

CUMULATIVE  
SUPPLEMENT 4  
JAN'97-APR'97

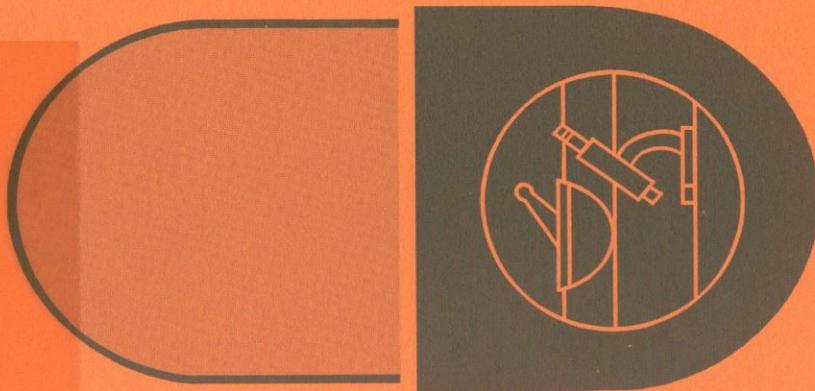
# APPROVED DRUG PRODUCTS

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



RM  
301.45  
.A66  
1997  
Apr  
Suppl

RM301.45 .A66 1997 Apr Suppi

Approved drug products with  
therapeutic equivalence

C:355661 M:174736 O:12937927

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

1.0

1.1

1.2

1.3

1.4

1.5

1.6

2.0

2.1

2.2

2.3

2.4

2.5

PATE

ADD 1 4 1997

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

Cumulative Supplement 4

APRIL 1997

CONTENTS

Library Use Only

	<i>PAGE</i>
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 .....	22
2.3 Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research List .....	24
2.4 Orphan Product Designations and Approvals List.....	25
2.5 Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution .....	29
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Exclusivity Terms .....	30
B. Patent and Exclusivity Lists.....	32

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS

17TH EDITION

CUMULATIVE SUPPLEMENT 4  
APRIL 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. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

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

Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision. [Strength(s) which already exist in the List will not be repeated for context.]

The 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 16th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 17th 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*, 16th 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 [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)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

CIBA GEIGY CORP  
(CIBA GEIGY)

NOVARTIS PHARMACEUTICAL CORP  
(NOVARTIS)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

CIBA GEIGY CORP PHARMACEUTICALS DIV  
(CIBA GEIGY)

NOVARTIS PHARMACEUTICAL CORP  
(NOVARTIS)

CIBA PHARMACEUTICAL CO  
DIV CIBA GEIGY CORP  
(CIBA)

NOVARTIS PHARMACEUTICAL 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 PHARMACEUTICAL CORP  
(NOVARTIS)

SANDOZ CONSUMER HEALTH  
CARE GROUP DIV SANDOZ PHARMACEUTICALS  
(SANDOZ)

NOVARTIS CONSUMER HEALTH INC  
(NOVARTIS)

SANDOZ PHARMACEUTICALS  
CORP DIV SANDOZ INC  
(SANDOZ)

NOVARTIS PHARMACEUTICAL CORP  
(NOVARTIS)

SANDOZ RESEARCH INSTITUTE INC  
(SANDOZ)

NOVARTIS PHARMACEUTICAL 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 acyclovir (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; 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.

The Prescription Drug Products and OTC Drug Product files will be available on a monthly basis in the near future.

## 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

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

<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 will no longer be included in the Multisource Drug Products total count, but will be included in the total count of the Drug Products Listed.

PRESCRIPTION DRUG PRODUCT LIST  
17TH EDITION  
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 4 / JAN '97 - APR '97

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL  
BUTALBITAL, ACETAMINOPHEN, CAFFEINE  
 GRAHAM DM 325MG; 50MG; 40MG  
 N88743 001  
 JUL 18, 1985  
 N88765 001  
 MAR 27, 1985  
 N89067 001  
 APR 19, 1985  
 N88743 001  
 JUL 18, 1985  
 N88765 001  
 MAR 27, 1985  
 N89067 001  
 APR 19, 1985

N17914 001  
N17914 001

2%; 0.05%  
2%; 0.05%

SOLUTION/DROPS; OTC  
 TRIDESILON  
 BAYER  
 ©

ACYCLOVIR

CAPSULE; ORAL  
ACYCLOVIR  
 AESGEN 200MG  
 N74833 001  
 APR 22, 1997  
ESI LEDERLE  
 N74872 001  
 APR 22, 1997  
LEK PHARM  
 N74750 001  
 APR 22, 1997  
LEMMON  
 N74828 001  
 APR 22, 1997  
MYLAN  
 N74727 001  
 APR 22, 1997  
NOVOPHARM  
 N74578 001  
 APR 22, 1997  
ROXANE  
 N74570 002  
 APR 22, 1997  
ZENITH GOLDLINE  
 N74674 001  
 APR 22, 1997  
ZOVIRAX  
 N18828 001  
 + GLAXO WELLCOME  
 JAN 25, 1985

SUSPENSION; ORAL  
ACYCLOVIR  
 ALPHARMA 200MG/5ML  
 N74738 001  
 APR 28, 1997

ZOVIRAX  
 + GLAXO WELLCOME 200MG/5ML  
 N19909 001  
 DEC 22, 1989

TABLET; ORAL

ACYCLOVIR  
 ESI LEDERLE 400MG  
 N74834 001  
 APR 24, 1997  
ESI LEDERLE  
 N74834 002  
 APR 24, 1997  
LEK PHARM  
 N74658 001  
 APR 22, 1997

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL  
HYDROCODONE BITARTRATE AND ACETAMINOPHEN  
 EON 500MG; 5MG  
 N40149 001  
 JAN 27, 1997  
 N40149 002  
 JAN 27, 1997  
 N40144 002  
 APR 25, 1997  
 N40155 001  
 APR 14, 1997  
 N40148 002  
 FEB 14, 1997

LORTAB

+ GRAHAM DM 500MG; 10MG  
 N40100 001  
 JAN 26, 1996  
 NORCO  
 + WATSON LABS 325MG; 10MG  
 N40148 001  
 FEB 14, 1997

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

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



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

INJECTABLE; INJECTION  
 AMINOSYN II 5% W/ ELECTROLYTES IN DEXTROSE 25% W/ CALCIUM  
 IN PLASTIC CONTAINER  
 @ ABBOTT  
 5%; 36.8MG/100ML; 25GM/100ML;  
 51MG/100ML; 22.4MG/100ML; 261MG/100ML;  
 205MG/100ML  
 N19683 004  
 NOV 07, 1988

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

INJECTABLE; INJECTION  
 CLINIMIX E 2.75/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 2.75%; 33MG/100ML; 10GM/100ML;  
 51MG/100ML; 261MG/100ML; 217MG/100ML;  
 112MG/100ML  
 N20678 002  
 MAR 26, 1997

CLINIMIX E 2.75/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 2.75%; 33MG/100ML; 25GM/100ML;  
 51MG/100ML; 261MG/100ML; 217MG/100ML;  
 112MG/100ML  
 N20678 005  
 MAR 26, 1997

CLINIMIX E 2.75/5 SULFITE-FREE W/ ELECT IN DEXTROSE 5% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 2.75%; 33MG/100ML; 5GM/100ML;  
 51MG/100ML; 261MG/100ML; 217MG/100ML;  
 112MG/100ML  
 N20678 001  
 MAR 26, 1997

CLINIMIX E 4.25/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 4.25%; 33MG/100ML; 10GM/100ML;  
 51MG/100ML; 261MG/100ML; 297MG/100ML;  
 77MG/100ML  
 N20678 009  
 MAR 26, 1997

CLINIMIX E 4.25/20 SULFITE-FREE W/ ELECT IN DEXTROSE 20% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 4.25%; 33MG/100ML; 20GM/100ML;  
 51MG/100ML; 261MG/100ML; 297MG/100ML;  
 77MG/100ML  
 N20678 011  
 MAR 26, 1997

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

INJECTABLE; INJECTION  
 CLINIMIX E 4.25/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 4.25%; 33MG/100ML; 25GM/100ML;  
 51MG/100ML; 261MG/100ML; 297MG/100ML;  
 77MG/100ML  
 N20678 012  
 MAR 26, 1997

CLINIMIX E 4.25/5 SULFITE-FREE W/ ELECT IN DEXTROSE 5% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 4.25%; 33MG/100ML; 5GM/100ML;  
 51MG/100ML; 261MG/100ML; 297MG/100ML;  
 77MG/100ML  
 N20678 008  
 MAR 26, 1997

CLINIMIX E 5/10 SULFITE-FREE W/ ELECT IN DEXTROSE 10% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 5%; 33MG/100ML; 10GM/100ML; 51MG/100ML;  
 261MG/100ML; 340MG/100ML;  
 59MG/100ML  
 N20678 016  
 MAR 26, 1997

CLINIMIX E 5/15 SULFITE-FREE W/ ELECT IN DEXTROSE 15% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 5%; 33MG/100ML; 15GM/100ML; 51MG/100ML;  
 261MG/100ML; 340MG/100ML;  
 59MG/100ML  
 N20678 017  
 MAR 26, 1997

CLINIMIX E 5/20 SULFITE-FREE W/ ELECT IN 20% DEXTROSE W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 5%; 33MG/100ML; 20GM/100ML; 51MG/100ML;  
 261MG/100ML; 340MG/100ML;  
 59MG/100ML  
 N20678 018  
 MAR 26, 1997

CLINIMIX E 5/25 SULFITE-FREE W/ ELECT IN DEXTROSE 25% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 5%; 33MG/100ML; 25GM/100ML; 51MG/100ML;  
 261MG/100ML; 340MG/100ML;  
 59MG/100ML  
 N20678 019  
 MAR 26, 1997

CLINIMIX E 5/35 SULFITE FREE W/ ELECT IN DEXTROSE 35% W/  
 CALCIUM IN PLASTIC CONTAINER  
 + BAXTER HLTHCARE  
 5%; 33MG/100ML; 35GM/100ML; 51MG/100ML;  
 261MG/100ML; 340MG/100ML;  
 59MG/100ML  
 N20678 021  
 MAR 26, 1997



RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 4 / JAN '97 - APR '97

ATRACURIUM BESYLATE  
 INJECTABLE; INJECTION  
ATRACURIUM BESYLATE PRESERVATIVE FREE  
 OHMEDA 10MG/ML  
 AP N74768 001 EQ 0.25% BASE; 1.75% N20619 001  
 JAN 23, 1997 APR 17, 1997

TRACRIUM  
 \* GLAXO WELLCOME 10MG/ML  
 AP N18831 001  
 NOV 23, 1983

AP N18831 002  
 JUN 20, 1985

TRACRIUM PRESERVATIVE FREE  
 \* GLAXO WELLCOME 10MG/ML  
 AP N18831 001  
 NOV 23, 1983

ATROPINE SULFATE, DIPHENOXYLATE HYDROCHLORIDE  
 TABLET; ORAL  
DIPHENOXYLATE HCL AND ATROPINE SULFATE  
 ROXANE 0.025MG; 2.5MG  
 @ 0.025MG; 2.5MG  
DIPHENOXYLATE HCL W/ ATROPINE SULFATE  
 KV PHARM 0.025MG; 2.5MG  
 @ 0.025MG; 2.5MG

AZITHROMYCIN DIHYDRATE  
 INJECTABLE; INJECTION  
 ZITHROMAX  
 + PFIZER EQ 500MG BASE/VIAL N50733 001  
 JAN 30, 1997

BETAXOLOL HYDROCHLORIDE; PILOCARPINE HYDROCHLORIDE  
 SUSPENSION/DROPS; OPHTHALMIC  
 BETOPTIC PILO  
 + ALCON EQ 0.25% BASE; 1.75% N20619 001  
 APR 17, 1997

BRETYLIUM TOSYLATE  
 INJECTABLE; INJECTION  
BRETYLIUM TOSYLATE IN DEXTROSE 5% IN PLASTIC CONTAINER  
 AP \* EAFTER HEALTHCARE 200MG/100ML N19837 002  
 APR 12, 1989  
 AP N19837 001  
 APR 12, 1989  
 @ 400MG/100ML N19837 002  
 APR 12, 1989  
 @ 400MG/100ML N19837 001  
 APR 12, 1989

BRIMONIDINE TARTRATE  
 SOLUTION/DROPS; OPHTHALMIC  
 ALPHAGAN  
 + ALLERGAN 0.5% N20490 001  
 MAR 13, 1997

BUTOCONAZOLE NITRATE  
 CREAM; VAGINAL  
 FEMSTAT ONE  
 + SYNTEX 2% N19881 001  
 FEB 07, 1997

BACITRACIN ZINC, HYDROCORTISONE, NEOMYCIN SULFATE, POLYMYXIN B SULFATE  
 OINTMENT; TOPICAL  
 CORTISPORIN  
 \* GLAXO WELLCOME  
 + MONARCH PHARMS  
 400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; N50168 002  
 5,000 UNITS/GM MAY 04, 1984  
 400 UNITS/GM; 1%; EQ 3.5MG BASE/GM; N50168 002  
 5,000 UNITS/GM MAY 04, 1984

BUTORPHANOL TARTRATE  
 INJECTABLE; INJECTION  
BUTORPHANOL TARTRATE PRESERVATIVE FREE  
 AP ABBOTT 1MG/ML N74620 001  
 JAN 22, 1997  
 AP 1MG/ML N74626 001  
 JAN 23, 1997  
 AP 2MG/ML N74620 002  
 JAN 22, 1997

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

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

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION  
BUTORPHANOL TARTRATE PRESERVATIVE FREE

<u>AP</u>	ABBOTT	2MG/ML	N74626 002	JAN 23, 1997	<u>AB</u>	EPITOL LEMMON	200MG	N70541 001	SEP 17, 1986
<u>AP</u>	STADOL	2MG/ML	N17857 004		<u>AB</u>	TEVA	200MG	N70541 001	SEP 17, 1986
<u>AP</u>	+ APOTHECON	2MG/ML	N17857 001		<u>AB</u>	TEVA	100MG	N73524 001	JUL 29, 1992
<u>AP</u>	+ APOTHECON	1MG/ML	N17857 002		<u>AB</u>	LEMMON	100MG	N73524 001	JUL 29, 1992
<u>AP</u>	+ APOTHECON	2MG/ML			<u>AB</u>	TEVA	100MG		

CALCIOTRIENE

SOLUTION; TOPICAL  
 DOVONEX  
 + BRISTOL MYERS SQUIBB 0.005%

			N20611 001	MAR 03, 1997					
--	--	--	------------	--------------	--	--	--	--	--

CAPTOPRIL

TABLET; ORAL

<u>AB</u>	CAPTOTEN	25MG	N18343 002		<u>AB</u>	LEMMON	10MG; 100MG	N73618 001	AUG 28, 1992
<u>AB</u>	+ BRISTOL MYERS SQUIBB	25MG	N18343 002		<u>AB</u>	LEMMON	25MG; 100MG	N73589 001	AUG 28, 1992
<u>AB</u>	PUREPAC PHARM	12.5MG	N74640 001	MAR 31, 1997	<u>AB</u>	TEVA	25MG; 250MG	N73607 001	AUG 28, 1992
<u>AB</u>		25MG	N74640 002	MAR 31, 1997	<u>AB</u>	TEVA	10MG; 100MG	N73618 001	AUG 28, 1992
<u>AB</u>		50MG	N74640 003	MAR 31, 1997	<u>AB</u>	TEVA	25MG; 100MG	N73589 001	AUG 28, 1992
<u>AB</u>		100MG	N74640 004	MAR 31, 1997	<u>AB</u>	TEVA	25MG; 250MG	N73607 001	AUG 28, 1992
<u>AB</u>	WOCKHARDT	12.5MG	N74532 001	MAR 28, 1997					
<u>AB</u>		25MG	N74532 002	MAR 28, 1997					
<u>AB</u>		50MG	N74532 003	MAR 28, 1997					
<u>AB</u>		100MG	N74532 004	MAR 28, 1997					

CARBAMAZEPINE

TABLET; ORAL

<u>AB</u>	ABBOTT				<u>AB</u>	EPITOL LEMMON	200MG	N70541 001	SEP 17, 1986
<u>AB</u>	STADOL				<u>AB</u>	TEVA	200MG	N70541 001	SEP 17, 1986
<u>AB</u>	+ APOTHECON				<u>AB</u>	TEVA	100MG	N73524 001	JUL 29, 1992
<u>AB</u>	+ APOTHECON				<u>AB</u>	LEMMON	100MG	N73524 001	JUL 29, 1992
<u>AB</u>	+ APOTHECON				<u>AB</u>	TEVA	100MG		

CARBIDOPOA; LEVODOPA

TABLET; ORAL

<u>AB</u>	ABBOTT				<u>AB</u>	LEMMON	10MG; 100MG	N73618 001	AUG 28, 1992
<u>AB</u>	STADOL				<u>AB</u>	LEMMON	25MG; 100MG	N73589 001	AUG 28, 1992
<u>AB</u>	+ BRISTOL MYERS SQUIBB	25MG	N18343 002		<u>AB</u>	LEMMON	25MG; 250MG	N73607 001	AUG 28, 1992
<u>AB</u>	PUREPAC PHARM	12.5MG	N74640 001	MAR 31, 1997	<u>AB</u>	TEVA	10MG; 100MG	N73618 001	AUG 28, 1992
<u>AB</u>		25MG	N74640 002	MAR 31, 1997	<u>AB</u>	TEVA	25MG; 100MG	N73589 001	AUG 28, 1992
<u>AB</u>		50MG	N74640 003	MAR 31, 1997	<u>AB</u>	TEVA	25MG; 250MG	N73607 001	AUG 28, 1992
<u>AB</u>		100MG	N74640 004	MAR 31, 1997					

CARISOPRODOL

TABLET; ORAL

<u>AA</u>	AMIDE PHARM						350MG	N40188 001	MAR 07, 1997
-----------	-------------	--	--	--	--	--	-------	------------	--------------

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

<u>AP</u>	LEMMON						EQ 250MG BASE/VIAL	N63016 001	MAR 14, 1989
-----------	--------	--	--	--	--	--	--------------------	------------	--------------

CEFAZOLIN SODIUM

INJECTABLE; INJECTION  
CEFAZOLIN SODIUM  
 LEMMON

<u>AP</u>	<u>EQ 500MG BASE/VIAL</u>	N63016 002	<u>AT</u>	<u>CHLORHEXIDINE GLUCONATE</u>	N74522 001
		MAR 14, 1989		SOLUTION; DENTAL	DEC 15, 1995
<u>AP</u>	<u>EQ 1GM BASE/VIAL</u>	N63016 003		<u>CHLORHEXIDINE GLUCONATE</u>	N74522 001
		MAR 14, 1989		LEMMON	DEC 15, 1995
<u>AP</u>	<u>EQ 5GM BASE/VIAL</u>	N63018 001			
		MAR 05, 1990			
<u>AP</u>	<u>EQ 10GM BASE/VIAL</u>	N63018 002			
		MAR 05, 1990			
<u>AP</u>	<u>EQ 250MG BASE/VIAL</u>	N63016 001			
		MAR 14, 1989			
<u>AP</u>	<u>EQ 500MG BASE/VIAL</u>	N63016 002			
		MAR 14, 1989			
<u>AP</u>	<u>EQ 1GM BASE/VIAL</u>	N63016 003			
		MAR 14, 1989			
<u>AP</u>	<u>EQ 5GM BASE/VIAL</u>	N63018 001			
		MAR 05, 1990			
<u>AP</u>	<u>EQ 10GM BASE/VIAL</u>	N63018 002			
		MAR 05, 1990			

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL  
CHLORHEXIDINE GLUCONATE  
 LEMMON

N74522 001  
 DEC 15, 1995  
 N74522 001  
 DEC 15, 1995

CHLOROPROCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
NESACAIN-MPF  
 ASTRA

N09435 003  
 N09435 006  
 MAY 02, 1996  
 N09435 004  
 N09435 007  
 MAY 02, 1996  
 N09435 003  
 N09435 004

CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC  
OPHTHCORT  
 + PARKE DAVIS

	10MG/GM; 5MG/GM;	N50201 002	<u>AA</u>	<u>CHLORPHENIRAMINE MALEATE</u>	N87164 001
	10,000 UNITS/GM				N87164 001
	10MG/GM; 5MG/GM;				
	10,000 UNITS/GM				

TABLET; ORAL  
CHLORPHENIRAMINE MALEATE  
 KY PHARM

N87164 001  
 N87164 001

CHLORAMPHENICOL PALMITATE

SUSPENSION; ORAL  
CHLOROMYCETIN PALMITATE  
 PARKE DAVIS

	EQ 150MG BASE/5ML	N62301 001			
	EQ 150MG BASE/5ML	N62301 001			

50MG

N88651 001  
 MAY 30, 1985  
 N88651 001  
 MAY 30, 1985

CHLORDIAZEPOXIDE

TABLET; ORAL  
 LIBERTABES  
 ROCHE

	10MG	N85481 001			
	10MG	N85481 001			

25MG

N88051 001  
 NOV 12, 1982  
 N19574 001  
 DEC 20, 1988  
 N19574 002  
 FEB 12, 1992  
 N19574 001  
 DEC 20, 1988

> DLT >  
 > ADD >

> DLT >  
 > ADD >

CHLORTHALIDONE

TABLET; ORAL  
THALITONE  
@ MONARCH PHARMS

25MG

N88051 001  
NOV 12, 1982

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION  
CIMETIDINE HCL

AP

EQ 300MG BASE/2ML

N74296 001  
MAR 28, 1997  
N74412 001  
MAR 28, 1997

AP

EQ 300MG BASE/2ML

CHLORZOXAZONE

TABLET; ORAL  
CHLORZOXAZONE  
LEMMON

500MG

N89859 001  
MAY 04, 1988  
N89859 001  
MAY 04, 1988

AA

EQ 300MG BASE/5ML

SOLUTION; ORAL  
CIMETIDINE HCL  
PHARM ASSOC

AA

EQ 300MG BASE/5ML

N74553 001  
JAN 27, 1997

500MG

MAY 04, 1988

AA

EQ 300MG BASE/5ML

CLEMASTINE FUMARATE

CIMETIDINE

TABLET; ORAL  
CIMETIDINE  
LEMMON

200MG

N74365 001  
FEB 28, 1995

AA

EQ 0.5MG BASE/5ML

N73399 001  
JUN 30, 1994

300MG

N74365 002  
FEB 28, 1995

AA

EQ 0.5MG BASE/5ML

N73399 001  
JUN 30, 1994

400MG

N74365 003  
FEB 28, 1995

AB

2.68MG

N73283 001  
JAN 31, 1992

800MG

N74365 004  
FEB 28, 1995

AB

1.34MG

N73282 001  
JAN 31, 1992

200MG

N74568 001  
FEB 27, 1997

AB

2.68MG

N73283 001  
JAN 31, 1992

300MG

N74568 002  
FEB 27, 1997

AB

1.34MG

N73282 001  
JAN 31, 1992

400MG

N74568 003  
FEB 27, 1997

AB

1.34MG

N73282 001  
JAN 31, 1992

800MG

N74566 001  
FEB 27, 1997

AB

1.34MG

N73282 001  
JAN 31, 1992

200MG

N74365 001  
FEB 28, 1995

AB

2.68MG

N73283 001  
JAN 31, 1992

300MG

N74365 002  
FEB 28, 1995

AB

1.34MG

N73282 001  
JAN 31, 1992

400MG

N74365 003  
FEB 28, 1995

AB

1.34MG

N73282 001  
JAN 31, 1992

800MG

N74365 004  
FEB 28, 1995

AB

1.34MG

N73282 001  
JAN 31, 1992

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

EQ 150MG BASE/ML

N62795 001  
DEC 21, 1987

EQ 150MG BASE/ML

N62795 001  
DEC 21, 1987

SOLUTION; TOPICAL  
CLINDAMYCIN PHOSPHATE  
LEMMON

AT

EQ 1% BASE

N62930 001  
JUN 28, 1989



CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION

CYCLOPHOSPHAMIDE

ELKINS SINN

200MG/VIAL

N88372 001

JUL 03, 1986

500MG/VIAL

N88373 001

JUL 03, 1986

1GM/VIAL

N88374 001

SEP 24, 1986

AB

CAPSULE; ORAL

DICYCLIMINE HCL

WEST WARD

10MG

N40204 001

FEB 28, 1997

DIETHYLSTILBESTROL

> DLT >

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

> DLT >

> DLT >

> ADD >

TABLET; ORAL

DIETHYLSTILBESTROL

LILLY

1MG

5MG

1MG

5MG

0.5MG

0.5MG

N04041 004

N04041 005

N04041 004

N04041 005

N83004 001

N83004 001

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

CERUBIDINE

RHONE POULENC RORER

EQ 20MG BASE/VIAL

EQ 20MG BASE/VIAL

EQ 20MG BASE/VIAL

EQ 20MG BASE/VIAL

N61876 001

N61876 001

N50484 001

N50484 001

> DLT >

> DLT >

> ADD >

> DLT >

> DLT >

> ADD >

DAUNORUBICIN HCL

BEDFORD

EQ 20MG BASE/VIAL

EQ 20MG BASE/VIAL

EQ 20MG BASE/VIAL

N64103 001

FEB 03, 1995

N64103 001

FEB 03, 1995

AP

INJECTABLE; INJECTION

DIMENHYDRINATE

ELKINS SINN

50MG/ML

50MG/ML

N84767 001

N84767 001

DELAVIRDINE MESYLATE

TABLET; ORAL

RESRIPTOR

+ PHARMACIA AND UPJOHN 100MG

N20705 001

APR 04, 1997

DOXAZOSIN MESYLATE

TABLET; ORAL

CARDURA

PFIZER

EQ 1MG BASE

EQ 8MG BASE

EQ 1MG BASE

EQ 8MG BASE

N19668 001

NOV 02, 1990

N19668 004

NOV 02, 1990

N19668 001

NOV 02, 1990

N19668 004

NOV 02, 1990

DEXAMETHASONE SODIUM PHOSPHATE

CREAM; TOPICAL

DECADRON

+ MERCK SHARP DOHME

EQ 0.1% PHOSPHATE

EQ 0.1% PHOSPHATE

EQ 0.1% PHOSPHATE

EQ 0.1% PHOSPHATE

N11983 002

N11983 002

DEXTHROXYXINE SODIUM

TABLET; ORAL

CHOLOXIN

KNOLL PHARM

1MG

1MG

N12302 005

N12302 005

ECONAZOLE NITRATE

CREAM; TOPICAL

SPECTAZOLE

+ J AND J

1%

N18751 001

DEC 23, 1982

ECONAZOLE NITRATE

CREAM; TOPICAL  
SPECTAZOLE  
\* JOHNSON RW

1%

N18751 001  
DEC 23, 1982

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

N74513 001  
MAR 14, 1986  
N74513 001  
MAR 14, 1996

ERYTHROMYCIN

SOLUTION; TOPICAL  
ERYTHROMYCIN  
AT STIEFEL

2%

N64127 001  
FEB 14, 1997

ETOPOSIDE

INJECTABLE; INJECTION

ETOPOSIDE  
IMMUNEX  
\* PFIZER  
AP SUPERGEN

20MG/ML  
20MG/ML

N74513 001  
MAR 14, 1986  
N74513 001  
MAR 14, 1996

FLUCONAZOLE

INJECTABLE; INJECTION

DIFLUCAN  
\* PFIZER

200MG/100ML

N19950 001  
JAN 29, 1990

DIFLUCAN IN DEXTROSE 5% IN PLASTIC CONTAINER  
+ PFIZER

200MG/100ML

N19950 003  
SEP 29, 1992  
N19950 005  
JUL 08, 1994

TABLET; ORAL-21  
ALESSE  
+ WYETH AYERST

0.02MG;0.1MG

N20683 001  
MAR 27, 1997

TABLET; ORAL-28  
ALESSE  
WYETH AYERST

0.02MG;0.1MG

N20683 002  
MAR 27, 1997

ETODOLAC

TABLET; ORAL  
ETODOLAC  
EON

400MG

N74903 001  
APR 11, 1997

> ADD >  
> ADD >

AB INVAMED

400MG

N74846 001  
FEB 28, 1997

> ADD >  
> ADD >

AB PUREPAC PHARM

400MG

N74819 001  
FEB 28, 1997

> ADD >  
> ADD >

AB ROYCE LABS

400MG

N74892 001  
APR 16, 1997

> ADD >  
> ADD >

AB ZENITH GOLDLINE

400MG

N74883 001  
FEB 28, 1997

> ADD >  
> ADD >

LODINE

AB WYETH AYERST

400MG

N18922 004  
JUL 29, 1993

> ADD >  
> ADD >

FLURBIPROFEN

TABLET; ORAL

FLURBIPROFEN  
SIDMAK LABS NJ

50MG

N74647 001  
APR 01, 1997

> ADD >  
> ADD >

AB

100MG

N74647 002  
APR 01, 1997

GLIPIZIDE

TABLET; ORAL

GLIPIZIDE  
SIDMAK LABS NJ

5MG

N74619 001  
APR 04, 1997

> ADD >  
> ADD >

AB

10MG

N74619 002  
APR 04, 1997

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL  
GRIFULVIN V  
J AND J

125MG/5ML  
125MG/5ML

N62483 001  
JAN 26, 1984  
N62483 001  
JAN 26, 1984

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

HYDROCORTISONE

CREAM; TOPICAL  
PROCTOCORT  
SOLVAY

1%

N83011 001

HYDROCORTISONE; UREA

CREAM; TOPICAL  
ALPHADERM  
@ BIOGLAN  
@ VIIVAN

1%; 10%  
1%; 10%

N86008 001  
N86008 001

GUANFACINE HYDROCHLORIDE

TABLET; ORAL  
GUANFACINE HCL  
AMIDE PHARM

EQ 1MG BASE  
EQ 2MG BASE  
EQ 1MG BASE  
EQ 2MG BASE

N74673 001  
FEB 28, 1997  
N74673 002  
FEB 28, 1997  
N74796 001  
JAN 27, 1997  
N74796 002  
JAN 27, 1997

> ADD >  
> DLT >

HEPARIN SODIUM

INJECTABLE; INJECTION  
HEP FLUSH KIT IN PLASTIC CONTAINER  
FUJISAWA

10 UNITS/ML  
100 UNITS/ML  
10 UNITS/ML  
100 UNITS/ML

N17029 017  
DEC 05, 1985  
N17029 018  
DEC 05, 1985  
N17029 017  
DEC 05, 1985  
N17029 018  
DEC 05, 1985

AP

AP

HEPARIN SODIUM  
FUJISAWA  
STERIS

20,000 UNITS/ML  
1,000 UNITS/ML  
1,000 UNITS/ML

N17029 004  
N17064 002  
N17064 002

AB

AB

AB

AB

10MG  
25MG  
50MG  
100MG

N87819 001  
JUN 23, 1982  
N87820 001  
JUN 23, 1982  
N87821 001  
JUN 23, 1982  
N87822 001  
JUN 23, 1982  
N87819 001  
JUN 23, 1982  
N87820 001  
JUN 23, 1982  
N87821 001  
JUN 23, 1982

HYDROCORTISONE

CREAM; TOPICAL  
DERMACORT  
MONARCH PHARMS  
SOLVAY  
PROCTOCORT  
MONARCH PHARMS

1%  
1%  
1%

N83011 002  
N83011 002  
N83011 001

@

@

@

10MG  
25MG  
50MG

N87819 001  
JUN 23, 1982  
N87820 001  
JUN 23, 1982  
N87821 001  
JUN 23, 1982  
N87822 001  
JUN 23, 1982

> ADD >  
> DLT >

> ADD >

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL  
HYDROXYZINE HCL  
@ KV PHARM

100MG

N87822 001  
JUN 23, 1982

N74679 001  
APR 02, 1997

HYDROXYZINE PAMOATE

CAPSULE; ORAL  
HY-PAM  
EON

EQ 25MG HCL

N87479 001

N74638 001  
APR 30, 1997

AB  
HYDROXYZINE PAMOATE  
EON

EQ 25MG HCL

N87479 001

N74637 001  
APR 03, 1997

IDARUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION  
IDAMYCIN PFS  
+ PHARMACIA AND UPJOHN

1MG/ML

N50734 001  
FEB 17, 1997

N18735 007  
JUL 06, 1992  
N20327 002  
OCT 12, 1994

IOPAMIDOL

INJECTABLE; INJECTION

IOPAMIDOL-250  
FUJISAWA

51%

N74679 001  
APR 02, 1997

IOPAMIDOL-300  
ABBOTT

61%

N74638 001  
APR 30, 1997

IOPAMIDOL-300  
FUJISAWA

51%

N74679 002  
APR 02, 1997

IOPAMIDOL-300 IN PLASTIC CONTAINER  
ABBOTT

51%

N74637 001  
APR 03, 1997

IOPAMIDOL-370  
FUJISAWA

76%

N74679 003  
APR 02, 1997

ISOVUE-250  
+ BRACCO

51%

N18735 007  
JUL 06, 1992

AP +

51%

N20327 002  
OCT 12, 1994

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ATROVENT

AN + BOEHRINGER INGELHEIM 0.02%

N20228 001  
SEP 29, 1993

AN DEY

0.02%

N74755 001  
JAN 10, 1997

IMIQUIMOD

CREAM; TOPICAL  
ALDARA  
+ 3M

5%

N20723 001  
FEB 27, 1997

INDAPAMIDE

TABLET; ORAL  
INDAPAMIDE  
MYLAN

1.25MG

N74461 002  
MAR 26, 1997

1.25MG

N74665 001  
APR 04, 1997

2.5MG

N74665 002  
APR 04, 1997

AB  
AB  
AB

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

ISONIAZID

SYRUP; ORAL

ISONIAZID  
CAROLINA MEDCL

50MG/5ML

N88235 001  
NOV 10, 1983

AA +

50MG/5ML

N88235 001  
NOV 10, 1983

LANIAZID  
LANNETT

50MG/5ML

N89243 001  
FEB 03, 1986

AA @

50MG/5ML

N89243 001  
FEB 03, 1986

ITRACONAZOLE

SOLUTION; ORAL  
SPORANOX  
+ JANSSEN

10MG/ML

N20657 001  
FEB 21, 1997

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

MECLIZINE HYDROCHLORIDE

TABLET; ORAL  
MECLIZINE HCL  
KV PHARM

12.5MG  
25MG  
12.5MG  
25MG  
12.5MG  
25MG

N85524 001  
N85523 001  
N85524 001  
N85523 001  
N40179 001  
JAN 30, 1997  
N40179 002  
JAN 30, 1997

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION  
LEUCOVORIN CALCIUM  
PHARMACHEMIE

EQ 50MG BASE/VIAL  
EQ 100MG BASE/VIAL

N89628 001  
APR 17, 1997  
N89915 001  
APR 17, 1997

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

TABLET; ORAL  
LEUCOVORIN CALCIUM  
PHARMACHEMIE

EQ 5MG BASE  
EQ 25MG BASE

N73099 001  
MAR 28, 1997  
N73101 001  
MAR 28, 1997

LEUPROLIDE ACETATE

INJECTABLE; INJECTION  
LUPRON DEPOT-3  
+ TAP HOLDINGS

11.25MG/VIAL

N20708 001  
MAR 07, 1997

LITHIUM CARBONATE

TABLET, EXTENDED RELEASE; ORAL  
LITHOBID  
SOLVAY  
+

300MG  
300MG

N18027 001  
N18027 001

LORAZEPAM

SOLUTION; ORAL  
LORAZEPAM  
+ ROXANE

0.5MG/5ML

N74648 001  
MAR 18, 1997

INJECTABLE; INJECTION

AB \* HUMEGON  
AB \* ORGANOON

75 IU/VIAL; 75 IU/VIAL  
75 IU/VIAL; 75 IU/VIAL  
150 IU/VIAL; 150 IU/VIAL  
150 IU/VIAL; 150 IU/VIAL

N20328 001  
SEP 01, 1994  
N20328 001  
SEP 01, 1994  
N20328 002  
SEP 01, 1994  
N20328 002  
SEP 01, 1994

AB REPRONAL  
AB FERRING

75 IU/VIAL; 75 IU/VIAL  
150 IU/VIAL; 150 IU/VIAL

N73598 001  
JAN 30, 1997  
N73599 001  
JAN 30, 1997

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL  
MEPERIDINE HCL  
ROXANE

50MG  
100MG

N40110 001  
MAR 12, 1997  
N40110 002  
MAR 12, 1997

METAPROTERENOL SULFATE

AA SYRUP; ORAL  
AA JVL  
METAPROTERENOL SULFATE

10MG/5ML

N74702 001  
MAR 24, 1997

METAPROTERENOL SULFATE

SYRUP; ORAL  
METAPROTERENOL SULFATE  
 1.0MG/5ML  
 @  
 MORTON GROVE  
 1.0MG/5ML

N71656 001  
 OCT 13, 1987  
 N71656 001  
 OCT 13, 1987

N71990 001  
 JAN 18, 1989

EQ 5MG BASE/ML

METFORMIN HYDROCHLORIDE

TABLET; ORAL  
 GLUCOPHAGE  
 BRISTOL MYERS SQUIBB 500MG  
 \* 850MG  
 500MG  
 + 850MG

N20357 001  
 DEC 29, 1994  
 N20357 002  
 DEC 29, 1994  
 N20357 001  
 MAR 03, 1995  
 N20357 002  
 MAR 03, 1995

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

0.5MG  
 0.5MG

METHACHOLINE CHLORIDE

POWDER FOR RECONSTITUTION; INHALATION  
 PROVOCHOLINE  
 METHAPHARM 100MG/VIAL  
 ROCHE 100MG/VIAL

N19193 001  
 OCT 31, 1986  
 N19193 001  
 OCT 31, 1986

N20208 001  
 AUG 17, 1992  
 N20208 001  
 AUG 17, 1992

0.75%  
 0.75%

METHOTREXATE SODIUM

INJECTABLE; INJECTION  
MEXATE-AQ PRESERVED  
 BRISTOL MYERS EQ 25MG BASE/ML  
 @ BRISTOL MYERS SQUIBB EQ 25MG BASE/ML

N89887 001  
 APR 14, 1989  
 N89887 001  
 APR 14, 1989

N74711 001  
 FEB 26, 1997  
 N74711 002  
 FEB 26, 1997  
 N74711 003  
 FEB 26, 1997

150MG  
 200MG  
 250MG

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION  
METOCLOPRAMIDE HCL  
 FAULDING EQ 5MG BASE/ML

N71990 001  
 JAN 18, 1989

N17739 001

2%

METOCLOPRAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION  
METOCLOPRAMIDE HCL  
 @ FAULDING EQ 5MG BASE/ML

TABLET; ORAL  
METOCLOPRAMIDE HCL  
 AB MUTUAL PHARM EQ 5MG BASE

N71536 002  
 JAN 16, 1997

METOLAZONE

TABLET; ORAL  
 MYKROX  
 MEDEVA

0.5MG

METRONIDAZOLE

GEL; VAGINAL  
 METROGEL-VAGINAL  
 + 3M 0.75%  
 \* CURATEK 0.75%

N20208 001  
 AUG 17, 1992  
 N20208 001  
 AUG 17, 1992

0.75%  
 0.75%

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL  
MEXILETINE HCL  
 WATSON LABS

N74711 001  
 FEB 26, 1997  
 N74711 002  
 FEB 26, 1997  
 N74711 003  
 FEB 26, 1997

150MG  
 200MG  
 250MG

MICONAZOLE NITRATE

LOTION; TOPICAL  
 MONISTAT-DERM  
 @ J AND J

N17739 001

2%

MICONAZOLE NITRATE

LOTION; TOPICAL  
MONISTAT-DERM  
© JOHNSON RW

2\*

N17739 001

EQ 250MG BASE

N20779 001  
MAR 14, 1997

MIRTAZAPINE

TABLET; ORAL  
REMERON  
\* ORGANOON

30MG

30MG

45MG

N20415 002  
JUN 14, 1996  
N20415 002  
JUN 14, 1996  
N20415 003  
MAR 17, 1997

NEOMYCIN SULFATE

POWDER; FOR RX COMPOUNDING

NEO-RX  
PHARMA TEK

100%  
100%

NEOMYCIN SULFATE

100%

N61579 001  
N61579 001  
N62385 001  
JUN 01, 1982

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES  
ROYCE LABS  
EQ 0.5MG BASE;  
EQ 50MG BASE

AB

N74736 001  
JAN 21, 1997

EQ 4MG BASE/5ML

N20605 001  
JAN 24, 1997

TALWIN NX

AB + SANOFI WINTHROP

EQ 0.5MG BASE;  
EQ 50MG BASE

N18733 001  
DEC 16, 1982

NEDOCROMIL SODIUM

AEROSOL, METERED; INHALATION

TILADE  
\* FISOONS  
1.75MG/INH  
+ RHONE POULENC RORER 1.75MG/INH

N19660 001  
DEC 30, 1992  
N19660 001  
DEC 30, 1992

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN  
\* PURDUE FREDERICK

10MG

20MG

40MG

+ PURDUE PHARMA

10MG

N20778 001  
MAR 14, 1997

EQ 50MG BASE/SCOOPFUL

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

NELFINAVIR MESYLATE

POWDER FOR RECONSTITUTION; ORAL

VIRACEPT  
+ AGOURON

N74868 001  
FEB 12, 1997



PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION

PROCHLORPERAZINE EDISYLATE

EQ 5MG BASE/ML

EQ 5MG BASE/ML

N89605 001  
JUL 08, 1987  
N89605 001  
JUL 08, 1987

AB

TABLET; ORAL

SELEGILINE HCL

LEMMON

5MG

N74744 001  
JAN 27, 1997

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

PROPANTHELINE BROMIDE

TABLET; ORAL

PROPANTHELINE BROMIDE

15MG

FAR PHARM

N88377 001  
DEC 08, 1983  
N88377 001  
DEC 08, 1983

BP

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

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

40MG

ROXANE

N70518 001  
JUL 07, 1986  
N70518 001  
JUL 07, 1986

AB

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

SAMARIUM SM 153 LEXIDRONAM PENTASODIUM

INJECTABLE; INJECTION

QUADRAMET

CYTOGEN

50mCi/ML

N20570 001  
MAR 28, 1997

AB

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

SELEGILINE HYDROCHLORIDE

CAPSULE; ORAL

ELDEPRYL

+ SOMERSET

5MG

5MG

N20647 001  
MAY 15, 1996  
N20647 001  
MAY 15, 1996

AB

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

TABLET; ORAL

SELEGILINE HCL

APOTHECON

5MG

N74672 001  
APR 01, 1997

AB

> ADD >  
> ADD >

SELEGILINE HYDROCHLORIDE

SODIUM NITROPRUSSIDE

INJECTABLE; INJECTION

NITROPRESS

ABBOTT

50MG/VIAL

50MG/VIAL

N71555 001  
NOV 16, 1987  
N71555 001  
NOV 16, 1987

AP

> ADD >  
> ADD >

SULFAMETHOXAZOLE

SUSPENSION; ORAL

GANTANOL

+ ROCHE

500MG/5ML

500MG/5ML

N13664 002  
N13664 002

AB

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

TAMSULOSIN HYDROCHLORIDE

CAPSULE; ORAL

FLOMAX

+ BOEHRINGER INGELHEIM 0.4MG

N20579 001  
APR 15, 1997

AB

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

TERFENADINE

TABLET; ORAL

SELDANE

+ HOECHST MARION RSSL

60MG

N18949 001  
MAY 08, 1985

AB

> ADD >  
> ADD >

TERFENADINE

BAKER NORTON

60MG

N74475 001  
JAN 03, 1997

AB

> ADD >  
> ADD >

TETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION

ACHROMYCIN

+ LEDERLE

250MG/VIAL

N50273 002

AB

> ADD >  
> ADD >

TETRACYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION

AP > ACHROMYCIN  
 > LEDERLE  
 > +  
 > 500MG/VIAL  
 > 250MG/VIAL  
 > 500MG/VIAL  
 > 250MG/VIAL  
 > 500MG/VIAL  
 > 250MG/VIAL  
 > 500MG/VIAL  
 > 500MG/VIAL

SUSPENSION; ORAL

AB > TETRACYCLINE HCL  
 > ALPHARMA  
 > 125MG/5ML  
 > 125MG/5ML  
 > 125MG/5ML  
 > 125MG/5ML

THALLOUS CHLORIDE, TL-201

INJECTABLE; INJECTION

AP > THALLOUS CHLORIDE TL 201  
 > DUPONT  
 > 1mCi/ML  
 > 1mCi/ML  
 > 1mCi/ML  
 > 1mCi/ML  
 > 1mCi/ML  
 > 1mCi/ML  
 > 1mCi/ML

THEOPHYLLINE

CAPSULE; ORAL

> DLT > THEOPHYLLINE  
 > DLT > KV PHARM  
 > DLT > 100MG  
 > DLT > 200MG  
 > ADD > 100MG  
 > ADD > 200MG

CAPSULE, EXTENDED RELEASE; ORAL

> DLT > SOMOPHYLLIN-CRT  
 > DLT > GRAHAM DM  
 > DLT > 50MG

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

> DLT > SOMOPHYLLIN-CRT  
 > DLT > GRAHAM DM  
 > DLT > 100MG  
 > DLT > 200MG  
 > DLT > 250MG  
 > DLT > 300MG  
 > ADD > 50MG  
 > ADD > 100MG  
 > ADD > 200MG  
 > ADD > 250MG  
 > ADD > 300MG  
 > ADD >

TILDURONATE DISODIUM

TABLET; ORAL

SKELID  
 + SANOFI

EQ 200MG BASE

N20707 001  
 MAR 07, 1997

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

AT > TIMOLOL MALEATE  
 > ADV REMEDIES  
 > EQ 0.25% BASE  
 > EQ 0.5% BASE  
 > EQ 0.25% BASE  
 > EQ 0.5% BASE  
 > EQ 0.25% BASE  
 > EQ 0.5% BASE  
 > EQ 0.25% BASE  
 > EQ 0.5% BASE

N74465 001  
 MAR 25, 1997  
 N74466 001  
 MAR 25, 1997  
 N74515 001  
 MAR 25, 1997  
 N74516 001  
 MAR 25, 1997  
 N74778 001  
 MAR 25, 1997  
 N74776 001  
 MAR 25, 1997  
 N74667 001  
 MAR 25, 1997  
 N74668 001  
 MAR 25, 1997

N85263 001  
 N85263 002  
 N85263 001  
 N85263 002  
 N87763 001  
 FEB 27, 1985

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

TIMOLOL MALEATE  
PACIFIC PHARMA

EQ 0.25% BASE

N74746 001  
MAR 25, 1997

EQ 0.5% BASE

N74747 001  
MAR 25, 1997

AB

CREAM; TOPICAL  
AVITA  
PENEDERM

0.025%

N20404 003  
JAN 14, 1997

AB

RETIN-A  
+ J AND J

0.025%

N19049 001  
SEP 16, 1988

TIOCONAZOLE

ONTIMENT; VAGINAL  
VAGISTAT-1  
\* BRISTOL MYERS

6.5%

N39355 001  
DEC 30, 1986

0.1%

N20475 001  
FEB 07, 1997

TOLMETIN SODIUM

TABLET; ORAL

TOLMETIN SODIUM  
BAKER NORTON

EQ 600MG BASE

N74399 001  
MAR 28, 1996

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

EQ 600MG BASE

N74729 001  
FEB 27, 1997

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

EQ 600MG BASE

N74399 001  
MAR 28, 1996

> ADD >  
> ADD >

ZENITH GOLDLINE

TRIHEXYPHENIDYL HYDROCHLORIDE

N87192 001  
SEP 08, 1982  
N87192 001  
SEP 08, 1982

TOPIRAMATE

TABLET; ORAL

TOPAMAX  
@ JOHNSON RW

400MG

N20505 006  
DEC 24, 1996

> ADD >  
> ADD >

2MG/5ML

N40177 001  
APR 17, 1997

TRAZODONE HYDROCHLORIDE

TABLET; ORAL

TRAZODONE HCL  
LEMMON

150MG

N74357 001  
APR 30, 1997

> ADD >  
> ADD >

200MG

N20719 001  
JAN 29, 1997

400MG

N20719 002  
JAN 29, 1997

200MG

N20720 001  
JAN 29, 1997

400MG

N20720 002  
JAN 29, 1997

VINCRIStINE SULFATE

INJECTABLE; INJECTION

AP \* VINCRESX  
 @ BRISTOL MYERS SQUIBB

5MG/VIAL

5MG/VIAL

N70867 001  
 JUL 12, 1988  
 N70867 001  
 JUL 12, 1988

AP \* VINCRIStINE SULFATE  
 FAULRING

5MG/VIAL

5MG/VIAL

N71561 001  
 APR 11, 1988  
 N71561 001  
 APR 11, 1988

ZINC ACETATE

CAPSULE; ORAL

GALZIN  
LEMMON

EQ 25MG ZINC

EQ 50MG ZINC

N20458 001  
 JAN 28, 1997  
 N20458 002  
 JAN 28, 1997

WARFARIN SODIUM

TABLET; ORAL

COUMADIN  
DUPONT MERCK

AB 1MG

AB 2MG

AB 2.5MG

AB 4MG

AB 5MG

AB 7.5MG

AB 10MG

+ WARFARIN SODIUM  
 BARR

AB 1MG

AB 2MG

AB 2.5MG

AB 4MG

AB 5MG

AB 7.5MG

AB 10MG

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

N40145 001  
 MAR 26, 1997  
 N40145 002  
 MAR 26, 1997  
 N40145 003  
 MAR 26, 1997  
 N40145 004  
 MAR 26, 1997  
 N40145 005  
 MAR 26, 1997  
 N40145 006  
 MAR 26, 1997  
 N40145 007  
 MAR 26, 1997

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL  
 COLD CAPSULE IV  
 \* GRAHAM DM 12MG; 75MG  
 12MG; 75MG  
 @ N18793 001  
 APR 25, 1985  
 N18793 001  
 APR 25, 1985  
 COLD CAPSULE V  
 GRAHAM DM 8MG; 75MG  
 8MG; 75MG  
 @ N18794 001  
 APR 23, 1985  
 N18794 001  
 APR 23, 1985

> DLT >  
 > DLT >  
 > DLT >

INSULIN SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION  
 VELOSULIN HUMAN  
 \* NOVO NORDISK 100 UNITS/ML  
 N19450 001  
 MAY 30, 1986

MICONAZOLE NITRATE

CREAM; VAGINAL  
 MICONAZOLE NITRATE  
 TARO 2%  
 N74444 001  
 JAN 13, 1997

CLEMASTINE FUMARATE

TABLET; ORAL  
 CLEMASTINE FUMARATE  
 LEMMON 1.34MG  
 TEVA 1.34MG  
 N73282 002  
 DEC 03, 1992  
 N73282 002  
 DEC 03, 1992

> ADD >  
 > ADD >

SUPPOSITORY; VAGINAL

MICONAZOLE NITRATE  
 G AND W LABS 100MG  
 + PERRIGO 100MG  
 N74414 001  
 APR 30, 1997  
 N74395 001  
 MAR 20, 1997

CROMOLYN SODIUM

SPRAY, METERED; NASAL  
 NASALCROM  
 + MCNEIL 5.2MG/SPRAY  
 N20463 001  
 JAN 03, 1997

MINOXIDIL

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

IBUPROFEN

TABLET; ORAL  
 JUNIOR STRENGTH MOTRIN  
 MCNEIL 100MG  
 + 100MG  
 N20602 001  
 JUN 10, 1996  
 N20602 001  
 JUN 10, 1996

NAPROXEN SODIUM

TABLET; ORAL  
 NAPROXEN SODIUM  
 INVAMED EQ 200MG BASE  
 NOVOPHARM EQ 200MG BASE  
 PERRIGO EQ 200MG BASE  
 PVT FORM EQ 200MG BASE  
 N74646 001  
 JAN 13, 1997  
 N74635 001  
 JAN 13, 1997  
 N74661 001  
 JAN 13, 1997  
 N74789 001  
 FEB 27, 1997

INSULIN SEMISYNTHETIC PURIFIED HUMAN

INJECTABLE; INJECTION  
 VELOSULIN BR HUMAN  
 + NOVO NORDISK 100 UNITS/ML  
 N19450 001  
 MAY 30, 1986

> ADD >  
 > ADD >  
 > ADD >

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 4/ APR 197

NO APRIL APPROVALS

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

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
8 Cyclopentyl 1,3-dipropylxant hine 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
Anagrelide TN= Agrylin	Treatment of essential thrombocytopenia.	Roberts Pharmaceutical Corp. Meridian Center III 6 Industrial Way West Eatontown, NJ 07724 DD=01/27/1988 MA=03/14/1997
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
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 April 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 extravasation 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
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
Lepirudin TN= Refludan	Treatment of heparin-associated thrombocytopenia Type II.	Behringwerke AG P.O. Box 1140 D-35001 Marburg Germany, DD=02/13/1997

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

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
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 patulous eustachian tube.	Ear Foundation 24209 Castillo Street, Suite 100 Santa Barbara, CA 93105 DD=02/18/1997

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

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
Porfiromycin TN= Promycin	Treatment of cervical cancer.	Vion Pharmaceuticals, Inc. Four Science Park New Haven, CT 06511 DD=03/13/1997
Zinc acetate TN= Galzin	Treatment of Wilson's disease.	Lemmon Company 1510 Delp Drive Kulpsville, PA 19443 DD=11/06/1985 MA=01/28/1997

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

---

NO APRIL 1997 ADDITIONS

## EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE EXCLUSIVITY COLUMN, 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 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

#### *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

#### *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

## EXCLUSIVITY TERMS

## PATENT USE CODE

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

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> >DLT>	ADENOSINE; ADENOSCAN	5070877	MAY 18, 2009	U-116		
	ADENOSINE; ADENOSCAN	5070877	DEC 10, 2008	U-116		
	ALBUTEROL SULFATE; COMBIVENT	5603918	JUN 09, 2015		NC	OCT 24, 1999
	ALBUTEROL SULFATE; PROVENTIL - HFA	5225183	JUL 06, 2010		NP	AUG 15, 1999
		5439670	JUL 06, 2010			
		5605674	FEB 25, 2014			
>ADD> >ADD> >ADD> >ADD>	ALENDRONATE SODIUM; FOSAMAX	5358941	DEC 02, 2012		I-185	APR 25, 2000
	ALENDRONATE SODIUM; FOSAMAX	4621077	NOV 04, 2003	U-114	I-185	APR 25, 2000
					NS	APR 25, 2000
					I-185	APR 25, 2000
	ANAGRELIDE HYDROCHLORIDE; AGRYLIN				ODE	MAR 14, 2004
	ANAGRELIDE HYDROCHLORIDE; AGRYLIN				ODE	MAR 14, 2004
					NCE	MAR 14, 2004
					ODE	MAR 14, 2004
					NCE	MAR 14, 2002
					NCE	DEC 17, 2001
	ATORVASTATIN CALCIUM; LIPITOR	4681893	MAY 30, 2006	U-161		
		5273995	DEC 28, 2010	U-162		
		5385929	MAY 04, 2014	U-59		
		4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
		5273995	DEC 28, 2010	U-162		
		5385929	MAY 04, 2014	U-59		
		4681893	MAY 30, 2006	U-161	NCE	DEC 17, 2001
		5273995	DEC 28, 2010	U-162		
		5385929	MAY 04, 2014	U-59		
	BECLOMETHASONE DIPROPIONATE; VANCERIL DOUBLE STRENGTH	4397839	JUL 01, 2005		NP	DEC 24, 1999
>ADD> >DLT>	BERACTANT; SURVANTA	4397839	AUG 10, 2000			
>ADD>	BETAXOLOL HYDROCHLORIDE; BETOPTIC PILO				NC	APR 17, 2000
	BRIMONIDINE TARTRATE; ALPHAGAN				NP	MAR 13, 2000
					NCE	SEP 06, 2001
	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
>ADD>	BUPROPION HYDROCHLORIDE; WELLBUTRIN	5358970	AUG 12, 2013			
	BUTENAFINE HYDROCHLORIDE; MENTAX	5021458	JUN 04, 2008	U-177		
	BUTOCONAZOLE NITRATE; FEMSTAT ONE	4078071	MAR 07, 1997			
	CABERGOLINE; DOSTINEX	4526892	JUL 02, 2002		NP	FEB 07, 2000
	CALCIPTRIENE; DOVONEX	4866048	SEP 12, 2006		NCE	DEC 23, 2001
	CALCIPTRIENE; DOVONEX				D-33	MAR 20, 2000
	CALCIPTRIENE; DOVONEX				NDF	DEC 29, 1998
		4866048	SEP 12, 2006		NCE	MAR 03, 2000
	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-175		DEC 29, 1998
>ADD> >DLT>	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-32		
>ADD>	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-175		
>DLT>	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-32		
>ADD>	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-175		
>DLT>	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	U-32		
>ADD>	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007			
>DLT>	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			
>ADD>	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007			
>DLT>	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2002			







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
020347 004	TERAZOSIN HYDROCHLORIDE;HYTRIN	5294615	APR 29, 2013	U-165 U-3		
020192 001	TERBINAFINE HYDROCHLORIDE;LAMISIL	4876248	OCT 24, 2006		I-180	JAN 21, 2000
020707 001	TILUDRONATE DISODIUM;SKELID	4980171	APR 06, 2009		NCE	MAR 07, 2002
020676 001	TIOCONAZOLE;VAGISTAT-1	4971800	NOV 20, 2007	U-178	NP	FEB 11, 2000
020404 003	TRETINOIN;AVITA	5045317	SEP 03, 2008	U-179		
020475 001	TRETINOIN;RETIN-A MICRO	4690825	OCT 04, 2005	U-134		
020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	4376858	MAY 09, 2004		NP	FEB 07, 2000
020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	4376858	OCT 31, 2000			
020719 001	TROGLITAZONE;PRELAY	5478852	SEP 15, 2013	U-163	NCE	JAN 29, 2002
		5457109	SEP 15, 2013	U-164		
		4572912	AUG 28, 2004			
		5104888	AUG 28, 2004			
020719 002	TROGLITAZONE;PRELAY	5602133	SEP 15, 2013	U-173		
		5478852	SEP 15, 2013	U-163	NCE	JAN 29, 2002
		5457109	SEP 15, 2013	U-164		
		4572912	AUG 28, 2004			
		5104888	AUG 28, 2004			
020720 001	TROGLITAZONE;REZULIN	5602133	SEP 15, 2013	U-173		
		5478852	SEP 15, 2013	U-163	NCE	JAN 29, 2002
		5457109	SEP 15, 2013	U-164		
		4572912	AUG 28, 2004			
		5104888	AUG 28, 2004			
020720 002	TROGLITAZONE;REZULIN	5602133	SEP 15, 2013	U-173		
		5478852	SEP 15, 2013	U-163	NCE	JAN 29, 2002
		5457109	SEP 15, 2013	U-164		
		4572912	AUG 28, 2004			
		5104888	AUG 28, 2004			
020665 001	VALSARTAN;DIOVAN	5602133	SEP 15, 2013	U-173		
020665 002	VALSARTAN;DIOVAN	5399578	SEP 15, 2013	U-3		
020471 001	ZILEUTON;ZYFLO	5399578	MAR 21, 2012	U-3		
020471 003	ZILEUTON;ZYFLO	4873259	FEB 10, 2007	U-168		
020458 001	ZINC ACETATE;GALZIN	4873259	FEB 10, 2007	U-168		
020458 002	ZINC ACETATE;GALZIN				NP	JAN 28, 2000
					ODE	JAN 28, 2004
					NP	JAN 28, 2000
					ODE	JAN 28, 2004



**Library Use Only**

ST. LOUIS COLLEGE OF PHARMACY



3 2201 90036 5624

RM301.45 .A66 1997 Apr Suppl

Approved drug products with  
therapeutic equivalence

C:355661 M:174736 O:12937927

Library Use Only