

JAN 1 1 1988

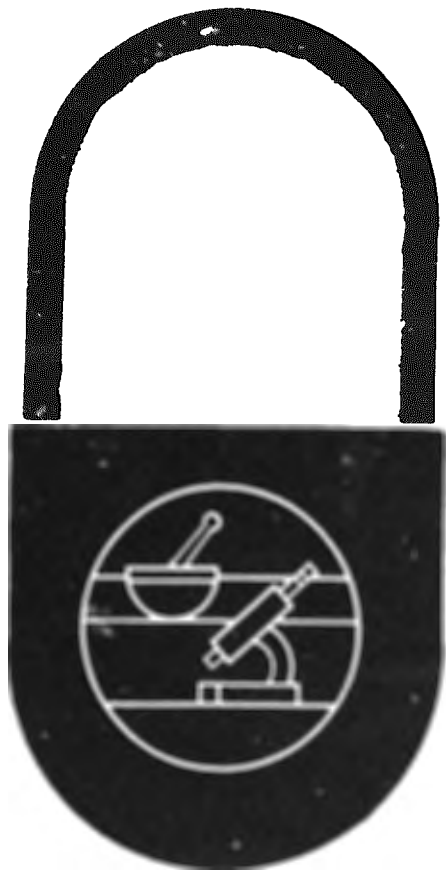
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CUMULATIVE  
SUPPLEMENT 10

JAN'88-OCT'88

CONTIN



# APPROVED DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

8<sup>TH</sup> EDITION

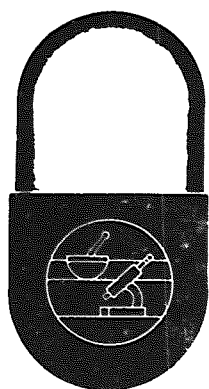
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

*Handwritten initials: J.A.*

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**APPROVED  
DRUG PRODUCTS**

**WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**9<sup>TH</sup> EDITION**

**CONTENTS**

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- OTC Drug Product List
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- Biopharmaceutic Guidance Availability
- ANDA Suitability Petitions
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APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS  
8TH EDITION

CUMULATIVE SUPPLEMENT 11

NOVEMBER 1988

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**APPROVED DRUG PRODUCTS**  
**with**  
**THERAPEUTIC EQUIVALENCE EVALUATIONS**  
**8th EDITION**  
**CUMULATIVE SUPPLEMENT 10**  
**OCTOBER 1988**

**1.0 INTRODUCTION**

**1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT**

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 8th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products in the Division of Blood and Blood Products approved under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

Products discontinued from marketing or products which have had their approval withdrawn for other than safety or effectiveness reasons, will be flagged in this Cumulative Supplement with the "ⓐ" symbol to designate their non-marketed status. All products having a "ⓐ" symbol in the 12th Cumulative Supplement of the 8th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 9th Edition.

**1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL**

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

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

**1.3 APPLICANT (NAME) CHANGES**

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

**APPLICANT (NAME) CHANGES**

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>NEW ABBREVIATED NAME</u>
AYERST LABORATORIES INC DIV AMERICAN HOME PRODUCTS CORP	WYETH AYERST LABORATORIES INC	WYETH AYERST LABS
NOVOCOL CHEMICAL MANUFACTURING COMPANY INC	NOVOCOL PHARMACEUTICAL INC	NOVOCOL PHARM
WYETH INC	WYETH AYERST LABORATORIES INC	WYETH AYERST LABS
WYETH LABORATORIES INC	WYETH AYERST LABORATORIES INC	WYETH AYERST LABS
MY K LABORATORIES INC	PHARMACEUTICAL BASICS INC	PHARM BASICS

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#### 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>MAR 1988</u>	<u>JUN 1988</u>	<u>SEP 1988</u>
DRUG PRODUCTS LISTED	9709	9528	9769	9993*
SINGLE SOURCE	2096 (21.6%)	1997 (21.0%)	1975 (20.2%)	1973 (19.7%)
MULTISOURCE	7613 (78.4%)	7531 (79.0%)	7794 (79.8%)	8020 (80.3%)
THERAPEUTICALLY EQUIVALENT	6691 (68.9%)	6660 (69.9%)	6937 (71.0%)	7161 (71.7%)
NOT THERAPEUTICALLY EQUIVALENT	848 ( 8.7%)	770 ( 8.1%)	757 ( 7.8%)	749 ( 7.5%)
EXCEPTIONS <sup>2</sup>	74 ( 0.8%)	101 ( 1.0%)	100 ( 1.0%)	110 ( 1.1%)
NEW MOLECULAR ENTITIES APPROVED	--	1	2	3
NUMBER OF APPLICANTS	349	361	378	387

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

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PREScription DRUG PRODUCT LIST  
8TH EDITION  
CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'88 - OCT'88

1

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL

BUTALBITAL AND ACETAMINOPHEN

> ADD > AB HALSEY DRUG 325MG;50MG N89568 001  
> ADD > 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

ACETAMINOPHEN; CODEINE PHOSPHATE

ELIXIR; ORAL

MYAPAP AND CODEINE

AA MY K LABS 120MG/5ML;12MG/5ML N87006 001  
/AA/ /MYAPAP W/ CODEINE/ /120MG/5ML;12MG/5ML/ /N87006/001/  
/AA/ /TYLENOL W/ CODEINE/ /120MG/5ML;12MG/5ML/ /N85057/001/  
/AA/ /MCNEIL/LABS/ 120MG/5ML;12MG/5ML N85057 001

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

AA BARR LABS 300MG;30MG N85794 001  
/AA/ /BOOTS/LABS/ /300MG;30MG/ /N87762/001/  
/DEC/10/1988/  
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  
/AA/ /ACETAMINOPHEN W/ CODEINE/ /300MG;30MG/ /N85794/001/

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN W/ CODEINE PHOSPHATE/

/AA/ /HALSEY/DRUG/ /300MG;60MG/ /N85549/001/  
/AA/ /TYLENOL W/ CODEINE/ /325MG;7.5MG/ /N85056/001/  
/AA/ /MCNEIL/LABS/ /325MG;15MG/ /N85056/002/  
/AA/ /325MG;30MG/ /N85056/003/  
/AA/ /325MG;60MG/ /N85056/004/  
AA MCNEIL PHARM 325MG;7.5MG N85056 001  
AA 325MG;15MG N85056 002  
AA 325MG;30MG N85056 003  
AA 325MG;60MG N85056 004  
/AA/ /TYLENOL W/ CODEINE NO. 1/ /300MG;7.5MG/ /N85055/001/  
AA MCNEIL PHARM 300MG;7.5MG N85055 001  
/AA/ /TYLENOL W/ CODEINE NO. 2/ /300MG;15MG/ /N85055/002/  
AA MCNEIL PHARM 300MG;15MG N85055 002  
/AA/ /TYLENOL W/ CODEINE NO. 3/ /300MG;30MG/ /N85055/003/  
AA MCNEIL PHARM 300MG;30MG N85055 003  
/AA/ /TYLENOL W/ CODEINE NO. 4/ /300MG;60MG/ /N85055/004/  
AA MCNEIL PHARM 300MG;60MG N85055 004

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

ACETAMINOPHEN AND HYDROCODONE BITARTRATE

> ADD > AA GRAHAM LABS 500MG;5MG N87336 001  
> ADD > JUL 08, 1982  
AA CO-GESIC 500MG;5MG N89360 001  
MAR 02, 1988  
> DLT > /LORGET-HD/ /N87336/001/  
> DLT > /AA/ /GRAHAM/LABS/ /500MG;5MG/ /JUL/08/1982/  
> DLT >

TABLET; ORAL

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  
AA LUCHEM PHARMS 500MG;5MG N89696 001  
APR 21, 1988  
AA MIKART 650MG;7.5MG N89689 001  
JUN 29, 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  
LD/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  
RAUTENSIN  
 /BP/ DORSEY/LABS/ 2MG/ N09215/001/  
 3 DORSEY LABS 2MG N09215 001  
RAUNILOID  
 /BP/ RIKER/LABS/ 2MG/ N08867/001/  
 RAUNILOID 2MG N08867 001  
 RIKER LABS

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL  
AMANTADINE HCL  
 /BP/ 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/ 3.5%/ N18875/001/  
NOV/08/1984/  
 3 ABBOTT LABS 3.5% N18875 001  
 AUG 08, 1984  
NEOPHAN/6.4%/  
KABIVITRUM/ 6.4%/ N18792/001/  
JAN/17/1984/  
 3 KABIVITRUM 6.4% N18792 001  
 JAN 17, 1984  
 TRAVASOL 10% IN PLASTIC CONTAINER  
 BAXTER 10% N18931 004  
 APR 27, 1988

AMINO ACIDS

INJECTABLE; INJECTION  
 > ADD > TROPHAMINE 10%  
 > ADD > KENDALL MCGAW 10%  
 > ADD > 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/100MLM N19714 001  
 SEP 12, 1988

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/100MLM 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/100MLM 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/100MLM 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/100MLM N19713 006  
 SEP 09, 1988

AMINOSYN II 3.5% IN DEXTROSE 5% IN PLASTIC CONTAINER  
 ABBOTT LABS 3.5%;5GM/100MLM N19713 002  
 SEP 09, 1988

AMINOSYN II 4.25% IN DEXTROSE 10% IN PLASTIC CONTAINER  
 ABBOTT LABS 4.25%;10GM/100MLM N19713 001  
 SEP 09, 1988

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION  
 AMINOSYN II 4.25% IN DEXTROSE 20% IN PLASTIC CONTAINER  
 ABBOTT LABS 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 N19713 005  
 SEP 09, 1988

AMINOSYN II 5% IN DEXTROSE 25% IN PLASTIC CONTAINER  
 ABBOTT LABS 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 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 N19712 001  
 SEP 08, 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  
 > DLT > /AMINO/3.5%/N/IN/PLASTIC/CONTAINER/  
 > DLT > /ABBOTT/LABS/ /3.5%;21MG/100ML;40MG/100ML;/  
 > DLT > /128MG/100ML;/  
 > DLT > /234MG/100ML/ /N18875/002/  
 > DLT > /AUG/08./1984/  
 > ADD > @ ABBOTT LABS 3.5%;21MG/100ML;40MG/100ML;  
 > ADD > 128MG/100ML;  
 > ADD > 234MG/100ML N18875 002  
 > ADD > AUG 08, 1984

AMINOCAPROIC ACID

INJECTABLE; INJECTION  
AMINOCAPROIC ACID  
 AP ABBOTT LABS 250MG/ML N70888 001  
 JUN 16, 1988

AMINOHIPPURATE SODIUM

INJECTABLE; INJECTION  
AMINOHIPPURATE SODIUM  
 AP MS&D 20% N05619 001  
 AP QUAD PHARMS 20% N89821 001  
 JUL 14, 1988

AMINOPHYLLINE

TABLET; ORAL  
AMINOPHYLLINE  
 /BD/ /BARR/LABS/ /100MG/ /N88297/001/  
 /BD/ /AUG/19./1983/  
 /BD/ /200MG/ /N88298/001/  
 /AUG/19./1983/  
 @ BARR LABS 100MG N88297 001  
 AUG 19, 1983  
 @ 200MG N88298 001  
 AUG 19, 1983  
 BD HALSEY DRUG 100MG N84674 001  
 /12/ /N84674/001/  
 /12/ /VALE/CHEM/ /100MG/ /N84533/001/  
 /12/ /VALE/CHEM/ /100MG/ /N84533/001/  
 BD VALE CHEM 100MG N84533 001

AMINOSALICYLATE SODIUM

TABLET; ORAL  
TEBACIN  
 /BP/ /CONSOL/MIDLAND/ /500MG/ /N07320/002/  
 @ CNSOL MIDLAND 500MG N07320 002

AMITRIPTYLINE HYDROCHLORIDE

TABLET; ORAL  
AMITRI  
 /AB/ /PARKE/DAVIS/ /10MG/ /N83934/001/  
 /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  
 > DLT > /AB/ /AMITRIPTYLINE HCL/ /10MG/ /N86744/001/  
 > DLT > /AB/ /LEDERLE/LABS/ /25MG/ /N86746/001/  
 > DLT > /AB/ /50MG/ /N86743/001/  
 > DLT > /AB/ /75MG/ /N86745/001/  
 > DLT > /AB/ /100MG/ /N86747/001/  
 > ADD > @ LEDERLE LABS 10MG N86744 001  
 > ADD > @ 25MG N86746 001  
 > ADD > @ 50MG N86743 001  
 > ADD > @ 75MG N86745 001  
 > ADD > @ 100MG N86747 001

AMITRIPTYLINE HYDROCHLORIDE; CHLORDIAZEPOXIDE

TABLET; ORAL  
CHLORDIAZEPOXIDE AND AMITRIPTYLINE HCL  
 AB PAR PHARM EQ 12.5MG BASE;5MG N72277 001  
 MAY 09, 1988  
 AB 25MG;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

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

AB	CLOMEL CHEMS	250MG	N62884 001
			FEB 25, 1988
AB		500MG	N62881 001
			FEB 25, 1988

POWDER FOR RECONSTITUTION; ORAL

POLYMOX

AB	BRSTL MYRS IND	125MG/5ML	N62885 001
			MAR 08, 1988
AB		250MG/5ML	N62885 002
			MAR 08, 1988

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

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

AMPICILLIN/AMPICILLIN TRIHYDRATE

CAPSULE; ORAL

AMPICILLIN

AB	CLOMEL CHEMS	EQ 250MG BASE	N62883 001
			FEB 25, 1988
AB		EQ 500MG BASE	N62882 001
			FEB 25, 1988
AB	LEDERLE LABS	EQ 250MG BASE	N62208 001
AB		EQ 500MG BASE	N62208 002

POLYCYLLIN

AB	BRSTL MYRS IND	EQ 250MG BASE	N62888 001
			MAR 04, 1988
AB		EQ 500MG BASE	N62888 002
			MAR 04, 1988

AMPICILLIN/AMPICILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

> DLT >	AYERST LABS	EQ 125MG BASE/5ML	N50019 002
> DLT >		EQ 250MG BASE/5ML	N50019 003
> DLT >		EQ 100MG BASE/ML	N50019 001
> ADD >	AYERST LABS	EQ 125MG BASE/5ML	N50019 002
> ADD >		EQ 250MG BASE/5ML	N50019 003
> ADD >		EQ 100MG BASE/ML	N50019 001

ANILERIDINE HYDROCHLORIDE

TABLET; ORAL

ANILERIDINE

MS&D

EQ 25MG BASE

N10585 002

EQ 25MG BASE

N10585 002

N10585 002

ANILERIDINE PHOSPHATE

INJECTABLE; INJECTION

ANILERIDINE

MS&D

EQ 25MG BASE/ML

N10520 003

EQ 25MG BASE/ML

N10520 003

N10520 003

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE COMPOUND

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

ORPHENADRINE COMPOUND DOUBLE STRENGTH

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

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

COMPOUND 65

AB	BANMAX PHARMS	389MG;32.4MG;65MG	N84553 002
			AUG 17, 1983

EQ 389MG;32.4MG;65MG

389MG;32.4MG;65MG

N84553 002

AUG 17, 1983

ASPIRIN; HYDROCODONE BITARTRATE

TABLET; ORAL  
AZDONE

CENTRAL PHARMS 500MG;5MG N89420 001  
JAN 25, 1988

ATENOLOL

TABLET; ORAL  
ATENOLOL

AB ICI PHARMS 50MG N72303 001  
JUL 15, 1988  
AB 100MG N72304 001  
JUL 15, 1988

TENORMIN

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

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL

~~/MOTOFEN/  
/CARNRICK/LABS/  
MOTOFEN~~ ~~/0.025MG;1MG/  
/N17744/002/~~  
CARNRICK LABS 0.025MG;1MG N17744 002

AZATHIOPRINE SODIUM

INJECTABLE; INJECTION

AZATHIOPRINE

AP QUAD PHARMS EQ 100MG BASE/VIAL N71056 001  
JUN 08, 1988

IMURAN

AP BURROUGHS WELLC EQ 100MG BASE/VIAL N17391 001

BACLOFEN

TABLET; ORAL

BACLOFEN

AB PHARM BASICS 10MG N71260 001  
MAY 06, 1988  
AB 20MG N71261 001  
MAY 06, 1988  
AB VITARINE 10MG N71901 001  
APR 13, 1988  
AB 20MG N71902 001  
APR 13, 1988

BACLOFEN

TABLET; ORAL

BACLOFEN

AB ZENITH LABS 10MG N72234 001  
JUL 21, 1988  
AB 20MG N72235 001  
JUL 21, 1988  
AB GEIGY PHARMS 10MG N17851 001  
AB LTORFAL DS GEIGY PHARMS 20MG N17851 003  
JAN 20, 1982

BENZTHIAZIDE

TABLET; ORAL

~~/BENZTHIAZIDE/  
/PRIVATE/FMLTNS/  
3 PRIVATE FMLTNS~~ ~~/50MG/  
50MG~~ ~~/N83206/001/  
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  
~~/0.5MG/  
/1MG/  
/2MG/~~ ~~/N88877/001/  
/APR/11/1985/  
/N88894/001/  
/APR/11/1985/  
/N88895/001/  
/APR/11/1985/~~  
AA PHARM BASICS 0.5MG N89211 001  
JUN 14, 1988  
AA 1MG N89212 001  
JUN 14, 1988  
AA 2MG N89213 001  
JUN 14, 1988

BENZTROPINE MESYLATE

TABLET; ORAL

BENZTROPINE MESYLATE

AA	QUANTUM PHARMS	0.5MG	N88514 001 JAN 31, 1984
AA		1MG	N88510 001 JAN 31, 1984
AA		2MG	N88511 001 JAN 31, 1984
/BP/		/0.5MG/	/N88514/001/ /JAN 31, 1984/
/BP/		/1MG/	/N88510/001/ /JAN 31, 1984/
/BP/		/2MG/	/N88511/001/ /JAN 31, 1984/
AA	SIDMAK LABS	0.5MG	N89058 001 AUG 10, 1988
AA		1MG	N89059 001 AUG 10, 1988
AA		2MG	N89060 001 AUG 10, 1988
<u>COGENTIN</u>			
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/

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
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BETAMETHASONE VALERATE

LOTION; TOPICAL

BETAMETHASONE VALERATE

AB	COPLEY PHARM	EQ 0.1% BASEM	N71883 001 APR 22, 1988
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BETAZOLE HYDROCHLORIDE

INJECTABLE; INJECTION

HISTALOG

/LILLY/

2 LILLY

/50MG/ML/  
50MG/ML

/N09344/001/  
N09344 001

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

BETHANECHOL CHLORIDE

AP	QUAD PHARMS	5MG/ML	N89815 001 APR 12, 1988
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AP	MS&D	5MG/ML	N06536 001
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BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

BRETYLIUM TOSYLATE

AP	LUITPOLD PHARMS	50MG/ML	N70891 001 JUL 26, 1988
AP	QUAD PHARMS	50MG/ML	N71181 001 FEB 16, 1988

BROMPHENIRAMINE MALEATE

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/	/BARR LABS/	/4MG/	/N84468/001/ N84468 001
	2 BARR LABS	4MG	

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

SOLUTION; INTRAPERITONEAL

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

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

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

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

INPERSOL W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

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

INPERSOL-LM W/ DEXTROSE 3.5% IN PLASTIC CONTAINER

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

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

INJECTABLE; INJECTION

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

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

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

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

DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

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

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

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

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

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

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

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

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

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

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

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

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

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 40MEG IN DEXTROSE 5% AND LACTATED

RINGER'S IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 5MEG IN DEXTROSE 5% AND LACTATED

RINGER'S IN PLASTIC CONTAINER

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

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

AP KENDALL MCGAW 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

> ADD > AA PIONEER PHARMS 350MG N89390 001  
 > ADD > OCT 13, 1988  
 AA VITARINE 350MG N89566 001  
 AUG 30, 1988

CARPHENAZINE MALEATE

> DLT > /TABLET;/ORAL/  
 > DLT > /PROXETAZINE/  
 > DLT > /NYETH/AYERST/LABS/ /25MG/  
 > ADD > @ NYETH AYERST LABS 25MG N12768/882/  
 > DLT > /50MG/ N12768 002  
 > ADD > @ 50MG /50MG/ N12768/884/  
 N12768 004

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 EQ 5GM BASE/VIAL N50461 004

CEFAZOLIN SODIUM

AP BEN VENUE LABS EQ 250MG BASE/VIALM N62894 001  
 JUL 21, 1988

AP EQ 500MG BASE/VIALM N62894 002  
 JUL 21, 1988

AP EQ 1GM BASE/VIALM N62894 003  
 JUL 21, 1988

AP EQ 5GM BASE/VIALM N62894 004  
 JUL 21, 1988

AP EQ 10GM BASE/VIALM N62894 005  
 JUL 21, 1988

AP ELKINS SINN EQ 250MG BASE/VIALM N62807 001  
 JAN 12, 1988

AP EQ 500MG BASE/VIALM N62807 002  
 JAN 12, 1988

AP EQ 1GM BASE/VIALM N62807 003  
 JAN 12, 1988

AP EQ 5GM BASE/VIALM N62807 004  
 JAN 12, 1988

AP EQ 10GM BASE/VIALM N62807 005  
 JAN 12, 1988

AP EQ 20GM BASE/VIALM N62807 006  
 JAN 12, 1988

CEFOTETAN DISODIUM

INJECTABLE; INJECTION  
 CEFOTAN  
 STUART PHARMS

EQ 10GM BASE/VIALM N50588 003  
 APR 25, 1988

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

AB	JEROME STEVENS	EQ 250MG BASEM	N62870 001 MAR 17, 1988
AB		EQ 500MG BASEM	N62869 001 MAR 17, 1988
AB	LABROS ATRAL	EQ 250MG BASEM	N62713 001 JUL 15, 1988
AB		EQ 500MG BASEM	N62713 002 JUL 15, 1988
AB	TAG PHARMS	EQ 250MG BASEM	N62821 001 FEB 05, 1988
AB		EQ 500MG BASEM	N62823 001 FEB 05, 1988
AB	YOSHITOMI PHARM	EQ 250MG BASEM	N62872 001 JUN 20, 1988
AB		EQ 500MG BASEM	N62871 001 JUL 05, 1988

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN

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

TABLET; ORAL

CEPHALEXIN

AB	VITARINE	EQ 250MG BASEM	N62863 001 AUG 11, 1988
AB		EQ 500MG BASEM	N62863 002 AUG 11, 1988
AB		EQ 1GM BASEM	N62863 003 AUG 11, 1988

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	250MGM	N62850 001 APR 22, 1988
AB		500MGM	N62851 001 APR 22, 1988
AB	VITARINE	250MGM	N62813 001 FEB 25, 1988
AB		500MGM	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

> DLT > /AB/	LEDERLE/LABS/	5MG/	N86892/001/
> DLT > /AB/		10MG/	N86876/001/
> DLT > /AB/		25MG/	N86893/001/
> ADD >	3 LEDERLE LABS	5MG	N86892 001
> ADD >	3	10MG	N86876 001
> ADD >	3	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
/AS/	/PUREPAC/PHARM/	/5MG/	/N85155/001/
/AS/		/10MG/	/N84939/002/
/AS/		/25MG/	/N85144/001/
	Q PUREPAC PHARM	5MG	N85155 001
	Q	10MG	N84939 002
	Q	25MG	N85144 001
/AS/	/LYSEN/	/5MG/	/N85107/002/
/AS/	/BANMAX/PHARMS/	/10MG/	/N85009/001/
/AS/		/25MG/	/N85108/001/
	Q BANMAX PHARMS	5MG	N85107 002
	Q	10MG	N85009 001
	Q	25MG	N85108 001

CHLORMERODRIN, HG-197

> DLT >	/INJECTABLE//INJECTION/		
> DLT >	/CHLORMERODRIN/HG/197/		
> DLT >	/SQUIBB/	/0.6-1.4MCI/ML/	/N17269/001/
> ADD >	Q SQUIBB	0.6-1.4MCI/ML	N17269 001

CHLOROQUINE PHOSPHATE

> DLT >	/INJECTABLE//INJECTION/		
> DLT >	/ARACEN/		
> DLT >	/STERLING/DRUG/	/EQ/40MG/BASE/ML/	/N06002/002/
> ADD >	Q STERLING DRUG	EQ 40MG BASE/ML	N06002 002

TABLET; ORAL

AA	<u>ARALEN</u>		
	STERLING DRUG	EQ 300MG BASE	N06002 001
AA	<u>CHLOROQUINE PHOSPHATE</u>		
	DANBURY PHARMA	EQ 300MG BASE	N88030 001
			DEC 21, 1982
/AA/		/EQ 300MG BASE/	/N88030/001/
			/DEC/21./1982/

CHLOROQUINE PHOSPHATE; PRIMAQUINE PHOSPHATE

> DLT >	/TABLET//ORAL/		
> DLT >	/ARALEN/PHOSPHATE/W//PRIMAQUINE/PHOSPHATE/		
> DLT >	/STERLING/DRUG/	/EQ/300MG/BASE//	/N14860/002/
> ADD >	Q STERLING DRUG	EQ 300MG BASE;	
> ADD >		EQ 45MG BASE	N14860 002

CHLOROTHIAZIDE

TABLET; ORAL

	<u>CHLOROTHIAZIDE</u>		
> DLT >/AS/	/LEDERLE/LABS/	/250MG/	/N86940/001/
> DLT >/AS/		/500MG/	/N86938/001/
> ADD >	Q LEDERLE LABS	250MG	N86940 001
> ADD >	Q	500MG	N86938 001

CHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

	<u>CHLOROTHIAZIDE W/ RESERPINE</u>		
/BP/	/BOLAR/PHARM/	/250MG;0.125MG/	/N84853/001/
	Q BOLAR PHARM	250MG;0.125MG	N84853 001

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

	<u>CHLORPHENIRAMINE MALEATE</u>		
/AA/	/BARR/LABS/	/4MG/	/N80700/001/
	Q BARR LABS	4MG	N80700 001

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

	<u>CHLORPROMAZINE HCL</u>		
AP	MARSAM PHARMS	25MG/MLM	N89563 001
			APR 15, 1988

TABLET; ORAL

	<u>CHLORPROMAZINE HCL</u>		
> DLT >/BP/	/LEDERLE/LABS/	/25MG/	/N84801/001/
> DLT >/BP/		/50MG/	/N84800/001/
> DLT >/BP/		/200MG/	/N84802/001/
> ADD >	Q LEDERLE LABS	25MG	N84801 001
> ADD >	Q	50MG	N84800 001
> ADD >	Q	200MG	N84802 001

CHLORTHALIDONE

TABLET; ORAL  
CHLORTHALIDONE  
 AB MUTUAL PHARM 25MG N89738 001 SEP 19, 1988  
 AB 50MG N89739 001 SEP 19, 1988  
 AB PIONEER PHARMS 50MG N89591 001 JUL 21, 1988

CHLORZOXAZONE

TABLET; ORAL  
CHLORZOXAZONE  
 AA BARR LABS 500MG N89895 001 MAY 04, 1988  
 AA CORD LABS 250MG N89852 001 MAY 04, 1988  
 AA 500MG N89853 001 MAY 04, 1988  
 AA LEMMON 500MG N89859 001 MAY 04, 1988  
 AA PARAFON FORTE DSC 500MG N11529 002 JUN 15, 1987  
 MCNEIL PHARM

CHOLESTYRAMINE

BAR, CHENABLE; ORAL  
 CHOLYBAR  
 PARKE DAVIS EQ 4GM RESIN/BARM N71621 001 MAY 26, 1988  
 EQ 4GM RESIN/BARM N71739 001 MAY 26, 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 BASE N50162 003 APR 14, 1988  
CLINDAMYCIN HCL  
 AB VITARINE EQ 75MG BASE N62910 001 JUL 05, 1988  
 AB EQ 150MG BASE N62910 002 JUL 05, 1988

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE  
 AP ABBOTT LABS EQ 150MG BASE/ML N62943 001 SEP 29, 1988  
 AP LOCH PHARMS EQ 150MG BASE/ML N62905 001 MAY 09, 1988  
 >\_ADD\_> AP MARSAM PHARMS EQ 150MG BASE/ML N62913 001 OCT 20, 1988  
 >\_ADD\_> AP ELKINS SINN EQ 150MG BASE/ML N62953 001 APR 21, 1988  
 AP LEDERLE PARNTLS EQ 150MG BASE/ML N62889 001 APR 25, 1988  
 AP LEMMON EQ 150MG BASE/ML N62900 001 JUN 08, 1988  
 AP LYPHOMED EQ 150MG BASE/ML N62747 001 JUN 03, 1988  
 AP QUAD PHARMS EQ 150MG BASE/ML N62877 001 MAR 15, 1988  
 AP SOLOPAK LABS EQ 150MG BASE/ML N62819 001 MAR 15, 1988  
 AP EQ 150MG BASE/ML 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% BASE N62811 001 SEP 01, 1988

CLOFIBRATE

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

CLOMIPHENE CITRATE

TABLET; ORAL  
~~/68/ /PLANTEX/ /50MG/~~  
 /N18361/001/  
 /MAR/22/1982/

CLOMIPHENE CITRATE

TABLET; ORAL  
SEROPHENE  
 AB SERONO LABS 50MG N18361 001  
 MAR 22, 1982

CLONIDINE

FILM, CONTROLLED RELEASE; PERCUTANEOUS  
 CATAPRES-TTS-1  
 BOEHR INGEL 0.1MG/24HR N18891 001  
 OCT 10, 1984  
 /2.5MG/ /N18891/001/  
 /OCT/10./1984/  
 CATAPRES-TTS-2  
 BOEHR INGEL 0.2MG/24HR N18891 002  
 OCT 10, 1984  
 /5MG/ /N18891/002/  
 /OCT/10./1984/  
 CATAPRES-TTS-3  
 BOEHR INGEL 0.3MG/24HR N18891 003  
 OCT 10, 1984  
 /7.5MG/ /N18891/003/  
 /OCT/10./1984/

CLONIDINE HYDROCHLORIDE

TABLET; ORAL  
CLONIDINE HCL  
 AB CORD LABS 0.1MG N70887 001  
 AUG 31, 1988  
 AB 0.2MG N70886 001  
 AUG 31, 1988  
 AB 0.3MG N71294 001  
 AUG 31, 1988  
 AB LEDERLE LABS 0.1MG N71783 001  
 APR 05, 1988  
 AB 0.2MG N71784 001  
 APR 05, 1988  
 AB 0.3MG N71785 001  
 APR 05, 1988  
 AB WARNER CHILCOTT 0.1MG N72138 001  
 JUN 13, 1988  
 AB 0.2MG N72139 001  
 JUN 13, 1988  
 AB 0.3MG N72140 001  
 JUN 13, 1988

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

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

CLOXACILLIN SODIUM

PONDER FOR RECONSTITUTION; ORAL  
CLOXACILLIN SODIUM  
 AA BIOCRAFT LABS EQ 125MG BASE/5ML N62268 001  
 /AA/ /EQ 125MG BASE/5ML/ /N62268/001/  
TEGOPEN  
 AA BRISTOL LABS EQ 125MG BASE/5ML N50192 001  
 /AA/ /EQ 125MG BASE/5ML/ N61453 001  
 /AA/ /EQ 125MG BASE/5ML/ /N50192/001/  
 /AA/ /EQ 125MG BASE/5ML/ /N61453/001/

COLCHICINE; PROBENECID

TABLET; ORAL  
 PROBENECID AND COLCHICINE  
 /BP/ /BEECHAM/LABS/ /0.5MG;500MG/ /N84321/001/  
 @ BEECHAM LABS 0.5MG;500MG N84321 001  
 PROBENECID W/ COLCHICINE  
 /BP/ /LEDERLE/LABS/ /0.5MG;500MG/ /N86954/001/  
 @ LEDERLE LABS 0.5MG;500MG N86954 001

COPPER

INTRAUTERINE DEVICE; INTRAUTERINE  
 INTRAUTERINE COPPER CONTRACEPTIVE  
 POP COUNCIL CBR APPROX 176MG COPPER<sub>2</sub> N18680 002  
 APR 29, 1988

CYCLACILLIN

TABLET; ORAL  
CYCLACILLIN  
 AB BIOCRAFT LABS 250MG N62895 001  
 AUG 04, 1988  
 AB 500MG N62895 002  
 AUG 04, 1988  
CYCLAPEN-M  
 AB NYETH AYERST LABS 250MG N50509 001  
 AB 500MG N50509 002

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL  
CYCLOBENZAPRINE HCL  
 AB DANBURY PHARMA 10MG N71611 001  
 MAY 03, 1989 : FEB 29, 1988  
FLEXERIL  
 AB MS&D 10MG N17821 002

CYCRIMINE HYDROCHLORIDE

> DLT > /TABLET; ORAL/  
 > DLT > /PAGITANE/  
 > DLT > /LILLY/ /1.25MG/ /N08951/001/  
 > ADD > @ LILLY 1.25MG N08951 001  
 > DLT > /2.5MG/ /N08951/002/  
 > ADD > @ 2.5MG N08951 002

CYTARABINE

INJECTABLE; INJECTION  
CYTOSAR-U  
 UPJOHN 1GM/VIAL N16793 003  
 2GM/VIAL N16793 004  
 DEC 21, 1987  
 DEC 21, 1987

DACARBAZINE

INJECTABLE; INJECTION  
DACARBAZINE  
 QUAD PHARMS 500MG/VIAL 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 DON 10MG N14399 007 FEB 11, 1982  
 AB 150MG N14399 006

DESONIDE

ointment; TOPICAL  
DESONEN  
 AB OWEN LABS 0.05% N71425 001 JUN 15, 1988  
TRIDESILON  
 AB MILES PHARM 0.05% N17426 001

DESOXYCORTICOSTERONE ACETATE

PELLET; IMPLANTATION  
PERCORTEN  
 /CIBA/PHARM/ 125MG/ N05151/001/  
 @ CIBA PHARM 125MG N05151 001

DEXAMETHASONE

TABLET; ORAL  
DEXAMETHASONE  
 /BP/ /BARR/LABS/ 0.25MG/ N84013/001/  
 /BP/ 0.25MG/ N84764/001/  
 /BP/ 0.5MG/ N84084/001/  
 /BP/ 0.75MG/ N84081/001/  
 /BP/ 0.75MG/ N84765/001/  
 /BP/ 1.5MG/ N84086/001/  
 /BP/ 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

DEXAMETHASONE; TOBRAMYCIN

ointment; OPHTHALMIC  
TOBRADEX  
 ALCON LABS 0.1%;0.3% N50616 001  
 SEP 28, 1988

SUSPENSION/DROPS; OPHTHALMIC  
TOBRADEX  
 ALCON LABS 0.1%;0.3% N50592 001  
 AUG 18, 1988

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL  
PHENERGAN N/ DEXTROMETHORPHAN/  
 /AA/ /MYETH/ATERS/LABS/ 1.5MG/5ML; 6.45MG/5ML/ N11265/002/  
 /APR/02./1984/

DEXTROSE

INJECTABLE; INJECTION  
DEXTROSE 10% IN PLASTIC CONTAINER  
 AP KENDALL MCGAN 10GM/100ML N19626 004  
 FEB 02, 1988  
DEXTROSE 2.5% IN PLASTIC CONTAINER  
 KENDALL MCGAN 2.5GM/100ML N19626 001  
 FEB 02, 1988

DEXTROSE

INJECTABLE; INJECTION  
DEXTROSE 5% IN PLASTIC CONTAINER  
 > ADD > AP ABBOTT LABS 50MG/ML N19222 001  
 > ADD > JUL 13, 1984  
 > DLT > /S/ /50MG/ML/ /N19222/001/  
 > DLT > /JUL/13/1984/  
 AP KENDALL MCGAN 5GM/100MLM N19626 002  
 FEB 02, 1988  
 DEXTROSE 7.7% IN PLASTIC CONTAINER  
 KENDALL MCGAN 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/  
 /0.375%/IN/PLASTIC/CONTAINER/  
 /ABBOTT/LABS/ /5GM/100ML;74.5MG/100ML// /N18876/001/  
 /300MG/100ML/ /JAN/17/1986/  
 /DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W//POTASSIUM/CHLORIDE/  
 /0.15%/IN/PLASTIC/CONTAINER/  
 /ABBOTT/LABS/ /5GM/100ML;149MG/100ML// /N18876/002/  
 /300MG/100ML/ /JAN/17/1986/  
 /DEXTROSE/5%/AND/SODIUM/CHLORIDE/0.3%/W//POTASSIUM/CHLORIDE/  
 /0.224%/IN/PLASTIC/CONTAINER/  
 /ABBOTT/LABS/ /5GM/100ML;224MG/100ML// /N18876/003/  
 /300MG/100ML/ /JAN/17/1986/  
 /DEXTROSE/5%/SODIUM/CHLORIDE/0.225%/POTASSIUM/CHLORIDE/  
 /0.15%/IN/PLASTIC/CONTAINER/  
 /ABBOTT/LABS/ /5GM/100ML;150MG/100ML// /N18365/001/  
 /225MG/100ML/ /JAN/17/1986/  
 /DEXTROSE 5% SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/  
 /0.222% IN PLASTIC CONTAINER/  
 /ABBOTT/LABS/ /5GM/100ML;222MG/100ML// /N18362/002/  
 /450MG/100ML/ /JAN/17/1986/  
 /DEXTROSE 5% SODIUM CHLORIDE 0.45% AND POTASSIUM CHLORIDE/  
 /0.3% IN PLASTIC CONTAINER/  
 /ABBOTT/LABS/ /5GM/100ML;294MG/100ML// /N18362/003/  
 /450MG/100ML/ /JAN/17/1986/  
 POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM  
 CHLORIDE 0.2% IN PLASTIC CONTAINER  
 KENDALL MCGAN 10GM/100ML;37MG/100ML;  
 200MG/100MLM N19630 031  
 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION  
 POTASSIUM CHLORIDE 0.037% IN DEXTROSE 10% AND SODIUM  
 CHLORIDE 0.45% IN PLASTIC CONTAINER  
 KENDALL MCGAN 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 MCGAN 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 MCGAN 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 MCGAN 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 MCGAN 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 MCGAN 5GM/100ML;37MG/100ML;  
 450MG/100MLM N19630 019  
 FEB 17, 1988  
 POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% AND SODIUM  
 CHLORIDE 0.9% IN PLASTIC CONTAINER  
 KENDALL MCGAN 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 MCGAN 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 MCGAN 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 MCGAN 10GM/100ML;75MG/100ML;  
 900MG/100MLM N19630 044  
 FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

	<u>POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER</u>		
AP	KENDALL MCGAW	5GM/100ML; 75MG/100ML; 200MG/100MLM	N19630 008 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER</u>		
AP	KENDALL MCGAW	5GM/100ML; 75MG/100ML; 330MG/100MLM	N19630 014 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>		
AP	KENDALL MCGAW	5GM/100ML; 75MG/100ML; 450MG/100MLM	N19630 020 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>		
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
	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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

	<u>POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER</u>		
	KENDALL MCGAW	5GM/100ML; 110MG/100ML; 330MG/100MLM	N19630 015 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>		
	KENDALL MCGAW	5GM/100ML; 110MG/100ML; 450MG/100MLM	N19630 021 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.11% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>		
	KENDALL MCGAW	5GM/100ML; 110MG/100ML; 900MG/100MLM	N19630 027 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER</u>		
	KENDALL MCGAW	10GM/100ML; 150MG/100ML; 200MG/100MLM	N19630 034 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER</u>		
	KENDALL MCGAW	10GM/100ML; 150MG/100ML; 450MG/100MLM	N19630 040 FEB 17, 1988
	<u>POTASSIUM CHLORIDE 0.15% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>		
	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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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

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

POTASSIUM CHLORIDE 0.15% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;150MG/100ML;  
110MG/100MLM N19630 004  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER  
KENDALL MCGAM 10GM/100ML;220MG/100ML;  
200MG/100MLM N19630 035  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
KENDALL MCGAM 10GM/100ML;220MG/100ML;  
450MG/100MLM N19630 041  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
KENDALL MCGAM 10GM/100ML;220MG/100ML;  
900MG/100MLM N19630 047  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;220MG/100ML;  
110MG/100MLM N19630 005  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;220MG/100ML;  
200MG/100MLM N19630 011  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;220MG/100ML;  
330MG/100MLM N19630 017  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;220MG/100ML;  
450MG/100MLM N19630 023  
FEB 17, 1988

POTASSIUM CHLORIDE 0.22% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;220MG/100ML;  
900MG/100MLM N19630 029  
FEB 17, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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

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

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
KENDALL MCGAM 10GM/100ML;300MG/100ML;  
450MG/100MLM N19630 042  
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
KENDALL MCGAM 10GM/100ML;300MG/100ML;  
900MG/100MLM N19630 048  
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER  
AP KENDALL MCGAM 5GM/100ML;300MG/100ML;  
200MG/100MLM N19630 012  
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER  
AP KENDALL MCGAM 5GM/100ML;300MG/100ML;  
330MG/100MLM N19630 018  
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
AP KENDALL MCGAM 5GM/100ML;300MG/100ML;  
450MG/100MLM N19630 024  
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
AP KENDALL MCGAM 5GM/100ML;300MG/100ML;  
900MG/100MLM N19630 030  
FEB 17, 1988

POTASSIUM CHLORIDE 0.3% IN DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER  
KENDALL MCGAM 5GM/100ML;300MG/100ML;  
110MG/100MLM N19630 006  
FEB 17, 1988

POTASSIUM CHLORIDE 10MG IN DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
AP ABBOTT LABS 5GM/100ML;74.5MG/100ML;  
450MG/100MLM N18362 009  
JUL 05, 1983

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

BEST COPY AVAILABLE

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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

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

AP 5GM/100ML;149MG/100ML;  
900MG/100MLM 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/100MLM N18365 002  
JUL 05, 1983

5GM/100ML;149MG/100ML;  
225MG/100MLM 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/100MLM N18876 006  
MAR 28, 1988

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

AP TRAVENOL LABS 5GM/100ML;75MG/100ML;  
900MG/100MLM 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/100MLM 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/100MLM 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/100MLM 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/100MLM N18876 007  
MAR 28, 1988

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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

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

AP 5GM/100ML;298MG/100ML;  
450MG/100MLM 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/100MLM N19691 005  
MAR 24, 1988

AP 5GM/100ML;298MG/100ML;  
900MG/100MLM N19691 008  
MAR 28, 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/100MLM N18365 009  
MAR 28, 1988

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

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

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

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

AP ABBOTT LABS 5GM/100ML;224MG/100ML;  
900MG/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/100MLM N18365 003  
JUL 05, 1983

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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

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

POTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.3% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.45% IN PLASTIC CONTAINER

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

POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUM

CHLORIDE 0.9% IN PLASTIC CONTAINER

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

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

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

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

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

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE

0.45% IN PLASTIC CONTAINER

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

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

POTASSIUM CHLORIDE 5MEQ IN DEXTROSE 5% AND SODIUM CHLORIDE

0.9% IN PLASTIC CONTAINER

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

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

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

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

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

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

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

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

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

DEXTROSE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

DEXTROSE 10% AND SODIUM CHLORIDE 0.11% IN PLASTIC  
CONTAINER

KENDALL MCGAN 10GM/100ML;110MG/100ML N19631 011  
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER

KENDALL MCGAN 10GM/100ML;200MG/100ML N19631 012  
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.33% IN PLASTIC  
CONTAINER

KENDALL MCGAN 10GM/100ML;330MG/100ML N19631 013  
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.45% IN PLASTIC  
CONTAINER

KENDALL MCGAN 10GM/100ML;450MG/100ML N19631 014  
FEB 24, 1988

DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP KENDALL MCGAN 10GM/100ML;900MG/100ML N19631 015  
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.11% IN PLASTIC  
CONTAINER

KENDALL MCGAN 2.5GM/100ML;  
110MG/100ML N19631 001  
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.2% IN PLASTIC  
CONTAINER

KENDALL MCGAN 2.5GM/100ML;  
200MG/100ML N19631 002  
FEB 24, 1988

DEXTROSE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER

KENDALL MCGAN 2.5GM/100ML;  
330MG/100MLM N19631 003  
FEB 24, 1988DEXTROSE 2.5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINERAP KENDALL MCGAN 2.5GM/100ML;  
450MG/100MLM N19631 004  
FEB 24, 1988

DEXTROSE 2.5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

KENDALL MCGAN 2.5GM/100ML;  
900MG/100MLM N19631 005  
FEB 24, 1988

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER

KENDALL MCGAN 5GM/100ML;110MG/100MLM N19631 006  
FEB 24, 1988DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINERAP KENDALL MCGAN 5GM/100ML;200MG/100MLM N19631 007  
FEB 24, 1988DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINERAP KENDALL MCGAN 5GM/100ML;330MG/100MLM N19631 008  
FEB 24, 1988DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINERAP KENDALL MCGAN 5GM/100ML;450MG/100MLM N19631 009  
FEB 24, 1988DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINERAP KENDALL MCGAN 5GM/100ML;900MG/100MLM N19631 010  
FEB 24, 1988DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUM

## INJECTABLE; INJECTION

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

## TABLET; ORAL

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

## TABLET; ORAL

Q-PAMAB QUANTUM PHARMS 2MG N72431 001  
APR 29, 1988  
AB 5MG N72432 001  
APR 29, 1988  
AB 10MG N72433 001  
APR 29, 1988DIAZOXIDE

## CAPSULE; ORAL

PROGLYCEM

MED MKTG SPEC 50MG N17425 001

a 100MG N17425 002

/s/SCHERING/ /50MG/ /N17425/001/

## INJECTABLE; INJECTION

DIAZOXIDEAP QUAD PHARMS 15MG/MLM 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, 198850MG N19201 002  
JUL 28, 198875MG N19201 003  
JUL 28, 1988DICYCLOMINE HYDROCHLORIDE

## SYRUP; ORAL

BENTYLMERRELL DON 10MG/5ML N07961 002  
OCT 15, 1984

&gt; ADD &gt; AA

&gt; ADD &gt;

&gt; ADD &gt;

&gt; ADD &gt; AA

DICYCLOMINE HCL

BARRE NATL 10MG/5ML N84479 001

DIETHYLCARBAMAZINE CITRATE

TABLET; ORAL  
~~NETPAZAN~~  
~~LEDERLE LABS~~ / ~~50MG~~ / ~~N06459/001~~  
 2 LEDERLE LABS 50MG N06459 001

DIFLORASONE DIACETATE

CREAM; TOPICAL  
~~DIFLORASONE DIACETATE~~  
~~UPJOHN~~ / ~~0.05%~~  
 2 UPJOHN 0.05%  
 N19259/001  
 AUG 28, 1985

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL  
~~DIPHENHYDRAMINE HCL~~  
~~LEDERLE LABS~~ / ~~25MG~~ / ~~N06874/001~~  
 > DLT > / ~~66~~ / ~~LEDERLE LABS~~ / ~~50MG~~ / ~~N06875/001~~  
 > DLT > / ~~66~~ / ~~LEDERLE LABS~~ / ~~25MG~~ / ~~N06874 001~~  
 > ADD > 2 LEDERLE LABS 25MG N06874 001  
 > ADD > 2 50MG N06875 001

DISOPYRAMIDE PHOSPHATE

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

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

~~DOPAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER~~  
 / ~~66~~ / ~~TRAVENOL LABS~~ / ~~80MG/100ML~~ / ~~N19615/001~~  
 / ~~66~~ / ~~160MG/100ML~~ / ~~N19615/002~~  
 / ~~66~~ / ~~320MG/100ML~~ / ~~N19615/003~~  
 / ~~66~~ / ~~640MG/100ML~~ / ~~N19615/004~~  
 / ~~NAR/27/1987~~  
 / ~~NAR/27/1987~~  
 / ~~NAR/27/1987~~  
 / ~~NAR/27/1987~~  
 / ~~NAR/27/1987~~

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL  
~~ADAPIN~~  
 AB PENNVALT EQ 150MG BASE N16987 007  
 APR 13, 1987  
~~DOXEPIN HCL~~  
 AB BARR LABS EQ 25MG BASEM N71502 001  
 FEB 18, 1988  
 AB EQ 50MG BASEM N71653 001  
 FEB 18, 1988  
 AB EQ 75MG BASEM N71654 001  
 FEB 18, 1988  
 AB EQ 100MG BASEM N71521 001  
 FEB 18, 1988  
 AB CHELSEA LABS EQ 75MG BASEM N71763 001  
 FEB 09, 1988  
 AB EQ 150MG BASEM N71764 001  
 FEB 09, 1988  
 AB LEDERLE LABS EQ 10MG BASEM N71685 001  
 JAN 05, 1988  
 AB EQ 25MG BASEM N71686 001  
 JAN 05, 1988  
 AB EQ 50MG BASEM N71673 001  
 JAN 05, 1988  
 AB EQ 75MG BASEM N71674 001  
 JAN 05, 1988  
 AB EQ 100MG BASEM N71675 001  
 JAN 05, 1988  
 AB EQ 150MG BASEM N71676 001  
 JAN 05, 1988  
 AB PUREPAC PHARM EQ 75MG BASEM N72386 001  
 SEP 08, 1988  
 AB EQ 100MG BASEM N72110 001  
 SEP 08, 1988  
 AB EQ 150MG BASEM N72387 001  
 SEP 08, 1988

DOXEPIN HYDROCHLORIDE

CONCENTRATE; ORAL

DOXEPIN HCL

AA MY K LABS EQ 10MG BASE/MLM N71918 001  
JUL 20, 1988

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

AB INTERPHARM EQ 50MG BASEM N62763 001  
SEP 02, 1988  
AB EQ 100MG BASEM N62763 002  
SEP 02, 1988  
AB VITARINE EQ 50MG BASEM N62780 001  
APR 12, 1988

INJECTABLE; INJECTION

DOXYCYCLINE

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

TABLET; ORAL

DOXYCYCLINE HYCLATE

AB INTERPHARM EQ 100MG BASEM N62764 001  
SEP 02, 1988

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

AP ABBOTT LABS 2.5MG/MLM N71981 001  
FEB 29, 1988  
> ADD > AP ASTRA PHARM PRODS 2.5MG/MLM N72018 001  
> ADD > OCT 20, 1988  
> ADD > AP 2.5MG/MLM N72019 001  
> ADD > OCT 19, 1988  
> ADD > AP 2.5MG/MLM N72020 001  
> ADD > OCT 19, 1988  
> ADD > AP 2.5MG/MLM N72021 001  
> ADD > OCT 19, 1988  
AP DUPONT CRI CARE 2.5MG/MLM N71645 001  
APR 07, 1988  
> ADD > AP LUITPOLD PHARMS 2.5MG/MLM N72123 001  
> ADD > OCT 24, 1988  
> ADD > AP 2.5MG/MLM N72335 001  
> ADD > OCT 24, 1988

DROPERIDOL

INJECTABLE; INJECTION

DROPERIDOL

AP QUAD PHARMS 2.5MG/MLM N71941 001  
AUG 17, 1988  
AP 2.5MG/MLM N71942 001  
AUG 17, 1988  
AP SOLOPAK LABS 2.5MG/MLM N71750 001  
SEP 06, 1988  
AP 2.5MG/MLM N71754 001  
SEP 06, 1988  
AP 2.5MG/MLM 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  
AP INNOVAR  
JANSSEN PHARMA 2.5MG/ML;  
EQ 0.05MG BASE/MLM N16049 001

DYDROGESTERONE

TABLET; ORAL

GYNOREST

> ADD > 3 KALI DUPHAR 5MG N17388 001  
> ADD > 3 10MG N17388 002  
> DLT > /TABLET;/ORAL/  
> DLT > /GYNOREST/  
> DLT > /REID/ROWEII/ /5MG/  
> DLT > /10MG/ /N17388/001/  
/N17388/002/

EDETATE CALCIUM DISODIUM

TABLET; ORAL

CALCIUM DISODIUM VERSENATE

> DLT > /RIKER/LABS/ /500MG/  
> ADD > 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 $\bar{m}$

N18998 005  
JUL 26, 1988

ENALAPRILAT

INJECTABLE; INJECTION  
VASOTEC

MS&D RES LABS 1.25MG/ML $\bar{m}$

N19309 001  
FEB 09, 1988

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HCL AND EPINEPHRINE

AP ABBOTT LABS 0.005MG/ML; 0.5 $\bar{m}$

N89635 001  
JUN 21, 1988

AP 0.005MG/ML; 1 $\bar{m}$

N89649 001  
JUN 21, 1988

AP 0.005MG/ML; 1.5 $\bar{m}$

N89645 001  
JUN 21, 1988

AP 0.005MG/ML; 1.5 $\bar{m}$

N89650 001  
JUN 21, 1988

AP 0.005MG/ML; 2 $\bar{m}$

N89651 001  
JUN 21, 1988

AP 0.01MG/ML; 1 $\bar{m}$

N89644 001  
JUN 21, 1988

AP 0.01MG/ML; 2 $\bar{m}$

N89646 001  
JUN 21, 1988

LIDOCAINE HCL N/ EPINEPHRINE

/66/ LEMMON /0.01MG/ML; 1 $\bar{m}$

/N85463/001/  
N85463 001

XYLOCAINE N/ EPINEPHRINE

AP ASTRA PHARM PRODS 0.005MG/ML; 0.5 $\bar{m}$

N06488 013  
N06488 018

AP 0.005MG/ML; 1 $\bar{m}$

NOV 13, 1986  
N06488 019

AP 0.005MG/ML; 2 $\bar{m}$

NOV 13, 1986

ERGOLOID MESYLATES

TABLET; ORAL

/66/ ERGOLOID MESYLATES/  
/CHELSEA/LABS/ 1MG/

/N88207/001/  
/MAR/22/1984/

ERGOLOID MESYLATES

TABLET; ORAL

GERDIAL

AB CHELSEA LABS 1MG

N88207 001  
MAR 22, 1984

TABLET; SUBLINGUAL

/66/ ERGOLOID MESYLATES/  
/RIKER/LABS/ 0.5MG/  
/66/ 1MG/

/N84868/001/  
/N85809/001/  
N84868 001  
N85809 001

3 RIKER LABS 0.5MG  
3 1MG

/66/ ERGOLOID MESYLATES/  
/CHELSEA/LABS/ 0.5MG/  
/66/ 1MG/

/N86189/001/  
/N86188/001/

GERDIAL

AA CHELSEA LABS 0.5MG  
AA 1MG

N86189 001  
N86188 001

ERYTHROMYCIN

SOLUTION; TOPICAL

ERYTHROMYCIN

AT NASKA PHARMA 2 $\bar{m}$

N62957 001  
JUL 21, 1988

ETS-22

AT PADDOCK LABS 2 $\bar{m}$

N62687 001  
FEB 05, 1988

ERYTHROMYCIN ESTOLATE; SULFISOXAZOLE ACETYL

SUSPENSION; ORAL

ILOSONE SULFA  
LILLY

EQ 125MG BASE/5ML;  
EQ 600MG BASE/5ML $\bar{m}$

N50599 001  
SEP 16, 1988

ERYTHROMYCIN ETHYLSUCCINATE

TABLET; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

AB MYLAN PHARMS EQ 400MG BASE $\bar{m}$

N62847 001  
SEP 14, 1988

TABLET, CHEWABLE; ORAL

ERYPED

AB ABBOTT LABS EQ 200MG BASE $\bar{m}$

N50297 003  
JUL 05, 1988

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL

ERYTHROMYCIN ETHYLSUCCINATE AND SULFISOXAZOLE ACETYL

AB BARR LABS EQ 200MG BASE/5ML;  
EQ 600MG BASE/5MLM N62759 001  
MAY 20, 1988

ERYZOLE

AB ALRA LABS EQ 200MG BASE/5ML;  
EQ 600MG BASE/5MLM N62758 001  
JUN 15, 1988

PEDIAZOLE

AB ROSS LABS EQ 200MG BASE/5ML;  
EQ 600MG BASE/5MLM N50529 001

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROCIN

AP ABBOTT LABS EQ 500MG BASE/VIALM N62586 001  
JAN 04, 1988  
AP EQ 1GM BASE/VIALM N62586 002  
JAN 04, 1988

ERYTHROMYCIN STEARATE

TABLET; ORAL

ERYTHROCIN

/BB/ /BRISTOL/LABS/ /EQ 250MG BASE/ /N61304/001/  
/BB/ /BRISTOL/LABS/ /EQ 250MG BASE/ /N61887/001/  
3 BRISTOL LABS EQ 250MG BASE N61304 001  
3 EQ 250MG BASE N61887 001

ERYPAR

/BB/ /PARKE/DAVIS/ /EQ 250MG BASE/ /N62032/001/  
/BB/ /PARKE/DAVIS/ /EQ 500MG BASE/ /N62032/002/  
3 PARKE DAVIS EQ 250MG BASE N62032 001  
3 EQ 500MG BASE N62032 002

ERYTHROCIN STEARATE

/BB/ /ABBOTT/LABS/ /EQ 125MG BASE/ /N60359/002/  
3 ABBOTT LABS EQ 125MG BASE N60359 002

ERYTHROMYCIN STEARATE

/BB/ /LEDERLE/LABS/ /EQ 250MG BASE/ /N62089/001/  
/BB/ /LEDERLE/LABS/ /EQ 500MG BASE/ /N62089/002/  
3 LEDERLE LABS EQ 250MG BASE N62089 001  
3 EQ 500MG BASE N62089 002

ERYTHROCIN

/BB/ /PFIZER/LABS/ /EQ 500MG BASE/ /N61791/002/  
3 PFIZER LABS EQ 500MG BASE N61791 002

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIABLOC

DUPONT CRI CARE 10MG/MLM N19386 001  
AUG 15, 1988

ESTRADIOL

FILM, CONTROLLED RELEASE; PERCUTANEOUS

ESTRADERM

CIBA PHARM 0.05MG/24HR N19081 002  
0.1MG/24HR N19081 003  
SEP 10, 1986  
/4MG/ /N19081/002/  
/4MG/ /SEP/10/1986/  
/4MG/ /N19081/003/  
/4MG/ /SEP/10/1986/

ESTRONE

INJECTABLE; INJECTION

ESTRONE

/BP/ /STERIS/LABS/ /5MG/ML/ /N65239/001/  
/BP/ /STERIS/LABS/ /5MG/ML/ N85239 001  
/BP/ /PARKE/DAVIS/ /1MG/ML/ /N63977/001/  
/BP/ /PARKE/DAVIS/ /5MG/ML/ /N63977/003/  
3 PARKE DAVIS 1MG/ML N03977 001  
3 5MG/ML N03977 003

ETHINYL ESTRADIOL

TABLET; ORAL

LYNORAL

> DLT > /BP/ /ORGANON/ /0.05MG/ /N65490/002/  
> DLT > /BP/ /ORGANON/ /0.01MG/ /N65490/003/  
> ADD > 3 ORGANON 0.01MG N05490 003  
> ADD > 3 0.05MG N05490 002

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

NORETHIN 1/35E-21

AB SEARLE PHARMS 0.035MG;1MG N71480 001  
APR 12, 1988

ETHINYL ESTRADIOL; NORETHINDRONE

<u>TABLET; ORAL-21</u>			
<u>NORETHINDRONE AND ETHINYL ESTRADIOL</u>			
<u>AB</u>	<u>WATSON LABS</u>	<u>0.035MG;0.5MG AND 1MG</u>	N71043 001 APR 01, 1988
<u>ORTHO-NOVUM 10/11-21</u>			
<u>AB</u>	<u>ORTHO PHARM</u>	<u>0.035MG;0.5MG AND 1MG</u>	N18354 001 JAN 11, 1982
<u>TABLET; ORAL-28</u>			
<u>NORETHIN 1/35E-28</u>			
<u>AB</u>	<u>SEARLE PHARMS</u>	<u>0.035MG;1MG</u>	N71481 001 APR 12, 1988
<u>NORETHINDRONE AND ETHINYL ESTRADIOL</u>			
<u>AB</u>	<u>WATSON LABS</u>	<u>0.035MG;0.5MG AND 1MG</u>	N71044 001 APR 01, 1988
<u>ORTHO-NOVUM 10/11-28</u>			
<u>AB</u>	<u>ORTHO PHARM</u>	<u>0.035MG;0.5MG AND 1MG</u>	N18354 002 JAN 11, 1982

ETHIODIZED OIL

/INJECTABLE;/INJECTION/  
/ETHIODOL/  
/FOUSERA/

/99%/

/N09190/001/

OIL; INTRALYMPHATIC, INTRAUTERINE  
ETHIODOL

SAVAGE LABS 99% N09190 001

FENOPROFEN CALCIUM

CAPSULE; ORAL  
FENOPROFEN CALCIUM

<u>AB</u>	<u>AM THERPTCS</u>	<u>EQ 200MG BASEM</u>	N72307 001 AUG 22, 1988
<u>AB</u>		<u>EQ 300MG BASEM</u>	N72308 001 AUG 22, 1988
<u>&gt; ADD &gt;</u>	<u>AB</u>	<u>EQ 200MG BASEM</u>	N72394 001 OCT 17, 1988
<u>&gt; ADD &gt;</u>	<u>AB</u>	<u>EQ 300MG BASEM</u>	N72395 001 OCT 17, 1988
<u>&gt; ADD &gt;</u>	<u>AB</u>	<u>EQ 200MG BASEM</u>	N72355 001 AUG 17, 1988 : JUL 05, 1988
<u>AB</u>	<u>HALSEY DRUG</u>	<u>EQ 300MG BASEM</u>	N72356 001 AUG 17, 1988 : JUL 05, 1988
<u>AB</u>	<u>PAR PHARM</u>	<u>EQ 200MG BASEM</u>	N72437 001 AUG 22, 1988
<u>AB</u>		<u>EQ 300MG BASEM</u>	N72438 001 AUG 22, 1988

FENOPROFEN CALCIUM

CAPSULE; ORAL  
FENOPROFEN CALCIUM

<u>AB</u>	<u>QUANTUM PHARMCS</u>	<u>EQ 200MG BASEM</u>	N72214 001 AUG 17, 1988 : APR 14, 1988
<u>AB</u>		<u>EQ 300MG BASEM</u>	N71738 001 AUG 17, 1988 : APR 14, 1988
<u>AB</u>	<u>WATSON LABS</u>	<u>EQ 200MG BASEM</u>	N72294 001 AUG 17, 1988 : JUL 08, 1988
<u>AB</u>		<u>EQ 300MG BASEM</u>	N72293 001 AUG 17, 1988 : JUL 08, 1988
<u>NALFON</u>			
<u>AB</u>	<u>DISTA PRODS</u>	<u>EQ 300MG BASE</u>	N17604 002
<u>AB</u>	<u>NALFON 200</u>	<u>EQ 200MG BASE</u>	N17604 003

TABLET; ORAL  
FENOPROFEN CALCIUM

<u>AB</u>	<u>AM THERPTCS</u>	<u>EQ 600MG BASEM</u>	N72309 001 AUG 17, 1988 : JUN 16, 1988
<u>AB</u>	<u>CHELSEA LABS</u>	<u>EQ 600MG BASEM</u>	N72407 001 AUG 17, 1988 : JUN 13, 1988
<u>&gt; ADD &gt;</u>	<u>AB</u>	<u>EQ 600MG BASEM</u>	N72396 001 OCT 17, 1988
<u>&gt; ADD &gt;</u>	<u>AB</u>	<u>EQ 600MG BASEM</u>	N72602 001 OCT 11, 1988
<u>&gt; ADD &gt;</u>	<u>AB</u>	<u>EQ 600MG BASEM</u>	N72357 001 AUG 17, 1988 : JUL 05, 1988
<u>AB</u>	<u>HALSEY DRUG</u>	<u>EQ 600MG BASEM</u>	N72326 001 AUG 17, 1988 : APR 20, 1988
<u>AB</u>	<u>LEDERLE LABS</u>	<u>EQ 600MG BASEM</u>	N72267 001 AUG 17, 1988 : JUN 08, 1988
<u>AB</u>	<u>MYLAN PHARMS</u>	<u>EQ 600MG BASEM</u>	N72267 001 AUG 17, 1988 : JUL 19, 1988
<u>AB</u>	<u>PAR PHARM</u>	<u>EQ 600MG BASEM</u>	N72429 001 AUG 17, 1988 : JUL 19, 1988
<u>AB</u>	<u>PHARM BASICS</u>	<u>EQ 600MG BASEM</u>	N72362 001 AUG 17, 1988 : JUN 16, 1988
<u>AB</u>	<u>PUREPAC PHARM</u>	<u>EQ 600MG BASEM</u>	N72274 001 MAY 02, 1988
<u>AB</u>	<u>QUANTUM PHARMCS</u>	<u>EQ 600MG BASEM</u>	N72194 001 AUG 17, 1988 : APR 14, 1988
<u>AB</u>	<u>WATSON LABS</u>	<u>EQ 600MG BASEM</u>	N72165 001 AUG 17, 1988 : JUL 08, 1988
<u>AB</u>	<u>ZENITH LABS</u>	<u>EQ 600MG BASEM</u>	N72557 001 AUG 29, 1988
<u>NALFON</u>			
<u>AB</u>	<u>DISTA PRODS</u>	<u>EQ 600MG BASE</u>	N17710 001

FERROUS SULFATE; FOLIC ACID

> DLT > /CAPSULE; ORAL/  
 > DLT > /FOLYRON/  
 > DLT > /LEDERLE LABS/  
 > ADD > 3 LEADERLE LABS

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

/N06012/003/  
 N06012 003

FLECAINIDE ACETATE

TABLET; ORAL  
 TAMBOCOR  
 RIKER LABS

50MG# N18830 004  
 AUG 23, 1988

150MG# N18830 003  
 JUN 03, 1988

FLUOCINOLONE ACETONIDE

CREAM; TOPICAL  
FLUOCINOLONE ACETONIDE

AT G&N LABS 0.01%# N89526 001  
 JUL 26, 1988

AT 0.025%# N89525 001  
 JUL 26, 1988

OIL; TOPICAL  
 DERMA-SMOOTH/FS  
 HILL DERM

0.01%# N19452 001  
 FEB 03, 1988

OINTMENT; TOPICAL  
FLUOCINOLONE ACETONIDE

AT G&N LABS 0.025%# N89524 001  
 JUL 26, 1988

FLUOCINONIDE

CREAM; TOPICAL  
FLUOCINONIDE

AB CLAY PARK LABS 0.05%# N71790 001  
 JUL 13, 1988 : APR 25, 1988

FLUDOURACIL

INJECTABLE; INJECTION  
FLUDOURACIL

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

PERMITIL

BP SCHERING 2.5MG N12034 004

BP 5MG N12034 005

BP 10MG N12034 006

1/2/ N12034/004/  
 1/2/ 2.5MG/  
 1/2/ 5MG/  
 1/2/ 10MG/  
 N12034/005/  
 N12034/006/

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL  
FLURAZEPAM HCL

AB HALSEY DRUG 15MG# N71808 001  
 JAN 07, 1988

AB 30MG# N71809 001  
 JAN 07, 1988

AB SUPERPHARM 15MG# N71659 001  
 AUG 04, 1988

AB 30MG# N71660 001  
 AUG 04, 1988

> ADD > FLURBIPROFEN

> ADD > TABLET; ORAL  
 > ADD > ANSAID  
 > ADD > UPJOHN 50MG<sub>M</sub> N18766 002  
 > ADD > OCT 31, 1988  
 > ADD > 100MG<sub>M</sub> N18766 003  
 > ADD > OCT 31, 1988

FOLIC ACID

TABLET; ORAL  
FOLIC ACID  
 /66/ /BARR/LABS/ /1MG/  
 N89177/001/  
 /JAN/08./1986/  
 N89177 001  
 JAN 08, 1986  
 @ BARR LABS 1MG

FUROSEMIDE

INJECTABLE; INJECTION  
FUROSEMIDE  
 /62/ /PARKE/DAVIS/ /10MG/ML/  
 N16420/001/  
 /FEB/26./1982/  
 N18420 001  
 FEB 26, 1982  
 AP WARNER CHILCOTT 10MG/ML

TABLET; ORAL  
FUROSEMIDE  
 AB BARR LABS 80MG<sub>M</sub> N70100 001  
 JAN 26, 1988  
 AB DANBURY PHARMA 80MG<sub>M</sub> N71594 001  
 FEB 09, 1988

GADOPENTETATE DIMEGGLUMINE

INJECTABLE; INJECTION  
 MAGNEVIST  
 BERLEX LABS 469.01MG/ML<sub>M</sub> N19596 001  
 JUN 02, 1988

GALLIUM CITRATE, GA-67

INJECTABLE; INJECTION  
 GALLIUM CITRATE GA 67  
 /MEDI/PHYSICS/ /1MCI/ML/  
 N17700/001/  
 N17700 001  
 @ MEDI PHYSICS 1MCI/ML

GENTAMICIN SULFATE; PREDNISOLONE ACETATE

SUSPENSION/DROPS; OPHTHALMIC  
 PRED-G  
 ALLERGAN PHARMS EQ 0.3% BASE; 1%<sub>M</sub> N50586 001  
 JUN 10, 1988

GLYCOPYRROLATE

INJECTABLE; INJECTION  
GLYCOPYRROLATE  
 AP ABBOTT LABS 0.2MG/ML<sub>M</sub> N89393 001  
 JUN 15, 1988

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC  
NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN  
 > ADD > AT IPHARM 0.025MG/ML; EQ 1.75MG BASE/ML;  
 > ADD > 10,000 UNITS/ML<sub>M</sub> N62818 001  
 > ADD > OCT 11, 1988

GUANABENZ ACETATE

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

HALOPERIDOL

TABLET; ORAL  
 HALDOL SOLUTAB  
 /3/MCNEIL/LABS/ /1MG/  
 @ MCNEIL PHARM 1MG N17079/001/  
 N17079 001  
 AB BARR LABS 5MG<sub>M</sub> N71212 001  
 JAN 07, 1988  
 AB 10MG<sub>M</sub> N71173 001  
 JAN 07, 1988  
 AB 20MG<sub>M</sub> N71177 001  
 JAN 07, 1988

HALOPERIDOL

TABLET; ORAL

HALOPERIDOL

<u>AB</u>	<u>BOLAR PHARM</u>	<u>0.5MG</u>	<u>N71571 001</u>
			<u>JUN 03, 1988</u>
<u>AB</u>		<u>1MG</u>	<u>N71572 001</u>
			<u>JUN 03, 1988</u>
<u>AB</u>		<u>2MG</u>	<u>N71573 001</u>
			<u>JUN 03, 1988</u>
<u>AB</u>		<u>5MG</u>	<u>N71374 001</u>
			<u>JUN 03, 1988</u>
<u>AB</u>		<u>10MG</u>	<u>N71375 001</u>
			<u>JUN 03, 1988</u>
<u>AB</u>		<u>20MG</u>	<u>N71376 001</u>
			<u>JUN 03, 1988</u>
<u>AB</u>	<u>CORD LABS</u>	<u>10MG</u>	<u>N71210 001</u>
			<u>MAR 11, 1988</u>
<u>AB</u>		<u>20MG</u>	<u>N71211 001</u>
			<u>MAR 11, 1988</u>

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALDOL

<u>/AA/</u>	<u>/MCNEIL/LABS/</u>	<u>/EQ 2MG BASE/ML/</u>	<u>/N15922/001/</u>
<u>AA</u>	<u>MCNEIL PHARM</u>	<u>EQ 2MG BASE/ML</u>	<u>N15922 001</u>
<u>AA</u>	<u>ROXANE LABS</u>	<u>EQ 2MG BASE/MLM</u>	<u>N72045 001</u>
			<u>APR 12, 1988</u>

INJECTABLE; INJECTION

HALOPERIDOL

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

HEPARIN SODIUM

INJECTABLE; INJECTION

HEP FLUSH KIT IN PLASTIC CONTAINER

<u>AP</u>	<u>LYPHOMED</u>	<u>10 UNITS/MLM</u>	<u>N17029 017</u>
			<u>DEC 05, 1985</u>
<u>AP</u>		<u>100 UNITS/MLM</u>	<u>N17029 018</u>
			<u>DEC 05, 1985</u>
<u>/AP/</u>	<u>/ABBOTT/LABS/</u>	<u>/100 UNITS/ML/</u>	<u>/N05264/010/</u>
	<u>ABBOTT LABS</u>	<u>100 UNITS/ML</u>	<u>N05264 010</u>

HEPARIN SODIUM

INJECTABLE; INJECTION

HEPARIN LOCK FLUSH IN PLASTIC CONTAINER

<u>AP</u>	<u>ABBOTT LABS</u>	<u>10 UNITS/ML</u>	<u>N05264 015</u>
			<u>MAY 21, 1985</u>
<u>AP</u>		<u>100 UNITS/ML</u>	<u>N05264 016</u>
			<u>MAY 21, 1985</u>
<u>&gt; DLT &gt;/AP/</u>	<u>HEPARIN SODIUM</u>	<u>/5,000 UNITS/ML/</u>	<u>/N17979/003/</u>
<u>&gt; ADD &gt;</u>	<u>LYPHOMED</u>	<u>5,000 UNITS/ML</u>	<u>N17979 003</u>
	<u>HEPARIN SODIUM IN PLASTIC CONTAINER</u>		
<u>AP</u>	<u>LYPHOMED</u>	<u>1,000 UNITS/MLM</u>	<u>N17029 013</u>
			<u>DEC 05, 1985</u>
<u>AP</u>		<u>5,000 UNITS/MLM</u>	<u>N17029 014</u>
			<u>DEC 05, 1985</u>
<u>AP</u>		<u>10,000 UNITS/MLM</u>	<u>N17029 015</u>
			<u>DEC 05, 1985</u>
<u>AP</u>		<u>20,000 UNITS/MLM</u>	<u>N17029 016</u>
			<u>DEC 05, 1985</u>

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

<u>/AP/</u>	<u>/ABBOTT/LABS/</u>	<u>/10,000 UNITS/100ML/</u>	<u>/N19339/003/</u>
	<u>ABBOTT LABS</u>	<u>10,000 UNITS/100ML</u>	<u>N19339 003</u>
			<u>MAR 27, 1985</u>

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

<u>AP</u>	<u>BAXTER</u>	<u>200 UNITS/100ML</u>	<u>N18609 001</u>
			<u>APR 28, 1982</u>
<u>/AP/</u>	<u>/TRAVENOL/LABS/</u>	<u>/200 UNITS/100ML/</u>	<u>/N18609/001/</u>
			<u>APR 28, 1982</u>

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

<u>/AP/</u>	<u>/ABBOTT/LABS/</u>	<u>/5,000 UNITS/100ML/</u>	<u>/N19339/001/</u>
	<u>ABBOTT LABS</u>	<u>5,000 UNITS/100ML</u>	<u>N19339 001</u>
			<u>MAR 27, 1985</u>

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

<u>AP</u>	<u>BAXTER</u>	<u>200 UNITS/100ML</u>	<u>N18609 002</u>
			<u>APR 28, 1982</u>
<u>/AP/</u>	<u>/TRAVENOL/LABS/</u>	<u>/200 UNITS/100ML/</u>	<u>/N18609/002/</u>
			<u>APR 28, 1982</u>



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HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

/AB/	/BANMAX/PHARMS/	/25MG/	/N86369/001/
/AB/		/50MG/	/N83554/001/
	3 BANMAX PHARMS	25MG	N86369 001
	3	50MG	N83554 001

HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

TABLET; ORAL

NORMOZIDE

/SCHERING/

/25MG;400MG/

3 SCHERING

25MG;400MG

TRANDATE HCL

GLAXO

25MG;100MG

AB

25MG;200MG

AB

25MG;300MG

AB

25MG;400MG

/TRANDATE-HCL/

/GLAXO/

/25MG;100MG/

/AB/

/25MG;200MG/

/AB/

/25MG;300MG/

/AB/

/25MG;400MG/

/N19046/004/  
/APR/06;/1987/  
N19046 004  
APR 06, 1987

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

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

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

AB

NOVOPHARM

15MG;250MG

AB

25MG;250MG

AB

30MG;500MG

AB

50MG;500MG

N71819 001  
APR 08, 1988  
N71820 001  
APR 08, 1988  
N71821 001  
APR 08, 1988  
N71822 001  
APR 08, 1988

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL

METHYLDOPA AND HYDROCHLOROTHIAZIDE

/AB/ /PUREPAC/PHARM/ /50MG;500MG/

3 PUREPAC PHARM

50MG;500MG

AB

MATSON LABS

15MG;250MG

AB

25MG;250MG

AB

30MG;500MG

AB

50MG;500MG

AB

ZENITH LABS

15MG;250MG

AB

25MG;250MG

AB

30MG;500MG

AB

50MG;500MG

/N70689/001/  
/APR/24;/1986/  
N70689 001  
APR 24, 1986  
N71920 001  
AUG 29, 1988  
N71921 001  
AUG 29, 1988  
N71922 001  
AUG 29, 1988  
N71923 001  
AUG 29, 1988  
N71458 001  
MAR 08, 1988  
N71459 001  
MAR 08, 1988  
N71460 001  
MAR 08, 1988  
N71461 001  
MAR 08, 1988

HYDROCHLOROTHIAZIDE; PINDOLOL

TABLET; ORAL

/VISAZIDE/

/SANDOZ/PHARMS/

/25MG;5MG/

3 SANDOZ PHARMS

25MG;5MG

3

25MG;10MG

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

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL AND HYDROCHLOROTHIAZIDE

AB

SIDMAK LABS

25MG;40MG

AB

25MG;80MG

AB

WARNER CHILCOTT

25MG;40MG

AB

25MG;80MG

N72042 001  
MAR 14, 1988  
N72043 001  
MAR 14, 1988  
N71771 001  
JAN 26, 1988  
N71772 001  
JAN 26, 1988

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL  
HYDROCHLOROTHIAZIDE N/ RESERPINE  
 /3/6005/PHARMA/ /25MG;0.125MG/ /N85421/001/  
 @ PHARMAFAIR 25MG;0.125MG N85421 001  
RESERPINE AND HYDROCHLOROTHIAZIDE  
 /BP/ /BARR/LABS/ /25MG;0.125MG/ /N84580/001/  
 /BP/ /BARR/LABS/ /50MG;0.125MG/ /N84579/001/  
 @ BARR LABS 25MG;0.125MG N84580 001  
 @ 50MG;0.125MG N84579 001

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL  
SPIRONOLACTONE N/ HYDROCHLOROTHIAZIDE  
 /AB/ /LEDERLE/LABS/ /25MG;25MG/ /N87511/001/  
 @ LEADERLE LABS 25MG;25MG N87511 001

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL  
TRIAMTERENE AND HYDROCHLOROTHIAZIDE  
 AB VITARINE 25MG;50MG N71737 001  
 FEB 12, 1988

TABLET; ORAL  
 MAXZIDE-25MG  
 MYLAN PHARMS 25MG;37.5MG N19129 003  
 MAY 13, 1988

TRIAMTERENE AND HYDROCHLOROTHIAZIDE  
 AB CORD LABS 50MG;75MG N72011 001  
 JUN 17, 1988  
 AB DANBURY PHARMA 50MG;75MG N71969 001  
 APR 17, 1988 : JAN 15, 1988  
 AB PAR PHARM 50MG;75MG N72337 001  
 MAY 11, 1988  
 AB QUANTUM PHARMS 50MG;75MG N71980 001  
 APR 17, 1988 : FEB 01, 1988

HYDROCORTISONE

CREAM; TOPICAL  
HYDROCORTISONE  
 AI NASKA PHARMA 1% N89706 001  
 MAR 10, 1988  
 AI 2.5% N89682 001  
 MAR 10, 1988  
 AI NMC LABS 1% N87795 001  
 MAY 03, 1983

HYDROCORTISONE

CREAM; TOPICAL  
HYDROTIX  
 AI SYOSSET LABS 1% N87427 001  
 APR 04, 1988  
 /AI/ /NMC/ /1%/  
 /AI/ /NMC/LABS/ /1%/  
 /N87795/001/  
 /MAY/03/1983/

LOTION; TOPICAL  
BETA-HC  
 AI BETA DERM 1% N89495 001  
 JAN 25, 1988  
 AI HYDROCORTISONE  
 NASKA PHARMA 1% N89705 001  
 APR 25, 1988

OINTMENT; TOPICAL  
HC (HYDROCORTISONE)  
 /3/C&M/PHARMA/ /0.5%/  
 /3/ /1%/  
 AI C&M PHARMA 1% N80481 002  
 AI HYDROCORTISONE  
 NASKA PHARMA 1% N89704 001  
 MAR 10, 1988

TABLET; ORAL  
 HYDROCORTISONE  
 /BP/ /BARR/LABS/ /20MG/  
 @ BARR LABS 20MG N83999 001

HYDROCORTISONE ACETATE

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

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL  
EPIFOAM  
 AI REED & CARNRICK 1%:1% N86457 001  
HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%  
 AI 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  
LOCODIN  
GIST/BROCADES 0.1% N19116/001  
FEB/25/1987  
LOCODIN  
 AT OWEN LABS 0.1% N19819 001  
 OCT 15, 1988

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

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

HYDROFLUMETHIAZIDE

TABLET; ORAL  
HYDROFLUMETHIAZIDE  
AB BOLAR/PHARM 50MG N88031/001  
APR/06/1983  
 N88031 001  
 APR 06, 1983

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
HYDROXYZINE HCL  
AB ALTANA 25MG/ML N87273/001  
APR/20/1982  
AB ALTANA 50MG/ML N87273/002  
APR/20/1982  
 @ ALTANA 25MG/ML N87273 001  
 APR 20, 1982  
 @ 50MG/ML 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 HALSEY DRUG 25MG N89117 001  
 MAY 02, 1988  
AB HALSEY DRUG 50MG N89396 001  
 MAY 02, 1988

IBUPROFEN

TABLET; ORAL  
IBU-TAB  
AB ALRA LABS 400MG N71058 001  
 AUG 11, 1988  
AB ALRA LABS 600MG N71059 001  
 AUG 11, 1988  
AB ALRA LABS 800MG N71965 001  
 AUG 11, 1988  
IBUPROFEN  
AB HALSEY DRUG 800MG N72137 001  
 FEB 05, 1988  
AB INVAMED 400MG N72064 001  
 JAN 14, 1988  
AB INVAMED 600MG N72065 001  
 JAN 14, 1988  
AB INVAMED 800MG N71938 001  
 JAN 14, 1988  
AB MEDICOPHARMA 400MG N71644 001  
 FEB 01, 1988  
AB PRIVATE FHLTNS 800MG N72300 001  
 JUL 01, 1988  
AB PUREPAC PHARM 800MG N71964 001  
 FEB 01, 1988

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL  
IMIPRAMINE HCL  
 > DLT > /68/ /LEDERLE/LABS/ /10MG/ /N86269/001/  
 > DLT > /68/ /25MG/ /N86267/001/  
 > DLT > /68/ /50MG/ /N86268/001/  
 > ADD > @ LEADERLE LABS 10MG N86269 001  
 > ADD > @ 25MG N86267 001  
 > ADD > @ 50MG N86268 001  
 /68/ /BRAND/ /N83827/001/  
 /68/ /BANMAX/PHARMS/ /25MG/ /N83827/002/  
 /68/ /50MG/ /N83827/003/  
 @ BANMAX PHARMS 10MG N83827 001  
 @ 25MG N83827 002  
 @ 50MG N83827 003

INDIUM IN-111 OXYQUINOLINE

/INJECTABLE;/INJECTION/  
 /INDIUM/IN-111/OXYQUINOLINE/  
 /AMERSHAM/ /N/A/ /N19044/001/  
 /DEC/23./1985/  
 INJECTABLE; INTRATHECAL  
 INDIUM IN-111 OXYQUINOLINE  
 AMERSHAM 1MCI/ML N19044 001  
 DEC 23, 1985

INDOCYANINE GREEN

INJECTABLE; INJECTION  
 CARDIO-GREEN  
 @ B-D MICROBIOL SYS 10MG/VIAL N11525 003  
 25MG/VIAL N11525 001  
 @ 40MG/VIAL N11525 004  
 50MG/VIAL N11525 002  
 /HYNH/WES/A/DUN/ /10MG/VIAL/ /N11525/003/  
 /40MG/VIAL/ /N11525/004/

INDOMETHACIN

CAPSULE; ORAL  
INDOMETHACIN  
 AB NOVOPHARM 25MG N71342 001  
 APR 18, 1988  
 AB 50MG N71343 001  
 APR 18, 1988

INDOMETHACIN

CAPSULE; ORAL  
INDOMETHACIN  
 AB VITARINE 25MG N71711 001  
 JUL 05, 1988  
 AB 50MG N71712 001  
 JUL 05, 1988

INSULIN PORK

INJECTABLE; INJECTION  
 /ILETIN/  
 /LILLY/ /500/UNITS/ML/ /N17931/001/  
 ILETIN I 500 UNITS/ML N17931 001  
 LILLY

IOHEXOL

INJECTABLE; INJECTION  
OMNIPAGUE 180  
 AP STERLING DRUG 38.8% N18956 001  
 DEC 26, 1985  
 /3/ /38.8% /N18956/001/  
 /DEC/26./1985/

IOTHALAMATE MEGGLUMINE

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

IRON DEXTRAN

INJECTABLE; INJECTION  
 /BIOFERDEX/  
 /62/ /FISONS/ /EQ 50MG IRON/ML/ /N17807/001/  
 @ FISONS EQ 50MG IRON/ML N17807 001

ISONIAZID

INJECTABLE; INJECTION  
 > ADD > ISONIAZID  
 > ADD > AP QUAD PHARMS 100MG/ML N89816 001  
 > ADD > OCT 28, 1988  
 > ADD > HYDRAZID  
 > ADD > AP SQUIBB 100MG/ML N08662 001  
 TABLET; ORAL  
 > DLT > /~~DON~~ ISONIAZID/  
 > DLT > /~~AA~~ /~~BC~~ /PHARMS/ /~~100MG~~/  
 > ADD > 3 DOW PHARMS 300MG N80330 002  
 > ADD > LANIAZID  
 AA LANNETT 300MG N89776 001  
 JUN 13, 1988

ISOSORBIDE DINITRATE

CAPSULE, CONTROLLED RELEASE; ORAL  
 DILATRATE-SR  
 BC REED & CARNICK 40MG N19790 001  
 SEP 02, 1988  
 ISORDIL  
 BC WYETH AYERST LABS 40MG N12882 002  
 JUL 29, 1988

TABLET; ORAL  
ISORDIL  
 AB WYETH 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

ISOSORBIDE DINITRATE  
 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

ISOSORBIDE DINITRATE

TABLET; ORAL  
ISOSORBIDE DINITRATE  
 AB PAR PHARM 30MG N87946 001  
 JAN 12, 1988

TABLET; SUBLINGUAL  
ISORDIL  
 AB WYETH AYERST LABS 2.5MG N12940 004  
 JUL 29, 1988  
 AB 5MG N12940 003  
 JUL 29, 1988  
 AB 10MG N12940 005  
 JUL 29, 1988  
 5MG N12940 002

ISOSORBIDE DINITRATE  
 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

TABLET, CONTROLLED RELEASE; ORAL  
 ISORDIL  
 WYETH AYERST LABS 40MG N12882 001  
 JUL 29, 1988

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
KETALAR  
 AP PARKE DAVIS EQ 10MG BASE/ML N16812 001  
 AP EQ 50MG BASE/ML N16812 002  
 AP EQ 100MG BASE/ML N16812 003  
KETAMINE HCL  
 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

LACTULOSE

SYRUP; ORAL			
<u>AA</u>	<u>CEPHULAC</u> /MERRELL/DOM/	<u>10GM/15ML</u>	<u>N17657/001</u>
<u>AA</u>	<u>CHRONULAC</u> MERRELL DOM	<u>10GM/15ML</u>	N17884 001
<u>AA</u>	<u>CONSTILAC</u> ALRA LABS	<u>10GM/15ML</u>	N71054 001 JUL 26, 1988
<u>CONSTULOSE</u>			
<u>AA</u>	BARRE NATL	<u>10GM/15ML</u>	N70288 001 AUG 15, 1988
<u>LACTULOSE</u>			
<u>AA</u>	MY K LABS	<u>10GM/15ML</u>	N71841 001 SEP 22, 1988
<u>AA</u>	<u>ROXANE/LABS/</u>	<u>10GM/15ML</u>	<u>N17906/001</u>
SYRUP; ORAL, RECTAL			
<u>CEPHULAC</u>			
<u>AA</u>	MERRELL DOM	<u>10GM/15ML</u>	N17657 001
<u>CHOLAC</u>			
<u>AA</u>	ALRA LABS	<u>10GM/15ML</u>	N71331 001 JUL 26, 1988
<u>ENULOSE</u>			
<u>AA</u>	BARRE NATL	<u>10GM/15ML</u>	N71548 001 AUG 15, 1988
<u>GENERLAC</u>			
<u>AA</u>	MY K LABS	<u>10GM/15ML</u>	N71842 001 SEP 27, 1988
<u>LACTULOSE</u>			
<u>AA</u>	KALI DUPHAR	<u>10GM/15ML</u>	N17906 001

LEUCOVORIN CALCIUM

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

LEVOCARNITINE

> ADD >	SOLUTION; ORAL		
> ADD >	<u>CARNITOR</u>		
> ADD >	<u>AA</u>	SIGMA TAU	<u>1GM/10ML</u>
> ADD >			N18948 002 APR 27, 1988
> ADD >	<u>VITACARN</u>		
> ADD >	<u>AA</u>	KENDALL MCGAN	<u>1GM/10ML</u>
> ADD >			N19257 001 APR 10, 1986

LEVODOPA

CAPSULE; ORAL			
<u>BENDOPA/</u>			
<u>BD</u>	<u>ICN/PHARMS/</u>	<u>100MG/</u>	<u>N16948/003/</u>
<u>BD</u>		<u>250MG/</u>	<u>N16948/001/</u>
<u>BD</u>		<u>500MG/</u>	<u>N16948/002/</u>
	ICN PHARMS	100MG	N16948 003
		250MG	N16948 001
		500MG	N16948 002

LEVONORDEFRIN; MEPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION			
<u>POLOCAINE W/ LEVONORDEFRIN</u>			
<u>AP</u>	ASTRA PHARM PRODS	<u>0.05MG/ML; 2%</u>	N89517 001 APR 14, 1988

LIDOCAINE HYDROCHLORIDE

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

LINCOMYCIN HYDROCHLORIDE

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

06/10/1988

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN'88 - OCT'88

LISINAPRIL

TABLET; ORAL

PRINIVIL

<u>AB</u>	MS&D RES LABS	<u>5MG</u>	N19558 001 DEC 29, 1987
<u>AB</u>		<u>10MG</u>	N19558 002 DEC 29, 1987
<u>AB</u>		<u>20MG</u>	N19558 003 DEC 29, 1987
<u>ZESTRIL</u>			
<u>AB</u>	EMPERIAL CHEM	<u>5MG</u>	N19777 001 MAY 19, 1988
<u>AB</u>		<u>10MG</u>	N19777 002 MAY 19, 1988
<u>AB</u>		<u>20MG</u>	N19777 003 MAY 19, 1988

LOPERAMIDE HYDROCHLORIDE

/SOLUTION; ORAL/  
/100ML/  
/JANSSEN/PARMA/

a JANSSEN PHARMA

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

/N19037/001/  
/JUL/31/1984/  
N19037 001  
JUL 31, 1984

LORAZEPAM

TABLET; ORAL

LORAZEPAM

<u>AS</u>	CORD LABS	<u>0.5MG</u>	N71193 001 APR 15, 1988
<u>AB</u>		<u>1MG</u>	N71194 001 APR 15, 1988
<u>AB</u>		<u>2MG</u>	N71195 001 APR 15, 1988
<u>AB</u>	WARNER CHILCOTT	<u>1MG</u>	N71038 001 JAN 12, 1988
<u>AS</u>		<u>2MG</u>	N71039 001 JAN 12, 1988

LOXAPINE SUCCINATE

CAPSULE; ORAL

LOXAPINE SUCCINATE

<u>AB</u>	WATSON LABS	<u>EQ 5MG BASE</u>	N72204 001 JUN 15, 1988
<u>AB</u>		<u>EQ 10MG BASE</u>	N72205 001 JUN 15, 1988
<u>AB</u>		<u>EQ 25MG BASE</u>	N72206 001 JUN 15, 1988
<u>AB</u>		<u>EQ 50MG BASE</u>	N72062 001 JUN 15, 1988
<u>LOXCITANE</u>			
<u>AB</u>	LEDERLE LABS	<u>EQ 5MG BASE</u>	N17525 001
<u>AB</u>		<u>EQ 10MG BASE</u>	N17525 002
<u>AB</u>		<u>EQ 25MG BASE</u>	N17525 003
<u>AB</u>		<u>EQ 50MG BASE</u>	N17525 004

MAPROTILINE HYDROCHLORIDE

TABLET; ORAL

MAPROTILINE HCL

<u>AB</u>	AM THERPTCS	<u>25MG</u>	N72129 001 JAN 14, 1988
<u>AB</u>		<u>50MG</u>	N72130 001 JAN 14, 1988
<u>AB</u>		<u>75MG</u>	N72131 001 JAN 14, 1988
> ADD >	<u>AB</u>	<u>25MG</u>	N72284 001 OCT 03, 1988
> ADD >	<u>AB</u>	<u>50MG</u>	N72285 001 OCT 03, 1988
> ADD >	<u>AB</u>	<u>75MG</u>	N72286 001 OCT 03, 1988
> ADD >	<u>AB</u>	<u>25MG</u>	N72162 001 JUN 01, 1988
<u>AB</u>	MYLAN PHARMS	<u>50MG</u>	N72163 001 JUN 01, 1988
<u>AB</u>		<u>75MG</u>	N72164 001 JUN 01, 1988
<u>AB</u>	WATSON LABS	<u>25MG</u>	
<u>AB</u>		<u>50MG</u>	
<u>AB</u>		<u>75MG</u>	

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

ANTIVERT

<u>AA</u>	ROERIG	<u>50MG</u>	N10721 001 JAN 20, 1982
<u>MECLIZINE HCL</u>			
<u>AA</u>	PAR PHARM	<u>50MG</u>	N89674 001 MAR 31, 1988

MECLOFENAMATE SODIUM

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

MEFENAMIC ACID

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

MEGESTROL ACETATE

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

MEPENZOLATE BROMIDE

/SOLUTION; ORAL/  
 /CANTIL/  
 /MERRELL/DOM/ 25MG/5ML/ N10679/004/  
 @ MERRELL DOM 25MG/5ML N10679 004

MEPROBAMATE

TABLET; ORAL  
MEPROBAMATE  
 /AB/ /MALLARD/ 400MG/ N15072/002/  
 @ MALLARD 400MG N15072 002

MEPROBAMATE

TABLET; ORAL  
MEPROBAMATE  
 /AB/ /PHARM/BASICS/ 400MG/ N87825/001/  
 /AB/ 400MG/ N87826/001/  
 @ PHARM BASICS 200MG N87825 001  
 @ 400MG N87826 001  
 MAR 18, 1982  
 MAR 18, 1982

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

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

MESTRANOL; NORETHYNODREL

TABLET; ORAL-20  
ENOVID  
 /AB/ /SEARLE/ 0.075MG;5MG/ N10976/004/  
 @ SEARLE 0.075MG;5MG N10976 004

/AB/ /ENOVID-E/  
 /SEARLE/ 0.1MG;2.5MG/ N10976/006/  
 @ SEARLE 0.1MG;2.5MG N10976 006

METAPROTERENOL SULFATE

SOLUTION; INHALATION  
ALUPENT  
 AN BOEHR INGEL 0.4% N18761 002  
 OCT 10, 1986

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

METAPROTERENOL SULFATE

SOLUTION; INHALATION

DEY-LUTE

AN	DEY LABS	0.4% <sup>M</sup>	N71786 001 AUG 05, 1988
AN		0.6%	N70804 001 AUG 17, 1987
		0.33% <sup>M</sup>	N71806 001 AUG 05, 1988
		0.5% <sup>M</sup>	N71805 001 AUG 05, 1988

METAPROTERENOL SULFATE

AN	ARMOUR PHARM	0.4% <sup>M</sup>	N71275 001 JUL 27, 1988
AN		0.6% <sup>M</sup>	N71018 001 JUL 27, 1988
<del>AN</del>	<del>DEY/LABS/</del>	<del>0.4%</del>	<del>N70804/001/</del> <del>AUG/17/1987/</del>
<del>AN</del>		<del>0.6%</del>	<del>N70805/001/</del> <del>AUG/17/1987/</del>
AN	MY K LABS	5% <sup>M</sup>	N72190 001 JUN 07, 1988
AN	PACO RES	0.4% <sup>M</sup>	N71855 001 JUL 14, 1988
AN		0.6% <sup>M</sup>	N71726 001 JUL 14, 1988

SYRUP; ORAL

METSOL

AA	MURO PHARM	10MG/5ML <sup>M</sup>	N72023 001 SEP 15, 1988
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TABLET; ORAL

ALUPENT

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

METAPROTERENOL SULFATE

AB	AM THERPTCS	10MG <sup>M</sup>	N72054 001 JUN 23, 1988
AB		20MG <sup>M</sup>	N72055 001 JUN 23, 1988
AB	PAR PHARM	10MG <sup>M</sup>	N72024 001 JUN 28, 1988
AB		20MG <sup>M</sup>	N72025 001 JUN 28, 1988
AB	PHARM BASICS	10MG <sup>M</sup>	N71013 001 JAN 25, 1988
AB		20MG <sup>M</sup>	N71014 001 JAN 25, 1988

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL

METHADONE

AA	MALLINCKRODT	10MG/ML	N17116 002
AA	METHADONE HCL INTENSOL	10MG/ML <sup>M</sup>	N89897 001 SEP 06, 1988
	ROXANE LABS		

METHIXENE HYDROCHLORIDE

> DLT >	/TABLET;/ORAL/		
> DLT >	/FREST/		
> DLT >	/DORSEY/LABS/	/1MG/	N13420/001/
> ADD >	@ DORSEY LABS	1MG	N13420 001

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

<del>AA</del>	<del>BARR/LABS/</del>	<del>500MG/</del>	<del>N84488/001/</del>
	@ BARR LABS	500MG	N84488 001

> DLT >	/METHOTREXATE/		
> DLT >	/TABLET;/ORAL/		
> DLT >	/METHOTREXATE/		
> DLT >	/LEDERLE/LABS/	/2.5MG/	N08085/002/

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE

LEDERLE LABS

EQ 1GM BASE/VIAL <sup>M</sup>	N11719 009 APR 07, 1988
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METHOTREXATE SODIUM

PHARMACHEMIE

EQ 25MG BASE/ML <sup>M</sup>	N89158 001 JUL 08, 1988
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> ADD >	TABLET; ORAL		
> ADD >	METHOTREXATE		
> ADD >	LEDERLE LABS	EQ 2.5MG BASE	N08085 002

METHOXSALEN

CAPSULE; ORAL  
~~OXSORALEN/~~  
~~ELDER PHARMS/~~ /10MG/ /N09048/001/  
 8-MOP  
 ELDER PHARMS 10MG N09048 001

METHYLCLOTHIAZIDE

TABLET; ORAL  
METHYLCLOTHIAZIDE  
 AB CORD LABS 2.5MG N89835 001  
 AUG 18, 1988  
 AB 5MG N89837 001  
 AUG 18, 1988

METHYLDOPA

TABLET; ORAL  
METHYLDOPA  
 AB CORD LABS 125MG N71700 001  
 MAR 02, 1988  
 AB HALSEY DRUG 125MG N71751 001  
 MAR 28, 1988  
 AB 250MG N71752 001  
 MAR 28, 1988  
 AB 500MG N71753 001  
 MAR 28, 1988  
 AB SIDMAK LABS 125MG N72126 001  
 JUL 07, 1988  
 AB 250MG N72127 001  
 JUL 07, 1988  
 AB 500MG N72128 001  
 JUL 07, 1988

METHYLPHENIDATE HYDROCHLORIDE

TABLET, CONTROLLED RELEASE; ORAL  
METHYLPHENIDATE HCL  
 AB MD PHARM 20MG N89601 001  
 JUN 01, 1988  
RETALIN-SR  
 AB CIBA PHARM 20MG N18029 001  
 MAR 30, 1982

METHYLPREDNISOLONE

TABLET; ORAL  
MEDROL  
 AB UPJOHN 24MG N11153 005  
 AB 32MG N11153 006  
METHYLPREDNISOLONE  
 > ADD > AB HEATHER DRUG 4MG N85650 001  
 > DLT > /BP/ /N85650/001/  
 AB PAR PHARM 16MG N89207 001  
 APR 25, 1988  
 AB 24MG N89208 001  
 APR 25, 1988  
 AB 32MG N89209 001  
 APR 25, 1988

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION  
METOCLOPRAMIDE HCL  
 AP MAURRY BIOL EQ 10MG BASE/2ML N70892 001  
 AUG 26, 1988  
 SYRUP; ORAL  
METOCLOPRAMIDE HCL  
 AA BARRE NATL EQ 5MG BASE/5ML N71340 001  
 AUG 18, 1988  
 TABLET; ORAL  
CLOPRA  
 AB QUANTUM PHARMS EQ 5MG BASE N72384 001  
 JUN 02, 1988  
METOCLOPRAMIDE HCL  
 AB SIDMAK LABS EQ 10MG BASE 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/ML N89443 001  
 JUN 01, 1988  
METURINE IODIDE  
 AP LILLY 2MG/ML N06632 003



NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

AP	<u>NALOXONE HCL</u>	<u>0.4MG/MLM</u>	N71083 001 JUL 28, 1988
AP	DUPONT CRI CARE		
AP		<u>1MG/MLM</u>	N71084 001 JUL 28, 1988
AP		<u>1MG/MLM</u>	N71311 001 JUL 28, 1988
AP	ELKINS SINN	<u>0.02MG/MLM</u>	N71272 001 MAY 24, 1988
AP		<u>1MG/MLM</u>	N71273 001 MAY 24, 1988
AP		<u>1MG/MLM</u>	N71274 001 MAY 24, 1988
AP		<u>1MG/MLM</u>	N71287 001 MAY 24, 1988
AP	INTL MEDTN SYS	<u>1MG/MLM</u>	N72076 001 MAR 24, 1988
AP		<u>1MG/MLM</u>	N72115 001 APR 27, 1988
AP	MARSAM PHARMS	<u>0.4MG/MLM</u>	N71811 001 JUL 19, 1988

NITROFURANTOIN

/CAPSULE; ORAL/  
/NITROFURANTOIN/  
/BOLAR/PHARM/  
@ BOLAR PHARM

/50MG/ 50MG	/N84326/001/ N84326 001
/100MG/ 100MG	/N84326/002/ N84326 002

TABLET; ORAL

/AB/ NITROFURANTOIN  
/BOLAR/PHARM/  
@ BOLAR PHARM

/100MG/ 100MG	/N80447/002/ N80447 002
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NITROFURANTOIN SODIUM

> DLT > /INJECTABLE; INJECTION/  
> DLT > /IVADANTIN/  
> DLT > /NORWICH/EATON/  
> ADD > @ NORWICH EATON

/EQ/180MG/BASE/VIAL/ EQ 180MG BASE/VIAL	/N12402/001/ N12402 001
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NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL  
MACRODANTIN

AB	NORWICH EATON	<u>50MG</u>	N16620 001
AB		<u>100MG</u>	N16620 002
AB	<u>NITROFURANTOIN MACROCRYSTALLINE</u>		
AB	BOLAR PHARM	<u>50MGM</u>	N70248 001 JUN 24, 1988
AB		<u>100MGM</u>	N70249 001 JUN 24, 1988

NITROGLYCERIN

INJECTABLE; INJECTION

AP	<u>NITROGLYCERIN</u>		
AP	LUITPOLD PHARMS	<u>5MG/MLM</u>	N71492 001 MAY 24, 1988
AP		<u>5MG/MLM</u>	N72034 001 MAY 24, 1988

OINTMENT; TOPICAL  
NITROGLYCERIN  
ALTANA

27M	N87355 001 JUL 08, 1988
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NIZATIDINE

CAPSULE; ORAL  
AXID

LILLY	150MGM	N19508 001 APR 12, 1988
	300MGM	N19508 002 APR 12, 1988

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL  
AVENTYL HCL

BD	LILLY	EQ 10MG BASE	N14684 001
BD		EQ 25MG BASE	N14684 002
/BP/		/EQ/10MG/BASE/	/N14684/001/
/BP/		/EQ/25MG/BASE/	/N14684/002/
BD	PAMELOR	EQ 10MG BASE	N18013 001
BD	SANDOZ PHARMS	EQ 25MG BASE	N18013 002
/BP/		/EQ/10MG/BASE/	/N18013/001/
/BP/		/EQ/25MG/BASE/	/N18013/002/

NYSTATIN

CREAM; TOPICAL

NYSTATIN

AT NASKA PHARMA 100,000 UNITS/GM N62949 001  
JUN 13, 1988

SUSPENSION; ORAL

NYSTATIN

AA THAMES PHARMA 100,000 UNITS/MLM N62876 001  
FEB 29, 1988

> ADD > OCTREOTIDE ACETATE

> ADD > INJECTABLE; INJECTION

SANDOSTATIN

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

OXACILLIN SODIUM

INJECTABLE; INJECTION

BACTOCILL

AP BEECHAM LABS EQ 10GM BASE/VIAL N61334 010

OXACILLIN SODIUM

> ADD > AP MARSAM PHARMS EQ 250MG BASE/VIALM N62856 001  
OCT 26, 1988  
> ADD > AP EQ 500MG BASE/VIALM N62856 002  
OCT 26, 1988  
> ADD > AP EQ 1GM BASE/VIALM N62856 003  
OCT 26, 1988  
> ADD > AP EQ 2GM BASE/VIALM N62856 004  
OCT 26, 1988  
> ADD > AP EQ 4GM BASE/VIALM N62856 005  
OCT 26, 1988  
> ADD > AP EQ 10GM BASE/VIALM N62984 001  
SEP 29, 1988

PROSTAPHLIN

> ADD > AP BRISTOL LABS EQ 250MG BASE/VIAL N50195 001  
> ADD > AP EQ 250MG BASE/VIAL N61490 001

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

AB AM THERPTCS 10MGM N71955 001  
MAR 03, 1988  
AB 15MGM N71956 001  
MAR 03, 1988  
AB 30MGM N71957 001  
MAR 03, 1988  
AB BARR LABS 15MG N71025 001  
AUG 10, 1987  
AB 30MG N71026 001  
AUG 10, 1987  
/BP/ 15MG/ N71025/001/  
AUG/10/1987/  
/BP/ 30MG/ N71026/001/  
AUG/10/1987/  
AB CHELSEA LABS 10MGM N71661 001  
MAR 02, 1988  
AB 15MGM N71662 001  
MAR 02, 1988  
AB 30MGM N71663 001  
MAR 02, 1988  
AB CORD LABS 10MGM N71813 001  
APR 19, 1988  
AB 15MGM N71756 001  
APR 19, 1988  
AB 30MGM N71814 001  
APR 19, 1988  
/BP/ 10MG/ N71713/001/  
OCT/20/1987/  
/BP/ 15MG/ N71714/001/  
OCT/20/1987/  
/BP/ 30MG/ N71715/001/  
OCT/20/1987/  
@ MYLAN PHARMS 10MG N71713 001  
OCT 20, 1987  
@ 15MG N71714 001  
OCT 20, 1987  
@ 30MG N71715 001  
OCT 20, 1987  
AB PUREPAC PHARM 10MGM N72251 001  
APR 14, 1988  
AB 15MGM N72252 001  
APR 14, 1988  
AB 30MGM N72253 001  
APR 14, 1988

OXAZEPAM

CAPSULE; ORAL

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

OXYBUTYNIN CHLORIDE

TABLET; ORAL

<u>AB</u>	<u>DITROPAN</u> MARION LABS	<u>5MG</u>	N17577 001
<u>AB</u>	<u>OXYBUTYNIN CHLORIDE</u> PHARM BASICS	<u>5MGm</u>	N70746 001 MAR 10, 1988

OXYPHENCYCLIMINE HYDROCHLORIDE

TABLET; ORAL

	DARICON <u>/BEECHAM/LABS/</u> PFIZER LABS	<u>/10MG/</u> 10MG	<u>/N11612/001/</u> N11612 001
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OXYTETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

<u>/AB/</u>	<u>OXYTETRACYCLINE HCL</u> <u>/PUREPAC/PHARM/</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

<u>AP</u>	<u>PANCURONIUM</u> ELKINS SINN	<u>1MG/MLm</u>	N72058 001 MAR 23, 1988
<u>AP</u>		<u>2MG/MLm</u>	N72059 001 MAR 23, 1988
<u>AP</u>		<u>2MG/MLm</u>	N72060 001 MAR 23, 1988
	<u>PANCURONIUM BROMIDE</u>		
<u>AP</u>	ASTRA PHARM PRODS	<u>1MG/MLm</u>	N72210 001 MAR 31, 1988
<u>AP</u>		<u>2MG/MLm</u>	N72211 001 MAR 31, 1988
<u>AP</u>		<u>2MG/MLm</u>	N72212 001 MAR 31, 1988
<u>AP</u>		<u>2MG/MLm</u>	N72213 001 MAR 31, 1988
<u>AP</u>	QUAD PHARMS	<u>1MG/MLm</u>	N72209 001 JUN 03, 1988
<u>AP</u>		<u>2MG/MLm</u>	N72208 001 JUN 03, 1988

PAVULON

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

PARAMETHADIONE

<u>/AB/</u>	<u>/CONCENTRATE; ORAL/</u> <u>/PARADIONE/</u> <u>/ABBOTT/LABS/</u>	<u>/300MG/ML/</u>	<u>/N06800/002/</u>
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SOLUTION; ORAL

<u>AA</u>	<u>PARADIONE</u> ABBOTT LABS	<u>300MG/ML</u>	N06800 002
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BEST COPY AVAILABLE

PENICILLAMINE

CAPSULE; ORAL  
CUPRIMINE  
MS&D

125MG	N19853 002
/125MG/	/N50376/002/
250MG	N19853 001
/250MG/	/N50376/001/

TABLET; ORAL  
DEPEN 250  
WALLACE LABS

250MG	N19854 001
/250MG/	/N50491/001/

PENICILLIN G POTASSIUM

INJECTABLE; INJECTION

PENICILLIN G POTASSIUM

AP	MARSAM PHARMS	1,000,000 UNITS/VIAL	N62991 001
			SEP 13, 1988
AP		5,000,000 UNITS/VIAL	N62991 002
			SEP 13, 1988
AP		10,000,000 UNITS/VIAL	N62991 003
			SEP 13, 1988
AP		20,000,000 UNITS/VIAL	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/
	3 PUREPAC PHARM	400,000 UNITS/5ML	N61740 002

TABLET; ORAL

PENICILLIN G POTASSIUM

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

PENICILLIN G SODIUM

INJECTABLE; INJECTION

PENICILLIN G SODIUM

AP	MARSAM PHARMS	5,000,000 UNITS/VIAL	N63014 001	> DLT >
			SEP 13, 1988	> DLT >
	/SQUIBB/SPA/	/5,000,000 UNITS/VIAL/	/N61935/001/	> DLT >
	SQUIBB SPA	5,000,000 UNITS/VIAL	N61935 001	> ADD >

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

/AA/	/PUREPAC/PHARM/	/EQ 250MG BASE/5ML/	/N61758/002/
	3 PUREPAC PHARM	EQ 250MG BASE/5ML	N61758 002

TABLET; ORAL

PENICILLIN V POTASSIUM

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

PERPHENAZINE

/STRIP/ORAL/  
/TRILAFON/

/SCHERING/	/2MG/5ML/	/N11294/002/
3 SCHERING	2MG/5ML	N11294 002

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
		35MG	N83684 001
		35MG	N83686 001
		35MG	N83687 001
		35MG	N84831 001
		35MG	N84834 001
		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  
IONAMIN-30  
 AB PENNALT EQ 30MG BASE N11613 002  
PHENTERMINE RESIN 30  
 AB QUANTUM PHARMS EQ 30MG BASEM N89120 001  
 FEB 04, 1988

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL  
~~PHENYLEPHRINE 1% / PROMETHAZINE 4%~~  
 /66/ /MYETH/ATERST/LABS/ /25MG/25ML; 4.25MG/25ML/ /N88604/003/  
 /APR/02./1986/

PIPERACETAZINE

/TABLET;/ORAL/  
~~10MG~~  
 /10MG/ /N13615/001/  
 10MG N13615 001  
 2 DON PHARMS /25MG/ /N13615/002/  
 2 25MG N13615 002

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

SOLUTION; ORAL  
 OCL  
 /2/ABBOTT/LABS/ /6GM/100ML; 75MG/100ML; 168MG/100ML;/ /N19284/001/  
 /146MG/100ML;/ /APR/30./1986/  
 /1.29GM/100ML/  
 ABBOTT LABS 6GM/100ML; 75MG/100ML; 168MG/100ML; N19284 001  
 146MG/100ML; APR 30, 1986  
 1.29GM/100ML

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

POWDER FOR RECONSTITUTION; ORAL  
~~COLOVAGE~~  
 /66/ /DYNAPHARM/ /227.1GM/PACKET; 2.82GM/PACKET;/ /N71320/001/  
 /6.36GM/PACKET; 5.53GM/PACKET;/ /APR/20./1988/  
 /21.5GM/PACKET/

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

POWDER FOR RECONSTITUTION; ORAL  
~~COLOVAGE~~  
 AA DYNAPHARM 227.1GM/PACKET; 2.82GM/PACKET; N71320 001  
 6.36GM/PACKET; 5.53GM/PACKET; APR 20, 1988  
 21.5GM/PACKET  
~~COLYTE~~  
 AB REED & CARNRICK 227.1GM/PACKET; 2.82GM/PACKET; N18983 004  
 6.36GM/PACKET; 5.53GM/PACKET; OCT 26, 1984  
 21.5GM/PACKETM

> ADD > POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

> ADD > SOLUTION/DROPS; OPHTHALMIC  
 > ADD > POLYTRIM  
 > ADD > BURROUGHS WELLC 10,000 UNITS/ML; N50567 001  
 > ADD > EQ 1MG BASE/MLM OCT 20, 1988

POTASSIUM AMINOSALICYLATE

> DLT > /POWDER;/ORAL/  
 > DLT > /POTASSIUM/AMINOSALICYLATE/  
 > DLT > /HEXCEL/CHEM/ /100%/ /N80098/001/  
 > ADD > 2 HEXCEL CHEM 100% N80098 001

POTASSIUM CHLORIDE

CAPSULE, CONTROLLED RELEASE; ORAL  
~~MICRO-K 30~~  
 AB ROBINS 10MEG N18238 002  
 MAY 14, 1984  
 /66/ /10MEG/ /N18238/002/  
 /MAY/14./1984/  
~~POTASSIUM CHLORIDE~~  
 AB KV PHARM 10MEG N70980 001  
 FEB 17, 1987  
 /66/ /10MEG/ /N70980/001/  
 /FEB/17./1987/

GRANULE FOR RECONSTITUTION, CR; ORAL  
 MICRO-K LS  
 ROBINS 20MEG/PACKETM

N19561 003  
 AUG 26, 1988

POTASSIUM CHLORIDE

INJECTABLE; INJECTION  
POTASSIUM CHLORIDE  
 AP STERIS LABS 2MEQ/MLM N89163 001  
 MAR 10, 1988

TABLET, CONTROLLED RELEASE; ORAL  
POTASSIUM CHLORIDE  
 BC ABBOTT LABS 8MEQM N18279 002  
 AUG 01, 1988

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION  
 > ADD > POTASSIUM CHLORIDE 20MEQ IN SODIUM CHLORIDE 0.9% IN  
 > ADD > PLASTIC CONTAINER  
 > ADD > AP ABBOTT LABS 149MG/100ML;  
 > ADD > 900MG/100MLM N19686 001  
 > ADD > OCT 17, 1988

> ADD > POTASSIUM CHLORIDE 40MEQ IN SODIUM CHLORIDE 0.9% IN  
 > ADD > PLASTIC CONTAINER  
 > ADD > AP ABBOTT LABS 298MG/100ML;  
 > ADD > 900MG/100MLM N19686 002  
 > ADD > OCT 17, 1988

POTASSIUM CITRATE

> ADD > POWDER FOR RECONSTITUTION; ORAL  
 > ADD > POTASSIUM CITRATE  
 > ADD > UNIV TEXAS 10MEQ/PACKETM N19647 002  
 > ADD > OCT 13, 1988

> ADD > 20MEQ/PACKETM N19647 001  
 > ADD > OCT 13, 1988

TABLET, CONTROLLED RELEASE; ORAL  
 > ADD > POTASSIUM CITRATE  
 > ADD > UNIV TEXAS 5MEQ N19071 001  
 > ADD > AUG 30, 1985

> DLT > URCIT-K/  
 > DLT > UNIV/TEXAS/ /5MEQ/ N19071/001/  
 > DLT > /AUG/30/1985/

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL  
MINIPRESS  
 AB PFIZER LABS 1MG N17442 002  
 AB 2MG N17442 003  
 AB 5MG N17442 001

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL  
PRAZOSIN HCL  
 AB ZENITH LABS 1MG N71994 001  
 MAY 16, 1989 : SEP 12, 1988

AB 2MG N71995 001  
 MAY 16, 1989 : SEP 12, 1988

AB 5MG N71745 001  
 MAY 16, 1989 : SEP 12, 1988

PREDNISOLONE

TABLET; ORAL  
PREDNISOLONE  
 /BX/ /BARR/LABS/ /5MG/ N84426/002/  
 3 BARR LABS 5MG N84426 002

/BX/ /STERANE/  
 /PFIZER/LABS/ /5MG/ N09996/001/  
 3 PFIZER LABS 5MG N09996 001

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC  
VASOCIDIN  
 IOLAB PHARMS EQ 0.23% PHOSPHATE;10%M 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

PREDNISON

TABLET; ORAL  
PREDNISON  
 AB SUPERPHARM 5MG N88865 001  
 OCT 25, 1984  
 AB 10MG N88866 001  
 OCT 25, 1984  
 AB 20MG N88867 001  
 OCT 25, 1984  
 /Bx/ /5MG/ /N88865/001/  
 /Bx/ /10MG/ /OCT/25/1984/  
 /Bx/ /20MG/ /N88866/001/  
 /OCT/25/1984/  
 /N88867/001/  
 /OCT/25/1984/

PROBUCOL

TABLET; ORAL  
 LORELCO  
 MERRELL DOW 500MG N17535 002  
 JUL 06, 1988

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL  
PROCAINAMIDE HCL  
 > DLT > /AB/ /LEDERLE/LABS/ /250MG/  
 > DLT > /AB/ /375MG/  
 > DLT > /AB/ /500MG/  
 > ADD > @ LEDERLE LABS 250MG N86942 001  
 > ADD > @ 375MG N86952 001  
 > ADD > @ 500MG N86943 001  
 N86943 001

INJECTABLE; INJECTION

PROCAINAMIDE HCL  
 AP WARNER CHILCOTT 100MG/MLM N89528 001  
 MAY 03, 1988  
 AP 500MG/MLM N89529 001  
 MAY 03, 1988

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION  
PROCHLORPERAZINE EDISYLATE  
 AP ELKINS SINN EQ 5MG BASE/MLM N89523 001  
 MAY 03, 1988

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION  
PROCHLORPERAZINE EDISYLATE  
 AP QUAD PHARMS EQ 5MG BASE/MLM N89637 001  
 FEB 01, 1988  
 AP EQ 5MG BASE/MLM N89638 001  
 FEB 01, 1988  
 AP STERLING DRUG EQ 5MG BASE/MLM N89703 001  
 APR 07, 1988

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
PROMETHAZINE HCL  
 AP MARSAM PHARMS 25MG/MLM N89463 001  
 MAY 02, 1988  
 AP 50MG/MLM N89477 001  
 MAY 02, 1988

TABLET; ORAL  
PROMETHAZINE HCL  
 /BP/ /BARR/LABS/ /12.5MG/  
 /BP/ /25MG/  
 /BP/ /50MG/  
 @ BARR LABS 12.5MG N84555 001  
 @ 25MG N84554 001  
 @ 50MG N84557 001  
 N84555 001

PROPIOLACTONE

SOLUTION; IRRIGATION  
 BETAPRONE  
 FOREST LABS N/A N11657 001

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL  
PROPOXYPHENE HCL  
 /BB/ /BANMAX/PHARMS/ /65MG/  
 @ BANMAX PHARMS 65MG N83184 001  
 /BB/ /BARR/LABS/ /65MG/  
 @ BARR LABS 65MG N83186 001

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PROPRANOLOL HYDROCHLORIDE

<u>TABLET; ORAL</u> <u>PROPRANOLOL HCL</u>			
<u>AB</u>	<u>INVAMED</u>	<u>10MG</u>	N71658 001 JUL 05, 1988
<u>AB</u>		<u>20MG</u>	N71687 001 JUL 05, 1988
<u>AB</u>		<u>40MG</u>	N71688 001 JUL 05, 1988
<u>AB</u>		<u>60MG</u>	N72197 001 JUL 05, 1988
<u>AB</u>		<u>80MG</u>	N71689 001 JUL 05, 1988
<u>AB</u>		<u>90MG</u>	N72198 001 JUL 05, 1988
<u>AB</u>	<u>LEDERLE LABS</u>	<u>10MG</u>	N72117 001 JUN 23, 1988
<u>AB</u>		<u>20MG</u>	N72118 001 JUN 23, 1988
<u>AB</u>		<u>40MG</u>	N72119 001 JUN 23, 1988
<u>AB</u>		<u>80MG</u>	N72120 001 JUN 23, 1988
<u>/AB/</u>	<u>/LEMMON/</u>	<u>/10MG/</u>	<u>/N70232/001/</u> <u>/OCT/07/1987/</u>
	<u>Q LEMMON</u>	<u>10MG</u>	N70232 001 OCT 07, 1987
<u>/AB/</u>	<u>/PARKE/DAVIS/</u>	<u>/10MG/</u>	<u>/N70438/001/</u> <u>/SEP/15/1986/</u>
<u>AB</u>	<u>SIDMAK LABS</u>	<u>10MG</u>	N71972 001 APR 06, 1988
<u>AB</u>		<u>20MG</u>	N71973 001 APR 06, 1988
<u>AB</u>		<u>40MG</u>	N71974 001 APR 06, 1988
<u>AB</u>		<u>60MG</u>	N71975 001 APR 06, 1988
<u>AB</u>		<u>80MG</u>	N71976 001 APR 06, 1988
<u>AB</u>		<u>90MG</u>	N71977 001 APR 06, 1988
<u>AB</u>	<u>SUPERPHARM</u>	<u>10MG</u>	N71515 001 JUN 08, 1988
<u>AB</u>		<u>20MG</u>	N71516 001 JUN 08, 1988
<u>AB</u>		<u>40MG</u>	N71517 001 JUN 08, 1988
<u>AB</u>		<u>80MG</u>	N71518 001 JUN 08, 1988
<u>AB</u>	<u>WARNER CHILCOTT</u>	<u>10MG</u>	N70438 001 SEP 15, 1986

PROPRANOLOL HYDROCHLORIDE

<u>TABLET; ORAL</u> <u>PROPRANOLOL HCL</u>			
<u>AB</u>	<u>ZENITH LABS</u>	<u>10MG</u>	N72063 001 JUL 29, 1988
<u>AB</u>		<u>20MG</u>	N72066 001 JUL 29, 1988
<u>AB</u>		<u>40MG</u>	N72067 001 JUL 29, 1988
<u>AB</u>		<u>60MG</u>	N72068 001 JUL 29, 1988
<u>AB</u>		<u>80MG</u>	N72069 001 JUL 29, 1988

PROTAMINE SULFATE

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

GUINESTROL

<u>TABLET; ORAL</u> <u>ESTROVIS</u>			
	<u>/PARKE/DAVIS/</u>	<u>/0.1MG/</u>	<u>/N16768/002/</u>
	<u>Q PARKE DAVIS</u>	<u>0.1MG</u>	N16768 002
	<u>Q</u>	<u>/0.2MG/</u>	<u>/N16768/003/</u>
		<u>0.2MG</u>	N16768 003

QUINIDINE SULFATE

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

RAUNOLFIA SERPENTINA

TABLET; ORAL  
 RAUVAL  
 BP @ VALE CHEM 50MG NO9108 002  
 /a/ /100mg/ /N09108/002/  
 BP 100MG NO9108 004  
 /a/ /50mg/ /N09108/002/

RESERPINE

TABLET; ORAL  
 RESERPINE  
 /BP/ /BARR/LABS/ /0.25mg/ /N00721/002/  
 @ BARR LABS 0.25MG N80721 002

RESERPINE; TRICHLORMETHIAZIDE

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

SECOBARBITAL SODIUM

CAPSULE; ORAL  
 SODIUM SECOBARBITAL  
 /a/ /BARR/LABS/ /100MG/ /N84225/001/  
 @ BARR LABS 100MG N84225 001

SODIUM BICARBONATE; TARTARIC ACID

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

SODIUM CHLORIDE

INJECTABLE; INJECTION  
 SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 AP KENDALL MCGAM 900MG/100MLM N19635 002  
 MAR 09, 1988  
 SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
 AP ABBOTT LABS 450MG/100MLM N19759 001  
 JUN 08, 1988

SODIUM CHLORIDE

INJECTABLE; INJECTION  
 SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER  
 AP KENDALL MCGAM 450MG/100MLM N19635 001  
 MAR 09, 1988  
 SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 > ADD > AP ABBOTT LABS 9MG/ML N19217 001  
 > ADD > JUL 13, 1984  
 > DLT > /a/ /9MG/ML/ /N19217/001/  
 > DLT > /JUL/13/1984/  
 SODIUM CHLORIDE 3% IN PLASTIC CONTAINER  
 AP KENDALL MCGAM 3GM/100MLM 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/100MLM 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  
 > DLT > /MALLINCKRODT/ /0.8-100MCI/ /N16515/002/  
 > ADD > @ MALLINCKRODT 0.8-100MCI N16515 002

SODIUM NITROPRUSSIDE

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

SODIUM SUCCINATE

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

SPIRONOLACTONE

TABLET; ORAL  
 SPIRONOLACTONE  
 /a/ /LEDERLE/LABS/ /25MG/ /N87634/001/  
 @ LEDERLE LABS 25MG N87634 001

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM

> ADD > AT STERIS LABS 10%  
> ADD > N89560 001  
OCT 18, 1988

SULFAMETHOXAZOLE

TABLET; ORAL

SULFAMETHOXAZOLE

/66/ /BARR/LABS/ /500MG/ /N87189/001/  
/JUL/25/1988/  
@ BARR LABS 500MG N87189 001  
JUL 25, 1988

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

SULFISOXAZOLE

TABLET; ORAL

SULFISOXAZOLE

/66/ /BARR/LABS/ /500MG/ /N84031/001/  
@ BARR LABS 500MG N84031 001  
/66/ /LEDERLE/LABS/ /500MG/ /N87649/001/  
@ LEDERLE LABS 500MG N87649 001

SULINDAC

TABLET; ORAL

CLINORIL

AB MS&D 150MG N17911 001  
AB 200MG N17911 002

SULINDAC

AB AM THERPTCS 150MG N72171 001  
MAY 23, 1988  
AB 200MG N72172 001  
MAY 23, 1988

SULINDAC

TABLET; ORAL

SULINDAC

AB DANBURY PHARMA 150MG N71891 001  
APR 03, 1990 : MAR 03, 1988  
AB 200MG N71795 001  
APR 03, 1990 : MAR 03, 1988

TECHNETIUM TC-99M ETIDRONATE KIT

INJECTABLE; INJECTION

/66/ /Medi Standards/ /N/A/  
/MEDIPHYSICS/ /N/A/  
@ MEDI PHYSICS N/A  
/66/ /OSTEOSCAN/ /N/A/  
/MALLINCKRODT/ /N/A/  
OSTEOSCAN N/A  
MALLINCKRODT N/A N17454 001

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/

ABBOTT LABS 10MG

/N19057/004/  
/AUG/07/1987/  
N19057 004  
AUG 07, 1987

TERCONAZOLE

SUPPOSITORY; VAGINAL

TERAZOL 3

ORTHO PHARM 80MG

N19641 001  
MAY 24, 1988

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

> ADD > AO QUAD PHARMS 100MG/MLM N89326 001  
 > ADD > OCT 28, 1988  
 > ADD > AO 200MG/MLM N89327 001  
 > ADD > OCT 28, 1988

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

TETRACYCLINE HCL

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

THEOPHYLLINE

ELIXIR; ORAL

THEOPHYLLINE

AA NASKA PHARMA 80MG/15MLM N89223 001  
 MAY 27, 1988  
 > ADD > AA THAMES PHARMA 80MG/15MLM N89626 001  
 > ADD > OCT 28, 1988

INJECTABLE; INJECTION

THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER

AP TRAVENOL LABS 320MG/100ML N18649 006  
 NOV 13, 1985

THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP ABBOTT LABS 320MG/100MLM N19211 006  
 JAN 20, 1988

TABLET, CONTROLLED RELEASE; ORAL

THEOLAIR-SR

BC RIKER LABS 250MG N86363 002  
 JUL 16, 1987  
 1250MG/ N86363/002/  
 JUL 16, 1987

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

> ADD > AB MUTUAL PHARM 100MG N89953 001  
 > ADD > OCT 07, 1988

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

AB PAR PHARM 150MG N89764 001  
 FEB 09, 1988  
 AB 200MG N89765 001  
 FEB 09, 1988  
 AB ROXANE LABS 25MG N88664 001  
 MAR 15, 1984

TIOCONAZOLE

/OINTMENT//NASINAL/  
 /NASISTAT/  
 /ROERIG/

16.5% N19155/001/  
 DEC/30, 1986/  
 6.5% N19355 001  
 DEC 30, 1986

TIOPRONIN

TABLET; ORAL

TIOPRONIN

UNIV TEXAS 100MG N19569 001  
 AUG 11, 1988

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

AB PHARM BASICS 100MG N71355 001  
 JAN 11, 1988

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

AB/BANMAX/PHARMS/ 500MG N86141/001/  
 500MG N86141 001

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

DESYREL

AB MEAD JOHNSON 150MG N18207 003  
 MAR 25, 1985

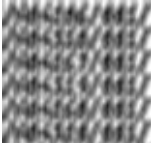
TRAZODONE HYDROCHLORIDE

TABLET; ORAL			
<u>TRAZODONE HCL</u>			
AB	PUREPAC PHARM	50MG	N71636 001 APR 18, 1988
AB		100MG	N71514 001 APR 18, 1988
AB	SIDMAK LABS	50MG	N71523 001 DEC 11, 1987
AB		100MG	N71524 001 DEC 11, 1987
/66/	/TRAZON-100/ /SIDMAK/LABS/	/100MG/	/N71524/001/ /DEC/11./1987/
AB	TRAZON-150 SIDMAK LABS	150MG	N71525 001 MAR 09, 1988
/66/	/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			
<u>TRIAMCINOLONE</u>			
/66/	/BARR/LABS/	/2MG/	
/66/		/2MG/	
/66/		/4MG/	
/66/		/4MG/	
/66/		/8MG/	
/66/		/8MG/	
/66/		/8MG/	
3	BARR LABS	2MG	N84286 001
3		2MG	N84318 001
3		4MG	N84267 001
3		4MG	N84319 001
3		8MG	N84268 001
3		8MG	N84320 001

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL			
<u>TRYMEX</u>			
/66/	/SAVAGE/LABS/	/0.5%/	/N88198/001/ /MAR/25./1983/
3	SAVAGE LABS	0.5%	N88198 001 MAR 25, 1983

TRIAZOLAM

TABLET; ORAL			
<u>HALCION</u>			
	UPJOHN	0.5MG	N17892/002/ /NOV/15./1982/
3	UPJOHN	0.5MG	N17892 002 NOV 15, 1982

TRICLOFOS SODIUM

SOLUTION; ORAL			
<u>TRICLOS</u>			
	MERRELL/DOW	/1.5GM/15ML/	/N16830/001/
3	MERRELL DOW	1.5GM/15ML	N16830 001
/TABLET;/ORAL/			
	MERRELL/DOW	/750MG/	/N16809/002/
3	MERRELL DOW	750MG	N16809 002

TRIDIHEXETHYL CHLORIDE

/INJECTABLE;/INJECTION/			
<u>PATHILON</u>			
	LEDERLE/LABS/	/10MG/ML/	/N09729/001/
3	LEDERLE LABS	10MG/ML	N09729 001

TRIFLUOPERAZINE HYDROCHLORIDE

INJECTABLE; INJECTION			
<u>STELAZINE</u>			
> ADD >	AP	EQ 2MG BASE/ML	N11552 005
> ADD >			
> ADD >	AP	EQ 2MG BASE/ML	N89893 001
> ADD >			OCT 17, 1988

† SEE SECTION 1.4 OF INTRODUCTION

TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL  
TRIFLUOPERAZINE HCL  
 AB BOLAR PHARM EQ 1MG BASEM N85975 001  
 JUN 23, 1988  
 AB EQ 2MG BASEM N85976 001  
 JUN 23, 1988  
 AB EQ 5MG BASEM N85973 001  
 JUN 23, 1988  
 AB EQ 10MG BASEM N88710 001  
 JUN 23, 1988

TRIMEPRAZINE TARTRATE

CAPSULE, CONTROLLED RELEASE; ORAL  
 TEMARIL  
 > ADD > HERBERT LABS EQ 5MG BASE N11316 004  
 > DLT > /SKAF/LABS/ /EQ/5MG/BASE/ /N11316/004/  
 SYRUP; ORAL  
 TEMARIL  
 > ADD > AA HERBERT LABS EQ 2.5MG BASE/5ML N11316 003  
 > DLT > /AA/ /SKAF/LABS/ /EQ/2.5MG/BASE/5ML/ /N11316/003/  
 TABLET; ORAL  
 TEMARIL  
 > ADD > HERBERT LABS EQ 2.5MG BASE N11316 001  
 > DLT > /SKAF/LABS/ /EQ/2.5MG/BASE/ /N11316/001/

TRIMETHOPRIM

TABLET; ORAL  
TRIMETHOPRIM  
 AB BARR LABS 100MG N70494 001  
 /AA/ /100MG/ /N70494/001/  
 /AA/ /100MG/ /N70494/001/  
 /AA/ /100MG/ /N70494/001/  
 @ 200MG N70495 001  
 MAR 14, 1986

TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL  
TRIPLENNAMINE HCL  
 /AA/ /BARR/LABS/ /50MG/ N80744/001/  
 @ BARR LABS 50MG N80744 001

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL  
 /MYK/LABS/  
 > DLT > /AA/ /MYK/LABS/ /1.25MG/5ML/  
 > DLT > /AA/ /MYK/LABS/ /1.25MG/5ML/  
 > DLT > /AA/ /MYK/LABS/ /1.25MG/5ML/  
 > ADD > @ MY K LABS 1.25MG/5ML N87963 001  
 > ADD > /AA/ /MYK/LABS/ /1.25MG/5ML/ /N87963/001/  
 /JAN/18./1983/  
 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  
 300MG N19594 002  
 DEC 31, 1987  
 /DEURSIL/  
 /CIBAPHARMEX/ /150MG/ /N19594/001/  
 /300MG/ /DEC/31./1987/  
 /DEC/31./1987/  
 /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  
VANGOCIN 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

*051, 001, 000001*

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

VANCOLEO

AP	LEDERLE LABS	<u>EQ 1GM BASE/VIALM</u>	N62682 002 MAR 30, 1988
AP		<u>EQ 5GM BASE/VIAL</u>	N62682 004 MAY 11, 1988
AP		<u>EQ 10GM BASE/VIALM</u>	N62682 005 MAY 11, 1988
		<u>EQ 2GM BASE/VIALM</u>	N62682 003 MAY 11, 1988

VANCOMYCIN HCL

AP	ABBOTT LABS	<u>EQ 500MG BASE/VIALM</u>	N62911 001 AUG 04, 1988
AP		<u>EQ 1GM BASE/VIALM</u>	N62912 001 AUG 04, 1988
AP	ELKINS SINN	<u>EQ 500MG BASE/VIALM</u>	N62879 001 AUG 02, 1988
AP		<u>EQ 1GM BASE/VIALM</u>	N62879 002 AUG 02, 1988
AP	QUAD PHARMS	<u>EQ 500MG BASE/VIALM</u>	N62845 001 JUL 15, 1988
AP		<u>EQ 1GM BASE/VIALM</u>	N62845 002 JUL 15, 1988

VANCOR

AP	ADRIA LABS	<u>EQ 500MG BASE/VIALM</u>	N62956 001 AUG 01, 1988
AP		<u>EQ 1GM BASE/VIALM</u>	N62956 002 AUG 01, 1988

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

CALAN

/SEARLE/

/160MG/

/N18817/004/  
/FEB/23/1988/

AB	SEARLE PHARMS	<u>40MG</u>	N18817 003 FEB 23, 1988
		<u>160MG</u>	N18817 004 FEB 23, 1988

ISOPTIN

AB	KNOLL PHARM	<u>40MG</u>	N18593 003 NOV 23, 1987
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VERAPAMIL HCL

AB	CORD LABS	<u>80MG</u>	N71423 001 MAY 24, 1988
AB		<u>120MG</u>	N71424 001 MAY 25, 1988

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

VERAPAMIL HCL

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

VINCRIStINE SULFATE

INJECTABLE; INJECTION

VINCRIX

AP	BRISTOL LABS	<u>5MG/VIALM</u>	N70867 001 JUL 12, 1988
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VINCRIStINE SULFATE

AP	BULL LABS	<u>1MG/VIALM</u>	N71559 001 APR 11, 1988
AP		<u>2MG/VIALM</u>	N71560 001 APR 11, 1988
AP		<u>5MG/VIALM</u>	N71561 001 APR 11, 1988
AP	QUAD PHARMS	<u>1MG/VIAL</u>	N71222 001 MAR 07, 1988
AP		<u>2MG/VIAL</u>	N71223 001 MAR 07, 1988
AP		<u>5MG/VIAL</u>	N71937 001 MAR 07, 1988

VINCRIStINE SULFATE PFS

AP	BULL LABS	<u>1MG/MLM</u>	N71484 001 APR 19, 1988
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WATER FOR INJECTION, STERILE

LIQUID; N/A

STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

AP	BAXTER	<u>100ZM</u>	N18632 002 APR 19, 1988
AP	KENDALL MCGAW	<u>100ZM</u>	N19633 001 FEB 29, 1988

XYLOSE

PONDER; ORAL  
~~/Xylose/~~  
~~/L/~~ /LYNE/LABS/  
© LYNE LABS

~~/25GM/BOT/~~  
25GM/BOT

~~/N18856/001/~~  
~~/MAR/26./1987/~~  
N18856 001  
MAR 26, 1987

ACETAMINOPHEN

SUPPOSITORY; RECTAL  
 NEOPAP  
 > DLT > /REBCON/PHARMS/ /120MG/ /N16401/001/  
 > ADD > ALCON LABS 120MG N16401 001  
 TYLENOL  
 MCNEIL CONSUMER 120MG N17756 002  
 650MG N17756 001  
 /MCNEIL/LABS/ /120MG/ /N17756/002/  
 /550MG/ /N17756/001/

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  
 COPLEY PHARM 12MG;75MG N71099 001  
 JUL 02, 1987

BUTYL METHOXYDIBENZOYLMETHANE; PADIMATE O

LOTION; TOPICAL  
 PHOTOPLEX  
 HERBERT LABS 3%;7% N19459 001  
 SEP 30, 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 3MG;120MG N19428 001  
 AUG 02, 1988

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  
 MYLAN PHARMS 200MG N71870 001  
 MAY 05, 1988  
 PRIVATE FMLTNS 200MG N72299 001  
 JUL 01, 1988  
 ZENITH LABS 200MG N72040 001  
 APR 29, 1988  
 NUPRIN  
 BRISTOL MYERS 200MG N72035 001  
 FEB 16, 1988  
 200MG N72036 001  
 FEB 16, 1988

> ADD >

FEB 18, 1983

INJECTABLE; INJECTION  
MIXTARD HUMAN 70/30  
NORDISK USA

30 UNITS/ML;  
70 UNITS/MLM

N19585 001  
MAR 11, 1988

INSULIN ZINC SUSP EXTENDED BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION  
HUMULIN U  
/LILLY/

/40 UNITS/ML/

© LILLY

40 UNITS/ML

/N19571/001/  
/JUN/10/1987/  
N19571 001  
JUN 10, 1987

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL  
IMODIUM A-D  
MCNEIL CONSUMER

1MG/5MLM

N19487 001  
MAR 01, 1988

NONOXYNOL-9

SPONGE; VAGINAL  
TODAY  
/LILLY/

/1GM/

WHITEHALL LABS

1GM

/N18683/001/  
/APR/01/1983/  
N18683 001  
APR 01, 1983

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~~REST COPY~~

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS / CUMULATIVE SUPPLEMENT NUMBER 10 / JAN '68 - OCT '68  
APPROVED UNDER SECTION 505 OF THE ACT LIST

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

INJECTABLE; INJECTION  
OPTISOL RED BLOOD CELL PRESERVATIVE SOLUTION  
TERUMO 0.9GM/100ML;0.877GM/100ML; N 880217  
0.525GM/100ML;0.03GM/100ML OCT 07, 1968

DEXTRAN 70, 6% IN SODIUM CHLORIDE 0.9%

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

~~/SOLUTION/~~  
~~/SOLUTION/CHEMICAL/STERILIZING/AGENT/~~  
~~/BETAPRONE/~~  
~~/ORAL/ONASAFEDIN/0.9GM/100ML/~~ ~~/N/11651/~~

**ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL**

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

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

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

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

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

## ORPHAN DRUG PRODUCTS WITH EXCLUSIVE APPROVAL

## DRUG PRODUCTS

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME DOSAGE FORM; ROUTE	APPLICANT	APPL. PROD. APPROVAL DATE	EXCLUSIVITY EXP. DATE
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
METHOTREXATE SODIUM EQ 20MG BASE/VIAL	METHOTREXATE INJECTABLE; INJECTION	LEDERLE LABS	11719 001 APR 07, 1988	ODE <sup>2</sup> APR 07, 1995

<sup>1</sup>ODE PERTAINS ONLY TO INDICATION I-79 (SEE EXCLUSIVITY TERMS)

<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. APPROVAL DATE	EXCLUSIVITY EXP. DATE
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
POTASSIUM CHLORIDE 10MEQ/PACKET	POTASSIUM CHLORIDE POWDER, FOR RECONSTITUTION	UNIV TEXAS	19647 002 OCT 13, 1988	ODE <sup>2</sup> AUG 30, 1992
POTASSIUM CHLORIDE 20MEQ/PACKET	POTASSIUM CHLORIDE POWDER, FOR RECONSTITUTION	UNIV TEXAS	19647 001 OCT 13, 1988	ODE <sup>2</sup> AUG 30, 1992
TIOPRONIN 100MG	TIOPRONIN TABLET; ORAL	UNIV TEXAS	19569 001 AUG 11, 1988	ODE AUG 11, 1995

<sup>2</sup>ODE PERTAINS ONLY TO INDICATION I-78 (SEE EXCLUSIVITY TERMS)

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

NO OCTOBER 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)	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.

### 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
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 SPRAY; TOPICAL	0.5%	88 P-0036/CP	ARENT, FOX, KINTNER, PLOTKIN & KAHN	NEW DOSAGE FORM	APPROVED AUG 19, 1988
CHLORZOXAZONE CAPSULE; ORAL	500MG	82 N-0032/ CP0006	MIKART	NEW DOSAGE FORM	APPROVED JAN 13, 1988

## ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (500ML/CONTAINER)	88 P-0011/CP	BAXTER HLTHCARE	NEW DOSAGE FORM NEW STRENGTH	APPROVED JUN 10, 1988
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

## ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
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

## ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
PREDNISOLONE SODIUM PHOSPHATE SOLUTION; ORAL	EQ 5MG BASE/ML	88 P-0235/CP	PAN AM PHARMS	NEW STRENGTH	APPROVED AUG 24, 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
THIOTEPA (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

## 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
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
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
CYCLOBENZAPRINE HYDROCHLORIDE TABLET; ORAL	15MG	86 P-0386/CP	CENTRAL PHARMS	NEW STRENGTH	DENIED AUG 15, 1988
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	100MG/ML (1ML/VIAL) (2ML/VIAL)	87 P-0283/CP	LYPHOMED	NEW DOSAGE FORM NEW STRENGTH	DENIED JAN 21, 1988

## ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
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
HYDROCODONE BITARTRATE; PROMETHAZINE HYDROCHLORIDE SYRUP; ORAL	2.5MG/5ML 6.25MG/5ML	85 P-0256/CP	MILKART	NEW COMBINATION	DENIED MAY 11, 1988
MAGNESIUM ASCORBATE INJECTABLE; INJECTION	10% 20%	88 P-0200/CP	RIM CONSULTING	NEW INGREDIENT	DENIED JUN 10, 1988

## ANDA SUITABILITY PETITIONS

## PETITIONS DENIED

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (50ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 1988
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (75ML/VIAL)	87 P-0090/CP	INTL MEDTN SYS	NEW STRENGTH	DENIED FEB 08, 1988
METOCLOPRAMIDE HYDROCHLORIDE INJECTABLE; INJECTION	1MG/ML (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-72 ~~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-79 ~~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  
 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

**EXCLUSIVITY TERMS****REFERENCES****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

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

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APPL/PROD	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		
19716 001	BETAMETHASONE DIPROPIONATE; DIPROLENE	4158055	JUN 12, 1996	U-34		
18644 001	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002		NP	AUG 01, 1991
18644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
18644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4507323	MAR 26, 2002			
19459 001	BUTYL METHOXYDIBENZOYLMETHANE; PHOTOPLEX	4387089	JUN 07, 2000		NP	SEP 30, 1991
17920 002	CIMETIDINE; TAGAMET	4024271	MAY 17, 1994		D-14	MAR 31, 1991
17920 003	CIMETIDINE; TAGAMET	3950333	APR 13, 1993		D-12	APR 30, 1989
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
18891 001	CLONIDINE; CATAPRES-TTS-1	3950333	APR 13, 1993		D-12	APR 30, 1989
18891 002	CLONIDINE; CATAPRES-TTS-2	4201211	MAY 06, 1997			
18891 003	CLONIDINE; CATAPRES-TTS-3	4060084	JUN 28, 1994			
19201 001	DICLOFENAC SODIUM; VOLTAREN	3996934	JUL 29, 1992			
19201 002	DICLOFENAC SODIUM; VOLTAREN	4201211	MAY 06, 1997			
19201 003	DICLOFENAC SODIUM; VOLTAREN	4060084	JUN 28, 1994			
18998 001	ENALAPRIL MALEATE; VASOTEC	3996934	JUL 29, 1992			
18998 002	ENALAPRIL MALEATE; VASOTEC	4201211	MAY 06, 1997			
18998 003	ENALAPRIL MALEATE; VASOTEC	4060084	JUN 28, 1994			
18998 005	ENALAPRIL MALEATE; VASOTEC	3996934	JUL 29, 1992		NCE	JUL 28, 1993
		3652762	MAR 28, 1989		NCE	JUL 28, 1993
		3652762	MAR 28, 1989		NCE	JUL 28, 1993
					I-74	JUN 24, 1991
					I-74	JUN 24, 1991
					I-74	JUN 24, 1991
		4374829	FEB 22, 2000		NCE	DEC 24, 1990
					I-74	JUN 24, 1991

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PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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; BREVIBLOC	4593119	JUN 03, 2003		NCE	DEC 31, 1991
		4387103	JUN 07, 2000	U-16		
>ADD>	19462 001 FAMOTIDINE; PEPCID				I-80	OCT 17, 1991
>ADD>	19462 002 FAMOTIDINE; PEPCID				I-80	OCT 17, 1991
>ADD>	19510 001 FAMOTIDINE; PEPCID				I-80	OCT 17, 1991
>ADD>	19527 001 FAMOTIDINE; PEPCID				I-80	OCT 17, 1991
	18830 003 FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996		NS	JUN 03, 1991
		3900481	AUG 19, 1992		NCE	OCT 31, 1990
	18830 004 FLECAINIDE ACETATE; TAMBOCOR	4005209	JAN 25, 1996			
		3900481	AUG 19, 1992		NCE	OCT 31, 1990
	19452 001 FLUOCINOLONE ACETONIDE; DERMA-SMOOTHIE/FS				NDF	FEB 03, 1991
	18936 001 FLUOXETINE HYDROCHLORIDE; PROZAC	4683235	JUL 28, 2004	U-30		
		4647591	MAR 03, 2004	U-28		
		4647591	MAR 03, 2004	U-29		
		4626549	DEC 02, 2003	U-26		
		4626549	DEC 02, 2003	U-27		
		4194009	APR 19, 1994			
>ADD>	18766 002 FLURBIPROFEN; ANSAID	3793457	FEB 19, 1993		NCE	DEC 31, 1991
>ADD>		3755427	AUG 28, 1990		NDF	OCT 31, 1991
>ADD>	18766 003 FLURBIPROFEN; ANSAID	3793457	FEB 19, 1993		NCE	DEC 31, 1991
>ADD>		3755427	AUG 28, 1990		NDF	OCT 31, 1991
	19404 001 FLURBIPROFEN SODIUM; OCUFEN	3793457	FEB 19, 1993			
	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			
	18061 001 HYDROCHLOROTHIAZIDE; TIMOLIDE 10-25	3655663	APR 11, 1989		D-2	FEB 03, 1991
	19129 003 HYDROCHLOROTHIAZIDE; MAXZIDE-25				D-15	MAY 13, 1991
	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

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APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
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	
19085 001	IPRATROPIUM BROMIDE; ATROVENT	3681500	AUG 01, 1991	NCE	DEC 29, 1991	
08107 001	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			ODE	AUG 31, 1995	
08107 002	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			I-79	AUG 31, 1995	
08107 003	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			ODE	AUG 31, 1995	
08107 004	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM			I-79	AUG 31, 1995	
				ODE	AUG 31, 1995	
19777 001	LISINAPRIL; ZESTRIL	4374829	FEB 22, 2000	I-79	AUG 31, 1995	
19777 002	LISINAPRIL; ZESTRIL	4374829	FEB 22, 2000	NCE	DEC 29, 1992	
19777 003	LISINAPRIL; ZESTRIL	4374829	FEB 22, 2000	NCE	DEC 29, 1992	
19487 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM A-D	3714159	JAN 30, 1990	NCE	DEC 29, 1992	
19643 003	LOVASTATIN; MEVACOR	4231938	NOV 04, 1999			
18006 001	MECLOFENAMATE SODIUM; MECLOMEN			NCE	AUG 31, 1992	
18006 002	MECLOFENAMATE SODIUM; MECLOMEN			I-68	AUG 30, 1991	
>ADD> 08085 002	METHOTREXATE SODIUM; METHOTREXATE			I-68	AUG 30, 1991	
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	
18654 001	MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999	I-72	MAR 23, 1991	
18654 002	MIDAZOLAM HYDROCHLORIDE; VERSED	4280957	DEC 20, 1999	NCE	DEC 20, 1990	
				NCE	DEC 20, 1990	

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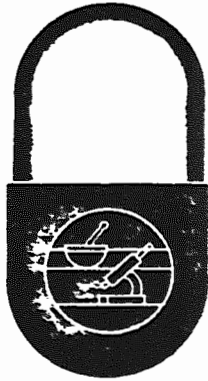
APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19501 001	MINOXIDIL; ROGAINE				NDF	AUG 17, 1991
19516 002	MORPHINE SULFATE; MS CONTIN				NDF	MAY 29, 1990
18677 001	NABILONE; CESAMET	4087545	MAY 02, 1997	U-7		
19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 1998		NCE	MAR 01, 1993
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
>ADD>	19667 001	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2000	NCE	OCT 21, 1993
>ADD>	19667 002	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2000	NCE	OCT 21, 1993
>ADD>	19667 003	OCTREOTIDE ACETATE; SANDOSTATIN	4395403	JUL 26, 2000	NCE	OCT 21, 1993
	19009 001	PIRIBUTEROL ACETATE; MAXAIR	4175128	NOV 20, 1996		
			3786160	JAN 15, 1993		
			3700681	OCT 24, 1989	NCE	DEC 30, 1991
			4259315	MAR 31, 1998		
>ADD>	19561 003	POTASSIUM CHLORIDE; MICRO-K LS			ODE	AUG 30, 1992
>ADD>	19647 001	POTASSIUM CITRATE; POTASSIUM CITRATE			ODE	AUG 30, 1992
>ADD>	19647 002	POTASSIUM CITRATE; POTASSIUM CITRATE				
	17535 002	PROBUCOL; LORELCO	3862332	JAN 21, 1992		
	17881 001	TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT; TECHNETIUM TC 99M	3872226	MAR 18, 1992	U-31	
			3863004	JAN 28, 1992		
19057 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
		4026894	MAY 31, 1994			
19057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
		4026894	MAY 31, 1994			
19057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
		4026894	MAY 31, 1994			
19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4251532	FEB 17, 2000	U-5	NCE	AUG 07, 1992
		4112097	SEP 05, 1995	U-5		
		4026894	MAY 31, 1994			
19057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	4026894	MAY 31, 1994			
19641 001	TERCONAZOLE; TERAZOL 3	4358449	NOV 09, 1999		NCE	DEC 31, 1992
					NDF	MAY 24, 1991

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APPL/PROD	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19569 001	TIOPRONIN; TIOPRONIN				NCE	AUG 11, 1993
18207 003	TRAZODONE HYDROCHLORIDE; DESYREL	4258027	MAR 24, 1998		ODE	AUG 11, 1995
19049 001	TRETINOIN; RETIN-A	4215104	JUL 29, 1997			
		3906108	SEP 16, 1992			
		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

# New 9th Edition



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