

CUMULATIVE
SUPPLEMENT
JANUARY

APPROVED
DRUG PRODUCTS

VALU

PHARMACEUTICAL EQUIVALENTS

INDEX

DRUGS

Prepared By
Division of Nonprescription Medicines
Office of Generic Technologies
Center for Drug Evaluation and Research, FDA

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

18TH EDITION

Cumulative Supplement 5

MAY 1998

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**APPROVED DRUG PRODUCTS
with
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18TH EDITION

**CUMULATIVE SUPPLEMENT 5
MAY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

NO APPLICANT NAME CHANGES - MAY 1998

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

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

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

1.4 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

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		
SINGLE SOURCE	2462 (25.6%)	2484 (25.6%)		
MULTISOURCE	7052 (73.3%)	7117 (73.3%)		
THERAPEUTICALLY EQUIVALENT	6673 (69.3%)	6746 (69.5%)		
NOT THERAPEUTICALLY EQUIVALENT	379 (4.0%)	371 (3.8%)		
EXCEPTIONS ¹	110 (1.1%)	110 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	--	8		
NUMBER OF APPLICANTS	551	529		

¹Amino 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 5 / JAN'98 - MAY'98

1

ACARBOSE

TABLET; ORAL	
PRECOSE	
© BAYER	
	<u>25MG</u>
	<u>N20482 004</u>
	<u>MAY 29, 1997</u>
	<u>25MG</u>
	<u>N20482 004</u>
	<u>MAY 29, 1997</u>

ACETAMINOPHEN: CODEINE PHOSPHATE

TABLET; ORAL	
<u>ACETAMINOPHEN AND CODEINE PHOSPHATE</u>	
ROYCE LABS	<u>300MG/15MG</u>
	<u>N89997 001</u>
	<u>DEC 28, 1994</u>
	<u>300MG/15MG</u>
	<u>N89997 001</u>
	<u>DEC 28, 1994</u>
	<u>300MG/15MG</u>
	<u>N89997 001</u>
	<u>DEC 28, 1994</u>
AA WATSON LABS	<u>300MG/15MG</u>
	<u>N89997 001</u>
	<u>DEC 28, 1994</u>
	<u>300MG/30MG</u>
	<u>N89998 001</u>
	<u>DEC 28, 1994</u>
	<u>300MG/60MG</u>
	<u>N89999 001</u>
	<u>DEC 28, 1994</u>

ACETAMINOPHEN: HYDROCODONE BITARTRATE

ELIXIR; ORAL	
<u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u>	
AA + MIKART	<u>500MG/15ML; 7.5MG/15ML</u>
	<u>N31051 001</u>
	<u>AUG 20, 1992</u>
AA PHARM ASSOC	<u>500MG/15ML; 7.5MG/15ML</u>
	<u>N40182 001</u>
	<u>MAR 13, 1998</u>

TABLET; ORAL	
<u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u>	
AA MALLINCKRODT	<u>500MG/7.5MG</u>
	<u>N40201 001</u>
	<u>FEB 27, 1998</u>
	<u>500MG/10MG</u>
	<u>N40201 002</u>
AA ROYCE LABS	<u>500MG/7.5MG</u>
	<u>N40201 002</u>
	<u>500MG/10MG</u>
	<u>N40201 002</u>
	<u>500MG/15MG</u>
	<u>N40201 002</u>
	<u>500MG/20MG</u>
	<u>N40201 002</u>

ACETAMINOPHEN: HYDROCODONE BITARTRATE

TABLET; ORAL	
<u>HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u>	
AA ROYCE LABS	<u>500MG/7.5MG</u>
	<u>N40123 001</u>
	<u>MAR 14, 1996</u>
	<u>500MG/7.5MG</u>
	<u>N40123 002</u>
	<u>MAR 14, 1996</u>
AA WATSON LABS	<u>500MG/2.5MG</u>
	<u>N40123 003</u>
	<u>MAR 04, 1996</u>
	<u>500MG/5MG</u>
	<u>N40122 001</u>
	<u>MAR 04, 1996</u>
	<u>500MG/7.5MG</u>
	<u>N40123 004</u>
	<u>MAR 04, 1996</u>
	<u>550MG/7.5MG</u>
	<u>N40123 001</u>
	<u>MAR 04, 1996</u>
	<u>650MG/10MG</u>
	<u>N40123 002</u>
	<u>MAR 04, 1996</u>
	<u>750MG/7.5MG</u>
	<u>N40122 002</u>
	<u>MAR 04, 1996</u>

ACETAMINOPHEN: OXYCODONE

CAPSULE; ORAL	
<u>OXYCODONE AND ACETAMINOPHEN</u>	
AA HALSEY	<u>500MG/5MG</u>
	<u>N40219 001</u>
	<u>JAN 22, 1998</u>

ACETAMINOPHEN: OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL	
<u>OXYCODONE AND ACETAMINOPHEN</u>	
AA ROYCE LABS	<u>500MG/5MG</u>
	<u>N40231 002</u>
	<u>OCT 18, 1997</u>
AA WATSON LABS	<u>500MG/5MG</u>
	<u>N40234 001</u>
	<u>OCT 30, 1997</u>

TABLET; ORAL

<u>OXYCODONE AND ACETAMINOPHEN</u>	
AA ROYCE LABS	<u>325MG/5MG</u>
	<u>N40171 001</u>
	<u>OCT 30, 1997</u>
AA WATSON LABS	<u>325MG/5MG</u>

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL

PROPOXYPHENE HCL AND ACETAMINOPHEN

AA NOVARTIS LABS ~~500MG; 65MG~~

AA WATSON LABS 650MG; 65MG

PROPOXYPHENE
DEC 16, 1998
N40139 001
DEC 16, 1996

ACETIC ACID, GLACIAL

SOLUTION; IRRIGATION, URETHRAL

ACETIC ACID 0.25% IN PLASTIC CONTAINER

AT B BRAUN 250MG/100ML

AT NOVARTIS ~~250MG/100ML~~

N18161 001
~~250MG/100ML~~

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

AB CHELSEA LABS 200MG

AB GENPHARM 200MG

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

TABLET; ORAL

ACYCLOVIR

AB COPLEY PHARM 400MG

AB 800MG

N75021 001
MAR 18, 1998
N75021 002

AB GENPHARM 400MG

AB 800MG

N74976 001
APR 13, 1998
N74976 002

AB NOVOPHARM 200MG

• 200MG

APR 13, 1998
N74556 001
APR 22, 1997

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR SODIUM

AP AESGEN EQ 500MG BASE/VIAL

N75015 001
APR 30, 1998

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR SODIUM

AP APOTHECON EQ 500MG BASE/VIAL

AP FUJISAWA EQ 1GM BASE/VIAL

> ADD > **AP** FUJISAWA EQ 500MG BASE/VIAL

> ADD > **AP** FUJISAWA EQ 1GM BASE/VIAL

> ADD > **AP** FUJISAWA EQ 1GM BASE/VIAL

N74897 001
FEB 27, 1998
N74897 002
FEB 27, 1998
N74930 001
MAY 13, 1998
N74930 002
MAY 13, 1998

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

AN HI TECH PHARMA EQ 0.5% BASE

N74543 001
JAN 15, 1998

SYRUP; ORALALBUTEROL SULFATE

AA HI TECH PHARMA EQ 2MG BASE/SML

N74749 001
JAN 30, 1998
N74302 001
SEP 10, 1998

AA NOVA EQ 2MG BASE/SML

N74302 001
SEP 30, 1994

ALPRAZOLAM

TABLET; ORAL

ALPRAZOLAM

AB GENEVA PHARMS 2MG

N74909 001
MAR 25, 1998
N74479 002
JAN 21, 1997

AB NOVARTIS 2MG

N74479 002
JAN 21, 1997
N74479 003
JAN 21, 1997

AB NOVARTIS 3MG

N74479 003
JAN 21, 1997

AB NOVARTIS 4MG

N74479 001
JAN 21, 1997

AB NOVARTIS 5MG

N74479 002
JAN 21, 1997

AB NOVARTIS 6MG

N74479 003
JAN 21, 1997

AB NOVARTIS 7MG

N74479 001
JAN 21, 1997

AB NOVARTIS 8MG

N74479 002
JAN 21, 1997

AB NOVARTIS 9MG

N74479 003
JAN 21, 1997

ALPROSTADIL

INJECTABLE; INJECTION

ALPROSTADIL

AP BEDFORD 0.5MG/ML

AP + PHARMACIA AND UPJOHN 0.5MG/ML

N74815 001
JAN 20, 1998N18484 001
N18485 001AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

SYMETREL

AB + EMDT MERCK 50MG/5ML

AA + ENDO PHARMS 50MG/5ML

TABLET; ORAL
SYMMETREL
+ ENDO PHARMS 100MG

N18473 002
N16023 002N18101 001
N18101 001AMCINONIDE

OINTMENT; TOPICAL

CYCLOCORT

+ LISTERINE 0.1%

+ WYETH AYERST 0.1%

N18474 002
N18498 001AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HCL AND HYDROCHLOROTHIAZIDE

AB ROYCE LABS EQ 5MG ANHYDROUS; 50MG

AB WATSON LABS EQ 5MG ANHYDROUS; 50MG

N18336 001
JUL 19, 1991
N73334 001
JUL 19, 1991AMIODARONE HYDROCHLORIDE

TABLET; ORAL

CORDARONE

AB + WYETH AYERST 200MG

N18972 001
DEC 24, 1985AMIODARONE HYDROCHLORIDE

TABLET; ORAL

PACKARD

AB UPSHER SMITH 200MG

N75135 001
APR 30, 1998AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE

TABLET; ORAL

PERPHENAZINE AND AMITRIPTYLINE HCL

AB WATSON LABS 10MG; 2MG
AB WATSON LABS 10MG; 4MG
AB WATSON LABS 25MG; 2MG
AB WATSON LABS 25MG; 4MG

OCT 17, 1991
N73009 001
OCT 17, 1991
N73008 001
OCT 17, 1991
N73010 001
OCT 17, 1991

AMMONIUM CHLORIDEINJECTABLE; INJECTION
AMMONIUM CHLORIDE 2.14%

AB B BRAUN 40MEQ/100ML
AB MCKEE 40MEQ/100ML

N85734 001
N85735 001AMRINONE LACTATEINJECTABLE; INJECTION
INOCOR

AB SHAW EQ 5MG ANHYDROUS
AB SHAW EQ 5MG BASE/ML

N18700 001
JUL 31, 1984

ARBUTAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

GENESA

+ GENESA

0.05MG/ML

N20420 001
SEP 12, 1997

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENADRINE

PAR PHARM

385MG;30MG;25MG

N75141 001
MAY 29, 1998

ORPHENADRINE FORTE

PAR PHARM

770MG;60MG;50MG

N75141 002
MAY 29, 1998

ATORVASTATIN CALCIUM

TABLET; ORAL

LIPITOR

WARNER LAMBERT EXPOR EQ 10MG BASE

N20702 001

EQ 20MG BASE

DEC 17, 1996

EQ 40MG BASE

N20702 002

EQ 40MG BASE

DEC 17, 1996

EQ 40MG BASE

N20702 003

EQ 40MG BASE

DEC 17, 1996

ASPIRIN; OXYCODONE HYDROCHLORIDE; OXYCODONE TEREPHTHALATE

TABLET; ORAL

OXYCODONE AND ASPIRIN

WATSON LABS

325MG;4.5MG;0.38MG

N40255 001
FEB 27, 1998

ATENOLOL; CHLORTHALIDONE

TABLET; ORAL

ATENOLOL AND CHLORTHALIDONE

MARTEC

50MG;25MG

N74404 001
MAY 14, 1998

100MG;25MG

N74404 002
MAY 14, 1998

ATORVASTATIN CALCIUM

TABLET; ORAL

LIPITOR

WARER LAMBERT

EQ 10MG BASE

N20420 001
SEP 17, 1998

EQ 20MG BASE

N20420 002
SEP 17, 1998

EQ 40MG BASE

N20420 003
SEP 17, 1998

RACITRACIN

POMONA FOR EX COMPOUNDING

RACITRACIN

RADROCK

5,000,000 UNITS/BOT

N20702 001

5,000,000 UNITS/BOT

JUL 27, 1993

N62456 001

JUL 27, 1993

BACITRACIN ZINC; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC

NEOSPORIN

ADVO 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

ADV PHARMS

400 UNITS/GM;EQ 3.5MG BASE/GM;

N64028 001

10,000 UNITS/GM

JAN 30, 1995

AT AKORN

500 UNITS/GM;

10,000 UNITS/GM

N64028 001

POLYSPORIN

ADVO PHARMS

400 UNITS/GM;EQ 3.5MG BASE/GM;

N64028 001

10,000 UNITS/GM

JAN 30, 1995

AT + MONARCH PHARMS

500 UNITS/GM;

10,000 UNITS/GM

N61229 001

BACLOFEN

TABLET; ORAL

BACLOFEN

AB	NOVARTIS	20MG	[REDACTED]
AB		30MG	[REDACTED]
AB	WATSON LABS	10MG	JAN 10, 1994 W73092 001
AB		20MG	JAN 28, 1994 W73093 001
			JAN 28, 1994

BEPRIDIL HYDROCHLORIDE

TABLET; ORAL

VASCOR

	NOVARTIS	300MG	[REDACTED]
*		400MG	[REDACTED]
+		300MG	[REDACTED]
*		400MG	N19002 002

DEC 28, 1990
N19002 003

DEC 28, 1990

BETAMETHASONE VALERATE

CREAM; TOPICAL

BETAMETHASONE VALERATE

AB	WELLCOME	[REDACTED]
*		EQ 0.1% BASE

N70053 001
JUN 10, 1986BRINZOLAMIDESUSPENSION/DROPS; OPHTHALMIC
AZOPT

+ ALCON

1%

N20816 001
APR 01, 1998BROMOCRIPTINE MESYLATE

TABLET; ORAL

BROMOCRIPTINE MESYLATE

AB	LEK PHARM	EQ 2.5MG BASE	N74631 001
AB	PARLODEL	EQ 2.5MG BASE	JAN 13, 1998

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDEINJECTABLE; INJECTION

ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER	B BRAUN	37MG/100ML; 5GM/100ML; 31MG/100ML;
		120MG/100ML; 330MG/100ML;
		80MG/100ML N19864 001

JUN 10, 1993

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATEINJECTABLE; INJECTION

ISOLYTE S IN DEXTROSE 5% IN PLASTIC CONTAINER	B BRAUN	35MG/100ML; 5GM/100ML; 30MG/100ML;
		74MG/100ML; 640MG/100ML; 500MG/100ML;
		74MG/100ML N19867 001

DEC 20, 1993

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDEINJECTABLE; INJECTION

DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER	B BRAUN	33MG/100ML; 5GM/100ML; 30MG/100ML;	M18256 001
		560MG/100ML	
		33MG/100ML; 5GM/100ML; 30MG/100ML;	N20009 001
		560MG/100ML	APR 17, 1992

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% IN RINGER'S IN PLASTIC CONTAINER

<u>AP</u>	MCGRAN		
<u>AP</u>			

CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

DEXTROSE 5% IN LACTATED RINGER'S IN PLASTIC CONTAINER

B BRAUN 20MG/100ML; 5GM/100ML; 30MG/100ML;
600MG/100ML; 310MG/100ML N17510 001MCGRAN 20MG/100ML; 5GM/100ML; 30MG/100ML;
600MG/100ML; 310MG/100ML N17510 001CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE

INJECTABLE; INJECTION

ISOLYTE E IN PLASTIC CONTAINER

B BRAUN 35MG/100ML; 30MG/100ML; 74MG/100ML;
640MG/100ML; 500MG/100ML;
74MG/100ML N19718 001
MCGRAN 35MG/100ML; 30MG/100ML; 74MG/100ML;
640MG/100ML; 500MG/100ML;
74MG/100ML N19718 001
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERfusion, CARDIAC

PLEGISOL IN PLASTIC CONTAINER

ABBOTT 17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML N18608 001
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERfusion/CARDIAC

PLEGISOL IN PLASTIC CONTAINER

+ ABBOTT 17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML N18608 001
FEB 26, 1982CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION

RINGER'S IN PLASTIC CONTAINER

<u>AP</u>	B BRAUN		
<u>AP</u>			

SOLUTION; IRRIGATION

RINGER'S IN PLASTIC CONTAINER

<u>AT</u>	B BRAUN		
<u>AT</u>			

CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE

INJECTABLE; INJECTION

LACTATED RINGER'S IN PLASTIC CONTAINER

<u>AP</u>	B BRAUN		
<u>AP</u>			
<u>AP</u>			

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN'98 - MAY'98

8

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

~~AB~~ NOVARTIS LABS 250MG
NATSON LABS 350MG

~~DEC 03, 1998~~
N60152 001
DEC 03, 1998

CEFACLOR

POWDER FOR RECONSTITUTION; ORAL

CEFACLOR

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

N64204 001
FEB 18, 1998
N64205 001
FEB 18, 1998
N64206 001
FEB 18, 1998
N64207 001
FEB 18, 1998

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

~~AP~~ FUJISAWA EQ 10GM BASE/VIAL N64170 001
AP EQ 20GM BASE/VIAL N64170 002
MAR 18, 1998 MAR 18, 1998

CEFUROXIME SODIUM

INJECTABLE; INJECTION

CEFUROXIME

~~AB~~ ASTRA EQ 750MG BASE/VIAL N64192 002
AP EQ 1.5GM BASE/VIAL N64192 001
AP EQ 7.5GM BASE/VIAL N64191 001
AP APR 16, 1998 APR 16, 1998 APR 16, 1998

CEPHALEXINPOWDER FOR RECONSTITUTION; ORAL
REFLEX

~~AB~~ + PARKDALE
EQ 100MG BASE/ML
EQ 100MG BASE/ML

~~DEC 03, 1998~~
N50406 003
N62117 001

CHLORAMPHENICOLCAPSULE; ORAL
CHLOROMYCETIN

~~AB~~ + PARKDALE
250MG
50MG
100MG

~~DEC 03, 1998~~
N60591 002
N60591 001
N60591 003

OINTMENT; OPHTHALMIC
CHLOROMYCETIN

~~AT~~ + PARKDALE
15

~~DEC 03, 1998~~
N50156 001

POWDER FOR RECONSTITUTION; OPHTHALMIC
CHLOROMYCETIN

~~AB~~ + PARKDALE
25MG/ML
25MG/VIAL

~~DEC 03, 1998~~
N50143 001

SOLUTION/DROPS; OPHTHALMIC
OPHTHOCHLOR

~~AT~~ + PARKDALE
0.5%

~~DEC 03, 1998~~
N61220 001

SOLUTION/DROPS; OTIC
CHLOROMYCETIN

~~AT~~ + PARKDALE
0.5%

~~DEC 03, 1998~~
N50205 001

CHLORAMPHENICOL; HYDROCORTISONE ACETATEPOWDER FOR RECONSTITUTION; OPHTHALMIC
CHLOROMYCETIN HYDROCORTISONE

~~AB~~ + PARKDALE
12.5MG/VIAL, 25MG/VIAL
12.5MG/VIAL, 25MG/VIAL

~~DEC 03, 1998~~
N50202 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 5 / JAN'98 - MAY'98

9

CHLORAMPHENICOL; HYDROCORTISONE ACETATE; POLYNYXIN B SULFATE

OINTMENT; OPHTHALMIC
OPHTHOCORT
• ~~NURSE DAVIS~~
10MG/GM; 1000 UNITS/GM
10,000 UNITS/GM

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

N50201 001
N50201 002

CHLORAMPHENICOL SODIUM SUCCINATE

INJECTABLE; INJECTION
CHLOROMYCETIN
AB • ~~NURSE DAVIS~~
AP • PARKEDALE
EQ 1GM BASE/VIAL

N50155 001

CHLORDIAZEPOXIDE

TABLET; ORAL
LIBRITABS
• ICN
5MG
10MG
25MG
• ROCHE
5MG
10MG
25MG

N85482 001
N85481 001
N85488 001
N85483 001
N85484 001
N85485 001

CHLORDIAZEPOXIDE HYDROCHLORIDE

CAPSULE; ORAL
LIBRIUM.
AB ICN
5MG
10MG
25MG
• ROCHE
5MG
25MG

N85461 001
N85472 001
N85475 001
N85473 001
N85474 001
N85476 001

CHLORHEXIDINE GLUCONATE

SOLUTION; DENTAL
PERIDEX
AP • PROCTER AND GAMBLE
EQ 1ML

N50202 001
JUN 13, 1998

CHLORHEXIDINE GLUCONATE

SOLUTION; 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

•
25MG/ML

JUN 13, 1998
N89563 001
APR 15, 1998

CHLORZOXAZONE

TABLET; ORAL
CHLORZOXAZONE
WATSON LABS

500MG

JUN 23, 1998
N81040 001
AUG 22, 1998

CHOLESTYRAMINE

PONDER; ORAL
CHOLESTYRAMINE
NOVOPHARM

EQ 4GM RESIN/PACKET

N74347 001
MAY 28, 1998
N74347 002
MAY 28, 1998

CHOLESTYRAMINE LIGHT
NOVOPHARM

EQ 4GM RESIN/PACKET

N74348 001
MAY 28, 1998
N74348 002
MAY 28, 1998

CHOLESTYRAMINE LIGHT
NOVOPHARM

EQ 4GM RESIN/PACKET

N74349 001
MAY 28, 1998
N74349 002
MAY 28, 1998

LOCHOLEST
EON

EQ 4GM RESIN/PACKET

N74561 001
AUG 15, 1996

CHOLESTYRAMINEPONDER; ORAL
LOCHOLEST

AB EON

<u>EQ 4GM RESIN/SCOOPFUL</u>	M74561 002
	AUG 15, 1996
	N74561 003
	AUG 15, 1996
	N74561 004
	AUG 15, 1996

LOCHOLEST LIGHT

AB EON

<u>EQ 4GM RESIN/PACKET</u>	M74562 001
	AUG 15, 1996
	N74562 002
	AUG 15, 1996
	N74562 003
	AUG 15, 1996
	N74562 004
	AUG 15, 1996

CIMETIDINETABLET; ORAL
CIMETIDINE

> DLT > AB	BAKER NORTON	<u>200MG</u>	
> DLT >		<u>300MG</u>	JUL 28, 1995
> DLT > AB		<u>300MG</u>	N74424 001
> DLT > AB		<u>400MG</u>	JUL 28, 1995
> DLT > AB		<u>400MG</u>	N74424 002
> DLT > AB		<u>400MG</u>	JUL 28, 1995
> DLT > AB		<u>400MG</u>	N74424 003
> DLT > AB		<u>400MG</u>	JUL 28, 1995
> ADD > AB	ZENITH LABS	<u>200MG</u>	N74424 004
> ADD > AB		<u>300MG</u>	JUL 28, 1995
> ADD > AB		<u>400MG</u>	N74424 005
> ADD > AB		<u>800MG</u>	JUL 28, 1995
> ADD >			

CIPROFLOXACIN HYDROCHLORIDEOINTMENT; OPHTHALMIC
CILOXAN
+ ALCON

EQ 0.3% BASE

N20369 001
MAR 30, 1998CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONESUSPENSION/DROPS; OTIC
CIPRO HC
+ BAYER

EQ 0.2% BASE; 1%

N20805 001
FEB 10, 1998CLEMASTINE FUMARATESYRUP; ORAL
CLEMASTINE FUMARATEAB MORTON GROVE EQ 0.5MG BASE/SNLN74863 001
MAR 13, 1998CLINDAMYCIN PHOSPHATECREAM; VAGINAL
CLEOCIN 3
+ PHARMACIA AND UPJOHN EQ 2% BASEN50680 002
MAR 02, 1998INJECTABLE; INJECTIONCLINDAMYCIN PHOSPHATEAB EQ 150MG BASE/MLN62913 001
OCT 20, 1998SOLUTION; TOPICALCLEOCIN T
PHARMACIA AND UPJOHN EQ 1% BASEN62363 001
FEB 08, 1992CLOMIPRAMINE HYDROCHLORIDECAPSULE; ORAL
CLOMIPRAMINE HCLAB MYLAN
25MG
50MG
75MGN74947 001
APR 30, 1998
N74947 002
APR 30, 1998
N74947 003
APR 30, 1998

CLONAZEPAN

> DLT > TABLET, ORAL
KLOPIN RAPIDLY DISINTEGRATING
+ ROCHE 0.125MG
DLT 0.25MG
DLT 0.5MG
DLT 1MG
DLT 2MG
DLT >
> ADD > TABLET, ORALLY DISINTEGRATING; ORAL
KLOPIN RAPIDLY DISINTEGRATING
+ ROCHE 0.125MG
ADD 0.25MG
ADD 0.5MG
ADD 1MG
ADD + 2MG
> ADD >

N20813 001
DEC 23, 1997
N20813 002
DEC 23, 1997
N20813 003
DEC 23, 1997
N20813 004
DEC 23, 1997
N20813 005
DEC 23, 1997

CROMOLYN SODIUM

SOLUTION/DROPS; OPHTHALMIC
CROLON
BAUSCH AND LOMB 41
AT 41
CROMOLYN SODIUM
ADV REMEDIES 41
OPTICRON
+ ALLERGAN 41
KODAK PHARMACEUTICALS 41

N74443 001
JAN 30, 1995
N74443 002
JAN 30, 1995
N74706 001
APR 29, 1998
N18155 001
OCT 03, 1984
N74443 003
OCT 03, 1998

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION
COLY-MYCIN M
+ PARKER DAVIS
+ PARKEDALE
EQ 150MG BASE/VIAL

N50108 001
N50108 002

CYANOCOBALAMIN

INJECTABLE; IM - SC
CYANOCOBALAMIN
MEDWICK 0.1MG/ML
> ADD > AP

N80650 001

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL
CYCLOBENZAPRINE HCL

AB 10MG
WATSON LABS 10MG

N74436 001
NOV 30, 1994

DACTINOMYCIN

INJECTABLE; INJECTION
COSMEGEN
+ MERCK 0.5MG/VIAL
MERCK SHARP DOWD 0.5MG/VIAL

N50682 001
NOV 30, 1994

CORTICOTROPIN

INJECTABLE; INJECTION
ACTH
+ PARKER DAVIS
+ PARKEDALE
25 UNITS/VIAL
40 UNITS/VIAL

N08317 001
N08317 002
N08317 003
N08317 004
N08317 005
N08317 006

DALTEPARIN SODIUM

INJECTABLE; INJECTION
FRAGMIN

N74443 001
NOV 30, 1994

DALTEPARIN SODIUM

INJECTABLE; INJECTION

FRAGMIN

+ PHARMACIA AND UPJOHN 10,000 IU/ML

N20287 004
JAN 30, 1998DANAZOL

CAPSULE; ORAL

DANAZOL

> ADD >	AB	BARR	50MG	N74582 003 MAY 29, 1998
> ADD >	AB		100MG	M74582 002 MAY 29, 1998
> ADD >		DANOCRINE		
> ADD >	AB	SANOFI	50MG	N17557 003
> ADD >	AB		100MG	N17557 004

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DAUNORUBICIN HCL PRESERVATIVE FREE

+ BEDFORD EQ 20MG BASE/VIAL

N50731 001
JAN 30, 1998DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28

MIRECTTE

+ ORGANON 0.15MG;0.02NG

N20713 001
APR 22, 1998DESOKIMETASONE

OINTMENT; TOPICAL

DESOKIMETASONE

AB ALTANA 0.25%

N73440 001
APR 01, 1998DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEPO-MEDROL

+ MEDICO

DEXAMETHASONE SODIUM PHOSPHATEN MEDICO
EQ 0.1MG PHOSPHATE/INN N13413 001N MEDICO
EQ 0.1MG PHOSPHATE/INN N14242 001DEXTOSE

INJECTABLE; INJECTION

DEXTOSE 10% IN PLASTIC CONTAINER

AP B BRAUN 10GM/100ML N18046 001

AP B BRAUN 5% IN PLASTIC CONTAINER N18046 002

AP B BRAUN 5GM/100ML N18730 001

AP B BRAUN 50MG/ML N18730 002

AP B BRAUN 100MG/ML N18730 003

AP B BRAUN 200MG/ML N18730 004

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

INJECTABLE; INJECTION

ISOLYTE P IN DEXTOSE 5% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;31MG/100ML;130MG/100ML;
26MG/100ML;320MG/100ML N19873 001

JUN 10, 1993

DEXTOSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDEINJECTABLE; INJECTION
ISOLYTE H IN DEXTOSE 5% IN PLASTIC CONTAINER
B BRAUN 5GM/100ML;30MG/100ML;97MG/100ML;
220MG/100ML;140MG/100ML N19844 001

JUN 10, 1993

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

INJECTABLE; INJECTION

ISOLYTE M IN DEXTROSE 5% IN PLASTIC CONTAINER

MCGAN 5GM/100ML;10MG/100ML;17MG/100ML;
22MG/100ML;140MG/100ML N19843 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

AP MCGAN 5GM/100ML;10MG/100ML;17MG/100ML;
22MG/100ML;140MG/100ML
500MG/100ML N19843 001
AUG 09, 1993

ISOLYTE S W/ DEXTROSE 5% IN PLASTIC CONTAINER

AP B BRAUN 5GM/100ML;30MG/100ML;37MG/100ML;
370MG/100ML;530MG/100ML;
500MG/100ML N18274 001

AP MCGAN 5GM/100ML;10MG/100ML;17MG/100ML;
22MG/100ML;140MG/100ML
500MG/100ML N18274 001

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, 1982

AP MCGAN 5GM/100ML;75MG/100ML N18744 002
NOV 09, 1982

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

INJECTABLE; INJECTION

ISOLYTE M IN D

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

MCGAN 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

AP B BRAUN 10GM/100ML;900MG/100ML N18047 001
B BRAUN 10GM/100ML;900MG/100ML N18047 001

DEXTROSE 5% AND SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP B BRAUN 5GM/100ML;900MG/100ML N18026 001
AP MCGAN 5GM/100ML;900MG/100ML N18026 001

DIAZEPAM

INJECTABLE; INJECTION

DIAZEPAM

AP MCGAN 5MG/ML N72371 001
JAN 29, 1993

AP MCGAN 5MG/ML N72371 001
JAN 29, 1993

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

> ADD > AB ALCON 0.1% †
> ADD > AB VOLTAREN
> ADD > AB + CIBA 0.1%
> ADD >

N20009 001
MAY 04, 1998N20037 001
MAR 28, 1991

† SEE SECTION 1.4 OF INTRODUCTION

DICYCLOMINE HYDROCHLORIDE

TABLET; ORAL

DICYCLOMINE HCL

~~BC~~ ~~MYLAN~~ ~~200MG~~
 • 20MG

N75107 001
 JUL 29, 1995
 N84600 001
 JUL 29, 1995

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL
TIAZAC

BC + BIOVAIL
 > ADD >
 > DLT >
 > DLT >
 > ADD > +
 > ADD >

300MG

N20401 004
 SEP 11, 1995
 N20401 005
 SEP 11, 1995
 N20401 005
 SEP 11, 1995

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

AB ALTANA 0.05%

N75107 001
 MAR 30, 1998

AB + PSORCON DERMIK LABS 0.05%

N20205 001
 NOV 20, 1992
 N75107 001
 NOV 20, 1992

INJECTABLE; INJECTION
DILTIAZEM HCL

AP ABBOTT 5MG/ML
 AP TAYLOR PHARMA 5MG/ML

N74941 001
 APR 15, 1998
 N75086 001
 APR 09, 1998

DILTIAZEM HYDROCHLORIDECAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HCL

AB2 MYLAN 120MG

N75124 002
 MAR 18, 1998

AB2 180MG

N75124 003
 MAR 18, 1998

AB2 240MG

N75124 001
 MAR 18, 1998

> DLT > BC TIAZAC
 > DLT > BC BIOVAIL
 > ADD > BC +
 > ADD > BC
 > DLT > BC
 > DLT > BC
 > ADD > BC +
 > ADD > BC
 > DLT > BC
 > DLT > BC
 > ADD > BC +.
 > ADD > BC
 > DLT > BC
 > DLT >

N75124 001
 SEP 11, 1995
 N20401 001
 SEP 11, 1995
 N20401 002
 SEP 11, 1995
 N20401 003
 SEP 11, 1995
 N20401 004
 SEP 11, 1995

DIPHENHYDRAMINE HYDROCHLORIDEELIXIR; ORAL
DIPHENHYDRAMINE HCL

BC THERAPEUTICS 12.5MG/5ML
 • 12.5MG/5ML

N75237 001
 JAN 25, 1998
 N83237 001
 JAN 25, 1998

DIPYRIDAMOLEINJECTABLE; INJECTION
DIPYRIDAMOLE

AP BEDFORD 5MG/ML

N74939 001
 APR 13, 1998

DOBUTAMINE HYDROCHLORIDEINJECTABLE; INJECTION
DOBUTAMINE HCL

AP MARSAM EQ 12.5MG BASE/ML
 AP EQ 12.5MG BASE/ML

N74279 001
 FEB 18, 1998
 N74995 001
 MAR 31, 1998

DORZOLAMIDE HYDROCHLORIDE; TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC
COSOPT
+ MERCK
EQ 2% BASE; EQ 0.5% BASE N20869 001
APR 07, 1998

DOXEPIN HYDROCHLORIDE

CAPSULE; ORAL
DOXEPIN HCL
ROYAL LABS
AB N72985 001
N72986 001
N72987 001
MAR 29, 1991
AB WATSON LABS EQ 10MG BASE
N72985 001
MAR 29, 1991
AB EQ 25MG BASE
N72986 001
MAR 29, 1991
AB EQ 50MG BASE
N72987 001
MAR 29, 1991

DOXORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
RUBEX
AP BRISTOL MYERS 100MG/VIAL
N62925 001
APR 13, 1989
100MG/VIAL
N62926 001
APR 13, 1989
AP BRISTOL MYERS SQUIBB 10MG/VIAL
N62926 001
APR 13, 1989
AP 50MG/VIAL
N62926 002
APR 13, 1989
100MG/VIAL
N62926 003
APR 13, 1989

EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION
EDROPHONIUM CHLORIDE
AP ABBOTT 10MG/ML
N40131 001
FEB 24, 1998

ENCAINIDE HYDROCHLORIDE

CAPSULE; ORAL
MERCK
BRISTOL MYERS SQUIBB 25MG
35MG
25MG
35MG

N18981 001
N18981 002
N18981 003
N18981 004
N18981 005
DEC 24, 1986
DEC 24, 1986

ENOXAPARIN SODIUM

INJECTABLE; INJECTION
LOVENOX
+ RHONE POULENC RORER 40MG/0.4ML
60MG/0.6ML
80MG/0.8ML
100MG/ML

N20164 002
JAN 30, 1998
N20164 003
MAR 27, 1998
N20164 004
MAR 27, 1998
N20164 005
MAR 27, 1998

EPTIFIBATIDE

> ADD >
> ADD > INJECTABLE; INJECTION
> ADD > INTEGRILIN
+ COR 75MG/100ML
> ADD > + 2MG/ML
> ADD >

N20718 002
MAY 18, 1998
N20718 001
MAY 18, 1998

ERYTHROMYCIN

OINTMENT; OPHTHALMIC
ERYTHROMYCIN
AP ADV 10MG/ML
AT AKORN 0.5%
OINTMENT; TOPICAL
ACNE-MYCIN
AT GENE-LAB 2%

N64030 001
JUL 18, 1996
N64030 002
JUL 18, 1996

FENFLURAMINE HYDROCHLORIDE

~~TRIADYL~~ 20MG
POSGRAN
+ ROERIG
●
20MG

N16618 001

FENOFIBRATE

CAPSULE; ORAL
LIPIDIL
● ABBOTT 100MG
● LABS POSGRAN 300MG
TRICOR (MICRONIZED)
+ ABBOTT 67MG

N19304 001
DEC 31, 1993
N19304 002
FEB 09, 1998

FENTANYL CITRATE

INJECTABLE; INJECTION

AP ~~ANESTH~~
AP + ~~ELKINS SINK~~
FENTANYL CITRATE PRESERVATIVE FREE
AP ABBOTT EQ 0.05MG BASE/ML
AP + ELKINS SINKN EQ 0.05MG BASE/ML
AP MARSAM EQ 0.05MG BASE/ML
SUBLIMASE
AP + JANSSEN EQ 0.05MG BASE/ML
SUBLIMASE PRESERVATIVE FREE
AP + JANSSEN EQ 0.05MG BASE/ML

N17286 001
SEP 24, 1991
N19101 001
JUL 11, 1984
N74917 001
FEB 03, 1998
N16619 001

FLOSEQUINAN

TABLET; ORAL
PROCTAL
KING PHARMS 20MG

N16619 002
DEC 10, 1993

FLOSEQUINAN

~~TRIADYL~~
●
20MG
●
50MG
● 75MG
● 100MG

~~TRIADYL~~
N19960 001
DEC 30, 1992
N19960 002
DEC 30, 1992
N19960 003
DEC 30, 1992

FLUOROURACIL

INJECTABLE; INJECTION
ADRUCIL

AP ~~FLUOROURACIL INJECTION~~
AP + 50MG/ML

~~FLUOROURACIL INJECTION~~
N81225 001
AUG 28, 1991

FLUPHENAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
FLUPHENAZINE DECANOATE

AO KING PHARMS 25MG/ML

N74966 001
APR 16, 1998

FLURANDRENOLIDE; NEOMYCIN SULFATE

~~CREME TOPICAL~~
* KELLY 0.05%;EQ 3.5MG BASE/GM
● 0.05%;EQ 3.5MG BASE/GM
N50346 001

~~CREME TOPICAL~~
* KELLY 0.05%;EQ 3.5MG BASE/GM
● 0.05%;EQ 3.5MG BASE/GM
N50345 001

FLUVOXAMINE MALEATE

TABLET; ORAL

LUVOX
• HOFFMAN

25MG

N20243 001

DEC 05, 1994
GEMFIBROZIL

CAPSULE; ORAL

LOPID

• PARKE DAVIS

300MG

N18422 004

N18422 001

N18422 002

TABLET; ORAL

LOPID

AB • PARKE DAVIS

600MG

NOV 20, 1986

N18422 003

NOV 20, 1986
GENTAMICIN SULFATE

INJECTABLE; INJECTION

GENTAMICIN SULFATE IN SODIUM CHLORIDE 0.9% IN PLASTIC

CONTAINER

AP B BRAUN

EQ 40MG BASE/100ML

N62814 008

AP

EQ 60MG BASE/100ML

N62814 009

AP

EQ 70MG BASE/100ML

N62814 010

AP

EQ 0.8MG BASE/ML

N62814 001

AP

EQ 80MG BASE/100ML

N62814 011

AP

EQ 90MG BASE/100ML

N62814 012

AP

EQ 100MG BASE/100ML

N62814 013

AP

EQ 1.2MG BASE/ML

N62814 002

AUG 28, 1987

IOVERSOL

INJECTABLE; INJECTION
OPTIRAY 240
+ MALLINCKRODT 514
> ADD >
> ADD >

OPTIRAY 320
+ MALLINCKRODT 684
OPTIRAY 350
+ MALLINCKRODT 744

N20923 001
MAY 28, 1998
N20923 002
MAY 29, 1998
N20923 003
MAY 28, 1998

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL
WYETH AYERST 33000
100MG
150MG

FEB 08, 1995
N19816 003
FEB 08, 1995
N19816 002
FEB 08, 1995

IPRATROPIUM BROMIDE

AEROSOL, METERED; INHALATION
ATROVENT
BOHRINGER INGELHEIM 0.018MG/INH
+ 0.018MG/INH

N19085 001
DEC 29, 1986
N19085 001
DEC 29, 1986

ISOSULFAN BLUE

INJECTABLE; INJECTION
LYMPHAZURIN
+ HIRSCH INDUS 17
+ US SURGCL 18

N18310 001

KETAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

KETALAR
+ PARKE DAVIS
AP + PARKADEL
AP +
AP + PARKADELE
AP +

N16812 002
N16812 003
N16812 001
N16812 002
N16812 003
N16812 001

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL
+ WYETH AYERST 100MG

N19816 003
MAY 28, 1998

LEPIRUDIN

INJECTABLE; INJECTION
REFLUDAN
+ HOECHST MARION RSSL 50MG/VIAL

N20807 001
MAR 06, 1998

LIDOCAINE; PRilocaine

DISC; TOPICAL
ENLA
+ ASTRA 2.5%; 2.5%

N20962 001
FEB 04, 1998

LORATADINE

> DLT >
> DLT >
> DLT >
> DLT >

TABLET; ORAL
CLARITIN REDITABS
SCHERING 10

FEB 23, 1996

> ADD >
> ADD >
> ADD >

TABLET, ORALLY DISINTEGRATING; ORAL
CLARITIN REDITABS
+ SCHERING 10MG

N20704 001
DEC 23, 1996

LORAZEPAM

TABLET; ORAL
LORAZEPAM
WONTEX LABS 10MG

OCT 22, 1995
OCT 22, 1995
OCT 22, 1995

LORAZEPAN

TABLET; ORAL

LORAZEPAN

<u>AB</u>	WATSON LABS	<u>2MG</u>
<u>AB</u>	NATSON LABS	<u>0.5MG</u>
<u>AB</u>		<u>1MG</u>
<u>AB</u>		<u>2MG</u>

M72925 001
M72926 001
OCT 31, 1991
M72927 001
OCT 31, 1991
M72928 001
OCT 31, 1991

LOTEPREDNOL ETABONATE

SUSPENSION/DROPS; OPHTHALMIC

ALREX

+ PHARMOS	0.2t
<u>LOTEMAX</u>	
+ PHARMOS	0.5t

N20803 001
MAR 09, 1998
N20583 001
MAR 09, 1998
N20841 001
MAR 09, 1998

LOXAPINE HYDROCHLORIDE

CONCENTRATE; ORAL

LOXITANE C

+ COCKSYS	EQ 25MG BASE/ML
+ WATSON LABS	EQ 25MG BASE/ML
<u>INJECTABLE; INJECTION</u>	
<u>LOXITANE IM</u>	

M72925 001
N17658 001
N18039 001
N18039 001

LOXAPINE SUCCINATE

CAPSULE; ORAL

LOXITANE

<u>AB</u>	COCKSYS	<u>EQ 5MG BASE</u>
<u>AB</u>		<u>EQ 10MG BASE</u>
<u>AB</u>		<u>EQ 25MG BASE</u>
<u>AB</u>	WATSON LABS	<u>EQ 5MG BASE</u>

M72925 001
M72925 001
M72925 001
M72925 001
M72925 001

LOXAPINE SUCCINATE

CAPSULE; ORAL

LOXITANE

<u>AB</u>	WATSON LABS	<u>EQ 10MG BASE</u>
<u>AB</u>		<u>EQ 25MG BASE</u>

N17525 002
N17525 003
N17525 004

TABLET; ORAL

LOXITANE

<u>AB</u>	COCKSYS	<u>EQ 10MG BASE</u>
<u>AB</u>		<u>EQ 25MG BASE</u>
<u>AB</u>		<u>EQ 50MG BASE</u>
<u>AB</u>	WATSON LABS	<u>EQ 10MG BASE</u>

N17525 005
N17525 006
N17525 007
N17525 008

MAFENIDE ACETATE

CREAM; TOPICAL

SULFAMYLON

<u>AB</u>	BERTEK PHARMS	<u>EQ 85MG BASE/GM</u>
<u>AB</u>		<u>EQ 165MG BASE/GM</u>

N16763 001
N16763 002

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

INJECTABLE; INJECTION

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

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

INJECTABLE; INJECTION

<u>ISOLYTE S IN PLASTIC CONTAINER</u>	<u>AP B BRAUN</u>	<u>30MG/100ML; 37MG/100ML; 370MG/100ML;</u>
		<u>530MG/100ML; 500MG/100ML</u>

N18252 001

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATEINJECTABLE; INJECTION
ISOLYTE 5 IN PLASTIC CONTAINER

AP B BRAUN 30MG/100ML;37MG/100ML;370MG/100ML;
530MG/100ML;500MG/100ML N19711 001
SEP 29, 1989

AP MCGRAW 10MG/100ML;17MG/100ML;170MG/100ML;
130MG/100ML;110MG/100ML N19711 001
10MG/100ML;17MG/100ML;170MG/100ML;
130MG/100ML;110MG/100ML N19711 001
SEP 29, 1989

MALATHIONLOTION; TOPICAL

OVIDE
• GEIGER 0.5%
N18613 001
AUG 02, 1982

• MEDICIS 0.5%
N18613 001
AUG 02, 1982

MANNITOLINJECTABLE; INJECTIONMANNITOL 10% IN PLASTIC CONTAINER

AP B BRAUN 10GM/100ML N20006 002
JUL 26, 1993

AP MCGRAW 10GM/100ML N20006 002
JUL 26, 1993

MANNITOL 15% IN PLASTIC CONTAINER

AP B BRAUN 15GM/100ML N20006 003
JUL 26, 1993

AP MCGRAW 15GM/100ML N20006 003
JUL 26, 1993

MANNITOL 20%

AP B BRAUN 20GM/100ML N14738 001
MCGRAW 20GM/100ML N14738 001

MANNITOL 20% IN PLASTIC CONTAINER

AP B BRAUN 20GM/100ML N20006 004
JUL 26, 1993

AP MCGRAW 20GM/100ML N20006 004
JUL 26, 1993

MANNITOL 5% IN PLASTIC CONTAINER

AP B BRAUN 5GM/100ML N20006 001
JUL 26, 1993

MANNITOLINJECTABLE; INJECTION

AP B BRAUN 5GM/100ML N20006 001
JUL 26, 1993

SOLUTION; IRRIGATION
RESECTISOL IN PLASTIC CONTAINER

B BRAUN 5GM/100ML N16772 002
MCGRAW 5GM/100ML N16772 002

MECAMYLAMINE HYDROCHLORIDETABLET; ORALINVERSINE

+ LAYTON 2.5MG
N10251 001
N10251 002

MEGESTROL ACETATETABLET; ORALMEGESTROL ACETATE

AB PHARMACHEMIE 40MG N74745 001
FEB 27, 1998

MEPERIDINE HYDROCHLORIDETABLET; ORALMEPERIDINE HCL

AA ROYCE LABS 50MG N40186 001
JUN 30, 1997

AA WATSON LABS 50MG N40186 001
JUN 30, 1997

MESTRANOL; NORETHINDRONETABLET; ORAL-21NORETHIN 1/50M-21

AB ROBERTS LABS 0.05MG/1MG N71539 001
APR 12, 1988

AB SEARLE 0.05MG/1MG N71539 001
APR 12, 1988

MESTRANOL; NORETHINDRONETABLET; ORAL-28
NORETHIN 1/50M-28

AB ROBERTS LABS 0.05MG/1.0MG

N71540 001
APR 12, 1998
N71540 001
APR 12, 1998

AB SEARLE 0.05MG/1.0MG

METHADONE HYDROCHLORIDECONCENTRATE; ORAL
METHADONE HCL

AA ROXANE 10MG/ML

N40180 001
APR 30, 1998TABLET; ORAL
METHADONE HCL> ADD > AA EON 5MG
> ADD >
> ADD > AA 10MG
> ADD >N40241 001
MAY 29, 1998
N40241 002
MAY 29, 1998TABLET, DISPERSIBLE; ORAL
METHADONE HCL

AA EON 40MG

N75082 001
MAR 25, 1998METHOCARBAMOLINJECTABLE; INJECTION
METHOCARBAMOL

AP MARSAN 100MG/ML

N79849 001
DEC 27, 1991
N89849 001
DEC 27, 1991METOCLOPRAMILE HYDROCHLORIDETABLET; ORAL
METOCLOPRAMIDE HCL

AB INVAMED [REDACTED]

N77436 001
APR 12, 1998
N77436 001
FEB 03, 1997METOCLOPRAMIDE HYDROCHLORIDETABLET; ORAL
METOCLOPRAMIDE HCL• INVAMED EQ 5MG BASE
EQ 10MG BASEN72436 001
JUN 22, 1999
N70850 001
FEB 03, 1997MEXILETINE HYDROCHLORIDECAPSULE; ORAL
MEXILETINE HCL

AB DANBURY PHARMA 150MG

N74865 001
APR 13, 1998
N74865 002
APR 13, 1998
N74865 003
APR 13, 1998AB 200MG
AB 250MGMITOMYCININJECTABLE; INJECTION
MITOMYCINAP SUPERGEN 5MG/VIAL
AP 20MG/VIALN64144 001
APR 30, 1998
N64144 002
APR 30, 1998MONTELUKAST SODIUMTABLET; ORAL
SINGULAR
+ MERCK

EQ 10MG BASE

N20829 002
FEB 20, 1998TABLET, CHEWABLE; ORAL
SINGULAIR
+ MERCK

EQ 5MG BASE

N20830 001
FEB 20, 1998

NALBUPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

NALBUPHINE HCL

AP KING PHARMS 10MG/ML

N74471 001
MAR 19, 1998
N74471 002
MAR 19, 1998NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

> DLT > AP Abbott 0.4MG/ML

N70172 001
SEP 24, 1986NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDESAB ROYCE LABS EQ 250MG BASE
EQ 50MG BASEN74480 001
JUN 11, 1997AB WATSON LABS EQ 0.5MG BASE;
EQ 50MG BASEN74736 001
JAN 21, 1997NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HCL> ADD > AB BARR 50MG
> ADD > REVIA
> ADD > AB + DUPONT MERCK 50MG
> ADD >N74918 001
MAY 08, 1998
N18932 001
NOV 20, 1984NAPROXENTABLET, DELAYED RELEASE; ORAL
EC-NAPROSYN

AB + SYNTEX 375MG

N20067 002
OCT 14, 1994NAPROXENTABLET, DELAYED RELEASE; ORAL
EC-NAPROSYN

AB + SYNTEX 500MG

N20067 003
OCT 14, 1994

AB NAPROXEN INVAMED 375MG

M75061 001
FEB 18, 1993

AB 500MG

M75061 002
FEB 18, 1993

AB PUREPAC PHARM 375MG

M74936 001
FEB 24, 1998

AB 500MG

M74936 002
FEB 24, 1998NAPROXEN SODIUMTABLET; ORAL
NAPROXEN SODIUM

AB AL HIKMA EQ 250MG BASE

N74480 002
FEB 18, 1998NARatriptan Hydrochloride

TABLET; ORAL

AMERGE GLAXO WELLCOME

EQ 1MG BASE

N20763 002
FEB 10, 1998

+ EQ 2.5MG BASE

N20763 001
FEB 10, 1998NEOMYCIN SULFATE

TABLET; ORAL

NEOMYCIN SULFATE

TEVA EQ 350MG BASE

N60304 001
N60304 001

+ EQ 350MG BASE

NEOMYCIN SULFATE; POLYMYXIN B SULFATESOLUTION; IRRIGATION
NEOSPORIN G.U. IRRIGANT

AB CHURG MEDICINE

N60787 001
N60787 001

NITROGLYCERIN

FILM, EXTENDED RELEASE; TRANSDERMAL
TRANSDERM-NITRO

~~BB~~ + NOVARTIS 03500/NN

N10140 001
FEB 27, 1998

PARICALCITOL

INJECTABLE; INJECTION
ZEMPLAR

+ ABBOTT 0.005MG/ML

N20819 001
APR 17, 1998

NORETHINDRONE

TABLET; ORAL
NOR-QD
+ SEARLE 0.35MG
+ WATSON LABS 0.35MG

N17050 001
N17060 001

PAROMONYCIN SULFATE

CAPSULE; ORAL
HUMATIN
~~AB~~ + PARKE DAVIS 50 250MG BASE
AB + PARKEDALE 50 250MG BASE

50 250MG BASE
50 250MG BASE

N60521 001
N60521 001
N60521 001
N62310 001

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
PRILOSEC
+ ASTRA MERCK 40MG

N19810 002
JAN 15, 1998

PENTOSAN POLYSULFATE SODIUM

CAPSULE; ORAL
ELMIRON
+ ALZA 100MG
+ BAKER NORTON 100MG

N20193 001
SEP 26, 1996
N20193 001
SEP 26, 1996

OXYBUTYNIN CHLORIDE

SYRUP; ORAL
DITROPAN
~~AA~~ + ALZA 5MG/5ML
~~AA~~ + HOECHST MARION RSSL 5MG/5ML

N18211 001
N18211 001

PERMETHRIN

CREAM; TOPICAL
ELIMITE
~~AB~~ + ALLERGAN 5%
~~AB~~ PERMETHRIN
ALPHARMA 5%

N19855 001
AUG 25, 1989
N74806 001
JAN 23, 1998

OXYTOCIN

INJECTABLE; INJECTION
PITOCIN
~~AP~~ + KING PHARMS 10 USP UNITS/ML
~~AP~~ + PARKEDALE 10 USP UNITS/ML

N18261 001
N18261 001

PHENAZOPYRIDINE HYDROCHLORIDE; SULFISOXAZOLE

TABLET; ORAL
AEO GANTRISIN
+ ROCHE 50MG;500MG
+ 50MG;500MG

N18258 001
AUG 31, 1990
N19358 001
AUG 31, 1990

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

PHENTERMINE HCL

> DLT > AB EON 37.5MG N88414 001
> DLT > @ 37.5MG OCT 19, 1983
> ADD > @ N88414 001
> ADD > OCT 19, 1983

TABLET; ORAL

PHENTERMINE HCL

> DLT > + EON 30MG N88605 001
> DLT > @ 30MG SEP 28, 1987
> ADD > @ N88605 001
> ADD > SEP 28, 1987

PHENTOLAMINE MESYLATE

INJECTABLE; INJECTION

PHENTOLAMINE MESYLATE

AP BEDFORD 5MG/VIAL N40235 001
AP REGITINE + NOVARTIS 5MG/VIAL NO8278 003

PINDOLOL

TABLET; ORAL

PINDOLOL

AB PUREPAC PHARM 5MG N74125 001
AB 10MG N74125 002
@ 5MG N74125 001
@ 10MG N74125 002
AB ROYCE LABS 5MG N74437 001
AB 10MG N74437 002
AB WATSON LABS 5MG FEB 27, 1995
AB 10MG N74437 001
FEB 27, 1995
N74437 002
FEB 27, 1995

PIPERACILLIN SODIUM; TAZOBACTAM SODIUM

INJECTABLE; INJECTION
ZOSYN IN PLASTIC CONTAINER
+ LEDERLE EQ 40MG BASE/ML;
EQ 5MG BASE/ML N50750 001
FEB 24, 1998
+ EQ 4GM BASE/100ML;
EQ 500MG BASE/100ML N50750 003
FEB 24, 1998
+ EQ 60MG BASE/ML;
EQ 7.5MG BASE/ML N50750 002
FEB 24, 1998

PIROXICAM

CAPSULE; ORAL

PIROXICAM

AB ROYCE LABS 10MG N74460 001
AB 20MG N74460 002
AP WATSON LABS 10MG N74460 001
AB 20MG N74460 002
SEP 29, 1995
SEP 29, 1995
SEP 29, 1995
SEP 29, 1995

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

POWDER FOR RECONSTITUTION; ORAL

AB INVAKO 215GM/BOT;2.97GM/BOT;6.74GM/BOT;
215GM/BOT;2.97GM/BOT;6.74GM/BOT N73098 001
AUG 31, 1993
@ 236GM/BOT;2.97GM/BOT;6.74GM/BOT
5.86GM/BOT;22.74GM/BOT N73098 001
AUG 31, 1993

POLYMYXIN B SULFATE

INJECTABLE; INJECTION

AB AEROBOPEN 500,000 U BASE/VIAL N62036 002
@ GLAXO WELLCOOME 500,000 U BASE/VIAL N62036 001
AB POLYMYXIN B SULFATE 500,000 U BASE/VIAL N62036 002
PEPSICO

POLYMYXIN B SULFATE

INJECTABLE; INJECTION

POLYMYXIN B SULFATE

AP + PFIZER EQ 500,000 U BASE/VIAL N60716 001
 POWDER; FOR RX COMPOUNDING
POLY-RX
 > DLT > AA PHARMA TEK 100,000,000 UNITS/BOT N61578 001
 > ADD > + 100,000,000 UNITS/BOT N61578 001
 > DLT > AA POLYMYXIN B SULFATE
 > DLT > AA PADDICK 100,000,000 UNITS/BOT N62489 001
 > DLT > AA 100,000,000 UNITS/BOT N62455 001
 > ADD > @ JUL 27, 1983
 > ADD > @ JUL 27, 1983

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
 • MCGAN 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
 • MCGAN 300MG/100ML;900MG/100ML N18722 004
 NOV 09, 1982

POLYMYXIN B SULFATE; TRIMETHOPRIM SULFATE

SOLUTION/DROPS; OPHTHALMIC
TRIMETHOPRIM SULFATE AND POLYMYXIN B SULFATE
AT ALCON 10,000 UNITS/ML
EQ 1MG BASE/ML N64211 001
 APR 13, 1998

PRAMIPEXOLE DIHYDROCHLORIDE

TABLET; ORAL
MIRAPEX
 PHARMACIA AND UPJOHN 0.5MG

N20667 006
 FEB 12, 1998

POTASSIUM CHLORIDE

INJECTABLE; INJECTION
POTASSIUM CHLORIDE

AP B BRAUN 2MEQ/ML N05870 001
AP MCGAN 2MEQ/ML N05870 001

PREDNISOLONE

SYRUP; ORAL
PRE-PRED
 > ADD > AA WE PHARMS 15MG/5ML N40192 001
 MAY 28, 1998
PRELONE
 > ADD > AA + MURO 15MG/5ML N89081 001
 FEB 04, 1986

POTASSIUM CHLORIDE; SODIUM CHLORIDE

INJECTABLE; INJECTION
 SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.075% IN
 PLASTIC CONTAINER
 • B BRAUN 75MG/100ML;900MG/100ML N18722 001
 NOV 09, 1982
 • MCGAN 75MG/100ML;900MG/100ML N18722 001
 NOV 09, 1982
 SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE 0.15% IN
 PLASTIC CONTAINER
 • B BRAUN 150MG/100ML;900MG/100ML N18722 002
 NOV 09, 1982
 • MCGAN 150MG/100ML;900MG/100ML N18722 002
 NOV 09, 1982

TABLET; ORAL
PREDNISOLONE
 BX DAWBURY PHARMA 5MG N80394 001
 BX + GENEVA PHARMS 5MG N80354 001
 BX + GENEVA PHARMS 5MG N80331 001
 BX + GENEVA PHARMS 5MG N80339 001

PRIMIDONE

SUSPENSION; ORAL
MY SOLINE
 + ELAN PHARMA 250MG/5ML N10401 001
 + NYETH AYERST 150MG/5ML N10401 001

PRIMIDONE

TABLET; ORAL
MY SOLINE
AB + ELAN PHARMA 250MG N09170 002
+ 50MG N09170 003
AB + WYETH AYERST 250MG N09170 002
+ 50MG N09170 003

PROCAINAMIDE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PROCAINAMIDE HCL
AB INVAMED 500MG N89284 001 JUN 23, 1986
@ 500MG N89284 001 JUN 23, 1986
DLT AB SIDMAR LABS NJ 250MG N88958 001 DEC 02, 1985
DLT AB @ 250MG N88958 001 DEC 02, 1985
ADD PROCAN SR
AB PARKE DAVIS 500MG N886065 001 N87510 001
AB 750MG N886065 001 N87510 001
AB + 1GM N886489 001 APR 01, 1982
AB + PARKADEL 500MG N886065 001 N87510 001
AB + 750MG N886489 001 APR 01, 1982
AB + 1GM N886489 001 JAN 16, 1985

PROCHLORPERAZINE EDISYLATE

INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE
AP MARSAN EQ 5MG BASE/ML N89675 001
@ EQ 5MG BASE/ML DEC 05, 1988
N89675 001 DEC 05, 1988
DEC 05, 1988
N89675 001 DEC 05, 1988

PROCHLORPERAZINE MALATE

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

PROGESTERONE

CAPSULE; ORAL
PROMETRUM
+ SCHERING PLOUGH 100MG
> ADD >
> ADD >
> ADD >
> ADD >

N19781 001
MAY 14, 1998

PROMETHAZINE HYDROCHLORIDE

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

PROPOXYPHENE HYDROCHLORIDE

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

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL
PROPRANOLOL HCL
AB INVAMED 100MG 171688 001
JUN 23, 1988

PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

PROPRANOLOL HCL

<u>AB</u>	<u>INNOMED</u>	<u>20MG</u>	<u>N71687 001</u>
<u>AB</u>		<u>40MG</u>	<u>JUL 05, 1988</u>
<u>AB</u>		<u>60MG</u>	<u>N71688 001</u>
<u>AB</u>		<u>80MG</u>	<u>N71689 001</u>
<u>AB</u>		<u>10MG</u>	<u>N71687 001</u>
		<u>10MG</u>	<u>JUL 05, 1988</u>
		<u>20MG</u>	<u>N71687 001</u>
		<u>40MG</u>	<u>JUL 05, 1988</u>
		<u>60MG</u>	<u>N71688 001</u>
		<u>80MG</u>	<u>JUL 05, 1988</u>
		<u>90MG</u>	<u>N71689 001</u>

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

<u>AB</u>	<u>PUREPAC PHARM</u>	<u>200MG</u>	<u>N74003 001</u>
		<u>200MG</u>	<u>N84003 001</u>

RANITIDINE HYDROCHLORIDE

SYRUP; ORAL

ZANTAC

GLAXO WELLCOMB

EQ 15MG BASE/ML+ EQ 15MG BASE/ML

<u>AB</u>	<u>RANBAXY</u>	<u>EQ 150MG BASE</u>	<u>N75000 001</u>
			<u>JAN 30, 1998</u>

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE HCLAB RANBAXY EQ 300MG BASEN75000 002
JAN 30, 1998RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

+ PROCTER AND GAMBLE 30MG

N20835 001
MAR 27, 1998SACROSIDASE

SOLUTION; ORAL

SUCRAID

+ ORPHAN MEDCL

8,500 IU/ML

N20772 001
APR 09, 1998SAQUINAVIR

CAPSULE; ORAL

FORTOVASE

+ ROCHE

NO 300MG BASE

N20828 001
NOV 07, 1997

+ 200MG

N20828 001
NOV 07, 1997SELEGILINE HYDROCHLORIDE

TABLET; ORAL

SELEGILINE HCLAB ESI LEDERLE 5MGN74641 001
AUG 02, 1996AB LEDERLE 5MGN74641 001
AUG 02, 1996AB STASON 5MGN74512 001
APR 30, 1998

SILDENAFIL CITRATE

TABLET; ORAL

VIAGRA

PFIZER

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

SODIUM CHLORIDE

INJECTABLE; INJECTION

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

<u>AP</u>	B BRAUN	<u>450MG/100ML</u>
		N19635 001
	©	450MG/100ML
<u>AP</u>	MCGRAW	<u>11.87GM/100ML</u>
		N18184 001
	©	<u>450MG/100ML</u>

<u>AP</u>	B BRAUN	<u>900MG/100ML</u>
<u>AP</u>		<u>900MG/100ML</u>
<u>AP</u>	MCGRAW	<u>900MG/100ML</u>
<u>AP</u>		<u>900MG/100ML</u>

© B BRAUN	<u>SODIUM CHLORIDE 3% IN PLASTIC CONTAINER</u>	3GM/100ML	N19635 003
© MCGRAW		3GM/100ML	MAR 09, 1988
© B BRAUN	<u>SODIUM CHLORIDE 5% IN PLASTIC CONTAINER</u>	5GM/100ML	N19635 004
© MCGRAW		5GM/100ML	MAR 09, 1988

SODIUM LACTATE

INJECTABLE; INJECTION

SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER

© B BRAUN	1.87GM/100ML	N18186 001
© MCGRAW	1.87GM/100ML	N18186 002
<u>AP</u>	<u>SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER</u>	<u>1.87GM/100ML</u>
<u>AP</u>		N20004 001

APR 21, 1992

SODIUM LACTATE

INJECTABLE; INJECTION

SODIUM LACTATE 1/6 MOLAR IN PLASTIC CONTAINER

<u>AP</u>		<u>1.87GM/100ML</u>	N18084 001
			APR 21, 1992

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL

KAYEXALATE

<u>AA</u>		<u>133.3GM/BOT</u>	N11287 001
<u>AA</u>	•	<u>453.6GM/BOT</u>	
<u>AA</u>	KIONEX	<u>454GM/BOT</u>	N40029 001
	PADDOCK		FEB 06, 1998

SOTALOL HYDROCHLORIDE

TABLET; ORAL

BETAPACE

<u>AP</u>	•	<u>BERLEX LABS</u>	120MG	N19865 005
			160MG	APR 10, 1994
<u>AP</u>		> DLT >		N19865 002
<u>AP</u>	©	> DLT >		OCT 10, 1992
<u>AP</u>	MCGRAW	> DLT >		N19865 003
<u>AP</u>		> DLT >		OCT 30, 1992
		> ADD >		N19865 005
		> ADD >		APR 20, 1994
		> ADD >		N19865 C02
		> ADD >		OCT 30, 1992
		> ADD >		N19865 003
		> ADD >		OCT 30, 1992

SOYBEAN OIL

INJECTABLE; INJECTION

INTRALIPID 30%

<u>AP</u>	+	<u>PHARMACIA AND UPJOHN 30%</u>	N19942 001
			DEC 30, 1993
<u>AP</u>	+	<u>LIPOSYN III 30%</u>	M20181 001
		30%	JAN 13, 1998
<u>AP</u>	+	<u>NUTRILIPID 10%</u>	
<u>AP</u>	+	<u>B BRAUN</u>	
		10%	N19531 001
			MAY 28, 1993

SOYBEAN OIL

INJECTABLE; INJECTION

NUTRILIPID 10%

AP + MCCAW 10%

N19531 001

MAY 28, 1993

NUTRILIPID 20%

AP + B BRAUN 20%

N19531 002

MAY 28, 1993

AP + MCCAW 20%

N19531 002

MAY 28, 1993

STREPTOMYCIN SULFATE

INJECTABLE; INJECTION

STREPTOMYCIN SULFATE

> DLT >
> AED >PFIZER
EQ 1GM BASE/2.5ML
EQ 1GM BASE/2.5ML

N60111 001

N60111 001

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION

SUCOSTRINAP + APOTHECON
@ 20MG/ML
20MG/ML

N08847 001

N08847 001

SUFENTANIL CITRATE

INJECTABLE; INJECTION

SUFENTAAP + AKORN
@ EQ 0.05MG BASE/ML

N19050 001

MAY 04, 1993

AP + JANSSEN
@ EQ 0.05MG BASE/ML

N19050 001

MAY 04, 1993

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

SMZ-TMP

AB TEVA 200MG/5ML:40MG/5ML

N18812 001

JAN 28, 1993

AB TEVA SMZ-TMP PEDIATRIC 200MG/5ML:40MG/5ML

N18812 002

JUN 10, 1993

SULFAMETHOXAZOLE; TRIMETHOPRIM

SUSPENSION; ORAL

SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB TEVA 200MG/5ML:40MG/5ML

N18812 001

JAN 28, 1993

AB 200MG/5ML:40MG/5ML

N18812 002

JUN 10, 1993

TABLET; ORAL

SMZ-TMPAB TEVA 400MG; 80MG
800MG; 160MG

N18242 001

N18242 002

AB SULFAMETHOXAZOLE AND TRIMETHOPRIM
TEVA 400MG; 80MG
800MG; 160MG

N18242 001

N18242 002

SULFASALAZINE

TABLET; ORAL

SULFASALAZINE

AB SUPERPHARM 500MG

N89339 001

OCT 26, 1987

@ 500MG

N89339 001

OCT 26, 1987

TACRINE HYDROCHLORIDE

CAPSULE; ORAL

COGNEX

PARKE DAVIS EQ 10MG BASE

N20070 001

SEP 09, 1993

EQ 20MG BASE

N20070 002

SEP 09, 1993

EQ 30MG BASE

N20070 003

SEP 09, 1993

EQ 40MG BASE

N20070 004

SEP 09, 1993

PARKE DAVIS PHARMS EQ 10MG BASE

N20070 001

SEP 09, 1993

EQ 20MG BASE

N20070 002

SEP 09, 1993

EQ 30MG BASE

N20070 003

SEP 09, 1993

EQ 40MG BASE

N20070 004

SEP 09, 1993

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
 TECHNETIUM TC 99M ALBUMIN AGGREGATED KIT
 BS DRAXIMAGE N/A
 BS MERCK SHARP DOHME N/A

N17881 001
 DEC 30, 1987
 N17881 001
 DEC 30, 1987

TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION
 HEPATOLITE
 DUPONT N/A
 DUPONT MERCK N/A

N18467 001
 MAR 16, 1982
 N18467 001
 MAR 16, 1982

TECHNETIUM TC-99M GLUCEPTATE KIT

INJECTABLE; INJECTION
TECHNESCAN GLUCEPTATE
 AP DRAXIMAGE N/A
 AP MERCK SHARP DOHME N/A

N18272 001
 JAN 27, 1982
 N18272 001
 JAN 27, 1982

TECHNETIUM TC-99M LIDOFENIN KIT

INJECTABLE; INJECTION
 TECHNESCAN HIDA
 DRAXIMAGE N/A
 MERCK N/A

N18489 001
 OCT 31, 1986
 N18489 001
 OCT 31, 1986

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
TECHNESCAN MDP KIT
 AP DRAXIMAGE N/A
 AP MERCK SHARP DOHME N/A

N18035 001
 N18035 001

TECHNETIUM TC-99M PENTETATE KIT

INJECTABLE; INJECTION
DTPA
 AP DRAXIMAGE N/A
 AP MERCK N/A

N18511 001
 DEC 29, 1989
 N18511 001
 DEC 29, 1989

TECHNETIUM TC-99M SULFUR COLLOID KIT

SOLUTION; INJECTION, ORAL
TECHNETIUM SULFUR COLLOID
 AP CIS N/A
 @ N/A

N17858 001
 N17858 001

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
HYTRIN
 AB ABBOTT EQ 1MG BASE
 AB + EQ 2MG BASE
 AB EQ 5MG BASE
 AB EQ 10MG BASE

N20347 001
 DEC 14, 1994
 N20347 002
 DEC 14, 1994
 N20347 003
 DEC 14, 1994
 N20347 004
 DEC 14, 1994

TERAZOSIN HCL
 AB GENEVA PHARMS EQ 1MG BASE
 AB EQ 2MG BASE
 AB EQ 5MG BASE
 AB EQ 10MG BASE

N74823 001
 MAR 30, 1998
 N74823 002
 MAR 30, 1998
 N74823 003
 MAR 30, 1998
 N74823 004
 MAR 30, 1998

TERBINAFINE

GEL; TOPICAL
 LMISIL
 + NOVARTIS 1%

N20846 001
 APR 29, 1998

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM
BX + THERATECH 2.5MG/24HR

N20489 001
SEP 29, 1995
N20489 001
SEP 29, 1995

THEOPHYLLINE

CAPSULE; ORAL
ELIXOPHYLLIN
BX FOREST LABS 100MG
BX + 200MG
@ 100MG
@ 200MG

N85545 001
JUL 31, 1984
N83921 001
JUL 31, 1984
N85545 001
JUL 31, 1984
N83921 001
JUL 31, 1984

CAPSULE, EXTENDED RELEASE; ORAL
ELIXOPHYLLIN SR
BC FOREST LABS 125MG
BC 250MG
@ 125MG
@ 250MG

N86826 001
JAN 29, 1985
N86826 002
JAN 29, 1985
N86826 001
JAN 29, 1985
N86826 002
JAN 29, 1985

TABLET; ORAL
QUIBRON-T
> ADD > + MONARCH PHARMS 300MG
> ADD >
> DLT > + ROBERTS LABS 300MG
> DLT >

N88656 001
AUG 22, 1985
N88656 001
AUG 22, 1985

TABLET, EXTENDED RELEASE; ORAL
QUIBRON-T/SR
> DLT > BC KING PHARMS 300MG
> DLT >
> ADD > BC MONARCH PHARMS 300MG
> ADD >

N87563 001
JUN 21, 1983
N87563 001
JUN 21, 1983

THIAMYLAL SODIUM

INJECTABLE; INJECTION
SUBTAN
+ PARKE DAVIS
+ PARKADEL
@
@
@

1GM/VIAL
2GM/VIAL
10GM/VIAL
1GM/VIAL
5GM/VIAL
10GM/VIAL

N07600 001
N07600 005
N07600 009
N07600 003
N07600 005
N07600 009

THIORIDAZINE HYDROCHLORIDE

CONCENTRATE; ORAL
THIORIDAZINE HCL

> ADD > AA PHARM ASSOC 100MG/ML

N40213 001
MAY 29, 1998

> ADD >

TIROFIBAN HYDROCHLORIDE

> ADD > INJECTABLE; INJECTION
> ADD > AGGRASTAT
> ADD > + MERCK

EQ 0.05MG BASE/ML N20913 001
MAY 14, 1998

> ADD >

EQ 0.25MG BASE/ML N20912 001
MAY 14, 1998

> ADD >

TOLCAPONE

TABLET; ORAL
TASMAR
ROCHE 100MG

+ 200MG N20697 001
JAN 29, 1998

N20697 002
JAN 29, 1998

TOLTERODINE TARTRATE

TABLET; ORAL
DETROL
PHARMACIA AND UPJOHN 1MG

N20771 001
MAR 25, 1998
N20771 002
MAR 25, 1998

+ 2MG

TROGLITAZONE

TABLET; ORAL
REZULIN
 AB PARKE DAVIS PHARMS 400MG

N20720 002
 JAN 29, 1997

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

AT AKORN 14
 @ 14

N88447 001
 AUG 28, 1985
 N88447 001
 AUG 28, 1985

UROFOLLITROPIN

INJECTABLE; INTRAMUSCULAR
 FERTINEX
 + SERONO 75 IU/AMP N19415 002
 SEP 18, 1986
 + 150 IU/AMP N19415 003
 SEP 18, 1986
 METRODIN
 + SERONO 75 IU/AMP N19415 002
 SEP 18, 1986
 + 150 IU/AMP N19415 003
 SEP 18, 1986

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION
VERAPAMIL HCL

AP MARGAM 1.5MG/ML N72233 001
 FEB 26, 1993
 AP 2.5MG/ML N73485 001
 SEP 27, 1993
 @ 2.5MG/ML N72233 001
 FEB 26, 1993
 @ 2.5MG/ML N73485 001
 SEP 27, 1993

VIDARABINE

INJECTABLE; INJECTION

VIRA-A
 + PARKE DAVIS EQ 187.4MG BASE/ML
 + PARKDALE EQ 187.4MG BASE/ML

N50523 001
 N50523 001

OINTMENT; OPHTHALMIC

VIRA-A
 + PARKE DAVIS 3g
 + PARKDALE 3g

N50486 001
 N50486 001

WATER FOR INJECTION, STERILE

LIQUID; N/A
STERILE WATER FOR INJECTION IN PLASTIC CONTAINER

AP B BRAUN 100g N19633 001
 FEB 29, 1988
 AP MCGAW 100g N19633 001
 FEB 29, 1988

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
+ HOECHST MARION RSSL 80MG;20MG
80MG;20MG
+ 160MG;40MG
GAVISCON-2
+ HOECHST MARION RSSL 160MG;40MG

N18685 001
DEC 09, 1983
N18685 001
DEC 09, 1983
N18685 002
DEC 09, 1983
N18685 002
DEC 09, 1983

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

IBUPROFEN

SUSPENSION; ORAL
CHILDREN'S ADVIL-FLAVORED
+ WHITEHALL ROBINS 100MG/5ML
100MG/5ML

N20589 002
NOV 07, 1997
N20589 002
NOV 07, 1997

CHLORHEXIDINE GLUCONATE

SOLUTION; TOPICAL
CHG SCRUB
ECOLAB 48
HUNTINGTON LABS 64
CIDA-STAT
ECOLAB 28
HUNTINGTON LABS 28

N19258 002
JUL 22, 1986
N19258 002
JUL 22, 1986
N19258 001
JUL 22, 1986
N19258 001
JUL 22, 1986

SUSPENSION/DROPS; ORAL
PEDIATRIC ADVIL
+ WHITEHALL ROBINS 100MG/2.5ML

N20812 001
JAN 30, 1998

TABLET; ORAL
IBUPRIN
GIVONAK LABS NJ 200MG
+ 200MG

N71773 001
JUL 16, 1987
N71773 001
JUL 16, 1987

TABLET, CHEWABLE; ORAL
JUNIOR STRENGTH MOTRIN
MCNEIL 100MG

N20601 003
NOV 15, 1996
N20601 003
NOV 15, 1996

MICONAZOLE NITRATE

CREAM; VAGINAL
MONISTAT 3
+ ADVANCED CARE PRODS 48

N20827 001
MAR 30, 1998

CLOTRIMAZOLE

TABLET; VAGINAL
GYNIX
COPELY PHARM 100MG

N73249 001
FEB 13, 1998

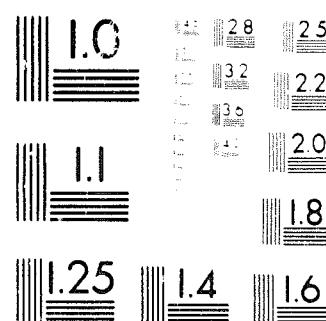
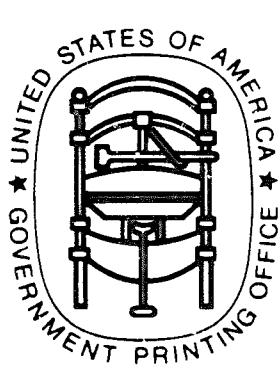
MINOXIDIL

SOLUTION; TOPICAL
MINOXIDIL (FOR MEN)
NU PHARM 28
MINOXIDIL (FOR WOMEN)
NU PHARM 28

N74924 001
APR 29, 1998
N74924 002
APR 29, 1998

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PAGE



NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL

NICOTROL

* NICOTROL

15MG/16HR

N20536 001

JUL 03, 1996

+ PHARMACIA AND UPJOHN 15MG/16HR

N20536 001

JUL 03, 1996

RANITIDINE HYDROCHLORIDE

TABLET, EFFERVESCENT; ORAL

ZANTAC 75

+ GLAXO WELLCOME

EQ 75MG BASE

N20745 001

FEB 26, 1998

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

CUMULATIVE SUPPLEMENT NUMBER 5 MAY '98

NO MAY 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 May 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
Aitretinoin 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
Aldesleukin TN= Proleukin	Treatment of metastatic melanoma.	Chiron Corporation 4560 Horton Street Emeryville, CA 94608 DD=09/10/1996 MA=01/09/1998
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

Orphan Product Designations and Approvals List
January 1998 through May 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
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-releasing factor, human TN= Xerecept	Treatment of peritumoral brain edema.	Neurobiological Technologies, Inc. 1387 Marina Way South Richmond, CA 94804 DD=04/06/1998
Dimethylsulfoxide TN=	Treatment of palmar-plantar erythrodysesthesia syndrome.	Cancer Technologies, Inc. 7301 East 22nd Street Suite 10E Tucson, AZ 85710 DD=04/06/1998

Orphan Product Designations and Approvals List
January 1998 through May 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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-diphosphate 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
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
Pentostatin TN=	Treatment of cutaneous T-cell lymphoma.	SuperGen, Inc. Two Annbel Lane, Suite 220 San Ramon, CA 94583 DD=03/27/1998
Phenylacetate TN=	For use as an adjunct to surgery, radiation therapy and chemotherapy for the treatment of patients with primary or	Targen Corporation 307 College Road East Princeton, NJ 08540 DD=03/06/1998

Orphan Product Designations and Approvals List
January 1998 through May 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
Recombinant humanized monoclonal antibody 5c8	Treatment of immune thrombocytopenic purpura.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/03/1998
Recombinant humanized monoclonal antibody 5c8	Treatment of systemic lupus erythematosus.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=02/18/1998
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= Sucraida	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.	Targon Corporation 307 College Road East Princeton, NJ 08540 DD=04/24/1998
TAK-603 TN=	Treatment of Crohn's disease.	TAP Holdings Inc. 2355 Waukegan Road Deerfield, IL 60015 DD=05/13/1998

Orphan Product Designations and Approvals List
January 1998 through May 1998

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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 Court, Sandyford Road Newcastle upon Tyne NE2 1XG England DD=05/12/1998
Thalidomide TN=	Treatment of primary brain malignancies.	EntreMed, Inc. 9610 Medical Center Drive, Suite 200 Rockville, MD 20850 DD=02/27/1998
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
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

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

NO MAY 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.

REFERENCES *NEW DOSING SCHEDULE*

- D-38** CONTINUOUS INFUSION AS AN ALTERNATE METHOD OF ADMINISTRATION
- D-39** 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..."
- D-40** ONCE-A-DAY DOSING REGIMEN
- D-41** 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

NEW INDICATION

- I-212** TREATMENT OF SYMPTOMS OF DRY MOUTH IN PATIENTS WITH SJOGREN'S SYNDROME
- I-213** TEMPORARY RELIEF OF PAIN AND PHOTOPHOBIA IN PATIENTS UNDERGOING CORNEAL REFRACTIVE SURGERY
- I-214** TREATMENT OF OSTEOPOROSIS
- I-215** PRE-PROCEDURAL APPLICATION TO ADULT MALE GENITAL SKIN PRIOR TO SITE-SPECIFIC SUBCUTANEOUS INFILTRATION WITH LIDOCAINE FOR THE REMOVAL OF GENITAL WARTS
- I-216** FOR THE LONG-TERM TWICE-DAILY (MORNING AND EVENING) ADMINISTRATION IN THE MAINTENANCE TREATMENT OF BRONCHOSPASM ASSOCIATED WITH COPD, INCLUDING CHRONIC BRONCHITIS AND EMPHYSEMA
- I-217** PREVENTION (DURING AND FOLLOWING HOSPITALIZATION) OF DEEP VEIN THROMBOSIS, WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY
- I-218** USE OF LIPITOR AS AN ADJUNCTIVE THERAPY TO DIET FOR THE TREATMENT OF PATIENTS WITH ELEVATED SERUM TRIGLYCERIDE LEVELS (FREDERICKSON TYPE IV)
- I-219** USE OF LIPITOR BY PATIENTS WITH PRIMARY DYSBETA LIPOPROTEINEMIA (FREDERICKSON TYPE III) WHO DO NOT RESPOND ADEQUATELY TO DIET
- I-220** TREATMENT OF EPISODIC HEARTBURN, ACID INDIGESTION AND SOUR STOMACH
- I-221** 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
- I-222** PREVENTION OF ISCHEMIC COMPLICATIONS OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION, WHEN CONCURRENTLY ADMINISTERED WITH ASPIRIN
- I-223** USE IN THE SYMPTOMATIC RELIEF OF RHINORRHEA ASSOCIATED WITH ALLERGIC AND NONALLERGIC PERENNIAL RHINITIS IN CHILDREN AGE 6-11 YEARS
- I-224** 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
- I-225** USE IN PATIENTS WITH PREVIOUS MI AND NORMAL CHOLESTEROL LEVELS, TO REDUCE RISK OF RECURRENT MI, MYOCARDIAL REVASCULARIZATION, AND CEREBROVASCULAR DISEASE EVENTS
- I-226** FIRST-LINE THERAPY FOR THE TREATMENT OF ADVANCED CARCINOMA OF THE OVARY IN COMBINATION WITH CISPLATIN
- I-227** SHORT-TERM TREATMENT OF SYMPTOMATIC GASTROESOPHAGEAL REFLUX DISEASE (GERD)

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

- 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

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 PARKINSON'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
- 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

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME		PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020802 001	ACETAMINOPHEN;EXCEDRIN (MIGRAINE)		5070877	DEC 10, 2008	U-116		
020059 001	ADENOSINE;ADENOSCAN		5731296	MAR 24, 2015	U-221		
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			
020420 001	ARBUTAMINE HYDROCHLORIDE;GENESA		5108363	APR 28, 2009	U-220		
			5234404	AUG 10, 2010	U-220		
			5395970	MAR 07, 2012			
>ADD>	020702 001	ATORVASTATIN CALCIUM;LIPITOR			I-218	JUL 10, 2001	
>ADD>	020702 002	ATORVASTATIN CALCIUM;LIPITOR			I-219	JUL 10, 2001	
>ADD>	020702 003	ATORVASTATIN CALCIUM;LIPITOR			I-218	JUL 10, 2001	
>ADD>	020702 003	ATORVASTATIN CALCIUM;LIPITOR			I-219	JUL 10, 2001	
>ADD>	020702 003	ATORVASTATIN CALCIUM;LIPITOR			I-218	JUL 10, 2001	
>ADD>	020702 003	ATORVASTATIN CALCIUM;LIPITOR			I-219	JUL 10, 2001	
>ADD>	020114 001	AZELASTINE HYDROCHLORIDE;ASTELIN	5164194	NOV 01, 2010	U-207		
	017573 001	BECLOMETHASONE DIPROPIONATE;VANCERIL	4364923	DEC 21, 1999			
	018521 001	BECLOMETHASONE DIPROPIONATE;VANCENASE	4364923	DEC 21, 1999			
	020486 001	BECLOMETHASONE DIPROPIONATE;VANCERIL DOUBLE STRENGTH	4364923	DEC 21, 1999			
	019408 001	BETAMETHASONE DIPROPIONATE;DIPROFENE	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>	020554 001	CALCIPOTRIENE;DOVONEX	4866048	DEC 29, 2007			
>ADD>	020611 001	CALCIPOTRIENE;DOVONEX	4866048	DEC 29, 2007			
	020313 002	CALCITONIN, SALMON;NIACALCIN	5733569	MAR 31, 2015	U-227		
>ADD>	020521 001	CALFACTANT;INFASURF				NCE	JUL 01, 2003
>ADD>	020838 001	CANDESARTAN CILEXETIL;ATACAND				NCE	JUN 04, 2003
>ADD>	020838 002	CANDESARTAN CILEXETIL;ATACAND	5703110	APR 18, 2011			
>ADD>	020838 002	CANDESARTAN CILEXETIL;ATACAND	5705517	APR 18, 2011			
			5196444	APR 18, 2011	U-3		
			5508297	FEB 24, 2014	U-3		
			5534534	JUL 09, 2013			
			5703110	APR 18, 2011			
			5705517	APR 18, 2011			
			5196444	APR 18, 2011	U-3		
			5508297	FEB 24, 2014	U-3		
			5534534	JUL 09, 2013			
			5703110	APR 18, 2011			
			5705517	APR 18, 2011			
			5196444	APR 18, 2011	U-3		
			5508297	FEB 24, 2014	U-3		
			5534534	JUL 09, 2013			
			5703110	APR 18, 2011			
			5705517	APR 18, 2011			
			5196444	APR 18, 2011	U-3		
			5508297	FEB 24, 2014	U-3		
			5534534	JUL 09, 2013			
			5703110	APR 18, 2011			
			5705517	APR 18, 2011			
			5196444	APR 18, 2011	U-3		
			5508297	FEB 24, 2014	U-3		
			5534534	JUL 09, 2013			
			5703110	APR 18, 2011			
			5705517	APR 18, 2011			
			5196444	APR 18, 2011	U-3		
			5508297	FEB 24, 2014	U-3		
			5534534	JUL 09, 2013			
020896 001	CAPECITABINE;XELODA					NCE	APR 30, 2003
020896 002	CAPECITABINE;XELODA					NCE	APR 30, 2003

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020712 001	CARBAMAZEPINE;CARBATROL	5326570	JUL 05, 2011	U-215		
	020712 002	CARBAMAZEPINE;CARBATROL	5326570	JUL 05, 2011	U-215		
>ADD>	020297 001	CARVEDILOL;COREG	5760069	JUN 07, 2015	U-233		
>ADD>	020297 002	CARVEDILOL;COREG	4503067	MAR 05, 2007	U-3		
>ADD>	020297 003	CARVEDILOL;COREG	5760069	JUN 07, 2015	U-233		
>ADD>	020297 004	CARVEDILOL;COREG	5760069	MAR 05, 2007	U-3		
>ADD>	020774 001	CHLORHEXIDINE GLUCONATE;PERIOCHIP	5760069	JUN 07, 2015	U-233		
>ADD>	020238 002	CIMETIDINE;TAGAMET HB				NP	MAY 15, 2001
	020369 001	CIPROFLOXACIN HYDROCHLORIDE;CILOXAN	4670444	JUN 02, 2004	U-223	D-41	JUN 05, 2001
	020805 001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO HC	4670444	DEC 09, 2003		NDF	MAR 30, 2001
	020780 001	CIPROFLOXACIN;CIPRO	4844902	FEB 11, 2008		NC	FEB 10, 2001
	020780 002	CIPROFLOXACIN;CIPRO	4670444	DEC 09, 2003			
	020839 001	CLOPIDOGREL BISULFATE;PLAVIX	4529596	JUL 05, 2003			
			4847265	FEB 12, 2008			
			5576328	JAN 31, 2014			
	017922 001	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
	017922 002	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
	017922 003	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
	018938 001	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
	018938 002	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013			
	019955 001	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013		I-40	MAR 25, 2001
	019955 002	DESNOPRESSIN ACETATE;DDAVP	5763407	DEC 23, 2013		I-40	MAR 25, 2001
>ADD>	020713 001	DESOGESTREL;MIRCETTE				NP	APR 22, 2001
	020037 001	DICLOFENAC SODIUM;VOLTAREN				I-213	FEB 25, 2001
>ADD>	020148 001	DINHYDROERGOTAMINE MESYLATE;MIGRALAN	4758423	JUL 31, 2001			
>ADD>			4462983	JUL 31, 2001	U-227		
>ADD>			5169849	DEC 08, 2009			
					U-227		
	020401 001	DILTIAZEN HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401 002	DILTIAZEN HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401 003	DILTIAZEN HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401 004	DILTIAZEN HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	020401 005	DILTIAZEN HYDROCHLORIDE;TIAZAC				I-133	JAN 30, 2001
	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
	020738 004	EPROSARTAN MESYLATE;TEVETEN	5185351	FEB 09, 2010	U-3		
	020738 005	EPROSARTAN MESYLATE;TEVETEN	5185351	FEB 09, 2010	U-3		
	020718 001	EPTIFIBATIDE;INTEGRILIN				NCE	MAY 18, 2003
	020718 002	EPTIFIBATIDE;INTEGRILIN				NCE	MAY 18, 2003
	020375 003	ESTRADIOL;CLIMARA	5223261	JUN 29, 2010			
	083209 001	ESTROGENS, ESTERIFIED;ESTRATAB				I-214	MAR 10, 2001
	086715 001	ESTROGENS, ESTERIFIED;ESTRATAB				I-214	MAR 10, 2001

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER		INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020363 001		FANCICLOVIR;FANVIR				NCE	JUN 29, 1999
020786 001		FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	4254129 5375693 5578610	APR 10, 1999 AUG 03, 2012 NOV 26, 2013		I-221	MAR 20, 2001
020180 001		FINASTERIDE;PROSCAR	4642384	FEB 10, 2004			
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 5712251	SEP 18, 2001 SEP 18, 2001	U-24 U-216		
020121 001		FLUTICASONE PROPIONATE;FLONASE	4260769	APR 07, 1999		I-224	OCT 31, 2000
020450 001		FOSPHENYTOIN SODIUM;CEREBYX	5563138	OCT 08, 2013			
020695 001		GREPAFLOXACIN HYDROCHLORIDE;RAXAR	5399578	MAR 21, 2012	U-3	NCE	DEC 23, 2001
020818 001		HYDROCHLOROTHIAZIDE;DIOVAN HCT			NC	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;DRONCA			ODE	ODE	FEB 25, 2005
016295 003		HYDROXYUREA;DRONCA			ODE	ODE	FEB 25, 2005
016295 004		HYDROXYUREA;DRONCA			ODE	ODE	FEB 25, 2005
020812 001		IBUPROFEN;PEDIATRIC ADVIL			NP	NP	JUN 16, 1998
020903 001		INTERFERON ALFA-2B;REBETRON	4530901 4211771 5767097	JUL 23, 2002 JUL 08, 1999 JAN 23, 2016	U-234 U-235	NP	JUN 03, 2001
>ADD>							
>ADD>							
>ADD>							
020393 001		IPRATROPIUM BROMIDE;ATROVENT	4942162	FEB 11, 2003		I-223	APR 01, 2001
019927 001		KETOCONAZOLE;NIZORAL				I-227	MAR 12, 2001
020406 001		LANSOPRAZOLE;PREVACID				I-227	MAR 12, 2001
020406 002		LANSOPRAZOLE;PREVACID	5180668	JAN 19, 2010		ODE	MAR 06, 2005
020807 001		LEPINUDIN;REFLUDAN				NCE	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			
020803 001		LOTEPREDNOL ETABONATE;ALREX	4996335 5540930	FEB 26, 2008 OCT 25, 2013	U-226	NCE	MAR 09, 2003
020583 001		LOTEPREDNOL ETABONATE;LOTEMAX	4996335 5540930	FEB 26, 2008 OCT 25, 2013		NCE	MAR 09, 2003

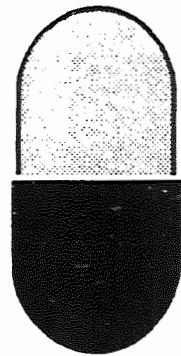
**PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020841 001	LOTEPREDNOL ETABONATE;LOTENAX	4996335 5540930	FEB 26, 2008 OCT 25, 2013		NCE	MAR 09, 2003
019832 003	MAFENIDE ACETATE;SULFANYLON				NDF ODE	JUN 05, 2001 JUN 05, 2005
019618 001	MESALANINE;ROMASA	4657900 RE33239	APR 14, 2004 MAY 12, 2004		D-40 NP	MAY 16, 2000 MAR 30, 2001
020208 001	METRONIDAZOLE;METROGEL-VAGINAL					
020827 001	NICONAZOLE NITRATE;NONISTAT 3					
020762 001	NOMETASONE FUMARATE 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					
020763 002	NARatriptan HYDROCHLORIDE;AMERGE					
020536 001	NICOTINE;NICOTROL	4915950	FEB 12, 2008			
020555 001	NIZATIDINE;AXID AR				I-220 D-39	APR 01, 2001 APR 01, 2001
>ADD>	020799 001 OFLOXACIN;FLOXIN					
>ADD>	019810 001 OMEPRAZOLE;PRILOSEC					
>ADD>	019810 002 OMEPRAZOLE;PRILOSEC					
>ADD>	020262 001 PACLITAXEL;TAXOL					
>ADD>	020819 001 PARICALCITOL;ZEMPLAR					
>ADD>	020237 001 PILOCARPINE HYDROCHLORIDE;SALAGEN					
>ADD>	020667 001 PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006			
>ADD>	020667 002 PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4843086	JUN 27, 2006	U-231		
>ADD>	020667 003 PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006	U-231		
>ADD>	020667 004 PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4843086	JUN 27, 2006	U-231		
>ADD>	020667 005 PRAMIPEXOLE DIHYDROCHLORIDE;MIRAPEX	4886812	DEC 12, 2006	U-231		
>ADD>	019898 002 PRAVASTATIN SODIUM;PRAVACHOL	4843086	JUN 27, 2006	U-231		
>ADD>	019898 003 PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
>ADD>	019898 004 PRAVASTATIN SODIUM;PRAVACHOL				I-225	MAR 27, 2001
>ADD>	019781 001 PROGESTERONE;PROMETRIUM				I-225	MAR 27, 2001
>ADD>	019627 002 PROPOFOL;DIPRIVAN				NP	MAY 14, 2001
020815 001	RALOXIFENE HYDROCHLORIDE;EVISTA	5731355	MAR 22, 2015	U-217		
>ADD>	020520 001 RANITIDINE HYDROCHLORIDE;ZANTAC 75	5731356	MAR 22, 2015	U-218		
>ADD>	021024 001 RIFAPENTINE;PRIFTIN	4418068	APR 03, 2001			
>ADD>	020835 001 RISEDRONATE SODIUM;ACTONEL	5393763	JUL 28, 2012	U-114		
>ADD>	020272 005 RISPERIDONE;RISPERDAL	5457117	JUL 28, 2012	U-114		
		5478847	MAR 02, 2014	U-114		
		5583122	DEC 10, 2013	U-22	I-228 NCE ODE	JUN 08, 2001 JUN 22, 2003 JUN 22, 2005
		5158952	OCT 27, 2009		I-37	MAR 27, 2003 OCT 17, 2000

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020772 001	SACROSIDASE;SUCRAID				ODE	APR 09, 2005
					NCE	APR 09, 2003
>ADD>					I-216	FEB 05, 2001
020236 001	SALMETEROL XINAFOATE;SEREVENT	5126375	FEB 12, 2008			
020692 001	SALMETEROL XINAFOATE;SEREVENT	D342994	JAN 06, 2008	U-211		
		5225445	FEB 12, 2008			
		5380922	JAN 10, 2012			
		5590645	MAR 01, 2011			
		5126375	FEB 12, 2008			
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
>ADD>						
020626 001	SUMATRIPTAN;IMITREX	5037845	AUG 06, 2008			
>ADD>		5307953	DEC 02, 2012			
>ADD>		5554639	SEP 10, 2013	U-232		
>ADD>		5705520	DEC 10, 2011	U-232		
>ADD>		5037845	AUG 06, 2008			
>ADD>		5307953	DEC 02, 2012			
>ADD>		5554639	SEP 10, 2013	U-232		
>ADD>		5705520	DEC 10, 2011	U-232		
>ADD>		5037845	AUG 06, 2008			
>ADD>		5307953	DEC 02, 2012			
>ADD>		5554639	SEP 10, 2013	U-232		
>ADD>		5705520	DEC 10, 2011	U-232		
>ADD>		4379454	FEB 17, 2001			
020791 001	TESTOSTERONE;TESTODERM	5292756	MAR 06, 2011	U-230	NCE	MAY 14, 2003
020912 001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5658929	MAR 06, 2011			
		5733919	OCT 23, 2016			
020913 001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT	5292756	MAR 06, 2011	U-230	NCE	MAY 14, 2003
		5658929	MAR 06, 2011			
		5733919	OCT 23, 2016			
020697 001	TOLCAPONE;TASMAR	5236952	AUG 17, 2010		NCE	JAN 29, 2003
020697 002	TOLCAPONE;TASMAR	5476875	DEC 19, 2012	U-219		
		5236952	AUG 17, 2010		NCE	JAN 29, 2003
		5476875	DEC 19, 2012	U-219		
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
020137 002	TORSEMIDE;DEMADEX				D-38	FEB 13, 2001
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		
020675 001	URSDODIOL;URSO	4859660	AUG 22, 2006			
>ADD>		4535186	DEC 13, 2007			
020699 001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR	4535186	DEC 13, 2007			
>ADD>		4535186	DEC 13, 2007			
>ADD>		4535186	DEC 13, 2007			
>ADD>		4535186	DEC 13, 2007			
020699 004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR	4535186	DEC 13, 2007			

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