

/N85009/001/

/AB/ /25MG/

/25MG/

/N85108/001/

2 BANMAX PHARMS

5MG

N85107 002

2

10MG

N85009 001

2

25MG

N85108 001

CHLORMERODRIN, HG-197

//INJECTABLE//INJECTION/
//CHLORMERODRIN/HG/197//

/SQUIBB/

/0.6-1.4MCI/ML/

/N17269/001/

2 SQUIBB

0.6-1.4MCI/ML

N17269 001

CHLOROQUINE HYDROCHLORIDE

//INJECTABLE//INJECTION/
//ARALEN//

2 STERLING DRUG

/EQ 40MG BASE/ML/

/N06002/002/

2 STERLING DRUG

EQ 40MG BASE/ML

N06002 002

CHLOROQUINE PHOSPHATE

TABLET; ORAL

ARALEN

AA STERLING DRUG

EQ 300MG BASE

N06002 001

AA CHLOROQUINE PHOSPHATE

DANBURY PHARMA

EQ 300MG BASE

N88030 001

/AB/

/EQ 300MG BASE/

DEC 21, 1982

/N88030/001/

/DEC 21, 1982/

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

MURAH
 AP BURROUGHS WELLC EQ 100MG BASE/VIAL N17391 001

BACLOFEN

TABLET; ORAL

BACLOFEN
 AB PHARM BASICS 10MG N71260 001
 MAY 06, 1988
 AB 20MG N71261 001
 MAY 06, 1988
 AB VITARINE 10MG N71901 001
 APR 13, 1988
 AB 20MG N71902 001
 APR 13, 1988
 AB ZENITH LABS 10MG N72234 001
 JUL 21, 1988
 AB 20MG N72235 001
 JUL 21, 1988
LTORRESAL
 AB GEIGY PHARMS 10MG N17851 001
LTORRESAL DS
 AB GEIGY PHARMS 20MG N17851 003
 JAN 20, 1982

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE
 /BP/ /PRIVATE/FMLTNS/ 50MG/ N83206/001/
 @ PRIVATE FMLTNS 50MG N83206 001

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE
 AA PAR PHARM 0.5MG N88877 001
 APR 11, 1985
 AA 1MG N88894 001
 APR 11, 1985
 AA 2MG N88895 001
 APR 11, 1985
 /BP/ /0.5MG/ /N88877/001/
 /BP/ /1MG/ /APR/11/1985/
 /BP/ /2MG/ /N88894/001/
 /APR/11/1985/
 /N88895/001/
 /APR/11/1985/
 AA PHARM BASICS 0.5MG N89211 001
 JUN 14, 1988
 AA 1MG N89212 001
 JUN 14, 1988
 AA 2MG N89213 001
 JUN 14, 1988
 AA QUANTUM PHARMCS 0.5MG N88514 001
 JAN 31, 1984
 AA 1MG N88510 001
 JAN 31, 1984
 AA 2MG N88511 001
 JAN 31, 1984
 /BP/ /0.5MG/ /N88514/001/
 /BP/ /1MG/ /JAN/31/1984/
 /BP/ /2MG/ /N88510/001/
 /JAN/31/1984/
 /N88511/001/
 /JAN/31/1984/
 AA SIDMAK LABS 0.5MG N89058 001
 AUG 10, 1988
 AA 1MG N89059 001
 AUG 10, 1988
 AA 2MG N89060 001
 AUG 10, 1988
COGENTIN
 AA MS&D 0.5MG N09193 004
 AA 1MG N09193 003
 AA 2MG N09193 002
 /BP/ /0.5MG/ /N09193/004/
 /BP/ /1MG/ /N09193/003/
 /BP/ /2MG/ /N09193/002/

CHOLESTYRAMINE

> <u>ADD</u> >	POWDER; ORAL		
> <u>ADD</u> >	QUESTRAN LIGHT		
> <u>ADD</u> >	BRISTOL MYERS	EQ 4GM RESIN/PACKETM	N19669 001
> <u>ADD</u> >			DEC 05, 1988
> <u>ADD</u> >		EQ 4GM RESIN/SCOOPFULM	N19669 003
> <u>ADD</u> >			DEC 05, 1988

CICLOPIROX OLAMINE

> <u>ADD</u> >	LOTION; TOPICAL		
> <u>ADD</u> >	LOPROX		
> <u>ADD</u> >	HOECHST	1/M	N19824 001
> <u>ADD</u> >			DEC 30, 1988

CISPLATIN

	INJECTABLE; INJECTION		
	PLATINOL-AQ		
	BRISTOL MYERS	1MG/MLM	N18057 004
			NOV 08, 1988

CLINDAMYCIN HYDROCHLORIDE

	CAPSULE; ORAL		
	<u>CLEOCIN</u>		
AB	UPJOHN MFG	EQ 75MG BASE	N61809 001
AB		EQ 150MG BASE	N61809 002
	CLEOCIN HCL		
	UPJOHN	EQ 300MG BASEM	N50162 003
			APR 14, 1988
	<u>CLINDAMYCIN HCL</u>		
AB	VITARINE	EQ 75MG BASEM	N62910 001
			JUL 05, 1988
AB		EQ 150MG BASEM	N62910 002
			JUL 05, 1988

CLINDAMYCIN PHOSPHATE

	INJECTABLE; INJECTION		
	<u>CLINDAMYCIN PHOSPHATE</u>		
AP	ABBOTT LABS	EQ 150MG BASE/MLM	N62943 001
			SEP 29, 1988
AP	ELKINS SINN	EQ 150MG BASE/MLM	N62953 001
			APR 21, 1988
AP	LEDERLE PARNTLS	EQ 150MG BASE/MLM	N62889 001
			APR 25, 1988

CLINDAMYCIN PHOSPHATE

	INJECTABLE; INJECTION		
	<u>CLINDAMYCIN PHOSPHATE</u>		
AP	LEMMON	EQ 150MG BASE/MLM	N62900 001
			JUN 08, 1988
AP	LOCH PHARMS	EQ 150MG BASE/MLM	N62905 001
			MAY 09, 1988
AP	LYPHOMED	EQ 150MG BASE/MLM	N62747 001
			JUN 03, 1988
AP	MARSAM PHARMS	EQ 150MG BASE/MLM	N62913 001
			OCT 20, 1988
AP	QUAD PHARMS	EQ 150MG BASE/MLM	N62877 001
			MAR 15, 1988
AP	SOLOPAK LABS	EQ 150MG BASE/MLM	N62819 001
			MAR 15, 1988
AP		EQ 150MG BASE/MLM	N62852 001
			MAR 17, 1988

SOLUTION; TOPICAL

	<u>OLECIT</u>		
AT	UPJOHN	EQ 1% BASE	N50537 001
AT		EQ 1% BASE	N62363 001
			FEB 08, 1982
	<u>CLINDAMYCIN PHOSPHATE</u>		
AT	BARRE NATL	EQ 1% BASEM	N62811 001
			SEP 01, 1988

CLOFIBRATE

	CAPSULE; ORAL		
	<u>CLOFIBRATE</u>		
AB	CORD LABS	500MG	N72191 001
			MAY 02, 1988

CLOMIPHENE CITRATE

	TABLET; ORAL		
	<u>CLOMIPHENE CITRATE</u>		
/AB/	/PLANTEX/	/50MG/	/N18361/001/
			/MAR/22, 1982/
> <u>ADD</u> >	<u>MILOPHENE</u>		
> <u>ADD</u> >	AB	MILEX PRODS	50MG
> <u>ADD</u> >			N72196 001
			DEC 20, 1988
	<u>SEROPHENE</u>		
AB	SERONO LABS	50MG	N18361 001
			MAR 22, 1982

CLONIDINE

FILM, CONTROLLED RELEASE; PERCUTANEOUS

CATAPRES-TTS-1

BOEHR INGEL

0.1MG/24HR

~~/2.5MG/~~N18891 001
OCT 10, 1984
~~/N18891/001/
OCT 10, 1984/~~

CATAPRES-TTS-2

BOEHR INGEL

0.2MG/24HR

~~/5MG/~~N18891 002
OCT 10, 1984
~~/N18891/002/
OCT 10, 1984/~~

CATAPRES-TTS-3

BOEHR INGEL

0.3MG/24HR

~~/7.5MG/~~N18891 003
OCT 10, 1984
~~/N18891/003/
OCT 10, 1984/~~CLONIDINE HYDROCHLORIDE

TABLET; ORAL

CLONIDINE HCL

AB CORD LABS

~~0.1MG~~

N70887 001

AUG 31, 1988

AB

~~0.2MG~~

N70886 001

AUG 31, 1988

AB

~~0.3MG~~

N71294 001

AUG 31, 1988

AB LEDERLE LABS

~~0.1MG~~

N71783 001

APR 05, 1988

AB

~~0.2MG~~

N71784 001

APR 05, 1988

AB

~~0.3MG~~

N71785 001

APR 05, 1988

AB WARNER CHILCOTT

~~0.1MG~~

N72138 001

JUN 13, 1988

AB

~~0.2MG~~

N72139 001

JUN 13, 1988

AB

~~0.3MG~~

N72140 001

JUN 13, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

AB

CHELSEA LABS

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~

AB

CORD LABS

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~

AB

PUREPAC PHARM

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~

AB

QUANTUM PHARMCS

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~

AB

WARNER CHILCOTT

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

AB

PUREPAC PHARM

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~

AB

WARNER CHILCOTT

~~3.75MG~~

AB

~~7.5MG~~

AB

~~15MG~~N71878 001
MAR 15, 1988
N71879 001
MAR 15, 1988
N71860 001
MAR 15, 1988
N72219 001
AUG 26, 1988
N72220 001
AUG 26, 1988
N72112 001
AUG 26, 1988
N71924 001
APR 25, 1988
N71925 001
APR 25, 1988
N71926 001
APR 25, 1988
N71549 001
SEP 12, 1988
N71550 001
SEP 12, 1988
N71522 001
SEP 12, 1988
N71774 001
MAR 01, 1988
N71775 001
MAR 01, 1988
N71776 001
MAR 01, 1988N72330 001
AUG 08, 1988
N72331 001
AUG 08, 1988
N72332 001
AUG 08, 1988
N71828 001
MAR 03, 1988
N71829 001
MAR 03, 1988
N71830 001
MAR 03, 1988

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

AB	WATSON LABS	3.75MG	N71852 001 FEB 09, 1988
AB		7.5MG	N71853 001 FEB 09, 1988
AB		15MG	N71854 001 FEB 09, 1988
<u>GEN-XENE</u>			
AB	ALRA LABS	3.75MG	N71787 001 APR 26, 1988
AB		7.5MG	N71788 001 APR 26, 1988
AB		15MG	N71789 001 APR 26, 1988

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

CLOXACILLIN SODIUM

AA	BIOCRAFT LABS	EQ 125MG BASE/5ML	N62268 001
/AB/		/EQ 125MG BASE/5ML/	/N62268/001/
<u>TEGOPEN</u>			
AA	BRISTOL LABS	EQ 125MG BASE/5ML	N50192 001
AA		EQ 125MG BASE/5ML	N61453 001
/AB/		/EQ 125MG BASE/5ML/	/N50192/001/
/AB/		/EQ 125MG BASE/5ML/	/N61453/001/

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

> ADD >	<u>PHERAZINE W/ CODEINE</u>		
> ADD >	AA	HALSEY DRUG	10MG/5ML; 6.25MG/5ML
> ADD >			N88739 001 DEC 23, 1988
> ADD >	<u>PROMETHAZINE HCL AND CODEINE PHOSPHATE</u>		
> ADD >	AA	PHARMS ASSOC	10MG/5ML; 6.25MG/5ML
> ADD >			N89647 001 DEC 22, 1988

COLCHICINE; PROBENECID

TABLET; ORAL

PROBENECID AND COLCHICINE

/BP/	BEECHAM LABS	0.5MG; 500MG	N84321/001/
	2 BEECHAM LABS	0.5MG; 500MG	N84321 001
PROBENECID W/ COLCHICINE			
/BP/	LEDERLE LABS	0.5MG; 500MG	N86954/001/
	2 LEDERLE LABS	0.5MG; 500MG	N86954 001

COPPER

INTRAUTERINE DEVICE; INTRAUTERINE

INTRAUTERINE COPPER CONTRACEPTIVE

POP COUNCIL CBR APPROX 176MG COPPER

N18680 002
APR 29, 1988CORTISONE ACETATE

TABLET; ORAL

CORTISONE ACETATE

BP	RICHLYN LABS	25MG	N09458 001
/P/		/25MG/	/N09458/001/

CYCLACILLIN

TABLET; ORAL

CYCLACILLIN

AB	BIOCRAFT LABS	250MG	N62895 001 AUG 04, 1988
AB		500MG	N62895 002 AUG 04, 1988
<u>CYCLAPEN-M</u>			
AB	MYETH AYERST LABS	250MG	N50509 001
AB		500MG	N50509 002

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HCL

AB	DANBURY PHARMA	10MG	N71611 001 MAY 03, 1989 : FEB 29, 1988
<u>FLEXERIL</u>			
AB	MS&D	10MG	N17821 002

CYCRIMINE HYDROCHLORIDE/TABLET; ORAL/
/FASITANE/
/LILLY/2 LILLY
2/1.25MG/
/2.5MG/
1.25MG
2.5MG/N88951/001/
/N88951/002/
N08951 001
N08951 002

CYTARABINE

INJECTABLE; INJECTION
CYTOSAR-U
UPJOHN

1GM/VIAL

N16793 003
DEC 21, 1987

2GM/VIAL

N16793 004
DEC 21, 1987

DACARBAZINE

INJECTABLE; INJECTION
DACARBAZINE
QUAD PHARMS

500MG/VIALM

N71563 001
MAY 06, 1988

DESIPRAMINE HYDROCHLORIDE

TABLET; ORAL
DESIPRAMINE HCL

AB CORD LABS

10MG

N72099 001
MAY 24, 1988

AB

25MG

N72100 001
MAY 24, 1988

AB

50MG

N72101 001
MAY 24, 1988

AB

75MG

N72102 001
JUN 20, 1988

AB

100MG

N72103 001
JUN 20, 1988

AB

150MG

N72104 001
JUN 20, 1988

AB VITARINE

10MG

N72167 001
FEB 03, 1988

AB

150MG

N72254 001
FEB 03, 1988

NORPRAMIN

AB MERRELL DOW

10MG

N14399 007
FEB 11, 1982

AB

150MG

N14399 006

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DDAVP

> DLT > /AMOUR/PHARM/

/0.004MG/ML/

/N18938/001/

> DLT >

/MAR/30/1984/

> ADD >

RORER PHARM

0.004MG/ML

N18938 001

> ADD >

MAR 30, 1984

DESONIDE

OINTMENT; TOPICAL

DESONEN

AB

OWEN LABS

0.05%

N71425 001
JUN 15, 1988

TRIDESILON

AB

MILES PHARM

0.05%

N17426 001

DESOXYCORTICOSTERONE ACETATE

PELLET; IMPLANTATION

PERCORTEN

/CIBA/PHARM/

/125MG/

/N05151/001/

2 CIBA PHARM

125MG

N05151 001

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

/BP/

/BARR/LABS/

/0.25MG/

/N84013/001/

/BP/

/BARR/LABS/

/0.25MG/

/N84764/001/

/BP/

/BARR/LABS/

/0.5MG/

/N84084/001/

/BP/

/BARR/LABS/

/0.75MG/

/N84081/001/

/BP/

/BARR/LABS/

/0.75MG/

/N84765/001/

/BP/

/BARR/LABS/

/1.5MG/

/N84086/001/

/BP/

/BARR/LABS/

/1.5MG/

/N84763/001/

2 BARR LABS

0.25MG

N84013 001

2

0.25MG

N84764 001

2

0.5MG

N84084 001

2

0.75MG

N84081 001

2

0.75MG

N84765 001

2

1.5MG

N84086 001

2

1.5MG

N84763 001

BP 2 RICHLYN LABS

0.75MG

N85376 001

/2/

/0.75MG/

/N85376/001/

DEXAMETHASONE; TOBRAMYCIN

OINTMENT; OPHTHALMIC

TOBRADEX

ALCON LABS

0.1%;0.3%

N50616 001
SEP 28, 1988

SUSPENSION/DROPS; OPHTHALMIC

TOBRADEX

ALCON LABS

0.1%;0.3%

N50592 001
AUG 18, 1988

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

/PHENEGAN W/ DEXTROMETHORPHAN/
/AA/ /WYETH/AYERST/LABS/ /15MG/5ML; 6.25MG/5ML/ /N11265/002/
/APR/02./1984/

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

AP KENDALL MCGAM 10GM/100MLM N19626 004
FEB 02, 1988

DEXTROSE 2.5% IN PLASTIC CONTAINER
KENDALL MCGAM 2.5GM/100MLM

N19626 001
FEB 02, 1988

/DEXTROSE/38.5%/IN/PLASTIC/CONTAINER/;
/ABBOTT/LABS/ /38.5GM/100ML/

/N18923/001/
/SEP/19./1984/
N18923 001
SEP 19, 1984

DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT LABS 50MG/ML N19222 001
JUL 13, 1984
/3/ /50MG/ML/ /N19222/001/
/JUL/13./1984/

AP KENDALL MCGAM 5GM/100MLM N19626 002
FEB 02, 1988

DEXTROSE 7.7% IN PLASTIC CONTAINER
KENDALL MCGAM 7.7GM/100MLM

N19626 003
FEB 02, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W/POTASSIUM/CHLORIDE/
/0.075%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;14.5MG/100ML/

/N18876/001/
/JAN/17./1986/

/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W/POTASSIUM/CHLORIDE/
/0.15%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;14.9MG/100ML/

/N18876/002/
/JAN/17./1986/

/DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W/POTASSIUM/CHLORIDE/
/0.224%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;22.4MG/100ML/

/N18876/003/
/JAN/17./1986/

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

/DEXTROSE/5%/SODIUM/CHLORIDE/0.225%/POTASSIUM/CHLORIDE/
/0.15%/IN/PLASTIC/CONTAINER/
/ABBOTT/LABS/ /5GM/100ML;15.0MG/100ML/

/22.5MG/100ML/ /N18365/001/

/DEXTROSE/5%/SODIUM/CHLORIDE/0.45%AND/POTASSIUM/CHLORIDE/
/0.224%/IN/PLASTIC/CONTAINER/
/AA/ /ABBOTT/LABS/ /5GM/100ML;22.4MG/100ML/

/45.0MG/100ML/ /N18362/002/

/DEXTROSE/5%/SODIUM/CHLORIDE/0.45%AND/POTASSIUM/CHLORIDE/
/0.32%IN/PLASTIC/CONTAINER/
/AA/ /ABBOTT/LABS/ /5GM/100ML;22.4MG/100ML/

/45.0MG/100ML/ /N18362/003/

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAM 10GM/100ML;37MG/100ML;
200MG/100MLM

N19630 031
FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAM 10GM/100ML;37MG/100ML;
450MG/100MLM

N19630 037
FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAM 10GM/100ML;37MG/100ML;
900MG/100MLM

N19630 043
FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAM 5GM/100ML;37MG/100ML;
110MG/100MLM

N19630 001
FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAM 5GM/100ML;37MG/100ML;
200MG/100MLM

N19630 007
FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAM 5GM/100ML;37MG/100ML;
330MG/100MLM

N19630 013
FEB 17, 1988

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAM 5GM/100ML;37MG/100ML;
450MG/100MLM

N19630 019
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 37MG/100ML;
900MG/100ML N19630 025
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 75MG/100ML;
200MG/100ML N19630 032
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 75MG/100ML;
450MG/100ML N19630 038
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 75MG/100ML;
900MG/100ML N19630 044
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML; 75MG/100ML;
200MG/100ML N19630 008
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.33% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML; 75MG/100ML;
330MG/100ML N19630 014
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML; 75MG/100ML;
450MG/100ML N19630 020
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML; 75MG/100ML;
900MG/100ML N19630 026
FEB 17, 1988

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 75MG/100ML;
110MG/100ML N19630 002
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 110MG/100ML;
200MG/100ML N19630 033
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 110MG/100ML;
450MG/100ML N19630 039
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 110MG/100ML;
900MG/100ML N19630 045
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 110MG/100ML;
110MG/100ML N19630 003
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 110MG/100ML;
200MG/100ML N19630 009
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.33% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 110MG/100ML;
330MG/100ML N19630 015
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 110MG/100ML;
450MG/100ML N19630 021
FEB 17, 1988

POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML; 110MG/100ML;
900MG/100ML N19630 027
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 150MG/100ML;
200MG/100ML N19630 034
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML; 150MG/100ML;
450MG/100ML N19630 040
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;150MG/100ML;
900MG/100MLM N19630 046
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;150MG/100ML;
200MG/100MLM N19630 010
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.33% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;150MG/100ML;
330MG/100MLM N19630 016
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;150MG/100ML;
450MG/100MLM N19630 022
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;150MG/100ML;
900MG/100MLM N19630 028
FEB 17, 1988

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAM 5GM/100ML;150MG/100ML;
110MG/100MLM N19630 004
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;220MG/100ML;
200MG/100MLM N19630 035
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;220MG/100ML;
450MG/100MLM N19630 041
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;220MG/100ML;
900MG/100MLM N19630 047
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAM 5GM/100ML;220MG/100ML;
110MG/100MLM N19630 005
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAM 5GM/100ML;220MG/100ML;
200MG/100MLM N19630 011
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.33% IN PLASTIC CONTAINER

KENDALL MCGAM 5GM/100ML;220MG/100ML;
330MG/100MLM N19630 017
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER

KENDALL MCGAM 5GM/100ML;220MG/100ML;
450MG/100MLM N19630 023
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAM 5GM/100ML;220MG/100ML;
900MG/100MLM N19630 029
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;300MG/100ML;
200MG/100MLM N19630 036
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.45% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;300MG/100ML;
450MG/100MLM N19630 042
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAM 10GM/100ML;300MG/100ML;
900MG/100MLM N19630 048
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE
0.2% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;300MG/100ML;
200MG/100MLM N19630 012
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE
0.33% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;300MG/100ML;
330MG/100MLM N19630 018
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE
0.45% IN PLASTIC CONTAINER

AP KENDALL MCGAM 5GM/100ML;300MG/100ML;
450MG/100MLM N19630 024
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAW 5GM/100ML;300MG/100ML;
900MG/100ML N19630 030
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAW 5GM/100ML;300MG/100ML;
110MG/100ML N19630 006
FEB 17, 1988

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

AP ABBOTT LABS 5GM/100ML;74.5MG/100ML;
450MG/100ML N18362 009
JUL 05, 1983

AP 5GM/100ML;149MG/100ML;
450MG/100ML N18362 005
MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;74.5MG/100ML;
900MG/100ML N19691 002
MAR 24, 1988

AP 5GM/100ML;149MG/100ML;
900MG/100ML N19691 004
MAR 24, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;74.5MG/100ML;
225MG/100ML N18365 002
JUL 05, 1983

5GM/100ML;149MG/100ML;
225MG/100ML N18365 006
MAR 28, 1988

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;74.5MG/100ML;
300MG/100ML N18876 001
JAN 17, 1986

5GM/100ML;149MG/100ML;
300MG/100ML N18876 006
MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 10MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP TRAVENOL LABS 5GM/100ML;75MG/100ML;
900MG/100ML N19308 004
APR 05, 1985

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

AP ABBOTT LABS 5GM/100ML;224MG/100ML;
450MG/100ML N18362 006
MAR 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;224MG/100ML;
900MG/100ML N19691 006
MAR 24, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML;
225MG/100ML N18365 008
MAR 28, 1988

POTASSIUM CHLORIDE 15MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML;
300MG/100ML N18876 007
MAR 28, 1988

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

AP ABBOTT LABS 5GM/100ML;149MG/100ML;
450MG/100ML N18362 010
JUL 05, 1983

AP 5GM/100ML;298MG/100ML;
450MG/100ML N18362 007
MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;149MG/100ML;
900MG/100ML N19691 005
MAR 24, 1988

AP 5GM/100ML;298MG/100ML;
900MG/100ML N19691 008
MAR 24, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;149MG/100ML;
225MG/100ML N18365 001

5GM/100ML;298MG/100ML;
225MG/100ML N18365 009
MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;298MG/100ML;
300MG/100ML N18876 008
MAR 28, 1988

POTASSIUM CHLORIDE 20MEQ IN DEXTROSE 5% IN SODIUM CHLORIDE
0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;149MG/100ML;
300MG/100ML N18876 002
JAN 17, 1986

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

AP ABBOTT LABS 5GM/100ML;224MG/100ML;
450MG/100ML N18362 002

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;224MG/100ML;
900MG/100ML N19691 007
MAR 24, 1988

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML;
225MG/100ML N18365 003
JUL 05, 1983

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;224MG/100ML;
300MG/100ML N18876 003
JAN 17, 1986

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

AP TRAVENOL LABS 5GM/100ML;224MG/100ML;
900MG/100ML N19308 006
APR 05, 1985

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

AP ABBOTT LABS 5GM/100ML;298MG/100ML;
450MG/100ML N18362 003

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;298MG/100ML;
900MG/100ML N19691 009
MAR 24, 1988

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;298MG/100ML;
225MG/100ML N18365 004
JUL 05, 1983

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM
CHLORIDE 0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;298MG/100ML;
300MG/100ML N18876 004
MAR 28, 1988

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

AP ABBOTT LABS 5GM/100ML;74.5MG/100ML;
450MG/100ML N18362 008
MAR 28, 1988

AP 5GM/100ML;149MG/100ML;
450MG/100ML N18362 004
MAR 28, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE
0.9% IN PLASTIC CONTAINER

AP ABBOTT LABS 5GM/100ML;74.5MG/100ML;
900MG/100ML N19691 001
MAR 24, 1988

AP 5GM/100ML;149MG/100ML;
900MG/100ML N19691 003
MAR 24, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE
0.225% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;74.5MG/100ML;
225MG/100ML N18365 005
MAR 28, 1988

5GM/100ML;149MG/100ML;
225MG/100ML N18365 007
MAR 28, 1988

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE
0.3% IN PLASTIC CONTAINER

ABBOTT LABS 5GM/100ML;74.5MG/100ML;
300MG/100ML N18876 005
MAR 28, 1988

5GM/100ML;149MG/100ML;
300MG/100ML N18876 009
MAR 28, 1988

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC

CONTAINER
KENDALL MCGAW 10GM/100ML;110MG/100MLM N19631 011
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;200MG/100MLM N19631 012
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC
CONTAINER
KENDALL MCGAW 10GM/100ML;330MG/100MLM N19631 013
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC
CONTAINER
KENDALL MCGAW 10GM/100ML;450MG/100MLM N19631 014
FEB 24, 1988

AP DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
KENDALL MCGAW 10GM/100ML;900MG/100MLM N19631 015
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC
CONTAINER
KENDALL MCGAW 2.5GM/100ML;
110MG/100MLM N19631 001
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC
CONTAINER
KENDALL MCGAW 2.5GM/100ML;
200MG/100MLM N19631 002
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.33% IN PLASTIC
CONTAINER
KENDALL MCGAW 2.5GM/100ML;
330MG/100MLM N19631 003
FEB 24, 1988

AP DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC
CONTAINER
KENDALL MCGAW 2.5GM/100ML;
450MG/100MLM N19631 004
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC
CONTAINER
KENDALL MCGAW 2.5GM/100ML;
900MG/100MLM N19631 005
FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;110MG/100MLM N19631 006
FEB 24, 1988

AP DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
KENDALL MCGAW 5GM/100ML;200MG/100MLM N19631 007
FEB 24, 1988

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;330MG/100MLM N19631 008
FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;450MG/100MLM N19631 009
FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
AP KENDALL MCGAW 5GM/100ML;900MG/100MLM N19631 010
FEB 24, 1988

DIATRIZOATE MEGGLUMINE; DIATRIZOATE SODIUM

INJECTABLE; INJECTION

RENOCAL-76
AP SQUIBB DIAGS 66%;10% N89347 001
JUN 01, 1988

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM
> ADD > AP STERLING DRUG 5MG/MLM N72079 001
> ADD > DEC 20, 1988

TABLET; ORAL

DIAZEPAM
AB PIONEER PHARMS 2MG N70787 001
AUG 02, 1988
AB 5MG N70788 001
AUG 02, 1988
AB 10MG N70776 001
AUG 02, 1988

G-PAM
AB QUANTUM PHARMCS 2MG N72431 001
APR 29, 1988
AB 5MG N72432 001
APR 29, 1988
AB 10MG N72433 001
APR 29, 1988

DIAZOXIDE

CAPSULE; ORAL

PROGLYCEN
MED MKTG SPEC 50MG N17425 001
100MG N17425 002
150MG N17425 001
/2/SCHERING/ /50MG/

DIAZOXIDE

INJECTABLE; INJECTION

AP	<u>DIAZOXIDE</u> QUAD PHARMS	<u>15MG/ML</u>	N71908 001 JAN 26, 1988
	SUSPENSION; ORAL PROGLYCEM MED MKTG SPEC /S/SCHERING/	50MG/ML /50MG/ML/	N17453 001 /N17453/001/

DICLOFENAC SODIUM

TABLET, ENTERIC COATED; ORAL

	VOLTAREN CIBA PHARM	25MG	N19201 001 JUL 28, 1988
		50MG	N19201 002 JUL 28, 1988
		75MG	N19201 003 JUL 28, 1988

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL

AA	<u>BENTYL</u> MERRELL DOW	<u>10MG/5ML</u>	N07961 002 OCT 15, 1984
AA	<u>DICYCLOMINE HCL</u> BARRE NATL	<u>10MG/5ML</u>	N84479 001

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL

	/HETRAZAN:/ /LEDERLE/LABS/ 2 LEDERLE LABS	/50MG/ 50MG	/N06459/001/ N06459 001
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DIFLORASONE DIACETATE

CREAM; TOPICAL

	/DIFLORASONE/DIACETATE:/ /UPJOHN/	/0.05%/ 0.05%	/N19259/001/ /N19259/001/ N19259 001 AUG 28, 1985
	2 UPJOHN		

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

/AA/	<u>DIPHENHYDRAMINE HCL</u> /LEDERLE/LABS/	/25MG/ 25MG	/N86874/001/ /N86875/001/ N86874 001
/AA/	2 LEDERLE LABS	50MG	N86875 001
AA	2 RICHLYN LABS	25MG	N80807 001
/2/		/25MG/	/N86867/001/

DISOPYRAMIDE PHOSPHATE

CAPSULE, CONTROLLED RELEASE; ORAL

AB	<u>DISOPYRAMIDE PHOSPHATE</u> KV PHARM	<u>EQ 100MG BASEM</u>	N71929 001 AUG 19, 1988
AB	<u>MORPACE CR</u> SEARLE	<u>EQ 100MG BASE</u>	N18655 001 JUL 20, 1982

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

AP	<u>DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER</u> BAXTER	<u>80MG/100ML</u>	N19615 001 MAR 27, 1987
AP		<u>160MG/100ML</u>	N19615 002 MAR 27, 1987
AP		<u>320MG/100ML</u>	N19615 003 MAR 27, 1987
		640MG/100ML	N19615 004 MAR 27, 1987
/AA/	/TRAVENOL/LABS/	/80MG/100ML/	/N19615/001/ /MAR/27/1987/
/AA/		/160MG/100ML/	/N19615/002/ /MAR/27/1987/
/AA/		/320MG/100ML/	/N19615/003/ /MAR/27/1987/
		/640MG/100ML/	/N19615/004/ /MAR/27/1987/

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

AB	<u>ADAPIN</u> PENWALT	<u>EQ 150MG BASE</u>	N16987 007 APR 13, 1987
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DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL

<u>DOXEPIN HCL</u>			
AB BARR LABS	<u>EQ 25MG BASEM</u>	N71502 001	
		FEB 18, 1988	
AB	<u>EQ 50MG BASEM</u>	N71653 001	
		FEB 18, 1988	
AB	<u>EQ 75MG BASEM</u>	N71654 001	
		FEB 18, 1988	
AB	<u>EQ 100MG BASEM</u>	N71521 001	
		FEB 18, 1988	
AB CHELSEA LABS	<u>EQ 75MG BASEM</u>	N71763 001	
		FEB 09, 1988	
AB	<u>EQ 150MG BASEM</u>	N71764 001	
		FEB 09, 1988	
AB LEDERLE LABS	<u>EQ 10MG BASEM</u>	N71685 001	
		JAN 05, 1988	
AB	<u>EQ 25MG BASEM</u>	N71686 001	
		JAN 05, 1988	
AB	<u>EQ 50MG BASEM</u>	N71673 001	
		JAN 05, 1988	
AB	<u>EQ 75MG BASEM</u>	N71674 001	
		JAN 05, 1988	
AB	<u>EQ 100MG BASEM</u>	N71675 001	
		JAN 05, 1988	
AB	<u>EQ 150MG BASEM</u>	N71676 001	
		JAN 05, 1988	
AB PUREPAC PHARM	<u>EQ 75MG BASEM</u>	N72386 001	
		SEP 08, 1988	
AB	<u>EQ 100MG BASEM</u>	N72110 001	
		SEP 08, 1988	
AB	<u>EQ 150MG BASEM</u>	N72387 001	
		SEP 08, 1988	

CONCENTRATE; ORAL

<u>DOXEPIN HCL</u>		
AA MY K LABS	<u>EQ 10MG BASE/MLM</u>	N71918 001
		JUL 20, 1988

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

<u>DOXYCYCLINE HYCLATE</u>		
AB INTERPHARM	<u>EQ 50MG BASEM</u>	N62763 001
		SEP 02, 1988
AB	<u>EQ 100MG BASEM</u>	N62763 002
		SEP 02, 1988
AB VITARINE	<u>EQ 50MG BASEM</u>	N62780 001
		APR 12, 1988

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION

<u>DOXYCYCLINE</u>		
AP BEN VENUE LABS	<u>EQ 100MG BASE/VIALM</u>	N62569 001
		MAR 09, 1988
AP	<u>EQ 200MG BASE/VIALM</u>	N62569 002
		MAR 09, 1988

TABLET; ORAL

<u>DOXYCYCLINE HYCLATE</u>		
AB INTERPHARM	<u>EQ 100MG BASEM</u>	N62764 001
		SEP 02, 1988

DROPERIDOL

INJECTABLE; INJECTION

<u>DROPERIDOL</u>		
AP ABBOTT LABS	<u>2.5MG/MLM</u>	N71981 001
		FEB 29, 1988
AP ASTRA PHARM PRODS	<u>2.5MG/MLM</u>	N72018 001
		OCT 20, 1988
AP	<u>2.5MG/MLM</u>	N72019 001
		OCT 19, 1988
AP	<u>2.5MG/MLM</u>	N72020 001
		OCT 19, 1988
AP	<u>2.5MG/MLM</u>	N72021 001
		OCT 19, 1988
AP DUPONT CRI CARE	<u>2.5MG/MLM</u>	N71645 001
		APR 07, 1988
AP LUITPOLD PHARMS	<u>2.5MG/MLM</u>	N72123 001
		OCT 24, 1988
AP	<u>2.5MG/MLM</u>	N72335 001
		OCT 24, 1988
AP QUAD PHARMS	<u>2.5MG/MLM</u>	N71941 001
		AUG 17, 1988
AP	<u>2.5MG/MLM</u>	N71942 001
		AUG 17, 1988
AP SOLOPAK LABS	<u>2.5MG/MLM</u>	N71750 001
		SEP 06, 1988
AP	<u>2.5MG/MLM</u>	N71754 001
		SEP 06, 1988
AP	<u>2.5MG/MLM</u>	N71755 001
		SEP 06, 1988

PROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE AND PROPERIDOL

AP	ABBOTT LABS	2.5MG/ML; EQ 0.05MG BASE/ML	N71982 001 MAY 04, 1988
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INNOVAR

AP	JANSSEN PHARMA	2.5MG/ML; EQ 0.05MG BASE/ML	N16049 001
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DYDROGESTERONE

/TABLET; ORAL/

/SYNOREST;/

/REID/ROWELL/

/5MG/

/N17388/001/

/10MG/

/N17388/002/

3 KALI DUPHAR

5MG

N17388 001

3

10MG

N17388 002

EDETATE CALCIUM DISODIUM

/TABLET; ORAL/

/CALCIUM DISODIUM VERSENATE;/

/RIKER/LABS/

/500MG/

/N08922/002/

TABLET; ORAL

CALCIUM DISODIUM VERSENATE

3 RIKER LABS 500MG

N08922 002

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

REVERSO

AP	ORGANON	10MG/ML	N89624 001 MAY 13, 1988
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ENALAPRIL MALEATE

TABLET; ORAL

VASOTEC

MS&D RES LABS 2.5MG

N18998 005
JUL 26, 1988ENALAPRILAT

INJECTABLE; INJECTION

VASOTEC

MS&D RES LABS 1.25MG/ML

N19309 001
FEB 09, 1988EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

AP	ABBOTT LABS	0.005MG/ML; 0.5%	N89635 001 JUN 21, 1988
AP		0.005MG/ML; 1%	N89649 001 JUN 21, 1988
AP		0.005MG/ML; 1.5%	N89645 001 JUN 21, 1988
AP		0.005MG/ML; 1.5%	N89650 001 JUN 21, 1988
AP		0.005MG/ML; 2%	N89651 001 JUN 21, 1988
AP		0.01MG/ML; 1%	N89644 001 JUN 21, 1988
AP		0.01MG/ML; 2%	N89646 001 JUN 21, 1988

LIDOCAINE HCL W/ EPINEPHRINE

/AP/	/LEMON/	/0.01MG/ML; 1%	/N85463/001/
	3 LEMON	0.01MG/ML; 1%	N85463 001

LIDOCAINE W/ EPINEPHRINE

AP	ASTRA PHARM PRODS	0.005MG/ML; 0.5%	N06488 013
AP		0.005MG/ML; 1%	N06488 018 NOV 13, 1986
AP		0.005MG/ML; 2%	N06488 019 NOV 13, 1986

ERGOLOID MESYLATES

TABLET; ORAL

ERGOLOID MESYLATES/

/AP/	/CHELSEA/LABS/	/1MG/	/N88207/001/
			/MAR 22, 1984/

GERMAL

AP	CHELSEA LABS	1MG	N88207 001 MAR 22, 1984
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TABLET; SUBLINGUAL

GERMAL/

/AP/	/RIKER/LABS/	/0.5MG/	/N84868/001/
/AP/		1MG	/N85809/001/
	3 RIKER LABS	0.5MG	N84868 001
	3	1MG	N85809 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL			
<u>ERGOLOID MESYLATES</u>			
/AA/	/CHelsea LABS/	/0.5MG/	/N6189/001/
/AA/		/1MG/	/N6188/001/
<u>GERMAL</u>			
AA	CHELSEA LABS	0.5MG	N86189 001
AA		1MG	N86188 001

ERYTHROMYCIN

SOLUTION; TOPICAL			
<u>ERYTHROMYCIN</u>			
AI	NASKA PHARMA	2% _M	N62957 001 JUL 21, 1988
<u>ETS-2%</u>			
AI	PADDOCK LABS	2% _M	N62687 001 FEB 05, 1988

TABLET, ENTERIC COATED; ORAL

<u>E-BASE</u>			
AB	BARR LABS	500MG _M	N62999 001 NOV 25, 1988
<u>ERY-TAB</u>			
	ABBOTT LABS	500MG	N62298 002

ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL

SUSPENSION; ORAL			
ILOSONE SULFA			
	LILLY	EQ 125MG BASE/5ML; EQ 600MG BASE/5ML _M	N50599 001 SEP 16, 1988

ERYTHROMYCIN ETHYLSUCCINATE

TABLET; ORAL			
<u>ERYTHROMYCIN ETHYLSUCCINATE</u>			
AB	MYLAN PHARMS	EQ 400MG BASE _M	N62847 001 SEP 14, 1988
TABLET, CHEWABLE; ORAL			
<u>ERY-PED</u>			
AB	ABBOTT LABS	EQ 200MG BASE _M	N50297 003 JUL 05, 1988

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL			
<u>ERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL</u>			
AB	BARR LABS	EQ 200MG BASE/5ML; EQ 600MG BASE/5ML _M	N62759 001 MAY 20, 1988
<u>ERYZOLE</u>			
AB	ALRA LABS	EQ 200MG BASE/5ML; EQ 600MG BASE/5ML _M	N62758 001 JUN 15, 1988
<u>PEDIAZOLE</u>			
AB	ROSS LABS	EQ 200MG BASE/5ML; EQ 600MG BASE/5ML _M	N50529 001

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION			
<u>ERYTHROCIN</u>			
AP	ABBOTT LABS	EQ 500MG BASE/VIAL _M	N62586 001 JAN 04, 1988
AP		EQ 1GM BASE/VIAL _M	N62586 002 JAN 04, 1988

ERYTHROMYCIN STEARATE

TABLET; ORAL			
<u>ERYTHROCIN</u>			
/AB/	/BRISTOL LABS/	/EQ 250MG BASE/	/N61304/001/
/AB/		/EQ 250MG BASE/	/N61304/001/
	2 BRISTOL LABS	EQ 250MG BASE	N61304 001
	2	EQ 250MG BASE	N61887 001
<u>ERY-PAR</u>			
/AB/	/PARKE DAVIS/	/EQ 250MG BASE/	/N62032/001/
/AB/		/EQ 500MG BASE/	/N62032/002/
	2 PARKE DAVIS	EQ 250MG BASE	N62032 001
	2	EQ 500MG BASE	N62032 002
<u>ERYTHROCIN STEARATE</u>			
/AB/	/ABBOTT LABS/	/EQ 125MG BASE/	/N60359/001/
	2 ABBOTT LABS	EQ 125MG BASE	N60359 002
<u>ERYTHROMYCIN STEARATE</u>			
/AB/	/LEDERLE LABS/	/EQ 250MG BASE/	/N62089/001/
/AB/		/EQ 500MG BASE/	/N62089/002/
	2 LEDERLE LABS	EQ 250MG BASE	N62089 001
	2	EQ 500MG BASE	N62089 002
<u>Pfizer-41</u>			
/AB/	/PFIZER LABS/	/EQ 500MG BASE/	/N61791/001/
	2 PFIZER LABS	EQ 500MG BASE	N61791 002

ETHINYL ESTRADIOL

/N65496/002/

N05490 003

N05490 002

ETHINYL ESTRADIOL; NORETHINDRONE

/N19081/003/
1444/14/1044/

N18354 002
JAN 11, 1982

/N09190/001/

N09190 001

/N14005/002/

2MG

N14005 002

FENOPROFEN CALCIUM

CAPSULE; ORAL

<u>FENOPROFEN CALCIUM</u>			
AB	AM THERPTCS	EQ 200MG BASEM	N72307 001
			AUG 22, 1988
AB		EQ 300MG BASEM	N72308 001
			AUG 22, 1988
AB	CORD LABS	EQ 200MG BASEM	N72394 001
			OCT 17, 1988
AB		EQ 300MG BASEM	N72395 001
			OCT 17, 1988
AB	HALSEY DRUG	EQ 200MG BASEM	N72355 001
			JUL 05, 1988
AB		EQ 300MG BASEM	N72356 001
			JUL 05, 1988
AB	PAR PHARM	EQ 200MG BASEM	N72437 001
			AUG 22, 1988
AB		EQ 300MG BASEM	N72438 001
			AUG 22, 1988
AB	QUANTUM PHARMCS	EQ 200MG BASEM	N72214 001
			APR 14, 1988
AB		EQ 300MG BASEM	N71738 001
			APR 14, 1988
AB	WATSON LABS	EQ 200MG BASEM	N72294 001
			JUL 08, 1988
AB		EQ 300MG BASEM	N72293 001
			JUL 08, 1988
	<u>HALFON</u>		
AB	DISTA PRODS	EQ 300MG BASE	N17604 002
	<u>HALFON 200</u>		
AB	DISTA PRODS	EQ 200MG BASE	N17604 003

TABLET; ORAL

<u>FENOPROFEN CALCIUM</u>			
AB	AM THERPTCS	EQ 600MG BASEM	N72309 001
			JUN 16, 1988
AB	CHELSEA LABS	EQ 600MG BASEM	N72407 001
			JUN 13, 1988
AB	CORD LABS	EQ 600MG BASEM	N72396 001
			OCT 17, 1988
AB	DANBURY PHARMA	EQ 600MG BASEM	N72602 001
			OCT 11, 1988
AB	HALSEY DRUG	EQ 600MG BASEM	N72357 001
			JUL 05, 1988
AB	LEDERLE LABS	EQ 600MG BASEM	N72326 001
			APR 20, 1988
AB	MYLAN PHARMS	EQ 600MG BASEM	N72267 001
			JUN 08, 1988
AB	PAR PHARM	EQ 600MG BASEM	N72429 001
			JUL 19, 1988
AB	PHARM BASICS	EQ 600MG BASEM	N72362 001
			JUN 16, 1988

FENOPROFEN CALCIUM

TABLET; ORAL

<u>FENOPROFEN CALCIUM</u>			
AB	PUREPAC PHARM	EQ 600MG BASEM	N72274 001
			MAY 02, 1988
AB	QUANTUM PHARMCS	EQ 600MG BASEM	N72194 001
			APR 14, 1988
AB	WATSON LABS	EQ 600MG BASEM	N72165 001
			JUL 08, 1988
AB	ZENITH LABS	EQ 600MG BASEM	N72557 001
			AUG 29, 1988
	<u>HALFON</u>		
AB	DISTA PRODS	EQ 600MG BASE	N17710 001

FERROUS SULFATE; FOLIC ACID

/CAPSULE; ORAL/
/POLYRON/
/LEDERLE LABS/
2 LEDERLE LABS

/182MG; 0.33MG/
182MG; 0.33MG

/N06012/003/
N06012 003

FLECAINIDE ACETATE

TABLET; ORAL

TAMBOCOR		
RIKER LABS	50MGM	N18830 004
		AUG 23, 1988
	150MGM	N18830 003
		JUN 03, 1988

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL

<u>FLUOCINOLONE ACETONIDE</u>			
AT	G&W LABS	0.01%M	N89526 001
			JUL 26, 1988
AT		0.025%M	N89525 001
			JUL 26, 1988

OIL; TOPICAL

DERMA-SMOOTHIE/FS		
HILL DERM	0.01%M	N19452 001
		FEB 03, 1988

OINTMENT; TOPICAL

<u>FLUOCINOLONE ACETONIDE</u>			
AT	G&W LABS	0.025%M	N89524 001
			JUL 26, 1988

FLUOCINONIDECREAM; TOPICAL
FLUOCINONIDE

AB CLAY PARK LABS 0.05%

N71790 001
APR 25, 1988

SOLUTION; TOPICAL

FLUOCINONIDE> ADD >
> ADD > AT BARRE NATL 0.05%
> ADD >N71535 001
DEC 02, 1988LIDEX> ADD > AT SYNTEX LABS 0.05%
> ADD >N18849 001
APR 06, 1984FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

AP BEN VENUE LABS 50MG/ML

N89508 001
JAN 26, 1988FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

FLUPHENAZINE HCL

AP QUAD PHARMS 2.5MG/ML

N89800 001
JUN 08, 1988

TABLET; ORAL

FLUPHENAZINE HCL

AB MYLAN PHARMS 1MG

N89801 001
AUG 12, 1988

AB 2.5MG

N89802 001
AUG 12, 1988

AB 5MG

N89803 001
AUG 12, 1988

AB 10MG

N89804 001
AUG 12, 1988

AB PAR PHARM 1MG

N89740 001
AUG 25, 1988

AB 2.5MG

N89741 001
AUG 25, 1988

AB 5MG

N89742 001
AUG 25, 1988

AB 10MG

N89743 001
AUG 25, 1988FLUPHENAZINE HYDROCHLORIDETABLET; ORAL
PERMITILBP SCHERING 2.5MG
BP 5MG
BP 10MG
/3/ /2.5MG/
/3/ /5MG/
/3/ /10MG/N12034 004
N12034 005
N12034 006
/N12034/004/
/N12034/005/
/N12034/006/FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HCL

AB HALSEY DRUG 15MG

N71808 001
JAN 07, 1988

AB 30MG

N71809 001
JAN 07, 1988

AB SUPERPHARM 15MG

N71659 001
AUG 04, 1988

AB 30MG

N71660 001
AUG 04, 1988FLURBIPROFEN

TABLET; ORAL

ANSAID

UPJOHN

50MG

N18766 002
OCT 31, 1988

100MG

N18766 003
OCT 31, 1988FOLIC ACID

TABLET; ORAL

FOLIC ACID

/66/ /BARR/LABS/ /1MG/

/N89177/001/
/JAN/88./1988/

3 BARR LABS 1MG

N89177 001
JAN 08, 1988FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

/62/ /PARKE/DAVIS/ /10MG/ML/

/N18428/001/
/FEB/88./1988/

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE
 AP WARNER CHILCOTT 10MG/ML N18420 001
 FEB 26, 1982

TABLET; ORAL

FUROSEMIDE
 AB BARR LABS 80MG N70100 001
 JAN 26, 1988
 AB DANBURY PHARMA 80MG N71594 001
 FEB 09, 1988

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION

MAGNEVIST
 BERLEX LABS 469.01MG/MLM N19596 001
 JUN 02, 1988

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION

GALLIUM CITRATE GA 67
 /MEDI/PHYSICS/ /1MCI/ML/ N17700/001/
 3 MEDI PHYSICS 1MCI/ML N17700 001

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

GENTAMICIN SULFATE
 AI PACO RES EQ 3MG BASE/MLM N62932 001
 NOV 07, 1988

GENTAMICIN SULFATE; PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC

PRED-G
 ALLERGAN PHARMS EQ 0.3% BASE;1% N50586 001
 JUN 10, 1988

GLYCOPYRROLATE

INJECTABLE; INJECTION

GLYCOPYRROLATE
 AP ABBOTT LABS 0.2MG/MLM N89393 001
 JUN 15, 1988

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN
 AI IPHARM 0.025MG/ML;EQ 1.75MG BASE/ML;
 10,000 UNITS/MLM N62818 001
 OCT 11, 1988

GUANABENZ ACETATE

TABLET; ORAL

/MYETH/AYERST/
 /MYETH/AYERST/LABS/ /EQ 16MG/BASE/ N18587/001/
 3 MYETH AYERST LABS EQ 16MG BASE /SEP/07/1982/
 N18587 003
 SEP 07, 1982

GUANFACINE HYDROCHLORIDE

TABLET; ORAL

TENEX
 > ADD > ROBINS 2MG N19032 002
 > ADD > 3MG NOV 07, 1988
 > ADD > N19032 003
 > ADD > NOV 07, 1988

HALOPERIDOL

TABLET; ORAL

HALDOL SOLUTAB
 /3/MCNEIL/LABS/ /1MG/ N17079/001/
 3 MCNEIL PHARM 1MG N17079 001
HALOPERIDOL
 AB BARR LABS 5MG N71212 001
 JAN 07, 1988
 AB 10MG N71173 001
 JAN 07, 1988
 AB 20MG N71177 001
 JAN 07, 1988

HALOPERIDOL

TABLET; ORAL

HALOPERIDOL

AB BOLAR PHARM 0.5MG

AB 1MG

AB 2MG

AB 5MG

AB 10MG

AB 20MG

AB CORD LABS 10MG

AB 20MG

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALDOL/AA/ /MCNEIL/LABS/ /EQ 2MG BASE/ML/ /N15922/001/
AA MCNEIL PHARM EQ 2MG BASE/ML N15922 001HALOPERIDOL

> ADD > AA COPLEY PHARM EQ 2MG BASE/ML N71617 001

> ADD > AA HALOPERIDOL INTENSOL

AA ROXANE LABS EQ 2MG BASE/ML N72045 001

INJECTABLE; INJECTION

HALOPERIDOL

AP LEMMON EQ 5MG BASE/ML N70713 001

AP EQ 5MG BASE/ML N70714 001

AP EQ 5MG BASE/ML N70744 001

HEPARIN SODIUM

INJECTABLE; INJECTION

HEP FLUSH KIT IN PLASTIC CONTAINER

AP LYPHOMED 10 UNITS/ML N17029 017

AP 100 UNITS/ML N17029 018

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH/AP/ /ABBOTT/LABS/ /100 UNITS/ML/ /N05264/010/
> DLT > /AP/ 2 ABBOTT LABS 100 UNITS/ML N05264 010
> ADD > /STERIS/LABS/ /100 UNITS/ML/ /N17064/001/
2 STERIS LABS 100 UNITS/ML N17064 001HEPARIN LOCK FLUSH IN PLASTIC CONTAINER

AP ABBOTT LABS 10 UNITS/ML N05264 015

AP 100 UNITS/ML MAY 21, 1985

AP 100 UNITS/ML N05264 016

AP 100 UNITS/ML MAY 21, 1985

HEPARIN SODIUM/AA/ /LYPHOMED/ /4,000 UNITS/ML/ /N17979/003/
2 LYPHOMED 5,000 UNITS/ML N17979 003> DLT > /AP/ /STERIS/LABS/ /4,000 UNITS/ML/ /N17064/015/
> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 015

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 016

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 017

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 018

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 019

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

> DLT > /AP/ 2 STERIS LABS 4,000 UNITS/ML N17064 006

HEPARIN SODIUM IN PLASTIC CONTAINER

AP LYPHOMED 1,000 UNITS/ML N17029 013

AP 5,000 UNITS/ML DEC 05, 1985

AP 10,000 UNITS/ML N17029 014

AP 20,000 UNITS/ML DEC 05, 1985

AP 20,000 UNITS/ML N17029 015

AP 20,000 UNITS/ML DEC 05, 1985

AP 20,000 UNITS/ML N17029 016

AP 20,000 UNITS/ML DEC 05, 1985

HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC

CONTAINER

/AP/ /ABBOTT/LABS/ /10,000 UNITS/100ML/ /N19339/003/
2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

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2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

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2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

2 ABBOTT LABS 10,000 UNITS/100ML N19339 003

HEPARIN SODIUMINJECTABLE; INJECTION

<u>HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>			
AB	ABBOTT LABS	5,000 UNITS/100ML	N19339 001 MAR 27, 1985
<u>HEPARIN SODIUM 2000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>			
AP	BAXTER	200 UNITS/100ML	N18609 002 APR 28, 1982
<u>HEPARIN SODIUM 20000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>			
AB	TRAVENOL LABS	200 UNITS/100ML	N18603 002 APR 28, 1982
<u>HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>			
AB	ABBOTT LABS	5,000 UNITS/100ML	N19339 004 MAR 27, 1985
AB		10,000 UNITS/100ML	N19339 002 MAR 27, 1985
<u>HEPARIN SODIUM 5000 UNITS AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>			
AP	BAXTER	500 UNITS/100ML	N18609 003 APR 28, 1982
AB	TRAVENOL LABS	500 UNITS/100ML	N18603 003 APR 28, 1982
<u>LIQUID HEPARIN SODIUM PRESERVATIVE FREE</u>			
AB	ORGANON	1,000 UNITS/ML	N00552 011 APR 11, 1986
AB		5,000 UNITS/ML	N00552 012 APR 11, 1986
AB		10,000 UNITS/ML	N00552 013 APR 11, 1986
<u>SODIUM HEPARIN</u>			
AB	LYPHOMED	5,000 UNITS/ML	N17033 002
AB		10,000 UNITS/ML	N17033 003
AB		20,000 UNITS/ML	N17033 004
AB	LYPHOMED	5,000 UNITS/ML	N17033 002
AB		10,000 UNITS/ML	N17033 003
AB		20,000 UNITS/ML	N17033 004

HEXOCYCLUM METHYLSULFATETABLET; ORAL

<u>HEXOCYCLUM METHYLSULFATE</u>			
AB	ABBOTT LABS	25MG	N10599 001
<u>HEXOCYCLUM METHYLSULFATE</u>			
AB	ABBOTT LABS	25MG	N10599 001

HYDRALAZINE HYDROCHLORIDETABLET; ORAL

<u>HYDRALAZINE HCL</u>			
AB	PUREPAC PHARM	50MG	N88178 001 AUG 15, 1983
<u>HYDRALAZINE HCL</u>			
AB	PUREPAC PHARM	50MG	N88178 001 AUG 15, 1983

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDECAPSULE; ORAL

<u>HYDRAL</u>			
AB	REID ROWELL	25MG; 25MG	N87608 001 FEB 08, 1982
AB		50MG; 50MG	N87213 001 FEB 08, 1982
AB		25MG; 25MG	N87608 001 FEB 08, 1982
AB		50MG; 50MG	N87213 001 FEB 08, 1982

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINETABLET; ORAL

<u>RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE</u>			
BP	REID ROWELL	25MG; 15MG; 0.1MG	N87210 001 OCT 28, 1983
BP	REID ROWELL	25MG; 15MG; 0.1MG	N88376 001 OCT 28, 1983
<u>RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE</u>			
AB	REID ROWELL	25MG; 15MG; 0.1MG	N87210 001 OCT 28, 1983
BP	REID ROWELL	25MG; 15MG; 0.1MG	N88376 001 OCT 28, 1983
<u>RESERPINE, HYDRALAZINE HCL AND HYDROCHLOROTHIAZIDE</u>			
AB	REID ROWELL	25MG; 15MG; 0.1MG	N87210 001 OCT 28, 1983
BP	REID ROWELL	25MG; 15MG; 0.1MG	N88376 001 OCT 28, 1983

HYDROCHLOROTHIAZIDESOLUTION; ORALHYDROCHLOROTHIAZIDE

AA	MY K LABS	50MG/5ML	N89661 001
			JUN 20, 1988
AA	ROXANE LABS	50MG/5ML	N88587 001
			JUL 02, 1984

TABLET; ORALHYDROCHLOROTHIAZIDE

/AA/	/BANMAX/PHARMS/	/25MG/	/N86369/001/
/AA/		/50MG/	/N83554/001/
	2 BANMAX PHARMS	25MG	N86369 001
	2	50MG	N83554 001
AB	WARNER CHILCOTT	25MG	N87586 001
			MAY 03, 1982
AB		50MG	N87587 001
			MAY 03, 1982
/AA/	/THOMPSON/	/25MG/	/N87586/001/
/AA/	/PARKE/DAVIS/	/25MG/	/N87587/001/
/AA/		/50MG/	/N87587/001/
			/MAY/03./1982/

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDETABLET; ORALNORMOZIDE/SCHERING/

2 SCHERING

/25MG;400MG/

25MG;400MG

/N19046/004/
/APR/06./1987/
N19046 004
APR 06, 1987

TRANDATE HGTGLAXO

AB 25MG;100MG

AB 25MG;200MG

AB 25MG;300MG

2

25MG;400MG

N19174 001
APR 10, 1987
N19174 002
APR 10, 1987
N19174 003
APR 10, 1987
N19174 004
APR 10, 1987

/TRANDATE HGT//GLAXO/

/AA/ /25MG;100MG/

/AA/ /25MG;200MG/

/AA/ /25MG;300MG/

/AA/ /25MG;400MG/

/N19174/001/
/APR/10./1987/
/N19174/002/
/APR/10./1987/
/N19174/003/
/APR/10./1987/
/N19174/004/
/APR/10./1987/

HYDROCHLOROTHIAZIDE; METHYLDOPATABLET; ORALMETHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	NOVOPHARM	15MG;250MG
AB		25MG;250MG
AB		30MG;500MG
AB		50MG;500MG
/AA/	/PUREPAC/PHARM/	/50MG;500MG/
	2 PUREPAC PHARM	50MG;500MG
AB	MATSON LABS	15MG;250MG
AB		25MG;250MG
AB		30MG;500MG
AB		50MG;500MG
AB	ZENITH LABS	15MG;250MG
AB		25MG;250MG
AB		30MG;500MG
AB		50MG;500MG

N71819 001
APR 08, 1988
N71820 001
APR 08, 1988
N71821 001
APR 08, 1988
N71822 001
APR 08, 1988
/N70689/001/
/APR/24./1986/
N70689 001
APR 24, 1986
N71920 001
AUG 29, 1988
N71921 001
AUG 29, 1988
N71922 001
AUG 29, 1988
N71923 001
AUG 29, 1988
N71458 001
MAR 08, 1988
N71459 001
MAR 08, 1988
N71460 001
MAR 08, 1988
N71461 001
MAR 08, 1988

HYDROCHLOROTHIAZIDE; PINDOLOLTABLET; ORAL/VISAZIDE//SANDOZ/PHARMS/

/25MG;5MG/

/25MG;10MG/

2 SANDOZ PHARMS

25MG;5MG

2

25MG;10MG

/N18872/001/
/JUL/22./1987/
/N18872/002/
/JUL/22./1987/
N18872 001
JUL 22, 1987
N18872 002
JUL 22, 1987

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

AB	SIDMAK LABS	25MG;40MG	N72042 001
			MAR 14, 1988
AB		25MG;80MG	N72043 001
			MAR 14, 1988
AB	WARNER CHILCOTT	25MG;40MG	N71771 001
			JAN 26, 1988
AB		25MG;80MG	N71772 001
			JAN 26, 1988
> ADD >	AB	ZENITH LABS	25MG;40MG
> ADD >			N71552 001
> ADD >	AB		25MG;80MG
> ADD >			DEC 01, 1988
			N71553 001
			DEC 01, 1988

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

HYDROCHLOROTHIAZIDE W/ RESERPINE

1/2	BOOTS/PHARMS/	25MG;0.125MG	N85421/001/
3	PHARMAFAIR	25MG;0.125MG	N85421 001
	RESERPINE AND HYDROCHLOROTHIAZIDE		
1/2	BARR/LABS/	25MG;0.125MG	N84566/001/
1/2		50MG;0.125MG	N84579/001/
3	BARR LABS	25MG;0.125MG	N84580 001
3		50MG;0.125MG	N84579 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE

1/2	LEDERLE/LABS/	25MG;25MG	N87511/001/
3	LEDERLE LABS	25MG;25MG	N87511 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	VITARINE	25MG;50MG	N71737 001
			FEB 12, 1988

TABLET; ORAL

MAXZIDE-25MG

MYLAN PHARMS

25MG;37.5MG

N19129 003
MAY 13, 1988

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	CORD LABS	50MG;75MG	N72011 001
			JUN 17, 1988

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

TRIAMTERENE AND HYDROCHLOROTHIAZIDE

AB	DANBURY PHARMA	50MG;75MG	N71969 001
			JAN 15, 1988
AB	PAR PHARM	50MG;75MG	N72337 001
			MAY 11, 1988
AB	QUANTUM PHARMCS	50MG;75MG	N71980 001
			FEB 01, 1988
AB	WATSON LABS	50MG;75MG	N71851 001
			NOV 30, 1988

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

AI	NASKA PHARMA	1/2	N89706 001
			MAR 10, 1988
AI		2.5/2	N89682 001
			MAR 10, 1988
AI	NMC LABS	1/2	N87795 001
			MAY 03, 1983

HYDROTEX

AI	SYOSSET LABS	1/2	N87427 001
			APR 04, 1988

1/2	HYMAC/		
1/2	NMC/LABS/	1/2	N87795/001/
			MAY/03/1983/

LOTION; TOPICAL

BETA-MC

AI	BETA DERM	1/2	N89495 001
			JAN 25, 1988

HYDROCORTISONE

AI	NASKA PHARMA	1/2	N89705 001
			APR 25, 1988

OINTMENT; TOPICAL

HC (HYDROCORTISONE)

1/2	C&H/PHARMA/	1/2	N80481/001/
1/2		1/2	N80481/001/
			N80481 002

AI	C&H PHARMA	1/2	N89704 001
			MAR 10, 1988
AI	NASKA PHARMA	1/2	

TABLET; ORAL

HYDROCORTISONE

1/2	BARR/LABS/	20MG/	N83999/001/
3	BARR LABS	20MG	N83999 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE
 AT STERIS LABS 1% EQ 3.5MG BASE/ML; N62874 001
 10,000 UNITS/MLM MAY 11, 1988

HYDROCORTISONE ACETATE

CREAM; TOPICAL
HYDROCORTISONE ACETATE
 /AT/ /THAMES/PHARMA/ /1%/
 /N89472/001/
 /JUN/13/1988/

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL
EPIFOAM
 AT REED & CARNRICK 1%:1% N86457 001
HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%
 AT COPLEY PHARM 1%:1% N89440 001
 MAY 17, 1988

HYDROCORTISONE ACETATE; UREA

CREAM; TOPICAL
CARMOL HC
 AT SYNTAX LABS 1%:10% N80505 001
HYDROCORTISONE ACETATE
 AT THAMES PHARMA 1%:10% N89472 001
 JUN 13, 1988

HYDROCORTISONE BUTYRATE

SOLUTION; TOPICAL
HYDROCORTISONE BUTYRATE
 AT GIST BROCADES 0.1% N19116 001
 FEB 25, 1987
 /LOCATED/
 /GIST/BROCADES/ /0.1%/
 /N19116/001/
 /FEB/25/1987/
LOCATED
 AT OWEN LABS 0.1% N19819 001
 SEP 15, 1988

HYDROFLUMETHIAZIDE

TABLET; ORAL
HYDROFLUMETHIAZIDE
 /AA/ /BOLAR/PHARM/ /50MG/
 2 BOLAR PHARM 50MG

/N88031/001/
 /APR/06/1983/
 N88031 001
 APR 06, 1983

HYDROXYPROPYL CELLULOSE

INSERT; OPHTHALMIC
 LACRISERT
 MS&D RES LABS 5MG N18771 001

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDROXYZINE HCL
 /AA/ /ALTANA/ /25MG/ML/
 /AA/ /25MG/ML/
 2 ALTANA 25MG/ML
 2 50MG/ML
 N87273 001
 APR 20, 1982
 N87273 002
 APR 20, 1982

SYRUP; ORAL
HYDROXYZINE HCL
 AA NASKA PHARMA 10MG/5MLM N88785 001
 FEB 03, 1988

TABLET; ORAL
HYDROXYZINE HCL
 AB HALSEY DRUG 10MG N89366 001
 MAY 02, 1988
 AB 25MG N89117 001
 MAY 02, 1988
 AB 50MG N89396 001
 MAY 02, 1988

IBUPROFEN

TABLET; ORAL

IBU-TAB

AB	ALRA LABS	400MG	N71058 001
			AUG 11, 1988
AB		600MG	N71059 001
			AUG 11, 1988
AB		800MG	N71965 001
			AUG 11, 1988
<u>IBUPROFEN</u>			
AB	HALSEY DRUG	800MG	N72137 001
			FEB 05, 1988
AB	INVAMED	400MG	N72064 001
			JAN 14, 1988
AB		600MG	N72065 001
			JAN 14, 1988
AB		800MG	N71938 001
			JAN 14, 1988
AB	MEDICOPHARMA	400MG	N71644 001
			FEB 01, 1988
AB	PRIVATE FMLTNS	800MG	N72300 001
			JUL 01, 1988
AB	PUREPAC PHARM	800MG	N71964 001
			FEB 01, 1988

> ADD > IFOSFAMIDE> ADD > INJECTABLE; INJECTION> ADD > IFEX> ADD > BRISTOL MYERS

		1GM/VIALM	N19763 001
			DEC 30, 1988
		3GM/VIALM	N19763 002
			DEC 30, 1988

> ADD >> ADD >IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

/AB/	/LEDERLE LABS/	/10MG/	/N86269/001/
/AB/		/25MG/	/N86267/001/
/AB/		/50MG/	/N86268/001/
	3 LEDERLE LABS	10MG	N86269 001
	3	25MG	N86267 001
	3	50MG	N86268 001

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

/AB/	/PRADINE/	/10MG/	/N83827/001/
/AB/	/BANMAX PHARMS/	/25MG/	/N83827/002/
/BP/		/50MG/	/N83827/003/
	3 BANMAX PHARMS	10MG	N83827 001
	3	25MG	N83827 002
	3	50MG	N83827 003

INDIUM IN-111 OXYQUINOLINE

/INJECTABLE; INJECTION/
/INDIUM IN-111 OXYQUINOLINE/
/AMERSHAM/

INJECTABLE; INJECTION

INDIUM IN-111 OXYQUINOLINE
AMERSHAM 1MCI/ML

/N19044/001/
/DEC 23, 1985/

N19044 001
DEC 23, 1985

INDOCYANINE GREEN

INJECTABLE; INJECTION

CARDIO-GREEN

3 B-D MICROBIOL SYS	10MG/VIAL	N11525 003
	25MG/VIAL	N11525 001
3	40MG/VIAL	N11525 004
	50MG/VIAL	N11525 002
/HYNAN/RES/A/DAN/	/10MG/VIAL/	/N11525/003/
	/40MG/VIAL/	/N11525/004/

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

AB	NOVOPHARM	25MG	N71342 001
			APR 18, 1988
AB		50MG	N71343 001
			APR 18, 1988
AB	VITARINE	25MG	N71711 001
			JUL 05, 1988
AB		50MG	N71712 001
			JUL 05, 1988

INSULIN PORK

INJECTABLE; INJECTION

/ILETIN/	/500 UNITS/ML/	/N17931/001/
/LILLY/		
ILETIN I	500 UNITS/ML	N17931 001
LILLY		

IOHEXOL

INJECTABLE; INJECTION

OMNIPAQUE 140	30.2%	N18956 005
STERLING DRUG		NOV 30, 1988
OMNIPAQUE 180		
/3/STERLING DRUG/	/38.8%/	/N18956/001/
		/DEC 26, 1985/
STERLING DRUG	38.8%	N18956 001
		DEC 26, 1985

IOTHALAMATE MEGLUMINE

SOLUTION; INTRAVESICAL

CYSTO-CONRAY II	17.2%	N17057 002
MALLINCKRODT		

SOLUTION; INTRAVESICAL, URETERAL

CYSTO-CONRAY	43%	N17057 001
MALLINCKRODT		

/SOLUTION; URETERAL/		
/CYSTO-CONRAY/		
/MALLINCKRODT/	/43%/	/N17057/001/
/CYSTO-CONRAY II/	/17.2%/	/N17057/002/
/MALLINCKRODT/		

IRON DEXTRAN

INJECTABLE; INJECTION

/DEXTRON/	/600 MG/100ML/	/N17807/001/
/FISONS/		
3 FISONS	EQ 50MG IRON/ML	N17807 001

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

AN	ISOETHARINE HCL	0.17%	N87390 001
	DEY LABS		
AN	ISOETHARINE HCL 3/F	0.08%	N89817 001
	DEY LABS		NOV 22, 1988
AN		0.1%	N89818 001
			NOV 22, 1988
AN		0.17%	N89819 001
			NOV 22, 1988
AN		0.25%	N89820 001
			NOV 22, 1988

ISONIAZID

INJECTABLE; INJECTION

AP	ISONIAZID	100MG/ML	N89816 001
	QUAD PHARMS		OCT 28, 1988
AP	HYDRAZID	100MG/ML	N08662 001
	SQUIBB		

TABLET; ORAL

AA	DOM-ISONIAZID	300MG	/N80330/002/
	3 DOM PHARMS		N80330 002
AA	LANAZID	300MG	N89776 001
	LANNETT		JUN 13, 1988

ISOSORBIDE DINITRATE

CAPSULE, CONTROLLED RELEASE; ORAL

BC	DILATRATE-SR	40MG	N19790 001
	REED & CARNRICK		SEP 02, 1988
BC	ISORDIL	40MG	N12882 002
	MYETH AYERST LABS		JUL 29, 1988

> ADD > IOVERSOL> ADD > INJECTABLE; INJECTION

> <u>ADD</u> >	OPTIRAY-160		N19710 003
> <u>ADD</u> >	MALLINCKRODT	34%	DEC 30, 1988
> <u>ADD</u> >	OPTIRAY-240		N19710 002
> <u>ADD</u> >	MALLINCKRODT	51%	DEC 30, 1988
> <u>ADD</u> >	OPTIRAY-320		N19710 001
> <u>ADD</u> >	MALLINCKRODT	68%	DEC 30, 1988

ISOSORBIDE DINITRATE

TABLET; ORAL

ISORDIL

AB	MYETH AYERST LABS	<u>5MG</u>	N12093 007
			JUL 29, 1988
AB		<u>10MG</u>	N12093 002
			JUL 29, 1988
AB		<u>20MG</u>	N12093 006
			JUL 29, 1988
AB		<u>30MG</u>	N12093 005
			JUL 29, 1988
		<u>40MG</u>	N12093 001
			JUL 29, 1988

ISOSORBIDE DINITRATE

AB	BARR LABS	<u>30MG</u>	N87564 001
			SEP 18, 1986
AB	CORD LABS	<u>5MG</u>	N86221 001
			JAN 07, 1988
AB		<u>10MG</u>	N86223 001
			JAN 07, 1988
AB		<u>20MG</u>	N89367 001
			APR 07, 1988
AB	DANBURY PHARMA	<u>5MG</u>	N86034 001
			JAN 06, 1988
AB		<u>10MG</u>	N86032 001
			JAN 07, 1988
AB	PAR PHARM	<u>30MG</u>	N87946 001
			JAN 12, 1988

TABLET; SUBLINGUAL

ISORDIL

AB	MYETH AYERST LABS	<u>2.5MG</u>	N12940 004
			JUL 29, 1988
AB		<u>5MG</u>	N12940 003
			JUL 29, 1988
AB		<u>10MG</u>	N12940 005
			JUL 29, 1988

ISOSORBIDE DINITRATE

AB	BARR LABS	<u>10MG</u>	N87545 001
			SEP 18, 1986
AB	CORD LABS	<u>2.5MG</u>	N86225 001
			FEB 19, 1988
AB		<u>5MG</u>	N86222 001
			FEB 19, 1988
AB	DANBURY PHARMA	<u>2.5MG</u>	N86033 001
			FEB 26, 1988
AB		<u>5MG</u>	N86031 001
			SEP 29, 1987

ISOSORBIDE DINITRATE

TABLET, CONTROLLED RELEASE; ORAL

ISORDIL

MYETH AYERST LABS	<u>40MG</u>	N12882 001
		JUL 29, 1988

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

KETALAR

AP	PARKE DAVIS	<u>EQ 10MG BASE/ML</u>	N16812 001
AP		<u>EQ 50MG BASE/ML</u>	N16812 002
AP		<u>EQ 100MG BASE/ML</u>	N16812 003

KETAMINE HCL

AP	QUAD PHARMS	<u>EQ 10MG BASE/ML</u>	N71949 001
			APR 11, 1988
AP		<u>EQ 50MG BASE/ML</u>	N71950 001
			APR 11, 1988
AP		<u>EQ 100MG BASE/ML</u>	N71951 001
			APR 11, 1988

LACTULOSE

SYRUP; ORAL

/AA/	<u>CEPHULAC/</u>	<u>/10GM/15ML/</u>	<u>/N17657/001/</u>
	<u>CHRONULAC</u>		

AA	MERRELL DOM	<u>10GM/15ML</u>	N17884 001
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AA	ALRA LABS	<u>10GM/15ML</u>	N71054 001
			JUL 26, 1988

AA	BARRE NATL	<u>10GM/15ML</u>	N70288 001
			AUG 15, 1988

AA	MY K LABS	<u>10GM/15ML</u>	N71841 001
			SEP 22, 1988

/AA/	<u>/ROXANE/LABS/</u>	<u>/10GM/15ML/</u>	<u>/N17986/001/</u>
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SYRUP; ORAL, RECTAL

CEPHULAC

AA	MERRELL DOM	<u>10GM/15ML</u>	N17657 001
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AA	ALRA LABS	<u>10GM/15ML</u>	N71331 001
			JUL 26, 1988

AA	BARRE NATL	<u>10GM/15ML</u>	N71548 001
			AUG 15, 1988

LACTULOSE

SYRUP; ORAL, RECTAL

GENERLAC

AA	MY K LABS	<u>10GM/15ML</u>	N71842 001 SEP 27, 1988
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LACTULOSE

AA	KALI DUPHAR	<u>10GM/15ML</u>	N17906 001
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LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM

AP	BEN VENUE LABS	<u>EQ 100MG BASE/VIAL</u>	N89717 001 MAR 28, 1988
AP	INTL PHARM	<u>EQ 3MG BASE/ML</u>	N89352 001 JUN 01, 1988
AP		<u>EQ 50MG BASE/VIAL</u>	N89353 001 JUN 01, 1988
AP	LEDERLE LABS	<u>EQ 3MG BASE/ML</u>	N08107 001
AP		<u>EQ 100MG BASE/VIAL</u>	N08107 004 MAY 23, 1988
AP	QUAD PHARMS	<u>EQ 100MG BASE/VIAL</u>	N89636 001 DEC 24, 1987

LEVOCARNITINE

SOLUTION; ORAL

CARNITOR

AA	SIGMA TAU	<u>1GM/10ML</u>	N18948 002 APR 27, 1988
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VITACARN

AA	KENDALL MCGAM	<u>1GM/10ML</u>	N19257 001 APR 10, 1986
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LEVODOPA

CAPSULE; ORAL

LEVODOPA

/BD/	/ICN/PHARMS/	<u>100MG</u>	/N16948/003/
/BD/		<u>250MG</u>	/N16948/001/
/BD/		<u>500MG</u>	/N16948/002/
	2 ICN PHARMS	100MG	N16948 003
	2	250MG	N16948 001
	2	500MG	N16948 002

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION

MELOCAINE W/ LEVONORDEFRIN

AP	ASTRA PHARM PRODS	<u>0.05MG/ML; 2%</u>	N89517 001 APR 14, 1988
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LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL

AP	ABBOTT LABS	<u>20%</u>	N89362 001 MAY 25, 1988
/AP/	/LEMMON/	<u>1%</u>	/N83627/001/
/AP/		<u>2%</u>	/N83627/002/
	2 LEMMON	1%	N83627 001
	2	2%	N83627 002

> DLT >	/INJECTABLE; INJECTION/		
> DLT >	/LIDOCAINE HCL W/ DEXTROSE/		
> DLT >	/AP/ ABBOTT LABS/	<u>5%</u>	/N83914/001/
> DLT >	/XYLOCAINE W/ DEXTROSE 7.5%/		
> DLT >	/AP/ ASTRA PHARM PRODS/	<u>1.5%</u>	/N16297/001/
> DLT >	/XYLOCAINE 5% W/ GLUCOSE 7.5%/		
> DLT >	/AP/ ASTRA PHARM PRODS/	<u>5%</u>	/N10496/002/
> DLT >			/JUL 07, 1982/

> ADD >	INJECTABLE; SPINAL		
> ADD >	<u>LIDOCAINE HCL W/ DEXTROSE</u>		
> ADD >	AP ABBOTT LABS	<u>5%</u>	N83914 001
> ADD >	XYLOCAINE W/ DEXTROSE 7.5%		
> ADD >	AP ASTRA PHARM PRODS	<u>1.5%</u>	N16297 001
> ADD >	<u>XYLOCAINE 5% W/ GLUCOSE 7.5%</u>		
> ADD >	AP ASTRA PHARM PRODS	<u>5%</u>	N10496 002 JUL 07, 1982
> ADD >			

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

LINCOCIN

AP	UPJOHN	<u>EQ 300MG BASE/ML</u>	N50317 001
AP	<u>LINCOMYCIN HCL</u>		
AP	QUAD PHARMS	<u>EQ 300MG BASE/ML</u>	N62784 001 MAR 14, 1988

LISINAPRIL

TABLET; ORAL

PRIMEVIL

AB MS&D RES LABS

5MG

N19558 001

DEC 29, 1987

AB

10MG

N19558 002

DEC 29, 1987

AB

20MG

N19558 003

DEC 29, 1987

> ADD >40MG

N19558 004

> ADD >

OCT 25, 1988

ZESTROL

AB IMPERIAL CHEM

5MG

N19777 001

MAY 19, 1988

AB

10MG

N19777 002

MAY 19, 1988

AB

20MG

N19777 003

MAY 19, 1988

LOPERAMIDE HYDROCHLORIDE/SOLUTION;/ORAL//IMMUN;//JANSSEN/PHARMA//1MG/5ML/

JANSSEN PHARMA

1MG/5ML/N19037/001//JUL/31/1984/

N19037 001

JUL 31, 1984

LORAZEPAM

TABLET; ORAL

LORAZEPAM

AB CORD LABS

0.5MG

N71193 001

APR 15, 1988

AB

1MG

N71194 001

APR 15, 1988

AB

2MG

N71195 001

APR 15, 1988

AB

WARNER CHILCOTT

1MG

N71038 001

JAN 12, 1988

AB

2MG

N71039 001

JAN 12, 1988

LOVASTATIN

TABLET; ORAL

MEVACOR

MS&D RES LABS

40MG

N19643 004

DEC 14, 1988

> ADD >> ADD >LOXAPINE SUCCINATE

CAPSULE; ORAL

LOXAPINE SUCCINATE

AB WATSON LABS

EQ 5MG BASE

N72204 001

JUN 15, 1988

AB

EQ 10MG BASE

N72205 001

JUN 15, 1988

AB

EQ 25MG BASE

N72206 001

JUN 15, 1988

AB

EQ 50MG BASE

N72062 001

JUN 15, 1988

LOXITANE

AB LEDERLE LABS

EQ 5MG BASE

N17525 001

AB

EQ 10MG BASE

N17525 002

AB

EQ 25MG BASE

N17525 003

AB

EQ 50MG BASE

N17525 004

MAPROTILINE HYDROCHLORIDE

TABLET; ORAL

MAPROTILINE HCL

AB AM THERPTCS

25MG

N72129 001

JAN 14, 1988

AB

50MG

N72130 001

JAN 14, 1988

AB

75MG

N72131 001

JAN 14, 1988

AB

MYLAN PHARMS

25MG

N72284 001

OCT 03, 1988

AB

50MG

N72285 001

OCT 03, 1988

AB

75MG

N72286 001

OCT 03, 1988

AB

WATSON LABS

25MG

N72162 001

JUN 01, 1988

AB

50MG

N72163 001

JUN 01, 1988

AB

75MG

N72164 001

JUN 01, 1988

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIEMETIC

AA ROERIG

50MG

N10721 001

JAN 20, 1982

MECLIZINE HCL

AA PAR PHARM

50MG

N89674 001

MAR 31, 1988

MECLOFENAMATE SODIUM

CAPSULE; ORAL
MECLOFENAMATE SODIUM
 AB CORD LABS EQ 50MG BASEM N72262 001
 NOV 29, 1988
 AB EQ 100MG BASEM N72263 001
 NOV 29, 1988
 AB PAR PHARM EQ 50MG BASEM N72077 001
 MAR 10, 1988
 AB EQ 100MG BASEM N72078 001
 MAR 10, 1988
 AB PHARM BASICS EQ 50MG BASEM N71007 001
 MAR 25, 1988
 AB EQ 100MG BASEM N71008 001
 MAR 25, 1988
 AB VITARINE EQ 50MG BASEM N71710 001
 JUN 15, 1988
 AB EQ 100MG BASEM N71684 001
 JUN 15, 1988

MEFENAMIC ACID

CAPSULE; ORAL
MEFENAMIC ACID
 AB VITARINE 250MG N72179 001
 APR 21, 1988
 AB PONSTEL
 PARKE DAVIS PR 250MG N15034 003

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE
 AB PAR PHARM 20MG N72422 001
 AUG 08, 1988
 AB 40MG N72423 001
 AUG 08, 1988

MEPENZOATE BROMIDE

/SOLUTION; ORAL/
 /CANTIL/
 /MERRELL/DOW/ 12MG/5ML/ N10679/004/
 2 MERRELL DOW 25MG/5ML N10679 004

MEPROBAMATE

TABLET; ORAL
MEPROBAMATE
 /AA/ /MALLARD/ /400MG/ N15072/002/
 2 MALLARD 400MG N15072 002
 /AA/ /PHARM/BASICS/ /400MG/ N87825/001/
 MAR 18, 1982
 /AA/ /400MG/ N87825/001/
 MAR 18, 1982
 2 PHARM BASICS 200MG N87825 001
 2 400MG N87826 001
 MAR 18, 1982
 /AA/ /STANLABS/PHARM/ /400MG/ N14474/004/
 2 STANLABS PHARM 400MG N14474 004

> ADD > MESNA

> ADD > INJECTABLE; INJECTION

> ADD > MESNEX

> ADD > BRISTOL MYERS 100MG/MLM

N19884 001

DEC 30, 1988

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21
NORETHIN 1/50M-21
 AB SEARLE PHARMS 0.05MG;1MG N71539 001
 APR 12, 1988
 AB NORETHINDRONE AND MESTRANOL
 WATSON LABS 0.05MG;1MG N70758 001
 JUL 01, 1988
 ORTHO-NOVUM 1/80 21
 /AA/ /ORTHO/PHARM/ /0.08MG;1MG/ N16715/001/
 2 ORTHO PHARM 0.08MG;1MG N16715 001
 ORTHO-NOVUM 2-21
 /AA/ /ORTHO/PHARM/ /0.1MG;2MG/ N12728/005/
 2 ORTHO PHARM 0.1MG;2MG N12728 005

TABLET; ORAL-28

NORETHIN 1/50M-28
 AB SEARLE PHARMS 0.05MG;1MG N71540 001
 APR 12, 1988
 AB NORETHINDRONE AND MESTRANOL
 WATSON LABS 0.05MG;1MG N70759 001
 JUL 01, 1988
 ORTHO-NOVUM 1/80 28
 /AA/ /ORTHO/PHARM/ /0.08MG;1MG/ N16715/002/
 2 ORTHO PHARM 0.08MG;1MG N16715 002

MESTRANOL; NORETHYNODREL

TABLET; ORAL-20

<u>ENOVIO</u>			
/AA/ /SEARLE/	/0.075MG;5MG/	/N10976/004/	
3 SEARLE	0.075MG;5MG	N10976 004	
<u>ENOVIO-11</u>			
/AA/ /SEARLE/	/0.1MG;2.5MG/	/N10976/006/	
3 SEARLE	0.1MG;2.5MG	N10976 006	

METAPROTERENOL SULFATE

SOLUTION; INHALATION

ALUPENT

AN	BOEHR INGEL	0.4%	N18761 002
			OCT 10, 1986

DEY-DOSE

AN	DEY LABS	5%	N70805 001
			AUG 17, 1987

DEY-LUTE

AN	DEY LABS	0.4% M	N71786 001
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AN		0.6%	N70804 001
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		0.33% M	N71806 001
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		0.5% M	N71805 001
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AUG 05, 1988

METAPROTERENOL SULFATE

AN	ARMOUR PHARM	0.4% M	N71275 001
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JUL 27, 1988

AN		0.6% M	N71018 001
----	--	-------------------	------------

JUL 27, 1988

/AA/ /DEY LABS/	/0.6% M /	/N70804/001/	
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/AUG 17, 1987/

/AA/	/5% M /	/N70805/001/	
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/AUG 17, 1987/

AN	MY K LABS	5% M	N72190 001
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JUN 07, 1988

AN	PACO RES	0.4% M	N71855 001
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JUL 14, 1988

AN		0.6% M	N71726 001
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JUL 14, 1988

SYRUP; ORAL

METAL

/AA/ /MURO PHARM/	/10MG/5ML/	/N72023/001/	
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/SEP 15, 1988/

PROMETA

AA	MURO PHARM	10MG/5ML	N72023 001
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SEP 15, 1988

METAPROTERENOL SULFATE

TABLET; ORAL

ALUPENT

AB	BOEHR INGEL	10MG	N15874 002
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AB		20MG	N15874 001
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METAPROTERENOL SULFATE

AB	AM THERPTCS	10MG M	N72054 001
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AB		20MG M	JUN 23, 1988
----	--	-------------------	--------------

AB	PAR PHARM	10MG M	N72055 001
----	-----------	-------------------	------------

AB		20MG M	JUN 23, 1988
----	--	-------------------	--------------

AB	PHARM BASICS	10MG M	N72024 001
----	--------------	-------------------	------------

AB		20MG M	JUN 28, 1988
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AB		20MG M	N72025 001
----	--	-------------------	------------

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

METHADONE

AA	MALLINCKRODT	10MG/ML	N17116 002
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METHADONE HCL INTENSOL

AA	ROXANE LABS	10MG/ML M	N89897 001
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SEP 06, 1988

METHAZOLAMIDE

TABLET; ORAL

NEPTAZANE

	LEDERLE LABS	25MG M	N11721 002
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MAR 04, 1988

METHIXENE HYDROCHLORIDE

/TABLET; ORAL/

TREST

	/DORSEY LABS/	/1MG/	/N13420/001/
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3 DORSEY LABS 1MG

N13420 001

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

/AA/ /BARR LABS/	/500MG/	/N84488/001/	
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3 BARR LABS 500MG

N84488 001

METHOTREXATE

~~/TABLET; ORAL/
/METHOTREXATE/
/LEDERLE LABS/~~

~~/2.5MG/~~~~/N00005/002/~~METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE

LEDERLE LABS

EQ 1GM BASE/VIALM

N11719 009
APR 07, 1988METHOTREXATE SODIUM

AP PHARMACHEMIE

EQ 25MG BASE/MLM

N89158 001
JUL 08, 1988

TABLET; ORAL

METHOTREXATE

BP LEDERLE LABS

EQ 2.5MG BASEM

N08085 002

METHOXSALEN

CAPSULE; ORAL

~~/OXDORALEN/~~~~/BP/ ELDER PHARMS/
8-MOP~~

ELDER PHARMS

~~/10MG/~~

10MG

~~/N00046/001/~~

N09048 001

METHYCLOTHIAZIDE

TABLET; ORAL

METHYCLOTHIAZIDE

AB CORD LABS

2.5MG

N89835 001
AUG 18, 1988

AB

5MG

N89837 001
AUG 18, 1988METHYLDOPA

TABLET; ORAL

METHYLDOPA

AB CORD LABS

125MG

N71700 001
MAR 02, 1988

AB

HALSEY DRUG

125MG

N71751 001
MAR 28, 1988

AB

250MG

N71752 001
MAR 28, 1988

AB

500MG

N71753 001
MAR 28, 1988METHYLDOPA

TABLET; ORAL

METHYLDOPA

AB SIDMAK LABS

125MG

N72126 001
JUL 07, 1988

AB

250MG

N72127 001
JUL 07, 1988

AB

500MG

N72128 001
JUL 07, 1988METHYLPHENIDATE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL

METHYLPHENIDATE HCL

AB MD PHARM

20MG

N89601 001
JUN 01, 1988AB RITALIN-SR

CIBA PHARM

20MG

N18029 001
MAR 30, 1982METHYLPREDNISOLONE

TABLET; ORAL

MEDROL

AB UPJOHN

24MG

N11153 005

AB

32MG

N11153 006

AB METHYLPREDNISOLONE

HEATHER DRUG

4MG

N85650 001

~~/BP/~~~~/4MG/~~~~/N05650/001/~~

AB PAR PHARM

16MG

N89207 001

AB

24MG

N89208 001

AB

32MG

N89209 001

APR 25, 1988

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

AP DUPONT CRI CARE

EQ 10MG BASE/2MLM

N70847 001
NOV 07, 1988

AP MAURRY BIOL

EQ 10MG BASE/2MLM

N70892 001
AUG 26, 1988

SYRUP; ORAL

METOCLOPRAMIDE HCL

AA BARRE NATL

EQ 5MG BASE/5MLM

N71340 001
AUG 18, 1988

METOCLOPRAMIDE HYDROCHLORIDE

SYRUP; ORAL

METOCLOPRAMIDE HCL

> ADD >	AA	PACO RES	EQ 5MG BASE/5MLM	N71665 001
> ADD >				DEC 05, 1988
> ADD >	AA	ROXANE LABS	EQ 5MG BASE/5MLM	N72038 001
> ADD >				DEC 05, 1988

TABLET; ORAL

GLOPRA

AB	QUANTUM PHARMCS	EQ 5MG BASEM	N72384 001
			JUN 02, 1988

METOCLOPRAMIDE HCL

AB	SIDMAK LABS	EQ 10MG BASEM	N71250 001
			FEB 03, 1988

REGLAN

AB	ROBINS	EQ 5MG BASE	N17854 002
			MAY 05, 1987

METOCURINE IODIDE

INJECTABLE; INJECTION

METOCURINE IODIDE

AP	QUAD PHARMS	2MG/MLM	N89443 001
			JUN 01, 1988

METURINE IODIDE

AP	LILLY	2MG/ML	N06632 003
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METOLAZONE

TABLET; ORAL

MYKROX
FISONS

/0.5MG/

/N19532/001/
/OCT/30, 1987/

MYKROX

FISONS

0.5MG

N19532 001
OCT 30, 1987METRIZAMIDE

INJECTABLE; INJECTION

AMIPAQUE

/STERLING/DRUG/

/13.5GM/VIAL/

/N17982/004/
/SEP/12, 1983/

2 STERLING DRUG

13.5GM/VIAL

N17982 004
SEP 12, 1983METRONIDAZOLE

GEL; TOPICAL

METROGEL

CURATEK PHARMS

0.75%M

N19737 001
NOV 22, 1988MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION

MEZLIN

MILES PHARM

EQ 20GM BASE/VIALM

N50549 005
MAR 02, 1988

EQ 20GM BASE/VIALM

N62372 004
MAR 02, 1988MINOXIDIL

SOLUTION; TOPICAL

ROGAINE

UPJOHN

2%M

N19501 001
AUG 17, 1988

TABLET; ORAL

MEHODYL

AB QUANTUM PHARMCS

2.5MGM

N72153 001
JUL 13, 1988MEHODYL

AB PAR PHARM

2.5MGM

N71826 001
NOV 14, 1988

AB

10MGM

N71839 001
NOV 14, 1988

> ADD > AB PHARM BASICS

2.5MGM

N71537 001
DEC 16, 1988

> ADD >

> ADD > MISOPROSTOL

> ADD >

TABLET; ORAL

> ADD >

CYTOTEC

> ADD >

SEARLE

0.2MGM

N19268 001
DEC 27, 1988

> ADD >

MITOMYCIN

INJECTABLE; INJECTION

MITAMYCIN

BRISTOL MYERS

40MG/VIALM

N62336 003
MAR 10, 1988

> DLT >

> DLT >

> ADD >

> ADD >

MORPHINE SULFATE

INJECTABLE; INJECTION

MORPHINE SULFATE

AP ABBOTT LABS 0.5MG/MLM

AP 1MG/MLM

TABLET, CONTROLLED RELEASE; ORAL

MS CONTIN

PURDUE FRDRK 60MGM

NAFCILLIN SODIUM

INJECTABLE; INJECTION

NAFCILLIN SODIUM

AP MARSAM PHARMS EQ 500MG BASE/VIALM

AP EQ 1GM BASE/VIALM

AP EQ 2GM BASE/VIALM

AP EQ 4GM BASE/VIALM

AP EQ 10GM BASE/VIALM

EQ 1.5GM BASE/VIALM

N71849 001
MAY 11, 1988
N71850 001
MAY 11, 1988N19516 002
APR 08, 1988N62844 001
OCT 26, 1988
N62844 002
OCT 26, 1988
N62844 004
OCT 26, 1988
N62844 005
OCT 26, 1988
N63008 001
SEP 29, 1988
N62844 003
OCT 26, 1988NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL

NAFTIN

HERBERT LABS

1/M

N19599 001
FEB 29, 1988NALIDIXIC ACID

TABLET; ORAL

NALIDIXIC ACID

AB DANBURY PHARMA 250MGM

AB 500MGM

AB 1GM

N71936 001
JUN 28, 1988
N72061 001
JUN 28, 1988
N71919 001
JUN 28, 1988NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

AP DUPONT CRI CARE 0.4MG/MLM

AP 1MG/MLM

AP 1MG/MLM

AP ELKINS SINN 0.02MG/MLM

AP 1MG/MLM

AP 1MG/MLM

AP 1MG/MLM

AP INTL MEDTN SYS 1MG/MLM

AP 1MG/MLM

> ADD > AP LYPHOMED 1MG/MLM

> ADD > AP MARSAM PHARMS 0.4MG/MLM

N71083 001
JUL 28, 1988
N71084 001
JUL 28, 1988
N71311 001
JUL 28, 1988
N71272 001
MAY 24, 1988
N71273 001
MAY 24, 1988
N71274 001
MAY 24, 1988
N71287 001
MAY 24, 1988
N72076 001
MAR 24, 1988
N72115 001
APR 27, 1988
N71604 001
DEC 16, 1988
N71811 001
JUL 19, 1988> ADD > NICARDIPINE HYDROCHLORIDE

CAPSULE; ORAL

CARDENE

SYNTEX LABS

20MGM

> ADD >

> ADD >

> ADD >

> ADD >

30MGM

N19488 001
DEC 21, 1988
N19488 002
DEC 21, 1988> ADD > NIMODIPINE

> ADD >

> ADD >

> ADD >

> ADD >

CAPSULE; ORAL

NIMOTOP

MILES PHARM

30MGM

N18869 001
DEC 28, 1988

NITROFURANTOIN

/CAPSULE; ORAL/
/NITROFURANTOIN/
/BOLAR/PHARM/
2 BOLAR PHARM

/50MG/
50MG
/100MG/
100MG

/N84326/001/
N84326 001
/N84326/002/
N84326 002

TABLET; ORAL

/68/ /NITROFURANTOIN/
/BOLAR/PHARM/
2 BOLAR PHARM

/100MG/
100MG

/N80447/002/
N80447 002

NITROFURANTOIN SODIUM

/INJECTABLE; INJECTION/
/NORMICH/EATON/
2 NORMICH EATON

/EQ/180MG/BASE/VIAL/
EQ 180MG BASE/VIAL

/N12402/001/
N12402 001

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL
MACRODANTIN

AB NORMICH EATON

50MG
100MG

N16620 001
N16620 002

AB NITROFURANTOIN MACROCRYSTALLINE
BOLAR PHARM

50MG

N70248 001
JUN 24, 1988
N70249 001
JUN 24, 1988

AB 100MG

NITROGLYCERIN

INJECTABLE; INJECTION

AP NITROGLYCERIN
LUITPOLD PHARMS

5MG/ML

N71492 001
MAY 24, 1988
N72034 001
MAY 24, 1988

AP 5MG/ML

OINTMENT; TOPICAL

NITROGLYCERIN
ALTANA

2%
2%
2%

N87355 001
JUL 08, 1988

NIZATIDINE

CAPSULE; ORAL
AXID
LILLY

150MG
300MG

N19508 001
APR 12, 1988
N19508 002
APR 12, 1988

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
AVENTYL HCL
LILLY

BD
BD
/BP/
/BP/

EQ 10MG BASE
EQ 25MG BASE
/EQ/10MG/BASE/
/EQ/25MG/BASE/

N14684 001
N14684 002
/N14684/001/
/N14684/002/

PAMELOR
BD SANDOZ PHARMS

BD
/BP/
/BP/

EQ 10MG BASE
EQ 25MG BASE
/EQ/10MG/BASE/
/EQ/25MG/BASE/

N18013 001
N18013 002
/N18013/001/
/N18013/002/

MYSTATIN

CREAM; TOPICAL

MYSTATIN
AT NASKA PHARMA

100,000 UNITS/GM

N62949 001
JUN 13, 1988

SUSPENSION; ORAL

MYSTATIN
AA THAMES PHARMA

100,000 UNITS/ML

N62876 001
FEB 29, 1988

TABLET; ORAL

MYSTATIN
> ADD > AA MUTUAL PHARM
> ADD >

500,000 UNITS

N62838 001
DEC 22, 1988

MYSTATIN; TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

MYSTATIN AND TRIAMCINOLONE ACETONIDE
> ADD > AT NASKA PHARMA
> ADD >

100,000 UNITS/GM; 0.1%
100,000 UNITS/GM; 0.1%
100,000 UNITS/GM; 0.1%

N63010 001
DEC 20, 1988

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOZ PHARMS

EQ 0.05MG BASE/MLM N19667 001
OCT 21, 1988
EQ 0.1MG BASE/MLM N19667 002
OCT 21, 1988
EQ 0.5MG BASE/MLM N19667 003
OCT 21, 1988

OXACILLIN SODIUM

INJECTABLE; INJECTION

BACTOCILL

AP BEECHAM LABS

EQ 10GM BASE/VIAL N61334 010

AP OXACILLIN SODIUM

EQ 250MG BASE/VIAL N62856 001

AP MARSAM PHARMS

OCT 26, 1988

AP

EQ 500MG BASE/VIAL N62856 002

OCT 26, 1988

AP

EQ 1GM BASE/VIAL N62856 003

OCT 26, 1988

AP

EQ 2GM BASE/VIAL N62856 004

OCT 26, 1988

AP

EQ 4GM BASE/VIAL N62856 005

OCT 26, 1988

AP

EQ 10GM BASE/VIAL N62984 001

SEP 29, 1988

PROSTAPHLIN

AP BRISTOL LABS

EQ 250MG BASE/VIAL N50195 001

AP

EQ 250MG BASE/VIAL N61490 001

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

AB AM THERPTCS

10MG N71955 001

MAR 03, 1988

AB

15MG N71956 001

MAR 03, 1988

AB

30MG N71957 001

MAR 03, 1988

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

AB BARR LABS

10MG

N70957 001

AUG 10, 1987

AB

15MG

N71025 001

AUG 10, 1987

AB

30MG

N71026 001

AUG 10, 1987

/BP/

/10MG/

/N71025/001/

AUG 10, 1987

/BP/

/15MG/

/N71025/001/

AUG 10, 1987

/BP/

/30MG/

/N71026/001/

AUG 10, 1987

AB

CHELSEA LABS

10MG

N71661 001

MAR 02, 1988

AB

15MG

N71662 001

MAR 02, 1988

AB

30MG

N71663 001

MAR 02, 1988

AB

CORD LABS

10MG

N71813 001

APR 19, 1988

AB

15MG

N71756 001

APR 19, 1988

AB

30MG

N71814 001

APR 19, 1988

/BP/ MYLAN PHARMS/

/10MG/

/N71713/001/

OCT 20, 1987

/BP/

/15MG/

/N71714/001/

OCT 20, 1987

/BP/

/30MG/

/N71715/001/

OCT 20, 1987

MYLAN PHARMS

10MG

N71713 001

OCT 20, 1987

3

15MG

N71714 001

OCT 20, 1987

3

30MG

N71715 001

OCT 20, 1987

AB

PUREPAC PHARM

10MG

N72251 001

APR 14, 1988

AB

15MG

N72252 001

APR 14, 1988

AB

30MG

N72253 001

APR 14, 1988

OXAZEPAM

CAPSULE; ORAL

AB	<u>OXAZEPAM</u> ZENITH LABS	<u>10MG</u>	N70943 001 AUG 03, 1987
AB		<u>15MG</u>	N70944 001 AUG 03, 1987
AB		<u>30MG</u>	N70945 001 AUG 03, 1987
/BP/		/10MG/	/N70943/001/ AUG 03, 1987/
/BP/		/15MG/	/N70944/001/ AUG 03, 1987/
/BP/		/30MG/	/N70945/001/ AUG 03, 1987/
AB	<u>SERAX</u> WYETH	<u>10MG</u>	N15539 002
AB		<u>15MG</u>	N15539 004
AB		<u>30MG</u>	N15539 006
/BP/		/10MG/	/N15539/002/ AUG 03, 1987/
/BP/		/15MG/	/N15539/004/ AUG 03, 1987/
/BP/		/30MG/	/N15539/006/ AUG 03, 1987/
AB	<u>ZAXOPAM</u> QUANTUM PHARMCS	<u>10MG</u>	N70650 001 MAR 01, 1988
AB		<u>15MG</u>	N70640 001 MAR 01, 1988
AB		<u>30MG</u>	N70641 001 MAR 01, 1988

> ADD > OXICONAZOLE NITRATE> ADD > CREAM; TOPICAL> ADD > OXISTAT> ADD > GLAXO> ADD >

EQ 1% BASE

N19828 001
DEC 30, 1988OXYBUTYNIN CHLORIDE

TABLET; ORAL

AB	<u>DITROPAM</u> MARION LABS	<u>5MG</u>	N17577 001
AB	<u>OXYBUTYNEN CHLORIDE</u> PHARM BASICS	<u>5MG</u>	N70746 001 MAR 10, 1988
> <u>ADD</u> >	AB QUANTUM PHARMCS	<u>5MG</u>	N72296 001 DEC 08, 1988
> <u>ADD</u> >	AB SIDMAK LABS	<u>5MG</u>	N71655 001 NOV 14, 1988

OXYPHENCYCLIMINE HYDROCHLORIDE

TABLET; ORAL

DARICON /BEECHAM/LABS/ PFIZER LABS	/10MG/ 10MG	/N11612/001/ N11612 001
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OXYPHENONIUM BROMIDE

> <u>DLT</u> >	/TABLET; ORAL/ /ANTRENYL/ /CIBA/PHARM/ 2 CIBA PHARM	/5MG/ 5MG	/N08492/002/ N08492 002
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OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

AB	<u>OXYTETRACYCLINE HCL</u> PUREPAC PHARM	/EQ 250MG BASE/ EQ 250MG BASE	/N60634/001/ N60634 001
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PANCURONIUM BROMIDE

INJECTABLE; INJECTION

AP	<u>PANCURONIUM</u> ELKINS SINN	<u>1MG/ML</u>	N72058 001 MAR 23, 1988
AP		<u>2MG/ML</u>	N72059 001 MAR 23, 1988
AP		<u>2MG/ML</u>	N72060 001 MAR 23, 1988

AP	<u>PANCURONIUM BROMIDE</u> ASTRA PHARM PRODS	<u>1MG/ML</u>	N72210 001 MAR 31, 1988
AP		<u>2MG/ML</u>	N72211 001 MAR 31, 1988
AP		<u>2MG/ML</u>	N72212 001 MAR 31, 1988
AP		<u>2MG/ML</u>	N72213 001 MAR 31, 1988
AP	QUAD PHARMS	<u>1MG/ML</u>	N72209 001 JUN 03, 1988
AP		<u>2MG/ML</u>	N72208 001 JUN 03, 1988

AP	<u>PAVULON</u> ORGANON	<u>1MG/ML</u>	N17015 002
AP		<u>2MG/ML</u>	N17015 001

PARAMETHADIONE

/CONCENTRATE; ORAL/
/PARADIONE/
/AA/ /ABBOTT LABS/

/300MG/ML/

/N06000/002/

SOLUTION; ORAL
PARADIONE

AA ABBOTT LABS

300MG/ML

N06000 002

PENICILLAMINE

CAPSULE; ORAL
CUPRIMINE
MS&D

125MG
/125MG/
250MG
/250MG/

N19853 002
/N50376/002/
N19853 001
/N50376/001/

TABLET; ORAL
DEPEN 250
WALLACE LABS

250MG
/250MG/

N19854 001
/N50491/001/

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

AP MARSAM PHARMS

1,000,000 UNITS/VIALM

N62991 001
SEP 13, 1988

AP

5,000,000 UNITS/VIALM

N62991 002
SEP 13, 1988

AP

10,000,000 UNITS/VIALM

N62991 003
SEP 13, 1988

AP

20,000,000 UNITS/VIALM

N62991 004
SEP 13, 1988

AP

SQUIBB

10,000,000 UNITS/VIAL

N60362 004

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN G POTASSIUM

/AA/ /PUREPAC/PHARM/

/400,000 UNITS/5ML/

/N61740/002/

2 PUREPAC PHARM

400,000 UNITS/5ML

N61740 002

TABLET; ORAL

PENICILLIN G POTASSIUM

/AA/ /PUREPAC/PHARM/

/250,000 UNITS/

/N61588/002/

/AA/ /PUREPAC/PHARM/

/400,000 UNITS/

/N61588/003/

2 PUREPAC PHARM

250,000 UNITS

N61588 002

2

400,000 UNITS

N61588 003

PENICILLIN G SODIUM

INJECTABLE; INJECTION

PENICILLIN G SODIUM

MARSAM PHARMS

5,000,000 UNITS/VIALM

N63014 001
SEP 13, 1988

/SQUIBB/SPA/

/5,000,000 UNITS/VIAL/

/N61935/001/

2 SQUIBB SPA

5,000,000 UNITS/VIAL

N61935 001

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

/AA/ /PUREPAC/PHARM/

/EQ 250MG BASE/5ML/

/N61758/002/

2 PUREPAC PHARM

EQ 250MG BASE/5ML

N61758 002

TABLET; ORAL

PENICILLIN V POTASSIUM

AB CLONMEL CHEMS

EQ 250MG BASEM

N62936 001
NOV 25, 1988

AB

EQ 500MG BASEM

N62935 001
NOV 23, 1988

/AA/ /PUREPAC/PHARM/

/EQ 250MG BASE/

/N61571/002/

/AA/ /PUREPAC/PHARM/

/EQ 500MG BASE/

/N61571/003/

2 PUREPAC PHARM

EQ 250MG BASE

N61571 002

2

EQ 500MG BASE

N61571 003

> ADD > PERGOLIDE MESYLATE

> ADD > TABLET; ORAL

> ADD > PERMAX

> ADD > LILLY

EQ 0.05MG BASEM

N19385 001
DEC 30, 1988

> ADD >

EQ 0.25MG BASEM

N19385 002

> ADD >

EQ 1MG BASEM

DEC 30, 1988

> ADD >

EQ 1MG BASEM

N19385 003

> ADD >

EQ 1MG BASEM

DEC 30, 1988

PERPHENAZINE

/STRIP; ORAL/

/TRILAFON/

/SCHERING/

2 SCHERING

/2MG/5ML/

2MG/5ML

/N11294/002/

N11294 002

PERPHENAZINE

TABLET; ORAL

PERPHENAZINE

> ADD > AB	CORD LABS	2MG	N89683 001
> ADD >			DEC 08, 1988
> ADD > AB		4MG	N89684 001
> ADD >			DEC 08, 1988
> ADD > AB		8MG	N89685 001
> ADD >			DEC 08, 1988
> ADD > AB		16MG	N89686 001
> ADD >			DEC 08, 1988

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

PHENDIMETRAZINE TARTRATE

/AA/	/BARR/LABS/	/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
/AA/		/35MG/	/N83644/001/
	2 BARR LABS	35MG	N83644 001
	2	35MG	N83684 001
	2	35MG	N83686 001
	2	35MG	N83687 001
	2	35MG	N84831 001
	2	35MG	N84834 001
	2	35MG	N84835 001

PHENMETRAZINE HYDROCHLORIDE

/TABLET;/ORAL/

/PRELUDIN;/

/BOEHR/INGEL/

2 BOEHR INGEL

/25MG/

25MG

/N10466/005/

N10460 005

PHENTERMINE RESIN COMPLEX

CAPSULE, CONTROLLED RELEASE; ORAL

IONAMIN-30

AB PENN WALT

EQ 30MG BASE

N11613 002

PHENTERMINE RESIN 30

AB QUANTUM PHARMS

EQ 30MG BASEM

N89120 001
FEB 04, 1988PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

/PHENERGAN VC/

/AA/ /NYETH/AYERST/LABS/ /4MG/5ML; 6.25MG/5ML/ /N88604/003/

/APR/02/1984/

PIPERACETAZINE

/TABLET;/ORAL/

/GUIDE;/

/DOW/PHARMS/

/10MG/

/N13615/001/

/25MG/

/N13615/002/

2 DOW PHARMS

10MG

N13615 001

2

25MG

N13615 002

PIRBUTEROL ACETATE

AEROSOL, METERED; INHALATION

/EXIREL/

> DLT > /PFIZER/LABS/

/EQ/0.2MG/BASE/INH/

/N19009/001/

> DLT >

> DLT >

/DEC/30/1986/

> ADD >

MAXAIR

> ADD >

RIKER LABS

EQ 0.2MG BASE/INH

N19009 001

> ADD >

DEC 30, 1986

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

POWDER FOR RECONSTITUTION; ORAL

> DLT > /E-2-EN PREP LYTE/

> DLT > /AA/ /E/2/EN/

/236GM/BOT; 2.97GM/BOT; 6.74GM/BOT/

> DLT >

/5.86GM/BOT; 22.74GM/BOT/ /N1278/001/

> DLT >

/NOV/21/1986/

POLYTELY

> DLT > /AA/ /BRAINTREE/LABS/

/236GM/BOT; 2.97GM/BOT; 6.74GM/BOT/

> DLT >

/5.86GM/BOT; 22.74GM/BOT/ /N19011/001/

> DLT >

/JUL/13/1984/

> ADD >

BRAINTREE LABS

236GM/BOT; 2.97GM/BOT; 6.74GM/BOT;

> ADD >

5.86GM/BOT; 22.74GM/BOT N19011 001

> ADD >

JUL 13, 1984

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

SOLUTION; ORAL

OCL

/3/ABBOTT/LABS/

/6GM/100ML;75MG/100ML;168MG/100ML;/

/146MG/100ML;/

/1.29GM/100ML/

/N19284/001/

/APR/30./1986/

ABBOTT LABS

6GM/100ML;75MG/100ML;168MG/100ML;

146MG/100ML;

1.29GM/100ML

N19284 001

APR 30, 1986

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

POWDER FOR RECONSTITUTION; ORAL

/COLOVAGE/

/AA/ /DYNAPHARM/

/227.1GM/PACKET;2.82GM/PACKET;/

/6.36GM/PACKET;5.53GM/PACKET;/

/21.5GM/PACKET/

/N71320/001/

/APR/20./1988/

COLOVAGE

AA DYNAPHARM

227.1GM/PACKET;2.82GM/PACKET;

6.36GM/PACKET;5.53GM/PACKET;

21.5GM/PACKET

N71320 001

APR 20, 1988

COLYTE

AA REED & CARNRICK

227.1GM/PACKET;2.82GM/PACKET;

6.36GM/PACKET;5.53GM/PACKET;

21.5GM/PACKET

N18983 004

OCT 26, 1984

> ADD > E-Z-EM PREP LYTE

> ADD > AA E Z EM

236GM/BOT;2.97GM/BOT;6.74GM/BOT;

5.86GM/BOT;22.74GM/BOT

N71278 001

NOV 21, 1988

> ADD > GLYCOPREP

> ADD > AA TOGA MED PRODS

236GM/BOT;2.97GM/BOT;6.74GM/BOT;

5.86GM/BOT;22.74GM/BOT

N72319 001

DEC 23, 1988

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC

POLYTRIM

BURROUGHS WELLC

10,000 UNITS/ML;

EQ 1MG BASE/MLM

N50567 001

OCT 20, 1988

POTASSIUM AMINOSALICYLATE

/POWDER//ORAL/

/POTASSIUM AMINOSALICYLATE/

/HEXCEL/CHEM/

/100%/

3 HEXCEL CHEM

100%

/N80098/001/

N80098 001

POTASSIUM CHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL

MICRO-K 10

AB ROBINS

10MEQ

N18238 002

MAY 14, 1984

/BC/

/10MEQ/

/N18238/002/

/MAY/14./1984/

POTASSIUM CHLORIDE

AB KV PHARM

10MEQ

N70980 001

FEB 17, 1987

/BC/

/10MEQ/

/N70980/001/

/FEB/17./1987/

GRANULE FOR RECONSTITUTION, CR; ORAL

MICRO-K LS

ROBINS

20MEQ/PACKETM

N19561 003

AUG 26, 1988

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

AP STERIS LABS

2MEQ/MLM

N89163 001

MAR 10, 1988

TABLET, CONTROLLED RELEASE; ORAL

POTASSIUM CHLORIDE

BC ABBOTT LABS

8MEQM

N18279 002

AUG 01, 1988

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEQ IN SODIUM CHLORIDE 0.9% INPLASTIC CONTAINER

AP ABBOTT LABS

149MG/100ML;

900MG/100MLM

N19686 001

OCT 17, 1988

POTASSIUM CHLORIDE 40MEQ IN SODIUM CHLORIDE 0.9% INPLASTIC CONTAINER

AP ABBOTT LABS

298MG/100ML;

900MG/100MLM

N19686 002

OCT 17, 1988

POTASSIUM CITRATE

POWDER FOR RECONSTITUTION; ORAL

POTASSIUM CITRATE

UNIV TEXAS

10MEQ/PACKETM

N19647 002

OCT 13, 1988

20MEQ/PACKETM

N19647 001

OCT 13, 1988

TABLET, CONTROLLED RELEASE; ORAL

POTASSIUM CITRATE

UNIV TEXAS

5MEQ

N19071 001

AUG 30, 1985

~~/UNIV TEXAS/~~~~/UNIV TEXAS/~~~~/5MEQ/~~~~/N19071/001/~~~~/AUG 30, 1985/~~PRALIDOXIME CHLORIDE

INJECTABLE; INJECTION

PRALIDOXIME CHLORIDE

QUAD PHARMS

1GM/VIALM

N72224 001

NOV 23, 1988

PROTOPAM CHLORIDE

WYETH AYERST LABS

1GM/VIAL

N14134 001

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

MINIPRESS

PFIZER LABS

1MG

N17442 002

AB

2MG

N17442 003

AB

5MG

N17442 001

PRAZOSIN HCL

ZENITH LABS

1MG

N71994 001

AB

MAY 16, 1989 : SEP 12, 1988

2MG

N71995 001

AB

MAY 16, 1989 : SEP 12, 1988

5MG

N71745 001

AB

MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

~~/BARR LABS/~~~~/5MG/~~~~/N84426/002/~~

3 BARR LABS

5MG

N84426 002

~~/STERANE/~~~~/PFIZER LABS/~~~~/5MG/~~~~/N09996/001/~~

3 PFIZER LABS

5MG

N09996 001

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

VASOCIDIN

IOLAB PHARMS

EQ 0.23% PHOSPHATE; 10%N

N18988 001

AUG 26, 1988

PREDNISONE

SOLUTION; ORAL

PREDNISONE

MY K LABS

5MG/5MLM

N89726 001

AUG 02, 1988

AA

ROXANE LABS

5MG/5ML

N88703 001

NOV 08, 1984

TABLET; ORAL

METICORTEN

SCHERING

1MG

N09766 002

> ADD >

BX

> DLT >

~~/3/~~~~/1MG/~~~~/N09766/002/~~PREDNISONE

CHELSEA LABS

50MG

N87772 001

JUL 13, 1982

> ADD >

AB

> ADD >

~~/BX/~~~~/50MG/~~~~/N87772/001/~~

> DLT >

~~/BX/~~~~/50MG/~~~~/JUL 13, 1982/~~

> DLT >

AB

SUPERPHARM

5MG

N88865 001

OCT 25, 1984

AB

10MG

10MG

N88866 001

OCT 25, 1984

AB

20MG

20MG

N88867 001

OCT 25, 1984

AB

1MG

1MG

N88865/001/

~~/BX/~~~~/5MG/~~~~/5MG/~~~~/OCT 25, 1984/~~~~/BX/~~~~/10MG/~~~~/10MG/~~~~/N88866/001/~~~~/BX/~~~~/20MG/~~~~/20MG/~~~~/OCT 25, 1984/~~~~/BX/~~~~/1MG/~~~~/1MG/~~~~/N88867/001/~~~~/BX/~~~~/50MG/~~~~/50MG/~~~~/OCT 25, 1984/~~PROBUCOL

TABLET; ORAL

LORELCO

MERRELL DOW

500MG

N17535 002

JUL 06, 1988

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

/AA/	/LEDERLE/LABS/	/250MG/	/N86942/001/
/AA/		/375MG/	/N86952/001/
/AA/		/500MG/	/N86943/001/
	2 LEDERLE LABS	250MG	N86942 001
	2	375MG	N86952 001
	2	500MG	N86943 001

INJECTABLE; INJECTION

PROCAINAMIDE HCL

AP	WARNER CHILCOTT	100MG/ML	N89528 001
			MAY 03, 1988
AP		500MG/ML	N89529 001
			MAY 03, 1988

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

AP	ELKINS SINN	EQ 5MG BASE/ML	N89523 001
			MAY 03, 1988
> ADD >	AP	MARSAM PHARMS	EQ 5MG BASE/ML
> ADD >			N89675 001
			DEC 05, 1988
AP	QUAD PHARMS	EQ 5MG BASE/ML	N89637 001
			FEB 01, 1988
AP		EQ 5MG BASE/ML	N89638 001
			FEB 01, 1988
AP	STERLING DRUG	EQ 5MG BASE/ML	N89703 001
			APR 07, 1988

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HCL

AP	MARSAM PHARMS	25MG/ML	N89463 001
			MAY 02, 1988
AP		50MG/ML	N89477 001
			MAY 02, 1988

TABLET; ORAL

PROMETHAZINE HCL

/BP/	/BARR/LABS/	/12.5MG/	/N84555/001/
/BP/		/25MG/	/N84554/001/
/BP/		/50MG/	/N84557/001/
	2 BARR LABS	12.5MG	N84555 001
	2	25MG	N84554 001
	2	50MG	N84557 001

PROPIOLACTONE

SOLUTION; IRRIGATION

BETAPRONE

FOREST LABS

N/A

N11657 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

/AA/	/BANMAX/PHARMS/	/65MG/	/N83184/001/
	2 BANMAX PHARMS	65MG	N83184 001
/AA/	/BARR/LABS/	/65MG/	/N83186/001/
	2 BARR LABS	65MG	N83186 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

AB	INVAMED	10MG	N71658 001
			JUL 05, 1988
AB		20MG	N71687 001
			JUL 05, 1988
AB		40MG	N71688 001
			JUL 05, 1988
AB		60MG	N72197 001
			JUL 05, 1988
AB		80MG	N71689 001
			JUL 05, 1988
AB		90MG	N72198 001
			JUL 05, 1988
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
/AA/	/LEHMAN/	/10MG/	/N70232/001/
	2 LEHMAN	10MG	OCT 07, 1987
/AA/	/PARKE/DAVIS/	/10MG/	/N70436/001/
			SEP 15, 1986

PROPRANOLOL HYDROCHLORIDE

<u>TABLET; ORAL</u>		
<u>PROPRANOLOL HCL</u>		
AB SIDMAK LABS	<u>10MG</u>	N71972 001
		APR 06, 1988
AB	<u>20MG</u>	N71973 001
		APR 06, 1988
AB	<u>40MG</u>	N71974 001
		APR 06, 1988
AB	<u>60MG</u>	N71975 001
		APR 06, 1988
AB	<u>80MG</u>	N71976 001
		APR 06, 1988
AB	<u>90MG</u>	N71977 001
		APR 06, 1988
AB SUPERPHARM	<u>10MG</u>	N71515 001
		JUN 08, 1988
AB	<u>20MG</u>	N71516 001
		JUN 08, 1988
AB	<u>40MG</u>	N71517 001
		JUN 08, 1988
AB	<u>80MG</u>	N71518 001
		JUN 08, 1988
AB WARNER CHILCOTT	<u>10MG</u>	N70438 001
		SEP 15, 1986
AB ZENITH LABS	<u>10MG</u>	N72063 001
		JUL 29, 1988
AB	<u>20MG</u>	N72066 001
		JUL 29, 1988
AB	<u>40MG</u>	N72067 001
		JUL 29, 1988
AB	<u>60MG</u>	N72068 001
		JUL 29, 1988
AB	<u>80MG</u>	N72069 001
		JUL 29, 1988

PROTAMINE SULFATE

<u>INJECTABLE; INJECTION</u>		
<u>PROTAMINE SULFATE</u>		
/BP/ /UPJOHN/	<u>50MG/VIAL/</u>	/N07413/001/
/BP/	<u>250MG/VIAL/</u>	/N07413/002/
		/AUG/02/1984/
3 UPJOHN	50MG/VIAL	N07413 001
2	250MG/VIAL	N07413 002
		AUG 02, 1984

QUINESTROL

/TABLET;/ORAL/		
/ESTROVIA;/		
/PARKE/DAVIS/	<u>0.1MG/</u>	/N16768/001/
	<u>0.2MG/</u>	/N16768/003/
3 PARKE DAVIS	0.1MG	N16768 002
2	0.2MG	N16768 003

QUINIDINE GLUCONATE

<u>TABLET, CONTROLLED RELEASE; ORAL</u>		
<u>QUINIDINE GLUCONATE</u>		
> ADD > AB	CORD LABS	<u>324MG</u>
> ADD >		
		N89894 001
		DEC 15, 1988

QUINIDINE SULFATE

<u>TABLET; ORAL</u>		
<u>QUINIDINE SULFATE</u>		
AB	CORD LABS	<u>300MG</u>
		N89839 001
		SEP 29, 1988

RANITIDINE HYDROCHLORIDE

> ADD >	SYRUP; ORAL	
> ADD >	ZANTAC	
> ADD >	GLAXO	EQ 15MG BASE/MLM
> ADD >		
		N19675 001
		DEC 30, 1988

RAUWOLFIA SERPENTINA

<u>TABLET; ORAL</u>		
<u>RAUVAL</u>		
BP VALE CHEM	50MG	N09108 002
BP	100MG	N09108 004
/2/	<u>50MG/</u>	/N09108/002/
/2/	<u>100MG/</u>	/N09108/004/

RESERPINE

<u>TABLET; ORAL</u>		
<u>RESERPINE</u>		
/BP/ /BARR/LABS/	<u>0.25MG/</u>	/N00721/001/
3 BARR LABS	0.25MG	N80721 002

RESERPINE; TRICHLORMETHIAZIDE

/TABLET;/ORAL/
/TRICHLORMETHIAZIDE/W/RESERPINE;/
/BP/ /BOLAR/PHARM/ /0.1MG;4MG/
 2 BOLAR PHARM 0.1MG;4MG
/N85248/001/
 N85248 001

SECOBARBITAL SODIUM

CAPSULE; ORAL
SODIUM SECOBARBITAL
/AA/ /BARR/LABS/ /100MG/
 2 BARR LABS 100MG
/N84225/001/
 N84225 001

SODIUM BICARBONATE; TARTARIC ACID

GRANULE, EFFERVESCENT; ORAL
 BAROS
> ADD > LAFAYETTE 460MG/GM;420MG/GM N18509 001
> ADD > AUG 07, 1985
> DLT > /MALLINCKRODT/ /460MG/GM;420MG/GM/
> DLT > /N18509/001/
/AUG/07/1985/

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 AP KENDALL MCGAM 900MG/100ML N19635 002
 MAR 09, 1988
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
 AP ABBOTT LABS 450MG/100ML N19759 001
 JUN 08, 1988
 AP KENDALL MCGAM 450MG/100ML N19635 001
 MAR 09, 1988
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 AP ABBOTT LABS 9MG/ML N19217 001
 JUL 13, 1984
/2/ /9MG/ML/
/N19217/001/
/JUL/13/1984/
SODIUM CHLORIDE 3% IN PLASTIC CONTAINER
 AP KENDALL MCGAM 3GM/100ML N19635 003
 MAR 09, 1988
 AP TRAVENOL LABS 3GM/100ML N19022 001
 NOV 01, 1983
SODIUM CHLORIDE 5% IN PLASTIC CONTAINER
 AP KENDALL MCGAM 5GM/100ML N19635 004
 MAR 09, 1988
 AP TRAVENOL LABS 5GM/100ML N19022 002
 NOV 01, 1983

SODIUM IODIDE, I-131

CAPSULE; ORAL
 SODIUM IODIDE I 131
/MALLINCKRODT/ /0.8-100HC1/
 2 MALLINCKRODT 0.8-100HC1
/N16515/001/
 N16515 002

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION
 NITROPRESS
 ABBOTT LABS 25MG/ML N71961 001
 AUG 01, 1988

SODIUM SUCCINATE

/INJECTABLE;/INJECTION/
/SODIUM/SUCCINATE;/
/ELKINS/SINN/ /30%/
 2 ELKINS SINN 30%
/N80516/001/
 N80516 001

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AA/ /LEDERLE/LABS/ /25MG/
 2 LEDERLE LABS 25MG
/N87634/001/
 N87634 001

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM
 AT STERIS LABS 10% N89560 001
 OCT 18, 1988

SULFAMETHOXAZOLE

TABLET; ORAL
SULFAMETHOXAZOLE
/AA/ /BARR/LABS/ /500MG/
 2 BARR LABS 500MG
/N87189/001/
/JUL/25/1983/
 N87189 001
 JUL 25, 1983

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

<u>TRIMETH/SULFA</u>			
AB	NASKA PHARMA	200MG/5ML;40MG/5ML	N72289 001 MAY 23, 1988
AB		200MG/5ML;40MG/5ML	N72398 001 MAY 23, 1988
AB		200MG/5ML;40MG/5ML	N72399 001 MAY 23, 1988

TABLET; ORAL

<u>SULFAMETHOXAZOLE AND TRIMETHOPRIM</u>			
> ADD >	AB	MARTEC PHARMS	400MG;80MG
> ADD >			N72408 001 DEC 07, 1988
<u>SULFAMETHOXAZOLE AND TRIMETHOPRIM DOUBLE STRENGTH</u>			
> ADD >	AB	MARTEC PHARMS	800MG;160MG
> ADD >			N72417 001 DEC 07, 1988

SULFISOXAZOLE

TABLET; ORAL

<u>SULFISOXAZOLE</u>			
/AB/	/BARR/LABS/	/500MG/	/N84031/001/
	3 BARR LABS	500MG	N84031 001
/AB/	/LEDERLE/LABS/	/500MG/	/N87649/001/
	3 LEDERLE LABS	500MG	N87649 001

SULINDAC

TABLET; ORAL

<u>CLINORIL</u>			
AB	MS&D	150MG	N17911 001
AB		200MG	N17911 002
<u>SULINDAC</u>			
AB	AM THERPTCS	150MG	N72171 001
			APR 03, 1990 : MAY 23, 1988
AB		200MG	N72172 001
			APR 03, 1990 : MAY 23, 1988
AB	DANBURY PHARMA	150MG	N71891 001
			APR 03, 1990 : MAR 03, 1988
AB		200MG	N71795 001
			APR 03, 1990 : MAR 03, 1988

> ADD > SUPROFEN

> ADD >	SOLUTION/DROPS; OPHTHALMIC		
> ADD >	PROFENAL		
> ADD >	ALCON LABS	1%	N19387 001
> ADD >			DEC 23, 1988

TECHNETIUM TC-99M ETIDRONATE KIT

INJECTABLE; INJECTION

/AB/	/MEDI/PHYSICS/	/N/A/	/N17667/001/
	3 MEDI PHYSICS	N/A	N17667 001
/AB/	/OSTEOSCAN/	/N/A/	/N17454/001/
	MALLINCKRODT	N/A	N17454 001

> ADD > TECHNETIUM TC-99M EXAMETAZINE KIT

> ADD > INJECTABLE; INJECTION

> ADD >	CERETEC		
> ADD >	AMERSHAM	N/A	N19829 001
> ADD >			DEC 30, 1988

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION

> DLT >	/616A/		
> DLT >	/AB/	/MEDI/PHYSICS/	/N/A/
> ADD >		<u>TECHNETIUM TC-99M PENTETATE KIT</u>	/N17264/002/
> ADD >	AP	MEDI PHYSICS	N/A
			N17264 002

TEMAZEPAM

CAPSULE; ORAL

<u>TEMAZEPAM</u>			
AB	CORD LABS	15MG	N71427 001
			JAN 12, 1988
AB		30MG	N71428 001
			JAN 12, 1988
AB	DURAMED PHARMS	15MG	N71708 001
			SEP 29, 1988
AB		30MG	N71709 001
			SEP 29, 1988

TERAZOSIN HYDROCHLORIDE

TABLET; ORAL

<u>HYTRIN</u>			
/AB/	/ABBOTT/LABS/	/10MG/	/N19057/004/
	ABBOTT LABS	10MG	N19057 004
			AUG 07, 1987

TERCONAZOLE

SUPPOSITORY; VAGINAL
TERAZOL 3
ORTHO PHARM

80MG

N19641 001
MAY 24, 1988

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

AQ QUAD PHARMS 100MG/ML

N89326 001
OCT 28, 1988

AQ 200MG/ML

N89327 001
OCT 28, 1988

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

AB LABROS ATRAL 250MG

N62752 001
AUG 12, 1988

AB 500MG

N62752 002
AUG 12, 1988

AB VITARINE 250MG

N61471 001

THEOPHYLLINE

ELIXIR; ORAL

THEOPHYLLINE

AA NASKA PHARMA 80MG/15ML

N89223 001
MAY 27, 1988

AA THAMES PHARMA 80MG/15ML

N89626 001
OCT 28, 1988

INJECTABLE; INJECTION

THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

AP TRAVENOL LABS 320MG/100ML

N18649 006
NOV 13, 1985

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT LABS 320MG/100ML

N19211 006
JAN 20, 1988

THEOPHYLLINE

TABLET, CONTROLLED RELEASE; ORAL

> DLT > /~~LABROS ATRAL~~/

> DLT > /~~AB~~/ /FOREST LABS/ /200MG/

> DLT > /~~BC~~/ /100MG/

> DLT > /~~BC~~/ /200MG/

> DLT > /~~BC~~/ /200MG/

> DLT > /~~BC~~/ /200MG/

> ADD > 2 FOREST LABS 100MG

> ADD > 2 200MG

> ADD > 2 300MG

> ADD > 2 300MG

> ADD > 2 300MG

> ADD > 2 300MG

THEOLAIR-SR
BC RIKER LABS

250MG

/250MG/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

AB MUTUAL PHARM 100MG

AB PAR PHARM 150MG

AB 200MG

AB ROXANE LABS 25MG

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL

> ADD > AA PACO RES EQ 5MG BASE/ML

> ADD > 71939 001

TIOCONAZOLE

/OINTMENT; VAGINAL/

/VAGISTAT/

/ROERIG/

2 ROERIG

/6.5%/

6.5%

/N88505/001/

/APR/03,/1985/

/N88503/001/

/APR/03,/1985/

/N88504/001/

/APR/03,/1985/

/N88503/001/

/APR/03,/1985/

/N88504/001/

/APR/03,/1985/

/N88505/001/

/APR/03,/1985/

/N86363/002/

/JUL/16,/1987/

/N86363/002/

/JUL/16,/1987/

/N89953/001/

/OCT/07,/1988/

/N89764/001/

/FEB/09,/1988/

/N89765/001/

/FEB/09,/1988/

/N88664/001/

/MAR/15,/1984/

/N71939/001/

/DEC/16,/1988/

/N19355/001/

/DEC/30,/1986/

/N19355/001/

/DEC/30,/1986/

TIOPRONIN

TABLET; ORAL
TIOPRONIN
UNIV TEXAS

100MG

N19569 001
AUG 11, 1988

TOLAZAMIDE

TABLET; ORAL
TOLAZAMIDE
AB PHARM BASICS

100MG

N71355 001
JAN 11, 1988

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE
/AB/ BANMAX PHARMS/
3 BANMAX PHARMS

100MG/
500MG

/N86141/001/
N86141 001

TRAZODONE HYDROCHLORIDE

TABLET; ORAL
DESYREL
AB HEAD JOHNSON

150MG

N18207 003
MAR 25, 1985

AB TRAZODONE HCL
PUREPAC PHARM

50MG

N71636 001
APR 18, 1988

AB 100MG

N71514 001
APR 18, 1988

AB SIDMAK LABS 50MG

N71523 001
DEC 11, 1987

AB 100MG

N71524 001
DEC 11, 1987

/AB/ /N84204/001/
/SIDMAK/LABS/ /100MG/

/N71524/001/
/DEC/11/1987/

AB TRAZON-150
SIDMAK LABS 150MG

N71525 001
MAR 09, 1988

/AB/ /N84204/001/
/SIDMAK/LABS/ /100MG/

/N71525/001/
/DEC/11/1987/

TRETINOIN

CREAM; TOPICAL
RETIN-A
ORTHO PHARM

0.025%^m

N19049 001
SEP 16, 1988

TRIAMCINOLONE

TABLET; ORAL
TRIAMCINOLONE
/BP/ BARR/LABS/

2MG

/N84266/001/

/BP/ 2MG

/N84318/001/

/BP/ 4MG

/N84267/001/

/BP/ 4MG

/N84319/001/

/BP/ 8MG

/N84268/001/

/BP/ 8MG

/N84320/001/

3 BARR LABS

2MG

N84286 001

3 2MG

N84318 001

3 4MG

N84267 001

3 4MG

N84319 001

3 8MG

N84268 001

3 8MG

N84320 001

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL
FLUTEX
AI SYOSSET LABS

0.025%^m

N87430 001
NOV 01, 1988

AI 0.1%^m

N87429 001
NOV 01, 1988

AI 0.5%^m

N87428 001
NOV 01, 1988

AI TRYMEX
/AI/ SAVAGE/LABS/

/0.5%^m/

/N88198/001/

3 SAVAGE LABS

0.5%

/MAR/25/1983/
N88198 001
MAR 25, 1983

OINTMENT; TOPICAL

FLUTEX
AI SYOSSET LABS

0.025%^m

N87375 001
NOV 01, 1988

AI 0.1%^m

N87377 001
NOV 01, 1988

AI 0.5%^m

N87376 001
NOV 01, 1988

† SEE SECTION 1.4 OF INTRODUCTION

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE

> ADD > AT	G&H LABS	0.025% ^m	N89795 001
> ADD >			DEC 23, 1988
> ADD > AT		0.1% ^m	N89796 001
> ADD >			DEC 23, 1988
> ADD > AT	NASKA PHARMA	0.5% ^m	N89913 001
> ADD >			DEC 23, 1988

TRIAZOLAM

TABLET; ORAL

HALCION

/UPJOHN/

/0.5MG/

a UPJOHN

0.5MG

/N17892/002/
 NOV 15, 1982/
 N17892 002
 NOV 15, 1982

TRICLOFOS SODIUM

/SOLUTION; ORAL/

/TRICLOS/

/MERRELL/DOW/

a MERRELL DOW

/1.5GM/15ML/
1.5GM/15ML

/N16830/001/
 N16830 001

/TABLET; ORAL/

/TRICLOS/

/MERRELL/DOW/

a MERRELL DOW

/750MG/
750MG

/N16809/002/
 N16809 002

TRIDIHETHYL CHLORIDE

/INJECTABLE; INJECTION/

/PATHILON/

/LEDERLE/LABS/

a LEDERLE LABS

/10MG/ML/
10MG/ML

/N09729/001/
 N09729 001

TRIFLUOPRAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

STELAZINE

AP

SK&F CO

EQ 2MG BASE/ML

N11552 005

AP

TRIFLUOPRAZINE HCL

QUAD PHARMS

EQ 2MG BASE/ML^m

N89893 001
 OCT 17, 1988

TRIFLUOPRAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPRAZINE HCL

AB

BOLAR PHARM

EQ 1MG BASE^m

N85975 001
 JUN 23, 1988

AB

EQ 2MG BASE^m

N85976 001
 JUN 23, 1988

AB

EQ 5MG BASE^m

N85973 001
 JUN 23, 1988

AB

EQ 10MG BASE^m

N88710 001
 JUN 23, 1988

TRIMEPAZINE TARTRATE

CAPSULE, CONTROLLED RELEASE; ORAL

TEMARIL

HERBERT LABS

/SK&F/LABS/

EQ 5MG BASE

/EQ/5MG/BASE/

N11316 004
 /N11316/004/

SYRUP; ORAL

TEMARIL

AA

HERBERT LABS

/AA/

/SK&F/LABS/

EQ 2.5MG BASE/5ML

/EQ 2.5MG BASE/5ML/

N11316 003
 /N11316/003/

TABLET; ORAL

TEMARIL

HERBERT LABS

/SK&F/LABS/

EQ 2.5MG BASE

/EQ/2.5MG/BASE/

N11316 001
 /N11316/001/

TRIMETHOPRIM

TABLET; ORAL

TRIMETHOPRIM

AB

BARR LABS

100MG

N70494 001
 JAN 22, 1986

/AA/

/200MG/

/N70495/001/
 /MAR/14, 1986/

/3/

/100MG/

/N70494/001/
 /JAN/22, 1986/

a

200MG

N70495 001
 MAR 14, 1986

TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL

TRIPLENNAMINE HCL

/AA/

/BARR/LABS/

a BARR LABS

/20MG/

50MG

/N00744/001/
 N80744 001

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL			
<u>Hytrin</u>	<u>1.25MG/5ML</u>	<u>N87963/001</u>	
<u>/AA/</u>	<u>/HYTRIN LABS/</u>	<u>JAN 18, 1983</u>	
2 MY K LABS	1.25MG/5ML	N87963 001	
		JAN 18, 1983	

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION			
<u>TUBOCURARINE CHLORIDE</u>			
AP	QUAD PHARMS	<u>3MG/ML</u>	N89442 001
			AUG 12, 1988

URSODIOL

CAPSULE; ORAL			
ACTIGALL			
2 CIBA PHARM	150MG	N19594 001	
	300MG	DEC 31, 1987	
		N19594 002	
		DEC 31, 1987	

<u>DEURSIL</u>	<u>150MG</u>	<u>N19594/001</u>	
<u>/SIPHARMEX/</u>	<u>/150MG/</u>	<u>/DEC 31, 1987/</u>	
	<u>/300MG/</u>	<u>N19594/002</u>	
		<u>/DEC 31, 1987/</u>	

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION			
<u>LYPHOCIN</u>			
AP	LYPHOMED	<u>EQ 1GM BASE/VIAL</u>	N62663 002
			JUL 31, 1987
AP		<u>EQ 5GM BASE/VIAL</u>	N62663 003
			JUN 03, 1988
<u>VANCOCIN HCL</u>			
AP	LILLY	<u>EQ 1GM BASE/VIAL</u>	N60180 002
			MAR 21, 1986
AP		<u>EQ 1GM BASE/VIAL</u>	N62476 002
			MAR 21, 1986
AP		<u>EQ 1GM BASE/VIAL</u>	N62716 002
			MAR 13, 1987
AP		<u>EQ 1GM BASE/VIAL</u>	N62812 002
			NOV 17, 1987
AP		<u>EQ 10GM BASE/VIAL</u>	N62812 003
			NOV 17, 1987

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION			
<u>VANCOLE</u>			
AP	LEDERLE LABS	<u>EQ 1GM BASE/VIAL</u>	N62682 002
			MAR 30, 1988
AP		<u>EQ 5GM BASE/VIAL</u>	N62682 004
			MAY 11, 1988
AP		<u>EQ 10GM BASE/VIAL</u>	N62682 005
			MAY 11, 1988
		<u>EQ 2GM BASE/VIAL</u>	N62682 003
			MAY 11, 1988
<u>VANCOMYCIN HCL</u>			
AP	ABBOTT LABS	<u>EQ 500MG BASE/VIAL</u>	N62911 001
			AUG 04, 1988
AP		<u>EQ 1GM BASE/VIAL</u>	N62912 001
			AUG 04, 1988
AP	ELKINS SINN	<u>EQ 500MG BASE/VIAL</u>	N62879 001
			AUG 02, 1988
AP		<u>EQ 1GM BASE/VIAL</u>	N62879 002
			AUG 02, 1988
AP	QUAD PHARMS	<u>EQ 500MG BASE/VIAL</u>	N62845 001
			JUL 15, 1988
AP		<u>EQ 1GM BASE/VIAL</u>	N62845 002
			JUL 15, 1988
<u>VANCOR</u>			
AP	ADRIA LABS	<u>EQ 500MG BASE/VIAL</u>	N62956 001
			AUG 01, 1988
AP		<u>EQ 1GM BASE/VIAL</u>	N62956 002
			AUG 01, 1988

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL			
<u>SEARLE</u>			
	<u>/SEARLE/</u>	<u>/160MG/</u>	<u>/N18817/004/</u>
AB	SEARLE PHARMS	<u>40MG</u>	<u>/FEB 23, 1988/</u>
			N18817 003
	2	160MG	FEB 23, 1988
			N18817 004
			FEB 23, 1988
<u>ISOPTIN</u>			
AB	KNOLL PHARM	<u>40MG</u>	N18593 003
			NOV 23, 1987
<u>VERAPAMIL HCL</u>			
AB	CORD LABS	<u>80MG</u>	N71423 001
			MAY 24, 1988
AB		<u>120MG</u>	N71424 001
			MAY 25, 1988

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

<u>VERAPAMIL HCL</u>			
AB	LEDERLE LABS	<u>80MG</u>	N71880 001 APR 05, 1988
AB		<u>120MG</u>	N71881 001 APR 05, 1988
AB	MUTUAL PHARM	<u>80MG</u>	N71488 001 JAN 13, 1988
AB		<u>120MG</u>	N71489 001 JAN 13, 1988

VINCRIStINE SULFATE

INJECTABLE; INJECTION

<u>VINCOREX</u>			
AP	BRISTOL LABS	<u>5MG/VIAL</u>	N70867 001 JUL 12, 1988
<u>VINCRIStINE SULFATE</u>			
AP	BULL LABS	<u>1MG/VIAL</u>	N71559 001 APR 11, 1988
AP		<u>2MG/VIAL</u>	N71560 001 APR 11, 1988
AP		<u>5MG/VIAL</u>	N71561 001 APR 11, 1988
AP	QUAD PHARMS	<u>1MG/VIAL</u>	N71222 001 MAR 07, 1988
AP		<u>2MG/VIAL</u>	N71223 001 MAR 07, 1988
AP		<u>5MG/VIAL</u>	N71937 001 MAR 07, 1988
<u>VINCRIStINE SULFATE PFS</u>			
AP	BULL LABS	<u>1MG/ML</u>	N71484 001 APR 19, 1988

WARFARIN POTASSIUM

<u>/TABLET;/ORAL/</u>			
<u>/ATHROMBIN-X;/</u>			
<u>/PURDUE/FDRK/</u>			
3	PURDUE FDRK	<u>5MG</u>	<u>/N11771/004/</u> N11771 004

WATER FOR INJECTION, STERILE

LIQUID; N/A

<u>STERILE WATER FOR INJECTION IN PLASTIC CONTAINER</u>			
AP	BAXTER	<u>100</u>	N18632 002 APR 19, 1988

WATER FOR INJECTION, STERILE

LIQUID; N/A

<u>STERILE WATER FOR INJECTION IN PLASTIC CONTAINER</u>			
AP	KENDALL MCGAM	<u>100</u>	N19633 001 FEB 29, 1988

XYLOSE

POWDER; ORAL

<u>/XYLOSE/</u>			
<u>/AA/ /LYNE LABS/</u>			
<u>/25G/BOT/</u>			
<u>/N18856/001/</u>			
<u>/MAR/26/1987/</u>			
N18856 001			
MAR 26, 1987			

3 LYNE LABS

25G/BOT

ACETAMINOPHEN

SUPPOSITORY; RECTAL

NEOPAP

/NEBCON/PHARMS/

/120MG/

/N16401/001/

ALCON LABS

120MG

N16401 001

TYLENOL

MCNEIL CONSUMER

120MG

N17756 002

650MG

N17756 001

/MCNEIL/LABS/

/120MG/

/N17756/002/

/650MG/

/N17756/001/

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; CONTROLLED RELEASE; ORAL

PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE

CENTRAL PHARMS

8MG;120MG

N19428 001

AUG 02, 1988

/PSEUDOEPHEDRINE/HCL/CHLORPHENIRAMINE/MALEATE/

/G/GRAHAM/LABS/

/8MG;120MG/

/N18844/001/

/MAR/20/1985/

GRAHAM LABS

8MG;120MG

N18844 001

MAR 20, 1985

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE

/TABLET;/CONTROLLED/RELEASE;/ORAL/

/BROMATAPP/

/COPLY PHARM/

/12MG;75MG/

/N71099/001/

/JUL/02/1987/

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

TABLET, CONTROLLED RELEASE; ORAL

RESPORAL

PIONEER PHARMS

6MG;120MG

N89139 001

JUN 16, 1988

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL

BROMATAPP

COPLY PHARM

12MG;75MG

N71099 001

JUL 02, 1987

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN DM

MYETH AYERST LABS

15MG/5ML;6.25MG/5ML

N11265 003

AUG 11, 1988

BUTYL METHOXYDIBENZOYL METHANE; PADIMATE O

LOTION; TOPICAL

PHOTOPLEX

HERBERT LABS

3%;72M

N19459 001

SEP 30, 1988

HYDROCORTISONE

OINTMENT; TOPICAL

HC (HYDROCORTISONE)

C&M PHARMA

0.5%

N80481 001

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL

PHARMASEAL SCRUB CARE

BAXTER

42M

N19793 001

DEC 02, 1988

> ADD >

> ADD >

> ADD >

CHLORPHENIRAMINE MALEATE

CAPSULE, CONTROLLED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE

CORD LABS

12MG

N70797 001

AUG 12, 1988

IBUPROFEN

TABLET; ORAL

IBU-TAB 200

ALRA LABS

200MG

N71057 001

AUG 11, 1988

IBUPROFEN

DANBURY PHARMA

200MG

N71905 001

MAR 08, 1988

INTERPHARM

200MG

N72199 001

MAY 23, 1988

INVAMED

200MG

N71807 001

FEB 25, 1988

MEDICOPHARMA

200MG

N71639 001

FEB 02, 1988

IBUPROFENTABLET; ORAL
IBUPROFEN

MYLAN PHARMS 200MG

N71870 001

MAY 05, 1988

PRIVATE FMLTNS 200MG

N72299 001

JUL 01, 1988

ZENITH LABS 200MG

N72040 001

APR 29, 1988

MUPRIN

BRISTOL MYERS 200MG

N72035 001

FEB 16, 1988

200MG

N72036 001

FEB 16, 1988

/JUL 16, 1988/

/N19012/001/

/MAY 18, 1988/

/200MG/

/N19012/003/

/JUL 29, 1987/

2 200MG

N19012 001

MAY 18, 1988

2 200MG

N19012 003

JUL 29, 1987

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE
SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION

MIXTARD HUMAN 70/30

NORDISK USA

30 UNITS/ML;

70 UNITS/ML

N19585 001

MAR 11, 1988

INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION

HUMULIN U

/LILLY/

/40 UNITS/ML/

/N19571/001/

/JUN 10, 1987/

2 40 UNITS/ML

N19571 001

JUN 10, 1987

INSULIN ZINC SUSP PURIFIED BEEF/PORK

> DLT > /INJECTABLE; INJECTION/

> DLT > /LENTARD/

> DLT > /SQUIBB/NOVO/

/100 UNITS/ML/

/N18384/001/

> ADD > 2 SQUIBB NOVO

100 UNITS/ML

N18384 001

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL

IMODIUM A-D

MCNEIL CONSUMER

1MG/5ML

N19487 001

MAR 01, 1988

NONOXYNOL-9

SPONGE; VAGINAL

TODAY

/9/1/

/16/

/N18683/001/

/APR 01, 1983/

WHITEHALL LABS

1GM

N18683 001

APR 01, 1983

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN VC

NYETH AYERST LABS

10MG/5ML; 6.25MG/5ML

N08604 004

AUG 11, 1988

TIOCONAZOLE

CREAM; TOPICAL

/TROST/

/2 PFIZER LABS/

/1/

/N18682/001/

/FEB 18, 1983/

TZ-3

2 PFIZER LABS

1%

N18682 001

FEB 18, 1983

ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE SOLUTION
USP WITH: AS-5: DEXTROSE USP; SODIUM CHLORIDE USP;
MANNITOL USP; ADENINE

INJECTABLE; INJECTION
OPTISOI. RED BLOOD CELL PRESERVATIVE SOLUTION
TERUMO
0.9GM/100ML;0.877GM/100ML;
0.525GM/100ML;0.03GM/100ML N 880217
OCT 07, 1988

No January 1989
approvals

DEXTRAN 70, 6% IN SODIUM CHLORIDE 0.9%

INJECTABLE; INJECTION
MACRODEX(R)
PHARMACIA INC 6GM/100ML;0.9GM/100ML N 06826

~~/BETADOLACTONE 442/
/SOLUTION; CHEMICAL/STERILIZING/AGENT/
/BETAPRONE/
/ONEAL/JONES&FELDMAN//996M/100ML/ /N/11651/~~

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

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).

ORPHAN DRUG EXCLUSIVE APPROVAL STATUS (CODED ODE) APPLIES ONLY TO THE APPROVED OR LICENSED INDICATION(S) FOR WHICH ORPHAN DRUG DESIGNATION HAS BEEN GRANTED PURSUANT TO SECTION 526 OF THE ACT.

FOR THE FOLLOWING DRUG PRODUCTS WITH ORPHAN DRUG EXCLUSIVE APPROVAL STATUS, THE SPONSOR HAS SEVEN YEARS OF EXCLUSIVE APPROVAL FOR THE APPROVED INDICATION BEGINNING ON THE DATE OF NDA, ANTIBIOTIC APPLICATION, OR BIOLOGICAL LICENSE APPROVAL FOR THE DRUG. NO SUBSEQUENT SPONSOR MAY RECEIVE APPROVAL OF AN NDA, BIOLOGICAL LICENSE, PAPER NDA, ANTIBIOTIC APPLICATION, ANDA, OR ABBREVIATED ANTIBIOTIC APPLICATION DURING THE SEVEN YEAR PERIOD FOR THE DRUG AND INDICATION(S) FOR WHICH ODE STATUS IS MAINTAINED UNLESS THE EXCLUSIVE APPROVAL HAS BEEN REVOKED AS DESCRIBED ABOVE OR THE SUBSEQUENT SPONSOR HAS OBTAINED WRITTEN CONSENT FROM THE SPONSOR WHO HAS RECEIVED EXCLUSIVE APPROVAL.

BIOLOGICAL PRODUCTS, ANTIBIOTICS, AND DRUGS THAT HAVE BEEN APPROVED UNDER SECTION 505 OR 507 OF THE ACT OR UNDER SECTION 351 OF THE PUBLIC HEALTH SERVICE ACT FOR MARKETING AND HAVE BEEN GIVEN ORPHAN DRUG EXCLUSIVE APPROVAL WILL BE NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. DRUG PRODUCTS THAT HAVE RECEIVED THE WRITTEN PERMISSION OF THE SPONSOR THAT HAS ORPHAN DRUG EXCLUSIVE APPROVAL TO BE APPROVED UNDER SECTION 527(b)(2) OF THE ACT ARE ALSO NOTED BY THE ABBREVIATION ODE IN THE PATENT AND EXCLUSIVITY INFORMATION ADDENDUM. THESE DRUG PRODUCTS DO NOT HAVE ANY EXCLUSIVE APPROVAL RIGHTS OF THEIR OWN, BUT CAN BE MARKETED BECAUSE OF THE CONSENT GIVEN BY THE SPONSOR THAT HAS EXCLUSIVE APPROVAL. THESE PRODUCTS ARE MARKED BY AN (*) NEXT TO THE APPLICANT'S NAME.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 8TH EDITION FOR A FULL LISTING OF ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

BIOLOGICAL PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	LICENSE NUMBER APPROVAL DATE	EXCLUSIVITY EXP. DATE
INTERFERON ALFA-2A	ROFERON-A INJECTABLE; INJECTION	ROCHE	136 NOV 21, 1988	ODE NOV 21, 1995
INTERFERON ALFA-2B	INTRON-A INJECTABLE; INJECTION	SCHERING	994 NOV 21, 1988	ODE NOV 21, 1995

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

DRUG PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	APPL. PROD. NO. APPROVAL DATE	EXCLUSIVITY EXP. DATE
ETHANOLAMINE OLEATE 50MG/ML	ETHAMOLIN INJECTABLE; INJECTION	GLAXO	19357 001 DEC 22, 1988	ODE DEC 22, 1995
IFOSFAMIDE 1GM/VIAL	IFEX INJECTABLE; INJECTION	BRISTOL MYERS	19763 001 DEC 30, 1988	ODE DEC 30, 1995
IFOSFAMIDE 3GM/VIAL	IFEX INJECTABLE; INJECTION	BRISTOL MYERS	19763 002 DEC 30, 1988	ODE DEC 30, 1995
LEUCOVORIN CALCIUM EQ 3MG BASE/ML	LEUCOVORIN CALCIUM INJECTABLE; INJECTION	LEDERLE LABS	08107 001 AUG 31, 1988	ODE ¹ AUG 31, 1995
LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL	LEUCOVORIN CALCIUM INJECTABLE; INJECTION	LEDERLE LABS	08107 002 AUG 31, 1988	ODE ¹ AUG 31, 1995
LEUCOVORIN CALCIUM EQ 100MG BASE/VIAL	LEUCOVORIN CALCIUM INJECTABLE; INJECTION	LEDERLE LABS	08107 004 AUG 31, 1988	ODE ¹ AUG 31, 1995
LEUCOVORIN CALCIUM EQ 60MG BASE/VIAL	LEUCOVORIN CALCIUM POWDER FOR RECONSTITUTION; ORAL	LEDERLE LABS	08107 003 AUG 31, 1988	ODE ¹ AUG 31, 1995

¹ODE PERTAINS ONLY TO INDICATION I-79 (SEE EXCLUSIVITY TERMS)

NO January 1989 approvals

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

DRUG PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	APPL. PROD. NO. APPROVAL DATE	EXCLUSIVITY EXP. DATE
MESNA 100MG/ML	MESNEX INJECTABLE; INJECTION	BRISTOL MYERS	19884 001 DEC 30, 1988	ODE DEC 30, 1995
METHOTREXATE SODIUM EQ 20MG BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 001 APR 07, 1988	ODE ² APR 07, 1995
METHOTREXATE SODIUM EQ 50MG BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 003 APR 07, 1988	ODE ² APR 07, 1995
METHOTREXATE SODIUM EQ 100MG BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 006 APR 07, 1988	ODE ² APR 07, 1995
METHOTREXATE SODIUM EQ 1GM BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 009 APR 07, 1988	ODE ² APR 07, 1995
METHOTREXATE SODIUM EQ 25MG BASE/ML	METHOTREXATE LPF INJECTABLE; INJECTION	LEDERLE LABS	11719 007 APR 07, 1988	ODE ² APR 07, 1995
METRONIDAZOLE 0.75%	METROGEL GEL; TOPICAL	CURATEK PHARMS	19737 001 NOV 22, 1988	ODE NOV 22, 1995
POTASSIUM CITRATE 10MEQ/PACKET	POTASSIUM CITRATE POWDER, FOR RECONSTITUTION; ORAL	UNIV TEXAS	19647 002 OCT 13, 1988	ODE AUG 30, 1992

²ODE PERTAINS ONLY TO INDICATION I-78 (SEE EXCLUSIVITY TERMS)

ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

DRUG PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	APPL. PROD. NO. APPROVAL DATE	EXCLUSIVITY EXP. DATE
POTASSIUM CITRATE 20MEQ/PACKET	POTASSIUM CITRATE POWDER, FOR RECONSTITUTION; ORAL	UNIV TEXAS	19647 001 OCT 13, 1988	ODE AUG 30, 1992
TIOPRONIN 100MG	TIOPRONIN TABLET; ORAL	UNIV TEXAS	19569 001 AUG 11, 1988	ODE AUG 11, 1995

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

Law 89

NO DECEMBER 1988 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, 8TH 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
ACETOHEXAMIDE (TABLET)	NOV 15, 1985	AUG 01, 1988
ALBUTEROL; METAPROTERENOL SULFATE (METERED DOSE INHALER)	AUG 25, 1988	
AMOXAPINE (TABLET)	SEP 10, 1987	AUG 05, 1988
ATENOLOL (TABLET)	OCT 06, 1988	
CARBAMAZEPINE (TABLET)	JAN 01, 1988	
CLINDAMYCIN (CAPSULE)	MAY 31, 1988	
CONJUGATED ESTROGEN (TABLET)*	DEC 17, 1988	
CYCLOBENZAPRINE HYDROCHLORIDE (TABLET)	JAN 25, 1988	
DOXYCYCLINE HYCLATE (CAPSULE AND TABLET)	APR 11, 1988	
ERYTHROMYCIN (CAPSULE, ENTERIC COATED PELLETS)	SEP 21, 1988	
FENOPROFEN (CAPSULE AND TABLET)	AUG 27, 1987	FEB 03, 1988
INDOMETHACIN (CAPSULE)	JUN 04, 1985	JAN 27, 1988
LEUCOVORIN CALCIUM (TABLET)	APR 28, 1987	AUG 04, 1988
MESTRANOL; NORETHYNODREL (TABLET)	MAY 13, 1988	
METAPROTERENOL SULFATE (TABLET)	MAR 18, 1988	
NORETHINDRONE; ETHINYL ESTRADIOL (TABLET)	MAR 18, 1988	
PRAZEPAM (CAPSULE AND TABLET)	JUL 26, 1988	
RIFAMPIN (CAPSULE)	SEP 08, 1988	
TIMOLOL MALEATE (TABLET)	AUG 09, 1988	

*THE METHODOLOGY IN THE BIOPHARMACEUTICAL AVAILABILITY GUIDANCE IS NO LONGER ACCEPTED BY THE AGENCY.

No Jan 1989 Petitions Approved
approvals or denials
 ANDA SUITABILITY PETITIONS

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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, 8TH 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
ACETYLCYSTEINE SOLUTION; INHALATION	20%	88 P-0237/CP	DEY LABS	NEW STRENGTH	APPROVED NOV 29, 1988
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	325MG 5MG	87 P-0376/ CP0002	ANABOLIC	NEW STRENGTH	APPROVED FEB 12, 1988
ASPIRIN; HYDROCODONE BITARTRATE TABLET; ORAL	650MG 5MG	87 P-0376/CP	ANABOLIC	NEW STRENGTH	APPROVED FEB 12, 1988
CHLORHEXIDINE GLUCONATE TOWELLETE; TOPICAL	4%	88 P-0295/CP	BRIAN PHARMS	NEW STRENGTH	APPROVED NOV 03, 1988
CHLORHEXIDINE GLUCONATE SPRAY; TOPICAL	0.5%	88 P-0036/CP	ARENT, FOX, KINTNER, PLOTKIN & KAHN	NEW DOSAGE FORM	APPROVED AUG 19, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CHLORZOXAZONE CAPSULE; ORAL	500MG	82 N-0032/ CP0006	MIKART	NEW DOSAGE FORM	APPROVED JAN 13, 1988
CISPLATIN INJECTABLE; INJECTION	1MG/ML (10ML/VIAL) (50ML/VIAL) (100ML/VIAL)	87 P-0421/CP	BULL LABS	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 29, 1988
CISPLATIN INJECTABLE; INJECTION	1MG/ML (20ML/VIAL)	88 P-0010/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	APPROVED APR 01, 1988
CLEMASTINE FUMARATE; PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULE, EXTENDED RELEASE; ORAL	EQ 1MG BASE 75MG	88 P-0350/CP	SCI CONSULTING	NEW DOSAGE FORM	APPROVED DEC 13, 1988
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (500ML/CONTAINER)	88 P-0011/CP	BAXTER HLTHCARE	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUN 10, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
FLUOROURACIL INJECTABLE; INJECTION	50MG/ML (5ML/VIAL)	88 P-0052/CP	BEN VENUE LABS	NEW STRENGTH	APPROVED MAR 21, 1988
HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE SOFT GELATIN CAPSULE; ORAL	1.5MG 5MG	88 P-0061/CP	KLEINFELD, KAPLAN AND BECKER	NEW DOSAGE FORM	APPROVED MAY 12, 1988
HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML 40MG/5ML	87 P-0399/CP	BURDITT, BOWLES, RADZIUS AND RUBERRY	NEW DOSAGE FORM	APPROVED FEB 16, 1988
HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML 80MG/5ML	87 P-0399/CP	BURDITT, BOWLES, RADZIUS AND RUBERRY	NEW DOSAGE FORM	APPROVED FEB 16, 1988
HYDROCHLOROTHIAZIDE; TRIAMTERENE TABLET; ORAL	25MG 50MG	87 P-0335/CP	PAR PHARM	NEW DOSAGE FORM	APPROVED FEB 26, 1988
LEUCOVORIN CALCIUM SOLUTION; ORAL	EQ 1MG BASE/ML	88 P-0149/CP	ROXANE LABS	NEW DOSAGE FORM	APPROVED JUL 25, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
MEPERIDINE HYDROCHLORIDE INJECTABLE; INJECTION	10MG/ML (50ML/CONTAINER)	88 P-0008/CP	LYPHOMED	NEW STRENGTH	APPROVED APR 01, 1988
METOCLOPRAMIDE HYDROCHLORIDE INTENSOL CONCENTRATE; ORAL	10MG/ML	88 P-0164/CP	ROXANE LABS	NEW STRENGTH	APPROVED JUN 28, 1988
NIFEDIPINE CAPSULE; ORAL	10MG	88 P-0072/ CP0002	MARTEC PHARMS	NEW DOSAGE FORM	APPROVED MAY 11, 1988
NIFEDIPINE CAPSULE; ORAL	20MG	88 P-0072/CP	MARTEC PHARMS	NEW DOSAGE FORM	APPROVED MAY 11, 1988
PHENYLPROPANOLAMINE HYDROCHLORIDE FILM, CONTROLLED RELEASE; PERCUTANEOUS	150MG	88 P-0265/CP	BIO AMERICAN	NEW DOSAGE FORM NEW STRENGTH NEW INDICATION	APPROVED OCT 07, 1988
PHENYTOIN SODIUM INJECTABLE; INJECTION	100MG/VIAL 250MG/VIAL	87 P-0367/CP	LYPHOMED	NEW DOSAGE FORM	APPROVED FEB 16, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
PREDNISOLONE SODIUM PHOSPHATE SOLUTION; ORAL	EQ 5MG BASE/ML	88 P-0235/CP	PAN AM PHARMS	NEW STRENGTH	APPROVED AUG 24, 1988
QUINIDINE SULFATE CAPSULE, EXTENDED RELEASE; ORAL	300MG	88 P-0277/CP	ROBINS	NEW DOSAGE FORM	APPROVED DEC 13, 1988
QUINIDINE GLUCONATE TABLET, CONTROLLED RELEASE; ORAL	648MG	87 P-0276/CP	FOREST LABS	NEW STRENGTH	APPROVED NOV 22, 1988
SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER INJECTABLE; INJECTION	900MG/100ML (100ML/CONTAINER)	87 P-0391/CP	LYPHOMED	NEW STRENGTH	APPROVED AUG 11, 1988
STERILE WATER IN PLASTIC CONTAINER INJECTABLE; INJECTION	100% (100ML/CONTAINER)	87 P-0392/CP	LYPHOMED	NEW STRENGTH	APPROVED AUG 11, 1988
THEOPHYLLINE CAPSULE, CONTROLLED RELEASE; ORAL	450MG	88 P-0119/CP	RIKER LABS	NEW STRENGTH	APPROVED MAY 11, 1988

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
THEOPHYLLINE CAPSULE, CONTROLLED RELEASE; ORAL	500MG	88 P-0226/CP	SAVAGE LABS	NEW STRENGTH	APPROVED AUG 25, 1988
THEOPHYLLINE SOLUTION; ORAL	160MG/15ML	88 P-0301/CP	FLEMING	NEW STRENGTH	APPROVED NOV 04, 1988
THIOTEPA, STERILE (WITH DILUENT) INJECTABLE; INJECTION	15MG/VIAL	87 P-0382/CP	LYPHOMED	NEW DOSAGE FORM	APPROVED MAY 12, 1988
VERAPAMIL HYDROCHLORIDE CAPSULE, CONTROLLED RELEASE; ORAL	120MG 240MG	87 P-0233/CP	SEARLE	NEW DOSAGE FORM NEW STRENGTH	APPROVED FEB 26, 1988
VINCRIStINE SULFATE INJECTABLE; INJECTION	1MG/ML (1.5ML/CONTAINER)	87 P-0210/CP	LYPHOMED	NEW STRENGTH	APPROVED JUL 28, 1987

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
BENZOYL METRONIDAZOLE SUSPENSION; ORAL	200MG/5ML	85 P-0258/CP	APKON LABS	NEW INGREDIENT (NEW ESTER)	DENIED MAR 19, 1986
BROMDIPHENHYDRAMINE HYDROCHLORIDE; HYDROCODONE BITARTRATE SOLUTION; ORAL	12.5MG/5ML 2.5MG/5ML	85 P-0255/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
BROMDIPHENHYDRAMINE HYDROCHLORIDE; HYDROCODONE BITARTRATE SYRUP; ORAL	12.5MG/5ML 2.5MG/5ML	85 P-0255/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
BROMPHENIRAMINE MALEATE; HYDROCODONE BITARTRATE; PHENYLPROPANOLAMINE HYDROCHLORIDE SYRUP; ORAL	2MG/5ML 2.5MG/5ML 12.5MG/5ML	85 P-0237/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
CYCLOBENZAPRINE HYDROCHLORIDE TABLET; ORAL	15MG	86 P-0386/CP	CENTRAL PHARMS	NEW STRENGTH	DENIED AUG 15, 1988

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	500MG/ML (1ML/VIAL) (2ML/VIAL) (4ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988
DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE, SUSTAINED RELEASE; ORAL	75MG	87 P-0355/CP	PARKE DAVIS	NEW DOSAGE FORM NEW STRENGTH	DENIED MAY 11, 1988
HYDROCODONE BITARTRATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL	1.66MG/5ML 5MG/5ML 6.25MG/5ML	85 P-0389/CP	UAD LABS	NEW COMBINATION	DENIED MAY 11, 1988

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
HYDROCODONE BITARTRATE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL	2.5MG/5ML 6.25MG/5ML	85 P-0256/CP	MIKART	NEW COMBINATION	DENIED MAY 11, 1988
IBUPROFEN LIQUID; ORAL	200MG/5ML	88 P-0291/ CP-0001	BIOCRAFT LABS	NEW DOSAGE FORM	DENIED DEC 15, 1988
IBUPROFEN LIQUID; ORAL	400MG/10ML	88 P-0291/ CP-0002	BIOCRAFT LABS	NEW DOSAGE FORM	DENIED DEC 15, 1988
MAGNESIUM ASCORBATE INJECTABLE; INJECTION	10% 20%	88 P-0200/CP	RIM CONSULTING	NEW INGREDIENT	DENIED JUN 10, 1988
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (50ML/VIAL) (75ML/VIAL) (100ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 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, 8TH 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-12~~ BEDTIME DOSING OF 800MG FOR TREATMENT
 D-12 BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE DUODENAL ULCER
 D-13 INCREASED MAXIMUM DAILY DOSAGE RECOMMENDATION
 D-14 BEDTIME DOSING OF 800MG FOR TREATMENT OF ACTIVE BENIGN GASTRIC ULCER
 D-15 SINGLE DAILY DOSE OF 25MG/37.5MG

NEW INDICATION

~~I-19~~ ANTIDOTE FOR ACETAMINOPHEN OVERDOSAGE
 I-19 CHOLANGIOPANCREATOGRAPHY
 I-72 PHOTOPHERESIS IN THE PALLIATIVE TREATMENT OF SKIN MANIFESTATIONS OF CUTANEOUS T-CELL LYMPHOMA
 IN PERSONS NOT RESPONSIVE TO OTHER TREATMENT
 I-73 FOLLICULAR STIMULATION IN IN VITRO FERTILIZATION
 I-74 MANAGEMENT OF CONGESTIVE HEART FAILURE
 I-75 ENDOSCOPIC RETROGRADE PANCREATOGRAPHY
 I-76 HERNIOGRAPHY
 I-77 KNEE ARTHROGRAPHY
 I-78 HIGH DOSE METHOTREXATE WITH LEUCOVORIN RESCUE IN COMBINATION WITH OTHER CHEMOTHERAPEUTIC AGENTS
 TO DELAY RECURRENCE IN PATIENTS WITH NONMETASTATIC OSTEOSARCOMA WHO HAVE UNDERGONE SURGICAL
 RESECTION OR AMPUTATION FOR THE PRIMARY TUMOR

EXCLUSIVITY TERMS

REFERENCES

NEW INDICATION

- I-79 RESCUE AFTER HIGH-DOSE METHOTREXATE THERAPY IN OSTEOSARCOMA
- I-80 SHORT-TERM TREATMENT OF ACTIVE BENIGN GASTRIC ULCER
- I-81 TREATMENT OF RHEUMATOID ARTHRITIS
- I-82 ADULT INTRA-ARTERIAL DIGITAL SUBTRACTION ANGIOGRAPHY OF THE HEAD, NECK, ABDOMINAL, RENAL AND PERIPHERAL VESSELS
- I-83 TREATMENT OF LIVER FLUKES

PATENT USE CODE

- U-26 METHOD OF TREATING ANIMALS SUFFERING FROM AN APPETITE DISORDER
- U-27 METHOD OF BLOCKING THE UPTAKE OF MONOAMINES BY BRAIN NEURONS IN ANIMALS
- U-28 METHOD FOR IMPROVING MEMORY IN MAMMALS
- U-29 METHOD FOR TREATING AMNESIA
- U-30 METHOD OF POTENTIATING CODEINE ANALGESIA IN MAMMALS
- U-31 USE IN LUNG SCANNING PROCEDURES
- U-32 TREATMENT OF VENTRICULAR AND SUPRAVENTRICULAR ARRHYTHMIAS
- U-33 METHOD FOR INHIBITING GASTRIC SECRETION IN MAMMALS
- U-34 TREATMENT OF INFLAMMATION
- U-35 PROCESS FOR INHIBITING THE SECRETION OF PROLACTIN IN MAMMALS
- U-36 PROCESS FOR TREATING A PATIENT SUFFERING FROM PARKINSON'S SYNDROME AND IN NEED OF TREATMENT
- U-37 METHOD FOR CHOLESTEROL LOWERING
- U-38 TREATMENT OF HUMANS SUFFERING FROM UNDESIRE UROTOXIC SIDE EFFECTS CAUSED BY CYTOSTATICALLY ACTIVE ALKYLATING AGENTS
- U-39 METHOD OF COMBATING PATHOLOGICALLY REDUCED CEREBRAL FUNCTIONS AND PERFORMANCE WEAKNESSES, CEREBRAL INSUFFICIENCY AND DISORDERS IN CEREBRAL CIRCULATION AND METABOLISM IN WARM-BLOODED ANIMALS
- U-40 METHOD OF EFFECTING CORONARY VASCULAR DILATION IN HUMANS AND ANIMALS

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
19489 001	ALBUTEROL SULFATE; VENTOLIN ROTACAPS	3705233	DEC 05, 1989			
18116 002	AMCINONIDE; CYCLOCORT	3644353	FEB 22, 1989		NDF	MAY 04, 1991
18498 001	AMCINONIDE; CYCLOCORT	4158055	JUN 12, 1996	U-34		
>ADD> 19402 001	ASTEMIZOLE; HISMANAL	4158055	JUN 12, 1996	U-34		
19716 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4219559	AUG 26, 1997		NCE NP	DEC 29, 1993 AUG 01, 1991
18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>DLT> 19489 001	BUTYL METHOXYDIBENZOYL METHANE; PHOTOPLEX	4387089	JUN 07, 2000		NP	SEP 30, 1991
>ADD> 19459 001	BUTYL METHOXYDIBENZOYL METHANE; PHOTOPLEX	4387089	JUN 07, 2000		NCE	SEP 30, 1993
>DLT> 18880 002	CARPROFEN; RIMADYL	3896145	JUL 22, 1994		NCE	DEC 31, 1992
>ADD> 18550 002	CARPROFEN; RIMADYL	3896145	JUL 22, 1994		NCE	DEC 31, 1992
>DLT> 18880 003	CARPROFEN; RIMADYL	3896145	JUL 22, 1994		NCE	DEC 31, 1992
>ADD> 18550 003	CARPROFEN; RIMADYL	3896145	JUL 22, 1994		NCE	DEC 31, 1992
>ADD> 19204 001	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		NCE	DEC 28, 1993
>ADD> 19204 002	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		NCE	DEC 28, 1993
>ADD> 19204 003	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		NCE	DEC 28, 1993
>ADD> 19574 001	CHLORTHALIDONE; THALITONE				NS	DEC 20, 1991
71621 001	CHOLESTYRAMINE; CHOLYBAR	4778676	OCT 18, 2005			
71739 001	CHOLESTYRAMINE; CHOLYBAR	4778676	OCT 18, 2005			
>ADD> 19824 001	CICLOPIROX OLAMINE; LOPROX	3883545	MAY 13, 1992		NCE	DEC 30, 1992
>ADD> 17920 002	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		NDF	DEC 30, 1991
17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993	D-14		MAR 31, 1991
17920 004	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994	D-12		APR 30, 1989
17920 005	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994	D-14		MAR 31, 1991
17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	3950333	APR 13, 1993	D-12		APR 30, 1989
18057 004	CISPLATIN; PLATINOL-AQ	4024271	MAY 17, 1994	D-14		MAR 31, 1991
18891 001	CLONIDINE; CATAPRES-TTS-1	3950333	APR 13, 1993	D-12		APR 30, 1989
18891 002	CLONIDINE; CATAPRES-TTS-2	4310515	JAN 12, 1999			
18891 003	CLONIDINE; CATAPRES-TTS-3	4177263	DEC 04, 1996			
		4201211	MAY 06, 1997			
		4060084	JUN 28, 1994			
		3996934	JUL 29, 1992			
		4201211	MAY 06, 1997			
		4060084	JUN 28, 1994			
		3996934	JUL 29, 1992			
		4201211	MAY 06, 1997			
		4060084	JUN 28, 1994			
		3996934	JUL 29, 1992			

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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
19201 001	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1989		NCE	JUL 28, 1993
19201 002	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1989		NCE	JUL 28, 1993
19201 003	DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1989		NCE	JUL 28, 1993
18998 001	ENALAPRIL MALEATE; VASOTEC				I-74	JUN 24, 1991
18998 002	ENALAPRIL MALEATE; VASOTEC				I-74	JUN 24, 1991
18998 003	ENALAPRIL MALEATE; VASOTEC				I-74	JUN 24, 1991
18998 005	ENALAPRIL MALEATE; VASOTEC	4374829	FEB 22, 2000		NCE	DEC 24, 1990
					I-74	JUN 24, 1991
19309 001	ENALAPRILAT; VASOTEC	4374829	FEB 22, 2000		NDF	FEB 09, 1991
18981 002	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
18981 003	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
18981 004	ENCAINIDE HYDROCHLORIDE; ENKAID	RE30811	DEC 20, 1996	U-32		
19386 001	ESMOLOL HYDROCHLORIDE; BREVILOL	4593119	JUN 03, 2003		NCE	DEC 31, 1991
		4387103	JUN 07, 2000	U-16		
>ADD>	19357 001	ETHANOLAMINE OLEATE; ETHAMOLIN			ODE	DEC 22, 1995
>ADD>					NP	DEC 22, 1991
	19462 001	FAMOTIDINE; PEPCID			I-80	OCT 17, 1991
	19462 002	FAMOTIDINE; PEPCID			I-80	OCT 17, 1991
	19510 001	FAMOTIDINE; PEPCID			I-80	OCT 17, 1991
	19527 001	FAMOTIDINE; PEPCID			I-80	OCT 17, 1991
	18830 003	FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996	NS	JUN 03, 1991
		3900481	AUG 19, 1992		NCE	OCT 31, 1990
	18830 004	FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996		
		3900481	AUG 19, 1992		NCE	OCT 31, 1990
	19452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTH/FS			NDF	FEB 03, 1991
	18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4683235	JUL 28, 2004	U-30	
		4647591	MAR 03, 2004	U-28		
		4647591	MAR 03, 2004	U-29		
		4626549	DEC 02, 2003	U-26		
		4626549	DEC 02, 2003	U-27		
>DLT>		4314081	FEB 02, 1999			
>ADD>		4314081	FEB 02, 2001			
		4194009	APR 19, 1994			
	18766 002	FLURBIPROFEN; ANSAID	3793457	FEB 19, 1993	NCE	DEC 31, 1991
		3755427	AUG 28, 1990		NDF	OCT 31, 1991
	18766 003	FLURBIPROFEN; ANSAID	3793457	FEB 19, 1993	NCE	DEC 31, 1991
		3755427	AUG 28, 1990		NDF	OCT 31, 1991
	19404 001	FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1993		

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
19596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4647447	MAR 03, 2004		NCE	JUN 02, 1993
18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993			
18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993			
>ADD> 19032 002	GUANFACINE HYDROCHLORIDE; TENEX	3632645	JAN 04, 1991		NCE	OCT 27, 1991
>ADD> 19032 003	GUANFACINE HYDROCHLORIDE; TENEX	3632645	JAN 04, 1991		NCE	OCT 27, 1991
18061 001	HYDROCHLOROTHIAZIDE; TIMOLIDE 10-25	3655663	APR 11, 1989		D-2	FEB 03, 1991
>ADD> 19129 003	HYDROCHLOROTHIAZIDE; MAXZIDE-25	4444769	APR 24, 2001		NS	MAY 13, 1991
>ADD> 19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1990		D-15	MAY 13, 1991
>ADD> 19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1990		ODE	DEC 30, 1995
>ADD> 19432 001	IOFETAMINE HYDROCHLORIDE I-123; SPECTAMINE	4360511	NOV 23, 1999		NCE	DEC 30, 1993
>DLT> 18956 002	IOHEXOL; OMNIPAQUE 240				NCE	DEC 30, 1993
					NCE	DEC 24, 1992
					I-19	JUL 29, 1991
					I-60	JUL 29, 1991
					I-75	JUL 29, 1991
					I-76	JUL 29, 1991
					I-77	JUL 29, 1991
18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-55	FEB 01, 1988
					I-58	FEB 01, 1988
					I-60	JUL 29, 1991
					I-77	JUL 29, 1991
18956 004	IOHEXOL; OMNIPAQUE 350				I-56	MAY 24, 1991
18956 005	IOHEXOL; OMNIPAQUE 140	4396597	JUL 14, 1998		I-77	JUL 29, 1991
		4250113	DEC 26, 1999		I-82	NOV 30, 1991
		4021481	MAY 03, 1994		NCE	DEC 26, 1990
>ADD> 19710 001	IOVERSOL; OPTIRAY-320				NS	NOV 30, 1991
>ADD> 19710 002	IOVERSOL; OPTIRAY-240				NCE	DEC 30, 1993
>ADD> 19710 003	IOVERSOL; OPTIRAY-160				NCE	DEC 30, 1993
19085 001	IPRATROPIUM BROMIDE; ATROVENT	3681500	AUG 01, 1991		NCE	DEC 30, 1993
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				NCE	DEC 29, 1991
					ODE	AUG 31, 1995
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-79	AUG 31, 1995
					ODE	AUG 31, 1995
08107 003	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-79	AUG 31, 1995
					ODE	AUG 31, 1995
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM				I-79	AUG 31, 1995
					ODE	AUG 31, 1995
					I-79	AUG 31, 1995

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
>DLT> 19888 001	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19558 001	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT> 19888 002	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19558 002	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT> 19888 003	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19558 003	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19558 004	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT> 19777 001	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19777 001	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT> 19777 002	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19777 002	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT> 19777 003	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD> 19777 003	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
19487 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D	3714159	JAN 30, 1990			
19643 003	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		NCE	AUG 31, 1992
>ADD> 19643 004	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999		NCE	AUG 31, 1992
18006 001	MECLOFENAMATE SODIUM; MECLOMEN				I-68	AUG 30, 1991
18006 002	MECLOFENAMATE SODIUM; MECLOMEN				I-68	AUG 30, 1991
>ADD> 19884 001	MESNA; MESNEX	4220660	SEP 02, 1997	U-38	ODE	DEC 30, 1995
>ADD> 08085 002	METHOTREXATE SODIUM; METHOTREXATE				NCE	DEC 30, 1993
11719 001	METHOTREXATE SODIUM; METHOTREXATE				I-81	OCT 31, 1991
					ODE	APR 07, 1995
11719 003	METHOTREXATE SODIUM; METHOTREXATE				I-78	APR 07, 1995
					ODE	APR 07, 1995
11719 006	METHOTREXATE SODIUM; METHOTREXATE				I-78	APR 07, 1995
					ODE	APR 07, 1995
11719 007	METHOTREXATE SODIUM; METHOTREXATE LPF				I-78	APR 07, 1995
					ODE	APR 07, 1995
11719 009	METHOTREXATE SODIUM; METHOTREXATE				I-78	APR 07, 1995
					ODE	APR 07, 1995
09048 001	METHOXSALEN; 8-MOP				I-72	MAR 23, 1991

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19737 001	METRONIDAZOLE; METROGEL				NDF	NOV 22, 1991
18654 001	MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999		ODE	NOV 22, 1995
18654 002	MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999		NCE	DEC 20, 1990
>DLT> 19436 001	MILRINONE LACTATE; MILRINONE LACTATE	4313951	FEB 02, 2001		NCE	DEC 20, 1990
>ADD> 19436 001	MILRINONE LACTATE; MILRINONE LACTATE	4313951	FEB 02, 2001		NCE	DEC 31, 1992
19501 001	MINOXIDIL; ROGAINE	4596812	FEB 13, 1996			
>ADD> 19268 001	MISOPROSTOL; CYTOTEC	4139619	FEB 13, 1996	U-37	NDF	AUG 17, 1991
>ADD>		4459310	JUL 10, 2001			
>ADD>		4301146	NOV 17, 1998			
>ADD>		4060691	JUN 22, 1993			
>ADD> 19297 001	MITOXANTRONE; NOVANTRONE	3965143	JUN 22, 1993		NCE	DEC 27, 1993
19516 002	MORPHINE SULFATE; MS CONTIN	4278689	JUL 14, 2000			
18677 001	NABILONE; CESAMET				NDF	MAY 29, 1990
19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4087545	MAY 02, 1997	U-7		
>ADD> 19488 001	NICARDIPINE HYDROCHLORIDE; CARDENE	4282251	AUG 04, 1998		NCE	MAR 01, 1993
>ADD> 18869 001	NIMODIPINE; NIMOTOP	3985758	OCT 12, 1993		NCE	DEC 21, 1993
>ADD>		3799934	MAR 26, 1991		NCE	DEC 28, 1993
>ADD>		3932645	JAN 13, 1993	U-40		
>ADD>		4406906	SEP 27, 2000	U-39		
19508 001	NIZATIDINE; AXID	4760075	MAY 03, 2000	U-33		
		4382090	MAY 03, 2000	U-33		
		4375547	MAR 01, 2000		NCE	APR 12, 1993
19508 002	NIZATIDINE; AXID	4760075	MAY 03, 2000	U-33		
		4382090	MAY 03, 2000	U-33		
		4375547	MAR 01, 2000		NCE	APR 12, 1993
19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2000		NCE	OCT 21, 1993
19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2000		NCE	OCT 21, 1993
19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2000		NCE	OCT 21, 1993
>ADD> 19828 001	OXICONAZOLE NITRATE; OXISTAT	4395403	JUL 26, 2000		NCE	OCT 21, 1993
>ADD> 19385 001	PERGOLIDE MESYLATE; PERMAX				NCE	DEC 30, 1993
>ADD>		4797405	JAN 10, 2006			
>ADD>		4180582	DEC 25, 1996	U-35		
>ADD>		4180582	DEC 25, 1996	U-36		
>ADD>		4166182	AUG 28, 1996		NCE	DEC 30, 1993
>ADD> 19385 002	PERGOLIDE MESYLATE; PERMAX	4797405	JAN 10, 2006			
>ADD>		4180582	DEC 25, 1996	U-35		
>ADD>		4180582	DEC 25, 1996	U-36		
>ADD>		4166182	AUG 28, 1996		NCE	DEC 30, 1993
>ADD> 19385 003	PERGOLIDE MESYLATE; PERMAX	4797405	JAN 10, 2006			
>ADD>		4180582	DEC 25, 1996	U-35		
>ADD>		4180582	DEC 25, 1996	U-36		
>ADD>		4166182	AUG 28, 1996		NCE	DEC 30, 1993
19009 001	PIRBUTEROL ACETATE; MAXAIR	4175128	NOV 20, 1996			
		3786160	JAN 15, 1993			
		3700681	OCT 24, 1989		NCE	DEC 30, 1991

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19561 003	POTASSIUM CHLORIDE; MICRO-K LS	4259315	MAR 31, 1998			
19647 001	POTASSIUM CITRATE; POTASSIUM CITRATE				ODE	AUG 30, 1992
19647 002	POTASSIUM CITRATE; POTASSIUM CITRATE				ODE	AUG 30, 1992
18714 001	PRAZIQUANTEL; BILTRICIDE				I-83	NOV 09, 1991
17535 002	PROBUCOL; LORELCO	3862332	JAN 21, 1992			
>ADD> 19675 001	RANITIDINE HYDROCHLORIDE; ZANTAC	4585790	APR 29, 2003		NCE	JUN 09, 1993
>ADD>		4521431	JUN 04, 2002		I-43	MAY 30, 1989
>ADD>		4128658	DEC 05, 1995		I-42	MAY 30, 1989
>DLT> 19530 001	SODIUM BENZOATE; UCEPHAN	4284647	AUG 18, 2000	U-24	NCE	DEC 23, 1992
>ADD> 19387 001	SUPROFEN; PROFENAL	4559343	DEC 17, 2002		NCE	DEC 24, 1990
>ADD>		4035376	JUL 12, 1996		NDF	DEC 23, 1991
17881 001	TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT; TECHNETIUM TC 99M	3872226	MAR 18, 1992			
19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	3863004	JAN 28, 1992	U-31		
		4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994			
		4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994			
		4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994			
		4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
>DLT> 19579 001	TERCONAZOLE; TERAZOL 7	4358449	NOV 09, 2001		NCE	DEC 31, 1992
>ADD> 19579 001	TERCONAZOLE; TERAZOL 7	4358449	NOV 09, 2001		NCE	DEC 31, 1992
>DLT> 19641 001	TERCONAZOLE; TERAZOL 3	4358449	NOV 09, 2001		NCE	DEC 31, 1992
>ADD> 19641 001	TERCONAZOLE; TERAZOL 3	4358449	NOV 09, 2001		NCE	DEC 31, 1992
19569 001	TIOPRONIN; TIOPRONIN				NDF	MAY 24, 1991
					NCE	AUG 11, 1993
18207 003	TRAZODONE HYDROCHLORIDE; DESYREL	4258027	MAR 24, 1998		ODE	AUG 11, 1995
>ADD> 19049 001	TRETINOIN; RETIN-A	4215104	JUL 29, 1997			
		3906108	SEP 16, 1992		NS	SEP 16, 1991
		3729568	APR 24, 1990			
19415 002	UROFOLLITROPIN; METRODIN				I-73	MAR 01, 1991
18817 003	VERAPAMIL HYDROCHLORIDE; CALAN				I-50	DEC 16, 1989
					I-51	DEC 16, 1989
18817 004	VERAPAMIL HYDROCHLORIDE; CALAN				I-50	DEC 16, 1989
					I-51	DEC 16, 1989