

CUMULATIVE
SUPPLEMENT 7
JUL'99

APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

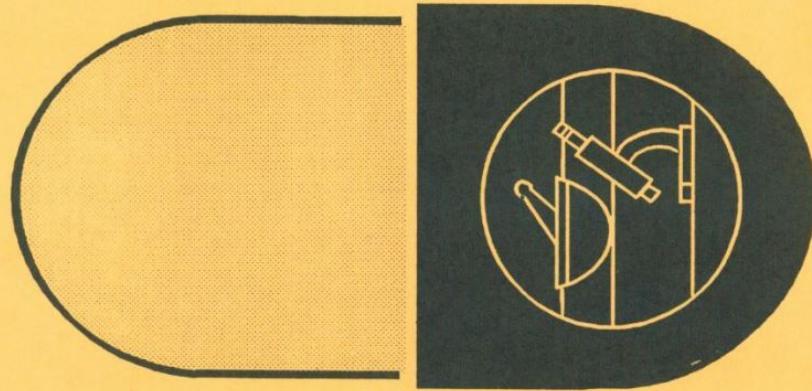
19TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

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THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

Cumulative Supplement 7

JULY 1999

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

19TH EDITION

**CUMULATIVE SUPPLEMENT 7
JULY 1999**

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, 19th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 and OTC Drug Product List 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.

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 19th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 20th 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 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.

APPLICANT NAME CHANGES

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

NO APPLICANT NAME CHANGES – JULY 1999

1.3 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) Falcon Pharms' (Alcon) 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.

1.4 AVAILABILITY OF THE EDITION

The 19th Edition of the Orange Book and its monthly cumulative supplements are available by subscription from the Government Printing Office:

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The telephone number to charge your subscription is 202-512-1800. The cost is \$78.00 annually.

The Approved Drug Products with Therapeutic Equivalence Evaluation (Orange Book) and related drug information is also available on the Internet at the Food and Drug Administration, Center for Drug Evaluation and Research, Drug Info page.

There is an Electronic Orange Book Query (EOB) at <http://www.fda.gov/cder/ob>. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product. The data is updated concurrently with the publication of the annual edition or monthly cumulative supplements.

The Internet version of the hard copy Orange Book annual edition is at
<http://www.fda.gov/cder/orange/adp.htm>.

The Internet version of the hard copy monthly supplement is at
<http://www.fda.gov/cder/orange/supplement/cspreface.htm>. Changes to the annual edition are listed separately by month.

There are ASCII text files of the Orange Book drug product data at
<http://www.fda.gov/cder/orange/obreadme.htm>. The drug product text files are zipped into zipobtxt.exe. The files are updated concurrently with the publication of the annual edition or monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 19th annual edition of the 1998 Orange Book Patent and Exclusivity List is at
<http://www.fda.gov/cder/orange/19bookpub.pdf>.

The current year Patent and Exclusivity cumulative supplement list that denotes the current month additions is at
<http://www.fda.gov/cder/orange/supplement/patents.pdf>.

The current listing of the Orphan Product Designations and Approvals is available at
<http://www.fda.gov/orphan/designat/list.htm>.

1.5 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 1998) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

COUNTS CUMULATIVE BY QUARTER

<u>CATEGORIES COUNTED</u>	<u>DEC 1998</u>	<u>MAR 1999</u>	<u>JUN 1999</u>	<u>SEP 1999</u>
DRUG PRODUCTS LISTED	9923	9975	10009	
SINGLE SOURCE	2504 (25.2%)	2520 (25.3%)	2523 (25.2%)	
MULTI SOURCE	7308 (73.6%)	7344 (73.6%)	7375 (73.7%)	
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)	6969 (69.9%)	7012 (70.1%)	
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)	375 (3.8%)	363 (3.6%)	
EXCEPTIONS	111 (1.1%)	111 (1.1%)	111 (1.1%)	
NEW MOLECULAR ENTITIES APPROVED	10	3	5	
NUMBER OF APPLICANTS	563	570	568	

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

PRESCRIPTION DRUG PRODUCT LIST
19TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN' 99 - JUL' 99

1

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

TABLET; ORAL
ACETAMINOPHEN, CAFFFEINE, AND DIHYDROCODEINE BITARTRATE
+ MIKART 712.8MG; 60MG; 32MG N40316 001
APR 28, 1999

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
ALLAY 500MG; 5MG N889907 001
NORTON HN JAN 13, 1989
AA ZENITH GOLDLINE 500MG; 5MG N889907 001
HYDROCODONE BITARTRATE AND ACETAMINOPHEN JAN 13, 1989
AA MALLINCKRODT 500MG; 5MG N889956 001
JUL 19, 1985
AA ZYDONE 500MG; 5MG N889956 001
MALLINCKRODT JUL 19, 1985

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN
DURAMED 500MG; 5MG N40289 001
MAR 16, 1999

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN
AMIDE PHARM 3.25MG; 5MG N40203 001
PERCOCEP MAR 15, 1999
AA

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN
ENDO PHARMS 3.25MG; 5MG N40330 001
PERCOCEP JUN 25, 1999
AA

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN
ENDO PHARMS 3.25MG; 2.5MG N40330 002
PERCOCEP JUN 25, 1999
AA

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN
ENDO PHARMS 3.25MG; 2.5MG N40330 001
PERCOCEP JUN 25, 1999
AA

TABLET; ORAL

OXYCODONE AND ACETAMINOPHEN
ENDO PHARMS 3.25MG; 2.5MG N40330 002
PERCOCEP JUN 25, 1999
AA

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100 AB TEVA 650MG; 100MG
@ 650MG; 100MG
JUN 12, 1985
N70107 001
JUN 12, 1985
N70107 001
JUN 12, 1985

ACITRETIN

CAPSULE; ORAL
SORIATANE HLR 1.0MG
N19821 001 OCT 28, 1996
N19821 002 OCT 28, 1996
N19821 001 OCT 28, 1996
N19821 002 OCT 28, 1996
N19821 001 OCT 28, 1996
N19821 002 OCT 28, 1996

ACYCLOVIR

CAPSULE; ORAL
ACYCLOVIR STASON 2.00MG
N75090 001 JAN 26, 1999

TABLET; ORAL
ACYCLOVIR CARLSBAD 4.00MG
N75382 001 APR 30, 1999
N75382 002 APR 30, 1999
AB AB AB AB

ACYCLOVIR SODIUM

INJECTABLE; INJECTION
ACYCLOVIR ABBOTT EQ 50MG BASE/ML
N75114 001 JUL 26, 1999
AB AB AB AB
ACYCLOVIR SODIUM EQ 50MG BASE/ML
AM PHARM PARTNERS EQ 50MG BASE/ML
N74930 001 MAY 13, 1998

<u>ACYCLOVIR SODIUM</u>	
INJECTABLE; INJECTION	
<u>ACYCLOVIR SODIUM</u>	
* A PHARM PARTNERS	EQ 50MG BASE/ML
AP	MERIDIAN MEDCL TECHN EQ 50MG BASE/ML
	N74930 001 MAY 13, 1998
	N75065 001 FEB 25, 1999
	A BUTEROL
	AEROSOL, METERED; INHALATION
AB	<u>ALBUTEROL</u>
	MEDEVA
	0.09MG/INH
AB	MEDEVA PHARMS MA
	0.09MG/INH
	ALBUTEROL SULFATE
	SOLUTION; INHALATION
AN	<u>ALBUTEROL SULFATE</u>
	HI TECH PHARMA
	EQ 0.083% BASE
	N75063 001 FEB 09, 1999
	SYRUP; ORAL
AA	<u>ALBUTEROL SULFATE</u>
	UDL
	EQ 2MG BASE/5ML
	ALITRETINOIN
	GEL; TOPICAL
	PANRETIN
	+ LIGAND
	EQ 0.1% BASE
	N20886 001 FEB 02, 1999
	ALLOPURINOL
	TABLET; ORAL
AB	<u>ZYLOPRIM</u>
	FARO PHARMS
	100MG
AB	+ GLAXO WELLCOME
AB	300MG
AB	100MG
AB	300MG
	N16084 001 N16084 001 N16084 001 N16084 002
	AMINO ACIDS
	INJECTABLE; INJECTION
	AMINNESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE
	FRESENIUS KABI 5.2%
	N18901 001 APR 06, 1984

AMINO ACIDS

**INJECTABLE; INJECTION
AMINES 5.2% ESSENTIAL**

INJECTABLE; INJECTION
 AMINES 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE
 PHARMACIA AND UPJOHN 5.2%
 NEOPHAM 6.4%
 @ FRESENIUS KABI 6.4%
 PHARMACIA AND UPJOHN 6.4%
 APR 06, 1984
 N18901 001
 JAN 17, 1984
 N18792 001
 JAN 17, 1984

W. PHARMACEUTICALS AND U.S. DRUGS	NOVAMINE 11.4%	PRESENIUS KABI	11.4%
PHARMACIA AND UPJOHN	NOVAMINE 15%	PRESENIUS KABI	15%

FRESENIUS KABI	15%
PHARMACIA AND UPJOHN	15%
NOVAMINE 8.5%	
@ FRESENIUS KABI	8.5%
PHARMACIA AND UPJOHN	8.5%

AMINO ACIDS; MAGNESIUM CHLORIDE; SODIUM ACETATE

CHLORIDE; SODIUM ACEIAI

PHARMACIA AND UPJOHN

568G/1

卷之三

MINTAHYLLE

INJECTABLE: INJECTION

AMINOPHYLLINE INJECTABLE, INJECTION

25MG/MG

卷之三

25MG/Ml @

AMIODARONE HYDROCHLORIDE

**TABLET; ORAL
AMIODARONE HCL**

INJECTABLE; INJECTION		TABLET; ORAL	
AMINES	5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE	AMITRIPTYLINE HCL	AMITRIPTYLINE HYDROCHLORIDE
PHARMACIA AND UPJOHN	5.2%	N18901 001 APR 06, 1994	AB ALPHAPHARM
NEOPHARM	6.4%	N18792 001 JAN 17, 1984	AB NOVOPHARM
@ FRESENIUS KABI	6.4%	N18792 001 JAN 17, 1984	
PHARMACIA AND UPJOHN	6.4%	N18792 001 JAN 17, 1984	
NOVAMINE 11.4%			INJECTABLE; INJECTION
FRESENIUS KABI	11.4%	N17957 003 AUG 09, 1982	AMITRIPTYLINE HCl
PHARMACIA AND UPJOHN	11.4%	N17957 003 AUG 09, 1982	SERTRALINE
NOVAMINE 15%	15%	N17957 004 NOV 28, 1986	ELAVIL
FRESENIUS KABI		> ADD >	* ZENECA
PHARMACIA AND UPJOHN	15%	> ADD >	+

10

ASPIRIN; BUTALBITAL; CAFFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL
BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE
325MG; 50MG; 40MG; 30MG

AB ENDO PHARMS N75351 001 MAR 05, 1999

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL
ORPHENADRINE CITRATE, ASPIRIN, AND CAFFEINE
385MG; 30MG; 25MG

AB STEVENS J N74988 001 APR 30, 1999

AB N74988 002 APR 30, 1999

> DLT > ASTEMIZOLE
> DLT > TABLET; ORAL
> DLT > HISTAMIN
> DLT > * TRANSTHEN
> DLT > 100MG

N73402 001 DEC 29, 1988

ATENOLOL
TABLET; ORAL
ATENOLOL
100MG

AB APOTHECON N73317 001 MAR 20, 1992
AB N73318 001 MAR 20, 1992

@ 50MG
@ 100MG

MAR 20, 1992
N73317 001
MAR 20, 1992
N73318 001
MAR 20, 1992

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL W/ ATROPINE SULFATE
0.025MG/2.5MG

AA ZENITH GOLDLINE 0.025MG; 2.5MG
@

INJECTABLE; INJECTION

PRE - PEN
* BAXTER
+ HOLLISTER STIER LABS

60 UMOLAR

N50114 001

N50114 001

AZATHIOPRINE

TABLET; ORAL
AZATHIOPRINE
50MG

AB APPLIED ANAL N75252 001 JUN 07, 1999

BACITRACIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT: OPHTHALMIC
BACITRACIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE
100 UNITS/GM; 1% EQ; 3.5MG BASE/GM;

AT * INTARSA 10,000 UNITS/GM N60731 002

@ 400 UNITS/GM; 1% EQ 3.5MG BASE/GM;
10,000 UNITS/GM N60731 002

AT PHARMADERM 100 UNITS/GM N60731 002

+ 400 UNITS/GM; 1% EQ 3.5MG BASE/GM;
10,000 UNITS/GM N62166 002

BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL
CORZIDE
APOTHECON

5MG; 40MG

AT N18647 001 MAY 25, 1983

5MG; 80MG

+ BRISTOL MYERS SQUIBB 5MG; 40MG

MAY 25, 1983

* 5MG; 80MG

MAY 25, 1983

BENZYL PENICILLOYL-POLYLYSINE

INJECTABLE; INJECTION

PRE - PEN
* BAXTER
+ HOLLISTER STIER LABS

60 UMOLAR

N50114 001

N50114 001

BETAMETHASONE DIPROPIONATE

OINTMENT, AUGMENTED; TOPICAL
BETAMETHASONE DIPROPIONATE
 AB ALTANA EQ 0.05% BASE

N75373 001
 JUN 22, 1999

FEMSTAT
 @ SYNTEX
 NOV 25, 1985

BETAMETHASONE VALERATE

AEROSOL; TOPICAL
 LUXIQ + CONNETICS EQ 0.12% BASE

N20934 001
 FEB 28, 1999

FEMSTAT ONE
 + KV PHARM
 * SYNTEX
 FEB 07, 1997

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 WELLBUTRIN * GLAXO WELLCOME 50MG

* 100MG
 * 150MG

WELLBUTRIN SR + GLAXO WELLCOME 50MG
 + 100MG
 150MG

N20358 001 OCT 04, 1996 N20358 002 OCT 04, 1996 N20358 003 OCT 04, 1996 N20358 001 OCT 04, 1996 N20358 002 OCT 04, 1996 N20358 003 OCT 04, 1996

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

NOV 27, 1991

SOLUTION; IRRIGATION ENDOSONL EXTRA

AKORN AT 0.154MG/ML; 0.92MG/ML; 0.184MG/ML;
 0.2MG/ML; 0.38MG/ML; 2.1MG/ML;
 7.14MG/ML; 0.42MG/ML NOV 27, 1991

AT ALLERGAN

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

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDEINJECTABLE, INJECTION ISOLYTE R/W DEXTROSE 5% IN PLASTIC CONTAINER B BRAUN

3.7MG/1.00ML; 5GM/100ML; 31MG/100ML;
 1.20MG/1.00ML; 3.30MG/100ML;
 8.80MG/1.00ML
 3.7MG/1.00ML; 5GM/100ML; 31MG/100ML;
 1.20MG/1.00ML; 3.30MG/100ML; 8.80MG/1.00ML NOV 25, 1985

N19215 001
 NOV 25, 1985

BUSULFAN

INJECTABLE; INJECTION BUSULFEX + ORPHAN MEDCL 6MG/ML

N20954 001 FEB 04, 1999

BUTOCONAZOLE NITRATE

CREAM; VAGINAL
 FEMSTAT
 * SYNTEX 2%

BUTOCONAZOLE NITRATE

CREAM; VAGINAL
 FEMSTAT
 @ SYNTEX

2%

N19215 001
 NOV 25, 1985

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

<u>ISOLYTE E/W DEXTROSE 5% IN PLASTIC CONTAINER</u>	<u>B BRAUN</u>	<u>3.5MG/100ML; 5GM/100ML; 3.0MG/100ML;</u>	<u>N50306 001</u>
		<u>7.4MG/100ML; 6.40MG/100ML; 500MG/100ML;</u>	<u>N50306 004</u>
		<u>74MG/100ML</u>	<u>N50306 002</u>
		<u>JAN 17, 1983</u>	<u>N18269 002</u>
	<u>④</u>	<u>3.5MG/100ML; 5GM/100ML; 3.0MG/100ML;</u>	<u>N50306 007</u>
		<u>7.4MG/100ML; 6.40MG/100ML; 500MG/100ML;</u>	<u>N50306 001</u>
		<u>74MG/100ML</u>	<u>N18269 002</u>
		<u>JAN 17, 1983</u>	<u>N50306 002</u>
			<u>N50306 006</u>
			<u>N50306 007</u>

CAPECITABINE

<u>TABLET; ORAL</u>	<u>XELODA</u>	<u>150MG</u>	<u>N20896 001</u>
			<u>APR 30, 1998</u>
	<u>ROCHE</u>	<u>150MG</u>	<u>N20896 001</u>
			<u>APR 30, 1998</u>

CAPTOPRIL

<u>TABLET; ORAL</u>	<u>CAPTOPRIL</u>	<u>12.5MG</u>	<u>N74590 004</u>
			<u>AUG 30, 1996</u>
			<u>>DLT ></u>
			<u>N74590 002</u>
			<u>AUG 30, 1996</u>
			<u>>DLT ></u>
			<u>N74590 001</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
			<u>N74590 003</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
			<u>N74590 004</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
			<u>N74590 002</u>
			<u>AUG 30, 1996</u>
			<u>>DLT ></u>
	<u>AB</u>	<u>25MG</u>	<u>N74590 001</u>
			<u>AUG 30, 1996</u>
			<u>>DLT ></u>
	<u>AB</u>	<u>50MG</u>	<u>N74590 001</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N74590 003</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N74590 004</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N74590 002</u>
			<u>AUG 30, 1996</u>
			<u>>DLT ></u>
	<u>AB</u>	<u>50MG</u>	<u>N74590 001</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N74590 003</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N74590 004</u>
			<u>AUG 30, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>DLT ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 002</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>25MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>50MG</u>	<u>N64081 001</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>100MG</u>	<u>N64081 003</u>
			<u>SEP 16, 1996</u>
			<u>>ADD ></u>
	<u>AB</u>	<u>12.5MG</u>	<u>N64081 004</u>
			<u>SEP 16, 1996</u>
			<u>></u>

CEFACTOR

POWDER FOR RECONSTITUTION; ORAL
SUSPENSION

EQ 1.87MG	BASE/5ML
EQ 2.50MG	BASE/5ML
EQ 3.75MG	BASE/5ML
EQ 1.25MG	BASE/5ML
EQ 1.87MG	BASE/5ML
EQ 2.50MG	BASE/5ML
EQ 3.75MG	BASE/5ML

CEFADROXIL/CEFAZOXIL HEMIHYDRATE

TABLET; ORAL	<u>CEFDROXIL</u>	AB	EO 1GM BASE
RANBAXY			

CEFTAZIDIME (ARGININE FORMULATION)

**INJECTABLE; INJECTION
PENTACEE**

卷之三

CHLOROTRIANISENE

CAPSULE, ORAL		NB4652 001
<u>CHLOROTRIANISENE</u>		NB4652 001
BANNER PHARMACAPS	12MG 12MG	NB4652 004
@		NB4652 004
TACE		NB4652 004
* HOBERT MARION R551	12MG 12MG	NB4652 004
*		
+ *		

CILOSTAZOL

TABLET; ORAL
PLETAL
OTSUKA

卷之三

CISPLATIN

> ADD >	<u>AP</u>	<u>CISPLATIN</u>	1MG/ML	N74735 001
> ADD >	<u>AP</u>	AM PHARM PARTNERS		JUL 16, 1999
> ADD >				
> ADD >	<u>AP</u>	<u>PLATINOL AQ</u>	1MG/ML	N18057 004
> ADD >	<u>AP</u>	+ BRISTOL MYERS		NOV 08, 1988
> ADD >				N18057 004
> ADD >				NOV 08, 1988
> DLT >				
> DLT >				
> DLT >				

CHOLESTYRAMINE

ZENITH GOLDLINE	<u>EQ 4GM RESIN/SCOOPFUL</u>	JUL 09, 1997
	<u>EQ 4 GM RESIN/PACKET</u>	N74471 002
	<u>EQ 4 GM RESIN/SCOOPFUL</u>	JUL 09, 1997
	<u>EQ 4 GM RESIN/SCOOPFUL</u>	N74471 001
	<u>EQ 4 GM RESIN/SCOOPFUL</u>	JUL 09, 1997
	<u>EQ 4 GM RESIN/SCOOPFUL</u>	N74471 002
	<u>EQ 4 GM RESIN/SCOOPFUL</u>	JUL 09, 1997

G1 INHIBITION BY OSBILITATE

CHYMOTRYPSIN

POWDER FOR RECONSTITUTION; OPHTHALMIC
 CATARASE * CIBA @ ZOLYSE ALCON
 300 UNITS/VIAL
 300 UNITS/VIAL
 750 UNITS/VIAL
 750 UNITS/VIAL

EQ 150MG BASE/ML	JUN 08, 1988 N63079 001
EQ 150MG BASE/ML	MAR 05, 1990 N62900 001
EQ 150MG BASE/ML	JUN 08, 1988 N63079 001

N62900 001
JUN 08, 1988
N63079 001
MAR 05, 1990

<u>CROMOLYN SODIUM</u>	SOLUTION/DROPS; OPHTHALMIC	
<u>CROMOPTIC</u>	4%	
<u>AT</u>	KING PHARMS	
	APR 27, 1999	
	N75088 001	
	OCT 22, 1986	
	N19523 001	
	OCT 22, 1986	
<u>CYSTEINE HYDROCHLORIDE</u>	INJECTABLE; INJECTION	
	CYSTEINE HCL	
	@ FRESENIUS KABI	
	7.25%	
	APR 01, 1999	
	N21041 001	
	APR 01, 1999	
<u>CYTARABINE</u>	INJECTABLE, LIPOSOMAL; INJECTION	
	DEPOCYT	
	+ DEPOTECHE	
	1.0MG/ML	
	APR 01, 1999	
	N64103 001	
	FEB 03, 1995	
	N64103 001	
	FEB 03, 1995	
<u>DAUNORUBICIN HYDROCHLORIDE</u>	INJECTABLE; INJECTION	
	CERUBIDINE	
	+ BEDFORD	
	*	
	EQ 20MG BASE/VIAL	
	EQ 20MG BASE/VIAL	
<u>DAUNORUBICIN HCL</u>	EQ 20MG BASE/VIAL	
	BIGMAR	
	MAY 25, 1999	
	N65000 001	
<u>DESMOPRESSIN ACETATE</u>	SPRAY, METERED; NASAL	
	DDAVP	
	AB + RHONE POULENC RORER	
	0.01MG/SPRAY	
	*	
	0.01MG/SPRAY	
	0.01MG/SPRAY	
<u>DESMOPRESSIN ACETATE</u>	BAUSCH AND LOMB	
	AB	
	APR 07, 1996	
	N17922 003	
	AUG 07, 1996	
	N17922 003	
	AUG 07, 1996	
<u>DEXTRAMPHETAMINE SULFATE</u>	TABLET; ORAL	
	ENDO PHARMS	
	AA	
	5MG	

DEXTOSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

<u>CONTAINER</u>		<u>SODIUM CHLORIDE 0.9% IN PLASTIC</u>		<u>DIAZEPAM</u>		<u>5MG/ML</u>	
<u>AP</u>	<u>B BRAUN</u>	<u>2.5GM/100ML; 4.50MG/100ML</u>	<u>N18030 001</u>	<u>AP</u>	<u>DLT</u>	<u>5MG/ML</u>	<u>N70930 001</u>
>	>	DEXTROSE 5% AND SODIUM CHLORIDE 0.1% IN PLASTIC CONTAINER	N18030 001	>	DELT	DEC 01, 1986	DEC 01, 1986
@	B BRAUN	5GM/100ML; 11.0MG/100ML	N18030 001	>	ADD	N70911 001	N70911 001
>	>	5GM/100ML; 11.0MG/100ML	N18030 005	>	ADD	AUG 28, 1986	AUG 28, 1986
@	B BRAUN	5GM/100ML; 11.0MG/100ML	N18030 005	>	ADD	N70930 001	N70930 001
AP	B BRAUN	5GM/100ML; 11.0MG/100ML	N18030 005	>	ADD	DEC 01, 1986	DEC 01, 1986
@	B BRAUN	5GM/100ML; 11.0MG/100ML	N18030 004				
AP	B BRAUN	5GM/100ML; 11.0MG/100ML	N18030 004				
		5GM/100ML; 0.33% IN PLASTIC CONTAINER	N18030 004				
		5GM/100ML; 3.30MG/100ML	N18030 003				
@	B BRAUN	5GM/100ML; 3.30MG/100ML	N18030 003				
AP	B BRAUN	DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER	N18030 002	>	ADD	<u>TABLET; ORAL</u>	<u>N75463 001</u>
		5GM/100ML; 4.50MG/100ML	N18030 002	>	ADD	<u>DICLOFENAC POTASSIUM</u>	<u>50MG</u>
		5GM/100ML; 4.50MG/100ML	N18030 002			<u>MYLAN</u>	<u>JUL 26, 1999</u>

DIAZEPAM

INJECTABLE; INJECTION

OTAZEDAM

GEL; RECTAL DIASSTAT + ATHENA		2.5MG / 0.5ML	N20648 001 JUL 29, 1997	<u>AB</u>	SOLUTION/DROPS; OPHTHALMIC <u>DICLOFENAC SODIUM</u> <u>ALCON</u>	<u>0.1%</u>	N20809 001 MAY 04, 1998
+ 5MG / ML		5MG / ML	N20648 002 JUL 29, 1997	<u>AB</u>	FALCON PHARMS	<u>0.1%</u>	N20809 001 MAY 04, 1998
+ 10MG / 2ML		10MG / 2ML	N20648 003 JUL 29, 1997	TABLET, DELAYED RELEASE; <u>DICLOFENAC SODIUM</u>		ORAL	
+ 15MG / 3ML		15MG / 3ML	N20648 004 JUL 29, 1997	<u>AB</u>	MARTEC	<u>50MG</u>	
+ 20MG / 4ML		20MG / 4ML	N20648 005 JUL 29, 1997	<u>AB</u>		<u>75MG</u>	N74986 001 FEB 26, 1999
+ ELAN PHARMS		2.5MG / 0.5ML	N20648 001 JUL 29, 1997	<u>AB</u>	NOVOPHARM	<u>50MG</u>	N74986 002 FEB 26, 1999
+ 5MG / ML		5MG / ML	N20648 002 JUL 29, 1997	> <u>ADD</u> > <u>AB</u>	SLIDMAK LABS NJ	<u>50MG</u>	N74723 001 MAR 30, 1999
+ 10MG / 2ML		10MG / 2ML	N20648 003 JUL 29, 1997	> <u>ADD</u> > <u>AB</u>		<u>75MG</u>	N74432 002 JUL 29, 1999
+ 15MG / 3ML		15MG / 3ML	N20648 004 JUL 29, 1997	> <u>ADD</u> > <u>AB</u>		<u>75MG</u>	N74432 003 JUL 29, 1999
+ 20MG / 4ML		20MG / 4ML	N20648 005 JUL 29, 1997		DICYCLOMINE HYDROCHLORIDE		
INJECTABLE; INJECTION DIAZEPAM STERISIS		5MG / ML	N70911 001 JUL 29, 1997	<u>AB</u>	TABLET; ORAL <u>DICYCLOMINE HCL</u> <u>LANNETT</u>	<u>20MG</u>	N40230 001 FEB 26, 1999

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA BX + BERLEX LABS 0 .025MG/24HR

ESTRADIOL
MENOREST AB

0 .0375MG/24HR

0 .05MG/24HR

0 .075MG/24HR

0 .1MG/24HR

0 .0375MG/24HR

0 .05MG/24HR

0 .075MG/24HR

0 .1MG/24HR

VIVELLE-DOT AB

NOVARTIS

0 .0375MG/24HR

0 .05MG/24HR

0 .075MG/24HR

0 .1MG/24HR

TABLET; ORAL

ESTRADIOL

MYLAN AB

0 .5MG

1MG

2MG

TABLET; VAGINAL

VAGIFEM AB

+ NOVO NORDISK 25 UGM

TABLET; ORAL

ESTRADIOL

DURAMED AB

0 .9MG

0 .625MG

N20375 004 MAR 05, 1999

N20538 001 JUL 31, 1996

N20538 003 JUL 31, 1996

N20538 002 JUL 31, 1996

N20538 004 JUL 31, 1996

N20538 001 JUL 31, 1996

N20538 002 JUL 31, 1996

N20538 004 JUL 31, 1996

N20538 001 JUL 31, 1996

N20538 002 JUL 31, 1996

N20538 004 JUL 31, 1996

N20538 001 JUL 31, 1996

ESTROGENS, CONJUGATED SYNTHETIC A

TABLET; ORAL

CENESTIN

+ DURAMED

0 .9MG

N20992 003 MAR 24, 1999

N20992 002 MAR 24, 1999

N20992 001 JUL 13, 1998

ESTRONE

INJECTABLE; INJECTION

NATURAL ESTROGENIC SUBSTANCE-ESTRONE

+ STERIS

> DLT >

> DLT >

> DLT >

> ADD >

> ADD >

@

2MG/ML

2MG/

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21		TABLET; ORAL	
<u>BREVICON 21-DAY</u>		<u>ETODOLAC</u>	
<u>AB</u>	<u>SEARLE</u>	<u>AB</u>	<u>NOVOPHARM</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>AB</u>	<u>AB</u>
<u>AB</u>	<u>NORINYL 1+35 21-DAY</u>	<u>N17566 001</u>	<u>400MG</u>
<u>AB</u>	<u>SEARLE</u>	<u>N17566 001</u>	<u>OCT 23, 1999</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>N17565 001</u>	<u>N74847 002</u>
<u>AB</u>	<u>TRI-NORINYL 21-DAY</u>	<u>N17565 001</u>	<u>APR 23, 1999</u>
* <u>SEARLE</u>			
+ <u>WATSON LABS</u>			
<u>TABLET; ORAL-28</u>		<u>ETOPOSIDE</u>	
<u>BREVICON 28-DAY</u>		<u>ETOPOSIDE; INJECTION</u>	
<u>AB</u>	<u>SEARLE</u>	<u>AP</u>	<u>STERIS</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>AP</u>	<u>20MG/ML</u>
<u>AB</u>	<u>NORINYL 1+35 28-DAY</u>	<u>> DLT ></u>	<u>20MG/ML</u>
<u>AB</u>	<u>SEARLE</u>	<u>> ADD ></u>	<u>20MG/ML</u>
<u>AB</u>	<u>WATSON LABS</u>	<u>> ADD ></u>	<u>20MG/ML</u>
<u>AB</u>	<u>TRI-NORINYL 28-DAY</u>	<u>> ADD ></u>	<u>20MG/ML</u>
<u>SEARLE</u>			
<u>WATSON LABS</u>			
<u>TABLET; ORAL-21</u>		<u>FERRIC SODIUM GLUCONATE</u>	
<u>LO/OVRAL</u>		<u>INJECTABLE; INJECTION</u>	
<u>AB</u>	<u>WYETH AYERST</u>	<u>AP</u>	<u>FERRILECT</u>
<u>AB</u>	<u>LOW-OGESTREL-21</u>	<u>+</u>	<u>R AND D LABS</u>
<u>SCS</u>			
<u>TABLET; ORAL-21</u>		<u>FLUOCINONIDE</u>	
<u>LO/OVRAL</u>		<u>OINTMENT; TOPICAL</u>	
<u>AB</u>	<u>WYETH AYERST</u>	<u>AB</u>	<u>FLUOCINONIDE</u>
<u>AB</u>	<u>LOW-OGESTREL-21</u>	<u>TARO</u>	<u>0.05%</u>
<u>SCS</u>			
<u>TABLET; ORAL-28</u>		<u>FLUOUROURACIL</u>	
<u>LO/OVRAL-28</u>		<u>INJECTABLE; INJECTION</u>	
<u>AB</u>	<u>WYETH AYERST</u>	<u>AP</u>	<u>FLUOUROURACIL</u>
<u>AB</u>	<u>LOW-OGESTREL-28</u>	<u>+</u>	<u>SMITH AND NEPHEW</u>
<u>SCS</u>			
<u>TABLET; ORAL-21</u>		<u>FLUOUROURACIL</u>	
<u>LO/OVRAL</u>		<u>INJECTABLE; INJECTION</u>	
<u>AB</u>	<u>WYETH AYERST</u>	<u>AP</u>	<u>FLUOUROURACIL</u>
<u>AB</u>	<u>LOW-OGESTREL-21</u>	<u>+</u>	<u>SMITH AND NEPHEW</u>
<u>SCS</u>			
<u>TABLET; ORAL-28</u>		<u>FLUOUROURACIL</u>	
<u>LO/OVRAL-28</u>		<u>INJECTABLE; INJECTION</u>	
<u>AB</u>	<u>WYETH AYERST</u>	<u>AP</u>	<u>FLUOUROURACIL</u>
<u>AB</u>	<u>LOW-OGESTREL-28</u>	<u>+</u>	<u>SMITH AND NEPHEW</u>
<u>SCS</u>			

GLYBURIDE

TABLET; ORAL
GLYBURIDE (MICRONIZED)
MOVA

AB 4.5MG

N74591 003
DEC 22, 1997

N74591 003
4.5MG

AB NOVOPHARM

AB 1.5MG

N74686 001
APR 20, 1999

AB 3MG

N74686 002
APR 20, 1999

AB 4.5MG

N74686 003
APR 20, 1999

AB 6MG

N74686 004
APR 20, 1999

GLYCOPYRROLATE

INJECTABLE; INJECTION

GLYCOPYRROLATE
STERIS

AB 0.2MG/ML

> DLT > AP

> DLT > AP

> ADD > AP

> ADD > AP

TABLET; ORAL

HORIZON PHARM

* ROBINS AS

ROBINUL FORTE

+ HORIZON PHARM

* ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

ROBINS AS

2MG

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

ROBINS AS

2MG

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

ROBINS AS

2MG

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

ROBINS AS

2MG

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

ROBINS AS

2MG

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

ROBINS AS

2MG

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

GENSIA SICOR PHARMS

EQ 50MG BASE/ML

N75393 001
MAY 11, 1999

N75393 002
MAY 11, 1999

AO

AO

DECEMBER 22, 1987

DEC 14, 1987

DEC 14, 1987

DEC 14, 1987

DEC 14, 1987

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

SOLOPAK

EQ 5MG BASE/ML

HALOPERIDOL

SOLOPAK

EQ 5MG BASE/ML

STERIS

STERIS

STERIS

STERIS

STERIS

STERIS

STERIS

TABLET; ORAL

HORIZON PHARM

* ROBINS AS

ROBINUL FORTE

+ HORIZON PHARM

* ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

1MG

1MG

* ROBINS AS

2MG

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

2MG

ROBINS AS

TABLET; ORAL

HORIZON PHARM

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH
@ SMITH AND NEPHEW

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

100 UNITS/ML
100 UNITS/ML
100 UNITS/ML
100 UNITS/ML
N88459 001
JUL 26, 1984
N88581 001
OCT 25, 1984
N88459 001
JUL 26, 1984
N88459 001
JUL 26, 1984
N88239 001
JUL 26, 1984
N88239 001
JUL 26, 1984
1,000 UNITS/ML
SMITH AND NEPHEW

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

1,000 UNITS/ML
@
HEPARIN SODIUM
SMITH AND NEPHEW

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL
HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE
HALSEY
1.5MG/5ML; 5MG/5ML

> ADD >
> ADD >

AA
HALSEY

N40285 001
JUL 19, 1999

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL
EDIPROLD
> DLT >
> DLT >
> ADD >
> DLT >
> DLT >
> ADD >
> ADD >

20MG/ML
20MG/ML
20MG/ML
20MG/ML
20MG/ML
20MG/ML
20MG/ML
20MG/ML

N40136 001
JUN 30, 1997
N40136 001
JUN 30, 1997
N88517 001
AUG 22, 1985
N88517 001
AUG 22, 1985
N88517 001
AUG 22, 1985

> ADD >
> ADD >

AT
THAMES
> ADD >

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL
AVALIDE
@ SANOFI
12.5MG; 75MG
12.5MG; 150MG

> ADD >
> ADD >
> ADD >

N20758 001
SEP 30, 1997
N20758 002
SEP 30, 1997

N40259 001
JUL 29, 1999

CREAM; TOPICAL
HYDROCORTISONE ACETATE
+ FERNDALE LABS 2.5%

N40259 001
JUL 29, 1999

TABLET; ORAL
AVALIDE
+ SANOFI
AVAPRO HCT
@ SANOFI
*
12.5MG; 7.5MG
12.5MG; 15.0MG

N20758 001
SEP 30, 1997
N20758 002
SEP 30, 1997

N75052 001
JUN 18, 1999

HYDROCORTISONE

CAPSULE; ORAL
TRIAMTERENE AND HYDROCHLOROTHIAZIDE
DURAMED
AB

N88239 001
JUL 26, 1984
N88239 001
JUL 26, 1984
AB
DURAMED
25MG; 37.5MG

N16199 001
N16199 001

N74171 001
MAY 27, 1994
N74171 001
MAY 27, 1994

N74171 001
MAY 27, 1994
N74171 001
MAY 27, 1994

HYDROCORTISONE SODIUM SUCCINATE

INJECTABLE; INJECTION HYDROCORTISONE SODIUM SUCCINATE

AP STERIS	EQ 100MG BASE/VI AL	N84737 002	AB + MCNEIL CONS
AP	EQ 100MG BASE/VI AL	N84738 001	
AP	EQ 250MG BASE/VI AL	N84737 001	
AP	EQ 500MG BASE/VI AL	N84747 001	
AP	EQ 1GM BASE/VI AL	N84748 001	
DLT >	EQ 100MG BASE/VI AL	N84737 002	TABLET; ORAL <u>IBUPROFEN</u>
DLT >	EQ 100MG BASE/VI AL	N84738 001	AB NORTON HS
DLT >	EQ 250MG BASE/VI AL	N84737 001	
DLT >	EQ 500MG BASE/VI AL	N84747 001	
DLT >	EQ 1GM BASE/VI AL	N84748 001	
ADD >	EQ 100MG BASE/VI AL	N84737 002	
ADD >	EQ 100MG BASE/VI AL	N84738 001	
ADD >	EQ 250MG BASE/VI AL	N84737 001	
ADD >	EQ 500MG BASE/VI AL	N84747 001	
ADD >	EQ 1GM BASE/VI AL	N84748 001	
ADD >	EQ 1GM BASE/VI AL	N84748 001	
ADD >	EQ 1GM BASE/VI AL	N84748 001	
ADD >	EQ 1GM BASE/VI AL	N84748 001	

HYDROXYAMPHEPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC

PAREDRINE	1%	AB	MOTRIN
+ AKORN PHARMICS	1%	AB	MCNEIL

HYDROXYUREA

CAPSULE; ORAL HYDROXYUREA

PAR PHARM	500MG	N75340 001	AB	MCNEIL CONS
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HYDROXYZINE HYDROCHLORIDE

INJECTABLE; INJECTION HYDROXYZINE HCL

SOLOPAK	2.5MG/ML	NB7591 001	TABLET, CHEWABLE; ORAL <u>MOTRIN</u>
	5.0MG/ML	N87593 001	MCNEIL
	5.0MG/ML	N87595 001	

HYDROXYZINE HCL

AP	2.5MG/ML	NB7591 001	\$0MG
AP	5.0MG/ML	N87591 001	N20135 001
AP	5.0MG/ML	N87593 001	NOV 16, 1994
AP	5.0MG/ML	N87595 001	N20135 002
ADD >	EQ	*	NOV 16, 1994
ADD >	EQ	*	N20135 001
ADD >	EQ	*	NOV 16, 1994

IBUPROFEN

SUSPENSION; ORAL

AB	100MG/5ML	N19842 001	
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SEP 19, 1989

IBUPROFEN

SUSPENSION; ORAL MOTRIN

AB + MCNEIL CONS	100MG/5ML	N19842 001	SEP 19, 1989
AB	400MG	N71145 001	SEP 23, 1986
AB	600MG	N71146 001	SEP 23, 1986
AB	800MG	N71769 001	MAY 08, 1987
AB	400MG	N71145 001	SEP 23, 1986
AB	600MG	N71146 001	SEP 23, 1986
AB	800MG	N71769 001	MAY 08, 1987
AB	300MG	N17463 003	SEP 23, 1986
AB	400MG	N17463 002	N17463 004
AB	600MG	N17463 005	MAY 22, 1985
AB	800MG	N20418 001	NOV 16, 1994
AB	400MG	N17463 003	
AB	600MG	N17463 002	
AB	800MG	N17463 004	
AB	100MG	N20418 001	NOV 16, 1994
AB	300MG	N17463 003	
AB	400MG	N17463 002	
AB	600MG	N17463 004	
AB	800MG	N20418 001	NOV 16, 1994
AB	100MG	N17463 005	
AB	100MG	N20418 001	NOV 16, 1994
AB	100MG	N20418 002	NOV 16, 1994
AB	100MG	N20418 004	

INDOMETHACIN

ISOETHARINE HYDROCHLORIDE

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

INJECTABLE: INJECTION ISOLYTE S PH 7.4 IN PLASTIC CONTAINER	
B BRAIN	
30MG/100ML; 37MG/100ML; 0	82MG/100ML;
370MG/100ML; 530MG/100ML; 5000ML;	N19006 001
12MG/100ML	APR 04 1984
30MG/100ML; 37MG/100ML; 0	82MG/100ML;
370MG/100ML; 530MG/100ML; 5000ML;	N19006 001
12MG/100ML	APR 04 1984

MEDROXYPROGESTERONE ACETATE

TABLET, ORAL			
CICRIN			
ESI			
	5MG		
	10MG		
@		2 . 5MG	
		5MG	
@			10MG
@			

MALATHION

<u>LOTION; TOPICAL OVIDE ® MEDICIS</u>	+	<u>MANNITOL</u>	<u>INJECTABLE; INJE MANNITOL 25% STERIS</u>	④
			<u>AP</u>	➤ ➤ ➤ ➤ ➤

MEPERIDINE HYDROCHLORIDE

TABLET, CHEWABLE; ORAL

VERMOX
* JANSSSEN
+ MCNEIL CONS
AB
AB

卷之三

MEPERIDINE HCL PRESERVATIVE FREE		
AP	+ ABBOTT	10MG/ML
AP	ASTRA PHARMS	10MG/ML
AP	FAULDING	10MG/ML
AP	INTL MEDICATION	10MG/ML
N81239 001 OCT 30, 1992		N88432 001 AUG 16, 1984
N17481 001		N81002 001 JUL 30, 1993
N17481 001		N40305 001 MAR 10, 1999
		N81309 001 AUG 30, 1993

METHYLDOPATE HYDROCHLORIDE

**INJECTABLE; INJECTION
METHYLDOPATE HCL
SMITH AND NEPHEW**

W70841 001	STERIS	500MG/100ML
JAN 02, 1987	> DLT >	
N70841 001	> DLT >	
JAN 02, 1987	> ADD >	@
	> ADD >	
	> ADD >	

METHYL PREDNISOLONE SODIUM SUCCINATE

**INJECTABLE; INJECTION
METHYLPREDNISOLONE SODIUM SUCCINATE**

N88693 001	+ ADVANCED CARE PRODS	1.2GM, 2%		N20968 001
JUL 22, 1982				JUN 30, 1999
N87030 001				
JUL 22, 1982				
N88543 001				
JUL 24, 1984				
N88544 001				
JUL 24, 1984				
N86653 001				
SUPPOSITORY; VAGINAL NICOTINOL NITRATE				
AB	ALPHARMA US PHARM	<u>200MG</u>		N73508 001
AB	KRC	<u>200MG</u>		NOV 19, 1993
				N73508 001
				NOV 19, 1993

METOCLOPRAMIDE HYDROCHLORIDE

**INJECTABLE; INJECTION
METOCLOPRAMIDE HCL
SMITH AND NEPHEW
EO 5MG BASE/ML**

N70623 001 MAR 02, 1987	<u>NADDOLOL</u>
N70623 001 MAR 02, 1987	TABLET; ORAL <u>CORGARD</u>
	<u>AB</u> APOTHECON <u>20MG</u>
	<u>AB</u> APOTHECON <u>40MG</u>
	<u>AB</u> APOTHECON <u>80MG</u>
	<u>AB</u> APOTHECON <u>120MG</u>
	<u>AB</u> APOTHECON <u>160MG</u>
	<u>AB</u> + BRISTOL MYERS SQUIBB <u>20MG</u>
N17386 001 N17386 001	N18063 005 OCT 28, 1986
	N18063 001
	N18063 002
	N18063 003
	N18063 004
	N18063 005 OCT 28, 1986

METOLAZONE

TABLET; ORAL
ZAROXOLYN
MEDEVA
+
2.5 MG
2.5 MG

METRONIDAZOLE

**INJECTABLE; INJECTION
METRONIDAZOLE
STERIS**

STERIS N70170 001
500MG/100ML APR 01, 1986
N70170 001
500MG/100ML APR 01, 1986
@

MICONAZOLE NITRATE

INSERT, CREAM; VAGINAL, TOPICAL
MONISTAT DUAL- PAK

MAR 23, 1999
N65005 002
EQ 100MG BASE

<u>NADOLOL</u>	TABLET; ORAL	<u>CORGARD</u>	<u>20MG</u>	N18063 005	OCT 28, 1986
		APOTHECON		N18063 001	
			<u>40MG</u>	N18063 002	
			<u>80MG</u>	N18063 003	
			<u>120MG</u>	N18063 004	
			<u>160MG</u>	N18063 005	
			<u>20MG</u>	BRISTOL MYERS SQUIBB	OCT 28, 1986

NADOLOL

TABLET; ORAL
CORGARD

BRISTOL MYERS SQUIBB 4.0MG
8.0MG
12.0MG
16.0MG

NALOXONE HYDROCHLORIDE

NANDROLONE PHENPROPIONATE

**INJECTABLE; INJECTION
DURABOLIN**

NALTREXONE HYDROCHLORIDE

TABLET: ORAL
NALTREXONE HCL
AMIDE PHARM 50MG B

COLLINE FILM, EXTENDED RELEASE; TRANSDERMAL PROSTEX

N19983	001	
JAN	28,	1992
N19983	002	
JAN	28,	1992
N19983	001	
JAN	28,	1992
N19983	002	
JAN	28,	1992

MAPPINGS

JUN 19, 1986

<u>NITROGLYCERIN</u>	<u>OXYBUTYNIN CHLORIDE</u>	
INJECTABLE; INJECTION NITROGLYCERIN ® SMITH AND NEPHEW	5MG/ML	N75039 001 JAN 29, 1999
> <u>ADD</u> > > <u>ADD</u> >	N70633 001 JUN 19, 1986	AA <u>OXYBUTYNIN CHLORIDE</u> MIKART 5MG/5ML
OINTMENT; TRANSDERMAL NITROGLYCERIN ALIANA	N87355 001 JUL 08, 1988	TABLET, EXTENDED RELEASE; ORAL DITROPAN XL + ALZA 15MG N20897 003 JUN 22, 1999
+ <u>OMEPRAZOLE</u>	N87355 001 JUL 08, 1988	OXYTETRACYCLINE CALCIUM
CAPSULE, DELAYED REL PELLETS; ORAL PRILOSEC * ASTRAL PHARMS	10MG N19810 003 OCT 05, 1995	SIRUP, ORAL TERRAMYCIN * PFIZER EQ 125MG BASE/5ML N60595 001
	N19810 003 N19810 003 OCT 05, 1995	OXYTETRACYCLINE HYDROCHLORIDE
	OCT 05, 1995	INJECTABLE; INJECTION TERRAMYCIN * PFIZER EQ 250MG BASE/VIAL N60586 001
	OCT 05, 1995	EQ 500MG BASE/VIAL N60586 002
	OCT 05, 1995	EQ 250MG BASE/VIAL N60586 001
	OCT 05, 1995	EQ 500MG BASE/VIAL N60586 002
<u>ONDANSETRON</u>		OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE
TABLET, ORALLY DISINTEGRATING; ORAL ZOFTRAN ODT GLAXO WELLCOME	EQ 4MG BASE N20781 001 JAN 27, 1999	QINTIMENT; OTIC TERRAMYCIN W/ POLYMYXIN * PFIZER EQ 5MG BASE/GM; 10,000 UNITS/GM N61841 001
+ <u>ORLISTAT</u>	EQ 8MG BASE N20781 002 JAN 27, 1999	EQ 5MG BASE/GM; 10,000 UNITS/GM N61841 001
CAPSULE; ORAL XENICAL + ROCHE	120MG N20766 001 APR 23, 1999	TABLET; VAGINAL TERRAMYCIN-POLYMYXIN * PFIZER EQ 100MG BASE; 100,000 UNITS N61009 001
		EQ 100MG BASE; 100,000 UNITS N61009 001
<u>OPHENADRINE CITRATE</u>		EQ 100MG BASE; 100,000 UNITS N61009 001
TABLET, EXTENDED RELEASE; ORAL OPHENADRINE CITRATE KIEL	100MG N40249 001 JAN 29, 1999	EQ 100MG BASE; 100,000 UNITS N61009 001
<u>AB</u>		

PAROXETINE HYDROCHLORIDE

CAPSULE; ORAL PAXIL	EQ 10MG BASE	N20885 001 OCT 09, 1998	<u>AB</u>	PENTOXIFYLLINE SIDMAR LABS NJ	<u>400MG</u>	N74874 001 MAY 25, 1999
SMITHKLINE BEPHC	EQ 20MG BASE	N20885 002 OCT 09, 1998	<u>AB</u>	TORPHARM	<u>400MG</u>	N75191 001 JUN 09, 1999
	EQ 30MG BASE	N20885 003 OCT 09, 1998	<u>AB</u>	PENTOXIL	<u>400MG</u>	N74962 001 MAR 31, 1999
*	EQ 40MG BASE	N20885 004 OCT 09, 1998	<u>AB</u>	UPSHER SMITH	<u>400MG</u>	
*	EQ 10MG BASE	N20885 001 OCT 09, 1998				N20184 001 DEC 30, 1999
*	EQ 20MG BASE	N20885 002 OCT 09, 1998				
*	EQ 30MG BASE	N20885 003 OCT 09, 1998				
*	EQ 40MG BASE	N20885 004 OCT 09, 1998				
						2003

PENTOXIFYLINE

PHENDIMETRAZINE TARTRATE

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL
PHENTERMINE HCL

AA + EON 3.0MG

N86945 001
JUL 20, 1983

MICRO-K
KV PHARM
ROBINS AH
MICRO-K 1.0
+ KV PHARM
* ROBINS AH

N18238 001
N18238 001

N18238 002
MAY 14, 1984

N18238 002
MAY 14, 1984

N18238 002
MAY 14, 1984

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

AB
AB
AB
AB
AB

MICRO-K PHARM
ROBINS AH
MICRO-K 1.0
+ KV PHARM
* ROBINS AH

N18238 003
N18238 003

N18238 002
AUG 26, 1988

N18238 003
N18238 003

N18238 002
AUG 26, 1988

PHENYTOIN SODIUM

INJECTABLE; INJECTION
PHENYTOIN SODIUM

AB
STERIS
@

50MG/ML
50MG/ML

N85434 001
N85434 001

N19561 003
N19561 003

N19561 003
AUG 26, 1988

PIOGILTAZONE HYDROCHLORIDE

> DLT >
> ADD >

> ADD >

TABLET; ORAL
ACTOS
TAKEDA

EQ 15MG BASE
EQ 30MG BASE
EQ 45MG BASE

N21073 001
JUL 15, 1999

N21073 002
JUL 15, 1999

N21073 003
JUL 15, 1999

N21073 004
JUL 15, 1999

N21073 005
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N21073 006
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N21073 007
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N21073 008
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N21073 009
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N21073 010
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N21073 011
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N21073 012
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N21073 070
JUL 15, 1999

N21073 071
JUL 15, 1999

N21073 072
JUL 15, 1999

N21073 073
JUL 15, 1999

N21073 074
JUL 15, 1999

N21073 075
JUL 15, 1999

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

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

10,000 UNITS/ML;
EQ 1MG BASE/ML

N64211 001
APR 13, 1998

POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE

INJECTABLE; INJECTION
THAM-E

* ABBOTT

370MG/VIAL; 1.75GM/VIAL;

36GM/VIAL

POTASSIUM CITRATE

POWDER FOR RECONSTITUTION; ORAL POTASSIUM CITRATE @ MISSION PHARMA	1.0MEQ/PACKET
	2.0MEQ/PACKET
	1.0MEQ/PACKET
	2.0MEQ/PACKET

PREDNISOLONE TE BUTATE

INJECTABLE; INJECTION
HYDROXYTUBA
+ MERCK
PREDNISOLONE TEBUTATE
STERIS
BP
OCT 13 1988
> ADD >
> DLT >
> DLT >
20MG/ML
20MG/ML
20MG/ML

PREDNISOLONE

SYRUP; ORAL
PREDNISOLONE
HALSEY
UDL

PREDNISOLONE ACETATE

INJECTABLE; INJECTION
 PREDNISOLONE ACETATE
 STERIS
 @
 > DLT >
 > ADD >

SUSPENSION/DROPS; OPHTHALMIC
ECONOPRED PLUS
 ALCON
 FALCON PHARMS

4.0MG/ML
 4.0MG/ML

AB
 AB

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EQ 20MG PHOSPHATE/ML
EQ 20MG PHOSPHATE/ML

INJECTABLE; INJECTION

PREDNISOLONE TEBTUATE INJECTABLE; INJECTION
HYDELTRA-TBA
MERCK BP DLT > 20MG/ML

**INJECTABLE; INJECTION
PROCHLORPERAZINE EDI**

SKINN AND McPHEE EQ 5MG BASE/ML DEC 04, 1986
AP DLT ADD ADD NS9251 001 DRC 04, 1986
NS9251 001 DEC 04, 1986

**INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE**

N89251 001
DEC 04, 1986
N89251 001
DEC 04, 1986

PROCAINAMIDE HYDROCHLORIDE

INJECTABLE; INJECTION	
PROCATAMIDE HCL	
SMITH AND NEPHEW	
100MG/ML	NBB8530 001
500MG/ML	NBB8531 001
100MG/ML	MAR 04 1985
500MG/ML	NBB8530 001
100MG/ML	MAR 04, 1985
500MG/ML	NBB8531 001
100MG/ML	MAR 04 1985
500MG/ML	NBB8530 001
100MG/ML	MAR 04, 1985
500MG/ML	NBB8531 001
STERIS	NBB8579 001
STERIS	NBB8580 001
100MG/ML	NBB87079 001
500MG/ML	NBB87080 001

TABLET; ORAL

<u>AB</u>	<u>* MERCK</u>	<u>500MG</u>	<u>500MG</u>
<u>AB</u>	<u>@ PROBENECID</u>	<u>500MG</u>	<u>500MG</u>
<u>AB</u>	<u>MELAN</u>	<u>500MG</u>	<u>500MG</u>
<u>AB</u>	<u>+ +</u>	<u>004</u>	<u>002</u>
<u>AB</u>		<u>N07898</u>	<u>N84211</u>
<u>AB</u>		<u>004</u>	<u>002</u>

PROCHLORPERAZINE EDISYLATE

**INJECTABLE; INJECTION
PROCHLORPERAZINE EDISYLATE
STERIS**

EQ 5MG BASE/ML
DLT ADD > ADD >
@

PROMAZINE HYDROCHLORIDE

INJECTABLE; INJECTION <u>PROMAZINE HCl</u> STERIS	④	SPARINE * WYETH AYERST
AP	④	IP

PROPOFOL INJECTABLE; INJECTION
DIPRIVAN
2 FLUID OZ.

* <u>PROPOFOL</u>	<u>GENSIA SICOR PHARMS</u>	<u>10MG/ML</u>
<u>PROPRANOLOL HYDROCHLORIDE</u>		
* <u>INJECTABLE ; INJECTION</u>	<u>INDERAL</u>	
* <u>WYETH AYER ST</u>	<u>+ PROPRANOLOL HCL</u>	<u>SMITH AND NEPHEW</u>

RANITIDINE HYDROCHLORIDE

**TABLET; ORAL
RANITIDINE HCL
GRANULES PHARMS**

三

NOVOPHARM NC

RISPERIDONE

JANSSEN

CAPSULE; ORAL NORVIR ABBOTT	SOLUTION; ORAL NORVIR ABBOTT	+ <hr/>	ROFECOXIB <hr/>	SUSPENSION; ORAL VIOXX
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<u>RANITIDINE HYDROCHLORIDE</u>	
<u>TABLET; ORAL</u>	
<u>RANITIDINE HCL</u>	
<u>GRANUTECH PHARMACEUTICALS</u>	
<u>AB</u>	
<u>AB</u>	NOVOPHARM NC
<u>AB</u>	
<u>AB</u>	
<u>AB</u>	PAR PHARM
<u>AB</u>	
<u>RISPERIDONE</u>	
<u>TABLET; ORAL</u>	
<u>RISPERDAL</u>	
<u>JANSSEN</u>	
	+
<u>RITONAVIR</u>	
<u>CAPSULE; ORAL</u>	
<u>NORVIR</u>	
<u>ABBOTT</u>	
	+
<u>SOLUTION; ORAL</u>	
<u>NORVIR</u>	
<u>ABBOTT</u>	
	+
<u>ROFECOXIB</u>	
<u>SUSPENSION; ORAL</u>	
<u>VIOXX</u>	
<u>MERCK</u>	

TABLET; ORAL
RANITIDINE HCL
GRANULES PHARMS

四三

NOVOPHARM NC

RISPERIDONE

JANSSEN +

CAPSULE; ORAL NORVIR ABBOTT	SOLUTION; ORAL NORVIR ABBOTT	+ <hr/>	ROFECOXIB <hr/>	SUSPENSION; ORAL VIOXX
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SPIRONOLACTONE

<u>TABLET: ORAL</u>	<u>AB</u>	<u>AB</u>
<u>SPIRONOLACTONE</u>		
<u>PUREPAC PHARM</u>		
<u>ADD ></u>	<u>ADD ></u>	<u>ADD ></u>
<u>ADD ></u>	<u>ADD ></u>	<u>ADD ></u>
<u>ADD ></u>	<u>ADD ></u>	<u>ADD ></u>

TACROLIMUS

SULFAMETHOXYAZOLE: TRIMETHOPRIM

<u>INJECTABLE: INJECTION</u>	<u>SULFAMETHOXAZOLE AND TRIMETHOPRIM</u>	<u>STERIS</u>
<u>DLT ></u>	<u>AP</u>	<u>80MG/ML; 16MG/ML</u>
<u>DLT ></u>	<u>ADD ></u>	<u>80MG/ML; 16MG/ML</u>

TACROLIMUS

APSSULE; ORAL
PROGRAF
FUJISAWA HLTHCARE
EO 1MG BASE

INJECTABLE: INJECTION

N71556 001
DEC 29, 1987

N71556 001
DEC 29, 1987

INJECTABLE: INFECTION

TC-99M MEDRONATE KIT

INJECTABLE: INJECTION

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

INJECTABLE; INJECTION

N50708 001
APR 08, 1994
N50708 003
AUG 24, 1998

TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

N17684 001
N17684 001
INJECTABLE; INJECTION
PYROLITE
C.I.S.
DUPONT PHARMS

CAPSULE; ORAL
TETRACYCLINE HCL
PIREPAC PHARM

<u>TERBUTALINE SULFATE</u>		
INJECTABLE; INJECTION		
BRETHINE	<u>1 MG/ML</u>	<u>1 MG/ML</u>
* NOVARTIS	+ <u>BRICanyl</u>	* HOECHST MARION RSSL
@		
	<u>1 MG/ML</u>	<u>1 MG/ML</u>
	N18571 001	N18571 001
	N17466 001	N17466 001

TABLET; ORAL		
BRETHINE		
NOVARTIS		
P	2 .5MG	N17849 001
P	5MG	N17849 002
P	2 .5MG	N17849 001
P	5MG	N17849 002
P	2 .5MG	N17618 001
P	5MG	N17618 002
P	2 .5MG	N17618 001
P	5MG	N17618 002
P	2 .5MG	N17618 001
P	5MG	N17618 002

TERIPARATIDE ACETATE

INJECTABLE; INJECTION PAATHAR	200 UNITS/VIAL
* RHONE POULENC RORER	200 UNITS/VIAL

TESTOSTERONE ENANTHATE

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TETRAACYCLINE HYDROCHLORIDE

N17684 001
N17684 001
INJECTABLE; INJECTION
PYROLITE
C.I.S.
DUPONT PHARMS

CAPSULE; ORAL
TETRACYCLINE HCL
PIREPAC PHARM

<u>RIBUTALINE SULFATE</u>		
INJECTABLE: INJECTION		
BRETHINE	<u>1MG / ML</u>	
* NOVARTIS	<u>1MG / ML</u>	
+		
<u>BRICanyl</u>	<u>1MG / ML</u>	
* HOCHST MARION RSSL	<u>1MG / ML</u>	
@		
N18571 001		
N18571 001		
N17466 001		
N17466 001		

TABLET; ORAL	BRETHINE NOVARTIS	2.5MG 5MG 2.5MG 5MG	2.5MG 5MG 2.5MG 5MG	2.5MG 5MG 2.5MG 5MG	N17849 001 N17849 002 N17849 001 N17849 002
+	+ BRICANTIL HOECHST MARION RSSL				N17618 001 N17618 002 N17618 001 N17618 002

RIPARATIDE ACETATE

INJECTABLE, INJECTION
 PARATHAR
 * RHONE POULENC RORER 200 UNITS/VIAL
 200 UNITS/VIAL
 DEC 23, 1987
 N19498 001
 N19498 001

TESTOSTERONE ENANTHATE
INJECTABLE; INJECTION
TESTOSTERONE ENANTHATE
STERILE
100MG/ML
100MG/ML
N85599 001
N85599 001

OCT 16, 1987

OCT 16, 1987

THIOTHIXENE HYDROCHLORIDE

CONCENTRATE; ORAL
THIOTHIXENE HCL
② ALPHARMA
EO 5MG BASE/ML

TIAGABINE HYDROCHLORIDE

TICLOPIDINE HYDROCHLORIDE

<u>TABLET; ORAL</u>	<u>TICLID</u>	*	<u>ROCHE</u>	@	<u>TICLOPIDINE HCL</u>	<u>TORPHARM</u>
> DLT >	<u>DLT</u>		AB	+	<u>SYNTEX</u>	
> DLT >	<u>DLT</u>		AB	+	<u>SYNTEX</u>	
> ADD >	<u>ADD</u>	>	AB	+	<u>SYNTEX</u>	

TIMOLOL MALEATE

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC <u>TIMOLOL MALEATE</u>	<u>AZCON</u>	EQ 0.25% BASE
		EQ 0.5% BASE
		EQ 0.25% BASE
		EQ 0.5% BASE
SOLUTION/DROPS; OPHTHALMIC <u>TIMOLOL MALEATE</u>	<u>FALCON PHARMS</u>	EQ 0.25% BASE
		EQ 0.5% BASE
SOLUTION/DROPS; OPHTHALMIC <u>TIMOLOL MALEATE</u>	<u>TRINITY DERMEUTICS</u>	EQ 0.25% BASE
		EQ 0.5% BASE

TIMOLOL MALEATE

SOLUTION/DROPS; OPHTHALMIC		N74466 00
<u>TIMOLOL MALEATE</u>		MAR 25 199
AT	AKORN	N7261 00
AT	ALCON	APR 28, 199
AT		N74262 00
@	FALCON PHARMS	APR 28, 199
		N74461 00
		APR 28, 199
		N74262 00
		APR 28, 199

TOBRAMYCIN

SOLUTION/DROPS; OPHTHALMIC <u>TOBREX</u>	*	ALCON	<u>0 . 3 %</u>
	+	FALCON PHARMS	<u>0 . 3 %</u>
<u>TRETINOIN</u>			
SOLUTION; TOPICAL <u>TRETINOIN</u>		MORTON GROVE	<u>0 . 05 %</u>
	IT		

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<u>CREAM</u>	<u>TOPICAL</u>	
<u>ARISTOCORT</u>		
<u>FUJISAWA</u>	<u>HLTHCARE</u>	
		<u>0.025%</u>
		<u>0.1%</u>
		<u>0.5%</u>
		<u>0.025%</u>
		<u>0.1%</u>
		<u>0.5%</u>
<u>ARISTOCORT A</u>		
<u>FUJISAWA</u>	<u>HLTHCARE</u>	
		<u>0.025%</u>
		<u>0.025%</u>
		<u>0.1%</u>
		<u>0.1%</u>

VERAPAMIL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
VERAPAMIL HCL

<u>MYLAN</u>	<u>120MG</u>
<u>B</u>	<u>180MG</u>
<u>B</u>	<u>240MG</u>
<u>B</u>	<u>120MG</u>
<u>VERELAN</u>	
<u>*</u>	<u>ELAN</u>

	*			1.80MG
	*			2.40MG
				<u>120MG</u>
				<u>180MG</u>
				2.40MG

INJECTABLE; INJECTION
VERAPAMIL HCL

TABLET, EXTENDED RELEASE; ORAL
URIDAMIN HCl
2 . 5MG /ML

WARFARIN SODIUM

**TABLET; ORAL
WARFARIN SOD**

ZANAMIVIR CAPSULE
 RELEN + GLA

TABLET; ORAL
WARFARIN SODIUM

NAMIVIR
CAPSULE; INHALATION
RELENZA
+ GLAXO WELLCOME
5MG

224

WARFARIN SODIUM

**TABLET; ORAL
COUMADIN**

* DUPONT MERCK

N09218 013
N09218 013
N09218 018
N09218 018
N09218 007
N09218 007

<u>IBUPROFEN</u>		<u>MICONAZOLE NITRATE</u>	
TABLET; ORAL IBUPROFEN LINK	200MG	SUPPOSITORY; VAGINAL MICONAZOLE NITRATE NNC	100MG N73507 001 NOV 19, 1993
NORTON HIN	200MG		
ZENITH GOLDLINE	200MG	<u>MINOXIDIL</u>	
JUNIOR STRENGTH IBUPROFEN PERRIGO	100MG	SOLUTION; TOPICAL MINOXIDIL (FOR MEN) PERRIGO	2% N75357 001 JUL 30, 1999
IBUPROFEN POTASSIUM		MINOXIDIL (FOR WOMEN) PERRIGO	2% N75357 002 JUL 30, 1999
CAPSULE; ORAL PROVEL * NOVARTIS	200MG	NICOTINE	
+ WHITEHALL ROBINS	200MG	FILM, EXTENDED RELEASE; TRANSDERMAL PROSTEEP + ELAN PHARM	1.1MG/24 HR N19983 003 DEC 23, 1998
MICONAZOLE NITRATE		+ 2.2MG/24 HR	N19983 004 DEC 23, 1998
CREAM, SUPPOSITORY; TOPICAL, VAGINAL M-ZOLE 3 COMBINATION PACK ALPHARMA US PHARM	2%, 200MG	NICOTINE POLACRILEX	
MICONAZOLE NITRATE COMBINATION PACK PERRIGO	2%, 200MG	GUM, CHEWING; Buccal NICOTINE POLACRILEX CIRCA	EQ 2 MG BASE N74507 001 MAR 15, 1999
SUPPOSITORY; VAGINAL MICONAZOLE NITRATE ALPHARMA US PHARM	100MG	EQ 4 MG BASE	N74707 001 MAR 19, 1999
		NONOXYNOL-9	
		SPONGE; VAGINAL TODAY @ ALLENDALE PHARMS	1GM N18683 001 APR 01, 1983
		@ WHITEHALL ROBINS	1GM N18683 001 APR 01, 1983

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL
120MG
PERRIGO

N75153 001
FEB 26, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HCL
NOVOPHARM
FAMAXX
ZANTAC 75
* GIAXO WELLCOMB
+ WARNER LAMBERT
EQ 75MG BASE
EQ 75MG BASE
EQ 75MG BASE
EQ 75MG BASE

N75094 001
JUN 21, 1999
N75132 001
N20520 001
DEC 19, 1995
N20520 001
DEC 19, 1995
N20520 001
DEC 19, 1995

TERBINAFINE HYDROCHLORIDE

CREAM; TOPICAL
LAMISIL
+ NOVARTIS
1%

N20980 001
MAR 09, 1999

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

CUMULATIVE SUPPLEMENT NUMBER 7 JUL '99

NO JULY 1999 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 July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
111Indium pentetreotide TN= SomatoTher	Treatment of somatostatin receptor positive neuroendocrine tumors.	Louisiana State University Medical Center Foundation 1600 Canal St. 10th Floor New Orleans, LA 70112 DD=06/10/1999
166Ho-DOTMP TN=	Treatment of multiple myeloma.	NeoRx Corporation 410 W. Harrison Seattle, WA 98119 DD=02/10/1999
6-hydroxymethylacylfulvene TN=	Treatment of histologically confirmed advanced or metastatic pancreatic cancer.	MGI Pharma, Inc. Suite 300E, Opus Center 9900 Bren Road East Minnetonka, MN 55343 DD=04/06/1999
6-hydroxymethylacylfulvene TN=	Treatment of ovarian cancer.	MGI Pharma, Inc. 9900 Bren Road East Suite 300E, Opus Center Minnetonka, MN 55343 DD=07/06/1999
6-hydroxymethylacylfulvene TN=	Treatment of renal cell carcinoma.	MGI Pharma, Inc. 9900 Bren Road East Suite 300 E, Opus Center Minnetonka, MN 55343 DD=07/27/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Alitretinoin TN= Panretin	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 MA=02/02/1999
Amifostine TN= Ethyol	Reduction of the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer.	U.S. Bioscience, Inc. One Tower Bridge 100 Front Street, Suite 400 Conshohocken, PA 19428 DD=05/12/1998 MA=06/24/1999
Antihemophilic factor/von Willebrand factor complex (human), dried, pasteurized TN= Humate-P	Treatment and prevention of bleeding in hemophilia A (classical hemophilia) in adult patients; and treatment of spontaneous and trauma-induced bleeding episodes in severe von Willebrand disease, and in mild and moderate von Willebrand disease where use of desmopressin is known or suspected to be inadequate in adult and pediatric patients.	Centeon Pharma GmbH Emil-von-Behring-Strasse 76 35041 Marburg Germany DD=10/16/1992 MA=04/01/1999
Artesunate TN=	Treatment of malaria.	World Health Organisation Special Programme for Research and Training in Tropical Diseases Via Appia Geneva 27, Switzerland, DD=07/19/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Atovaquone TN= Mepron	Prevention of Pneumocystis carinii pneumonia (PCP) in high-risk, HIV-infected patients defined by a history of one or more episodes of PCP and/or a peripheral CD4+ (T4 helper/inducer) lymphocyte count less than or equal to 200/mm ³ .	Glaxo Wellcome Research and Development 5 Moore Drive PO Box 13398 Research Triangle Park, NC 27709 DD=08/14/1991 MA=01/05/1999
Autologous DNP-conjugated tumor vaccine TN= M-Vax	For adjuvant therapy in melanoma patients with surgically resectable lymph node metastasis (Stage III and limited Stage IV disease).	Avax Technologies, Inc. 4520 Main St. Suite 930 Kansas City, MO 64111 DD=02/23/1999
Beraprost TN=	Treatment of pulmonary arterial hypertension associated with any New York Heart Association classification (Class I, II, III, or IV).	United Therapeutics Corporation 68 T.W. Alexander Drive, PO Box 14186 Research Triangle Park, NC 27709 DD=04/29/1999
Bexarotene TN= Targretin	Treatment of cutaneous T-cell lymphoma.	Ligand Pharmaceuticals, Inc. 10275 Science Center Dr. San Diego, CA 92121 DD=06/18/1999
Bleomycin TN= Blenoxane	Treatment of pancreatic cancer.	Genetronics, Inc. 11199 Sorrento Valley Rd. San Diego, CA 92121 DD=02/09/1999

Orphan Product Designations and Approvals List

July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Busulfan TN= Busulfex	As preparative therapy in the treatment of malignancies with bone marrow transplantation.	Orphan Medical, Inc. 13911 Ridgedale Drive Suite 475 Minnetonka, MN 55305 DD=07/28/1994 MA=02/04/1999
CT-2584 mesylate TN=	Treatment of adult soft tissue sarcoma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Suite 400 Seattle, WA 98119 DD=04/16/1999
CT-2584 mesylate TN=	Treatment of malignant mesothelioma.	Cell Therapeutics, Inc. 201 Elliott Ave. West Seattle, WA 98119 DD=04/16/1999
Coagulation factor VIIa (recombinant) TN= NovoSeven	Treatment of bleeding episodes in hemophilia A or B patients with inhibitors to Factor VIII or Factor IX.	Novo Nordisk Pharmaceuticals, Inc. 100 Overlook Center Suite 200 Princeton, NJ 08540 DD=06/06/1988 MA=03/25/1999
Cytarabine liposomal TN= DepoCyt	Treatment of neoplastic meningitis.	DepoTech Corporation 10450 Science Center Drive San Diego, CA 92121 DD=06/02/1993 MA=04/01/1999
Decitabine TN=	Treatment of myelodysplastic syndromes.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Decitabine TN=	Treatment of chronic myelogenous leukemia.	Pharmachemie B.V. Swensweg 5 2031 GA Haarlem, The Netherlands DD=03/08/1999
Denileukin diftitox TN= Ontak	Treatment of patients with persistent or recurrent cutaneous T-cell lymphoma whose malignant cells express the CD25 component of the IL-2 receptor.	Seragen, Inc. 97 South Street Hopkinton, MA 01748 DD=08/21/1996 MA=02/05/1999
Doxorubicin liposome TN= Doxil	Treatment of ovarian cancer.	Alza Corporation 1550 Plymouth St. PO Box 7210 Mountain View, CA 94039 DD=11/04/1998 MA=06/28/1999
Epoprostenol TN= Flolan	Treatment of secondary pulmonary hypertension due to intrinsic precapillary pulmonary vascular disease.	Glaxo Wellcome Inc. Five Moore Dr. PO Box 13398 Research Triangle Park, NC 27709 DD=03/22/1999
Etanercept TN= Enbrel	Reduction in signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.	Immunex Corporation 51 University St. Seattle, WA 98101 DD=10/27/1998 MA=05/27/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Etanercept TN= Enbrel	Treatment of Wegener's granulomatosis.	Stone, MD, MPH, John H. Johns Hopkins Vasculitis Center, Division of Rheumatology 1830 East Monument St., Suite 7500 Baltimore, MD 21205 DD=04/06/1999
Fluoxetine TN= Prozac	Treatment of autism.	Hollander, MD, Eric Mt. Sinai School of Medicine, Dept. of Psychiatry Box 1230, One Gustave L. Levy Place New York, NY 10029 DD=04/30/1999
Humanized MAb (IDE-C-131) to CD40L TN=	Treatment of systemic lupus erythematosus.	Idec Pharmaceuticals Corporation 3030 Callan Rd. San Diego, CA 92121 DD=02/09/1999
Interferon beta-1a (recombinant human) TN= Avonex	Treatment of pulmonary fibrosis.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=01/07/1999
Iodine I-131 radiolabeled chimeric MAb tumor necrosis treatment (TNT-1B) TN= 131I-chTNT-1	Treatment of glioblastoma multiforme and anaplastic astrocytoma.	Technicclone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Japanese encephalitis vaccine (live, attenuated) TN=	Prevention of Japanese encephalitis.	Boran Pharmaceuticals 3F, Koryo Academytel, 437-3 Ahyun-Dong, Mapo-Gu, Seoul 121-010 South Korea, DD=05/19/1999
L-5-hydroxytryptophan TN=	Treatment of tetrahydrobiopterin deficiency.	Watson Laboratories, Inc. 311 Bonnie Circle P.O. Box 1900 Corona, CA 91718 DD=01/20/1999
Lactic acid TN= Aphthaid	Treatment of severe aphthous stomatitis in severely, terminally immunocompromised patients.	Frontier Pharmaceutical, Inc. SUNY Farmingdale Conklin Hall Farmingdale, NY 11735 DD=06/29/1999
Lidocaine patch 5% TN= Lidoderm Patch	For relief of allodynia (painful hypersensitivity), and chronic pain in post-herpetic neuralgia.	Hind Health Care, Inc. 3707 Williams Rd., Suite 101 San Jose, CA 95117 DD=10/24/1995 MA=03/19/1999
Lisofylline TN=	Treatment of patients undergoing induction therapy for acute myeloid leukemia.	Cell Therapeutics, Inc. 201 Elliot Ave. W., Suite 400 Seattle, WA 98119 DD=06/10/1999
Marijuana TN=	Treatment of HIV-associated wasting syndrome.	Multidisciplinary Association for Psychedelic Studies, Inc. 3 Francis St. Belmont, MA 02478 DD=05/25/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Murine MAAb to polymorphic epithelial mucin, human milk fat globule 1 TN= Theragyn	Adjuvant treatment of ovarian cancer.	Antisoma West Africa House Hanger Lane London W5 3QR, UK DD=03/22/1999
N-acetylgalactosamine-4-sulfatas e, recombinant human TN=	Treatment of mucopolysaccharidosis Type VI (Maroteaux-Lamy syndrome).	BioMarin Pharmaceutical, Inc. 11 Pimental Court Novato, CA 94949 DD=02/17/1999
Parovirus B19 (recombinant VP1 and VP2; S.frugiperda cells) vaccine TN= MEDI-491	Prevention of transient aplastic crisis in patients with sickle cell anemia.	MedImmune, Inc. 35 West Watkins Mill Rd. Gaithersburg, MD 20878 DD=05/07/1999
Pegylated arginine deiminase TN= Hepacid	Treatment of hepatocellular carcinoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=03/26/1999
Pegylated arginine deiminase TN= Melanocid	Treatment of invasive malignant melanoma.	Phoenix Pharmacologics, Inc. 115 John Robert Thomas Dr. Exton, PA 19341 DD=04/12/1999
Recombinant human C1-esterase inhibitor TN=	Prophylactic treatment of angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel, Belgium DD=02/23/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Recombinant human C1-esterase inhibitor TN=	Treatment of (acute attacks of) angioedema caused by hereditary or acquired C1-esterase inhibitor deficiency.	Pharming N.V. Cipalstreet 3 B-2440 Geel, Belgium DD=02/23/1999
Recombinant human insulin-like growth factor-I/insulin -like growth factor binding protein-3 TN=	Treatment of major burns that require hospitalization.	Celtrix Pharmaceuticals, Inc. 3055 Patrick Henry Dr. Santa Clara, CA 95054 DD=06/15/1999
Recombinant human nerve growth factor TN=	Treatment of HIV-associated sensory neuropathy.	Genentech, Inc. 1 DNA Way South San Francisco, CA 94080 DD=04/16/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of solid organ transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Recombinant humanized MAb 5c8 TN=	Prevention of rejection of pancreatic islet cell transplants.	Biogen, Inc. 14 Cambridge Center Cambridge, MA 02142 DD=03/22/1999
Rifalazil TN=	Treatment of pulmonary tuberculosis.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=04/13/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
SCH 58500 TN=	Treatment of primary ovarian cancer.	Schering Corporation 2000 Galloping Hill Rd. Kenilworth, NJ 07033 DD=04/12/1999
Sodium 1,3-propanedisulfonate TN=	Treatment of secondary amyloidosis.	Neurochem, Inc. 7220 Frederick Banting, Suite 100 Saint-Laurent, Quebec Canada H4S 2A1 DD=04/06/1999
Sodium dichloroacetate TN= Ceresine	Treatment of severe head injury.	Cypros Pharmaceutical Corporation 2714 Loker Avenue West Carlsbad, CA 92008 DD=06/14/1999
Somatropin [rDNA] TN= Genotropin	Treatment of short stature in patients with Prader-Willi syndrome.	Pharmacia & Upjohn 7000 Portage Rd. 0633-298-113 Kalamazoo, MI 49001 DD=07/06/1999
Synthetic human secretin TN=	For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 1550 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic human secretin TN=	For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999
Synthetic human secretin TN=	For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/16/1999

Orphan Product Designations and Approvals List
July 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Synthetic porcine secretin TN=	For use in the evaluation of porcine exocrine pancreas function.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Synthetic porcine secretin TN=	For use in obtaining desquamated pancreatic cells for cytopathologic examination in pancreatic carcinoma.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Synthetic porcine secretin TN=	For use in the diagnosis of gastrinoma associated with Zollinger-Ellison syndrome.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999
Thalidomide TN= Thalomid	Treatment of Crohn's disease.	Celgene Corporation 7 Powder Horn Dr. Warren, NJ 07059 DD=04/06/1999
Tobramycin TN= Tobi	Treatment of bronchiectasis patients infected with Pseudomonas aeruginosa.	PathoGenesis Corporation 201 Elliott Avenue West Suite 150 Seattle, WA 98119 DD=06/18/1999
Transgenic human alpha 1 antitrypsin TN=	Treatment of emphysema secondary to alpha 1 antitrypsin deficiency.	PPL Therapeutics (Scotland) Limited Roslin, Edinburgh EH25 9PP Scotland U.K. DD=05/19/1999

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

NO JULY 1999 ADDITIONS

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 19TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

NP* NEW PRODUCT (MINT FLAVORED)

REFERENCES *NEW DOSING SCHEDULE*

D-50 INFORMATION FOR USE OF CORVERT IN POST-CARDIAC SURGERY PATIENTS

NEW INDICATION

- I-250 PRIMARY PREVENTION OF CORONARY HEART DISEASE IN PATIENTS WITHOUT SYMPTOMATIC CARDIOVASCULAR DISEASE WHO HAVE AVERAGE TO MODERATELY ELEVATED TOTAL-C AND LDL-C AND BELOW AVERAGE HDL-C
- I-251 TREATMENT OF GENERALIZED ANXIETY DISORDER
- I-252 NEW COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS METFORMIN
- I-253 COMBINATION USE OF PRECOSE FOR PATIENTS WITH TYPE 2 DIABETES TREATED WITH DIET PLUS INSULIN
- I-254 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS (LOSS OF BONE MASS)
- I-255 PREVENTION OF PNEUMOCYSTIS CARINII PNEUMONIA (PCP)
- I-256 USE IN TREATMENT OF SMALL CELL LUNG CANCER SENSITIVE DISEASE AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY
- I-257 TREATMENT OF CHRONIC HEPATITIS B ASSOCIATED WITH EVIDENCE OF HEPATITIS B VIRAL REPLICATION AND ACTIVE LIVER INFLAMMATION
- I-258 FOR PERENNIAL NONALLERGIC RHINITIS FOR AGES FOUR AND ABOVE
- I-259 PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT), WHICH MAY LEAD TO PULMONARY EMBOLISM, IN PATIENTS UNDERGOING HIP REPLACEMENT SURGERY
- I-260 EXPANDED PEDIATRIC USE IN CHILDREN YOUNGER THAN ONE MONTH OF AGE TO BIRTH (WITH A GESTATIONAL AGE OF 37 WEEKS OR GREATER)
- I-261 TREATMENT OF SOCIAL ANXIETY DISORDER
- I-262 TREATMENT OR PREVENTION OF BRONCHOSPASM WITH REVERSIBLE OBSTRUCTIVE AIRWAY DISEASE AND FOR THE PREVENTION OF EXERCISE INDUCED BRONCHOSPASM IN CHILDREN AGES 4-12
- I-263 TREATMENT OF UNSTABLE ANGINA AND NON-Q-WAVE MYOCARDIAL INFARCTION FOR THE PREVENTION OF ISCHEMIC COMPLICATIONS IN PATIENTS ON CONCURRENT ASPIRIN THERAPY
- I-264 PREVENTION OF NAUSEA AND VOMITING ASSOCIATED WITH RADIATION, INCLUDING TOTAL BODY IRRADIATION (TBI) AND FRACTIONATED ABDOMINAL RADIATION
- I-265 TREATMENT OF ATOPIC DERMATITIS IN PEDIATRIC PATIENTS 6 YEARS AND OLDER
- I-266 USE OF TOPAMAX AS ADJUNCTIVE THERAPY IN PEDIATRIC PATIENTS AGES 2-16 YEARS WITH PARTIAL ONSET SEIZURES
- I-267 USE IN PEDIATRIC PATIENTS 3 MONTHS OLD AND OLDER-FOR CORTICOSTEROID-RESPONSIVE DERMATOSES

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

PATENT USE CODE

- U-254 USE OF AGGRASTAT IN COMBINATION WITH HEPARIN
- U-255 IMPROVED WAKEFULNESS IN PATIENTS WITH EXCESSIVE DAYTIME SLEEPINESS ASSOCIATED WITH NARCOLEPSY
- U-256 TREATMENT OF HIV INFECITON IN COMBINATION WITH ONE OR MORE ADDITIONAL HIV ANTIVIRAL AGENTS
- U-257 TREATMENT OF HIV INFECTION
- U-258 TREATMENT OF NEURODEGENERATIVE DISEASES
- U-259 TREATMENT OF ANDROGENIC ALOPECIA BY ORAL ADMINISTRATION OF DRUG SUBSTANCE
- U-260 REDUCTION OF INTRAOOCULAR PRESSURE IN PATIENTS WITH OPEN ANGLE GLAUCOMA AND OCULAR HYPERTENSION WHO ARE INTOLERANT OF OTHER IOP LOWERING MEDICATIONS OR INSUFFICIENTLY RESPONSIVE TO ANOTHER IOP LOWERING MEDICATION
- U-261 TREATING BENIGN PROSTATIC HYPERPLASIA WITH A GENUS OF COMPOUNDS, INCLUDING FINASTERIDE
- U-262 TREATING BENIGN PROSTATIC HYPERTROPHY WITH FINASTERIDE
- U-263 METHOD OF TREATING A MALIGNANT CONDITION THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING LEUKEMIA OR LYMPHOMA IN A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVENOUS ADMINISTRATION OF BUSULFAN.
- U-264 METHOD OF TREATING A MALIGNANT DISEASE THROUGH PARENTERAL ADMINISTRATION OF BUSULFAN. METHOD FOR TREATING A PATIENT UNDERGOING A BONE MARROW TRANSPLANT THROUGH INTRAVASCULAR ADMINISTRATION OF BUSULFAN.
- U-265 USE AS A LAXATIVE
- U-266 OSTEOARTHRITIS
- U-267 METHOD FOR PREVENTING HEARTBURN
- U-268 ACROMEGALY
- U-269 EXCESS GH-SECRETION OR GASTRO-INTESTINAL DISORDERS
- U-270 METHOD FOR IMPROVING THE TIME FOR ADMINISTRATION OR THE TIME BETWEEN CHANGES OF GIVING SETS FOR THE DRUG PRODUCT
- U-271 METHOD OF TREATING TUMORS
- U-272 METHOD OF TREATING CARCINOMA
- U-273 CUTANEOUS T-CELL LYMPHOMA
- U-274 ZANAMIVIR FOR INHALATION
- U-275 METHOD OF USE OF THE DRUG SUBSTANCE
- U-276 METHOD OF USE OF LEVOBUPIVACAINE
- U-277 NEUROLOGICAL AND OTHER DISORDERS (TREATMENT OF EPILEPSY, BID ORAL DOSING)
- U-278 METHOD OF USE OF THE INDICATION OF THE DRUG PRODUCT

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
020482 004	ACARBOSE; PRECOSE					I-252	SEP 29, 2001
>ADD>	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010	U-134	I-253	SEP 29,	2001
>ADD>	ADAPALENE; DIFFERIN	RE34440	MAR 31, 2010	U-275			
>ADD>	ADAPALENE; DIFFERIN	4717720	MAY 31, 2010	U-134			
>ADD>	ALBUTEROL SULFATE PROVENTIL-HFA	RE34440	MAY 31, 2010	U-275			
020503 001	ALBUTEROL SULFATE VENTOLIN	4594359	JUN 10, 2003		I-262	JUN 02,	2002
019621 001	ALITRETNINOIN; PANRETIN			ODE	FEB 02,	2006	
020886 001				NCE	FEB 02,	2004	
020221 001	AMIFOSTINE; ETHYOL			ODE	JUN 24,	2006	
021007 001	AMPRENAVIR; AGENERASE			NCE	APR 15,	2004	
021007 002	AMPRENAVIR; AGENERASE			NCE	APR 15,	2004	
021039 001	AMPRENAVIR; AGENERASE			ODE	JAN 05,	2006	
020500 001	ATOVAQUONE; MEPRON	5585397	DEC 17, 2013		I-255	JAN 05,	2002
020711 002	BUPROPTION HYDROCHLORIDE; ZYBAN	5763493	AUG 12, 2013				
020711 003	BUPROPTION HYDROCHLORIDE; ZYBAN	5763493	AUG 12, 2013	ODE	FEB 04,	2006	
020954 001	BUSULFAN; BUSULFEX	5430057	SEP 30, 2013	U-263	FEB 04,	2002	
>ADD>	CALCITONIN, SALMON; MIACALCIN	5559148	MAY 24, 2015	U-264	NDF	FEB 04,	2002
020313 002	CAPECITABINE; XELODA	5759965	JUN 02, 2015				
020896 001	CAPECITABINE; XELODA	5472949	DEC 14, 2013	ODE			
>ADD>	CAPECITABINE; XELODA	4966891	NOV 08, 2013	U-271			
>ADD>	CARBAMAZEPINE; CARBATROL	5472949	DEC 14, 2013	U-271			
>ADD>	CARBAMAZEPINE; CARBATROL	4966891	NOV 08, 2008	U-272			
>ADD>	CARBAMAZEPINE; CARBATROL	5912013	JUN 15, 2016	U-277			
>ADD>	CELECOXIB; CELEBREX	5760068	JUN 02, 2015	U-277			
020998 002	CELECOXIB; CELEBREX	5466823	NOV 30, 2013	ODE			
		5563165	NOV 30, 2013	NS	MAY 24,	2002	
020740 005	CERIVASTATIN SODIUM; BAYCOL	5006530	JAN 17, 2009				
		5177080	NOV 26, 2011				
		5142051	JUN 26, 2010				
		4277479	AUG 29, 1999				
		4277479	AUG 29, 1999	NCE	JAN 15,	2004	
		4670444	DEC 09, 2003	NCE	JAN 15,	2004	
>ADD>	CIPROFLOXACIN HYDROCHLORIDE; CIPRO	5286754	FEB 15, 2011	U-36			
>ADD>	CISAPRIDE MONOHYDRATE; PROPULSID QUICKSOLV	5648093	JUL 15, 2014				
				ODE	APR 01,	2006	
				NP	APR 01,	2002	
				I-263	MAY 25,	2002	
020638 001	CIDOFUVIR; VISTIDE			I-259	MAR 30,	2002	
020863 001	CILOSTAZOL; PLETAL			I-263	MAY 25,	2002	
020863 002	CILOSTAZOL; PLETAL			I-259	MAR 30,	2002	
019537 004	CIPROFLOXACIN HYDROCHLORIDE; CIPRO			I-263	MAY 25,	2002	
>ADD>	CISAPRIDE MONOHYDRATE; PROPULSID QUICKSOLV			I-259	MAR 30,	2002	
020767 001	CYTARABINE; DEPOCT						
021041 001							
020287 001	DALTEPARIN SODIUM; FRAGMIN						
020287 003	DALTEPARIN SODIUM; FRAGMIN						
020287 004	DALTEPARIN SODIUM; FRAGMIN						

PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
PEDIATRIC Exclusivity
and PEDI represent Pediatric Exclusivity

*PED represent pediatric exclusively

APPL/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	EXPIRES NUMBER	CODE	CODE	EXPIRES
017922 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
017922 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
017922 003	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
018938 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
018938 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
019955 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
019955 002	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29,	2013	
074752 001	DILTIAZEM HYDROCHLORIDE; CARTIA XT	4814470	MAY 14,	2010	
074752 003	DILTIAZEM HYDROCHLORIDE; CARTIA XT	5438072	NOV 22,	2013	
074752 004	DILTIAZEM HYDROCHLORIDE; CARTIA XT	569582	JUL 03,	2012	
020449 001	DOCETAXEL; TAXOTERE	5714512	JUL 03,	2012	
020862 001	DOXERCALCIFEROL; HECTOROL	5602116	APR 03,	2015	
>ADD>	050718 001 DOXORUBICIN HYDROCHLORIDE; DOXIL	5707980	FEB 11,	2017	
>ADD>	020972 001 EFAVIRENZ; SUSTIVA	5811423	AUG 07,	2012	U-256
020972 002	EFAVIRENZ; SUSTIVA	5519021	MAY 21,	2013	
020972 003	EFAVIRENZ; SUSTIVA	5663169	SEP 02,	2014	U-257
020375 001	ESTRADIOL; CLIMARA	5811423	MAY 21,	2013	
020375 002	ESTRADIOL; CLIMARA	5519021	MAY 21,	2013	
020375 003	ESTRADIOL; CLIMARA	5663169	SEP 02,	2014	U-257
020375 004	ESTRADIOL; CLIMARA	5811423	AUG 07,	2012	U-256
020908 001	ESTRADIOL; VAGIFEM	5811423	AUG 07,	2012	I-254
020992 002	ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN	5811423	MAR 05,	2000	I-254
020992 003	ESTROGENS, CONJUGATED SYNTHETIC A; CENESTIN	5811423	MAR 05,	2000	I-254
020527 003	ESTROGENS, CONJUGATED; PREMPRO 14/14	5811423	MAR 05,	2000	I-254
020363 001	FAMCICLOVIR; FAMVIR	5826831	MAY 02,	2006	
020363 003	FAMCICLOVIR; FAMVIR	5547948	JAN 17,	2015	U-96
020325 001	FAMOTIDINE; PEPCID AC	5246937	SEP 21,	2010	
020801 001	FAMOTIDINE; PEPCID AC	5854267	DEC 29,	2015	U-267
019304 002	FENOFLIBRATE; TRICOR (MICRONIZED)	4895726	JAN 19,	2009	
020747 001	FENTANYL CITRATE; ACTIQ	5246937	DEC 29,	2015	
020747 002	FENTANYL CITRATE; ACTIQ	5854267	DEC 29,	2015	
020747 003	FENTANYL CITRATE; ACTIQ	5854267	DEC 29,	2015	
020747 004	FENTANYL CITRATE; ACTIQ	5854267	DEC 29,	2015	
020747 005	FENTANYL CITRATE; ACTIQ	5854267	DEC 29,	2015	
020747 006	FENTANYL CITRATE; ACTIQ	5854267	DEC 29,	2015	
020955 001	FERRIC SODIUM GLUCONATE, FERRLECIT	58555912	FEB 28,	2015	
020625 001	FEXOFENADINE HYDROCHLORIDE; ALLEGRA	5738872	FEB 28,	2015	

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE CODE	EXCLUS EXPIRES
020788 001	FINASTERIDE; PROPECIA	5571817 5886184 4760071 5886184 4377384	NOV 05, 2013 NOV 19, 2012 JUN 19, 2006 NOV 19, 2012 MAR 22, 2000	U-259 U-262 U-261 I-265 AUG 18, 2002
020180 001	FINASTERIDE; PROSCAR			
>ADD>	019452 001 FLUOCINOLONE ACETONIDE; DERMA-SMOOTHÉ / FS FLUOXETINE HYDROCHLORIDE; PROZAC	4314081 4626149 4314081 4626149	FEB 02, DEC 02, FEB 02, DEC 02,	2001 2003 2001 2003
020974 001	FLUOXETINE HYDROCHLORIDE; PROZAC			
>ADD>	019958 001 FLUTICASONE PROPIONATE; CUTIVATE FLUTICASONE PROPIONATE; FLONASE GABAPENTIN; NEURONTIN	4087344 5084379 4087344 5084379 4801577 5767082	JAN 16, JAN 02, JAN 16, JAN 02, FEB 05, JUN 16,	2000 2010 2000 2010 2007 2015
020974 002	GABAPENTIN; NEURONTIN			
>ADD>	021057 001 GANIRELIX ACETATE; ANTAGON			
>ADD>	020305 001 GRANSETRON HYDROCHLORIDE; KYTRIL	5270317	MAR 20,	2011
>ADD>	020305 002 GRANSETRON HYDROCHLORIDE; KYTRIL HYDROCHLORTHAZIDE; AVAILIDE			
020758 003	I BUTILIDE FUMARATE; CORVERT ITRACONAZOLE; SPORANOX ITRACONAZOLE; SPORANOX ITRACONAZOLE; SPORANOX	4791111 4791111 4791111 4267179	DEC 23, DEC 23, DEC 23, JUN 23,	2005 2005 2005 2000
020491 001				
020083 001	KETOTIFEN FUMARATE; ZADITOR LAMIVUDINE; EPIVIR LAMIVUDINE; EPIVIR-HBV	5905082 5047407 5532246 5905082 5047407 5532246	MAY 18, FEB 08, JUL 02, MAY 18, FEB 08, JUL 02,	2016 2009 2013 2016 2009 2013
020657 001				
020966 001				
>ADD>	021066 001 LAMIVUDINE; EPIVIR-HBV LAMOTRIGINE; LAMICTAL CD LAMOTRIGINE; LAMICTAL CD LATANOPROST; XALATAN	5905082 5047407 5532246 5905082 5047407 5532246	MAY 18, FEB 08, JUL 02, MAY 18, FEB 08, JUL 02,	2016 2009 2013 2016 2009 2013
020764 001				
020764 002				
020764 003				
020597 001				
>ADD>	020517 002 LEUPROLIDE ACETATE; LUPRON DEPOT-4 LEVALBUTEROL HYDROCHLORIDE; XOPENEX LEVALEUTEROL HYDROCHLORIDE; XOPENEX	5296504 5422368 4599353 4652441	MAR 22, MAR 22, JUL 28, NOV 01,	2011 2011 2006 2004
020837 001				
020837 002				
>ADD>	020997 001 LEVOBIPIVACAINE HYDROCHLORIDE; CHIROCAINE LEVOBIPIVACAINE HYDROCHLORIDE; CHIROCAINE	5708011 5708011 5708011	OCT 13, OCT 13, OCT 13,	2014 2014 2014
020997 002				
>ADD>	020997 003 LEVORGESTREL; PLAN B			
>ADD>	021045 001 LIDOCAINE; EMLA LIDOCAINE; LIDODERM LISINOPRIL; ZESTRI			
019941 001				
020612 001				
019777 006	LISINOPRIL; ZESTRI	4374829	DEC 30,	2001

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	019643 002	LOVASTATIN; MEVACOR	JUN 15, 2001	I-250	MAR 11, 2002
>ADD>	019643 003	LOVASTATIN; MEVACOR	JUN 15, 2001	I-250	MAR 11, 2002
>ADD>	019643 004	LOVASTATIN; MEVACOR	JUN 15, 2001	I-250	MAR 11, 2002
>ADD>	020969 001	METHOXSALEN; UVADEX	JUL 30, 2008	U-273	NP FEB 25, 2002
>ADD>	020968 001	MICONAZOLE NITRATE; MONISTAT DUAL- PAK	MAR 12, 2008	NP	JUN 30, 2002
>ADD>	020682 001	MIGLITOL; GLYSET	APR 11, 2009	NP	JUN 30, 2002
020682 002	MIGLITOL; GLYSET	JAN 27, 2009	U-111	U-111	U-111
020682 003	MIGLITOL; GLYSET	JAN 27, 2009	U-111	U-111	U-111
020717 001	MODAFINIL; PROVIGIL	MAR 09, 1999	OCT 06, 2014	U-255	U-255
020717 002	MODAFINIL; PROVIGIL	MAY 22, 2007	U-255	NP*	DEC 23, 2001
018612 003	NICOTINE POLACRILEX; NICORETTE (MINT)	AUG 12, 2014	NP*	DEC 23, 2001	DEC 23, 2001
020066 003	NICOTINE POLACRILEX; NICORETTE (MINT)	JUL 13, 2016	ODE	NOV 25, 2005	NP*
020385 001	NICOTINE; NICOTROL	JUL 13, 2016	ODE	NOV 25, 2005	NP*
021008 001	OCTREOTIDE ACETATE; SANDOSTATIN LAR	MAR 09, 1999	OCT 06, 2014	U-255	U-255
>ADD>	021008 002	OCTREOTIDE ACETATE; SANDOSTATIN LAR	MAY 22, 2007	NP	DEC 23, 2001
>ADD>	021008 002	OCTREOTIDE ACETATE; SANDOSTATIN LAR	JUL 13, 2016	ODE	NOV 25, 2005
>ADD>	021008 003	OCTREOTIDE ACETATE; SANDOSTATIN LAR	MAR 21, 2002	U-268	U-268
>ADD>	020766 001	ORLISTAT; XENICAL	JUL 23, 2013	ODE	NOV 25, 2005
020897 001	OXYBUTYNIN CHLORIDE; DITROPAN XL	MAY 22, 2015	NP	APR 23, 2004	DEC 16, 2001
020897 002	OXYBUTYNIN CHLORIDE; DITROPAN XL	MAY 22, 2015	NP	APR 23, 2004	DEC 16, 2001

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	EXCLUS CODE	EXCLUS EXPRIES
>ADD> 021073 003	PIOGLITAZONE HYDROCHLORIDE;ACTOS	4444779 4687777 5710183 5714520	JUL 27, 1999 JAN 17, 2006 JUL 14, 2015 MAR 22,	NCE	JUL 15, 2004	
>ADD> 020698 001	POLYETHYLENE GLYCOL 3350;MIRALAX	5714520*PED	SEP 22, 2015	U-265 NP	FEB 18, 2002	
>ADD> 019627 002	PROPOFOL;DIPRIVAN	5731355 5731355*PED	MAR 22, 2015 SEP 22, 2015	U-217		
>ADD>		5731355*PED	SEP 22, 2015	U-217		
>ADD>		5731356	MAR 22, 2015	U-218		
>ADD>		5731356*PED	SEP 22, 2015	U-218		
>ADD>		5908869	MAR 22, 2015	U-270		
>ADD>		5908869*PED	SEP 22, 2015	U-270		
075102 001	PROPOFOL; PROPOFOL	4879288	MAR 20, 2007	PC	OCT 16, 1999	
020639 004	QUETiapine FUMARATE; SERQUEL			NCE	SEP 26, 2002	
>ADD> 020973 001	RABEPRAZOLE SODIUM;ACIPHEX			NCE	AUG 19, 2004	
>ADD> 020973 002	RABEPRAZOLE SODIUM;ACIPHEX			NCE	AUG 19, 2004	
>ADD> 075094 001	RANITIDINE HYDROCHLORIDE; RANITIDINE HCL			PC	JAN 13, 2000	
>ADD> 020984 001	RAPACURONIUM BROMIDE; RAPLON			NCE	AUG 18, 2004	
>ADD> 020984 002	RAPACURONIUM BROMIDE; RAPLON			NCE	AUG 18, 2004	
>ADD> 020903 001	RIBAVIRIN; REBTOL					
>ADD> 020272 007	RISPERIDONE;RISPERDAL			U-90	D-37	OCT 17, 2000
020272 008	RISPERIDONE;RISPERDAL			U-90	D-37	OCT 17, 2000
020865 001	RIZATRIPTAN BENZOATE;MAXALT-MLT					
>ADD> 020865 002	RIZATRIPTAN BENZOATE;MAXALT-MLT					
>ADD> 021042 001	ROFECOXIB;VIOXX					
021042 002	ROFECOXIB;VIOXX					
021052 001	ROFECOXIB;VIOXX					
021052 002	ROFECOXIB;VIOXX					
021071 002	ROSIGLITAZONE MALEATE;AVANDIA					
021071 003	ROSIGLITAZONE MALEATE;AVANDIA					
021071 004	TECHNETIUM TC-99M DEPREOTIDE; TECHNETIUM TC99M DEPREOTIDE KIT					
>ADD> 021012 001	TEMOZOLOMIDE;TEMODAL	5260291	NOV 09, 2010	NCE	AUG 03, 2004	
>ADD> 021029 001	TEMOZOLOMIDE;TEMODAL	5260291	NOV 09, 2010	ODE	AUG 11, 2004	
>ADD> 021029 002	TEMOZOLOMIDE;TEMODAL	5260291	NOV 09, 2010	NCE	AUG 11, 2004	
>ADD> 021029 003	TEMOZOLOMIDE;TEMODAL	5260291	NOV 09, 2010	ODE	AUG 11, 2004	
>ADD> 021029 004	TEMOZOLOMIDE;TEMODAL	5260291	NOV 09, 2010	NCE	AUG 11, 2004	
>ADD> 074823 001	TERAZOSIN HYDROCHLORIDE;TERAZOSIN HCL			ODE	AUG 11, 2004	
>ADD> 074823 002	TERAZOSIN HYDROCHLORIDE;TERAZOSIN HCL			PC	FEB 08, 2000	
				PC	FEB 08, 2000	

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>ADD>	074823 003	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL	4680291	JUL 14, 2004	U-73	PC	FEB 08, 2000
>ADD>	074823 004	TERAZOSIN HYDROCHLORIDE; TERAZOSIN HCL	4755334	DEC 30, 2006	U-73	PC	FEB 08, 2000
	020980 001	TERBINAFINE HYDROCHLORIDE; LAMISIL				NCE	DEC 30, 1999
020846 001	TERBINAFINE; LAMISIL						
019762 001	TESTOSTERONE; TESTODERM	5840327	AUG 15, 2016				
019762 002	TESTOSTERONE; TESTODERM	5840327	AUG 15, 2016				
020646 005	TIAGABINE HYDROCHLORIDE; GABITRIL	5010090	OCT 07, 2008				
020912 001	TIROFIBAN HYDROCHLORIDE; AGGRASTAT	5354760	MAR 24, 2012				
020913 001	TIROFIBAN HYDROCHLORIDE; AGGRASTAT	5292756	MAY 14, 2012				
		5880136	SEP 27, 2010				
		5292756	MAY 14, 2012				
		5880136	SEP 27, 2010				
>ADD>	020505 001	TOPIRAMATE; TOPAMAX					
>ADD>	020505 002	TOPIRAMATE; TOPAMAX					
>ADD>	020505 003	TOPIRAMATE; TOPAMAX					
>ADD>	020505 004	TOPIRAMATE; TOPAMAX					
>ADD>	020505 005	TOPIRAMATE; TOPAMAX					
>ADD>	020505 006	TOPIRAMATE; TOPAMAX					
>ADD>	020844 001	SPRINKLE					
>ADD>	020844 002	SPRINKLE					
>ADD>	020844 003	SPRINKLE					
020671 001	TOPOTECAN HYDROCHLORIDE; HYCAMTIN						
020699 001	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR						
020699 002	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR						
020699 003	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR						
020699 004	VENLAFAXINE HYDROCHLORIDE; EFFEXOR XR						
019614 004	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007				
020943 001	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007				
020943 002	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007				
020943 003	VERAPAMIL HYDROCHLORIDE; VERELAN PM	4863742	JUN 19, 2007				
020859 001	ZALEPLON; SONATA	4626538	JUN 23, 2003				
	ZANAMIVIR; RELenza	4626538	JUN 23, 2003				
>ADD>	020859 002	D379506	MAY 27, 2011				
>ADD>	021036 001	4778054	OCT 18, 2005				
>ADD>		4811731	JUL 29, 2006				
>ADD>		5035237	JUL 30, 2008				
>ADD>		5360817	NOV 01, 2011				
>ADD>		5648379	JUL 15, 2014				
>ADD>		46227432	DEC 09, 2003				
			U-274				