

CUMULATIVE  
SUPPLEMENT 8  
JAN'93-AUG'93

# APPROVED DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

13<sup>TH</sup> EDITION

ST. LOUIS COLLEGE OF PHARMACY LIBRARY  
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

Rm  
300  
.A66  
1993  
Aug  
Suppl

RM301.45 .A66 1993 Aug Suppl

Approved drug products with  
therapeutic equivalence

C:355661 M:174736 O:12937927

1.0 INT  
1.1  
1.2  
1.3  
1.4  
1.5

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

2.1 DF  
2.2  
2.3  
2.4  
2.5  
2.6  
2.7

PATENT

APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

Cumulative Supplement 8

AUGUST 1993

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APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS

13TH EDITION

CUMULATIVE SUPPLEMENT 8

AUGUST 1993

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, 13th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.)

Additions new 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.

Deletions new 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 containing overstruck print. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The overstruck print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements for this edition. However, the overstruck print in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements.

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 13th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 14th Edition.

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

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

<u>Products</u>	<u>Federal Register Reference</u>
Nitroglycerin (capsule, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (film, extended release; transdermal*)	JUL 15, 1993 (58 FR 38129)
Nitroglycerin (tablet, controlled release;oral)	SEP 07, 1984 (49 FR 35428)
Nitroglycerin (tablet, controlled release;buccal)	JUL 05, 1985 (50 FR 27688)

\*The Federal Register of July 15, 1993 (58 FR 38129) announced that the FDA was revoking the temporary exemption for nitroglycerin in a transdermal delivery system. Marketing of a drug product that is the subject of a conditionally approved ANDA may continue by meeting the requirements listed in the Federal Register. Firms wishing to submit a new ANDA before a drug product is approved (NDA or ANDA) and appears in the List should submit a 505(b)(2) application following the directions contained in the Federal Register. Nitro-Dur has been selected as the reference listed drug. The preamble to the final rule (57 FR 17958) states if there are multiple NDA's, the reference listed drug generally will be the market leader. This is the basis upon which Nitro-Dur was selected. In addition, the preamble states that, in multiple NDA situations, a product not designated as the reference listed drug and not shown to be bioequivalent to the reference listed drug may be shielded from generic competition. This is the case with Summit's Transderm-Nitro. The Office of Generic Drugs (OGD) has been requested to have a second listed drug as provided for in the Final Rule. OGD has granted this request. Therefore, at the time that Schering's and Summit's supplements are fully approved and their products are entered into the List, we will have two reference listed drugs for the nitroglycerin transdermal systems. Firms may, therefore, elect to conduct bioequivalence studies against either of these products. It is conceivable that a non-referenced listed drug may be fully approved and appear in the List; in this case, the Agency's referenced listed drug will not change and a 505(b)(2) application will be appropriate until the reference listed drugs are fully approved. Once they are fully approved, a 505(j) application will be the appropriate mechanism for an ANDA submission.

### 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; or when an applicant name is changed to meet internal publication standards. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial approved product lines are transferred between applicants, each approved product involved will appear as an applicant name change in the Cumulative Supplement.

#### APPLICANT NAME CHANGES

##### FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)

##### NEW APPLICANT NAME (NEW ABBREVIATED NAME)

AH ROBINS CO  
(ROBINS)

AH ROBINS CO  
(ROBINS AH)

ASTRA PHARMACEUTICAL PRODUCTS INC  
(ASTRA)

ASTRA USA INC  
(ASTRA)

BAKER CUMMINS PHARMACEUTICALS INC  
(BAKER CUMMINS)

BAKER NORTON PHARMACEUTICALS INC  
(BAKER NORTON)

BENEDICT NUCLEAR PHARMACEUTICALS INC  
(BENEDICT)

NORTH AMERICAN CHEMICAL CORPORATION  
(NORTH AM CHEM)

BOLAR PHARMACEUTICAL CO INC  
(BOLAR)

CIRCA PHARMACEUTICALS INC  
(CIRCA)

CIS US INC  
(CIS)

CIS US INC  
(CIS US)

CUTTER BIOLOGICAL DIV  
MILES LABORATORIES INC  
(CUTTER)

MILES LABORATORIES INC  
(MILES LABS)

DANBURY PHARMACAL INC  
(DANBURY)

DANBURY PHARMACAL INC  
(DANBURY PHARMA)

FUJISAWA PHARMACEUTICAL CO  
(FUJISAWA)

FUJISAWA USA INC  
(FUJISAWA)

HERBERT LABORATORIES DIV  
SMITH KLINE AND FRENCH CO  
(HERBERT)

ALLERGAN HERBERT DIV ALLERGAN INC  
(ALLERGAN HERBERT)

APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

ICI PHARMACEUTICALS GROUP  
DIV ICI AMERICAS  
(ICI)

ZENECA PHARMACEUTICALS GROUP  
(ZENECA)

LYPHOMED DIV FUJISAWA USA INC  
(LYPHOMED)

FUJISAWA USA INC  
(FUJISAWA)

ROXANE LABORATORIES INC  
(ROXANE)

ROXANE LABORATORIES INC  
(ROXANE LABS)

RW JOHNSON PHARMACEUTICAL RESEARCH  
INSTITUTE DIV MCNEILAB  
(JOHNSON RW)

RW JOHNSON PHARMACEUTICAL RESEARCH  
INSTITUTE DIV ORTHO PHARMACEUTICAL  
CORP  
(JOHNSON RW)

SCHIAPPARELLI SEARLE  
(SCHIAPPARELLI SEARLE)

SCS PHARMACEUTICALS  
(SCS PHARMS)

SOMERSET PHARMACEUTICALS INC  
(SOMERSET)

SOMERSET PHARMACEUTICALS INC  
(SOMERSET PHARMS)

STERLING DRUG INC  
(STERLING)

STERLING WINTHROP INC  
(STERLING WINTHROP)

1.4 USP MONOGRAPH TITLE ADDITIONS OR CHANGES

The U.S. Pharmacopeia (USP) periodically makes additions to or changes in monograph titles. Some of these additions or changes may affect dosage form terms listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (ADP). Instead of making the change in each affected product, the Cumulative Supplement (CS) will list applicable monograph title and dosage form additions or changes in this section. These will appear as soon as the modified USP monograph title is official. It is possible for these additions or changes to be listed in this section before all applicant holders have made labeling modifications.

The monograph title additions or changes shown below will remain in this section in each succeeding supplement of this edition. Once the next edition of the ADP is published, the products affected by the title additions or changes will be displayed with the new dosage form in the appropriate drug list. As notification to the reader, these monograph title additions or changes will also be listed in a special section of the ADP.

USP MONOGRAPH TITLE ADDITIONS OR CHANGES

FORMER USP MONOGRAPH TITLE  
(FORMER ADP DOSAGE FORM; ROUTE)

NEW USP MONOGRAPH TITLE  
(NEW ADP DOSAGE FORM; ROUTE)

THERE WERE NO USP MONOGRAPH TITLE ADDITIONS OR CHANGES DURING THE MONTH OF AUGUST 1993.

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 1992) 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 1992</u>	<u>MAR 1993</u>	<u>JUN 1993</u>	<u>SEP 1993</u>
DRUG PRODUCTS LISTED	9488	9392	9194	2119 (23.0%)
SINGLE SOURCE	2245 (23.7%)	2243 (23.9%)	7075 (77.7%)	7149 (76.1%)
MULTISOURCE	7243 (76.3%)	7149 (76.1%)	6357 (69.1%)	6432 (68.5%)
THERAPEUTICALLY EQUIVALENT	6516 (68.6%)	562 (5.9%)	555 (6.1%)	577 (6.1%)
NOT THERAPEUTICALLY EQUIVALENT	577 (6.1%)	155 (1.7%)	163 (1.8%)	150 (1.6%)
EXCEPTIONS <sup>1</sup>	—	3	2	—
NEW MOLECULAR ENTITIES APPROVED	477	484	508	—
NUMBER OF APPLICANTS				x

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

## PRESCRIPTION DRUG PRODUCT LIST

13TH EDITION CUMULATIVE SUPPLEMENT NUMBER 8 / JAN '93 - AUG '93

ACETAMINOPHEN; BUTALBITAL; CAFFEINEACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL <u>AMOQUAN</u> /AA/ /HALSTAD/	/345MG; 50MG; 40MG/ 325MG; 50MG; 40MG	/N87628 001 N87628 001 OCT 01, 1986	>DLT> >DLT> >DLT> >ADD> >ADD>	/N87628/661/ /N87628/1986/ /N87628/001 /AA/	/BANDAS HN/ /BOEHRINGER MANNHEIM 500MG; 5MG 500MG; 5MG a FOREST PHARMS	/500MG; 5MG/ /500MG; 5MG a FOREST PHARMS	/500MG; 5MG/ /500MG; 5MG a FOREST PHARMS	/N87628/661/ /N87628/1986/ /N87628/001 /AA/
--	--	---	---	--	--	--	--	--

## TABLET; ORAL

ESTETICFOREST PHARMS

a FOREST PHARMS

325MG; 50MG; 40MG

DEC 23, 1988

N89660 001

/PFC/2.7./1988/

/N89660/661/

/N89660/1988/

/N89660/001/

/N89660/1986/









AMERICAN SOUTHWEST

AMERICAN SODIUM

**AMETOTOL INJECTION**

INJECTABLE; INJECTION	
<u>AMPCILLIN SODIUM</u>	
AP	HANFORD
AP	EQ 125MG BASE/VIAL
AP	EQ 250MG BASE/VIAL
AP	EQ 500MG BASE/VIAL
AP	EQ 500MG BASE/VIAL
AP	EQ 1GM BASE/VIAL
AP	EQ 1GM BASE/VIAL
AP	EQ 2GM BASE/VIAL
AP	EQ 2GM BASE/VIAL
AP	EQ 10GM BASE/VIAL
AP	EQ 125MG BASE/VIAL
AP	EQ 2GM BASE/VITAL
AP	/EQ 500MG BASE/VITAL/
AP	/EQ 1GM BASE/VITAL/
AP	/EQ 2GM BASE/VITAL/
AP	EQ 500MG BASE/VIAL
AP	EQ 1GM BASE/VIAL
AP	EQ 2GM BASE/VIAL
AP	EQ 4GM BASE/VIAL
PENBRITIN-S	
③	/N/ETHYL/ALERT/
③	WYETH AYERST
N63143 001	APR 15, 1993
N63145 001	APR 15, 1993
N63146 001	APR 15, 1993
N63147 001	APR 15, 1993
N62772 001	APR 15, 1993
N63139 001	APR 15, 1993
N63140 001	APR 15, 1993
N63141 001	APR 15, 1993
N63142 001	APR 15, 1993
N62779 001	JUL 12, 1993
N62779 002	JUL 12, 1993
/N/6565 001/	/APR 04, 1985/
/N/6565 002/	/APR 04, 1985/
/N/6565 003/	/JUN 24, 1986/
N62565 001	APR 04, 1985
N62565 002	APR 04, 1985
N62565 003	JUN 24, 1986
N60072 006	/N/66672/6666/

**INJECTABLE: INJECTION**

> DLT > /AB/ /POLYCYCLIC-N/ /PR3131/ /N/

N63143 001  
APR 15, 1993  
N63145 001  
APR 15, 1993  
N63146 001  
APR 15, 1993  
N63147 001  
APR 15, 1993  
N62772 001  
APR 15, 1993  
N63139 001  
APR 15, 1993  
N63140 001  
APR 15, 1993  
N63141 001  
APR 15, 1993  
N63142 001  
APR 15, 1993  
N62797 001  
JUL 12, 1993  
N62797 002  
JUL 12, 1993  
/ /N62565 /001/ /AP/ /1985/ /ADD/ > ADD > AP  
/ /N62565 /002/ /AP/ /1985/ /ADD/ > ADD > AP  
/ /N62565 /003/ /AP/ /1985/ /ADD/ > ADD > AP  
/ /N62565 /004/ /AP/ /1986/ /ADD/ > ADD > AP  
/ /N62565 /005/ /AP/ /1986/ /ADD/ > ADD > AP  
APR 04, 1985  
N62565 002  
APR 04, 1985  
N62565 003  
JUN 24, 1986  
/ /N50672 /006/ /AP/ /ADD/ > ADD > AP  
N50672 006  
APR 04, 1985  
N62565 001  
APR 04, 1985  
N62565 002  
JUN 24, 1986  
/ /EQ 145MG /BASE/VIAL/ /EQ 125MG /BASE/VIAL/ /EQ 250MG /BASE/VIAL/ /EQ 1GM /BASE/VIAL/ /EQ 2GM /BASE/VIAL/ /EQ 10GM /BASE/VIAL/ +

**PRINCIPAL APOTHECON**

INJECTABLE : INJECTION		
> DLL >	/EQ_145MG BASE^VIAL	/N61395_001
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N62860_001
> DLL >/AP/	/EQ_125MG BASE^VIAL	FEB 05, 1988
> DLL >	/EQ_125MG BASE^VIAL	/N62860_002
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_003
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N62860_003
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_004
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_005
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_006
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_007
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_008
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_009
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_010
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_011
> DLL >/AP/	/EQ_125MG BASE^VIAL	/FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_012
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N62860_002
> DLL >/AP/	/EQ_125MG BASE^VIAL	FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_003
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N62860_003
> DLL >/AP/	/EQ_125MG BASE^VIAL	FEB 05, 1988
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N61395_004
> DLL >/AP/	/EQ_125MG BASE^VIAL	/N62738_001
> ADD >	PRINCIPEN	
> ADD > AP	APOTHECON	
> ADD > AP	EQ 125MG BASE^VIAL	N61395_001
> ADD > AP	EQ 125MG BASE^VIAL	N62860_001
> ADD > AP	EQ 250MG BASE^VIAL	FEB 05, 1988
> ADD > AP	EQ 250MG BASE^VIAL	N61395_002
> ADD > AP	EQ 250MG BASE^VIAL	N62860_002
> ADD > AP	EQ 250MG BASE^VIAL	FEB 05, 1988
> ADD > AP	EQ 500MG BASE^VIAL	N61395_003
> ADD > AP	EQ 500MG BASE^VIAL	N62860_003
> ADD > AP	EQ 500MG BASE^VIAL	FEB 05, 1988
> ADD > AP	EQ 1GM BASE^VIAL	N61395_004
> ADD > AP	EQ 1GM BASE^VIAL	N62738_001
> ADD > AP	EQ 1GM BASE^VIAL	FEB 19, 1987
> ADD > AP	EQ 1GM BASE^VIAL	N62860_004
> ADD > AP	EQ 2GM BASE^VIAL	FEB 05, 1988
> ADD > AP	EQ 2GM BASE^VIAL	N61395_005
> ADD > AP	EQ 2GM BASE^VIAL	N62738_002
> ADD > AP	EQ 2GM BASE^VIAL	FEB 19, 1987
> ADD > AP	EQ 2GM BASE^VIAL	N62860_005
> ADD > AP	EQ 10GM BASE^VIAL	FEB 05, 1988
> ADD > AP	EQ 10GM BASE^VIAL	N61395_006











CALCITONIN, SALMONINJECTABLE; INJECTION

SALCITAN  
/AP/ + RHONE POULENC RORER //166-150ML/  
MIACALCIN  
/Sandoz/  
③ SANDOZ 100 IU/ML

CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE

SOLUTION; IRRIGATION

ENDOSOL EXTRA  
AI ALLERGAN 0.154MG/ML; 0.92MG/ML; 0.184MG/ML;  
0.2MG/ML; 0.38MG/ML; 2.1MG/ML;  
7.14MG/ML; 0.42MG/ML NOV 27, 1991

ENDOSOL PLUS  
/Allergan/

/6-154mg/; 6-92mg/; 6-184mg/; /6-2mg/; 6-38mg/; 6-2.1mg/; /6-7.14mg/; 6-0.42mg/ /Nov 27, 1991/

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER  
MCGAW 37MG/100ML; 5GM/100ML; 31MG/100ML;  
120MG/100ML; 520MG/100ML;  
88MG/100ML JUN 10, 1993

CALCIUM GLUCONATE

INJECTABLE; INJECTION  
CALCIUM GLUCONATE  
/AP/ + ABBOTT  
/AP/ ③ LILLY  
/AP/ /Lymphomed/  
③ LYMPHOMED

CARBENICILLIN DISODIUMINJECTABLE; INJECTION

GEOPEN  
/AP/ /Roerig/  
/AP/ /AP/  
/AP/ /AP/  
/AP/ /AP/  
ROERIG  
JUL 03, 1986

PROOPEN  
/AP/ /SmithKline Beecham/  
/AP/ /AP/  
/AP/ /AP/  
/AP/ /AP/  
SMITHKLINE BEECHAM  
③  
EQ 1GM BASE/VIAL  
EQ 2GM BASE/VIAL  
EQ 5GM BASE/VIAL  
EQ 10GM BASE/VIAL  
EQ 1GM BASE/VIAL  
EQ 2GM BASE/VIAL  
EQ 5GM BASE/VIAL  
EQ 10GM BASE/VIAL  
EQ 1GM BASE/VIAL  
EQ 2GM BASE/VIAL  
EQ 5GM BASE/VIAL  
EQ 10GM BASE/VIAL  
EQ 20GM BASE/VIAL

CARBINDOXAMINE MALEATE

/AP/ /Oral/  
/AP/ /Oral/  
/AP/ /Johnson & Johnson/  
③ JOHNSON & JOHNSON  
4MG

CARTSOPRODOL

/AP/ /Oral/  
/AP/ /Oral/  
/AP/ /Wallace/  
③ WALLACE

TABLET; ORAL

CARTSOPRODOL  
/AP/ /Pioneer/Pharm/  
③ PIONEER PHARMS  
/AP/ /Beta/  
/AP/ /Schering/  
③ SCHERING

/AP/ /90396/001/  
/AP/ /90396/1988/  
N83390 001  
OCT 13, 1988

/N11155/001/

N12155 001

CARTEOLOL HYDROCHLORIDESOLUTION/DROPS; OPHTHALMIC  
OPTIPRESS  
BRISTOL MYERS SQUIBB / 12/OTSUKA 12  
/N19972/001/  
N19972 001  
MAY 23, 1990CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL

DURICEF> ADD > AB + BRISTOL MYERS SQUIBB EQ 500MG BASE  
> DLT > AB // #/ /HEAD/ /John/ /EQ 500MG BASE/POWDER FOR RECONSTITUTION; ORALDURICEF> ADD > AB + BRISTOL MYERS SQUIBB EQ 125MG BASE/5ML  
> ADD > AB + EQ 250MG BASE/5ML  
> ADD > AB + EQ 500MG BASE/5ML  
> DLT > AB // #/ /HEAD/ /John/ /EQ 125MG BASE/5ML/  
> DLT > AB // #/ /HEAD/ /John/ /EQ 250MG BASE/5ML/  
> DLT > AB // #/ /HEAD/ /John/ /EQ 500MG BASE/5ML/TABLET; ORALDURICEF> ADD > AB + BRISTOL MYERS SQUIBB EQ 1GM BASE  
> DLT > AB // #/ /HEAD/ /John/ /EQ 1GM BASE/CEFAMANDOLE NAFAATEINJECTABLE; INJECTION  
MANDOL  
+ LILLY

EQ 10GM BASE/VIAL

N50504 004

CEFMENOXIME HYDROCHLORIDEINJECTABLE; INJECTION/CETEX//TAP/CEFAZOLIN SODIUMINJECTABLE; INJECTIONCEFAZOLIN SODIUM/PEN/ /VENUE/CEFAZOLIN SODIUM/PEN/ /VIAL/CEFAZOLIN SODIUM/PEN/ /VIAL/CEFAZOLIN SODIUMINJECTABLE; INJECTIONCEFAZOLIN SODIUM/PEN/ /VIAL/CEFAZOLIN SODIUM

CEFONCID SODIUM

INJECTABLE; INJECTION  
MONOCID  
SMITHKLINE BEECHAM

EQ 1GM BASE/VIAL  
*/fɛtən/ /bɛkʃəf/ /vɪəl/*  
JUL 26, 1993  
*/N56576/ /664/*  
N50694 002  
EQ 2GM BASE/VIAL  
*/fɛtən/ /bɛkʃəf/ /vɪəl/*  
MAY 23, 1984  
N50579 003

a

&gt; ADD &gt;

CEFOTAXIME SODIUM

INJECTABLE; INJECTION  
CLAFORAN  
HOECHST ROUSSEL

N50547 001

CEFOTETAN DISODIUM

INJECTABLE; INJECTION  
CEFOTAN  
*/s̥f̥ət̥ən/*  
*/f̥ɛt̥ən/ /bɛs̥/ /vɪəl/*  
+ ZENECA  
+  
EQ 1GM BASE/VIAL  
N50588 001  
DEC 27, 1985  
EQ 2GM BASE/VIAL  
N50588 002  
DEC 27, 1985  
EQ 1GM BASE/VIAL  
N63293 001  
APR 29, 1993  
EQ 2GM BASE/VIAL  
N63293 002  
APR 29, 1993

EQ 1GM BASE/VIAL  
N50694 002  
JUL 30, 1993  
EQ 40MG BASE/ML  
N50694 001  
JUL 30, 1993

EQ 1GM BASE/VIAL  
N63293 001  
APR 29, 1993

CEFTAZIDIME SODIUM

INJECTABLE; INJECTION  
CEFTAZIDIME SODIUM IN PLASTIC CONTAINER  
+ ZENECA  
+  
EQ 20MG BASE/ML  
N50694 002  
JUL 30, 1993  
EQ 40MG BASE/ML  
N50694 001  
JUL 30, 1993

EQ 1GM BASE/VIAL  
N50694 002  
JUL 30, 1993

CEFOTIAM HYDROCHLORIDE

INJECTABLE; INJECTION  
/CERADON/  
*/t̥a:kəd̥ən/*  
*/f̥ɛt̥ən/ /bɛs̥/ /vɪəl/*  
*/N56661/ /661/*  
*/f̥ɛt̥ən/ /bɛs̥/ /vɪəl/*  
/f̥ɛt̥ən/ /bɛs̥/ /vɪəl/

EQ 10MG BASE/ML  
AP

EQ 20MG BASE/ML  
AP

EQ 40MG BASE/ML  
AP

CEFOTIAM HYDROCHLORIDE

INJECTABLE; INJECTION  
/CERADON/  
*/t̥a:kəd̥ən/*

EQ 1GM BASE/VIAL  
*/f̥ɛt̥ən/ /bɛs̥/ /vɪəl/*  
JUL 26, 1993  
*/N56576/ /664/*  
N50601 001  
DEC 30, 1988

INJECTABLE; INJECTION  
MEFOXIN IN PLASTIC CONTAINER  
MERCK

EQ 40MG BASE/ML  
AP

CEPIRAMIDE SODIUM

INJECTABLE; INJECTION  
CEPIRAMIDE SODIUM  
/WYETH AYERST/  
*/f̥ɛt̥ən/ /bɛs̥/ /vɪəl/*  
+  
WYETH AYERST  
+  
EQ 1GM BASE/VIAL  
N50633 003  
JAN 31, 1989

EQ 2GM BASE/VIAL  
N50633 002  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 005  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 003  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 005  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 003  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 005  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 003  
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EQ 10GM BASE/VIAL  
N50633 005  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 003  
JAN 31, 1989

EQ 10GM BASE/VIAL  
N50633 005  
JAN 31, 1989

EQ 10MG BASE/ML  
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EQ 20MG BASE/ML  
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CEETIZETIME SUMMIT

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INJECTABLE; INJECTION  
CEFIZOX  
FUJISAWA

EQ 500MG BASE/VIAL  
EQ 10GM BASE/VIAL

ADD >  
ADD >

<u>APOTHECON</u>	<u>EQ 250MG BASE</u>	<u>N63063 001</u>
> ADD > AB		SEP 29, 1989
> ADD >		N63063 002
> ADD > AB		SEP 29, 1989
> ADD >		/N63063/d01
> DLT > AB/		/S63063/d01
/DLT/		/N63063/d02
/DLT/		/S63063/d02
<u>CEPHALECTIN</u>	<u>EQ 250MG BASE</u>	<u>N62973 001</u>
<u>APOTHECON</u>	<u>EQ 500MG BASE</u>	<u>N62974 001</u>
> ADD > AB		NOV 08, 1988
> ADD >		NOV 23, 1988
> ADD > AB		/N62973/d01
> ADD >		/S62973/d01
> DLT > AB/		/N62973/d02
/DLT/		/S62973/d02
/DLT/		/N62974/d02

**INJECTABLE; INJECTION  
ROCEPHIN**

<b>ROCHE</b>  <b>ROCEPHIN w/ DEXTROSE IN PLASTIC CONTAINER</b> <i>/rō'fēfēn/ /dĕk'strōz/ /plăs'tik kən'tān'ēr/    <b>EQ 250MG BASE/VIAL</b>  <b>EQ 500MG BASE/VIAL</b>  <b>EQ 1GM BASE/VIAL</b>    <b>EQ 10MG BASE/ML</b> </i>
<b>② ROCHE</b>

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

CELEBROXTIME SODIUM

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MISSION PHARMA 2.5GM/PACKET

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**CEPHAPIRIN SODIUM**

INJECTABLE; INJECTION

/dL/ <sup>1</sup>	/dL/ <sup>2</sup>	/dL/ <sup>3</sup>	/dL/ <sup>4</sup>	/dL/ <sup>5</sup>	/dL/ <sup>6</sup>	/dL/ <sup>7</sup>	/dL/ <sup>8</sup>	/dL/ <sup>9</sup>	/dL/ <sup>10</sup>
/dL/ <sup>1</sup>	/dL/ <sup>2</sup>	/dL/ <sup>3</sup>	/dL/ <sup>4</sup>	/dL/ <sup>5</sup>	/dL/ <sup>6</sup>	/dL/ <sup>7</sup>	/dL/ <sup>8</sup>	/dL/ <sup>9</sup>	/dL/ <sup>10</sup>
/dL/ <sup>1</sup>	/dL/ <sup>2</sup>	/dL/ <sup>3</sup>	/dL/ <sup>4</sup>	/dL/ <sup>5</sup>	/dL/ <sup>6</sup>	/dL/ <sup>7</sup>	/dL/ <sup>8</sup>	/dL/ <sup>9</sup>	/dL/ <sup>10</sup>
/dL/ <sup>1</sup>	/dL/ <sup>2</sup>	/dL/ <sup>3</sup>	/dL/ <sup>4</sup>	/dL/ <sup>5</sup>	/dL/ <sup>6</sup>	/dL/ <sup>7</sup>	/dL/ <sup>8</sup>	/dL/ <sup>9</sup>	/dL/ <sup>10</sup>
/dL/ <sup>1</sup>	/dL/ <sup>2</sup>	/dL/ <sup>3</sup>	/dL/ <sup>4</sup>	/dL/ <sup>5</sup>	/dL/ <sup>6</sup>	/dL/ <sup>7</sup>	/dL/ <sup>8</sup>	/dL/ <sup>9</sup>	/dL/ <sup>10</sup>

SEP 12, 1983  
N17813 001

CHLORDIAZEPOXI

CAPSULE / EXTENDED/ RÉLÉASÉ / DRALI

/N17813/661/  
/SF12,1/661/  
N17813 001  
SEP 12, 1983

## CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL  
CHLORDIAZEPOXIDE HC

PIONEER PHARMS / ZETTE

/EG\_500MG\_BASE\_VIAL/ /AP/ /LY\_PHRMED/

## CHLOROTHIAZIDE; METHYLDOPA

#### TABLET: ORAL

N16016 001  
150MG ; 250MG  
MSD

ALDOCOLOR-250

N16016 002  
N16016 003  
MSD + +

1176 1185 1191  
1196 1205 1211  
1216 1225 1231  
1236 1245 1251  
1256 1265 1271  
1276 1285 1291  
1296 1305 1311  
1316 1325 1331  
1336 1345 1351  
1356 1365 1371  
1376 1385 1391  
1396 1405 1411  
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1936 1945 1951  
1956 1965 1971  
1976 1985 1991  
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5916 5925 5931  
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5956 5965 5971  
5976 5985 5991  
5996 6005 6011

NOV/83: 1887

NOVEMBER, 1987

250MG;250MG

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/Hřešíš?

/EQ IGM BASE/VIAL  
/N60132/001/  
EQ IGM BASE/VIAL  
N60132 001





CLOXACILLIN SODIUM

POWDER FOR RECONSTITUTION; ORAL

TEGOPEN

> ADD > AA  
> DLT > AA  
> ADD > APOTHECON  
/PENICILLIN/

CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HC W/ CODEINE

> ADD >  
> ADD >  
> DLT > AA  
> DLT >  
> DLT >  
> ADD >

a PENNEX PHARMS

10MG/5ML; 15MG/5ML;

6.25MG/5ML

/10MG/5ML; 15MG/5ML/

/6.25MG/2.5ML/

CORTICOTROPIN

INJECTABLE; INJECTION

H.P. ACTHAR GEL

/ACTHAR/

## CYANOCOBALAMIN

INJECTABLE : INJECTION		
RUBBUTATE	/	
BEL-HA/	/	
1/100	/	
1/100	/	
1/100	/	
② BEL MAR		
③		
③		
③		
③		

## CYCLACILLIN

## CYCLIZINE LACTATE

INJECTABLES / INJECTION

CYCLOPENTADIONE INHOCOMIII CRISAE

**TABLET; ORAL  
CYCLOBERZAPRINE HCL  
INVAMED  
AB**

## CYCLOPHOSPHAMIDE

## CYCLOPHOSPHAMIDE

INJECTABLE; INJECTION		MEOSAR	
AP	ADRIA	<u>100MG/VIAL</u>	
AP		<u>200MG/VIAL</u>	
AP		<u>500MG/VIAL</u>	
AP		<u>1GM/VIAL</u>	
AP		<u>2GM/VIAL</u>	

## CYPROHEPTADINE HYDROCHLORIDE

N87001 001  
 NOV 04, 1982  
 /N87001/001  
 /N87001/002  
 SYRUP; ORAL  
CYPROHEPTADINE HCL  
 3 PENNEX PHARMS  
 > ADD >  
 > ADD >  
 > DLT > AA/  
 > DLT >  
 2MG/5ML  
 /4MG/5ML/  
 N50508 001  
 N50508 002  
 N50508 003

/N866676/PP/

DESLANDSIDE  
/dɛslændsɪd/  
/dɛslændsɪd/  
NO9282 002





<u>DIAZEPAM</u>			
AP	INJECTABLE; INJECTION <u>DIAZEPAM</u> MARSAM	5MG/ML	/AP/ / <u>MARSAM</u> /
AP		5MG/ML	JAN 29, 1993
AP		5MG/ML	N72371 001
AP		5MG/ML	JAN 29, 1993
/AP/	VALTO <sup>TM</sup> /Röchle/ ROCHE	/AP/ / <u>Röchle</u> /	N72397 001
	+ KABI	5MG/ML	/N16987/001/ N16987 001
INJECTABLE; INTRAVENOUS			
AP	DIZAC	5MG/ML	N19287 001
	+ KABI		JUN 18, 1993
<u>TABLET; ORAL</u>			
	<u>DIAZEPAM</u>	2MG	N70903 001
③	FERNDALE	5MG	APR 01, 1987
③		10MG	N70904 001
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/	APR 01, 1987
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/	N70905 001
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>DLT</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>DLT</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>ADD</u> /> <u>DLT</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>ADD</u> /> <u>DLT</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>ADD</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>ADD</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>DLT</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
/AP/	/ <u>PHARM/PAKTS/</u> /	/AP/ > <u>DLT</u> /> <u>AB</u> /	/AP/ / <u>PHARM/PAKTS/</u> /
③	ZENITH	2MG	N70360 001
③		5MG	SEP 04, 1985
			N70361 001
			SEP 04, 1985
<u>DIAZOXIDE</u>			
CAPSULE; ORAL			
	PROGLYCEM	50MG	/ <u>PROGLYCEM</u> /
	+ BAKER MORTON	/ <u>BAKER MORTON</u> /	
			/N17425/001/
<u>DIACETYLDIETHYLAMINE</u>			
SOLID			
			/N16987/001/
<u>DIACETYL DIOXIDE</u>			
SOLID			
			/N16987/001/
<u>DIACETYL DIOXIDE</u>			
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<u>DIACETYL DIOXIDE</u>			
SOLID			
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## DICYCLOMINE HYDROCHLORIDE

## DILTAZEM HYDROCHLORIDE

## DILTAZEM HYDROCHLORIDE



DROPERIDOL

## INJECTABLE; INJECTION

## EDTA DISSODIUM

N20164 001  
MAR 29, 1998  
**INJECTABLE; INJECTION**  
LOVENOX  
RHONE POULENC RORER 30MG/0.3ML  
N84456/001/  
N84356 001  
**INJECTABLE; INJECTION**  
DVTENON EDETAIE/  
750mg/50ml/  
STERIS/  
a STERIS

## FLORNITHINE HYDROCHLORIDE

<u>LIDOCAINE HCL AND EPINEPHRINE</u>	<u>0.01MG/ML; 2%</u>	N40057 00
<u>STERLING MINTROP</u>	<u>0.01MG/ML; 2%</u>	FEB 26, 1997
<u>AP</u>	<u>AP</u>	N40057 00
<u>NOV 28, 1990</u>	<u>AP</u>	FEB 26, 1997
<u>200MG/ML</u>	<u>0.02MG/ML; 2%</u>	
<u>© MERRELL DOW</u>	<u>/4015/41/</u>	
<u>/N19879 002</u>	<u>/N19879/662/</u>	
<u>11/26/1990</u>	<u>/N19879/662/</u>	

## **ENCAINIDE HYDROCHLORIDE**

N80757 00  
EDITIONEDTNE: DDOCATNE HYDROCHIORTDF  
CAPSULE! ORAL!  
ENKATD/  
+ / BPISTP/  
/N164664/  
0.01MG/ML; 2:  
3

THE PRACTICAL PHRASE /

N80750 00  
N80755 00  
N80759 00  
N80758 00  
N80759 00

ERGOLOID MESYLATES

TABLET; ORAL  
HYDERGINE  
SHANDONG  
a SANDOZ

## **ENOXACIN**

TABLET; ORAL

+ RHONE POULENC RORET 400MGS	200MGS	 <i>J. P. POULENC / PARIS / 1991</i> <i>POULENC RORET</i> <i>PARIS</i> <i>1991</i>
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## ENOXAPARIN SODIUM

N20164 001  
MAR 29, 1995

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION  
INJECTABLE HCL AND EPINEPHRINE  
 STERLING WINTRUP      0.01MG/ML ; 22  
0.02MG/ML ; 22

N80757/00  
N80820 00  
N80757 00  
  
/0.01NG/ML;22  
0.01NG/ML;1X  
0.01NG/ML;22  
  
© BEL MAR  
©

INEPHRINE; PROCAINE HYDROCHLORIDE  
INJECTABLE; INJECTION  
PROCAINE HCl w/ EPINEPHRINE  
100 mg / 10 ml = 1:1000  
1000 mg / 100 ml = 1:1000

ERGOLOID MESYLATES

TABLE I; ORAL HYDGERINE /SANDOZ/ 0.5MG N17993 00

ERGOLOID MESYLATES

TABLET; SUBLINGUAL  
HYDROXYLATED ERGOT ALKALOIDS  
/0.5MG/  
0.5MG/  
③ ZENITH

/N87186/001/  
 N87186 001

ERGOTAMINE TARTRATE

TABLET; SUBLINGUAL  
ERGOMAR  
/F1501\$/  
/2MG/  
AA LOTUS  
2MG

/N87693/001/  
 N87693 001  
 FEB 24, 1983

TABLET; SUBLINGUAL

ERGOTAMINE TARTRATE  
/F1501\$/  
/2MG/  
③ PADDOK

N50610 001

NOV 07, 1986

ERYTHROMYCIN

SOLUTION; TOPICAL  
ERYTHRA-DERM  
/PADDOK/  
/100%/  
③ PADDOK

100%

NOV 07, 1986

SOLUTION; TOPICAL

ERYTHRA-DERM  
/AT PADDOK

2Z

FEB 05, 1988

N62687 001

FEB 05, 1988

N62957 001

JUL 21, 1988

N62825 001

OCT 23, 1987

N62825/001

/PADDOK/

/PADDOK/

N62687/001

ERYTHROMYCIN LACTOBIONATEINJECTABLE; INJECTION

ERITHROMYCIN LACTOBIONATE  
AP GENIA  
EQ 500MG BASE/VIAL

AP EQ 1GM BASE/VIAL  
/6P/ /1,3P,4H,5P/  
/6P/ /6P,6P,6P/

/6P/ /6P,6P,6P/ /6P,6P,6P/  
/6P/ /6P,6P,6P/

3 LYPHOMED  
EQ 500MG BASE/VIAL  
EQ 1GM BASE/VIAL  
/6P/ /6P,6P,6P/

3 LYPHOMED  
EQ 500MG BASE/VIAL  
EQ 1GM BASE/VIAL  
/6P/ /6P,6P,6P/

N63253 001 JUL 30, 1993  
N63253 002 JUL 30, 1993  
N62604 001 NOV 24, 1996  
N62604 002 NOV 24, 1996

N62604 001 NOV 24, 1996  
N62604 002 NOV 24, 1996

10MG/ML AUG 15, 1998  
250MG/ML DEC 31, 1998

/1,3P,4H,5P/  
/1,3P,4H,5P/

/1,3P,4H,5P/  
/1,3P,4H,5P/

/1,3P,4H,5P/  
/1,3P,4H,5P/

N19386 001 AUG 15, 1998  
N19386 002 DEC 31, 1998  
/1,3P,4H,5P/  
/1,3P,4H,5P/

/1,3P,4H,5P/  
/1,3P,4H,5P/

NB1295 001 JUN 30, 1993  
BRISTOL MYERS SQUIBB 0.5MG

ESTRADIOL

TABLET; ORAL  
ESTRACE  
BRISTOL MYERS SQUIBB 0.5MG

/6P/ /6P,6P,6P/

AB ROBERTS

AB ROBERTS

AB ROBERTS

N20216 001  
/6P,6P,6P/

AA ZARONTEK

AA PARKE DAVIS

ESTROGENS, CONJUGATEDTABLET; ORAL

PREMARIN  
+ WYETH AYERST  
/4/  
1.25MG  
/1,2,5H,6/  
2.5MG

N04782 001  
/N04782/002/  
/N04782/003/  
N04782 002

ESTROXYLATE

TABLET; ORAL  
OPEN 1.25  
/1,2,5H,6/  
1.5MG

NB3220 002  
/N04782/004/  
NB3220 003

TABLET; ORAL  
OPEN 2.5  
+ ABBOTT  
3MG  
/3H,6/

NB3220 003  
/N04782/005/

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21  
NORETHEN 1/35E-21  
AB ROBERTS  
/6P/ /6P,6P,6P/

/6P/ /6P,6P,6P/

AB ROBERTS  
/6P/ /6P,6P,6P/

ESTROGENS, CONJUGATEDSYRUP; ORAL

ETHOSUXIMIDE  
AA COPLEY  
250MG/5ML

NB1306 001  
/N11481/001/  
APR 12, 1998  
/APR 12, 1998/  
JUL 30, 1993

NB0258 001  
/N0258/001/  
APR 12, 1998  
/APR 12, 1998/  
JUL 30, 1993

#### **ETHYNODIOL DIACETATE; MESTRANOL**

ELI LUDWIGS/ONE ACETONIDE

## FLUOCINOLONE ACETONIDE

/TABLET /DRAWING  
/OULET-21/  
/+ // SEARIE  
/ a SEARIE

OINTMENT; TOPICAL  
FLUOCORTOLONE ACETONIDE  
/PHARMDERM/ /0.025%/  
 a PHARMDERM 0.025%  
 /61/  
FLUOCORTOLONE ACETONIDE  
/PHARMDERM/ /0.025%/  
 a PHARMDERM 0.025%  
 /61/  
 /DEC 16, 1988  
 NBB046 00  
 /DEC 16, 1988

SEARLE

## ETIDRONATE DISODIUM

**INJECTABLE; INJECTION  
DIDRONEEL**

+ MGII

EFIBRAME

SUSPENSION; ORAL  
FELBATOL

ג'נָעַמְלָא

CAPSULE; ORAL  
PROZAC  
LILLY  
EQ 10MG BASE  
N18936 00  
DEC 23, 199

**FLUPHENAZINE DECANOATE  
INJECTABLE, INJECTION**

N16727 00  
N16727 00  
**PROUDHON DEGANGE**  
+ APOTHECON  
/S/16/ /  
25MG CHL/  
/250g/ML/

**FLUPHENAZINE ENANTHATE**  
**INJECTABLE; INJECTION**

N16110 00  
N16114/00

## FLUPHENAZINE HYDROCHLORIDE

EUROSEMIDE

CENTRIBUTE; ORAL	<u>PROLUDIN</u>	APOTHECON
> ADD > AA		
> ADD >		
> DLT > 66/		/S/16/
> DLT >		

<u>Elixir; Oral</u>	<u>Fluphenazine HCl</u>	<u>Copley</u>	<u>AA</u>
		<u>Prolidithon</u>	<u>AA</u>

**INJECTABLE; INJECTION**  
**PROLIDEXIN**  
 $\frac{\text{ADD}}{\text{DLT}} > \frac{\text{AP}}{\text{AP/DLT}} > \frac{\text{AP}}{\text{AP}}$  + **APOTHECON**  
/SQUIBBS/

TABLET; ORAL  
**PROLTXIN** APOTHECON

/TABLET; EXTENDED RELEASE; ORAL/  
PERMITTIL  
+ / SCHERRING /  
a SCHERRING

**TABLETS; ORAL  
FOLIC ACID  
PIONEER/PHARMS/  
66/**

EUROSENIIDE		SOLUTION; ORAL <u>EUROSENIIDE</u>	PENEX PHARMS	10MG/ML
N70533 001	> <u>ADD</u> > <u>AA</u>	> <u>ADD</u> > <u>AA</u>	/PHARM/BASIS/	/10MG/ML/
NOV 07, 1985	> <u>ADD</u> > <u>DLT</u>	/		
/N70533/001/	> <u>DLT</u> > <u>AA</u>			
/NOV 07/1985/	> <u>DLT</u> > <u>AA</u>			

N70655 001	> ADD > AA	PENNEX PHARMS	10MG/ML
NOV 07, 1985	> ADD >	/PENNEX/	
N70533/001	> ADD > AA/		
NOV 07, 1985	> DLT > AA/		
N70533/001	> DLT > AA/		

TABLET; ORAL  
EUROSEXEIDE  
/PARACETAMOL/  
/ /  
/ 466G/  
/N18649/6661

/ 89/	/ 85/	a WARNER CHILCOTT
/ 85/	/ 85/	a 20MG
		40MG
		80MG
/ JAN 31, 1983	N18419 001	JAN 31, 1983
/ NOV 13, 1984	N18419 002	JAN 31, 1983
	N18419 003	NOV 13, 1984
	N18419 004	NOV 13, 1984

### GADODIAMIDE

STERLING WINTHROP 287MG/ML  
N20123 001 JAN 08, 1993

سیده نازنین احمدی

<u>AB</u>	MYLAN	<u>300MG</u>	N73466 001 JAN 25, 1993
<u>AB</u>	PUREPAC	<u>300MG</u>	N72929 001 JAN 29, 1993
<u>LOPD</u>	+ PARKE DAVIS	<u>300MG</u>	N18422 002

N88949 001  
SEP 13, 1985







## HYDROCHLOROTHIAZIDE; LABETALOL HYDROCHLORIDE

HYDROCOMBINE

TABLET; ORAL  
HORMOZIDE  
/ SHERING/

IRANIAN LITERATURE

/	/		
/25MG; 200MG/	/		
/25MG; 300MG/	/		
		③ GLAXO	
		③	
N19174; 001	N19174; 001	N19174; 001	N19174; 001
/Apd 16/1987/	/Apd 16/1987/	/Apd 16/1987/	/Apd 16/1987/
/APD 16/1987/	/APD 16/1987/	/APD 16/1987/	/APD 16/1987/
LOTION; TOPICAL	ACTICORT	ACTICORT	ACTICORT
25MG; 100MG	N19174; 003	BAKER NORTON	BAKER NORTON
	/Apd 16/1987/	/Apd 16/1987/	/Apd 16/1987/
25MG; 200MG	N19174; 002	/AT/ > DLT /	/AT/ > DLT /
	/Apd 16/1987/	> DLT > /AT/	> DLT > /AT/
25MG; 300MG	N19174; 003	> ADD >	> ADD >
	/Apd 16/1987	> ADD >	> ADD >
		③ SOLVAY	12.

HYDROCHLOROTHIAZIDE; HISINOPBIL

TABLET; ORAL <u>ZESTORETIC 20/12.5</u> <u>/HYPERTEN/CHF/H</u>		AT FOUGERA	2.5%
AB/	/12.5MG;2.5MG/	/At/	/At/
AB	ZENECA	12.5MG;20MG	3 PHARMADERM
AB/	<u>ZESTORETIC 20/25</u> <u>/HYPERTEN/CHF/H</u>	/25MG;20MG/	
AB	ZENECA	25MG;20MG	
			SUSPENSION; OTIC <u>HYDROCHLOROTHIAZIDE; SPIRONOLACTONE</u>
			/At/ /Néfendil Sulfate; Polymyxin B Sulfate; /Pharmaderm/ /Hydrochlorothiazide/
			NB11203 001 MAY 28, 1993 /Néfendil Sulfate; Polymyxin B Sulfate; /Pharmaderm/ /Hydrochlorothiazide/ NBB8942 001 FEB 09, 1987
			NB2617/001 /Néfendil Sulfate; Polymyxin B Sulfate; /Pharmaderm/ /Hydrochlorothiazide/

#### TABLET; ORAL

AB/ /UPSHER SMITH/ /25MG; 25MG/  
③ UPSHER SMITH 25MG; 25MG  
/N87553/001  
N87553 001  
10,000 UNITS/ML  
NE2617 001  
SEP 18, 1985

HURCURI ISUNE

OINTMENT; TOPICAL  
HYDROCORTISONE

FUGERA	<u>2.5%</u>	NB1203 001
t/	/ <u>PHARMADERM</u> /	MAY 28, 1993
a PHARMADERM	1/	/NB8842/ /d1/
		/fEB/d1/ /1987/
		NB8842 001
		FEB 09, 1987

SUSPENSION; OTIC

a PHARMAFAIR 1½;EQ 3.5MG BASE/ML;  
10,000 UNITS./ML N62617 001  
/PFE/1000/1,500/  
SEP 18, 1985

**HYDROCORTISONE** • **NEOMYCIN SULFATE** • **POLYMYXIN B SULFATE**

## HYDROXYZINE HYDROCHLORIDE

INJECTABLE INJECTION

N86258 001  
N86258 002

## **HYDROCORTISONE ACETATE**

FEB 03, 1988  
/N6745/661/  
/FB/65/1966/  
N87294 001  
APR 12, 1982  
/N67294/661/  
/APP/12/1982/

SEP 24, 1985

N88785 001  
FEB 03, 1988  
/N88785/001/  
/FEB/03/1988/  
N887294 001  
APR 12, 1982  
/N887294/001/  
/APR/12/1982/

## HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

N86826  
N86827  
N86828  
N86829  
N86830  
N86831

N88836  
N88837  
N88838  
N88839  
N88840

## **HYDROXYCOBALAMIN**

N71145 001

EP 23, 1981

N/11-40 902  
EP 23, 1986

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May 08, 1987

/Nfd328/fdd1/

356 / 665 // 1.085 /

N70328 001

UG 06, 1985

IBUPROFEN

TABLET; ORAL  
*/Ibuprofen/  
/ibuprofen/*  
*/ibuprofen/  
/ibuprofen/*  
*/ibuprofen/  
/ibuprofen/*

*/N11145/061/  
/SEP 23, 1986/  
/N11145/061/  
/SEP 23, 1986/  
/N11145/061/  
/NAY/08/1987/*

IDOXURIDINE  
*/Dinitroimidazole/  
/Stoxil/  
//SMITHKLINE BEECHAM/ 6.5%/  
② SMITHKLINE BEECHAM*

INDAPAMIDE  
*Iodopuride*

INDAPAMIDE  
*/Stoxil/  
/SMITHKLINE BEECHAM/ 6.5%/  
② SMITHKLINE BEECHAM 0.1%*

SOLUTION/DROPS; OPHTHALMIC

INDAPAMIDE  
*/Stoxil/  
/SMITHKLINE BEECHAM/ 6.5%/  
② SMITHKLINE BEECHAM 0.1%*

INDAPAMIDE  
*Tablet; Oral*

LOZOL  
*Rhone PoulenC Rorer 1.25mg*

IODOHIPPURATE SODIUM, I-131

INJECTABLE; INJECTION

IODOHIPPURATE SODIUM I-131  
*AP/*  
*SORIN*  
*/0.246G/ML/  
0.2MCL/ML*

IOHEXOL

INJECTABLE; INJECTION  
*/OMnipaque 240/  
/STERLING/*  
*/36.6%/*

INJECTABLE; INJECTION  
*/OMnipaque 240/  
/STERLING/*  
*/51.6%/*

*/N18956/061/  
/DEC 07, 1989/*

IOHEXOL

INJECTABLE; INJECTION  
*/OMnipaque 300/  
/STERLING/*  
*/54.7%/*

*/N18956/061/  
/DEC 07, 1989/*

SOLUTION; INJECTION, ORAL, RECTAL  
*OMnipaque 180  
+ STERLING*  
*38.8%*

*N18956 001  
DEC 26, 1985  
N18956 002  
DEC 26, 1985  
N18956 003  
DEC 26, 1985*

INJECTABLE; INJECTION  
*OMnipaque 240  
+ STERLING*  
*51.8%*

*N18956 001  
DEC 26, 1985  
N18956 002  
DEC 26, 1985  
N18956 003  
DEC 26, 1985*

LOTROLAN  
*/Injektionslösung/  
/Lotrolan/  
/BERLEX/*

*/Eq/196MG/Iodine/ML/  
/Eq/246MG/Iodine/ML/  
/Eq/246MG/Iodine/ML/  
③ BERLEX  
EQ 190MG IODINE/ML  
EQ 240MG IODINE/ML  
N19580 001  
DEC 07, 1989  
N19580 002  
DEC 07, 1989*

IRON DEXTRAN

INJECTABLE; INJECTION  
*Infused  
BP + Schein Pharm  
/Iron/dextran/  
/BP/*  
*/Eq/500MG IRON/ML  
Eq 500MG IRON/ML  
N17441 001  
/N17441/661/*



ISOSORBIDE MONONITRATEKETOPROFEN

TABLET; ORAL MONKET BX SCHWARZ PHARMA	20MG 10MG	N20215 001 JUN 30, 1993 N20215 002 JUN 30, 1993	CAPSULE; ORAL KETOPROFEN AB LEDERLE	25MG 50MG	JAN 29, 1993 N74014 002 JAN 29, 1993 N74014 003
> ADD > > ADD > > ADD > > ADD > > ADD >					
TABLET, EXTENDED RELEASE; ORAL. IMDUR ③ SCHERRING PLOUGH	30MG	N20225 001 AUG 12, 1993 N20225 002 AUG 12, 1993	LACTULOSE		
> ADD > > ADD > > ADD >					
<u>KANAMYCIN SULFATE</u>					
CAPSULE; ORAL KANTREX APOTHECON	EQ 500MG BASE	N62726 001 MAR 06, 1987 /N62726/001/ /MAR/06/1987/	AA EVALOSE COPELY	10GM/15ML	N73497 001 MAY 28, 1993
> ADD > > ADD > > DLT > > DLT >	/P <sub>1</sub> P <sub>2</sub> P <sub>3</sub> P <sub>4</sub> /P <sub>5</sub> P <sub>6</sub> /				
<u>INJECTABLE; INJECTION</u>					
KANTREX APOTHECON	EQ 75MG BASE/2ML EQ 500MG BASE/2ML EQ 1GM BASE/2ML /EQ 75MG BASE/2ML/ /EQ 500MG BASE/2ML/ /EQ 1GM BASE/2ML/	N61901 003 N61901 001 N61901 002 /N61901/003/ /N61901/002/ /N61901/002/	AA LACTULOSE ③ PENNEX PHARMS > DLT >/AA/ > DLT >	10GM/15ML 10GM/15ML	N71841 001 SEP 22, 1988 /P <sub>1</sub> P <sub>2</sub> P <sub>3</sub> P <sub>4</sub> /1988/
> ADD > AP > ADD > AP > ADD > AP > DLT > AP > DLT > AP	/K <sub>1</sub> K <sub>2</sub> K <sub>3</sub> K <sub>4</sub> /P <sub>5</sub> P <sub>6</sub> /				
<u>SMITHKLINE BEECHAM</u>					
③ ③					
> ADD > > ADD > > DLT > > DLT >					
<u>SOLUTION; ORAL, RECTAL</u>					
ACI <sub>2</sub> AC					
TECHNILAB					
MERRELL DOW					
EMULOSE BARRE					
> ADD > > ADD > > DLT > > DLT >					
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CEPHI <sub>2</sub> AC					
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<u>LACTULOSE</u>	SOLUTION; ORAL, RECTAL <u>HEPTALAC</u> COPLEY	LACTULOSE 3 SOLVAY / <u>PORTALAC</u> / 3 SOLVAY /
AA		AA /



<u>LITHIUM CITRATE</u>		<u>MASOPROCOL</u>	<u>N19940 001</u>
SYRUP; ORAL		CREAM; TOPICAL	SEP 04, 1992
<u>LITHIUM CITRATE</u>	PENNEX PHARMS	ACTINEX + BLOCK DRUG	/N19940/001/ /SEP 04/1992/
		10%	
		/+//CHMEX/	
EQ 300MG CARBONATE/EML	N70755 001		
MAY 21, 1986			
/EQ 300MG CARBONATE/EML	/N19940/001/ /MAY 21/1986/		
/PHARM/BESTICS/			

<u>LORATADINE</u>	<u>MENADIOL SODIUM DIPHOSPHATE</u>	
TABLET; ORAL CLARITIN + SCHERING	10MG APR 12, 1993	N19658 001 /N19658/001/ /TABLT; ORAL/ /SINUS AYST/ / /ROCHE/ /10MG/ML/ 5MG/ML 10MG/ML 37.5MG/ML
<u>MAFENTIDE ACETATE</u>		
CREAM; TOPICAL SULFAMYLYON + HICKAM /STERLING/	EQ 85MG BASE/GM /EQ/85MG/BASE/GM/	N16763 001 /N16763/001/ /TABLT; ORAL/ /SINUS AYST/ / /ROCHE/ /5MG/ 5MG
<u>MANGANESE SULFATE</u>		
INJECTABLE; INJECTION MANGANESE SULFATE FUJISAWA	EQ 0.1MG MANGANESE/ML /EQ/0.1MG/MANGANESE/ML/	N19228 001 MAY 05, 1987 /N19228/001/ /MAY/05./1987/
<u>MANNITOL</u>		
INJECTABLE; INJECTION MANNITOL 10% IN PLASTIC CONTAINER MCGAN	10GM/100ML AP	N20006 002 JUL 26, 1993 /44661/ TABLET; ORAL ME PROBAMATE /44661/ /EFF/LAB5/
MANNITOL		
INJECTABLE; INJECTION MANNITOL 10% IN PLASTIC CONTAINER MCGAN	15GM/100ML AP	N20006 003 JUL 26, 1993 a LEE LABS 400MG
MANNITOL		
INJECTABLE; INJECTION MANNITOL 20% IN PLASTIC CONTAINER MCGAN	20GM/100ML AP	N20006 004 JUL 26, 1993 /44661/ TABLET; ORAL ME PROBAMATE /44661/ /EFF/LAB5/
MANNITOL		
INJECTABLE; INJECTION MANNITOL 5% IN PLASTIC CONTAINER MCGAN	5GM/100ML AP	N20006 001 JUL 26, 1993 /44661/ TABLET; ORAL ME PROBAMATE /44661/ /EFF/LAB5/







## METRONIDAZOLE

TABLET; ORAL

116 / SAVAGE /

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2 SAVAGE

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## MEZLOCETIN SODIUM MONOHYDRATE

INJECTABLES: INJECTION

ES 100 BASE/MIA  
MILES

MICROZONE ENTITRATE

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MONISTAT 7<sup>®</sup>  
/lightheaded/ /dizziness/  
/nausea/vaginal cream, suppository; topical, vaginal  
monistat-7

+ JOHNSON RW  
2%; 200MG

OPTIONAL FORM  
RIGHTS STATEMENT  
+ JOHNSON/RM  
a JOHNSON RM

/SUPPOORT//VAGINAL/  
/MENSTRAT//  
/JOHNSON/RW/

/N1.7739/001  
N17739 001

NAB T1 ONE

CAPSULE / CRITIQUE

/MAR/15, /1982/

1MG

N18677/001  
DEC 26, 1985

MOBICIZINE HYDROCHLORIDE

TABLET; ORAL  
ETHMOZINE

JUN 16, 1990	N19753 001
JUN 17, 1990	N19753 002
JUN 18, 1990	N19753 003
JUN 19, 1990	
JUN 20, 1990	

/N1867/1865/  
DEC/26, 1985  
NI8677 001  
DEC 26 1985

## NAFCILLIN SODIUM

## NALOXONE HYDROCHLORIDE

INJECTABLES: INJECTION

AFCIL APOTHECON

INJECTION TABS

1. ମାର୍ଗନ / ପୁରୁଷ / 2. ମାର୍ଗନ / ମହିଳା / 3. ମାର୍ଗନ / ମହିଳା / 4. ମାର୍ଗନ / ମହିଳା /

e DUPONT 0 .4MG/ML  
 e 1MG/ML  
 e 1MG/ML

<u>NANDROLONE DECAONATE</u>	INJECTABLE; INJECTION	<u>NANDROLONE DECAONATE</u>	/LyPhomed/	/100MG/ML/	/NBB62290/6661
/Ad/		/Ad/	/Ad/	/200MG/ML/	/NBB62290/1983
				100MG/ML	/NBB62290/001
				200MG/ML	OCT 03, 1983
					NBB62290/001
					OCT 14, 1983

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MAPBOXEN SOUTIEN

TABLET; ORAL

N18164 001  
N18164 003  
SEP 30, 1987  
N74106 001  
AUG 31, 1993  
N74106 002  
AUG 31, 1993

היכל סוכנות הדגל

/θə'zɪkənətɪv/ /lɪf'fɔːrɪd/ /θə'zɪkənətɪv/ /lɪf'fɔːrɪd/ /θə'zɪkənətɪv/ /lɪf'fɔːrɪd/ /θə'zɪkənətɪv/ /lɪf'fɔːrɪd/

NOV 17, 1986

NEW MOUNTAIN STATE

MICHTICIN SOLN-ALL  
TABLET; ORAL  
NEOMYCIN SULFATE  
/EON/ /AHS/  
/AAS/ <sup>a</sup>EON LABS

N61586 001

## NAPROXEN SODIUM

N8164 001

N18164 003

SEP 30, 1981

AUG 31, 1993  
N74106 002

NITROEUBANTOIN·MACROCRYSTALLINE

## NIACIN

a WALLACE

/500MG

TABLET; ORAL  
NEACTIN  
/NÉAKTÍN/  
a ZENITH

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL				
ADALAT CC	BC	MILES	30MG	
	BC		60MG	
	BC		90MG	
	BC		PROCARDIA XL	
	BC	+ PFIZER		30MG

BC +	90MG
	/ʒdʒʃ/
	/ʃdʒʃ/
	/ʃdʒʃ/

## NITROFURANTOIN

**ZENITH**  
METROFURANTOIN  
/ZÉNITH/  
TABLET; ORAL

N80078 001

OINTMENT; TOPICAL  
HISTATIN  
BARRE  
AT /  
/ASKA/

100,000 UNITS/GM / 1,666,666 UNITS/GM/ N62840 001 NOV 13, 1987 /N62840/666/ /NOV 13, 1987/

N62949 001  
JUN 13, 1988  
/N62949/001/  
/JUN/13/1988/  
N64022 001  
JAN 29, 1993

100,000 UNITS/GM  
100,000 UNITS/GM

<u>NYSTATIN</u>	CREAM; TOPICAL <u>NYSTATIN</u> BARRE	/Nɪʃtən/ AT	TARO AT
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N62949 001  
JUN 13 1988  
/N62949/661  
/ JUN 13 / 1988  
N64022 001

N74234 001  
JUL 26, 1993  
N74234 002  
JUL 26, 1993  
N74234 003  
JUL 26, 1993  
N74234 004  
JUL 26, 1993

## NORTRIPTYLINE HYDROCHLORIDE

**INJECTABLE; INJECTION  
NITRO-BID**

/N83180 001  
/N83180 001

JUL 30, 1993  
N72781 001

**NIFEDIPINE**  
CAPSULE; ORAL  
HIFEDIPINE  
FLEMINGTON  
B 10MG

N74234 001  
JUL 26, 1993  
N74234 002  
JUL 26, 1993  
N74234 003  
JUL 26, 1993  
N74234 004  
JUL 26, 1993  
N74234 005  
JUL 26, 1993

EQ 10MG BASE    EQ 25MG BASE    EQ 50MG BASE    EQ 75MG BASE

NORTRI  
CAPS  
HO

N62949 001  
JUN 13 1988  
/N62949/661  
/JUN 13 /1988  
N64022 001

100,000 UNITS/GM  
100,000 UNITS/GM

<u>NYSTATIN</u>	CREAM; TOPICAL <u>NYSTATIN</u> BARRE	/Nɪʃtən/ AT	TARO AT
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N62949 001  
JUN 13 1988  
/N62949/661  
/ JUN 13 / 1988  
N64022 001



OXPRENOLOL HYDROCHLORIDE

/CIBA/ /DRA/L/  
/PARKE DAVIS/  
/+/ CIBA/

/4.6H5/

/N18166/

/1983/

/N18166/001/

/1983/

/N18166/002/

/1983/

/N18166/003/

/1983/

/N18166/004/

/1983/

/N18166/005/

/1983/

PAREMETHASONE ACETATE

TABLET; ORAL

HALDRONE

/+// /1.5H5/

20MG

DEC 28, 1983

N18166 001

40MG

DEC 28, 1983

N18166 002

80MG

DEC 28, 1983

N18166 003

160MG

DEC 28, 1983

N18166 004

DEC 28, 1983

N18166 005

DEC 28, 1983

N18166 006

DEC 28, 1983

N18166 007

DEC 28, 1983

N18166 008

DEC 28, 1983

N18166 009

DEC 28, 1983

N18166 010

DEC 28, 1983

N18166 011

DEC 28, 1983

N18166 012

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N18166 013

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N18166 014

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N18166 019

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N18166 098

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N18166 100

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N18166 101

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N18166 102

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N18166 103

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N18166 104

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N18166 110

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N18166 111

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N18166 112

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N18166 113

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N18166 114

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N18166 115

DEC 27, 1984

N18166 116

DEC 27, 1984

N18166 117

DEC 27, 1984

N18166 118

DEC 27, 1984

N18166 119

DEC 27, 1984

N1

PENITENTIARY ROTACSTIM

## PENICILLIN V POTASSIUM

POWDER FOR RECONSTITUTION; ORAL

PENICILLIN	/AAA/	/666,666 UNITS/5ML/
BIOCRAFT	/AAA/	200,000 UNITS/5ML
BIOCRAFT	/AAA/	/666,666 UNITS/5ML/
PENICILLIN	/AAA/	200,000 UNITS/5ML
PENICILLIN	/AAA/	/666,666 UNITS/5ML/
PENICILLIN	/AAA/	400,000 UNITS/5ML
APOTHECON	/AAA/	/666,666 UNITS/5ML/
APOTHECON	/AAA/	200,000 UNITS/5ML
APOTHECON	/AAA/	/666,666 UNITS/5ML/
APOTHECON	/AAA/	400,000 UNITS/5ML

TARI ET AL.

LAUREL, GRAE BENETTI IN G. BOTASSI

REVIEWS IN SOROCATNE

NICILLIN G PROCAINE

### **INJECTABLE; INJECTION**

/N63276/661/  
N83279 001

REFLECTIONS

N20091.001  
AUG 13, 1993  
100%  
+ ALLIANCE PHARM

PAPER FOR RECONSTITUTION: QBAI

POWER FOR RECONSTRUCTION, CHINA

TABLET; ORAL

## **PERMETHRIN**

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN'93 - AUG'93  
PERMETHRIN  
PHENTERMINE HYDROCHLORIDE  
CAPSULE; ORAL  
PHENTERMINE HCL  
@ ZENITH  
/ 66/  
/ MAR 31, 1986/  
N19435 001  
1/2/  
BURROUGHS WELLCOME  
17.

## PHENTERMINE HYDROCHLORIDE

<u>PERPHENAZINE</u>	/'fɛfənæzɪn/	/fɛfənæzɪn/
@ BURROUGHS WELLCOME	/'bʌrəθʊs 'welkəm/	/bʌrəθʊs 'welkəm/
a	/ə/	/ə/
	THEATRE /'θeɪtə/	/θeɪtə/
	TELEPHONE /'telɪfən/	/telɪfən/
	SCHERING /'ʃerɪŋ/	/ʃerɪŋ/
	AMG /'æmɡ/	/æmɡ/

DEBPHENAZINE

## PHENDIMETRAZINE TARTRATE

CAPSULE; ORAL

1A/ 7E133

/APPENDIX

3 FERNDALE	35MG
/ VETRA /	/ 35MG /
/ AAA /	/ 35MG /
a FOREST PHARMS /	35MG
a FOREST PHARMS	
	<u>PHENMETRAZINE TARTRATE</u>
/ AAA /	/ 35MG /
/ ANABOLICS /	/ 35MG /
a ANABOLICS	35MG
/ FERNDALE /	/ 35MG /

## DHENTE BTMNE HYDROCHIOTIDE

CAPSULE; ORAL		
ADTIPEN-P	/ 50MG/	
/ 66/ / LENTON/		
/ 66/ / DESTIN/		
/ 66/ / FERD/	/ 50MG/	
a FERNDALE	30MG	
		ZOMG
		PHENOTERMIN HCL
		31FMN

<u>10MG</u>	<u>AB</u>	N73609 001 MAR 29, 1993
<u>5MG</u>	<u>AB</u>	N74125 001 APR 28, 1993
<u>10MG</u>	<u>AB</u>	N74125 002 APR 28, 1993
	PUREPAC	

N73608 001  
MAR 29, 1993

N73609 001  
MAR 29, 1993  
N74125 001  
APR 28, 1993

1070

**TABLET; ORAL  
PITHOLOL**

**ZENITH**  
**EMG**  
**10ME**

## PIROXICAM

CAPSULE; ORAL  
PIROXICAM  
MEPHAGA AG

<u>△CH12</u>	N74116 001 JUN 15, 1993
<u>20MG</u>	N74118 001 JUN 15, 1993
<u>10MG</u>	N73535 001 MAR 12, 1993
<u>20MG</u>	N73536 001 MAR 12, 1993
<u>10MG</u>	N73651 001 FEB 26, 1993
<u>20MG</u>	N73651 002 FEB 26, 1993

POLY(ETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE; ANHYDROS

POWDER FOR RECONSTITUTION: QBAI

PEG-LYTE  
INVANED

MATERIALS AND METHODS

CAPSULE, EXTENDED RELEASE; ORAL  
K-LEASE  
11/1997

<u>SAVAGE</u>	<u>8MEQ</u>	<u>10 MEQ</u>
N73398 001	JAN 28, 1992	MAR 28, 1990
/N73398 001	N72427 001	MAR 28, 1990
/JAN 28, 1992		
/N73398 001		
/MAR 28, 1990		

## POTASSIUM CHLORIDE

INJECTABLE; INJECTION  
ROTASSET<sup>TM</sup> SHIOTTE

TABLET, EXTENDED RELEASE; ORAL	
K48	AB ALRA
	<u>8MEQ</u>
KAON CL	/ADRI/
	SAVAGE
KAON CL-10	/ADRI/
	SAVAGE
/BC/	/ADRI/
BC	SAVAGE

N70998 001  
JAN 25, 1993  
/N17646/001/  
N17646 001  
/N17646/001/  
1.0MEQ

POTASSIUM CITRATE

/PROLOGUE/PACKET	/FOR RECONSTITUTION/;/DATA/	/N19647/001/
/PROLOGUE/PACKET	/PASSION/CITRATE/	/DC/T/13/1988/
/+//UNIV/TX/	/HOMEQ/PACKET/	/N19647/002/
		/DC/T/13/1988/
a UNIV TX	1OMEQ/PACKET	N19647 002
		OCT 13, 1988
a	2OMEQ/PACKET	N19647 003

TABLET, EXTENDED RELEASE; ORAL  
POTASSIUM CITRATE  
1.5 // 100 mg/TX/  
+ UNIV TX      10MEQ      5MEQ

/NY9971/061/  
/AUS/36/1985/  
N19071 002  
AUG 31, 1992  
N19071 001  
AUG 30, 1985



PROCAINAMIDE HYDROCHLORIDE

## CAPSULE; ORAL

PRONESTYL  
/AP/  
/SCOTT/EP/> DLT >/AB/  
> DLT >/AB/  
> DLT >/AB/+/+/  
  
/150MG/  
/375MG/  
/500MG/

## INJECTABLE; INJECTION

PROGATINAMIDE HCL  
/AP/  
/SCOTT/EP/  
  
/100MG/ML/  
/500MG/ML/  
/1000MG/ML/  
/5000MG/ML/

/AP/

+

APOTHECON

/AP/

+

/SCOTT/EP/

/AP/

## PROPRANOLOL HYDROCHLORIDE

SOLUTION; ORAL PROPRANOLOL HCL 1/4/PIKAR/6545/	> DLT > > DLT > > DLT > > DLT >	/4.61g/54L/ /4.61g/54L/ /4.61g/54L/ /4.61g/54L/	/N11484/d61/ /MAR/03/1999/ /N11485/d61/ /MAR/03/1999/	/SUSPENSION; ORAL/ /ANTIMINTH/ /+//ROERIC/	/E9/2504/EEAE/5M1/ /N16685/d61/
--	--	--	--	--	------------------------------------

SUSPENSION / DRAI /  
FEDERAL /  
WETH / AERST /  
100554 /  
100536 / 001 /  
AP /  
AP /  
TCH /  
ROCHE  
MESTHON  
INDICATION

**MESTITON**  
/mē'shētōn/  
**SYRUP; ORAL**  
/sēr'ēp; ôr'äl/  
DEC 12, 1986  
10MG/ML  
N19556 001  
© WYETH AYERST

**PROPRANOLOL HCL** /**μ**/ **MYLAN** 60MG  
TABLET; ORAL  
**MESTINON** /**μ**/ **μ**/  
N72275 001 JUN 09, 1989

**PROPYLIODONE**  
 /suspenSIon/ /INTRAATHACHEAL/  
 /pInoStIc/ /oTc/ /  
 /GLAXO/ /60%/  
 a GLAXO  
**TABLET, EXTENDED RELEASE; ORAL**  
**MESTINON**  
 /‡/ /tCn/  
 + ROCHE  
 /180mg/  
 NO9309 002  
 /N11665/661/  
 NL11665 001

PROTAMINE SULFATE  
PYRIDOXINE HYDROCHLORIDE  
INJECTABLE: INJECTION

<u>PROTATONE SULFATE</u>	<u>10MG/ML</u>	<u>/AP/</u>	<u>/16665-56-1/</u>
<u>QUAD/</u>	<u>10MG/ML</u>	<u>/AP/</u>	<u>/16665-56-1/</u>
<u>QUAD/</u>	<u>10MG/ML</u>	<u>/AP/</u>	<u>/16665-56-1/</u>
<u>QUAD/</u>	<u>10MG/ML</u>	<u>/AP/</u>	<u>/16665-56-1/</u>

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE	/A/ /E/ /P/ /T/ /P/ /S/			
SYRUP; ORAL /HIS-TAFF- LIFE/AES/	/T/ /M/ /G/ /L/ /I/ /E/ /L/	/N/ /E/ /G/ /Z/ /I/ /E/ /L/	/N/ /E/ /G/ /Z/ /I/ /E/ /L/	/N/ /E/ /G/ /Z/ /I/ /E/ /L/



SODIUM BICARBONATE

/INJECTABLE; /INJECTION  
/SODIUM BICARBONATE, IN/PLASTIC CONTAINER/  
/6.36g/

/Abbott/  
/Abbott/

0.9MEQ/ML

1MEQ/ML

a ABBOTT

a

INJECTABLE; INJECTION

BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP FUJISANA 2MG/ML

/Abbott/  
/Abbott/

SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER

a FUJISANA 23.4% IN PLASTIC CONTAINER

/Abbott/  
/Abbott/

AP FUJISANA 23.4% IN PLASTIC CONTAINER

/Abbott/  
/Abbott/

SODIUM CHROMATE, CR-51

AP FUJISANA 2MC1/VIAL

/Abbott/  
/Abbott/

SODIUM IODIDE, I-131

AP FUJISANA 50 UCI

/Abbott/  
/Abbott/

SODIUM IODIDE I 131

AP FUJISANA 100 UCI

/Abbott/  
/Abbott/

SODIUM CHROMATE, CR-51

INJECTABLE; INJECTION

CHROMOTYPE SODIUM

/Abbott/  
/Abbott/

a SQUIBB

a

SODIUM IODIDE, I-131

CAPSULE; ORAL

SODIUM IODIDE I 131

/Abbott/  
/Abbott/

a CIS

a

SOLUTION; ORAL

SODIUM IODIDE I 131

/Abbott/  
/Abbott/

CIS

a

SODIUM POLYSTYRENE SULFONATE

/POWDER; ORAL, RECTAL  
/SODIUM POLYSTYRENE SULFONATE

N88786 001

SEP 11, 1984

/Abbott/  
/Abbott/

/SEP 11, 1984</u

## SULFAME THI ZOLE

TABLET; ORAL  
THIOSULFIL  
/WYETH/AYE  
© WYETH AYE

## SULFAMETHOXAZOLE

TABLET; ORAL  
/gānt/ AND /dōl-psi/  
/gānt/

SUII FAMETHOXYAZOLE: TRIMETHOXYBUTIN

**SUSPENSION; ORAL  
TRIMETH/SULFA**

1

SULFISOXAZOLE

TABLET; ORAL  
SULFISOKAZOLE  
/HEATHER/  
/

SUL ETIPOXAZOLE ACETYL

/EMULSION / DRALI /  
/ LIPO SANTISINI /  
/ ROCHE /  
/ ROCHE

SULFISOXAZOLE DIOLAMINE  
/DINTENIT/ /OPHTHALMIC/  
/SANTISTIN/  
/ROCHE/  
a ROCHE

SII TWO

/N445545/445/  
NO8595 001

/11/15/03/  
N12715

DISCUSSION: 90

TRIMETHSULFA  
BARRE

/NASKA/

1

**SULFISOKAZOL**

© HEATHER

**LIFISUAZULE ACETYL**

SULFISOXAZOLE DIOLAMINE  
/DINTENIT/ /OPHTHALMIC/  
/SANTISTIN/  
/ROCHE/  
a ROCHE

511 Tunc

TABLET; ORAL  
SULINDAC  
MYLAN

TAMOXIFEN CITRATE  
TABLET; ORAL  
NOLVADEX  
/ + / ſ t u ã r t /  
+ ZENECA

INJECTABLE; INJECTION  
A-N-STANDOUS/AGGREGATED/ALBUMIN  
1000 U.S.P.  
2 NORTH AMERICAN  
N.Y.

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION  
/AMERSHAM MEDRONATE KIT/  
P/ /AMERSHAM/

N/A

③ AMERSHAM

/N/A/ /N/A/ /  
/AUG 65/ 1982/  
N/A 335 001  
AUG 06 1982

TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR





DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 8 / JAN '93 - AUG '93

## TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL  
TICLID  
+ SYNTAX

N19977 002 > ADD > + SKF  
ACT 21.1991 > ADD >  
EQ 10MG BASE  
PANMAIL

125MG N19979 001  
125MG MAR 24, 1993  
125MG /N19979-001/  
125MG /DC/ 31/1993/  
125MG /DC/ 31/1993/  
TRAZODONE HYDROCHLORIDE

### TIMOLOL MALEATE

TABLET; ORAL  
**TIMOLOL MALEATE**  
NOVOBPHARM

<u>NOVOPHARM</u>	<u>5MG</u>
	<u>10MG</u>
	<u>20MG</u>

## TOEPLITZ SODIUM

**CAPSULE; ORAL  
TOLMETIN SODIUM**

TORSEMEIDE INJECTAB  
DEMADE + BOEH

TABLET; ORAL  
DEMADEX  
+ BOEHRINGER

> ADD > TRANLYCYPROMINE SULFATE

TABLET; ORAL  
PARNATE  
+ SKF

TRAZODONE HYDROCHLORIDE

## TABLET; ORAL

> ADD >	AB	APOTHECON
> ADD >	AB	+ 50MG
> ADD >	AB	100MG
> ADD >	AB	150MG
> ADD >		300MG
> ADD >		
> ADD >	AB	/50MG/ /100MG/ /150MG/ /300MG/
> ADD >	AB	/ERÖTÖL/TÖRÉS/
> DLT >	AB	/+/ /DLT/
> DLT >	AB	/DLT/
> DLT >	AB	/DLT/
> DLT >	AB	/DLT/
> DLT >	AB	/DLT/
N18207 001		
N18207 002		
N18207 003		
MAR 25, 1985		
N18207 004		
NOV 07, 1988		
/N18207/001		
/N18207/002		
/N18207/003		
/MAR 25, 1985		
/N18207/004		
/NOV 07, 1988		

AB TRAZODONE HCL 50MG  
AB MUTUAL PHARM 100MG

TRETINOIN  
/SHABE/ /TOPICAL/  
/RETIN-A/  
/+ /JOHNSON RM/  
a JOHNSON RM  
/6:65%/  
0.05%  
/N16921/6662  
N16921 002

AEROSOL, METTERED; INHALATION  
AZMACORT  
+ RHONE POULENC RORER 0.1MG/INH  
/4.25mg/INH/  
/4/

#### AEROSOL; METERED; INHALATION

AZ-1ACUR | + PHONE POHLENC BOREB 0.7

/D:2556/INH/



TRIFLUROMAZINE

/SUSPENSION; /ORAL/  
/YESPRIN/  
/SQUIB/  
a APOTHECON

/EQ/50MG HCL/5ML  
EQ 50MG HCL/5ML

TRIFLUROMAZINE HYDROCHLORIDEINJECTABLE; INJECTION

> ADD > AP + APOTHECON  
> ADD > AP +  
> DLT > AP /  
> DLT > AP /

/TAF/ /  
/YESPRIN/  
/SQUIB/  
a SQUIB  
a a

/50MG/  
/10MG/  
/5MG/  
10MG  
25MG  
50MG

N11123 004  
N11123 001  
/N11123 004/  
/N11123 001/  
N11123 001  
N11123 002  
N11123 003

TUBOCURARINE CHLORIDEINJECTABLE; INJECTION

> ADD > AA  
a HEATHER/  
NYLOS TRADING  
/TAF/ /AP/

/50MG/  
/10MG/  
/5MG/  
3MG/ML

N11325 004  
N11325 001  
/N11325 004/  
/N11325 001/  
AA

TRIPELENNAMINE HYDROCHLORIDETABLET; ORAL

/TREPENNAMINE HCL  
/HEATHER/  
a HEATHER  
NYLOS TRADING  
/TAF/ /AP/

TRIPELENNAMINE HCL

/N03939/001/  
N83989 001  
N85412 001  
/N05412/001/

TRIHEXYPHENIDYL HYDROCHLORIDE

SYRUP; ORAL  
TRIHEXYPHENIDYL HCL  
a PENNEX PHARMS  
/TAF/ /AP/

> ADD > AA  
> ADD >  
> DLT > AA/  
> DLT >

N85622 001  
/N05622/001/  
AA

250MG  
/PENNEX/PAKCS/  
AB PHARMACAPS

N73484 001  
/N05444/001/  
/AUG/12/1986/  
N89442 001  
AUG 12, 1988

250MG  
/TAF/ /AP/

JUN 29, 1993

TRIMEPRAZINE TARTRATE

SYRUP; ORAL  
TRIMEPRAZINE TARTRATE  
a PENNEX PHARMS  
/S/PENNEX/PAKCS/

N88285 001  
APR 11, 1985  
/N06285/001/  
AP/ /TAF/ /AP/

250MG/5ML  
/PENNEX/PAKCS/  
AP PHARMACAPS

APR 29, 1993

TUBOCURARINE CHLORIDE

INJECTABLE; INJECTION  
TUBOCURARINE CHLORIDE  
a QUAD  
/TAF/ /AP/

N70866 001  
/N0666/001/  
/JUL/01/1986/  
/JUL/01/1986/

JUL 01, 1986

VALPROIC ACID

SYRUP; ORAL  
VALPROIC ACID  
a PHARMACAPS  
/TAF/ /AP/

N73484 001  
/N05444/001/  
/AUG/12/1986/  
N89442 001  
AUG 12, 1988

JUN 29, 1993

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION  
VANCOMYCIN HCL IN PLASTIC CONTAINER  
+ LILLY  
/TAF/ /AP/

N50671 001  
/N10671/001/  
APR 29, 1993

APR 29, 1993

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION  
VERAPAMIL HCL  
a MARSAM  
/TAF/ /AP/

N72233 001  
/N12637/001/  
FEB 26, 1993

FEB 26, 1993

TRIOXSALEN

TABLET; ORAL  
TRISORALEN  
/ELDER/  
ICN  
/5MG/  
5MG

2.5MG/ML  
/TAF/ /AP/

N72233 001  
/N12637/001/  
FEB 26, 1993

FEB 26, 1993



ZINC SULFATE

/INJECTABLE//INJECTION/  
/ZINC/SULFATE/  
/LYPHOMED/

@ LYPHOMED

/Ed./1Mg/ZINC/ML/  
/N19229/002  
MAY 05, 1987

/N19229/002/  
/MAY/85/1987/  
N19229 002





DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST  
CUMULATIVE SUPPLEMENT NUMBER 8 / AUG '93

INDIUM<sup>111</sup> CHLORIDE

SOLUTION: INJECTION  
INDICLOR  
AMERSHAM

N19862  
DEC 29, 1992

N/A

**LIST OF ORPHAN PRODUCT DESIGNATIONS & APPROVALS**  
*[January thru August 1993]*

NAME Generic/Chemical TN= Trade Name	INDICATION DESIGNATED	SPONSOR & ADDRESS DD=Date Designated MA=Marketing Approval
8-METHOXALEN TN= UVADEX	FOR USE IN CONJUNCTION WITH THE UVAR PHOTOPHERESIS TO TREAT DIFFUSE SYSTEMIC SCLEROSIS.	THERAKOS, INCORPORATED 201 BRANDYWINE PARKWAY WEST CHESTER PA 19380 DD 06/22/93 MA / /
AMINOSALICYLATE SODIUM TN=	TREATMENT OF CROHN'S DISEASE.	SYNCOM PHARMACEUTICALS, INC. 155 PASSAIC AVENUE FAIRFIELD NJ 07004 DD 04/06/93 MA / /
AMINOSIDINE TN= GABBROMICINA	TREATMENT OF TUBERCULOSIS.	UNIVERSITY OF ILLINOIS AT CHICAGO 833 SOUTH WOOD STREET M/C 886 ROOM 176 CHICAGO IL 60612 DD 05/14/93 MA / /
AMIODARONE TN= AMIO-AQUEOUS	TREATMENT OF INCESSANT VENTRICULAR TACHYCARDIA.	ACADEMIC PHARMACEUTICALS, INC. 25720 SAUNDERS ROAD NORTH LAKE FOREST IL 60045 DD 08/17/93 MA / /
ANTI-THYMOCYTE SERUM TN= NASHVILLE RABBIT ANTI-THYMOCYTE SERUM	TREATMENT OF ALLOGRAFT REJECTION, INCLUDING SOLID ORGAN (KIDNEY, LIVER, HEART, LUNG, AND PANCREAS) AND BONE MARROW TRANSPLANTATION.	APPLIED MEDICAL RESEARCH 1600 HAYES STREET NASHVILLE TN 37203 DD 06/02/93 MA / /
APOMORPHINE HCl INJECTION TN=	TREATMENT OF THE ON-OFF FLUCTUATIONS ASSOCIATED WITH LATE-STAGE PARKINSON'S DISEASE.	BRITANNIA PHARMACEUTICALS LTD FORM HOUSE, BRIGHTON ROAD REDHILL, SURREY UK DD 04/22/93 MA / /
ATOVAQUONE TN= MEPRON	TREATMENT AND SUPPRESSION OF TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
ATOVAQUONE TN= MEPRON	PRIMARY PROPHYLAXIS OF HIV-INFECTED PERSONS AT HIGH RISK FOR DEVELOPING TOXOPLASMA GONDII ENCEPHALITIS.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 03/16/93 MA / /
CLADRIBINE TN= LEUSTATIN INJECTION	TREATMENT OF NON-HODGKIN'S LYMPHOMA.	R.W.JOHNSON RESEARCH INSTITUTE ROUTE 202 SOUTH, P.O. BOX 300 RARITAN NJ 08869-0602 DD 04/19/93 MA / /
COLFOSCERIL PALMITATE, CETYL ALCOHOL, TYLOXAPOL TN= EXOSURF	TREATMENT OF ADULT RESPIRATORY DISTRESS SYNDROME.	BURROUGHS WELLCOME COMPANY 3030 CORNWALLIS ROAD RESEARCH TRIANGLE PK NC 27709 DD 01/11/93 MA / /
CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR GENE TN=	TREATMENT OF CYSTIC FIBROSIS.	GENETIC THERAPY, INC. 19 FIRSTFIELD ROAD GAITHERSBURG MD 20878 DD 01/08/93 MA / /
DEPOFOAM ENCAPSULATED CYTARABINE TN=	TREATMENT OF NEOPLASTIC MENINGITIS.	KIM, SINIL M.D. UCSD CANCER CENTER/0812 SAN DIEGO CA 92103 DD 06/02/93 MA / /
DISODIUM CLDRONATE TN=	TREATMENT OF HYPERCALCEMIA OF MALIGNANCY.	DISCOVERY EXPERIMENTAL & DEVELOPMENT, INC 29949 S.R. 54 WEST WESLEY CHAPEL FL 33543 DD 06/16/93 MA / /

**CUMULATIVE LIST OF DESIGNATIONS & APPROVALS**

<b>NAME</b> Generic/Chemical TN= Trade Name	<b>INDICATION DESIGNATED</b>	<b>SPONSOR &amp; ADDRESS</b> DD=Date Designated MA=Marketing Approval
FACTOR XIII, RECOMBINANT TN=	TREATMENT OF CONGENITAL FACTOR XIII DEFICIENCY.	ZYMOGENETICS, INC. 4225 ROOSEVELT WAY SEATTLE WA 98105 DD 04/22/93 MA / /
HUMANIZED ANTI-TAC TN=	PREVENTION OF ACUTE RENAL ALLOGRAFT REJECTION.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 03/05/93 MA / /
HUMANIZED ANTI-TAC TN=	PREVENTION OF ACUTE GRAFT-VS-HOST DISEASE FOLLOWING BONE MARROW TRANSPLANTATION.	HOFFMANN-LA ROCHE, INC. 340 KINGSLAND STREET NUTLEY NJ 07110 DD 03/05/93 MA / /
IMMUNE GLOBULIN INTRAVENOUS (HUMAN) TN= GAMIMUNE N	INFECTION PROPHYLAXIS IN PEDIATRIC PATIENTS AFFECTED WITH THE HUMAN IMMUNODEFICIENCY VIRUS.	MILES, INC. 4TH & PARKER STREETS BERKELEY CA 94710 DD 02/18/93 MA / /
INTERFERON BETA (RECOMBINANT HUMAN) TN=	TREATMENT OF PRIMARY BRAIN TUMORS.	BIOGEN, INC. 14 CAMBRIDGE CENTER CAMBRIDGE MA 02142 DD 01/13/93 MA / /
LIPOSOMAL DAUNORUBICIN TN= DAUNOXOME	TREATMENT OF PATIENTS WITH ADVANCED HIV-ASSOCIATED KAPOSI'S SARCOMA.	VESTAR, INC. 650 CLIFFSIDE DRIVE SAN DIMAS CA 91773 DD 05/14/93 MA / /
METHOTREXATE TN= RHEUMATREX	TREATMENT OF JUVENILE RHEUMATOID ARTHRITIS.	LEDERLE LABORATORIES 401 N. MIDDLETOWN ROAD PEARL RIVER NY 10965-1299 DD 08/23/93 MA / /
MODAFINIL TN=	TREATMENT OF EXCESSIVE DAYTIME SLEEPINESS IN NARCOLEPSY.	CEPHALON, INC. 145 BRANDYWINE PARKWAY WEST CHESTER PA 19380-4245 DD 03/15/93 MA / /
MONOCLONAL ANTIBODY FOR IMMUNIZATION AGAINST LUPUS NEPHRITIS TN=	TREATMENT OF LUPUS NEPHRITIS.	MEDCLONE, INC. 2435 MILITARY AVENUE LOS ANGELES CA 90064 DD 01/07/93 MA / /
MONOLaurin TN= GLYROLIN	TREATMENT OF CONGENITAL PRIMARY ICHTHYOSIS.	CELLEGY PHARMACEUTICALS, INC. 371 BEL MARIN KEYS, SUITE 210 NOVATO CA 94949 DD 04/29/93 MA / /
MYTOmycin-C TN=	TREATMENT OF REFRACTORY GLAUCOMA AS AN ADJUNCT TO AB EXTERNO GLAUCOMA SURGERY.	IOP INCORPORATED 3100 AIRWAY AVENUE COSTA MESA CA 92626 DD 08/23/93 MA / /
NITRIC OXIDE TN=	TREATMENT OF PERSISTENT PULMONARY HYPERTENSION IN THE NEWBORN.	ANAQUEST, INCORPORATED 110 ALLEN ROAD LIBERTY CORNER NJ 07938 DD 06/22/93 MA / /
PRIMAQUINE PHOSPHATE TN=	FOR USE IN COMBINATION WITH CLINDAMYCIN HYDROCHLORIDE IN THE TREATMENT OF PNEUMOCYSTIS CARINII PNEUMONIA ASSOCIATED WITH ACQUIRED IMMUNODEFICIENCY SYNDROME.	STERLING WINTHROP INC. 90 PARK AVENUE NEW YORK NY 10016 DD 07/23/93 MA / /
PROTEIN C CONCENTRATE TN= PROTEIN C CONCENTRATE (HUMAN) VAPOR HEATED, IMMUNO	FOR USE IN THE PREVENTION AND TREATMENT OF PURPURA FULMINANS IN MENINGOCOCCEMIA.	IMMUNO CLINICAL RESEARCH CORP. 750 LEXINGTON AVENUE, 19TH FLOOR NEW YORK NY 10022 DD 04/22/93 MA / /

**CUMULATIVE LIST OF DESIGNATIONS & APPROVALS**

<b>NAME</b> Generic/Chemical <i>TN= Trade Name</i>	<b>INDICATION DESIGNATED</b>	<b>SPONSOR &amp; ADDRESS</b> <i>DD=Date Designated</i> <i>MA=Marketing Approval</i>
PROTIRELIN TN=	PREVENTION OF INFANT RESPIRATORY DISTRESS SYNDROME ASSOCIATED WITH PREMATURITY.	UCB PHARMACEUTICALS, INC. 5505-A ROBIN HOOD ROAD NORFOLK VA 23513 DD 08/24/93 MA / /
PULMONARY SURFACTANT REPLACEMENT, PORCINE TN= CUROSURF	FOR THE TREATMENT AND PREVENTION OF RESPIRATORY DISTRESS SYNDROME IN PREMATURE INFANTS.	CHIESI PHARMACEUTICALS, INC. 150 DANBURY ROAD RIDGEFIELD CT 06877 DD 08/02/93 MA / /
RII RETINAMIDE TN=	TREATMENT OF MYELODYSPLASTIC SYNDROMES.	SPARTA PHARMACEUTICALS, INCORPORATED PO BOX 13288 RESEARCH TRIANGLE PK NC 27709 DD 05/06/93 MA / /
RILUZOLE TN=	TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS.	RHONE-POULENC RORER PHARM. 500 ARCOLA ROAD, PO BOX 1200 COLLEGEVILLE PA 19426-0107 DD 03/16/93 MA / /
ROQUINIMEX TN= LINOMIDE	TO PROLONG TIME TO RELAPSE IN LEUKEMIA PATIENTS WHO HAVE UNDERGONE AUTOLOGOUS BONE MARROW TRANSPLANTATION.	KABI PHARMACIA, INC. 800 CENTENNIAL AVENUE PISCATAWAY NJ 08855-1327 DD 07/01/93 MA / /
SECALCIFEROL TN= OSTEO-D	TREATMENT OF FAMILIAL HYPOPHOSPHATEMIC RICKETS.	LEMMON COMPANY 650 CATHILL ROAD SELLERSVILLE PA 18960 DD 07/26/93 MA / /
SOMATROPIN TN= BIOTROPIN	TREATMENT OF CACHEXIA ASSOCIATED WITH AIDS.	BIO-TECHNOLOGY GENERAL CORPORATION 1250 BROADWAY, 20th FLOOR NEW YORK NY 10001 DD 02/12/93 MA / /
SUCRALFATE TN=	TREATMENT OF ORAL MUCOSITIS AND STOMATITIS FOLLOWING RADIATION THERAPY FOR HEAD AND NECK CANCER.	FUISZ TECHNOLOGIES, LTD. 3810 CONCORDE PARKWAY, SUITE 100 CHANTILLY VA 22021 DD 07/15/93 MA / /
THALIDOMIDE TN=	TREATMENT OF THE CLINICAL MANIFESTATIONS OF MYCOBACTERIAL INFECTION CAUSED BY MYCOBACTERIUM TUBERCULOSIS AND NON-TUBERCULOUS MYCOBACTERIA.	CELGENE CORPORATION 7 POWDER HORN DRIVE WARREN NJ 07059 DD 01/12/93 MA / /
TOREMIFENE TN= ESTRINEX	TREATMENT OF DESMOID TUMORS.	ADRIA LABORATORIES P.O. BOX 16529 COLUMBUS OH 43216-6529 DD 08/17/93 MA / /
TRETINOIN TN= TRETINOIN LF, IV	TREATMENT OF ACUTE AND CHRONIC LEUKEMIA.	ARGUS PHARMACEUTICALS, INC. 3400 RESEARCH FOREST DRIVE THE WOODLANDS TX 77381 DD 01/14/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN 1 TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 COUNTS LESS THAN 200 CELLS PER MM <sup>3</sup> .	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /
TUMOR NECROSIS FACTOR-BINDING PROTEIN II TN=	TREATMENT OF SYMPTOMATIC PATIENTS WITH THE ACQUIRED IMMUNODEFICIENCY SYNDROME INCLUDING ALL PATIENTS WITH CD4 T-CELL COUNTS LESS THAN 200 CELLS PER MM <sup>3</sup> .	SERONO LABORATORIES, INC. 100 LONGWATER CIRCLE NORWELL MA 02061 DD 01/06/93 MA / /

**CUMULATIVE LIST OF DESIGNATIONS & APPROVALS**

**NAME**

Generic/Chemical  
TN= Trade Name

**INDICATION DESIGNATED****SPONSOR & ADDRESS**

DD= Date Designated  
MA= Marketing Approval

VASOACTIVE INTESTINAL  
POLYPEPTIDE  
TN=

TREATMENT OF ACUTE ESOPHAGEAL FOOD IMPACTION.

RESEARCH TRIANGLE  
PHARMACEUTICALS  
200 WESTPARK CORPORATE CENTER  
DURHAM NC 27713  
DD 06/23/93 MA / /

**Orphan Drug Approvals**

ANTIHEMOPHILIC FACTOR  
(RECOMBINANT)  
TN= KOGENATE

PROPHYLAXIS AND TREATMENT OF BLEEDING IN INDIVIDUALS  
WITH HEMOPHILIA A OR FOR PROPHYLAXIS WHEN SURGERY IS  
REQUIRED IN INDIVIDUALS WITH HEMOPHILIA A.

MILES, INC.  
4TH & PARKER STREETS  
BERKELEY CA 94701  
DD 09/25/89 MA 02/25/93

CLADRIBINE  
TN= LEUSTATIN INJECTION

TREATMENT OF HAIRY CELL LEUKEMIA.

R.W.JOHNSON RESEARCH INSTITUTE  
ROUTE 202, PO BOX 300  
RARITAN NJ 08869-0602  
DD 11/15/90 MA 02/26/93

FELBAMATE  
TN= FELBATOL

TREATMENT OF LENNOX-GASTAUT SYNDROME.

WALLACE LABORATORIES  
301B COLLEGE ROAD EAST  
PRINCETON NJ 08540  
DD 01/24/89 MA 07/29/93

INTERFERON BETA, RECOMBINANT  
HUMAN  
TN=BETASERON

TREATMENT OF MULTIPLE SCLEROSIS.

CHIRON CORPORATION  
4560 HORTON STREET  
EMERYVILLE CA 94608  
DD 11/17/88 MA 07/23/93

LEUPROLIDE ACETATE  
TN= LUPRON INJECTION

TREATMENT OF CENTRAL PRECOCIOUS PUBERTY.

TAP PHARMACEUTICALS, INC.  
2355 WAUKEGAN ROAD  
DEERFIELD IL 60015  
DD 07/25/88 MA 04/16/93

LEVOMETHADYL ACETATE  
HYDROCHLORIDE  
TN=ORLAAM

TREATMENT OF HEROIN ADDICTS SUITABLE FOR MAINTENANCE ON  
OPIATE AGONISTS.

BIODEVELOPMENT CORPORATION  
1300 NORTH 17TH STREET, SUITE  
300  
ARLINGTON VA 22209-2306  
DD 01/24/84 MA 07/09/93

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

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NO AUGUST 1993 ADDITIONS

## BIOPHARMACEUTIC GUIDANCE AVAILABILITY

DRUG NAME (DOSAGE FORM)	DATE	REVISED DATE
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THE FOLLOWING IS A LIST OF GUIDANCES AVAILABLE FOR *IN VIVO* BIOEQUIVALENCE STUDIES AND *IN VITRO* DISSOLUTION TESTING. COMMENTS AND SUGGESTIONS CONCERNING THESE GUIDANCES ARE ENCOURAGED AND SHOULD BE SENT TO THE DIVISION OF BIOEQUIVALENCE (HFD-650, MPN-2 ROOM 279) 5600 FISHERS LANE, ROCKVILLE, MD 20857.

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF BIOPHARMACEUTIC GUIDANCE AVAILABILITY DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

BUMETANIDE (TABLET)	APR 23, 1993
BUSIPRONE HYDROCHLORIDE (TABLET)	AUG 13, 1993
CEFACLOR (CAPSULE AND SUSPENSION)	APR 23, 1993
CAPTOPRIL (TABLET)	MAY 13, 1993
CHOLESTRYRAMINE (POWDER)	JUL 15, 1993
GLIPIZIDE (TABLET)	APR 23, 1993
GLYBURIDE (TABLET)	APR 23, 1993
GUANABENZ ACETATE (TABLET)	APR 23, 1993
INDAPAMIDE (TABLET)	APR 23, 1993
KETOPROFEN (CAPSULE)	APR 23, 1993
ORAL EXTENDED (CONTROLLED RELEASE)	SEP 09, 1993
PINDOLOL (TABLET)	APR 23, 1993
RANITIDINE HYDROCHLORIDE (TABLET)	APR 23, 1993
TRIAZOLAM (TABLET)	DEC 24, 1992

## ANDA SUITABILITY PETITIONS

## PETITIONS APPROVED

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

REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 13TH EDITION FOR A FULL LISTING OF ANDA SUITABILITY PETITIONS DATA. ONLY NEW DATA WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

AMINOSALICYLIC ACID GRANULES, ENTERIC-COATED; ORAL	4GM/PACKET	92 P-0356/ CP1	JACOBUS	NEW DOSAGE FORM NEW STRENGTH	APPROVED MAR 03, 1993
CARBOPLATIN INJECTABLE; INJECTION	10MG/ML (5ML/VIAL) (15ML/VIAL) (45ML/VIAL)	92 P-0467/ CP1	BULL	NEW DOSAGE FORM	APPROVED MAY 20, 1993
CHLORPROMAZINE HYDROCHLORIDE SOLUTION; ORAL	25MG/5ML	92 P-0284/ CP1	UDL	NEW STRENGTH	APPROVED JAN 07, 1993
DOBUTAMINE HYDROCHLORIDE INJECTABLE; INJECTION	EQ 12.5MG BASE/ML (40ML/VIAL)	92 P-0365/ CP1	LYPHOMED	NEW STRENGTH	APPROVED FEB 11, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (12.5MG/VIAL)	92 P-0355/ CP1	LEDERLE	NEW STRENGTH	APPROVED JAN 07, 1993
ETOPOSIDE INJECTABLE; INJECTION	20MG/ML (50ML/CONTAINER)	91 P-0460/ CP1	ABBOTT	NEW STRENGTH	APPROVED FEB 11, 1993
LACTULOSE CRYSTAL; ORAL	10GM/PACKET	92 P-0370/ CP1	BENNETT AND COMPANY	NEW DOSAGE FORM	APPROVED JAN 07, 1993
METHYLPHENIDATE HYDROCHLORIDE; TABLET, EXTENDED RELEASE; ORAL	10MG	92 P-0400/ CP1	MD PHARM	NEW STRENGTH	APPROVED MAR 22, 1993
PREDNISOLONE SYRUP; ORAL	10MG/5ML	92 P-0439/ CP1	WE PHARMS	NEW STRENGTH	APPROVED MAY 20, 1993
TRIMETHOPRIM SOLUTION; ORAL	25MG/5ML	92 P-0500/ CP1	ASCENT PHARMS	NEW DOSAGE FORM	APPROVED MAY 20, 1993

## 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, 13TH 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-20      SINGLE 32MG DOSE

### REFERENCES NEW INDICATION

- I-87 RENAL IMAGING AGENT FOR USE IN CHILDREN
- I-88 MANAGEMENT OF ENDOMETRIOSIS
- I-89 EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE
- I-90 INTENSIVE CARE UNIT SEDATION
- I-91 MONOTHERAPY USE FOR HYPERTENSION
- I-92 ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE
- I-93 PREVENTION OF EXERCISE-INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS
- I-94 USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITATE VISUALIZATION OF LESIONS IN THE BODY [EXCLUDING THE HEART]

### REFERENCES PATENT USE CODE

- U-74 METHOD OF PROVIDING HYPNOTIC EFFECT
- U-75 RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS
- U-76 USE TO IMAGE A SUBJECT WITH A MAGNETIC RESONANCE IMAGING SYSTEM
- U-77 TREATMENT OF SYMPTOMS OF SEASONAL ALLERGIC RHINITIS
- U-78 ULCERATIVE COLITIS
- U-79 SYMPTOMATIC TREATMENT OF PATIENTS WITH NOCTURNAL HEARTBURN DUE TO GERD

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
18473 001	ALBUTEROL; VENTOLIN			I-93	JUL 20,	1996
19489 001	ALBUTEROL SULFATE; VENTOLIN ROTACAPS	4851229	JUN 14, 2005	I-93	JUL 20,	1996
19604 001	ALBUTEROL SULFATE; VOLMAX	4777049	OCT 11, 2005			
19604 002	ALBUTEROL SULFATE; VOLMAX	4751071	JUN 14, 2005	U-15	NS	DEC 23, 1995
20258 001	APRACLONIDINE HYDROCHLORIDE; IOPIDINE	4517199	MAY 14, 2002			
19402 001	ASTEMIZOLE; HISMANAL	4219559	AUG 26, 1999	NCE	DEC 29,	1993
20045 001	AVOBENZONE; SHADE UVAGUARD	4522807	JUN 11, 2002	NC	DEC 07,	1995
19807 001	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4387089	JUN 07, 2002			
19807 002	BETAXOLOL HYDROCHLORIDE; KERLEDEX	4252984	AUG 30, 1999			
20186 001	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
20186 002	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NC	FEB 26, 1996
20186 003	BISOPROLOL FUMARATE; ZIAC	4258062	MAR 24, 1998	U-63	NCE	JUL 31, 1997
20210 001	CISAPRIDE MONOHYDRATE; PROPULSID	4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998
20210 002	CISAPRIDE MONOHYDRATE; PROPULSID	4962115	OCT 09, 2007	U-79	NCE	JUL 29, 1998
>ADD>	CLADRIBINE; LEUSTATIN					
>ADD>						
19287 001	DIAZEPAM; DIZAC	5212326	JAN 29, 2008			
18723 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
18723 002	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
18723 003	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
19680 001	DIVALPROEX SODIUM; DEPAKOTE	5212326	JAN 29, 2008			
19794 001	DIVALPROEX SODIUM; DEPAKOTE CP	5212326	JAN 29, 2008			
19794 002	DIVALPROEX SODIUM; DEPAKOTE CP	5212326	JAN 29, 2008			
18651 001	DRONABINOL; MARINOL	5212326	JAN 29, 2008			
18651 002	DRONABINOL; MARINOL	5212326	JAN 29, 2008			
18651 003	DRONABINOL; MARINOL	5212326	JAN 29, 2008			
199616 004	ENOXACIN; PENETREX	4359578	NOV 16, 2001	NCE	DEC 31,	1996
199616 005	ENOXACIN; PENETREX	4359578	NOV 16, 2001	NCE	DEC 31,	1996
20164 001	ENOXAPARIN SODIUM; LOVENOX					

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
> <u>ADD</u> >	20189 001 FELBAMATE; FELBATOL			NCE	JUL 29,	1998
> <u>ADD</u> >	20189 002 FELBAMATE; FELBATOL			ODE	JUL 29,	2000
> <u>ADD</u> >	20189 003 FELBAMATE; FELBATOL			NCE	JUL 29,	1998
> <u>ADD</u> >	20073 001 FLUMAZENIL; MAZICON	4316839	MAR 03, 2003	ODE	JUL 29,	2000
	18936 006 FLUOXETINE HYDROCHLORIDE; PROZAC	4314081	FEB 02, 2001	NCE	DEC 20,	1996
		4194009	APR 19, 1994	U-12		
		4018895	APR 19, 1994	U-64	NCE	SEP 27, 1996
		4215113	JUN 06, 2000	NCE	JAN 08,	1998
		4687659	AUG 18, 2004	U-76	I-94	AUG 17, 1996
		4957939	MAR 03, 2004			
20068 001	FOSCARNET SODIUM; FOSCAVIR	4188	FEB 02, 1996	NCE	MAY 08,	1994
20123 001	GADODIAMIDE; OMNISCAN	4188	FEB 02, 1996	I-88	FEB 02,	1996
19596 001	GADOPENTETATE DIIMEGLUMINE; MAGNEVIST	4188	FEB 02, 1996	I-91	MAY 11,	1996
17783 003	GLIPIZIDE; GLUCOTROL	4188	FEB 02, 1996	I-91	MAY 11,	1996
19726 001	GOSERELIN ACETATE; ZOLADEX	4188	FEB 02, 1996	NCE	JAN 11,	1994
19032 001	GUANFACINE HYDROCHLORIDE; TENEX	4188	FEB 02, 1996	NDF	DEC 07,	1995
19032 002	GUANFACINE HYDROCHLORIDE; TENEX	4188	FEB 02, 1996	NCE	JAN 11,	1994
19891 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID	4188	FEB 02, 1996	NDF	DEC 07,	1995
19892 001	HYDROMORPHONE HYDROCHLORIDE; DILAUDID	4188	FEB 02, 1996	NCE	JAN 11,	1994
18538 002	INDAPAMIDE; LOZOL	4188	FEB 02, 1996	NDF	DEC 07,	1995
19710 005	IOVERSOL; OPTIRAY 350	4188	FEB 02, 1996	NS	APR 29,	1996
20215 001	ISOSORBIDE MONONITRATE; MONOKET	4188	FEB 02, 1996	NCE	JUL 06,	1993
20215 002	ISOSORBIDE MONONITRATE; MONOKET	4188	FEB 02, 1996	NCE	DEC 30,	1996
> <u>ADD</u> >	20225 001 ISOSORBIDE MONONITRATE; IMDUR	4188	FEB 02, 1996	NS	JUN 30,	1996
> <u>ADD</u> >	20225 002 ISOSORBIDE MONONITRATE; IMDUR	4188	FEB 02, 1996	NCE	DEC 30,	1996
> <u>ADD</u> >	19084 001 KETOCONAZOLE; NIZORAL	4335125	JUN 15, 1999	NCE	AUG 12,	1996
> <u>ADD</u> >	19700 001 KETOROLAC TROMETHAMINE; ACULAR	5110433	MAY 05, 2009	NDF	DEC 30,	1996
		4454151	JUN 12, 2001	NCE	AUG 12,	1996
		4089969	MAY 16, 1997	NDF	JAN 27,	1996
				NDF	NOV 30,	1994
				NDF	NOV 09,	1995

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PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
20263 001	LEUPROLIDE ACETATE; LUPRON	4917893	MAR 24, 2004	NP	APR 16, 1996	
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
		4005063	JAN 25, 1996	ODE	APR 16, 2000	
20263 002	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004	NP	APR 16, 1996	
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
		4005063	JAN 25, 1996	ODE	APR 16, 2000	
20263 003	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004	NP	APR 16, 1996	
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
		4005063	JAN 25, 1996	ODE	APR 16, 2000	
20263-004	LEUPROLIDE ACETATE; LUPRON DEPOT-PED	4917893	MAR 24, 2004	NP	APR 16, 1996	
		4849228	JUL 18, 2006			
		4728721	MAR 01, 2005			
		4677191	JUN 30, 2004			
		4652441	MAR 24, 2004			
		4005063	JAN 25, 1996	ODE	APR 16, 2000	
18948 001	LEVOCARNITINE; CARNITOR	4728721	MAR 01, 2005	I-86	DEC 16, 1995	
18948 002	LEVOCARNITINE; CARNITOR	4677191	JUN 30, 2004	ODE	DEC 16, 1999	
20315 001	LEVOMETHADYL ACETATE HYDROCHLORIDE; ORLAAM	4652441	MAR 24, 2004	I-86	DEC 16, 1995	
		4005063	JAN 25, 1996	ODE	DEC 16, 1999	
		4728721	MAR 01, 2005	NCE	DEC 16, 1999	
		4677191	JUN 30, 2004	JUL 09, 1998		
		4652441	MAR 24, 2004	ODE	DEC 16, 1999	
		4005063	JAN 25, 1996	OBE	DEC 16, 1999	
19558 001	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001	I-92	JUN 09, 1996	
19558 002	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001	I-92	JUN 09, 1996	
19558 003	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001	I-92	JUN 09, 1996	
19558 004	LISINOPRIL; PRINIVIL	4374829	DEC 30, 2001	I-92	JUN 09, 1996	

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19777 001	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001	1-92	JUN 09,	1996
19777 002	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001	1-92	JUN 09,	1996
19777 003	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001	1-92	JUN 09,	1996
19777 004	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001	1-92	JUN 09,	1996
19777 005	LISINOPRIL; ZESTRIL	4374829	DEC 30, 2001	1-92	JUN 09,	1996
20013 001	LOMEFLOXACIN HYDROCHLORIDE; MAXAQUIN	4528287	MAY 05, 2005	U-36	NCE	FEB 21, 1997
19658 001	LORATADINE; CLARITIN	4282233	AUG 04, 1998	U-77	NCE	APR 12, 1998
20049 001	MESALAMINE; PENTASA	4496553	JAN 29, 2002	U-78	NP	MAY 10, 1996
20098 001	MIVACURUM CHLORIDE; MIVACRON	4761418	JAN 22, 2006	NCE	JAN 22,	1997
20098 002	MIVACURUM CHLORIDE; MIVACRON IN DEXTROSE 5%	4761418	JAN 22, 2006	NCE	JAN 22,	1997
19583 001	NABUMETONE; RELAFEN	4420639	DEC 13, 2002	NCE	DEC 24,	1996
19583 002	NABUMETONE; RELAFEN	4420639	DEC 13, 2002	NCE	DEC 24,	1996
20109 001	NAFARELIN ACETATE; SYNAREL	4234571	NOV 18, 1999	NCE	FEB 13,	1995
19356 001	NAFTIFINE HYDROCHLORIDE; NAFTIN	4282251	AUG 04, 2000	NCE	MAR 01,	1993
20150 001	NICOTINE; NICOTROL	4915950	APR 10, 2007	NP	APR 22,	1995
20150 002	NICOTINE; NICOTROL	4915950	APR 10, 2007	NP	APR 22,	1995
20150 003	NICOTINE; NICOTROL	4915950	APR 10, 2007	NP	APR 22,	1995
20066 001	NICOTINE POLACRILEX; NICORETTE DS	4695578	JAN 03, 2005	NCE	JAN 13,	1994
20198 001	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
20198 002	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
20198 003	NIFEDIPINE; ADALAT CC	4892741	JAN 09, 2007			
19921 001	OFLOXACIN; OCUFLOX	4382892	MAY 10, 2000			
20007 001	ONDANSETRON HYDROCHLORIDE; ZOFTRAN	4695578	JAN 03, 2005	D-20	FEB 02,	1996
>ADD>	20103 001 ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004	1-9	AUG 13,	1996
>ADD>	20103 002 ONDANSETRON HYDROCHLORIDE; ZOFRAN	4695578	SEP 22, 2004	NCE	JAN 04,	1996
>DLT>	20036 001 PAMIDRONATE DISODIUM; AREDIA	3962432	JUL 16, 1996	U-53	NCE	OCT 31, 1996
>ADD>	20036 001 PAMIDRONATE DISODIUM; AREDIA	3962432	JUL 01, 1997	U-53	NCE	OCT 31, 1996
>ADD>	20036 003 PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			
>ADD>	20036 004 PAMIDRONATE DISODIUM; AREDIA	4711880	DEC 08, 2004			
>ADD>	20091 001 PERFLUBRON; IMAGENT	3962432	JUL 16, 1996	U-53	NCE	OCT 31, 1996
>ADD>	20014 001 PIRBUTEROL ACETATE; MAXAIR	4664107	MAY 12, 2004	NCE	AUG 13,	1998
19795 001	PODOFILOX; CONDYLOX					
19898 004	PRAVASTATIN SODIUM; PRAVACHOL	4346227	AUG 24, 1999	NCE	DEC 13,	1995
19568 001	PREDNICKARBATE; DERMATOP	4242334	DEC 30, 1999	NE	OCT 31,	1996
				U-50	SEP 23,	1994

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API/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
19627 001	PROPOFOL; DIPRIVAN			I-90	MAR 08, 1996	
50689 001	RIFABUTIN;			ODE	DEC 23, 1999	
19839 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005	NCE	DEC 30, 1996	
19839 002	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005	NCE	DEC 30, 1996	
19839 003	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005	NCE	DEC 30, 1996	
19839 004	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518	DEC 31, 2005	NCE	DEC 30, 1996	
19766 001	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 002	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 003	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
19766 004	SIMVASTATIN; ZOCOR	4444784	DEC 24, 2005	U-59	NCE	DEC 23, 1997
20134 001	STRONTIUM CHLORIDE, SR-89; METASTRON			NCE	JUN 18, 1998	
19050 001	SUFENTANIL CITRATE; SUFENTA			NR	MAR 19, 1996	
20080 001	SUMATRIPTAN SUCCINATE; IMITREX	4816470	MAR 28, 2006	U-72	I-89	MAR 19, 1996
19882 001	TECHNETIUM TC-99M MERTIATIDE KIT; TECHNESCAN MAG3	4730000	JAN 30, 2006	U-36	I-87	NOV 27, 1995
20043 003	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	4730000	JAN 30, 2006	U-36	NCE	JAN 30, 1997
20043 004	TEMAFLOXACIN HYDROCHLORIDE; OMNIFLOX	5030632	JUL 09, 2008	U-70	NS	OCT 25, 1994
18163 003	TEMAZEPAM; RESTORIL	4591592	NOV 01, 2005			
19979 001	TICLOPIDINE HYDROCHLORIDE; TICLID	4051141	SEP 27, 1996	NCE	OCT 31, 1996	
19979 002	TICLOPIDINE HYDROCHLORIDE; TICLID	4591592	NOV 01, 2005			
>ADD> 136 001	TORSEMIDE; DEMADEX	4051141	SEP 27, 1996	NCE	OCT 31, 1996	
>ADD> 20136 002	TORSEMIDE; DEMADEX			NCE	AUG 23, 1998	
>ADD> 20136 003	TORSEMIDE; DEMADEX			NCE	AUG 23, 1998	
>ADD> 20136 004	TORSEMIDE; DEMADEX			NCE	AUG 23, 1998	
>ADD> 20137 002	TORSEMIDE; DEMADEX			NCE	AUG 23, 1998	
18207 004	TRAZODONE HYDROCHLORIDE; DESTREL	4258027	MAR 24, 1998			
18776 003	VECURONIUM BROMIDE; NORCURON	4215104	JUL 29, 1997			
19908 001	ZOLPIDEM TARTRATE; AMBIEN	4297351	OCT 27, 1998			
19908 002	ZOLPIDEM TARTRATE; AMBIEN	4237126	DEC 02, 1997			
		4382938	MAY 10, 2000	U-74	NCE	APR 30, 1994
		4382938	MAY 10, 2000	U-74	NCE	DEC 16, 1997
					NCE	DEC 16, 1997

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19862 001	INDIUM 111 CHLORIDE; INDICLOR				NCE	DEC 29, 1997
841207 001	PENTASTARCH 10% IN SODIUM CHLORIDE 0.9%; PENTASPA				ODE	MAY 19, 1994
860909 001	PERFLUORODECALIN; FLUOSOL	3911138	OCT 07, 1994	NCE	DEC 26, 1994	
900278 001	SATUMOMAB PENDETIDE; ONCOSCINT	4252827	FEB 24, 1998	ODE	DEC 29, 1999	

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