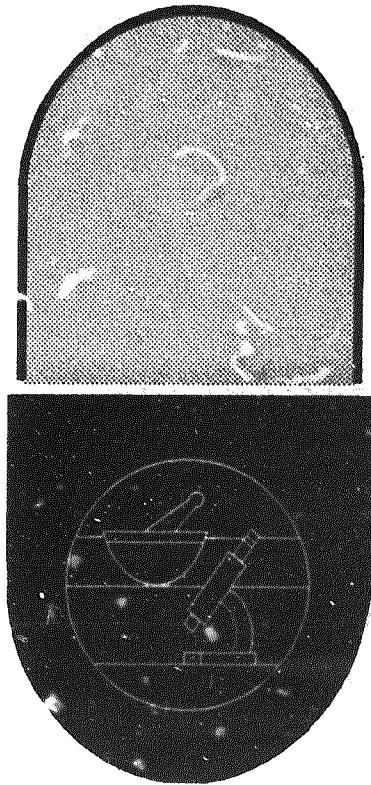


DEC 21 1998

0499-K-03

HC 20.4715.998/Suppl 7 CUMULATIVE  
SUPPLEMENT 7  
JAN'98-JUL'98



# APPROVED DRUG PRODUCTS

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

18<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 INFORMATION TECHNOLOGY  
DIVISION OF DATA MANAGEMENT AND SERVICES

1998

CJ 99010704

c

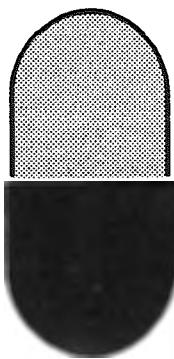
**Prepared By**  
**Division of Data Management and Services**  
**Office of Information Technology**  
**Center for Drug Evaluation and Research, FDA**

*I*

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## *New 19th Edition*



### **APPROVED DRUG PRODUCTS**

WITH  
THERAPEUTIC EQUIVALENCE EVALUATIONS

**19<sup>TH</sup> EDITION  
1999**

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

*See Subscription Form Inside Back Cover*

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**18TH EDITION**

**Cumulative Supplement 7**

**JULY 1998**

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*III*

**APPROVED DRUG PRODUCTS  
with  
THERAPEUTIC EQUIVALENCE EVALUATIONS**

**18TH EDITION**

**CUMULATIVE SUPPLEMENT 7  
JULY 1998**

**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, 18th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations, over-the-counter (OTC) drug products that require approved applications as a condition of marketing, drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

The Patent and Exclusivity Lists are arranged in alphabetical order by active ingredient name. For those products with multiple active ingredients, only the first active ingredient (in alphabetical sort) will appear. In addition, the trade name will be displayed to the right of the active ingredient name for each product. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Patent and Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the patent and/or exclusivity expires. Refer to the Patent and Exclusivity Terms section in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Information regarding drug patents and exclusivity for an approved product will appear in this addendum as it is received and may not correspond with the month the drug product is approved and published in the Rx/OTC sections of the Cumulative Supplement.

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 18th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 19th Edition.

## 1.2 APPLICANT NAME CHANGES

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



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

#### APPLICANT NAME CHANGES

FORMER APPLICANT NAME  
(FORMER ABBREVIATED NAME)

ASTRA MERCK INC  
(ASTRA MERCK)

ASTRA USA INC  
(ASTRA)

DUPONT RADIOPHARMACEUTICALS DIV  
(DUPONT)

FUJISAWA USA INC  
(FUJISAWA)

NEW APPLICANT NAME  
(NEW ABBREVIATED NAME)

ASTRA PHARMACEUTICALS LP  
(ASTRA PHARMS)

ASTRA PHARMACEUTICALS LP  
(ASTRA PHARMS)

DUPONT PHARMACEUTICALS COMPANY  
(DUPONT PHARMS)

AMERICAN PHARMACEUTICAL PARTNERS INC  
(AM PHARM PARTNERS)

#### **1.3 ACYCLOVIR 200MG TABLET-REFERENCE LISTED DRUG**

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

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

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

#### **1.4 DICLOFENAC SODIUM OPHTHALMIC SOLUTION 0.1%**

Two NDAs have been approved for diclofenac sodium ophthalmic solution 0.1% (DSOS), (1) Ciba's NDA 20-037 for Voltaren and (2) Alcon's NDA 20-809 for DSOS. Alcon was required to do a study comparing their DSOS to Voltaren and to a placebo control in post cataract surgical inflammation. This study was necessary to demonstrate that the different formulation of the Alcon drug product did not affect the safety and/or effectiveness of the proposed drug product for this indication. Prior to the approval of Alcon's DSOS Ciba did clinical studies and was approved for two additional indications for the temporary relief of pain and photophobia in patients undergoing corneal refractive surgery. Three years of Waxman-Hatch marketing exclusivity was granted to Ciba for these two new uses.

Since the treatment of pain has a different site of action than the anti-inflammatory or photophobia indications the Agency did not have information to support a recommendation that the Alcon and Ciba DSOS are therapeutically equivalent for the treatment of pain. The designation of therapeutic equivalence at this time applies only to the anti-inflammatory indication. The therapeutic equivalence designation will apply to the photophobia indication upon expiration of Ciba's marketing exclusivity.

#### **1.5 FOLLITROPIN ALFA AND BETA**

Based on available data derived from physico-chemical tests and bioassay, follitropin alfa and follitropin beta are indistinguishable.

#### **1.6 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 available on Internet: Prescription Drug Product List; OTC Drug Products; Discontinued Drug Products; Prescription and OTC Drug Product Patent and Exclusivity Data; and Appendices.

These files may be accessed on the Internet's World Wide Web. 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.

## **1.7 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 section 505 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 1997) 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 1997</u>	<u>MAR 1998</u>	<u>JUN 1998</u>	<u>SEP 1998</u>
DRUG PRODUCTS LISTED	9624	9711	9768	
SINGLE SOURCE	2462 (25.6%)	2484 (25.6%)	2494 (25.6%)	
MULTISOURCE	7052 (73.3%)	7117 (73.3%)	7164 (73.3%)	
THERAPEUTICALLY EQUIVALENT	6673 (69.3%)	6746 (69.5%)	6790 (69.5%)	
NOT THERAPEUTICALLY EQUIVALENT	379 ( 4.0%)	371 ( 3.8%)	374 ( 3.8%)	
EXCEPTIONS <sup>1</sup>	110 ( 1.1%)	110 ( 1.1%)	110 ( 1.1%)	
NEW MOLECULAR ENTITIES APPROVED	--	8	9	
NUMBER OF APPLICANTS	551	529	538	

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

## PRESCRIPTION DRUG PRODUCT LIST

18TH EDITION

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

1

ACARBOSETABLET; ORAL  
PRECOSE

© BAYER

25MG

N20482 004  
MAY 29, 1997  
N20482 004  
MAY 29, 1997ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFINE> ADD > AB + MIKART 500MG; 50MG; 40MG  
> ADD > AB WATSON LABS 500MG; 50MG; 40MG  
> ADD >  
> ADD >N89451 001  
MAY 23, 1988  
N40267 001  
JUL 30, 1998ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATEAA ROYCE LABS 300MG; 15MG  
AA 300MG; 10MG  
AA 300MG; 60MG  
AA WATSON LABS 300MG; 15MG  
AA 300MG; 30MG  
AA 300MG; 60MGN89997 001  
DEC 28, 1994  
N89998 001  
DEC 28, 1994  
N89999 001  
DEC 28, 1994  
N89997 001  
DEC 28, 1994  
N89998 001  
DEC 28, 1994  
N89999 001  
DEC 28, 1994ACETAMINOPHEN; HYDROCODONE BITARTRATE

ELIXIR; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHENAA + MIKART 500MG/15ML; 7.5MG/15ML  
AA PHARM ASSOC 500MG/15ML; 7.5MG/15MLN81051 001  
AUG 28, 1992  
N40182 001  
MAR 13, 1998TABLET; ORAL  
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA MALLINCKRODT 500MG; 7.5MG

N40201 001  
FEB 27, 1998ACETAMINOPHEN; HYDROCODONE BITARTRATETABLET; ORAL  
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

AA MALLINCKRODT 500MG; 10MG

N40201 002

AA ROYCE LABS 500MG; 7.5MG

N40201 003

AA 500MG; 5MG

N40201 004

AA 500MG; 2.5MG

N40201 005

AA 500MG; 10MG

N40201 006

AA 750MG; 7.5MG

N40201 007

AA WATSON LABS 500MG; 2.5MG

N40201 008

AA 500MG; 5MG

N40201 009

AA 500MG; 7.5MG

N40201 004

AA 650MG; 7.5MG

N40201 001

AA 650MG; 10MG

N40201 002

AA 750MG; 7.5MG

N40201 003

AA WATSON LABS 500MG; 2.5MG

N40201 004

AA 500MG; 5MG

N40201 005

AA 500MG; 7.5MG

N40201 006

AA 650MG; 7.5MG

N40201 007

AA 650MG; 10MG

N40201 008

AA 750MG; 7.5MG

N40201 009

AA WATSON LABS 500MG; 2.5MG

N40201 004

AA 500MG; 5MG

N40201 005

AA 500MG; 7.5MG

N40201 006

AA 650MG; 7.5MG

N40201 007

AA 650MG; 10MG

N40201 008

AA 750MG; 7.5MG

N40201 009

ACETAMINOPHEN; OXYCODONECAPSULE; ORAL  
OXYCODONE AND ACETAMINOPHEN

AA HALSEY 500MG; 5MG

N40219 001

JAN 22, 1998

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDECAPSULE; ORAL  
OXYCODONE AND ACETAMINOPHEN

AA ROYCE LABS 500MG; 5MG

N40224 001

OCT 30, 1997

AA WATSON LABS 500MG; 5MG

N40234 001

OCT 30, 1997

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

2

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL <u>OXYCODONE AND ACETAMINOPHEN</u>	
AA	DURAMED <u>325MG;5MG</u>
AA	ROYAL LABS <u>325MG;5MG</u>
AA	WATSON LABS <u>325MG;5MG</u>

N40272 001  
JUN 30, 1998  
N40171 001  
OCT 30, 1997  
N40171 001  
OCT 30, 1997

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL <u>PROPOXYPHENE HCL AND ACETAMINOPHEN</u>	
AA	ROYAL LABS <u>650MG;65MG</u>
AA	WATSON LABS <u>650MG;65MG</u>

N40139 001  
DEC 16, 1996  
N40139 001  
DEC 16, 1996

ACETIC ACID, GLACIAL

SOLUTION; IRRIGATION, URETHRAL <u>ACETIC ACID 0.25% IN PLASTIC CONTAINER</u>	
AT	B BRAUN <u>250MG/100ML</u>
AT	MCGRAW <u>250MG/100ML</u>

N18161 001  
N18161 001

ACYCLOVIR

CAPSULE; ORAL <u>ACYCLOVIR</u>	
AB	CHELSEA LABS <u>200MG</u>
AB	GENPHARM <u>200MG</u>

N75101 001  
APR 15, 1998  
N74977 001  
APR 13, 1998

TABLET; ORAL  
ACYCLOVIR

AB	COPLEY PHARM <u>400MG</u>
AB	<u>800MG</u>
AB	GENPHARM <u>400MG</u>
AB	<u>800MG</u>

N75021 001  
MAR 18, 1998  
N75021 002  
MAR 18, 1998  
N74976 001  
APR 13, 1998  
N74976 002  
APR 13, 1998

ACYCLOVIR

TABLET; ORAL <u>ACYCLOVIR</u>	
*	NOVOPHARM <u>200MG</u>
*	<u>200MG</u>

N74899 001  
APR 22, 1997  
N74556 001  
APR 22, 1997

ACYCLOVIR SODIUM

INJECTABLE; INJECTION <u>ACYCLOVIR SODIUM</u>	
AP	AESGEN <u>EQ 500MG BASE/VIAL</u>
AP	APOTHECON <u>EQ 500MG BASE/VIAL</u>
AP	<u>EQ 1GM BASE/VIAL</u>
> DLT >	FUJISAWA <u>EQ 50MG BASE/ML</u>
> DLT >	<u>EQ 50MG BASE/ML</u>
> ADD >	<u>EQ 50MG BASE/ML</u>
> ADD >	<u>EQ 50MG BASE/ML</u>

N75015 001  
APR 30, 1998  
N74897 001  
FEB 27, 1998  
N74897 002  
FEB 27, 1998  
N74898 001  
MAY 13, 1998  
N74930 001  
MAY 13, 1998

ADENOSINE

INJECTABLE; INJECTION <u>ADENOCARD</u>	
+	FUJISAWA HLTHCARE <u>3MG/ML</u>
*	MEDCO RET <u>3MG/ML</u>
ADENOSCAN	+ FUJISAWA HLTHCARE <u>3MG/ML</u>
*	MEDCO RET <u>3MG/ML</u>

N19937 002  
OCT 30, 1998  
N74898 001  
OCT 30, 1998  
N20059 001  
MAY 18, 1995  
N74930 001  
MAY 18, 1995

ALBUTEROL SULFATE

SOLUTION; INHALATION <u>ALBUTEROL SULFATE</u>	
AN	BAUSCH AND LOMB <u>EQ 0.5% BASE</u>
AN	HI TECH PHARMA <u>EQ 0.5% BASE</u>

N75050 001  
JUN 18, 1998  
N74543 001  
JAN 15, 1998

ALBUTEROL SULFATE

SYRUP; ORAL  
**ALBUTEROL SULFATE**  
 AA HI TECH PHARMA EQ 2MG BASE/5ML N74749 001  
 JAN 30, 1998  
 N74302 002  
 JAN 30, 1994  
 NOVA EQ 2MG BASE/5ML N74302 001  
 SEP 30, 1994  
 EQ 2MG BASE/5ML N74302 001  
 SEP 30, 1994

ALPRAZOLAM

TABLET; ORAL  
**ALPRAZOLAM**  
 AB GENEVA PHARMS 2MG N74909 001  
 MAR 25, 1998  
 N74479 001  
 JAN 21, 1997  
 N74479 002  
 JAN 21, 1997  
 N74479 003  
 JAN 21, 1997  
 ROYCE LABS 0.25MG N74479 001  
 JAN 21, 1997  
 N74479 002  
 JAN 21, 1997  
 N74479 003  
 JAN 21, 1997  
 WATSON LABS 0.25MG N74479 001  
 JAN 21, 1997  
 N74479 002  
 JAN 21, 1997  
 N74479 003  
 JAN 21, 1997  
 0.5MG  
 1MG

ALPROSTADIL

INJECTABLE; INJECTION  
**ALPROSTADIL**  
 AP BEDFORD 0.5MG/ML N74815 001  
 JAN 20, 1998  
 AP PROSTIN VR PEDIATRIC  
 PHARMACIA AND UPJOHN 0.5MG/ML N18484 001  
 0.5MG/ML

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL  
**SYMETREL**  
 AA \* ENDOW PHARMS 50MG/5ML N16023 001  
 N16023 002  
 AA + ENDOW PHARMS 50MG/5ML N16023 002

AMANTADINE HYDROCHLORIDE

TABLET; ORAL  
**SYMETREL**  
 AA \* ENDOW PHARMS 100MG N18101 001  
 100MG  
 N18101 001

AMCINONIDE

OINTMENT; TOPICAL  
**CYCLOCORT**  
 AB \* ENDOWS 0.1% N18498 001  
 + WYETH AYERST 0.1%  
 N18498 001

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL  
**AMILORIDE HCL AND HYDROCHLOROTHIAZIDE**  
 AB WATSON LABS N73334 001  
 JUL 19, 1991  
 N73334 001  
 AB WATSON LABS EQ 5MG ANHYDROUS; 50MG N73334 001  
 JUL 19, 1991

AMIODARONE HYDROCHLORIDE

TABLET; ORAL  
**CORDARONE**  
 AB + WYETH AYERST 200MG N18972 001  
 DEC 24, 1985  
 AB PACERONE 200MG N75135 001  
 UPSHER SMITH APR 30, 1998

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL  
**PERPHENAZINE AND AMITRIPTYLINE HCL**  
 AA \* ENDOWS 200MG



RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

4

AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL  
PERPHENAZINE AND AMITRIPTYLINE HCL

<u>AB</u>	WATSON LABS	<u>10MG;2MG</u>	N73007 001
<u>AB</u>		<u>10MG;4MG</u>	N73009 001
<u>AB</u>		<u>25MG;2MG</u>	N73008 001
<u>AB</u>		<u>25MG;4MG</u>	N73010 001

OCT 17, 1991  
OCT 17, 1991  
OCT 17, 1991  
OCT 17, 1991

AMMONIUM CHLORIDE

INJECTABLE; INJECTION  
AMMONIUM CHLORIDE 2.14%

• B BRAUN	40MEQ/100ML	N85734 001
• I.V. BAG	40MEQ/100ML	N85734 001

AMOXICILLIN

> ADD >	TABLET; ORAL		
> ADD >	AMOXIL		
> ADD >	+ SMITHKLINE BEECHAM	500MG	N50754 002
> ADD >			JUL 10, 1998
> ADD >	+	875MG	N50754 001
> ADD >			JUL 10, 1998

AMRINONE LACTATE

INJECTABLE; INJECTION  
INOCOR

• BAG	EQ 5MG BASE/ML	N18700 002
+	EQ 5MG BASE/ML	N18700 001

JUL 31, 1984  
JUL 31, 1984

ARBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
GENESA

* GENESIA	0.05MG/ML	N74404 001
		SEP 12, 1997

ARBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION  
GENESA  
+ GENESIA AUTOMEDICS

0.05MG/ML

N74404 001  
SEP 12, 1997

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL  
ORPHEMESISIC

<u>AB</u>	PAR PHARM	<u>385MG;30MG;25MG</u>
-----------	-----------	------------------------

N75141 001  
MAY 29, 1998

<u>AB</u>	ORPHEMESISIC FORTE	<u>770MG;60MG;50MG</u>
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N75141 002  
MAY 29, 1998

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL  
OXYCODONE AND ASPIRIN

> ADD >	AA HALSEY	<u>325MG;4.5MG;0.38MG</u>
> ADD >	AA WATSON LABS	<u>325MG;4.5MG;0.38MG</u>

M40260 001  
JUL 17, 1998  
M40255 001  
FEB 27, 1998

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL  
ATENOLOL AND CHLORTHALIDONE

<u>AB</u>	MARTEC	<u>50MG;25MG</u>
		<u>100MG;25MG</u>

N74404 001  
MAY 14, 1998  
N74404 002  
MAY 14, 1998

ATORVASTATIN CALCIUM

TABLET; ORAL  
LIPITOR

DAVIS DAVIDS	<u>10MG;20MG</u>
DAVIS DAVIDS	<u>20MG;40MG</u>
DAVIS DAVIDS	<u>40MG;80MG</u>
DAVIS DAVIDS	<u>80MG;160MG</u>

ATORVASTATIN CALCIUM

TABLET; ORAL  
**LIPITOR**  
 WARNER LAMBERT EXPOR EQ 10MG BASE  
 EQ 20MG BASE  
 + EQ 40MG BASE

N20702 001  
 DEC 17, 1996  
 N20702 002  
 DEC 17, 1996  
 N20702 003  
 DEC 17, 1996

ATRACURIUM BESYLATE

INJECTABLE; INJECTION  
**ATRACURIUM BESYLATE**  
 > ADD > AP MARSAM 10MG/ML N74945 001  
 > ADD > **ATRACURIUM BESYLATE PRESERVATIVE FREE**  
 > ADD > AP MARSAM 10MG/ML N74944 001  
 > ADD >

BACITRACIN

OINTMENT; TOPICAL; COMPOUND  
**BACITRACIN**  
 PARACET 5,000,000 UNITS/BOT N62454 001  
 5,000,000 UNITS/BOT N62455 001  
 \* 5,000,000 UNITS/BOT N62456 001  
 JUL 27, 1983

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC  
**NEOSPORIN**  
 AT \* GELATO MEDIZONE 100 UNITS/GM; EQ 3.5MG BASE/GM; N62457 001  
 AT + MONARCH PHARMS 400 UNITS/GM; EQ 3.5MG BASE/GM; N50417 001  
 10,000 UNITS/GM

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC  
**BACITRACIN ZINC AND POLYMYXIN B SULFATE**  
 AT \* GELATO MEDIZONE 100 UNITS/GM; EQ 3.5MG BASE/GM; N62458 001  
 10,000 UNITS/GM

BACITRACIN ZINC; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC  
**BACITRACIN ZINC AND POLYMYXIN B SULFATE**  
 AT AKORN 500 UNITS/GM;  
 10,000 UNITS/GM M64028 001  
 JAN 30, 1995  
 POLYSPORIN  
 AT \* GELATO MEDIZONE 100 UNITS/GM; N62459 001  
 10,000 UNITS/GM  
 AT + MONARCH PHARMS 500 UNITS/GM;  
 10,000 UNITS/GM M61229 001

BACLOFEN

TABLET; ORAL  
**BACLOFEN**  
 AB ROCH LABS 20MG M73092 001  
 300 MG; 1000 M73093 001  
 AB 20MG M73092 001  
 WATSON LABS 10MG M73092 001  
 AB 20MG M73093 001  
 JAN 28, 1994  
 JAN 28, 1994

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL  
**VASCOR**  
 JHEIMSON INC 300MG M19002 002  
 \* 400MG M19002 003  
 + 300MG N19002 002  
 DEC 28, 1990  
 N19002 003  
 \* 400MG N19002 003  
 DEC 28, 1990

BETAMETHASONE VALERATE

CREAM; TOPICAL  
**BETAMETHASONE VALERATE**  
 AB 100G M19002 001  
 M19002 002



CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATEINJECTABLE; INJECTION  
ISOLYTE E IN PLASTIC CONTAINER

**Abbott** 33MG/100ML; 30MG/100ML; 70MG/100ML;  
600MG/100ML; 500MG/100ML;  
800MG/100ML

N19718 001  
FEB 29, 1982CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDESOLUTION; PERfusion, CARDIAC  
PLEGISOL IN PLASTIC CONTAINER

**Abbott** 17.6MG/100ML; 325.3MG/100ML;  
119.3MG/100ML; 643MG/100ML N18608 001

FEB 26, 1982

SOLUTION; PERfusion/CARDIAC  
PLEGISOL IN PLASTIC CONTAINER

+ **Abbott** 17.6MG/100ML; 325.3MG/100ML;  
119.3MG/100ML; 643MG/100ML N18608 001

FEB 26, 1982

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTION  
RINGER'S IN PLASTIC CONTAINER

**AP B BRAUN** 33MG/100ML; 30MG/100ML;  
860MG/100ML

N18721 001

NOV 09, 1982

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

N20002 001

APR 17, 1992

**AB NOGAM** [REDACTED]  
[REDACTED]

N18681 001

NOV 09, 1982

**AB** [REDACTED]  
[REDACTED]

N18682 001

NOV 17, 1982

SOLUTION; IRRIGATION  
RINGER'S IN PLASTIC CONTAINER

**AT B BRAUN** 33MG/100ML; 30MG/100ML;  
860MG/100ML

N18156 001

&gt; DLT &gt;

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDESOLUTION; IRRIGATION  
RINGER'S IN PLASTIC CONTAINER

**AT NOGAM** [REDACTED]  
[REDACTED]

N18631 001

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM LACTATEINJECTABLE; INJECTION  
LACTATED RINGER'S IN PLASTIC CONTAINER

**AP B BRAUN** 20MG/100ML; 30MG/100ML; 600MG/100ML;  
310MG/100ML

N19632 001

FEB 29, 1988

0 20MG/100ML; 30MG/100ML; 600MG/100ML;  
310MG/100ML

N18023 001

**AT NOGAM** [REDACTED]  
[REDACTED]

N18632 001

0 20MG/100ML; 30MG/100ML; 600MG/100ML;  
310MG/100ML

N18633 001

SOLUTION; IRRIGATION  
LACTATED RINGER'S IN PLASTIC CONTAINER

**AT B BRAUN** 20MG/100ML; 30MG/100ML; 600MG/100ML;  
310MG/100ML

N18681 001

DEC 27, 1982

**AT NOGAM** [REDACTED]  
[REDACTED]

N18634 001

CANDESARTAN CILEXETILTABLET; ORAL  
ATACAND

**ATACAND** [REDACTED]  
[REDACTED]

N18635 001

OCT 04, 1992

**ATACAND** [REDACTED]  
[REDACTED]

N18636 001

OCT 04, 1992

## Rx DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'96 - JUL'96

CANDESARTAN CILEXETILTABLET; ORAL  
ATACAND

[REDACTED]

CAPTOPRIL

TABLET; ORAL

Captopril

WATSON LABS

M74451 004

FEB 13, 1996

CAPTOPRIL; HYDROCHLOROTHIAZIDE

N20838 001

JUN 04, 1996

N20838 002

JUN 04, 1996

N20838 003

JUN 04, 1996

N20838 004

JUN 04, 1996

N20838 005

JUN 04, 1996

N20838 006

JUN 04, 1996

N20838 007

JUN 04, 1996

N20838 008

JUN 04, 1996

N20838 009

JUN 04, 1996

N20838 010

JUN 04, 1996

N20838 011

JUN 04, 1996

N20838 012

JUN 04, 1996

N20838 013

JUN 04, 1996

N20838 014

JUN 04, 1996

N20838 015

JUN 04, 1996

N20838 016

JUN 04, 1996

N20838 017

JUN 04, 1996

N20838 018

JUN 04, 1996

N20838 019

JUN 04, 1996

N20838 020

JUN 04, 1996

N20838 021

JUN 04, 1996

N20838 022

JUN 04, 1996

N20838 023

JUN 04, 1996

CAPTOPRIL

TABLET; ORAL

Captopril

WATSON LABS

M74451 002

FEB 13, 1996

M74451 003

FEB 13, 1996

M74451 004

FEB 13, 1996

M74451 005

FEB 13, 1996

M74451 006

FEB 13, 1996

M74451 007

FEB 13, 1996

M74451 008

FEB 13, 1996

M74451 009

FEB 13, 1996

M74451 010

FEB 13, 1996

M74451 011

FEB 13, 1996

M74451 012

FEB 13, 1996

M74451 013

FEB 13, 1996

M74451 014

FEB 13, 1996

M74451 015

FEB 13, 1996

M74451 016

FEB 13, 1996

M74451 017

FEB 13, 1996

M74451 018

FEB 13, 1996

M74451 019

FEB 13, 1996

M74451 020

FEB 13, 1996

M74451 021

FEB 13, 1996

M74451 022

FEB 13, 1996

M74451 023

FEB 13, 1996

M74451 024

FEB 13, 1996

M74451 025

FEB 13, 1996

M74451 026

FEB 13, 1996

CAPTOPRIL

TABLET; ORAL

Captopril

WATSON LABS

M74451 001

FEB 13, 1996

M74451 002

FEB 13, 1996

M74451 003

FEB 13, 1996

M74451 004

FEB 13, 1996

M74451 005

FEB 13, 1996

M74451 006

FEB 13, 1996

M74451 007

FEB 13, 1996

M74451 008

FEB 13, 1996

M74451 009

FEB 13, 1996

M74451 010

FEB 13, 1996

M74451 011

FEB 13, 1996

M74451 012

FEB 13, 1996

M74451 013

FEB 13, 1996

M74451 014

FEB 13, 1996

M74451 015

FEB 13, 1996

M74451 016

FEB 13, 1996

M74451 017

FEB 13, 1996

M74451 018

FEB 13, 1996

M74451 019

FEB 13, 1996

M74451 020

FEB 13, 1996

M74451 021

FEB 13, 1996

M74451 022

FEB 13, 1996

M74451 023

FEB 13, 1996

M74451 024

FEB 13, 1996

M74451 025

FEB 13, 1996

CAPTOPRIL

TABLET; ORAL

Captopril

WATSON LABS

M74451 001

FEB 13, 1996

M74451 002

FEB 13, 1996

M74451 003

FEB 13, 1996

M74451 004

FEB 13, 1996

M74451 005

FEB 13, 1996

M74451 006

FEB 13, 1996

M74451 007

FEB 13, 1996

M74451 008

FEB 13, 1996

M74451 009

FEB 13, 1996

M74451 010

FEB 13, 1996

M74451 011

FEB 13, 1996

M74451 012

FEB 13, 1996

M74451 013

FEB 13, 1996

M74451 014

FEB 13, 1996

M74451 015

FEB 13, 1996

M74451 016

FEB 13, 1996

M74451 017

FEB 13, 1996

M74451 018

FEB 13, 1996

M74451 019

FEB 13, 1996

M74451 020

FEB 13, 1996

M74451 021

FEB 13, 1996

M74451 022

FEB 13, 1996

M74451 023

FEB 13, 1996

M74451 024

FEB 13, 1996

M74451 025

FEB 13, 1996

CAPTOPRIL

TABLET; ORAL

Captopril

WATSON LABS

M74451 001

FEB 13, 1996

M74451 002

FEB 13, 1996

M74451 003

FEB 13, 1996

M74451 004

FEB 13, 1996

M74451 005

FEB 13, 1996

M74451 006

FEB 13, 1996

M74451 007

FEB 13, 1996

M74451 008

FEB 13, 1996

M74451 009

FEB 13, 1996

M74451 010

FEB 13, 1996

M74451 011

FEB 13, 1996

M74451 012

FEB 13, 1996

M74451 013

FEB 13, 1996

M74451 014

FEB 13, 1996

M74451 015

FEB 13, 1996

M74451 016

FEB 13, 1996

M74451 017

FEB 13, 199

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

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CARBAMAZEPINECAPSULE, EXTENDED RELEASE; ORAL  
CARBATROL

*	WATSON LABS	200MG	N20712 001 SEP 30, 1997
+	SHIRE	200MG	N20712 002 SEP 30, 1997
+		300MG	

CARBIDOPATABLET; ORAL  
LODOSYN

> DLT >	*	DUPONT MERCK	25MG	N17830 003
> ADD >	+	DUPONT PHARMS	25MG	

CARBIDOPA; LEVODOPATABLET; ORAL  
SINemet

> DLT >	AB	DUPONT MERCK	100MG; 100MG	N17555 002
> DLT >	AB	*	25MG; 250MG	N17555 003
> DLT >	AB	*	25MG; 250MG	N17555 002
> ADD >	AB	DUPONT PHARMS	100MG; 100MG	N17555 001
> ADD >	AB	DUPONT PHARMS	25MG; 100MG	N17555 003
> ADD >	AB	*	25MG; 250MG	N17555 002

TABLET, EXTENDED RELEASE; ORAL  
SINemet CR

> DLT >		DUPONT MERCK	25MG; 100MG	N19856 002
> DLT >		*	50MG; 200MG	N19856 002
> DLT >	*		50MG; 200MG	MAY 30, 1991
> DLT >	*		50MG; 200MG	N19856 002
> ADD >		DUPONT PHARMS	25MG; 100MG	DEC 24, 1992
> ADD >		DUPONT PHARMS	25MG; 100MG	N19856 001
> ADD >	*		50MG; 200MG	MAY 30, 1991

CARISOPRODOLTABLET; ORAL  
CARISOPRODOL

AB	ROYCE LABS	350MG	N40152 001 DEC 03, 1996
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CARISOPRODOLTABLET; ORAL  
CARISOPRODOL

AB	WATSON LABS	350MG
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N40152 001  
DEC 03, 1996CEFACLORPOWDER FOR RECONSTITUTION; ORAL  
CEFACLOR

AB	MARSAM	EQ 125MG BASE/5ML
AB		EQ 187MG BASE/5ML
AB		EQ 250MG BASE/5ML
AB		EQ 375MG BASE/5ML

N64204 001  
FEB 18, 1998  
N64205 001  
FEB 18, 1998  
N64206 001  
FEB 18, 1998  
N64207 001  
FEB 18, 1998CEFAZOLIN SODIUMINJECTABLE; INJECTION  
CEFAZOLIN SODIUM

AP	FUJISAWA	EQ 10GM BASE/VIAL
AP		EQ 20GM BASE/VIAL

N64170 001  
MAR 18, 1998  
N64170 002  
MAR 18, 1998CEFTIZOXIME SODIUMINJECTABLE; INJECTION  
CEFTIZOX

*	FUJISAWA	EQ 200MG BASE/VIAL
*		EQ 400MG BASE/VIAL
*		EQ 600MG BASE/VIAL
*		EQ 100MG BASE/VIAL

SEP 15, 1983  
N50560 002  
SEP 15, 1983

+	FUJISAWA HLTHCARE	EQ 500MG BASE/VIAL
+		EQ 1GM BASE/VIAL

CEFTIZOXIME SODIUM

INJECTABLE; INJECTION

CEFIZOX

+ FUJISAWA HLTHCARE

EQ 2GM BASE/VIAL

N50560 003

SEP 15, 1993

EQ 10GM BASE/VIAL

N50560 005

MAR 19, 1993

CEFIZOX IN DEXTROSE 5% IN PLASTIC CONTAINER

+ FUJISAWA

EQ 100MG BASE/ML

N50589 002

OCT 03, 1984

CEFIZOX IN PLASTIC CONTAINER

+ FUJISAWA

EQ 20MG BASE/ML

N50589 003

APR 13, 1995

EQ 40MG BASE/ML

N50589 004

APR 13, 1995

CEFUROXIME SODIUM

INJECTABLE; INJECTION

CEFUROXIME

AB ASTRA PHARMS

EQ 750MG BASE/VIAL

N64192 002

APR 16, 1998

AP

EQ 1.5GM BASE/VIAL

N64192 001

APR 16, 1998

AP

EQ 7.5GM BASE/VIAL

N64191 001

APR 16, 1998

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

AB ZENITH GOLDLINE

EQ 250MG BASE

N61969 001

AB

EQ 500MG BASE

N61969 002

AB

ZENITH LABS

N61969 001

AB

EQ 1000MG BASE

N61969 003

POWDER FOR RECONSTITUTION; ORAL

KEFLEX

+ LILLY

EQ 1000MG BASE/ML

N62117 001

EQ 1000MG BASE/ML

N62117 001

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

KEFLEX

+ LILLY

EQ 1000MG BASE/ML

N50406 003

EQ 1000MG BASE/ML

N62117 001

CHLORAMPHENICOL

CAPSULE; ORAL

CHLOROMYCETIN

+ PARKEDALE

250MG

N60591 002

50MG

N60591 001

100MG

N60591 003

OINTMENT; OPHTHALMIC

CHLOROMYCETIN

+ PARKEDALE

1%

N50156 001

POWDER FOR RECONSTITUTION; OPHTHALMIC

CHLOROMYCETIN

+ PARKEDALE

25MG/VIAL

N50143 001

SOLUTION/DROPS; OPHTHALMIC

OPHTHOCHLOR

+ PARKEDALE

0.5%

N61220 001

SOLUTION/DROPS; OTIC

CHLOROMYCETIN

+ PARKEDALE

0.5%

N50205 001

CHLORAMPHENICOL; HYDROCORTISONE ACETATE

POWDER FOR RECONSTITUTION; OPHTHALMIC

CHLOROMYCETIN HYDROCORTISONE

+ PARKEDALE

12.5MG/VIAL; 25MG/VIAL

N50202 001

12.5MG/VIAL

N50202 001

CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYMYXIN B SULFATEOINTMENT; OPHTHALMIC  
OPHTHOCORT

♦ PARKER DAWS

10MG/GM; 10MG/GM;

10,000 UNITS/GM  
10MG/GM; 5MG/GM;  
10,000 UNITS/GM

N50201 002

N50201 002

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION

CHLOROMYCETIN

AB ♦ PARKER DAWS

AP ♦ PARKEDALE

EQ 1GM BASE/VIAL

N50155 001

N50155 001

CHLORDIAZEPOXIDETABLET; ORAL  
LIBRITABS

+ ICN

5MG

N85482 001

6

10MG

N85481 001

6

25MG

N85488 001

6

5MG

N85482 001

6

10MG

N85483 001

6

25MG

N85489 001

CHLORDIAZEPOXIDE HYDROCHLORIDECAPSULE; ORAL  
LIBRIUM

AB ICN

5MG

N85461 001

AB

10MG

N85472 001

AB

25MG

N85475 001

AB ♦ ROCHE

N85462 001

AB ♦

N85472 001

AB ♦

N85478 001

CHLORHEXIDINE GLUCONATESOLUTION; DENTAL  
PERIDEX

AB ♦ PHOTOFAX AND GEMCO

0.12%

N19028 001

AUG 13, 1998

CHLORHEXIDINE GLUCONATESOLUTION; DENTAL  
PERIDEX

AT + ZILA

0.12%

N19028 001

AUG 13, 1998

TABLET; DENTAL  
PERIOCHIP  
+ PERIO PRODS (IS)

2.5MG

N20774 001

MAY 15, 1998

CHLORPROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

CHLORPROMAZINE HCL

AB

25MG/ML

N89563 001

APR 15, 1998

CHLORZOXAZONETABLET; ORAL  
CHLORZOXAZONE

AB

N81040 001

AUG 22, 1998

AB WATSON LABS

500MG

CHOLESTYRAMINE

POWDER; ORAL

CHOLESTYRAMINE

AB NOVOPHARM

EQ 4GM RESIN/PACKET

N74347 001

MAY 28, 1998

AB NOVOPHARM

EQ 4GM RESIN/SCOOPFUL

N74347 002

MAY 28, 1998

AB CHOLESTYRAMINE LIGHT

NOVOPHARM EQ 4GM RESIN/PACKET

N74348 001

MAY 28, 1998

AB NOVOPHARM

EQ 4GM RESIN/SCOOPFUL

N74348 002

MAY 28, 1998

AB LOCHOLEST

EON EQ 4GM RESIN/PACKET

N74561 001

AUG 15, 1998

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

12

CHOLESTYRAMINE

POWDER; ORAL

LOCHOLEST

<u>AB</u>	<u>EON</u>	<u>EQ 4GM RESIN/SCOOPFUL</u>	<u>N74561 002</u>	<u>AUG 15, 1996</u>	<u>&gt; ADD &gt;</u>	<u>AA</u>	<u>COPLEY PHARM</u>	<u>EQ 300MG BASE/5ML</u>	<u>N74859 001</u>
		<u>EQ 4GM RESIN/PACKET</u>	<u>N74561 003</u>	<u>AUG 15, 1996</u>	<u>&gt; ADD &gt;</u>				<u>JUL 09, 1998</u>
		<u>EQ 4GM RESIN/SCOOPFUL</u>	<u>N74561 004</u>	<u>AUG 15, 1996</u>					

LOCHOLEST LIGHT

<u>AB</u>	<u>EON</u>	<u>EQ 4GM RESIN/PACKET</u>	<u>N74562 001</u>	<u>AUG 15, 1996</u>	<u>&gt; ADD &gt;</u>	<u>AA</u>	<u>CIPROFLOXACIN HYDROCHLORIDE</u>	<u>EQ 0.3% BASE</u>	<u>N20369 001</u>
		<u>EQ 4GM RESIN/SCOOPFUL</u>	<u>N74562 002</u>	<u>AUG 15, 1996</u>	<u>&gt; ADD &gt;</u>				<u>MAR 30, 1998</u>
		<u>EQ 4GM RESIN/PACKET</u>	<u>N74562 003</u>	<u>AUG 15, 1996</u>	<u>&gt; ADD &gt;</u>				
		<u>EQ 4GM RESIN/SCOOPFUL</u>	<u>N74562 004</u>	<u>AUG 15, 1996</u>	<u>&gt; ADD &gt;</u>				

CIMETIDINE

<u>AA</u>	<u>SOLUTION; ORAL CIMETIDINE HCL DURAMED</u>	<u>300MG/5ML</u>	<u>N75110 001</u>	<u>JUN 18, 1998</u>	<u>&gt; DLT &gt;</u>	<u>AA</u>	<u>CISAPRIDE MONOHYDRATE</u>	<u>EQ 10MG BASE</u>	<u>N20767 001</u>
					<u>&gt; DLT &gt;</u>				<u>NOV 07, 1998</u>
<u>AB</u>	<u>TABLET; ORAL CIMETIDINE RAVENSBOROUGH</u>	<u>200MG</u>	<u>N74424 001</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>	<u>AA</u>	<u>TABLET; ORAL PROPULSID QUICKSOLV + JANSSEN</u>	<u>EQ 20MG BASE</u>	<u>N20767 002</u>
		<u>300MG</u>	<u>N74424 002</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>				<u>NOV 07, 1998</u>
<u>AB</u>	<u>400MG</u>	<u>N74424 003</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>	<u>&gt; ADD &gt;</u>	<u>AA</u>	<u>TABLET, ORALLY DISINTEGRATING; ORAL PROPULSID QUICKSOLV + JANSSEN</u>	<u>EQ 20MG BASE</u>	<u>N20767 001</u>
		<u>500MG</u>	<u>N74424 004</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>				<u>NOV 07, 1998</u>
<u>AB</u>	<u>ZENITH LABS</u>	<u>200MG</u>	<u>N74424 001</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>	<u>AA</u>	<u>CITALOPRAM HYDROBROMIDE</u>	<u>TABLET; ORAL CELEXA FOREST LABS</u>	<u>EQ 20MG BASE</u>
		<u>300MG</u>	<u>N74424 002</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>				<u>JUL 17, 1998</u>
<u>AB</u>	<u>400MG</u>	<u>N74424 003</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>	<u>&gt; ADD &gt;</u>	<u>AA</u>		<u>EQ 40MG BASE</u>	<u>N20822 003</u>
		<u>500MG</u>	<u>N74424 004</u>	<u>JUL 28, 1995</u>	<u>&gt; ADD &gt;</u>				<u>JUL 17, 1998</u>
<u>AB</u>					<u>&gt; ADD &gt;</u>	<u>AA</u>		<u>EQ 60MG BASE</u>	<u>N20822 004</u>
					<u>&gt; ADD &gt;</u>				<u>JUL 17, 1998</u>

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL

CIMETIDINE HCL

<u>AA</u>	<u>COPLEY PHARM</u>	<u>EQ 300MG BASE/5ML</u>

JUL 09, 1998CIPROFLOXACIN HYDROCHLORIDE

OINTMENT; OPHTHALMIC

CILOXAN

+ ALCON

<u>AA</u>	<u>EQ 0.3% BASE</u>

MAR 30, 1998CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE

SUSPENSION/DROPS; OTIC

CIPRO HC

+ BAYER

<u>AA</u>	<u>EQ 0.2% BASE; 1%</u>

FEB 10, 1998CISAPRIDE MONOHYDRATE

TABLET; ORAL

PROPULSID QUICKSOLV

+ JANSSEN

<u>AA</u>	<u>EQ 10MG BASE</u>

NOV 07, 1998

TABLET, ORALLY DISINTEGRATING; ORAL

PROPULSID QUICKSOLV

+ JANSSEN

<u>AA</u>	<u>EQ 20MG BASE</u>

NOV 07, 1998CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CELEXA

FOREST LABS

<u>AA</u>	<u>EQ 20MG BASE</u>

JUL 17, 1998

<u>AA</u>	<u>EQ 40MG BASE</u>

N20822 003

<u>AA</u>	<u>EQ 60MG BASE</u>

JUL 17, 1998

<u>AA</u>	<u>EQ 60MG BASE</u>

N20822 004

<u>AA</u>	<u>EQ 60MG BASE</u>

JUL 17, 1998

## **CLEMASTINE FUMARATE**

**SYRUP; ORAL  
CLEMASTINE FUMARATE  
MORTON GROVE** **NO. 0.5MG BASE/5ML** **M74063 001**  
**AA** **MAR 13, 1998**

## **CLINDAMYCIN PHOSPHATE**

**CREAM; VAGINAL  
CLOSOIN 3  
+ PHARMACIA AND UPJOHN EQ 2% BASE** NS0680 002  
**MAR 02, 1998**

**INJECTABLE; INJECTION  
CLINDAMYCIN PHOSPHATE**

**EQ 150MG BASE/ML**

**SOLUTION: TOPICAL**

EQ 1st BASE  
N62363 001  
FEB 08, 1982

## **CLOMIPRAMINE HYDROCHLORIDE**

**CAPSULE; ORAL  
CLONIPRAMINE HCL**

<b>AB</b>	<b>MYLAN</b>	<b>25MG</b>	<b>M74947 001</b>
<b>AB</b>		<b>50MG</b>	<b>APR 30, 1998</b>
<b>AB</b>		<b>50MG</b>	<b>M74947 002</b>
<b>AB</b>		<b>75MG</b>	<b>APR 30, 1998</b>
<b>AB</b>		<b>75MG</b>	<b>M74947 003</b>
			<b>APR 30, 1998</b>

#### CLONAZEPAM

**RECORDED AND INDEXED  
BY RICH**

**CLONAZEPAM**

## **COLISTIMETATE SODIUM**

**INJECTABLE; INJECTION  
COLV-MYCIN M**

• **PARKDALE** EQ 150MG BASE/VIAL N50108

## CORTICOTROPIN

CROMOLYN SODIUMSOLUTION/DROPS; OPHTHALMIC

AT CROMOLY  
BAUSCH AND LOMB 45  
#  
AT CROMOLYN SODIUM  
ADV REMEDIES 45  
AT + OPTICROM  
ALLERGAN 45  
# RENAZOL 45

N74443 001  
JAN 30, 1995  
N74706 001  
APR 29, 1998  
N18155 001  
OCT 03, 1984  
N74443 001  
JAN 30, 1995

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL  
CYCLOBENZAPRINE HCL  
AB WATSON LABS 10MG  
AB WATSON LABS 10MG

N74443 001  
JAN 30, 1995  
N74436 001  
NOV 30, 1994

DACTINOMYCIN

INJECTABLE; INJECTION  
COSMEGEN  
+ MERCK  
# MERCK SHIRE DOUGIE 0.5MG/VIAL  
0.5MG/VIAL

N50682 001  
N50682 001

DALTEPARIN SODIUM

INJECTABLE; INJECTION  
FRAGMIN  
# PHARMACEIA AND UROLOGIC 10,000 IU/0.5ML  
+ 10,000 IU/ML

N20287 004  
JAN 30, 1998  
N20287 004  
JAN 30, 1998

DANAZOLCAPSULE; ORAL

AB DANAZOL  
BARR 50MG  
AB 100MG  
AB DAMOCRIME  
SANOFI 50MG  
AB 100MG

N74582 003  
MAY 29, 1998  
N74582 002  
MAY 29, 1998  
N17557 003  
N17557 004

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION  
CRUBIDINE  
+ BEDFORD EQ 20MG BASE/VIAL  
> ADD >  
> ADD >  
> DLT >  
> DLT >  
DAUNORUBICIN HCL  
# DAUNORUBICIN HCL PRESERVATIVE FREE  
AB + BEDFORD EQ 20MG BASE/VIAL  
AB GENSIA SICOR PHARMS EQ 20MG BASE/VIAL

N64103 001  
FEB 03, 1995  
# DAUNORUBICIN HCL PRESERVATIVE FREE  
AB + BEDFORD EQ 20MG BASE/VIAL  
AB GENSIA SICOR PHARMS EQ 20MG BASE/VIAL

N50731 001  
JAN 30, 1998  
N64212 001  
JUN 23, 1998

DESOGESTREL; ETHINYLEDIESTRADIOL

TABLET; ORAL-28  
NIRCETTE  
+ ORGANON 0.15MG; 0.02MG

N20713 001  
APR 22, 1998

DESOXIMETASONE

GEL; TOPICAL  
DESOXIMETASONE  
AB TARO 0.05%  
> ADD >  
> ADD >  
> ADD >  
TOPICORT  
AB + HOECHST MARION RSSL 0.05%  
> ADD >

N74904 001  
JUL 14, 1998  
# DESOXIMETASONE  
AB TARO 0.05%  
AB + HOECHST MARION RSSL 0.05%

N18586 001  
MAR 29, 1998

OINTMENT; TOPICAL

DESOXIMETASONE  
AB ALTANA 0.25%

N73440 001  
APR 01, 1998

DEXAMETHASONE SODIUM PHOSPHATE

AEROSOL; INHALED; INHALATION

DEXAVENT

+ MEDeva

@

EQ 0.1MG PHOSPHATE/INH  
EQ 0.1MG PHOSPHATE/INH  
N13413 001  
N13413 001DISC; NASAL

DEXAVENT

+ MEDeva

@

EQ 0.1MG PHOSPHATE/INH  
EQ 0.1MG PHOSPHATE/INH  
N14242 001  
N14242 001DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXEDRINE

&gt; DLT &gt; AA + SMITHKLINE BECKMAN

SMG

N84939 001  
N84935 001

&gt; ADD &gt; AA DEXTROSTAT

SMG

N84051 001  
N84051 001

&gt; DLT &gt; AA SHIRE RICHWOOD

SMG

N84051 001  
N84051 001

&gt; ADD &gt; AA +

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 10% IN PLASTIC CONTAINER

B BRAUN 10GM/100ML

N18046 001  
N18048 001

DEXTROSE 5% IN PLASTIC CONTAINER

B BRAUN 5GM/100ML

N16730 001  
N16730 002

B BRAUN 50MG/ML

N16710 001  
N16730 002

MCGRAW 5GM/100ML

N16730 002

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE

INJECTABLE; INJECTION

ISOLYTE P IN DEXTROSE 5% IN PLASTIC CONTAINER

B BRAUN 5GM/100ML; 31MG/100ML; 130MG/100ML;

26MG/100ML; 320MG/100ML N19873 001

JUN 10, 1993

MCGRAW

5GM/100ML; 31MG/100ML; 130MG/100ML;

26MG/100ML; 320MG/100ML N19873 001

JUN 10, 1993

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE

INJECTABLE; INJECTION

ISOLYTE H IN DEXTROSE 5% IN PLASTIC CONTAINER

B BRAUN 5GM/100ML; 30MG/100ML; 97MG/100ML;

220MG/100ML; 140MG/100ML N19844 001

JUN 10, 1993

MCGRAW

5GM/100ML; 30MG/100ML; 97MG/100ML;

220MG/100ML; 140MG/100ML N19844 001

JUN 10, 1993

DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION

ISOLYTE S IN DEXTROSE 5% IN PLASTIC CONTAINER

AP B BRAUN 5GM/100ML; 30MG/100ML; 37MG/100ML;

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

500MG/100ML N19843 001

AUG 09, 1993

MCGRAW

5GM/100ML; 30MG/100ML; 37MG/100ML;

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

500MG/100ML N19843 001

AUG 09, 1993

AP MCGRAW

5GM/100ML; 30MG/100ML; 37MG/100ML;

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

500MG/100ML N19843 001

AUG 09, 1993

AP B BRAUN

5GM/100ML; 30MG/100ML; 37MG/100ML;

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

500MG/100ML N19874 001

AUG 09, 1993

AP MCGRAW

5GM/100ML; 30MG/100ML; 37MG/100ML;

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

500MG/100ML N19874 001

AUG 09, 1993

DEXTROSE; POTASSIUM CHLORIDE

INJECTABLE; INJECTION

POTASSIUM CHLORIDE 0.075% IN DEXTROSE 5% IN PLASTIC

CONTAINER

AP B BRAUN 5GM/100ML; 75MG/100ML N18744 001

NOV 09, 1992

AP MCGRAW

5GM/100ML; 75MG/100ML N18744 001

NOV 09, 1992

DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC;  
SODIUM ACETATE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

ISOLYTE M IN DEXTROSE 5% IN PLASTIC CONTAINER  
 B BRAUN 5GM/100ML;150MG/100ML;130MG/100ML;  
 280MG/100ML;91MG/100ML N19870 001  
 JUN 10, 1993  
 MCGRAW 5GM/100ML;150MG/100ML;130MG/100ML;  
 280MG/100ML;91MG/100ML N19870 001  
 JUN 10, 1993

DEXTROSE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

DEXTROSE 10% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 B BRAUN 10GM/100ML;900MG/100ML N18047 001  
 MCGRAW 10GM/100ML;900MG/100ML N18047 001  
 DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER  
 B BRAUN 5GM/100ML;900MG/100ML N18026 001  
 MCGRAW 5GM/100ML;900MG/100ML N18026 001

DIAZEPAM

## INJECTABLE; INJECTION

DIAZEPAM  
 AP MANSAN 5MG/ML N72371 001  
 JAN 29, 1993  
 B 5MG/ML N72371 001  
 JAN 29, 1993

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC  
DICLOFENAC SODIUM  
 AB ALCON 0.1%<sup>†</sup> N20809 001  
 MAY 04, 1998  
 B VOLTAREN CIBA 0.1% N20037 001  
 MAR 28, 1991

DICYCLOMINE HYDROCHLORIDETABLET; ORAL  
DICYCLOMINE HCL

AB WAKER 20MG  
 B 20MG

N84600 001  
 JUL 29, 1985  
 N84600 001  
 JUL 29, 1985

DIFLORASONE DIACETATECREAM; TOPICAL  
DIFLORASONE DIACETATE

AB ALTANA 0.05%  
 AB PSORCOM 0.05%  
 B DERMIK LABS 0.05%

N75187 001  
 MAR 30, 1998  
 N20205 001  
 NOV 20, 1992  
 N20205 001  
 NOV 20, 1992

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL  
CARTIA XT

AB ANDRX PHARMS 120MG  
 > ADD >  
 > ADD >

N74752 002  
 JUL 09, 1998  
 N74752 001  
 JUL 09, 1998  
 N74752 003  
 JUL 09, 1998  
 N74752 004  
 JUL 09, 1998

DILTIAZEM HCL

AB2 MYLAN 120MG  
 AB2 180MG  
 AB2 240MG  
 BC TIAZAC 120MG  
 BC BIOMARIL 120MG  
 BC 120MG  
 BC 180MG

N75124 002  
 MAR 18, 1998  
 N75124 003  
 MAR 18, 1998  
 N75124 001  
 MAR 18, 1998  
 N20461 001  
 SEP 11, 1995  
 N20461 001  
 SEP 11, 1995  
 N20461 002  
 SEP 11, 1995

<sup>†</sup> SEE SECTION 1.4 OF INTRODUCTION

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

TIAZAC  
BC + BIOVAIL 180MG

BC 240MG

BC + 240MG

BC 300MG

BC + 300MG

BC 360MG

+ 360MG

INJECTABLE; INJECTION

DILTIAZEM HCL

AP ABBOTT 5MG/ML

AP TAYLOR PHARMA 5MG/ML

N20401 002

SEP 11, 1995

N20401 003

SEP 11, 1995

N20401 004

SEP 11, 1995

N20401 005

SEP 11, 1995

N20401 006

SEP 11, 1995

N20401 007

SEP 11, 1995

N20401 008

SEP 11, 1995

N20401 009

SEP 11, 1995

N20401 010

SEP 11, 1995

N20401 011

SEP 11, 1995

N74941 001

APR 15, 1998

N75086 001

APR 09, 1998

DINOPROSTONEINSERT, EXTENDED RELEASE; VAGINAL  
CERVIDIL

&gt; DLT &gt; + FOREST LABS 10MG

&gt; DLT &gt; + FOREST LABS 10MG

&gt; ADD &gt; + FOREST LABS 10MG

&gt; ADD &gt; + FOREST LABS 10MG

N20411 001

MAR 30, 1995

N20411 001

MAR 30, 1995

DIPHENHYDRAMINE HYDROCHLORIDEELIXIR; ORAL  
DIPHENHYDRAMINE HCL

WATSON LABS 12.5MG/5ML

+ MERCK 12.5MG/5ML

N63237 001

JAN 25, 1982

N63237 001

JAN 25, 1982

DIPYRIDAMOLE

INJECTABLE; INJECTION

DIPYRIDAMOLE

AP BEFORD

5MG/ML

N74939 001  
APR 13, 1998DISOPYRAMIDE PHOSPHATE

CAPSULE, EXTENDED RELEASE; ORAL

DISOPYRAMIDE PHOSPHATE

+ KV PHARM EQ 100MG BASE

N71929 001  
AUG 19, 1988DOBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

DOBUTAMINE HCL

AP LUITPOLD

EQ 12.5MG BASE/ML

N74545 001  
JUN 25, 1998

AP MARSAM

EQ 12.5MG BASE/ML

N74279 001  
FEB 18, 1998

AP

EQ 12.5MG BASE/ML

N74995 001  
MAR 31, 1998DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC

COSOPT

+ MERCK

EQ 2% BASE; EQ 0.5% BASE N20869 001  
APR 07, 1998DOXEPIPIN HYDROCHLORIDE

CAPSULE; ORAL

DOXEPIPIN HCL

AP

EQ 10MG BASE

AP

EQ 10MG BASE

AP

EQ 10MG BASE

AP WATSON LABS

EQ 10MG BASE

MAR 29, 1991

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN '98 - JULY '98

10

## **DOXEPIN HYDROCHLORIDE**

CAPSULE, ORAL <u>DOXEPIN HCL</u>	EQ 25MG BASE	W72986 001
AB WATSON LABS		MAR 29, 1991
AB	EQ 50MG BASE	W72987 001
		MAR 29, 1991

## **DOXORUBICIN HYDROCHLORIDE**

INJECTABLE; INJECTION  
RUBEX  
BRISTOL MYERS SQUIBB 10MG/VIAL  
50MG/VIAL  
100MG/VIAL

APR 13, 1989  
M62926 002

APR 13, 1989  
M62926 003

APR 13, 1989

## DYPHYLLINE

**INJECTION, INJECTION  
NITROGLYCERINE**  
\* Teva  
② 250MG/ML  
250MG/ML

## **EDROPHONIUM CHLORIDE**

**INJECTABLE; INJECTION  
EDROPHONIUM CHLORIDE**

**AP ABBOTT 10MG/ML N40131 001**  
**FEB 24 1998**

## **ENCAINIDE HYDROCHLORIDE**

CAPSULE; DRUG  
ENZYME  
ELASTOL MYERS EQUINE 25MG  
NDC 981 002  
DEC 31, 1996

## **ENCAINIDE HYDROCHLORIDE**

● 25MG N18981 002  
● 35MG DEC 24, 1986  
N18981 003  
DEC 24, 1986

#### **ENOXAPARIN SODIUM**

INJECTABLE, INJECTION LOVENOX		
+ RHONE POULENC RORER	40MG/0.4ML	N20164 002
+	60MG/0.6ML	JAN 30, 1998
+	80MG/0.8ML	N20164 003
+	100MG/ML	MAR 27, 1998
		N20164 004
		MAR 27, 1998
		N20164 005
		MAR 27, 1998

EFTIFIBATIDE

**INJECTABLE; INJECTION  
INTEGRILIN**

+ COR	75MG/100ML	N20718 002
+	2MG/ML	MAY 18, 1998
		N20718 001
		MAY 18, 1998

## **KRYTHROMYCIN**

AT OINTMENT; OPHTHALMIC  
ERYTHROMYCIN  
AKORN 0.5% 0.5g  
N64030 001  
JUL 18 1996

## OINTMENT; TOPICAL

• CLOTHES  
• SHIRT  
• TIE  
• JACKET  
• PANTS  
• SHOES

ERYTHROMYCIN

OINTMENT; TOPICAL  
AKNE-MYCIN

+ EM INDS

2%

N50584 001  
JAN 10, 1985

TABLET, DELAYED RELEASE; ORAL

E-MYCIN

~~AB~~ \* ~~RECORDS UNKNOWN~~ ~~333MG~~

~~AB~~ ERY-TAB ~~333MG~~

~~AB~~ + ~~250MG~~

~~AB~~ + ~~333MG~~

~~AB~~ + ~~333MG~~

~~AB~~ + ~~500MG~~

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

~~AB~~ ~~RECORDS UNKNOWN~~ ~~500MG/5ML~~

~~AB~~ ~~RECORDS UNKNOWN~~ ~~500MG/5ML~~

M60272 002

M60272 003

M62298 001

M62298 002

M62298 003

MAR 29, 1982

M62298 004

M62298 002

BISMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

BREVIBLOC

+ BAXTER PHARM PROD 10MG/ML

N19386 001

AUG 15, 1988

100MG/ML

N19386 003

DEC 31, 1986

250MG/ML

N19386 002

~~AB~~ CERUBICA ~~250MG/ML~~

~~AB~~ ~~250MG/ML~~

~~AB~~ ~~250MG/ML~~

ESTAZOLAM

TABLET; ORAL

ESTAZOLAM

WATSON LABS

2MG

2MG

1MG

ESTRADIOL CYCIONATEINJECTABLE; INJECTION  
DEPO-ESTRADOL

BRISTOL MYERS SQUIBB	1MG/ML
	3MG/ML

N85470 001  
N85470 002ESTRADIOL VALERATEINJECTABLE; INJECTION  
DELESTROGEN

AO + BRISTOL MYERS SQUIBB	20MG/ML
AO +	40MG/ML
AO +	10MG/ML
AO +	2MG/ML
AO +	4MG/ML
AO +	8MG/ML

N09402 004  
N09402 003  
N09402 002  
N09402 001  
N09402 000  
N09402 003ESTRADIOL VALERATE; TESTOSTERONE ENANTHATEINJECTABLE; INJECTION  
DELADUMONE

> ADD >	BRISTOL MYERS SQUIBB	4MG/ML; 90MG/ML
> DLT >		
> ADD >	DELADUMONE OB	
> DLT >	BRISTOL MYERS SQUIBB	8MG/ML; 180MG/ML

N09545 001  
N09545 000  
N09545 002  
N09545 000ESTRONEINJECTABLE; INJECTION  
THEERLIN

PARKER DAVIS	1MG/ML
	2MG/ML
	5MG/ML
PARKEDALE	1MG/ML
	2MG/ML
	5MG/ML

N03977 002  
N03977 000  
N03977 003  
N03977 001  
N03977 002  
N03977 003ETHINYL ESTRADIOL; LEVONORGESTRELTABLET; ORAL-21  
LEVILITE

> ADD >	BERLEX LABS	0.02MG; 0.1MG
> ADD >		
> ADD >		

N20860 001  
JUL 13, 1998ETHINYL ESTRADIOL; LEVONORGESTRELTABLET; ORAL-21  
LEVORA 0.15/30-21

> ADD >	WATSON LABS	0.03MG; 0.15MG
---------	-------------	----------------

N73592 001  
DEC 13, 1993

> ADD >	TABLET; ORAL-28 LEVILITE BERLEX LABS	0.02MG; 0.1MG
> ADD >	LEVORA 0.15/30-28	
> ADD >	WATSON LABS	0.03MG; 0.15MG

N20860 002  
JUL 13, 1998  
N73594 001  
DEC 13, 1993ETHINYL ESTRADIOL; NORETHINDRONETABLET; ORAL-21  
NORETHIN 1/35E-21

> DLT >	WATSON LABS	0.035MG; 1MG
> ADD >		

N71480 001  
APR 12, 1988

> DLT >	TABLET; ORAL-28 NORETHIN 1/35E-28	
> DLT >	WATSON LABS	0.035MG; 1MG
> ADD >		
> ADD >		

N71491 001  
APR 12, 1988ETODOLACCAPSULE; ORAL  
ETODOLAC

> ADD >	AESGEN	300MG
> ADD >	TARO	200MG
> ADD >		300MG

N74929 001  
JAN 30, 1998  
N75078 001  
APR 30, 1998  
N75078 002  
APR 30, 1998

ETODOLAC

TABLET; ORAL

ETODOLAC

<u>AB</u>	<u>CHELSEA LABS</u>	<u>400MG</u>
<u>AB</u>	<u>MYLAN</u>	<u>400MG</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>400MG</u>
<u>AB</u>	<u>TARO</u>	<u>400MG</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>400MG</u>

N75069 001  
APR 16, 1998  
N75104 001  
FEB 06, 1998  
N75074 001  
MAR 11, 1998  
N74892 001  
APR 16, 1997

TABLET, EXTENDED RELEASE; ORAL  
LODINE XL

+ WYETH AYERST 500MG

N20584 003  
JAN 20, 1998ETOPOSIDE

INJECTABLE; INJECTION

ETOPOSIDE

<u>AP</u>	<u>MARSAM</u>	<u>20MG/ML</u>
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N74968 001  
JAN 09, 1998ETOPOSIDE PHOSPHATE

INJECTABLE; INJECTION

ETOPOSIDE

+ BRISTOL MYERS SQUIBB EQ 100MG BASE/VIAL  
ETOPOPHOS PRESERVATIVE FREE  
+ BRISTOL MYERS SQUIBB EQ 100MG BASE/VIAL  
+ EQ 500MG BASE/VIAL

N20457 001  
MAY 17, 1996  
N20906 001  
FEB 27, 1998

FAMOTIDINETABLET, ORALLY DISINTEGRATING; ORAL  
PEPCID RPD

MERCK 20MG

N20752 001  
MAY 28, 1998FAMOTIDINETABLET, ORALLY DISINTEGRATING; ORAL  
PEPCID RPD  
+ MERCK

40MG

N20752 002  
MAY 28, 1998FENFLURAMINE HYDROCHLORIDETABLET; ORAL  
FENFLURAMINE  
+ MERCK SINN

20MG

N16618 001  
N16618 001FENOFLIBRATECAPSULE; ORAL  
LIPIDIL  
+ ABBOTT

100MG

N19304 001  
DEC 31, 1993  
N19304 001  
DEC 31, 1993+ ELKINS SINKIN  
TRICOR (MICRONIZED)

67MG

N19304 002  
FEB 09, 1998FENTANYL CITRATE

INJECTABLE; INJECTION

FENTANYL CITRATE

EQ 0.05MG BASE/ML

N16619 001  
N16619 001

+ MERRING PHARM

EQ 0.05MG BASE/ML

N16619 001  
N16619 001FENTANYL CITRATE PRESERVATIVE FREE  
+ ABBOTT

EQ 0.05MG BASE/ML

N72786 001  
SEP 24, 1991

+ ELKINS SINKIN

EQ 0.05MG BASE/ML

N19101 001  
JUL 11, 1984

+ MARSAM

EQ 0.05MG BASE/ML

N74917 001  
FEB 03, 1998

+ JANSSEN

EQ 0.05MG BASE/ML

N16619 001  
N16619 001

SUBLIMASE PRESERVATIVE FREE

EQ 0.05MG BASE/ML

FLCSEQUINAN

CREAM; ORAL  
TOPICAL  
KING PHARMS 50MG  
75MG  
100MG  
50MG  
75MG  
100MG

FLCSEQUINAN  
CREAM; ORAL  
TOPICAL  
KING PHARMS  
50MG  
75MG  
100MG  
DEC 30, 1992  
N19960 002  
DEC 30, 1992  
N19960 003  
DEC 30, 1992

FLUOCINONIDE

CREAM; TOPICAL  
FLUOCINONIDE  
AB DRAXIS HLTH 0.05%  
AB TARO 0.05%

N72494 001  
JAN 19, 1989  
N72494 001  
JAN 19, 1989

FLUOROURACIL

INJECTABLE; INJECTION  
ADRUCIL  
AP PHARMACEIA AND UROJOHN 50MG/ML  
AP + 50MG/ML

N81225 001  
AUG 28, 1991  
N81225 001  
AUG 28, 1991

FLUPHENAZINE DECANOATE

INJECTABLE; INJECTION  
FLUPHENAZINE DECANOATE  
AO KING PHARMS 25MG/ML

N74966 001  
APR 16, 1998

FLURANDRENOLIDE; NEOMYCIN SULFATE

CREAM; TOPICAL CONTAINER	0.05%; EQ 3.5MG BASE/GM	N50346 001
CREAM; TOPICAL CONTAINER	0.05%; EQ 3.5MG BASE/GM	N50345 001

FLUVOXAMINE MALEATE

TABLET; ORAL LUVOX	25MG	N20243 001
© SOLVAY	25MG	DEC 05, 1994

GEMFIBROZIL

CAPSULE; ORAL LOPID	200MG	N18422 001
© PARKE DAVIS	300MG	N18422 002
© PARKE DAVIS PHARMS	200MG	N18422 001
© PARKE DAVIS	300MG	N18422 002

TABLET; ORAL

<u>GEMFIBROZIL</u>	600MG	N75034 001
AB TORPHARM	600MG	JUL 20, 1998

LOPID

AB © PARKE DAVIS	600MG	N18422 003
AB + PARKE DAVIS PHARMS	600MG	N18422 003

GENTAMICIN SULFATE

INJECTABLE; INJECTION GENTAMICIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER	EQ 40MG BASE/100ML	N62814 008
AP B BRAUN	EQ 40MG BASE/100ML	AUG 28, 1987

## **GENTAMICIN SULFATE**

## **INJECTABLE; INJECTION**

**GENTAMICIN SULPHATE IN SODIUM CHLORIDE 0.9% IN PLASTIC**

#### **GENTAMICIN SULFATE**

## **INJECTABLE; INJECTION**

**GENTAMICIN SULPHATE IN SODIUM CHLORIDE 0.9% IN PLASTIC**

## **GLUCAGON HYDROCHLORIDE RECOMBINANT**

## **INJECTABLE; INJECTION**

**GLUCAGEN**  
+ NOVO NORDISK EQ 1MG BASE/VIAL N20918 001  
JUN 22 1998

## **GLYBURIDE**

**TABLET; ORAL**

### **GLYBURIDE (MICRONIZED)**

<u>AB</u>	INVAMED	<u>1.5MG</u>	M75174 001
<u>AB</u>		<u>3MG</u>	JUN 22, 1998
<u>AB</u>	NYLAN	<u>1.5MG</u>	M75174 002
<u>AB</u>		<u>3MG</u>	JUN 22, 1998
<u>AB</u>		<u>1.5MG</u>	M74792 001
<u>AB</u>		<u>3MG</u>	JUN 26, 1998
<u>AB</u>		<u>1.5MG</u>	M74792 002
<u>AB</u>		<u>3MG</u>	JUN 26, 1998

**GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE**

**SOLUTION/DROPS; OPHTHALMIC**

**NEOSPORIN**  
0.025MG/ML, EQ 1.75MG BASE/ML;  
10,000 UNITS/ML N60582 001

GRANisetron Hydrochloride

TABLET; ORAL  
KYTRIL  
© SMITHKLINE BEECHAM EQ 2MG BASE  
N20305 002  
JUN 15, 1998

Grepafloxacin Hydrochloride

TABLET; ORAL  
RAKAR  
© RAKAR PHARMACEUTICALS EQ 200MG BASE  
EQ 400MG BASE  
+ EQ 600MG BASE  
N20695 001 NOV 06, 1997  
N20695 002 MAY 14, 1998  
N20695 003 MAY 14, 1998

Guanfacine Hydrochloride

TABLET; ORAL  
GUANFACINE HCL  
AB WATSON LABS EQ 1MG BASE  
AB EQ 2MG BASE  
N74762 001 JUN 25, 1997  
N74762 002 JUN 25, 1997

Haloperidol

TABLET; ORAL  
HALOPERIDOL  
AB EQ 2MG BASE  
AB EQ 5MG BASE  
AB EQ 10MG BASE  
AB EQ 20MG BASE  
N72516 001 FEB 25, 1993  
N72517 001 FEB 25, 1993

Haloperidol

TABLET; ORAL  
HALOPERIDOL  
AB 0.5MG  
AB 1MG  
AB 2MG  
AB 5MG  
AB 10MG  
AB 20MG

N71071 001 NOV 03, 1986  
N71072 001 NOV 03, 1986  
N71073 001 NOV 03, 1986  
N71074 001 NOV 03, 1986  
N71075 001 AUG 04, 1987  
N71076 001 AUG 04, 1987

Haloperidol Decanoate

INJECTABLE; INJECTION  
HALOPERIDOL DECANOATE  
AO BEDFORD EQ 50MG BASE/ML  
M74811 001 JAN 30, 1998

Haloperidol Lactate

INJECTABLE; INJECTION  
HALOPERIDOL  
AB EQ 5MG BASE/ML  
AB EQ 5MG BASE/ML  
AB EQ 5MG BASE/ML  
AB EQ 5MG BASE/ML  
N72516 001 FEB 25, 1993  
N72517 001 FEB 25, 1993

Heparin Sodium

INJECTABLE; INJECTION  
HEP FLUSH KIT IN PLASTIC CONTAINER  
© AM PHARM PARTNERS 10 UNITS/ML

M17029 017 DEC 05, 1995

> ADD >  
> ADD >

## **HEPARIN SODIUM**

> <u>ADD</u> >		<b>INJECTABLE; INJECTION HEP FLUSH KIT IN PLASTIC CONTAINER</b>	
> <u>ADD</u> >		© FUJISAWA	10 UNITS/ML
> <u>DLT</u> >		©	100 UNITS/ML
> <u>DLT</u> >		©	100 UNITS/ML
> <u>DLT</u> >		©	100 UNITS/ML
> <u>DLT</u> >		<b>HEPARIN LOCK FLUSH AM PHARM PARTNERS</b>	<b>10 UNITS/ML</b>
> <u>ADD</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>ADD</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>ADD</u> > AP		© FUJISAWA	10 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>ADD</u> >		<b>HEPARIN LOCK FLUSH PRESERVATIVE FREE © AM PHARM PARTNERS</b>	<b>10 UNITS/ML</b>
> <u>ADD</u> >		©	100 UNITS/ML
> <u>ADD</u> >		© FUJISAWA	10 UNITS/ML
> <u>ADD</u> >		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>ADD</u> >		<b>HEPARIN LOCK FLUSH PRESERVATIVE FREE © AM PHARM PARTNERS</b>	<b>10 UNITS/ML</b>
> <u>ADD</u> >		©	100 UNITS/ML
> <u>ADD</u> >		© FUJISAWA	10 UNITS/ML
> <u>ADD</u> >		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>DLT</u> > AP		© FUJISAWA	100 UNITS/ML
> <u>ADD</u> > AP		<b>HEPARIN SODIUM AM PHARM PARTNERS</b>	
> <u>ADD</u> > AP		©	5,000 UNITS
> <u>ADD</u> > AP		©	5,000 UNITS
> <u>ADD</u> > AP		©	10,000 UNITS
> <u>ADD</u> > AP		©	20,000 UNITS

#### **HEPARIN SODIUM**

HEPARIN SODIUM

## INJECTABLE; INJECTION

HEPARIN SODIUM 2,000 UNITS IN SODIUM CHLORIDE 0.9% IN  
PLASTIC CONTAINER

• B BRAUN	200 UNITS/100ML	N19042 002
		MAR 29, 1985
• MCGRAN	200 UNITS/100ML	N19042 002
		MAR 29, 1985

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

AP B BRAUN	4,000 UNITS/100ML	N19952 001
		JUL 20, 1992
AP MCGRAN	4,000 UNITS/100ML	N19952 001
		JUL 20, 1992
<u>HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5%</u>		
AP ABBOTT	5,000 UNITS/100ML	N18911 009
		JAN 30, 1985
AP	10,000 UNITS/100ML	N18911 008
		JAN 30, 1985
•	5,000 UNITS/100ML	N18911 009
		JAN 30, 1985
•	10,000 UNITS/100ML	N18911 008
		JAN 30, 1985

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

AP B BRAUN	5,000 UNITS/100ML	N19952 004
		JUL 20, 1992
AP	10,000 UNITS/100ML	N19952 005
		JUL 20, 1992
•	5,000 UNITS/100ML	N19134 001
		MAR 29, 1985
AP MCGRAN	5,000 UNITS/100ML	N19952 004
		JUL 20, 1992
AP	10,000 UNITS/100ML	N19952 005
		JUL 20, 1992
•	5,000 UNITS/100ML	N19134 001
		MAR 29, 1985

HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN  
PLASTIC CONTAINER

• B BRAUN	5,000 UNITS/100ML	N19802 005
		JUL 20, 1992
•	10,000 UNITS/100ML	N19802 002
		JUL 20, 1992
• MCGRAN	5,000 UNITS/100ML	N19802 005
		JUL 20, 1992
•	10,000 UNITS/100ML	N19802 002
		JUL 20, 1992

HEPARIN SODIUM

## INJECTABLE; INJECTION

HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN  
PLASTIC CONTAINER

• B BRAUN	5,000 UNITS/100ML	N19135 001
		MAR 29, 1985
•	5,000 UNITS/100ML	N19802 003
		JUL 20, 1992
• MCGRAN	5,000 UNITS/100ML	N19135 001
		MAR 29, 1985
•	5,000 UNITS/100ML	N19802 003
		JUL 20, 1992
<u>HEPARIN SODIUM 5,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER</u>		
• B BRAUN	1,000 UNITS/100ML	N19042 004
		MAR 29, 1985
• MCGRAN	1,000 UNITS/100ML	N19042 004
		MAR 29, 1985

HEPARIN SODIUM IN PLASTIC CONTAINER

AM PHARM PARTNERS	<u>1,000 UNITS/ML</u>	N17029 013
	<u>5,000 UNITS/ML</u>	DEC 05, 1985
	<u>10,000 UNITS/ML</u>	N17029 014
	<u>20,000 UNITS/ML</u>	DEC 05, 1985
	<u>40,000 UNITS/ML</u>	N17029 015
	<u>80,000 UNITS/ML</u>	DEC 05, 1985
	<u>160,000 UNITS/ML</u>	N17029 016

FUJISAWA	<u>1,000 UNITS/ML</u>	DEC 05, 1985
	<u>5,000 UNITS/ML</u>	N17029 013
	<u>10,000 UNITS/ML</u>	DEC 05, 1985
	<u>20,000 UNITS/ML</u>	N17029 014
	<u>40,000 UNITS/ML</u>	DEC 05, 1985
	<u>80,000 UNITS/ML</u>	N17029 015
	<u>160,000 UNITS/ML</u>	DEC 05, 1985

HEPARIN SODIUM PRESERVATIVE FREE

AM PHARM PARTNERS	<u>1,000 UNITS/ML</u>	N17029 010
*	<u>1,000 UNITS/ML</u>	APR 28, 1986
*	<u>1,000 UNITS/ML</u>	N17629 010
*	<u>1,000 UNITS/ML</u>	APR 28, 1986

FUJISAWA	<u>1,000 UNITS/ML</u>	N17651 009
*	<u>10 UNITS/ML</u>	JUN 26, 1984
*	<u>10 UNITS/ML</u>	N17652 009
*	<u>10 UNITS/ML</u>	JUN 26, 1984

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL  
**AVAPRO HCT**  
 • SANOFI 12.5MG;75MG N20758 001  
 + 12.5MG;150MG N20758 002  
 SEP 30, 1997  
 SEP 30, 1997  
IRBESARTAN HYDROCHLOROTHIAZIDE  
 • SANOFI 12.5MG;75MG N20758 003  
 + 12.5MG;150MG N20758 004  
 SEP 30, 1997  
 SEP 30, 1997

HYDROCHLOROTHIAZIDE; METHYLDOPA

TABLET; ORAL  
**METHYLDOPA AND HYDROCHLOROTHIAZIDE**  
 AB ADVANCED 15MG;25MG N70829 001  
 AB 25MG;250MG N70830 001  
 • 15MG;250MG N70829 001  
 MAR 09, 1987  
 • 25MG;250MG N70830 001  
 MAR 09, 1987

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL  
**SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE**  
 AB GENEVA PHARMS 25MG;25MG N86881 001  
 AB SPIRONOLACTONE W/ HYDROCHLOROTHIAZIDE  
 GENEVA PHARMS 25MG;25MG N86881 002

HYDROCHLOROTHIAZIDE; TRIAMTERENE

CAPSULE; ORAL  
**TRIAMTERENE AND HYDROCHLOROTHIAZIDE**  
 AB BARR 25MG;37.5MG N74970 001  
 JAN 06, 1998

TABLET; ORAL  
**TRIAMTERENE AND HYDROCHLOROTHIAZIDE**  
 AB BARR 25MG;37.5MG N71251 002  
 MAY 05, 1998

HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL  
**DIOVAN HCT**  
 NOVARTIS 12.5MG;80MG N20818 001  
 + 12.5MG;160MG N20818 002  
 MAR 06, 1998  
 MAR 06, 1998

HYDROCORTISONE

CREAM; TOPICAL  
**ANUSOL HC**  
 AT PARKEDALE 2.5% N88250 001  
 JUN 06, 1984  
 AT PARKEDALE 2.5% N88250 001  
 JUN 06, 1984

SOLUTION; TOPICAL

**TEXACORT**  
 AT + GILLETTE 1% N80425 001  
 AT + MEDICIS 1% N80425 001

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OTIC  
**CORTISPORIN**  
 • GILLETTE 1% N60613 001  
 AT + MONARCH PHARMS 10,000 UNITS/ML; N60613 001  
 10,000 UNITS/ML; N60613 001  
 10,000 UNITS/ML; N60613 001

HYDROMORPHONE HYDROCHLORIDE

SOLUTION; ORAL  
**DILAUDID**  
 AA + KNOELL PHARM 5MG/5ML N19891 001  
 DEC 07, 1992  
 > ADD > AA HYDROMORPHONE HCL 5MG/5ML N74653 001  
 > ADD > AA ROXANE 5MG/5ML JUL 29, 1998

TABLET; ORAL

**DILAUDID**  
 AB + KNOELL PHARM 5MG N19892 001  
 DEC 07, 1992

## RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

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HYDROMORPHONE HYDROCHLORIDE

> ADD > TABLET; ORAL  
HYDROMORPHONE HCL  
> ADD > AB ROXANE 8MG N74597 001  
> ADD JUL 29, 1998

HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC  
PAREMYD  
+ AKORN 1% 0.25% N19261 001  
JAN 30, 1992  
\* ALLERGAN 1% 0.25% N19261 001  
JAN 30, 1992

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL  
HYDROXYCHLOROQUINE SULFATE  
AB MYLAN 200MG N40274 001  
MAY 29, 1998  
AB HYDROXYCHLOROQUINE SULFATE 200MG N40133 001  
ROYCE LABS NOV 30, 1995  
N40133 001  
NOV 30, 1995  
AB WATSON LABS 200MG N40133 001  
NOV 30, 1995

HYDROXYUREA

CAPSULE; ORAL  
DROXIA  
BRISTOL MYERS SQUIBB 300MG N16295 003  
200MG N16295 002  
300MG FEB 25, 1998  
+ 400MG N16295 003  
FEB 25, 1998  
N16295 004  
FEB 25, 1998  
HYDREA  
AB + BRISTOL MYERS SQUIBB 500MG N16295 001  
AB SQUIBB 500MG N16295 001  
HYDROXYUREA  
AB DURAMED 500MG N75020 001  
JUL 30, 1998

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL  
HYDROXYZINE HCL  
BX ROXANE LABS 200MG N81149 001  
MAR 18, 1994  
BX 200MG N81149 001  
MAR 18, 1994  
BX 200MG N81149 001  
MAR 18, 1994  
BX 200MG N81149 001  
MAR 18, 1994  
AB WATSON LABS 10MG N81149 001  
MAR 18, 1994  
AB 25MG N81150 001  
MAR 18, 1994  
AB 50MG N81151 001  
MAR 18, 1994

IBUPROFEN

SUSPENSION; ORAL  
CHILDREN'S ADVIL  
BX AM SONG PRODS 100MG/5ML N19833 002  
SEP 19, 1989  
N19833 002  
SEP 19, 1989  
BX WHITEHALL ROBINS 100MG/5ML N19833 001  
SEP 19, 1989  
AB IBUPROFEN ALPHARMA 100MG/5ML N74978 001  
MAR 25, 1998  
AB NOTRIN + MCNEIL 100MG/5ML N19842 001  
SEP 19, 1989  
N19842 001  
SEP 19, 1989

TABLET; ORAL  
IBUPROFEN

BEST BUY  
JUN 14, 1998  
@ 400MG JAN 14, 1988  
@ 600MG N72065 001  
JAN 14, 1988  
@ 800MG N71938 001  
JAN 14, 1988

> ADD > AB  
> ADD >

INDAPAMIDE

TABLET; ORAL

INDAPAMIDE

> ADD >	<u>AB</u>	ALPHAPHARM	<u>1.25MG</u>
> ADD >			<u>2.5MG</u>
> ADD >	<u>AB</u>		<u>2.5MG</u>
> ADD >	<u>AB</u>	TEVA	<u>1.25MG</u>

N75105 001
JUL 23, 1998
N75105 002
JUL 23, 1998
N74498 002
FEB 12, 1998

INDOMETHACIN

CAPSULE; ORAL

INDOMETHACIN

<u>AB</u>	EON	<u>75MG</u>
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N74464 001
MAY 28, 1998

IOPAMIDOL

INJECTABLE; INJECTION

IOPAMIDOL

<u>AP</u>	ELKINS SINK	<u>51%</u>
<u>AP</u>	<u>IOPAMIDOL-250</u>	<u>51%</u>
<u>AP</u>	ABBOTT	<u>51%</u>
<u>AP</u>	<u>IOPAMIDOL-300</u>	<u>61%</u>
<u>AP</u>	<u>IOPAMIDOL-370</u>	<u>76%</u>

N74629 004
MAR 31, 1998
N75005 001
FEB 24, 1998
N75005 002
FEB 24, 1998
N75005 003
FEB 24, 1998

IOTROLAN

INJECTABLE; INTRATHECAL

OSMOVIST 190

BERLEX	40.6%
BERLEX LABS	40.6%
OSMOVIST 240	51.3%

N19580 002
DEC 07, 1989
N19580 001
DEC 07, 1989
N19580 002
DEC 07, 1989

IOTROLAN

INJECTABLE; INTRATHECAL

OSMOVIST 240

BERLEX LABS

51.3%

N19580 002

DEC 07, 1989

IOVERSOL

INJECTABLE; INJECTION

OPTIRAY 240

+ MALLINCKRODT

51t

N20923 001

MAY 28, 1998

OPTIRAY 320

+ MALLINCKRODT

68t

N20923 002

MAY 29, 1998

OPTIRAY 350

+ MALLINCKRODT

74t

N20923 003

MAY 28, 1998

IPRATROPIUM BROMIDE

AEROSOL, METERED; INHALATION

ATROVENT

RESCINERGIC INHALATION 0.018MG/ACTV

0.018MG/INH

N19085 001

DEC 29, 1986

ISOSORBIDE DINITRATE

TABLET; SUBLINGUAL

ISOSORBIDE

ISOSORBIDE

50MG

N16191 001

APR 01, 1996

&gt; DLT &gt;

ISOSORBIDE

50MG

N16191 002

APR 01, 1996

&gt; DLT &gt;

ISOSORBIDE

2.5MG

N16191 001

APR 01, 1996

&gt; ADD &gt;

ISOSORBIDE

5MG

N16191 001

APR 01, 1996

&gt; ADD &gt;

ISOSORBIDE

5MG

N16191 001

APR 01, 1996

&gt; ADD &gt;



Rx DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'98 - JUL'98

### **LISINOPRIL**

**TABLET; ORAL**  
**ZESTRIL**  
**AB ZESTRIL 10MG N19777 001**  
**AB + ZESTRIL 10MG N19777 002**  
**MAY 19, 1988 MAY 19, 1988**

#### LORATADINE

**TABLET, ORAL  
CLARITIN REDITABS  
SCHERING** 10MG N20704 001  
DEC 23, 1996

## LORAZEPAM

INJECTABLE; INJECTION			
<u>LORAZEPAM</u>			
> <u>ADD</u> >	AP	AKORN	<u>2MG/ML</u>
> <u>ADD</u> >	AP	TAYLOR	<u>2MG/ML</u>
> <u>ADD</u> >	AP		
> <u>ADD</u> >	AP		
TABLET; ORAL			
<u>LORAZEPAM</u>			
AB	ROYCE LABS	<u>0.25MG</u>	N72928 001
AB		<u>1MG</u>	OCT 31, 1991
AB		<u>2MG</u>	N72927 001
AB		<u>2MG</u>	OCT 31, 1991
AB		<u>2MG</u>	N72928 001
AB	WATSON LABS	<u>0.5MG</u>	OCT 31, 1991
AB		<u>1MG</u>	N72927 001
AB		<u>2MG</u>	OCT 31, 1991
AB		<u>2MG</u>	N72928 001
AB		<u>2MG</u>	OCT 31, 1991

**LOTEPREDNOL ETABONATE**

<b>SUSPENSION/DROPS; OPHTHALMIC</b>		
<b>ALREX</b>		N20803 001
+ PHARMOS	0.2%	MAR 09, 1998
<b>LOTEMAX</b>		N20583 001
+ PHARMOS	0.5%	MAR 09, 1998
+	0.5%	N20841 001
+		MAR 09, 1998

## **LOXAPINE HYDROCHLORIDE**

CONCENTRATE; ORAL		
LOXITANE C	EQ 25MG BASE/ML	N17658 001
* COHMGYS		
+ WATSON LABS	EQ 25MG BASE/ML	N17658 001
INJECTABLE; INJECTION		
LOXITANE IM		
* COHMGYS	EQ 50MG BASE/ML	N18039 001
+ WATSON LABS	EQ 50MG BASE/ML	N18039 001

#### **LOXAPINE SUCCINATE**

MAFENIDE ACETATE

CREAM; TOPICAL  
SULFAMYLYON  
+ BERTEK PHARMS EQ 85MG BASE/GM N16763 001  
N16763 001  
N16763 001  
POWDER FOR RECONSTITUTION; TOPICAL  
SULFAMYLYON  
+ MYLAN 5% N19832 003  
JUN 05, 1998

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE;  
MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE;  
SODIUM PHOSPHATE, DIBASIC

INJECTABLE; INJECTION  
ISOLYTE S PH 7.4 IN PLASTIC CONTAINER  
B BRAUN 30MG/100ML; 37MG/100ML; 0.82MG/100ML;  
370MG/100ML; 530MG/100ML; 500MG/100ML;  
12MG/100ML N19696 001  
SEP 29, 1989  
MCGRAN 30MG/100ML; 37MG/100ML; 0.82MG/100ML;  
370MG/100ML; 530MG/100ML; 500MG/100ML;  
12MG/100ML N19696 001  
SEP 29, 1989

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM  
CHLORIDE; SODIUM GLUCONATE

INJECTABLE; INJECTION  
ISOLYTE S IN PLASTIC CONTAINER  
AP B BRAUN 30MG/100ML; 37MG/100ML; 370MG/100ML;  
530MG/100ML; 500MG/100ML N18252 001  
AP 30MG/100ML; 37MG/100ML; 370MG/100ML;  
530MG/100ML; 500MG/100ML N19711 001  
SEP 29, 1989  
AP MCGRAN 30MG/100ML; 37MG/100ML; 0.82MG/100ML;  
370MG/100ML; 530MG/100ML; 500MG/100ML;  
12MG/100ML N19711 001  
SEP 29, 1989

MALATHION

LOTION; TOPICAL  
OVIDE  
+ GENECAINE  
N18613 001  
AUG 02, 1982  
+ MEDICIS 0.5%

MANNITOL

INJECTABLE; INJECTION  
MANNITOL 10% IN PLASTIC CONTAINER  
AP B BRAUN 10GM/100ML N20006 002  
JUL 26, 1993  
AP MCGRAN 10GM/100ML N20006 002  
JUL 26, 1993  
MANNITOL 15% IN PLASTIC CONTAINER  
AP B BRAUN 15GM/100ML N20006 003  
JUL 26, 1993  
AP MCGRAN 15GM/100ML N20006 003  
JUL 26, 1993  
MANNITOL 20%  
AP B BRAUN 20GM/100ML N14738 001  
MCGRAN 20GM/100ML N14738 001  
MANNITOL 20% IN PLASTIC CONTAINER  
AP B BRAUN 20GM/100ML N20006 004  
JUL 26, 1993  
AP MCGRAN 20GM/100ML N20006 004  
JUL 26, 1993  
MANNITOL 5% IN PLASTIC CONTAINER  
AP B BRAUN 5GM/100ML N20006 001  
JUL 26, 1993  
AP MCGRAN 5GM/100ML N20006 001  
JUL 26, 1993

SOLUTION; IRRIGATION  
RESECTISOL IN PLASTIC CONTAINER  
B BRAUN 5GM/100ML N16772 002  
MCGRAN 5GM/100ML N16772 002

MECAMYLAMINE HYDROCHLORIDE

TABLET; ORAL  
INVERSINE  
+ LAYTON 2.5MG N10251 001  
N10251 001  
+ MERCK SHARP DOHME 2.5MG

MEGESTROL ACETATE

TABLET; ORAL  
MEGESTROL ACETATE  
 PHARMACHEMIE 40MG

N74745 001  
 FEB 27, 1998

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL  
MEPERIDINE HCL  
 ROXANE LABS 50MG

N40186 001  
 JUN 30, 1997

AA WATSON LABS 50MG

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL  
 PENTASA  
 \* NORCROS MINI-CAPS 250MG

N20049 001  
 MAY 10, 1993

+ ROBERTS LABS 250MG

N20049 001  
 MAY 10, 1993

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21  
NORETHIN 1/50M-21  
 AB Searle 0.05MG; 1MG

N71539 001  
 APR 12, 1988

TABLET; ORAL-28  
NORETHIN 1/50M-28  
 AB Searle 0.05MG; 1MG

N71540 001  
 APR 12, 1988

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

METHADONE HYDROCHLORIDE

CONCENTRATE; ORAL  
METHADONE HCL  
 ROXANE 10MG/ML

N40180 001  
 APR 30, 1998

TABLET; ORAL  
METHADONE HCL  
 EON 5MG

N40241 001  
 MAY 29, 1998

TABLET, DISPERSIBLE; ORAL  
METHADONE HCL  
 EON 10MG

N75082 001  
 MAR 25, 1998

METHOCARBAMOL

INJECTABLE; INJECTION

AB NERFAM 100MG/ML

N89849 001  
 DEC 27, 1991

METOCLOPRAMIDE HYDROCHLORIDE

TABLET; ORAL  
METOCLOPRAMIDE HCL  
 AB 10MG/ML

N72436 001  
 JUN 22, 1989

AB EQ 5MG BASE  
 AB EQ 10MG BASE

N70650 001  
 FEB 03, 1987

METOPROLOL TARTRATE

INJECTABLE; INJECTION  
METOPROLOL TARTRATE

> ADD > AB ABBOTT 1MG/ML

N75160 001  
 JUL 06, 1998

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL  
MEXILETINE HCL  
AB DANBURY PHARMA 150MG  
AB 200MG  
AB 250MG

N74865 001 APR 13, 1998  
N74865 002 APR 13, 1998  
N74865 003 APR 13, 1998

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL  
KADIAN

\* FAULDING SVCS 30MG

N74862 001  
JUL 07, 1998

TABLET, EXTENDED RELEASE; ORAL  
MORPHINE SULFATE

AB GENERICS 15MG

N74862 001

AB 30MG

JUL 07, 1998

AB 60MG

N74862 003

AB 100MG

JUL 07, 1998

AB 200MG

N74769 001

MS CONTIN 15MG

JUL 02, 1998

AB + PURDUE FREDERICK 30MG

N74769 002

AB + 60MG

JUL 02, 1998

AB + 100MG

N74516 004

AB + 200MG

JAN 16, 1990

AB + 300MG

N74516 005

AB + 400MG

SEP 12, 1989

AB + 500MG

N74516 001

AB + 600MG

MAY 29, 1987

AB + 700MG

N74516 002

AB + 800MG

APR 08, 1988

AB + 900MG

N74516 004

AB + 1000MG

JAN 16, 1990

AB + 1100MG

N74516 005

AB + 1200MG

SEP 12, 1989

MITOMYCIN

INJECTABLE; INJECTION  
MITOMYCIN  
AP SUPERGEN

5MG/VIAL  
20MG/VIAL

N64144 001 APR 30, 1998  
N64144 002 APR 30, 1998

MONTELUKAST SODIUM

TABLET; ORAL  
SINGULAR  
+ MERCK

EQ 10MG BASE

N20829 002 FEB 20, 1998

TABLET, CHEWABLE; ORAL  
SINGULAIR  
+ MERCK

EQ 5MG BASE

N20830 001 FEB 20, 1998

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL  
KADIAN

+ FAULDING 20MG

N20616 001 JUL 03, 1996

NADOLOL

+ FAULDING 50MG

N20616 002 JUL 03, 1996

TABLET; ORAL

+ FAULDING 100MG

N20616 003 JUL 03, 1996

CORGARD

+ FAULDING 200MG

N20616 004 JUL 03, 1996

AB BRISTOL MYERS SQUIBB 20MG

M18063 005

+ FAULDING 400MG

N20616 005 JUL 03, 1996

AB 400MG

OCT 28, 1986

+ FAULDING 800MG

N20616 006 JUL 03, 1996

AB 800MG

M18063 001

+ FAULDING 1200MG

N20616 007 JUL 03, 1996

AB 1200MG

M18063 002

+ FAULDING 1600MG

N20616 008 JUL 03, 1996

AB 1600MG

M18063 003

NADOLOL

TABLET; ORAL  
**CORGARD**  
 > ADD > AB + BRISTOL MYERS SQUIBB 160MG  
 > DLT > AB \*  
 > DLT >  
 > DLT > AB \*  
 > DLT > AB \*  
 > DLT > AB \*  
 > DLT > AB \*

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION  
**NALBUPHINE HCL**  
 AP KING PHARMS 10MG/ML  
 AP 20MG/ML

M74471 001  
 MAR 19, 1998  
 M74471 002  
 MAR 19, 1998

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION  
**NALOXONE HCL**  
 AP ABBOTT 0.4MG/ML  
 @ 0.4MG/ML

M70172 001  
 SEP 24, 1998  
 N70172 001  
 SEP 24, 1998

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL  
**PENTAZOCINE AND NALOXONE HYDROCHLORIDES**  
 AB ROYAL LABS EQ 0.25MG/50MG  
 EQ 0.5MG/50MG  
 AB WATSON LABS EQ 0.5MG BASE;  
 EQ 50MG BASE

M74736 001  
 JAN 21, 1997  
 M74736 001  
 JAN 21, 1997

NALTREXONE HYDROCHLORIDE

TABLET; ORAL  
**NALTREXONE HCL**  
 AB BARR 50MG  
 AB REVIA DUPONT MERCK 50MG

M74918 001  
 MAY 08, 1998

M18932 001  
 NOV 20, 1984

NAPROXEN

TABLET, DELAYED RELEASE; ORAL  
**EC-NAPROXIN**  
 AB + SYNTEX 375MG  
 AB + 500MG  
**NAPROXEN**  
 AB INVAMED 375MG  
 AB 500MG  
 AB PUREPAC PHARM 375MG  
 AB 500MG  
 AB TEVA 375MG  
 AB 500MG

M20067 002  
 OCT 14, 1994

M20067 003  
 OCT 14, 1994

M75061 001  
 FEB 18, 1998

M75061 002  
 FEB 18, 1998

M74936 001  
 FEB 24, 1998

M74936 002  
 FEB 24, 1998

M75227 001  
 JUN 30, 1998

M75227 002  
 JUN 30, 1998

NAPROXEN SODIUM

TABLET; ORAL  
**NAPROXEN SODIUM**  
 AB AL HIKMA EQ 250MG BASE

M74480 002  
 FEB 18, 1998

NARatriptan Hydrochloride

TABLET; ORAL  
**AMERGE**  
 GLAXO WELLCOME EQ 1MG BASE

N20763 002  
 FEB 10, 1998

NARatriptan Hydrochloride

TABLET; ORAL  
AMERGE  
+ GLAXO WELLCOME

EQ 2.5MG BASE

N20763 001  
FEB 10, 1998NEOMYCIN SULFATE

TABLET; ORAL  
NEOMYCIN SULFATE  
TEVA

EQ 350MG BASE  
EQ 350MG BASEN60304 001  
N60304 001NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION; IRRIGATION  
NEOSPORIN G.U. IRRIGANT

AT GLAXO WELLCOME EQ 40MG BASE/ML;  
200,000 UNITS/ML

AT MONARCH PHARMS EQ 40MG BASE/ML;  
200,000 UNITS/ML

N60707 001  
N60707 001NICARDIPIINE HYDROCHLORIDE

CAPSULE; ORAL  
NICARDIPIINE HCL

AB GENPHARM 20MG

AB 30MG

N74928 001  
MAR 19, 1998  
N74928 002  
MAR 19, 1998NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL  
MINITRAN

AB 3M 0.1MG/HR

AB1 0.1MG/HR

AB 0.2MG/HR

AB1 0.2MG/HR

N89771 001  
AUG 30, 1996  
N89771 001  
AUG 30, 1996  
N89772 001  
AUG 30, 1996  
N89772 001  
AUG 30, 1996NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL  
MINITRAN

AB 3M	0.4MG/HR	N89773 001 AUG 30, 1996
AB1	0.4MG/HR	N89773 001 AUG 30, 1996
AB	0.4MG/HR	N89774 001 AUG 30, 1996
AB1	0.6MG/HR	N89774 001 AUG 30, 1996
AB *	0.1MG/HR	M20145 001 APR 04, 1995
AB1 *	0.1MG/HR	M20145 001 APR 04, 1995
AB *	0.2MG/HR	M20145 002 APR 04, 1995
AB1 *	0.2MG/HR	M20145 002 APR 04, 1995
AB *	0.3MG/HR	M20145 004 APR 04, 1995
AB1 *	0.4MG/HR	M20145 004 APR 04, 1995
AB *	0.5MG/HR	M20145 005 APR 04, 1995
AB1 *	0.6MG/HR	M20145 005 APR 04, 1995
AB2 MYLAN	0.1MG/HR	N75033 001 FEB 06, 1998
AB	0.2MG/HR	N74609 001 AUG 30, 1996
AB2	0.2MG/HR	N74609 001 AUG 30, 1996
AB	0.3MG/HR	N74607 001 AUG 30, 1996
AB2	0.4MG/HR	N74607 001 AUG 30, 1996
AB	0.4MG/HR	N74607 001 AUG 30, 1996
AB2	0.6MG/HR	N74559 001 AUG 30, 1996
AB2 + NOVARTIS	0.1MG/HR	N20144 001 FEB 27, 1996
AB *	0.2MG/HR	N20144 002 FEB 27, 1996

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL  
TRANSDERM-NITRO

<u>AB2</u> + NOVARTIS	<u>0.2MG/HR</u>	M20144 002 FEB 27, 1996 N20144 003 FEB 27, 1996
<u>AB</u> *	<u>0.4MG/HR</u>	N20144 003 FEB 27, 1996
<u>AB2</u> +	<u>0.4MG/HR</u>	M20144 003 FEB 27, 1996
<u>AB</u> *	<u>0.4MG/HR</u>	N20144 003 FEB 27, 1996
<u>AB2</u> +	<u>0.6MG/HR</u>	M20144 004 FEB 27, 1996 N20144 003 FEB 27, 1996
<u>AB</u> *	<u>0.6MG/HR</u>	N20144 003 FEB 27, 1996

NORETHINDRONE

TABLET; ORAL  
NOR-QD  
\* ~~WATSON~~  
+ WATSON LABS

0.35MG  
0.35MG  
N17060 001

NYSTATIN

SUSPENSION; ORAL  
NYSTATIN

AA UDL 100,000 UNITS/ML

M64142 001  
JUN 25, 1998

OLANZAPINE

TABLET; ORAL  
ZYPREXA  
@ LILLY

15MG  
20MG  
N20592 005  
SEP 09, 1997  
N20592 006  
SEP 09, 1997

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

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL  
PRILOSEC  
+ ASTRA MERCK

40MG  
N19810 002  
JAN 15, 1998

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL  
NORFLEX

AB + 3M  
ORPHENADRINE CITRATE  
INVAMED

N12157 001  
N40284 001  
JUN 19, 1998

OXYBUTYNIN CHLORIDE

SYRUP; ORAL  
DITROPAN

AA + ALZA  
ANDRESEN KARSTAD BASE

N18211 001  
N18212 001

TABLET; ORAL  
DITROPAN

AB + ALZA  
ANDRESEN KARSTAD BASE

N17577 001  
N17578 001

OXYTOCIN

INJECTABLE; INJECTION  
PITOCIN

AB \* ~~ELI LILLY~~  
AB + PARKEDALE

10 USP UNITS/ML  
10 USP UNITS/ML

N18260 001  
N18261 001

PARICALCITOL

INJECTABLE; INJECTION  
ZEMPLAR  
+ ABBOTT

0.005MG/ML

N20819 001  
APR 17, 1998

PAROMOMYCIN SULFATE

CAPSULE; ORAL  
HUMATIN

AB \* PARKS DAVIS  
AB + PARKEDALE

EQ 250MG BASE  
EQ 250MG BASE  
EQ 250MG BASE

N60511 001  
N62310 001  
M60521 001  
N62310 001

AB PAROMOMYCIN SULFATE  
CARACO

EQ 250MG BASE

N64171 001  
JUN 30, 1997

PAROMOMYCIN SULFATE

CAPSULE; ORAL  
PAROMOMYCIN SULFATE

AB CANACO 50 250MG TABS N884171 001  
JUN 30, 1987

PENTOSAN POLYSULFATE SODIUM

CAPSULE; ORAL  
ELMIRON

+ ALZA 100MG N20193 001  
SEP 26, 1996

\* BAKER NORTON 100MG N20193 001  
SEP 26, 1996

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL  
PENTOXIFYLLINE

> ADD > AB BIOVAIL 400MG N75028 001  
JUL 20, 1998

PERMETHRIN

CREAM; TOPICAL  
ELIMITE

AB + ALLERGAN 5% N19855 001  
AUG 25, 1989

AB PERMETHRIN 5% N74806 001  
ALPHARMA JAN 23, 1998

PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

TABLET; ORAL  
AZO GRANTRISIN

+ ROCHE 50MG;500MG N19358 001  
AUG 31, 1990

@ 50MG;500MG N19358 001  
AUG 31, 1990

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL  
PHENTERMINE HCL

AB EON 37.5MG N88414 001  
OCT 19, 1983  
\* 37.5MG N88414 001  
OCT 19, 1983

TABLET; ORAL  
PHENTERMINE HCL

\* EON 30MG N88605 001  
SEP 28, 1987  
\* 30MG N88605 001  
SEP 28, 1987

PHENTOLAMINE MESYLATE

INJECTABLE; INJECTION  
PHENTOLAMINE MESYLATE

AB BEDFORD SMG/VIAL N40235 001  
MAR 11, 1998

AB REGITINE SMG/VIAL N08278 003  
NOVARTIS

PINDOLOL

TABLET; ORAL  
PINDOLOL

AB DUREPAC PHARM 5MG N74125 001  
APR 28, 1993  
\* 5MG N74125 002  
APR 28, 1993

\* 5MG N74125 001  
APR 28, 1993  
\* 10MG N74125 002  
APR 28, 1993

\* 10MG N74437 001  
FEB 27, 1995  
\* 10MG N74437 002  
FEB 27, 1995

\* 10MG N74437 001  
FEB 27, 1995  
\* 10MG N74437 002  
FEB 27, 1995

AB ROYCE LABS 5MG

AB 10MG N74437 001  
FEB 27, 1995

AB WATSON LABS 5MG

AB 10MG N74437 001  
FEB 27, 1995

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION  
ZOSYN IN PLASTIC CONTAINER  
+ LEDERLE            EQ 40MG BASE/ML;  
                      EQ 5MG BASE/ML  
+                    EQ 4GM BASE/100ML;  
                      EQ 500MG BASE/100ML  
+                    EQ 60MG BASE/ML;  
                      EQ 7.5MG BASE/ML

N50750 001  
FEB 24, 1998  
N50750 003  
FEB 24, 1998  
N50750 002  
FEB 24, 1998

POLYMYXIN B SULFATE

INJECTABLE; INJECTION  
POLYMYXIN B SULFATE

> DLT >	<u>AP</u>	<u>Pfizer</u>	<u>EQ 500,000 U BASE/VIAL</u>	<u>N60716 001</u>
	<u>AA</u>	<u>POLY-RX</u>	<u>100,000,000 UNITS/BOT</u>	<u>N61578 001</u>
	<u>AA</u>	<u>POLYMYXIN B SULFATE</u>	<u>100,000,000 UNITS/BOT</u>	<u>N62455 001</u>
	<u>AA</u>	<u>Paddock</u>	<u>100,000,000 UNITS/BOT</u>	<u>JUL 27, 1983</u>
	<u>@</u>		<u>100,000,000 UNITS/BOT</u>	<u>N62455 001</u>

PIROXICAM

CAPSULE; ORAL  
PIROXICAM

<u>AB</u>	<u>ROYCE LABS</u>	<u>10MG</u>	<u>N74460 001</u>
<u>AB</u>		<u>20MG</u>	<u>N74460 002</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>10MG</u>	<u>N74460 001</u>
<u>AB</u>		<u>20MG</u>	<u>N74460 002</u>

SEP 29, 1995  
SEP 29, 1995  
SEP 29, 1995  
SEP 29, 1995

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE, ANHYDROUSPOWDER FOR RECONSTITUTION; ORAL

<u>AA</u>	<u>INVAMED</u>	<u>236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT; 22.74GM/BOT</u>	<u>N73098 001</u>
			AUG 31, 1993
<u>@</u>		<u>236GM/BOT; 2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT; 22.74GM/BOT</u>	<u>N73098 001</u>
			AUG 31, 1993

POLYMYXIN B SULFATEINJECTABLE; INJECTION

<u>AP</u>	<u>* GLAXO WELLCOMB</u>	<u>EQ 500,000 U BASE/VIAL</u>	<u>N62036 001</u>
	<u>@ POLYMYXIN B SULFATE</u>	<u>EQ 500,000 U BASE/VIAL</u>	<u>N62036 001</u>
> ADD >	<u>AP</u>	<u>+ BEDFORD</u>	<u>EQ 500,000 U BASE/VIAL</u>

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC  
TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE

<u>AT</u>	<u>ALCON</u>	<u>10,000 UNITS/ML, EQ 1MG BASE/ML</u>	<u>N64211 001</u>
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APR 13, 1998

POTASSIUM CHLORIDE

INJECTABLE; INJECTION  
POTASSIUM CHLORIDE

<u>AP</u>	<u>B BRAUN</u>	<u>2MEQ/ML</u>	<u>N85870 001</u>
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N85870 001

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION  
SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN  
PLASTIC CONTAINER

<u>@ B BRAUN</u>	<u>75MG/100ML; 900MG/100ML</u>	<u>N18722 001</u>
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NOV 09, 1982

<u>@ MCGRAN</u>	<u>75MG/100ML; 900MG/100ML</u>	<u>N18722 001</u>
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NOV 09, 1982

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN  
PLASTIC CONTAINER

<u>@ B BRAUN</u>	<u>150MG/100ML; 900MG/100ML</u>	<u>N18722 002</u>
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NOV 09, 1982

<u>@ MCGRAN</u>	<u>150MG/100ML; 900MG/100ML</u>	<u>N18722 002</u>
-----------------	---------------------------------	-------------------

NOV 09, 1982

POTASSIUM CHLORIDE; SODIUM CHLORIDE

## INJECTABLE; INJECTION

SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER  
 @ B BRAUN 220MG/100ML; 900MG/100ML N18722 003 NOV 09, 1982  
 @ MCGRAW 220MG/100ML; 900MG/100ML N18722 003 NOV 09, 1982  
 SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER  
 @ B BRAUN 300MG/100ML; 900MG/100ML N18722 004 NOV 09, 1982  
 @ MCGRAW 300MG/100ML; 900MG/100ML N18722 004 NOV 09, 1982

PRAMIPEXOLE DIHYDROCHLORIDE

## TABLET; ORAL

MIRAPEX  
 PHARMACIA AND UPJOHN 0.5MG

N20667 006  
 FEB 12, 1998

PREDNISOLONESYRUP; ORAL  
PRE-PRED

> DLT > AA WE PHARMS 15MG/5ML N40192 001 MAY 28, 1998

> DLT > AA WE PHARMS 15MG/5ML N40192 001 MAY 28, 1998

> ADD > AA WE PHARMS 15MG/5ML N40192 001 MAY 28, 1998

> ADD > AA + MURO 15MG/5ML N89081 001 FEB 04, 1986

TABLET; ORAL  
 PREDNISOLONE

BX DABURU PHARMA 5MG N80354 001

BX + GENEVA PHARMS 5MG N80354 001

@ GENEVA PHARMS 5MG N80339 001

5MG N80339 001

PRIMIDONE

## SUSPENSION; ORAL

MYSOLINE  
 + ELAN PHARMA 250MG/5ML N10401 001  
 \* NYETH AYERST 250MG/5ML N10401 001

## TABLET; ORAL

MYSOLINE  
 AB + ELAN PHARMA 250MG N09170 002  
 + NYETH AYERST 50MG N09170 003  
 AB + NYETH AYERST 250MG N09170 002  
 \* 50MG N09170 003

PROCAINAMIDE HYDROCHLORIDETABLET, EXTENDED RELEASE; ORAL  
PROCAINAMIDE HCL

AB INVAMED	500MG	N89284 001
@	500MG	JUN 23, 1986
AB SIOMAR LABS NJ	250MG	N89284 001
@	250MG	JUN 23, 1986
AB PROCAN SR PARKER DAVIS	500MG	N88958 001
AB	750MG	JUN 23, 1986
AB *	1GM	APR 01, 1982
AB + PARKEDALE	500MG	N88958 001
AB +	750MG	APR 01, 1982
AB +	1GM	N88489 001
		JAN 16, 1985

PROCHLORPERAZINE EDISYLATEINJECTABLE; INJECTION  
PROCHLORPERAZINE EDISYLATE

AP MARKIN	EQ 5MG BASE/ML	N89675 001
@	EQ 5MG BASE/ML	DEC 05, 1988
		N89675 001
		DEC 05, 1988

PROCHLORPERAZINE MALEATE

TABLET; ORAL  
PROCHLORPERAZINE MALEATE  
**AB** TRIGEN EQ 5MG BASE N40268 001 FEB 27, 1998  
**AB** EQ 10MG BASE N40268 002 FEB 27, 1998  
**AB** ZENITH GOLDLINE EQ 5MG BASE N40162 001 JAN 20, 1998  
**AB** EQ 10MG BASE N40162 002 JAN 20, 1998

PROGESTERONE

CAPSULE; ORAL  
 PROMETRIUM  
 + SCHERING PLOUGH 100MG

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION  
PROMETHAZINE HCL  
**AP** MARSAN 25MG/ML N89463 001 MAY 02, 1988  
**AP** 50MG/ML N89477 001 MAY 02, 1988  
@ 25MG/ML N89463 001 MAY 02, 1988  
@ 50MG/ML N89477 001 MAY 02, 1988

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL  
PROPOXYPHENE HCL  
**AB** EUREPAC PHARM 65MG N83278 001  
@ 65MG N83278 001

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL  
PROPRANOLOL HCL  
**AB** INVANCO 10MG N71658 001 JUL 05, 1988

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL  
PROPRANOLOL HCL  
**AB** INVANCO 20MG N71658 001 JUL 05, 1988  
**AB** 40MG N71687 001 JUL 05, 1988  
**AB** 60MG N71688 001 JUL 05, 1988  
**AB** 80MG N71689 001 JUL 05, 1988  
**AB** 90MG N72197 001 JUL 05, 1988  
@ 10MG N71658 001 JUL 05, 1988  
@ 20MG N71687 001 JUL 05, 1988  
@ 40MG N71688 001 JUL 05, 1988  
@ 60MG N71689 001 JUL 05, 1988  
@ 80MG N71689 001 JUL 05, 1988  
@ 90MG N72198 001 JUL 05, 1988

QUINIDINE SULFATE

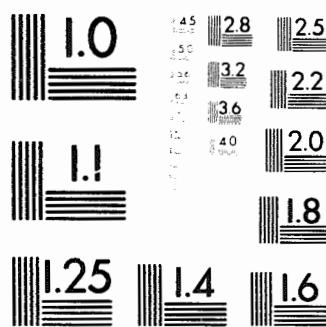
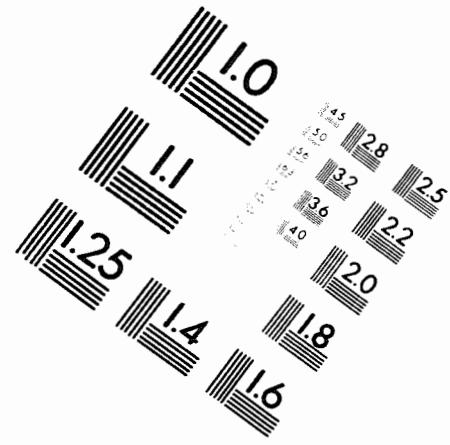
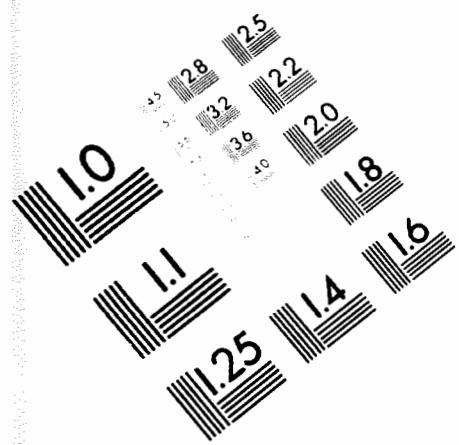
TABLET; ORAL  
QUINIDINE SULFATE  
**AB** EUREPAC PHARM 200MG N84003 001  
@ 200MG N84003 001

TABLET, EXTENDED RELEASE; ORAL

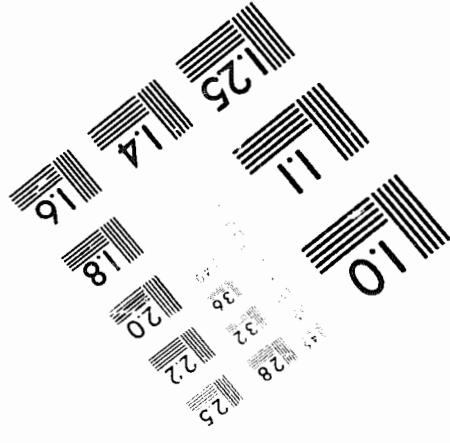
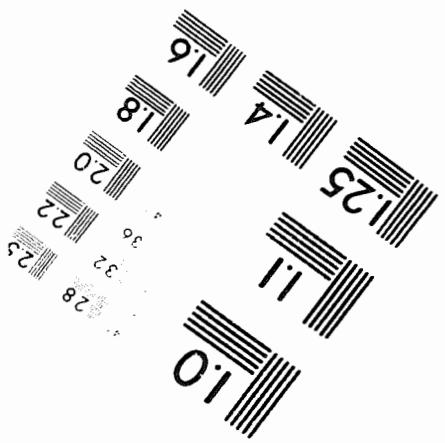
QUINIDEX  
**AB** + ROBINS AH 300MG N12796 002  
**AB** + WYETH AYERST 300MG N12796 002

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL  
 ZANTAC  
 GLAXO WELLCOME 15MG BASE/ML N19675 001 DEC 30, 1988  
+ EQ 15MG BASE/ML N19675 001 DEC 30, 1988



6"



RANITIDINE HYDROCHLORIDE

TABLET; ORAL  
RANITIDINE HCL

> ADD > AB MYLAN EQ 150MG BASE N74552 001 > ADD >  
> ADD > AB EQ 300MG BASE N74552 002 > ADD >  
> ADD > AB RANBAXY EQ 150MG BASE N75000 001 > ADD >  
AB EQ 300MG BASE N75000 002

JUL 30, 1998  
JUL 30, 1998  
JAN 30, 1998  
JAN 30, 1998

RIFAMPIN

CAPSULE; ORAL  
RIFADIN

AB HOECHST MARION RSSL 150MG N62303 001  
AB RIFAMPIN EON 150MG N64150 002

JAN 02, 1998

RIFAPENTINE

TABLET; ORAL  
PRIFTIN

+ HOECHST MARION RSSL 150MG N21024 001

JUN 22, 1998

RISEDRONATE SODIUM

TABLET; ORAL  
ACTONEL

+ PROCTER AND GAMBLE 30MG N20835 001

MAR 27, 1998

RIZATRIPTAN BENZOATE

TABLET; ORAL  
MAXALT

> DLT > AB MERCK EQ 5MG BASE N74641 001  
> DLT > \* EQ 10MG BASE N74641 002  
> DLT >

JUN 29, 1998  
JUN 29, 1998

RIZATRIPTAN BENZOATE

TABLET, ORALLY DISINTEGRATING; ORAL  
MAXALT

MERCK EQ 5MG BASE N20864 001  
+ EQ 10MG BASE N20864 002  
MAXALT-MLT EQ 5MG BASE N20865 001  
+ EQ 10MG BASE N20865 002

JUN 29, 1998  
N20864 001  
N20864 002  
JUN 29, 1998  
N20865 001  
N20865 002  
JUN 29, 1998

SACROSIDASE

SOLUTION; ORAL  
SUCRAID

+ ORPHAN MEDCL 8,500 IU/ML

N20772 001  
APR 09, 1998

SAQUINAVIR

CAPSULE; ORAL  
FORTOVASE

\* ROCHE EQ 200MG BASE N74623 001  
+ 200MG

NOV 07, 1997  
N20828 001  
NOV 07, 1997

SELEGILINE HYDROCHLORIDE

TABLET; ORAL  
SELEGILINE HCL

AB ESI LEDERLE 5MG N74641 001  
AB LEDERLE 5MG N74641 001  
AB STASON 5MG N74912 001  
APR 30, 1998

SILDENAFIL CITRATE

TABLET; ORAL  
VIAGRA  
PFIZER

25MG	N20895 001
50MG	N20895 002
+	N20895 003
100MG	MAR 27, 1998

50MG	N20895 002
+	N20895 003
100MG	MAR 27, 1998

SIMVASTATIN

TABLET; ORAL  
ZOCOR  
MERCK

5MG	N19766 001
+	N19766 004
5MG	N19766 001
40MG	N19766 004
+	N19766 005
80MG	JUL 10, 1998

5MG	N19766 001
40MG	N19766 004
+	N19766 005
80MG	JUL 10, 1998

SODIUM CHLORIDE

INJECTABLE; INJECTION  
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AP	B BRAUN	450MG/100ML	M19635 001
AP	+	450MG/100ML	N18184 001
AP	MECHAN	450MG/100ML	M19635 001
AP	MECHAN	450MG/100ML	M19635 001
AP	B BRAUN	900MG/100ML	M17464 001
AP	B BRAUN	900MG/100ML	M19635 002
AP	MECHAN	900MG/100ML	M17464 001
AP	MECHAN	900MG/100ML	M19635 002
AP	B BRAUN	3GM/100ML	N19635 003

B BRAUN	900MG/100ML	M17464 001
B BRAUN	900MG/100ML	M19635 002
MECHAN	900MG/100ML	M17464 001
MECHAN	900MG/100ML	M19635 002
B BRAUN	3GM/100ML	N19635 003

B BRAUN	3GM/100ML	N19635 003
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SODIUM CHLORIDE

INJECTABLE; INJECTION  
SODIUM CHLORIDE 3% IN PLASTIC CONTAINER

Q MCGRAW	3GM/100ML	N19635 003
Q B BRAUN	5GM/100ML	MAR 09, 1998
Q MCGRAW	5GM/100ML	N19635 004
Q MCGRAW	5GM/100ML	MAR 09, 1998

SODIUM LACTATE

INJECTABLE; INJECTION  
SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER

Q B BRAUN	1.87GM/100ML	N18186 001	
Q MCGRAW	1.87GM/100ML	N18186 001	
AP	B BRAUN	1.87GM/100ML	M20004 001
AP	MECHAN	1.87GM/100ML	M20004 001

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL  
KAYEXALATE

AA	SHAW	442.4GM/BOT	M11287 001
AA	+	453.6GM/BOT	M11287 001
AA	KIONEX	454GM/BOT	M40029 001
AA	PADDOK	454GM/BOT	FEB 06, 1998

SOTALOL HYDROCHLORIDE

TABLET; ORAL  
BETAPACE

Q MERCK	220MG	M19865 001
Q MERCK	220MG	M19865 002
Q MERCK	220MG	M19865 003
Q MERCK	120MG	M19865 005

## **SOTALOL HYDROCHLORIDE**

TABLET; ORAL  
BETAPACE  
+ BERLEX LABS 160MG  
240MG

## **SOYBEAN OIL**

<u>AP</u>	<u>INJECTABLE; INJECTION</u>	
	<u>INTRALIPID 30%</u>	
	+ PHARMACIA AND UPJOHN	<u>30%</u>
<u>AP</u>	<u>LIPOSYN III 30%</u>	
	+ ABBOTT	<u>30%</u>
<u>AP</u>	<u>NUTRILIPID 10%</u>	
	+ B BRAUN	<u>10%</u>
<u>AP</u>	<u>MCGRAW</u>	<u>10%</u>
<u>AP</u>	<u>NUTRILIPID 20%</u>	
	+ B BRAUN	<u>20%</u>
<u>AP</u>	<u>MCGRAW</u>	<u>20%</u>

## **STREPTOMYCIN SULFATE**

INJECTABLE: INJECTION  
STREPTOMYCIN SULFATE

<u>AP</u>	PFIZER	EQ 1GM BASE/VIAL EQ 1GM BASE/2.5ML
<u>AP</u>	PHARMA TEK	EQ 1GM BASE/2.5ML EQ 1GM BASE/VIAL

## SUCCINYLCHOLINE CHLORIDE

**INJECTABLE; INJECTION  
SUCOSTRIN**

## **SUCRALFATE**

**TABLET; ORAL  
SUCRALFATE  
AB RATIOPHARM 1G**

## **SUFENTANIL CITRATE**

**INJECTABLE; INJECTION**  
**SUFENTA**  
**AP + AKORN**      **EQ 0.05MG BASE/ML**      **N19050 001**  
**AP + JANSEN**      **EQ 0.05MG BASE/ML**      **M19050 001**  
                        **MAY 04, 1984**  
                        **MAY 04, 1984**

#### **SULFACETAMIDE SODIUM**

SOLUTION/DROPS; OPHTHALMIC  
CLOMIPRAMINE HCl 10%  
N80025 001

## SULFAMETHOKAZOLE; TRIMETHOPRIM

**SUSPENSION; ORAL**

**TABLET: ORA**

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SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL

AB	TEVA	<del>400MG; 80MG</del>	N18242 001
AB		<del>800MG; 160MG</del>	N18242 002

SULFASALAZINE

TABLET; ORAL

AB	<del>SULFASALAZINE</del>	<del>500MG</del>	N89338 001
		500MG	N89339 001

SULFASALAZINE

500MG

N89338 001

OCT 26, 1997

N89339 001

OCT 26, 1997

TACRINE HYDROCHLORIDE

CAPSULE; ORAL

COGNEX

PARKE DAVIS

*		<del>EQ 10MG BASE</del>	<del>N20070 001</del>
		<del>EQ 20MG BASE</del>	<del>N20070 002</del>
		<del>EQ 30MG BASE</del>	<del>N20070 003</del>
*		<del>EQ 40MG BASE</del>	<del>N20070 004</del>
	PARKE DAVIS PHARMS	EQ 10MG BASE	N20070 001
		EQ 20MG BASE	N20070 002
		EQ 30MG BASE	N20070 003
+		EQ 40MG BASE	N20070 004

EQ 10MG BASE

EQ 20MG BASE

EQ 30MG BASE

EQ 40MG BASE

N20070 001

SEP 09, 1993

N20070 002

SEP 09, 1993

N20070 003

SEP 09, 1993

N20070 004

SEP 09, 1993

TACROLIMUS

CAPSULE; ORAL

PROGRAF

FUJISAWA

*		<del>EQ 10MG BASE</del>	<del>N20070 001</del>
		<del>EQ 20MG BASE</del>	<del>N20070 002</del>

EQ 10MG BASE

EQ 20MG BASE

EQ 30MG BASE

EQ 40MG BASE

N20070 001

SEP 09, 1993

N20070 002

SEP 09, 1993

N20070 003

SEP 09, 1993

N20070 004

SEP 09, 1993

TACROLIMUS

CAPSULE; ORAL

PROGRAF

FUJISAWA

\*

FUJISAWA

TECHNETIUM TC-99M LIDOFENIN KIT

INJECTABLE; INJECTION  
TECHNECAN HIDA  
DRAXIMAGE

N/A

N18489 001  
OCT 31, 1996  
N18489 002  
OCT 31, 1996

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION  
TECHNECAN MDP KIT

AP DRAXIMAGE  
AP MERCK SHARP DOWNE

N/A

N18035 001  
N18035 002

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION  
DTPA

AP DRAXIMAGE  
AP MERCK

N/A

N18511 001  
DEC 29, 1996  
N18511 002  
DEC 29, 1996

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL  
~~TECHNETIUM COLLOID~~

AP CIS  
AP ~~TECHNETIUM~~  
AP ERGOCCO

N/A

N17858 001  
N17858 001  
N16923 001  
N16923 001

> DLT >  
> DLT >  
> ADD >

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL  
HYTRIN

AB ABBOTT  
AB +  
AB

EQ 1MG BASE  
EQ 2MG BASE  
EQ 5MG BASE

M20347 001  
DEC 14, 1994  
M20347 002  
DEC 14, 1994  
M20347 003  
DEC 14, 1994

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL  
HYTRIN

AB ABBOTT

EQ 10MG BASE

N20347 004

DEC 14, 1994

AB TERAZOSIN HCL  
GENEVA PHARMS

EQ 1MG BASE

N74823 001

MAR 30, 1998

AB EQ 2MG BASE

EQ 2MG BASE

N74823 002

MAR 30, 1998

AB EQ 5MG BASE

EQ 5MG BASE

N74823 003

MAR 30, 1998

AB EQ 10MG BASE

EQ 10MG BASE

N74823 004

MAR 30, 1998

TERBINAFINE

GEL; TOPICAL  
LAMISIL  
+ NOVARTIS

1%

N20846 001

APR 29, 1998

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL  
ANDRODERM

2.5MG/24HR

N20489 001

SEP 29, 1995

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL  
ACHROMYCIN V

AB ESI LEDERLE  
AB +  
AB

250MG

N50278 003

500MG

N50278 001

500MG

N50278 002

500MG

N50278 003

TABLET; ORAL  
SUMYCIN

250MG

N61147 003

500MG

N61147 002

50MG

N61147 001

TETRACYCLINE HYDROCHLORIDE

TABLET; ORAL  
SUMYCIN  
• APOTHECON

> ADD > 100MG

N61147 002

THALIDOMIDE

CAPSULE; ORAL  
THALOMID  
+ CELGENE

> ADD > 50MG

N20785 001

JUL 16, 1998

THEOPHYLLINE

CAPSULE, ORAL  
THEOPHYLLINE

RX FOREST LABS

100MG

N85545 001

JUL 31, 1984

RX \*

200MG

N83921 001

\*

100MG

N85545 001

JUL 31, 1984

\*

200MG

N83921 001

JUL 31, 1984

CAPSULE, EXTENDED RELEASE; ORAL

THEOPHYLLINE SR

FOREST LABS

125MG

N88626 001

JAN 29, 1985

FOREST LABS

250MG

N88626 002

JAN 29, 1985

\*

125MG

N88626 001

JAN 29, 1985

\*

250MG

N88626 002

JAN 29, 1985

TABLET; ORAL  
QUIBRON-T

+ MONARCH PHARMS

300MG

N88656 001

AUG 22, 1985

\*

ROBERTS LABS

300MG

N88656 002

AUG 22, 1985

TABLET, EXTENDED RELEASE; ORAL

QUIBRON-T/SR

FOREST LABS

300MG

N87563 001

JUN 21, 1983

THEOPHYLLINE

TABLET, EXTENDED RELEASE; ORAL  
QUIBRON-T/SR

MONARCH PHARMS

300MG

N87563 001

JUN 21, 1983

THIAMYLAL SODIUM

INJECTABLE; INJECTION

SUSPENSION

• PARKER DAVIS

1GM/VIAL

5GM/VIAL

10GM/VIAL

N87600 003

N87600 005

N87600 008

N87600 003

N87600 005

N87600 009

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL

THIORIDAZINE HCL

AA PHARM ASSOC

100MG/ML

N40213 001

MAY 29, 1998

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLID

• ROCHE

125MG

N19979 001

MAR 24, 1993

> ADD >

> ADD >

+

250MG

N19979 002

OCT 31, 1991

> ADD >

> DLT >

• SWEDAX

250MG

N19979 001

MAR 24, 1993

> DLT >

• \*

250MG

N19979 002

OCT 31, 1991

TIROFIBAN HYDROCHLORIDE

INJECTABLE; INJECTION

AGGRASTAT

+ MERCK

EQ 0.05MG BASE/ML

N20913 001

MAY 14, 1998

TICLOPIBAN HYDROCHLORIDEINJECTABLE; INJECTION  
AGGRASTAT

+ MERCK

EQ 0.25MG BASE/ML

N20912 001  
MAY 14, 1998TOLCAPONETABLET; ORAL  
TASMAR  
ROCHE

100MG

N20697 001  
JAN 29, 1998

+

200MG

N20697 002  
JAN 29, 1998TOLTERODINE TARTRATETABLET; ORAL  
DETROL  
PHARMACIA AND UPJOHN 1MGN20771 001  
MAR 25, 1998

+

2MG

N20771 002  
MAR 25, 1998TORSEMIDEINJECTABLE; INJECTION  
DEMADEX

+ ROCHE

10MG/ML

N20137 002  
AUG 23, 1993  
N20137 002  
AUG 23, 1993TABLET; ORAL  
DEMADEX

+ ROCHE

5MG

N20136 001  
AUG 23, 1993

+ ROCHE

5MG

N20136 001  
AUG 23, 1993

+ ROCHE

5MG

N20136 001  
AUG 23, 1993

+ ROCHE

5MG

N20136 001  
AUG 23, 1993TORSEMIDETABLET; ORAL  
DEMADEX  
ROCHE

10MG

N20136 002

20MG

AUG 23, 1993

100MG

N20136 003

+

AUG 23, 1993

N20136 004

AUG 23, 1993

TRETINOINCREAM; TOPICAL  
AVITA

0.025%

N20404 003

GEL; TOPICAL  
AVITA

0.025%

N20400 001

BX PENEADERM

JAN 29, 1998

RETIN-A

BX + JOHNSON AND JOHNSON 0.025%

N17579 002

SOLUTION; TOPICAL

AT + JOHNSON AND JOHNSON 0.05%

N16921 001

TRETINOIN

AT COPLEY PHARM 0.05%

N76873 001

JUN 19, 1998

TRIAMCINOLONE ACETONIDECREAM; TOPICAL  
TRIAMCINOLONE ACETONIDE  
+ ALPHARMA 0.025%

N87797 001

JUN 07, 1992

## **TRIFLUOPERAZINE HYDROCHLORIDE**

**TABLET; ORAL  
TRIFLUOPERAZINE HCL**

<u>AB</u>	ZENITH GOLDLINE	<u>EQ 1MG BASE</u>	N87612 001 NOV 19, 1982
<u>AB</u>		<u>EQ 2MG BASE</u>	N87613 001 NOV 19, 1982
<u>AB</u>	ZENITH GOLDLINE	<u>EQ 1MG BASE</u>	N87612 001 NOV 19, 1982
<u>AB</u>		<u>EQ 2MG BASE</u>	N87613 001 NOV 19, 1982

## **TRIHEXYPHENIDYL HYDROCHLORIDE**

**TABLET; ORAL  
TRIMETHYLPHENIDYL HCL**

**M** CIRCA 200 M40184 001  
**M** 500 FEB 06, 1998  
M40184 002  
FEB 06, 1998

## **TRIMETHAPHAN CAMSYLATE**

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**50MG/ML**

## **TRIMETREXATE GLUCURONATE**

**INJECTABLE; INJECTION  
NEUTREXIN**

> ADD > + US BIOSCIENCE EQ 200MG BASE/VIAL N20326 002  
> ADD > JUL 31, 1998

### **TROGLITAZONE**

**TABLET; ORAL  
REZULIN**

220711 001  
220712 1997  
220714 002  
220715 1997

## **TROGLITTAZONE**

**TABLET; ORAL  
REZULIN**

AB		200MG	N20720 001 JAN 29, 1997
AB	PARKE DAVIS PHARMS	200MG	
AB		300MG	N20720 003 AUG 04, 1997
AB		400MG	N20720 002 JAN 29, 1997

## **TROPICAMIDE**

**SOLUTION/DROPS; OPHTHALMIC  
TROPICAMIDE**

N88447 001  
AUG 28 1985  
N88447 001  
AUG 28 1985

#### **UROFOLLITROPIN**

**INJECTABLE; INTRAMUSCULAR  
FERTIMEX**

<b>FERTINERA</b>			
+ SERONO	75 IU/AMP	N19415 002	
	150 IU/AMP	SEP 18, 1986	
		N19415 003	
		SEP 18, 1986	
<b>FERTINERA</b>			
* SERONO	75 IU/AMP	N19415 004	
	150 IU/AMP	SEP 18, 1986	
		N19415 005	
		SEP 18, 1986	

## VERAPAMIL HYDROCHLORIDE

**INJECTABLE; INJECTION  
VERAPAMIL HCL**

N72233 001  
FEB 26, 1993

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION  
VERAPAMIL HCl  
• MARSAN

2.5MG/ML.

M73405 001  
SEP 27, 1993

VIDARABINE

INJECTABLE; INJECTION  
VIRA-A  
• PARKDALE

EQ 187.4MG BASE/ML

M50523 001

ointment; OPHTHALMIC  
VIRA-A  
• PARKDALE

3%

M50406 001

WATER FOR INJECTION, STERILE

Liquid, n/a  
AP 9 BRAUN 1000  
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER M19633 001  
FEB 29, 1998

ACETAMINOPHEN; ASPIRIN; CAFFEINE

TABLET, ORAL  
EXCEDRIN (MIGRAINE)  
+ BRISTOL MYERS 250MG;250MG;65MG N20802 001  
JAN 14, 1998

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE

TABLET, CHEWABLE; ORAL  
GAVISCON  
\* [REDACTED] 80MG;20MG  
N18685 001  
DEC 09, 1983  
+ 160MG;40MG N18685 002  
DEC 09, 1983

GAVISCON-2  
\* [REDACTED]

CHLORHEXYDINE GLUCONATE

SOLUTION; TOPICAL  
CMG SCRUB  
ECOLAB 4 fl oz N19258 002  
JUL 22, 1986  
[REDACTED]  
[REDACTED]  
CIDA-STAT  
ECOLAB 2 fl oz N19258 001  
JUL 22, 1986  
[REDACTED]  
[REDACTED]

CIMETIDINE

TABLET; ORAL  
CIMETIDINE  
LEK PHARM 100MG N75122 001  
JUN 19, 1998  
200MG N75122 002  
JUN 19, 1998  
NOVOPHARM 200MG N74961 001  
JUN 19, 1998

CIMETIDINE

TABLET; ORAL  
CIMETIDINE  
PERRIGO 100MG N74972 001  
JUN 19, 1998  
PHARM FORM 200MG N74963 001  
JUN 19, 1998  
TORPHARM 100MG N74948 001  
JUN 19, 1998

CLOTRIMAZOLE

TABLET; VAGINAL  
GYMIX  
COPELY PHARM 100MG N73249 001  
FEB 13, 1998

IBUPROFEN

SUSPENSION; ORAL  
CHILDREN'S ADVIL-FLAVORED  
\* [REDACTED] 100MG/5ML  
N20589 002  
NOV 07, 1997

SUSPENSION/DROPS; ORAL  
PEDIATRIC ADVIL  
+ WHITENALL ROBINS 100MG/2.5ML N20812 001  
JAN 30, 1998

TABLET; ORAL  
IBUPRIN

\* 200MG N71773 001  
JUL 16, 1987  
IBUPROFEN  
NOVOPHARM 200MG N74931 001  
JUL 20, 1998  
PHARM FORM 200MG N74782 001  
JUL 06, 1998

TABLET, CHEWABLE; ORAL  
JUNIOR STRENGTH MOTRIN

IMIPROZIN

TABLET, CHEWABLE; ORAL  
JUNIOR STRENGTH MOTILIN  
+ MCNEIL 100MG

N20601 003  
NOV 15, 1996

NICONAZOLE NITRATE

CREAM; VAGINAL  
MONISTAT 3  
+ ADVANCED CARE PROS 4%

N20827 001  
MAR 30, 1998

IMITIDINE\_NITROCHLORIDE

TABLET, HYPERSCENT; ORAL  
ZANTAC 75  
+ GIAXO WELLCOME EQ 75MG BASE

N20745 001  
FEB 26, 1998

MINOXIDILSOLUTION; TOPICAL

MINOXIDIL (FOR MEN)  
NOVELX 2%

N74924 001  
APR 29, 1998  
NOVELX 2%  
NOVELX 2%

MINOXIDIL (FOR WOMEN)  
NOVELX 2%

N74924 002  
APR 29, 1998  
NOVELX 2%  
NOVELX 2%

NAPROXEN SODIUM

TABLET; ORAL  
NAPROXEN SODIUM  
PAR PHARM EQ 200MG BASE

N75168 001  
JUL 20, 1998

NICOTINEFILM, EXTENDED RELEASE; TRANSDERMAL

NICOTROL  
NOVELX  
NOVELX

N20536 001  
JUL 03, 1996

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT ADMINISTERED BY THE  
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

**CUMULATIVE SUPPLEMENT NUMBER 7 JUL '98**

**NO JULY 1998 APPROVALS**

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

**Orphan Product Designations and Approvals List  
January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
1,5-(Butylimino) Treatment of Fabry's disease. -1,5 dideoxy,D-glucit ol TN=		Oxford GlycoSciences 10, The Quadrant Abington Science Park, Abington Oxfordshire OX14 3YS UK, DD=05/12/1998
1,5-(Butylimino) Treatment of Gaucher disease. -1,5 dideoxy,D-glucit ol TN=		Oxford GlycoSciences 10, The Quadrant Abington Science Park, Abington Oxfordshire OX14 3YS UK, DD=05/29/1998
Aldesleukin TN= Proleukin	Treatment of metastatic melanoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/10/1996 MA=01/09/1998
Aldesleukin TN= Proleukin	Treatment of acute myelogenous leukemia.	Chiron Corporation 4560 Horton St. Emeryville, CA 94608 DD=07/31/1998
Aliperetinate TN= Panretin	For the topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma.	Ligand Pharmaceuticals Inc. 10275 Science Center Drive San Diego, CA 92121 DD=03/24/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Alpha-galactosidase A TN=	Long-term enzyme replacement therapy for the treatment of Fabry disease.	Transkaryotic Therapies Inc. 195 Albany St. Cambridge, MA 02139 DD=06/22/1998
Amifostine TN= Ethyol	Reduction of the incidence and severity of radiation-induced xerostomia.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street, Suite 400 Conshohocken, PA 19428 DD=05/12/1998
Arsenic trioxide TN=	Treatment of acute promyelocytic leukemia.	PolaRx, Inc. 787 7th Ave., 48th Floor New York, NY 10019 DD=03/03/1998
Basiliximab TN= Simulect	Prophylaxis of solid organ rejection.	Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, NJ 07936 DD=12/12/1997 MA=05/12/1998
Beclomethasone dipropionate TN=	For oral administration in the treatment of intestinal graft-versus-host disease.	George B. McDonald, M.D. Fred Hutchinson Cancer Research Center 1100 Fairview Avenue North (SC-113); PO Box 19024 Seattle, WA 98109 DD=03/27/1998
Benzydamine hydrochloride TN= Tantum	Prophylactic treatment of oral mucositis resulting from radiation therapy for head and neck cancer.	Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661 DD=05/18/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Bindarit TN=	Treatment of lupus nephritis.	Angelini Pharmaceuticals, Inc. 70 Grand Avenue River Edge, NJ 07661 DD=02/03/1998
Carbamylglutamic acid TN=	Treatment of N-acetylglutamate synthetase deficiency.	Orphan Europe Immeuble "Le Guillaumet" 60 avenue du President Wilson 92046 Paris France, DD=01/20/1998
Corticotropin-re human TN= Xerecept	Treatment of peritumoral brain leasing factor, edema.	Neurobiolcgical Technologies, Inc. 1387 Marina Way South Richmond, CA 94804 DD=04/06/1998
Dimethylsulfoxid e TN=	Treatment of palmar-plantar erythrodysesthesia syndrome.	Cancer Technclgical Inc. 7301 East 22nd Street Suite 10E Tucson, AZ 85710 DD=04/06/1998
Filgrastim TN= Neupogen	Reduction in the duration of neutropenia, fever, antibiotic use, and hospitalization, following induction and consolidation treatment for acute myeloid leukemia.	Amgen, Inc. 1840 DeHavilland Drive Thousand Oaks, CA 91320 DD=11/07/1996 MA=04/02/1998
Fructose-1,6-dip hosphate TN=	Treatment of painful vaso-occlusive episodes associated with sickle cell disease.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=05/29/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Hydroxyurea TN= Droxia	Treatment of patients with sickle cell anemia as shown by the presence of hemoglobin S.	Bristol-Myers Squibb Pharmaceutical Research Institute P.O. Box 4000 Princeton, NJ 08543 DD=10/01/1990 MA=02/25/1998
L-baclofen TN=	Treatment of trigeminal neuralgia.	Pharmascience, Inc. 8400 Darnley Road Montreal, Quebec Canada H4T 1M4, DD=01/06/1998
Lepirudin TN= Refluden	Treatment of heparin-associated thrombocytopenia type II.	Hoechst Marion Roussel Frankfurt am Main Germany DD=02/13/1997 MA=03/06/1998
Liposomal Cyclosporin A TN= Cyclospire	For aerosolized administration in the prevention and treatment of lung allograft rejection and pulmonary rejection events associated with bone marrow transplantation.	Vernon Knight, M.D. Baylor College of Medicine, Dept. of Molecular Physiology One Baylor Plaza Houston, TX 77030 DD=04/30/1998
Liposomal N-Acetylgucosaminyl-N-Acetyl muramyl-L-Ala-D-isoglutyl-L-Ala-glycerolidpalmitoyl TN= Immather	Treatment of osteosarcoma.	Endorex Corp. 900 North Shore Drive Lake Bluff, IL 60044 DD=06/10/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Liposomal N-Acetylglucosaminyl-N-Acetylmuramyl-L-Ala-D-isoglycero-D-palmitoyl TN= ImmTher	Treatment of Ewing's sarcoma.  For use as an adjunctive topical solution antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.	Endorex Corp. 900 North Shore Drive Lake Bluff, IL 60044 DD=06/10/1998
Mafenide acetate TN= Sulfamylon solution	Treatment of renal cell carcinoma.	Mylan Laboratories, Inc. 781 Chestnut Ridge Road P.O. Box 4310 Morgantown, WV 26504 DD=07/18/1990 MA=06/05/1998
PEGASYS TN=	Treatment of cutaneous T-cell lymphoma.	Hoffman-La Roche Inc. 340 Kingsland St. Nutley, NJ 07110 DD=07/13/1998
Pentostatin TN=	For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.	SuperGen, Inc. Two Annbel Lane, Suite 220 San Ramon, CA 94583 DD=03/27/1998
Phenylacetate TN=		Targen Corporation 307 College Road East Princeton, NJ 08540 DD=03/06/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Pilocarpine HCl TN= Salagen	Treatment of xerostomia and keratoconjunctivitis sicca in Sjogren's syndrome patients.	MGI Pharma, Inc. 9900 Bren Road East Suite 300E Minneapolis, MN 55343 DD=02/28/1992 MA=02/11/1998
Prostaglandin E1 enol ester (AS-013) TN=	Treatment of Fontaine Stage IV chronic critical limb ischemia.	Alpha Therapeutic Corp. 5555 Valley Blvd. Los Angeles, CA 90032 DD=06/12/1998
Radiolabeled monoclonal antibody to CD22 antigen on B-cells TN= LymphoCIDE	Treatment of non-Hodgkin's lymphoma.	Immunomedics, Inc. 300 American Rd. Morris Plains, NJ 07950 DD=07/13/1998
Recombinant bactericidal/permeability-increasing protein TN= Neuprex	Treatment of severe meningococcal disease.	Xoma Corporation 2910 Seventh Street Berkeley, CA 94710 DD=06/22/1998
Recombinant human Clara Cell 10kDa protein TN=	Prevention of neonatal bronchopulmonary dysplasia in premature neonates with respiratory distress syndrome.	Claragen, Inc. 335 Paint Branch Drive College Park, MD 20742 DD=07/13/1998
Recombinant humanized monoclonal antibody 5c8 TN=	Treatment of immune thrombocytopenic purpura.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/03/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Recombinant humanized monoclonal antibody 5c8 TN=	Treatment of systemic lupus erythematosus.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/18/1998
Rifapentine TN= Priftin	Treatment of pulmonary tuberculosis.	Hoechst Marion Roussel P.O. Box 9627 H3-M2516 Kansas City, MO 64134 DD=06/09/1995 MA=06/22/1998
Rifaximin TN= Normix	Treatment of hepatic encephalopathy.	Salix Pharmaceuticals, Inc. 3600 W. Bayshore Road Palo Alto, CA 94303 DD=02/10/1998
S-adenosylmethio nine TN=	Treatment of AIDS-myelopathy.	Di Rocco, Alessandro M.D. Beth Israel Medical Center, Dept. of Neurology Philips Building, Suite 2Q; 10 Union Square New York, NY 10003 DD=04/30/1998
Sacrosidase TN= Sucraid	Treatment of congenital sucrase-isomaltase deficiency.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=12/10/1993 MA=04/09/1998
Sodium phenylbutyrate TN=	For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or recurrent malignant glioma.	Targen Corporation 307 College Road East Princeton, NJ 08540 DD=04/24/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
TAK-603 TN=	Treatment of Crohn's disease.	TAP Holdings Inc. 2355 Waukegan Road Deerfield, IL 60015 DD=05/13/1998
Tacrolimus TN= Prograf	Prophylaxis of graft-versus-host-disease.	Fujisawa USA, Inc. 3 Parkway North Center Deerfield, IL 60015 DD=04/06/1998
Tetrabenazine TN=	Treatment for moderate/severe tardive dyskinesia.	Lifehealth Limited Richmond House, Old Brewery Ccourt, Sandyford Road Newcastle upon Tyne NE2 1XG England, DD=05/12/1998
Thalidomide TN= Thalomid	Treatment of erythema nodosum leprosum.	Celgene Corporation P.O. Box 4914 7 Powder Horn Drive Warren, NJ 07059 DD=07/26/1995 MA=07/16/1998
Thalidomide TN=	Treatment of primary brain malignancies.	EntreMed, Inc. 9610 Medical Center Drive, Suite 200 Rockville, MD 20850 DD=02/27/1998
Thalidomide TN=	Treatment of Kaposi's sarcoma.	EntreMed, Inc. 9610 Medical Center Dr., Suite 200 Rockville, MD 20850 DD=07/29/1998
Thymalfasin TN= Zadaxin	Treatment of DiGeorge anomaly with immune defects.	SciClone Pharmaceuticals, Inc. 901 Mariner's Island Blvd. San Mateo, CA 94404 DD=01/08/1998

**Orphan Product Designations and Approvals List**  
**January 1998 through July 1998**

Name  
Generic Name  
TN=Trade Name

Indication Designated

Sponsor & Address  
DD= Date Designated  
MA=Marketing Approval

Tiapride  
TN=

Treatment of Tourette's  
syndrome.

Synthelabo Research,  
Inc.  
400 Plaza Drive  
Secaucus, NJ 07094  
DD=04/21/1998

Transgenic human Treatment of cystic fibrosis.  
alpha 1  
antitrypsin  
TN=

PPL Therapeutics  
(Scotland) Limited  
Roslin, Edinburgh  
EH25 9PP Scotland  
U.K.,  
DD=03/06/1998

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

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**NO JULY 1998 ADDITIONS**

## PATENT AND EXCLUSIVITY TERMS PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 18TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). ONLY NEW CODES WILL BE ADDED TO THE CUMULATIVE SUPPLEMENT.

### ABBREVIATIONS

#### PED PEDIATRIC EXCLUSIVITY

#### REFERENCES NEW DOSING SCHEDULE

- |      |   |
|------|---|
| D-38 | <b>CONTINUOUS INFUSION AS AN ALTERNATE METHOD OF ADMINISTRATION</b>   |
| D-39 | <b>CHANGE IN TIME TO TAKE THE DRUG PRIOR TO A MEAL TO PREVENT MEAL-INDUCED HEARTBURN SYMPTOMS FROM "...1/2-1 HOUR BEFORE EATING..." TO "...RIGHT BEFORE EATING OR UP TO 60 MIN BEFORE CONSUMING..."</b> |
| D-40 | <b>ONCE-A-DAY DOSING REGIMEN</b>  |
| D-41 | <b>DRUG MAY BE DOSED RIGHT BEFORE A MEAL OR ANY TIME UP TO 30 MIN BEFORE EATING OR DRINKING FOOD AND BEVERAGES THAT WOULD BE EXPECTED TO CAUSE SYMPTOMS</b>   |
| D-42 | <b>TEN DAY DOSING REGIMEN FOR TRIPLE THERAPY, PREVACID IN COMBINATION WITH CLARITHROMYCIN AND AMOXICLIN, FOR THE ERADICATION OF H. PYLORI IN PATIENTS WITH DUODENAL ULCER DISEASE</b>                   |

#### NEW INDICATION

- |       |  |
|-------|--|
| I-212 | <b>TREATMENT OF SYMPTOMS OF DRY MOUTH IN PATIENTS WITH SJOGREN'S SYNDROME</b>  |
| I-213 | <b>TEMPORARY RELIEF OF PAIN AND PHOTOPHOBIA IN PATIENTS UNDERGOING CORNEAL REFRACTIVE SURGERY</b>  |
| I-214 | <b>TREATMENT OF OSTEOPOROSIS</b>   |
| I-215 | <b>PRE-PROCEDURAL APPLICATION TO ADULT MALE GENITAL SKIN PRIOR TO SITE-SPECIFIC SUBCUTANEOUS INFILTRATION WITH LIDOCAINE FOR THE REMOVAL OF GENITAL WARTS</b>                                      |
| I-216 | <b>FOR THE LONG-TERM TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD, INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA</b>            |
| I-217 | <b>PREVENTION (DURING AND FOLLOWING HOSPITALIZATION) OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY</b>                             |
| I-218 | <b>USE OF LIPITOR AS AN ADJUNCTIVE THERAPY TO DIET FOR THE TREATMENT OF PATIENTS WITH ELEVATED SERUM TRIGLYCERIDE LEVELS (FREDERICKSON TYPE IV)</b>  |
| I-219 | <b>USE OF LIPITOR BY PATIENTS WITH PRIMARY DYSBETA LIPOPROTEINEMIA (FREDERICKSON TYPE III) WHO DO NOT RESPOND ADEQUATELY TO DIET</b>   |
| I-220 | <b>TREATMENT OF EPISODIC HEARTBURN, ACID INDIGESTION AND SOUR STOMACH</b>  |
| I-221 | <b>TREATMENT OF BENIGN PROSTATIC HYPERPLASIA (BPH) IN MEN WITH AN ENLARGED PROSTATE TO IMPROVE SYMPTOMS, REDUCE THE RISK OF ACUTE URINARY RETENTION AND REDUCE THE RISK OF THE NEED OF SURGERY</b> |
| I-222 | <b>PREVENTION OF ISCHEMIC COMPLICATIONS OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION, WHEN CONCURRENTLY ADMINISTERED WITH ASPIRIN</b>   |
| I-223 | <b>USE IN THE SYMPTOMATIC RELIEF OF RHINORRHEA ASSOCIATED WITH ALLERGIC AND NONALLERGIC PERENNIAL RHINITIS IN CHILDREN AGE 6-11 YEARS</b>  |
| I-224 | <b>FOR THE USE IN PEDIATRIC PATIENTS 4 TO 11 YEARS OF AGE FOR THE MANAGEMENT OF THE NASAL SYMPTOMS OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS</b>   |
| I-225 | <b>USE IN PATIENTS WITH PREVIOUS MI AND NORMAL CHOLESTEROL LEVELS, TO REDUCE RISK OF RECURRENT MI, MYOCARDIAL REVASCULARIZATION, AND CEREBROVASCULAR DISEASE EVENTS</b>                            |
| I-226 | <b>FIRST-LINE THERAPY FOR THE TREATMENT OF ADVANCED CARCINOMA OF THE OVARY IN COMBINATION WITH CISPLATIN</b>   |

## PATENT AND EXCLUSIVITY TERMS

### *NEW INDICATION*

- I-227 SHORT-TERM TREATMENT OF SYMPTOMATIC GASTROESOPHAGEAL REFLUX DISEASE (GERD)
- I-228 PREVENTION OF MEAL INDUCED HEARTBURN AT A DOSE OF 75MG TAKEN 30-60 MIN PRIOR TO A MEAL
- I-229 PRILosec (omeprazole), amoxicillin and clarithromycin for the eradication of H. pylori in patients with duodenal ulcer disease
- I-230 IN COMBINATION WITH CISPLATIN, FOR THE FIRST-LINE TREATMENT OF NON-SMALL CELL LUNG CANCER IN PATIENTS WHO ARE NOT CANDIDATES FOR POTENTIALLY CURATIVE SURGERY AND/OR RADIATION
- I-231 TREATMENT OF PATIENTS WITH LOCALLY ADVANCED OR METASTATIC BREAST CANCER AFTER FAILURE OF PRIOR CHEMOTHERAPY
- I-232 TREATMENT OF RECURRENT MUCOCUTANEOUS HERPES SIMPLEX INFECTIONS IN HIV-AFFECTED PATIENTS AT A DOSE OF 500MG TWICE DAILY
- I-233 PROPHYLACTIC USE TO REDUCE PERIOPERATIVE BLOOD LOSS AND THE NEED FOR BLOOD TRANSFUSION IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS IN THE COURSE OF CORONARY ARTERY BYPASS GRAFT SURGERY
- I-234 FOR USE IN COMBINATION WITH CISPLATIN FOR THE FIRST-LINE TREATMENT OF PATIENTS WITH INOPERABLE LOCALLY ADVANCED (STAGE IIIA OR IIIB) OR METASTATIC (STAGE IV) NON-SMALL CELL LUNG CANCER

### *PATENT USE CODE*

- U-215 TREATMENT OF EPILEPSY TWICE DAILY. TREATING A PATIENT BY ADMINISTERING CARBAMAZEPINE IN A DOSAGE FORM CAPABLE OF MAINTAINING BLOOD CONCENTRATION FROM 4-12MCG/ML OVER 12 HOURS
- U-216 TREATMENT OF ADENOCARCINOMA, INCLUDING STAGE B2-C, BY ADMINISTERING AN AGONIST OF LR-RH AND FLUTAMIDE
- U-217 METHOD OF PRODUCING ANESTHESIA
- U-218 METHOD FOR LIMITING THE POTENTIAL FOR MICROBIAL GROWTH IN THE DRUG PRODUCT
- U-219 TREATMENT OF PARKISON'S DISEASE
- U-220 METHOD OF DIAGNOSIS
- U-221 SELECTIVE VASODILATION BY CONTINUOUS ADENOSINE INFUSION
- U-222 METHOD OF TREATING PAGETS DISEASE USING ACTONEL
- U-223 TREATMENT OF BACTERIAL CONJUNCTIVITIS CAUSED BY SUSCEPTIBLE STRAINS OF MICROORGANISMS
- U-224 CONTROLLING INTRAOCCULAR PRESSURE
- U-225 METHOD FOR DELIVERY
- U-226 METHOD OF ENHANCING THE DISSOLUTION PROFILE OF A PHARMACEUTICAL FROM A SOLID DOSAGE FORM CONTAINING THE PHARMACEUTICAL AND SIMETHICONE
- U-227 NASAL ADMINISTRATION
- U-228 ASTHMA
- U-229 CARDIAC INSUFFICIENCY (CONGESTIVE HEART FAILURE)
- U-230 PREVENTION OF ACUTE CARDIAC ISCHEMIC EVENTS
- U-231 USE IN PARKINSON'S DISEASE
- U-232 METHOD OF TREATING MIGRAINE

## PATENT AND EXCLUSIVITY TERMS

### *PATENT USE CODE*

- U-233 DECREASING MORTALITY CAUSED BY CONGESTIVE HEART FAILURE
- U-234 METHOD OF USING RIBAVIRIN TO TREAT VIRAL INFECTIONS IN MAMMALS
- U-235 METHOD OF MODULATING TH1 AND TH2 RESPONSE IN ACTIVATED T CELLS OF A HUMAN  
COMPRISING ADMINISTERING RIBAVIRIN TO THE T CELLS IN A DOSAGE WHICH PROMOTES THE  
TH1 RESPONSE AND SUPPRESSES THE TH2 RESPONSE
- U-236 TREATING MALE PATTERN BALDNESS WITH 0.05 TO 3 MG/DAY
- U-237 METHOD OF PERFORMING NMR IMAGING WITH A PATIENT COMPRISING ADMINISTERING TO THE  
PATIENT AN EFFECTIVE AMOUNT OF CONTRAST AGENT DISCLOSED IN THE CLAIMS
- U-238 IMAGING A BODY TISSUE AND SUBJECTING TO NMR TOMOGRAPHY, ADMINISTERING AN AMOUNT  
OF PHARMACEUTICAL AGENT FOR AFFECTING THE RELAXATION TIMES OF ATOMS IN BODY  
TISSUES UNDERGOING NMR DIAGNOSIS, WHEREBY THE IMAGE CONTRAST IS ENHANCED....
- U-239 TREATING OR CONTROLLING OCULAR INFLAMMATION WHICH COMPRISES TOPICALLY  
ADMINISTERING TO THE Affected EYE A COMPOSITION COMPRISING A NSAID, A POLYMERIC  
QUATERNARY AMMONIUM COMPOUND AND BORIC ACID
- U-240 TREATMENT OF ACUTE MIGRAINE ATTACKS
- U-241 FOR SHORT-TERM TREATMENT ACTIVE DUODENAL ULCER, MAINTENANCE THERAPY FOR  
DUODENAL ULCER PATIENTS AT REDUCED DOSAGE AFTER HEALING OF ACTIVE ULCER, SHORT-  
TERM TREATMENT ACTIVE BENIGN GASTRIC ULCER & GERD, PATHOLOGICAL  
HYPERSECRETOORY CONDITIONS
- U-242 USE OF FOLLITROPIN ALPHA ALONE IN IN-VITRO FERTILIZATION
- U-243 TOPICAL ADMINISTRATION

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**  
**\*PED and PED represent Pediatric Exclusivity**

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020482 004	ACARBOSE;PRECOSE	4904769	FEB 27, 2007		NCE	SEP 06, 2000
020802 001	ACETAMINOPHEN;EXCEDRIN (MIGRAINE)	5070877	DEC 10, 2008	NP		JAN 14, 2001
020059 001	ADENOSINE;ADENOSCAN	5731296	MAR 24, 2015	U-116 U-221		
>ADD>		5766573	JUN 16, 2015			
020503 001	ALBUTEROL SULFATE;PROVENTIL-HFA	5804570	FEB 17, 2015			
020560 001	ALENDRONATE SODIUM;FOSAMAX	5804570	FEB 17, 2015			
>ADD>		5804570	FEB 17, 2015			
020560 002	ALENDRONATE SODIUM;FOSAMAX	5804570	FEB 17, 2015			
>ADD>		5804570	FEB 17, 2015			
020560 003	ALENDRONATE SODIUM;FOSAMAX	5804570	FEB 17, 2015			
020511 001	AMLEXANOX;APNTHASOL	5362737	NOV 08, 2011		U-243	
019787 001	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
019787 002	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
019787 003	AMLODIPINE BESYLATE;NORVASC	4572909	JUL 31, 2006			
>ADD>		5108363	APR 28, 2009	U-220	I-233	AUG 28, 2001
020304 001	APROTININ BOVINE;TRASYLOL	5234404	AUG 10, 2010	U-220		
020420 001	ARbutamine HYDROCHLORIDE;GENESA	5395970	MAR 07, 2012			
020702 001	ATORVASTATIN CALCIUM;LIPITOR	4681893	SEP 24, 2009	U-161	I-218	JUL 10, 2001
020702 002	ATORVASTATIN CALCIUM;LIPITOR	4681893	SEP 24, 2009	U-161	I-218	JUL 10, 2001
020702 003	ATORVASTATIN CALCIUM;LIPITOR	4681893	SEP 24, 2009	U-161	I-218	JUL 10, 2001
					I-219	JUL 10, 2001
					I-219	JUL 10, 2001
020114 001	AZELASTINE HYDROCHLORIDE;ASTELIN	5164194	NOV 01, 2010		U-207	
018521 001	BECLOMETHASONE DIPROPIONATE;VANCENASE	4364923	DEC 21, 1999			
017573 001	BECLOMETHASONE DIPROPIONATE;VANCERIL	4364923	DEC 21, 1999			
020486 001	BECLOMETHASONE DIPROPIONATE;VANCERIL DOUBLE STRENGTH	4364923	DEC 21, 1999			
019408 001	BETAMETHASONE DIPROPIONATE;DIPROLENE	4489070	MAY 13, 2003			
020816 001	BRINZOLAMIDE;AZOPT	5240923	AUG 31, 2010	U-224	NCE	APR 01, 2003
		5378703	AUG 31, 2010	U-224		
		5461081	OCT 24, 2012	U-225		
>ADD>		5731000	AUG 12, 2013			
020711 002	BUPROPION HYDROCHLORIDE;ZYBAN	5731000	AUG 12, 2013			
020711 003	BUPROPION HYDROCHLORIDE;ZYBAN	5021458	OCT 18, 2010		U-177	
020524 001	BUTENAFINE HYDROCHLORIDE;MENTAX	4866048	DEC 29, 2007			
020554 001	CALCIPOTRIENE;DOVONEX	4866048	DEC 29, 2007			
020611 001	CALCIPOTRIENE;DOVONEX	5733569	MAR 31, 2015	U-227		
020313 002	CALCITONIN, SALMON;MIACALCIN	5196444	APR 18, 2011			
020521 001	CALFACTANT;INFASURF PRESERVATIVE FREE	5508297	FEB 24, 2014	U-3	NCE	JUL 01, 2003
020838 001	CANDESARTAN CILEXETIL;ATACAND	5534534	JUL 09, 2013	U-3	NCE	JUN 04, 2003
		5703110	APR 18, 2011			
		5705517	APR 18, 2011			
020838 002	CANDESARTAN CILEXETIL;ATACAND	5196444	APR 18, 2011	U-3	NCE	JUN 04, 2003
		5508297	FEB 24, 2014	U-3		
		5534534	JUL 09, 2013			
		5703110	APR 18, 2011			
020838 003	CANDESARTAN CILEXETIL;ATACAND	5196444	APR 18, 2011	U-3	NCE	JUN 04, 2003
		5508297	FEB 24, 2014	U-3		
		5534534	JUL 09, 2013			
		5703110	APR 18, 2011			
		5705517	APR 18, 2011			
		5196444	APR 18, 2011			
		5508297	FEB 24, 2014			
		5534534	JUL 09, 2013			
		5703110	APR 18, 2011			
		5705517	APR 18, 2011			
		5196444	APR 18, 2011			
		5508297	FEB 24, 2014			
		5534534	JUL 09, 2013			
		5703110	APR 18, 2011			
		5705517	APR 18, 2011			

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020838 004	CANDESARTAN CILEXETIL;ATACAND	5196444 5508297 5534534 5703110 5705517	APR 18, 2011 FEB 24, 2014 JUL 09, 2013 APR 18, 2011 APR 18, 2011	U-3 U-3	NCE	JUN 04, 2003
020896 001	CAPECITABINE;XELODA				NCE	APR 30, 2003
020896 002	CAPECITABINE;XELODA				NCE	APR 30, 2003
020712 001	CARBAMAZEPINE;CARBATROL	5326570	JUL 05, 2011	U-215		
020712 002	CARBAMAZEPINE;CARBATROL	5326570	JUL 05, 2011	U-215		
020297 001	CARVEDILOL;COREG	4503067	MAR 05, 2007	U-3		
020297 002	CARVEDILOL;COREG	5760069	JUN 07, 2015	U-233		
020297 003	CARVEDILOL;COREG	4503067	MAR 05, 2007	U-3		
020297 004	CARVEDILOL;COREG	5760069	JUN 07, 2015	U-233		
020774 001	CHLORHEXIDINE GLUCONATE;PERIODIC				NP	MAY 15, 2001
020238 002	CIMETIDINE;TAGAMET HB	4670444	JUN 02, 2004	U-223	D-41	JUN 05, 2001
020369 001	CIPROFLOXACIN HYDROCHLORIDE;CILOXAN	4670444	DEC 09, 2003		NDF	MAR 30, 2001
020805 001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO HC	4844902	FEB 11, 2008		NC	FEB 10, 2001
020780 001	CIPROFLOXACIN;CIPRO	4670444	DEC 09, 2003			
020780 002	CIPROFLOXACIN;CIPRO	4670444	DEC 09, 2003			
020822 002	CITALOPRAM HYDROBROMIDE;CELEXA				NCE	JUL 17, 2003
020822 003	CITALOPRAM HYDROBROMIDE;CELEXA				NCE	JUL 17, 2003
020822 004	CITALOPRAM HYDROBROMIDE;CELEXA				NCE	JUL 17, 2003
020839 001	CLOPIDOGREL BISULFATE;PLAVIX	4529596 4847265 5576328	JUL 05, 2003 FEB 12, 2008 JAN 31, 2014			
017922 001	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
017922 002	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
017922 003	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
018938 001	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
018938 002	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
019955 001	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013		I-40	MAR 25, 2001
019955 002	DESMOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013		I-40	MAR 25, 2001
020713 001	DESOGESTREL;MIRETTE				NP	APR 22, 2001
020344 001	DEXFENFLURAMINE HYDROCHLORIDE;REDUX	4309445	FEB 19, 2004	U-133		
020809 001	DICLOFENAC SODIUM;DICLOFENAC SODIUM	5603929 5653972	NOV 16, 2014 NOV 16, 2014	U-239 U-239		
020037 001	DICLOFENAC SODIUM;VOLTAREN	4758423	JUL 31, 2001	U-227		
020148 001	DINHYDROERGOTAMINE MESYLATE;MIGRAL	4462983 5169849	JUL 31, 2001 DEC 08, 2009		1-213	FEB 25, 2001
020401 001	DILTIAZEM HYDROCHLORIDE;TIAZAC				U-227	
020401 002	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
020401 003	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
020401 004	DILTIAZEM HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001

PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020401 005	DILTIAZEM HYDROCHLORIDE; TIAZAC				I-133	JAN 30, 2001
	020449 001	DOCETAXEL; TAXOTERE			I-231	JUN 22, 2001	
>ADD>	020690 001	DONEPEZIL HYDROCHLORIDE; ARICEPT	4895841	NOV 25, 2010			
	020690 002	DONEPEZIL HYDROCHLORIDE; ARICEPT	4895841	NOV 25, 2010			
	020869 001	DORZOLAMIDE HYDROCHLORIDE; COSOPT				NC	APR 07, 2001
	020164 001	ENOXAPARIN SODIUM; LOVENOX				I-217	JAN 30, 2001
	020164 002	ENOXAPARIN SODIUM; LOVENOX				I-222	MAR 27, 2001
						I-222	MAR 27, 2001
						I-217	JAN 30, 2001
>ADD>	020738 004	EPROSARTAN MESYLATE; TEVETEN	5185351	FEB 09, 2010	U-3		
	020738 005	EPROSARTAN MESYLATE; TEVETEN	5185351	FEB 09, 2010	U-3		
>ADD>	020718 001	EPTIFIBATIDE; INTEGRILIN	5756451	NOV 11, 2014		NCE	MAY 18, 2003
>ADD>	020718 002	EPTIFIBATIDE; INTEGRILIN	5686570	NOV 11, 2014		NCE	MAY 18, 2003
>ADD>	020718 002	EPTIFIBATIDE; INTEGRILIN	5756451	NOV 11, 2014			
	020375 003	ESTRADIOL; CLIMARA	5686570	NOV 11, 2014			
	083209 001	ESTROGENS, ESTERIFIED; ESTRATAB	5223261	JUN 29, 2010		I-214	MAR 10, 2001
	086715 001	ESTROGENS, ESTERIFIED; ESTRATAB				I-214	MAR 10, 2001
	020363 001	FAMCICLOVIR; FAMVIR				NCE	JUN 29, 1999
>ADD>	020363 002	FAMCICLOVIR; FAMVIR				I-232	JUN 12, 2001
>ADD>	020363 003	FAMCICLOVIR; FAMVIR				I-232	JUN 12, 2001
	020752 001	FAMOTIDINE; PEPCID RPD	4283408	OCT 15, 2000			
			4305502	DEC 15, 1998			
			4371516	JAN 31, 2000	U-241		
	020752 002	FAMOTIDINE; PEPCID RPD	4283408	OCT 15, 2000			
			4305502	DEC 15, 1998			
			4371516	JAN 31, 2000	U-241		
>ADD>	020625 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	4254129	FEB 18, 2001		U-139	
>ADD>	020786 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA-D	4254129	FEB 18, 2001	NCE	JUL 25, 2001	
			5375693	AUG 03, 2012			
			5578610	NOV 26, 2013			
			5547957	OCT 15, 2013	U-236		
	020788 001	FINASTERIDE; PROPECIA			I-221	MAR 20, 2001	
	020180 001	FINASTERIDE; PROSCAR					
	018830 001	FLECAINIDE ACETATE; TAMBOCOR	4642384	FEB 10, 2004			
	018830 002	FLECAINIDE ACETATE; TAMBOCOR	4642384	FEB 10, 2004			
	018830 003	FLECAINIDE ACETATE; TAMBOCOR	4642384	FEB 10, 2004			
	018830 004	FLECAINIDE ACETATE; TAMBOCOR	4642384	FEB 10, 2004			
	018554 001	FLUTAMIDE; EULEXIN	4472382	SEP 18, 2001	U-24		
			5712251	SEP 18, 2001	U-216		
	020121 001	FLUTICASONE PROPIONATE; FLONASE				I-224	OCT 31, 2000
	020378 001	FOLLITROPIN ALFA/BETA; GONAL-F	4589402	JUL 26, 2004	U-242		
			5767251	JUN 16, 2015			
	020378 002	FOLLITROPIN ALFA/BETA; GONAL-F	4589402	JUL 26, 2004	U-242		
			5767251	JUN 16, 2015			
>ADD>	020961 001	FOMIVIRSEN SODIUM; VITRAVENE PRESERVATIVE FREE			NCE	AUG 26, 2003	
	020450 001	FOSPHENYTOIN SODIUM; CEREBYX	4260769	APR 07, 2003			
	019596 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	5560903	OCT 01, 2013			

**PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD> 020460 001	GANCICLOVIR;CYTOVENE	4423050	MAY 21, 2001	U-64		
>ADD>		4642346	JUN 24, 2005			
>ADD>		4507305	MAY 12, 2001	U-64		
>ADD> 020509 001	GEMCITABINE HYDROCHLORIDE;GEMZAR	5563138	OCT 08, 2013	I-234	AUG 26, 2001	
>ADD> 020509 002	GEMCITABINE HYDROCHLORIDE;GEMZAR	5399578	MAR 21, 2012	I-234	AUG 26, 2001	
>ADD> 020695 001	GREPAFLOXACIN HYDROCHLORIDE;RAXAR	5563138	OCT 08, 2013	U-3	NCE	DEC 23, 2001
>ADD> 020818 001	HYDROCHLOROTHIAZIDE;DIOVAN HCT	5399578	MAR 21, 2012	U-3	NC	MAR 06, 2001
020818 002	HYDROCHLOROTHIAZIDE;DIOVAN HCT	5399578	MAR 21, 2012	U-3	NCE	DEC 23, 2001
020716 001	HYDROCODONE BITARTRATE;VICOPROFEN	4587252	DEC 18, 2004	U-55	NC	MAR 06, 2001
016295 002	HYDROXYUREA;DROXIA				OOE	FEB 25, 2005
016295 003	HYDROXYUREA;DROXIA				OOE	FEB 25, 2005
016295 004	HYDROXYUREA;DROXIA				OOE	FEB 25, 2005
>ADD> 019771 001	IBUPROFEN;ADVIL COLD AND SINUS	4552899	NOV 12, 2002			
>ADD>		4552899*PED	MAY 12, 2003			
>ADD> 019833 002	IBUPROFEN;CHILDREN'S ADVIL	4788220	NOV 29, 2005			
>ADD>		4788220*PED	MAY 29, 2006			
>ADD> 020589 001	IBUPROFEN;CHILDREN'S ADVIL	4788220	JUL 08, 2007		NP	JUN 16, 1998
>ADD>		4788220*PED	JAN 08, 2008		PED	DEC 16, 1998
>ADD> 020516 001	IBUPROFEN;CHILDREN'S MOTRIN	5374659	DEC 20, 2011		NP	JUN 16, 1998
>ADD>		5374659*PED	JUN 20, 2012		PED	DEC 16, 1998
>ADD> 020601 001	IBUPROFEN;CHILDREN'S MOTRIN	5215755	JUN 01, 2010		NP	NOV 15, 1999
>ADD>		5215755*PED	DEC 01, 2010		PED	MAY 15, 2000
>ADD> 020603 001	IBUPROFEN;CHILDREN'S MOTRIN	5374659	DEC 20, 2011		NP	JUN 16, 1998
>ADD>		5374659*PED	JUN 20, 2012		PED	DEC 16, 1998
>ADD> 020267 002	IBUPROFEN;JUNIOR STRENGTH ADVIL				NP	JUN 16, 1998
>ADD>					PED	DEC 16, 1998
>ADD> 020601 003	IBUPROFEN;JUNIOR STRENGTH MOTRIN	5215755	JUN 01, 2010		NP	NOV 15, 1999
>ADD>		5215755*PED	DEC 01, 2010		PED	MAY 15, 2000
>ADD> 020602 001	IBUPROFEN;JUNIOR STRENGTH MOTRIN				NP	JUN 16, 1998
>ADD>					PED	DEC 16, 1998
>ADD> 019842 001	IBUPROFEN;MOTRIN	5374659	DEC 20, 2011			
>ADD>		5374659*PED	JUN 20, 2012			
>ADD> 020135 001	IBUPROFEN;MOTRIN	5215755	JUN 01, 2010			
>ADD>		5320855	JUN 14, 2011			
>ADD>		5215755*PED	DEC 01, 2010			
>ADD>		5320855*PED	DEC 14, 2011			
>ADD> 020135 002	IBUPROFEN;MOTRIN	5215755	JUN 01, 2010			
>ADD>		5320855	JUN 14, 2011			
>ADD>		5215755*PED	DEC 01, 2010			
>ADD>		5320855*PED	DEC 14, 2011			
>ADD> 020812 001	IBUPROFEN;PEDIATRIC ADVIL				NP	JUN 16, 1998
>ADD>					PED	DEC 16, 1998
020903 001	INTERFERON ALFA-2B;REBETRON	4530901	JUL 23, 2002		NP	JUN 03, 2001
		4211771	JUL 08, 1999	U-234		
		5767097	JAN 23, 2016	U-235		
020923 001	IOVERSOL;OPTIRAY 240	4396598	DEC 30, 2002			
020923 002	IOVERSOL;OPTIRAY 320	4396598	DEC 30, 2002			

**PRESCRIPTION AND OTC DRUG PRODUCT  
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020923 003	IOVERSOL;OPTIRAY 350	4396598	DEC 30, 2002			
020393 001	IPRATROPIUM BROMIDE;ATROVENT			I-223	APR 01, 2001	
>ADD> 020571 001	IRINOTECAN HYDROCHLORIDE;CANTOSAR	4604463	AUG 20, 2007			
020657 001	ITRACONAZOLE;SPORANOX	4267179	JUN 23, 2000			
019927 001	KETOCONAZOLE;NIZORAL	4942162	FEB 11, 2003			
>ADD> 020261 001	LAMOTRIGINE;LAMICTAL			ODE	AUG 24, 2005	
>ADD> 020241 002	LAMOTRIGINE;LAMICTAL			ODE	AUG 24, 2005	
>ADD> 020241 003	LAMOTRIGINE;LAMICTAL			ODE	AUG 24, 2005	
>ADD> 020241 004	LAMOTRIGINE;LAMICTAL			ODE	AUG 24, 2005	
>ADD> 020241 005	LAMOTRIGINE;LAMICTAL			ODE	AUG 24, 2005	
>ADD> 020241 006	LAMOTRIGINE;LAMICTAL			ODE	AUG 24, 2005	
>ADD> 020764 001	LAMOTRIGINE;LAMICTAL CD			ODE	AUG 24, 2005	
>ADD> 020764 002	LAMOTRIGINE;LAMICTAL CD			ODE	AUG 24, 2005	
>ADD> 020764 003	LAMOTRIGINE;LAMICTAL CD			ODE	AUG 24, 2005	
020406 001	LANSOPRAZOLE;PREVACID			I-227	MAR 12, 2001	
020406 002	LANSOPRAZOLE;PREVACID			D-42	JUL 20, 2001	
020807 001	LEPIRUDIN;REFLUDAN	5180668	JAN 19, 2010	I-227	MAR 12, 2001	
				D-42	JUL 20, 2001	
				ODE	JUL 20, 2001	
				NCE	MAR 06, 2005	
					MAR 06, 2003	
019732 001	LEUPROLIDE ACETATE;LUPRON DEPOT	5716640	SEP 02, 2013			
020011 001	LEUPROLIDE ACETATE;LUPRON DEPOT	5716640	SEP 02, 2013			
020517 001	LEUPROLIDE ACETATE;LUPRON DEPOT	5716640	SEP 02, 2013			
020263 002	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263 003	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263 004	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263 005	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020263 006	LEUPROLIDE ACETATE;LUPRON DEPOT-PED	5716640	SEP 02, 2013			
020708 001	LEUPROLIDE ACETATE;LUPRON DEPOT-3	5716640	SEP 02, 2013			
020517 002	LEUPROLIDE ACETATE;LUPRON DEPOT-4	5716640	SEP 02, 2013			
019941 001	LIDOCAINE;EMLA			I-215	FEB 04, 2001	
020962 001	LIDOCAINE;EMLA			NP	FEB 04, 2001	
020606 001	LOPERAMIDE HYDROCHLORIDE;IMODIUM ADVANCED	5716641	MAY 21, 2012	U-226		
020803 001	LOTEPREDNOL ETABONATE;ALREX	4996335	FEB 26, 2008	NCE	MAR 09, 2003	
		5540930	OCT 25, 2013			
020583 001	LOTEPREDNOL ETABONATE;LOTEMAX	4996335	FEB 26, 2008	NCE	MAR 09, 2003	
		5540930	OCT 25, 2013			
020841 001	LOTEPREDNOL ETABONATE;LOTEMAX	4996335	FEB 26, 2008	NCE	MAR 09, 2003	
		5540930	OCT 25, 2013			
019832 003	MAFENIDE ACETATE;SULFONYLON			NDF	JUN 05, 2001	
				ODE	JUN 05, 2005	
020652 001	MANGAFODIPIR TRISODIUM;TESLASCAN	4933456	JUN 12, 2007			
		4992554	FEB 12, 2008			
		5091169	FEB 25, 2009			
		5223243	JUN 29, 2010	U-237		
		4647447	MAR 03, 2004	U-238		
019618 001	MESALAMINE;ROWASA	4657900	APR 14, 2004			
		RE33239	MAY 12, 2004			
020208 001	METRONIDAZOLE;METROGEL-VAGINAL			D-40	MAY 16, 2000	

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020827 001		MICONAZOLE NITRATE;MONISTAT 3				NP	MAR 30, 2001
020762 001		HOMETASONE FUROATE MONOHYDRATE;NASONEX	4472393	SEP 18, 2001			
020830 001		MONTELUKAST SODIUM;SINGULAIR	5565473	NOV 30, 2010	U-228	NCE	FEB 20, 2003
020829 002		MONTELUKAST SODIUM;SINGULAR	5565473	NOV 30, 2010	U-228	NCE	FEB 20, 2003
020763 001		NARATRIPTAN HYDROCHLORIDE;AMERGE				NCE	FEB 10, 2003
020763 002		NARATRIPTAN HYDROCHLORIDE;AMERGE				NCE	FEB 10, 2003
020536 001		NICOTINE;NICOTROL	4915950	FEB 12, 2008		I-220	APR 01, 2001
020555 001		NIZATIDINE;AXID AR				D-39	APR 01, 2001
						NDF	DEC 16, 2000
>ADD>	020799 001	OFLOXACIN;FLOXIN					
	020688 001	OLOPATADINE HYDROCHLORIDE;PATAROL	5116863	DEC 18, 2010			
	019810 001	OMEPRAZOLE;PRILOSEC				I-229	JUN 29, 2001
	019810 002	OMEPRAZOLE;PRILOSEC				I-229	JUN 29, 2001
	020262 001	PACLITAXEL;TAXOL				I-226	APR 09, 2001
>ADD>	020819 001	PARICALCITOL;ZEMPLAR				I-230	JUN 30, 2001
	020710 001	PAROXETINE HYDROCHLORIDE;PAXIL	5811436	SEP 22, 2015		NCE	APR 17, 2003
	020237 001	PILOCARPINE HYDROCHLORIDE;SALAGEN				ODE	FEB 11, 2005
						I-212	FEB 11, 2001
	020667 001	PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006			
			4843086	JUN 27, 2006	U-231		
	020667 002	PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006		U-231	
			4843086	JUN 27, 2006	U-231		
	020667 003	PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006		U-231	
			4843086	JUN 27, 2006	U-231		
	020667 004	PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006		U-231	
			4843086	JUN 27, 2006	U-231		
	020667 005	PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006		U-231	
			4843086	JUN 27, 2006	U-231		
	019898 002	PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
	019898 003	PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
	019898 004	PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
	019781 001	PROGESTERONE;PROMETRIUM				NP	MAY 14, 2001
	019627 002	PROPOFOL;DIPRIVAN	5731355	MAR 22, 2015	U-217		
			5731356	MAR 22, 2015	U-218		
	020815 001	RALOXIFENE HYDROCHLORIDE;EVISTA	4418068	APR 03, 2001			
			5393763	JUL 28, 2012	U-114		
			5457117	JUL 28, 2012	U-114		
			5478847	MAR 02, 2014	U-114		
	020520 001	RANITIDINE HYDROCHLORIDE;ZANTAC 75				I-228	JUN 08, 2001
	021024 001	RIFAPENTINE;PRIFTIN				NCE	JUN 22, 2003
						ODE	JUN 22, 2005
	020835 001	RISEDRONATE SODIUM;ACTONEL	5583122	DEC 10, 2013	U-222	NCE	MAR 27, 2003
	020272 005	RISPERIDONE;RISPERDAL	5158952	OCT 27, 2009		D-37	OCT 17, 2000
>ADD>	020864 001	RIZATRIPTAN BENZOATE;MAXALT	5602162	MAY 10, 2015	U-240	NCE	JUN 29, 2003
>ADD>	020864 002	RIZATRIPTAN BENZOATE;MAXALT	5298520	JAN 28, 2012	U-240	NCE	JUN 29, 2003
>ADD>	020865 001	RIZATRIPTAN BENZOATE;MAXALT-MLT	5602162	MAY 10, 2015	U-240	NCE	JUN 29, 2003
			4305502	DEC 15, 1998			
			5298520	JAN 28, 2012	U-240		
			4758598	DEC 15, 1998			
			4371516	FEB 01, 2000			

**PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA**  
**\*PED and PED represent Pediatric Exclusivity**

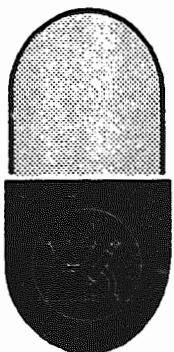
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>ADD> 020865 002	RIZATRIPTAN BENZOATE;MAXALT-MLT	5602162 4305502 5298520 4758598 4371516	MAY 10, 2015 DEC 15, 1998 JAN 28, 2012 DEC 15, 1998 FEB 01, 2000	U-240	NCE	JUN 29, 2003
				U-240		
>ADD> 020533 001	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE;NAROPIN	4870086	JUL 28, 2010			
>ADD> 020533 003	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE;NAROPIN	4870086	JUL 28, 2010			
>ADD> 020533 004	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE;NAROPIN	4870086	JUL 28, 2010			
>ADD> 020533 005	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE;NAROPIN	4870086	JUL 28, 2010			
020772 001	SACROSIDASE;SUCRAID				ODE NCE	APR 09, 2005 APR 09, 2003
020236 001	SALMETEROL XINAFOATE;SEREVENT	5126375	FEB 12, 2008			
020692 001	SALMETEROL XINAFOATE;SEREVENT	5225445 5380922 5590645 5126375 0342994	FEB 12, 2008 JAN 10, 2012 MAR 01, 2011 FEB 12, 2008 JAN 04, 2008	U-211	I-216	FEB 05, 2001
>ADD> 020828 001	SAQUINAVIR;FORTOVASE	5196438	NOV 19, 2012			
020443 001	SERMORELIN ACETATE;GEREF	4517181	MAY 14, 2002			
020443 002	SERMORELIN ACETATE;GEREF	4703035 4517181 4703035	DEC 28, 2004 MAY 14, 2002 DEC 28, 2004			
020895 001	SILDENAFIL CITRATE;VIAGRA	5250534	JUN 18, 2011		NCE	MAR 27, 2003
020895 002	SILDENAFIL CITRATE;VIAGRA	5250534	JUN 18, 2011		NCE	MAR 27, 2003
020895 003	SILDENAFIL CITRATE;VIAGRA	5250534	JUN 18, 2011		NCE	MAR 27, 2003
019676 001	SOMATROPIN, BIOSYNTHETIC;NUTROPIN				ODE	OCT 29, 2004
019676 002	SOMATROPIN, BIOSYNTHETIC;NUTROPIN				ODE	OCT 29, 2004
020181 001	SOYBEAN OIL;LIPOSYN III 30%				NP	JAN 13, 2001
020626 001	SUMATRIPTAN;IMITREX	5037845 5307953 5554639 5705520	AUG 06, 2008 DEC 02, 2012 SEP 10, 2013 DEC 10, 2011	U-232 U-232		
020626 002	SUMATRIPTAN;IMITREX	5037845 5307953 5554639 5705520	AUG 06, 2008 DEC 02, 2012 SEP 10, 2013 DEC 10, 2011	U-232 U-232		
020626 003	SUMATRIPTAN;IMITREX	5037845 5307953 5554639 5705520	AUG 06, 2008 DEC 02, 2012 SEP 10, 2013 DEC 10, 2011	U-232 U-232		
020791 001	TESTOSTERONE;TESTODERM	4379454	FEB 17, 2001		NCE	JUL 16, 2003
020785 001	THALIDOMIDE;THALOMID				ODE	JUL 16, 2005
020912 001	TIROFIBAN HYDROCHLORIDE;AGRASSTAT	5292756 5658929 5733919	MAR 08, 2011 MAR 08, 2011 OCT 23, 2016	U-230	NCE	MAY 14, 2003
020913 001	TIROFIBAN HYDROCHLORIDE;AGRASSTAT	5292756 5658929 5733919	MAR 08, 2011 MAR 08, 2011 OCT 23, 2016	U-230	NCE	MAY 14, 2003

PRESCRIPTION AND OTC DRUG PRODUCT  
PATENT AND EXCLUSIVITY DATA  
\*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020697 001	TOLCAPONE;TASMAR	5236952 5476875	AUG 17, 2010 DEC 19, 2012	U-219	NCE	JAN 29, 2003
020697 002	TOLCAPONE;TASMAR	5236952 5476875	AUG 17, 2010 DEC 19, 2012	U-219	NCE	JAN 29, 2003
020771 001	TOLTERODINE TARTRATE;DETROL	5382600	JAN 17, 2012		NCE	MAR 25, 2003
020771 002	TOLTERODINE TARTRATE;DETROL	5382600	JAN 17, 2012		NCE	MAR 25, 2003
<u>&gt;ADD&gt;</u>	020671 001 TOPOTECAN HYDROCHLORIDE;HYCANTIN	5004758	MAY 28, 2010		D-38	FEB 13, 2001
020137 002	TORSEMIDE;DEMADEX					
020528 001	TRANDOLAPRIL;MAVIK	5744496	APR 28, 2015	U-229		
020528 002	TRANDOLAPRIL;MAVIK	5744496	APR 28, 2015	U-229		
020528 003	TRANDOLAPRIL;MAVIK	5744496	APR 28, 2015	U-229		
<u>&gt;ADD&gt;</u>	020719 001 TROGLITAZONE;PRELAY	4572912	NOV 09, 2008			
<u>&gt;ADD&gt;</u>	020719 002 TROGLITAZONE;PRELAY	4572912	NOV 09, 2008			
<u>&gt;ADD&gt;</u>	020719 003 TROGLITAZONE;PRELAY	4572912	NOV 09, 2008			
<u>&gt;ADD&gt;</u>	020720 001 TROGLITAZONE;REZULIN	4572912	NOV 09, 2008			
<u>&gt;ADD&gt;</u>	020720 002 TROGLITAZONE;REZULIN	4572912	NOV 09, 2008			
<u>&gt;ADD&gt;</u>	020720 003 TROGLITAZONE;REZULIN	4572912	NOV 09, 2008			
	020675 001 URSODIOL;URSO	4859660	AUG 22, 2006			
	020699 001 VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR	4535186	DEC 13, 2007			
	020699 002 VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR	4535186	DEC 13, 2007			
	020699 003 VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR	4535186	DEC 13, 2007			
	020699 004 VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR	4535186	DEC 13, 2007			
	020388 001 VINORELBINE TARTRATE;NAVELBINE	4307100	JUL 08, 2002			
<u>&gt;ADD&gt;</u>	020471 001 ZILEUTON;ZYFLO	4873259	DEC 10, 2010	U-168		
<u>&gt;ADD&gt;</u>	020471 003 ZILEUTON;ZYFLO	4873259	DEC 10, 2010	U-168		

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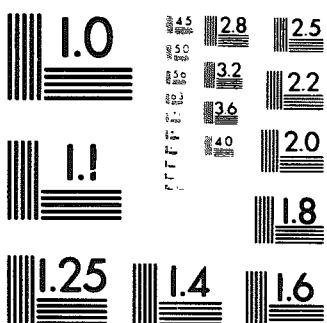
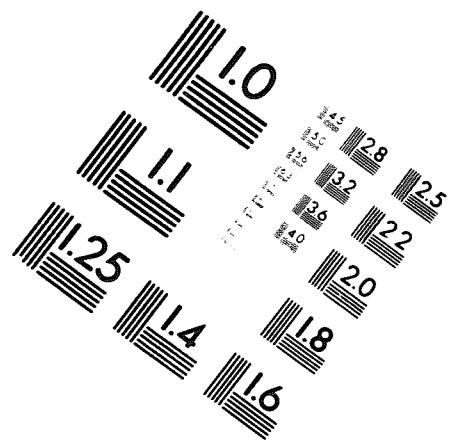
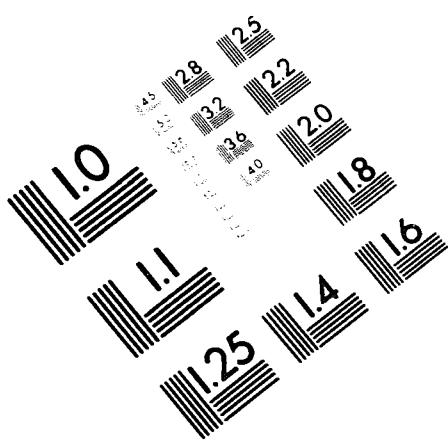
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