

**CUMULATIVE
SUPPLEMENT 6
JUNE 2000**

APPROVED DRUG PRODUCTS

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

20TH EDITION



RM
301.45
.A66
2000
June
Suppl

**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**

2000

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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

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Cumulative Supplement 6

June 2000

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**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

20TH EDITION

**CUMULATIVE SUPPLEMENT 6
JUNE 2000**

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, 20th 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 20th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 21st 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)

GALDERMA LABS INC
(GALDERMA)

GALDERMA LABORATORIES LP
(GALDERMA LABS LP)

GLOBAL PHARMACEUTICAL CORP
(GLOBAL PHARM)

IMPAX LABORATORIES INC
(IMPAX LABS)

HOECHST MARION ROUSSEL INC
(HOECHST MARION RSSL)

AVENTIS PHARMACEUTICALS INC
(AVENTIS PHARMS)

RHONE POULENC RORER PHARMACEUTICALS INC
(RHONE POULENCE RORER)

AVENTIS PHARMACEUTICALS PRODUCTS INC
(AVENTIS PHARM PROD)

TAP HOLDINGS INC
(TAP HOLDINGS)

TAP PHARMACEUTICAL PRODUCTS INC
(TAP PHARM)

ZENECA INC
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP
(ASTRAZENECA PHARMS)

ZENECA LTD
(ZENECA)

ASTRAZENECA UK LTD
(ASTRAZENECA UK)

ZENECA PHARMACEUTICALS DIV ZENECA INC
(ZENECA)

ASTRAZENECA PHARMACEUTICALS LP
(ASTRAZENECA PHARMS)

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 20th 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 \$90.00 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 20th annual edition of the 1999 Orange Book Patent and Exclusivity List is at <http://www.fda.gov/cder/orange/20bookpub.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 Drug Price Competition and Patent Term Restoration Act requires that patent information be filed with all newly submitted Section 505 drug applications. To facilitate industry submission of the information, a patent submission sample format is available in HTML and PDF format at:
<http://www.fda.gov/cder/orange/patdecl.pdf>
<http://www.fda.gov/cder/orange/patdecl.html>

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 1999) 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 1999</u>	<u>MAR 2000</u>	<u>JUN 2000</u>	<u>SEP 2000</u>
DRUG PRODUCTS LISTED	10045	10082	10186	
SINGLE SOURCE	2599 (25.9%)	2596 (25.7%)	2617 (25.7%)	
MULTISOURCE	7335 (73.0%)	7375 (73.2%)	7458 (73.2%)	
THERAPEUTICALLY EQUIVALENT	6986 (69.5%)	7040 (69.8%)	7132 (70.0%)	
NOT THERAPEUTICALLY EQUIVALENT	349 (3.5%)	335 (3.3%)	326 (3.2%)	
EXCEPTIONS ¹	111 (1.1%)	111 (1.1%)	111 (1.1%)	
NEW MOLECULAR ENTITIES APPROVED	0	6	11	
NUMBER OF APPLICANTS	576	575	580	

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

PRESCRIPTION DRUG PRODUCT LIST
20TH EDITION
RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

ACETAMINOPHEN; BUTALBITAL

TABLET; ORAL
PHRENILIN FORTE
AB + AMARIN PHARMS

650MG;50MG
N88831 001
JUN 19, 1985
N88831 001
JUN 19, 1985

AB * CARRICK

TABLET; ORAL
PHRENILIN

AB + AMARIN PHARMS
325MG;50MG
N87811 001
JUN 19, 1985
N87811 001
JUN 19, 1985

AB * CARRICK

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE
AA / AMARIN PHARMS
120MG/5ML;12MG/5ML
AA / CARRICK
120MG/5ML;12MG/5ML
N86024 001
N86024 001

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN
AA UCB
325MG;10MG

+ 325MG;7.5MG

AA VINTAGE PHARMS

325MG;10MG

AA

500MG;10MG

AA

660MG;10MG

AA

LORTAB
UCB
325MG;5MG

325MG;5MG

@

NORCO
+ WATSON LABS

325MG;10MG

325MG;10MG

*

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE HCL AND ACETAMINOPHEN
AB WATSON LABS

650MG;EQ 25MG BASE
N74699 001
MAR 24, 2000

AB

TALACEN
AB + SANOFI SYNTHELABO

650MG;EQ 25MG BASE
N18458 001
SEP 23, 1982
N18458 001
SEP 23, 1982
N18458 001
SEP 23, 1982

AB *

ACETOHEXAMIDE

TABLET; ORAL

ACETOHEXAMIDE
AB BARR

500MG
N70870 001
FEB 09, 1987
N70870 001
FEB 09, 1987

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

AB

AB +

AB DYNELOR

AB ELLI

AB *

AB *

AB *

ADAPALENE

CREAM; TOPICAL

DIFFERIN
+ GALDERMA LABS LP

0.1%
N20748 001
MAY 26, 2000

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL
AB MERRISSON

0.09MG/INH
N74072 001
AUG 01, 1996
N74072 001
AUG 01, 1996

AB SIDMAK LABS CA

0.09MG/INH

<u>AMRINONE LACTATE</u>					
	INJECTABLE; INJECTION				
<u>AP</u>	<u>AMRINONE LACTATE</u>	<u>EQ 5MG BASE/ML</u>	<u>EQ 5MG BASE/ML</u>	N75542 001	
	+ BAXTER PHARM PROD			MAY 10, 2000	
<u>ARDEPARIN SODIUM</u>					
	INJECTABLE; INJECTION				
	NORMIFLO				
	+ PHARMACIA AND UPJOHN	5,000 UNITS/0.5ML		N20227 002	
				MAY 23, 1997	
		10,000 UNITS/0.5ML		N20227 001	
				MAY 23, 1997	
	* WYETH AYERST	5,000 UNITS/0.5ML		N20227 002	
				MAY 23, 1997	
		10,000 UNITS/0.5ML		N20227 001	
				MAY 23, 1997	
> <u>ADD</u> >	<u>ARGATROBAN</u>				
> <u>ADD</u> >	INJECTABLE; INJECTION				
> <u>ADD</u> >	ACOVA				
> <u>ADD</u> >	+ TX BIOTECH	100MG/ML		N20883 001	
> <u>ADD</u> >				JUN 30, 2000	
	<u>ARTICAINE HYDROCHLORIDE; EPINEPHRINE</u>				
	INJECTABLE; INJECTION				
	SEPTOCAINE				
	+ DEPROCO	4%; EQ 0.01MG BASE/ML		N20971 001	
				APR 03, 2000	
<p>ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E</p>					
<p>INJECTABLE; INJECTION</p>					
<p>KABI VITE PED F + W KIT</p>					
<p>* FRESENIUS KABI</p>					
	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, 17MG/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 IU/10ML; N/A			N20176 001	DEC 29, 1993
<p>VITAPED</p>					
<p>@ FRESENIUS KABI</p>					
	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, 17MG/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 IU/10ML; N/A			N20176 001	DEC 29, 1993
<p>ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE</p>					
<p>TABLET; ORAL</p>					
<p>DIPHENOXYLATE HCL AND ATROPINE SULFATE</p>					
<u>AA</u>	<u>PAR PHARM</u>	<u>0.025MG; 2.5MG</u>		N40357 001	MAY 02, 2000
<p>ATROPINE SULFATE; EDROPHONIUM CHLORIDE</p>					
<p>INJECTABLE; INJECTION</p>					
<p>ENLON-PLUS</p>					
	+ BAXTER PHARM PROD	0.14MG/ML; 10MG/ML		N19677 001	NOV 06, 1991
				N19678 001	NOV 06, 1991
		0.14MG/ML; 10MG/ML		N19677 001	NOV 06, 1991
	* CHREDA			N19678 001	NOV 06, 1991
		0.14MG/ML; 10MG/ML		N19678 001	NOV 06, 1991

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OPTIVAR
+ ASTA

N21127 001
MAY 22, 2000

25MG
50MG

N84441 001
N87444 001
N84408 001
N84441 001
N87444 001

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE
GENEVA PHARMS TECH

AA
AA
AA
AA
AA
AA
AA

N72264 001
FEB 27, 1989
N72265 001
FEB 27, 1989
N72266 001
FEB 27, 1989
N72264 001
FEB 27, 1989
N72265 001
FEB 27, 1989
N72266 001
FEB 27, 1989

0.5MG
1MG
2MG
0.5MG
1MG
2MG

10MG
25MG
50MG
10MG
25MG
50MG

N86262 001
N86263 001
N85882 003
N86262 001
N86263 001
N85882 003

MYOTONACHOL
GLENWOOD

N72264 001
FEB 27, 1989
N72265 001
FEB 27, 1989
N72266 001
FEB 27, 1989

5MG
10MG
25MG
5MG
10MG
25MG

N84188 001
N84188 003
N84188 004
N84188 001
N84188 003
N84188 004

BETAXOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
BETAXOLOL
AKORN

> ADD >
> DLT >
> DLT >

AT
AT
*

EQ 0.5% BASE
EQ 0.5% BASE
EQ 0.5% BASE

N75386 001
JUN 30, 2000
N19270 001
AUG 30, 1985
N19270 001
AUG 30, 1985

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

N06536 003
N06536 002
N06536 004
N06536 005
N06536 003
N06536 002
N06536 004
N06536 005
N89095 001
DEC 19, 1985
MAY 29, 1984
N89441 001
MAY 29, 1984
N89096 001
DEC 19, 1985
N89095 001
DEC 19, 1985
MAY 29, 1984
N88441 001
MAY 29, 1984
N88441 001
MAY 29, 1984
N89096 001
DEC 19, 1985

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION
URECHOLINE
MERCK

AA
AA
AA
AA

N06536 001
N06536 001

5MG/ML
5MG/ML

N84408 001

5MG
10MG
25MG
50MG

N89096 001
DEC 19, 1985
N89096 001
DEC 19, 1985
MAY 29, 1984
N88441 001
MAY 29, 1984
N88441 001
MAY 29, 1984
N89096 001
DEC 19, 1985

BETHANECHOL CHLORIDE
DANBURY PHARMA

N84408 001

50MG

N89096 001
DEC 19, 1985

BEXAROTENE

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

GEL; TOPICAL
TARGRETIN
+ LIGAND

1*

N21056 001
JUN 28, 2000
> DLT >
> DLT >
> DLT >
> ADD >
> ADD >
> ADD >
> ADD >

TABLET; ORAL

BUSPAR
* BRISTOL MYERS SQUIBB 15MG
30MG
15MG
30MG

N18731 003
APR 22, 1996
N18731 004
APR 22, 1996
N18731 003
APR 22, 1996
N18731 004
APR 22, 1996

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLEOMYCIN
FAULDING

AP EQ 15 UNITS BASE/VIAL
MAR 10, 2000
AP EQ 30 UNITS BASE/VIAL
MAR 10, 2000
AP EQ 15 UNITS BASE/VIAL
JUN 27, 2000
AP EQ 30 UNITS BASE/VIAL
JUN 27, 2000

GENSIA SICOR PHARMS

INJECTABLE; INJECTION
BUTORPHANOL TARTRATE
ABBOTT

N75559 001
MAR 20, 2000
N75559 002
MAR 20, 2000

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
BRETYLIUM TOSYLATE
ASTRAZENECA

AP 50MG/ML
50MG/ML

N71151 001
AUG 10, 1987
N71151 001
AUG 10, 1987

CALCIUM CHLORIDE

INJECTABLE; INJECTION
CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER
+ ABBOTT

N21117 001
JAN 28, 2000

BUPROPION HYDROCHLORIDE

TABLET; ORAL
BUPROPION HCL
INVANED

AB 75MG
AB 100MG
AB 75MG
AB 100MG

N75584 001
FEB 07, 2000
N75584 002
FEB 07, 2000
N75491 001
APR 17, 2000
N75491 002
APR 17, 2000

SOLUTION; PERFUSION, CARDIAC
CARDIOPLEGIC IN PLASTIC CONTAINER
BAXTER HLTHCARE

N75323 001
APR 21, 2000

PLEGISOL IN PLASTIC CONTAINER
+ ABBOTT

N18608 001
FEB 26, 1982
N18608 001
FEB 26, 1982

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML

17.6MG/100ML; 325.3MG/100ML;
119.3MG/100ML; 643MG/100ML

CANDICIDIN

OVINTMENT, VAGINAL

VANOBID
 @ AVENTIS PHARMS 0.6MG/GM
 * HOECHST MARION RESSL 0.6MG/GM

N61596 001
 N63596 001

125MG/5ML
 125MG/5ML

N50749 001
 DEC 04, 1997
 N50749 001
 DEC 04, 1997

TABLET, VAGINAL

VANOBID
 @ AVENTIS PHARMS 3MG
 * HOECHST MARION RESSL 3MG

N61613 001
 N63613 001

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA
MYLAN 25MG;100MG

N75091 002
 APR 21, 2000

EQ 500MG BASE/VIAL
 EQ 1GM BASE/VIAL
 EQ 2GM BASE/VIAL

N64200 001
 MAR 24, 2000
 N64200 002
 MAR 24, 2000
 N64200 003
 MAR 24, 2000

TINEMET CR

DUPONT PHARMS 25MG;100MG
 25MG;100MG

N19856 002
 DEC 24, 1992
 N19856 002
 DEC 24, 1992

EQ 10GM BASE/VIAL
 EQ 20GM BASE/VIAL

N64201 001
 MAR 24, 2000
 N64201 002
 MAR 24, 2000

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL
ALCON 1%

N75476 001
 JAN 03, 2000

EQ 500MG BASE/VIAL
 EQ 1GM BASE/VIAL
 EQ 2GM BASE/VIAL
 EQ 10GM BASE/VIAL

N50547 001
 N50547 002
 N50547 003
 N50547 004

AT

BAUSCH AND LOMB 1%

N75546 001
 JAN 20, 2000

* HOECHST MARION RESSL

OCUPRESS

CIBA 1%

N19972 001
 MAY 23, 1990

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL
 CEDAX

+ DJ PHARMA

EQ 400MG BASE

N50685 002
 DEC 20, 1995

CEFDINIR

CAPSULE; ORAL

OWNICEF

+ ABBOTT

300MG
 300MG

* SCHERING PLOUGH

EQ 400MG BASE

N50685 002
 DEC 20, 1995

* PARKE DAVIS

EQ 90MG BASE/5ML

N50686 001
 DEC 20, 1995

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

CERTIBUTEN DIHYDRATE

POWDER FOR RECONSTITUTION; ORAL

- CEDEX
- + DJ PHARMA
- * SCHERING PLOUGH
- * EQ 180MG BASE/5ML

- N50686 002
- DEC 20, 1995
- N50686 001
- DEC 20, 1995
- N50686 002
- DEC 20, 1995

CEFTRIAXONE SODIUM, LIDOCAINE

INJECTABLE; INJECTION

- ROCEPHIN KIT
- + HLR
- + EQ 1GM BASE/VIAL,N/A;N/A, N50585 006
- * EQ 500MG BASE/VIAL,N/A;N/A, N50585 007
- * EQ 1GM BASE/VIAL,N/A;N/A, N50585 006
- * EQ 500MG BASE/VIAL,N/A;N/A, N50585 007

- MAY 08, 1996
- MAY 08, 1996
- MAY 08, 1996
- MAY 08, 1996

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

- ROCEPHIN
- + HLR
- + EQ 250MG BASE/VIAL
- + EQ 500MG BASE/VIAL
- + EQ 1GM BASE/VIAL
- + EQ 2GM BASE/VIAL
- + EQ 10GM BASE/VIAL
- * EQ 250MG BASE/VIAL
- * EQ 500MG BASE/VIAL
- * EQ 1GM BASE/VIAL
- * EQ 2GM BASE/VIAL
- * EQ 10GM BASE/VIAL

- N50585 001
- DEC 21, 1984
- N50585 002
- DEC 21, 1984
- N50585 003
- DEC 21, 1984
- N50585 004
- DEC 21, 1984
- N50585 005
- DEC 21, 1984
- N50585 001
- DEC 21, 1984
- N50585 002
- DEC 21, 1984
- N50585 003
- DEC 21, 1984
- N50585 004
- DEC 21, 1984
- N50585 005
- DEC 21, 1984

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL

- KEFLEX
- * LILLY
- * AB
- * AB
- * AB
- * AB

- EQ 125MG BASE/5ML
- EQ 250MG BASE/5ML
- EQ 250MG BASE/5ML
- EQ 250MG BASE/5ML
- EQ 125MG BASE/5ML
- EQ 250MG BASE/5ML

- N50406 001
- N50406 002
- N62117 003
- N62117 003
- N50406 001
- N50406 002

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL

- EVOXAC
- + SNOWBRAND
- EQ 30MG BASE

- N20989 002
- JAN 11, 2000

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

- @ HLR
- + EQ 10MG BASE/ML
- + EQ 20MG BASE/ML
- + EQ 40MG BASE/ML
- @ ROCHE
- * EQ 10MG BASE/ML
- * EQ 20MG BASE/ML
- * EQ 40MG BASE/ML

- N50624 001
- FEB 11, 1987
- N50624 002
- FEB 11, 1987
- N50624 003
- FEB 11, 1987
- N50624 001
- FEB 11, 1987
- N50624 002
- FEB 11, 1987
- N50624 003
- FEB 11, 1987

CHENODIOL

TABLET; ORAL

- CHENIX
- @ AXCAN
- EQ 250MG
- @ AXCAN SCANDIPHARM
- EQ 250MG

- N18513 002
- JUL 28, 1983
- N18513 002
- JUL 28, 1983

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE
 4MG
 @ IMPAX LABS

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

SUSPENSION; ORAL
 PROPULSID
 @ JANSSEN

N20398 001
 SEP 15, 1995

CICLOPIROX

CREAM; TOPICAL
 LOPROX
 + AVENTIS PHARMS 0.77%

EQ 10MG BASE
 EQ 20MG BASE
 EQ 10MG BASE
 EQ 20MG BASE

N20210 001
 JUL 29, 1993
 N20210 002
 DEC 23, 1993
 N20210 001
 JUL 29, 1993
 N20210 002
 DEC 23, 1993

CICLOPIROX OLAMINE

CREAM; TOPICAL
 LOPROX
 * HOECHST MARION ROSS 1%

N18748 001
 DEC 30, 1982

INJECTABLE; INJECTION
 CISPLATIN
 GENSIA SICOR PHARMS

N74814 001
 MAY 16, 2000
 N74656 001
 MAY 16, 2000

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
 CIMETIDINE HCL
 NOVEX

N75560 001
 MAR 15, 2000

EQ 40MG BASE
 EQ 60MG BASE
 EQ 40MG BASE
 EQ 60MG BASE

N20822 003
 JUL 17, 1998
 N20822 004
 JUL 17, 1998
 N20822 003
 JUL 17, 1998
 N20822 004
 JUL 17, 1998

CISAPRIDE MONOHYDRATE

SUSPENSION; ORAL
 PROPULSID
 * JANSSEN

N20398 001
 SEP 15, 1995

INJECTABLE; INJECTION
 CLADRIBINE
 BEDFORD

N75405 001
 FEB 28, 2000

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

CYANOCOBALAMIN

INJECTABLE; INJECTION

CYANOCOBALAMIN
 @ AVENTIS PHARMS 1MG/ML
 HOECHST MARION ROSS 1MG/ML

AP

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

N80564 001
 N80564 001

SOLUTION; ORAL

SANGCYA
 SANGSTAT MEDCL 100MG/ML
 @ 100MG/ML

N64195 001
 OCT 31, 1998
 N64195 001
 OCT 31, 1998

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CYCLOPENTOLATE HCL
 ALCON UNIVERSAL 1%

AT

N89162 001
 JAN 24, 1991
 N89162 001
 JAN 24, 1991

DAUNORUBICIN CITRATE

INJECTABLE, LIPOSOMAL; INJECTION

DAUNOXOME EQ 2MG BASE/ML
 + GILEAD EQ 2MG BASE/ML
 * NEXSTAR

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

N50704 002
 APR 08, 1996
 N50704 002
 APR 08, 1996

CYCLOSPORINE

CAPSULE; ORAL

CYCLOSPORINE
 ABBOTT 25MG

AB

N65003 001
 MAY 12, 2000

AB

50MG

N65003 002
 MAY 12, 2000

AB

100MG

N65003 003
 MAY 12, 2000

AB

25MG

N65017 002
 JAN 13, 2000

AB

100MG

N65017 001
 JAN 13, 2000

NEORAL

NOVARTIS

AB

25MG

N50715 001
 JUL 14, 1995

AB

50MG

N50715 003
 JUL 14, 1995

AB

100MG

N50715 002
 JUL 14, 1995

EX

25MG

N50715 001
 JUL 14, 1995

EX

50MG

N50715 003
 JUL 14, 1995

EX

100MG

N50715 002
 JUL 14, 1995

SOLUTION; ORAL

CYCLOSPORINE
 ABBOTT 100MG/ML

AB

N65025 001
 MAR 03, 2000

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION

DAUNORUBICIN HCL
 AP + BEDFORD EQ 5MG BASE/ML
 * EQ 5MG BASE/ML

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

N50731 001
 JAN 30, 1998

N50731 001
 JAN 30, 1998

N50731 001
 JAN 30, 1998

N65035 001
 JAN 24, 2000

N64212 002
 MAY 03, 1999

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

DECILOMICIN
 * FEDERLE 150MG
 @ 150MG

N50262 001
 N50262 001

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

DESMOPRESSIN ACETATE
 AP BEDFORD 0.004MG/ML

N74575 001
 FEB 18, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

DESMOPRESSIN ACETATE
 INJECTABLE; INJECTION
DESMOPRESSIN ACETATE PRESERVATIVE FREE
 BEDFORD 0.004MG/ML
 N74574 001
 FEB 18, 2000

AT
 SPRAY, METERED; NASAL
 STIMATE
 + AVENTIS BEHRING 0.15MG/SPRAY
 N20355 001
 MAR 07, 1994
 * CENITEON 0.15MG/SPRAY
 N20355 001
 MAR 07, 1994

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE
 ALCON UNIVERSAL 0.1%;EQ 3.5MG BASE/ML;
 10,000 UNITS/ML
 N62721 001
 NOV 17, 1986
AT
 STERIS 0.1%;EQ 3.5MG BASE/ML;
 10,000 UNITS/ML
 N62721 001
 NOV 17, 1986

DEXAMETHASONE SODIUM PHOSPHATE
 SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE
 ALCON UNIVERSAL EQ 0.1% PHOSPHATE
 N88771 001
 JAN 16, 1985

AT
 SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE
 STERIS EQ 0.1% PHOSPHATE
 N88771 001
 JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE
 SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE
 ALCON UNIVERSAL EQ 0.1% PHOSPHATE;
 EQ 3.5MG BASE/ML
 N62714 001
 JUL 21, 1986

AT
 SUPPOSITORY; VAGINAL
 DV
 @ AVENTIS PHARMS 0.7MG
 N83517 001

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE
 STERIS EQ 0.1% PHOSPHATE;
 EQ 3.5MG BASE/ML
 N62714 001
 JUL 21, 1986

DICLOFENAC POTASSIUM
 TABLET; ORAL
DICLOFENAC POTASSIUM
 GENEVA PHARMS TECH 50MG
 N75229 001
 NOV 20, 1998
AB
 INVAMED 50MG
 N75229 001
 NOV 20, 1998

DICLOFENAC SODIUM
 SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM
 FALCON PHARMS 0.1%[†]
 0.1%
 N20809 001
 MAY 04, 1998
AB
 VOLTAREN 0.1%
 * CIBA 0.1%
 N20809 001
 MAY 04, 1998

AT
 TABLET, EXTENDED RELEASE; ORAL
DICLOFENAC SODIUM
 BIOVAIL 100MG
 N75492 001
 FEB 11, 2000

AB
 VOLTAREN-XR
 + NOVARTIS 100MG
 N20254 001
 MAR 08, 1996
 * 100MG
 N20254 001
 MAR 08, 1996

DIENESTROL
 SUPPOSITORY; VAGINAL
 DV
 @ AVENTIS PHARMS 0.7MG
 N83517 001

† SEE SECTION 1.3 OF INTRODUCTION

DIENESTROL

SUPPOSITORY; VAGINAL

DV

* HOECHST MARION RSSL 0.7MG

N81517 001

EQ 240MG HCL

N20506 003
OCT 04, 1996

DIFLORASONE DIACETATE

CREAM; TOPICAL

DIFLORASONE DIACETATE

AB TARO 0.05%

N75508 001
APR 24, 2000

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HCL

AA
AA

GLOBAL PHARM
25MG
50MG
25MG
50MG

IMPAX LABS
®

N80807 001
N80807 002
N80807 001
N80807 002

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

AB3 BIOVAIL 120MG

120MG

AB3 180MG

180MG

AB3 240MG

240MG

AB3 300MG

300MG

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

ZONALON

+ BIOGLAN PHAR

5%

* MEDICIS

5%

N20126 001
APR 01, 1994
N20126 001
APR 01, 1994

INJECTABLE; INJECTION

DILTIAZEM HCL

AP ABBOTT 5MG/ML

N75004 001
FEB 16, 2000

DOXERCALCIFEROL

INJECTABLE; INJECTION

HECTOROL

+ BONE CARE

2 UGM/ML

N21027 001
APR 06, 2000

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL

TIAMATE

* HOECHST MARION RSSL EQ 120MG HCL

* EQ 180MG HCL

* EQ 240MG HCL

+ MERCK EQ 120MG HCL

+ EQ 180MG HCL

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

EON

> ADD >

> ADD >

> ADD >

> ADD >

AB

AB

AB

AB

HALSEY

N20506 001
OCT 04, 1996

N20506 002
OCT 04, 1996

N20506 003
OCT 04, 1996

N20506 001
OCT 04, 1996

N20506 002
OCT 04, 1996

N20506 002
OCT 04, 1996

EQ 50MG BASE

EQ 100MG BASE

EQ 50MG BASE

EQ 100MG BASE

N65032 001

JUN 30, 2000

N65032 002

JUN 30, 2000

N65041 001

APR 28, 2000

N65041 002

APR 28, 2000

DOXYCYCLINE

CAPSULE; ORAL
MONODOX
OCLASSEN

AB EQ 50MG BASE
AB EQ 100MG BASE
* EQ 50MG BASE
* EQ 100MG BASE

N50641 002
FEB 10, 1992
N50641 001
DEC 29, 1989
N50641 002
FEB 10, 1992
N50641 001
DEC 29, 1989

SOLUTION; TOPICAL
SANSAC
HEALTHPOINT

AT 2%

N62522 001
JAN 24, 1985

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL
PEDIAMYCIN
ROSS LABS

AB EQ 200MG BASE/5ML
@ EQ 200MG BASE/5ML

N62305 001
N62305 001

ENFLURANE

LIQUID; INHALATION

ETHRANE
+ BAXTER PHARM PROD
AN * OHMEDA

99.9%
99.9%

N17087 001
N17087 001

SUSPENSION/DROPS; ORAL

PEDIAMYCIN
* ROSS LABS
@

N62305 002
N62305 002

TABLET, CHEWABLE; ORAL

PEDIAMYCIN
ROSS LABS
AB EQ 200MG BASE
@ EQ 200MG BASE

N62305 001
N62306 001

ERGOTAMINE TARTRATE

TABLET, SUBLINGUAL

ERGOMAR
LOTUS-BIOCHEM

2MG

N87693 001
FEB 24, 1983

2MG

N87693 001
FEB 24, 1983

ERGOSTAT
PARKE DAVIS

2MG

N88337 001
JUN 08, 1984

2MG

N88337 001
JUN 08, 1984

WIGRETTES
* ORGANO

2MG

N86750 001
JUL 29, 1982

2MG

N86750 001
JUL 29, 1982

ERYTHROMYCIN

SOLUTION; TOPICAL

SANSAC
GALDERMA LABS

2%

N62522 001
JAN 24, 1985

ESTRADIOL

CREAM; VAGINAL

ESTRACE
* BRISTOL MYERS SQUIBB 0.01%

+ WARNER CHILCOTT 0.01%

N86069 001
JAN 31, 1984
N86069 001
JAN 31, 1984

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA
AB 0.05MG/24HR

+ BERLEX LABS

AB 0.1MG/24HR

BX 0.05MG/24HR

BX 0.1MG/24HR

BX 0.05MG/24HR

BX 0.1MG/24HR

BX 0.05MG/24HR

BX 0.1MG/24HR

BX 0.05MG/24HR

BX 0.1MG/24HR

N20375 001
DEC 22, 1994
N20375 002
DEC 22, 1994
N20375 001
DEC 22, 1994
N20375 002
DEC 22, 1994
N21048 001
SEP 20, 1999

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

ESTRADIOL

BX CYGNUS-CA

0.075MG/24HR

N21048 002

BX CYGNUS-CA

0.1MG/24HR

SEP 20, 1999

@ JOHNSON RW

0.05MG/24HR

SEP 20, 1999

@

0.075MG/24HR

SEP 20, 1999

@

0.1MG/24HR

SEP 20, 1999

AB MYLAN TECHNOLOGIES

0.05MG/24HR

SEP 20, 1999

AB

0.1MG/24HR

FEB 24, 2000

AB

0.1MG/24HR

FEB 24, 2000

TABLET; ORAL

ESTRADIOL

AB APPLIED ANAL

0.5MG

N40138 001

AB

1MG

JAN 30, 1998

AB

2MG

JAN 30, 1998

AB

0.5MG

JAN 30, 1998

AB

1MG

JAN 30, 1998

AB

2MG

JAN 30, 1998

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

* CYPROS

+ QUESTCOR PHARM

50MG/ML

DEC 22, 1988

+ QUESTCOR PHARM

50MG/ML

DEC 22, 1988

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

TRIVORA-21

AB SEARLE

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,

0.125MG

DEC 18, 1997

N74538 001

AB WATSON LABS

0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG,

0.125MG

DEC 18, 1997

N74538 001

TABLET; ORAL-28

TRIVORA-28

AB SEARLE

0.03MG, 0.04MG, 0.03MG, 0.05MG, 0.075MG,

0.125MG

DEC 18, 1997

N74538 002

AB WATSON LABS

0.03MG, 0.04MG, 0.03MG; 0.05MG, 0.075MG,

0.125MG

DEC 18, 1997

N74538 002

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

OVCN-35

* BRISTOL MYERS SQUIBB

+ WARNER CHILCOTT

@ OVCN-50

@ BRISTOL MYERS SQUIBB

@ WARNER CHILCOTT

TABLET; ORAL-28

OVCN-35

BRISTOL MYERS SQUIBB

WARNER CHILCOTT

OVCN-50

BRISTOL MYERS SQUIBB

WARNER CHILCOTT

TABLET; ORAL

ETODOLAC

TABLET; ORAL

ETODOLAC

AB TARO PHARM INDS

500MG

N75074 002

APR 25, 2000

N18127 001

N18127 001

N18128 001

N18128 001

N18128 001

N18128 001

N17716 001

N17716 001

N17576 001

N17576 001

N17576 001

N17576 001

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION
CORLOPAM
+ ABBOTT
* ELAN PHARMA

EQ 10MG BASE/ML
EQ 10MG BASE/ML

N19922 001
SEP 23, 1997
N19922 001
SEP 23, 1997

INJECTABLE; INJECTION
ROMAZICON
+ HLR
* ROCHE

0.1MG/ML
0.1MG/ML

N20073 001
DEC 20, 1991
N20073 001
DEC 20, 1991

FENTANYL CITRATE

INJECTABLE; INJECTION
SUBLIMAZE PRESERVATIVE FREE
+ AKORN MFG
* JANSSEN

EQ 0.05MG BASE/ML
EQ 0.05MG BASE/ML

N16619 001
N16619 001

INJECTABLE; INJECTION
FLUOROURACIL
GENSIA SICOR PHARMS

50MG/ML
50MG/ML

N40333 001
JAN 27, 2000
N40334 001
FEB 25, 2000

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL
ALLEGRA
AVENTIS PHARMS

30MG
60MG
180MG

N20872 001
FEB 25, 2000
N20872 002
FEB 25, 2000
N20872 004
FEB 25, 2000

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE
* ROBERTS LABS
+ SHIRE LABS
TABLET; ORAL
FUROXONE
* ROBERTS LABS
+ SHIRE LABS

50MG/15ML
50MG/15ML

N11323 002
N11323 002

FLOXURIDINE

INJECTABLE; INJECTION
FLOXURIDINE
BEDFORD

500MG/VIAL
500MG/VIAL
500MG/VIAL

N75387 001
APR 16, 2000
N16929 001
N16929 001

GABAPENTIN
SOLUTION; ORAL
NEURONTIN
+ PARKE DAVIS

250MG/5ML

N21129 001
MAR 02, 2000

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN
PFIZER

150MG
150MG

N20322 001
JUN 10, 1994
N19949 004
JUN 30, 1994

INJECTABLE; INJECTION
MAGNEVIST
+ BERLEX LABS

469.01MG/ML

N21037 001
MAR 10, 2000

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

HYDRALAZINE HCL

GENSIA SICOR PHARMS

20MG/ML

N40373 001

FEB 23, 2000

N40136 001

JUN 30, 1997

N40136 001

JUN 30, 1997

20MG/ML

20MG/ML

20MG/ML

AP

AP + LUITPOLD

*

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

HYDROCHLOROTHIAZIDE

MYLAN

12.5MG

N75640 001

JAN 28, 2000

N20504 001

DEC 27, 1996

N20504 001

DEC 27, 1996

12.5MG

12.5MG

12.5MG

AB

AB + WATSON LABS

*

TABLET; ORAL

HYDROCHLOROTHIAZIDE

GLOBAL PHARM

@ IMPAX LABS

100MG

100MG

N85098 001

N85098 001

AB

HYDROCORTISONE

CREAM; TOPICAL

NUTRACORT

GALDERMA LABS

0.5%

1%

1%

0.5%

AT

AT

AT

AT

HEALTHPOINT

@

GEL; TOPICAL

NUTRACORT

@ GALDERMA LABS

@ HEALTHPOINT

1%

1%

N84698 001

N84698 001

AT

AT

AT

AT

LOTION; TOPICAL

NUTRACORT

GALDERMA LABS

0.5%

1%

N80443 002

N80443 003

AT

AT

HYDROCORTISONE

LOTION; TOPICAL

NUTRACORT

GALDERMA LABS

2.5%

N87644 001

AUG 24, 1982

N80443 003

N87644 001

AUG 24, 1982

AT

AT

AT

AT

@

HEALTHPOINT

1%

2.5%

0.5%

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

ALCON UNIVERSAL

1%;EQ 3.5MG BASE/ML;

10,000 UNITS/ML

N62874 001

MAY 11, 1988

N62874 001

MAY 11, 1988

AT

AT

AT

AT

1%;EQ 3.5MG BASE/ML;

10,000 UNITS/ML

1%;EQ 3.5MG BASE/ML;

10,000 UNITS/ML

SUSPENSION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

ALCON UNIVERSAL

1%;EQ 3.5MG BASE/ML;

10,000 UNITS/ML

N62488 001

NOV 06, 1985

N62488 001

NOV 06, 1985

AT

AT

AT

AT

1%;EQ 3.5MG BASE/ML;

10,000 UNITS/ML

1%;EQ 3.5MG BASE/ML;

10,000 UNITS/ML

HYDROCORTISONE ACETATE; PRAMOXYNE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

EPIFOAM

SCHWARZ PHARMA

PROCTOFOAM HC

SCHWARZ PHARMA

1%;1%

N86457 001

1%;1%

1%;1%

N86195 001

DISC; TOPICAL

EPIFOAM

SCHWARZ PHARMA

PROCTOFOAM HC

SCHWARZ PHARMA

1%;1%

N86457 001

1%;1%

1%;1%

N86195 001

HYDROCORTISONE BUTYRATE

CREAM; TOPICAL
 LOCOID
 @ GALDERMA LABS 0.1% N18795 001
 @ YAMANOUCHI 0.1% N18795 001
 JAN 07, 1983
 JAN 07, 1983
 N21081 001
 APR 20, 2000

OINTMENT; TOPICAL
 LOCOID
 @ GALDERMA LABS 0.1% N19106 001
 @ YAMANOUCHI 0.1% N19106 001
 JUL 03, 1984
 JUL 03, 1984

SOLUTION; TOPICAL
 LOCOID
 @ GALDERMA LABS 0.1% N19819 001
 @ YAMANOUCHI 0.1% N19819 001
 SEP 15, 1988
 SEP 15, 1988

HYDROCORTISONE VALERATE

CREAM; TOPICAL
 HYDROCORTISONE VALERATE 0.2%
 AB CLAY PARK N75666 001
 MAY 24, 2000

HYDROXYUREA

CAPSULE; ORAL
 HYDROXYUREA 250MG
 DURAMED N75020 002
 JUN 26, 2000

INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION
 NOVOLOG 100 UNITS/ML
 + NOVO NORDISK N20986 001
 JUN 07, 2000

INSULIN GLARGINE

INJECTABLE; INJECTION
 LANTUS
 + AVENTIS PHARMS 100 UNITS/ML
 N21081 001
 APR 20, 2000

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
 HUMALOG MIX 50/50
 + LILLY 50 UNITS/ML; 50 UNITS/ML N21018 001
 DEC 22, 1999
 HUMALOG MIX 75/25
 + LILLY 25 UNITS/ML; 75 UNITS/ML N21017 001
 DEC 22, 1999

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
 HUMALOG MIX 50/50
 * LILLY 100 UNITS/ML N21018 001
 DEC 22, 1999
 HUMALOG MIX 75/25
 * LILLY 100 UNITS/ML N21017 001
 DEC 22, 1999

INULIN

INJECTABLE; INJECTION
 INULIN AND SODIUM CHLORIDE
 * CYFROS 100MG/ML N02282 001
 + QUESTCOR PHARM 100MG/ML N02282 001

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
 GLOFIL-125
 CYFROS 250-300 uCi/ML N17279 001
 QUESTCOR PHARM 250-300 uCi/ML N17279 001

> ADD >
 > ADD >

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN/2000 - JUN/2000

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
IPRATROPIUM BROMIDE
AN STERIPAK

0.02%

N75313 001
FEB 07, 2000

AB N75313 001

TABLET, EXTENDED RELEASE; ORAL
ISOSORBIDE MONONITRATE

30MG

JAN 13, 2000
N75395 001

MAR 16, 2000
N75395 002

MAR 16, 2000
N75395 003

MAR 16, 2000
N75448 001

ISOPROTERENOL HYDROCHLORIDE

AEROSOL, METERED; INHALATION

ISUPREL
* SANOFI SYNTHELABO
@ 0.103MG/INH
0.103MG/INH

SOLUTION; INHALATION

ISUPREL
* SANOFI SYNTHELABO
@ 0.5%
1%
0.5%
1%

ISOSORBIDE DINITRATE

TABLET, EXTENDED RELEASE; ORAL

ISORDIN
* WYETH AYERST

40MG

40MG

ISOSORBIDE DINITRATE

INWOOD LABS

40MG

40MG

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL

IMDUR

120MG

+ SCHERING

120MG

120MG

ISOSORBIDE MONONITRATE

DEXCEL LTD

60MG

N75522 001

APR 17, 2000

AP

BEDFORD

EQ 10MG BASE/ML

N40335 001

APR 25, 2000

EQ 10MG BASE/ML

N40147 001

JUN 25, 1997

N40147 001

JUN 25, 1997

N40347 001

APR 25, 2000

N40335 001

APR 20, 2000

KETOCONAZOLE

CREAM; TOPICAL

KETOCONAZOLE

TEVA

2%

2%

2%

N75581 001

APR 25, 2000

N19084 001

DEC 31, 1985

N19084 001

DEC 31, 1985

N1927 001

AUG 31, 1990

N1927 001

AUG 31, 1990

N1927 001

AUG 31, 1990

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION

LEUCOVORIN CALCIUM PRESERVATIVE FREE

AP + ABBOTT

EQ 10MG BASE/ML

N40147 001

JUN 25, 1997

N40147 001

JUN 25, 1997

N40347 001

APR 25, 2000

N40335 001

APR 20, 2000

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION
VIADUR
+ ALZA

EQ 65MG BASE

N21088 001
MAR 03, 2000

GRANULE, FOR RECONSTITUTION; ORAL
ZYVOX
+ PHARMACIA AND UPJOHN 100MG/5ML

N21132 001
APR 18, 2000

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETAXON
+ ALCON

EQ 0.5% BASE

N21114 001
FEB 23, 2000

INJECTABLE; INJECTION
ZYVOX
+ PHARMACIA AND UPJOHN 200MG/100ML

N21131 001
APR 18, 2000

LEVOBUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHIROCAINE
DARWIN DISCOVERY

EQ 2.5MG BASE/ML

N20997 001
AUG 05, 1999

EQ 5MG BASE/ML

N20997 002
AUG 05, 1999

EQ 7.5MG BASE/ML

N20997 003
AUG 05, 1999

EQ 2.5MG BASE/ML

N20997 004
AUG 05, 1999

EQ 5MG BASE/ML

N20997 002
AUG 05, 1999

EQ 7.5MG BASE/ML

N20997 003
AUG 05, 1999

LORAZEPAM

INJECTABLE; INJECTION
LORAZEPAM

2MG/ML

N74793 001
MAR 16, 2000

4MG/ML

N74793 002
MAR 16, 2000

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN

2MG

N08720 001
DEC 19, 1991

2MG

N08720 001
DEC 19, 1991

INJECTABLE; INJECTION
MAGNESIUM SULFATE

500MG/ML

N75151 001
APR 25, 2000

AP + AM PHARM PARTNERS

500MG/ML

N19316 001
SEP 08, 1986

*

500MG/ML

N19316 001
SEP 08, 1986

LEVORPHANOL TARTRATE

ROXANE

2MG

N74278 001
MAR 31, 2000

TABLET; ORAL

10MG
10MG

N83242 001
N83242 001

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE
PHARMACHEMIE

AA 40MG N74745 001
FEB 27, 1998
AB 40MG N74745 001
FEB 27, 1998

MELOXICAM

TABLET; ORAL
MOBIC
+ BOEHRINGER INGELHEIM 7.5MG

N20938 001
APR 13, 2000

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
MENOTROPINS
@ FERRING

75 IU/VIAL;75 IU/VIAL N73598 001
JAN 30, 1997
150 IU/VIAL;150 IU/VIAL N73599 001
JAN 30, 1997

REPRONEX
FERRING

AA 75 IU/VIAL;75 IU/VIAL N73598 001
JAN 30, 1997
AB 150 IU/VIAL;150 IU/VIAL N73599 001
JAN 30, 1997

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL
MALLINCKRODT

> AA 50MG N40352 001
> ADD > JUN 13, 2000
> AA 100MG N40352 002
> ADD > JUN 13, 2000

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION
WYAMINE SULFATE
* WYETH ABERIST

EQ 30MG BASE/ML N08248 001
EQ 30MG BASE/ML N08248 001

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
NORINYL
@ SEARLE
@ WATSON LABS

N13625 004
N13625 004

TABLET; ORAL-21
NORINYL 1+50 21-DAY
SEARLE
WATSON LABS

N13625 002
N13625 002

METAPROTERENOL SULFATE

SOLUTION; INHALATION
ALUPENT

N17659 001
N17659 001

AN * BOEHRINGER INGELHEIM 5%
+
AN PROMETA
MURO

N73340 001
MAR 30, 1992
N73340 001
MAR 30, 1992

SYRUP; ORAL

N75235 001
JAN 27, 2000

AA METAPROTERENOL SULFATE
NOVEX 10MG/5ML

METHIMAZOLE

TABLET; ORAL
METHIMAZOLE
APPLIED ANAL

N40320 001
MAR 31, 2000
N40320 002
MAR 31, 2000
N40350 001
MAR 29, 2000
N40350 002
MAR 29, 2000

AB 5MG

AB 10MG

AB 5MG

AB 10MG

AB TAPAZOLE
LILLY

N07517 002
N07517 004
N07517 002
N07517 004

AB 5MG

AB 10MG

* 10MG

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

AB + MEDEVA 10MG

* 13MG

AB METHYLIN ER

MALLINCKRODT 10MG

AB 20MG

METHYLTESTOSTERONE

TABLET, ORAL

BP ORETON METHYL

BF SCHERING

@ 10MG

@ 25MG

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

AB MIDAZOLAM HCL

ABBOTT

> ADD > EQ 1MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 1MG BASE/ML

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

AB MIDAZOLAM HCL

BEDFORD

> ADD > EQ 5MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

> ADD > EQ 1MG BASE/ML

> ADD > EQ 5MG BASE/ML

N75247 001

JUN 23, 2000

N75249 001

JUN 23, 2000

N75421 002

JUN 20, 2000

N75421 001

JUN 20, 2000

N75455 001

JUN 20, 2000

N75243 001

JUN 20, 2000

N75243 002

JUN 20, 2000

N75396 001

JUN 20, 2000

N75396 002

JUN 20, 2000

N75484 001

JUN 20, 2000

N75481 001

JUN 30, 2000

N75494 001

JUN 30, 2000

N75494 002

JUN 30, 2000

N18654 002

MAY 26, 1987

N18654 001

DEC 20, 1985

N18654 002

MAY 26, 1987

N18654 001

DEC 20, 1985

N63065 002

JUN 10, 1999

N63065 002

JUN 10, 1999

EQ 5MG BASE

EQ 75MG BASE

EQ 75MG BASE

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

AB MINOCYCLINE HCL

+ DANBURY PHARMA

*

*

> ADD >

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL
SINGULAIR
MERCK

N20830 002
MAR 03, 2000

EQ 4MG BASE

EQ 0.1MG BASE/ML

N20459 001
APR 17, 1995

N20459 002
APR 17, 1995

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE
ESI LEADERLE

N75407 001
JAN 28, 2000

15MG

EQ 1MG BASE/ML

N20459 001
APR 17, 1995

N20459 002
APR 17, 1995

NABUMETONE

TABLET; ORAL
NABUMETONE
COPELEY PHARM

N75179 001
JUN 06, 2000

750MG

EQ 0.5MG BASE;

N75523 001
MAR 17, 2000

N75189 001
MAY 26, 2000

500MG

EQ 50MG BASE

RELAFEN

SMITHKLINE BEECHAM

N19583 001
DEC 24, 1991

500MG

50MG

N19583 002
DEC 24, 1991

750MG

50MG

N19583 003
DEC 24, 1991

500MG

50MG

N19583 002
DEC 24, 1991

750MG

N19583 001
DEC 24, 1991

750MG

N19583 002
DEC 24, 1991

750MG

NADOLOL

TABLET; ORAL
CORCARD
APOTHECON

N18063 001
N18063 001

40MG

375MG

N75061 001
FEB 18, 1998

N75061 002
FEB 18, 1998

NAFCILLIN SODIUM

TABLET; ORAL
UNIPEN
* WYETH AYERST

N50462 001
N50462 001

EQ 500MG BASE
EQ 500MG BASE

500MG

N83115 001

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION
REVEX
+ BAXTER PHARM PROD

EQ 0.1MG BASE/ML

N20459 001
APR 17, 1995

EQ 1MG BASE/ML

N20459 002
APR 17, 1995

* OHMEDA

EQ 0.1MG BASE/ML

N20459 001
APR 17, 1995

* *

EQ 1MG BASE/ML

N20459 002
APR 17, 1995

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

RANBAXY

N75523 001
MAR 17, 2000

EQ 0.5MG BASE;

N75523 001
MAR 17, 2000

EQ 50MG BASE

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HCL

EON

N75434 001
MAR 08, 2000

50MG

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

NAPROXEN

GENEVA PHARMS TECH

N75061 001
FEB 18, 1998

375MG

N75061 002
FEB 18, 1998

500MG

375MG

N75061 001
FEB 18, 1998

500MG

N75061 002
FEB 18, 1998

NIACIN

TABLET; ORAL

NIACIN

GLOBAL PHARM

500MG

N83115 001

NIACIN

TABLET; ORAL

NIACIN
@ IMPAX LABS

500MG

N83115 001

CAPSULE; ORAL

NORTRIPTYLIN HCL
TARO

EQ 10MG BASE

N75520 004

MAY 08, 2000

AA UPSHER SMITH

500MG

N40378 001

MAY 03, 2000

EQ 25MG BASE

MAY 08, 2000

AA

500MG

N75520 001

MAY 08, 2000

EQ 50MG BASE

MAY 08, 2000

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC
+ BAYER

30MG

N20198 001

APR 21, 1993

OCTREOTIDE ACETATE

BC *

30MG

N20198 001

APR 21, 1993

INJECTABLE; INJECTION

SANDOSTATIN
NOVARTIS

AB ELAN PHARM

30MG

N75128 001

MAR 10, 2000

EQ 0.2MG BASE/ML

N19667 004

JUN 12, 1991

AB

30MG

N75128 001

MAR 10, 2000

EQ 1MG BASE/ML

JUN 12, 1991

NITROFURAZONE

CREAM; TOPICAL

FURACIN
* ROBERTS LABS

0.2%

N83789 001

+ SHIRE LABS

0.2%

N83789 001

SANDOSTATIN LAR

NOVARTIS

0.2%

N05795 001

N05795 001

EQ 10MG BASE/VIAL

N21008 001

AT * ROBERTS LABS

0.2%

N05795 001

N05795 001

EQ 20MG BASE/VIAL

NOV 25, 1998

AT + SHIRE LABS

0.2%

N05795 001

N05795 001

EQ 10MG BASE/VIAL

NOV 25, 1998

NITROGLYCERIN

TABLET; SUBLINGUAL

NITROSTAT
PARKE DAVIS

0.3MG

N21134 001

MAY 01, 2000

TABLET; ORAL

ZYPREXA
LILLY

2.5MG

N20592 001

SEP 30, 1996

+ ROBERTS LABS

0.4MG

N21134 002

MAY 01, 2000

1.0MG

N20592 004

SEP 30, 1996

+ ROBERTS LABS

0.6MG

N21134 003

MAY 01, 2000

1.5MG

N20592 005

SEP 09, 1997

+ ROBERTS LABS

0.6MG

N20592 001

SEP 30, 1996

2.5MG

N20592 001

SEP 30, 1996

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

OLANZAPINE

TABLET; ORAL
ZYPREXA
LILLY

10MG N20592 004
15MG N20592 005
15MG N20592 005
15MG N20592 005

N20553 001
DEC 12, 1995
N20553 001
DEC 12, 1995

+

TABLET, ORALLY DISINTEGRATING; ORAL
ZYPREXA ZYDIS
LILLY

5MG N21086 001
10MG N21086 002
15MG N21086 003
20MG N21086 004

N20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998
N20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998

+

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

AB EON 100MG N40327 001
AB GENEVA PHARMS TECH 100MG N40284 001
AB IMPAX PHARM 100MG N40368 001
AB INVAMED 100MG N40284 001

N20987 001
FEB 02, 2000

> ADD >
> ADD >

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL
NOVARTIS

150MG N21014 001
300MG N21014 002
600MG N21014 003

N75595 001
FEB 28, 2000
N75595 002
FEB 28, 2000
N75595 003
FEB 28, 2000
N75030 003
FEB 22, 2000
N75286 001
DEC 27, 1999
N75286 002
JUN 30, 1999
N75286 003
JUN 30, 1999
N75286 001
DEC 27, 1999
N75286 002
JUN 30, 1999

+

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BX * OXYCONTIN 10MG
+ PURDUE PHARMA
10MG

N20553 001
DEC 12, 1995
N20553 001
DEC 12, 1995

BX ROXICODONE
* ROXANE

10MG
30MG
10MG
30MG

N20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998
N20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
PROTONIX
+ WYETH AYERST

EQ 40MG BASE

N20987 001
FEB 02, 2000

PEMOLINE

TABLET; ORAL
PEMOLINE
AMIDE PHARM

AB 18.75MG
AB 37.5MG
AB 75MG
AB 18.75MG
AB 18.75MG

N75595 001
FEB 28, 2000
N75595 002
FEB 28, 2000
N75595 003
FEB 28, 2000
N75030 003
FEB 22, 2000
N75286 001
DEC 27, 1999
N75286 002
JUN 30, 1999
N75286 003
JUN 30, 1999
N75286 001
DEC 27, 1999
N75286 002
JUN 30, 1999

COPLEY PHARM

18.75MG

GENEVA PHARMS TECH

18.75MG

37.5MG

75MG

18.75MG

37.5MG

INVAMED

18.75MG

37.5MG

<u>PEMOLINE</u>									
TABLET; ORAL									
<u>PEMOLINE</u>									
<u>AB</u>	<u>75MG</u>	<u>N75286 003</u>	<u>ACEON</u>	<u>8MG</u>	<u>N20184 003</u>				
		<u>JUN 30, 1999</u>	<u>SOLVAY</u>		<u>DEC 30, 1993</u>				
<u>AB</u>	<u>18.75MG</u>	<u>N75328 001</u>	SOLVAY PHARMA	2MG	N20184 001				
		<u>APR 19, 2000</u>			DEC 30, 1993				
<u>AB</u>	<u>37.5MG</u>	<u>N75328 002</u>		4MG	N20184 002				
		<u>APR 19, 2000</u>			DEC 30, 1993				
<u>AB</u>	<u>75MG</u>	<u>N75328 003</u>		8MG	N20184 003				
		<u>APR 19, 2000</u>			DEC 30, 1993				
TABLET, CHEWABLE; ORAL									
<u>CYLEKT</u>									
<u>AB</u>	<u>37.5MG</u>	<u>N17703 001</u>							
		<u>N17703 001</u>							
<u>AB</u>	<u>37.5MG</u>	<u>N75555 001</u>							
		<u>FEB 18, 2000</u>							
<u>PEMOLINE</u>									
<u>AB</u>	<u>37.5MG</u>								
<u>PENTAMIDINE ISETHIONATE</u>									
INJECTABLE; INJECTION									
<u>PENTACARINAT</u>									
<u>AB</u>	<u>300MG/VIAL</u>	<u>N73447 001</u>							
		<u>APR 28, 1994</u>							
<u>AB</u>	<u>300MG/VIAL</u>	<u>N73447 001</u>							
		<u>APR 28, 1994</u>							
<u>PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE</u>									
PASTE; TOPICAL									
SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE									
AGENTS									
+ US ARMY	<u>50g; 50g</u>	<u>N21084 001</u>							
		<u>FEB 17, 2000</u>							
<u>PERINDOPRIL ERBUMINE</u>									
TABLET; ORAL									
<u>ACEON</u>									
<u>AB</u>	<u>2MG</u>	<u>N20184 001</u>							
		<u>DEC 30, 1993</u>							
<u>AB</u>	<u>4MG</u>	<u>N20184 002</u>							
		<u>DEC 30, 1993</u>							
<u>PERINDOPRIL ERBUMINE</u>									
TABLET; ORAL									
<u>ACEON</u>									
<u>AB</u>	<u>15MG/5ML</u>	<u>N40322 001</u>							
		<u>JAN 19, 2000</u>							
<u>PERINDOPRIL ERBUMINE</u>									
TABLET; ORAL									
<u>ACEON</u>									
<u>AB</u>	<u>5MG</u>	<u>N80780 001</u>							
		<u>N80780 001</u>							
<u>AB</u>	<u>5MG</u>	<u>N80322 001</u>							
		<u>N80322 001</u>							
<u>AB</u>	<u>5MG</u>	<u>N80322 001</u>							
		<u>N80322 001</u>							
<u>PERINDOPRIL ERBUMINE</u>									
SOLUTION/DROPS; OPHTHALMIC									
<u>PREDNISOLONE SODIUM PHOSPHATE</u>									
<u>AT</u>	<u>EQ 0.11% PHOSPHATE</u>	<u>N81043 001</u>							
		<u>OCT 24, 1991</u>							
<u>AT</u>	<u>EQ 0.9% PHOSPHATE</u>	<u>N81044 001</u>							
		<u>OCT 24, 1991</u>							
<u>AT</u>	<u>EQ 0.11% PHOSPHATE</u>	<u>N81043 001</u>							
		<u>OCT 24, 1991</u>							
<u>AT</u>	<u>EQ 0.9% PHOSPHATE</u>	<u>N81044 001</u>							
		<u>OCT 24, 1991</u>							

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

AT EQ 0.23% PHOSPHATE; 10% N73630 001

MAY 27, 1993

N73630 001

MAY 27, 1993

AT EQ 0.23% PHOSPHATE; 10%

PROGESTERONE

CAPSULE; ORAL

PROMETRIUM

UNIMED PHARMS

100MG

200MG

300MG

N19781 001

MAY 14, 1998

N19781 002

OCT 15, 1999

N19781 003

OCT 15, 1999

PREDNISONE

SYRUP; ORAL

LIQUID PRED

* MURQ

@

5MG/5ML

5MG/5ML

N87611 002

SEP 07, 1982

N87611 002

SEP 07, 1982

> ADD >

> ADD >

> ADD >

> ADD >

25MG/ML

50MG/ML

N40372 001

JUN 08, 2000

N40372 002

JUN 08, 2000

TABLET; ORAL

FREDNICEN-M

CENT PHARMS

@

SCHWARZ PHARMA

PREDNISONE

PHOENIX LABS NY

@

5MG

20MG

5MG

20MG

N84655 001

N84655 001

N80321 001

N83807 001

N80321 001

N83807 001

PROPACARINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC

PROPACARINE HCL

TAYLOR PHARMA

0.5%

N40277 001

MAR 16, 2000

PROCHLORPERAZINE

SUPPOSITORY; RECTAL

COMPRO

PADDOCK

25MG

N40246 001

JUN 28, 2000

> ADD >

> ADD >

> ADD >

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL

VENTAIRE

@ AVENTIS PHARMS

2MG

* HOECHST MARION ROSS

N83459 001

N83459 001

PROGESTERONE

CAPSULE; ORAL

PROMETRIUM

SCHERING PLOUGH

100MG

200MG

300MG

N19781 001

MAY 14, 1998

N19781 002

OCT 15, 1999

N19781 003

OCT 15, 1999

QUINIDINE SULFATE

TABLET; ORAL

QUINIDINE SULFATE

@ PHARMAVITE

200MG

200MG

N84627 001

N84627 001

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

RAMITIDINE HYDROCHLORIDE

TABLET; ORAL
RAMITIDINE
 @ RANBAXY

EQ 150MG BASE
 EQ 300MG BASE

> ADD >
 > ADD >

N75439 001
 APR 19, 2000
 N75439 002
 APR 19, 2000

5MG/1.5ML
 10MG/1.5ML
 15MG/1.5ML

N21148 001
 JUN 20, 2000
 N21148 002
 JUN 20, 2000
 N21148 003
 JUN 20, 2000

SOMATROPIN RECOMBINANT

INJECTABLE; INJECTION
 NORDITROPIN
 @ NOVO NORDISK

+

RESERPINE

TABLET; ORAL
 RESERPINE
 @ GLOBAL PHARM
 @ IMPAX LABS

0.1MG
 0.25MG
 0.1MG
 0.25MG

N09627 001
 N09627 002
 N09627 001
 N09627 002

SOTALOL HYDROCHLORIDE

TABLET; ORAL
 BETAPACE
 @ BERLEX LABS

80MG
 120MG
 160MG
 240MG

N19865 001
 OCT 30, 1992
 N19865 005
 APR 20, 1994
 N19865 002
 OCT 30, 1992
 N19865 003
 OCT 30, 1992

RIVASTIGMINE TARTRATE

CAPSULE; ORAL
 EXELON
 @ NOVARTIS

EQ 1.5MG BASE
 EQ 3MG BASE
 EQ 4.5MG BASE
 EQ 6MG BASE

N20823 003
 APR 21, 2000
 N20823 004
 APR 21, 2000
 N20823 005
 APR 21, 2000
 N20823 006
 APR 21, 2000

80MG
 120MG
 160MG
 240MG

N19865 001
 OCT 30, 1992
 N19865 005
 APR 20, 1994
 N19865 002
 OCT 30, 1992
 N19865 003
 OCT 30, 1992

SOLUTION; ORAL
 EXELON
 @ NOVARTIS

EQ 2MG BASE/ML

N21025 001
 APR 21, 2000

80MG
 120MG
 160MG

N21151 001
 FEB 22, 2000
 N21151 002
 FEB 22, 2000
 N21151 003
 FEB 22, 2000

SODIUM FLUORIDE, F-18

INJECTABLE; INTRAVENOUS
 FLUORINE F-18
 @ NYCOMED AMERSHAM

2mCi/ML

N17042 001

80MG
 120MG
 160MG
 240MG

N75366 001
 MAY 01, 2000
 N75366 002
 MAY 01, 2000
 N75366 003
 MAY 01, 2000
 N75366 004
 MAY 01, 2000

SOTALOL HYDROCHLORIDE

TABLET; ORAL
SOTALOL HCL
GENPHARM

AB 80MG N75237 001
MAY 01, 2000
AB 120MG N75237 002
MAY 01, 2000
AB 160MG N75237 003
MAY 01, 2000
AB 240MG N75237 004
MAY 01, 2000
AB TEVA N75429 001
MAY 01, 2000
AB 120MG N75429 002
MAY 01, 2000
AB 160MG N75429 003
MAY 01, 2000
AB 240MG N75429 004
MAY 01, 2000

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM
ALCON UNIVERSAL 10%
~~10%~~

AT N89560 001
OCT 18, 1988
AX ~~N89560 001~~
~~OCT 18, 1988~~

TAMOXIFEN CITRATE

TABLET; ORAL
TAMOXIFEN CITRATE
@ MYLAN
@ PHARMACHEMIE

> ADD >
> ADD >
EQ 10MG BASE N74732 001
JUN 26, 2000
EQ 10MG BASE N74539 001
MAY 31, 2000

TELMISARTAN

TABLET; ORAL
MICARDIS
+ BOEHRINGER INGELHEIM 20MG

N20850 003
APR 04, 2000

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
TERAZOSIN HCL
MYLAN

AB EQ 1MG BASE N75140 002
FEB 11, 2000
AB EQ 2MG BASE N75140 003
FEB 11, 2000
AB EQ 5MG BASE N75140 001
FEB 11, 2000
AB EQ 10MG BASE N75140 004
FEB 11, 2000

TABLET; ORAL
TERAZOSIN HCL
INVAMED

AB EQ 1MG BASE N74657 001
APR 28, 2000
AB EQ 2MG BASE N74657 002
APR 28, 2000
AB EQ 5MG BASE N74657 003
APR 28, 2000
AB EQ 10MG BASE N74657 004
APR 28, 2000
AB NOVOPHARM N74446 001
MAY 18, 2000
AB EQ 2MG BASE N74446 002
MAY 18, 2000
AB EQ 5MG BASE N74446 003
MAY 18, 2000
AB EQ 10MG BASE N74446 004
MAY 18, 2000
AB ZENITH GOLDLINE N74530 001
APR 21, 2000
AB EQ 2MG BASE N74530 002
APR 21, 2000
AB EQ 5MG BASE N74530 003
APR 21, 2000
AB EQ 10MG BASE N74530 004
APR 21, 2000

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM
THERATECH

AX 5MG/24HR N20489 002
MAY 02, 1997
AX 2.5MG/24HR N20489 001
SEP 29, 1995

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM

BX + WATSON LABS 5MG/24HR
+ 2.5MG/24HR

N20489 002
MAY 02, 1997
N20489 001
SEP 29, 1995

GEL; TOPICAL
ANDROGEL

+ UNIMED PHARMS 1%

N21015 001
FEB 28, 2000

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-PHYLLIN

@ AVENTIS PHARM PROD 60MG
@ 125MG
@ 250MG

N85206 001
MAY 24, 1982
N85203 001
MAY 24, 1982
N85205 001
MAY 24, 1982
N85203 001
MAY 24, 1982
N85205 001
MAY 24, 1982
N85206 001
MAY 24, 1982

BC RHONE-POULENC RORER 125MG

BC 250MG
60MG

THIAMINE HYDROCHLORIDE

INJECTABLE; INJECTION

BETALIN S
AP * MILLY

100MG/ML
100MG/ML

AP * THIAMINE HCL
AM PHARM PARTNERS
+ 100MG/ML
100MG/ML

N80853 001
N80853 001
N80556 001
N80556 001

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL

TICLOPIDINE HCL
DANBURY PHARMA

250MG

N75309 001
APR 26, 2000

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

AB CHELSEA LABS 500MG
AB * 500MG
AB * EON 500MG
@ 500MG

N86109 001
N86109 001
N12678 001
N12678 001

TRETINOLIN

GEL; TOPICAL

RETIN-A

AB + JOHNSON AND JOHNSON 0.025%
BT * 0.025%

N17579 002
N17579 002

TRETINOLIN

AB SPEAR PHARMS 0.025%

N75529 001
FEB 22, 2000

TRIAMCINOLONE ACETONIDE

OINTMENT; TOPICAL

ARISTOCORT A

AT * FUJISAWA HEALTHCARE 0.5%
AT 0.5%

N80745 003
N80745 003

FLUTEX

AT ZENITH GOLDLINE 0.025%
AT 0.025%

N87375 001
N87375 001

AT + 0.025%

N87375 001
NOV 01, 1988

AT 0.1%

N87377 001
NOV 01, 1988

AT + 0.1%

N87376 001
NOV 01, 1988

AT 0.5%

N87376 001
NOV 01, 1988

AT + 0.5%

N87376 001
NOV 01, 1988

KENALOG

AT * APOTHECON 0.025%
AT 0.025%
AT 0.1%
AT 0.1%

N11600 003
N11600 003

N11600 001
N11600 001

SPRAY, METERED; NASAL

TRI-NASAL

+ MURCO 0.05MG/SPRAY

N20120 001
FEB 04, 2000

TRIHENYDROL HYDROCHLORIDE

TABLET; ORAL
TRIHENYDROL HCL

AA WEST WARD 2MG
 AA 5MG

N40337 002
 FEB 16, 2000
 N40337 001
 FEB 16, 2000

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
 PRIMSOL
 ASCENT PERS

EQ 25MG BASE/5ML
 EQ 25MG BASE/5ML
 EQ 50MG BASE/5ML

N74374 001
 JUN 23, 1995
 N74374 001
 JUN 23, 1995
 N74973 001
 JAN 24, 2000

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
 NEUTREXIN
 + MEDIMMUNE ONCOLOGY
 * US BIOSCIENCE

EQ 25MG BASE/VIAL
 EQ 25MG BASE/VIAL

N20326 001
 DEC 17, 1993
 N20326 001
 DEC 17, 1993

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION
 TRELSTAR DEPOT
 + DEBIO RECHERCHE

EQ 3.75MG BASE/VIAL

N20715 001
 JUN 15, 2000

TROGLITAZONE

TABLET; ORAL
 PRELAY
 SANKYO

AB 200MG
 AB 300MG

N20719 001
 JAN 29, 1997
 N20719 003
 AUG 04, 1997

TROGLITAZONE

TABLET; ORAL
 PRELAY
 SANKYO

AB 400MG
 @ 200MG
 @ 300MG
 @ 400MG

N20719 002
 JAN 29, 1997
 N20719 001
 JAN 29, 1997
 N20719 003
 AUG 04, 1997
 N20719 002
 JAN 29, 1997

REZULIN

PARKE DAVIS PHARMS

AB 200MG
 AB 300MG
 AB 400MG
 @ 200MG
 @ 300MG
 @ 400MG

N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997
 N20720 001
 JAN 29, 1997
 N20720 003
 AUG 04, 1997
 N20720 002
 JAN 29, 1997

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
 TROPICAMIDE

AT 1%
 AT 1%

N89172 001
 DEC 28, 1990
 N89172 001
 DEC 28, 1990

URSODIOL

CAPSULE; ORAL
 ACTIGALL
 + NOVARTIS

AB 300MG
 * 300MG

N19594 002
 DEC 31, 1987
 N19594 002
 DEC 31, 1987

AB URSODIOL
 AMIDE PHARM

N75517 001
 MAR 14, 2000

URSODIOL

CAPSULE; ORAL
URSODIOL
AB COPLEY PHARM

300MG
 N75592 001
 MAY 25, 2000

VITAMIN A

CAPSULE; ORAL
VITAMIN A
AA GLOBAL PHARM
 @ IMPAX LABS

50,000 USP UNITS
50,000 USP UNITS
 N80952 001
 N80952 001

TABLET; ORAL

URSO
 * AXCAN
 + AXCAN SCANDIPHARM

250MG
 N20675 001
 DEC 10, 1997
 N20675 001
 DEC 10, 1997

VITAMIN A PALMITATE

CAPSULE; ORAL
VITAMIN A
AA GLOBAL PHARM
 @ IMPAX LABS
 @

EQ 50,000 UNITS BASE
EQ 50,000 UNITS BASE
EQ 50,000 UNITS BASE
 N80953 001
 N80955 001
 N80953 001
 N80955 001

VECURONIUM BROMIDE

INJECTABLE; INJECTION
VECURONIUM BROMIDE
 BEDFORD

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

10MG/VIAL
 N75549 001
 JUN 13, 2000
20MG/VIAL
 N75549 002
 JUN 13, 2000

ZOLMITRIPTAN

TABLET; ORAL
 ZOMIG
 IPR

2.5MG
 5MG
 2.5MG
 5MG
 N20768 001
 NOV 25, 1997
 N20768 002
 NOV 25, 1997
 N20768 001
 NOV 25, 1997
 N20768 002
 NOV 25, 1997

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 COVERA-HS
 SEARLE

180MG
 N20552 001
 FEB 26, 1996
180MG
 N20552 001
 FEB 26, 1996
240MG
 N20552 002
 FEB 26, 1996
240MG
 N20552 002
 FEB 26, 1996

ZONISAMIDE

CAPSULE; ORAL
 ZONEGRAN
 + DAINIPPON

100MG
 N20789 001
 MAR 27, 2000

VERTEPORFIN

INJECTABLE; INJECTION
 VISUDYNE
 + QLT

15MG/VIAL
 N21119 001
 APR 12, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN
PERRIGO 650MG

N75077 001
FEB 25, 2000

CLOTRIMAZOLE

CREAM; VAGINAL
TRIVAGIZOLE 3
+ TARO

2*

N21143 001
APR 12, 2000

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER
* BAYER 650MG
650MG
@ MEASURIN
* BAYER 650MG
650MG

N16030 001
N16030 001
N16030 002
N16030 002

200MG
200MG

N74782 001
JUL 06, 1998
N74782 001
JUL 06, 1998

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
E-Z SCRUB
BECTON DICKINSON 4*

N73416 001
MAR 14, 2000

200MG
200MG

N74931 001
JUL 20, 1998
N74931 001
JUL 20, 1998

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CONTAC
@ SMITHKLINE 8MG; 75MG
+ 8MG; 75MG

N18099 001
N18099 001

2MG
2MG
2MG

N73254 001
JUL 30, 1993
N73254 001
JUL 30, 1993
N75232 001
JAN 06, 2000

CIMETIDINE

TABLET; ORAL
CIMETIDINE
LEINER 200MG
NOVOPHARM 200MG

N74961 001
JUN 19, 1998
N74961 001
JUN 19, 1998

EQ 200MG BASE
EQ 200MG BASE

N74635 001
JAN 13, 1997
N74635 001
JAN 13, 1997

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 6 / JAN'2000 - JUN'2000

PERMETHRIN

LOTION; TOPICAL
 PERMETHRIN
 + ALPHARMA

1%

N75014 001
 MAR 28, 2000

SOLUTION; TOPICAL
 LAMISIL AT
 + NOVARTIS

1%

N21124 001
 MAR 17, 2000

TERBINAFINE HYDROCHLORIDE

PIPERONYL BUTOXIDE; PYRETHRINS

AEROSOL; TOPICAL
 RID MOUSSE
 + PFIZER

4%;EQ 0.33% BASE

N21043 001
 MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

CHELSEA LABS

EQ 75MG BASE

N75212 001
 JAN 14, 2000

CHEMINOR DRUGS

EQ 75MG BASE

N75294 001
 MAR 28, 2000

GENPHARM

EQ 75MG BASE

N75497 001
 JAN 14, 2000

LEINER

EQ 75MG BASE

N75094 001
 JUN 21, 1999

RANBAXY

EQ 75MG BASE

N75132 001
 JAN 14, 2000

EQ 75MG BASE

N75254 001
 JAN 14, 2000

TORPHARM

EQ 75MG BASE

N75167 001
 MAY 04, 2000

ZENITH GOLDLINE

EQ 75MG BASE

N75296 001
 JAN 14, 2000

RANITIDINE HCL

NOVOPHARM

EQ 75MG BASE

N75094 001
 JUN 21, 1999

TABLET, EFFERVESCENT; ORAL

ZANTAC 75

* GLAXO WELLCOME

EQ 75MG BASE

N20745 001
 FEB 26, 1998

@ WARNER LAMBERT

EQ 75MG BASE

N20745 001
 FEB 26, 1998

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

CUMULATIVE SUPPLEMENT NUMBER 6 JUNE '00

NO JUNE 2000 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 Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
1- (11-dodecylamino-10-hydr Treatment of hormone refractory oxyundecyl) -3,7-dimethylxa prostate carcinoma. nthine hydrogen methanesulfonate		Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400
TN=		Seattle WA 98119 DD= 1/18/00 MA=
3- (3,5-Dimethyl-1H-2ylmeth Treatment of von Hippel-Lindau ylene) -1,3-dihydro-indol-2 disease. -one		Sugen, Inc. 230 East Grand Ave. South San Francisco CA 94080
TN=		DD= 3/23/00 MA=
Angiotensin 1-7	Treatment of neutropenia associated with autologous bone marrow transplantation.	Maret Pharmaceuticals 4041 MacArthur Blvd. Suite 375 Newport Beach CA 92660 DD= 2/16/00 MA=
TN=		
Arsenic trioxide	Treatment of multiple myeloma.	Cell Therapeutics, Inc. 201 Elliott Ave. West, Suite Seattle WA 98119
TN=Atrivex		DD= 4/28/00 MA=
Bis(4-fluorophenyl)phenyla Treatment of sickle cell disease. cetamide		ICAgen Inc. Ion Channel Advances PO Box 14487 Durham NC 27709 DD= 3/2/00 MA=
TN=		

Orphan Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Brimonidine TN= Alphagan	Treatment of anterior ischemic optic neuropathy.	Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine CA 92623-9534 DD= 2/7/00 MA=
Centruroides immune F(ab)2 TN= Alacramyn	Treatment of scorpion envenomations requiring medical attention.	Silanes Laboratories S.A. de Amores #1034 Col Del Valle C.P. 03100 Mexico D.F. DD= 6/12/00 MA=
Cisplatin/epinephrine TN= IntraDose	Treatment of squamous cell carcinoma of the head and neck.	Matrix Pharmaceutical, Inc. 34700 Campus Drive Fremont CA 94555-3612 DD= 4/3/00 MA=
DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2 TN= Leuvectin	Treatment of renal cell carcinoma.	Vical Incorporated 9373 Towne Center Dr. Suite 100 San Diego CA 92121-3088 DD= 4/28/00 MA=
Ethyl eicosapentaenoate TN=	Treatment of Huntington's disease.	Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA=

Orphan Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Fluorouracil TN=	Treatment of glioblastoma multiforme.	Ethypharm SA 194 Bureaux de la Colline - 92213 Saint-Cloud Cedex France FR DD= 6/29/00 MA=
Halofuginone TN= Stenorol	Treatment of systemic sclerosis.	Collgard Biopharmaceuticals Textile House, 2 Koifman St. Tel-Aviv 68012 Israel IL DD= 2/7/00 MA=
Histamine TN= Maxamine	For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.	Maxim Pharmaceuticals, Inc. 8899 University Center Lane Suite 400 San Diego CA 92122 DD= 2/1/00 MA=
Hypericin TN=	Treatment of cutaneous T-cell lymphoma.	Nexell Therapeutics, Inc. 2751 Centerville Rd., Suite Wilmington DE 19808 DD= 2/7/00 MA=
IL-4 Pseudomonas Toxin Fusion Protein (IL-4(38-37)-PE38KDEL) TN=	Treatment of astrocytic glioma.	Neurocrine Biosciences, Inc. 10555 Science Center Dr. San Diego CA 92121 DD= 4/6/00 MA=

Orphan Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Iodine I 131 bis(indium-diethylenetriam inepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab') ₂ bispecific monoclonal antibody TN= Pentacea	Treatment of small-cell lung cancer.	IBC Pharmaceuticals, L.L.C. 300 American Rd. Morris Plains NJ 07950 DD= 2/22/00 MA=
Levodopa and carbidopa TN= Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215 DD= 1/18/00 MA=
Liposomal nystatin TN= Nyotran	Treatment of invasive fungal infections.	Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands TX 77381-1191 DD= 6/13/00 MA=
Meropenem TN= Merrem IV	Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms.	Zeneca Pharmaceuticals 1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437 DD= 4/27/00 MA=
Natural human lymphoblastoid interferon-alpha TN=	Treatment of Behcet's disease.	Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo TX 79101-3206 DD= 1/18/00 MA=

Orphan Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Omega-3 (n-3) polyunsaturated fatty acids TN=Omacor	Treatment of IgA nephropathy.	Pronova Biocare, AS PO Box 420 1327 Lysaker Norway DD= 5/4/00 MA=
Phenylbutyrate TN=	Treatment of acute promyelocytic leukemia.	Elan Corporation 1300 Gould Dr. Gainesville GA 30504 DD= 1/19/00 MA=
Recombinant glycine2-human glucagon-like peptide-2 TN=	Treatment of short bowel syndrome.	NPS Allelix Corp. 6850 Goreway Dr. Mississauga, Ontario L4V 1V7 Canada CA DD= 6/29/00 MA=
Recombinant human antithrombin III TN=	Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.	AT III LLC c/o Genzyme Corporation 15 Pleasant St. Connector, Framingham MA 01701 DD= 4/6/00 MA=
Recombinant human insulin-like growth factor-I TN=PV802	Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines.	GroPep Pty Ltd. Gate 11, Victoria Dr. Adelaide SA 5000 Australia AU DD= 2/16/00 MA=

Orphan Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Remacemide	Treatment of Huntington's disease.	AstraZeneca LP 725 Chesterbrook Blvd. Wayne PA 19087-5677
TN= Ecovia		DD= 3/6/00 MA=
rSP-C lung surfactant	Treatment of adult respiratory distress syndrome.	Byk Gulden Pharmaceuticals Byk-Gulden StraBe 2 78467 Konstanz Germany DE
TN= Venticute		DD= 4/3/00 MA=
Soluble complement receptor type 1	Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.	Avant Immunotherapeutics, 119 Fourth Ave. Needham MA 02494-2725
TN=		DD= 3/6/00 MA=
Synthetic human secretin	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4176
TN=		DD= 3/7/00 MA=
Synthetic porcine secretin	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring MD 20905-4176
TN=		DD= 3/7/00 MA=

Orphan Products Designations and Approvals List
January through June, 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Technetium Tc 99m pterotetramide	For the identification of ovarian carcinomas.	Endocyte, Inc. 1205 Kent Ave. Lafayette IN 47906
TN=		DD= 2/16/00 MA=
Tetraiodothyroacetic acid	Suppression of thyroid stimulating hormone in patients with well-differentiated cancer of the thyroid gland.	Danforth, Jr., MD, Elliot University of Vermont 84 Beartown Rd. Underhill VT 05489
TN=		DD= 5/1/00 MA=
Thymalfasin	Treatment of hepatocellular carcinoma.	SciClone Pharmaceuticals, 901 Mariner's Blvd., Suite San Mateo CA 94404
TN= Zadaxin		DD= 3/6/00 MA=
Vapreotide	Treatment of esophageal variceal hemorrhage patients with portal hypertension.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH
TN= Octastatin		DD= 1/10/00 MA=
Vapreotide	Treatment of gastrointestinal and pancreatic fistulas.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH
TN= Octastatin		DD= 1/10/00 MA=
Vapreotide	Prevention of early postoperative complications following pancreatic resection.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH
TN= Octastatin		DD= 3/6/00 MA=

Orphan Products Designations and Approvals List
January through June, 2000

Name:
Generic Name
TN=Trade Name

Indication Designated:

Sponsor & Address
DD=Date Designated
MA=Marketing Approval

vigabatrin

Treatment of infantile spasms.

Aventis Pharmaceuticals Inc.
P.O. Box 9627
Kansas City MO 64137

TN= Sabril

DD= 6/12/00 MA=

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

NO JUNE 2000 ADDITIONS

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	ACETAMINOPHEN; ACETAMINOPHEN	6080756	JUL 05, 2016		PC	NOV 12, 2000
>ADD>	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE	6080756	JUL 05, 2016			
>ADD>	ALATROFLOXACIN MESYLATE; TROVAN PRESERVATIVE	6008207	JUN 06, 2015	U-303 M-3		NOV 24, 2002
	ALENDRONATE SODIUM; FOSAMAX	6008207	JUN 06, 2015	U-303 M-3		NOV 24, 2002
	ALENDRONATE SODIUM; FOSAMAX	6008207	JUN 06, 2015	U-303 M-3		NOV 24, 2002
	ALOSETRON SODIUM; FOSAMAX	6008207	JUN 06, 2015	U-303 M-3		NOV 24, 2002
	ALOSETRON HYDROCHLORIDE; LOTRONEX				NCE	FEB 09, 2005
	AMIFOSTINE; ETHYOL				I-283	JUN 24, 2002
	AMIFOSTINE; ETHYOL				I-283	JUN 24, 2002
	AMPRENAVIR; AGENERASE	5723490	MAR 03, 2013	U-257		
	AMPRENAVIR; AGENERASE	5646180	JUL 08, 2014	U-257		
	AMPRENAVIR; AGENERASE	5585397	DEC 17, 2013			
	AMPRENAVIR; AGENERASE	5723490	MAR 03, 2015	U-257		
	AMPRENAVIR; AGENERASE	5646180	JUL 08, 2014	U-257		
	AMPRENAVIR; AGENERASE	5585397	DEC 17, 2013			
	AMPRENAVIR; AGENERASE	5723490	MAR 03, 2015	U-257		
	AMPRENAVIR; AGENERASE	5646180	JUL 08, 2014	U-257		
	AMPRENAVIR; AGENERASE	RE36617	DEC 27, 2009			
>ADD>	ANASTROZOLE; ARIMIDEX	5164194	NOV 01, 2010		NCE	JUN 30, 2005
>ADD>	ARGATROBAN; ACOVA	5164194*	MAY 01, 2011		NC	APR 03, 2003
>ADD>	ARTICAININE HYDROCHLORIDE; SEPTOCAINE				NCE	NOV 01, 2001
>ADD>	AZELASTINE HYDROCHLORIDE; OPTIVAR				NDF	MAY 22, 2003
>ADD>	BALSALAZIDE DISODIUM; COLAZAL				PED	MAY 01, 2002
>ADD>	BEXAROTENE; TARGRETIN				PED	NOV 22, 2003
>ADD>	BEXAROTENE; TARGRETIN				NCE	JUL 18, 2005
>ADD>	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062	MAR 24, 2000	U-63		DEC 29, 2006
	BISOPROLOL FUMARATE; ZEBETA	4258062*PED	SEP 24, 2000	U-63		DEC 29, 2006
	BLEOMYCIN SULFATE; BLENOXANE	4182763	MAY 22, 2000	U-13	ODE	FEB 20, 2003
	BUPROPION HYDROCHLORIDE; ZYBAN	5015646	MAY 14, 2008		D-54	SEP 10, 2002
	BUPROPION HYDROCHLORIDE; ZYBAN	4182763*PED	NOV 22, 2000		D-54	SEP 10, 2002
	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646*PED	NOV 14, 2008	U-13		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
018731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22, 2000	U-13		
		5015646	MAY 14, 2008			
		4182763*PED	NOV 22, 2000	U-13		
		5015646*PED	NOV 14, 2008			
018731 003	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646	MAY 14, 2008			
		4182763	MAY 22, 2000	U-13		
		4182763*PED	NOV 22, 2000	U-13		
		5015646*PED	NOV 14, 2008			
018731 004	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22, 2000	U-13		
		5015646	MAY 14, 2008			
		4182763*PED	NOV 22, 2000			
		5015646*PED	NOV 14, 2008	U-13		
020793 001	CAFFEINE CITRATE; CAFICIT	6051567	AUG 02, 2019		ODE	SEP 21, 2006
018874 001	CALCIOTRIOL; CALCIJEX	6051567	AUG 02, 2019			
018874 002	CALCIOTRIOL; CALCIJEX	5902821	FEB 07, 2016	U-313		
020297 001	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020297 002	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020297 003	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020297 004	CARVEDILOL; COREG	5902821	FEB 07, 2016	U-313		
020740 001	CERIVASTATIN SODIUM; BAYCOL				D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
>ADD>					D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
>ADD>					D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
>ADD>					D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
>ADD>					D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
>ADD>					D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
>ADD>					D-59	JUL 21, 2003
>ADD>					I-303	JUL 21, 2003
020740 002	CERIVASTATIN SODIUM; BAYCOL	4855290	AUG 08, 2006		NCE	JAN 11, 2005
>ADD>		5340821	AUG 23, 2011	U-309		
>ADD>		5580880	JUN 06, 2015	U-310		
020740 003	CERIVASTATIN SODIUM; BAYCOL				NC	JUL 14, 2003
>ADD>					NDF	MAY 26, 2003
>ADD>					NP	NOV 24, 2001
>ADD>					NCE	MAY 26, 2005
020740 004	CERIVASTATIN SODIUM; BAYCOL				U-323	
>ADD>					U-323	
>ADD>					U-323	
020740 005	CERIVASTATIN SODIUM; BAYCOL				U-323	
>ADD>					U-323	
>ADD>					U-323	
020740 006	CERIVASTATIN SODIUM; BAYCOL				U-323	
>ADD>					U-323	
>ADD>					U-323	
020989 002	CEVIMELINE HYDROCHLORIDE; EVOXAC					
>ADD>						
020832 001	CHLORHEXIDINE GLUCONATE; CHLORAPREP					
021142 001	CLOBETASOL PROPIONATE; OLUX FOAM					
021143 001	CLOTIRIMAZOLE; TRIVAGIZOLE 3					
021141 001	COLESEVELAM HYDROCHLORIDE; WELCHOL					

PRESCRIPTION AND OTC DRUG PRODUCT
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
020907 001	ESTRADIOL;ACTIVELLE	5108995	APR 28, 2009	U-311	I-295 APR 11, 2003
021040 001	ESTRADIOL;ORTHO-PREFEST	5382573	JAN 17, 2012		
020584 001	ETODOLAC;LODINE XL	4966768*	APR 30, 2008		
020584 002	ETODOLAC;LODINE XL	4966768	OCT 30, 2007		
020584 003	ETODOLAC;LODINE XL	4966768*	APR 30, 2008		
019304 002	FENOFIBRATE;TRICOR (MICRONIZED)	4966768	OCT 30, 2007		
019304 003	FENOFIBRATE;TRICOR (MICRONIZED)	4966768*	APR 30, 2008		
019304 004	FENOFIBRATE;TRICOR (MICRONIZED)	4966768	OCT 30, 2007		
020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	4966768*	APR 30, 2008		
020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	4966768	OCT 30, 2007		
020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017		
		5578610	NOV 26, 2013		
		5932247	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		5578610	NOV 26, 2013		
		5932247	FEB 28, 2015		
		5855912	FEB 28, 2015		
		4254129	FEB 17, 2001		
		6037353	MAR 14, 2017		
		5578610	NOV 26, 2013		
		5932247	FEB 28, 2015		
		5855912	FEB 28, 2015		
020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017		
		6037353	MAR 14, 2017		
		6039974	MAR 14, 2017		
		4416682	JUN 02, 2001		
		4404216	JAN 29, 2004		
020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	4087544	JAN 16, 2000		
019949 004	FLUCONAZOLE;DIFLUCAN	5084479	JAN 02, 2010		
020378 001	FOLLITROPIN ALFA/BETA;GONAL-F	4894476*	NOV 02, 2008		
020378 002	FOLLITROPIN ALFA/BETA;GONAL-F	4894476*	NOV 02, 2008		
020235 001	GABAPENTIN;NEURONTIN	4087544*	JUL 16, 2000		
		4087544*	JUL 02, 2010		
		4894476	MAY 02, 2008		
		6054482	MAY 02, 2008		
		6054482*	APR 25, 2017		
		4894476	OCT 25, 2017		
		5084479	MAY 02, 2008		
		4087544	JAN 02, 2010		
		5084479*	JAN 16, 2000		
		4894476*	JUL 02, 2010		
		4087544*	JUL 16, 2000		
		6054482	JUL 16, 2000		
		6054482*	APR 25, 2017		
		6054482*	OCT 25, 2017		
020235 002	GABAPENTIN;NEURONTIN	4087544	JAN 02, 2010		
		5084479*	JAN 16, 2000		
		4894476*	JUL 02, 2010		
		4087544*	JUL 16, 2000		
		6054482	JUL 16, 2000		
		6054482*	APR 25, 2017		
		6054482*	OCT 25, 2017		

>ADD>
 >ADD>

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/PEX EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020235 003	GABAPENTIN; NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
		5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
		4894476	MAY 02, 2008			
		4087544*PED	JUL 16, 2000	U-86		
		5084479*PED	JUL 02, 2010			
020882 001	GABAPENTIN; NEURONTIN	4894476*PED	NOV 02, 2008			
		6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017	U-106		
		4087544	JAN 16, 2000			
		4894476	MAY 02, 2008			
		5084479	JAN 02, 2010	U-258		
		4087544*PED	JUL 02, 2010	U-258		
		4894476*PED	JUL 16, 2000	U-106		
020882 002	GABAPENTIN; NEURONTIN	6054482	APR 25, 2017			
		6054482*PED	OCT 25, 2017	U-106		
		4087544	JAN 16, 2000			
		4894476	MAY 02, 2008			
		5084479	JAN 02, 2010	U-258		
021037 001	GADOPENTETATE DIMETHYLAMINE; MAGNEVIST	4087544*PED	JUL 16, 2000	U-258		
		4894476*PED	NOV 02, 2008	U-106		
		5084479*PED	JUL 02, 2010	U-258		
		6054482	APR 25, 2017	U-258		
		6054482*PED	OCT 25, 2017			
		5362475	NOV 08, 2011			
		5560903	OCT 01, 2013			
		4647447	MAR 03, 2004			
		4957939	MAR 03, 2004			
		4963344	MAR 03, 2004			
		4507305	MAY 21, 2001	U-64		
		4423050	MAY 21, 2001	U-64		
		4355032	JUN 23, 2003	U-64		
		4642346	JUN 24, 2005			
020460 002	GANCICLOVIR; CYTOVENE	5606040	FEB 25, 2014		ODE	MAY 17, 2007
		5693762	DEC 02, 2014		NCE	MAY 17, 2005
		5739116	APR 14, 2015			
		5767285	JUN 16, 2015			
		5773001	JUN 30, 2015	U-320		
		4970198	NOV 30, 2007			
		5079233	JAN 07, 2009			
		5585089	DEC 17, 2013			
		5981589	MAY 24, 2014			
		6054430	MAY 24, 2014			
		021174 001	GEMTUZUMAB OZOGAMICIN; MYLOTARG			
020622 001	GLATIRAMER ACETATE; COPAXONE					
020125 001	HYDROCHLOROTHIAZIDE; ACCURETIC				NC	DEC 28, 2002

PRESCRIPTION AND OTC DRUG PRODUCT
 PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020125 002	HYDROCHLOROTHIAZIDE; ACCURETIC				NC	DEC 28, 2002
020125 003	HYDROCHLOROTHIAZIDE; ACCURETIC	4374829	DEC 29, 2001		NC	DEC 28, 2002
019778 001	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001			
019778 002	HYDROCHLOROTHIAZIDE; PRINZIDE	4374829	DEC 29, 2001	U-3		
019778 003	HYDROCHLOROTHIAZIDE; PRINZIDE	4220660	MAR 06, 2001	U-21		
019763 003	IFOSFAMIDE; IFEX/MESNEX KIT	4220660	MAR 06, 2001	U-21		
019763 004	IFOSFAMIDE; IFEX/MESNEX KIT				NCE	JUN 07, 2005
020986 001	INSULIN ASPART RECOMBINANT; NOVOLOG				PED	OCT 20, 2005
021081 001	INSULIN GLARGINE; LANTUS				NCE	APR 20, 2005
020563 001	INSULIN LISPRO; HUMALOG				NCE	APR 04, 2003
021018 001	INSULIN LISPRO; HUMALOG MIX 50/50	5474978	JUN 16, 2014	U-111	D-56	DEC 22, 2002
020563 002	INSULIN LISPRO; HUMALOG PEN	5514646	MAY 07, 2013	U-111	D-56	APR 04, 2003
020571 001	IRINOTECAN HYDROCHLORIDE; CAMPTOSAR				NCE	JUN 14, 2001
019084 001	KETOCONAZOLE; NIZORAL	4942162	FEB 11, 2003		I-299	APR 20, 2003
020857 001	LAMIVUDINE; COMBIVIR	5905082	MAY 18, 2016	U-248		
020564 001	LAMIVUDINE; EPIVIR	5047407	NOV 17, 2009			
020596 001	LAMIVUDINE; EPIVIR	5047407	NOV 17, 2009			
021088 001	LEUPROLIDE ACETATE; VIADUR	5728396	JAN 30, 2017	U-316	NP	MAR 03, 2003
		5922547	JUN 13, 2017			
		5985305	JAN 30, 2017			
020837 001	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5362755	NOV 08, 2011	U-332		
>ADD>		5547994	AUG 20, 2013	U-332		
>ADD>		5760090	JAN 05, 2010	U-332		
>ADD>		5844002	AUG 20, 2013	U-332		
020837 002	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5362755	NOV 08, 2011	U-332		
>ADD>		5547994	NOV 08, 2011	U-332		
>ADD>		5760090	AUG 20, 2013	U-332		
>ADD>		5844002	JAN 05, 2010	U-332		
021114 001	LEVOBETAXOLOL HYDROCHLORIDE; BETAXON				NP	FEB 23, 2003
020612 001	LIDOCAINE; LIDODERM				NP	MAR 19, 2002
021130 001	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
021130 002	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
021131 001	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
021132 001	LINEZOLID; ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
019558 001	LISINAPRIL; PRINIVIL	4374829	DEC 29, 2001			
019558 002	LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001			
019558 003	LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001			
019558 004	LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001			
019558 006	LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001			
019777 001	LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001			
019777 002	LISINOPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 003	LISINOPRIL; ZESTRIL				I-288	FEB 07, 2003

PREScription AND OTC DRUG PRODUCT
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019777 004	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 005	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
019777 006	LISINAPRIL; ZESTRIL				I-288	FEB 07, 2003
020038 001	MELOXICAM; MOBIC				NCE	APR 13, 2005
020049 001	MESALAMINE; PENTASA	4980173	JAN 29, 2002	U-78		
020357 001	METFORMIN HYDROCHLORIDE; GLUCOPHAGE				PED	SEP 03, 2000
020357 002	METFORMIN HYDROCHLORIDE; GLUCOPHAGE				NCE	MAR 03, 2000
020357 005	METFORMIN HYDROCHLORIDE; GLUCOPHAGE				PED	SEP 03, 2000
019815 001	MIDODRINE HYDROCHLORIDE; PROAMATINE				NCE	MAR 03, 2000
019815 002	MIDODRINE HYDROCHLORIDE; PROAMATINE				NCE	SEP 03, 2000
020830 002	MONTELUKAST SODIUM; SINGULAIR				ODE	SEP 06, 2003
020152 001	NEFAZODONE HYDROCHLORIDE; SERZONE	5565473	NOV 30, 2010	U-228	I-300	SEP 06, 2003
020152 002	NEFAZODONE HYDROCHLORIDE; SERZONE				NS	MAR 03, 2003
020152 003	NEFAZODONE HYDROCHLORIDE; SERZONE				NCE	MAR 03, 2003
020152 004	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012			FEB 20, 2003
020152 005	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012			
020152 006	NEFAZODONE HYDROCHLORIDE; SERZONE	5256664	APR 28, 2012			
020381 001	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331		
020381 002	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331		
020381 003	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331		
020381 004	NIACIN; NIASPAN	6080428	MAY 27, 2017	U-331		
020381 005	NIACIN; NIASPAN TITRATION ST	6080428	MAY 27, 2017	U-331		
021134 001	NITROGLYCERIN; NITROSTAT				NDF	MAY 01, 2003
021134 002	NITROGLYCERIN; NITROSTAT				NDF	MAY 01, 2003
021134 003	NITROGLYCERIN; NITROSTAT				NDF	MAY 01, 2003
019921 001	OFLOXACIN; OCUFLOX	4382892	SEP 02, 2003			
020592 001	OLANZAPINE; ZYPREXA	4551456	NOV 14, 2003	U-80		
020592 002	OLANZAPINE; ZYPREXA				I-297	MAR 17, 2003
020592 003	OLANZAPINE; ZYPREXA				I-297	MAR 17, 2003
020592 004	OLANZAPINE; ZYPREXA				I-297	MAR 17, 2003
020592 005	OLANZAPINE; ZYPREXA				I-297	MAR 17, 2003
020592 006	OLANZAPINE; ZYPREXA				I-297	MAR 17, 2003
021086 001	OLANZAPINE; ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	MAR 17, 2003
		5229382	APR 23, 2011	U-324		SEP 30, 2001
		5605897	FEB 25, 2014	U-325		
		5627178	APR 23, 2011	U-326		
		5736541	MAR 24, 2015	U-328		
		5817655	APR 23, 2011	U-327		
		5817656	APR 23, 2011	U-326		

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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PEX EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021086 002	OLANZAPINE; ZYPREXA ZYDIS	5457895 5229382 5605897 5627178 5736541 5817655 5817656 5457895 5736541 5817655 5817656 5229382 5605897 5627178 5736541 5817655 5817656	SEP 30, 2013 APR 23, 2011 FEB 25, 2014 APR 23, 2011 MAR 24, 2015 APR 23, 2011 APR 23, 2011 SEP 30, 2013 MAR 24, 2015 APR 23, 2011 APR 23, 2011 APR 23, 2011 FEB 25, 2014 APR 23, 2011 MAR 24, 2015 APR 23, 2011 APR 23, 2011	U-324 U-325 U-326 U-328 U-327 U-326 U-324 U-325 U-326 U-328 U-327 U-326	NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE	SEP 30, 2001
021086 003	OLANZAPINE; ZYPREXA ZYDIS	5457895 5736541 5817655 5817656 5229382 5605897 5627178 5736541 5817655 5817656	SEP 30, 2013 MAR 24, 2015 APR 23, 2011 APR 23, 2011 APR 23, 2011 FEB 25, 2014 APR 23, 2011 MAR 24, 2015 APR 23, 2011 APR 23, 2011	U-328 U-327 U-326 U-324 U-325 U-326 U-328 U-327 U-326	NCE NCE NCE NCE NCE NCE NCE NCE NCE NCE	SEP 30, 2001
021086 004	OLANZAPINE; ZYPREXA ZYDIS	5457895 5229382 5605897 5627178 5736541 5817655 5817656	SEP 30, 2013 APR 23, 2011 FEB 25, 2014 APR 23, 2011 MAR 24, 2015 APR 23, 2011 APR 23, 2011	U-324 U-325 U-326 U-328 U-327 U-326	NCE NCE NCE NCE NCE NCE NCE	SEP 30, 2001
020688 001	OLOPATADINE HYDROCHLORIDE; PATANOL	4559330	JUL 31, 2004	U-58	I-301	MAR 20, 2003
019715 001	OLSALAZINE SODIUM; DIPENTUM	5955488	NOV 14, 2015			
020781 001	ONDANSETRON; ZOFRAN ODT	6063802	NOV 14, 2015			
		5578628	JUN 24, 2006	U-330		
		4695578	JUN 25, 2005	U-330		
		4753789	JUN 24, 2006	U-329		
020781 002	ONDANSETRON; ZOFRAN ODT	5955488 6063802 5578628 4695578 4753789 6004996	NOV 14, 2015 NOV 14, 2015 JUN 24, 2006 JUN 25, 2005 JUN 24, 2006 JUN 24, 2006 JAN 06, 2018	U-330 U-330 U-330 U-330 U-330 U-330		
020766 001	ORLISTAT; XENICAL	4758579	JUL 19, 2005			
021014 001	OXCARBAZEPINE; TRILEPTAL	5246925	SEP 21, 2010	U-314		
021014 002	OXCARBAZEPINE; TRILEPTAL	5587497	DEC 24, 2013			
021014 003	OXCARBAZEPINE; TRILEPTAL	6080759	MAY 19, 2015			
020262 001	PACLITAXEL; TAXOL	6063927	APR 23, 2019			
020987 001	PANTOPRAZOLE SODIUM; PROTONIX	6080759	MAY 19, 2015			
020819 001	PARICALCITOL; ZEMPLAR	6063927	APR 23, 2019			
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL					
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL					

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL USE EXPIRES	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6080759	MAY 19, 2015		FEB 17, 2005
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6063927	APR 23, 2019		JUN 09, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6080759	MAY 19, 2015		I-304 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6063927	APR 23, 2019		I-287 FEB 10, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6080759	MAY 19, 2015		I-286 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6063927	APR 23, 2019		D-51 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6080759	MAY 19, 2015		I-281 JUN 09, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6063927	APR 23, 2019		I-304 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6080759	MAY 19, 2015		I-287 FEB 10, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6063927	APR 23, 2019		I-286 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL	6080759	MAY 19, 2015		D-51 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL CR	6062927	APR 23, 2019		I-304 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL CR	6080759	MAY 19, 2015		I-287 FEB 10, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL CR	6063927	APR 23, 2019		I-286 JAN 18, 2003
>ADD>	PAROXETINE HYDROCHLORIDE; PAXIL CR	6080759	MAY 19, 2015		D-51 JAN 18, 2003
>ADD>	PERFLUOROPOLYMETHYLISOPROPYL ETHER; SKIN EXPOSURE REDUCT	5607979	MAY 30, 2015		I-281 JUN 09, 2003
>ADD>	PRAVASTATIN SODIUM; PRAVACHOL				I-304 JAN 18, 2003
>ADD>	PRAVASTATIN SODIUM; PRAVACHOL				I-287 FEB 10, 2003
>ADD>	PRAVASTATIN SODIUM; PRAVACHOL				I-286 JAN 18, 2003
>ADD>	PRAVASTATIN SODIUM; PRAVACHOL				D-51 JAN 18, 2003
>ADD>	PREDNISOLONE SODIUM PHOSPHATE; PEDIAPRED	4448774	DEC 22, 2002		I-281 JUN 09, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583*PED	AUG 15, 2009		I-304 JAN 18, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5466700	AUG 30, 2013		I-287 FEB 10, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009	U-156	I-286 JAN 18, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5466700*PED	MAR 01, 2014		D-51 JAN 18, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009	U-156	I-281 JUN 09, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5466700	AUG 30, 2013		I-304 JAN 18, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583*PED	AUG 15, 2009		I-287 FEB 10, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5466700*PED	MAR 01, 2014		I-286 JAN 18, 2003
>ADD>	REMIFENTANIL HYDROCHLORIDE; ULTIVA				D-51 JAN 18, 2003

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020630 003	REMIFENTANIL HYDROCHLORIDE; ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
		5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
		5019583*	PED AUG 15, 2009		PED	JAN 12, 2002
020903 001	RIBAVIRIN; REBETOL	5466700*	PED MAR 01, 2014	U-156	NCE	JUL 12, 2001
020835 001	RISERDONATE SODIUM; ACTONEL	6051252	DEC 22, 2017		I-292	APR 14, 2003
					I-291	APR 14, 2003
					I-290	APR 14, 2003
					I-293	APR 14, 2003
020588 001	RISPERIDONE; RISPERDAL	5453425	JUL 11, 2014		U-322 NCE	APR 21, 2005
		5616587	JUL 11, 2014		U-322	
020659 001	RITONAVIR; NORVIR	6037157	JUN 26, 2016		U-322 NCE	APR 21, 2005
		5674882	OCT 07, 2014		U-322	
		5886036	DEC 29, 2012		U-322 NCE	APR 21, 2005
020823 003	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007		U-322	
020823 004	RIVASTIGMINE TARTRATE; EXELON	5602176	FEB 11, 2014		U-322 NCE	APR 21, 2005
020823 005	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007		U-322	
020823 006	RIVASTIGMINE TARTRATE; EXELON	5602176	FEB 11, 2014		U-322 NCE	APR 21, 2005
021025 001	RIVASTIGMINE TARTRATE; EXELON	4948807	AUG 14, 2007		U-322	
020864 001	RIZATRIPTAN BENZOATE; MAXALT	5602162	FEB 11, 2014		U-322 NCE	APR 21, 2005
020864 002	RIZATRIPTAN BENZOATE; MAXALT	5602162	FEB 11, 2014		U-322	
021042 001	ROFECOXIB; VIOXX	6063811	MAY 16, 2017		U-266	
021042 002	ROFECOXIB; VIOXX	6063811	MAY 16, 2017		U-266	
021052 001	ROFECOXIB; VIOXX	6063811	MAY 16, 2017		U-266	
021052 002	ROFECOXIB; VIOXX	6063811	MAY 16, 2017		U-266	
021071 002	ROSIGLITAZONE MALEATE; AVANDIA	5002953	AUG 30, 2008		I-289	APR 03, 2003
021071 003	ROSIGLITAZONE MALEATE; AVANDIA	5741803	APR 21, 2015		U-329	
		5002953	AUG 30, 2008		U-329 I-289	APR 03, 2003
021071 004	ROSIGLITAZONE MALEATE; AVANDIA	5741803	APR 21, 2015		U-329	
		5002953	AUG 30, 2008		U-329 I-289	APR 03, 2003
020990 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	5741803	APR 21, 2015		U-329	
		4536518	DEC 30, 2005		U-286	
		4940731	AUG 30, 2009		U-312	
021179 001	SEVELAMER HYDROCHLORIDE; RENAGEL	5496545	AUG 11, 2013		U-246 NCE	OCT 30, 2003
		5667775	SEP 16, 2014		U-246	
021179 002	SEVELAMER HYDROCHLORIDE; RENAGEL	5496545	AUG 11, 2013		U-246 NCE	OCT 30, 2003
		5667775	SEP 16, 2014		U-246	

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020281 002	TRAMADOL HYDROCHLORIDE; ULTRAM					
074973 001	TRIMETHOPRIM HYDROCHLORIDE; PRIMISOL					
020326 001	TRIMETREXATE GLUCURONATE; NEUTREXIN	5763449	AUG 07, 2016		PED	FEB 21, 2002
020326 002	TRIMETREXATE GLUCURONATE; NEUTREXIN	5962461	AUG 07, 2016		PED	SEP 03, 2000
020715 001	TRIPTORELIN PAMOATE; TRELSTAR DEPOT	6017922	MAY 18, 2018		NCE	MAR 03, 2000
020719 001	TROGLITAZONE; PRELAY	6017922	MAY 18, 2018		D-44	AUG 21, 2001
020719 002	TROGLITAZONE; PRELAY					
020719 003	TROGLITAZONE; PRELAY					
020720 001	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317	NCE	JUN 15, 2005
020720 002	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317		
020720 003	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317		
020552 001	VERAPAMIL HYDROCHLORIDE; COVERA-HS	6046202	SEP 15, 2013	U-317		
		5232705	AUG 31, 2010			
		5200196	JAN 22, 2008			
		5141752	JUN 27, 2006			
		5082668	JAN 21, 2009			
		5030456	NOV 07, 2008			
		4946687	OCT 02, 2007			
		5785994	OCT 22, 2009	U-315		
		5232705	AUG 31, 2010			
		5200196	JAN 22, 2008			
		5141752	JUN 27, 2006			
		5082668	JAN 21, 2009			
		5030456	NOV 07, 2008			
		4946687	OCT 02, 2007			
		5785994	OCT 22, 2009	U-315		
		5232705	AUG 31, 2010			
		5200196	JAN 22, 2008			
		5141752	JUN 27, 2006			
		5082668	JAN 21, 2009			
		5030456	NOV 07, 2008			
		4946687	OCT 02, 2007			
		5785994	OCT 22, 2009	U-315		
020552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS					
021119 001	VERTEPORFIN; VISUDYNE					
021036 001	ZANAMIVIR; RELENZA					
020789 001	ZONISAMIDE; ZONEGRAN					
					NCE	APR 12, 2005
					I-294	APR 26, 2003
					NCE	MAR 27, 2005

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, 20TH 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

NPP NEW PATIENT POPULATION

REFERENCES

NEW DOSING SCHEDULE

- D-51 OPTIONAL STARTING DOSE OF 40MG/DAY
 D-52 ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY
 D-53 USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE
 D-54 USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS
 D-55 ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)
 D-56 ADDITION OF POSTPRANDIAL DOSING
 D-57 3-HOUR INFUSION OF TAXOL GIVEN EVERY THREE WEEKS AT A DOSE OF 175MG/M2 FOLLOWED BY CISPLATIN AT A DOSE OF 75MG/M2 FOR THE FIRST-LINE TREATMENT OF ADVANCED OVARIAN CANCER
 D-58 CHANGE IN DOSING INTERVAL TO ONCE-DAILY ADMINISTRATION
 D-59 REDUCTION OF ELEVATED LDL-C IN A NEW, HIGHER STRENGTH TABLET, 0.8MG, AND FOR EXTENSION OF THE DOSAGE RANGE TO 0.8MG DAILY

NEW INDICATION

- I-283 TO REDUCE THE INCIDENCE OF MODERATE TO SEVERE XEROSTOMIA IN PATIENTS UNDERGOING POST-OPERATIVE RADIATION TREATMENT FOR HEAD AND NECK CANCER, WHERE THE RADIATION PORT INCLUDES A SUBSTANTIAL PORTION OF THE PAROTID GLANDS
 I-286 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE III
 I-287 USE OF PRAVASTATIN IN PATIENTS WITH EVIDENT CORONARY HEART DISEASE TO REDUCE THE RISK OF TOTAL MORTALITY BY REDUCING CORONARY DEATH
 I-288 CHANGES SEVERAL SECTIONS OF THE PACKAGE INSERT TO INCORPORATE STATEMENTS CONCERNING THE USE OF HIGH DOSES OF LISINAPRIL TO REDUCE THE RISK OF THE COMBINED OUTCOMES OF MORTALITY AND HOSPITALIZATION IN PATIENTS WITH CONGESTIVE HEART FAILURE
 I-289 USE OF AVANDIA IN COMBINATION WITH A SULFONYLUREA IN PATIENTS WITH TYPE 2 DIABETES MELLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL
 I-290 TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS
 I-291 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS
 I-292 TREATMENT OF POSTMENOPAUSAL OSTEOPOROSIS
 I-293 TREATMENT OF CORTICOSTEROID-INDUCED OSTEOPOROSIS

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

- I-294 TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS
- I-295 PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS
- I-296 LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY
- I-297 SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER
- I-298 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA
- I-299 USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM
- I-300 PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE
- I-301 TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS
- I-302 TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME
- I-303 INCREASING HDL-CHOLESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS
- I-304 TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV

MISCELLANEOUS EXCLUSIVITY CODES

- M-2 APPROVAL FOR ADDITION TO CLINICAL PHARMACOLOGY SECTION OF THE LABEL REGARDING (1) IMPROVEMENT IN BONE MINERAL DENSITY IN CHILDHOOD-ONSET ADULT GROWTH HORMONE DEFICIENT PATIENTS AND (2) INCREASES IN SERUM ALKALINE PHOSPHATASE
- M-3 ADDITION OF EFFICACY AND SAFETY INFORMATION IN WHICH FOSAMAX WAS USED CONCOMITANTLY WITH ESTROGEN ALONE OR WITH ESTROGEN PLUS PROGESTIN

PATENT USE CODE

- U-266 RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS; MANAGEMENT OF ACUTE PAIN IN ADULTS; TREATMENT OF PRIMARY DYSMENORRHEA
- U-309 TREATING SJOEGREN SYNDROME
- U-310 TREATMENT OF XEROSTOMIA
- U-311 HORMONE REPLACEMENT
- U-312 PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER
- U-313 TREATMENT OF CONGESTIVE HEART FAILURE
- U-314 METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY
- U-315 METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT
- U-316 METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER
- U-317 METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE
- U-318 TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE
- U-319 TREATMENT OF MICROBIAL INFECTIONS
- U-320 INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA
- U-321 REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS
- U-322 TREATMENT OF ALZHEIMER'S DEMENTIA
- U-323 USE AS A BILE ACID SEQUESTRANT
- U-324 METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE
- U-325 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE
- U-326 METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER

PATENT AND EXCLUSIVITY TERMS*PATENT USE CODE*

- U-327 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE
- U-328 METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH
- U-329 USE OF AVANDIA AS MONOTHERAPY, IN COMBINATION WITH METFORMIN, AND IN COMBINATION WITH SULFONYLUREAS TO IMPROVE GLYCEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS
- U-330 TREATMENT OF NAUSEA AND VOMITING
- U-331 METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
- U-332 TREATMENT OR PREVENTION OF BRONCHOSPASM