

**CUMULATIVE
SUPPLEMENT 9
JAN'89-SEP'89**



APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

9TH EDITION

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

Prepared By
Division of Drug Information Resources
Office of Management
Center for Drug Evaluation and Research, FDA

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS
9TH EDITION

CUMULATIVE SUPPLEMENT 9

SEPTEMBER 1989

CONTENTS

	PAGE
1.0 INTRODUCTION	iii
1.1 How to Use the Cumulative Supplement	iii
1.2 Products Requiring Revised Labeling for Full Approval	v
1.3 Applicant (Name) Changes	v
1.4 Corrections to the 9th Edition	vi
1.5 Rescission of Approval Letters	vi
1.6 Report of Counts for the Prescription Drug Product List	vii
2.0 DRUG PRODUCT LISTS	
2.1 Prescription Drug Product List	1
2.2 OTC Drug Product List	45
2.3 Drug Products in the Division of Blood and Blood Products Approved Under Section 505 of the Act List	47
2.4 Orphan Drug Designations	48
2.5 Drug Products Which Must Demonstrate <u>in vivo</u> Bioavailability Only if Product Fails to Achieve Adequate Dissolution	54
2.6 Biopharmaceutic Guidance Availability	55
2.7 ANDA Suitability Petitions	56
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Exclusivity Terms	60
B. Patent and Exclusivity Lists	62

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1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

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under Section 505 of the Act, and products discontinued from marketing or products which have had their approval withdrawn for other than safety or efficacy reasons.

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

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

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

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

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

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

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

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

1.2 PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL

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

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

1.3 APPLICANT (NAME) CHANGES

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

APPLICANT (NAME) CHANGES

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>NEW ABBREVIATED NAME</u>
DUPONT CRITICAL CARE SUB EI DUPONT DE NEMOURS & COMPANY INC	DUPONT PHARMACEUTICALS DIV EI DUPONT DE NEMOURS & CO INC	DUPONT PHARMS
INTERNATIONAL PHARMACEUTICAL PRODUCTS INC	NORBROOK AMERICA INC	NORBROOK AM
MAURRY BIOLOGICAL CO INC	NORBROOK AMERICA INC	NORBROOK AM
MCNEIL PHARMACEUTICAL DIVISION OF MCNEIL LABORATORIES INC	RW JOHNSON PHARM RESEARCH INST DIV MCNEILAB INC	RW JOHNSON

APPLICANT (NAME) CHANGES

<u>FORMER APPLICANT (NAME)</u>	<u>NEW APPLICANT (NAME)</u>	<u>NEW ABBREVIATED NAME</u>
ORTHO PHARMACEUTICAL CORP	RW JOHNSON PHARM RESEARCH INST DIV ORTHO PHARM CORP	RW JOHNSON
SCHERING CORP	SCHERING CORP SUB SCHERING PLOUGH CORP	SCHERING

1.4 CORRECTIONS TO THE 9TH EDITION

- The locator tabs for the "OTC Drug Product List" and the "Product Name Index Listed by Applicant" were not printed within the List.
- The locator tabs for the "Drug Products Which Must Demonstrate in vivo Bioavailability Only If Product Fails to Achieve Adequate Dissolution," "ANDA Suitability Petitions," "Product Name Index," and "Product Name Index Listed by Applicant" were placed incorrectly within the List.
- On page 3-374, "ANDA Suitability Petitions," the heading "Petitions Approved" should read "Petitions Denied."

1.5 RESCISSION OF APPROVAL LETTERS

On August 3, 1989, the Agency, in separate letters to Par Pharmaceutical and American Therapeutics, Inc. (ATI), rescinded the approval letters of June 5 and June 23, 1989, respectively, for chlorzoxazone 500mg tablets. The approvals were rescinded because of substantial deficiencies in manufacturing practices discovered by the Agency at each firm at the time of each approval. These products are considered unapproved new drugs that cannot be marketed.

The Agency is assessing all current information available to make a fair and final determination concerning the adequacy of Par's and ATI's manufacturing practices with regard to these ANDAs. An opportunity for hearing, as required by Section 505(c)(1), will be provided should the Agency determine it cannot approve these applications.

1.6 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 1988) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product, provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

CATEGORIES COUNTED	DEC 1988	MAR 1989	JUN 1989	SEP 1989
DRUG PRODUCTS LISTED	10091	10157	10137	
SINGLE SOURCE	1983 (19.7%)	1993 (19.6%)	1982 (19.6%)	
MULTISOURCE	8108 (80.3%)	8164 (80.4%)	8155 (80.4%)	
THERAPEUTICALLY EQUIVALENT	7242 (71.8%)	7321 (72.1%)	7341 (72.4%)	
NOT THERAPEUTICALLY EQUIVALENT	743 (7.4%)	726 (7.1%)	701 (6.9%)	
EXCEPTIONS ¹	118 (1.1%)	117 (1.2%)	113 (1.1%)	
NEW MOLECULAR ENTITIES APPROVED	--	3	4	
NUMBER OF APPLICANTS	374	393	394	

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

viii

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

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL	
<u>ACETAMINOPHEN AND CODEINE PHOSPHATE</u>	
/AA/	/DURAMED/PHARMS/ /300MG;15MG/ /N88353/001/ /FEB/06/1984/
/AA/	/300MG;30MG/ /N88354/001/ /FEB/06/1984/
/AA/	/300MG;60MG/ /N88355/001/ /FEB/06/1984/
3	DURAMED PHARMS 300MG;15MG N88353 001 FEB 06, 1984
3	300MG;30MG N88354 001 FEB 06, 1984
3	300MG;60MG N88355 001 FEB 06, 1984
AA	PUREPAC PHARM 300MG;30MG N86681 001
> ADD > AA	300MG;60MG N86683 001
	500MG;15MG N89511 001
	500MG;30MG N89512 001
	500MG;60MG N89513 001
	APR 25, 1989
	APR 25, 1989
	APR 25, 1989

<u>ACETAMINOPHEN W/ CODEINE PHOSPHATE</u>	
/AA/	/PBI/ /300MG;30MG/ /N87919/001/ /JUN/22/1982/
/AA/	/300MG;60MG/ /N87920/001/ /JUN/22/1982/
3	PBI 300MG;30MG N87919 001 JUN 22, 1982
3	300MG;60MG N87920 001 JUN 22, 1982
/AA/	/PUREPAC/PHARM/ /300MG;30MG/ /N86681/001/ /FEB/06/1984/
/AA/	/300MG;60MG/ /N86683/001/ /FEB/06/1984/
/AA/	/WHITE/TN/PAULSN/ /300MG;30MG/ /N84360/001/ /FEB/06/1984/
3	WHITE TN PAULSN 300MG;30MG N84360 001 FEB 06, 1984
3	300MG;60MG N85607 001 MAR 20, 1984
/AA/	/CODEINE PHOSPHATE AND ACETAMINOPHEN/ /ICN/PHARMS/ /300MG;30MG/ /N85896/001/ /MAR/20/1984/
/AA/	/ICN PHARMS 300MG;30MG N85896 001 MAR 20, 1984
/AA/	/PAPA-DEINE #3/ /VANGARD/LABS/ /300MG;30MG/ /N88715/001/ /MAR/20/1984/
3	VANGARD LABS 300MG;30MG N88715 001 MAR 20, 1984
/AA/	/PAPA-DEINE #4/ /VANGARD/LABS/ /300MG;60MG/ /N88715/001/ /MAR/20/1984/
3	VANGARD LABS 300MG;60MG N88715 001 MAR 20, 1984

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL	
<u>ALLEY</u>	
AA	LUCHEM PHARMS 500MG;5MG N89907 001 JAN 13, 1989
TABLET; ORAL	
<u>ANEXIA</u>	
AA	BEECHAM LABS 500MG;5MG N89160 001 APR 23, 1987
/AA/	/ANEXIA-5/ /BEECHAM/LABS/ /500MG;5MG/ /N89160/001/ /APR/23/1987/
HYDROCODONE BITARTRATE AND ACETAMINOPHEN	
MIKART	
	500MG;2.5MG N89698 001 AUG 25, 1989
	500MG;7.5MG N89699 001 AUG 25, 1989

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL	
<u>OXYCODONE AND ACETAMINOPHEN</u>	
AA	HALSEY DRUG 500MG;5MG N89994 001 MAY 04, 1989
TYLOX	
AA	MCNEIL PHARM 500MG;5MG N88790 001 DEC 12, 1984
TABLET; ORAL	
<u>OXYCODONE/5/APAP/500/</u>	
/AA/	/DUPONT/PHARMS/ 500MG;2.5MG /N85910/001/ /JAN/12/1989/
/AA/	/OXYCODONE/5/APAP/500/ /DUPONT/PHARMS/ 500MG;5MG /N85911/001/ /JAN/12/1989/
/AA/	/ROXICET 5/500/ /FOXANE/LABS/ 500MG;5MG /N85911/001/ /JAN/12/1989/
	ROXANE LABS 500MG;5MG N89775 001 JAN 12, 1989

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

CAPSULE; ORAL	
TYLOX	
/AA/	/MCNEIL/LABS/ 500MG;4.5MG;0.38MG /N85375/001/ /JAN/12/1989/
3	RW JOHNSON 500MG;4.5MG;0.38MG N85375 001 JAN 12, 1989

ALLOPURINOL

TABLET; ORAL

LOPURIN

/AB/ /BOOTS/PHARMAS/ /100MG/

/AB/ /BOOTS/PHARMAS/ /300MG/

/AB/ /BOOTS/USA/ /100MG/

AB BOOTS USA /300MG/

/AB/ /BOOTS/USA/ /100MG/

AB BOOTS USA /300MG/

3 100MG

3 300MG

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

/BARR/LABS/ /5MG;50MG/

/BARR/LABS/ /5MG;50MG/

BARR LABS 5MG;50MG

DEC 25, 1990 : MAY 10, 1988

AMINO ACIDS

INJECTABLE; INJECTION

/AMINOSYN/11/3.5%N/IN/PLASTIC/CONTAINER/

/ABBOTT/LABS/ /3.5%N/

3 ABBOTT LABS 3.5%

OCT 10, 1986

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

/AMINOSYN/3.5%N/DEXTROSE/25%N/IN/PLASTIC/CONTAINER/

/ABBOTT/LABS/ /3.5%N;25%N/100ML/

3 ABBOTT LABS 3.5%;25GM/100ML

OCT 11, 1984

/AMINOSYN/3.5%N/DEXTROSE/5%N/IN/PLASTIC/CONTAINER/

/ABBOTT/LABS/ /3.5%N;5%N/100ML/

3 ABBOTT LABS 3.5%;5GM/100ML

OCT 11, 1984

AMINO ACIDS; DEXTROSE

INJECTABLE; INJECTION

TRAVASOL 2.75% IN DEXTROSE 10% IN PLASTIC CONTAINER

BAXTER 2.75%;10GM/100ML N19520 002

SEP 23, 1988

TRAVASOL 2.75% IN DEXTROSE 15% IN PLASTIC CONTAINER

BAXTER 2.75%;15GM/100ML N19520 003

SEP 23, 1988

TRAVASOL 2.75% IN DEXTROSE 20% IN PLASTIC CONTAINER

BAXTER 2.75%;20GM/100ML N19520 004

SEP 23, 1988

TRAVASOL 2.75% IN DEXTROSE 25% IN PLASTIC CONTAINER

BAXTER 2.75%;25GM/100ML N19520 005

SEP 23, 1988

TRAVASOL 2.75% IN DEXTROSE 5% IN PLASTIC CONTAINER

BAXTER 2.75%;5GM/100ML N19520 001

SEP 23, 1988

TRAVASOL 4.25% IN DEXTROSE 10% IN PLASTIC CONTAINER

BAXTER 4.25%;10GM/100ML N19520 007

SEP 23, 1988

TRAVASOL 4.25% IN DEXTROSE 15% IN PLASTIC CONTAINER

BAXTER 4.25%;15GM/100ML N19520 008

SEP 23, 1988

TRAVASOL 4.25% IN DEXTROSE 20% IN PLASTIC CONTAINER

BAXTER 4.25%;20GM/100ML N19520 009

SEP 23, 1988

TRAVASOL 4.25% IN DEXTROSE 25% IN PLASTIC CONTAINER

BAXTER 4.25%;25GM/100ML N19520 010

SEP 23, 1988

TRAVASOL 4.25% IN DEXTROSE 5% IN PLASTIC CONTAINER

BAXTER 4.25%;5GM/100ML N19520 006

SEP 23, 1988

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

INJECTABLE; INJECTION

/AMINOSYN/11/3.5%N/IN/PLASTIC/CONTAINER/

/ABBOTT/LABS/ /3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

/3.5%N;100ML/100ML/

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

25MG; 2MG
25MG; 4MG
50MG; 4MG

AB
AB
AB

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

5

AMMONIUM LACTATE

LOTION; TOPICAL
LAC-HYDRIN
/BRISTOL MYERS/

/EQ 12% ACID/

WESTWOOD PHARMS

EQ 12% ACID

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

AMPICILLIN/AMPCILLIN TRIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

AMPCILLIN

CLONMEL CHEMS

EQ 125MG BASE/5ML

EQ 250MG BASE/5ML

N62982 001
FEB 10, 1989
N62982 002
FEB 10, 1989

AMOXAPINE

TABLET; ORAL

AMOXAPINE

WATSON LABS

25MG

50MG

100MG

150MG

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

ASENDIN

LEDERLE LABS

25MG

50MG

100MG

150MG

N18021 001
N18021 002
N18021 003
N18021 004

AMOXICILLIN

CAPSULE; ORAL

AMOXICILLIN

LEMON

250MG

500MG

1250MG

1500MG

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

/TAS/PHARMS/

POWDER FOR RECONSTITUTION; ORAL

AMOXICILLIN

NOVOPHARM

250MG/5ML

N63001 001
JAN 06, 1989

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

INJECTABLE; INJECTION

TENORMIN

ICI PHARM

0.5MG/ML

N19058 001
SEP 13, 1989

ATENOLOL

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

INJECTABLE; INJECTION

TENORMIN

ICI PHARM

0.5MG/ML

N19058 001
SEP 13, 1989

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL W/ ASPIRIN & CAFFEINE

/AB/ /BOTS/LABS/ /325MG; 50MG; 40MG/

AB PHARMAFAIR

325MG; 50MG; 40MG

/N87048/002/
/DEC/09, 1983/
N87048 002
DEC 09, 1983

ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL W/ ASPIRIN AND CAFFEINE

/AA/ /CHELSEA/LABS/ /389MG; 32.4MG; 65MG/

3 CHELSEA LABS

389MG; 32.4MG; 65MG

/N85732/002/
/SEP/03, 1984/
N85732 002
SEP 03, 1984

ASPIRIN; CARISOPRODOL

TABLET; ORAL

CARISOPRODOL AND ASPIRIN

AB PAR PHARM 325MG; 200MG

N89594 001
MAR 31, 1989

ATENOLOL

BENZONATATE

TABLET; ORAL

TENOLOL

> ADD > AB
> ADD > AB
> DLT > AB
> DLT > AB

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

ICI PHARM
/STUART/PHARMS/
/STUART/PHARMS/

CAPSULE; ORAL

TESSALON

/100MG/
100MG

/PUPONT/PHARMS/
FOREST LABS

/N11210/001/
N11210 001

BENZTROPINE MESYLATE

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

AA

/AA/

/AA/

/AA/

/AA/

/AA/

/AA/

/AA/

/AA/

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AA

AA

AA

AA

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AA

AA

AA

AA

AA

AA

AA

AA

AA

AA

0.5MG

1MG

2MG

N72264 001

FEB 27, 1989

N72265 001

FEB 27, 1989

N72266 001

FEB 27, 1989

N72267 001

FEB 27, 1989

N72268 001

FEB 27, 1989

BETAMETHASONE DIPROPIONATE

CREAM; TOPICAL

DIPROLOLENE

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

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/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

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/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/EQ/0.05%/BASE/

/N19408/001/
/JAN/31, 1986/

/N19409/001/
/APR/27, 1987/

/N19410/001/
/JAN/31, 1986/

/N19411/001/
/APR/27, 1987/

/N19412/001/
/JAN/31, 1986/

/N19413/001/
/APR/27, 1987/

/N19414/001/
/JAN/31, 1986/

/N19415/001/
/APR/27, 1987/

/N19416/001/
/JAN/31, 1986/

/N19417/001/
/APR/27, 1987/

/N19418/001/
/JAN/31, 1986/

/N19419/001/
/APR/27, 1987/

/N19420/001/
/JAN/31, 1986/

/N19421/001/
/APR/27, 1987/

/N19422/001/
/JAN/31, 1986/

/N19423/001/
/APR/27, 1987/

/N19424/001/
/JAN/31, 1986/

/N19425/001/
/APR/27, 1987/

/N19426/001/
/JAN/31, 1986/

/N19427/001/
/APR/27, 1987/

/N19428/001/
/JAN/31, 1986/

CREAM, AUGMENTED; TOPICAL

DIPROLOLENE

SCHERING

DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

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DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

SCHERING

DIPROLOLENE AF

SCHERING

LOTION; TOPICAL

DIPROLOLENE

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

/BX/ /SCHERING/

BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL
DIPROLENE
SCHERING

EQ 0.05% BASE

N18741 001
JUL 27, 1983

TABLET; ORAL

BROMPHENIRAMINE MALEATE

/AA/ /CHLSEA/LABS/ /4MG/
3 CHLSEA LABS 4MG
/AA/ /CORD/LABS/ /4MG/
3 CORD LABS 4MG

/N85769/001/
N85769 001
/N83215/001/
N83215 001

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

/AA/ /CHLSEA/LABS/ /5MG/
/AA/ /CHLSEA/LABS/ /10MG/
/AA/ /CHLSEA/LABS/ /25MG/
3 CHLSEA LABS 5MG
3 10MG
3 25MG

/N85841/001/
/N85842/001/
/N85843/001/
N85841 001
N85842 001
N85839 001

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

/BRETILUM TOSYLATE IN DEXTROSE 5%/
/ABBOTT/LABS/ /200MG/100ML/
/ABBOTT/LABS/ /400MG/100ML/
/ABBOTT/LABS/ /800MG/100ML/
3 ABBOTT LABS 200MG/100ML
3 400MG/100ML
3 800MG/100ML

/N19005/002/
/APR 16, 1986/
/N19005/003/
/APR 16, 1986/
/N19005/001/
/APR 16, 1986/
/N19005/002/
APR 16, 1986
/N19005/003/
APR 16, 1986
/N19005/001/
APR 16, 1986

BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP BAXTER 200MG/100ML
AP 400MG/100ML
AP 800MG/100ML

N19837 002
APR 12, 1989
N19837 001
APR 12, 1989

BROMPHENIRAMINE MALEATE

ELIXIR; ORAL

BROMPHENIRAMINE MALEATE

> DLT > /AA/ /BAPRE/NATL/ /2MG/5ML/
> ADD > 3 BARRE NATL 2MG/5ML
/AA/ /PBI/ /2MG/5ML/
3 PBI 2MG/5ML

/N86936/001/
N86936 001
/N87964/001/
/JAN 25, 1983/
N87964 001
JAN 25, 1983

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE;
PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL

> DLT > /AA/ /BIPHETANE DC/
> DLT > /PBI/
> DLT > /2MG/5ML; 10MG/5ML; /
> DLT > /12.5MG/5ML/

/N88904/001/
/FEB 21, 1985/

MYPHETANE DC

PBI

2MG/5ML; 10MG/5ML;
12.5MG/5ML

N88904 001
FEB 21, 1985

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE;
PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

/AA/ /BIPHETANE DC/
/MURO/PHARM/

/2MG/5ML; 10MG/5ML; /
/30MG/5ML/

/N89681/001/
/DEC 22, 1988/

BROMFED-DM

MURO PHARM

2MG/5ML; 10MG/5ML;
30MG/5ML

N89681 001
DEC 22, 1988

BUPROPION HYDROCHLORIDE

/TABLET; ORAL/
/WELBUTRIN/
/3/BURROUGHS/

/50MG/
/75MG/
/100MG/

/N18644/001/
/DEC 30, 1985/
/N18644/002/
/DEC 30, 1985/
/N18644/003/
/DEC 30, 1985/

BUPROPION HYDROCHLORIDE

TABLET; ORAL
WELLBUTRIN
BURROUGHS WELLC

50MG
75MG
100MG

NI8644 001
DEC 30, 1985
NI8644 002
DEC 30, 1985
NI8644 003
DEC 30, 1985

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

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

INJECTABLE; INJECTION
ISOLYTE E IN PLASTIC CONTAINER
KENDALL MCGAW

35MG/100ML; 30MG/100ML; 74MG/100ML;
640MG/100ML; 500MG/100ML;
74MG/100ML

NI9718 001
SEP 29, 1989

BUTABARBITAL SODIUM

TABLET; ORAL
BUTABARBITAL SODIUM
/CHELSEA/LABS/

15MG/
30MG/
15MG
30MG
30MG
30MG

NI85764 001
NI85772 001
NI85772 001
NI85772 001
NI85772 001

/AT/
/ABBOTT/LABS/
ABBOTT LABS

33MG/100ML; 30MG/100ML;
33MG/100ML; 30MG/100ML;
33MG/100ML; 30MG/100ML;
860MG/100ML

NI8444 001
NI8462 001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; IRRIGATION

RINGER'S IN PLASTIC CONTAINER

CALCIOTONIN, SALMON

INJECTABLE; INJECTION
CALCIMAR
/ROGER/PHARM/
ROGER PHARM

400 IU/VIAL/
400 IU/VIAL

NI7497 001

INJECTABLE; INJECTION
LACTATED RINGER'S IN PLASTIC CONTAINER

/AP/
/CUTTER/BIOL/
CUTTER BIOL

40MG/100ML; 30MG/100ML;
40MG/100ML; 30MG/100ML;
40MG/100ML; 30MG/100ML;
310MG/100ML

NI8417 001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

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

SOLUTION; INTRAPERITONEAL

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

AT
BAXTER

18.3MG/100ML; 1.5MG/100ML;
5.08MG/100ML; 538MG/100ML;
448MG/100ML

NI7512 004

448MG/100ML
448MG/100ML
448MG/100ML
448MG/100ML

/AT/

INJECTABLE; INJECTION
PARAPLATIN
BRISTOL SQUIBB

50MG/VIAL
150MG/VIAL
450MG/VIAL

NI9880 001
MAR 03, 1989
NI9880 002
MAR 03, 1989
NI9880 003
MAR 03, 1989

SOLUTION; IRRIGATION

LACTATED RINGER'S IN PLASTIC CONTAINER

AT
BAXTER

20MG/100ML; 30MG/100ML; 600MG/100ML;
310MG/100ML

NI9933 001
AUG 29, 1989

CARBOPLATIN

CEFAZOLIN

INJECTABLE; INJECTION
PROCTER & KEMPLE
UPJOHN

/EQ 0.25MG BASE/ML/

ULTRACEF

BRISTOL LABS

EQ 125MG BASE/5ML
EQ 125MG BASE/5ML
EQ 250MG BASE/5ML
EQ 250MG BASE/5ML
MAR 16, 1982
MAR 16, 1982

CARBOPROST TROMETHAMINE

INJECTABLE; INJECTION
HEBAMATE
UPJOHN

EQ 0.25MG BASE/ML

N17989 001

CEFAZOLIN SODIUM

CARTISOPRODOL

TABLET; ORAL
CARTISOPRODOL
CORD LABS

350MG

N81025 001
APR 13, 1989

EQ 250MG BASE/VIAL

N63016 001
MAR 14, 1989
N63016 002
MAR 14, 1989
N63016 003
MAR 14, 1989

CARTEOLOL HYDROCHLORIDE

TABLET; ORAL
CARTROL
ABBOTT LABS

10MG

N19204 003
DEC 28, 1988

/TAS/PHARM

EQ 500MG BASE/VIAL
EQ 1GM BASE/VIAL
/EQ 1MG BASE/VIAL
/EQ 250MG BASE/VIAL
/EQ 500MG BASE/VIAL

N63016 001
MAR 14, 1989
N63016 002
MAR 14, 1989
N63016 003
MAR 14, 1989
N63016 004
MAR 14, 1989
N63016 005
MAR 14, 1989
N63016 006
MAR 14, 1989
N63016 007
MAR 14, 1989
N63016 008
MAR 14, 1989
N63016 009
MAR 14, 1989
N63016 010
MAR 14, 1989

CEFAZOLIN

CAPSULE; ORAL

CEFAZOLIN

BIOCRAFT LABS

EQ 500MG BASE

N62695 001

FEB 10, 1989

BIOCRAFT LABS

EQ 500MG BASE

N63017 001

JAN 05, 1989

POWDER FOR RECONSTITUTION; ORAL

CEFAZOLIN

BIOCRAFT LABS

EQ 125MG BASE/5ML

N62698 001

MAR 01, 1989

BIOCRAFT LABS

EQ 250MG BASE/5ML

N62698 002

MAR 01, 1989

BIOCRAFT LABS

EQ 500MG BASE/5ML

N62698 003

MAR 01, 1989

CEFIXIME

POWDER FOR RECONSTITUTION; ORAL

SUPRAX

LEDERLE LABS

100MG/5ML

N50622 001
APR 28, 1989

TABLET; ORAL

SUPRAX

LEDERLE LABS

200MG

N50621 001

APR 28, 1989

400MG

N50621 002

APR 28, 1989

CEFTPIRAMIDE SODIUM

INJECTABLE; INJECTION
CEFTPIRAMIDE SODIUM
MYETH AYERST LABS

EQ 1GM BASE/VIALM
EQ 2GM BASE/VIALM
EQ 10GM BASE/VIALM

N50633 002
JAN 31, 1989
N50633 003
JAN 31, 1989
N50633 005
JAN 31, 1989

POWDER FOR RECONSTITUTION; ORAL

CEPHALEXIN
LEMMON

AB EQ 125MG BASE/5ML
AB EQ 250MG BASE/5ML
AB EQ 250MG BASE/5MLM
/AB/ /TAG/PHARMS/
/AB/ /EQ 125MG BASE/5ML/
/AB/ /EQ 250MG BASE/5ML/

N62873 001
MAY 23, 1988
N62867 001
APR 15, 1988
N62987 001
JUL 25, 1989
/N62873/001/
/MAY 23, 1988/
/N62867/001/
/APR 15, 1988/

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION
FORTAZ IN PLASTIC CONTAINER
GLAXO

EQ 10MG BASE/MLM
EQ 20MG BASE/MLM
EQ 40MG BASE/MLM

N50634 001
APR 28, 1989
N50634 002
APR 28, 1989
N50634 003
APR 28, 1989

TABLET; ORAL
CEPHALEXIN
BIOCRAFT LABS

AB EQ 250MG BASEM
AB EQ 500MG BASEM

N63023 001
JAN 12, 1989
N63024 001
JAN 12, 1989

CEFUROXIME SODIUM

INJECTABLE; INJECTION
ZINACEF IN PLASTIC CONTAINER
GLAXO

EQ 15MG BASE/MLM
EQ 30MG BASE/MLM

N50643 001
APR 28, 1989
N50643 002
APR 28, 1989

CERULETIDE DIETHYLAMINE

INJECTABLE; INJECTION/
/TYPTRAN/
/ADRIA/LABS/
@ ADRIA LABS

/0.02MG/ML/
0.02MG/ML
/N18246/001/
N18296 001

CEPHALEXIN

CAPSULE; ORAL

CEFANEX
BRISTOL MYERS

EQ 250MG BASEM
EQ 500MG BASEM

N63063 001
SEP 29, 1989
N63063 002
SEP 29, 1989

CEPHALEXIN
LEMMON

EQ 250MG BASE
EQ 500MG BASE

N62821 001
FEB 05, 1988
N62823 001
FEB 05, 1988
/N62821/001/
/FEB 05, 1988/
/N62823/001/
/FEB 05, 1988/

/AB/ /TAG/PHARMS/

/EQ 250MG BASE/

/EQ 500MG BASE/

CHLORDIAZEPOXIDE HCL

FERRANTE

> ADD > AB
> ADD > AB
> ADD > AB

5MG
10MG
25MG
25MG

N85118 001
N85119 001
N85120 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CHLOROQUINE HYDROCHLORIDE

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
CHLORDIAZEPOXIDE HCL

/AB/	/5MG/	/N87234/001/
/AB/	/10MG/	/N87237/001/
/AB/	/25MG/	/N87231/001/
	5MG	N87234 001
	10MG	N87037 001
	25MG	N87231 001
/AB/	/5MG/	/N88705/001/
/AB/	/10MG/	/JAN/18./1985/
/AB/	/25MG/	/N88706/001/
/AB/	/25MG/	/JAN/18./1985/
/AB/	/25MG/	/N88707/001/
/AB/	/25MG/	/JAN/18./1985/
	5MG	N88705 001
	10MG	JAN 18, 1985
	25MG	N88706 001
	25MG	JAN 18, 1985
	25MG	N86494 001
	25MG	N88707 001
	25MG	JAN 18, 1985
/AB/	/5MG/	/N85118/001/
/AB/	/10MG/	/N85119/001/
/AB/	/25MG/	/N85120/001/
/AB/	/5MG/	/N84706/001/
/AB/	/10MG/	/N84706/001/
/AB/	/25MG/	/N84706/001/
	5MG	N84706 001
	10MG	N84700 001
	25MG	N84705 001
/AB/	/5MG/	/N88129/001/
/AB/	/10MG/	/MAR/28./1983/
/AB/	/25MG/	/MAR/28./1983/
	5MG	N88129 001
	10MG	MAR 28, 1983
	25MG	N88100 001
	25MG	MAR 28, 1983
	25MG	N88130 001
	25MG	MAR 28, 1983

CHLOROQUINE HYDROCHLORIDE

INJECTABLE; INJECTION/
ARALEN/
3/STERLING DRUGS/

/EQ/40MG/BASE/ML/

/N86002/002/

CHLOROQUINE HYDROCHLORIDE

INJECTABLE; INJECTION
ARALEN HCL
STERLING DRUG

EQ 40MG BASE/ML

N86002 002

CHLORPHENIRAMINE MALEATE

TABLET; ORAL

CHLORPHENIRAMINE MALEATE

/AA/	/3/EDDY'S PHARM/	/4MG/	/N83753/001/
/AA/	3 CHELSEA LABS/	4MG	/N85139/001/
/AA/	3 LEDERLE LABS/	4MG	/N85139/001/
/AA/	3 LEDERLE LABS/	4MG	/N86941/001/
/AA/	3 PHARMAFAIR	4MG	/N86941 001
			N83753 001

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE AND PHENYLPROPANOLAMINE HCL

/BC/	/CHELSEA LABS/	/12MG;75MG/	/N88681/001/
	3 CHELSEA LABS	12MG;75MG	/SEP/29./1987/
			N88681 001
AB	CORD LABS	12MG;75MG	SEP 29, 1987
			N88940 001
			JAN 26, 1989
AB	ORNAD	12MG;75MG	N12152 004
/BC/	SK&F LABS	/12MG;75MG/	/N12152/004/

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL
TUSSIONEX
FISONS

	EQ 8MG MALEATE/5ML;	N19111 001
	EQ 10MG BITARTRATE/5ML	DEC 31, 1987
	/EQ/8MG/MALEATE/5ML/	/N19111/001/
	/EQ/10MG/BITARTRATE/5ML/	/DEC/31./1987/

CHYMOPAPAININJECTABLE; INJECTION/DISCISE/
/BOOTS/PHARMS//12.500 UNITS/VIAL/

a BOOTS USA

12,500 UNITS/VIAL

/N18625/001/
/JAN 18, 1984/N18625 001
JAN 18, 1984CAPSULE; ORALCLORAZEPATE DIPOTASSIUM/AD/
/CHELSEA LABS//3.75MG//N71878/001/
/MAR 15, 1988//AD/
/1.5MG//N71879/001/
/MAR 15, 1988//AD/
/1.5MG//N71860/001/
/MAR 15, 1988//AD/
/3.75MG//N71878 001/
MAR 15, 1988

a

N71879 001

a

MAR 15, 1988

a

N71860 001

15MG

MAR 15, 1988

CLINDAMYCIN HYDROCHLORIDECAPSULE; ORALCLINDAMYCIN HCLBIOCRAFT LABSEQ 75MG BASEMN63027 001
SEP 20, 1989EQ 150MG BASEMN63029 001
SEP 20, 1989> ADD > AB
> ADD >
> ADD > AB
> ADD >CLINDAMYCIN PHOSPHATEINJECTABLE; INJECTIONCLEOCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER
UPJOHN

N50639 001

AUG 30, 1989

N50639 002

AUG 30, 1989

CLINDAMYCIN PHOSPHATE

AP ASTRA PHARM

EQ 150MG BASE/MLM

N62928 001

FEB 13, 1989

N62908 001

FEB 01, 1989

N63068 001

AUG 28, 1989

AP DUPONT CRI CARE

EQ 150MG BASE/MLM

AP LEDERLE PARNTLS

EQ 150MG BASE/MLMLOTION; TOPICALCLEOCIN TUPJOHNEQ 1% BASEM

N50600 001

MAY 31, 1989

SOLUTION; TOPICALCLINDAMYCIN PHOSPHATE

AI COPLEY PHARM

EQ 1% BASEM

N62944 001

JAN 11, 1989

N62930 001

JUN 28, 1989

AI LEMMON

EQ 1% BASEM

> ADD > CLOZAPINE

> ADD > TABLET; ORAL

CLOZARIL

SANDOZ

25MGH

N19758 001

SEP 26, 1989

N19758 002

SEP 26, 1989

EQ 125MG BASE/5MLM

N62978 001

APR 06, 1989

POWDER FOR RECONSTITUTION; ORAL

CLOXACILLIN SODIUM

AA NOVOPHARM

CLOXACILLIN SODIUM

a

N72013 001

a

N72014 001

a

N72015 001

3.75MG

DEC 15, 1987

7.5MG

DEC 15, 1987

15MG

DEC 15, 1987

TABLET; ORALCLORAZEPATE DIPOTASSIUM/AD/
/LEDERLE LABS//3.75MG//N72013/001/
/DEC 15, 1987//AD/
/1.5MG//N72014/001/
/DEC 15, 1987//AD/
/1.5MG//N72015/001/
/DEC 15, 1987/

a

N72013 001

a

N72014 001

a

N72015 001

3.75MG

DEC 15, 1987

7.5MG

DEC 15, 1987

15MG

DEC 15, 1987

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '89 - SEP '89

DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTIONPOTASSIUM CHLORIDE 30MEQ IN DEXTROSE 5% AND SODIUMCHLORIDE 0.45% IN PLASTIC CONTAINER

BAXTER

5GM/100ML; 224MG/100ML;
450MG/100MLN18008 008
APR 28, 1982> ADD >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >> DLT >
> DLT >
> ADD >
> ADD >

TABLET; ORAL

DIAZEPAM

/NARTEC/PHARM/

/10MG/

3 MARTEC PHARM

10MG

/N17262/001/
/APR/25, 1989/
N72402 001
APR 25, 1989POTASSIUM CHLORIDE 40MEQ IN DEXTROSE 5% AND SODIUMCHLORIDE 0.45% IN PLASTIC CONTAINER

BAXTER

5GM/100ML; 300MG/100ML;
450MG/100MLN18008 009
APR 28, 1982> ADD >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >> DLT >
> DLT >
> ADD >
> ADD >DICLOFENAC SODIUMTABLET, DELAYED RELEASE; ORAL
VOLTAREN

/CIBA/PHARM/

/25MG/

/50MG/

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

/25MG/

DEXTROSE; SODIUM CHLORIDEINJECTABLE; INJECTIONDEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

/CUTTER/BIOL/

5GM/100ML; 90MG/100ML;
5GM/100ML; 900MG/100ML/N18500/001/
N18500 001> DLT >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >
> ADD >

/25MG/

GEIGY PHARMS

25MG

50MG

75MG

/N14261/001/
/JUL/28, 1988/
/N14261/002/
/JUL/28, 1988/
/N14261/003/
/JUL/28, 1988/
/N14261/004/
/JUL/28, 1988/
N19201 001
JUL 28, 1988
N19201 002
JUL 28, 1988
N19201 003
JUL 28, 1988DIATRIZOATE MEGLUMINEINJECTABLE; INJECTION

/CARDIOGRAPHIN/

/SQUIBB/

3 SQUIBB

/85%/
85%/N11620/002/
N11620 002

CAPSULE; ORAL

DICYCLOMINE HCL

PIONEER PHARMS

10MG

N89361 001
JAN 10, 1989DIATRIZOATE MEGLUMINE; DIATRIZOATE SODIUMINJECTABLE; INJECTION

HYPAQUE-M

/STERILING DRUG

MD-76

/60%:30%/
60%:30%/N10220/002/
N10220 002

MALLINCKRODT

66%:10%:24%

N19292 001
SEP 29, 1989

TABLET; ORAL

HETRAZAN

/3/LEDERLE/LABS/

LEDERLE LABS

/50MG/
50MG/N06459/001/
N06459 001DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HCL

/CHELSEA/LABS/

3 CHELSEA LABS

/25MG/
25MG/N85741/001/
N85741 001

TABLET; ORAL
DIETHYLPROPION HCL
/AA/ /CHLSEA/LABS/
25MG

/N85741/001/
N85741 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '89 - SEP '89

17

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM SR

MARION LABS

60MG

90MG

120MG

180MG

N19471 001

JAN 23, 1989

N19471 002

JAN 23, 1989

N19471 003

JAN 23, 1989

N19471 004

JAN 23, 1989

TABLET; ORAL

DISULFIRAM

/BX/ /CHLSEA/LABS/

/250MG/

/500MG/

2 CHELSEA LABS

2

250MG

500MG

/N87973/001/

/AUG 05, 1983/

/N87974/001/

/AUG 05, 1983/

/N87973/001/

/AUG 05, 1983/

N87973 001

AUG 05, 1983

N87974 001

AUG 05, 1983

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

/25MG/

25MG

/25MG/

/50MG/

25MG

25MG

50MG

/50MG/

50MG

50MG

50MG

50MG

50MG

50MG

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50MG

50MG

50MG

50MG

50MG

50MG

/AA/

/CHLSEA/LABS/

2 CHELSEA LABS

/AA/

/VANGARD/LABS/

2 VANGARD LABS

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

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2 WHITE TN PAULSN

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

/AA/

/WHITE TN PAULSN/

2 WHITE TN PAULSN

> ADD >

> ADD >

> ADD >

> ADD >

CAPSULE, DELAYED REL PELLETS; ORAL

DEPAKOTE

ABBOTT LABS

EQ 125MG BASEM

N19680 001

SEP 12, 1989

DOPAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOPAMINE HCL

ABBOTT LABS

40MG/ML

80MG/ML

40MG/ML

80MG/ML

40MG/ML

80MG/ML

40MG/ML

80MG/ML

40MG/ML

80MG/ML

40MG/ML

80MG/ML

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80MG/ML

40MG/ML

80MG/ML

40MG/ML

80MG/ML

40MG/ML

80MG/ML

DOXEPIH HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIH HCL

QUANTUM PHARMCS

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

AB

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AB

AB

AB

AB

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

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EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

EQ 100MG BASEM

EQ 150MG BASEM

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

ADRIAMYCIN PFS

ADRIA LABS

AP

AP

AP

AP

AP

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

2MG/ML

N50629 001

DEC 23, 1987

N50629 002

MAY 03, 1988

N72375 001

MAR 15, 1989

N72376 001

MAR 15, 1989

N72375 001

MAR 15, 1989

FLUOCINOLONE ACETONIDE

/DEL/ /TOPICAL/
/FLUONID/
@ HERBERT LABS

0.025%

N87300 001
MAY 27, 1982

/10MS/
10MG

TABLET; ORAL
ANDROID-F
/BP/ /BP/ /PHARM/
BP ICN PHARMS

/N87146/001/
N87196 001

FLUOCINONIDE

CREAM; TOPICAL
FLUOCINONIDE
LEMMON

0.052M

N72488 001
FEB 06, 1989
N72490 001
FEB 07, 1989

/10MS/
10MG

FLUOXYMESTERONE
/BP/ /BP/ /PHARM/
BP ICN PHARMS

/N88221/001/
MAY 05, 1983
MAY 05, 1983

AB
VASODERM E
TICAN PHARM

0.05%

N72494 001
JAN 19, 1989
/N72444/001/
/JAN/19/1989/

15MG

FLURAZEPAM HCL
AB CHELSEA LABS

N72368 001
MAR 30, 1989

/AB/ /T/ /ROKCO/
/N72369 001
MAR 30, 1989

30MG

FLUTAMIDE
CAPSULE; ORAL
EULEXIN
SCHERING

N18554 001
JAN 27, 1989

GEL; TOPICAL
FLUOCINONIDE
LEMMON

0.052M

N72537 001
FEB 07, 1989

125MG

AB
LIDEX
SYNTEX LABS

0.05%

N17373 001

SOLUTION; TOPICAL
FLUOCINONIDE
LEMMON

0.052M

N72511 001
FEB 07, 1989
N72857 001
AUG 02, 1989

1MG

TABLET; ORAL
FOLIC ACID
/BP/ /BP/ /PHARM/
@ BOOTS USA

/N84158/001/
N84158 001

AT
THAMES PHARMA

0.052M

N72857 001
AUG 02, 1989

1MG

TABLET; ORAL
FOLIC ACID
/BP/ /BP/ /PHARM/
@ BOOTS USA

/N85141/002/
N85141 002

> ADD > FLUOROMETHOLONE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC
FML-S
ALLERGAN PHARMS

0.1%; 0.32M

N19525 001
SEP 29, 1989

1MG

TABLET; ORAL
FOLIC ACID
/BP/ /BP/ /PHARM/
@ BOOTS USA

/N87828/001/
N87828 001

FLUOROMETHOLONE ACETATE; TOBRAMYCIN

SUSPENSION/DROPS; OPHTHALMIC
TOBRASONE
ALCON LABS

0.1%; 0.32M

N50628 001
JUL 21, 1989

1MG

TABLET; ORAL
FOLIC ACID
/BP/ /BP/ /PHARM/
@ BOOTS USA

/N80691/002/
N80691 002

GANCICLOVIR SODIUM

INJECTABLE; INJECTION
CYTOVENE

SYNTEX LABS

EQ 500MG BASE/VIAL

N19661 001
JUN 23, 1989

> ADD > AB

TABLET; ORAL

HALOPERIDOL

LEDERLE LABS

0.5MG

N72727 001

SEP 19, 1989

> ADD > AB

N72728 001

SEP 19, 1989

> ADD > AB

N72729 001

SEP 19, 1989

> ADD > AB

N72730 001

SEP 19, 1989

> ADD > AB

N72731 001

SEP 19, 1989

> ADD > AB

N72732 001

SEP 19, 1989

GEMFIBROZIL

CAPSULE; ORAL

LOPID

/PARKE/DAVIS/

@ PARKE DAVIS

/200MG/

N18422 001

N18422 001

TABLET; ORAL

LOPID

PARKE DAVIS

600MG

N18422 003

NOV 20, 1986

GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

/CHELSEA/LABS/

@ CHELSEA LABS

/2MG/

N86178 001

N86178 001

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

/STERIS/LABS/

/2,000 UNITS/VIAL

N17016 009

DEC 27, 1984

> DLT >

> DLT >

> ADD >

> ADD >

INJECTABLE; INJECTION

HEPARIN SODIUM

STERIS LABS

/2/

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

ABBOTT LABS

200 UNITS/100ML

N18916 010

JUN 23, 1989

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

BAXTER

4,000 UNITS/100ML

N18814 001

OCT 31, 1983

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

ABBOTT LABS

4,000 UNITS/100ML

N19805 001

JAN 25, 1989

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

ABBOTT LABS

200 UNITS/100ML

N18916 011

JUN 23, 1989

HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABS

5,000 UNITS/100ML

N19805 002

JAN 25, 1989

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

BAXTER/

1500 UNITS/100ML

N18609 003

APR 28, 1982

N18609 003

APR 28, 1982

N18609 003

APR 28, 1982

HYDROLAZINE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE; RESERPINE

AB PRINZIDE 25
MS&D RES LABS

N19778 002
FEB 16, 1989

TABLET; ORAL
/H.P./
/HYDROLAZINE; HYDROCHLOROTHIAZIDE; RESERPINE/
/CHLSEA/LABS/
25MG; 15MG; 0.1MG

AB ZESTORETIC 20/25
IMPERIAL CHEM

N19888 002
JUL 20, 1989

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

23

HYDROCHLOROTHIAZIDE; METHYLDOPA

HYDROCHLOROTHIAZIDE; TRIAMTERENE

TABLET; ORAL

AB METHYLDOPA AND HYDROCHLOROTHIAZIDE
DANBURY PHARMA

N70958 001
FEB 06, 1989

N70959 001
JAN 19, 1989

N71069 001
JAN 19, 1989

N70960 001
FEB 06, 1989

N72507 001
JUN 02, 1989

N72508 001
JUN 02, 1989

N72509 001
JUN 02, 1989

N72510 001
JUN 02, 1989

HYDROCORTISONE

CREAM; TOPICAL

HYDROCORTISONE

2.5%
N89754 001
FEB 01, 1989

1%
N89273 001
FEB 17, 1989

HYDROCHLOROTHIAZIDE; RESERPINE

TABLET; ORAL

AB /H.P./
/WHITE/TN/PAULSN/
3 WHITE TN PAULSN
HYDROCHLOROTHIAZIDE W/ RESERPINE

N85338 001
N85420 001

N85420 001
N85420 001

N85420 001
N85420 001

N85420 001
N85420 001

HYDROCORTISONE

3 WHITE TN PAULSN

10MG
20MG

HYDROCORTISONE ACETATE

CREAM; TOPICAL

HYDROCORTISONE ACETATE

1%
N89914 001
JAN 03, 1989

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

AB SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE
CHLSEA/LABS/
3 CHLSEA LABS

N86026 001
N86026 001

N86026 001
N86026 001

N86026 001
N86026 001

N86026 001
N86026 001

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL; TOPICAL

EPIFOAM

3 WHITE TN PAULSN

10MG
20MG

HYDROCORTISONE ACETATE 1% AND PRAMOXINE HCL 1%

COPILEY PHARM

1%
N89440 001
MAY 17, 1988

N86026 001
N86026 001

N86026 001
N86026 001

N86026 001
N86026 001

N86026 001
N86026 001

1%
N86457 001

1%
N86457 001

1%
N86457 001

1%
N86457 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION
A-HYDROCORT

AP	ABBOTT LABS	EQ 100MG BASE/VIALM	N89577 001 APR 11, 1989
AP		EQ 250MG BASE/VIALM	N89578 001 APR 11, 1989
AP		EQ 500MG BASE/VIALM	N89579 001 APR 11, 1989
AP		EQ 1GM BASE/VIALM	N89580 001 APR 11, 1989

CAPSULE; ORAL
HYDROXYZINE PAMOATE

AB/	CHELSEA LABS	EQ 100MG HCL	N86728 001 OCT 05, 1982
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N86728 001
OCT 05, 1982

HYDROFLUMETHIAZIDE

TABLET; ORAL

HYDROFLUMETHIAZIDE
AB/ CHELSEA LABS

AB/	CHELSEA LABS	50MG	N88528 001 AUG 15, 1984
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SUSPENSION; ORAL
CHILDREN'S ADVIL
WHITEHALL LABS

AB/	WHITEHALL LABS	100MG/5MLM	N19833 002 SEP 19, 1989
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N19833 002
SEP 19, 1989

PEDIA PROFEN
MCNEIL CONSUMER

AB/	MCNEIL CONSUMER	100MG/5MLM	N19842 001 SEP 19, 1989
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N19842 001
SEP 19, 1989

HYDROXOCOBALAMIN

INJECTABLE; INJECTION

HYDROXOCOBALAMIN
LYPHOMED

AB/	LYPHOMED	1MG/ML	N84421 001 AUG 15, 1984
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TABLET; ORAL
IBUPROFEN

AB/	BOOTS LABS	600MG	N70083 001 FEB 22, 1985
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N70083 001
FEB 22, 1985

BOOTS USA

AB/	BOOTS USA	600MG	N70556 001 JUN 14, 1985
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N70556 001
JUN 14, 1985

HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDROXYZINE HCL
PHARMAFAIR

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

RUFEN
BOOTS PHARMS

AB/	BOOTS PHARMS	400MG	N18197 001 FEB 22, 1985
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N18197 001
FEB 22, 1985

AB/	BOOTS PHARMS	400MG	N18197 001 FEB 22, 1985
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N18197 001
FEB 22, 1985

AB/	BOOTS PHARMS	400MG	N18197 001 FEB 22, 1985
-----	--------------	-------	----------------------------

N18197 001
FEB 22, 1985

AB/	BOOTS PHARMS	400MG	N18197 001 FEB 22, 1985
-----	--------------	-------	----------------------------

N18197 001
FEB 22, 1985

AB/	BOOTS PHARMS	400MG	N18197 001 FEB 22, 1985
-----	--------------	-------	----------------------------

N18197 001
FEB 22, 1985

AB/	BOOTS PHARMS	400MG	N18197 001 FEB 22, 1985
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N18197 001
FEB 22, 1985

LIOIRIX (14;13)TABLET; ORAL

EUTHROID-0.5

PARKE DAVIS

EUTHROID-1

PARKE DAVIS

EUTHROID-2

PARKE DAVIS

EUTHROID-3

PARKE DAVIS

THYROLAR-0.25

RORER PHARM

THYROLAR-0.5

RORER PHARM

THYROLAR-1

RORER PHARM

THYROLAR-2

RORER PHARM

THYROLAR-3

RORER PHARM

THYROLAR-5

RORER PHARM

0.03MG;0.0075MG

N16680 001

0.06MG;0.015MG

N16680 002

0.12MG;0.03MG

N16680 003

0.18MG;0.045MG

N16680 004

0.0125MG;0.0031MG

N16807 001

0.025MG;0.00625MG

N16807 005

0.05MG;0.0125MG

N16807 004

0.1MG;0.025MG

N16807 002

0.15MG;0.0375MG

N16807 003

0.25MG;0.0625MG

N16807 006

INJECTABLE; INJECTION

ISOLYTE S PH 7.4 IN PLASTIC CONTAINER

KENDALL MCGAW

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

370MG/100ML;530MG/100ML;500MG/100ML;

12MG/100MLM

N19696 001

SEP 29, 1989

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE;

SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION

ISOLYTE S IN PLASTIC CONTAINER

KENDALL MCGAW

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

530MG/100ML;

500MG/100MLM

N19711 001

SEP 29, 1989

MALATHIONLISINAPRILTABLET; ORALFRINTIVIL

AB MS&D RES LABS

40MG

N19558 004

OCT 25, 1988

ZESTRIL

AB IMPERIAL CHEM

40MG

N19777 004

MAY 19, 1988

> ADD >

> ADD >

> ADD >

> ADD >

> DLT >

> DLT >

> DLT >

> DLT >

LOTION; TOPICAL

OVIDE

GENDERM

0.5%

N18613 001

AUG 02, 1982

/LOTION; TOPICAL/

/PHIDDERM/

/S/PURDUE/FRDPRK/

/0.5%/

/N18613/001/

/AUG 02, 1982/

LITHIUM CARBONATECAPSULE; ORALLITHIUM CARBONATE

AB PBI

300MG

N72542 001

FEB 01, 1989

SOLUTION; IRRIGATION

/RESPECTISOL/

/KENDALL MCGAW/

S KENDALL MCGAW

/56M/100ML/

56M/100ML

/N16704/002/

N16704 002

MEBENDAZOLE

TABLET, CHEMABLE; ORAL

VERMOX

/JANSSEN/PHARMA/

JANSSEN RES

/100MG/

100MG

/N17481/001/

N17481 001

> DLT >

> ADD >

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

28

MECLIZINE HYDROCHLORIDE

TABLET; ORAL

MECLIZINE HCL
/AA/ /VANGARD LABS/

/12.5MG/

/AA/

/25MG/

3 VANGARD LABS

12.5MG

3

25MG

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

AB BARR LABS

EQ 50MG BASEM

AB

EQ 100MG BASEM

N72848 001

MAR 20, 1989

N72809 001

MAR 20, 1989

/N87877/001/

/APR/20, 1982/

/N87820/001/

/JAN/04, 1982/

N87877 001

APR 20, 1982

N87820 001

JAN 04, 1982

MEPERIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

MEPERIDINE HCL

ASTRA PHARM

25MG/MLM

N89781 001

MAR 31, 1989

50MG/MLM

N89782 001

MAR 31, 1989

50MG/MLM

N89783 001

MAR 31, 1989

50MG/MLM

N89784 001

MAR 31, 1989

75MG/MLM

N89785 001

MAR 31, 1989

100MG/MLM

N89786 001

MAR 31, 1989

100MG/MLM

N89787 001

MAR 31, 1989

100MG/MLM

N89788 001

MAR 31, 1989

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

/3/BOOTS/PHARM/

/CHelsea/LABS/

3 CHELSEA LABS

/LEDERLE/LABS/

3 LEDERLE LABS

3 PHARMAFAIR

/VANGARD/LABS/

3 VANGARD LABS

/WHITE/TN/PAULSN/

/AA/ /WHITE TN PAULSN

/AA/ 3

/400MG/

/600MG/

600MG

/400MG/

400MG

400MG

/400MG/

400MG

400MG

400MG

400MG

400MG

400MG

400MG

400MG

/N84153/001/

/N85719/001/

N85719 001

/N86299/001/

N86299 001

N84153 001

/N88011/001/

/JUL/14, 1982/

N88011 001

JUL 14, 1982

/N83336/001/

/N83442/001/

N83330 001

N83442 001

MESNA

METHYLPREDNISOLONE

TABLET; ORAL

METHYLPREDNISOLONE

AB CHELSEA LABS

4MG

N86161 001

FEB 09, 1982

/4MG/

/N86161/001/

/16MG/

/FEB/09/1982/

/16MG/

/N86161/001/

16MG

/FEB/09/1982/

3

N86159 001

FEB 09, 1982

METHYLPREDNISOLONE ACETATE

/ENEMA; RECTAL/

/MEDROL/

/UPJOHN/

3 UPJOHN

/40MG/BOT/

40MG/BOT

METHYLTESTOSTERONE

TABLET; BUCCAL

ANDROID 5

/BROWN/PHARM/

ICN PHARMS

/5MG/

5MG

/N87222/001/

N87222 001

TABLET; ORAL

ANDROID 10

/BROWN/PHARM/

ICN PHARMS

/10MG/

10MG

/N86450/001/

N86450 001

ANDROID 25

/BROWN/PHARM/

ICN PHARMS

/25MG/

25MG

/N87147/001/

N87147 001

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION

METOCLOPRAMIDE HCL

AP ABBOTT LABS

EQ 10MG BASE/2MLM

N70505 001

JUN 23, 1989

AP

EQ 10MG BASE/2MLM

N70506 001

JUN 22, 1989

AP BULL LABS

EQ 10MG BASE/2MLM

N71990 001

JAN 18, 1989

AP DUPONT CRI CARE

EQ 10MG BASE/2MLM

N71291 001

MAR 03, 1989

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL

METOCLOPRAMIDE HCL

AB

EQ 5MG BASE

N72436 001

JUN 22, 1989

> DLT >

/EQ 10MG BASE/

/N70598 001/

> DLT >

/EQ 10MG BASE

/FEB/02/1987/

> ADD >

EQ 10MG BASE

N70598 001

> ADD >

EQ 10MG BASE

FEB 02, 1987

METOPROLOL TARTRATE

TABLET; ORAL

LOPRESSOR

AB

GEIGY PHARMS

50MG

N17963 001

AB

100MG

N17963 002

AB

METOPROLOL TARTRATE

AB

HENRY SCHEIN

50MG

N71690 001

AB

100MG

N71691 001

DEC 21, 1993

DEC 21, 1993

DEC 21, 1993

DEC 21, 1993

METIRIZAMIDE

INJECTABLE; INJECTION

AMIPAQUE

AB

/STERLING/

/2.5GM/VIAL/

/N17982 003/

3

STERLING DRUG

2.5GM/VIAL

SEP 12, 1983

SEP 12, 1983

SEP 12, 1983

SEP 12, 1983

SEP 12, 1983

MOMETASONE FUROATE

LOTION; TOPICAL

ELOCON

AB

0.1%

N19796 001

MAR 30, 1989

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MS CONTIN
PURDUE FRDRK

> ADD >
> ADD >

N19516 003
SEP 12, 1989

15MG

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION
NALOXONE HCL
ASTRA PHARM

0.02MG/ML

N72081 001
APR 11, 1989

0.02MG/ML

N72082 001
APR 11, 1989

0.02MG/ML

N72083 001
APR 11, 1989

0.02MG/ML

N72084 001
APR 11, 1989

0.02MG/ML

N72085 001
APR 11, 1989

0.4MG/ML

N72086 001
APR 11, 1989

0.4MG/ML

N72087 001
APR 11, 1989

0.4MG/ML

N72088 001
APR 11, 1989

0.4MG/ML

N72089 001
APR 11, 1989

0.4MG/ML

N72090 001
APR 11, 1989

1MG/ML

N72091 001
APR 11, 1989

1MG/ML

N72092 001
APR 11, 1989

1MG/ML

N72093 001
APR 11, 1989

NAPHAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

MURO'S OPCON

0.1%

N87506 001

0.1%

AT BAUSCH & LOMB

N87506 001

NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

/SQUIBB/

/ED 350MG BASE/

EQ 350MG BASE

N60365 001

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION
NALBUPHINE HCL
ABBOTT LABS

10MG/ML

N70914 001
FEB 03, 1989

10MG/ML

N70915 001
FEB 03, 1989

20MG/ML

N70916 001
FEB 03, 1989

20MG/ML

N70917 001
FEB 03, 1989

20MG/ML

N70918 001
FEB 03, 1989

10MG/ML

N72070 001
APR 10, 1989

10MG/ML

N72071 001
APR 10, 1989

10MG/ML

N72072 001
APR 10, 1989

20MG/ML

N72073 001
APR 10, 1989

20MG/ML

N72074 001
APR 10, 1989

20MG/ML

N72075 001
APR 10, 1989

20MG/ML

ASTRA PHARM

NIACIN

TABLET; ORAL

NIACIN
/AA/ /CHELSEA LABS/
a CHELSEA LABS

/500MG/
500MG

/N65172/001/
N85172 001

NIFEDIPINE

CAPSULE; ORAL

NIFEDIPINE
CHASE LABS

10MG

N72409 001

AB

10MG

JUL 04, 1990 : JUL 10, 1989

AB

10MG

N72579 001 +

AB

20MG

APR 28, 1989

PROCARDIA
PFIZER

10MG

N18482 001

/AB/ /PFIZER LABS/
/20MG/

10MG

JUL 24, 1986

/AB/ /PFIZER LABS/
/20MG/

10MG

/N18482/001/
/N18482/002/
/JUL/24, 1986/

TABLET, EXTENDED RELEASE; ORAL

PROCARDIA XL

PFIZER

30MG

N19684 001

60MG

SEP 06, 1989

90MG

SEP 06, 1989

90MG

SEP 06, 1989

NITROFURANTOIN

TABLET; ORAL

NITROFURANTOIN
/AB/ /CHELSEA LABS/
a CHELSEA LABS

/50MG/
100MG

/N65172/001/
/N65172/002/
N85797 001

100MG

N85796 001

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN MACROCRYSTALLINE
/BOLAR PHARM/
/50MG/

/100MG/

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

50MG

100MG

100MG

100MG

100MG

100MG

100MG

100MG

100MG

100MG

100MG

100MG

100MG

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100MG

100MG

FEB 03, 1989
N62711 005
FEB 03, 1989
N62711 006
FEB 03, 1989

EQ 4GM BASE/VIALM
EQ 10GM BASE/VIALM

AP
AP

1 RELATED EFFECTIVE DATE PERMISSIBLE EXPIRY DATE

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN 89 - SEP 89

33

OXANDROLONE

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

/TABLET;/ORAL/
/ANAVAR/
/SEARLE/
3 SEARLE

/2.5MG/
2.5MG

/SOLUTION;/ORAL/
/PARADIONE/
/ABBOTT/LABS/
3 ABBOTT LABS

/N13718/001/
N13718 001

/N06800/002/
N06800 002

OXYBUTYRIN CHLORIDE

TABLET; ORAL
OXYBUTYRIN CHLORIDE
AB BOLAR PHARM

5MG

TABLET; ORAL
LEVATOL
/VILLY/

10MG/
10MG
REED & CARNRICK

PENBUTOLOL SULFATE

N72485 001
APR 19, 1989

10MG/
10MG

OXYTOCIN

INJECTABLE; INJECTION
/OXYTOCIN/10 USP/UNITS/IN/DEXTRROSE/5%/
/ABBOTT/LABS/

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

/1 USP/UNIT/100ML/

/2 USP/UNITS/100ML/

1 USP UNIT/100ML

2 USP UNITS/100ML

/OXYTOCIN/20 USP/UNITS/IN/DEXTRROSE/5%/
/ABBOTT/LABS/

2 USP UNITS/100ML

/OXYTOCIN/5 USP/UNITS/IN/DEXTRROSE/5%/
/ABBOTT/LABS/

1 USP UNIT/100ML

/N19185/004/
MAR 29, 1985
N19185 003
MAR 29, 1985
/N19185/002/
MAR 29, 1985
/N19185/001/
MAR 29, 1985
N19185 001
MAR 29, 1985

/SUSPENSION;/ORAL/
/BICILLIN/
/MYETH/AYERST/LABS/
3 MYETH AYERST LABS

/300,000 UNITS/5ML/
300,000 UNITS/5ML

/N50126/002/
N50126 002

PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN V POTASSIUM

AA CLONMEL CHEMS

EQ 125MG BASE/5MLM

N62981 001
FEB 10, 1989

EQ 250MG BASE/5MLM

N62981 002
FEB 10, 1989

PENTAMIDINE ISETHIONATE

POWDER FOR RECONSTITUTION; INHALATION

NEBUPENT

LYPHOMED

300MG/VIALM

N19887 001
JUN 15, 1989

PENTOBARBITAL SODIUM

CAPSULE; ORAL

PENTOBARBITAL SODIUM

/AA/
/WHITE/TN/PAULSN/
3 WHITE TN PAULSN

/100MG/
100MG

/N83338/001/
N83338 001

N72320 001
JAN 19, 1989
N72321 001
JAN 19, 1989

1MG/MLM

2MG/MLM

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
PANCURONIUM BROMIDE

AP ABBOTT LABS

AP ABBOTT LABS

PERMETHRIN

CREAM; TOPICAL
ELIMITE
BURROUGHS WELLC

5/M

N19855 001
AUG 25, 1989

N07953 001

PHENYLEPHRINE HYDROCHLORIDE; PYRILAMINE MALEATE

SOLUTION/DROPS; OPHTHALMIC
PREFRIN-A
ALLERGAN PHARMS

0.12%; 0.1%

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

/AA/ /DI-METREX/
/PRIVATE/FMLTNS/
@ PRIVATE FMLTNS

/15MG/
35MG

/N85698/001/
N85698 001

CAPSULE; ORAL
PHENYTOIN SODIUM
/3/600TS/PHARMS/
@ PHARMAFAIR

/100MG/
100MG

/N85435/001/
N85435 001

PHENDIMETRAZINE TARTRATE

/AA/ /CHELSEA/LABS/
/AA/ /CHELSEA/LABS/
/AA/ /CHELSEA/LABS/
/AA/ /CHELSEA/LABS/
@ CHELSEA LABS
@
@
@
@
@ PRIVATE FMLTNS

/15MG/
35MG
35MG
35MG
35MG
35MG
35MG
35MG

/N85767/001/
N85767 001
/N85768/001/
N85768 001
/N85770/001/
N85770 001
/N85773/001/
N85773 001
/N85775/001/
N85775 001
/N85777/001/
N85777 001
/N85779/001/
N85779 001
/N85781/001/
N85781 001
/N85783/001/
N85783 001
/N85785/001/
N85785 001
/N85787/001/
N85787 001
/N85789/001/
N85789 001
/N85791/001/
N85791 001
/N85793/001/
N85793 001
/N85795/001/
N85795 001
/N85797/001/
N85797 001
/N85799/001/
N85799 001

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

POWDER FOR RECONSTITUTION; ORAL
/60LYTE/
/BRAINTREE/LABS/
/2.36GM/BOT; 2.97GM/BOT; 6.74GM/BOT;
/5.86GM/BOT; 22.74GM/BOT;
/N19011/001/
/JUL 13, 1984/

/N85435/001/
N85435 001

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

/AA/ /PHENTERMINE HCL/
/CHELSEA/LABS/
@ CHELSEA LABS

/30MG/
30MG

/N85740/001/
MAR 21, 1985
N85740 001
MAR 21, 1985

AA REED & CARNRICK

240GM/BOT; 2.98GM/BOT; 6.72GM/BOT;
5.84GM/BOT; 22.72GM/BOT

N18983 007
JUN 12, 1987
/2.40GM/BOT; 2.98GM/BOT; 6.72GM/BOT;
/5.84GM/BOT; 22.72GM/BOT;
/N18983/001/
/JUN 12, 1987/

TABLET; ORAL

/AA/ /PHENTERMINE HCL/
/CHELSEA/LABS/
@ CHELSEA LABS

/8MG/
8MG

/N85739/001/
N85739 001

AA BRAINTREE LABS

236GM/BOT; 2.97GM/BOT; 6.74GM/BOT;
5.86GM/BOT; 22.74GM/BOT

N19011 001
JUL 13, 1984

PHENYL AMINOSALICYLATE

/POWDER; ORAL/
/PHENY-PAS-TEBANIN/
@ PURDUE FRDRK

/50MG/
50MG

/N11695/002/
N11695 002

/10MEQ/
10MEQ

/N19439/002/
JUN 13, 1986

/TABLET; ORAL/
/PHENY-PAS-TEBANIN/
@ PURDUE FRDRK

/500MG/
500MG

/N11695/003/
N11695 003

/20MEQ/
20MEQ

/N19439/001/
/JUN 13, 1986/

POTASSIUM CHLORIDE

POTASSIUM CHLORIDE; SODIUM CHLORIDE

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

36

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HCL DANBURY PHARMA

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
AB	EQ 2MG BASEH	MAY 16, 1989	JAN 11, 1989	N72333 001
AB	EQ 5MG BASEH	MAY 16, 1989	JAN 11, 1989	N72609 001
AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72705 001
AB	EQ 2MG BASEH	MAY 16, 1989	MAR 15, 1989	N72706 001
AB	EQ 5MG BASEH	MAY 16, 1989	MAR 15, 1989	N72707 001
AB	EQ 1MG BASEH	MAY 16, 1989	MAR 15, 1989	N72573 001
AB	EQ 2MG BASEH	MAY 16, 1989	FEB 28, 1989	N72574 001
AB	EQ 5MG BASEH	MAY 16, 1989	FEB 28, 1989	N72575 001
AB	EQ 1MG BASEH	MAY 16, 1989	FEB 28, 1989	N72991 001
AB	EQ 2MG BASEH	MAY 16, 1989	APR 26, 1989	N72921 001
AB	EQ 5MG BASEH	MAY 16, 1989	APR 26, 1989	N72992 001
AB	EQ 1MG BASEH	MAY 16, 1989	APR 26, 1989	N71994 001
AB	EQ 2MG BASEH	MAY 16, 1989	SEP 12, 1988	N71995 001
AB	EQ 5MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001
AB	EQ 1MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001
AB	EQ 2MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001
AB	EQ 5MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001

PREDNISOLONE

SYRUP; ORAL PRELONE MURO PHARM

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 17, 1989	N89654 001
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PREDNISOLONE

TABLET; ORAL

PREDNISOLONE

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
AB	EQ 2MG BASEH	MAY 16, 1989	JAN 11, 1989	N72333 001
AB	EQ 5MG BASEH	MAY 16, 1989	JAN 11, 1989	N72609 001
AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72705 001
AB	EQ 2MG BASEH	MAY 16, 1989	MAR 15, 1989	N72706 001
AB	EQ 5MG BASEH	MAY 16, 1989	MAR 15, 1989	N72707 001
AB	EQ 1MG BASEH	MAY 16, 1989	MAR 15, 1989	N72573 001
AB	EQ 2MG BASEH	MAY 16, 1989	FEB 28, 1989	N72574 001
AB	EQ 5MG BASEH	MAY 16, 1989	FEB 28, 1989	N72575 001
AB	EQ 1MG BASEH	MAY 16, 1989	FEB 28, 1989	N72991 001
AB	EQ 2MG BASEH	MAY 16, 1989	APR 26, 1989	N72921 001
AB	EQ 5MG BASEH	MAY 16, 1989	APR 26, 1989	N72992 001
AB	EQ 1MG BASEH	MAY 16, 1989	APR 26, 1989	N71994 001
AB	EQ 2MG BASEH	MAY 16, 1989	SEP 12, 1988	N71995 001
AB	EQ 5MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001
AB	EQ 1MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001
AB	EQ 2MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001
AB	EQ 5MG BASEH	MAY 16, 1989	SEP 12, 1988	N71745 001

PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM

SUSPENSION/DROPS; OPHTHALMIC

AT	BAUSCH & LOMB	0.5%; 10%	N88089 001
AT	MURO PHARM	0.5%; 10%	DEC 28, 1982

PREDNISONE

SOLUTION; ORAL PREDNISONE INTENSOL ROXANE LABS

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
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SYRUP; ORAL PREDNISONE INTENSOL ROXANE LABS

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
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TABLET; ORAL

DELTAONE UPJOHN

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
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PREDNISONE CORD LABS

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
----	--------------	--------------	--------------	------------

HALSEY DRUG ROXANE LABS

AB	EQ 1MG BASEH	MAY 16, 1989	JAN 11, 1989	N72352 001
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PREDNISONE

TABLET; ORAL

PREDNISONE

/BX/ /VANGARD/LABS/

/BX/ /5MG/

/20MG/

3 VANGARD LABS

5MG

20MG

3

/AB/ /WHITE/TN/PAULSN/

/10MG/

/2.5MG/

/5MG/

/20MG/

3 WHITE TN PAULSN

2.5MG

5MG

10MG

20MG

/SERVISONE/

/BX/ /LEDERLE/LABS/

3 LEDERLE LABS

/5MG/

5MG

PROCAINAMIDE HYDROCHLORIDE

CAPSULE; ORAL

PROCAINAMIDE HCL

/AB/ /VANGARD/LABS/

/250MG/

/500MG/

3 VANGARD LABS

250MG

500MG

3

INJECTABLE; INJECTION

PROCAINAMIDE HCL

/AB/ /PHARMAFAIR/

/100MG/ML/

/500MG/ML/

3 PHARMAFAIR

100MG/ML

500MG/ML

3

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

PROCAINAMIDE HCL

AB INWOOD LABS

500MG

N89840 001
MAR 06, 1989

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

AP ELKINS SINN

EQ 5MG BASE/ML

N89903 001
AUG 29, 1989

PROGESTERONE

INJECTABLE; INJECTION

PROGESTERONE

3 LILLY

/25MG/ML/

25MG/ML

/N844238/002/
N09238 002

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

/ZIPAN-25/

3 ALTANA

/25MG/ML/

25MG/ML

/N83997/001/
N83997 001

/ZIPAN-50/

3 ALTANA

/50MG/ML/

50MG/ML

/N83997/002/
N83997 002

TABLET; ORAL

PROMETHAZINE HCL

/3/BOOTS/PHARMS/

3

/12.5MG/

12.5MG

/N84160/001/
N84160 001

3

25MG

/N84166/001/
N84166 001

3

50MG

/N84539/001/
N84539 001

/BP/ /CHELSEA/LABS/

3

/12.5MG/

12.5MG

/N85986/001/
N85986 001

3

25MG

/N85684/001/
N85684 001

3

50MG

/N85664/001/
N85664 001

/N88824/001/
N88824 001

/NOV 20, 1985

/NOV 20, 1985

/NOV 20, 1985

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

PROPOXYPHENE HCL

/AA/ /CHELSEA/LABS/
@ CHELSEA LABS

/65MG/
65MG

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

INDERAL LA

AB MYETH AYERST LABS

60MG

AB 80MG

AB 120MG

AB 160MG

PROPRANOLOL HCL

AB INWOOD LABS

60MG

AB 80MG

AB 120MG

AB 160MG

SOLUTION; ORAL

PROPRANOLOL HCL

AA PBI

20MG/5ML

AA 40MG/5ML

AA ROXANE LABS

20MG/5ML

AA 40MG/5ML

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

/AB/

/LEDERLE/LABS/

/10MG/

/AB/

/20MG/

/AB/

/40MG/

/AB/

/80MG/

@ LEDERLE LABS

10MG

@

20MG

@

40MG

@

80MG

AB MYLAN PHARMS

60MG

PROPYLTIODONE

SUSPENSION; INTRATRACHEAL

/PIONOSIL/AQUEDUS/

/GLAXO/

@ GLAXO

> DLT >

> DLT >

> ADD >

/50%/

50%

PROPYLTHIOURACIL

TABLET; ORAL

PROPYLTHIOURACIL

/@BOOTS/PHARMS/

@ BOOTS USA

/BO/ /CHELSEA/LABS/

@ CHELSEA LABS

/50MG/

50MG

/50MG/

50MG

/N72117/001/
JUN 23, 1988
/N72118/001/
JUN 23, 1988
/N72119/001/
JUN 23, 1988
/N72120/001/
JUN 23, 1988
/N72275/001/
JUN 09, 1989

N72117 001
JUN 23, 1988
N72118 001
JUN 23, 1988
N72119 001
JUN 23, 1988
N72120 001
JUN 23, 1988
N72275 001
JUN 09, 1989

/N09309/001/
N09309 001

/N84075/001/
N84075 001
/N85201/001/
N85201 001

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

AP / AB / ICN PHARMS / ROCHE /

5MG/ML / 5MG/ML / N09830 001 / N09830 001 /

SYRUP; ORAL

MESTINON

ICN PHARMS / ROCHE /

60MG/5ML / 60MG/5ML / N15193 001 / N15193 001 /

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '89 - SEP '89

39

PYRIDOSTIGMINE BROMIDE

TABLET; ORAL

MESTINON

ICN PHARMS / ROCHE /

60MG / 60MG /

N09829 002 / N09829 002 /

TABLET, EXTENDED RELEASE; ORAL

MESTINON

ICN PHARMS / ROCHE /

180MG / 180MG /

N11665 001 / N11665 001 /

QUINIDINE GLUCONATE

INJECTABLE; INJECTION

QUINIDINE GLUCONATE

LILLY / 80MG/ML /

N07529 002 / N07529 002 / FEB 10, 1989

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

MUTUAL PHARM

100MG /

N81029 001 / N81029 001 /

200MG /

N81030 001 / N81030 001 /

300MG /

N81031 001 / N81031 001 /

200MG /

N87837 001 / N87837 001 /

200MG /

N85444 001 / N85444 001 /

200MG /

N85444 001 / N85444 001 /

RESERPINE

TABLET; ORAL

RESERPINE

ROXANE /

0.25MG /

N09859 002 / N09859 002 /

0.1MG /

N11185 001 / N11185 001 /

0.1MG /

N11185 001 / N11185 001 /

PYRIDOSTIGMINE BROMIDE

INJECTABLE; INJECTION

MESTINON

AP / AB / ICN PHARMS / ROCHE /

5MG/ML / 5MG/ML / N09830 001 / N09830 001 /

SYRUP; ORAL

MESTINON

ICN PHARMS / ROCHE /

60MG/5ML / 60MG/5ML / N15193 001 / N15193 001 /

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '89 - SEP '89

39

RIFAMPIN

CAPSULE; ORAL

RIFADIN

AB / AB / PDA PHARMS /

400MG / 400MG /

N50420 001 / N50420 001 /

AB MERRELL DOW

150MG

N62303 001 / N62303 001 /

INJECTABLE; INJECTION

RIFADIN

MERRELL DOW

600MG/VIAL

N50627 001 / N50627 001 /

MAY 25, 1989

SAFFLOWER OIL

INJECTABLE; INJECTION /

10% / 10% /

N18203 001 / N18203 001 /

20% / 20% /

N18614 001 / N18614 001 /

SECOBARBITAL SODIUM

CAPSULE; ORAL

SECOBARBITAL SODIUM

AA / AA / WHITE TN PAULSN /

100MG / 100MG /

N85798 001 / N85798 001 /

AA / AA / CHELSEA LABS /

100MG / 100MG /

N85792 001 / N85792 001 /

SECRETIN

INJECTABLE; INJECTION

SECRETIN-FERRING

FERRING LABS

75CU/VIAL

N18290 001 / N18290 001 /

SECRETIN-KABI /

75CU/VIAL /

N18290 001 / N18290 001 /

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

40

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
ELDEPRYL
SOMERSET PHARMS 5MG

SODIUM IODIDE, I-123

CAPSULE; ORAL
SODIUM IODIDE I 123
AA BENEDICT NUCLIR

N19334 001
JUN 05, 1989

200 UCI

N18671 002
MAY 27, 1982

AA MALLINCKRODT
AA MEDI PHYSICS

AA MALLINCKRODT

100 UCI

N71909 001
FEB 28, 1989

SELENOMETHIONINE, SE-75

INJECTABLE; INJECTION
SELENOMETHIONINE SE 75

/MALLINCKRODT/
a MALLINCKRODT
a MEDI PHYSICS

/100 UCI/ML/
100 UCI/ML
/250 UCI/ML/
250 UCI/ML

SODIUM PHOSPHATE, P-32

SOLUTION; INJECTION, ORAL
/PHOSPHORUS/
a SQUIBB

/1-8MCI/VIAL/
1-8MCI/VIAL

/N10927/001/
N10927 001

SILVER SULFADIAZINE

CREAM; TOPICAL

SSD
/AB/ /BOOTS/FLINT/

AB BOOTS USA

/N18578/001/
/FEB/25/1982/
N18578 001
FEB 25, 1982

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
SODIUM POLYSTYRENE SULFONATE
AA CAROLINA MED

454GM/BOTh

N89910 001
JAN 19, 1989

SINCALIDE

INJECTABLE; INJECTION
KINEVAC

/SQUIBB/
SQUIBB DIAGS

/0.005MG/VIAL/
0.005MG/VIAL

/2MG/VIAL/
2MG/VIAL

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

SODIUM CHLORIDE

INJECTABLE; INJECTION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

/AB/ /CUTTER/BIOL/
a CUTTER BIOL
/AB/ /CUTTER/BIOL/
a CUTTER BIOL

/N18503/001/
N18503 001
/N18502/001/
N18502 001

SPIRONOLACTONE

TABLET; ORAL
SPIRONOLACTONE
/AB/ /VANGARD/LABS/
a VANGARD LABS

/25MG/
25MG

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

SOLUTION; IRRIGATION

/BI/ /CUTTER/BIOL/
a CUTTER BIOL

/N18247/001/
N18247 001

THEOPHYLLINE

capsule; oral

ELIXOPHYLLIN

/BX/ /BERLEX/LABS/

/BX/

BX FOREST LABS

BX

/100MG/

/200MG/

100MG

200MG

/N85545/001/

/JUL/31/1984/

/N83921/001/

/JUL/31/1984/

N85545 001

JUL 31, 1984

N83921 001

JUL 31, 1984

capsule, extended release; oral

SLO-BID

RORER PHARM

BC

BC

THEO-DUR SPRINKLE

KEY PHARMS

75MG

N89539 001

MAY 10, 1989

N89540 001

MAY 10, 1989

N88015 001

SEP 10, 1985

SEP 10, 1985

ELIXIR; ORAL

ELIXOPHYLLIN

/AA/ /BERLEX/LABS/

/AA/ FOREST LABS

SUSPENSION; ORAL

ELIXICON

/BERLEX/LABS/

FOREST LABS

/100MG/5ML/

100MG/5ML

/80MG/15ML/

80MG/15ML

/N85186/001/

N85186 001

/N85502/001/

N85502 001

TABLET; ORAL

QUIBRON-T

BRISTOL MYERS

/HEAD/JOHNSON/

300MG

/300MG/

N88656 001

AUG 22, 1985

/N88656/001/

/AUG/22/1985/

TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR

BRISTOL MYERS

/BC/ /HEAD/JOHNSON/

300MG

/300MG/

N87563 001

JUN 21, 1983

/N87563/001/

/JUN/21/1983/

N85328 001

N86998 001

/N85328/001/

/N86998/001/

100MG

200MG

/100MG/

/200MG/

THEO-DUR

KEY PHARMS

/BC/

/BC/

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL

THEOPHYLLINE

INWOOD LABS

AB

AB

/BC/

/BC/

100MG

200MG

/100MG/

/200MG/

N88320 001

FEB 21, 1985

N88321 001

FEB 21, 1985

/N88320/001/

/FEB/21/1985/

/N88321/001/

/FEB/21/1985/

THIORIDAZINE HYDROCHLORIDE

TABLET; ORAL

THIORIDAZINE HCL

/CHELSEA/LABS/

/AB/

3 CHELSEA LABS

15MG

/15MG/

/N88562/001/

/MAY/11/1984/

N88562 001

MAY 11, 1984

THIOETHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL

THIOETHIXENE HCL

PACO RES

EQ 1MG BASE/MLM

N71917 001

SEP 20, 1989

> ADD >

> ADD >

INJECTABLE; INJECTION

NAVANE

/ROERIG/

ROERIG

/EQ/5MG/ML/

EQ 10MG BASE/VIAL

/N16904/002

N16904 002

TILOLOL MALEATE

TABLET; ORAL

BLOCADREN

NS&D

AB

AB

AB

AB

5MG

10MG

20MG

N18017 001

N18017 002

N18017 004

N72269 001

APR 11, 1989 : MAR 14, 1989

N72270 001

APR 11, 1989 : MAR 14, 1989

N72271 001

APR 11, 1989 : MAR 14, 1989

APR 11, 1989 : MAR 14, 1989

TIHOLOL MALEATE

TABLET; ORAL

TIHOLOL MALEATE
CORD LABS

AB	5MG	N72550 001
		APR 13, 1989
AB	10MG	N72551 001
		APR 13, 1989
AB	20MG	N72552 001
		APR 13, 1989
AB	5MG	N72001 001
		APR 11, 1989 : JAN 10, 1989
AB	10MG	N72002 001
		APR 11, 1989 : JAN 10, 1989
AB	20MG	N72003 001
		APR 11, 1989 : JAN 10, 1989
AB	5MG	N72466 001
		MAY 19, 1989
AB	10MG	N72467 001
		MAY 19, 1989
AB	20MG	N72468 001
		MAY 19, 1989

QUANTUM PHARMCS

TOBRAMYCIN SULFATE

INJECTABLE; INJECTION

NEBCIN
LILLY

AP	EQ 10MG BASE/ML	N50477 005
AP	EQ 10MG BASE/ML	N62008 004
AP	EQ 10MG BASE/ML	N62707 001
		APR 29, 1987
AP	EQ 40MG BASE/ML	N62008 001
		N62945 001
AP	EQ 10MG BASE/ML	AUG 09, 1989
		N62945 002
AP	EQ 40MG BASE/ML	AUG 09, 1989

TOBRAMYCIN SULFATE
MARSAM PHARMSTOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE
VANGUARD LABS

AB	500MG	N87876/001
		APR 20, 1982

VANGUARD LABS

TOLMETIN SODIUM

TABLET; ORAL

TOLECTIN 600
MCNEIL PHARM

EQ 600MG BASE	N17628 002
	MAR 08, 1989

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL
LEHMON

AB	50MG	N72192 001
		FEB 02, 1989
AB	100MG	N72193 001
		FEB 02, 1989

TRIAMCINOLONE

TABLET; ORAL

TRIAMCINOLONE
/BP/ /CHELSEA LABS/
a CHELSEA LABS

4MG	N85834/001
	N85834 001

TRIAMCINOLONE ACETONIDE

CREAM; TOPICAL

TRIAMCINOLONE ACETONIDE
TOPIDERM

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

TRICHLORMETHIAZIDE

TABLET; ORAL

TRICHLORMETHIAZIDE
/BP/ /CHELSEA LABS/
a CHELSEA LABS

2MG	N86458/001
	N86458 001

TRIMEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL

ARTANE
LEDERLE LABS

2MG/5ML	N06773 009
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RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN'89 - SEP'89

44

TRIHENYPHENIDYL HYDROCHLORIDE

WATER FOR IRRIGATION, STERILE

ELIXIR; ORAL
TRIHENYPHENIDYL HCL
AA LIQUIPHARM

2MG/5MLM

N89514 001
APR 07, 1989

LIQUID; IRRIGATION

STERILE WATER IN PLASTIC CONTAINER
/AT/ CUTTER/BIOI/ 100%
a CUTTER BIOL

/N18246/001/
N18246 001

TABLET; ORAL

TRIHENYPHENIDYL HCL
/AA/ VANGARD LABS/

2MG

a VANGARD LABS

ZIDOVUDINE

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

/N88035/001/
/JUL/30/1982/
N88035 001
JUL 30, 1982

SYRUP; ORAL

RETROVIR

BURROUGHS WELLC

50MG/5MLM

N19910 001
SEP 28, 1989

TRIPLENNAMINE HYDROCHLORIDE

TABLET; ORAL

TRIPLENNAMINE HCL
/AA/ CHELSEA LABS/

50MG/50MG

/N85188/001/
N85188 001

TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIPROLIDINE HCL
/BARRE NATL/
a BARRE NATL
/HALSEY/DRUG/

1.25MG/5ML/
1.25MG/5ML/
1.25MG/5ML/

/N85940/001/
N85940 001
/N88735/001/
/JAN/17/1985/
N88735 001
JAN 17, 1985

HALSEY DRUG

1.25MG/5ML

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

VERAPAMIL HYDROCHLORIDE

TABLET; ORAL

VERAPAMIL HCL
AB CHELSEA LABS

40MG

N72799 001
APR 28, 1989

AB MYLAN PHARMS

80MG

N71482 001
FEB 15, 1989

AB SIDMAK LABS

120MG

N71483 001
FEB 15, 1989

AB SIDMAK LABS

80MG

N72124 001
JAN 26, 1989

AB

120MG

N72125 001
JAN 26, 1989

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN
G&M LABS

325MG

N18060 003
DEC 18, 1986

SUSPENSION, EXTENDED RELEASE; ORAL
CORSYM
FISONS

EQ 4MG MALEATE/5ML;
EQ 37.5MG HCL/5ML

N18050 001
JAN 04, 1984
/N18050/001/
/JAN/04/1984/

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL
FOAMICON
INVAMED

80MG;20MG

N72687 001
JUN 28, 1989

/PENNALT/
/EQ/4MG/MALEATE/5ML;
/EQ/37.5MG/HCL/5ML/

DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE

/SYRUP; 001/
/PHENERGAN/ DEXTROMETHORPHAN/
/MYETH/AYERST/LABS/

/15MG/5ML; 6.25MG/5ML;
/N11265/001/
/AUG/11/1988/

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
BIOSCRUB
KW GRIFFEN

4/M

N19822 001
MAR 31, 1989

CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

/PSEUDO-CHLOR/
/KV/PHARM/
PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE
KV PHARM

/12MG;120MG/
12MG;120MG

/N71455/001/
MAR 01, 1989

PSEUDOEPHEDRINE HCL/CHLORPHENIRAMINE MALEATE
/GRAHAM/LABS/

/8MG;120MG/

2 GRAHAM LABS

8MG;120MG

/N18844/001/
MAR 20, 1985

SYRUP; ORAL

DIPHENHYDRAMINE HCL
NASKA PHARMA

12.5MG/5ML

N70497 001
APR 25, 1989

IBUPROFEN

TABLET; ORAL
IBUPROFEN

/CHELSEA/LABS/

/200MG/

2 CHELSEA LABS

200MG

/N71765/001/
SEP/04/1987/

N71765 001
SEP 04, 1987
N72249 001
JAN 10, 1989

MUTUAL PHARM

200MG

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

PENNTUSS
FISONS

EQ 4MG MALEATE/5ML;
EQ 10MG BASE/5ML

N18928 001
AUG 14, 1985

/PENNALT/

/EQ/4MG/MALEATE/5ML;
/EQ/10MG/BASE/5ML/

/N18928/001/
AUG/14/1985/

IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET; ORAL
COADVIL

WHITEHALL LABS

200MG;30MG

N19771 001
SEP 19, 1989

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

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '89 - SEP '89

46

INSULIN BIOSYNTHETIC HUMAN; INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN

INJECTABLE; INJECTION
HUMULIN 70/30
LILLY

30 UNITS/ML;
70 UNITS/ML

N19717 001
APR 25, 1989

POVIDONE-IODINE

SPONGE; TOPICAL
/POVIDONE-IODINE/
/PESSEF/MED/

/26%/
/N19446/001/
/NOV/29/1985/

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
VISINE II
PFIZER

0.025/M

N19407 001
MAR 31, 1989

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
TRIPROLIDINE AND PSEUDOEPHEDRINE HCL
KV PHARM

N71798 001
MAR 16, 1989

SYRUP; ORAL
/MIFED/
/PBI/

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

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

PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

/SYRUP; ORAL/
/PHEP/001/
/3/WETH/AT/ST/LAB/

/10MG/5ML; 6.25MG/5ML;
/AUG/11/1988/

PSEUDOEPHEDRINE POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL
PSEUDO-12
FISONS

EQ 60MG HCL/5ML

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

/PENNA/

/EQ/60MG/HCL/5ML/

POVIDONE-IODINE

SOLUTION; TOPICAL
E-Z PREP
BECTON DICKINSON

10/M

N19382 001
JUL 25, 1989

POVIDONE IODINE
BAXTER

1/M

N19522 001
MAR 31, 1989

SPONGE; TOPICAL
E-Z PREP
BECTON DICKINSON

5/M

N19382 002
JUL 25, 1989

E-Z PREP 220
BECTON DICKINSON

5/M

N19382 003
JUL 25, 1989

E-Z SCRUB 201
BECTON DICKINSON

20%

N19240 001
NOV 29, 1985

E-Z SCRUB 241
BECTON DICKINSON

10%

N19476 001
JAN 07, 1987

/PESSEF/MED/

/N19476/001/
/JAN/07/1987/

DRUG PRODUCTS IN THE DIVISION OF BLOOD AND BLOOD PRODUCTS APPROVED UNDER SECTION 505 OF THE ACT LIST
CUMULATIVE SUPPLEMENT NUMBER 9 / JAN '89 - SEP '89

NO SEPTEMBER 1989 APPROVALS

ORPHAN DRUG DESIGNATIONS

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

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

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

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

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

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ANTIHEMOPHILIC FACTOR (RECOMBINANT) TRADE: NOT ESTABLISHED	PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.	MILES, INC. CUTTER BIOLOGICAL ELKHART, IN 46515
GENERIC: GRANULOCYTE MACROPHAGE-COLONY STIMULATING FACTOR, RECOMBINANT E. COLI [RGM-CSF] TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE THERMAL INJURIES IN PATIENTS WITH GREATER THAN 40% FULL OR PARTIAL THICKNESS BURNS. TREATMENT OF PATIENTS WITH MYELODYSPLASTIC SYNDROME. TREATMENT OF APLASTIC ANEMIA.	SCHERING CORPORATION 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033
GENERIC: HUMAN IGM MONOCLONAL ANTIBODY (C-58) TO CYTOMEGALOVIRUS (CMV) TRADE: CENTOVID	TREATMENT OF CYTOMEGALOVIRUS (CMV) INFECTIONS IN BONE MARROW TRANSPLANT PATIENTS. PROPHYLAXIS OF CMV INFECTIONS IN BONE MARROW TRANSPLANT PATIENTS.	CENTOCOR, INC. 244 GREAT VALLEY PKWY MALVERN, PA 19355
GENERIC: INDIVIM IN 111 MURINE MONOCLONAL ANTIBODY B72.3 TRADE: ONCOSCINT OV103	DETECTION OF OVARIAN CANCER.	CYTOGEN CORPORATION 201 COLLEGE RD. EAST PRINCETON, NJ 08540
GENERIC: INDIVIM IN 111 MURINE MONOCLONAL ANTIBODY FAB TO MYOSIN TRADE: MYOSCINT	DIAGNOSING MYOCARDITIS.	CENTOCOR, INC. 244 GREAT VALLEY PKWY MALVERN, PA 19355

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

NAME OF BIOLOGICAL	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: INTERFERON ALFA-2A (RECOMBINANT) TRADE: ROFERON-A	TREATMENT OF CHRONIC MYELOGENOUS LEUKEMIA (CML).	HOFFMAN-LA ROCHE 340 KINGSLAND STREET NUTLEY, NJ 07110
GENERIC: IODINE I 131 MURINE MONOCLONAL ANTIBODY IGG2A TO B CELL TRADE: IMMURAIT, LL-2-I-131	TREATMENT OF B-CELL LEUKEMIA AND B-CELL LYMPHOMA.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060
GENERIC: MONOCLONAL FACTOR IX TRADE: NOT ESTABLISHED	REPLACEMENT TREATMENT AND PROPHYLAXIS OF HEMORRHAGIC COMPLICATIONS OF HEMOPHILIA B.	ARMOUR PHARMACEUTICAL COMPANY 920A HARVEST DRIVE SUITE 200 BLUE BELL, PA 19422
GENERIC: RICIN (BLOCKED) CONJUGATED MURINE MONOCLONAL ANTIBODY (ANTI-MY ⁹) TO MYELOID CELLS (CD-33) TRADE: ANTI-MY ⁹ -BR	TREATMENT OF MYELOID LEUKEMIAS.	IMMUNOGEN, INC. 148 SIDNEY STREET CAMBRIDGE, MA 02139
GENERIC: TECHNETIUM TC 99M MURINE MONOCLONAL ANTIBODY TO HUMAN ALPHA-FETOPROTEIN TRADE: IMMURAIT, AFP-TC99M	DETECTION HEPATOCELLULAR CARCINOMA AND HEPATOBLASTOMA. DETECTION OF ALPHA-FETOPROTEIN (AFP) PRODUCING GERM CELL TUMORS.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060
GENERIC: TECHNETIUM TC 99M MURINE MONOCLONAL ANTIBODY TO HUMAN CHORIONIC GONADOTROPIN (HCG) TRADE: IMMURAIT, HCG-TC99M	DETECTION OF HCG PRODUCING TUMORS SUCH AS GERM CELL TUMORS AND TROPHOBLASTIC CELL TUMORS.	IMMUNOMEDICS, INC. 150 MT. BETHEL RD. WARREN, NJ 07060

GENERIC: TECHNETIUM TC 99M MURINE MONOCLONAL
ANTIBODY TO HUMAN CHORIONIC
GONADOTROPIN (HCG)
TRADE: IMMURAD, HCG-TC99M

DETECTION OF HCG PRODUCING TUMORS
SUCH AS GERM CELL TUMORS AND
TROPHOBLASTIC CELL TUMORS.

IMMUNOMEDICS, INC.
150 MT. BETHEL RD.
W/ARREN, NJ 07060

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: ADENOSINE TRADE: NOT ESTABLISHED	FOR USE IN CONJUNCTION WITH BCNU IN THE TREATMENT OF BRAIN TUMORS.	MEDCO RES INC. 8733 BEVERLY BLVD. SUITE 404 LOS ANGELES, CA 90048
GENERIC: BROMHEXINE HCL TRADE: NOT ESTABLISHED	TREATMENT OF MILD TO MODERATE KERATOCONJUNCTIVITIS SICCICA IN PATIENTS WITH SJOJGREN'S SYNDROME.	BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. 90 EAST RIDGE P.O. BOX 368 RIDGEFIELD, CT 06877
GENERIC: CALCIUM ACETATE TRADE: NOT ESTABLISHED	TREATMENT OF HYPERPHOSPHATEMIA IN END STAGE RENAL DISEASE (ESRD).	PHARMEDIC COMPANY 130 EXMOOR COURT DEERFIELD, IL 60015
GENERIC: CITRIC ACID, GLUCONO-DELTA-LACTONE, AND MAGNESIUM CARBONATE TRADE: RENACIDIN	TREATMENT OF RENAL AND BLADDER CALCULI OF THE APATITE OR STRUVITE VARIETY.	UNITED GUARDIAN, INC. 230 MARCUS BLVD. HAUPPUGUE, NY 11788
GENERIC: DIHEMATOPORPHYRIN ETHERS TRADE: PHOTOFRIN II	USE FOR THE PHOTODYNAMIC THERAPY OF PATIENTS WITH PRIMARY OR RECURRENT OBSTRUCTING (EITHER PARTIALLY OR COMPLETELY) ESOPHAGEAL CARCINOMA.	QLT PHOTOTHERAPEUTICS, INC. NORTH MIDDLETOWN ROAD PEARL RIVER, NY 10965
GENERIC: ETHIOFOS TRADE: ETHYOL	USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN AND CYCLOPHOSPHAMIDE IN THE TREATMENT OF OVARIAN CARCINOMA. USE AS A CHEMOPROTECTIVE AGENT FOR CISPLATIN IN THE TREATMENT OF METASTATIC MELANOMA.	U.S. BIOSCIENCE, INC 920-B HARVEST DRIVE P.O. BOX 220 BLUE BELL, PA 19422

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: FLUDARABINE PHOSPHATE TRADE: NOT ESTABLISHED	TREATMENT OF NON-HODGKIN'S LYMPHOMA (NHL).	TRITON BIOSCIENCES 1501 HARBOR BAY PARKWAY ALAMEDA, CA 94501
GENERIC: GANCICLOVIR (DHPG) TRADE: CYTOVENE*/**	TREATMENT OF CYTOMEGALOVIRUS (CMV) RETINITIS IN IMMUNOCOMPROMISED INDIVIDUALS, INCLUDING PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS)*/**. [JUN 23, 1996]	SYNTEX (U.S.A.), INC. 3401 HILLVIEW AVENUE PALO ALTO, CA 94304
GENERIC: HUMAN GROWTH HORMONE, RECOMBINANT TRADE: NOT ESTABLISHED	TREATMENT OF CHILDREN OF SHORT STATURE ASSOCIATED WITH CHRONIC RENAL FAILURE.	GENETECH, INC. 460 PT SAN BRUNO BLVD. SOUTH SAN FRANCISCO, CA 94080
GENERIC: HUMAN GROWTH HORMONE RELEASING FACTOR TRADE: NOT ESTABLISHED	FOR THE LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ADEQUATE ENDOGENOUS GROWTH HORMONE SECRETION.	HOFFMAN-LA ROCHE, INC. 340 KINGSLAND ST. NUTLEY, NJ 07110
GENERIC: ILOPROST TRADE: NOT ESTABLISHED	TREATMENT OF RAYNAUD'S PHENOMENON SECONDARY TO SYSTEMIC SCLEROSIS.	BERLEX LABORATORIES 110 EAST HANOVER AVE CEDAR KNOLLS, NJ 07927
GENERIC: L-CYCLOSERINE TRADE: NOT ESTABLISHED	TREATMENT OF GAUCHER'S DISEASE.	THE CITY COLLEGE CITY UNIVERSITY OF N.Y. MEDICAL SCHOOL CONVENT AVE. @ 138 ST. N.Y., NY 10031
GENERIC: LYSINE ACETYSALICYLATE TRADE: ASPEGIC	TREATMENT OF PAIN AND FEVER SECONDARY TO SICKLE CELL DISEASE CRISIS.	G.D. SEARLE & CO. 4901 SEARLE PKWY SKOKIE, IL 60077

GENERIC: LYSINE ACETYL SALICYLATE
TRADE: ASPEGIC

TREATMENT OF PAIN AND FEVER SECONDARY TO SICKLE
CELL DISEASE CRISIS.

G.D. SEARLE & CO.
4901 SEARLE PKWY
SKOKIE, IL 60077

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

NAME OF DRUG	DESIGNATED USE [EXCLUSIVITY EXPIRATION DATE]	SPONSOR NAME AND ADDRESS
GENERIC: NG-29 TRADE: NOT ESTABLISHED	FOR THE ASSESSMENT OF THE CAPACITY OF THE PITUITARY GLAND TO RELEASE GH IN CHILDREN OF SHORT STATURE POSSIBLY DUE TO GH DEFICIENCY.	FERRING LABORATORIES MONTEBELLO PARK 75 MONTEBELLO RD. SUFFERN, NY 10901
GENERIC: PENTAMIDINE ISETHIONATE (INHALATION) TRADE: NEBUPENT*/** (FORMERLY PENTAM 300)	PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP) IN PATIENTS AT HIGH RISK OF DEVELOPING THIS DISEASE. [JUN 15, 1996]	LYPHOMED, INC. 2020 RUBY STREET MELROSE PARK, IL 60160
GENERIC: POLOXAMER 188, N.F. TRADE: RHEOTHRIX COPOLYMER	TREATMENT OF SICKLE CELL CRISIS.	CYTRX CORPORATION 150 TECHNOLOGY PARKWAY TECHNOLOGY PARK/ATLANTA NORCROSS, GA 30092
GENERIC: SELEGILINE HCL TRADE: ELDEPRYL*/** (FORMERLY DEPRENVL)	ADJUNCT IN THE MANAGEMENT OF PARKINSONIAN PATIENTS BEING TREATED WITH LEVODOPA/CARBIDOPA WHO EXHIBIT DETERIORATION IN THE QUALITY OF THEIR RESPONSE TO THIS THERAPY*/**. [JUNE 05, 1996]	SOMERSET PHARMACEUTICALS ONE OLDE TOWNE COURT BERNARDSVILLE, NJ 07924
GENERIC: SOMATROPIN TRADE: SAIZEN	ENHANCEMENT OF NITROGEN RETENTION IN HOSPITALIZED PATIENTS SUFFERING FROM SEVERE BURNS.	SERONO LABORATORIES 100 LONGWATER CIRCLE NORWELL, MA 02061
GENERIC: T4 ENDONUCLEASE V, LIPOSOME ENCAPSULATED TRADE: T4N5	TO PREVENT CUTANEOUS NEOPLASMS AND OTHER SKIN ABNORMALITIES ASSOCIATED WITH PATIENTS DIAGNOSED WITH XERODERMA PIGMENTOSUM (XP).	APPLIED GENETICS, INC. 205 BUFFALO AVENUE FREEPORT, NY 11520
GENERIC: TROLEANDOMYCIN TRADE: NOT ESTABLISHED	TREATMENT OF SEVERE STEROID-REQUIRING ASTHMA	STANLEY SZEFLER, MD NATIONAL JEWISH CENTER FOR IMMUNOLOGY AND RESPIRATORY MEDICINE 1400 JACKSON STREET DENVER, CO 80206

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

NO SEPTEMBER 1989 ADDITIONS

BIOPHARMACEUTIC GUIDANCE AVAILABILITY

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

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

DRUG NAME (DOSAGE FORM)

DATE

REVISED DATE

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

ANDA SUITABILITY PETITIONS

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

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

PETITIONS APPROVED

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

DRUG NAME DOSAGE FORM; ROUTE	STRENGTH (CONTAINER SIZE)	DOCKET NUMBER	PETITIONER	REASON FOR PETITION	STATUS
CYCLOPHOSPHAMIDE INJECTABLE; INJECTION	20MG/ML (250ML/CONTAINER)	88 P-0379/CP	BAXTER	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 01, 1989
HALOPERIDOL CONCENTRATE; ORAL	EQ 0.5MG/5ML	89P-0088/CP	UDL LABS	NEW STRENGTH	APPROVED MAY 11, 1989

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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

ANDA SUITABILITY PETITIONS

PETITIONS APPROVED

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

ANDA SUITABILITY PETITIONS

PETITIONS DENIED

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

EXCLUSIVITY TERMS

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

REFERENCES
NEW INDICATION

- ~~I-72~~
I-73 **FOLLICULAR STIMULATION IN IN VITRO FERTILIZATION**
STIMULATE THE DEVELOPMENT OF MULTIPLE FOLLICLES/OOCYTES IN OVULATORY PATIENTS PARTICIPATING IN AN IN VITRO FERTILIZATION PROGRAM
- I-84 ADJUNCTIVE THERAPY TO DIET TO REDUCE THE RISK OF CORONARY ARTERY DISEASE
- I-85 SELECTIVE ADULT VISCERAL ARTERIOGRAPHY
- I-86 METASTATIC BREAST CANCER IN PREMENOPAUSAL WOMEN AS AN ALTERNATIVE TO OOPHORECTOMY OR OVARIAN IRRADIATION
- I-87 TREATMENT OF TINEA PEDIS
- I-88 CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS IN THE SPINE AND ASSOCIATED TISSUES
- I-89 PEDIATRIC MYELOGRAPHY
- I-90 ORAL USE OF DILUTED OMNIPAQUE INJECTION IN ADULTS FOR CONTRAST ENHANCED COMPUTED TOMOGRAPHY OF THE ABDOMEN
- I-91 ORAL USE IN ADULTS FOR PASS-THROUGH EXAMINATION OF THE GASTROINTESTINAL TRACT
- I-92 PEDIATRIC CONTRAST ENHANCEMENT OF COMPUTED TOMOGRAPHIC HEAD IMAGING
- I-93 ARTHROGRAPHY OF THE SHOULDER JOINTS IN ADULTS
- I-94 RADIOGRAPHY OF THE TEMPOROMANDIBULAR JOINT IN ADULTS
- I-95 CONTRAST ENHANCEMENT AGENT TO FACILITATE VISUALIZATION OF LESIONS OF THE CENTRAL NERVOUS SYSTEM IN CHILDREN (2 YEARS OF AGE AND OLDER)
- I-96 TREATMENT OF ACUTE MYOCARDIAL INFARCTION

EXCLUSIVITY TERMS

REFERENCES

PATENT USE CODE

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

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

62

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	18240 001 ATENOLOL; TENORMIN	3663607	MAY 16, 1989		I-96	SEP 13, 1992
>ADD>	18240 002 ATENOLOL; TENORMIN	3663607	MAY 16, 1989		I-96	SEP 13, 1992
>ADD>	19058 001 ATENOLOL; TENORMIN				NDF	SEP 13, 1992
	19459 001 AVBENZONE; PHOTOPLEX	4387089	JUN 07, 2002		NCE	SEP 30, 1993
	19716 001 BETAMETHASONE DIPROPIONATE; DIPROLENE	4775529	OCT 04, 2005		NP	AUG 01, 1991
	19270 001 BETAXOLOL HYDROCHLORIDE; BETOPTIC	4252984	AUG 30, 1999		NCE	AUG 30, 1990
>ADD>	18644 001 BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
>ADD>	18644 002 BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
>ADD>	18644 003 BUPROPION HYDROCHLORIDE; WELLBUTRIN	3885046	MAY 20, 1994	U-18		
	18469 001 CALCIUM CHLORIDE; BSS PLUS	4550022	OCT 29, 2002			
		4443432	APR 17, 2001			
	19880 001 CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 002 CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19880 003 CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-50	NCE	MAR 03, 1994
	19537 002 CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
	19537 003 CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
	19537 004 CIPROFLOXACIN HYDROCHLORIDE; CIPRO	4670444	JUN 02, 2004	U-54	NCE	OCT 22, 1992
>ADD>	19758 001 CLOZAPINE; CLOZARIL	4670444	JUN 02, 2004		NCE	SEP 26, 1994
>ADD>	19758 002 CLOZAPINE; CLOZARIL				NCE	SEP 26, 1994
>ADD>	71611 001 CYCLOBENZAPRINE HYDROCHLORIDE; CYCLOBENZAPRINE HCL			PC	NCE	SEP 26, 1994
	19201 001 DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	NOV 15, 1989
	19201 002 DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
	19201 003 DICLOFENAC SODIUM; VOLTAREN	3652762	MAR 28, 1991		NCE	JUL 28, 1993
	19471 001 DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
				NP	NP	JAN 23, 1992
	19471 002 DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
				NP	NP	JAN 23, 1992
	19471 003 DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
				NP	NP	JAN 23, 1992
	19471 004 DILTIAZEM HYDROCHLORIDE; CARDIZEM SR	4721619	JAN 26, 2005		NCE	NOV 05, 1992
				NP	NP	JAN 23, 1992
	19386 003 ESMOLOL HYDROCHLORIDE; BREVIBLOC	4387103	JUN 07, 2000	U-16	NCE	DEC 31, 1991
					NCE	JAN 27, 1994
	18554 001 FLUTAMIDE; EULEXIN	4474813	NOV 30, 1993			
		4472382	SEP 18, 2001	U-42		
		4329364	MAY 11, 1999	U-41		
	19596 001 GADOPENTETATE DIMEGLUMINE; MAGNEVIST	4507305	OCT 19, 1999	U-53		
		4423050	OCT 19, 1999	U-52		
	19661 001 GANCICLOVIR SODIUM; CYTOVENE	4355032	OCT 19, 1999	U-51		
					ODE	JUN 23, 1996
					NCE	JUN 23, 1994

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
18422 001	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
18422 002	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
18422 003	GEMFIBROZIL; LOPID	3674836	JAN 04, 1993		I-84	JAN 17, 1992
19778 001	HYDROCHLOROTHIAZIDE; PRINZIDE 12.5	4472380	SEP 18, 2001		NCE	DEC 29, 1992
		4374829	DEC 30, 2001		NC	FEB 16, 1992
19778 002	HYDROCHLOROTHIAZIDE; PRINZIDE 25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
		4374829	DEC 30, 2001		NC	FEB 16, 1992
19888 002	HYDROCHLOROTHIAZIDE; ZESTORETIC 20/25	4472380	SEP 18, 2001		NCE	DEC 29, 1992
		4374829	DEC 30, 2001		NC	FEB 16, 1992
>ADD>	IBUPROFEN; COADVIL				NCE	DEC 29, 1992
>ADD>	19833 002 IBUPROFEN; CHILDREN'S ADVIL	4788220	NOV 29, 2005		NC	SEP 19, 1992
>ADD>	19842 001 IBUPROFEN; PEDIA PROFEN				NDF	SEP 19, 1992
	18956 001 IOHEXOL; OMNIPAQUE 180				I-89	JUN 30, 1992
	18956 002 IOHEXOL; OMNIPAQUE 240				I-90	JUN 30, 1992
					NR	JUN 30, 1992
					I-92	JUL 28, 1992
					I-93	JUL 28, 1992
					I-85	MAR 31, 1992
18956 003	IOHEXOL; OMNIPAQUE 300	4021481	MAY 03, 1994		I-90	JUN 30, 1992
					NR	JUN 30, 1992
					I-94	JUL 28, 1992
					I-92	JUL 28, 1992
					I-85	MAR 31, 1992
					NR	JUN 30, 1992
					I-90	JUN 30, 1992
					I-91	JUN 30, 1992
					I-93	JUL 28, 1992
					NS	JUN 30, 1992
					NCE	DEC 30, 1993
18956 006	IOHEXOL; OMNIPAQUE 210	4396597	JUL 14, 1998		NCE	DEC 30, 1993
		4250113	DEC 26, 1999		NCE	DEC 30, 1993
		4021481	MAY 03, 1994	U-46	NCE	DEC 30, 1993
19710 001	IOVERSOL; OPTIRAY 320	4396598	AUG 02, 2000	U-47	NCE	DEC 30, 1993
		4396598	AUG 02, 2000	U-48	NCE	DEC 30, 1993
19710 002	IOVERSOL; OPTIRAY 240	4396598	AUG 02, 2000	U-49	ODE	AUG 31, 1995
19710 003	IOVERSOL; OPTIRAY 160	4396598	AUG 02, 2000		I-79	AUG 31, 1995
08107 005	LEUCOVORIN CALCIUM; LEUCOVORIN CALCIUM	4396598	AUG 02, 2000		NCE	APR 09, 1990
					NP	JAN 26, 1992
19732 001	LEUPROLIDE ACETATE; LUPRON DEPOT	4005063	JAN 25, 1996		NS	JUN 28, 1992
					NCE	DEC 29, 1992
19219 002	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN	3649691	MAR 14, 1991		NCE	MAY 02, 1994
19814 001	LEVOBUNOLOL HYDROCHLORIDE; BETAGAN	3649691	MAR 14, 1991		NCE	MAY 02, 1994
19777 004	LISINAPRIL; ZESTRIL	4374829	DEC 30, 2001		NCE	MAY 02, 1994
19578 001	MEFLOQUINE HYDROCHLORIDE; MEFLOQUINE HCL				NCE	MAY 02, 1994
19591 001	MEFLOQUINE HYDROCHLORIDE; LARIAM				NCE	MAY 02, 1994

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

64

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
17646 001	MENOTROPINS; PERGONAL				I-73	AUG 23, 1992
17646 002	MENOTROPINS; PERGONAL	4808610	FEB 28, 2006		I-73	AUG 23, 1992
19625 001	MOMETASONE FUROATE; ELOCON	4775529	OCT 04, 2005		NCE	APR 30, 1992
19796 001	MOMETASONE FUROATE; ELOCON	4472393	SEP 18, 2001		NDF	MAR 30, 1992
19599 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000		NCE	MAR 01, 1993
>ADD>					I-87	APR 05, 1992
19684 001	NIFEDIPINE; PROCARDIA XL				NDF	SEP 06, 1992
>ADD>					NDF	SEP 06, 1992
19684 003	NIFEDIPINE; PROCARDIA XL				NDF	SEP 06, 1992
19508 001	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
19508 002	NIZATIDINE; AXID	4375547	MAR 01, 2002		NCE	APR 12, 1993
19810 001	OMEPRazole; LOSEC	4786505	NOV 22, 2005	U-55	NCE	SEP 14, 1994
>ADD>		4255431	MAR 10, 1998			
19407 001	OXYMETAZOLINE HYDROCHLORIDE; VISINE II				NDF	MAY 30, 1989
19887 001	PENTAMIDINE ISETHIONATE; NEBUPENT				ODE	JUN 15, 1996
19855 001	PERMETHRIN; ELIMITE	4024163	MAY 17, 1996		NDF	JUN 15, 1992
18796 001	PILOCARPINE HYDROCHLORIDE; PILOPINE HS	4271143	JUN 02, 1998		NCE	MAR 31, 1991
19334 001	SELEGILINE HYDROCHLORIDE; ELDEPRYL				NDF	AUG 25, 1992
19640 001	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				NCE	JUN 05, 1994
19640 004	SOMATROPIN, BIOSYNTHETIC; HUMATROPE				ODE	JUN 05, 1996
18737 001	SULCONAZOLE NITRATE; SULCOSYN				NR	MAY 10, 1992
17970 001	TAMOXIFEN CITRATE; NOLVADEX	4055652	OCT 25, 1996		NCE	AUG 30, 1990
19829 001	TECHNETIUM TC-99M EXAMETAZIME KIT; CERETEC				NDF	FEB 28, 1992
18321 001	TECHNETIUM TC-99M OXIDRONATE KIT; OSTEOSCAN-HDP				I-86	MAR 16, 1992
17628 002	TOLMETIN SODIUM; TOLECTIN 600	4789736	DEC 06, 2005		NCE	DEC 30, 1993
19594 001	URSODIOL; ACTIGALL	4497744	FEB 05, 2002			
19594 002	URSODIOL; ACTIGALL	4432963	FEB 21, 2001			
19910 001	ZIDOVUDINE; RETROVIR	4247534	JAN 27, 1998			
		4233284	NOV 11, 1997			
		3752826	AUG 14, 1990			
		RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		
		RE30910	JAN 07, 1994	U-43		
		RE30910	JAN 07, 1994	U-44		
		RE30910	JAN 07, 1994	U-45		

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