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CUMULATIVE
SUPPLEMENT 6
JUN'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

1999

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

19TH EDITION

Cumulative Supplement 6

JUNE 1999

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

19TH EDITION

**CUMULATIVE SUPPLEMENT 6
JUNE 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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, OTC Drug Product List, and the Patent and Exclusivity Data are indicated by the symbol >**DLT**> (DELETE) to the left of the line. The >**DLT**> symbol is dropped in subsequent Cumulative Supplements for that item. The shaded print remains in the Prescription Drug Product List and OTC Drug Product Lists in all Cumulative Supplements (hard copy only) for this edition. However, the overstruck data in the Patent and Exclusivity Data is dropped in subsequent Cumulative Supplements (hard copy).

Products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 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 – JUNE 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	10009
SINGLE SOURCE	2504 (25.2%)	2520 (25.3%)	2523 (25.2%)	2523 (25.2%)
MULTISOURCE	7308 (73.6%)	7344 (73.6%)	7375 (73.7%)	7375 (73.7%)
THERAPEUTICALLY EQUIVALENT	6934 (69.9%)	6969 (69.9%)	7012 (70.1%)	7012 (70.1%)
NOT THERAPEUTICALLY EQUIVALENT	374 (3.8%)	375 (3.8%)	363 (3.6%)	363 (3.6%)
EXCEPTIONS	111 (1.1%)	111 (1.1%)	111 (1.1%)	111 (1.1%)
NEW MOLECULAR ENTITIES APPROVED	10	3	5	5
NUMBER OF APPLICANTS	563	570	568	568

¹Amino acid-containing products of varying composition (see Introduction page xxv of the 1st)

PRESCRIPTION DRUG PRODUCT LIST
19TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN' 99 - JUN' 99

1

ACETAMINOPHEN; CAFFEINE; DIHYDROCODEINE BITARTRATE

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

N70107 001
JUN 12, 1985

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100
@ TEVA
650MG; 100MG

N70107 001
JUN 12, 1985

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL
ALLAY
NORTON HN
500MG; 5MG
AA
ZENITH GOLDLINE
500MG; 5MG
AA
HYDROCODONE BITARTRATE AND ACETAMINOPHEN
MALLINCKRODT
500MG; 5MG
AA
ZYDONE
MALLINCKRODT
500MG; 5MG
JUL 19, 1985
JUL 19, 1985

N89907 001
JAN 13, 1989
N89907 001
JAN 13, 1989
N88956 001
JUL 19, 1985
N88956 001
JUL 19, 1985

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

CAPSULE; ORAL
SORIATANE
HLR
+
ROCHE
*
*
*
*

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

CAPSULE; ORAL
OXYCODONE AND ACETAMINOPHEN
DURAMED
500MG; 5MG
AA

N40289 001
MAR 16, 1999

TABLET; ORAL
OXYCODONE AND ACETAMINOPHEN
AMIDE PHARM
3.25MG; 5MG
PERCOCET
ENDO PHARMS
3.25MG; 5MG
> ADD >
> ADD >
> ADD >

N40203 001
MAR 15, 1999
N40330 002
JUN 25, 1999
N40330 001
JUN 25, 1999
ACYCLOVIR SODIUM
+ AM PHARM PARTNERS
*
*

TABLET; ORAL
ACYCLOVIR
CARLSBAD
AB
4.00MG
8.00MG
AB

N75090 001
JAN 26, 1999

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100
TEVA
650MG; 100MG
AA

N70107 001
JUN 12, 1985

CAPSULE; ORAL
ACYCLOVIR
STAISON
AB
2.00MG

N75382 001
APR 30, 1999

TABLET; ORAL
ACYCLOVIR
CARLSBAD
AB
4.00MG
8.00MG
AB

N75382 002
APR 30, 1999

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100
TEVA
650MG; 100MG
AA

N70107 001
JUN 12, 1985

TABLET; INJECTION
ACYCLOVIR SODIUM
+ AM PHARM PARTNERS
EQ 50MG BASE/ML
EQ 50MG BASE/ML

N74930 001
MAY 13, 1998

INJECTABLE; INJECTION
ACYCLOVIR SODIUM
+ AM PHARM PARTNERS
EQ 50MG BASE/ML
EQ 50MG BASE/ML

N74930 001
MAY 13, 1998

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL
PROPACET 100
TEVA
650MG; 100MG
AA

N70107 001
JUN 12, 1985

TABLET; TECHN EQ 50MG BASE/ML
MERIDIAN MEDCL PARTNERS
AP

N75065 001
FEB 25, 1999

<u>ALBUTEROL</u>	AEROSOL, METERED; INHALATION <u>ALBUTEROL</u> MEDEVA	<u>0.09MG/INH</u>	N72273 001 AUG 14, 1996 N72273 001 AUG 14, 1996	INJECTABLE; INJECTION CERNEVIT-12 + BAXTER HLTHCARE	11.2 IU/VIAL; 12.5MG/VIAL; 60 UGM/VIAL; 200 IU/VIAL; 5.5MG/VIAL; 4.14 UGM/VIAL; 4.6MG/VIAL; 17.25MG/VIAL; 4.53MG/VIAL; 4.14MG/VIAL; 3.51MG/VIAL; 3,500 IU/VIAL	N20924 001 APR 06, 1999
<u>ALBUTEROL SULFATE</u>	SOLUTION; INHALATION <u>ALBUTEROL SULFATE</u> HI TECH PHARMA	<u>EQ 0.083% BASE</u>	N75063 001 FEB 09, 1999	<u>ALPROSTADIL</u>	INJECTABLE; INJECTION APLROSTADIL GENSIA SICOR PHARMS	N75196 001 APR 30, 1999
<u>ALBUTEROL SULFATE</u>	SYRUP; ORAL <u>ALBUTEROL SULFATE</u> UDL	<u>EQ 2MG BASE/5ML</u>	N75262 001 MAR 30, 1999	<u>AMCINONIDE</u>		
<u>ALLTRETINOIN</u>	GEL; TOPICAL PANRETIN + LIGAND	<u>EQ 0.1% BASE</u>	N20886 001 FEB 02, 1999	CREAM; TOPICAL CYCLOCORT ④ FUJISAWA HLTHCARE + LEDERLE *	0.025% 0.1% 0.025% 0.1%	N18116 001 N18116 002 N18116 001 N18116 002
<u>ALLOPURINOL</u>	TABLET; ORAL <u>ZYLOPRIM</u> FARO PHARMS	<u>100MG</u> <u>300MG</u> <u>400MG</u> <u>300MG</u>	N16084 001 N16084 002 N16084 001 N16084 002	LOTION; TOPICAL CYCLOCORT ④ FUJISAWA HLTHCARE + LEDERLE *	0.1% 0.1% 0.1% 0.1%	N19229 001 JUN 13, 1988 N19229 001 JUN 13, 1988
<u>AMINO ACIDS</u>	INJECTABLE; INJECTION AMINEX 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE FRESENIUS KABI	> ADD > > ADD >				N18901 001 APR 06, 1984

AMINO ACIDS

INJECTABLE; INJECTION AMINES 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE PHARMACIA AND UPJOHN 5.2%	N18901 004 FEB 06, 1984	TABLET; ORAL <u>EREDID</u> ROCHE	10MG 25MG 50MG 75MG 100MG 10MG 25MG 50MG 75MG 100MG 10MG 25MG 50MG 75MG 100MG
NEOPHAM 6.4% @ FRESENIUS KABI 6.4%	N18792 001 JAN 17, 1984 N18792 001 JAN 17, 1984	<u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u>	10MG 25MG 50MG 75MG 100MG 10MG 25MG 50MG 75MG 100MG 10MG 25MG 50MG 75MG 100MG
© PHARMACIA AND UPJOHN 6.4% NOVAMINE 11.4% FRESENIUS KABI 11.4%	N17957 003 AUG 09, 1982 N17957 003 AUG 09, 1982	<u>AB</u> <u>AB</u> <u>AB</u>	10MG 25MG 50MG 75MG 100MG 10MG 25MG 50MG 75MG 100MG 10MG 25MG 50MG 75MG 100MG
PHARMACIA AND UPJOHN 11.4% NOVAMINE 15% FRESENIUS KABI 15% PHARMACIA AND UPJOHN 15% NOVAMINE 8.5% @ FRESENIUS KABI 8.5% © PHARMACIA AND UPJOHN 8.5% AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE	N17957 004 NOV 28, 1986 N17957 004 NOV 28, 1986 N17957 002 AUG 09, 1982 N17957 002 AUG 09, 1982	<u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u>	CAPSULE; ORAL <u>AMOXICILLIN</u> RANBAXY POWDER FOR RECONSTITUTION; ORAL <u>AMOXIL</u> SMITHKLINE BEECHAM + POWDER FOR RECONSTITUTION; ORAL <u>AMOXIL</u> SMITHKLINE BEECHAM 200MG/5ML 200MG/5ML 400MG/5ML 400MG/5ML

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION VEINAMINE 8% @ FRESENIUS KABI 5.6MG/100ML; 3.88MG/100ML; N17957 001 © PHARMACIA AND UPJOHN 8.61MG/100ML; 2.11MG/100ML; N17957 001 5.6MG/100ML; 3.88MG/100ML; N17957 001	N50761 001 APR 15, 1999 N50761 002 APR 15, 1999	TABLET, CHEWABLE; ORAL <u>AMOXIL</u> SMITHKLINE BEECHAM	200MG 400MG
<u>AMIODARONE HYDROCHLORIDE</u>			
TABLET; ORAL <u>AMIODARONE HCL</u> ALPHAPHARM	200MG 200MG	> <u>ADD</u> > <u>ADD</u> > <u>ADD</u> > <u>ADD</u>	50MG/VIAL 50MG/VIAL
AB NOVOPHARM	APR 16, 1999	+ +	100MG/VIAL 100MG/VIAL

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION AMPHOTEC + ALZA	N50729 001 NOV 22, 1996 N50729 002 NOV 22, 1996
--	--

AMPHOTERICIN B

INJECTABLE; LIPID COMPLEX; INJECTION
 AMPHOTERICIN B
 * SQUIBS
 * *
 > DLT >
 > DLT >
 > DLT >
 > DLT >

N50729 001
 NOV 22, 1996
 N50729 002
 NOV 22, 1996

AMPRENAVIR

CAPSULE; ORAL
 AGENERASE
 GLAXO WELLCOME
 +
 SOLUTION; ORAL
 AGENERASE
 + GLAXO WELLCOME

N21007 001
 APR 15, 1999
 N21007 002
 APR 15, 1999

ATENOLOL

N21039 001
 APR 15, 1999
 > DLT >
 > DLT >
 > ADD >
 > ADD >

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A; PALMITATE; VITAMIN EATENOLOL

KABIVITE PED F + W KIT
 + FRESENIUS KABI
 * *
 > ADD >
 > DLT >

N/A, 80MG/VIAL; N/A, 0.02MG/VIAL; N/A,
 0.001MG/VIAL; 400 IU/10ML, N/A; N/A,
 0.14MG/VIAL; N/A, 1.7MG/VIAL; N/A,
 5MG/VIAL; 0.2MG/10ML, N/A; N/A,
 1MG/VIAL; N/A, 1.4MG/VIAL; N/A,
 1.2MG/VIAL; EQ 2, 300 UNITS BASE/10ML,
 N/A; 7 TU/10ML, N/A
 N20176 001
 DEC 29, 1993
 0.001MG/VIAL; N/A, 0.02MG/VIAL; N/A,
 0.14MG/VIAL; N/A, 1.7MG/VIAL; N/A,
 5MG/VIAL; 0.2MG/10ML, N/A; N/A,
 1MG/VIAL; N/A, 1.4MG/VIAL; N/A,
 1.2MG/VIAL; EQ 2, 300 UNITS BASE/10ML,
 N/A; 7 TU/10ML, N/A
 N20176 001
 DEC 29, 1993
 0.001MG/VIAL; N/A, 0.02MG/VIAL; N/A,
 0.14MG/VIAL; N/A, 1.4MG/VIAL; N/A,
 1.2MG/VIAL; EQ 2, 300 UNITS BASE/10ML,
 N/A; 7 TU/10ML, N/A

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE
 CAPSULE; ORAL
 BUTALBITAL, ASPIRIN, CAFFEINE, AND CODEINE PHOSPHATE
 ENDO PHARMS 325MG; 50MG; 40MG; 30MG N75351 001
 MAR 05, 1999

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE
 TABLET; ORAL
 ORPHENADRINE CITRATE, ASPIRIN, AND CAFFEINE
 STEVENS J 385MG; 30MG; 25MG N74988 001
 APR 30, 1999

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE
 TABLET; ORAL
 ORPHENADRINE CITRATE, ASPIRIN, AND CAFFEINE
 AB STEVENS J 385MG; 30MG; 25MG N74988 002
 APR 30, 1999

ASTEMIZOLE
 TABLET; ORAL
 HISMANAL
 * JANNSSEN 10MG N19402 001
 DEC 29, 1988

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE
 TABLET; ORAL
 HISMANAL
 * JANNSSEN 10MG N19402 001
 DEC 29, 1988

ATENOLOL
 TABLET; ORAL
 ATENOLOL
 * ZEPHTECON 100MG N19402 001
 DEC 29, 1992

ATENOLOL
 TABLET; ORAL
 ATENOLOL
 * ZEPHTECON 100MG N19402 001
 DEC 29, 1992

ATROPOINE SULFATE; DIPHENOXYLATE HCL W/ ATROPOINE SULFATE
 TABLET; ORAL
 DIPHENOXYLATE HCL W/ ATROPOINE SULFATE
 ZENITH GOLDLINE 0.025MG/2.5MG N86727 001
 DEC 29, 1993
 0.025MG/2.5MG N86727 001

AZATHIOPRINE

TABLET; ORAL
AZATHIOPRINE
APPLIED ANAL
50MG

> ADD >
AB
> ADD >
AB
> ADD >

N75252 001
JUN 07, 1999

> ADD >
AB
> ADD >

BACITRAVIN; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

OINTMENT; OPHTHALMIC
BACITRAVIN-NEOMYCIN-POLYMYXIN W/ HYDROCORTISONE ACETATE
AT * ALTANA
100 UNITS/GM 1%: EQ 3.5MG BASE/GM;
10,000 UNITS/GM N60731 002
400 UNITS/GM 1%: EQ 3.5MG BASE/GM;
10,000 UNITS/GM N60731 002
100 UNITS/GM 1%: EQ 3.5MG BASE/GM;
10,000 UNITS/GM N60731 002
400 UNITS/GM 1%: EQ 3.5MG BASE/GM;
10,000 UNITS/GM N62166 002
10,000 UNITS/GM 1%: EQ 3.5MG BASE/GM;
10,000 UNITS/GM N62166 002

> DLT >
AT
> DLT >
AT
> ADD >
@
> ADD >
> DLT >
AT
> DLT >
AT
> ADD >
> ADD >

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
WELLBUTRIN
* GLAXO WELLCOME
50MG
*u
100MG
*u
150MG
*u
200MG
*u
250MG

BENDROFLUMETHIAZIDE; NADOLOL

TABLET; ORAL
CORZIDE
APOTHECON
5MG; 40MG
5MG; 80MG
+
BRISTOL MYERS SQUIBB
5MG; 40MG
5MG; 80MG
*

N18647 001
MAY 25, 1983
N18647 002
MAY 25, 1983
N18647 001
MAY 25, 1983
N18647 002
MAY 25, 1983

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

BUSULFAN

INJECTABLE; INJECTION
BUSULFEX
+ ORPHAN MEDCL
6MG/ML

N50114 001
N50114 001

> DLT >
> ADD >

BUTOCONAZOLE NITRATE

CREAM; VAGINAL
FEMSTAT
* SWITZER

N19215 001

NOV 25, 1985

BETAMETHASONE DIPROPIONATE

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

N75373 001
JUN 22, 1999

FEB 28, 1999

BETAMETHASONE VALERATE

AEROSOL; TOPICAL
LUXIQ
+ CONNETICS
EQ 0.12% BASE

N20934 001
FEB 28, 1999

TABLET, EXTENDED RELEASE; ORAL
WELLBUTRIN
*u
GLAXO WELLCOME
50MG
OCT 04, 1996
N20358 001
OCT 04, 1996
N20358 002
OCT 04, 1996
N20358 003
OCT 04, 1996

INJECTABLE; INJECTION
BUSULFEX
+ ORPHAN MEDCL
6MG/ML

N20954 001
FEB 04, 1999

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'99 - JUN'99

BUTOCONAZOLE NITRATE

CREAM; VAGINAL
FEMSTAT

@ SYNTEX

2%

FEMSTAT ONE
+ KV PHARM
* SYNTEX
2%
* SYNTEX
2%
* SYNTEX
2%

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

SOLUTION; IRRIGATION
ENDOSOL EXTRA

AT

AKORN

0.154MG/ML; 0.92MG/ML; 0.184MG/ML;
0.2MG/ML; 0.38MG/ML; 2.1MG/ML;
7.14MG/ML; 0.42MG/ML
N20079 001
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
N20079 001
NOV 27, 1991

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE

ISOLYTE E/W

DEXTROSE 5% IN PLASTIC CONTAINER

CAPECITABINE

TABLET; ORAL
XELODA

HLR

ROCTIV

150MG

CAPTOPRIL

TABLET; ORAL
Captopril

BAKER NORTON

12.5MG

N74590 004

B. BRAUN

3.7MG/1.00ML; 5GM/1.00ML; 31MG/1.00ML;

120MG/1.00ML; 33.0MG/1.00ML;

8.8MG/1.00ML

3.7MG/1.00ML; 5GM/1.00ML; 31MG/1.00ML;
120MG/1.00ML; 33.0MG/1.00ML;
8.8MG/1.00ML

N18271 001
NOV 27, 1991

74MG/1.00ML

3.5MG/1.00ML; 5GM/1.00ML; 30MG/1.00ML;

120MG/1.00ML; 50MG/1.00ML;

7.4MG/1.00ML

3.5MG/1.00ML; 5GM/1.00ML; 30MG/1.00ML;
74MG/1.00ML; 640MG/1.00ML; 500MG/1.00ML;

N18269 002
JAN 17, 1983

74MG/1.00ML

3.5MG/1.00ML; 5GM/1.00ML; 30MG/1.00ML;

74MG/1.00ML; 640MG/1.00ML; 500MG/1.00ML;

7.4MG/1.00ML

3.5MG/1.00ML; 5GM/1.00ML; 30MG/1.00ML;
74MG/1.00ML; 640MG/1.00ML; 500MG/1.00ML;

N18269 002
JAN 17, 1983

74MG/1.00ML

3.5MG/1.00ML; 5GM/1.00ML; 30MG/1.00ML;

74MG/1.00ML; 640MG/1.00ML; 500MG/1.00ML;

7.4MG/1.00ML

3.5MG/1.00ML; 5GM/1.00ML; 30MG/1.00ML;
74MG/1.00ML; 640MG/1.00ML; 500MG/1.00ML;

N18269 002
JAN 17, 1983

CARBENICILLIN DISODIUM

<u>INJECTABLE; INJECTION</u>	
GEOGEN	EQ 1GM BASE/VIAL
* ROERIG	EQ 2GM BASE VIAL
*	EQ 5GM BASE/VIAL
*	EQ 10GM BASE/VIAL
*	EQ 30GM BASE/VIAL
②	EQ 1GM BASE/VIAL
②	EQ 2GM BASE/VIAL
②	EQ 5GM BASE/VIAL
②	EQ 10GM BASE/VIAL
②	EQ 30GM BASE/VIAL

CARTEBOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC	AP
OCUPRESS	1%
+ CIBA	
④ OTSUKA	1%

CEFADROXIL/CEFADROXIL HEMIHYDRATE

CAPSULE; ORAL	AP
CEFDROXIL	
BARR	
EQ 500MG BASE	

TABLET; ORAL	AP
CEFDROXIL	
RANBAXY	

N65018 001

APR 23, 1999

CEFTAZIDIME (ARGININE FORMULATION)

<u>INJECTABLE; INJECTION</u>	
CEPTAZ	1GM/VIAL
* GLAXO WELLCOME	
AP	
+	

CERIVASTATIN SODIUM

<u>TABLET; ORAL</u>	
BAYCOL	0.3MG
* BAYER	0 .3 MG
AP	N50646 002
JUN 26, 1997	

CEFTAZIDIME (ARGININE FORMULATION)

N50646 002	SEP 27, 1990
N50646 003	SEP 27, 1990
N50646 004	SEP 27, 1990
N50646 005	SEP 27, 1990
MAY 24, 1999	

<u>CHLOROTRIANISENE</u>		<u>CLOBETASOL PROPIONATE</u>	
> DLT >	<u>AA</u>	CAPSULE; ORAL <u>CHLOROTRIANISENE</u> BANNER PHARMA CAPS	12MG N84652 001 N84652 001 0.05%
> DLT >	<u>@</u>	TACE	12MG N88102 004 0.05%
> ADD >		HÖECHST MARION RISSEL	12MG N88102 004 0.05%
> DLT >	<u>AA</u>	+ HOECHST MARION RSSL	12MG N88102 004 0.05%
> ADD >			
<u>CHLORPROMAZINE HYDROCHLORIDE</u>		<u>CLOBETASOL PROPIONATE</u>	
CONCENTRATE; ORAL <u>CHLORPROMAZINE HCL</u>	<u>AA</u>	PHARM ASSOC	100MG/ML N40224 001 JAN 26, 1999
<u>CHOLESTYRAMINE</u>		<u>CLOXACILLIN SODIUM</u>	
POWDER; ORAL <u>CHOLESTYRAMINE</u> BAKER NORTON	<u>AB</u>	EQ 4 GM RESIN/PACKET	N74771 001 JUL 09, 1997 N74771 002 JUL 09, 1998 N74771 003 JUL 09, 1998 N74771 004 JUL 09, 1997 N74771 002 JUL 09, 1997 N74771 002 JUL 09, 1997 N74555 002 SEP 30, 1998
ZENITH GOLDLINE	<u>AB</u>	EQ 4 GM RESIN/SCCOOPFUL	
COBLEY PHARM	<u>AB</u>	EQ 4 GM RESIN/SCCOOPFUL	
CILOSTAZOL	<u>AB</u>	CHOLESTYRAMINE LIGHT	
TABLET; ORAL PLETAL OTSUKA		50MG 100MG +	N20863 001 JAN 15, 1999 N20863 002 JAN 15, 1999
<u>CLOZAPINE</u>		<u>CLOZAPINE</u>	
			TABLET; ORAL CLOZAPINE CREIGHTON
			AB 25MG 100MG 2.5MG
			AB GENEVA PHARMS 2.5MG
			AB N74546 001 AUG 30, 1996 N74546 002 AUG 30, 1996 N74546 001 AUG 30, 1996

<u>CLOZAPINE</u>	<u>CYTARABINE</u>	
TABLET; ORAL <u>CLOZAPINE</u>	100MG AB GENEVA PHARMS	N74546 002 AUG 30, 1996 + DEPOTech 10MG/ML
TABLET; ORAL <u>CLOZAPINE</u>	25MG AB MYLAN	N75417 001 MAY 27, 1999
TABLET; ORAL <u>CLOZAPINE</u>	100MG AB	N75417 002 MAY 27, 1999
<u>COLISTIMETHATE SODIUM</u>	<u>DAUNORUBICIN HYDROCHLORIDE</u>	
INJECTABLE; INJECTION <u>COLISTIMETHATE</u>	EQ 150MG BASE/VIAL AP + PHARMA TEK	N64216 001 FEB 26, 1999
INJECTABLE; INJECTION <u>COLY-MYCIN M</u>	EQ 150MG BASE/VIAL AP + PARKDALE	N50108 002 EQ 150MG BASE/VIAL N50108 002
<u>CROMOLYN SODIUM</u>	<u>DESMOPRESSIN ACETATE</u>	
CAPSULE; ORAL <u>GASTROCRON</u> * MEDeva @	100MG AB	N19188 001 DEC 22, 1989 N19188 001 DEC 22, 1989 100MG AB
SOLUTION/DROPS; OPHTHALMIC <u>CROMOLYN SODIUM</u>	4% AT ALCON	N75282 001 JUN 16, 1999
> ADD > > ADD >	AT CROMOPTIC KING PHARMS	N75088 001 APR 27, 1999 4% AT ALCON
<u>CYSTEINE HYDROCHLORIDE</u>	<u>DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE</u>	
INJECTABLE; INJECTION CYSTEINE HCL @ FRESENIUS KABI	7.25%	N19523 001 OCT 22, 1986
> ADD > > ADD > > DLT > > DLT >	@ PHARMACIA AND UPJOHN AT + FALCON PHARMS	N19523 001 OCT 22, 1986 7.25% AT + FALCON PHARMS 10,000 UNITS/ML
<u>MAXITROL</u>	<u>OPHTHALMIC</u>	
AT * ALCON	0.1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N50065 002
AT + FALCON PHARMS	0.1%; EQ 3.5MG BASE/GM; 10,000 UNITS/GM	N50065 002
<u>SUSPENSION/DROPS; OPHTHALMIC</u>	<u>MAXITROL</u>	
AT * ALCON	0.1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N50023 002
AT + FALCON PHARMS	0.1%; EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N50023 002

DEXTRAMPHETAMINE SULFATE

TABLET; ORAL
DEXTRAMPHETAMINE SULFATE
5MG

AA
 ENDO PHARMS
 MAY 13, 1999

DEXTROSE; SODIUM CHLORIDE

INJECTABLE; INJECTION

DEXTROSE 5% AND SODIUM CHLORIDE 0.11% IN PLASTIC CONTAINER
B BRAVIN
 5GM/100ML; 110MG/100ML N18030 003
 @ ADD >
 DEXTROSE 5% AND SODIUM CHLORIDE 0.2% IN PLASTIC CONTAINER
B BRAVIN
 5GM/100ML; 200MG/100ML N18030 004
 @ ADD >
 DEXTROSE 5% AND SODIUM CHLORIDE 0.33% IN PLASTIC CONTAINER
B BRAVIN
 5GM/100ML; 330MG/100ML N18030 003
 @ ADD >
 DEXTROSE 5% AND SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER
B BRAVIN
 5GM/100ML; 450MG/100ML N18030 002
 @ ADD >

DIAZEPAM

GEL; RECTAL
DIASTAT
 * ANHEXIA

2 .5MG/0 .5ML

5MG/ML

10MG/2ML

15MG/3ML

20MG/4ML

25MG/5ML

30MG/6ML

35MG/7ML

40MG/8ML

45MG/9ML

50MG/10ML

55MG/11ML

60MG/12ML

65MG/13ML

70MG/14ML

75MG/15ML

80MG/16ML

85MG/17ML

90MG/18ML

95MG/19ML

100MG/20ML

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM
.1%

AA
 FALCON PHARMS
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 MARTEC
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 NOVOPHARM
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 LANNETT
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 MARTEC
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 NOVOPHARM
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 LANNETT
 MAY 04, 1998

DEXTROSE; SODIUM CHLORIDE

TABLET, DELAYED RELEASE; ORAL
DICLOFENAC SODIUM
.1%

AB
 NOVOPHARM
 MAY 04, 1998

* SEE SECTION 1.3 OF INTRODUCTION

EPINEPHRINE

INJECTABLE, INJECTION
SUS-PHENINE
 * FOREST LABS 5MG/ML
SUS-PHENINE SULFITE-FREE
FOREST LABS 1.5MG/AMP
 + 5MG/ML

N07942 001
 N07942 003
 MAR 24, 1999
 MAR 24, 1999
 MAR 24, 1999
 MAR 24, 1999
 MAR 24, 1999

ESTROGENS, CONJUGATED SYNTHETIC AESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA 0 .025MG/24HR
 BX + BERLEX LABS

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 003
JUL 31, 1996
N20538 002
JUL 31, 1996
N20538 004
JUL 31, 1996
N20538 001
JUL 31, 1996
N20538 003
JUL 31, 1996
N20538 002
JUL 31, 1996
N20538 004
JUL 31, 1996

ESTRADIOL
MENOREST
AB 0 .0375MG/24HR
AB 0 .05MG/24HR
AB 0 .075MG/24HR
AB 0 .1MG/24HR

VIVELLE-DOT
NOVARTIS
AB 0 .0375MG/24HR
AB 0 .05MG/24HR
AB 0 .075MG/24HR
AB 0 .1MG/24HR

ESTRADIOL
CENESTIN
DIAZOMED
AB 0 .9MG
N07942 001
N07942 003
MAR 24, 1999
N07942 002
MAR 24, 1999
N07942 003
MAR 24, 1999

ESTROPIPATE
CREAM; VAGINAL
OPEN
* ABOTT
+ PHARMACIA AND UPJOHN 1.5MG/GM
N844710 001

ESTROPIPATE
TABLET; ORAL
OPEN .625
* ABOTT
PHARMACIA AND UPJOHN 0 .75MG
N83220 001
AB 0 .75MG
AB OPEN 1.25
* ABOTT
PHARMACIA AND UPJOHN 1.5MG
N83220 002
AB 1.5MG
AB OPEN 2.5
* ABOTT
PHARMACIA AND UPJOHN 3MG
N83220 003
AB 3MG
AB OPEN 5
* ABOTT
PHARMACIA AND UPJOHN 6MG
N83220 004
AB 6MG

ETHINYL ESTRADIOL; LEVONORGESTREL
TABLET; ORAL-21
LEVYLITE
BERLEX LABS
AB 0 .02MG; 0 .1MG
N20860 001
JUL 13, 1998
N20860 001
JUL 13, 1998

ETHINYL ESTRADIOL; NORETHINDRONE
TABLET; ORAL-21
BREVICON 21-DAY
AB 0 .035MG; 0 .5MG
N27566 001

ETHINYL ESTRADIOL; NORETHINDRONETABLET; ORAL-21

BREVICON 21-DAY
AB WATSON LABS 0 .035MG; 0 .5MG

NORINYL 1+35 21-DAY
AB WATSON LABS 0 .035AG; 1AG
AB TRI-NORINYL 21-DAY
SEARLE

+ WATSON LABS 0 .035MG; 0 .35MG; 0 .5MG

0 .035MG, 0 .035MG; 0 .5MG, 1MG N18977 001
AP 13, 1984
0 .035MG, 0 .035MG; 0 .5MG, 1MG N18977 001
AP 13, 1984
0 .035MG, 0 .035MG; 0 .5MG, 1MG N18977 001
AP 13, 1984

TABLET; ORAL-28

BREVICON 28-DAY
SEARLE
AB WATSON LABS 0 .035MG; 0 .5MG

NORINYL 1+35 28-DAY
SEARLE
AB WATSON LABS 0 .035MG; 1MG

AB TRI-NORINYL 28-DAY
SEARLE

WATSON LABS 0 .035MG; 0 .15MG; 0 .5MG; 1MG N18977 002
AP 13, 1984

0 .035MG, 0 .035MG; 0 .5MG, 1MG N18977 002
AP 13, 1984

WATSON LABS

0 .035MG, 0 .035MG; 0 .5MG, 1MG N18977 002
AP 13, 1984

TABLET; ORAL

PROZAC

SEARLE

ETODOLAC
TABLET; ORAL
ETODOLAC
NOVOPHARM

400MG
500MG

N74847 001

APR 23, 1999

N74847 002

APR 23, 1999

ETOPOSIDE

INJECTABLE; INJECTION
VEPESID
* BRISTOL

20MG/ML

N18768 001

NOV 10, 1983

N18768 001

NOV 10, 1983

EUROSEMIDE

INJECTABLE; INJECTION
FUROSEMIDE
ABOTT

10MG/ML

N75241 001

MAY 28, 1999

N20955 001
FEB 18, 1999

N40291 001
MAR 24, 1999

N20974 001
MAR 09, 1999

N20974 002
MAR 09, 1999

N20974 003
MAR 09, 1999

N20974 004
MAR 09, 1999

N20974 005
MAR 09, 1999

N20974 006
MAR 09, 1999

N20974 007
MAR 09, 1999

N20974 008
MAR 09, 1999

N20974 009
MAR 09, 1999

N20974 010
MAR 09, 1999

N20974 011
MAR 09, 1999

GALLAMINE TRIETHIODIDE

INJECTABLE; INJECTION
PLAXEDIL
 * DAVIS AND GECK
 # @
 # @

20MG/ML
 100MG/ML
 20MG/ML
 100MG/ML

N07842 001
 N07842 002
 N07842 001
 N07842 002

AO
AT

AO
AT

N75393 001
 MAY 11, 1999
 N75393 002
 MAY 11, 1999

HALOPERIDOL DECANATE

INJECTABLE; INJECTION
HALOPERIDOL DECANATE
 GENSIA SICOR PHARMS

EQ 50MG BASE/ML
EQ 100MG BASE/ML

N20758 001
 SEP 30, 1997
 N20758 002
 SEP 30, 1997
 N20758 003
 AUG 31, 1998

GLYCOPYRROLATE

SOLID/DRUG; Ophthalmic
GENTAMICIN SULFATE
FALCON
FALCON PHARMS

EQ 0.1% BASE
EQ 0.3% BASE

N62196 001
 N62196 001

AO
AT

AO
AT

N20758 001
 SEP 30, 1997
 N20758 002
 SEP 30, 1997
 N20758 003
 AUG 31, 1998

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL
AVALIDE
 @ SANOFI

12.5MG; 75MG
 12.5MG; 150MG
 12.5MG; 300MG

N20758 001
 SEP 30, 1997
 N20758 002
 SEP 30, 1997
 N20758 003
 SEP 30, 1997

+
 AVAPRO HCT
 @ SANOFI

12.5MG; 75MG
 12.5MG; 150MG

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

 AVAPRO HCT
 @ SANOFI

12.5MG; 75MG
 12.5MG; 150MG

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

DEC 22, 1997
 N7451 003
 DEC 22, 1997
 N7451 003
 DEC 22, 1997
 N7451 003

12.5MG; 75MG
 12.5MG; 150MG

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

DEC 22, 1997
 N7451 003
 DEC 22, 1997
 N7451 003
 DEC 22, 1997
 N7451 003

12.5MG; 75MG
 12.5MG; 150MG

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

APR 20, 1999
 N74686 001
 APR 20, 1999
 N74686 002
 APR 20, 1999
 N74686 003
 APR 20, 1999
 N74686 004
 APR 20, 1999

12.5MG; 75MG
 12.5MG; 150MG
 12.5MG; 300MG

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

APR 20, 1999
 N74686 001
 APR 20, 1999
 N74686 002
 APR 20, 1999
 N74686 003
 APR 20, 1999
 N74686 004
 APR 20, 1999

12.5MG; 75MG
 12.5MG; 150MG
 12.5MG; 300MG

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

> ADD >
 AB
 > ADD >
 AB
 > ADD >
 AB

25MG; 37.5MG
 25MG; 37.5MG

N75052 001
 JUN 18, 1999

HYDROCORTISONE

ENEMA; RECTAL
CORTENEMA
 + SOLVAY
 HYDROCORTISONE
 COPLEY PHARM
 AB
 # BX

100MG/60ML
 100MG/60ML
 100MG/60ML
 100MG/60ML

N16199 001
 MAY 27, 1994
 N16199 001
 MAY 27, 1994
 N16199 001
 MAY 27, 1994

HYDROCORTISONE

TABLET; ORAL
 ROBINUL
 + HORIZON PHARM
 * ROBINS AH
 ROBINUL FORTE
 + HORIZON PHARM
 * ROBINS AH

1MG
 1MG
 2MG
 2MG
 6MG

N12827 001
 N12827 001
 N12827 001
 N12827 002
 N12827 002

HYDROXYAMPHETAMINE HYDROBROMIDE

SOLUTION/DROPS; OPHTHALMIC
PAREDREINE
+ AKORN
* PHARMICS

1%
1%

HYDROXYUREA

CAPSULE; ORAL
HYDROXYUREA

AB
PAR PHARM

500MG

IBUPROFEN

SUSPENSION; ORAL
MOTRIN

AB
* MCNEIL

100MG/5ML

AB
+ MCNEIL CONS

100MG/5ML

TABLET; ORAL
IBUPROFEN
NORTON HN

400MG

ZENITH GOLDLINE

AB

4.00MG

IPRATROPIUM BROMIDE

AB

6.00MG

IPRATROPIUM BROMIDE

AB

8.00MG

MOTRIN

AB
MCNEIL

100MG

400MG

600MG

800MG

MCNEIL CONS

AB

300MG

400MG

IBUPROFEN

TABLET; ORAL

MOTRIN

AB
+ MCNEIL

600MG

800MG

1000MG

1200MG

1400MG

1600MG

IBUPROFEN

TABLET, CHEWABLE; ORAL

MOTRIN

AB
+ MCNEIL

50MG

100MG

50MG

MCNEIL CONS

AB
+ MCNEIL

100MG

100MG

INDOMETHACIN

TABLET; ORAL

INDOMETHACIN

AB
EON

75MG

INDOMETHACIN

TABLET; ORAL

INDOMETHACIN

AB
EON

75MG

INDOMETHACIN

TABLET, EXTENDED RELEASE; ORAL

INDOMETHACIN

AB
EON

75MG

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

AN
ALPHARMA

0.02%

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

ISOETHARINE HCL

AN
AN

0.08%

AN
AN

0.1%

N17463 004
N0004 004
N0004 004
N17463 005
MAY 22, 1985
N20418 001
NOV 16, 1994

N17463 004
N0004 004
N17463 005
MAY 22, 1985
N20418 001
NOV 16, 1994

N20335 001
NOV 16, 1994
N20135 002
NOV 16, 1994
N20135 001
NOV 16, 1994
N20135 002
NOV 16, 1994

NB6651 002
NB6651 003
NB6651 003

ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION <u>ISOETHARINE HCL</u>	0.1%	N86651 003	> ADD >	10MG	N18662 002
AN + INTL MEDICATION	0.167%	N86651 005	> ADD >	20MG	MAY 07, 1982
AN	0.167%	N86651 005	> ADD >	20MG	N18662 004
AN +	0.25%	N86651 007	> ADD >	40MG	MAR 28, 1983
AN	0.25%	N86651 007	> ADD >	40MG	N18662 003
AN +	0.08%	N86651 002	+ DLT >	10MG	MAY 07, 1982
AN	0.08%	N86651 002	+ DLT >	10MG	N18662 002
<u>ISOETHARINE HCL 5/E</u> dex	0.08%	N89817 001	> DLT >	200MG	N18662 004
AN *		NOV 22, 1988	> DLT >	200MG	MAY 07, 1982
AN *		N89818 001	> DLT >	200MG	N18662 003
AN *		NOV 22, 1988	> DLT >	200MG	MAY 07, 1982
AN *		N89819 001	> DLT >	200MG	N18662 003
AN *		NOV 22, 1988	> DLT >	200MG	MAY 07, 1982
AN *		N89820 001	> DLT >	200MG	N18662 003

ISOTRETINOIN

CAPSULE; ORAL ACCUTANE	10MG	N18662 002	
HLR	20MG	MAY 07, 1982	
+ ADD >	40MG	N18662 003	
+ ADD >	40MG	MAY 07, 1982	
+ ADD >	40MG	N18662 002	
+ ADD >	40MG	MAY 07, 1982	
+ ADD >	40MG	N18662 004	
+ ADD >	40MG	MAY 07, 1982	
+ ADD >	40MG	N18662 003	
+ ADD >	40MG	MAY 07, 1982	
+ ADD >	40MG	N18662 003	
+ ADD >	40MG	MAY 07, 1982	
<u>ITRACONAZOLE</u>			
INJECTABLE; SPORANOX	10MG/ML	N20966 001	
+ JANSSEN		MAR 30, 1999	
<u>KETOCONAZOLE</u>			
TABLET; ORAL KETOCONAZOLE	200MG	N75314 001	
MUTUAL PHARMA	200MG	JUN 15, 1999	
+ ADD >	AB	N74971 001	
+ ADD >	AB	JUN 15, 1999	
+ ADD >	AB	N75362 001	
+ ADD >	AB	JUN 15, 1999	
+ ADD >	AB	N73319 001	
+ ADD >	AB	JUN 15, 1999	
+ ADD >	AB	N75273 001	
+ ADD >	AB	JUN 15, 1999	
+ ADD >	AB	N18533 001	
+ ADD >	AB	AUG 21, 1990	
+ ADD >	AB	N88124 001	
+ ADD >	AB	AUG 21, 1990	
+ ADD >	AB	N88124 001	
+ ADD >	AB	AUG 21, 1990	
<u>ISOSORBIDE DINITRATE</u>			
TABLET; ORAL SORBITRATE	10MG	N18533 001	
ZENECA	30MG	N18533 001	
@			

KETOPROFEN

<u>CAPSULE, EXTENDED RELEASE; ORAL</u>	
<u>KETOPROFEN</u>	
<u>AB ANDRX PHARMS</u>	<u>100MG</u>
<u>AB</u>	<u>150MG</u>
<u>AB</u>	<u>200MG</u>
<u>ORUVAIL WYETH AYERST</u>	<u>100MG</u>
<u>AB</u>	<u>150MG</u>
<u>AB</u>	<u>100MG</u>
<u>AB</u>	<u>150MG</u>
<u>AB</u>	<u>200MG</u>
<u>N75270 002 MAR 24, 1999</u>	<u>100MG FARO PHARMS</u>
<u>N75270 003 MAR 24, 1999</u>	<u>200MG</u>
<u>N75270 001 MAR 24, 1999</u>	<u>300MG</u>
<u>N19816 003 FEB 08, 1995</u>	<u>400MG</u>
<u>N19816 002 FEB 08, 1995</u>	<u>100MG GIAKO WELLCOME</u>
<u>N19816 003 FEB 08, 1995</u>	<u>200MG</u>
<u>N19816 002 FEB 08, 1995</u>	<u>300MG</u>
<u>N19816 004 FEB 08, 1995</u>	<u>400MG</u>

LABETALOL HYDROCHLORIDE

<u>TABLET; ORAL</u>	
<u>TRANDATE</u>	
<u>AB FARO PHARMS</u>	<u>100MG</u>
<u>AB</u>	<u>200MG</u>
<u>AB</u>	<u>300MG</u>
<u>N18716 001 MAY 24, 1985</u>	<u>N18716 002 MAY 24, 1985</u>
<u>N18716 002 AUG 01, 1984</u>	<u>N18716 003 AUG 01, 1984</u>
<u>N18716 003 AUG 01, 1984</u>	<u>N18716 004 AUG 01, 1984</u>
<u>N18716 004 AUG 01, 1984</u>	<u>N18716 001 MAY 24, 1985</u>
<u>N18716 001 MAY 24, 1985</u>	<u>N18716 002 AUG 01, 1984</u>
<u>N18716 002 AUG 01, 1984</u>	<u>N18716 003 AUG 01, 1984</u>
<u>N18716 003 AUG 01, 1984</u>	<u>N18716 004 AUG 01, 1984</u>

KETOROLAC TROMETHAMINE

<u>INJECTABLE; INJECTION</u>	
<u>KETOROLAC TROMETHAMINE</u>	
<u>AP ABBOTT 15MG/ML</u>	<u>SOLUTION; ORAL</u>
<u>AP 30MG/ML</u>	<u>EPTIVR-HBV</u>
<u>AP 15MG/ML</u>	<u>* GIAKO WELLCOME</u>
<u>AP 30MG/ML</u>	<u>SMG/ML</u>
<u>AP 30MG/ML</u>	<u>SMG/ML</u>
<u>AP 30MG/ML</u>	<u>SMG/ML</u>
<u>N74993 001 JAN 27, 1999</u>	<u>N21004 001 DEC 08, 1998</u>
<u>N74993 002 JAN 27, 1999</u>	<u>N20596 002 DEC 08, 1998</u>
<u>N75222 001 APR 26, 1999</u>	<u>+</u>
<u>N75222 002 APR 26, 1999</u>	<u>TABLET; ORAL</u>
<u>N75222 001 APR 26, 1999</u>	<u>EPTIVR-HBV</u>
<u>N75222 001 APR 26, 1999</u>	<u>* GIAKO WELLCOME</u>
<u>N75284 001 APR 26, 1999</u>	<u>100MG</u>
<u>N75284 001 JUN 23, 1999</u>	<u>100MG</u>
<u>N75284 001 JUN 23, 1999</u>	<u>LEUCOVORIN CALCIUM</u>

> ADD > AB STDMAK LABS CA 10MGLABETALOL HYDROCHLORIDE

<u>INJECTABLE; INJECTION</u>	
<u>LABETALOL HCL</u>	
<u>AP BEDFORD 5MG/ML</u>	<u>LEUCOVORIN CALCIUM PRESERVATIVE FREE</u>
<u>AP + ABBOTT</u>	<u>EQ 10MG BASE/ML</u>
<u>N40147 001 JUN 25, 1997</u>	<u>EQ 10MG BASE/ML</u>
<u>N40056 001 MAY 23, 1995</u>	<u>EQ 200MG BASE/VIAL</u>
<u>N40147 001 JUN 25, 1997</u>	<u>EQ 10MG BASE/ML</u>

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM PRESERVATIVE FREE
EQ 200MG BASE/VIAL

<u>AP</u>	<u>+ BEDFORD</u>	<u>EQ 200MG BASE/VIAL</u>	<u>N40056 001</u>	<u>MAY 23, 1995</u>
<u>AP</u>	<u>BIGMAR</u>	<u>EQ 10MG BASE/ML</u>	<u>N40286 001</u>	<u>FEB 26, 1999</u>
<u>AP</u>	<u>GENSIA SICOR PHARMS</u>	<u>EQ 200MG BASE/VIAL</u>	<u>N40258 001</u>	<u>FEB 26, 1999</u>
<u>> ADD ></u>	<u>AB</u>	<u>EQ 10MG BASE/ML</u>	<u>N40332 001</u>	<u>JUN 28, 1999</u>

TABLET; ORAL
LEUCOVORIN CALCIUM
INVAMED
EQ 15MG BASE

<u>AB</u>	<u>WELLCOVORIN</u>	<u>EQ 5MG BASE</u>	<u>N75327 001</u>	<u>MAR 24, 1999</u>
<u>AB</u>	<u>GLAXO WELLCOME</u>	<u>EQ 5MG BASE</u>	<u>N18342 001</u>	<u>JUL 08, 1983</u>
<u>AB</u>	<u>*</u>	<u>EQ 25MG BASE</u>	<u>N18342 002</u>	<u>JUL 08, 1983</u>
<u>AB</u>	<u>@</u>	<u>EQ 5MG BASE</u>	<u>N18342 001</u>	<u>JUL 08, 1983</u>
<u>AB</u>	<u>@</u>	<u>EQ 25MG BASE</u>	<u>N18342 002</u>	<u>JUL 08, 1983</u>

LEVALBUTEROL HYDROCHLORIDE
SOLUTION; INHALATION
XOPENEX
+ SEPRACOR
+ +
EQ 0 .021% BASE
EQ 0 .042% BASE

<u>AB</u>	<u>N20837 001</u>	<u>MAR 25, 1999</u>
<u>AB</u>	<u>N20837 002</u>	<u>MAR 25, 1999</u>

LIDOCAINE

FILM, EXTENDED RELEASE; TRANSDERMAL
LIDODERM
+ HIND HLTHCARE
700MG/12HR

<u>N20612 001</u>	<u>MAR 19, 1999</u>
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LOPERAMIDE HYDROCHLORIDE

CAPSULE; ORAL
IMODIUM
* TRANSSEN
AB
+ MCNEIL CONS
@

<u>N16782 001</u>	<u>N16782 001</u>
<u>N16834 001</u>	<u>N16834 001</u>
<u>N16980 001</u>	<u>N16980 001</u>
<u>N17694 001</u>	<u>N17694 001</u>
<u>2MG</u>	<u>2MG</u>
<u>2MG</u>	<u>2MG</u>
<u>2MG</u>	<u>2MG</u>

LIDOCAINE; PRilocaine

<u>AEROSOL TOPICAL</u>	<u>EMLA</u>	<u>N20962 001</u>
<u>*</u>	<u>ASTRA PHARMS</u>	<u>2.5%;2.5%</u>
<u>DISC; TOPICAL</u>	<u>EMLA</u>	<u>FEB 04, 1998</u>
<u>*</u>	<u>ASTRA PHARMS</u>	<u>2.5%;2.5%</u>
<u>N20962 001</u>	<u>FEB 04, 1998</u>	<u>N20962 001</u>
<u>3.0MG</u>	<u>ZESTRIL</u>	<u>JAN 20, 1999</u>
<u>N19777 006</u>	<u>ZENECA</u>	<u></u>
<u>3.00MG</u>	<u>LITHIUM CARBONATE</u>	<u></u>
<u>N16782 001</u>	<u>CAPSULE; ORAL</u>	<u></u>
<u>N16782 001</u>	<u>LITHONATE</u>	<u></u>
<u>3.00MG</u>	<u>SOLVAY</u>	<u></u>
<u>3.00MG</u>	<u>@</u>	<u></u>
<u>TABLET; ORAL</u>	<u>LITHIUM CARBONATE</u>	<u></u>
<u>AB</u>	<u>EFIZER</u>	<u>300MG</u>
<u>AB</u>	<u>+ LITHOTABS</u>	<u>300MG</u>
<u>AB</u>	<u>* SOLVAY</u>	<u>300MG</u>
<u>300MG</u>	<u>@</u>	<u>300MG</u>

MEPERIDINE HYDROCHLORIDE

<u>INJECTABLE; INJECTION</u>	
<u>MEPERIDINE HCL PRESERVATIVE FREE</u>	
<u>10MG/ML</u>	
<u>AP</u>	<u>MALLINCKRODT</u>
	<u>STERIS</u>
	<u>10MG/ML</u>
<u>SYRUP; ORAL</u>	
<u>DEMEROL</u>	
<u>AA + ABBOTT</u>	<u>50MG/5ML</u>
<u>AA</u>	<u>SNORET</u>
	<u>50MG/5ML</u>
<u>TABLET; ORAL</u>	
<u>DEMEROL</u>	
<u>AA + ABBOTT</u>	<u>50MG</u>
<u>AA</u>	<u>100MG</u>
<u>AA + SNORET</u>	<u>50MG</u>
<u>AA</u>	<u>100MG</u>
	<u>100MG</u>
<u>MEPERIDINE HCL</u>	
<u>AA AMIDE PHARM</u>	<u>50MG</u>
<u>AA</u>	<u>100MG</u>
	<u>100MG</u>

METHOTREXATE SODIUM

<u>INJECTABLE; INJECTION</u>	
<u>METHOTREXATE</u>	
<u>BIGMAR</u>	
<u>AP</u>	<u>EQ 25MG BASE/ML</u>
<u>METHOTREXATE PRESERVATIVE FREE</u>	
<u>EQ 25MG BASE/ML</u>	
<u>AP</u>	<u>AP</u>
<u>EQ 1GM BASE/VIAL</u>	
<u>AP</u>	<u>AP</u>
<u>METHOTREXATE SODIUM</u>	
<u>* LEDERLE</u>	
<u>AP + LEDERLE</u>	<u>EQ 1GM BASE/VIAL</u>
<u>METHOTREXATE SODIUM PRESERVATIVE FREE</u>	
<u>EQ 1GM BASE/VIAL</u>	
<u>AP</u>	<u>AP</u>
<u>N11719 009</u>	<u>APR 07, 1988</u>
<u>N11719 009</u>	<u>APR 07, 1988</u>
<u>N40263 001</u>	<u>FEB 26, 1999</u>
<u>N40265 001</u>	<u>FEB 26, 1999</u>
<u>N40266 001</u>	<u>FEB 26, 1999</u>
<u>N11719 009</u>	<u>APR 07, 1988</u>
<u>N40233 001</u>	<u>JUN 17, 1999</u>
<u>INJECTABLE; INJECTION</u>	
<u>LETOXONE</u>	
<u>* INNOMEX</u>	
<u>20MG/ML</u>	
<u>20MG/ML</u>	
<u>20MG/ML</u>	
<u>N15865 001</u>	
<u>N15865 001</u>	
<u>METHOXSALLEN</u>	
<u>N20357 001</u>	<u>MAR 03, 1995</u>
<u>N20357 003</u>	<u>MAR 03, 1995</u>
<u>N20357 003</u>	<u>NOV 05, 1998</u>
<u>N20357 004</u>	<u>NOV 05, 1998</u>
<u>N20357 004</u>	<u>NOV 05, 1998</u>
<u>N20357 001</u>	<u>MAR 03, 1995</u>
<u>500MG</u>	<u>N20357 003</u>
<u>625MG</u>	<u>NOV 05, 1998</u>
<u>750MG</u>	<u>N20357 004</u>
<u>500MG</u>	<u>NOV 05, 1998</u>
<u>625MG</u>	<u>N20357 001</u>
<u>750MG</u>	<u>NOV 05, 1998</u>
<u>AA</u>	<u>METOLAZONE</u>
<u>AA</u>	<u>TABLET; ORAL</u>
	<u>ZAROXOLYN</u>
	<u>MEDEVIA</u>
	<u>2.5MG</u>
	<u>2.5MG</u>
	<u>> DLT ></u>
	<u>> ADD ></u>

MICONAZOLE NITRATE

> ADD > INSERT, CREAM; VAGINAL, TOPICAL
 > ADD > MONISTAT DUAL- PAK
 > ADD > + ADVANCED CARE PRODS 1.2GM, 2%

MICONAZOLE NITRATE

AB ALPHARMA US PHARM 200MG
 AB NMC 200MG

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCYCLINE HCL
 + DANBURY PHARMA

AB GLOBAL PHARM EQ 50MG BASE
 AB EQ 100MG BASE

NADOLOL

TABLET; ORAL
CORGARD
 AB APOTHECON

20MG
 AB 40MG
 AB 80MG
 AB 120MG
 AB 160MG
 AB 20MG
 AB 40MG
 AB 80MG
 AB 120MG
 AB 160MG
 AB *

MICONAZOLE NITRATE

> ADD > TABLET; ORAL
NALTREXONE HCL
 AB AMIDE PHARM 50MG
 N75274 001
 MAY 26, 1999

NAPROXEN

AB TABLET, DELAYED RELEASE; ORAL
NAPROXEN
 AB SIDMAK LABS CA 375MG
 NOV 19, 1993
 N73508 001
 NOV 19, 1993
 N73508 001
 AB 500MG

MINOCYCLINE HYDROCHLORIDENICOTINE

AB FILM, EXTENDED RELEASE; TRANSDERMAL
FROSTEP
 * ELIAN PHARM 11MG/24HR
 AB 22MG/24HR
 MAR 23, 1999
 N65005 001
 MAR 23, 1999
 N65005 002
 MAR 23, 1999
 AB 11MG/24HR
 AB 22MG/24HR
 AB 11MG/24HR
 AB 22MG/24HR
 AB *

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

NITROGLYCERIN

AB OINTMENT; TRANSDERMAL
NITROGLYCERIN
 AB ALTANA 2%
 AB +
 OCT 28, 1986
 N18063 005
 OCT 28, 1986
 N18063 001
 N18063 002
 N18063 003
 N18063 004
 N18063 005
 OCT 28, 1986
 N18063 001
 N18063 002
 N18063 003
 N18063 004

NB 7355 001
 JUL 08, 1988
 NB 7355 001
 JUL 08, 1988

2%
 +

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL
PRILOSEC
 * ASTRA PHARMS 10MG
 N19910 003
 OCT 05, 1995

<u>OMEPRAZOLE</u>	<u>OXYTETRACYCLINE CALCIUM</u>			
CAPSULE, DELAYED REL PELLETS; ORAL PRILOSEC	SYRUP; ORAL TERAMYCIN * PFIZER @	EQ 125MG BASE/5ML EQ 125MG BASE/5ML	N60595 001	N60595 001
ASTRA PHARMS 10MG	N19810 003	OCT 05, 1995		
<u>ONDANSETRON</u>	<u>OXYTETRACYCLINE HYDROCHLORIDE</u>			
TABLET, ORALLY DISINTEGRATING; ORAL ZOFTRAN ODT	INJECTABLE; INJECTION TERAMYCIN * PFIZER *	EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL	N60586 001	N60586 002
GLAXO WELLCOME +	N20781 001 JAN 27, 1999	EQ 4MG BASE EQ 8MG BASE	N60586 002	N60586 002
	N20781 002 JAN 27, 1999	EQ 8MG BASE		
<u>ORLISTAT</u>	<u>OXYTETRACYCLINE HYDROCHLORIDE; POLYMYXIN B SULFATE</u>			
CAPSULE; ORAL XENICAL + ROCHE	OINTMENT; OTIC TERAMYCIN W/ POLYMYXIN * PFIZER @	EQ 5MG BASE/GM; 10,000 UNITS/GM EQ 5MG BASE/GM; 10,000 UNITS/GM	N61841 001	N61841 001
120MG	N20766 001 APR 23, 1999			
<u>ORPHENADRINE CITRATE</u>	<u>TABLET, VAGINAL TERAMYCIN-POLYMYXIN</u>			
TABLET, EXTENDED RELEASE; ORAL ORPHENADRINE CITRATE	* PFIZER @	EQ 100MG BASE; 100,000 UNITS EQ 100MG BASE; 100,000 UNITS	N61009 001	N61009 001
AB KIEL 100MG	N40249 001 JAN 29, 1999			
<u>OXYBUTYNIN CHLORIDE</u>	<u>PAROXETINE HYDROCHLORIDE</u>			
SYRUP; ORAL OXYBUTYNIN CHLORIDE	TABLET, EXTENDED RELEASE; ORAL PAXIL CR			
AA MIKART 5MG/5ML	+ SMITHKLINE BECHAM	EQ 12.5MG BASE	N20936 001	N20936 001
			FEB 16, 1999	
			N20936 002	
TABLET, EXTENDED RELEASE; ORAL DITROPAN XL + ALZA 15MG	+ PEMOLINE	EQ 25MG BASE	FEB 16, 1999	
> ADD >	N20897 003 JUN 22, 1999			
> ADD >				
<u>PEMOLINE</u>	<u>TABLET; ORAL CYLBERT</u>			
	AB ABBOTT 37.5MG			N16832 002

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
MICRO-K 10
AB + KV PHARM 10MEQ
AB * ROBBINS AH 10MEQ

GRANULE, FOR RECONSTITUTION ER; ORAL
 MICRO-K LS
 @ KV PHARM
 @ ROBBINS AH

20MEQ/PACKET
 20MEQ/PACKET

POTASSIUM CHLORIDE; SODIUM CHLORIDE; TROMETHAMINE
 INJECTABLE; INJECTION
 THAM-E
 * ABBOTT
 @ TRINITY TX

3.70MG/VIAL; 1.75GM/VIAL;
 3.6GM/VIAL
 3.70MG/VIAL; 1.75GM/VIAL;
 3.6GM/VIAL

N13025 001
 N13025 001
 OCT 13, 1988

POTASSIUM CITRATE

POWDER FOR RECONSTITUTION; ORAL
 POTASSIUM CITRATE
 @ MISSION PHARMA
 @ TRINITY TX
 @ UDL

10MEQ/PACKET
 20MEQ/PACKET
 10MEQ/PACKET
 20MEQ/PACKET

N19647 002
 OCT 13, 1988
 N19647 001
 OCT 13, 1988
 N19647 002
 OCT 13, 1988
 N19647 001
 OCT 13, 1988

PREDNISOLONE

SYRUP; ORAL
PREDNISOLONE
AA HALSEY
AA UDL

15MG/5ML
15MG/5ML

PREDNISOLONE ACETATE

CAPSULE, SUSPENSION/DROPS; OPHTHALMIC
ECONOPRED PLUS
AB ALCON
AB FALCON PHARMS
1%

N18238 002
 MAY 14, 1984
 N18248 002
 MAY 14, 1984

PREDNISOLONE SODIUM PHOSPHATE

INJECTABLE; INJECTION
 HYDROTRASOL
 * MERCK
 @ MERCK

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

N19561 003
 AUG 26, 1988
 N19561 003
 AUG 26, 1988

PROBENECID

TABLET; ORAL
BENEMID
AB * MERCK
 @ PROBENECID
AB MERCK
AB + MERCK

500MG
 500MG
 500MG
 500MG

PROPOFOL

INJECTABLE; INJECTION
DIPRIVAN
AB + ZENECA
 *
AB GENSTIA SICOR PHARMS
AB +

1.0MG/ML
 1.0MG/ML
 1.0MG/ML
 1.0MG/ML

N19627 002
 JUN 11, 1996
 N19627 002
 JUN 11, 1996
 N75102 001
 JAN 04, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HCL
AB GRANUTEC PHARMS
AB
AB

EQ 150MG BASE
 EQ 300MG BASE

N40287 001
 MAY 28, 1999
 N40323 001
 MAY 13, 1999

N74488 001
 JUL 31, 1997
 N74488 002
 JUL 31, 1997

RANITIDINE HYDROCHLORIDE

<u>TABLET; ORAL</u>			
<u>RANITIDINE HCl</u>			
<u>AB</u>	NOVOPHARM NC	<u>EQ 150MG BASE</u>	N74488 001 JUL 31, 1997
<u>AB</u>		<u>EQ 300MG BASE</u>	N74488 002 JUL 31, 1997
<u>AB</u>	PAR PHARM	<u>EQ 150MG BASE</u>	N75180 001 JAN 28, 1999
<u>AB</u>		<u>EQ 300MG BASE</u>	N75180 002 JAN 28, 1999

RISPERIDONE

<u>TABLET; ORAL</u>			
<u>RISPERIDONE</u>			
		<u>0 . 25MG</u>	N20272 008 MAY 10, 1999
		<u>0 . 5MG</u>	N20272 007 JAN 27, 1999
		<u>+</u>	

RITONAVIR

<u>CAPSULE; ORAL</u>			
<u>RITONAVIR</u>			
<u>> ADD</u>		<u>> ADD</u>	200MG
<u>> ADD</u>		<u>> ADD</u>	200MG
	<u>ABBO</u>	<u>> DLT</u>	
		<u>> DLT</u>	
		<u>> DLT</u>	

SOLUTION; ORAL

<u>SOLUTION; ORAL</u>			
<u>NORVIR</u>			
<u>ABBO</u>	<u>80MG/ML</u>	<u>80MG/ML</u>	N20659 801 MAR 01, 1996
	<u>+</u>		N20659 001 MAR 01, 1996
<u>ROFECOXIB</u>		<u>> DLT</u>	<u>> DLT</u>
		<u>> DLT</u>	<u>> DLT</u>

SUSPENSION; ORAL

<u>SUSPENSION; ORAL</u>			
<u>VIOXX</u>			
<u>MERCK</u>	<u>1 . 5MG / 5ML</u>	<u>25MG / 5ML</u>	N21052 001 MAY 20, 1999
	<u>+</u>		N21052 002 MAY 20, 1999

SELEGILINE HYDROCHLORIDE

<u>TABLET; ORAL</u>			
<u>SELEGILINE HYDROCHLORIDE</u>			
<u>ELESPRISE</u>		<u>EQ 200MG</u>	N20628 001 DEC 06, 1995
<u>@ SOMERSET</u>		<u>EQ 200MG</u>	N20628 004 DEC 06, 1995
		<u>EQ 200MG</u>	N19334 001 JUN 05, 1999

SELEGILINE HYDROCHLORIDE

TABLET; ORAL
SELEGILINE HCL
AB + SOMERSET 5MG

> ADD > AP + FRESENIUS KABI 10%
INTRALIPID 10%
PHARMACIA AND UPJOHN 10%
INTRALIPID 20%
> ADD > AP + FRESENIUS KABI 20%
PHARMACIA AND UPJOHN 20%
INTRALIPID 30%
> ADD > AP + FRESENIUS KABI 30%
PHARMACIA AND UPJOHN 30%
INTRALIPID 10%
PHARMACIA AND UPJOHN 10%
INTRALIPID 20%
> DLT >

SULFACETAMIDE SODIUM
SOLUTION/DROPS; OPHTHALMIC
SODIUM SULFACETAMIDE
AKORN 10%
15%
20%
@ 10%
@ 15%
@ 30%
SULFACETAMIDE SODIUM
AKORN 10%
30%

TACROLIMUS

CAPSULE; ORAL
PROGRAF
* RIKISAWA HEALTHCARE

N19334 001
JUN 05, 1989

SOYBEAN OIL

INJECTABLE; INJECTION
INTRALIPID 10%
FRESENIUS KABI 10%
PHARMACIA AND UPJOHN 10%
INTRALIPID 20%
FRESENIUS KABI 20%
PHARMACIA AND UPJOHN 20%
INTRALIPID 30%
FRESENIUS KABI 30%
PHARMACIA AND UPJOHN 30%
INTRALIPID 10%
PHARMACIA AND UPJOHN 10%
INTRALIPID 20%
> DLT >

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT

INJECTABLE; INJECTION
A-N STANNOUS AGGREGATED ALBUMIN
@ NORTH AM CHEM^S N/A
@ SYNCOR PHARMS N/A
PULMOLITE
BS CIS
BS DUPONT PHARMS
N/A
N/A

TECHNETIUM TC-99M ALBUMIN COLLOID KIT

INJECTABLE; INJECTION
MICROLITE
CIS N/A
DUPONT PHARMS N/A
N/A
OCT 14, 1983
N87998 001
OCT 14, 1983
N87998 001
OCT 14, 1983

TECHNETIUM TC-99M DISOFENIN KIT

INJECTABLE; INJECTION
HEPATOLITE
CIS N/A
DUPONT PHARMS N/A
N/A
MAR 25, 1983
N18263 001
MAR 25, 1983
N18263 001
MAR 25, 1983

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION
OSTEOLITE
AP CIS N/A
AP DUPONT PHARMS N/A
N/A
MAY 25, 1999
N40216 001
MAY 25, 1999

N17972 001
N17972 001

TECHNETIUM TC-99M PYRO/TRIMETA PHOSPHATES KIT

<u>INJECTABLE; INJECTION</u>			
PYROLITE	N/A	N17684	001
CIS	N/A	N17684	003
DISPON PHARM			
<u>TERBUTALINE SULFATE</u>			
<u>INJECTABLE; INJECTION</u>		<u>THEOPHYLLINE</u>	
<u>BRETHINE</u>	<u>1MG/ML</u>	<u>N18571</u>	<u>001</u>
<u>AP</u> *	<u>NOVARTIS</u>	<u>N18571</u>	<u>001</u>
+ <u>BRICanyl</u>	<u>1MG/ML</u>	<u>N17466</u>	<u>001</u>
<u>AP</u> *	<u>HOECHST MARION RUSSEL</u>	<u>1MG/ML</u>	<u>N17466</u>
@			
<u>TABLET; ORAL</u>		<u>THEOPHYLLINE</u>	
BRETHINE	2.5MG	N17849	001
NOVARTIS	5MG	N17849	002
*	2.5MG	N17849	001
> DLT >	5MG	N17849	002
> DLT >	2.5MG	N17849	001
> ADD >	5MG	N17849	002
> ADD >			
+ <u>BRICanyl</u>			
HOECHST MARION RUSSEL	2.5MG	N17618	001
*	5MG	N17618	002
> DLT >	2.5MG	N17618	001
> ADD >	5MG	N17618	002
> ADD >			
<u>TERIPARATIDE ACETATE</u>		<u>THIOTHIXENE HYDROCHLORIDE</u>	
<u>INJECTABLE; INJECTION</u>		<u>CONCENTRATE; ORAL</u>	
PARATHIAR		N19498	001
* RHONE POULENC RORER	200 UNITS/VIAL	N19498	001
		DEC 23, 1987	
@			
<u>TETRACYCLINE HYDROCHLORIDE</u>		<u>EQ 5MG BASE/ML</u>	
<u>CAPSULE; ORAL</u>		<u>THIOTHIXENE HCL</u>	
<u>TETRACYCLINE HCL</u>			
<u>FREENG PHARM</u>			
*			
@			

TRIAMCINOLONE ACETONIDE

GEL; TOPICAL ARISTOCORT @ LEDERLE	0.1%	NB3380 001
OINTMENT; TOPICAL ARISTOCORT	0.1% 0.5%	N80750 004 N80745 002 N80750 001 N80745 002
AT AT + @ FUJISAWA HLTHCARE	0.1% 0.5% 0.5% 0.5%	N80750 003 N80745 003 N88781 001 OCT 05, 1984
AT AT + @ LEDERLE	0.1% 0.5% 0.5% 0.5%	N80750 003 N80745 003 N88781 001 OCT 05, 1984
AT FUJISAWA HLTHCARE AT + @ ARISTOCORT A	0.1% 0.5% 0.5% 0.5%	N80750 003 N80745 003 N88781 001 OCT 05, 1984
AT AT + @ LEDERLE	0.1% 0.5% 0.5% 0.5%	N80750 003 N80745 003 N88781 001 OCT 05, 1984

VALRUBICIN

SOLUTION; VALSTAR PRESERVATIVE FREE * ANTHRA NB3380 001	N20892 001 SEP 25, 1998
OINTMENT; INTRAVESICAL VALSTAR PRESERVATIVE FREE + ANTHRA 40MG/ML	N20892 001 SEP 25, 1998
VERAPAMIL HYDROCHLORIDE	
CAPSULE, EXTENDED RELEASE; ORAL VERAPAMIL HCL MYLAN	N75138 001 APR 20, 1999
AB	120MG
AB	180MG
AB	240MG
VERELAN	
* ELAN	120MG
*	180MG
*	240MG
AB + ELAN PHARM	120MG
AB +	180MG
AB +	240MG
TABLET, EXTENDED RELEASE; ORAL VERAPAMIL HCL DURAMED	N75072 001 MAY 25, 1999
AB	120MG
AB	240MG
WARFARIN SODIUM	N75072 003 MAY 25, 1999
TABLET; ORAL COUDADIN * DIFONT MERCK	N75072 003 MAY 25, 1999
AB	2MG
POWDER FOR RECONSTITUTION; ORAL PYLORI-CHEK BREATH TEST + ALIMENTERICS 100MG/VIAL	N09218 013 FEB 04, 1999

WARFARIN SODIUM

TABLET; ORAL

COUMADIN
DUPONT MERCK

AB
AB
AB
AB
AB
+

2MG
2.5MG
2.5MG
5MG
5MG

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

ACETAMINOPHEN

SUPPOSITORY; RECTAL
ACEPHEN * G AND W LABS
120MG 325MG
> DLT >
> DLT >
> DLT >
> DLT >
> ADD >
> ADD >
> ADD >
> ADD >

GEORG 120MG
120MG
325MG
650MG
ACETAMINOPHEN
ASCENT PEDS 120MG
325MG
650MG
120MG
> ADD > + UPSHERR SMITH
> DLT > INFANTS' FEVERALL
ASCENT PEDS 80MG
> ADD > UPSHERR SMITH
> DLT >
> DLT >

CIMETIDINE

TABLET; ORAL
CIMETIDINE
ZENITH GOLDLINE 200MG
N18060 001
N18060 003
DEC 18, 1986
N18060 002
N18060 001
N18060 003
DEC 18, 1986
N18060 002
> ADD >
> ADD >
CLOTRIMAZOLE
CREAM; TOPICAL
LOTRIMIN AF
SCHERING PLUGH
N18337 003
SEP 12, 1983
N18337 002
N18337 001
N18337 003
SEP 12, 1983
N18337 002
N18337 001
N18337 004
AUG 26, 1992
N18337 004
AUG 26, 1992
EPINEPHRINE BITARRATE

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CONTACT * SMITHKLINE
© PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE
CENT PHARMS 8MG; 7.5MG
8MG; 7.5MG
+ 8MG; 7.5MG
TABLET, EXTENDED RELEASE; ORAL
CONTACT NOVARTIS
> DLT >
> DLT >
> ADD >
> ADD >

N18099 001
N18099 001
N18099 001
MAY 07, 1984
N18809 001
MAY 07, 1984
N18809 001
MAY 07, 1984
N19613 001
JUN 13, 1986
N19613 001
JUN 13, 1986
N18115 001
N18115 001
N10374 003
N10374 003
* 3MG
@
IBUPROFEN
IBUPROFEN
ALPHARMA
100MG/5ML
0.3MG/INH
0.3MG/INH
MEDITHALER-EPI
* 3MG
@
SUSPENSION; ORAL
IBUPROFEN
ALPHARMA
100MG/5ML
APR 30, 1999
N75010 001
MAR 01, 1999
N75139 001
MAR 01, 1999
N71144 001
JAN 20, 1987
NORTON INN
200MG
200MG
NORTON INN
200MG

IBUPROFEN

TABLET; ORAL
IBUPROFEN
NORTON 
200MGS
200MGS
ZENITH GOLDLINE
200MG
200MG
JUNIOR STRENGTH IBUPROFEN
PERRIGO
100MG
APR 22, 1999

IBUPROFEN POTASSIUM

CAPSULE; ORAL
PROVEL
 NOVARTIS
200MGS
+ WHITEHALL ROBINS
200MG
MICONAZOLE NITRATE
PERRIGO
2%,200MG
APR 20, 1999

NICOTINE

FILM, EXTENDED RELEASE; TRANSDERMAL
PROSTEP
+ ELIAN PHARM
22MG/24HR
+
> ADD >
> ADD >
> ADD >
> ADD >
N72901 001
DEC 19, 1991
N72903 001
DEC 19, 1991
N71144 001
JAN 20, 1987
N72901 001
DEC 19, 1991
N72903 001
DEC 19, 1991
N75367 001
APR 22, 1999

NICOTINE POLACRILEX
GUM, CHEWING; BUCCAL,
NICOTINE POLACRILEX
CIRCA
EQ 2MG BASE
EQ 4MG BASE

N74507 001
MAR 15, 1999
N74707 001
MAR 19, 1999

NONOXYNOL-9

SPONGE; VAGINAL
TODAY
@ ALLENDALE PHARMS
1GM
@ WHITEHALL ROBINS
1GM
#20402 001
APR 20, 1995
N20402 001
APR 20, 1995

MICONAZOLE NITRATE

CREAM, SUPPOSITORY; TOPICAL, VAGINAL
M-ZOLE 3 COMBINATION PACK
ALPHARMA US PHARM
2%,200MG
MICONAZOLE NITRATE COMBINATION PACK
PERRIGO
2%,200MG
APR 20, 1999

PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
PSEUDOEPHEDRINE HCL
PERRIGO
1.20MG
N75153 001
FEB 26, 1999

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE HCL
NOVOPHARM
RANITIDINE
ZANTAC 75
GIAXO WELLCOMS
EQ 75MG BASE
EQ 75MG BASE
EQ 75MG BASE
N73507 001
NOV 19, 1993
N73507 001
NOV 19, 1993
100MGS
NNMC
EQ 75MG BASE
EQ 75MG BASE
N75094 001
JUN 21, 1999
N75132 001
DEC 19, 1995

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
ZANTAC 75
+ WARNER LAMBERT

EQ 75MG BASE

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 6 JUN '99

NO JUNE 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
June 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
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

Orphan Product Designations and Approvals List

June 1999

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Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
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

Orphan Product Designations and Approvals List
June 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
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

Orphan Product Designations and Approvals List
June 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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
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

Orphan Product Designations and Approvals List
June 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-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.	Technicleone Corporation 14282 Franklin Ave. Tustin, CA 92780 DD=02/12/1999

Orphan Product Designations and Approvals List

June 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 Academtel, 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
June 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Murine MAb 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-sulfatase, recombinant human TN=	Treatment of mucopolysaccharidosis Type VIe, (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
June 1999

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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 Hendry 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
June 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
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
Synthetic porcine secretin TN=	For use in the evaluation of exocrine pancreas function.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=06/18/1999

Orphan Product Designations and Approvals List
June 1999

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
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 JUNE 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

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

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

U-256	TREATMENT OF HIV INFECTION 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

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	EXCLUS EXPIRES
020482 004	ACARBOSE; PRECOSE			I-252	SEP 29, 2001
020503 001	ALBUTEROL SULFATE; PROVENTIL-HFA ALITRETNINOIN; PANRETIN			I-253	SEP 29, 2001
020886 001				I-262	JUN 02, 2002
>ADD>	020221 001 AMIFOSTINE; ETHYOL AMPRENAVR; AGENERASE AMPRENAVR; AGENERASE AMPRENAVR; AGENERASE ATOVACONE; MEPRON			ODE	FEB 02, 2006
021007 001				NCE	FEB 02, 2004
021007 002				ODE	JUN 24, 2006
021039 001				NCE	APR 15, 2004
020500 001				NCE	APR 15, 2004
020711 002	BUPROPION HYDROCHLORIDE; ZYBAN BUPROPION HYDROCHLORIDE; ZYBAN BUSULFAN; BUSULFEX	5763493	AUG 12, 2013	NCE	APR 15, 2004
020711 003		5763493	AUG 12, 2013	ODE	JAN 05, 2006
020954 001		5430057	SEP 30, 2013	I-255	JAN 05, 2002
020313 002	CALCITONIN, SALMON; MIACALCIN CELECOXIB; CELEBREX	5559148	MAY 24, 2015	U-263	FEB 04, 2006
020998 001		5759565	JUN 02, 2015	U-264	FEB 04, 2002
020998 002		5466068	JUN 02, 2015	NDF	
		5466823	NOV 30, 2013	U-19	
020740 005	CERIVASTATIN SODIUM; BAYCOL	5563165	NOV 30, 2013	NS	MAY 24, 2002
020638 001	CIDOFUVIR; VISTIDE CILOSTAZOL; PLETAL CISAPRIDE MONOHYDRATE; PROPULSID QUICKSOLV CYTARABINE; DEPOCYT	5006530	JAN 17, 2009	NP	APR 01, 2006
020863 001		5177080	NOV 26, 2011	APR 01,	2002
020863 002		5142051	JUN 26, 2010	I-263	MAY 25,
>ADD>	020863 002 CILOSTAZOL; PLETAL CISAPRIDE MONOHYDRATE; PROPULSID QUICKSOLV CYTARABINE; DEPOCYT	4277479	AUG 29, 1999	I-259	MAR 30, 2002
020767 001		4277479	AUG 29, 1999	I-263	MAY 25,
021041 001		5648093	JUL 15, 2014	I-259	MAR 30, 2002
020287 001	DALTEPARIN SODIUM; FRAGMIN	5763407	JUN 29, 2013	I-263	MAY 25,
020287 003	DALTEPARIN SODIUM; FRAGMIN	5763407	JUN 29, 2013	I-259	MAR 30, 2002
020287 004	DALTEPARIN SODIUM; FRAGMIN	5763407	JUN 29, 2013	I-259	MAR 30, 2002
017922 001	DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013	PC	DEC 19, 1999
017922 002		5763407	JUN 29, 2013	PC	DEC 19, 1999
017922 003		5763407	JUN 29, 2013	PC	DEC 19, 1999
>ADD>	018938 001 DESMOPRESSIN ACETATE; DDAVP	5763407	JUN 29, 2013		
018938 002		5763407	JUN 29, 2013		
019955 001		5763407	JUN 29, 2013		
019955 002		5763407	JUN 29, 2013		
>ADD>	074752 001 DILTIAZEM HYDROCHLORIDE; CARTIA XT DILTIAZEM HYDROCHLORIDE; CARTIA XT DILTIAZEM HYDROCHLORIDE; CARTIA XT	4814470	MAY 14, 2010		
>ADD>	074752 003 DILTIAZEM HYDROCHLORIDE; CARTIA XT	5438072	NOV 22, 2013		
>ADD>	020449 004 DOCEPAXEL; TAXOTERE	5698582	JUL 03, 2012		
>ADD>		5714512	JUL 03, 2012		

PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL USE CODE	EXCL CODE	EXCLUS EXPIRES
>ADD> 050718 001 020972 001	DOXORUBICIN HYDROCHLORIDE; DOXIL EFAVIRENZ; SUSTIVA	5811423 5519021 5663169 5811423 5519021 5663169 5519021 5663169 5519021 5663169 5811423	AUG 07, 2012 MAY 21, 2013 SEP 02, 2014 AUG 07, 2012 MAY 21, 2013 SEP 02, 2014 MAY 21, 2013 SEP 02, 2014 MAY 21, 2013 SEP 02, 2014 AUG 07,	U-256 U-257 U-257 U-256 U-257 U-257 U-256 U-257 U-257 U-256 U-256	ODE	JUN 28, 2006
020972 002	EFAVIRENZ; SUSTIVA	5223261	JUN 29, 2010	NP	NP	I-254 I-254
020972 003	EFAVIRENZ; SUSTIVA	4826831 5547948 5246937 5246937 5854267 5854267 4895726 5738872 5571817 5886184 4760071 5886184 4377584 4314081 4626549 4314081 4626549 4087544 5084479 4087544 5084479 5270317	MAY 02, 2006 JAN 17, 2015 SEP 21, 2010 SEP 21, 2010 DEC 29, 2015 DEC 29, 2015 JAN 19, 2009 FEB 28, 2015 NOV 05, 2013 NOV 19, 2012 JUN 19, 2006 NOV 19, 2012 MAR 22, 2000 FEB 02, 2001 DEC 02, 2003 FEB 02, 2001 DEC 02, 2003 JAN 16, 2000 JAN 02, 2010 JAN 16, 2000 JAN 02, 2010 MAR 20,	U-96 U-96 U-96 U-267 I-258 MAR 05, 2002 MAR 05, 2002 MAR 05, 2002 MAR 26, 2002 MAR 24, 2002 MAR 24, 2002	MAR 05, MAR 05, MAR 05, MAR 26, MAR 24, MAR 24,	
020375 001 020375 002 020375 003 020375 004 020908 001 020992 002 020992 003 020527 003	ESTRADIOL; CLIMARA ESTRADIOL; CLIMARA ESTRADIOL; CLIMARA ESTRADIOL; VAGIFEM ESTROGENS, CONJUGATED ESTROGENS, CONJUGATED ESTROGENS, CONJUGATED ESTROGENS, CONJUGATED; PREMPRO 14/14	520801 001 020363 001 020363 003 020325 001 019304 002 020747 001 020747 002 020747 003 020747 004 020747 005 020747 006 020955 001 020625 001	FAMCICLOVIR; FAMVIR FAMCICLOVIR; FAMVIR FAMOTIDINE; PEPCID AC FAMOTIDINE; PEPCID AC FENOFLIBRATE; TRICOR (MICRONIZED) FENTANYL CITRATE; ACTIQ FENTANYL CITRATE; ACTIQ FENTANYL CITRATE; ACTIQ FENTANYL CITRATE; ACTIQ FENTANYL CITRATE; ACTIQ FENTANYL CITRATE; ACTIQ FERRIC SODIUM GLUCONATE; FERRILECT FEXOFENADINE HYDROCHLORIDE; ALLEGRA	NP NP NP NP NP NP NP NP NP NP NP NP NP NCE	NOV 04, 2001 NOV 04, 2001 NOV 04, 2001 NOV 04, 2001 NOV 04, 2001 NOV 04, 2001 NOV 04, 2001 FEB 18, 2004	
>ADD> 020788 001 020180 001	FINASTERIDE; PROPECIA FINASTERIDE; PROSCAR	4314081 4626549 4314081 4626549 4087544 5084479 4087544 5084479	FEB 02, 2001 DEC 02, 2003 FEB 02, 2001 DEC 02, 2003 JAN 16, 2000 JAN 02, 2010 JAN 16, 2000 JAN 02, 2010 JAN 16, 2000 JAN 02, 2010 JAN 16, 2000 JAN 02, 2010	U-106 U-258 U-106 U-258 U-106 U-258 U-106 U-258	DEC 11, 2001	
020974 001 020974 002	FLUOXETINE HYDROCHLORIDE; PROZAC FLUOXETINE HYDROCHLORIDE; PROZAC	4314081 4626549 4314081 4626549 5811423 5519021 5663169 5811423 5519021 5663169 5519021 5663169 5519021 5663169 5811423	FEB 02, 2001 DEC 02, 2003 FEB 02, 2001 DEC 02, 2003 AUG 07, 2012 MAY 21, 2013 SEP 02, 2014 MAY 21, 2013 SEP 02, 2014 MAY 21, 2013 SEP 02, 2014 MAY 21, 2013 SEP 02, 2014 AUG 07,	U-106 U-258 U-106 U-258 U-256 U-256 U-256 U-256 U-256 U-256 U-256 U-256	SEP 30, 2002 MAY 13, 2002	
020121 001 020882 001 020882 002	FLUTICASONE PROPIONATE; FLONASE GABAPENTIN; NEURONTIN GABAPENTIN; NEURONTIN	5270317		D-50		
>ADD> 020758 003 020491 001	HYDROCHLOROTHIAZIDE; AVALIDE IBUTILIDE FUMARATE; CONVERT					

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	EXCLUS EXPIRES
020936 002	PAROXETINE HYDROCHLORIDE;PAXIL CR	5872132 4839177 5422123 4721723 5900423 5710183 5908869	MAY 19, 2015 JUN 13, 2006 JUN 06, 2012 DEC 29, MAY 19, JUL 14, MAR 22,	NDF U-265 NP U-270	FEB 16, 2002 PC NCE PC	
>ADD> 020698 001 019627 002	POLYETHYLENE GLYCOL 3350;MIRALAX PROPOFOL;DIPRIVAN PROPOFOL;PROPOFOL	4879288 5914128 5158952 4804663 4804663 5158952 5474995 5691374	MAR 20, 2007 DEC 22, DEC 29, DEC 29, DEC 29, DEC 29, DEC 29, JUN 24, NOV 25,		OCT 16, SEP 26, JAN 14, OCT 17,	1999 2002 2000 2000
>ADD> 075102 001	QUETIAPINE FUMARATE;SERQUEL					
>ADD> 020639 004	RANITIDINE HYDROCHLORIDE;RANITIDINE HCL					
>ADD> 075094 001	RIBAVIRIN;REBETOL					
>ADD> 020903 001	RISPERIDONE;RISPERDAL					
>ADD> 020272 007	RISPERIDONE;RISPERDAL					
021042 008	RISPERIDONE;RISPERDAL					
021042 001	ROFECOXIB;VIQX					
021042 002	ROFECOXIB;VIQXX					
021052 001	ROFECOXIB;VIQXX					
021052 002	ROFECOXIB;VIQXX					
021071 002	ROSIGLITAZONE MALEATE;AVANDIA					
021071 003	ROSIGLITAZONE MALEATE;AVANDIA					
021071 004	ROSIGLITAZONE MALEATE;AVANDIA					
>ADD> 020980 001	TERBINAFINE HYDROCHLORIDE;LAMISIL	4680291 4755534	JUL 14, DEC 30,	2004	U-73 U-73	2004 2004
>ADD> 020846 001	TERBINAFINE;LAMISIL	5840327 5840327 501090 5354760	AUG 15, AUG 15, OCT 07, MAR 24,	2016 2016 2008 2012		2004 2004 2004 2004
>ADD> 019762 001	TESTOSTERONE;TESTODERM					
>ADD> 019762 002	TESTOSTERONE;TESTODERM					
>ADD> 020646 005	TIAGABINE HYDROCHLORIDE;GABITRIL					
>ADD> 075089 001	TICLOPIDINE HYDROCHLORIDE;TICLOPIDINE HCL					
020912 001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT					
020913 001	TIROFIBAN HYDROCHLORIDE;AGGRASTAT					
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 4863742 4863742 4863742	JUN 19, JUN 19, JUN 19, JUN 19,	2007 2007 2007 2007		2001 2002 2002 2002
020943 001	VERAPAMIL HYDROCHLORIDE;VERELAN PM					
020943 002	VERAPAMIL HYDROCHLORIDE;VERELAN PM					
020943 003	VERAPAMIL HYDROCHLORIDE;VERELAN PM					