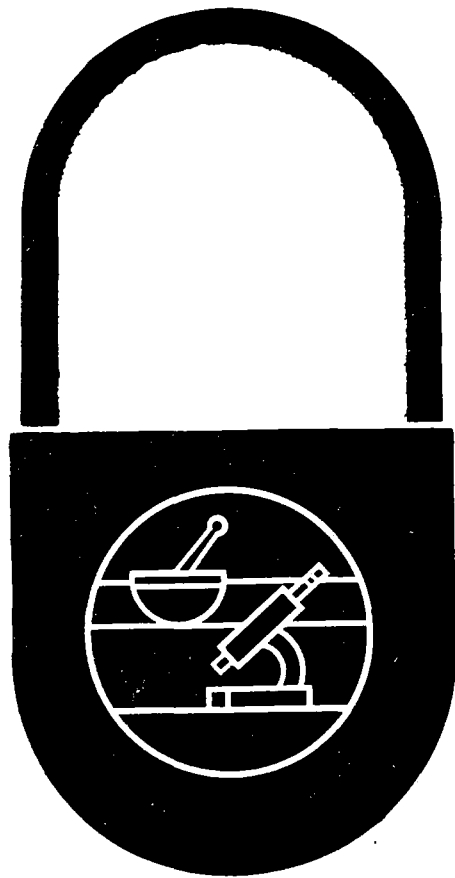


**CUMULATIVE  
SUPPLEMENT 12  
JAN'88-DEC'88**



# **APPROVED DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**8<sup>TH</sup> EDITION**

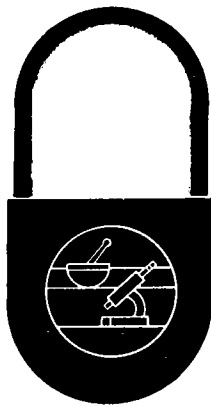
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MANAGEMENT**

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### **APPROVED DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**9<sup>TH</sup> 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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.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)
Tranlycpromine 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 QUARTER<sup>1</sup>

<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 <sup>2</sup>	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.

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

<sup>2</sup>Amino 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 500MG;50MG;40MG 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  
HYAPAP W/ CODEINE  
/AA/ /HY/R/LABS/ /120MG/5ML;12MG/5ML/ /N87006/001/  
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/  
ACETAMINOPHEN W/ CODEINE PHOSPHATE  
/AA/ /HALSEY/DRUG/ /300MG;60MG/ /N86549/001/  
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  
TYLENOL W/ CODEINE NO. 1  
/AA/ /MCNEIL/LABS/ /300MG;7.5MG/ /N85055/001/  
AA MCNEIL PHARM 300MG;7.5MG N85055 001  
TYLENOL W/ CODEINE NO. 2  
/AA/ /MCNEIL/LABS/ /300MG;15MG/ /N85055/002/  
AA MCNEIL PHARM 300MG;15MG N85055 002  
TYLENOL W/ CODEINE NO. 3  
/AA/ /MCNEIL/LABS/ /300MG;30MG/ /N85055/003/  
AA MCNEIL PHARM 300MG;30MG N85055 003  
TYLENOL W/ CODEINE NO. 4  
/AA/ /MCNEIL/LABS/ /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  
CO-GENIC  
AA CENTRAL PHARMS 500MG;5MG N89360 001  
MAR 02, 1988  
LORCET-HD  
/AA/ /GRAHAM/LABS/ /500MG;5MG/ /N87336/001/  
/JUL/08/1982/

TABLET; ORAL

> ADD >  
> ADD > AA HYCOPAP  
> ADD > CHARLOTTE PHARM 500MG;5MG N89971 001  
DEC 02, 1988  
AA 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 LUCHEM PHARMS 500MG; 5MG N89696 001  
 APR 21, 1988  
 AA MIKART 650MG; 7.5MG N89689 001  
 JUN 29, 1988  
 > ADD > AA WATSON LABS 500MG; 5MG N89883 001  
 > ADD >  
 > ADD > VICODIN ES  
 > ADD > KNOLL PHARM 750MG; 7.5MG N89736 001  
 > ADD > DEC 01, 1988  
 > ADD > DEC 09, 1988

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL  
PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN  
 AB HALSEY DRUG 325MG; 50MG N72105 001  
 MAY 13, 1988  
 AB 650MG; 100MG N72106 001  
 MAY 13, 1988  
 AB MYLAN PHARMS 650MG; 100MG N72195 001  
 FEB 16, 1988

ACETAZOLAMIDE

TABLET; ORAL  
ACETAZOLAMIDE  
 AB MUTUAL PHARM 125MG N89752 001  
 JUN 22, 1988  
 AB 250MG N89753 001  
 JUN 22, 1988  
DIAMOX  
 AB LEDERLE LABS 125MG N08943 001

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION  
ACETAZOLAMIDE SODIUM  
 AP QUAD PHARMS 500MG/VIAL N89619 001  
 JAN 13, 1988  
DIAMOX  
 AP LEDERLE LABS 500MG/VIAL N09388 001

ACETOHYDROXAMIC ACID

TABLET; ORAL  
 LITHOSTAT  
 MISSION PHARMA 250MG N18749 001  
 MAY 31, 1983  
 /W/O/RES/ /250MG/ /N18749/001/  
 /MAY/31/1983/

ALBUTEROL SULFATE

CAPSULE; INHALATION  
 VENTOLIN ROTACAPS  
 GLAXO EQ 0.2MG BASEM N19489 001  
 MAY 04, 1988

ALSEROXYLON

TABLET; ORAL  
RAUJENSIN  
 /BP/ /DORSEY/LABS/ /2MG/ /N09215/001/  
 2 DORSEY LABS 2MG N09215 001  
RAUWOLID  
 /BP/ /RIKER/LABS/ /2MG/ /N08867/001/  
 RAUWOLID 2MG N08867 001  
 RIKER LABS

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL  
AMANTADINE HCL  
 /AB/ /REID/ROWELL/ /100MG/ /N71000/001/  
 /SEP/04/1986/  
SYMADINE  
 AB REID ROWELL 100MG N71000 001  
 SEP 04, 1986

AMCINONIDE

LOTION; TOPICAL  
 CYCLOCORT  
 LEDERLE LABS 0.1% N19729 001  
 JUN 13, 1988

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL  
AMILORIDE HCL AND HYDROCHLOROTHIAZIDE  
 AB BARR LABS 5MG;50MG N71111 001  
 MAY 10, 1988

AMINO ACIDS

INJECTABLE; INJECTION  
 AMINOSYN 3.5% IN PLASTIC CONTAINER  
 /ABBOTT/LABS/ 13.5% /N18875/001/  
 /AUG/08/1984/  
 3 ABBOTT LABS 3.5% N18875 001  
 AUG 08, 1984  
 /NEOPHAN/6.4% /N18792/001/  
 /KABIVITRUM/ 16.4% /JAN/17/1984/  
 3 KABIVITRUM 6.4% 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

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

AMINOCAPROIC ACID

## INJECTABLE; INJECTION

<del>AMICAR</del>		
> ADD > AP	LEDERLE LABS	250MG/ML
> DLT > AP	LEDERLE/PARNTIS	250MG/ML
		N15229 002 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 MSD 20% N05619 001  
 AP QUAD PHARMS 20% N89821 001 JUL 14, 1988

AMINOPHYLLINE

TABLET; ORAL

AMINOPHYLLINE

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

AMINOSALICYLATE SODIUM

TABLET; ORAL

TEBACIN

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

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL

AMITRI

/AB/ PARKE/DAVIS/ /10MG/ N83939/001  
 /AB/ /25MG/ N83937/001  
 /AB/ /50MG/ N83938/002  
 /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  
 @ LEDERLE LABS 10MG N86744 001  
 @ 25MG N86746 001  
 @ 50MG N86743 001  
 @ 75MG N86745 001  
 @ 100MG N86747 001

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL

CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL

> ADD > AB DANBURY PHARMA EQ 12.5MG BASE;5MG N72052 001 DEC 16, 1988  
 > ADD > AB EQ 25MG BASE;10MG N72053 001 DEC 16, 1988  
 > ADD > AB PAR PHARM EQ 12.5MG BASE;5MG N72277 001 MAY 09, 1988  
 AB EQ 25MG BASE;10MG N72278 001 MAY 09, 1988  
 AB PHARM BASICS EQ 12.5MG BASE;5MG N70477 001 JAN 12, 1988  
 AB EQ 25MG BASE;10MG 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	CLONMEL CHEMS	<u>250MG</u>	N62884 001 FEB 25, 1988
AB		<u>500MG</u>	N62881 001 FEB 25, 1988

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

AB	CLONMEL 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> 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	CLONMEL 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	2 LEDERLE LABS	EQ 250MG BASE	N62208 001
2	2	EQ 500MG BASE	N62208 002
AB	<u>POLYCILLIN</u> 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

PENICILLIN

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



ANILERIDINE HYDROCHLORIDE

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

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

/N10585/002/  
N10585 002

ANILERIDINE PHOSPHATE

/INJECTABLE;/INJECTION/  
/LERITINE;/  
/MS&D/  
@ 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<sup>m</sup> N71564 001  
JUN 23, 1988

ORPHENADRINE COMPOUND DOUBLE STRENGTH

AB VITARINE 770MG;60MG;50MG<sup>m</sup> N71565 001  
JUN 23, 1988

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL  
COMPOUND 65

/BA/ /BANMAX/PHARMS/

/38.9MG;32.4MG;65MG/  
389MG;32.4MG;65MG

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

ASPIRIN; HYDROCODONE BITARTRATE

TABLET; ORAL  
AZDONE

CENTRAL PHARMS 500MG;5MG<sup>m</sup> N89420 001  
JAN 25, 1988

ASPIRIN; MEPROBAMATE

TABLET; ORAL  
MEPRO-ASPIRIN

AB VITARINE 325MG;200MG N89127 001  
MAR 02, 1987

ASPIRIN; MEPROBAMATE

TABLET; ORAL  
MEPROGESTIC

/BA/ /VITARINE/

/325MG;200MG/  
/N89127/001/  
/MAR/02/1987/

ASPIRIN; METHOCARBAMOL

TABLET; ORAL  
METHOCARBAMOL AND ASPIRIN

AB PAR PHARM 325MG;400MG<sup>m</sup> N89657 001  
NOV 04, 1988

> ADD > ASTEMIZOLE

> ADD > TABLET; ORAL  
> ADD > HISSMANAL  
> ADD > JANSSEN PHARMA 10MG<sup>m</sup> N19402 001  
> ADD > DEC 29, 1988

ATENOLOL

TABLET; ORAL  
ATENOLOL

AB ICI PHARMS 50MG<sup>m</sup> N72303 001  
JUL 15, 1988

AB 100MG<sup>m</sup> N72304 001  
JUL 15, 1988

TENORMIN

AB STUART PHARMS 50MG N18240 001  
AB 100MG N18240 002

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL  
MOTOFEN

/BA/ /CARNRICK/LABS/

/0.025MG;1MG/  
/N17744/002/  
N17744 002

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION  
AZATHIOPRINE

AP QUAD PHARMS EQ 100MG BASE/VIAL<sup>m</sup> 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 10MGX N71260 001  
MAY 06, 1988

AB 20MGX N71261 001  
MAY 06, 1988

AB VITARINE 10MGX N71901 001  
APR 13, 1988

AB 20MGX N71902 001  
APR 13, 1988

AB ZENITH LABS 10MGX N72234 001  
JUL 21, 1988

AB 20MGX N72235 001  
JUL 21, 1988

LIORESAL

AB GEIGY PHARMS 10MG N17851 001

LIORESAL DS

AB GEIGY PHARMS 20MG N17851 003  
JAN 20, 1982

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE

/BP/ PRIVATE/FMLTNS/ 50MG/ 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 0.5MGX N89211 001  
JUN 14, 1988

AA 1MGX N89212 001  
JUN 14, 1988

AA 2MGX 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 0.5MGX N89058 001  
AUG 10, 1988

AA 1MGX N89059 001  
AUG 10, 1988

AA 2MGX N89060 001  
AUG 10, 1988

COGENTIN

MS&D

AA 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/

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  
~~/HISTALOS/~~  
~~/LILLY/~~  
 @ 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/  
 @ BARR LABS 4MG /N04468/001/  
 N04468 001

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE;  
 PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL  
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/ /N71810/001/  
 > DLT > /ABBOTT/LABS/ /0.75%/ /DEC/11/1987/  
 > DLT >

SENORCAINE  
 > DLT > /AA/ /ASTRA/PHARM/PRODS/ /0.75%/ /N71202/001/  
 > DLT > /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 > SENORCAINE  
 > ADD > AP ASTRA PHARM PRODS 0.75% N71202 001  
 > ADD > APR 15, 1987

> DLT > /BUPIVACAINE/HYDROCHLORIDE;/DEXTROSE/

> DLT > /INJECTABLE;/INJECTION/  
 > DLT > /MARCAINE/SPINAL/  
 > DLT > /@/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/	16.35MG/ML;140.1MG/ML;	
> DLT >		1461.8MG/ML	/N17506/001/
> ADD >	STERLING DRUG	0.35MG/ML;140.1MG/ML;	
> ADD >		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
AI	BAXTER	25.7MG/100ML;3.5GM/100ML; 5.08MG/100ML;538MG/100ML; 448MG/100ML	N17512 011 NOV 18, 1985
AI	ABBOTT LABS	25.7MG/100ML;3.5GM/100ML; 15.2MG/100ML;567MG/100ML; 392MG/100MLM	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/100MLM	N18379 008 JUN 24, 1988
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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/100MLM	N19634 001 FEB 24, 1988
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DEXTROSE 4% IN MODIFIED LACTATED RINGER'S IN PLASTIC CONTAINER

	KENDALL MCGAW	4MG/100ML;4GM/100ML;6MG/100ML; 120MG/100ML;62MG/100MLM	N19634 002 FEB 24, 1988
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DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

AP	KENDALL MCGAW	20MG/100ML;5GM/100ML;30MG/100ML; 600MG/100ML; 310MG/100MLM	N19634 003 FEB 24, 1988
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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/100MLM	N19685 005 OCT 17, 1988
AP		20MG/100ML;5GM/100ML;179MG/100ML; 600MG/100ML; 310MG/100MLM	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/100MLM	N19685 007 OCT 17, 1988
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CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

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

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

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

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND LACTATED RINGER'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 LACTATED RINGER'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 LACTATED RINGER'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

CARPHENAZINE MALEATE

~~/TABLET;/ORAL/~~

~~/PROKETAZINE;/~~

~~/WYETH/AYERST/LABS/~~

2 WYETH AYERST LABS

2

~~/25MG/~~

~~/50MG/~~

25MG

50MG

~~/N12768/002/~~

~~/N12768/004/~~

N12768 002

N12768 004

CARPROFEN

~~/TABLET;/ORAL/~~

~~/RINADYL;/~~

~~/ROCHE/~~

2 ROCHE

2

~~/100MG/~~

~~/150MG/~~

100MG

150MG

~~/N18556/002/~~

~~/DEC/31/1987/~~

~~/N18556/003/~~

~~/DEC/31/1987/~~

N18550 002

DEC 31, 1987

N18550 003

DEC 31, 1987

> ADD > CARTEOLOL HYDROCHLORIDE

> ADD >

TABLET; ORAL

> ADD >

CARTROL

> ADD >

ABBOTT LABS

> ADD >

2.5MG N19204 001

> ADD >

5MG N19204 002

> ADD >

10MG N19204 003

> ADD >

10MG N19204 003

> ADD >

10MG N19204 003

N19204 001

DEC 28, 1988

N19204 002

DEC 28, 1988

N19204 003

DEC 28, 1988

CEFACLOR

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  
AP CEFAZOLIN SODIUM  
BEN VENUE LABS

EQ 5GM BASE/VIAL N50461 004  
EQ 250MG BASE/VIALM N62894 001  
JUL 21, 1988  
EQ 500MG BASE/VIALM N62894 002  
JUL 21, 1988  
EQ 1GM BASE/VIALM N62894 003  
JUL 21, 1988  
EQ 5GM BASE/VIALM N62894 004  
JUL 21, 1988  
EQ 10GM BASE/VIALM N62894 005  
JUL 21, 1988  
EQ 250MG BASE/VIALM N62807 001  
JAN 12, 1988  
EQ 500MG BASE/VIALM N62807 002  
JAN 12, 1988  
EQ 1GM BASE/VIALM N62807 003  
JAN 12, 1988  
EQ 5GM BASE/VIALM N62807 004  
JAN 12, 1988  
EQ 10GM BASE/VIALM N62807 005  
JAN 12, 1988  
EQ 20GM BASE/VIALM N62807 006  
JAN 12, 1988

> ADD >  
> ADD > AP ZOLICEF  
> ADD > BRISTOL MYERS  
> ADD > AP  
> ADD >

EQ 500MG BASE/VIALM N62831 001  
DEC 09, 1988  
EQ 1GM BASE/VIALM N62831 002  
DEC 09, 1988

CEFOTETAN 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  
> ADD >

EQ 1GM BASE/VIALM N50601 001  
DEC 30, 1988

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

AB JEROME STEVENS

EQ 250MG BASEM N62870 001  
MAR 17, 1988

AB EQ 500MG BASEM N62869 001

AB LABROS ATRAL EQ 250MG BASEM N62713 001

AB EQ 500MG BASEM N62713 002

AB SQUIBB MARK EQ 250MG BASEM N62973 001

AB EQ 500MG BASEM N62974 001

AB TAG PHARMS EQ 250MG BASEM N62821 001

AB EQ 500MG BASEM N62823 001

AB YOSHITOMI PHARM EQ 250MG BASEM N62872 001

AB EQ 500MG BASEM N62871 001

MAR 17, 1988  
MAR 17, 1988  
JUL 15, 1988  
JUL 15, 1988  
NOV 08, 1988  
NOV 23, 1988  
FEB 05, 1988  
FEB 05, 1988  
JUN 20, 1988  
JUL 05, 1988

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

AB TAG PHARMS

EQ 125MG BASE/5MLM N62873 001  
MAY 23, 1988  
EQ 250MG BASE/5MLM N62867 001  
APR 15, 1988

AB EQ 250MG BASE/5MLM

TABLET; ORAL

CEPHALEXIN

AB VITARINE

EQ 250MG BASEM N62863 001  
AUG 11, 1988

AB EQ 500MG BASEM N62863 002

AB EQ 1GM BASEM N62863 003

AUG 11, 1988  
AUG 11, 1988

AB KEFLET  
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/  
@ LEADERLE LABS 5MG N86892 001  
@ 10MG N86876 001  
@ 25MG N86893 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL

CHLORDIAZEPOXIDE HCL

AB PIONEER PHARMS 10MG N89533 001  
JUL 15, 1988  
AB 25MG N89558 001  
JUL 15, 1988  
/AB/ /PUREPAC/PHARM/ /5MG/ N85155/001/  
/AB/ /10MG/ N84939/002/  
/AB/ /25MG/ N85144/001/  
@ PUREPAC PHARM 5MG N85155 001  
@ 10MG N84939 002  
@ 25MG N85144 001  
/AB/ /LYSEN/ /5MG/ N85167/002/  
/AB/ /BANMAX/PHARMS/ /10MG/ N85009/001/  
/AB/ /25MG/ N85108/001/  
@ BANMAX PHARMS 5MG N85107 002  
@ 10MG N85009 001  
@ 25MG N85108 001

CHLORMERODRIN, HG-197

/INJECTABLE;/INJECTION/  
/CHLORMERODRIN/HG/197;/  
/SQUIBB/

/0.6-1.4MCI/ML/ N17269/001/  
@ SQUIBB 0.6-1.4MCI/ML N17269 001

CHLOROQUINE HYDROCHLORIDE

/INJECTABLE;/INJECTION/  
/ARALEN/

/STERLING/DRUG/ /EQ/40MG/BASE/ML/ N06002/002/  
@ STERLING DRUG EQ 40MG BASE/ML N06002 002

CHLOROQUINE PHOSPHATE

TABLET; ORAL

ARALEN

AA STERLING DRUG EQ 300MG BASE N06002 001  
AA DANBURY PHARMA EQ 300MG BASE N88030 001  
DEC 21, 1982  
/AA/ /EQ 300MG BASE/ N88030/001/  
/DEC/21/1982/

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

IMURAH  
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  
LIORESAL  
AB GEIGY PHARMS 10MG N17851 001  
LIORESAL DS  
AB GEIGY PHARMS 20MG N17851 003  
 JAN 20, 1982

BENZTHIAZIDE

TABLET; ORAL

BENZTHIAZIDE  
/BP/ /PRIVATE/FMLTNS/ 50MG/ 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/  
/BP/ /1MG/ /APR/11/1985/  
/BP/ /2MG/ /N88894/001/  
AA PHARM BASICS 0.5MG /APR/11/1985/  
 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/  
AA SIDMAK LABS 0.5MG /JAN/31/1984/  
 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

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

CICLOPIROX OLAMINE

LOTION; TOPICAL  
 > ADD > LOPROX  
 > ADD > HOECHST 1/2M N19824 001  
 > ADD > DEC 30, 1988

CISPLATIN

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

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL  
CLEOCIN  
 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  
CLINDAMYCIN HCL  
 AB VITARINE EQ 75MG BASEM N62910 001  
 JUL 05, 1988  
 AB EQ 150MG BASEM N62910 002  
 JUL 05, 1988

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION  
CLINDAMYCIN PHOSPHATE  
 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  
CLINDAMYCIN PHOSPHATE  
 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

CLEOCIN T  
 AT UPJOHN EQ 1% BASE N50537 001  
 AT EQ 1% BASE N62363 001  
 FEB 08, 1982  
CLINDAMYCIN PHOSPHATE  
 AT BARRE NATL EQ 1% BASEM N62811 001  
 SEP 01, 1988

CLOFIBRATE

CAPSULE; ORAL  
CLOFIBRATE  
 AB CORD LABS 500MG N72191 001  
 MAY 02, 1988

CLOMIPHENE CITRATE

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

CLONIDINE

FILM, CONTROLLED RELEASE; PERCUTANEOUS

CATAPRES-TTS-1

BOEHR INGEL

0.1MG/24HR

~~12.5MG~~

N18891 001  
OCT 10, 1984  
~~N18891/001/  
10/11/1984~~

CATAPRES-TTS-2

BOEHR INGEL

0.2MG/24HR

~~15MG~~

N18891 002  
OCT 10, 1984  
~~N18891/002/  
10/11/1984~~

CATAPRES-TTS-3

BOEHR INGEL

0.3MG/24HR

~~17.5MG~~

N18891 003  
OCT 10, 1984  
~~N18891/003/  
10/11/1984~~

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

N71878 001  
MAR 15, 1988

AB

7.5MG

N71879 001  
MAR 15, 1988

AB

15MG

N71860 001  
MAR 15, 1988

AB CORD LABS

3.75MG

N72219 001  
AUG 26, 1988

AB

7.5MG

N72220 001  
AUG 26, 1988

AB

15MG

N72112 001  
AUG 26, 1988

AB PUREPAC PHARM

3.75MG

N71924 001  
APR 25, 1988

AB

7.5MG

N71925 001  
APR 25, 1988

AB

15MG

N71926 001  
APR 25, 1988

AB QUANTUM PHARMCS

3.75MG

N71549 001  
SEP 12, 1988

AB

7.5MG

N71550 001  
SEP 12, 1988

AB

15MG

N71522 001  
SEP 12, 1988

AB WARNER CHILCOTT

3.75MG

N71774 001  
MAR 01, 1988

AB

7.5MG

N71775 001  
MAR 01, 1988

AB

15MG

N71776 001  
MAR 01, 1988

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

AB PUREPAC PHARM

3.75MG

N72330 001  
AUG 08, 1988

AB

7.5MG

N72331 001  
AUG 08, 1988

AB

15MG

N72332 001  
AUG 08, 1988

AB WARNER CHILCOTT

3.75MG

N71828 001  
MAR 03, 1988

AB

7.5MG

N71829 001  
MAR 03, 1988

AB

15MG

N71830 001  
MAR 03, 1988

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

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

CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

CLOXACILLIN SODIUM

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

CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHERAZINE W/ CODEINE

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

COLCHICINE; PROBENECID

TABLET; ORAL

PROBENECID AND COLCHICINE

<u>/BP/</u>	<u>/BEECHAM/LABS/</u>	<u>/0.5MG; 500MG/</u>	<u>/N84321/001/</u>
	2 BEECHAM LABS	0.5MG; 500MG	N84321 001
<u>/BP/</u>	<u>/LEDERLE/LABS/</u>	<u>/0.5MG; 500MG/</u>	<u>/N86954/001/</u>
	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, 1988
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CORTISONE ACETATE

TABLET; ORAL

CORTISONE ACETATE

BP	RICHLYN LABS	<u>25MG</u> <u>/25MG/</u>	N09458 001 <u>/N09458/001/</u>
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CYCLACILLIN

TABLET; ORAL

CYCLACILLIN

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

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

CYCLOBENZAPRINE HCL

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

CYCRIMINE HYDROCHLORIDE

/TABLET; ORAL/  
/FASITANE;/  
/LILLY/

2 LILLY	<u>1.25MG</u> <u>/2.5MG/</u>	<u>/N88951/001/</u> <u>/N88951/002/</u>
2	1.25MG 2.5MG	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 > /RORER/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

DESOWEN  
AB OWEN LABS 0.05% N71425 001  
JUN 15, 1988

TRIDESILON  
AB MILES PHARM 0.05% N17426 001

DESOXYCORTICOSTERONE ACETATE

PELLET; IMPLANTATION

/PERCORTEN/ /125MG/ /N05151/001/  
& CIBA/PHARM/ 125MG N05151 001

DEXAMETHASONE

TABLET; ORAL  
DEXAMETHASONE

/BP/ /BARR/LABS/ /0.25MG/ /N84013/001/  
& /0.25MG/ /N84764/001/  
& /0.5MG/ /N84084/001/  
& /0.75MG/ /N84081/001/  
& /0.75MG/ /N84765/001/  
& /1.5MG/ /N84086/001/  
& /1.5MG/ /N84763/001/  
& BARR LABS 0.25MG N84013 001  
& 0.25MG N84764 001  
& 0.5MG N84084 001  
& 0.75MG N84081 001  
& 0.75MG N84765 001  
& 1.5MG N84086 001  
& 1.5MG N84763 001  
BP & RICHLYN LABS 0.75MG N85376 001  
& /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

DEXTRONETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL  
 /PHENEGAN W/ DEXTRONETHORPHAN/  
 /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/ /N18923/001/  
 /ABBOTT/LABS/ /38.5GM/100ML/ /SEP/19./1984/  
 3 ABBOTT LABS 38.5GM/100ML 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/ /N18676/001/  
 /ABBOTT/LABS/ /5GM/100ML;14.5MG/100ML/ /JAN/17./1986/  
 /300MG/100ML/ /N18676/001/  
 /DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W/POTASSIUM/CHLORIDE/  
 /0.15%/IN/PLASTIC/CONTAINER/ /N18676/002/  
 /ABBOTT/LABS/ /5GM/100ML;14.9MG/100ML/ /JAN/17./1986/  
 /300MG/100ML/ /N18676/002/  
 /DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W/POTASSIUM/CHLORIDE/  
 /0.224%/IN/PLASTIC/CONTAINER/ /N18676/003/  
 /ABBOTT/LABS/ /5GM/100ML;22.4MG/100ML/ /JAN/17./1986/  
 /300MG/100ML/ /N18676/003/

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION  
 /DEXTROSE/5%/SODIUM/CHLORIDE/0.225%/POTASSIUM/CHLORIDE/  
 /0.15%/IN/PLASTIC/CONTAINER/ /N18365/001/  
 /ABBOTT/LABS/ /5GM/100ML;150MG/100ML/ /JAN/17./1986/  
 /225MG/100ML/ /N18365/001/  
 /DEXTROSE/5%/SODIUM/CHLORIDE/0.45%AND/POTASSIUM/CHLORIDE/  
 /0.225%/IN/PLASTIC/CONTAINER/ /N18362/002/  
 /ABBOTT/LABS/ /5GM/100ML;225MG/100ML/ /JAN/17./1986/  
 /450MG/100ML/ /N18362/002/  
 /DEXTROSE/5%/SODIUM/CHLORIDE/0.45%AND/POTASSIUM/CHLORIDE/  
 /0.32%IN/PLASTIC/CONTAINER/ /N18362/003/  
 /ABBOTT/LABS/ /5GM/100ML;224MG/100ML/ /JAN/17./1986/  
 /450MG/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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM N19630 040  
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDEDEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

	INJECTABLE; INJECTION				
	POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER				
	KENDALL MCGAW	10GM/100ML;150MG/100ML; 900MG/100MLM	N19630 046		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	5GM/100ML;150MG/100ML; 200MG/100MLM	N19630 010		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	5GM/100ML;150MG/100ML; 330MG/100MLM	N19630 016		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	5GM/100ML;150MG/100ML; 450MG/100MLM	N19630 022		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	5GM/100ML;220MG/100ML; 110MG/100MLM	N19630 005		
			FEB 17, 1988		
	INJECTABLE; INJECTION				
	POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER				
	KENDALL MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	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 MCGAW	10GM/100ML;300MG/100ML; 900MG/100MLM	N19630 048		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	5GM/100ML;300MG/100ML; 200MG/100MLM	N19630 012		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	5GM/100ML;300MG/100ML; 330MG/100MLM	N19630 018		
			FEB 17, 1988		
	<u>POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>				
AP	KENDALL MCGAW	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/100MLM	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
	<u>POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;224MG/100ML; 450MG/100ML	N18362 002
AP	<u>POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;224MG/100ML; 900MG/100MLM	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
	<u>POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	TRAVENOL LABS	5GM/100ML;224MG/100ML; 900MG/100ML	N19308 006 APR 05, 1985
	<u>POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;298MG/100ML; 450MG/100ML	N18362 003
AP	<u>POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;298MG/100ML; 900MG/100MLM	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/100MLM	N18876 004 MAR 28, 1988
	<u>POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;74.5MG/100ML; 450MG/100MLM	N18362 008 MAR 28, 1988
AP	<u>POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;74.5MG/100ML; 900MG/100MLM	N19691 001 MAR 24, 1988
AP	<u>POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER</u>	ABBOTT LABS	5GM/100ML;74.5MG/100ML; 225MG/100MLM	N18365 005 MAR 28, 1988
	POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE 0.225% IN PLASTIC CONTAINER	ABBOTT LABS	5GM/100ML;149MG/100ML; 225MG/100MLM	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/100MLM	N18876 005 MAR 28, 1988
			5GM/100ML;149MG/100ML; 300MG/100MLM	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/100ML N19631 011  
 FEB 24, 1988

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

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

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

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

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

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

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

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

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

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

DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER  
 AP KENDALL MCGAW 5GM/100ML;200MG/100ML 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/100ML N19631 008  
 FEB 24, 1988

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

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 AP KENDALL MCGAW 5GM/100ML;900MG/100ML 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/ML 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 PHARMS 2MG N72431 001  
 APR 29, 1988

AB 5MG N72432 001  
 APR 29, 1988

AB 10MG N72433 001  
 APR 29, 1988

DIAZOXIDE

CAPSULE; ORAL  
 PROGLYCEM  
 MED MKTG SPEC 50MG N17425 001  
 100MG N17425 002  
 2 1/2 SCHERING/ 50MG/ N17425/001/

DIAZOXIDE

INJECTABLE; INJECTION  
DIAZOXIDE  
 AP QUAD PHARMS 15MG/ML N71908 001  
 JAN 26, 1988

SUSPENSION; ORAL  
 PROGLYCEM  
 MED MKTG SPEC 50MG/ML N17453 001  
 /S/SCHERING/ /50MG/ML/ /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  
BENTYL  
 AA MERRELL DOW 10MG/5ML N07961 002  
 OCT 15, 1984

AA DICYCLOMINE HCL  
 BARRE NATL 10MG/5ML N84479 001

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL  
 /HETRAZAN:/  
 /LEDERLE/LABS/ 50MG/50MG /N06459/001/  
 @ LEADERLE LABS 50MG N06459 001

DIFLORASONE DIACETATE

CREAM; TOPICAL  
 /DIFLORASONE/DIACETATE:/  
 /UPJOHN/ 0.05% /N19259/001/  
 @ UPJOHN 0.05% /AUG/28/1985/  
 N19259 001  
 AUG 28, 1985

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL  
DIPHENHYDRAMINE HCL  
 /AA/ /LEDERLE/LABS/ 25MG /N86874/001/  
 /AA/ 25MG /N86875/001/  
 @ LEADERLE LABS 25MG N86874 001  
 @ 50MG N86875 001  
 AA RICHLYN LABS 25MG N80807 001  
 /A/ /25MG/ /N80807/001/

DISOPYRAMIDE PHOSPHATE

CAPSULE, CONTROLLED RELEASE; ORAL  
DISOPYRAMIDE PHOSPHATE  
 AB KV PHARM EQ 100MG BASEM N71929 001  
 AUG 19, 1988

AB MORPACE CR  
 SEARLE EQ 100MG BASE N18655 001  
 JUL 20, 1982

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER  
 AP BAXTER 80MG/100ML N19615 001  
 MAR 27, 1987

AP 160MG/100ML N19615 002  
 MAR 27, 1987

AP 320MG/100ML N19615 003  
 MAR 27, 1987

640MG/100ML N19615 004  
 MAR 27, 1987

/AA/ /TRAVENOL/LABS/ 80MG/100ML /N19615/001/  
 /AA/ 160MG/100ML /MAR/27/1987/  
 /AA/ 320MG/100ML /N19615/002/  
 /MAR/27/1987/  
 /AA/ 640MG/100ML /N19615/003/  
 /MAR/27/1987/  
 /N19615/004/  
 /MAR/27/1987/

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL  
ADAPIN  
 AB PENWALT EQ 150MG BASE N16987 007  
 APR 13, 1987

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL		
<u>AB</u>	<u>DOXEPIN HCL</u> BARR LABS	<u>EQ 25MG BASEM</u> N71502 001 FEB 18, 1988
<u>AB</u>		<u>EQ 50MG BASEM</u> N71653 001 FEB 18, 1988
<u>AB</u>		<u>EQ 75MG BASEM</u> N71654 001 FEB 18, 1988
<u>AB</u>		<u>EQ 100MG BASEM</u> N71521 001 FEB 18, 1988
<u>AB</u>	CHELSEA LABS	<u>EQ 75MG BASEM</u> N71763 001 FEB 09, 1988
<u>AB</u>		<u>EQ 150MG BASEM</u> N71764 001 FEB 09, 1988
<u>AB</u>	LEDERLE LABS	<u>EQ 10MG BASEM</u> N71685 001 JAN 05, 1988
<u>AB</u>		<u>EQ 25MG BASEM</u> N71686 001 JAN 05, 1988
<u>AB</u>		<u>EQ 50MG BASEM</u> N71673 001 JAN 05, 1988
<u>AB</u>		<u>EQ 75MG BASEM</u> N71674 001 JAN 05, 1988
<u>AB</u>		<u>EQ 100MG BASEM</u> N71675 001 JAN 05, 1988
<u>AB</u>		<u>EQ 150MG BASEM</u> N71676 001 JAN 05, 1988
<u>AB</u>	PUREPAC PHARM	<u>EQ 75MG BASEM</u> N72386 001 SEP 08, 1988
<u>AB</u>		<u>EQ 100MG BASEM</u> N72110 001 SEP 08, 1988
<u>AB</u>		<u>EQ 150MG BASEM</u> N72387 001 SEP 08, 1988
CONCENTRATE; ORAL		
<u>AA</u>	<u>DOXEPIN HCL</u> MY K LABS	<u>EQ 10MG BASE/MLM</u> N71918 001 JUL 20, 1988
<u>DOXYCYCLINE HYCLATE</u>		
CAPSULE; ORAL		
<u>AB</u>	<u>DOXYCYCLINE HYCLATE</u> INTERPHARM	<u>EQ 50MG BASEM</u> N62763 001 SEP 02, 1988
<u>AB</u>		<u>EQ 100MG BASEM</u> N62763 002 SEP 02, 1988
<u>AB</u>	VITARINE	<u>EQ 50MG BASEM</u> N62780 001 APR 12, 1988

DOXYCYCLINE HYCLATE

INJECTABLE; INJECTION		
<u>AP</u>	<u>DOXYCYCLINE</u> BEN VENUE LABS	<u>EQ 100MG BASE/VIALM</u> N62569 001 MAR 09, 1988
<u>AP</u>		<u>EQ 200MG BASE/VIALM</u> N62569 002 MAR 09, 1988
TABLET; ORAL		
<u>AB</u>	<u>DOXYCYCLINE HYCLATE</u> INTERPHARM	<u>EQ 100MG BASEM</u> N62764 001 SEP 02, 1988
<u>DROPERIDOL</u>		
INJECTABLE; INJECTION		
<u>AP</u>	<u>DROPERIDOL</u> ABBOTT LABS	<u>2.5MG/MLM</u> N71981 001 FEB 29, 1988
<u>AP</u>	ASTRA PHARM PRODS	<u>2.5MG/MLM</u> N72018 001 OCT 20, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N72019 001 OCT 19, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N72020 001 OCT 19, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N72021 001 OCT 19, 1988
<u>AP</u>	DUPONT CRI CARE	<u>2.5MG/MLM</u> N71645 001 APR 07, 1988
<u>AP</u>	LUITPOLD PHARMS	<u>2.5MG/MLM</u> N72123 001 OCT 24, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N72335 001 OCT 24, 1988
<u>AP</u>	QUAD PHARMS	<u>2.5MG/MLM</u> N71941 001 AUG 17, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N71942 001 AUG 17, 1988
<u>AP</u>	SOLOPAK LABS	<u>2.5MG/MLM</u> N71750 001 SEP 06, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N71754 001 SEP 06, 1988
<u>AP</u>		<u>2.5MG/MLM</u> N71755 001 SEP 06, 1988

DROPERIDOL; FENTANYL CITRATE

INJECTABLE; INJECTION  
FENTANYL CITRATE AND DROPERIDOL  
 AP ABBOTT LABS 2.5MG/ML;  
 EQ 0.05MG BASE/MLM N71982 001  
 MAY 04, 1988

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

DYDROGESTERONE

~~/TABLET;/ORAL/  
 /SYNCREST;/  
 /REID/ROWELL/~~ 15MG/  
 10MG/  
 5MG  
 10MG

N17388/001/  
 N17388/002/  
 N17388 001  
 N17388 002

EDETATE CALCIUM DISODIUM

~~/TABLET;/ORAL/  
 /CALCIUM/DISODIUM/VERSENATE;/  
 /RIKER/LABS/~~ 500MG/  
 500MG/

N08922/002/

TABLET; ORAL  
 CALCIUM DISODIUM VERSENATE  
 3 RIKER LABS 500MG N08922 002

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION  
REVERSOL  
 AP ORGANON 10MG/MLM N89624 001  
 MAY 13, 1988

ENALAPRIL MALEATE

TABLET; ORAL  
 VASOTEC  
 MS&D RES LABS 2.5MG N18998 005  
 JUL 26, 1988

ENALAPRILAT

INJECTABLE; INJECTION  
 VASOTEC  
 MS&D RES LABS 1.25MG/MLM N19309 001  
 FEB 09, 1988

EPINEPHRINE; 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

~~/AP/~~ LIDOCAINE HCL W/ EPINEPHRINE  
~~/LEMMON/~~ 0.01MG/ML;1% N85463/001/  
 3 LEMMON 0.01MG/ML;1% N85463 001

XYLOCAINE 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/  
~~/AA/~~ ~~/CHELSEA/LABS/~~ 1MG/ N88207/001/  
 N88207/001/  
 MAR/22,1984/

GERDOL  
 AB CHELSEA LABS 1MG N88207 001  
 MAR 22, 1984

TABLET; SUBLINGUAL  
~~/AA/~~ GERDOL/  
~~/AA/~~ ~~/RIKER/LABS/~~ 1MG/ N84868/001/  
 3 RIKER LABS 0.5MG N84868 001  
 3 1MG N85809 001

ERGOLOID MESYLATES

TABLET; SUBLINGUAL			
<u>ERGOLOID MESYLATES</u>			
<u>AA</u>	<u>CHelsea/LABS</u>	<u>0.5MG</u>	<u>N66188/001</u>
<u>AA</u>		<u>1MG</u>	<u>N66188/001</u>
<u>GERMAL</u>			
<u>AA</u>	<u>CHelsea LABS</u>	<u>0.5MG</u>	<u>N86189 001</u>
<u>AA</u>		<u>1MG</u>	<u>N86188 001</u>

ERYTHROMYCIN

SOLUTION; TOPICAL			
<u>ERYTHROMYCIN</u>			
<u>AI</u>	<u>NASKA PHARMA</u>	<u>2ZM</u>	<u>N62957 001</u> <u>JUL 21, 1988</u>
<u>ETS-22</u>			
<u>AI</u>	<u>PADDOCK LABS</u>	<u>2ZM</u>	<u>N62687 001</u> <u>FEB 05, 1988</u>
TABLET, ENTERIC COATED; ORAL			
<u>E-BASE</u>			
<u>AB</u>	<u>BARR LABS</u>	<u>500MG</u>	<u>N62999 001</u> <u>NOV 25, 1988</u>
<u>ERY-TAB</u>			
	<u>ABBOTT LABS</u>	<u>500MG</u>	<u>N62298 002</u>

ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL

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

ERYTHROMYCIN ETHYLSUCCINATE

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

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

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

ERYTHROMYCIN LACTOBIONATE

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

ERYTHROMYCIN STEARATE

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

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION  
BREVIBLOC  
DUPONT CRI CARE

10MG/MLM

N19386 001  
AUG 15, 1988

ESTRADIOL

FILM, CONTROLLED RELEASE; PERCUTANEOUS  
ESTRADERM  
CIBA PHARM

0.05MG/24HR

N19081 002  
SEP 10, 1986

0.1MG/24HR

N19081 003  
SEP 10, 1986  
/4mg/  
/8mg/  
/19081/002/  
/SEP/10./1986/  
/19081/003/  
/SEP/10./1986/

ESTRAMUSTINE PHOSPHATE SODIUM

CAPSULE; ORAL  
EMCYT

> ADD >  
> DLT >

PHARMACIA LABS  
/ROCHE/

EQ 140MG PHOSPHATE  
/EQ/140MG/PHOSPHATE/

N18045 001  
/N18045/001/

ESTRONE

INJECTABLE; INJECTION  
ESTRONE

/BP/ /STERIS/LABS/  
STERIS LABS  
THEELIN  
/BP/ /PARKE/DAVIS/  
/BP/ 2 PARKE DAVIS  
2

/5MG/ML/  
5MG/ML  
/1MG/ML/  
/5MG/ML/  
1MG/ML  
5MG/ML

/N85239/001/  
N85239 001  
/N03977/001/  
/N03977/003/  
N03977 001  
N03977 003

> ADD >

ETHANOLAMINE OLEATE

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

INJECTABLE; INJECTION  
ETHAMOLIN  
GLAXO

50MG/MLM

N19357 001  
DEC 22, 1988

ETHINYL ESTRADIOL

TABLET; ORAL  
/L/NORAL/

/BP/ /ORGANON/

2 ORGANON  
2

/0.05MG/  
/0.01MG/  
0.01MG  
0.05MG

/N05490/002/  
/N05490/003/  
N05490 003  
N05490 002

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

AB NORETHIN 1/35E-21

SEARLE PHARMS 0.035MG;1MG

N71480 001  
APR 12, 1988

AB NORETHINDRONE AND ETHINYL ESTRADIOL

NATSON LABS 0.035MG;0.5MG AND 1MG

N71043 001  
APR 01, 1988

AB ORTHO-NOVUM 10/11-21

ORTHO PHARM 0.035MG;0.5MG AND 1MG

N18354 001  
JAN 11, 1982

TABLET; ORAL-28

AB NORETHIN 1/35E-28

SEARLE PHARMS 0.035MG;1MG

N71481 001  
APR 12, 1988

AB NORETHINDRONE AND ETHINYL ESTRADIOL

NATSON LABS 0.035MG;0.5MG AND 1MG

N71044 001  
APR 01, 1988

AB ORTHO-NOVUM 10/11-28

ORTHO PHARM 0.035MG;0.5MG AND 1MG

N18354 002  
JAN 11, 1982

ETHIODIZED OIL

/INJECTABLE;/INJECTION/  
/ETHIODOL/

/FOUSERA/

/99%/

/N09190/001/

OIL; INTRALYMPHATIC, INTRAUTERINE

ETHIODOL

SAVAGE LABS 99%

N09190 001

ETHYLESTRENOL

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

/TABLET;/ORAL/  
/MAXIBOLIN/

/ORGANON/

/2MG/  
2MG

/N14005/002/  
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>NALFON</u>		
AB	DISTA PRODS	EQ 300MG BASE N17604 002
AB	<u>NALFON 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>NALFON</u>		
AB	DISTA PRODS	EQ 600MG BASE N17710 001

FERROUS SULFATE; FOLIC ACID

<u>/CAPSULE; ORAL/</u>		
<u>/POLYRON/</u>		
<u>/LEDERLE LABS/</u>	<u>/182MG; 0.33MG/</u>	<u>/N06012/003/</u>
<u>2 LEADERLE LABS</u>	182MG; 0.33MG	N06012 003

FLECAINIDE ACETATE

TABLET; ORAL		
<u>TAMBOCOR</u>		
	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% N89526 001 JUL 26, 1988
AT		0.025% N89525 001 JUL 26, 1988
OIL; TOPICAL		
<u>DERMA-SMOOTH/FS</u>		
	HILL DERM	0.01% N19452 001 FEB 03, 1988
OINTMENT; TOPICAL		
<u>FLUOCINOLONE ACETONIDE</u>		
AT	G&W LABS	0.025% N89524 001 JUL 26, 1988



FLUOCINONIDE

CREAM; TOPICAL  
FLUOCINONIDE  
AB CLAY PARK LABS 0.05%  
N71790 001  
APR 25, 1988

SOLUTION; TOPICAL  
FLUOCINONIDE  
> ADD > AT BARRE NATL 0.05%  
> ADD >  
N71535 001  
DEC 02, 1988

LIDEX  
> ADD > AT SYNTEX LABS 0.05%  
> ADD >  
N18849 001  
APR 06, 1984

FLUOROURACIL

INJECTABLE; INJECTION  
FLUOROURACIL  
AP BEN VENUE LABS 50MG/ML  
N89508 001  
JAN 26, 1988

FLUPHENAZINE 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, 1988

FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL  
PERMITIL  
BP SCHERING 2.5MG N12034 004  
BP 5MG N12034 005  
BP 10MG N12034 006  
/3/ /2.5MG/ /N12034/004/  
/3/ /5MG/ /N12034/005/  
/3/ /10MG/ /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, 1988

FLURBIPROFEN

TABLET; ORAL  
ANSAID  
UPJOHN 50MG N18766 002  
100MG OCT 31, 1988  
N18766 003  
OCT 31, 1988

FOLIC ACID

TABLET; ORAL  
FOLIC ACID  
/66/ /BARR/LABS/ /1MG/ /N89177/001/  
3 BARR LABS 1MG /N89177/001/  
JAN 08, 1988

FUROSEMIDE

INJECTABLE; INJECTION  
FUROSEMIDE  
/66/ /PARKE/DAVIS/ /10MG/ML/ /N18428/001/  
/FEB/26./1982/

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/  
 @ MEDI PHYSICS @ N17700 001  
 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; N62818 001  
 10,000 UNITS/MLM OCT 11, 1988

GUANABENZ ACETATE

TABLET; ORAL  
 /MYETHIN/  
 /MYETH/AYERST/LABS/ /EQ/16MG/BASE/ N18587 003  
 @ MYETH AYERST LABS EQ 16MG BASE SEP 07, 1982

GUANFACINE HYDROCHLORIDE

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

HALOPERIDOL

TABLET; ORAL  
 HALDOL SOLUTAB  
 /@/MCNEIL/LABS/ /1MG/ N17079 001  
 @ MCNEIL PHARM  
 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	<u>0.5MG</u>	N71571 001 JUN 03, 1988
AB		<u>1MG</u>	N71572 001 JUN 03, 1988
AB		<u>2MG</u>	N71573 001 JUN 03, 1988
AB		<u>5MG</u>	N71374 001 JUN 03, 1988
AB		<u>10MG</u>	N71375 001 JUN 03, 1988
AB		<u>20MG</u>	N71376 001 JUN 03, 1988
AB	CORD LABS	<u>10MG</u>	N71210 001 MAR 11, 1988
AB		<u>20MG</u>	N71211 001 MAR 11, 1988

**HALOPERIDOL LACTATE**

**CONCENTRATE; ORAL**

**HALDOL**

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

> ADD >	AA	COPLEY PHARM	EQ 2MG BASE/MLM	N71617 001 DEC 01, 1988
> ADD >	AA	HALOPERIDOL INTENSOL ROXANE LABS	EQ 2MG BASE/MLM	N72045 001 APR 12, 1988

**INJECTABLE; INJECTION**

**HALOPERIDOL**

AP	LEMMON	EQ 5MG BASE/MLM	N70713 001 MAY 17, 1988
AP		EQ 5MG BASE/MLM	N70714 001 MAY 17, 1988
AP		EQ 5MG BASE/MLM	N70744 001 MAY 17, 1988

**HEPARIN SODIUM**

**INJECTABLE; INJECTION**

**HEP FLUSH KIT IN PLASTIC CONTAINER**

AP	LYPHOMED	<u>10 UNITS/ML</u>	N17029 017 DEC 05, 1985
AP		<u>100 UNITS/ML</u>	N17029 018 DEC 05, 1985

**HEPARIN SODIUM**

**INJECTABLE; INJECTION**

**HEPARIN LOCK FLUSH**

/AP/	/ABBOTT/LABS/	/100 UNITS/ML/	/N05264/010/
> DLT >	> ABBOTT LABS	100 UNITS/ML	N05264 010
> ADD >	/STERIS/LABS/	/100 UNITS/ML/	/N17064/001/
	> STERIS LABS	100 UNITS/ML	N17064 001
	AP	HEPARIN LOCK FLUSH IN PLASTIC CONTAINER ABBOTT LABS	10 UNITS/ML N05264 015 MAY 21, 1985
	AP	100 UNITS/ML	N05264 016 MAY 21, 1985

**HEPARIN SODIUM**

/AA/	/LYPHOMED/	/4,000 UNITS/ML/	/N17064/003/
> DLT >	> LYPHOMED	5,000 UNITS/ML	N17979 003
> DLT >	/STERIS/LABS/	/4,000 UNITS/ML/	/N17064/015/
> DLT >	> STERIS LABS	2,500 UNITS/ML	N17064 015
> ADD >		3,000 UNITS/ML	N17064 016
> DLT >		4,000 UNITS/ML	N17064 017
> ADD >		6,000 UNITS/ML	N17064 018
> DLT >		7,500 UNITS/ML	N17064 019
> ADD >		40,000 UNITS/ML	N17064 006

**HEPARIN SODIUM IN PLASTIC CONTAINER**

AP	LYPHOMED	1,000 UNITS/ML	N17029 013 DEC 05, 1985
AP		5,000 UNITS/ML	N17029 014 DEC 05, 1985
AP		10,000 UNITS/ML	N17029 015 DEC 05, 1985
AP		20,000 UNITS/ML	N17029 016 DEC 05, 1985

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

/AA/	/ABBOTT/LABS/	/10,000 UNITS/100ML/	/N19339/003/
	> ABBOTT LABS	10,000 UNITS/100ML	N19339 003 MAR 27, 1985

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

AP	BAXTER	200 UNITS/100ML	N18609 001 APR 28, 1982
/AA/	/TRAVENOL/LABS/	/100 UNITS/100ML/	/N18609/001/
			N18609 001 APR 28, 1982

HEPARIN SODIUM

INJECTABLE; INJECTION

<u>HEPARIN SODIUM 10,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>			
/AP/	//ABBOTT/LABS/	/5,000 UNITS/100ML/	/N19339/001/ MAR/27,1985/
Q	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>			
/AP/	//TRAVENOL/LABS/	/200 UNITS/100ML/	/N18609/002/ APR/28,1982/
<u>HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER</u>			
/AP/	//ABBOTT/LABS/	/5,000 UNITS/100ML/	/N19339/004/ MAR/27,1985/
/AP/		/10,000 UNITS/100ML/	/N19339/002/ MAR/27,1985/
Q	ABBOTT LABS	5,000 UNITS/100ML	N19339 004 MAR 27, 1985
Q		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
/AP/	//TRAVENOL/LABS/	/500 UNITS/100ML/	/N18609/003/ APR/28,1982/
<u>Liquation Sodium Preservative Free</u>			
/AP/	//ORGANON/	/1,000 UNITS/ML/	/N00552/011/ APR/11,1986/
/AP/		/5,000 UNITS/ML/	/N00552/012/ APR/11,1986/
/AP/		/10,000 UNITS/ML/	/N00552/013/ APR/11,1986/
Q	ORGANON	1,000 UNITS/ML	N00552 011 APR 11, 1986
Q		5,000 UNITS/ML	N00552 012 APR 11, 1986
Q		10,000 UNITS/ML	N00552 013 APR 11, 1986
<u>SODIUM HEPARIN</u>			
/AP/	//LYPHOMED/	/5,000 UNITS/ML/	/N17033/002/ MAR/27,1985/
/AP/		/10,000 UNITS/ML/	/N17033/003/ MAR/27,1985/
/AP/		/20,000 UNITS/ML/	/N17033/004/ MAR/27,1985/
Q	LYPHOMED	5,000 UNITS/ML	N17033 002
Q		10,000 UNITS/ML	N17033 003
Q		20,000 UNITS/ML	N17033 004

HEXOCYCLUM METHYLSULFATE

TABLET; ORAL

<u>TRAL</u>			
/2/	ABBOTT/LABS/	/25MG/	/N10599/001/
<u>TABLET; ORAL TRAL</u>			
	ABBOTT LABS	25MG	N10599 001

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

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

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

<u>HYDRAL</u>			
AB	REID ROWELL	25MG;25MG	N87608 001 FEB 08, 1982
AB		50MG;50MG	N87213 001 FEB 08, 1982
/2/		/25MG;25MG/	/N87608/001/ FEB/08,1982/
/2/		/50MG;50MG/	/N87213/001/ FEB/08,1982/

HYDRALAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; 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
Q		25MG;15MG;0.1MG	N87210 001
/2/		/25MG;15MG;0.1MG/	/N88376/001/ OCT/28,1983/
<u>RESERPINE; HYDROCHLOROTHIAZIDE; AND HYDRALAZINE/HCL</u>			
/BP/	//LEDERLE/LABS/	/25MG;15MG;0.1MG/	/N87709/001/ MAY/13,1982/
Q	LEDERLE LABS	25MG;15MG;0.1MG	N87709 001 MAY 13, 1982

HYDROCHLOROTHIAZIDE

SOLUTION; ORAL

HYDROCHLOROTHIAZIDE

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

TABLET; ORAL

HYDROCHLOROTHIAZIDE

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

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL

NORMOZIDE

/SCHERING/

3 SCHERING

/25MG;400MG/	N19046/004/ APR/06/1987
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TRANDATE HGT

GLAXO

2

3

3

25MG;100MG	N19174 001 APR 10, 1987
25MG;200MG	N19174 002 APR 10, 1987
25MG;300MG	N19174 003 APR 10, 1987
25MG;400MG	N19174 004 APR 10, 1987

TRANDATE HGT

GLAXO

/AA/		/25MG;100MG/	N19174/001/ APR/10/1987
/AA/		/25MG;200MG/	N19174/002/ APR/10/1987
/AA/		/25MG;300MG/	N19174/003/ APR/10/1987
/AA/		/25MG;400MG/	N19174/004/ APR/10/1987

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB	NOVOPHARM	15MG;250MG	N71819 001 APR 08, 1988
AB		25MG;250MG	N71820 001 APR 08, 1988
AB		30MG;500MG	N71821 001 APR 08, 1988
AB		50MG;500MG	N71822 001 APR 08, 1988
/AA/	PUREPAC/PHARM	50MG;500MG	N70689/001/ APR/24/1986
3	PUREPAC PHARM	50MG;500MG	N70689 001 APR 24, 1986
AB	MATSON LABS	15MG;250MG	N71920 001 AUG 29, 1988
AB		25MG;250MG	N71921 001 AUG 29, 1988
AB		30MG;500MG	N71922 001 AUG 29, 1988
AB		50MG;500MG	N71923 001 AUG 29, 1988
AB	ZENITH LABS	15MG;250MG	N71458 001 MAR 08, 1988
AB		25MG;250MG	N71459 001 MAR 08, 1988
AB		30MG;500MG	N71460 001 MAR 08, 1988
AB		50MG;500MG	N71461 001 MAR 08, 1988

HYDROCHLOROTHIAZIDE; PINDOLOL

TABLET; ORAL

/SANDOZ/

/SANDOZ/PHARMS/

/25MG;5MG/	N18872/001/ JUL/22/1987
/25MG;10MG/	N18872/002/ JUL/22/1987
3 SANDOZ PHARMS	25MG;5MG N18872 001 JUL 22, 1987
3	25MG;10MG N18872 002 JUL 22, 1987

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL			
<u>PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE</u>			
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 DEC 01, 1988
> ADD >	AB		25MG;80MG
> ADD >			N71553 001 DEC 01, 1988

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL			
<u>HYDROCHLOROTHIAZIDE W/ RESERPINE</u>			
	3/BOOTS/PHARMS/	25MG;0.125MG	N85421/001
	3 PHARMAFAIR	25MG;0.125MG	N85421 001
<u>RESERPINE AND HYDROCHLOROTHIAZIDE</u>			
1/8/	1/BARR/LABS/	25MG;0.125MG	N84580/001
1/8/		50MG;0.125MG	N84579/001
	3 BARR LABS	25MG;0.125MG	N84580 001
	3	50MG;0.125MG	N84579 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL			
<u>SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE</u>			
1/8/	1/LEDERLE/LABS/	25MG;25MG	N87511/001
	3 LEDERLE LABS	25MG;25MG	N87511 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL			
<u>TRIAMTERENE AND HYDROCHLOROTHIAZIDE</u>			
AB	VITARINE	25MG;50MG	N71737 001 FEB 12, 1988
TABLET; ORAL			
<u>MAXZIDE-25MG</u>			
	MYLAN PHARMS	25MG;37.5MG	N19129 003 MAY 13, 1988
<u>TRIAMTERENE AND HYDROCHLOROTHIAZIDE</u>			
AB	CORD LABS	50MG;75MG	N72011 001 JUN 17, 1988

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL			
<u>TRIAMTERENE AND HYDROCHLOROTHIAZIDE</u>			
AB	DANBURY PHARMA	50MG;75MG	N71969 001 JAN 15, 1988
AB	PAR PHARM	50MG;75MG	N72337 001 MAY 11, 1988
AB	QUANTUM PHARMS	50MG;75MG	N71980 001 FEB 01, 1988
AB	WATSON LABS	50MG;75MG	N71851 001 NOV 30, 1988

HYDROCORTISONE

CREAM; TOPICAL			
<u>HYDROCORTISONE</u>			
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
<u>HYDROTEX</u>			
AI	SYOSSET LABS	1/2	N87427 001 APR 04, 1988
<u>HYMAC</u>			
1/8/	1/NC/LABS/	1/2	N87795/001 MAY/03/1983/

LOTION; TOPICAL

<u>BETA-MC</u>			
AI	BETA DERM	1/2	N89495 001 JAN 25, 1988
<u>HYDROCORTISONE</u>			
AI	NASKA PHARMA	1/2	N89705 001 APR 25, 1988

OINTMENT; TOPICAL

<u>HC (HYDROCORTISONE)</u>			
	1/3/C&M/PHARMA/	1/2	N80481/001
	1/2/	1/2	N80481/002
AI	C&M PHARMA	1/2	N80481 002
<u>HYDROCORTISONE</u>			
AI	NASKA PHARMA	1/2	N89704 001 MAR 10, 1988

TABLET; ORAL			
<u>HYDROCORTISONE</u>			
1/8/	1/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;  
 10,000 UNITS/MLM N62874 001  
 MAY 11, 1988

HYDROCORTISONE ACETATE

CREAM; TOPICAL  
HYDROCORTISONE ACETATE  
 /AT/ /THAMES/PHARMA/ /1%/  
 N86472/001/  
 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 SYNTEX 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/  
 AT OMEN LABS 0.1% N19819 001  
 SEP 15, 1988

HYDROFLUMETHIAZIDE

TABLET; ORAL  
HYDROFLUMETHIAZIDE  
 /AA/ /BOLAR/PHARM/ /50MG/  
 B 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/  
 B ALTANA 25MG/ML  
 B 50MG/ML  
 N87273/001/  
 APR/20./1982/  
 N87273/001/  
 APR/20./1982/  
 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	<u>400MG</u>	N71058 001 AUG 11, 1988
AB		<u>600MG</u>	N71059 001 AUG 11, 1988
AB		<u>800MG</u>	N71965 001 AUG 11, 1988

IBUPROFEN

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

> ADD > IFOSFAMIDE

> ADD > INJECTABLE; INJECTION

> ADD > IFEX

> ADD > BRISTOL MYERS 1GM/VIALM

> ADD > N19763 001  
DEC 30, 1988

> ADD > 3GM/VIALM N19763 002

> ADD > DEC 30, 1988

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

PRASINE

/AB/	/BANMAX/PHARMS/	/10MG/	/N83827/001/
/AB/		/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/ /N/A/

/N19044/001/  
/DEC 23, 1985/

INJECTABLE; INJECTION

INDIUM IN-111 OXYQUINOLINE  
AMERSHAM 1MCI/ML

N19044 001  
DEC 23, 1985

INDOCYANINE GREEN

INJECTABLE; INJECTION

CARDIO-GREEN  
3 B-D MICROBIOL SYS

10MG/VIAL	N11525 003
25MG/VIAL	N11525 001
40MG/VIAL	N11525 004
50MG/VIAL	N11525 002
/10MG/VIAL/	/N11525/003/
/40MG/VIAL/	/N11525/004/

/HYNAN/WES/A/DLN/

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

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



INSULIN PORK

INJECTABLE; INJECTION

<u>ILETIN</u> <u>LILLY</u> ILETIN I LILLY	<u>500 UNITS/ML</u>	<u>N17931/001</u>
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IOHEXOL

INJECTABLE; INJECTION

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

IOTHALAMATE MEGLUMINE

SOLUTION; INTRAVESICAL

CYSTO-CONRAY II MALLINCKRODT	17.2%	N17057 002
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SOLUTION; INTRAVESICAL, URETERAL

CYSTO-CONRAY MALLINCKRODT	43%	N17057 001
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<u>SOLUTION; URETERAL</u> <u>CYSTO-CONRAY</u> <u>MALLINCKRODT</u>	<u>13%</u>	<u>N17057/001</u>
<u>CYSTO-CONRAY II</u> <u>MALLINCKRODT</u>	<u>17.2%</u>	<u>N17057/002</u>

> ADD > IOVERSOL

INJECTABLE; INJECTION

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

IRON DEXTRAN

INJECTABLE; INJECTION

<u>IRON DEXTRAN</u> <u>FISONS</u>	<u>EQ 50MG IRON/ML</u>	<u>N17807/001</u>
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ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

<u>ISOETHARINE HCL</u> DEY LABS	<u>0.17%</u>	N87390 001
<u>ISOETHARINE HCL S/F</u> DEY LABS	<u>0.09%</u>	N89817 001 NOV 22, 1988
	<u>0.1%</u>	N89818 001 NOV 22, 1988
	<u>0.17%</u>	N89819 001 NOV 22, 1988
	<u>0.25%</u>	N89820 001 NOV 22, 1988

ISONIAZID

INJECTABLE; INJECTION

<u>ISONIAZID</u> QUAD PHARMS	<u>100MG/ML</u>	N89816 001 OCT 28, 1988
<u>HYDRAZID</u> SGUIBB	<u>100MG/ML</u>	N08662 001

TABLET; ORAL

<u>DOM-ISONIAZID</u> <u>DOM PHARMS</u>	<u>300MG</u>	<u>N80330/002</u> N80330 002
<u>LANAZID</u> LANNETT	<u>300MG</u>	N89776 001 JUN 13, 1988

ISOSORBIDE DINITRATE

CAPSULE, CONTROLLED RELEASE; ORAL

<u>DILATRATE-SR</u> REED & CARRICK	<u>40MG</u>	N19790 001 SEP 02, 1988
<u>ISORDIL</u> MYETH AYERST LABS	<u>40MG</u>	N12882 002 JUL 29, 1988

ISOSORBIDE DINITRATE

TABLET; ORAL			
<u>ISORDIL</u>			
AB	MYETH AYERST LABS	5MG	N12093 007 JUL 29, 1988
AB		10MG	N12093 002 JUL 29, 1988
AB		20MG	N12093 006 JUL 29, 1988
AB		30MG	N12093 005 JUL 29, 1988
		40MG	N12093 001 JUL 29, 1988
<u>ISOSORBIDE DINITRATE</u>			
AB	BARR LABS	30MG	N87564 001 SEP 18, 1986
AB	CORD LABS	5MG	N86221 001 JAN 07, 1988
AB		10MG	N86223 001 JAN 07, 1988
AB		20MG	N89367 001 APR 07, 1988
AB	DANBURY PHARMA	5MG	N86034 001 JAN 06, 1988
AB		10MG	N86032 001 JAN 07, 1988
AB	PAR PHARM	30MG	N87946 001 JAN 12, 1988
TABLET; SUBLINGUAL			
<u>ISORDIL</u>			
AB	MYETH AYERST LABS	2.5MG	N12940 004 JUL 29, 1988
AB		5MG	N12940 003 JUL 29, 1988
AB		10MG	N12940 005 JUL 29, 1988
<u>ISOSORBIDE DINITRATE</u>			
AB	BARR LABS	10MG	N87545 001 SEP 18, 1986
AB	CORD LABS	2.5MG	N86225 001 FEB 19, 1988
AB		5MG	N86222 001 FEB 19, 1988
AB	DANBURY PHARMA	2.5MG	N86033 001 FEB 26, 1988
AB		5MG	N86031 001 SEP 29, 1987

ISOSORBIDE DINITRATE

TABLET, CONTROLLED RELEASE; ORAL			
<u>ISORDIL</u>			
	MYETH AYERST LABS	40MG	N12882 001 JUL 29, 1988
<u>KETAMINE HYDROCHLORIDE</u>			
INJECTABLE; INJECTION			
<u>KETALAR</u>			
AP	PARKE DAVIS	EQ 10MG BASE/ML	N16812 001
AP		EQ 50MG BASE/ML	N16812 002
AP		EQ 100MG BASE/ML	N16812 003
<u>KETAMINE HCL</u>			
AP	QUAD PHARMS	EQ 10MG BASE/ML	N71949 001 APR 11, 1988
AP		EQ 50MG BASE/ML	N71950 001 APR 11, 1988
AP		EQ 100MG BASE/ML	N71951 001 APR 11, 1988
<u>LACTULOSE</u>			
SYRUP; ORAL			
AA	<del>CEPHULAC</del> MERRELL/DOM	<del>10GM/15ML</del>	<del>N17657/001</del>
AA	<del>CHROLAC</del> MERRELL DOM	10GM/15ML	N17884 001
AA	<del>CONSTILAC</del> ALRA LABS	10GM/15ML	N71054 001 JUL 26, 1988
AA	<del>CONSTULOSE</del> BARRE NATL	10GM/15ML	N70288 001 AUG 15, 1988
AA	<del>LACTULOSE</del> MY K LABS	10GM/15ML	N71841 001 SEP 22, 1988
AA	<del>ROXANE/LABS</del>	<del>10GM/15ML</del>	<del>N17986/001</del>
SYRUP; ORAL, RECTAL			
AA	<del>CEPHULAC</del> MERRELL DOM	10GM/15ML	N17657 001
AA	<del>CHOLAC</del> ALRA LABS	10GM/15ML	N71331 001 JUL 26, 1988
AA	<del>ENULOSE</del> BARRE NATL	10GM/15ML	N71548 001 AUG 15, 1988

LACTULOSE

SYRUP; ORAL, RECTAL  
GENERLAC  
 AA HY K LABS 10GM/15MLM N71842 001  
 SEP 27, 1988  
LACTULOSE  
 AA KALI DUPHAR 10GM/15ML N17906 001

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION  
LEUCOVORIN CALCIUM  
 AP BEN VENUE LABS EQ 100MG BASE/VIALM N89717 001  
 MAR 28, 1988  
 AP INTL PHARM EQ 3MG BASE/MLM N89352 001  
 JUN 01, 1988  
 AP EQ 50MG BASE/VIALM N89353 001  
 JUN 01, 1988  
 AP LEDERLE LABS EQ 3MG BASE/ML N08107 001  
 AP EQ 100MG BASE/VIALM N08107 004  
 MAY 23, 1988  
 AP QUAD PHARMS EQ 100MG BASE/VIAL N89636 001  
 DEC 24, 1987

LEVOCARNITINE

SOLUTION; ORAL  
CARNITOR  
 AA SIGMA TAU 1GM/10MLM N18948 002  
 APR 27, 1988  
VITACARN  
 AA KENDALL MCGAM 1GM/10ML N19257 001  
 APR 10, 1986

LEVODOPA

CAPSULE; ORAL  
LEVODOPA  
 /BD/ /ICN/PHARMS/ 100MG /N16948/003/  
 /BD/ 250MG /N16948/001/  
 /BD/ 500MG /N16948/002/  
 a ICN PHARMS 100MG N16948 003  
 a 250MG N16948 001  
 a 500MG N16948 002

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
MELOCAINE M/ LEVONORDEFRIN  
 AP ASTRA PHARM PRODS 0.05MG/ML; 2ZM N89517 001  
 APR 14, 1988

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
LIDOCAINE HCL  
 AP ABBOTT LABS 20ZM N89362 001  
 MAY 25, 1988  
 /AP/ /LEMMON/ 1Z /N83627/001/  
 /AP/ 2Z /N83627/002/  
 a LEMMON 1Z N83627 001  
 a 2Z N83627 002  
 > DLT > /INJECTABLE; INJECTION/  
 > DLT > /LIDOCAINE HCL W/ DEXTROSE 1Z/  
 > DLT > /AP/ /ABBOTT/LABS/ 5Z /N83914/001/  
 > DLT > /XYLOCAINE W/ DEXTROSE 1.5Z/  
 > DLT > /AP/ /ASTRA/PHARM/PRODS/ 1.5Z /N16297/001/  
 > DLT > /XYLOCAINE 5Z W/ GLUCOSE 7.5Z/  
 > DLT > /AP/ /ASTRA/PHARM/PRODS/ 5Z /N10496/001/  
 > DLT > /JUL/07/1982/

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

LINCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION  
LINCOCTIN  
 AP UPJOHN EQ 300MG BASE/ML N50317 001  
LINCOMYCIN HCL  
 AP QUAD PHARMS EQ 300MG BASE/MLM N62784 001  
 MAR 14, 1988

LISINAPRIL

TABLET; ORAL

PRIMEVEL

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 OCT 25, 1988

ZESTREL

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/  
/IMMOTUM/~~

~~/JANSSEN/PHARMA/~~

~~/1MG/5ML/~~

o 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

>_ADD_>	MS&D RES LABS	40MG	N19643 004 DEC 14, 1988
>_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

ANTIVERT

AA	ROERIG	50MG	N10721 001 JAN 20, 1982
AA	<u>MECLIZINE HCL</u> 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 POHSTEL  
 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

MEPENZOLATE BROMIDE

/SOLUTION;/ORAL/  
 /CASTLE/  
 /MERRILL/DOW/  
 a MERRILL DOW 125MG/5ML /N10679/004/  
 25MG/5ML N10679 004

MEPROBAMATE

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

> ADD > MESNA  
 > ADD > INJECTABLE; INJECTION  
 > ADD > MESNEX  
 > ADD > BRISTOL MYERS 100MG/MLM N19884 001  
 > ADD > DEC 30, 1988

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21  
NORETHIN 1/50M-21  
 AB SEARLE PHARMS 0.05MG;1MG N71539 001 APR 12, 1988  
NORETHINDRONE AND MESTRANOL  
 AB WATSON LABS 0.05MG;1MG N70758 001 JUL 01, 1988  
 > DLT > /AA/ ORTHO-NOVUM 1/80 21 /0.08MG;1MG/ /N16715/001/  
 > ADD > a ORTHO PHARM 0.08MG;1MG N16715 001  
 > DLT > /AA/ ORTHO-NOVUM 2-21 /0.1MG;2MG/ /N12728/005/  
 > ADD > a 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  
NORETHINDRONE AND MESTRANOL  
 AB WATSON LABS 0.05MG;1MG N70759 001 JUL 01, 1988  
 > DLT > /AA/ ORTHO-NOVUM 1/80 28 /0.08MG;1MG/ /N16715/002/  
 > ADD > a ORTHO PHARM 0.08MG;1MG N16715 002

MESTRANOL; NORETHYNODREL

TABLET; ORAL-20

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

METAPROTERENOL SULFATE

SOLUTION; INHALATION

ALUPENT

AN	BOEHR INGEL	0.4%	N18761 002 OCT 10, 1986
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DEY-DOSE

AN	DEY LABS	5%	N70805 001 AUG 17, 1987
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DEY-LUTE

AN	DEY LABS	0.4% <del>M</del>	N71786 001 AUG 05, 1988
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AN		0.6%	N70804 001 AUG 17, 1987
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0.33%~~M~~

0.5%~~M~~

METAPROTERENOL SULFATE

AN	ARMOUR PHARM	0.4% <del>M</del>	N71275 001 JUL 27, 1988
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AN		0.6% <del>M</del>	N71018 001 JUL 27, 1988
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/AA/ /DEY/LABS/	/0.6% <del>/</del>	/N70804/001/	
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/AA/	/2% <del>/</del>	/N70805/001/	
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AN	MY K LABS	5% <del>M</del>	N72190 001 JUN 07, 1988
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AN	PACO RES	0.4% <del>M</del>	N71855 001 JUL 14, 1988
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AN		0.6% <del>M</del>	N71726 001 JUL 14, 1988
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SYRUP; ORAL

METSAL

/AA/ /MURO/PHARM/	/10MG/5ML/	/N72023/001/	
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PROMETA

AA	MURO PHARM	10MG/5ML	N72023 001 SEP 15, 1988
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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 <del>M</del>	N72054 001 JUN 23, 1988
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AB		20MG <del>M</del>	N72055 001 JUN 23, 1988
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AB	PAR PHARM	10MG <del>M</del>	N72024 001 JUN 28, 1988
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AB		20MG <del>M</del>	N72025 001 JUN 28, 1988
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AB	PHARM BASICS	10MG <del>M</del>	N71013 001 JAN 25, 1988
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AB		20MG <del>M</del>	N71014 001 JAN 25, 1988
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METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

METHADONE

AA	MALLINCKRODT	10MG/ML	N17116 002
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METHADONE HCL INTENSOL

AA	ROXANE LABS	10MG/ML <del>M</del>	N89897 001 SEP 06, 1988
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METHAZOLAMIDE

TABLET; ORAL

NEPTAZANE

	LEDERLE LABS	25MG <del>M</del>	N11721 002 MAR 04, 1988
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> ADD >

> ADD >

METHIXENE HYDROCHLORIDE

TABLET; ORAL

TREST

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

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

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

METHOTREXATE

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

~~12.5MG /~~

~~N06666/001 /~~

METHOTREXATE SODIUM

INJECTABLE; INJECTION  
METHOTREXATE  
LEDERLE LABS

EQ 1GM BASE/VIALM

N11719 009  
APR 07, 1988

METHOTREXATE SODIUM  
PHARMACHEMIE

AP

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 /~~

~~N09048/001 /~~

10MG

N09048 001

METHYCLOTHIAZIDE

TABLET; ORAL  
METHYCLOTHIAZIDE

AB

CORD LABS

2.5MGM

N89835 001  
AUG 18, 1988

AB

5MGM

N89837 001  
AUG 18, 1988

METHYLDOPA

TABLET; ORAL  
METHYLDOPA

AB

CORD LABS

125MGM

N71700 001  
MAR 02, 1988

AB

HALSEY DRUG

125MGM

N71751 001  
MAR 28, 1988

AB

250MGM

N71752 001  
MAR 28, 1988

AB

500MGM

N71753 001  
MAR 28, 1988

METHYLDOPA

TABLET; ORAL  
METHYLDOPA

AB

SIDMAK LABS

125MGM

N72126 001  
JUL 07, 1988

AB

250MGM

N72127 001  
JUL 07, 1988

AB

500MGM

N72128 001  
JUL 07, 1988

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL  
METHYLPHENIDATE HCL

AB

MD PHARM

20MGM

N89601 001  
JUN 01, 1988

AB

RITALIN-SR  
CIBA PHARM

20MG

N18029 001  
MAR 30, 1982

METHYLPREDNISOLONE

TABLET; ORAL  
MEDROL

AB

UPJOHN

24MG

N11153 005

AB

32MG

N11153 006

AB

METHYLPREDNISOLONE

AB

HEATHER DRUG

4MG

N85650 001

AB

PAR PHARM

16MGM

~~N85650/001 /~~  
N89207 001

AB

24MGM

APR 25, 1988

AB

24MGM

N89208 001

AB

32MGM

APR 25, 1988

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  
CLOPRA  
 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

METOLAZONE

TABLET; ORAL  
 /MYKROX/  
 /PENNYLIT/  
 MYKROX  
 FISONS 0.5MG N19532 001  
 OCT 30, 1987  
 /N19532/001/  
 /OCT/30, /1987/

METRIZAMIDE

INJECTABLE; INJECTION  
 AMIPAQUE  
 > DLT > /STERLING/DRUG/ /13.5GM/VIAL/ N17982/004/  
 > DLT > /SEP/12, /1983/  
 > ADD > 2 STERLING DRUG 13.5GM/VIAL N17982 004  
 > ADD > SEP 12, 1983

METRONIDAZOLE

GEL; TOPICAL  
 METROGEL  
 CURATEK PHARMS 0.752M N19737 001  
 NOV 22, 1988

MEZLOCILLIN SODIUM MONOHYDRATE

INJECTABLE; INJECTION  
 MEZLIN  
 MILES PHARM EQ 20GM BASE/VIALM N50549 005  
 MAR 02, 1988  
 EQ 20GM BASE/VIALM N62372 004  
 MAR 02, 1988

MINOXIDIL

SOLUTION; TOPICAL  
 ROGAINE  
 UPJOHN 22M N19501 001  
 AUG 17, 1988

TABLET; ORAL  
MENODYL  
 AB QUANTUM PHARMCS 2.5MG N72153 001  
 JUL 13, 1988

MINOXIDIL  
 AB PAR PHARM 2.5MG N71826 001  
 NOV 14, 1988  
 AB 10MG N71839 001  
 NOV 14, 1988  
 > ADD > AB PHARM BASICS 2.5MG N71537 001  
 > ADD > DEC 16, 1988

> ADD > MISOPROSTOL  
 > ADD > TABLET; ORAL  
 > ADD > CYTOTEC  
 > ADD > SEARLE 0.2MG N19268 001  
 > ADD > DEC 27, 1988

MITOMYCIN

INJECTABLE; INJECTION  
 MUTAMYCIN  
 BRISTOL MYERS 40MG/VIALM N62336 003  
 MAR 10, 1988



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, 1988

N19516 002  
APR 08, 1988

N62844 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, 1988

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL

NAFTIN

HERBERT LABS 1/M

N19599 001  
FEB 29, 1988

NALIDIXIC 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, 1988

NALOXONE 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

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

N19488 001  
DEC 21, 1988  
N19488 002  
DEC 21, 1988

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

30MGM

> ADD > NIMODIPINE

CAPSULE; ORAL

NIMOTOP

MILES PHARM 30MGM

N18869 001  
DEC 28, 1988

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

<b><u>NITROFURANTOIN</u></b>				<b><u>NIZATIDINE</u></b>			
<b><u>/CAPSULE; ORAL/</u></b>				<b>CAPSULE; ORAL</b>			
<b><u>/NITROFURANTOIN/</u></b>				<b>AXID</b>			
<b><u>/BOLAR/PHARM/</u></b>				<b>LILLY</b>			
	<b><u>/50MG/</u></b>		<b><u>/N84326/001/</u></b>		<b>150MG</b>		<b>N19508 001</b>
	<b>50MG</b>		<b>N84326 001</b>				<b>APR 12, 1988</b>
	<b><u>/100MG/</u></b>		<b><u>/N84326/002/</u></b>		<b>300MG</b>		<b>N19508 002</b>
	<b>100MG</b>		<b>N84326 002</b>				<b>APR 12, 1988</b>
<b>TABLET; ORAL</b>				<b><u>NORTRIPTYLINE HYDROCHLORIDE</u></b>			
<b><u>/68/</u></b>				<b>CAPSULE; ORAL</b>			
<b><u>/BOLAR/PHARM/</u></b>				<b>AVENTYL HCL</b>			
	<b><u>/100MG/</u></b>		<b><u>/N80447/002/</u></b>		<b>BD LILLY</b>		<b>EQ 10MG BASE</b>
	<b>100MG</b>		<b>N80447 002</b>		<b>BD</b>		<b>EQ 25MG BASE</b>
<b><u>NITROFURANTOIN SODIUM</u></b>				<b><u>/BP/</u></b>			
<b><u>/INJECTABLE; INJECTION/</u></b>				<b><u>/BP/</u></b>			
<b><u>/IVADANTIN/</u></b>				<b>PAMELOR</b>			
<b><u>/NORMICH/EATON/</u></b>				<b>BD SANDOZ PHARMS</b>			
	<b><u>/EQ/180MG/BASE/VIAL/</u></b>		<b><u>/N12402/001/</u></b>		<b>EQ 10MG BASE</b>		<b>N18013 001</b>
	<b>EQ 180MG BASE/VIAL</b>		<b>N12402 001</b>		<b>BD</b>		<b>EQ 25MG BASE</b>
<b><u>NITROFURANTOIN, MACROCRYSTALLINE</u></b>				<b><u>/BP/</u></b>			
<b>CAPSULE; ORAL</b>				<b><u>/BP/</u></b>			
<b><u>MACRODANTIN</u></b>				<b>MYSTATIN</b>			
<b>AB</b>	<b>NORMICH EATON</b>	<b>50MG</b>	<b>N16620 001</b>	<b>CREAM; TOPICAL</b>			
<b>AB</b>		<b>100MG</b>	<b>N16620 002</b>	<b><u>MYSTATIN</u></b>			
<b>AB</b>	<b>BOLAR PHARM</b>	<b>50MG</b>	<b>N70248 001</b>	<b>AI</b>	<b>NASKA PHARMA</b>	<b>100,000 UNITS/GM</b>	<b>N62949 001</b>
<b>AB</b>		<b>100MG</b>	<b>N70249 001</b>	<b>SUSPENSION; ORAL</b>			
			<b>JUN 24, 1988</b>	<b><u>MYSTATIN</u></b>			
			<b>N70249 001</b>	<b>AA</b>	<b>THAMES PHARMA</b>	<b>100,000 UNITS/ML</b>	<b>N62876 001</b>
			<b>JUN 24, 1988</b>	<b>FEB 29, 1988</b>			
<b><u>NITROGLYCERIN</u></b>				<b><u>TABLET; ORAL</u></b>			
<b>INJECTABLE; INJECTION</b>				<b><u>MYSTATIN</u></b>			
<b><u>NITROGLYCERIN</u></b>				<b>MUTUAL PHARM</b>			
<b>AP</b>	<b>LUITPOLD PHARMS</b>	<b>5MG/ML</b>	<b>N71492 001</b>	<b>500,000 UNITS</b>			
<b>AP</b>		<b>5MG/ML</b>	<b>N72034 001</b>	<b>N62838 001</b>			
			<b>MAY 24, 1988</b>	<b>DEC 22, 1988</b>			
			<b>N72034 001</b>	<b><u>NYSTATIN; TRIAMCINOLONE ACETONIDE</u></b>			
			<b>MAY 24, 1988</b>	<b>CREAM; TOPICAL</b>			
<b>ointment; TOPICAL</b>				<b><u>MYSTATIN AND TRIAMCINOLONE ACETONIDE</u></b>			
<b><u>NITROGLYCERIN</u></b>				<b>NASKA PHARMA</b>			
	<b>ALTANA</b>	<b>2%</b>	<b>N87355 001</b>	<b>100,000 UNITS/GM; 0.1%</b>			
			<b>JUL 08, 1988</b>	<b>N63010 001</b>			
				<b>DEC 20, 1988</b>			

OCTREOTIDE ACETATE

INJECTABLE; INJECTION  
SANDOSTATIN  
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/VIALM N61334 010  
AP OXACILLIN SODIUM EQ 250MG BASE/VIALM N62856 001  
MARSAM PHARMS OCT 26, 1988  
AP EQ 500MG BASE/VIALM N62856 002  
OCT 26, 1988  
AP EQ 1GM BASE/VIALM N62856 003  
OCT 26, 1988  
AP EQ 2GM BASE/VIALM N62856 004  
OCT 26, 1988  
AP EQ 4GM BASE/VIALM N62856 005  
OCT 26, 1988  
AP EQ 10GM BASE/VIALM N62984 001  
SEP 29, 1988  
AP PROSTAPHLIN EQ 250MG BASE/VIAL N50195 001  
BRISTOL LABS 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  
O MYLAN PHARMS 10MG N71713 001  
OCT 20, 1987  
O 15MG N71714 001  
OCT 20, 1987  
O 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/		<u>10MG/</u>	<u>/N70943/001/</u> <u>AUG/03/1987/</u>
/BP/		<u>15MG/</u>	<u>/N70944/001/</u> <u>AUG/03/1987/</u>
/BP/		<u>30MG/</u>	<u>/N70945/001/</u> <u>AUG/03/1987/</u>
AB	<u>SERAX</u> WYETH	<u>10MG</u>	N15539 002
AB		<u>15MG</u>	N15539 004
AB		<u>30MG</u>	N15539 006
/BP/		<u>10MG/</u>	<u>/N15539/002/</u>
/BP/		<u>15MG/</u>	<u>/N15539/004/</u>
/BP/		<u>30MG/</u>	<u>/N15539/006/</u>
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% BASEM

N19828 001  
DEC 30, 1988

OXYBUTYNIN 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	<u>5MG</u>	N72296 001 DEC 08, 1988
> <u>ADD</u> >	AB	<u>5MG</u>	N71655 001 NOV 14, 1988

OXYPHENCYCLIMINE HYDROCHLORIDE

TABLET; ORAL

	DARICON /BEECHAM/LABS/ PFIZER LABS	<u>10MG/</u> 10MG	<u>/N11612/001/</u> N11612 001
	<u>OXYPHENONIUM BROMIDE</u>		
> <u>DLT</u> >	/TABLET;/ORAL/		
> <u>DLT</u> >	/ANTRENYL;/		
> <u>DLT</u> >	/CIBA/PHARM/	<u>5MG/</u>	<u>/N08492/002/</u>
> <u>ADD</u> >	© CIBA PHARM	5MG	N08492 002

OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

AB	<u>OXYTETRACYCLINE HCL</u> /PUREPAC/PHARM/	<u>EQ 250MG BASE/</u> EQ 250MG BASE	<u>/N60634/001/</u> 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/ /500MG/ML/ /N66800/002/~~

SOLUTION; ORAL  
PARADIONE  
AA ABBOTT LABS 300MG/ML N06800 002

PENICILLAMINE

CAPSULE; ORAL  
CUPRIMINE  
MS&D 125MG N19853 002  
/125MG/ /N58376/002/  
250MG N19853 001  
/250MG/ /N58376/001/

TABLET; ORAL  
DEPEN 250 N19854 001  
WALLACE LABS 250MG /250MG/ /N58491/001/

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION  
PENICILLIN G POTASSIUM

AP MARSAM PHARMS 1,000,000 UNITS/VIAL<sup>m</sup> N62991 001  
SEP 13, 1988

AP 5,000,000 UNITS/VIAL<sup>m</sup> N62991 002  
SEP 13, 1988

AP 10,000,000 UNITS/VIAL<sup>m</sup> N62991 003  
SEP 13, 1988

AP 20,000,000 UNITS/VIAL<sup>m</sup> 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/~~  
PUREPAC PHARM 400,000 UNITS/5ML N61740 002

TABLET; ORAL  
PENICILLIN G POTASSIUM

~~/AA/ /PUREPAC/PHARM/ /250,000 UNITS/~~  
~~/AA/ /PUREPAC/PHARM/ /400,000 UNITS/~~  
PUREPAC PHARM 250,000 UNITS N61588 002  
PUREPAC PHARM 400,000 UNITS N61588 003

PENICILLIN G SODIUM

INJECTABLE; INJECTION  
PENICILLIN G SODIUM  
MARSAM PHARMS 5,000,000 UNITS/VIAL<sup>m</sup> N63014 001  
SEP 13, 1988

~~/SQUIBB/SPA/ /5,000,000 UNITS/VIAL/ /N61935/001/~~  
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/~~  
PUREPAC PHARM EQ 250MG BASE/5ML N61758 002

TABLET; ORAL  
PENICILLIN V POTASSIUM

AB CLONMEL CHEMS EQ 250MG BASE<sup>m</sup> N62936 001  
NOV 25, 1988

AB EQ 500MG BASE<sup>m</sup> N62935 001  
NOV 23, 1988

~~/AA/ /PUREPAC/PHARM/ /EQ 250MG BASE/~~  
~~/AA/ /PUREPAC/PHARM/ /EQ 500MG BASE/~~  
PUREPAC PHARM EQ 250MG BASE N61571 002  
PUREPAC PHARM EQ 500MG BASE N61571 003

> ADD > PERGOLIDE MESYLATE

> ADD > TABLET; ORAL  
> ADD > PERMAX  
> ADD > LILLY EQ 0.05MG BASE<sup>m</sup> N19385 001  
DEC 30, 1988

> ADD > EQ 0.25MG BASE<sup>m</sup> N19385 002  
DEC 30, 1988

> ADD > EQ 1MG BASE<sup>m</sup> N19385 003  
DEC 30, 1988

PERPHENAZINE

~~/SQUIBB/ ORAL/~~  
~~/TRILAFON/~~  
~~/SCHERING/~~  
SCHERING 2MG/5ML/ N11294 002  
2MG/5ML/ 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/ /N83684/001/  
 /AA/ /35MG/ /N83686/001/  
 /AA/ /35MG/ /N83687/001/  
 /AA/ /35MG/ /N84831/001/  
 /AA/ /35MG/ /N84834/001/  
 /AA/ /35MG/ /N84835/001/  
 3 BARR LABS 35MG N83644 001  
 3 35MG N83684 001  
 3 35MG N83686 001  
 3 35MG N83687 001  
 3 35MG N84831 001  
 3 35MG N84834 001  
 3 35MG N84835 001

PHENMETRAZINE HYDROCHLORIDE

/TABLET;/ORAL/  
 /PRELUDIN/  
 /BOEHR/INGEL/ /25MG/ /N10460/005/  
 3 BOEHR INGEL 25MG N10460 005

PHENTERMINE RESIN COMPLEX

CAPSULE, CONTROLLED RELEASE; ORAL  
TONAMIN-30  
 AB PENWALT EQ 30MG BASE N11613 002  
PHENTERMINE RESIN 30  
 AB QUANTUM PHARMCS EQ 30MG BASE# N89120 001  
 FEB 04, 1988

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL  
 /PHENERGAN VC/  
 /AA/ /NYE.H/AYERST/LABS/ /100ML/6.25MG/5ML/ /N08604/003/  
 /APR/02/1984/

PIPERACETAZINE

/TABLET;/ORAL/  
 /GUIDE/  
 /DOW/PHARMS/ /10MG/ /N13615/001/  
 /25MG/ /N13615/002/  
 3 DOW PHARMS 10MG N13615 001  
 3 25MG N13615 002

PIRIBUTEROL ACETATE

AEROSOL, METERED; INHALATION  
 /EXIREL/  
 > DLT > /PFIZER/LABS/ /EQ/0.2MG/BASE/INH/ /N19009/001/  
 > DLT > /DEC/30/1988/  
 > DLT >  
 > ADD > MAXAIR  
 > ADD > RIKER LABS EQ 0.2MG BASE/INH N19009 001  
 > ADD > DEC 30, 1988

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

POWDER FOR RECONSTITUTION; ORAL  
 > DLT > /E-Z-EM PREP LYTE/  
 > DLT > /AA/ /E/Z/EM/ /236GM/BOT;4.97GM/BOT;6.74GM/BOT/ /N19011/001/  
 > DLT > /5.86GM/BOT;22.74GM/BOT/ /JUL/13/1984/  
 > DLT >  
 > DLT > /AA/ /BRAINTREE/LABS/ /236GM/BOT;4.97GM/BOT;6.74GM/BOT/ /N19011/001/  
 > DLT > /5.86GM/BOT;22.74GM/BOT/ /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

/S/ABBOTT/LABS/

/6GM/100ML;75MG/100ML;168MG/100ML;/  
/146MG/100ML;/  
/1.29GM/100ML/

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

/AA/ /COLCHITTE/  
/DYNAPHARM/

/227.1GM/PACKET;2.82GM/PACKET;/  
/6.36GM/PACKET;5.53GM/PACKET;/  
/21.5GM/PACKET/

AA COLOVAGE  
DYNAPHARM

227.1GM/PACKET;2.82GM/PACKET;  
6.36GM/PACKET;5.53GM/PACKET;  
21.5GM/PACKET  
N71320 001  
APR 20, 1988

AA COLYTE  
REED & CARNRICK

227.1GM/PACKET;2.82GM/PACKET;  
6.36GM/PACKET;5.53GM/PACKET;  
21.5GM/PACKE  
N18983 004  
OCT 26, 1984

> ADD > E-2-EH 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 >

> ADD >

> ADD >

> ADD >

> ADD >

GLYCOPREP

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%  
@ HEXCEL CHEM 100%

/N80098/001/  
N80098 001

POTASSIUM CHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL

MICRO-K 10

AB ROBINS 10MEG

N18238 002  
MAY 14, 1984  
/N18238/002/  
/MAY 14, 1984/

/BC/ /10MEG/

POTASSIUM CHLORIDE

AB KV PHARM 10MEG

N70980 001  
FEB 17, 1987  
/N70980/001/  
/FEB 17, 1987/

/BC/ /10MEG/

GRANULE FOR RECONSTITUTION, CR; ORAL

MICRO-K LS

ROBINS 20MEG/PACKETM

N19561 003  
AUG 26, 1988

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

AP STERIS LABS 2MEG/MLM

N89163 001  
MAR 10, 1988

TABLET, CONTROLLED RELEASE; ORAL

POTASSIUM CHLORIDE

BC ABBOTT LABS 8MEGM

N18279 002  
AUG 01, 1988

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 20MEG IN SODIUM CHLORIDE 0.9% IN

PLASTIC CONTAINER

AP ABBOTT LABS 149MG/100ML;  
900MG/100MLM

N19686 001  
OCT 17, 1988

POTASSIUM CHLORIDE 40MEG IN SODIUM CHLORIDE 0.9% IN

PLASTIC 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  
20MEQ/PACKETM

N19647 002  
OCT 13, 1988  
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

AP

1GM/VIALM

N72224 001  
NOV 23, 1988

PROTOPAM CHLORIDE  
WYETH AYERST LABS

AP

1GM/VIAL

N14134 001

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

MEMIPRESS  
PFIZER LABS

AB  
AB  
AB

1MG  
2MG  
5MG

N17442 002  
N17442 003  
N17442 001

PRAZOSIN HCL  
ZENITH LABS

AB  
AB  
AB

1MG  
2MG  
5MG

N71994 001  
MAY 16, 1989 : SEP 12, 1988  
N71995 001  
MAY 16, 1989 : SEP 12, 1988  
N71745 001  
MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

TABLET; ORAL

PREDNISOLONE  
~~BARR LABS~~  
BARR LABS

~~/BX/~~  
~~/BX/~~

~~5MG~~  
5MG  
~~5MG~~  
5MG

~~N84426/002~~  
N84426 002  
~~N09996/001~~  
N09996 001

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

VASOCIDIN

IOLAB PHARMS

EQ 0.23% PHOSPHATE;10% N18988 001  
AUG 26, 1988

PREDNISONE

SOLUTION; ORAL

PREDNISONE

AA

MY K LABS

5MG/5MLM

N89726 001  
AUG 02, 1988

AA

ROXANE LABS

5MG/5ML

N88703 001  
NOV 08, 1984

TABLET; ORAL

METICORTEN

SCHERING

> ADD >  
> DLT >

BX

/3/

1MG  
~~1MG~~

N09766 002  
~~N09766/002~~

PREDNISONE

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

AB

CHELSEA LABS

50MG

N87772 001  
JUL 13, 1982  
~~N87772/001~~  
~~JUL 13, 1982~~

AB

SUPERPHARM

5MG

N88865 001  
OCT 25, 1984  
N88866 001  
OCT 25, 1984  
N88867 001  
OCT 25, 1984

AB

10MG

AB

20MG

~~/BX/~~

~~5MG~~

~~/BX/~~

~~10MG~~

~~/BX/~~

~~20MG~~

PROBUCOL

TABLET; ORAL

LORELCO

MERRELL DOW

500MG

N17535 002  
JUL 06, 1988



PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

	<u>PROCAINAMIDE HCL</u>		
<del>/AA/</del>	<del>/LEDERLE/LABS/</del>	<del>/250MG/</del>	<del>/N86942/001/</del>
<del>/AA/</del>		<del>/375MG/</del>	<del>/N86952/001/</del>
<del>/AA/</del>		<del>/500MG/</del>	<del>/N86943/001/</del>
	3 LEDERLE LABS	250MG	N86942 001
	3	375MG	N86952 001
	3	500MG	N86943 001

INJECTABLE; INJECTION

	<u>PROCAINAMIDE HCL</u>		
AP	WARNER CHILCOTT	100MG/ML	N89528 001 MAY 03, 1988
AP		500MG/ML	N89529 001 MAY 03, 1988

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

	<u>PROCHLORPERAZINE EDISYLATE</u>		
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

	<u>PROMETHAZINE HCL</u>		
AP	MARSAM PHARMS	25MG/ML	N89463 001 MAY 02, 1988
AP		50MG/ML	N89477 001 MAY 02, 1988

TABLET; ORAL

	<u>PROMETHAZINE HCL</u>		
<del>/BP/</del>	<del>/BARR/LABS/</del>	<del>/12.5MG/</del>	<del>/N84555/001/</del>
<del>/BP/</del>		<del>/25MG/</del>	<del>/N84554/001/</del>
<del>/BP/</del>		<del>/50MG/</del>	<del>/N84557/001/</del>
	3 BARR LABS	12.5MG	N84555 001
	3	25MG	N84554 001
	3	50MG	N84557 001

PROPIOLACTONE

SOLUTION; IRRIGATION

	BETAPRONE		
	FOREST LABS	N/A	N11657 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

	<u>PROPOXYPHENE HCL</u>		
<del>/AA/</del>	<del>/BANMAX/PHARMS/</del>	<del>/65MG/</del>	<del>/N83184/001/</del>
	3 BANMAX PHARMS	65MG	N83184 001
<del>/AA/</del>	<del>/BARR/LABS/</del>	<del>/65MG/</del>	<del>/N83186/001/</del>
	3 BARR LABS	65MG	N83186 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

	<u>PROPRANOLOL HCL</u>		
AB	INVAMED	10MG	N71658 001 JUL 05, 1988
AB		20MG	N71687 001 JUL 05, 1988
AB		50MG	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		50MG	N72119 001 JUN 23, 1988
AB		80MG	N72120 001 JUN 23, 1988
<del>/AA/</del>	<del>/LEHMAN/</del>	<del>/10MG/</del>	<del>/N70232/001/</del>
	3 LEHMAN	10MG	<del>/OCT/07/1987/</del> N70232 001 OCT 07, 1987
<del>/AA/</del>	<del>/PARKE/DAVIS/</del>	<del>/10MG/</del>	<del>/N70438/001/</del>
			<del>/SEP/15/1986/</del>

PROPRANOLOL HYDROCHLORIDE

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

PROTAMINE SULFATE

INJECTABLE; INJECTION  
PROTAMINE SULFATE  
 /BP/ /UPJOHN/ /50MG/VIAL/ /N07413/001/  
 /BP/ /UPJOHN/ /250MG/VIAL/ /N07413/002/  
 3 UPJOHN 50MG/VIAL /N07413/004/  
 2 250MG/VIAL /N07413/002/  
 AUG 02, 1984

QUINESTROL

/TABLET; ORAL/  
 /ESTROVIA/  
 /PARKE/DAVIS/  
 3 PARKE DAVIS 0.1MG /N16768/002/  
 2 0.2MG /N16768/003/  
 N16768 002  
 N16768 003

QUINIDINE GLUCONATE

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

QUINIDINE SULFATE

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

RANITIDINE HYDROCHLORIDE

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

RAUWOLFIA SERPENTINA

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

RESERPINE

TABLET; ORAL  
 RESERPINE  
 /BP/ /BARR/LABS/ /0.25MG/ /N80721/002/  
 2 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 > /MALLINCKRODT/ /460MG/GM;420MG/GM/ AUG 07, 1988  
> DLT > /N18509/001/  
> DLT > /AUG/07/1988/

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/ /0.8-100MCI/  
 2 MALLINCKRODT 0.8-100MCI  
/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

TRIMETH/SULFA  
~~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

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

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE  
~~/AB/~~ ~~/BARR/LABS/~~ ~~/500MG/~~ ~~/N84031/001/~~  
~~3 BARR LABS~~ N84031 001  
~~/AB/~~ ~~/LEDERLE/LABS/~~ ~~/500MG/~~ ~~/N87649/001/~~  
~~3 LEDERLE LABS~~ N87649 001

SULINDAC

TABLET; ORAL

CLINDORIL  
~~AB~~ MS&D ~~150MG~~ N17911 001  
~~AB~~ ~~200MG~~ N17911 002  
SULINDAC  
~~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  
~~OSTEOSCAN~~ N/A

~~> 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 >~~ ~~/BARR/~~  
~~> DLT >~~ ~~/AB/~~ ~~/MEDI/PHYSICS/~~ ~~/N/A/~~ ~~/N17264/002/~~  
~~> ADD >~~ TECHNETIUM TC-99M PENTETATE KIT  
~~> ADD >~~ ~~AB~~ MEDI PHYSICS N/A N17264 002

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM  
~~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

HYTRIN  
~~/3/~~ ~~/ABBOTT/LABS/~~ ~~/10MG/~~ ~~/N19057/004/~~  
~~ABBOTT LABS~~ 10MG N19057 004  
 AUG 07, 1987

TERCONAZOLE

SUPPOSITORY; VAGINAL  
TERAZOL 3  
ORTHO PHARM

80MG~~M~~ N19641 001  
MAY 24, 1988

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION  
TESTOSTERONE CYPIONATE

AQ QUAD PHARMS 100MG/ML~~M~~ N89326 001  
OCT 28, 1988  
AQ 200MG/ML~~M~~ N89327 001  
OCT 28, 1988

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL  
TETRACYCLINE HCL

AB LABROS ATRAL 250MG~~M~~ N62752 001  
AUG 12, 1988  
AB 500MG~~M~~ N62752 002  
AUG 12, 1988  
AB VITARINE 250MG~~M~~ N61471 001

THEOPHYLLINE

ELIXIR; ORAL  
THEOPHYLLINE

AA NASKA PHARMA 80MG/15ML~~M~~ N89223 001  
MAY 27, 1988  
AA THAMES PHARMA 80MG/15ML~~M~~ N89626 001  
OCT 28, 1988

INJECTABLE; INJECTION

THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

AP TRAVENOL LABS 320MG/100ML~~M~~ N18649 006  
NOV 13, 1985  
AP THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER  
ABBOTT LABS 320MG/100ML~~M~~ N19211 006  
JAN 20, 1988

THEOPHYLLINE

TABLET, CONTROLLED RELEASE; ORAL

> DLT > /~~1000MG~~/ N88505/001/  
> DLT > /66/ /FOREST/LABS/ /1000MG/ /APR/03,/1985/  
> DLT > /~~1000MG~~/ N88503/001/  
> DLT > /66/ /1000MG/ /APR/03,/1985/  
> DLT > /~~200MG~~/ N88504/001/  
> DLT > /66/ /200MG/ /APR/03,/1985/  
> ADD > 3 FOREST LABS 100MG N88503 001  
> ADD > 3 200MG N88504 001  
> ADD > 3 300MG N88505 001  
> ADD > APR 03, 1985

THEOLAIR-SR  
BC RIKER LABS

250MG N86363 002  
/250MG/ JUL 16, 1987  
/N86363/002/  
/JUL/16,/1987/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

AB MUTUAL PHARM 100MG~~M~~ N89953 001  
OCT 07, 1988  
AB PAR PHARM 150MG~~M~~ N89764 001  
FEB 09, 1988  
AB 200MG~~M~~ N89765 001  
FEB 09, 1988  
AB ROXANE LABS 25MG~~M~~ N88664 001  
MAR 15, 1984

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOTHIXENE HCL

> ADD > AA PACO RES EQ 5MG BASE/ML~~M~~ N71939 001  
> ADD > DEC 16, 1988

TRICONAZOLE

/OINTMENT; VAGINAL/  
/VAGISTAT;/  
/ROERIG/

3 ROERIG 6.5% /6.5%/

/N19355/001/  
/DEC/30,/1986/  
N19355 001  
DEC 30, 1986

TIOPRONIN

TABLET; ORAL  
TIOPRONIN  
UNIV TEXAS

100MGM N19569 001  
AUG 11, 1988

TOLAZAMIDE

TABLET; ORAL  
TOLAZAMIDE  
AB PHARM BASICS

100MGM N71355 001  
JAN 11, 1988

TOLBUTAMIDE

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

500MG/ 500MG  
/N86141/001/  
N86141 001

TRAZODONE HYDROCHLORIDE

TABLET; ORAL  
DESYREL  
AB HEAD JOHNSON

150MG N18207 003  
MAR 25, 1985

AB TRAZODONE HDL  
PUREPAC PHARM

50MGM N71636 001  
APR 18, 1988

AB 100MGM

N71514 001  
APR 18, 1988

AB SIDMAK LABS 50MG

N71523 001  
DEC 11, 1987

AB 100MG

N71524 001  
DEC 11, 1987

/AB/ /TRAZON-100/  
/SIDMAK/LABS/ /100MG/

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

AB TRAZON-150  
SIDMAK LABS 150MGM †

N71525 001  
MAR 09, 1988

/AB/ /TRAZON-50/  
/SIDMAK/LABS/ /50MG/

/N71523/001/  
/DEC/11./1987/

TRETINOIN

CREAM; TOPICAL  
RETIN-A  
ORTHO PHARM

0.025% N19049 001  
SEP 16, 1988

TRIAMCINOLONE

TABLET; ORAL  
TRIAMCINOLONE  
/BP/ BARR/LABS/

/BP/	/2MG/	/N84266/001/
/BP/	/2MG/	/N84318/001/
/BP/	/4MG/	/N84267/001/
/BP/	/4MG/	/N84319/001/
/BP/	/8MG/	/N84268/001/
/BP/	/8MG/	/N84320/001/
@ BARR LABS	2MG	N84286 001
@	2MG	N84318 001
@	4MG	N84267 001
@	4MG	N84319 001
@	8MG	N84268 001
@	8MG	N84320 001

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL  
FLUTEX  
AI SYOSSET LABS

0.025% N87430 001  
NOV 01, 1988  
0.1% N87429 001  
NOV 01, 1988  
0.5% N87428 001  
NOV 01, 1988

AI TRYMEX  
/AI/ /SAVAGE/LABS/

/0.5%/ /N88198/001/  
/MAR/25./1983/  
0.5% N88198 001  
MAR 25, 1983

OINTMENT; TOPICAL  
FLUTEX  
AI SYOSSET LABS

0.025% N87375 001  
NOV 01, 1988  
0.1% N87377 001  
NOV 01, 1988  
0.5% N87376 001  
NOV 01, 1988

† SEE SECTION 1.4 OF INTRODUCTION

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

TRIAMCINOLONE ACETONIDE

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

TRIAZOLAM

TABLET; ORAL

HALCION

/UPJOHN/

3 UPJOHN

/0.5MG/

0.5MG

/N17882/002/  
/NOV/15/1982/  
N17892 002  
NOV 15, 1982

TRICLOFOS SODIUM

/SOLUTION;/ORAL/

/TRICLOS/

/MERRELL/DOW/

3 MERRELL DOW

/1.5GM/15ML/

1.5GM/15ML

/N16830/001/  
N16830 001

/TABLET;/ORAL/

/TRICLOS/

/MERRELL/DOW/

3 MERRELL DOW

/750MG/

750MG

/N16809/002/  
N16809 002

TRIDIHETHYL CHLORIDE

/INJECTABLE;/INJECTION/

/PATHILON/

/LEDERLE/LABS/

3 LEDERLE LABS

/10MG/ML/

10MG/ML

/N09729/001/  
N09729 001

TRIFLUOPERAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

STELAZINE

AP

SK&F CO

EQ 2MG BASE/ML

N11552 005

AP

TRIFLUOPERAZINE HCL

QUAD PHARMS

EQ 2MG BASE/ML<sup>m</sup>

N89893 001  
OCT 17, 1988

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL

TRIFLUOPERAZINE HCL

AB

BOLAR PHARM

EQ 1MG BASE<sup>m</sup>

N85975 001  
JUN 23, 1988

AB

EQ 2MG BASE<sup>m</sup>

N85976 001  
JUN 23, 1988

AB

EQ 5MG BASE<sup>m</sup>

N85973 001  
JUN 23, 1988

AB

EQ 10MG BASE<sup>m</sup>

N88710 001  
JUN 23, 1988

TRIMEPRAZINE TARTRATE

CAPSULE, CONTROLLED RELEASE; ORAL

TEMARIL

HERBERT LABS

/SK&F/LABS/

EQ 5MG BASE

/EQ/5MG/BASE/

N11316 004  
/N11316/004/

SYRUP; ORAL

TEMARIL

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

AB

/200MG/

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

/3/

/100MG/

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

3

200MG

N70495 001  
MAR 14, 1986

TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL

TRIPLENNAMINE HCL

AA

/BARR/LABS/

3 BARR LABS

/20MG/

50MG

/N80744/001/  
N80744 001

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL  
 /66/ Hydroli/  
 /NTR/LABS/ 1.25MG/5ML/  
 @ MY K LABS 1.25MG/5ML  
 /N87963/001/  
 /JAN/18/1983/  
 N87963 001  
 JAN 18, 1983

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION  
TUBOCURARINE CHLORIDE  
 AP QUAD PHARMS 3MG/MLM  
 N89442 001  
 AUG 12, 1988

URSODIOL

CAPSULE; ORAL  
 ACTIGALL  
 @ CIBA PHARM 150MG  
 N19594 001  
 DEC 31, 1987  
 300MG  
 N19594 002  
 DEC 31, 1987  
 /DEUMSII/  
 /SIPHARME/ 150MG/  
300MG/  
 /N19594/001/  
 /DEC/31/1987/  
 /N19594/002/  
 /DEC/31/1987/

VANCOMYCIN HYDROCHLORIDE

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

VANCOMYCIN HYDROCHLORIDE

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

VERAPAMIL HYDROCHLORIDE

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



VERAPAMIL HYDROCHLORIDE

TABLET; ORAL  
VERAPAMIL HCL  
 AB LEIDERLE LABS 80MG~~M~~ N71880 001  
 APR 05, 1988  
 AB 120MG~~M~~ N71881 001  
 APR 05, 1988  
 AB MUTUAL PHARM 80MG~~M~~ N71488 001  
 JAN 13, 1988  
 AB 120MG~~M~~ N71489 001  
 JAN 13, 1988

VINCRIStINE SULFATE

INJECTABLE; INJECTION  
VINCUREX  
 AP BRISTOL LABS 5MG/VIAL~~M~~ N70867 001  
 JUL 12, 1988  
VINCRIStINE SULFATE  
 AP BULL LABS 1MG/VIAL~~M~~ N71559 001  
 APR 11, 1988  
 AP 2MG/VIAL~~M~~ N71560 001  
 APR 11, 1988  
 AP 5MG/VIAL~~M~~ N71561 001  
 APR 11, 1988  
 AP QUAD PHARMS 1MG/VIAL~~M~~ N71222 001  
 MAR 07, 1988  
 AP 2MG/VIAL~~M~~ N71223 001  
 MAR 07, 1988  
 AP 5MG/VIAL~~M~~ N71937 001  
 MAR 07, 1988  
VINCRIStINE SULFATE PFB  
 AP BULL LABS 1MG/ML~~M~~ N71484 001  
 APR 19, 1988

WARFARIN POTASSIUM

~~/TABLET;/ORAL/  
 /ATHROMBIN-X;/  
 /PURDUE/FRDRK/ 15MG/  
 3 PURDUE FRDRK 5MG~~ ~~/N11771/004/  
 N11771 004~~

WATER FOR INJECTION, STERILE

LIQUID; N/A  
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER  
 AP KENDALL MCGAM 100~~M~~ N19633 001  
 FEB 29, 1988

XYLOSE

POWDER; ORAL  
~~/AA/~~ ~~/XYLOSE/~~ ~~/25GM/BOT/~~  
~~/LYNE/LABS/~~ ~~/N18856/001/~~  
~~/MAR/26/1987/~~  
 3 LYNE LABS 25GM/BOT N18856 001  
 MAR 26, 1987

WATER FOR INJECTION, STERILE

LIQUID; N/A  
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER  
 AP BAXTER 100~~M~~ N18632 002  
 APR 19, 1988

ACETAMINOPHEN

SUPPOSITORY; RECTAL

NEOPAP			
/NEPCON/PHARMS/	/120MG/	/N16401/001/	
ALCON LABS	120MG	N16401 001	
TYLENOL			
MCNEIL CONSUMER	120MG	N17756 002	> DLT >
	650MG	N17756 001	> DLT >
/MCNEIL/LABS/	/120MG/	/N17756/002/	> DLT >
	/650MG/	/N17756/001/	> ADD >

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE

/TABLET;/CONTROLLED/RELEASE;/ORAL/			
/BROMATAPP/			
/COPLY/PHARM/	/12MG;75MG/	/N71099/001/	
		/JUL/02/1987/	

BROMPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL			
BROMATAPP			
COPLY PHARM	12MG;75MG	N71099 001	
		JUL 02, 1987	

BUTYL METHOXYDIBENZOYL METHANE; PADIMATE O

LOTION; TOPICAL			
PHOTOPLEX			
HERBERT LABS	3%;72M	N19459 001	
		SEP 30, 1988	

CHLORHEXIDINE GLUCONATE

Sponge; TOPICAL			
PHARMASEAL SCRUB CARE			
BAXTER	42M	N19793 001	
		DEC 02, 1988	

CHLORPHENIRAMINE MALEATE

Capsule, CONTROLLED RELEASE; ORAL			
CHLORPHENIRAMINE MALEATE			
CORD LABS	12MG	N70797 001	
		AUG 12, 1988	

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	

DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE

Tablet, CONTROLLED RELEASE; ORAL

RESPORAL			
PIONEER PHARMS	6MG;120MG	N89139 001	
		JUN 16, 1988	

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

Syrup; ORAL

PHENERGAN DM			
NYETH AYERST LABS	15MG/5ML;6.25MG/5ML	N11265 003	
		AUG 11, 1988	

HYDROCORTISONE

Ointment; TOPICAL

HC (HYDROCORTISONE)			
C&M PHARMA	0.5%	N80481 001	

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	

IBUPROFEN

TABLET; ORAL  
IBUPROFEN

MYLAN PHARMS 200MG  
PRIVATE FMLTNS 200MG  
ZENITH LABS 200MG

MUPRIN

BRISTOL MYERS 200MG  
200MG

~~/D/PHN/~~ ~~/200MG/~~  
~~/200MG/~~

2 200MG  
2 200MG

N71870 001  
MAY 05, 1988  
N72299 001  
JUL 01, 1988  
N72040 001  
APR 29, 1988

N72035 001  
FEB 16, 1988  
N72036 001  
FEB 16, 1988  
~~/N19812/881/~~  
~~/MAY/16./1988/~~  
~~/N19812/883/~~  
~~/JUL/29./1987/~~  
N19012 001  
MAY 18, 1984  
N19012 003  
JUL 29, 1987

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL  
IMODIUM A-D

MCNEIL CONSUMER 1MG/5MLM

N19487 001  
MAR 01, 1988

NONOXYNOL-9

SPONGE; VAGINAL  
TODAY

~~/9/1/~~ ~~/16/~~

WHITEHALL LABS 1GM

~~/N18683/881/~~  
~~/APR/01./1983/~~  
N18683 001  
APR 01, 1983

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PHENERGAN VC

NYETH AYERST LABS 10MG/5ML; 6.25MG/5MLM

N08604 004  
AUG 11, 1988

INSULIN SEMISYNTHETIC PURIFIED HUMAN; INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION  
MIXTARD HUMAN 70/30  
NORDISK USA

30 UNITS/ML;  
70 UNITS/MLM

N19585 001  
MAR 11, 1988

TIOCONAZOLE

CREAM; TOPICAL

~~/TIOCONAZOLE/~~  
~~/3/PFIZER/LABS/~~

~~/1%~~

~~/N18682/881/~~  
~~/FEB/18./1983/~~

TZ-3

3 PFIZER LABS

1%

N18682 001  
FEB 18, 1983

INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION  
HUMULIN U

~~/LILLY/~~

~~/40/UNITS/ML/~~

~~/N19571/881/~~  
~~/JUN/10./1987/~~  
N19571 001  
JUN 10, 1987

INSULIN ZINC SUSP PURIFIED BEEF/PORK

> DLT > ~~/INJECTABLE;/INJECTION/~~  
> DLT > ~~/LENTARD;/~~  
> DLT > ~~/SQUIBB/NOVO/~~  
> ADD > 2 SQUIBB NOVO

~~/100/UNITS/ML/~~  
100 UNITS/ML

~~/N18384/881/~~  
N18384 001

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

~~/BETAPRONE 442/  
/SOLUTION; CHEMICAL/STERILIZING/AGENT/  
/BETAPRONE/  
/ONEAL/JONES/FEIDMAN//996M/100ML/ /N/1653/~~

## 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 <sup>1</sup> AUG 31, 1995
LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL	LEUCOVORIN CALCIUM INJECTABLE; INJECTION	LEDERLE LABS	08107 002 AUG 31, 1988	ODE <sup>1</sup> AUG 31, 1995
LEUCOVORIN CALCIUM EQ 100MG BASE/VIAL	LEUCOVORIN CALCIUM INJECTABLE; INJECTION	LEDERLE LABS	08107 004 AUG 31, 1988	ODE <sup>1</sup> AUG 31, 1995
LEUCOVORIN CALCIUM EQ 60MG BASE/VIAL	LEUCOVORIN CALCIUM POWDER FOR RECONSTITUTION; ORAL	LEDERLE LABS	08107 003 AUG 31, 1988	ODE <sup>1</sup> AUG 31, 1995

<sup>1</sup>ODE 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 <sup>2</sup> APR 07, 1995
METHOTREXATE SODIUM EQ 50MG BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 003 APR 07, 1988	ODE <sup>2</sup> APR 07, 1995
METHOTREXATE SODIUM EQ 100MG BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 006 APR 07, 1988	ODE <sup>2</sup> APR 07, 1995
METHOTREXATE SODIUM EQ 1GM BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 009 APR 07, 1988	ODE <sup>2</sup> APR 07, 1995
METHOTREXATE SODIUM EQ 25MG BASE/ML	METHOTREXATE LPF INJECTABLE; INJECTION	LEDERLE LABS	11719 007 APR 07, 1988	ODE <sup>2</sup> 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

<sup>2</sup>ODE 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

*Jan 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	
<del>CONJUGATED ESTROGEN (TABLET)*</del>	<del>DEC 17, 1988</del>	
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 numbered  
 approvals vs denials*

ANDA SUITABILITY PETITIONS

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 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	DEC 29, 1993
18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN				NP	AUG 01, 1991
18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
>DLT>	<del>19489 001</del>	<del>BUTYL METHOXYDIBENZOYL METHANE; PHOTOPLEX</del>	<del>4387089</del>	<del>JUN 07, 2000</del>		
>ADD>	19459 001	BUTYL METHOXYDIBENZOYL METHANE; PHOTOPLEX	4387089	JUN 07, 2000		
>DLT>	<del>18550 002</del>	<del>CARPROFEN; RIMADYL</del>	<del>3896145</del>	<del>JUL 22, 1994</del>		
>ADD>	18550 002	CARPROFEN; RIMADYL	3896145	JUL 22, 1994		
>DLT>	<del>18550 003</del>	<del>CARPROFEN; RIMADYL</del>	<del>3896145</del>	<del>JUL 22, 1994</del>		
>ADD>	18550 003	CARPROFEN; RIMADYL	3896145	JUL 22, 1994		
>ADD>	19204 001	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		
>ADD>	19204 002	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		
>ADD>	19204 003	CARTEOLOL HYDROCHLORIDE; CARTROL	3910924	OCT 07, 1992		
>ADD>	19574 001	CHLORTHALIDONE; THALITONE				
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		
>ADD>	17920 002	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		
17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		NDF	DEC 30, 1991
17920 004	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
17920 005	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		D-12	APR 30, 1989
17924 001	CIMETIDINE HYDROCHLORIDE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
18057 004	CISPLATIN; PLATINOL-AQ	3950333	APR 13, 1993		D-12	APR 30, 1989
18891 001	CLONIDINE; CATAPRES-TTS-1	4310515	JAN 12, 1999		D-14	MAR 31, 1991
18891 002	CLONIDINE; CATAPRES-TTS-2	4177263	DEC 04, 1996		D-12	APR 30, 1989
18891 003	CLONIDINE; CATAPRES-TTS-3	4201211	MAY 06, 1997			
		4060084	JUN 28, 1994			
		3996934	JUL 29, 1992			
		4201211	MAY 06, 1997			
		4060084	JUN 28, 1994			
		3996934	JUL 29, 1992			

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

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
>ADD>	19357 001	ETHANOLAMINE OLEATE; ETHAMOLIN	4387103	JUN 07, 2000	U-16	
>ADD>					ODE	DEC 22, 1995
	19462 001	FAMOTIDINE; PEPCID			NP	DEC 22, 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	I-80	OCT 17, 1991
			3900481	AUG 19, 1992	NS	JUN 03, 1991
	18830 004	FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996	NCE	OCT 31, 1990
			3900481	AUG 19, 1992		
	19452 001	FLUOCINOLONE ACETONIDE; DERMA-SMOOTH/FS			NCE	OCT 31, 1990
	18936 001	FLUOXETINE HYDROCHLORIDE; PROZAC	4683235	JUL 28, 2004	NDF	FEB 03, 1991
			4647591	MAR 03, 2004	U-30	
			4647591	MAR 03, 2004	U-28	
			4626549	DEC 02, 2003	U-29	
			4626549	DEC 02, 2003	U-26	
>DLT>			<del>4314081</del>	<del>FEB 02, 1999</del>	U-27	
>ADD>			4314081	FEB 02, 2001		
	18766 002	FLURBIPROFEN; ANSAID	4194009	APR 19, 1994		
			3793457	FEB 19, 1993		
			3755427	AUG 28, 1990	NCE	DEC 31, 1991
	18766 003	FLURBIPROFEN; ANSAID	3793457	FEB 19, 1993	NDF	OCT 31, 1991
			3755427	AUG 28, 1990	NCE	DEC 31, 1991
	19404 001	FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1993	NDF	OCT 31, 1991



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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
					D-15	MAY 13, 1991
>ADD>	19763 001	IFOSFAMIDE; IFEX	3732340	MAY 08, 1990	ODE	DEC 30, 1995
>ADD>					NCE	DEC 30, 1993
>ADD>	19763 002	IFOSFAMIDE; IFEX	3732340	MAY 08, 1990	ODE	DEC 30, 1995
>ADD>					NCE	DEC 30, 1993
>DLT>	<del>19432 001</del>	<del>IOPETAMINE HYDROCHLORIDE I-123; SPECTAMINE</del>	<del>4360511</del>	<del>NOV 23, 1990</del>	<del>NCE</del>	<del>OCT 24, 1992</del>
>ADD>	19432 001	IOPETAMINE HYDROCHLORIDE I-123; SPECTAMINE	4360511	NOV 23, 2001	NCE	DEC 24, 1992
	18956 002	IOHEXOL; OMNIPAQUE 240			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
					I-77	JUL 29, 1991
	18956 005	IOHEXOL; OMNIPAQUE 140	4396597	JUL 14, 1998	I-82	NOV 30, 1991
			4250113	DEC 26, 1999	NCE	DEC 26, 1990
			4021481	MAY 03, 1994	NS	NOV 30, 1991
>ADD>	19710 001	IOVERSOL; OPTIRAY-320			NCE	DEC 30, 1993
>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 29, 1991
	08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			ODE	AUG 31, 1995
					I-79	AUG 31, 1995
	08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			ODE	AUG 31, 1995
					I-79	AUG 31, 1995
	08107 003	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			ODE	AUG 31, 1995
					I-79	AUG 31, 1995
	08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			ODE	AUG 31, 1995
					I-79	AUG 31, 1995

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>DLT>	19888 007 LISINAPRIL; PRINIVIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
>ADD>	19558 001 LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT>	19888 002 LISINAPRIL; PRINIVIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
>ADD>	19558 002 LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT>	19888 003 LISINAPRIL; PRINIVIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
>ADD>	19558 003 LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>ADD>	19558 004 LISINAPRIL; PRINIVIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT>	19777 001 LISINAPRIL; ZESTRIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
>ADD>	19777 001 LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT>	19777 002 LISINAPRIL; ZESTRIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
>ADD>	19777 002 LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	DEC 29, 1992
>DLT>	19777 003 LISINAPRIL; ZESTRIL	4374829	FEB 22, 2000		NCE	DEC 29, 1992
>ADD>	19777 003 LISINAPRIL; 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-78	APR 07, 1995
					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>	<del>19436 001</del>	<del>4313951</del>	<del>FEB 02, 2001</del>		<del>NCE</del>	<del>DEC 20, 1990</del>
>ADD>	19436 001	4313951	FEB 02, 2001		NCE	DEC 31, 1992
19501 001	MINOXIDIL; ROGAINE	4596812	FEB 13, 1996			
>ADD>	19268 001	4139619	FEB 13, 1996		NDF	AUG 17, 1991
>ADD>		4459310	JUL 10, 2001	U-37		
>ADD>		4301146	NOV 17, 1998			
>ADD>		4060691	JUN 22, 1993			
>ADD>		3965143	JUN 22, 1993		NCE	DEC 27, 1993
>ADD>	19297 001	4278689	JUL 14, 2000			
19516 002	MORPHINE SULFATE; MS CONTIN				NDF	MAY 29, 1990
18677 001	NABILONE; CESAMET					
19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4087545	MAY 02, 1997	U-7		
>ADD>	19488 001	4282251	AUG 04, 1998		NCE	MAR 01, 1993
>ADD>	18869 001	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				NCE	OCT 21, 1993
>ADD>	19385 001				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	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	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	4797405	JAN 10, 2006			
		4180582	DEC 25, 1996	U-35		
		4180582	DEC 25, 1996	U-36		
		4166182	AUG 28, 1996		NCE	DEC 30, 1993
		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> <del>19530 001</del>	<del>SODIUM BENZOATE; UCEPHAN</del>	<del>4284647</del>	<del>AUG 18, 1998</del>	<del>U-24</del>	<del>NCE</del>	<del>DEC 23, 1992</del>
>ADD> 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> <del>19579 001</del>	<del>TERCONAZOLE; TERAZOL 7</del>	<del>4358449</del>	<del>NOV 09, 1999</del>		<del>NCE</del>	<del>DEC 31, 1992</del>
>ADD> 19579 001	TERCONAZOLE; TERAZOL 7	4358449	NOV 09, 2001		NCE	DEC 31, 1992
>DLT> <del>19641 001</del>	<del>TERCONAZOLE; TERAZOL 3</del>	<del>4358449</del>	<del>NOV 09, 1999</del>		<del>NCE</del>	<del>DEC 31, 1992</del>
>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
					ODE	AUG 11, 1995
18207 003	TRAZODONE HYDROCHLORIDE; DESYREL	4258027	MAR 24, 1998			
>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