

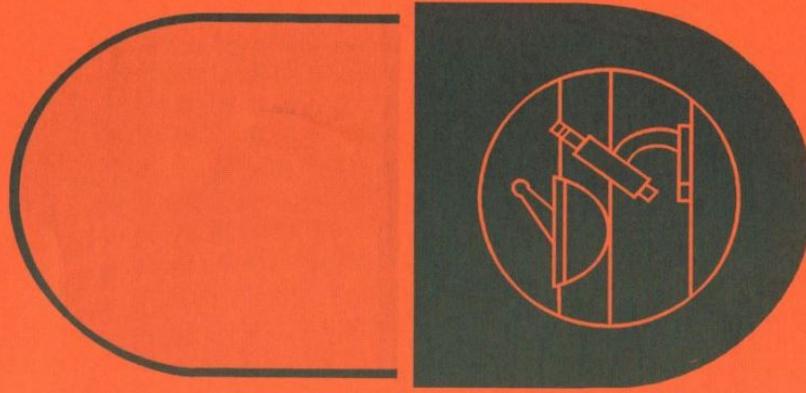
CUMULATIVE  
SUPPLEMENT 7  
JAN'97-JUL'97

# APPROVED DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

17<sup>TH</sup> EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MANAGEMENT  
DIVISION OF DATABASE MANAGEMENT



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

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### **APPROVED DRUG PRODUCTS**

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

**18<sup>TH</sup> EDITION  
1998**

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#### **CONTENTS**

- Prescription Drug Product List
- OTC Drug Product List
- Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List
- Discontinued Drug Product List
- Orphan Drug Product Designations
- Drug Products Which Must Demonstrate *in vivo* Bioavailability Only if Product Fails to Achieve Adequate Dissolution
- Patent and Exclusivity Information

*See Subscription Form Inside Back Cover*

Approved drug products with  
therapeutic equivalence

C:355661 M:174736 O:12937927

## APPROVED DRUG PRODUCTS

with

## THERAPEUTIC EQUIVALENCE EVALUATIONS

### 17TH EDITION

#### Cumulative Supplement 7

JULY 1997

#### CONTENTS

## Library Use Only

PAGE

1.0	INTRODUCTION .....	iii
1.1	How to Use the Cumulative Supplement .....	iii
1.2	Court Order Affecting Uruguay Round Agreements Act-Extended Patents .....	iv
1.3	Applicant Name Changes .....	v
1.4	Acyclovir 200 mg Tablet-Reference Listed Drug .....	vii
1.5	Availability of the Publication and Updating Procedures .....	vii
1.6	Report of Counts for the Prescription Drug Product List .....	viii
2.0	DRUG PRODUCT LISTS .....	
2.1	Prescription Drug Product List.....	1
2.2	OTC Drug Product List.....	45
2.3	Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List .....	48
2.4	Orphan Product Designations and Approvals List.....	49
2.5	Drug Products Which Must Demonstrate <i>in vivo</i> Bioavailability Only if Product Fails to Achieve Adequate Dissolution .....	55
<b>PATENT AND EXCLUSIVITY INFORMATION ADDENDUM</b>		
A.	Patent and Exclusivity Terms .....	56
B.	Patent and Exclusivity Lists.....	58

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**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**17TH EDITION**

**CUMULATIVE SUPPLEMENT 7  
JULY 1997**

**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, 17th 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 with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals 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 with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research 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. Also shown is the application number and product number (FDA's internal file number) for reference purposes. 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. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and 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 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.)

New additions to the Prescription Drug Product List, OTC Drug Product 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.

New deletions to the Prescription Drug Product List, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**DLT**> (DELETE) to the left of the line. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition. However, the overstruck data in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements (hard copy).

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 17th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 18th Edition.

## 1.2 COURT ORDER AFFECTING URUGUAY ROUND AGREEMENTS ACT-EXTENDED PATENTS

As a result of the April 4, 1996, decision of the United States Court of Appeals for the Federal Circuit in Merck, et al. v. Kessler, patent expiration dates for certain patents subject to patent term extensions under the Uruguay Round Agreements Act and to the patent term extension provisions at 35 U.S.C. § 156 may be changed. FDA has published a notice in the March 14, 1997, *Federal Register* advising NDA and NADA

applicants that patent expiration dates changed by the Merck decision must be submitted within 60 days. Because there may be changes in listed patents as a result of the Merck decision, users of this publication should consult the most recent supplement, and are encouraged to confirm that patent information upon which they intend to rely is current. (See the *Patent and Exclusivity Addendum* to the *Approved Drug Products with Therapeutic Equivalence Evaluations*, 17th Edition that explains the background information on this court decision).

### **1.3 APPLICANT NAME CHANGES**

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. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will automatically reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. However, when the applicant name change is one which may not be easily recognized or located in the listing (e.g., White Towne Paulsen [Former Abbreviated Name] is changed to Whiteworth Towne PLSN [New Abbreviated Name], the name change will appear in this section and will be identified with an asterisk.

#### APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

CIBA GEIGY CORP  
(CIBA GEIGY)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

NOVARTIS PHARMACEUTICALS CORP  
(NOVARTIS)

APPLICANT NAME CHANGES

<u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u>
CIBA GEIGY CORP PHARMACEUTICALS DIV (CIBA GEIGY)	NOVARTIS PHARMACEUTICALS CORP (NOVARTIS)
CIBA PHARMACEUTICAL CO DIV CIBA GEIGY CORP (CIBA)	NOVARTIS PHARMACEUTICALS CORP (NOVARTIS)
CIBA SELF MEDICATION INC DIV CIBA GEIGY CORP (CIBA)	NOVARTIS CONSUMER HEALTH INC (NOVARTIS)
CIBA VISION CORP (CIBA)	CIBA VISION CORPORATION A NOVARTIS COMPANY (CIBA)
CIBA VISION OPHTHALMICS DIV CIBA VISION CORP (CIBA)	CIBA VISION CORPORATION A NOVARTIS COMPANY (CIBA)
FERRING LABORATORIES INC (FERRING)	FERRING PHARMACEUTICALS INC (FERRING)
GEIGY PHARMACEUTICALS DIV CIBA GEIGY CORP (GEIGY)	NOVARTIS PHARMACEUTICALS CORP (NOVARTIS)
LEMMON CO SUB TAG PHARMACEUTICAL INC (LEMMON)	BIOCRAFT LABORATORIES INC (BIOCRAFT) <b>THEN CHANGED TO</b> TEVA PHARMACEUTICALS USA (TEVA)
SANDOZ CONSUMER HEALTH CARE GROUP DIV SANDOZ PHARMACEUTICALS (SANDOZ)	NOVARTIS CONSUMER HEALTH INC (NOVARTIS)
SANDOZ PHARMACEUTICALS CORP DIV SANDOZ INC (SANDOZ)	NOVARTIS PHARMACEUTICALS CORP (NOVARTIS)
SANDOZ RESEARCH INSTITUTE INC (SANDOZ)	NOVARTIS PHARMACEUTICALS CORP (NOVARTIS)
SANOFI WINTHROP INC (SANOFI WINTHROP)	SANOFI PHARMACEUTICAL INC (SANOFI)
SURVIVAL TECHNOLOGY INC (SURVIVAL TECH)	MERIDIAN MEDICAL TECHNOLOGIES INC (MERIDIAN MEDCL TECHN)

#### 1.4 ACYCLOVIR 200MG TABLET-REFERENCE LISTED DRUG

Novapharm's single source acyclovir tablets have been declared to be a reference listed drug for the 200 mg tablet in addition to the acylcovir (Zovirax) 800 mg tablet of the innovator. A generic firm wishing to submit an ANDA for a duplicate of the 200 mg acyclovir tablet will be eligible for a waiver of the *in vivo* determination of bioequivalence (1) if their product is proportionally similar in its active and inactive ingredients to their own 800 mg acyclovir tablet and (2) by doing an acceptable comparative dissolution test (dissolution profile) against Novopharm's 200 mg acyclovir reference listed drug.

Before a waiver of the *in vivo* determination of bioequivalence can be granted for the 200 mg acyclovir tablet, the generic firm must have completed an acceptable fasting and fed study comparing their acyclovir 800 mg tablet against the Zovirax 800 mg tablet.

For further information on the study designs, you should contact the Division of Bioequivalence, Office of Generic Drugs.

#### 1.5 AVAILABILITY OF THE PUBLICATION AND UPDATING PROCEDURES

The *Approved Drug Products with Therapeutic Equivalence Evaluations* (Prescription Drug Products, OTC Drug Products and the Discontinued Drug Product Lists) is available on diskette, on a quarterly basis, from the National Technical Information Service. The telephone number for the Subscription Department is (703) 487-6430. Written inquiries regarding this subscription may be forwarded to 5285 Port Royal Road Springfield, VA 22161.

The following *Approved Drug Products with Therapeutic Equivalence Evaluations* files are now available on Internet and are updated each October and April: Prescription Drug Product List; OTC Drug Products; Discontinued Drug Products; Prescription and OTC Drug Product Patent and Exclusivity Data; and Appendices. The update in October will include drug products that have been approved through August and the update in April will include drug products that have been approved through December.

These files may be accessed on the Internet's World Wide Web. FDA's Internet site replaced the Agency's electronic bulletin board. To access the CDER Home Page, use this Uniform Resource Locator (URL): <http://www.fda.gov/cder>. You do not need an Internet connection to reach the FDA Home Page; you can use the free dial-up connection (800) 222-0185 for text based, non-graphical use only. For further assistance, please call (301) 443-4908.

## 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 1996) 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

	<u>DEC 1996*</u>	<u>MAR 1997</u>	<u>JUN 1997</u>	<u>SEP 1997</u>
DRUG PRODUCTS LISTED	9392	9493	9533	2388 (25.0%)
SINGLE SOURCE	2383 (25.4%)	2387 (25.1%)	2388 (25.0%)	
MULTISOURCE	6905 (73.5%)	6991 (73.7%)	7031 (73.8%)	
THERAPEUTICALLY EQUIVALENT	6463 (68.8%)	6549 (69.0%)	6626 (69.5%)	
NOT THERAPEUTICALLY EQUIVALENT	442 (4.7%)	442 (4.7%)	405 (4.3%)	
EXCEPTIONS <sup>1</sup>	104 (1.1%)	115 (1.2%)	114 (1.2%)	
NEW MOLECULAR ENTITIES APPROVED	--	6	6	
NUMBER OF APPLICANTS	650	662	682	8

<sup>1</sup>Amino acid-containing products of varying composition (see Introduction, page xx of the List).

\*Exceptions were originally included in the total count of the Multisource Drug Products. Beginning with December 1996, exceptions were no longer included in the Multisource Drug Products total count, but included in the total count of the Drug Products Listed.

PRESCRIPTION DRUG PRODUCT LIST  
17TH EDITION

ACARBOSE

TABLET; ORAL  
PRECOSA  
BAYER  
25MG

## ACETAMINOPHEN: PROPOXYPHENE NAPSYLATE

AB AB TABLET; ORAL PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN 650MG; 100MG VINTAGE PHARMS N74843 001 FEB 12, 1997

ACETAMINOPHEN; BUTALBITAL; CAFFINE

## **HACETAMINOPHEN; HYDROCODONE BITARTRATE**

TABLET; ORAL HYDROCODONE BITARTRATE AND ACETAMINOPHEN		CAPSULE; ORAL ACYCLOVIR	
EON	500MG; 5MG	AESGEN	200MG
	<u>750MG; 7.5MG</u>	<u>AB</u>	<u>N74833 001</u>
	JAN 27, 1997		APR 22, 1997
	<u>500MG; 2.5MG</u>	<u>AB</u>	<u>N7472 001</u>
VINTAGE PHARMS	JAN 27, 1997		APR 22, 1997
	<u>650MG; 7.5MG</u>	<u>AB</u>	<u>N7450 001</u>
	JAN 25, 1997		APR 22, 1997
	<u>500MG; 10MG</u>	<u>AB</u>	<u>N74828 001</u>
WATSON LABS	JAN 25, 1997		APR 22, 1997
	<u>500MG; 10MG</u>	<u>AB</u>	<u>N74727 001</u>
LORTAB	JAN 14, 1997		APR 22, 1997
* GRAHAM DM	FEB 14, 1997		<u>N74578 001</u>
	<u>500MG; 10MG</u>	<u>AB</u>	APR 22, 1997
	JAN 26, 1996		<u>N74570 002</u>
	<u>500MG; 10MG</u>	<u>AB</u>	APR 22, 1997
	JAN 26, 1996		<u>N74828 001</u>
	<u>500MG; 10MG</u>	<u>AB</u>	APR 22, 1997
	JUN 25, 1997		<u>N74674 001</u>
NORCO	JUN 25, 1997		APR 22, 1997
+ WATSON LABS			<u>N74148 001</u>
			APR 14, 1997

## ACYCLOVIR

CAPSULE; ORAL ACYCLOVIR	<u>200MG</u>	N74833 001 APR 22, 1997
	AESGEN	N74872 001 APR 22, 1997
B	ESI LEDERLE	N74750 001 APR 22, 1997
B	LEK PHARM	N74828 001 APR 22, 1997
B	LEXICON	N74727 001 APR 22, 1997
B	MYLAN	N74578 001 APR 22, 1997
B	NOVOPHARM	N74570 002 APR 22, 1997
B	ROXANE	N74828 001 APR 22, 1997
B	TEVA	N74674 001 APR 22, 1997
B	ZENITH GOLDLINE	

<u>ACYCLOVIR</u>		<u>ACYCLOVIR SODIUM</u>	
<u>CAPSULE; ORAL</u>		<u>INJECTABLE; INJECTION</u>	
<u>AB + ZOVIRAX</u>	<u>200MG</u>	<u>ACYCLOVIR SODIUM</u>	
<u>SUSPENSION; ORAL</u>		<u>ABBOTT</u>	
<u>ACYCLOVIR</u>	<u>200MG/5ML</u>	<u>AP</u>	<u>N74663 001</u>
<u>ALPHARMA</u>		<u>AP</u>	<u>APR 22, 1997</u>
<u>AB + ZOVIRAX</u>	<u>200MG/5ML</u>	<u>AP</u>	<u>N74758 001</u>
<u>GLAXO WELLCOME</u>		<u>AP</u>	<u>APR 22, 1997</u>
<u>TABLET; ORAL</u>		<u>EQ 500MG BASE/VIAL</u>	
<u>ACYCLOVIR</u>	<u>400MG</u>	<u>EQ 500MG BASE/VIAL</u>	
<u>ESI LEDERLE</u>		<u>EQ 1GM BASE/VIAL</u>	
<u>AB</u>	<u>800MG</u>	<u>EQ 1GM BASE/VIAL</u>	
<u>LEK PHARM</u>	<u>400MG</u>	<u>EQ 500MG BASE/VIAL</u>	
<u>AB</u>	<u>800MG</u>	<u>EQ 1GM BASE/VIAL</u>	
<u>NOVOPHARM</u>	<u>400MG</u>	<u>EQ 500MG BASE/VIAL</u>	
<u>AB</u>	<u>800MG</u>	<u>EQ 500MG BASE/ML</u>	
<u>PUREPAC PHARM</u>	<u>200MG</u>	<u>EQ 25MG BASE/ML</u>	
<u>AB</u>	<u>400MG</u>	<u>APR 22, 1997</u>	
<u>ZENITH GOLDLINE</u>	<u>800MG</u>	<u>N74834 001</u>	
<u>AB</u>	<u>400MG</u>	<u>APR 24, 1997</u>	
<u>ZOVIRAX</u>	<u>800MG</u>	<u>N74834 002</u>	
<u>GLAXO WELLCOME</u>		<u>AP + ZOVIRAX</u>	
<u>AB +</u>	<u>400MG</u>	<u>AP + GLAXO WELLCOME</u>	
<u>TABLET; ORAL</u>		<u>APR 22, 1997</u>	
<u>ACYCLOVIR</u>	<u>400MG</u>	<u>N18603 001</u>	
<u>ESI LEDERLE</u>		<u>OCT 22, 1982</u>	
<u>AB</u>	<u>800MG</u>	<u>N18603 002</u>	
<u>LEK PHARM</u>	<u>400MG</u>	<u>JUN 29, 1989</u>	
<u>AB</u>	<u>800MG</u>	<u>N74658 001</u>	
<u>NOVOPHARM</u>	<u>400MG</u>	<u>N74658 002</u>	
<u>AB</u>	<u>800MG</u>	<u>N74556 002</u>	
<u>PUREPAC PHARM</u>	<u>200MG</u>	<u>APR 22, 1997</u>	
<u>AB</u>	<u>400MG</u>	<u>N74556 003</u>	
<u>ZENITH GOLDLINE</u>	<u>800MG</u>	<u>APR 22, 1997</u>	
<u>AB</u>	<u>400MG</u>	<u>N74836 001</u>	
<u>ZOVIRAX</u>	<u>800MG</u>	<u>JUN 05, 1997</u>	
<u>GLAXO WELLCOME</u>		<u>ALPRAZOLAM</u>	
<u>AB +</u>	<u>400MG</u>	<u>APR 22, 1997</u>	
<u>TABLET; ORAL</u>		<u>TABLET; ORAL</u>	
<u>ACYCLOVIR</u>		<u>ALPRAZOLAM</u>	
<u>ROYCE LABS</u>		<u>AB</u>	<u>0.25MG</u>
<u>AB</u>		<u>AB</u>	<u>0.5MG</u>
<u>N20089 001</u>		<u>AB</u>	<u>1MG</u>
<u>AB</u>	<u>800MG</u>	<u>APR 30, 1991</u>	
<u>AB</u>	<u>800MG</u>	<u>N20089 002</u>	
<u>AB</u>		<u>APR 30, 1991</u>	
<u>ACYCLOVIR SODIUM</u>		<u>N74479 001</u>	
<u>ABBOTT</u>		<u>JAN 21, 1997</u>	
<u>AP</u>		<u>N74479 002</u>	
<u>EQ</u>		<u>JAN 21, 1997</u>	
<u>AP</u>		<u>N74479 003</u>	
<u>AP</u>		<u>JAN 21, 1997</u>	



<u>AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; BUTYLPHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE</u>	<u>AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE</u>
INJECTABLE; INJECTION CLINIMIX E 4.25/20 SULFITE-FREE W/ ELECT IN DEXTROSE 20% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 4.25%; 3.3MG/100ML; 20GM/100ML; 5.1MG/100ML; 261MG/100ML; 29.7MG/100ML; 7.7MG/100ML N20678 011 MAR 26, 1997	INJECTABLE; INJECTION CLINIMIX E 5/35 SULFITE FREE W/ ELECT IN DEXTROSE 3.5% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 5%; 3.3MG/100ML; 35GM/100ML; 51MG/100ML; 261MG/100ML; 340MG/100ML; 59MG/100ML N20678 021 MAR 26, 1997
CLINIMIX E 4.25/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 4.25%; 3.3MG/100ML; 25GM/100ML; 5.1MG/100ML; 261MG/100ML; 29.7MG/100ML; 7.7MG/100ML N20678 012 MAR 26, 1997	AMINOPHYLLINE INJECTABLE; INJECTION <u>AMINOPHYLLINE</u> AP * SEARLE 25MG/ML @ 25MG/ML
CLINIMIX E 4.25/5 SULFITE-FREE W/ ELECT IN DEXTROSE 5% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 4.25%; 3.3MG/100ML; 5GM/100ML; 5.1MG/100ML; 261MG/100ML; 29.7MG/100ML; 7.7MG/100ML N20678 008 MAR 26, 1997	AMINOPHYLLINE ELKINS SINN 25MG/ML AP + PHARMA SERVE NY 25MG/ML @ 25MG/ML
CLINIMIX E 5/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 5%; 3.3MG/100ML; 10GM/100ML; 51MG/100ML; 26.1MG/100ML; 340MG/100ML; 5.9MG/100ML N20678 016 MAR 26, 1997	AMINOPHYLLINE ELKINS SINN 25MG/ML AP + PHARMA SERVE NY 25MG/ML @ 25MG/ML
CLINIMIX E 5/15 SULFITE-FREE W/ ELECT IN DEXTROSE 15% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 5%; 3.3MG/100ML; 15GM/100ML; 51MG/100ML; 26.1MG/100ML; 340MG/100ML; 5.9MG/100ML N20678 017 MAR 26, 1997	TABLET; ORAL AMINOPHYLLINE HALSEY 100MG BD @ 100MG
CLINIMIX E 5/20 SULFITE-FREE W/ ELECT IN 20% DEXTROSE W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 5%; 3.3MG/100ML; 20GM/100ML; 51MG/100ML; 26.1MG/100ML; 340MG/100ML; 5.9MG/100ML N20678 018 MAR 26, 1997	TABLET; EXTENDED RELEASE; ORAL PHILCOONTIN 225MG * PURDUE FREDBRICK 225MG @ 225MG
CLINIMIX E 5/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/ CALCIUM IN PLASTIC CONTAINER + BAXTER HLTHCARE 5%; 3.3MG/100ML; 25GM/100ML; 51MG/100ML; 26.1MG/100ML; 340MG/100ML; 5.9MG/100ML N20678 019 MAR 26, 1997	AMITRIPTYLINE HYDROCHLORIDE TABLET; ORAL AMITRIPTYLINE HCL BP HALSEY 10MG BP 5.0MG BP 7.5MG @ 100MG
	N85923 001 N85925 001 N85926 001 MAY 20, 1993 N85927 001 MAY 20, 1993



ASPIRIN; BUTALBITAL

<u>ASPIRIN; BUTALBITAL</u>		<u>ATRACURIUM BESYLATE</u>	
TABLET; ORAL ASOCAL ④ SAVAGE LABS	650MG; 50MG	N88305 001 OCT 13, 1983	AP INJECTABLE; INJECTION <u>ATRACURIUM BESYLATE PRESERVATIVE FREE</u> ABBOTT 1.0MG/ML
		> ADD > ④ ADD >	AP BEDFORD 1.0MG/ML
			AP FAULDING 1.0MG/ML
			AP OHMEDA 1.0MG/ML
TABLET; ORAL CODEODIN HULSEY ④	3.25MG; 4.5MG; 0.3MG	N87464 001 JUL 01, 1982 N87464 001 JUL 01, 1982	AP * TRACRIUM GLAXO WELLCOME 1.0MG/ML
	3.25MG; 4.5MG; 0.3MG		AP + TRACRIUM PRESERVATIVE FREE GLAXO WELLCOME 1.0MG/ML
			AP + GLAXO WELLCOME 1.0MG/ML
ATENOLOL			N18831 001 NOV 23, 1983
			N18831 001 NOV 23, 1983
<u>ATENOLOL</u>		<u>ATROPOINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE</u>	
TABLET; ORAL ATENOLOL ④		N74499 001 JUL 30, 1997 N74101 001	TABLET; ORAL <u>DIPHENOXYLATE HCL AND ATROPOINE SULFATE</u> ROXANE 0.025MG; 2.5MG ④ DIPHENOXYLATE HCL W/ ATROPOINE SULFATE ICON 0.025MG; 2.5MG
		> ADD > ④ ADD >	N86057 001 N86057 001
		> ADD > ④ ADD >	NB195 001 P&G 0.025MG
		> ADD > ④ ADD >	P&G 0.025MG
		> ADD > ④ ADD >	N887195 001 FEB 16, 1982
			N885649 001 N885659 001
<u>ATRACURIUM BESYLATE</u>		<u>AZITHROMYCIN DIHYDRATE</u>	
		N74633 001 AP	IBC 23, 1996 N74901 001
		1.0MG/ML AP	JUL 18, 1997 N74740 001
		1.0MG/ML AP	MAR 28, 1997 N74784 001
		1.0MG/ML AP	JUN 11, 1997 N74753 001
		1.0MG/ML AP	JAN 23, 1997 N74633 001
		1.0MG/ML AP	DEC 23, 1996
<u>ATRACURIUM BESYLATE PRESERVATIVE FREE</u>		<u>INJECTABLE; INJECTION ZITHROMAX</u>	
			EQ 500MG BASE/VIAL + PFIZER
			N50733 001 JAN 30, 1997



## **BBLEOMYCIN SULFATE**

**INJECTABLE; INJECTION  
BLEOMYCIN SULFATE  
PHARMACIA AND UPJO**

EQ 30 UNITS BASE/VIAL JUN 01, 1996 N64084 002 JUN 01, 1996

### BRETYLIUM TOSYLATE

**INJECTABLE; INJECTION  
BRETYLUM TOSYLA TE I  
\* BAXTER HOSPITAL**

4.900MG/ 4.900ML	400MG/ 100ML	200MG/ 100ML	400MG/ 100ML
④	④	④	④

**SOLUTION/DROPS; OPH  
ALPHAGAN  
†  
ALKERGAN**

<u>BROMfenac sodium</u>	
- ADD >	CAPSULE; ORAL
- ADD >	DURACT
- ADD >	+ WYETH AYERST
- ADD >	EQ 25MG BASE

BUNDESSTADT

AEROSOL, METERED; NASAL  
RHINOCORT<sup>®</sup>  
ASTRA<sup>®</sup>

## BUDESONIDE

POWDER, METERED; INHALATION  
PULMICORT  
+ ASTRA 0.1

JUN 24, 1997  
N20441 003  
JUN 24, 1997

## BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL WELLBUTRIN	100MG	100MG	100MG
+ GLAXO WELLCOME			
+	150MG	150MG	150MG
 ZYBAN			
GLAXO WELLCOME			
+			
+			

N19881 001  
FEB 07, 1997

N74620 001  
JAN 22, 1997  
N74626 001  
JAN 23, 1997  
N74620 002  
JAN 22, 1997  
N74622 002  
JAN 23, 1997

INJECTABLE; INJECTION  
BUTORPHANOL TARTRATE PRESERVATIVE FREE

JAN 22, 1997  
**N74626** 001  
JAN 23, 1997  
**N74620** 002  
JAN 22, 1997  
**N74626** 002  
JAN 23, 1997

BUTORPHANOL TARTRATE

## INJECTABLE; INJECTION

STADOL  
AP + APOTHECON 2MG/ML  
STADOL PRESERVATIVE FREE  
AP + APOTHECON 1MG/ML  
2MG/ML  
AP +

CALCIPOTRIENE

SOLUTION; TOPICAL  
DOVONEX  
+ BRISTOL MYERS SQUIBB 0.005%

N20611 001  
MAR 03, 1997  
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE;  
SODIUM LACTATE

INJECTABLE; INJECTION  
DEXTROSE 4% IN MODIFIED LACTATED RINGER'S IN PLASTIC  
CONTAINER  
MCGAW

4MG/100ML; 4GM/100ML; 6MG/100ML;  
120MG/100ML; 62MG/100ML N19634 002

120MG/100ML; 62MG/100ML FEB 24, 1988

4MG/100ML; 4GM/100ML; 6MG/100ML;  
120MG/100ML; 62MG/100ML N19634 002

120MG/100ML; 62MG/100ML FEB 24, 1988

4MG/100ML; 4GM/100ML; 5CH/100ML;  
600MG/100ML; 310MG/100ML N17510 001

20MG/100ML; 5GM/100ML; 30MG/100ML;  
600MG/100ML; 310MG/100ML N17510 001

CAPTOPRIL

## TABLET; ORAL

<u>CAPOTEN</u> AB + BRISTOL MYERS SQUIBB	2.5MG 2.5MG	N18343 002 N18343 002
<u>CAPTOPRIL</u> AB EGIS PHARMS	12.5MG	N74748 004 N74748 004
<u>CAPTOPRIL</u> AB	2.5MG	N74748 002 N74748 002
<u>CAPTOPRIL</u> AB	5.0MG	N74748 001 N74748 001
<u>CAPTOPRIL</u> AB	10.0MG	MAY 29, 1997 N74748 003
<u>CAPTOPRIL</u> AB	12.5MG	MAY 29, 1997 N74640 001
<u>CAPTOPRIL</u> AB	25MG	MAR 31, 1997 N74640 002
<u>CAPTOPRIL</u> AB	5.0MG	MAR 31, 1997 N74640 003
<u>CAPTOPRIL</u> AB	10.0MG	MAR 31, 1997 N74640 004
<u>CAPTOPRIL</u> AB	12.5MG	MAR 31, 1997 N74677 004
<u>CAPTOPRIL</u> AB	25MG	MAY 30, 1997 N74677 002
<u>CAPTOPRIL</u> AB	5.0MG	MAY 30, 1997 N74677 001
<u>CAPTOPRIL</u> AB	10.0MG	MAY 30, 1997 N74677 003
<u>CAPTOPRIL</u> AB	12.5MG	MAY 30, 1997 N74677 001
<u>CAPTOPRIL</u> AB	25MG	MAY 30, 1997 N74677 002
<u>CAPTOPRIL</u> AB	5.0MG	MAY 30, 1997 N74677 001
<u>CAPTOPRIL</u> AB	10.0MG	MAY 30, 1997 N74677 003
<u>CAPTOPRIL</u> AB	12.5MG	MAY 30, 1997 N74532 001
<u>CAPTOPRIL</u> AB	25MG	MAR 28, 1997 N74532 002
<u>CAPTOPRIL</u> AB	5.0MG	MAR 28, 1997 N74532 003
<u>CAPTOPRIL</u> AB	10.0MG	MAR 28, 1997 N74532 004

CARBAMAZEPINE

<u>CARBAMAZEPINE</u> AB	20.0MG	N70541 001 SEP 17, 1986
<u>CARBAMAZEPINE</u> AB	20.0MG	N70541 001 SEP 17, 1986
<u>CARBAMAZEPINE</u> AB	20.0MG	N70541 001 SEP 17, 1986

CARBAMAZEPINE

TABLET, CHEWABLE; ORAL  
EPITOL

AB LEMMON  
AB TEVA

CARBIDOPA; LEVODOPA

TABLET; ORAL  
CARBIDOPA AND LEVODOPA

AB LEMMON  
AB TEVA

TABLET; ORAL  
CARISOPRODOL

AA AMIDE PHARM

CARVEDILOL

TABLET; ORAL  
CARISOPRODOL

AA AMIDE PHARM

CEFAZOLIN SODIUM

INJECTABLE; INJECTION  
CEFAZOLIN SODIUM

<u>AB</u>	LEMMON	<u>EQ</u> 500MG BASE/VIAL	N63016 002
<u>AB</u>	JUL 29, 1992	<u>EQ</u> 1GM BASE/VIAL	MAR 14, 1989
<u>AB</u>	N73524 001	<u>EQ</u> 5GM BASE/VIAL	N63016 003
<u>AB</u>	JUL 29, 1992	<u>EQ</u> 5GM BASE/VIAL	MAR 14, 1989
<u>AB</u>		<u>EQ</u> 10GM BASE/VIAL	N63018 001
<u>AB</u>		<u>EQ</u> 250MG BASE/VIAL	MAR 05, 1990
<u>AB</u>		<u>EQ</u> 500MG BASE/VIAL	N63016 002
<u>AB</u>		<u>EQ</u> 250MG BASE/VIAL	MAR 05, 1990
<u>AB</u>		<u>EQ</u> 500MG BASE/VIAL	N63016 001
<u>AB</u>		<u>EQ</u> 10GM BASE/VIAL	MAR 14, 1989
<u>AB</u>		<u>EQ</u> 250MG BASE/VIAL	N63016 002
<u>AB</u>		<u>EQ</u> 500MG BASE/VIAL	MAR 14, 1989
<u>AB</u>		<u>EQ</u> 1GM BASE/VIAL	N63016 003
<u>AB</u>		<u>EQ</u> 5GM BASE/VIAL	MAR 14, 1989
<u>AB</u>		<u>EQ</u> 10GM BASE/VIAL	N63018 001
<u>AB</u>		<u>EQ</u> 250MG BASE/VIAL	MAR 05, 1990
<u>AB</u>		<u>EQ</u> 500MG BASE/VIAL	N63018 002
<u>AB</u>		<u>EQ</u> 10GM BASE/VIAL	MAR 05, 1990

TABLET, CHEWABLE; ORAL  
CEFAZOLIN SODIUM

AB HANFORD GC  
N40188 001  
MAR 07, 1997

CEFUROXIME AXETIL

POWDER FOR RECONSTITUTION; ORAL

<u>AB</u>	GLAXO WELLCO	<u>EQ</u> 125MG BASE/5ML	N50672 001
		<u>EQ</u> 125MG BASE/5ML	JUN 30, 1994
		<u>EQ</u> 125MG BASE/5ML	N50672 001
		<u>EQ</u> 250MG BASE/5ML	JUN 30, 1994
		<u>EQ</u> 250MG BASE/5ML	N50672 002
			APR 29, 1997

CEFUROXIME SODIUM

<u>AB</u>	CEFTIN	<u>EQ</u> 125MG BASE/5ML	N64125 001
	*	<u>EQ</u> 125MG BASE/5ML	JUN 30, 1994
		<u>EQ</u> 1.5GM BASE/VIAL	N64125 002
		<u>EQ</u> 7.5GM BASE/VIAL	MAY 30, 1997
		<u>EQ</u> 750MG BASE/VIAL	N64124 001
		<u>EQ</u> 750MG BASE/VIAL	MAY 30, 1997
		<u>EQ</u> 750MG BASE/VIAL	JAN 10, 1986



<u>CHLORHEXIDINE GLUCONATE</u>			
SOLUTION; DENTAL			
<u>CHLORHEXIDINE GLUCONATE</u>			
LEMMON	AT	AT	TEVA

CHLORPHALIDONE TABLET; ORAL  
THALITONE \* HORUS THAL MONARCH I  
BX

DEC 15, 1995	N#4522 001
DEC 15, 1995	N#4522 001
DEC 15, 1995	

CHLOROPROCAINE HYDROCHLORIDE		2%		3%	
INJECTABLE; INJECTION		2%		3%	
NESACALINE-MPF		2%		3%	
NASTRA	*				
AP	+				
AP	+				
AP	+				
AP	+				

CHLORPHENIRAMINE MALEATE  
TABLET; ORAL  
CHLORPHENIRAMINE MALEATE  
K.Y. PHARM.  
© KLOOMIN  
HALSBY  
AA AA

<u>CHLORTHALIDONE</u>	TABLET; ORAL <u>CHLORTHALIDONE</u> ® LEMMON	PUREPAC PHARM AB	> DLT > > DLT > > ADD > > ADD >	® @ TEVA
				THALITONE EX HORUS THERAP

<u>CHLORTHALIDONE</u>	TABLET; ORAL THALITONE † HORUS THI	<u>CHLORZOXAZONE</u>	TABLET; ORAL CHLORZOXAZONE LEMMON
N74522 001 DEC 15, 1995	BX	MONARCH F + ④	TEVA AA
N74522 001 DEC 15, 1995			
N09435 003 NO9435 006 MAY 02, 1996		N09435 003 NO9435 004 NO9435 007 MAY 02, 1996	N09435 003 NO9435 004 NO9435 005 MAY 02, 1996

<u>CHOLESTYRAMINE</u>	<u>POWDER; ORAL CHOLESTYRAMINE</u>	<u>BAKER NOR</u>	<u>CYCLOPIROX</u>	<u>GEL; TOPICAL LODROX</u>	<u>+ HOECHST M</u>
N87164 001	> <u>ADD</u> >	<u>AB</u>	> <u>ADD</u> >	> <u>ADD</u> >	> <u>ADD</u> >
N87164 001	> <u>ADD</u> >	<u>AB</u>	> <u>ADD</u> >	> <u>ADD</u> >	> <u>ADD</u> >
N83629 001	> <u>ADD</u> >		> <u>ADD</u> >	> <u>ADD</u> >	> <u>ADD</u> >
N83629 001	> <u>ADD</u> >		> <u>ADD</u> >	> <u>ADD</u> >	> <u>ADD</u> >
N88651 001					

N88140 001  
AUG 11, 1983  
N88140 001  
AUG 11, 1983  
TABLET; ORAL  
CIMETIDINE  
KIRKMAN  
200MG  
AB  
MAY 30, 1985  
N88051 001  
NOV 12, 1982  
N88051 001  
NOV 12, 1982  
CIMETIDINE  
N74365 001  
PEB 28, 1995

CIMETIDINE

<u>TABLET; ORAL</u>	
<u>CIMETIDINE</u>	
<u>LEMMON</u>	
<u>AB</u>	<u>300MG</u>
<u>AB</u>	<u>400MG</u>
<u>AB</u>	<u>800MG</u>
<u>AB</u>	<u>SIDMAK LABS NJ</u>
<u>AB</u>	<u>200MG</u>
<u>AB</u>	<u>300MG</u>
<u>AB</u>	<u>400MG</u>
<u>AB</u>	<u>800MG</u>
<u>AB</u>	<u>200MG</u>
<u>AB</u>	<u>300MG</u>
<u>AB</u>	<u>400MG</u>
<u>AB</u>	<u>800MG</u>
<u>TEVA</u>	

CLEMASTINE FUMARATE

<u>SYRUP; ORAL</u>	
<u>CLEMASTINE FUMARATE</u>	
<u>TEVA</u>	
<u>AB</u>	<u>EQ 0.5MG BASE/5ML</u>
<u>TABLET; ORAL</u>	
<u>CLEMASTINE FUMARATE</u>	
<u>LEMMON</u>	
<u>AB</u>	<u>2.68MG</u>
<u>AB</u>	<u>1.34MG</u>
<u>AB</u>	<u>2.68MG</u>
<u>AB</u>	<u>1.34MG</u>

CIMETIDINE HYDROCHLORIDE

<u>INJECTABLE; INJECTION</u>	
<u>CIMETIDINE HCL</u>	
<u>SANOFI</u>	
<u>AP</u>	<u>EQ 300MG BASE/2ML</u>
<u>AP</u>	<u>EQ 300MG BASE/2ML</u>
<u>SOLUTION; ORAL</u>	
<u>CIMETIDINE HCL</u>	
<u>PHARM ASSOC</u>	
<u>AB</u>	<u>EQ 300MG BASE/5ML</u>

SOLUTION; TOPICAL

<u>CLINDAMYCIN PHOSPHATE</u>	
<u>FOUGERA</u>	
<u>AT</u>	<u>EQ 1% BASE</u>
<u>AT</u>	<u>LEMMON</u>
<u>AT</u>	<u>EQ 1% BASE</u>
<u>AT</u>	<u>MORTON GROVE</u>
<u>AT</u>	<u>EQ 1% BASE</u>
<u>AT</u>	<u>TEVA</u>

<u>SYRUP; ORAL</u>	
<u>CLEMASTINE FUMARATE</u>	
<u>LEMMON</u>	
<u>AB</u>	<u>EQ 0.5MG BASE/5ML</u>

<u>SYRUP; ORAL</u>	
<u>CLEMASTINE FUMARATE</u>	
<u>LEMMON</u>	
<u>AB</u>	<u>EQ 0.5MG BASE/5ML</u>

<u>CREAM; TOPICAL</u>	
<u>CORMAX</u>	
<u>HEALTHPOINT</u>	
<u>AB</u>	<u>0.05%</u>

## CLOMIPRAMINE HYDROCHLORIDE

## CODEINE PHOSPHATE: PROMETHAZINE HYDROCHLORIDE

<u>CLONAZEPAM</u>	CAPSULE; INHALATION INTAL	N16990 001 N16990 001
TABLET; ORAL + KLONOPIK + ROCHE	* FISONS + RHONE POULENC RORER	2.0MG 2.0MG
	SOLUTION; INHALATION INTAL	2.0MG/ML
	* FISONS	1.0MG/ML
	SOLUTION/DROPS; OPHTHALMIC OPTICROM	4 %
	@ FISONS	
	@ RHONE POULENC RORER	4 %
	SPRAY, METERED, NASAL NASALCROM	
	* FISONS	5.4MG/SPRAY
<u>CLORAZEPATE DIPOTASSIUM</u>		
CAPSULE; ORAL CLORAZEPATE DIPOTASSIUM PUREPAC PHARM	7.5MG	
AB	1.5MG	
AB	7.5MG	
AB	1.5MG	

## CODEINE PHOSPHATE: PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL  
FEVERAZINE w/ CODEINE  
HALSEY  
10MG/5ML; 6.25MG/5ML

CYANOCORAIAMTN

**INJECTABLE; INJECTION  
COBALТИUM  
STREPTIS**

NB3013 001  
NB3064 001  
NB3013 001

CYANOCOBALAMIN

INJECTABLE; INJECTION  
COBAVITE  
 @ STERIS

CYANOCOBALAMIN  
 STERIS  
 ®

AP

N83064 001  
 1MG/ML

N83120 001  
 N83120 001  
 0.1MG/ML  
 0.1MG/ML

N88373 001  
 JUL 03, 1986  
 N88374 001  
 SEP 24, 1986

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58

N/A; N/A  
 DICOPAC KIT  
 BERSHAM  
 MEDI PHYSICS

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

N83064 001  
 1MG/ML

N17406 001  
 N17406 001  
 1GM/ML

N88373 001  
 JUL 03, 1986  
 N88374 001  
 SEP 24, 1986

CYCLOPENTOLATE HYDROCHLORIDE

AK-PENTOLATE  
 AKORN

N40164 001  
 JAN 13, 1997  
 N40165 001  
 JAN 13, 1997

N88371 001  
 JUL 03, 1986  
 N88372 001  
 JUL 03, 1986

CYCLOGYL  
 AT + ALCON

1%  
 2%  
 2%

N88371 001  
 JUL 03, 1986  
 N88372 001  
 JUL 03, 1986

CYCLOPHOSPHAMIDE

ASTA

ELKINS SINN

100MG/VIAL  
 200MG/VIAL  
 500MG/VIAL  
 1GM/VIAL

N88371 001  
 JUL 03, 1986  
 N88372 001  
 JUL 03, 1986  
 N88373 001  
 JUL 03, 1986  
 N88374 001  
 SEP 24, 1986

DAUNORUBICIN HYDROCHLORIDE

ASTA

ELKINS SINN

100MG/VIAL  
 200MG/VIAL  
 500MG/VIAL  
 1GM/VIAL

N88371 001  
 JUL 03, 1986  
 N88372 001  
 JUL 03, 1986  
 N88373 001  
 JUL 03, 1986  
 N88374 001  
 SEP 24, 1986

CYANOPHOSPHAMIDE

ASTA

ELKINS SINN

AP

100MG/VIAL  
 200MG/VIAL  
 500MG/VIAL  
 1GM/VIAL

N88371 001  
 JUL 03, 1986  
 N88372 001  
 JUL 03, 1986  
 N88373 001  
 JUL 03, 1986  
 N88374 001  
 SEP 24, 1986

### CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION  
CYCLOPHOSPHAMIDE  
ELKINS SINN

N88373 001  
 JUL 03, 1986  
 N88374 001  
 SEP 24, 1986

N12142 001  
 AUG 30, 1982  
 N12142 002  
 AUG 30, 1982  
 N12142 003  
 AUG 30, 1982

N12142 004  
 AUG 30, 1982  
 N12142 005  
 AUG 30, 1982  
 N12142 006  
 AUG 30, 1982  
 N12142 007  
 AUG 30, 1982  
 N12142 008  
 AUG 30, 1982

N12142 009  
 AUG 30, 1982

N12142 010  
 AUG 30, 1982

N12142 011  
 AUG 30, 1982  
 N12142 012  
 AUG 30, 1982  
 N12142 013  
 AUG 30, 1982  
 N12142 014  
 AUG 30, 1982

N12142 015  
 AUG 30, 1982

N12142 016  
 AUG 30, 1982

N12142 017  
 AUG 30, 1982

N12142 018  
 AUG 30, 1982

N12142 019  
 AUG 30, 1982  
 N12142 020  
 AUG 30, 1982

N12142 021  
 AUG 30, 1982  
 N12142 022  
 AUG 30, 1982

N12142 023  
 AUG 30, 1982

N12142 024  
 AUG 30, 1982

N12142 025  
 AUG 30, 1982

N12142 026  
 AUG 30, 1982

N12142 027  
 AUG 30, 1982

N12142 028  
 AUG 30, 1982

N12142 029  
 AUG 30, 1982

N12142 030  
 AUG 30, 1982

N12142 031  
 AUG 30, 1982

N12142 032  
 AUG 30, 1982

N12142 033  
 AUG 30, 1982

N12142 034  
 AUG 30, 1982

N12142 035  
 AUG 30, 1982

N12142 036  
 AUG 30, 1982

N12142 037  
 AUG 30, 1982

N12142 038  
 AUG 30, 1982

N12142 039  
 AUG 30, 1982

N12142 040  
 AUG 30, 1982

N12142 041  
 AUG 30, 1982

N12142 042  
 AUG 30, 1982

N12142 043  
 AUG 30, 1982

N12142 044  
 AUG 30, 1982

N12142 045  
 AUG 30, 1982

N12142 046  
 AUG 30, 1982

N12142 047  
 AUG 30, 1982

N12142 048  
 AUG 30, 1982

N12142 049  
 AUG 30, 1982

N12142 050  
 AUG 30, 1982

N12142 051  
 AUG 30, 1982

N12142 052  
 AUG 30, 1982

N12142 053  
 AUG 30, 1982

N12142 054  
 AUG 30, 1982

N12142 055  
 AUG 30, 1982

N12142 056  
 AUG 30, 1982

N12142 057  
 AUG 30, 1982

N12142 058  
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DELAVIDINE MESYLATE

TABLET; ORAL RESCRIPTOR + PHARMACIA AND UPJOHN 100MG	N20705 001 APR 04, 1997	> ADD > > ADD > > ADD > > ADD >	AT BAUSCH AND LOMB 0.1% EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N64063 001 JUL 25, 1994
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DESERPIDINE

TABLET; ORAL HARMONYL * ABBOTT @	N10796 002 N10796 002	CREAM, TOPICAL DECADRON * MERCK SHARP DOHME @	EQ 0.1% PHOSPHATE EQ 0.1% PHOSPHATE	N11983 002 N11983 002
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DESPRAMELINE HYDROCHLORIDE

TABLET; ORAL <u>DESPRAMELINE HCL</u> AB SIDMAK LABS NJ	N71803 001 MAY 29, 1997	AP	<u>DEXAMETHASONE SODIUM PHOSPHATE</u> STERILES @	N84355 001 N84355 001
AB	N71804 001 MAY 29, 1997	AP	<u>DEXTORESE; POTASSIUM CHLORIDE</u>	

INJECTABLE; INJECTION POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 001 SEP 29, 1989
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 001 SEP 29, 1989

INJECTABLE; INJECTION POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 002 SEP 29, 1989
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 002 SEP 29, 1989

INJECTABLE; INJECTION POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 002 SEP 29, 1989
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 002 SEP 29, 1989

INJECTABLE; INJECTION POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 003 SEP 29, 1989
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 003 SEP 29, 1989

INJECTABLE; INJECTION POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 005 SEP 29, 1989
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 005 SEP 29, 1989

INJECTABLE; INJECTION POTASSIUM CHLORIDE 0.037% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 005 SEP 29, 1989
POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC CONTAINER MCGRAN	5GM/100ML; 37MG/100ML	N19699 005 SEP 29, 1989

DEXTOSE; SODIUM CHLORIDE

## DIAZEPAM

		INJECTABLE; INJECTION
> DLT >	AP	DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER MCCAW
> ADD >	④	10GM/100ML; 900MG/100ML 10GM/100ML; 900MG/100ML N18047 001 N18047 001
		DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER MCCAW
	④	5GM/100ML; 500MG/100ML 5GM/100ML; 500MG/100ML N18026 001 N18026 001

TABLET; ORAL

<u>DIAZEPAM</u>	<u>AB</u>	N70996 001
	<u>AB</u>	AUG 15, 1986
	<u>5MG</u>	N70956 001
	<u>10MG</u>	AUG 15, 1986
	<u>2MG</u>	N70987 001
	<u>5MG</u>	AUG 15, 1986
	<u>10MG</u>	N70996 001
	<u>@</u>	AUG 15, 1986
	<u>@</u>	N70956 001
	<u>@</u>	AUG 15, 1986

## **DEXTBOTHYROIDINE SODIUM**

DIAZEPAM

## INJECTABLE; INJECTION

TABLET; ORAL  
**DIAZEPAM**  
HAWAIIAN SKY

DIFLUNISAL

<u>ADD</u>	<u>&gt;</u>	<u>AB</u>	<u>DANBURY PHARMA</u>
<u>ADD</u>	<u>&gt;</u>	<u>AB</u>	<u>DANBURY PHARMA</u>
<u>ADD</u>	<u>&gt;</u>	<u>AB</u>	<u>DANBURY PHARMA</u>
<u>ADD</u>	<u>&gt;</u>	<u>AB</u>	<u>DANBURY PHARMA</u>

## **DIRITHROMYCIN**

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL	<u>DILTIAZEM HCL</u>	N74910 001 MYLAN	60MG	EQ 1MG BASE	N19668 001 NOV 02, 1990
			90MG	EQ 8MG BASE	N19668 004 NOV 02, 1990
			120MG	EQ 1IMG BASE	N19668 001 NOV 02, 1990
				+	N19668 004 NOV 02, 1990
				*	N19668 001 NOV 02, 1990

DIMENHYDRINATE

INJECTABLE; INJECTION		DOXYCYCLINE HYCLYATE	
DIMENTHYDRINATE		CAPSULE, COATED PELLETS; ORAL	
EXKINS SINK	SONG /ML 50MG /ML	DORYX	EQ 100MG BASE
④		PARKER DAVIS	EQ 100MG BASE
		AB	WARNER CHILCOTT
		> DLT >	
		> DLT >	
		> ADD >	
		> ADD >	

**INJECTABLE; INJECTION  
DIPHENHYDRAMINE HCL**

N83533 001 10MG/ML	<u>DIPYRIDAMOLE</u>	TABLET: ORAL <u>DIPYRIDAMOLE</u> CHELSEA LABS	50MG	N87160 001 JUN 07, 1996
N18751 001 DEC 23, 1982	<u>CREAM: TOPICAL</u> + J AND J	SPECTAZOLE 1%	*	JOHNSON, RW 1%
N18751 001 DEC 23, 1982				

SOLUTION; TOPICAL  
ERYTHROMYCIN  
STIEFEL

N64127 001  
FEB 14, 1997

<u>ESTAZOLAM</u>		<u>ETODOLAC</u>		<u>CAPSULE; ORAL</u>		<u>LODINE</u>		<u>INJECTABLE; INJECTION</u>	
> ADD >	AB	TABLET; ORAL <u>ESTAZOLAM</u> TEVA	1MG	N74921 001	JUL 10, 1997	AB	WYETH AYERST	2.00MG	N18922 002
> ADD >	AB		2MG	N74921 002	JUL 10, 1997	AB	+	3.00MG	JAN 31, 1991
> ADD >	AB	ZENITH GOLDLINE	1MG	N74926 001	JUL 03, 1997	TABLET; ORAL <u>ETODOLAC</u>		4.00MG	N18922 003
> ADD >	AB		2MG	N74926 002	JUL 03, 1997	AB	ENDO LABS		JAN 31, 1991
> ADD >	AB	PROSOM	1MG	N19080 001	DEC 26, 1990	AB	EON	4.00MG	N74903 001
> ADD >	AB	ABBOTT	2MG	N19080 002	DEC 26, 1990	> ADD >	GENEVA PHARMS	4.00MG	APR 11, 1997
> ADD >	AB	+		N20683 001	MAR 27, 1997	> ADD >	INVAMED	4.00MG	N74839 001
> ADD >	AB			N20683 002	MAR 27, 1997	AB	PUREPAC PHARM	4.00MG	JUL 11, 1997
<u>ETHINYL ESTRADIOL; LEVONORGESTREL</u>				N20683 003	MAR 27, 1997	AB	ROYCE LABS	4.00MG	N74892 001
TABLET; ORAL-21 ALESSIE			0.02MG; 0.1MG	N20683 004	MAR 27, 1997	AB	ZENITH GOLDLINE	4.00MG	APR 16, 1997
+ WYETH AYERST				N20683 005	MAR 27, 1997	AB	LODINE	4.00MG	FEB 28, 1997
TABLET; ORAL-28 ALESSIE			0.02MG; 0.1MG	N20683 006	MAR 27, 1997	AB	WYETH AYERST	4.00MG	N74819 001
WYETH AYERST				N20683 007	MAR 27, 1997	<u>ETOPOSIDE</u>			FEB 28, 1997
				N20683 008	MAR 27, 1997	AB			N74892 004
				N20683 009	MAR 27, 1997	AB			JUL 29, 1993
<u>ETODOLAC</u>		<u>ETOPOSIDE</u>		<u>LODINE</u>		<u>TOPOBUK</u>		<u>2.00MG/ML</u>	
> ADD >	AB	CAPSULE; ORAL <u>ETODOLAC</u> ENDO LABS	200MG	N74842 001	JUL 17, 1997	> ADD >	PIERRE FABRE	2.00MG/ML	N74513 001
> ADD >	AB		300MG	N74842 002	JUL 17, 1997	> ADD >	SUPERGEN	2.00MG/ML	N74813 001
> ADD >	AB	MYLAN	200MG	N74932 001	JUL 17, 1997	AB			JUL 09, 1997
> ADD >	AB		300MG	N74932 002	MAY 16, 1997	MAY 16, 1997			N74513 001
> ADD >	AB	ZENITH GOLDLINE	200MG	N74899 001	JUL 08, 1997	AB	FLECAINIDE ACETATE		MAR 14, 1996
> ADD >	AB		300MG	N74899 002	JUL 08, 1997	AB	TABLET; ORAL TAMBOCOR	\$0.00G	N18830 004
> ADD >	AB			N74899 003	JUL 08, 1997	AB	@@ 3.00		ADD 23, 1988
> ADD >	AB			N74899 004	JUL 08, 1997	AB			

## FLECAINIDE ACETATE

**TABLET; ORAL  
TAMBOCOR**

N88360 001  
JAN 16, 1984  
~~N88360 001~~  
JAN 16, 1984  
0.025%  
@ ALPHARMA  
NDC AT  
ADD ADD DLT DLT  
ADD ADD DLT DLT

FLUOCINOLONE ACETONIDE 0.01%  
 @ ALPHARMA  
 ADD > ADD > DLT > DLT >  
 NDC: 0001-1111-11  
 JAN 16, 1984  
 N88361 001  
 JAN 16, 1984

OINTMENT; TOPICAL <u>SYNALAR</u>	<u>AT</u> + <u>AT</u> * <u>SYNTEX</u>	0.025% <u>0.025%</u>	N13960 001 N13960 001
SOLUTION; TOPICAL <u>SYNALAR</u>	<u>AT</u> + <u>AT</u> * <u>SYNTEX</u>	0.01% <u>0.01%</u>	N15296 001 N15296 001

ENTROPY

SPRAY, METERED; NASAL	
NASALIDE	
+ DURA	0 .025MG / SPRAY
+ SYNTEX	0 .025MG / SPRAY
NASAREL	
+ DURA	0 .025MG / SPRAY
+ SYNTEX	0 .025MG / SPRAY

## FLUOCINOLONE ACETONIDE

CREAM : TOPTCAT

N88360 001  
JAN 16, 1984  
~~N88360 001~~  
~~JAN 16, 1984~~

FLUOCINOLONE ACETONIDE 0.01%  
 @ ALPHARMA  
 ADD > ADD > DLT > DLT >  
 NDC: 0001-1111-11  
 JAN 16, 1984  
 N88361 001  
 JAN 16, 1984  
 N88361 001  
 JAN 16, 1984  
 SYNALAR

AT	+	MEDICIS	0.01%	N112787	004	N116161	002
AT	+		0.025%	N112787	002	N116161	002
AT	+		0.025%	N112787	005		
AT	+		0.01%	N112787	004		
AT	+		0.025%	N112787	002		
AT	+		0.025%	N112787	005		
		SYNTEX					
		SYNALAR - HP					
		MEDICIS	0.2%				
		SYNTEX	0.2%				

OINTMENT; TOPICAL <u>SYNALAR</u>	<u>AT</u> + <u>AT</u> <u>AT</u>	0.025% <u>0.025%</u>	N13960 001 N13960 001
SOLUTION; TOPICAL <u>SYNALAR</u>	<u>AT</u> + <u>AT</u> <u>AT</u>	0.01% <u>0.01%</u>	N15296 001 N15296 001

#### CREAM: TOPICAL

<u>NEO-SYNALAR</u>	0.025% ; EQ	3.5MG BASE/GM	N60700 001	N16908 002
+ MEDICIS	0.025% ; EQ	3.5MG BASE/GM	N60700 001	N16908 002
<u>SYNTEX</u>				
<u>FLUCCINONIDE</u>				
CREAM; TOPICAL				
<u>LIDEX</u>				
AB + MEDICIS			0.05%	
<u>AB *</u>			0.05%	
<u>SYNTEX</u>				

FLUOCINONIDE

CREAM; TOPICAL  
LIDEX  
AB + MEDICIS  
AB \* SYNTAX  
0.05%  
N16908 002  
N16908 002



TEPIDE

GUANFACINE HYDROCHLORIDE

TABLET; ORAL <u>GLIPIZIDE</u>		N74619 001 APR 04, 1997 N74619 002 APR 04, 1997	<u>5MG</u> <u>SIDMAK LABS NJ</u>	<u>AB</u> <u>AMIDE PHARM</u>	<u>EQ 1MG BASE</u>	N74673 001 FEB 28, 1997 N74673 002 FEB 28, 1997
<u>TABLET; ORAL <u>ELUTETHIMIDE</u></u>		<u>10MG</u>		<u>AB</u>	<u>EQ 2MG BASE</u>	<u>N74796 001</u>
		<u>MYLAN</u>		<u>AB</u>	<u>EQ 1MG BASE</u>	<u>JAN 27, 1997</u>
		<u>AB</u>		<u>AB</u>	<u>EQ 2MG BASE</u>	<u>N74796 002</u>
		<u>ROYCE LABS</u>		<u>AB</u>	<u>EQ 1MG BASE</u>	<u>JAN 27, 1997</u>
		<u>AB</u>		<u>AB</u>	<u>EQ 2MG BASE</u>	<u>N74762 001</u>
<u>TABLET; ORAL <u>GLUTETHIMIDE</u></u>		<u>500MG</u>		<u>AB</u>	<u>EQ 1MG BASE</u>	<u>JUN 25, 1997</u>
		<u>HASKELL</u>		<u>AB</u>	<u>EQ 2MG BASE</u>	<u>N74762 002</u>
		<u>OCT 10, 1985</u>		<u>AB</u>	<u>EQ 1MG BASE</u>	<u>JUN 25, 1997</u>
		<u>N89459 001</u>		<u>AB</u>	<u>EQ 2MG BASE</u>	<u>OCT 10, 1986</u>
		<u>OCT 10, 1985</u>		<u>AB</u>	<u>EQ 1MG BASE</u>	<u>OCT 10, 1986</u>

MICROCRYSTALLINE BITUMEN

SUSPENSION; ORAL GRIFULVIN V + J AND J	125MG/5ML 125MG/5ML	N50448 001 N62483 001	JAN 26, 1984	HALOG WESTWOOD SOUTHS @ <u>&gt; DLT &gt;</u> <u>&gt; ADD &gt;</u>	N17818 001 N17818 001
* JOHNSON RN	125MG/5ML 125MG/5ML	N50448 001 N62483 001	JAN 26, 1984	HALOPERIDOL DECANATE HALDOL INJECTABLE; INJECTION + JOHNSON RW	N18701 001 JAN 14, 1986 N18701 002 JAN 31, 1997
TABLET; ORAL GRIFULVIN V J AND J	250MG 250MG 500MG 500MG	N60618 002 N62279 002 N60618 003 N62279 003	N60618 002 N62279 002 N60618 001 N62279 001	HALDOL DECANATE 50 * JOHNSON RW HALDOL DECANATE 50 * JOHNSON RW	N18701 002 OCT 31, 1989 N18701 001 JAN 14, 1986
* JOHNSON RN	250MG 500MG 500MG 1.25MG 1.25MG 25.0MG 25.0MG 500MG 500MG 1.25MG 1.25MG	N60618 002 N62279 002 N60618 003 N62279 003 N60618 001 N62279 001 N60618 002 N62279 002 N60618 003 N62279 003 N60618 001 N62279 001	N60618 002 N62279 002 N60618 003 N62279 003 N60618 001 N62279 001 N60618 002 N62279 002 N60618 003 N62279 003 N60618 001 N62279 001	HEPARIN SODIUM INJECTABLE; INJECTION HEP FLUSH KIT IN PLASTIC CONTAINER FUJISAWA AP	N17029 017 N17029 017

INJECTABLE; INJECTION  
HEP FLUSH KIT IN PLASTIC CONTAINER  
10 UNITS/ML  
FUJISAWA  
AP

HEPARIN SODIUM

INJECTABLE; INJECTION  
HEP FLUSH KIT IN PLASTIC CONTAINER

100 UNITS/ML

AP FUJISAWA

④ 10 UNITS/ML

AP 100 UNITS/ML

④

HEPARIN SODIUM

FUJISAWA

SYNTESIS

④

20,000 UNITS/ML

1,000 UNITS/ML

1,000 UNITS/ML

AP

AP

④

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL  
HYDROPAINE

HALSEY

④

1.5MG/5ML; 5MG/5ML

1.5MG/5ML; 5MG/5ML

N88066 001

JUN 28, 1985

N88066 001

JUN 28, 1985

AP

AT

HYDROCHLOROTHIAZIDE, MOEXIPRIL HYDROCHLORIDE

TABLET; ORAL

UNIRETIC

SCHWARZ PHARMA

12.5MG; 7.5MG

DEC 05, 1985

N17029 018

DEC 05, 1985

N17029 017

DEC 05, 1985

N17029 018

DEC 05, 1985



HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION  
HYDROMORPHONE HCL  
SANOFI

10MG/ML

N74598 001  
JUN 19, 1997

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL  
HYDROXYZINE HCL  
KYSEY

25MG

10MG

50MG

100MG

N89117 001  
MAY 02, 1988

N89117 001  
MAY 02, 1988

N87819 001  
JUN 23, 1992

N87820 001  
JUN 23, 1992

N87821 001  
JUN 23, 1992

N87822 001  
JUN 23, 1992

N87819 001  
JUN 23, 1992

N87820 001  
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N87822 001  
JUN 23, 1992

N87821 001  
JUN 23, 1992

N87822 001  
JUN 23, 1992

IBUPROFEN

SUSPENSION; ORAL  
IBU  
@ KNOLL PHARM

100MG/5ML

N19784 001  
DEC 18, 1989

IBUPROFEN

SUSPENSION; ORAL  
IBU  
@ KNOLL PHARM

100MG/5ML

N19784 001  
DEC 18, 1989

IBUPROFEN

TABLET; ORAL  
IBUPROFEN  
PUREPAC PHARM

800MG

800MG

N71964 001  
FEB 01, 1988

IDARUBICIN HYDROCHLORIDE

TABLET; ORAL  
IDARUBICIN HYDROCHLORIDE  
IFEX

800MG

800MG

N50734 001  
FEB 17, 1997

INFECTABLE; INJECTION

IFEX  
\* BRISTOL MYERS SQUIBB  
1GM/VIAL

3GM/VIAL

1GM/VIAL

N19763 001  
DEC 30, 1988

INFECTABLE; INJECTION

IFEX/MESNEX KIT  
+ BRISTOL MYERS SQUIBB 1GM/VIAL; 100MG/ML

3GM/VIAL; 100MG/ML

+

N19763 001  
OCT 10, 1992

N19763 004  
OCT 10, 1992

N19763 001  
OCT 10, 1992

IBUPROFEN

SUSPENSION; ORAL  
IBU  
@ KNOLL PHARM

100MG/5ML

+

N19784 001  
DEC 18, 1989

<u>IMIQUIMOD</u>		<u>LOPAMIDOL</u>	
CREAM; TOPICAL ALDARA + 3M	5%	N20723 001 FEB 27, 1997	AP <u>INJECTABLE; INJECTION</u> <u>LOPAMIDOL-300</u> FUJISAWA 61%
INDAPAMIDE			AP <u>INJECTABLE; INJECTION</u> <u>LOPAMIDOL-300</u> ABBOTT 61%
TABLET; ORAL <u>INDAPAMIDE</u> AB MYLAN	<u>1.25MG</u>	N74461 002 MAR 26, 1997	AP <u>INJECTABLE; INJECTION</u> <u>LOPAMIDOL-370</u> FUJISAWA 76%
AB NOVOPHARM	<u>1.25MG</u>	N74665 001 APR 04, 1997	AP <u>INJECTABLE; INJECTION</u> <u>LOPAMIDOL-370</u> FUJISAWA 76%
AB	<u>2.5MG</u>	N74665 002 APR 04, 1997	AP <u>INJECTABLE; INJECTION</u> <u>LOPAMIDOL-370</u> FUJISAWA 76%
<u>INDIUM IN-111 OXYQUINOLINE</u>		<u>INDIUM IN-111 OXYQUINOLINE</u>	
INJECTABLE; INJECTION AMERSHAM	1mCi/ML	N19044 001 DEC 23, 1985	AN <u>SOLUTION; INHALATION</u> <u>ATROVENT</u> + BOEHRINGER INGELHEIM 0.02%
MEDI PHYSICS	1mCi/ML	N19044 001 DEC 23, 1985	AN <u>SOLUTION; INHALATION</u> <u>IPRATROPIUM BROMIDE</u> DEY 0.02%
<u>INDOCYANINE GREEN</u>		<u>ISONIAZID</u>	
INJECTABLE; INJECTION CARDIO-GREEN + AKORN	25MG/VIAL 50MG/VIAL	N11525 001 N11525 002 N11525 001 N11525 002	AA <u>SYRUP; ORAL</u> <u>ISONIAZID</u> + CAROLINA MEDCL 50MG/5ML
+ BECTON DICKINSON	25MG/VIAL 50MG/VIAL	> ADD > > ADD > > DLT > > DLT >	AA MIKART 50MG/5ML
+ *	50MG/VIAL	> ADD > > ADD >	AA <u>LANIZID</u> LANNETT 50MG/5ML
<u>LOPAMIDOL</u>		<u>LOPAMIDOL</u>	
INJECTABLE; INJECTION <u>LOPAMIDOL-250</u> AP FUJISAWA	<u>51%</u>	N74679 001 APR 02, 1997	AP <u>INJECTABLE; INJECTION</u> <u>LOPAMIDOL-300</u> ABBOTT 61%
AP	<u>51%</u>	N74638 001 APR 30, 1997	AA <u>TABLET; ORAL</u> <u>ISONIAZID</u> MIKART 100MG
<u>N88235 001</u>		<u>N88235 001</u>	
NOV 10, 1983		NOV 10, 1983	
N88235 001		N88235 001	
NOV 10, 1983		NOV 10, 1983	
N88235 001		N88235 001	
JUL 21, 1997		JUL 21, 1997	
N88243 001		N88243 001	
FEB 03, 1986		FEB 03, 1986	
N88243 001		N88243 001	
FEB 03, 1986		FEB 03, 1986	
N40090 001		N40090 001	
JUN 26, 1997		JUN 26, 1997	



LEUCOVORIN CALCIUM

**INJECTABLE; INJECTION  
LEUCOVORIN CALCIUM**

<u>P</u>	GENSTA	<u>EQ 350MG BASE/VIAL</u>
<u>P</u>	IMMUNEX	<u>EQ 350MG BASE/VIAL</u>
<u>P</u>	PHARMACHEMIE	<u>EQ 50MG BASE/VIAL</u>
<u>P</u>		<u>EQ 100MG BASE/VIAL</u>
<u>P</u>		<u>EQ 5MG BASE</u>
<u>B</u>		<u>EQ 25MG BASE</u>
<u>B</u>		<u>EQ 50MG BASE</u>

TABLET; ORAL  
LEUCOVORIN CALCIUM  
PHARMACHEMIE

LEUPROLIDE ACETATE

<u>LITHIUM CARBONATE</u>	
TABLET, EXTENDED RELEASE	
LITHOBID	
SOFTGEL	
+ TAP HOLDINGS	
LUPRON DEPOT-4	
+ TAP HOLDINGS	
LUPRON DEPOT-3	
+ TAP HOLDINGS	
INJECTABLE; INJECTION	

TOPAZEDAM

MAGNESIUM SULFATE

**INJECTABLE; INJECTION  
MAGNESIUM SULFATE**

N40174 001	FUJISAWA	500MG/ML	N19316 001
JUN 12, 1997	+	500MG/ML	SEP 08, 1986
NO8107 005			N19316 001
APR 05, 1989			SEP 08, 1986
N89628 001	MAGNESIUM SULFATE IN DEXTROSE 5% IN PLASTIC CONTAINER ABBOTT	1GM/100ML	
APR 17, 1997	+	1GM/100ML	N20488 001
N89915 001			JUL 11, 1995
APR 17, 1997			N20488 001
N73099 001	MAGNESIUM SULFATE IN PLASTIC CONTAINER ABBOTT	4GM/100ML	JUL 11, 1995
MAR 28, 1997	+ +	80MG/ML	N20309 001
N73101 001			JUN 24, 1994
MAR 28, 1997			N20309 002
		4GM / 100ML	JUN 24, 1994
		80MG / ML	N20309 001
			JUN 24, 1994
			N20309 002

INJECTABLE; INJECTION  
HUMEGON  
\* ORGANON  
75 IU/VIAL; 15 IU/VIAL  
75 IU/VIAL; 15 IU/VIAL  
150 IU/VIAL; 150 IU/VIAL  
 AB \*  
 AB \*  
 AB \*  
 N74648 001  
 MAR 18, 1997  
 0.5MG/5ML  
 N20328 001  
 SEP 01, 1994  
 N20328 001  
 SEP 01, 1994  
 N20328 002  
 SEP 01, 1994

MENOTROPINS (FSH; LH)

<u>HUMEGON</u>	<u>ORGANON</u>	<u>PERRING</u>
AB	AB	AB
AB	AB	AB
AB	AB	AB

## METAPROTERENOL SULFATE

<u>150 IU/VIAL; 150 IU/VIAL</u>	<u>N20328 002</u>	<u>SEP 01, 1994</u>	<u>N74702 001</u>	<u>MAR 24, 1997</u>
<u>75 IU/VIAL; 75 IU/VIAL</u>	<u>N73598 001</u>	<u>JUN 30, 1997</u>	<u>N71656 001</u>	<u>OCT 13, 1987</u>
<u>75 IU/VIAL; 75 IU/VIAL</u>	<u>N73598 001</u>	<u>JAN 30, 1997</u>	<u>N74702 001</u>	<u>MAR 24, 1997</u>
<u>150 IU/VIAL; 150 IU/VIAL</u>	<u>N73599 001</u>	<u>JAN 30, 1997</u>	<u>N71656 001</u>	<u>OCT 13, 1987</u>
<u>150 IU/VIAL; 150 IU/VIAL</u>	<u>N73599 001</u>			

## MEPERIDINE HYDROCHLORIDE

TABLET; OR

<del>N84804 001</del> <del>N84804 002</del> <del>N84804 002</del>	<b>PUREPAC PHARM</b> <hr/> <b>200MG</b> <b>400MG</b> <b>200MG</b> <b>400MG</b>	<del>&gt; DLT &gt;</del> <del>AA</del> <del>AA</del> <del>&gt; ADD &gt;</del> <del>②</del> <del>&gt; ADD &gt;</del> <del>③</del> <del>&gt; ADD &gt;</del> <del>④</del>	<b>TABLET; ORAL</b> <b>METHAZOLAMIDE</b> <b>APPLIED ANAL</b>	<u><b>25MG</b></u> <u><b>50MG</b></u>
<del>N40011 001</del> <del>JUL 17, 1997</del> <del>N40011 002</del> <del>JUL 17, 1997</del>				

## METHAZOLAMIDE

TABLET; ORAL  
**METHAZOLAMIDE**  
APPLIED ANAL  
25MG  
50MG

METHOCARBAMOL

TABLET; ORAL  
METHOCARBAMOL  
 AA  
 AB  
 TABLET; ORAL  
PUREPAC PHARM

500MG	AB
750MG	AB
500MG	AB
750MG	AB
	AB

METHOTREXATE SODIUM

INJECTABLE; INJECTION  
MEXATE-AQ PRESERVED  
 AP

EQ 25MG BASE/ML

④ BRISTOL MYERS SQUIBB EQ 25MG BASE/ML  
 ONSORALEN-ULTRA

+ ICN

CAPSULE; ORAL  
 ONSORALEN-ULTRA  
 + ICN  
 10MG

CAPSULE; LIQUID FILLED; ORAL  
 ONSORALEN-ULTRA  
 + ICN  
 10MG

N19600 001

OCT 30, 1986

METRONIDAZOLEINJECTABLE; INJECTIONMETRONIDAZOLE

STERIS

@

500MG/100ML

N70042 001

DEC 20, 1994

N70042 001

DEC 20, 1994

MEXILETINE HYDROCHLORIDECAPSULE; ORALMEXILETINE HCL

WATSON LABS

AB EQ 50MG BASE

EQ 100MG BASE

AB +

AB +

AB +

N74711 001

FEB 26, 1997

N74711 002

FEB 26, 1997

N74711 003

FEB 26, 1997

MYCOPHENOLATE MOFETILTABLET; ORAL

REMERON

+ ORGANON

30MG

+ 45MG

N20415 002

JUN 14, 1996

N20415 002

JUN 14, 1996

N20415 003

MAR 17, 1997

N17739 001

DEC 20, 1994

N17739 001

MICONAZOLE NITRATELOTION; TOPICALMONISTAT-DERM

® JOHNSON &amp; WILSON

2%

N17739 001

MIBEPRADIL DIHYDROCHLORIDETABLET; ORALPOSICOR

ROCHE

AB EQ 50MG BASE

AB EQ 100MG BASE

AB +

AB +

AB +

N20689 001

JUN 20, 1997

N20689 002

JUN 20, 1997

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDETABLET; ORALPENTAZOCINE AND NALOXONE HYDROCHLORIDES

AB ROYCE LABS

EQ 0.5MG BASE;

EQ 50MG BASE

N74736 001

JAN 21, 1997

N18040 001

DEC 16, 1982

N18040 001

MICONAZOLE NITRATECREAM; TOPICALMONISTAT-DERM

+ J AND J

+ JOHNSON &amp; WILSON

2%

N17494 001

DEC 05, 1983

N87598 001

OCT 05, 1983

N87599 001

OCT 06, 1983

N17494 001



NOREPINEPHRINE BITARTRATE

INJECTABLE; INJECTION  
 LEVOPHED  
 + ABBOTT  
 \* SANOFI WINSTROP

EQ 1MG BASE/ML  
 EQ 1MG BASE/ML

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL  
NORTRIPTYLINE HCL  
INVAMED  
AB EQ 10MG BASE  
AB EQ 25MG BASE  
AB EQ 50MG BASE  
AB EQ 75MG BASE

N74835 001  
 JUN 30, 1997  
 N74835 002  
 JUN 30, 1997  
 N74835 003  
 JUN 30, 1997  
 N74835 004  
 JUN 30, 1997

N62387 001  
 JUL 29, 1982  
 N62387 001  
 JUL 29, 1982

OINTMENT; TOPICAL  
MYKINAC  
@ ALPHARMA  
AA NMC  
> ADD >  
> ADD >  
> DLT >  
> DLT >

OINTMENT; TOPICAL  
MYKINAC  
@ ALPHARMA  
AA NMC  
> ADD >  
> ADD >  
> DLT >  
> DLT >

SUSPENSION; ORAL  
NYSTATIN  
ALPHARMA  
AA  
> DLT >  
> DLT >  
> ADD >  
> ADD >

100,000 UNITS/ML  
 100,000 UNITS/ML

N62571 001  
 OCT 29, 1985  
 N62571 001  
 OCT 29, 1985

N20553 001  
 DEC 12, 1995  
 N20553 002  
 DEC 12, 1995  
 N20553 003  
 DEC 12, 1995  
 N20553 001  
 DEC 12, 1995

ONDANSETRON HYDROCHLORIDE

SOLUTION; ORAL  
ZOFRAN  
+ GLAXO WELLCOME  
 N07513 001  
 N07513 001  
 JAN 24, 1997

OXACILLIN SODIUM

CAPSULE; ORAL  
BACTOCILL  
SMITHKLINE BEECHAM  
AB EQ 250MG BASE  
AB EQ 250MG BASE  
AB OXACILLIN SODIUM  
AB APOTHECOS  
AB \*  
AB @  
AB @

N61336 001  
 N61336 001  
 N61450 002  
 N61450 001  
 N61450 002  
 N61450 001  
 N61450 001

N86742 001

N86742 001

OXTRIPTYLLINE

TABLET, EXTENDED RELEASE; ORAL  
CHOLEDYL SA  
PARKES DAVIS  
AA WARNER CHILCOTT  
> DLT >  
> ADD >

OXYBUTYNIN CHLORIDE

SYRUP; ORAL  
OXYBUTYNIN CHLORIDE  
MORTON GROVE  
AA  
N62731 001  
SEP 22, 1986  
N62731 001  
SEP 22, 1986

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
OXYCONTIN  
PURDUE FREDERICK  
AA  
> DLT >  
> DLT >  
> ADD >  
> ADD >

100,000 UNITS/ML  
 100,000 UNITS/ML

N74868 001  
 FEB 12, 1997

5MG/5ML

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL  
OXYCONTIN  
+ PURDUE PHARMA 20MG  
> DLT >  
> ADD >

TABLET; ORAL  
ANADROL-50  
\* SYNTAX  
+ UNITEMD 50MG  
50MG

OXYTOCIN

SOLUTION; NASAL  
SYNTOCINON  
+ NOVARTIS @  
40 USP UNITS/ML  
40 USP UNITS/ML

PROMOMYCIN SULFATECAPSULE; ORAL

AB + PARKE DAVIS EQ 250MG BASE  
AB PAROMOMYCIN SULFATE  
CARACO EQ 250MG BASE

PAROXETINE HYDROCHLORIDE

SUSPENSION; ORAL  
PAXIL  
+ SMITHKLINE BEECHAM EQ 10MG BASE/5ML

PENTOXIFYLLINE

> ADD >	> ADD >	TABLET, EXTENDED RELEASE; ORAL <u>PENTOXIFYLLINE</u>
N20553 002 DEC 12, 1995	> ADD >	ESTI LEDERLE 400MG
N20553 003 DEC 12, 1995	> ADD >	MYLAN 400MG
N20553 004 JAN 06, 1997	> ADD >	PUREPAC PHARM 400MG
> ADD >		TRENTAL + HOECHST MARION RSSL 400MG
> ADD >		N18631 001 AUG 30, 1984

PERINDOPRIL ERBUMINE

TABLET ORAL  
ACEON

RHONE POULENCE RORER 20MG	N20184 001
4MG	DBC 30, 1993
8MG	N20184 002
2MG	DEC 30, 1993
4MG	N20184 003
8MG	DEC 30, 1993
2MG	N20184 001
4MG	DEC 30, 1993
8MG	N20184 002
2MG	DEC 30, 1993
4MG	N20184 003
8MG	DEC 30, 1993

N12285 001  
N12285 001  
CAPSULE, EXTENDED RELEASE; ORAL  
PHENDIMETRAZINE TARTRATE

BC JUN 30, 1997	N87914 001
GRAHAM DR 105MG	N88220 001
105MG	AUG 16, 1982
BC	N88228 001
105MG	AUG 16, 1982
BC	N88062 001
105MG	SEP 13, 1982
BC	N88063 001
105MG	SEP 10, 1982
BC	NB8111 001
105MG	OCT 18, 1982



<u>POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE</u>	> ADD >	<u>PRAMIPEXOLE DIHYDROCHLORIDE HYDRATE</u>
SOLUTION/DROPS; OPHTHALMIC	> ADD >	TABLET; ORAL
TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE	> ADD >	MIRAPEX
BAUSCH AND LOMB 10,000 UNITS/ML; EQ 1MG BASE/ML	> ADD >	PHARMACIA AND UPJOHN 1MG
AT FEB 14, 1997	N64120 001	N20667 003 JUL 01, 1997
POTASSIUM CHLORIDE	@ ADD >	N20667 004 JUL 01, 1997
	> ADD >	N20667 005 JUL 01, 1997
	> ADD >	JUL 01, 1997
INJECTABLE; INJECTION		
POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER		
AP * ABBOTT	14.9MG/ML	<u>PREDNISOLONE</u>
AP *	14.9MG/ML	TABLET; ORAL
②	74.5MG/100ML	PREDNISOLONE
②	14.9MG/ML	BX PURBAC PHARM
AP * BAXTER HLTCHCARE	74.6MG/100ML	SMG 5MG
AP *	14.9MG/ML	N80325 001 N80325 001
+	74.6MG/100ML	
+	14.9MG/ML	
AP * ABBOTT	14.9GM/100ML	<u>PREDNISOLONE ACETATE</u>
②	1.49GM/100ML	INJECTABLE; INJECTION
AP *	1.49GM/100ML	PREDNISOLONE ACETATE
+	1.49GM/100ML	STERIS
+	1.49GM/100ML	②
AP * ABBOTT	1.49GM/100ML	<u>PREDNISOLONE SODIUM PHOSPHATE</u>
②	1.49GM/100ML	SOLUTION; ORAL
AP *	1.49GM/100ML	PEDIAPRED
+	1.49GM/100ML	* FISONS
AP *	1.49GM/100ML	EQ 5MG BASE/5ML
+	1.49GM/100ML	N19157 001 MAY 28, 1986
		N19157 001 MAY 28, 1986
		N19157 001 MAY 28, 1986
		MAY 28, 1986
> ADD >		<u>PREDNISONE</u>
> ADD >		TABLET; ORAL
> ADD >		MIRAPEX
> ADD >		PHARMACIA AND UPJOHN 0.125MG
> ADD >	0.25MG	N20667 001 JUL 01, 1997
> ADD >		N20667 002 JUL 01, 1997
> ADD >		



## **PROPRANOLOL HYDROCHLORIDE**

TABLET; ORAL PROPRANOLOL HCL		TABLET; ORAL RAUWOLFIA SERPENTINA	
AB	> DLT	60MG N70519 001 SEP 24, 1986 > ADD	@ ZENITH GOLDLINE 50MG N11521 001 N11521 002
AB	> DLT	80MG N70520 001 JUL 07, 1986 > DLT	@ ZENITH LABS 50MG N11521 001 N11521 002
AB	> DLT	90MG N70521 001 SEP 24, 1986 RESERPINE	@ ZENITH LABS 40MG N11521 001 N11521 002
10MG		N70516 001 JUL 07, 1986 TABLET; ORAL RESERPINE	N80753 001 N80753 002
10MG		N70517 001 JUL 07, 1986 BP	N80753 001 N80753 002
20MG		N70518 001 JUL 07, 1986 PUREPAC PHARM	N80753 001 N80753 002
40MG		N70519 001 JUL 07, 1986 BP	N80753 001 N80753 002
60MG		N70519 001 SEP 24, 1986 @ ZENITH GOLDLINE	N80753 001 N80753 002
80MG		N70520 001 JUL 07, 1986 @ ZENITH LABS	N11185 001 N11185 002
90MG		N70521 001 SEP 24, 1986 @ ZENITH LABS	N11185 001 N11185 002

RAUWOLFIA SERPENTINA

N70519 001 SEP 24, 1986	> ADD > > ADD > > DLT > > DLT >	RAUWOLFIA SERPENTINA @ ZENITH GOLDLINE	5.0 MG 1.00 MG 5.0 MG 1.00 MG	N11521 001 N11521 002 N11521 001 N11521 002
N70520 001 JUL 07, 1986	> ADD > > ADD > > DLT > > DLT >	ZENITH LABS @ ZENITH LABS @ ZENITH LABS @ ZENITH LABS	5.0 MG 1.00 MG 5.0 MG 1.00 MG	N11521 001 N11521 002 N11521 001 N11521 002
N70516 001 JUL 07, 1986	> ADD > > ADD > > DLT > > DLT >	RESERPINE		
N70517 001 JUL 07, 1986	> ADD > > ADD > > DLT > > DLT >	TABLET; ORAL RESERPINE		
N70518 001 JUL 07, 1986	> ADD > > ADD > > DLT > > DLT >	PUREPAC PHARM BP	0.1 MG 0.25 MG 0.1 MG 0.25 MG	N80753 002 N80753 001 N80753 002 N80753 001
N70519 001 SEP 24, 1986	> ADD > > ADD > > DLT > > DLT >	ZENITH GOLDLINE @ ZENITH GOLDLINE @ ZENITH GOLDLINE @ ZENITH GOLDLINE	0.1 MG 0.25 MG 0.1 MG 0.25 MG	N80753 002 N80753 001 N11185 001 N11185 002
N70521 001 SEP 24, 1986	> ADD > > ADD > > DLT > > DLT >	ZENITH LABS @ ZENITH LABS @ ZENITH LABS @ ZENITH LABS	0.1 MG 0.25 MG 0.1 MG 0.25 MG	N11185 002 N11185 001 N11185 002 N11185 001

PYRIDOXINE HYDROCHLORIDE

INJECTABLE; INJECTION  
PYRIDOXINE HCL  
500MG  
ORAL  
CAPSULE; ORAL  
RIFAMPIN  
300MG  
AB EON  
N83760 001  
N83760 001  
100MG/ML  
100MG/ML  
@  
P

PANTITIDINE HYDROCHLORIDE

ADD >	<u>AB</u>	TABLET; ORAL <u>RANITIDINE HCL</u> GRANUTEC PHARMS	<u>EQ 150MG BASE</u>	N74488 001 JUL 31, 1997	INJECTABLE; INJECTION QUADRAMET CYTOGEN	50mCi /ML	N20570 001 MAR 28, 1997
ADD >	<u>AB</u>		<u>EQ 300MG BASE</u>	N74488 002 JUL 31, 1997			
ADD >	<u>AB</u>				<u>SECOBARBITAL SODIUM</u>		
ADD >	<u>AB</u>	<u>ZANTAC 150</u> GLAXO WELLCOME	<u>EQ 150MG BASE</u>	N18703 001 JUN 09, 1983	CAPSULE; ORAL <u>SECOBARBITAL</u> HALSIX®	<u>100MG</u> 100MG	N84676 001 N84676 001
ADD >	<u>AB</u>	<u>ZANTAC 300</u> + GLAXO WELLCOME	<u>EQ 300MG BASE</u>	N18703 002 DEC 09, 1985			
ADD >	<u>AB</u>						

SAMARIUM SM 153 LEXIDRONAM PENTASORIUM

INJECTABLE ; INJECTION		<u>SECOBARBITAL SODIUM</u>
QUADRAMET	50mCi/ML	CAPSULE; ORAL
CYTOGEN		SODIUM SECOBARBITAL
		100MG 1.00MG
		HALSEY
		@
N20570 001		N84676 001
MAR 28, 1997		N84676 001





THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL SOMOPHYLLIN-CRT GRAHAM DM	BC	④	100MG 200MG 250MG 300MG
		④	50MG
		④	100MG
		④	200MG
		④	250MG
		④	300MG

## TIMOLOL MALEATE

## THIAMINE HYDROCHLORIDE

**INJECTABLE: INJECTION  
THIAMINE HCL  
STERILE**

## **TRILUDRONATE DISODIUM**

**TABLET; ORAL  
SKELID**

## TIOCONAZOLE

N20707 001  
MAP 07 1997  
3Q 200MG BASE

TMOT 01

SOLUTION/DROPS ; OPHTHALMIC			
BETIMOL	EQ 0.25% BASE	EQ 0.5% BASE	EQ 0.5% BASE
KLEIRAS	*	*	*
OY STAR	+ OY STAR	+ OY STAR	+ OY STAR

## TIOCONAZOLE

VAGINAL  
VAGISTAT-1  
CREAM

DBC 30, 1986  
N19355 001

四

TABLE I : ORAL TOLBUTAMIDE PURERPAC PHARM	
> DLT	>
> DLT	>
> ADD	>
> ADD	>
> ADD	>
	@

JUN 17, 1985  
N88950 001  
JUN 17, 1985  
N88950 001

TABLET; ORAL  
TOLMETIN SODIUM  
BAKER NORTON

E9 600MG BASE N74399 001  
MAR 28, 1996

<u>TOLMETIN SODIUM</u>		<u>TRIAMCINOLONE</u>	
<u>AB</u>	TABLET; ORAL <u>TOLMETIN SODIUM</u> LIMONON	EQ 600MG BASE	TABLET; ORAL TRIAMCINOLONE BP PURÉPAC PHARM
AB	④ TEVA	EQ 600MG BASE	BP BP ④ ④
AB	ZENITH GOLDLINE	EQ 600MG BASE	FEB 27, 1997 N74729 001 FEB 27, 1997 N74729 001 FEB 27, 1997 N74399 001 MAR 28, 1996
<u>TOPIRAMATE</u>		<u>TRIAMCINOLONE ACETONIDE</u>	
			LOTION; TOPICAL <u>TRIAMCINOLONE ACETONIDE</u> 0.1% BP ALPHARMA
			SEP 08, 1982 N87192 001 SEP 08, 1982 N87192 001 SEP 08, 1982
<u>TOREMIFENE CITRATE</u>		<u>TRIAMCINOLONE DIACETATE</u>	
			INJECTABLE; INJECTION TRIAMCINOLONE DIACETATE STERIS 40MG/ML 40MG/ML
			N85529 001 N85529 001
<u>TRAZODONE HYDROCHLORIDE</u>		<u>TRIFLUOPERAZINE HYDROCHLORIDE</u>	
			TABLET; ORAL <u>TRIFLUOPERAZINE HCL</u> EQ 1IMG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE
			N40209 001 JUL 07, 1997 N40209 002 JUL 07, 1997 N40209 003 JUL 07, 1997 N40209 004 JUL 07, 1997
<u>TRIHEXYPHENIDYL HYDROCHLORIDE</u>		<u>CAPSULE EXTENDED RELEASE; ORAL</u>	
			CAPSULE EXTENDED RELEASE; ORAL ARTANE + LIFERLE ④
			N12947 001 N12947 001
<u>TRIPOFENONE</u>		<u>RETIN-A</u>	
			GEL; TOPICAL RETIN-A MICRO + ADV POLYMER 0.1%
			N20475 001 FEB 07, 1997
<u>TRIPOFENONE</u>		<u>RETIN-A</u>	
			0.025% 0.025%
			JAN 14, 1997 N19049 001 SEP 16, 1998
<u>TRIPOFENONE</u>		<u>RETIN-A</u>	
			0.025% 0.025%
			JAN 14, 1997 N19049 001 SEP 16, 1998
<u>TRIPOFENONE</u>		<u>RETIN-A</u>	
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			JAN 14, 1997 N19049 001 SEP 16, 1998
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			JAN 14, 1997 N19049 001 SEP 16, 1998

TRIHEXYPHENIDYL HYDROCHLORIDE

ELIXIR; ORAL  
TRIHEXYPHENIDYL HCL  
AA PHARM ASSOC 2MG/5ML

TRIMETHOPRIM

TABLET; ORAL  
PROLOPRIM  
GLAXO WELLCOME 200MG  
AB + 200MG  
TRIMEPX 200  
AB \* ROCHE 200MG  
(@) 200MG

TROGLITAZONE

TABLET; ORAL  
PRELAY  
SANRYO 200MG  
AB 400MG  
REZULIN  
PARKE DAVIS 200MG  
AB 400MG

UREA C-14  
CAPSULE; ORAL  
+ TRI MED SPECLTS 1 uCi  
PYTEST KIT  
+ TRI MED SPECLTS 1 uCi

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION  
VANCOCIN HCL IN PLASTIC CONTAINER  
EQ 500MG BASE/100ML  
N50671 001  
APR 29, 1993  
APR 29, 1993  
EQ 500MG BASE/100ML  
N50671 001  
APR 29, 1993

TRIMETHOPRIM

VERAPAMIL HYDROCHLORIDE

TABLET; EXTENDED RELEASE; ORAL  
ISOPTIN SR 120MG  
AB + KNOLL PHARM  
VERAPAMIL HCL 120MG  
AB MYLAN

NOV 09, 1982  
NOV 09, 1982  
NOV 09, 1982  
NOV 09, 1982

VINCRISTINE SULFATE

INJECTABLE; INJECTION  
VINCREX 5MG/VIAL  
AB \* BRISTOL MYERS  
@ BRISTOL MYERS SQUIBB 5MG/VIAL  
VINCRISTINE SULFATE 5MG/VIAL  
FADING 5MG/VIAL  
AB + 5MG/VIAL

NOV 09, 1982  
NOV 09, 1982  
NOV 09, 1982  
NOV 09, 1982

WARFARIN SODIUM

TABLET; ORAL  
COUMADIN 1MG  
AB DUPONT MERCK 2MG  
AB + AB 2.5MG  
AB 4MG  
N20617 001  
MAY 09, 1997  
N20617 002  
MAY 09, 1997  
AB AB + 5MG  
AB AB + 7.5MG  
AB AB + 10MG

N09218 022  
MAR 01, 1990  
N09218 013  
N09218 018  
N09218 023  
AUG 24, 1993  
N09218 007  
N09218 016  
N09218 005

WARFARIN SODIUM

TABLET; ORAL

WARFARIN SODIUM  
BARR

<u>AB</u>	<u>1MG</u>	N40145 001 MAR 26, 1997
<u>AB</u>	<u>2MG</u>	N40145 002 MAR 26, 1997
<u>AB</u>	<u>2.5MG</u>	N40145 003 MAR 26, 1997
<u>AB</u>	<u>4MG</u>	N40145 004 MAR 26, 1997
<u>AB</u>	<u>5MG</u>	N40145 005 MAR 26, 1997
<u>AB</u>	<u>7.5MG</u>	N40145 006 MAR 26, 1997
<u>AB</u>	<u>10MG</u>	N40145 007 MAR 26, 1997

ZINC ACETATE

CAPSULE; ORAL

GALZIN  
TEVA

+	EQ 25MG ZINC	N20458 001 JAN 28, 1997
	EQ 50MG ZINC	N20458 002 JAN 28, 1997

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDECLOTRIMAZOLE

<u>CAPSULE, EXTENDED RELEASE; ORAL</u>		<u>CLOTRIMAZOLE</u>
COLD CAPSULE IV * GRAHAM DM	12MG; 75MG	CREAM, SUPPOSITORIY; TOPICAL, VAGINAL GYNE-LOTRIMIN 3 COMBINATION PACK + SCHERING PLOUGH 1%, 200MG
②	12MG; 75MG	N20526 002 JUL 29, 1996
COLD CAPSULE V GRAHAM DM	8MG; 75MG	GYNE-LOTRIMIN COMBINATION PACK + SCHERING PLOUGH 1%, 100MG
②	8MG; 75MG	N20289 002 APR 26, 1993
TABLET, EXTENDED RELEASE; ORAL		MYCELEX-7 COMBINATION PACK 1%, 100MG
> ADD >		BAYER
> ADD >		N20389 002 JUN 23, 1994
> ADD >	12MG; 75MG	CREAM, TABLET; TOPICAL, VAGINAL GYNE-LOTRIMIN 3 COMBINATION PACK + SCHERING PLOUGH 1%, 200MG
> DLT >		N20526 002 JUL 29, 1996
> DLT >		GYNE-LOTRIMIN COMBINATION PACK + SCHERING PLOUGH 1%, 100MG
> DLT >		N20289 002 APR 26, 1993
> DLT >		MYCELEX-7 COMBINATION PACK 1%, 100MG
> DLT >		BAYER
> DLT >		N20389 002 JUN 23, 1994
<u>CAPSULE, EXTENDED RELEASE; ORAL</u>		<u>STOPPOSITORIY; VAGINAL</u>
CODIMAL-L.A. 12 + CENT PHARMS	12MG; 120MG	GYNE-LOTRIMIN + SCHERING PLOUGH 100MG
② SCHWARZ PHARMA	12MG; 120MG	N17717 002 NOV 30, 1990
PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE KY PHARM	12MG; 120MG	GYNE-LOTRIMIN 3 + SCHERING PLOUGH 200MG
②	12MG; 120MG	N18935 001 APR 15, 1985
		N18935 001 APR 15, 1985
		N18935 001 APR 15, 1985
		N71455 001 MAR 01, 1989
		N71455 001 MAR 01, 1989
		MAR 01, 1989
		TABLET; VAGINAL GYNE-LOTRIMIN + SCHERING PLOUGH 100MG
		N17717 002 NOV 30, 1990
<u>CLEMASTINE FUMARATE</u>		
TABLET; ORAL		
CLEMASTINE FUMARATE LEMNON	1.34MG	N73282 002 DEC 03, 1992
TEVA	1.34MG	N73282 002 DEC 03, 1992
		GYNE-LOTRIMIN 3 + SCHERING PLOUGH 200MG
		MYCELEX-7 BAYER 100MG
		N20525 001 JUL 29, 1996
		N18182 002 DEC 26, 1991

## CROMOLYN SODIUM

**SPRAY, METERED; NASAL  
NASALCROM  
+ PHARMACIA AND UPJOHN 5.2MGS/SPRAY**

N20463 001  
JAN 03, 1997

I BUPROFEN

TABLET; ORAL  
IBUPROFEN  
PURÉPAC PHARM

260

200MC

20

ECONOMIC

100MG

200MG

200MG

2001

200

INSULIN SEMISYNTETIC PURIFIED HUMAN

MULTINOMIAL

VELOSULIN HUMAN + NOVO NORDISK	100 UNITS/ML
VELOSULIN HUMAN + NOVO NORDISK	100 UNITS/ML

N74767 001  
FEB 28, 1997

## LOPERAMIDE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL  
IMODIUM A-D  
+ MCNEIL  
2MG  
N20448 001  
TIT 24 1000

TOKYO METROPOLITAN GOVERNMENT

TABLET, CHEWABLE; ORAL  
IMODIUM ADVANCED  
+ MCNEIL  
2MG; 125MG

N20606 001  
JUN 26, 1996

MICONAZOLE NITRATE

CREAM; VAGINAL  
MICONAZOLE NITRATE  
DEBROCO

N74444 001

CREAM, SUPPOSITORY; TOPICAL, VAGINAL  
M-ZOLE 7 DUAL PACK 2% 100MG  
ALPHARMA N74586 001

CHAPTER 1  
INTRODUCTION

MICONAZOLE NITRATE  
G AND W LABS 100MG  
+ PERRIGO 100MG

SOLUTION: TOPICAL  
MINOXIDIL (FOR MEN)  
MORTON GROVE  
2%  
N74767 001  
FEB 28, 1997

NAPROXEN SODIUM

TABLET; ORAL  
NAPROXEN SODIUM  
GRANUTEC  
INVAMED  
  
NOVOPHARM  
PERRIGO  
PVT FORM

EQ 200MG BASE	N74635 001
EQ 200MG BASE	JAN 13, 1997
EQ 200MG BASE	N74646 001
EQ 200MG BASE	JAN 13, 1997
EQ 200MG BASE	N74635 001
EQ 200MG BASE	JAN 13, 1997
EQ 200MG BASE	N74661 001
EQ 200MG BASE	JAN 13, 1997
EQ 200MG BASE	N74789 001
	FEB 27, 1997

PERMETHRIN

LOTION; TOPICAL  
NIX  
+ WARNER LAMBERT 1%  
\* WARNER WELLCOME 1%

N19918 001
MAY 02, 1990
N19918 001
MAY 02, 1990

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

CAPSULE; EXTENDED RELEASE; ORAL  
TRIPROLIDINE AND PSEUDOEPHEDRINE HYDROCHLORIDES  
KV PHARM

12.0MG; 5MG	N71798 001
12.0MG; 5MG	MAR 16, 1989
12.0MG; 5MG	N71798 001
12.0MG; 5MG	MAR 16, 1989

@

SODIUM FLUORIDE; TRICLOSAN

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

PASTE; DENTAL  
COLGATE TOTAL  
+ COLGATE PALMOLIVE 0 . 24% ; 0 . 3%  
N20231 001  
JUL 11, 1997

TIOCONAZOLE

OINTMENT; VAGINAL  
VAGISTAT-1  
+ BRISTOL MYERS SQUIBB 6 . 5%  
N20676 001  
FEB 11, 1997

DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST  
CUMULATIVE SUPPLEMENT NUMBER 7/ JULY '97

NO JULY APPROVALS

**This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.**

**Orphan Product Designations and Approvals List  
January 1997 through July 1997**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
15AU81 TN=	Treatment of primary pulmonary hypertension.	Lung Rx, Inc. 2 Davis Drive P.O. Box 13169 Research Triangle Park, NC 27709 DD=06/04/1997
8 Cyclopentyl 1,3-dipropylxanthine TN=	Treatment of cystic fibrosis.	SciClone Pharmaceuticals, Inc. 901 Mariner's Island Boulevard Suite 315 San Mateo, CA 94404 DD=03/24/1997
9-cis-retinoic acid TN=	Prevention of retinal detachment due to proliferative vitreoretinopathy.	Allergan, Inc. 2525 Dupont Drive P.O. Box 19534 Irvine, CA 92623 DD=01/02/1997
Allogeneic peripheral blood mononuclear cells sensitized against patient alloantigens by mixed lymphocyte culture TN= CYTOIMPLANT	Treatment of pancreatic cancer.	Applied Immunotherapeutics, LLC 14132 E. Firestone Boulevard Santa Fe Springs, CA 90670 DD=06/13/1997
Anagrelide TN= Agrylin	Treatment of essential thrombocythemia.	Roberts Pharmaceutical Corp. Meridian Center III 6 Industrial Way West Eatontown, NJ 07724 DD=01/27/1988 MA=03/14/1997

**Orphan Product Designations and Approvals List**  
**January 1997 through July 1997**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
B2036-PEG TN= Trovert	Treatment of acromegaly.	Sensus Corporation Suite 430, 98 San Jacinto Boulevard Austin, TX 78701 DD=06/24/1997
Beta alethine TN= Betathine	Treatment of multiple myeloma.	Dovetail Technologies, Inc. 10615 Mantz Road Silver Spring, MD 20903 DD=03/24/1997
Beta alethine TN= Betathine	Treatment of metastatic melanoma.	Dovetail Technologies, Inc. 10615 Mantz Road Silver Spring, MD 20903 DD=03/24/1997
Busulfan TN=	Treatment of primary brain malignancies.	Sparta Pharmaceuticals, Inc. 111 Rock Road Horsham, PA 19044 DD=07/07/1997
CY-1503 TN= Cylexin	Treatment of neonates and infants undergoing cardiopulmonary bypass during surgical repair of congenital heart lesions.	Cytel Corporation 3525 John Hopkins Court San Diego, CA 92121 DD=07/18/1997
Coagulation Factor IX (recombinant) TN= BeneFix	Treatment of hemophilia B.	Genetics Institute, Inc. 87 Cambridge Park Drive Cambridge, MA 02140 DD=10/03/1994 MA=02/11/1997

**Orphan Product Designations and Approvals List**  
**January 1997 through July 1997**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Dehydroepiandrosterone sulfate sodium TN=	To accelerate the re-epithelialization of donor sites in those hospitalized burn patients who must undergo autologous skin grafting.	Pharmadigm, Inc. 2401 Foothill Drive Salt Lake City, UT 84109 DD=01/28/1997
Dehydroepiandrosterone sulfate sodium TN=	Treatment of serious burns requiring hospitalization.	Pharmadigm, Inc. 2401 Foothill Drive Salt Lake City, UT 84109 DD=01/29/1997
Dimethylsulfoxide TN=	Topical treatment for the prevention of soft tissue injury following extravastion of cytotoxic drugs.	Cancer Technologies, Inc. 7301 East 22nd Street Suite 10E Tucson, AZ 85710 DD=04/15/1997
Enadoline hydrochloride TN=	Treatment of severe head injury.	Warner-Lambert Company Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor, MI 48105 DD=01/28/1997
Fampridine TN=	Treatment of chronic, incomplete spinal cord injury.	Acorda Therapeutics, Inc. 145 West 58th Street Suite 8J New York, NY 10019 DD=06/02/1997
Gp100 adenoviral gene therapy TN=	Treatment of metastatic melanoma.	Genzyme Corporation P.O. Box 9322 One Mountain Road Framingham, MA 01701 DD=03/25/1997

**Orphan Product Designations and Approvals List**  
**January 1997 through July 1997**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Human retinal pigmented epithelial cells on collagen microcarriers TN= Spheramine	Treatment of Hoehn and Yahr stage 3 and 4 Parkinson's disease.	Theracell, Inc. 50 Division Street, Suite 503 Somerville, NJ 08876 DD=07/18/1997
Icodextrin 7.5% with Electrolytes Peritoneal Dialysis Solution TN= Extraneal (with 7.5% Icodextrin) Peritoneal Dialysis Solutio	Treatment of those patients having end stage renal disease and requiring peritoneal dialysis treatment.	Baxter Healthcare Corporation Renal Division 1620 Waukegan Road Waukegan, IL 60085 DD=07/18/1997
Lepirudin TN= Refludan	Treatment of heparin-associated thrombocytopenia Type II.	Behringwerke AG P.O. Box 1140 D-35001 Marburg Germany, DD=02/13/1997
Levocarnitine TN= Carnitor	Treatment of zidovudine-induced mitochondrial myopathy.	Sigma-Tau Pharmaceuticals, Inc. 800 S. Frederick Avenue, Suite 300 Gaithersburg, MD 20877 DD=04/07/1997
MART-1 adenoviral gene therapy for malignant melanoma TN=	Treatment of metastatic melanoma.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=03/28/1997

**Orphan Product Designations and Approvals List**  
**January 1997 through July 1997**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Oxandrolone TN= Oxandrin	Treatment of patients with Duchenne's muscular dystrophy and Becker's muscular dystrophy.	Bio-Technology General Corporation 70 Wood Avenue South Iselin, NJ 08830 DD=04/22/1997
Paclitaxel TN= Taxol	Treatment of AIDS-related Kaposi's sarcoma.	Bristol-Myers Squibb Pharmaceutical Research Institute 5 Research Parkway P.O. Box 5100 Wallingford, CT 06492 DD=03/25/1997
Paclitaxel TN= Paxene	Treatment of AIDS-related Kaposi's sarcoma.	Baker Norton Pharmaceuticals, Inc. 4400 Biscayne Boulevard Miami, FL 33137 DD=04/15/1997
Patul-end TN=	Treatment of patentous eustachian tube.	Ear Foundation 24209 Castillo Street, Suite 100 Santa Barbara, CA 93105 DD=02/18/1997
Poly-ICLC TN=	Treatment of primary brain tumors.	Salazar, Andres M. M.D. and Levy, Hilton B. Ph.D. 3202 Cleveland Avenue N.W. Washington, DC 20008 DD=03/17/1997

**Orphan Product Designations and Approvals List**  
**January 1997 through July 1997**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Porcine Sertoli cells aseptically prepared for intracerebral co-implantation with fetal neural tissue TN= N-Graft	Treatment of Hoehn and Yahr stage four and five Parkinson's disease.	Theracell, Inc. 50 Division Street Suite 503 Somerville, NJ 08876 DD=06/24/1997
Porfiromycin TN= Promycin	Treatment of cervical cancer.	Vion Pharmaceuticals, Inc. Four Science Park New Haven, CT 06511 DD=03/13/1997
Retroviral vector, R-GC and GC gene 1750 TN=	Treatment of Gaucher disease.	Genzyme Corporation One Kendall Square Cambridge, MA 02139 DD=05/06/1997
Suramin TN=	Treatment of metastatic hormone-refractory prostate cancer.	Warner-Lambert Company Parke-Davis Pharmaceutical Research Division 2800 Plymouth Road Ann Arbor, MI 48105 DD=05/06/1997
Toremifene TN= Fareston	Hormonal therapy of metastatic carcinoma of the breast.	Orion Corporation P.O. Box 65 02101 ESPOO Finland, DD=09/19/1991 MA=05/29/1997
Zinc acetate TN= Galzin	Treatment of Wilson's disease.	Lemmon Company 1510 Delp Drive Kulpssville, PA 19443 DD=11/06/1985 MA=01/28/1997

DRUG PRODUCTS WHICH MUST DEMONSTRATE *IV/VIVO* BIOAVAILABILITY ONLY  
IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

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NO JULY 1997 ADDITIONS

## PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 17TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

### REFERENCES NEW DOSING SCHEDULE

- D-33      ONCE DAILY DOSING FOR PLAQUE PSORIASIS
- D-34      EVERY FOUR MONTHS DOSAGE REGIMEN

### NEW INDICATION

- I-177      TREATMENT OF MODERATE ACNE VULGARIS IN FEMALES, GREATER OR EQUAL TO 15 YEARS OF AGE, WHO HAVE NO KNOWN CONTRAINDICATIONS TO ORAL CONTRACEPTIVE THERAPY, DESIRE CONTRACEPTION, HAVE ACHIEVED MENARCHE AND ARE UNRESPONSIVE TO TOPICAL ANTI-ACNE MEDICATIONS
- I-178      TREATMENT OF ONCHOMYCOSIS OF THE FINGERNAIL WITHOUT CONCOMITANT ONCHOMYCOSIS OF THE TOENAIL WITH A PULSE DOSING REGIMEN
- I-179      NOSOCOMIAL PNEUMONIA-MILD TO MODERATE AND SEVERE CAUSED BY HAEMOPHILUS INFLUENZAE OR KLEBSIELLA PNEUMONIAE
- I-180      TREATMENT OF PLANTAR TINEA PEDIS (MOCCASIN TYPE)
- I-181      TREATMENT OF PATIENTS WITH COMPLEX PARTIAL SEIZURES WITH AND WITHOUT SECONDARY GENERALIZATION
- I-182      TREATMENT OF GROWTH FAILURE ASSOCIATED WITH TURNER SYNDROME
- I-183      MAINTENANCE THERAPY IN THE MANAGEMENT OF MILD TO MODERATE ASTHMA IN PEDIATRIC PATIENTS AGES 6-11
- I-184      TREATMENT OF PANIC DISORDER AT A RECOMMENDED DOSE RANGE OF 1 TO 2 MG/DAY (MAXIMUM OF 4MG)
- I-185      PREVENTION OF OSTEOPOROSIS IN POSTMENOPAUSAL WOMEN
- I-186      TREATMENT OF TINEA (PITYRIASIS) VERSICOLOR CAUSED BY OR PRESUMED TO BE CAUSED BY PITYROSPORUM ORBICULARE (ALSO KNOWN AS MALASSEZIA FURFUR OR M. ORBICULARE)
- I-187      PREVENTION OF FRACTURES IN THE TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
- I-188      TREATMENT OF ACUTE SINUSITIS AND ACUTE EXACERBATION OF CHRONIC SINUSITIS
- I-189      TREATMENT OF ACUTE OTITIS MEDIA IN PEDIATRIC PATIENTS
- I-190      PLANAR IMAGING AS A SECOND LINE DIAGNOSTIC DRUG AFTER MAMMOGRAPH TO ASSIST IN THE EVALUATION OF BREAST LESIONS IN PATIENTS WITH AN ABNORMAL MAMMOGRAM OR A PALPABLE BREAST MASS
- I-191      ENDOMETRIAL THINNING AGENT PRIOR TO ENDOMETRIAL ABLATION FOR DYSFUNCTIONAL UTERINE BLEEDING
- I-192      THE PREVENTION OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING ABDOMINAL SURGERY WHO ARE AT RISK FOR THROMBOEMBOLIC COMPLICATIONS AND A NEW DOSAGE REGIMEN, 40MG ONCE DAILY, FOR THIS INDICATION
- I-193      TREATMENT OF PANIC DISORDER IN A RECOMMENDED DOSE RANGE OF 50 TO 200MG/DAY
- I-194      CONGESTIVE HEART FAILURE
- I-195      USE OF LANSOPRAZOLE IN COMBINATION WITH CLARITHROMYCIN AND AMOXICILLIN FOR THE ERADICATION OF HELICOBACTER PYLORI IN PATIENTS WITH ACTIVE DUODENAL ULCER DISEASE OR A ONE-YEAR HISTORY OF DUODENAL ULCER
- I-196      ACUTE TREATMENT OF ACTIVE BENIGN GASTRIC ULCER
- I-197      MAINTENANCE OF HEALING OF DUODENAL ULCER
- I-198      USE OF LANSOPRAZOLE IN COMBINATION WITH AMOXICILLIN FOR THE ERADICATION OF HELICOBACTER PYLORI IN PATIENTS WITH ACTIVE DUODENAL ULCER DISEASE OR A ONE-YEAR HISTORY OF A DUODENAL ULCER

**PATENT AND EXCLUSIVITY TERMS  
PATENT USE CODE**

- U-161 METHOD OF INHIBITING CHOLESTEROL BIOSYNTHESIS IN A PATIENT
- U-162 METHOD OF USE TO INHIBIT CHOLESTEROL SYNTHESIS IN A HUMAN SUFFERING FROM HYPERCHOLESTEROLEMIA
- U-163 METHOD OF USING TROGLITAZONE TO TREAT IMPAIRED GLUCOSE TOLERANCE TO PREVENT OR DELAY THE ONSET OF NONINSULIN-DEPENDENT DIABETES MELLITUS
- U-164 METHOD OF USING TROGLITAZONE TO PREVENT OR DELAY THE ONSET OF NONINSULIN-DEPENDENT DIABETES MELLITUS IN A DEFINED POPULATION OF PATIENTS
- U-165 TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA
- U-166 TREATMENT OF H. PYLORI ASSOCIATED DUODENAL ULCER
- U-167 METHOD FOR TREATING HIV-1 INFECTION
- U-168 METHOD OF INHIBITING LIPOXYGENASE ACTIVITY IN A MAMMAL WHICH IS THE MODE OF ACTION IN THE TREATMENT OF ASTHMA
- U-169 METHODS OF USING THE COMPOUND/DRUG PRODUCT AS A CONTRAST AGENT IN MAGNETIC RESONANCE IMAGING
- U-170 METHOD OF OBTAINING AN MR IMAGE USING THE COMPOSITION/DRUG PRODUCT AS A CONTRAST AGENT
- U-171 METHODS OF USING THE COMPOUND/DRUG PRODUCT AS AN ORAL CONTRAST AGENT IN MAGNETIC RESONANCE IMAGING OF THE GASTROINTESTINAL TRACT
- U-172 TREATMENT OF GENITAL WARTS
- U-173 ADMINISTRATION TO A HOST SUFFERING FROM GESTATIONAL DIABETES
- U-174 USE AS AN ANTIHISTAMINE AGENT
- U-175 METHOD OF TREATING MALIGNANT TUMORS
- U-176 METHOD OF TREATING A PATIENT SUFFERING FROM LISTED CONDITIONS, INCLUDING SPECIFIC PSYCHOSIS
- U-177 FUNGICIDE
- U-178 FACILITATED ADHERENCE OF AGENTS TO SKIN
- U-179 ENHANCED CUTANEOUS PENETRATION OF A DERMALLY-APPLIED PHARMACOLOGICALLY ACTIVE AGENT
- U-180 TREATMENT OF ADULT AND PEDIATRIC PATIENTS (OVER SIX MONTHS OF AGE) WITH ADVANCED HIV INFECTION
- U-181 PRODUCING ALPHA ADRENERGIC ANTAGONISTIC ACTION IN A HOST
- U-182 USE OF SALMETEROL IN PATIENTS WITH REVERSIBLE AIRWAY OBSTRUCTION
- U-183 TREATMENT OF CONDITIONS CAUSED BY DISTURBANCE OF NEURONAL 5HT FUNCTION
- U-184 TREATING ALLERGIC EYE DISEASES IN HUMANS
- U-185 METHOD OF TREATING HYPERTENSION
- U-186 METHOD FOR TREATING GI DISORDERS CAUSED BY H. PYLORI WHICH COMPRISES ADMINISTRATION OF RANITIDINE BISMUTH CITRATE AND CLARITHROMYCIN FOR A GREATER THAN ADDITIVE EFFECT
- U-187 THERAPEUTIC TREATMENT OF CALCIFIC TUMORS
- U-188 TREATMENT OF H. PYLORI ASSOCIATED DUODENAL ULCER
- U-189 ENHANCEMENT OF THE BIOAVAILABILITY OF THE DRUG SUBSTANCE
- U-190 USE OF RITONAVIR IN COMBINATION WITH ANY REVERSE TRANSCRIPTASE INHIBITOR
- U-191 METHOD OF TREATMENT FOR CONTROLLING AND LOWERING INTRAOCULAR PRESSURE IN A HUMAN
- U-192 USE IN TREATING ALLERGIC REACTIONS
- U-193 PSORIASIS
- U-194 TREATING AGINA PECTORIS AND HIGH BLOOD PRESSURE
- U-195 METHOD FOR THE DIAGNOSIS OF GASTROINTESTINAL DISORDERS BY UREA ISOTOAC OR NITROGEN LABELED CARBON
- U-196 TREATMENT OF METASTATIC BREAST CANCER IN POSTMENOPAUSAL WOMEN WITH ESTROGEN RECEPTOR POSITIVE TUMORS
- U-198 TREATMENT METASTATIC CARCINOMA OF OVARY AFTER FIRST-LINE FAILURE OR SUBSEQUENT CHEMOTHERAPY, TREATMENT OF BREAST CANCER AFTER FAILURE OF COMBINATION CHEMOTHERAPY FOR METASTATIC DISEASE AND SECOND-LINE TREATMENT OF AIDS-RELATED KAPOSI'S SARCOMA

PREScription AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020059 001	ADENOSINE; ADENOSCAN	5070877	MAY 18, 2009	U-116	NC	OCT 24, 1999
020291 001	ALBUTEROL SULFATE; COMBIVENT	5603918	JUN 09, 2015		NP	AUG 15, 1999
020503 001	ALBUTEROL SULFATE; PROVENTIL-HFA	522183	JUL 06, 2010			
020560 001	ALENDRONATE SODIUM; FOSAMAX	5439470	JUL 06, 2010			
020560 002	ALENDRONATE SODIUM; FOSAMAX	5605674	FEB 25, 2014			
020560 003	ALENDRONATE SODIUM; FOSAMAX					
020221 001	AMIFOSTINE; ETHYOL	5358941	DEC 02, 2012			
>ADD> >ADD>	ANAGRELIDE HYDROCHLORIDE; AGGRYLIN	4621077	NOV 04, 2003	U-114	NS	
020333 001	ANAGRELIDE HYDROCHLORIDE; AGGRYLIN	5591731	JUL 31, 2012	I-187	APR 25,	2000
020333 002	ANAGRELIDE HYDROCHLORIDE; AGGRYLIN					
020227 002	ARDEPARIN SODIUM; NORMIFLO	4681893	MAY 30, 2006			
020702 001	ATORVASTATIN CALCIUM; LIPITOR	5273995	DEC 28, 2010	U-161	ODE	MAR 14, 2004
020702 002	ATORVASTATIN CALCIUM; LIPITOR	5365929	MAY 04, 2014	U-162	NCE	MAR 14, 2004
020702 003	ATORVASTATIN CALCIUM; LIPITOR	4681893	MAY 30, 2006	U-161	NCE	MAR 14, 2004
		5273995	DEC 28, 2010	U-162	NCE	MAR 14, 2004
		5385929	DEC 28, 2010	U-162	NCE	MAR 14, 2004
		5385929	MAY 04, 2014	U-161	NCE	MAR 14, 2004
		4681893	MAY 30, 2006	U-161	NCE	MAR 14, 2004
		5273995	DEC 28, 2010	U-162	NCE	MAR 14, 2004
		5385929	MAY 04, 2014	U-161	NCE	MAR 14, 2004
020486 001	BECLOMETHASONE DIPROPIONATE; VANCERIL DOUBLE STRENGTH	4397839	JUL 01, 2005			
020032 001	BERACTAN; SURVANTA	5635172	JUN 03, 2014	U-191	NC	DEC 24, 1999
020619 001	BETAXOLOL HYDROCHLORIDE; BETOPTIC PILO				NP	APR 17, 2000
020490 001	BRIMONIDINE TARTRATE; ALPHAGAN				NP	MAR 13, 2000
>ADD>	BROMfenac Sodium; Duract	4907583	MAR 13, 2002			
020535 002	BUDESONIDE; PULMICORT	4524769	JUN 25, 2002			
020441 002	BUDESONIDE; PULMICORT	4668218	APR 11, 2006			
020441 003	BUDESONIDE; PULMICORT	4907583	MAR 13, 2002			
018644 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4524769	JUN 25, 2002			
018644 003	BUPROPION HYDROCHLORIDE; WELLBUTRIN	4668218	APR 11, 2006			
020711 002	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
020711 003	BUPROPION HYDROCHLORIDE; ZYBAN	5358970	AUG 12, 2013			
		5427798	AUG 12, 2013			
		RE33994	AUG 18, 2004			
		5358970	AUG 12, 2013			
		5427798	AUG 12, 2013			
		RE33994	AUG 18, 2004			

PREScription AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020524 001	BUTENAFINE HYDROCHLORIDE;MENTAX	5021458	JUN 04, 2008	U-177	NP	FEB 07, 2000
019881 001	BUTOCONAZOLE NITRATE;FEMSTAT ONE	4078071	MAR 07, 1997		NCE	DEC 23, 2001
020664 001	CABERGOLINE;DOSTINEX	4526892	JUL 02, 2002		D-33	MAR 20, 2000
020273 001	CALCIOPOTRIENE;DOVONEX	4866048	DEC 29, 2007		NCE	DEC 29, 1998
020554 001	CALCIOPOTRIENE;DOVONEX	4866048	SEP 12, 2006		NDF	MAR 03, 2000
020611 001	CALCIOPOTRIENE;DOVONEX				NCE	DEC 29, 1998
>ADD>						
019880 001	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	U-175	I-194	MAY 29, 2000
019880 002	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	U-175	I-194	MAY 29, 2000
019880 003	CARBOPLATIN;PARAPLATIN	4657927	APR 14, 2004	U-175	I-194	MAY 29, 2000
>ADD>						
020297 001	CARVED ILOL;COREG				NCE	JUN 26, 2002
020297 002	CARVED ILOL;COREG				NCE	JUN 26, 2002
020297 003	CARVED ILOL;COREG				NCE	JUN 26, 2002
>ADD>						
020297 004	CARVED ILOL;COREG				NCE	JUN 26, 2002
020740 001	CERIVASTATIN SODIUM;BAYCOL				NCE	JUN 26, 2002
020740 002	CERIVASTATIN SODIUM;BAYCOL				NCE	JUN 26, 2002
020740 003	CERIVASTATIN SODIUM;BAYCOL				NCE	JUN 26, 2002
020740 004	CERIVASTATIN SODIUM;BAYCOL				NCE	JUN 26, 2002
019835 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007		I-188	JUL 21, 2000
019835 002	CETIRIZINE HYDROCHLORIDE;ZTREC	4525358	JUN 25, 2007		NDF	JUN 03, 2000
020346 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC	4525358	JUN 25, 2007		I-188	JUL 21, 2000
020519 001	CICLOPIROX;LOPROX	5286754	FEB 15, 2011			
019537 001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO	4670444	DEC 09, 2003	U-36		
>ADD>						
019537 002	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-188	JUN 03, 2000
019537 003	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-188	JUN 03, 2000
019537 004	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-188	JUN 03, 2000
019847 001	CIPROFLOXACIN;CIPRO	4705789	NOV 10, 2004		I-179	OCT 21, 1999
019857 001	CIPROFLOXACIN;CIPRO IN DEXTROSE 5%	4808583	FEB 28, 2006		I-179	OCT 21, 1999
019858 001	CIPROFLOXACIN;CIPRO IN SODIUM CHLORIDE 0.9%	4705789	NOV 10, 2004		I-179	OCT 21, 1999
017533 001	CLONAZEPAM;KLOONOPIN				I-184	APR 09, 2000
017533 002	CLONAZEPAM;KLOONOPIN				I-184	APR 09, 2000
017533 003	CLONAZEPAM;KLOONOPIN				I-184	APR 09, 2000
017533 005	CLONAZEPAM;KLOONOPIN				I-184	APR 09, 2000
017533 006	CLONAZEPAN;KLOONOPIN				I-184	APR 09, 2000
020463 001	CROMOLYN SODIUM-NASALCROM	5164377	OCT 03, 2010		NP	JAN 03, 2000
020430 001	DANAPAROID SODIUM;ORGAN	5563142	OCT 08, 2013		NCE	APR 04, 2002
020705 001	DELAVIRDINE MESTYLATE;RESCRIPTOR	5500413	JUN 29, 2013			
017922 001	DESMOPRESSIN ACETATE;DDAVP	5500413	JUN 29, 2013			
>ADD>						
>ADD>	DESMOPRESSIN ACETATE;DDAVP	5500413	JUN 29, 2013			
>ADD>	DESMOPRESSIN ACETATE;DDAVP	5442931	JUN 29, 2013			
>ADD>	DESMOPRESSIN ACETATE;DDAVP	5500413	JUN 29, 2013			
>ADD>	DESMOPRESSIN ACETATE;DDAVP	5500413	JUN 29, 2013			
>ADD>	DESMOPRESSIN ACETATE;DDAVP	5500413	JUN 29, 2013			
>ADD>	DESMOPRESSIN ACETATE;DDAVP	5462740	OCT 31, 2012			
>ADD>	DIAZEPAM;DIASTAT				NDF	JUL 29, 2000
>ADD>					ODE	JUL 29, 2004

PREScription AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>						
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020648 002	DIAZEPAM;DIASTAT	5462740	OCT 31, 2012	NDF	JUL 29,	2000
020648 003	DIAZEPAM;DIASTAT	5462740	OCT 31, 2012	ODE	JUL 29,	2004
020648 004	DIAZEPAM;DIASTAT	5462740	OCT 31, 2012	NDF	JUL 29,	2000
020648 005	DIAZEPAM;DIASTAT	5462740	OCT 31, 2012	ODE	JUL 29,	2004
020037 001	DICLOFENAC SODIUM;VOLTAREN	4960799	OCT 03, 2007	NDF	JUL 29,	2000
020154 002	DIDANOSINE;VIDEX	4829088	APR 14, 2007	U-180		
020154 003	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
020154 004	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
020154 005	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
020155 003	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
020155 004	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
020155 005	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
020156 001	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
018723 001	DIVALPROEX SODIUM;DEPAKOTE	4988731	JAN 29, 2008	NP	JUN 20,	1999
018723 002	DIVALPROEX SODIUM;DEPAKOTE	4472380	SEP 18, 2001	NP	JUN 20,	1999
018723 003	DIVALPROEX SODIUM;DEPAKOTE	4374829	DEC 30, 2001	NP	JUN 20,	1999
019680 001	DIVALPROEX SODIUM;DEPAKOTE	4703038	OCT 07, 2005	U-3	1-192	MAY 06, 2000
020668 001	ENALAPRIL MALEATE;LEXCEL	4335139	JUN 15, 1999	NP	JUN 20,	1999
>ADD>						
020164 001	ENOKAPARIN SODIUM;LOVENOX	4539333	SEP 03, 2002	NP	JUN 20,	1999
020444 001	EPOPROSTENOL SODIUM;FLOLAN	4883812	MAY 12, 2006	U-185		
020444 002	EPOPROSTENOL SODIUM;FLOLAN	4338325	JUL 06, 1999	NP	JUN 20,	1999
020417 001	ESTRADIOL;FEMPATCH	4338325	SEP 03, 2002	NP	JUN 20,	1999
020683 001	ETHINYL ESTRADIOL;ALESE	4338325	JUL 06, 1999	NP	JUN 20,	1999
020683 002	ETHINYL ESTRADIOL;ALESE	4338325	JUL 06, 1999	NP	JUN 20,	1999
019697 001	ETHINYL ESTRADIOL;ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
019697 002	ETHINYL ESTRADIOL;ORTHO TRI-CYCLEN	4544554	SEP 26, 2003	U-66	I-177	DEC 31, 1999
018922 005	ETODCLACLODINE	RE35524	AUG 04, 2007	NP	JUN 28,	1999
020457 001	ETOPOSIDE PHOSPHATE;ETOPHOS	4906463	MAR 06, 2008	NP		
020457 001	ETOPOSIDE PHOSPHATE;ETOPHOS	5006342	APR 09, 2008	NP		
020410 001	FERUMOXSTAT;GASTROMARK	5219554	JUN 15, 2010	NCE	DEC 06,	2001
>ADD>						
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4770183 SEP 13, 2005 U-169

PREScription AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

PREScription AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
> <u>ADD</u> >	020011 001	LEUPROLIDE ACETATE;LUPRON DEPOT	5643607 5631020 5631021 4954298 5480656	JUL 01, 2014 MAY 20, 2014 MAY 20, 2014 NOV 01, 2004 JAN 02, 2013			
> <u>ADD</u> >	020517 001	LEUPROLIDE ACETATE;LUPRON DEPOT	5643607 5631020 5631021 4954298 4677191	JUL 01, 2014 MAY 20, 2014 MAY 20, 2014 JUL 01, 2014			
> <u>ADD</u> > > <u>ADD</u> >	020517 002	LEUPROLIDE ACETATE;LUPRON DEPOT -4	5643607 4728721 4849228	JUL 03, 2005 MAY 01, 2006 JUL 18, 2006			
> <u>ADD</u> >	020263 002	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5631020 5631021 4652411 5476663 5480656	MAY 20, 2014 MAY 20, 2014 NOV 01, 2004 APR 17, 2007 JAN 02, 2013			
> <u>ADD</u> >	020263 003	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5575987 4917893 4954298 5330767 5643607 5480656	NOV 19, 2013 NOV 01, 2004 NOV 01, 2004 NOV 01, 2004 JUL 01, 2014 JAN 02, 2013			
> <u>ADD</u> >	020263 004	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5631020 5631021 4954298 5643607 5480656 5631020	MAY 20, 2014 MAY 20, 2014 NOV 01, 2004 JUL 01, 2014 JAN 02, 2013 MAY 20, 2014			
> <u>ADD</u> >	020263 005	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5631021 4954298 5643607 5480656 5631020 5631021	MAY 20, 2014 NOV 01, 2004 JUL 01, 2014 JAN 02, 2013 MAY 20, 2014 MAY 20, 2014			
> <u>ADD</u> >	020263 006	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	4954298 5643607 5480656 5631020 5631021	NOV 01, 2004 JUL 01, 2014 JAN 02, 2013 MAY 20, 2014 MAY 20, 2014			
> <u>ADD</u> >	020580 001	LIPASE;COTAZYM	4954298	NOV 01, 2004	NP	DEC 09, 1999	

PREScription AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

API/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>						
020606 001	LOPERAMIDE HYDROCHLORIDE; IMODIUM ADVANCED	5248505	JUL 28, 2010	NC	JUN 26, 2000	
>ADD>	LORATADINE; CLARITIN	5612054	SEP 28, 2010	U-142	APR 12, 1998	
020641 001	LORATADINE; CLARITIN REDITABS	4659716	APR 21, 2004	U-77		
020704 001		4282233	JUN 19, 2002			
>ADD>	METFORMIN HYDROCHLORIDE; GLUCOPHAGE	4659716	APR 21, 2004	U-142	NC	
020357 001	METFORMIN HYDROCHLORIDE; GLUCOPHAGE	4808605	NOV 10, 2007	U-194	NC	MAR 03, 2000
020357 002	MIBEFRADIL DIHYDROCHLORIDE; POSICOR	4808605	NOV 10, 2007	U-194	NC	MAR 03, 2000
020689 001	MIBEFRADIL DIHYDROCHLORIDE; POSICOR	2222222	SEP 05, 1997			JUN 20, 2002
020689 002	MITOXANTRONE HYDROCHLORIDE; NOVANTRONE	5637320	JUN 10, 2014			
>ADD>	NAPROXEN SODIUM; NAPRELAN	5637320	JUN 10, 2014			
019297 001	NAPROXEN SODIUM; NAPRELAN	5637320	JUN 10, 2014			
020353 001	NAPROXEN SODIUM; NAPRELAN	5637320	JUN 10, 2014			
020353 002	NAPROXEN SODIUM; NAPRELAN	5637320	JUN 10, 2014			
020353 003	NAPROXEN SODIUM; NAPRELAN	5637320	JUN 10, 2014			
019660 001	NEDOCROMIL SODIUM; TILADE	5484926	OCT 07, 2013	U-183	MAR 06, 2000	
020778 001	NEFINAVIR MESYLATE; VIRACEPT	5684926	OCT 07, 2013	NC	MAR 14, 2002	
020779 001	NEFINAVIR MESYLATE; VIRACEPT	5366972	NOV 22, 2011	U-167	NC	MAR 14, 2002
020636 001	NEVRAPINE; VIRAMUNE					JUN 21, 2001
>ADD>	NIACIN; NIASPAN					
020381 001	NIACIN; NIASPAN					
>ADD>	NIACIN; NIASPAN					
020381 002	NIACIN; NIASPAN					
>ADD>	NIACIN; NIASPAN					
020381 003	NIACIN; NIASPAN					
>ADD>	NIACIN; NIASPAN					
020381 004	NIACIN; NIASPAN					
>ADD>	NIACIN; NIASPAN TITRATION STARTER PAC					
020714 001	NICOTINE; NICOTROL	5605897	FEB 25, 2014	U-176		
020592 001	OLANZAPINE; ZYPREXA	5605897	FEB 25, 2014	U-176		
020592 002	OLANZAPINE; ZYPREXA	5605897	FEB 25, 2014	U-176		
020592 003	OLANZAPINE; ZYPREXA	5605897	FEB 25, 2014	U-176		
020592 004	OLANZAPINE; ZYPREXA	4871865	OCT 03, 2006	U-174		
020688 001	OLOPATADINE HYDROCHLORIDE; PATANOL	4923892	MAY 08, 2007			
019810 001	OMEPRAZOLE; PRILOSEC	5116863	MAY 26, 2009			
019810 003	OMEPRAZOLE; PRILOSEC	5641805	JUN 24, 2014	U-184		
020605 001	ONDANSETRON HYDROCHLORIDE; ZOFTRAN	4636499	MAY 30, 2005			
>ADD>	PACLITAXEL; TAXOL	5093342	FEB 02, 2010	U-166		
020262 001	PAROXETINE HYDROCHLORIDE; PAXIL	5599794	FEB 04, 2014	U-166		
020031 001	PAROXETINE HYDROCHLORIDE; PAXIL	5629305	FEB 04, 2014	U-188		
020031 002	PAROXETINE HYDROCHLORIDE; PAXIL	4753789	JUN 24, 2006	U-44		
020031 003	PAROXETINE HYDROCHLORIDE; PAXIL	4695578	JUN 25, 2005	U-183		
020031 004	PAROXETINE HYDROCHLORIDE; PAXIL	5578628	JUN 24, 2006	U-44		
>ADD>	5641803	AUG 03, 2012	U-198			
020262 001	PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12	I-150	MAY 07, 1999
020031 002	PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12	I-150	MAY 07, 1999
020031 003	PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12	I-150	MAY 07, 1999
020031 004	PAROXETINE HYDROCHLORIDE; PAXIL	4721723	DEC 29, 2006	U-12	I-150	MAY 07, 1999

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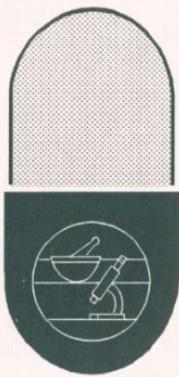
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PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020579 001	TAMSULOSIN HYDROCHLORIDE; FLOMAX	4868216 4731478 4703063 4772475 5089509 5089509	SEP 19, 2006 OCT 27, 2004 OCT 27, 2004 FEB 27, 2006 FEB 18, 2009 FEB 18, 2009	U-181	NCE	APR 15, 2002
>ADD> >ADD> >ADD> 020600 001 020600 002 019785 003 019057 001	TAZAROTENE; TAZORAC TAZAROTENE; TAZORAC TECHNETIUM TC-99M SESTAMIBI KIT; MIRALUMA TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207 5294615 5504207 5294615	APR 29, 2013 APR 29, 2013 APR 29, 2013 APR 29, 2013	U-165 U-3	NCE NCE JUN 13, 2002 JUN 13, 2002	MAY 23, 2000
019057 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207 5294615	APR 29, 2013 APR 29, 2013	U-165 U-3		
019057 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207 5294615	APR 29, 2013 APR 29, 2013	U-165 U-3		
019057 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5504207 5294615	APR 29, 2013 APR 29, 2013	U-165 U-3		
020347 001	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
020347 002	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
020347 003	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
020347 004	TERAZOSIN HYDROCHLORIDE; HYTRIN	5294615	APR 29, 2013	U-165		
020192 001 020707 001	TERBINAFINE HYDROCHLORIDE; LAMISIL TILDURONATE DISODIUM; SKELID	4876248 4980171	OCT 24, 2006 APR 06, 2009	U-178	JAN 21, 2000 MAR 07, 2002	
020676 001 020497 001	TIOCONAZOLE; VAGISTAT-1 TOREMIFENE CITRATE; FARESTON	46696949	SEP 29, 2004	U-196	NP NCE ODE	FEB 29, 2000 MAY 29, 2002 MAY 29, 2004
020404 003	TRETINOIN; AVITA	4971800 5043317 4690825	NOV 20, 2007 SEP 03, 2008 OCT 04, 2005	U-178 U-179 U-134		
>ADD>	TRETINOIN; RETIN-A MICRO TRIMETHOPRIM HYDROCHLORIDE; PRIMSOL TRIME TREXATE GLUCURONATE; NEUTREXIN TROGLITAZONE; PRELAY	4376858 4572912 5104888 5478852 5457109 5602133 4572912 5104888 5479852 5457109 5602133	MAY 09, 2004 AUG 28, 2004 AUG 28, 2004 SEP 15, <td>NP I-189 NCE</td> <td>FEB 07, 2000 JUN 17, 2000 JAN 29, 2002</td>	NP I-189 NCE	FEB 07, 2000 JUN 17, 2000 JAN 29, 2002	
020719 002	TROGLITAZONE; PRELAY	5104888 5479852 5457109 5602133	AUG 28, <td>U-163 U-164 U-173</td> <td></td> <td></td>	U-163 U-164 U-173		

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PATENT AND EXCLUSIVITY DATA**

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020720 001	TROGLITAZONE;REZULIN	5457109 5602133 5478852 4572912 5104888	SEP 15, SEP 15, SEP 15, AUG 28, AUG 28,	2013 2013 2013 2004 2004	U-164 U-173 U-163 U-173 U-173	JAN 29, 2002
020720 002	TROGLITAZONE;REZULIN	5602133 4572912 5104888 5478852 5457109	AUG 28, AUG 28, AUG 28, SEP 15, SEP 15,	2013 2004 2004 2013 2013	U-173 U-173 U-163 U-164 U-164	JAN 29, 2002
>>ADD>	UREA C-14;PYTEST	4830010	MAY 15,	2006	U-195	MAY 09, 2002
>>ADD>	UREA C-14;PYTEST KIT	4830010	MAY 15,	2006	U-195	MAY 09, 2002
020665 001	VALSARTAN;DIOVAN	5399578	MAR 21,	2012	U-3	
020665 002	VALSARTAN;DIOVAN	5399578	MAR 21,	2012	U-3	
020547 001	ZAFIRLUKAST;ACCOLATE	5612367	MAR 18,	2014	U-189	
		5583152	AUG 22,	2006		
		4873259	FEB 10,	2007	U-168	
020471 001	ZILEUTON;ZYFLO	4873259	FEB 10,	2007	U-168	
020471 003	ZILEUTON;ZYFLO				NP	JAN 28, 2000
020458 001	ZINC ACETATE;GALZIN				ODE	JAN 28, 2004
020458 002	ZINC ACETATE;GALZIN				NP	JAN 28, 2000

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