

CUMULATIVE
SUPPLEMENT 7
JULY 2000

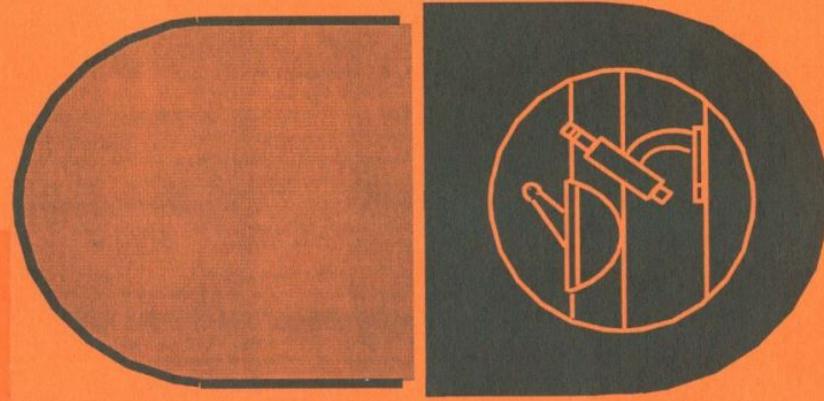
APPROVED DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF INFORMATION TECHNOLOGY
DIVISION OF DATA MANAGEMENT AND SERVICES

2000



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APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

Cumulative Supplement 7

July 2000

CONTENTS

	<i>PAGE</i>
1.0 INTRODUCTION	iii
1.1 How to Use the Cumulative Supplement	iii
1.2 Applicant Name Changes	iv
1.3 Diclofenac Sodium Ophthalmic Solution.....	v
1.4 Availability of the Edition	vi
1.5 Report of Counts for the Prescription Drug Product List.....	vii
DRUG PRODUCT LISTS	
Prescription Drug Product List.....	1-1
OTC Drug Product List	2-1
Drug Products with Approval under Section 505 of the Act	
Administered by the Center for Biologics Evaluation and Research List.....	3-1
Orphan Product Designations and Approvals List	4-1
Drug Products Which Must Demonstrate <i>in vivo</i> Bioavailability	
Only if Product Fails to Achieve Adequate Dissolution	5-1
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM	
A. Patent and Exclusivity Lists	A-1
B. Patent and Exclusivity Terms.....	B-1

**APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS**

20TH EDITION

**CUMULATIVE SUPPLEMENT 7
JULY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

<u>FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)</u>	<u>NEW APPLICANT NAME (NEW ABBREVIATED NAME)</u>
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	2617 (25.7%)
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	111 (1.1%)	111 (1.1%)	111 (1.1%)	
NEW MOLECULAR ENTITIES APPROVED	0	6	11	
NUMBER OF APPLICANTS	576	575	580	

¹Amino 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 7 / JAN' 2000 - JUL' 2000

ACETAMINOPHEN; BUTALBITAL

<u>CAPSULE; ORAL PHENYLIN FORTE</u>		<u>ACETAMINOPHEN; HYDROCODONE BITARTRATE</u>	
<u>AB</u>	+ <u>AMARIN PHARMS</u>	<u>650MG; 50MG</u>	N88831 001 JUN 19 1985 <u>N88831 001</u> JUN 19 1985
<u>AB</u>	* <u>CARHICK</u>	<u>650MG; 50MG</u>	<u>AA</u> <u>AA</u> <u>AA</u>
<u>TABLET; ORAL PHENYLIN</u>		<u>325MG; 50MG</u>	LORTAB 325MG; 50MG JUN 19 1985 <u>N87811 001</u> JUN 19 1985 <u>N87811 001</u> JUN 19 1985
<u>AB</u>	+ <u>AMARIN PHARMS</u>	<u>325MG; 50MG</u>	<u>AA</u> @ NORCO
<u>AB</u>	* <u>CARHICK</u>		<u>AA</u> + <u>WATSON LABS</u> * <u>325MG; 50MG</u> JUN 19 1985
<u>ACETAMINOPHEN; CODEINE PHOSPHATE</u>			<u>325MG; 10MG</u> JUN 19 1985
<u>SUSPENSION; ORAL ACETAMINOPHEN AND CODEINE PHOSPHATE</u>			<u>325MG; 10MG</u> JUN 19 1985
<u>AB</u>	<u>AMARIN PHARMS</u>	<u>120MG/5ML; 12MG/5ML</u>	N86024 001 N86024 001
<u>AB</u>	<u>CARHICK</u>	<u>120MG/5ML; 12MG/5ML</u>	
<u>ACETAMINOPHEN; HYDROCODONE BITARTRATE</u>		<u>ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE</u>	
<u>TABLET; ORAL HYDROCODONE BITARTRATE AND ACETAMINOPHEN</u>		<u>TABLET; ORAL PENTAZOCINE HCL AND ACETAMINOPHEN</u>	
<u>AB</u>	BARR	<u>500MG; 2.5MG</u>	<u>AB</u> WATSON LABS 650MG; EQ 25MG BASE
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>500MG; 5MG</u>	<u>AB</u> TALACEN + SANOFI SYNTHELABO 650MG; EQ 25MG BASE
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>500MG; 7.5MG</u>	<u>AB</u> * 650MG; EQ 25MG BASE
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>500MG; 10MG</u>	<u>ACETOHEXAMIDE</u>
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>650MG; 7.5MG</u>	<u>TABLET; ORAL ACETOHEXAMIDE</u>
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>650MG; 10MG</u>	<u>AB</u> * 650MG 500MG
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>750MG; 7.5MG</u>	<u>AB</u> + <u>DIRECTOR</u> * AB
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>750MG; 10MG</u>	<u>AB</u> * 250MG 500MG
> ADD > <u>AB</u>	> ADD > <u>AB</u>	<u>325MG; 10MG</u>	<u>AB</u> * 250MG 500MG
> ADD > <u>AB</u>	MALLINCKRODT	<u>325MG; 10MG</u>	<u>AB</u> * N13378 002 N13378 001
> ADD > <u>AB</u>	UCB	<u>325MG; 7.5MG</u>	<u>AB</u> * N13378 002 N13378 001
	+		

<u>ADAPALENE</u>								
CREAM; TOPICAL DIFERIN + GALDERMA LABS LP	0.1%	MAY 26, 2000	N20748 001	INJECTABLE; INJECTION OPTISON + MALLINCKRODT	10MG/ML * MOLECULAR BIOSYSTEMS 10MG/ML DLT >	N20899 001 DEC 31, 1997 N20899 001 DEC 31, 1997	MULTI-12 + SABEX	2 IU/ML; 20MG/ML; 12 UGM/ML; 40 IU/ML; 1 UGM/ML; 3MG/ML; 80 UGM/ML; 8MG/ML; 0.8MG/ML; 0.72MG/ML; 0.6MG/ML; 600 IU/ML
								MAY 18, 2000 N21163 001
								MAY 18, 2000 N21163 001
<u>ALBUMIN HUMAN</u>								
INJECTABLE; INJECTION OPTISON + MALLINCKRODT	10MG/ML * MOLECULAR BIOSYSTEMS 10MG/ML DLT >	N20899 001 DEC 31, 1997 N20899 001 DEC 31, 1997	ALTRETAMINE	CAPSULE; ORAL HEXALEN + MEDIMMUNE ONCOLOGY	50MG * US BIOSCIENCE	N19926 001 DEC 26, 1990 N19926 001 DEC 26, 1990		
<u>ALBUTEROL</u>								
AEROSOL, METERED; INHALATION <u>ALBUTEROL</u> MEDEX	0.09MG/ACTN 0.09MG/TINH AB SIDMAK LABS CA	N74072 001 AUG 01, 1996 N74072 001 AUG 01, 1996	<u>AMANTADINE HYDROCHLORIDE</u>	CAPSULE; ORAL <u>AMANTADINE HCL</u> AB GENEVA PHARMS TECH AB INVAMED	100MG 100MG * US BIOSCIENCE	N71293 001 FEB 18, 1987 N71293 001 FEB 18, 1987		
<u>ALBUTEROL SULFATE</u>								
SOLUTION; INHALATION <u>ALBUTEROL SULFATE</u> BAUSCH AND LOMB	EQ 0.083% BASE	N75358 001 MAR 29, 2000	<u>AMIFOSTINE</u>	INJECTABLE; INJECTION ETHYOL + MEDIMMUNE ONCOLOGY	500MG/VIAL * US BIOSCIENCE	N20221 001 DEC 08, 1995 N22321 001 DEC 08, 1995		
<u>ALOSETRON HYDROCHLORIDE</u>								
TABLET; ORAL LOTRONEX + GLAXO WELLCOME	EQ 1MG BASE	N21107 001 FEB 09, 2000						
<u>AMINO ACIDS</u>								
INJECTABLE; INJECTION MOVATTE 15% SOFTITE FREE IN PLASTIC CONTAINER BAXTER HLTCHC	15%	> DLT > > DLT > > DLT >						

AMINO ACIDS

<u>INJECTABLE; INJECTION</u>							
NOVAMINE 15% SULFITE FREE IN PLASTIC CONTAINER	15%						
@ BAXTER HLTHCARE							
> ADD >		N20107 001	> DLT >				
> ADD >		FEB 05, 1993	> DLT >				
> ADD >			> DLT >				
TROPHAMINE		N19018 001	> DLT >				
@@ BAXTER		JUL 20, 1984	> ADD >				
6%		N19018 001	> ADD >				
+ TROPHAMINE 1.0%		JUL 20, 1984	> ADD >				
@@ BAXTER		N19018 003	> ADD >				
+		SEP 07, 1988					
		N19018 003					
		SEP 07, 1988					
<u>AMINOPHYLLINE</u>							
<u>TABLET; ORAL</u>							
<u>AMINOPHYLLINE</u>							
@@ GLEBE PHARM		N84574 001					
@@ IMPAX LABS		N84576 001					
@		N84574 001					
		N84576 001					
<u>AMIODARONE HYDROCHLORIDE</u>							
<u>TABLET; ORAL</u>							
AMIODARONE HCL							
+ EON		400MG					
		N75315 002					
		JUN 30, 2000					
<u>AMRINONE LACTATE</u>							
<u>INJECTABLE; INJECTION</u>							
AMRINONE		EQ 5MG BASE/ML					
AP BEDFORD		N75513 001					
		MAY 09, 2000					
<u>AMRINONE LACTATE</u>		EQ 5MG BASE/ML					
AP BAXTER PHARM PROD		N75542 001					
		MAY 10, 2000					

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOKINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL
DIPHENOXYLATE HCL AND ATROPINE SULFATE
0.025MG; 2.5MG

AA PAR PHARM 0.025MG; 2.5MG

MAY 02, 2000

INJECTABLE INJECTION
AQUIVITE DPD P + W KIT
@ FRESENTUS KABI

N/A, 80MG/VIAL; N/A, 0.02MG/VIAL; N/A,
0.061MG/VIAL; 4.00 IU/10ML; N/A; N/A,
0.14MG/VIAL; N/A, 1.7MG/VIAL; N/A,
5MG/VIAL; 0.2MG/1.0ML; N/A; N/A,
1MG/VIAL; N/A, 1.4MG/VIAL; N/A,
1.2MG/VIAL; EQ 2,300 UNITS BASE/10ML;
N/A, 7 TU/1.0ML; N/A
DEC 29, 1993

N/A, 80MG/VITAL; N/A, 0.02MG/VITAL; N/A,
0.001MG/VITAL; 4.00 IU/10ML; N/A; N/A,
0.14MG/VITAL; N/A, 1.7MG/VITAL; N/A,
5MG/VITAL; 0.2MG/1.0ML; N/A; N/A,
1MG/VITAL; N/A, 1.4MG/VITAL; N/A,
1.2MG/VITAL; EQ 2,300 UNITS BASE/10ML;
N/A; 7 TU/10ML; N/A
N20176 001
DEC 29, 1993

AZELASTINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
OPTIVAR
+ ASTA 0.05%

MAY 22, 2000

> ADD > ATOVAQUONE; PROGUANIL HYDROCHLORIDE

> ADD > TABLET; ORAL
MALARONE
+ GLAXO WELLCOME
250MG; 100MG
N21078 001
JUL 14, 2000
> ADD >

> ADD > BALSALAZIDE DISODIUM
CAPSULE; ORAL
COLAZAL
+ SALIX
750MG
N20610 001
JUL 18, 2000

ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE

TABLET; ORAL
MOTOPEN
+ AMARIN PHARMS 0.025MG; 1MG
0.025MG; 1.25MG

TABLET; ORAL
BENZTROPINE MESYLATE
GENEVA PHARMS TECH 0.5MG

AA AA AA

N72264 001
FEB 27, 1989

N72265 001
FEB 27, 1989

N72266 001
FEB 27, 1989

> ADD > MOTOPEN HALF-STRENGTH
@ AMARIN PHARMS 0.025MG; 0.5MG
0.025MG; 0.5MG

> DLT > @ CARNHETOK 1MG
2MG

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE
AKORN

0.5MG

* MERCK
* ROSS
* ROBERTS LABS

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

BETHANECHOL CHLORIDE
INJECTABLE; INJECTION
URECHOLINE
* MERCK

EQ 0.5% BASE
AT AKORN
BETOPTIC
AT + ALCON
EQ 0.5% BASE

EQ 0.5% BASE
AT + ALCON
EQ 0.5% BASE

EQ 0.5% BASE
AT + ALCON
EQ 0.5% BASE

N75386 001
JUN 30, 2000
N19270 001
AUG 30, 1985
N19270 00
AUG 30, 1985
N19270 00
AUG 30, 1985

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION
URECHOLINE
* MERCK
@

N06536 001
N06536 001

BETHANECHOL CHLORIDE
TABLETT; ORAL
BAMBURY PHARMS

1.0MG

* ROBERTS LABS
* ROBERTS LABS

N84408 001
N84411 001
N87444 001

BEXAROTENE
GEL; TOPICAL
TARGETIN
+ LIGAND
1%

N06536 001
N06536 001
N06536 001

N06536 001
N06536 001
N06536 001
N06536 001
N06536 001

BLEOMYCIN SULFATE
INJECTABLE; INJECTION
BLEOMYCIN
PAULDING
AP

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

EQ 15 UNITS BASE/VIAL
N65031 001
MAR 10, 2000

BLEOMYCIN SULFATE

INJECTABLE; INJECTION
BLEOMYCIN
FAULDING EQ 30 UNITS BASE
AP EQ 15 UNITS BASE/VIAL
AP GENSIA SICOR PHARMS EQ 15 UNITS BASE/VIAL
AP EQ 30 UNITS BASE/VIAL

N65031 002
 MAR 10, 2000
 N65033 001
 JUN 27, 2000
 N65033 002
 JUN 27, 2000

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

BUPROPION HYDROCHLORIDE

TABLET; ORAL
BUPROPION HCL
AB
INVAMED
AB
MYLAN
AB
100MG
75MG
100MG

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

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL
BRISTOL MYERS SQUIBB
AB
30MG
15MG
30MG

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

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

BRETYLIUM TOSYLATE

TABLET; INJECTION
BRETYLIUM TOSYLATE
ASTRAZENECA
50MG/ML
AB
50MG/ML

N11694 006
 MAR 29, 1984
 N11694 006
 MAR 29, 1984

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

BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

SYRUP; ORAL
DIMETANE DC
AB * ROBINS AR
2MG/5ML 10MG/5ML
12.5MG/5ML
2MG/5ML; 1.0MG/5ML;
1.2.5MG/5ML
MYPHETANE DC
MORTON GROVE
2MG/5ML 10MG/5ML
12.5MG/5ML
2MG/5ML; 1.0MG/5ML;
12.5MG/5ML
AB +
AB
AB

N88904 001
 FEB 21, 1985
 N88904 001
 FEB 21, 1985
 N21117 001
 JAN 28, 2000

CALCIUM CHLORIDE
INJECTABLE; INJECTION
BUTORPHANOL TARTRATE
AB
1MG/ML
2MG/ML

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

BUPROPION HYDROCHLORIDE

TABLET; ORAL
BUPROPION HCL
AB
INVAMED
75MG

N75584 001
 FEB 07, 2000

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERfusion, CARDIAC <u>CARDIOPLEGIC IN PLASTIC CONTAINER</u> BAXTER HLTLCARE	17.6MG/100ML; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML	N75323 001	APR 21, 2000	N19856 002
AT + ABBOTT	<u>PLEGISOL IN PLASTIC CONTAINER</u> 17.6MG/100ML; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML	N18608 001	FEB 26, 1982	N75476 001
*	17.6MG/100ML; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML	N18608 001	FEB 26, 1982	JAN 03, 2000
				N75546 001
				JAN 20, 2000
CANDICIDIN				N19972 001
OINTMENT; VAGINAL VANOGBID @ AVENTIS PHARMS * HOECHST MARION RSSL	0.6MG/GM 0.6MG/GM	N61596 001 N61596 001		MAY 23, 1990
				N19972 001
				MAY 23, 1990
TABLET; VAGINAL VANOGBID @ AVENTIS PHARMS * HOECHST MARION RSSL	3MG 3MG	N61613 001 N61613 001	> ADD > > ADD > > ADD > > ADD >	EQ 500MG BASE/VIAL CEFAZOLIN AND DEXTROSE + B BRAUN
				EQ 500MG BASE/VIAL CEFAZOLIN AND DEXTROSE + B BRAUN
CAPTOPRIL; HYDROCHLORTIAZIDE				
TABLET; ORAL CAPTOPRIL AND HYDROCHLORTIAZIDE DANBURY PHARMS	50MG; 25MG 50MG; 25MG	N74832 001 DEC 29, 1997 N74832 001	> DLT > > DLT > > ADD > > ADD >	N64169 002 EQ 1GM BASE/VIAL CEFDINIR CEFDINIR
				AUG 14, 1998
				N64169 002
				AUG 14, 1998
CARBIDOPA; LEVODOPA				
TABLET, EXTENDED RELEASE; ORAL CARBIDOPA AND LEVODOPA	25MG; 100MG	N75091 002	APR 21, 2000	N50739 001
AB MYLAN				DEC 04, 1997
				N50739 001
AB SINemet CR DUPONT PHARMS	25MG; 100MG	N19856 002	DEC 24, 1992	DEC 04, 1997
				N50749 001
				DEC 04, 1997

CEFDINIR

DINIR POWDER FOR RECONSTITUTION; ORAL
OMNICEF * PARKE DAVIS 125MG/1

CEFOXITIN SODIUM
INJECTABLE; INJECT
MEFOXIN
MEDCO

CECETOXITIN SODIUM
INJECTABLE; INJECTION
MEFOXIN
M&P DIVISION

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION ROCEPHIN + HLR	EQ 2GM BASE/VIAL	N50585 004 DEC 21, 1984
+ ROCHS	EQ 10GM BASE/VIAL	N50585 005 DEC 21, 1984
* ROCHS	EQ 25MG BASE/VIAL	N50585 001 DEC 21, 1984
EQ 50MG BASE/VIAL	N50585 002 DEC 21, 1984	
EQ 100MG BASE/VIAL	N50585 003 DEC 21, 1984	
EQ 200MG BASE/VIAL	N50585 004 DEC 21, 1984	
EQ 400MG BASE/VIAL	N50585 005 DEC 21, 1984	
EQ 1GM BASE/VIAL @ HLR	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987
+ ROCHS	EQ 20MG BASE/ML	N50624 002 FEB 11, 1987
+ ROCHS	EQ 40MG BASE/ML	N50624 003 FEB 11, 1987
EQ 10MG BASE/ML @ HLR	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987
* ROCHS	EQ 20MG BASE/ML	N50624 002 FEB 11, 1987
* ROCHS	EQ 40MG BASE/ML	N50624 003 FEB 11, 1987

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL KEFLEX		
AB	*	EQ 125MG BASE/5ML
AB	*	EQ 250MG BASE/5ML
AB	*	EQ 250MG BASE/5ML
AB	+	EQ 250MG BASE/5ML
N50406 001 DEC 21, 1984	@	EQ 125MG BASE/5ML
N50406 002 DEC 21, 1984	@	EQ 250MG BASE/5ML
N50406 003 DEC 21, 1984	@	EQ 250MG BASE/5ML
N50406 004 DEC 21, 1984	@	EQ 250MG BASE/5ML
N50406 005 DEC 21, 1984	@	EQ 250MG BASE/5ML
N50406 006 DEC 21, 1984	@	EQ 250MG BASE/5ML
N50406 007 MAY 08, 1996		
N50406 008 MAY 08, 1996		
N50406 009 MAY 08, 1996		
N50406 010 MAY 08, 1996		
N50406 011 MAY 08, 1996		
N50406 012 MAY 24, 1999		
N50406 013 MAY 24, 1999		
N50406 014 MAY 24, 1999		
N50406 015 MAY 24, 1999		
N50406 016 JUL 24, 2000		

CERIVASTATIN SODIUM

TABLET; ORAL BAYCOL	0 . 4 MG
EQ 100MG BASE/VIAL	0 . 4 MG
EQ 100MG BASE/VIAL	0 . 4 MG
EQ 100MG BASE/VIAL	0 . 8 MG
CEVIMELINE HYDROCHLORIDE	
CAPSULE; ORAL EVOXAC + SNOWBRAND	
EQ 30MG BASE	
N20989 002 JAN 11, 2000	

CHENODIOL

TABLET; ORAL CHENIX	250MG
EQ 1GM BASE/VIAL, N/A; N/A, 1%	N18513 002 JUL 28, 1983
EQ 500MG BASE/VIAL, N/A; N/A, 1%	N18513 002 JUL 28, 1983
EQ 1GM BASE/VIAL, N/A; N/A, 1%	AXCAN SCANDIPHARM 250MG
EQ 500MG BASE/VIAL, N/A; N/A, 1%	CHLORPHENIRAMINE MALEATE
EQ 1GM BASE/VIAL, N/A; N/A, 1%	TABLET; ORAL CHLORPHENIRAMINE MALEATE GLOBAL PHARM 4MG @ IMPAX LABS
EQ 500MG BASE/VIAL, N/A; N/A, 1%	N80809 001 N80809 001

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION ROCEPHIN KIT + HLR	EQ 1GM BASE/VIAL, N/A; N/A, 1%	N50585 006 MAY 08, 1996
+ ROCHS	EQ 500MG BASE/VIAL, N/A; N/A, 1%	N50585 007 MAY 08, 1996
* ROCHS	EQ 1GM BASE/VIAL, N/A; N/A, 1%	N50585 008 MAY 08, 1996
* ROCHS	EQ 500MG BASE/VIAL, N/A; N/A, 1%	N50585 009 MAY 08, 1996
* ROCHS	EQ 500MG BASE/VIAL, N/A; N/A, 1%	N50585 010 MAY 08, 1996

CICLOPIROX

CREAM; TOPICAL
LOPROX
+ AVENTIS PHARMS 0.77%
N18748 001
DEC 30, 1982

LOTION; TOPICAL
LOPROX
+ AVENTIS PHARMS 0.77%
N19824 001
DEC 30, 1988

CICLOPIROX OLAMINE

CREAM; TOPICAL
LOPROX
* RECHST MARION RESI 1%
N18748 001
DEC 30, 1982

LOTION; TOPICAL
LOPROX
* RECHST MARION RESI 1%
N19824 001
DEC 30, 1988

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
CIMETIDINE HCL
AA NOVEX EQ 300MG BASE/5ML
N75560 001
MAR 15, 2000

CISAPRIDE MONOHYDRATE
SUSPENSION; ORAL
PROHESID
* JANSSEN EQ 1MG BASE/ML
@ EQ 1MG BASE/ML
N20198 001
SEP 15, 1995

CISAPRIDE MONOHYDRATE

SUSPENSION; ORAL
PROHESID
* JANSSEN EQ 1MG BASE
@ EQ 20MG BASE
N20210 001
JUL 29, 1993
N20210 002
DEC 23, 1993

CLADRIBINE

INJECTABLE; INJECTION
CLADRIBINE
AP BEDFORD
N20822 003
JUL 17, 1998
N20822 004
JUL 17, 1998
N20822 003
JUL 17, 1998
N20822 004
JUL 17, 1998
N20822 003
JUL 17, 1998

CLARITHROMYCIN

TABLET; ORAL
BIAXIN
ABOTT
EQ 10MG BASE
EQ 20MG BASE
N20210 001
JUL 29, 1993
N20210 002
DEC 23, 1993
N50662 001
OCT 31, 1993

CISAPRIDE MONOHYDRATE

TABLET; ORAL
PROHESID
* JANSSEN EQ 10MG BASE
@ EQ 20MG BASE
N74814 001
MAY 16, 2000
N74656 001
MAY 16, 2000

CISPLATIN
INJECTABLE; INJECTION
CISPLATIN
AP GENSIA SICOR PHARMS 1MG/ML
AP PHARMACHEMIE 1MG/ML

CITALOPRAM HYDROBROMIDE
TABLET; ORAL
CELEXA
FOREST LABS
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
N20822 003
JUL 17, 1998

CLADRIBINE
INJECTABLE; INJECTION
CLADRIBINE
AP BEDFORD
N75405 001
FEB 28, 2000

CLARITHROMYCIN
TABLET; ORAL
BIAXIN
ABOTT
EQ 250MG

CLARITHROMYCIN

TABLET; ORAL
BIAXIN
+ ABBOTT 250MG
OCT 31, 1991

TABLET, EXTENDED RELEASE; ORAL
BIAXIN XL
+ ABBOTT 500MG
MAR 03, 2000

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM
AB TARO 3 .75MG
N575731 001 APR 27, 2000
N575731 002 APR 27, 2000
N575731 001 APR 27, 2000

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
CLEOCIN T
AB + PHARMACIA AND UPJOHN EQ 1% BASE
EQ 1% BASE
N50615 001 JAN 07, 1987
N50615 001 JAN 07, 1987
AB CLINDAMYCIN PHOSPHATE
ALTANA EQ 1% BASE
N64160 001 JAN 28, 2000

TABLET; ORAL
CLOXACILLIN SODIUM
AB AROTHROSICON
@ CLOXAPEN
SANKYO INC BRECK
AB +

CAPSULE; ORAL
CLOXACILLIN SODIUM
AB AROTHROSICON
@ CLOXAPEN
SANKYO INC BRECK
AB +

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM
AB TARO 3 .75MG
N75731 001 APR 27, 2000
N75731 002 APR 27, 2000
N75731 001 APR 27, 2000

SOLUTION; TOPICALCLINDAMYCIN PHOSPHATE

AT CLAY PARK EQ 1% BASE
MAY 25, 2000

TABLET; ORAL
COLESEVELAM HYDROCHLORIDE
AB WELCHOL
@ SANKYO PHARMA INC
+ SANKYO PHARMA INC
375MG

TABLET; ORAL
COLESEVELAM HYDROCHLORIDE
AB WELCHOL
@ SANKYO PHARMA INC
+ SANKYO PHARMA INC
375MG

CLOBETASOL PROPIONATE

AEROSOL; TOPICAL
OLUX FOAM
+ CONNETICS 0.05%
CREAM; TOPICAL
CLOBETASOL PROPIONATE
AB TARO 0.05%
N75633 001 MAY 17, 2000

TABLET; ORAL
CORTISONE ACETATE
AB CORTISONE ACETATE
SANKYO PHARMA
@ IMPAX LABS 25MG

TABLET; ORAL
CORTISONE ACETATE
AB CORTISONE ACETATE
SANKYO PHARMA
@ IMPAX LABS 25MG

TABLET; ORAL
CORTISONE ACETATE
AB CORTISONE ACETATE
SANKYO PHARMA
@ IMPAX LABS 25MG

TABLET; ORAL
CORTISONE ACETATE
AB CORTISONE ACETATE
SANKYO PHARMA
@ IMPAX LABS 25MG

TABLET; ORAL
CORTISONE ACETATE
AB CORTISONE ACETATE
SANKYO PHARMA
@ IMPAX LABS 25MG

<u>CROMOLYN SODIUM</u>		<u>CYCLOSPORINE</u>	
CONCENTRATE; ORAL GASTROTRON	100MG/5ML * MEDEVA	N20479 001 FEB 29, 1996	CAPSULE; ORAL <u>CYCLOSPORINE</u> AB EON <u>25MG</u> 100MG <u>100MG</u>
SOLUTION; INHALATION <u>CROMOLYN SODIUM</u> STERIPAK	10MG/ML	N75271 001 JAN 18, 2000	AB NEORAL NOVARTIS <u>25MG</u>
AN WARRICK PHARMS	10MG/ML	N75437 001 APR 21, 2000	AB AB + <u>50MG</u> <u>100MG</u>
SOLUTION, CONCENTRATE; ORAL GASTROCROM + MEDEVA	100MG/5ML	N20479 001 FEB 29, 1996	EX EX EX * <u>25MG</u> 100MG <u>100MG</u>
CYANOCOBALAMIN			SOLUTION; ORAL <u>CYCLOSPORINE</u> AB ABBOTT <u>100MG/ML</u>
INJECTABLE; INJECTION CYANOCOBALAMIN © AVENTIS PHARMS HOECHST MARION RSSL	1MG/ML 1ML/ML	N80564 001 N80564 001	AB SANOFIA SANOFIA <u>100MG/ML</u>
CYCLOPENTOLATE HYDROCHLORIDE			AB @ <u>100MG/ML</u>
SOLUTION/DROPS; OPHTHALMIC CYCLOPENTOLATE HCL AT ALCON UNIVERSAL	1%	N89162 001 JAN 24, 1991 N89162 001 JAN 24, 1991	DAUNORUBICIN CITRATE DAUNOXOME + GILEAD INJECTABLE, LIPOSOMAL; INJECTION EQ 2MG BASE/ML
CYCLOSPORINE			INJECTABLE, LIPOSOMAL; INJECTION DAUNORUBICIN CITRATE DAUNOXOME + GILEAD NEXSTAR EQ 2MG BASE/ML
CAPSULE; ORAL <u>CYCLOSPORINE</u> AB	25MG ABOTT	N65003 001 MAY 12, 2000 N65003 002 MAY 12, 2000 N65003 003 MAY 12, 2000	DAUNORUBICIN HYDROCHLORIDE INJECTABLE; INJECTION DAUNORUBICIN HCL AP + BEDFORD <u>50 5MG BASE/ML</u>
			N50704 002 APR 08, 1996 N50704 002 APR 08, 1996 N50731 001 JAN 30, 1998

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'2000 - JUL'2000

1-13

DAUNORUBICIN HYDROCHLORIDEINJECTABLE; INJECTIONDAUNORUBICIN HCL

* BEDFORD

EQ 5MG BASE/ML

AP GENSIA SICOR PHARMS

EQ 5MG BASE/ML

+ EQ 50MG BASE/VIAL

N50262 001

N50262 001

MAY 03, 1999

DEMECLOCYCLINE HYDROCHLORIDECAPLET; ORALDECLOXYCLIN

* LABORATORIES

EQ 150MG

N50262 001

MAY 03, 1999

DESMOPRESSIN ACETATEINJECTABLE; INJECTIONDESMOPRESSIN ACETATE

0.004MG/ML

AP BEDFORD

DESMOPRESSIN ACETATE PRESERVATIVE FREE

0.004MG/ML

AP BEDFORD

N74575 001

FEB 18, 2000

N74574 001

FEB 18, 2000

SPRAY, METERED; NASALSTIMATE

+ AVENTIS BEHRING

EQ 0.15MG/SPRAY

* CENTREON

EQ 0.15MG/SPRAY

N20355 001

MAR 07, 1994

N20355 001

MAR 07, 1994

DESOGESTREL; ETHINYL ESTRADIOLTABLET; ORAL-28

* MIRCETTE

* OROSIGNE

0.15MG; 0.02MG

0.15MG, N/A; 0.02MG, 0.01MG

APR 22, 1998 N20713 001

APR 22, 1998 N20713 001

> DLT >

> DLT >

> ADD >

> DLT >

> DLT >

> ADD >

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATESUSPENSION/DROPS; OPHTHALMICNEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

AT ALCON UNIVERSAL 0.1% / EQ 3.5MG BASE/ML,

10,000 UNITS/ML

NOV 17, 1986 N62721 001

JAN 24, 2000 N65035 001

N64212 002

MAY 03, 1999 N50262 001

MAY 03, 1999 N50262 001

MAY 03, 1999 N50262 001

DEXAMETHASONE SODIUM PHOSPHATESOLUTION/DROPS; OPHTHALMIC, OTICDEXAMETHASONE SODIUM PHOSPHATE

AT ALCON UNIVERSAL EQ 0.1% PHOSPHATE

NOV 17, 1986 N88771 001

JAN 16, 1985 N88771 001

SOLUTION/DROPS; OPHTHALMIC, OTICDEXAMETHASONE SODIUM PHOSPHATE

AT STERIS EQ 0.1% PHOSPHATE

NOV 16, 1986 N88771 001

JAN 16, 1985 N88771 001

SOLUTION/DROPS; OPHTHALMIC, OTICNEOMYCIN SULFATE-Dexamethasone Sodium Phosphate

AT ALCON UNIVERSAL EQ 0.1% PHOSPHATE,

EQ 3.5MG BASE/ML

NOV 17, 1986 N62714 001

JUL 21, 1986 N62714 001

JUL 21, 1986 N62714 001

DEZOCINEINJECTION; INTRAVENOUSDILUTION

* ASTHANECA 5MG/ML

* LOMFEML 10MG/ML

* OMNEX 10MG/ML

* OMNEX 20MG/ML

* OMNEX 40MG/ML

5MG/ML

NOV 08, 1989 N19082 001

DEC 29, 1989 N19082 001

NOV 08, 1989 N19082 001

DEC 29, 1989 N19082 001

NOV 08, 1989 N19082 001

DEC 29, 1989 N19082 001

DEZOCINE

> ADD [>] INJECTABLE; INJECTION
DALGAN
④ ASTRazeneca 10MG/ML
15MG/ML
@
> ADD [>]
> ADD [>]
> ADD [>]
> ADD [>]

N19082 002
DEC 29, 1989
N19082 003
DEC 29, 1989

N83517 001

DIENESTROL

SUPPOSITORy; VAGINAL
DV
* HORNET MARION RESE 0.7MG
@
DIFLORASONE DIACETATE

SUPPOSITORy; VAGINAL
DV

* HORNET MARION RESE 0.7MG

DIFLORASONE DIACETATE

DICLOFENAC POTASSIUM

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

N75508 001
APR 24, 2000

CREAM; TOPICAL
DIFLORASONE DIACETATE

AB TARO 0.05%

DILTIAZEM HYDROCHLORIDE

AB TARO 0.05%

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL
BIOVAAIL 120MG

AB3 180MG

AB3 240MG

AB3 300MG

INJECTABLE; INJECTION

DILTIAZEM HCL
ABBOTT 5MG/ML

N75004 001
FEB 16, 2000

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL

TIAZEM RESE

N75492 001
FEB 11, 2000

N20254 001
MAR 08, 1996
N20254 001
MAR 08, 1996

N20506 001
OCT 04, 1996
N20506 001
OCT 04, 1996
N20506 001
OCT 04, 1996
N20506 001
OCT 04, 1996

N20506 001
OCT 04, 1996
N20506 002
OCT 04, 1996

DIENESTROL

SUPPOSITORy; VAGINAL
DV

* AVENTIS PHARMS 0.7MG

N83517 001

+ SEE SECTION 1.3 OF INTRODUCTION

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN' 2000 - JUL' 2000

1-15

<u>DILTIAZEM MALATE</u>			
TABLET, EXTENDED RELEASE; ORAL			
TIAMATE	EQ 240MG HCL	N20506 003	N50641 002
+ MERCK	OCT 04, 1996	FEB 10, 1992	
		N50641 001	
		DEC 29, 1989	
		N50641 003	
		FEB 10, 1992	
		N50641 004	
		FEB 29, 1989	
<u>DIPHENHYDRAMINE HYDROCHLORIDE</u>			
CAPSULE; ORAL			
DIPHENHYDRAMINE HCL			
GLOBAL PHARM	\$8807 001		
\$8807 002			
\$8807 001	> ADD >		
25MG			
25MG			
50MG			
50MG			
<u>DOXEPIN HYDROCHLORIDE</u>			
CREAM; TOPICAL			
ZONALON		N20126 001	N21145 001
+ BIOLAN PHAR	5%	APR 01, 1994	JUL 27, 2000
		#20126 001	
		APR 01, 1994	
<u>DOXERCALCIFEROL</u>			
INJECTABLE; INJECTION			
HECTOROL		N21027 001	N87693 001
+ BONE CARE	2 UGM/ML	APR 06, 2000	APR 24, 1983
<u>DOXYCYCLINE</u>			
CAPSULE; ORAL			
DOXYCYCLINE			
AB	EQ 50MG BASE	N65032 001	N88337 001
EON		JUN 30, 2000	JUN 08, 1983
		N65032 002	N88337 001
		JUN 30, 2000	JUN 08, 1984
		N65041 001	N88337 001
		APR 28, 2000	JUL 29, 1982
		N65041 002	N86750 001
		APR 28, 2000	JUL 29, 1982
<u>DOXYCYCLINE</u>			
CAPSULE; ORAL			
DOXYCYCLINE			
AB	EQ 50MG BASE	N65032 001	N88337 001
EON		JUN 30, 2000	JUN 08, 1983
		N65032 002	N88337 001
		JUN 30, 2000	JUN 08, 1984
		N65041 001	N88337 001
		APR 28, 2000	JUL 29, 1982
		N65041 002	N86750 001
		APR 28, 2000	JUL 29, 1982

ERYTHROMYCIN

SOLUTION; TOPICAL
SANSAC
GALDERMA LABS

AT HEALTHPOINT
AT HEALTHPOINT 2%

N62522 001
JAN 24, 1985
N62522 001
JAN 24, 1985

ERYTHROMYCIN ETHYLSSUCINATE

GRANULE; ORAL
PEDIAMYCIN
ROSS LABS

AB ROSS LABS
@

SUSPENSION/DROPS; ORAL
PEDIAMYCIN
ROSS LABS

EQ 100MG BASE/5ML
EQ 200MG BASE/5ML
EQ 100MG BASE/2.5ML
EQ 100MG BASE/2.5ML

TABLET, CHEWABLE; ORAL
PEDIAMYCIN
ROSS LABS

AB ROSS LABS
@

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL <u>ESTRADIOL</u> <u>CYGRUS CA</u>	<u>0.075MG/24HR</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>002</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>003</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>001</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>002</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>003</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>001</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>002</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N21048</u> <u>003</u>
<u>EX</u>	<u>EX</u>	<u>SEP 20, 1999</u>	<u>N75233</u> <u>001</u>
<u>EX</u>	<u>EX</u>	<u>FEB 24, 2000</u>	<u>N75182</u> <u>001</u>
<u>EX</u>	<u>EX</u>	<u>FEB 24, 2000</u>	

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA
+ BERLEX LABS

AB + BERLEX LABS
AB +

ESTRADIOL
ESTRACE
* BRISTOL MYERS SQUIBB 0.01%

AB +

ESTRADIOL
ESTRACE
* + WARNER CHILCOTT 0.01%

AB +

ESTRADIOL
CYGRUS CN
EX *
EX *

N21048 001
SEP 20, 1999

ESTRADIOL

SOLUTION; TOPICAL
ESTRADIOL

EX CYGRUS CA
EX

N62305 001
N62305 001

@ JOHNSON RW

0.05MG/24HR
0.075MG/24HR

0.05MG/24HR
0.075MG/24HR

@ JOHNSON RW

0.05MG/24HR
0.075MG/24HR

FILM; ORAL
ESTRADIOL
APPLIED ANAL

AB ESTRADIOL
AB

0.5MG
1MG

2MG
3MG

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'2000 - JUL'2000

1-17

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

TRIVORA-21

SPARKLE

0.03MG, 0.04MG, 0.03MG; 0.035MG, 0.075MG
0.125MG
N74538 001
DEC 16, 1997

TABLET; ORAL-28

TRIVORA-28

SPARKLE

0.03MG, 0.04MG, 0.03MG; 0.035MG, 0.075MG
0.125MG
N74538 002
DEC 18, 1997

TABLET; ORAL-21

OVCON-35

* BRISTOL MYERS SQUIBB

+ WARNER CHILCOTT

OVCON-50

* BRISTOL MYERS SQUIBB

@ WARNER CHILCOTT

0.035MG; 0.4MG
0.035MG; 0.4MG
0.035MG; 0.4MG
0.035MG; 1MG
0.05MG; 1MG
0.05MG; 1MG
N18127 001
N18128 001
N18128 001
N18128 001
N18128 001
N18128 001

TABLET; ORAL-28

OVCON-35

WARNER CHILCOTT

OVCON-50

* BRISTOL MYERS SQUIBB

WARNER CHILCOTT

0.035MG; 0.4MG
0.035MG; 0.4MG
0.035MG; 0.4MG
0.035MG; 1MG
0.05MG; 1MG
0.05MG; 1MG
N17716 001
N17716 001
N17576 001
N17576 001

ETODOLAC

CAPSULE; ORAL

ETODOLAC

TORPHARM

200MG

300MG

> ADD

> ADD

> ADD

> ADD

ETODOLAC

TABLET; ORAL

ETODOLAC

TARO PHARM IND'S

500MG

N75074 002

APR 25, 2000

N75665 002

JUL 31, 2000

N75665 001

JUL 31, 2000

PENOLDOPAM MESYLATE

INJECTABLE; INJECTION

CORLOPAM

+ ABBOTT

* ELAN PHARMA

EQ 10MG BASE/ML

N19922 001

SEP 23, 1997

N19922 001

SEP 23, 1997

FENTANYL CITRATE

INJECTABLE; INJECTION

SUBLIMAZE PRESERVATIVE FREE

N16619 001

N16619 001

N16619 001

N16619 001

EQ 0.05MG BASE/ML

EQ 0.05MG BASE/ML

PEOPENADINE HYDROCHLORIDE

TABLET; ORAL
ALLEGRA
AVENTIS PHARMS
3 0MG
6 0MG
+
18 0MG

INJECTABLE; INJECTION
FLOXURIDINE
BEDFORD
AP
5 00MG/VIAL

TABLET; ORAL
DIFLUUCAN
FUSZEX
AP
FUDR
+ *
5 00MG/VIAL
\$ 00MG/VIAL

TABLET; ORAL
FLUCONAZOLE
FUSZEX
AP
FUDR
+ *
15 0MG
15 0MG

TABLET; ORAL
ROMAZICON
+ HLR
* KOCHE
0 .1MG/ML

INJECTABLE; INJECTION
ROMAZICON
+ HLR
* KOCHE
0 .1MG/ML

INJECTABLE; INJECTION
FLUOROURACIL
GENSIA SICOR PHARMS
5 00MG/ML

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL
AP
GENSIA SICOR PHARMS
5 00MG/ML

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

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

N75387 001
APR 16, 2000

N16929 001
N16929 001

SUSPENSION; ORAL
FUROXONE
* ROBERTS LABS
+ SHIRE LABS
\$ 00MG/15ML
5 00MG/15ML

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

TABLET; ORAL
FUROXONE
* ROBERTS LABS
+ SHIRE LABS
100MG
100MG

GABAPPETIN

SOLUTION; ORAL
NEURONTIN
+ PARKE DAVIS
250MG/5ML

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

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST
+ BERLEX LABS

INJECTABLE; INJECTION
FLUOROURACIL
AP
GENSIA SICOR PHARMS
5 00MG/ML

N40333 001
JAN 27, 2000

N21129 001
MAR 02, 2000

N21037 001
MAR 10, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'2000 - JUL'2000

GENTUZUMAB OZOGAMICIN		GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE	
INJECTABLE; INJECTION		SOLUTION/DROPS; OPHTHALMIC NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN	
MYLOTARG + WYETH AYERST	5MG/VIAL	N21174 001 MAY 17, 2000	N62818 001 OCT 11, 1988
	®		0.025MG/ML; EQ 1.75MG BASE/ML; 10,000 UNITS/ML
			10,000 UNITS/ML
			OCT 11, 1988
GENTAMICIN SULFATE		GREPPAFLOXACIN HYDROCHLORIDE	
INJECTABLE; INJECTION		N61739 001 N61739 001	N20695 001 NOV 06, 1997
GRAMYCIN SCHERING	®	N62251 002 N62251 002	N20695 002 NOV 06, 1997
GENTAMICIN SULFATE BENKEME SINH	AP +	> DLT > DLT > DLT > DLT > DLT > DLT > DLT > DLT *	GLAXO WELLCOGS EQ 200MG BASE EQ 400MG BASE EQ 600MG BASE EQ 200MG BASE OTSUKA EQ 400MG BASE EQ 600MG BASE +
SOLUTION/DROPS; OPHTHALMIC GENTAMICIN SULFATE ALCON UNIVERSAL		N62523 001 NOV 25, 1985 N62523 001 NOV 25, 1985	N20695 001 NOV 06, 1997 N20695 002 NOV 06, 1997
STERIS		EQ 0.3% BASE	MAY 14, 1998
		EQ 0.3% BASE	N20695 003 MAY 14, 1998
GLYBURIDE		GRISEOFULVIN, ULTRAMICROCRYSTALLINE	
TABLET; ORAL		N20055 003 MAR 08, 2000	N50475 001 NOV 06, 1997
GLYBURIDE (MICRONTIZED)	6MG AVENTIS PHARMS	AB AB	AB AB AB AB AB AB
			GRIS-PEG ABEROLAN HERBERT PEDINOL AB
GLYBURIDE; METFORMIN HYDROCHLORIDE		HALOPERIDOL DECANOATE	
> ADD >		N21178 001 JUL 31, 2000 N21178 002	N75440 001 FEB 28, 2000
> ADD >	TABLET; ORAL GLUCOVANCE	JUL 31, 2000 N21178 003	N75440 002 FEB 28, 2000
> ADD >	BRISTOL MYERS SQUIBB 1.25MG; 250MG	JUL 31, 2000 N21178 003	N75440 002 FEB 28, 2000
> ADD >	2.5MG; 500MG	JUL 31, 2000 N21178 003	
> ADD >	5MG; 500MG	JUL 31, 2000 N21178 003	
> ADD >	+	AO	AO
> ADD >		EO 50MG BASE/ML EO 100MG BASE/ML	

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE
AO KING PHARMS

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

N75176 001
 FEB 09, 2000
 N75176 002
 FEB 09, 2000

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK PLUSH
@ STERIS

100 UNITS/ML
 100 UNITS/ML
HEPARIN SODIUM
STERIS

5,000 UNITS/ML
10,000 UNITS/ML
20,000 UNITS/ML
40,000 UNITS/ML
5,000 UNITS/ML
10,000 UNITS/ML
20,000 UNITS/ML
40,000 UNITS/ML

HISTRELIN ACETATE
SUPPRELIN
@ ROBERTS LABS

EQ 0.2MG BASE/ML
 EQ 0.5MG BASE/ML
 EQ 1MG BASE/ML
 + SHIRE LABS

EQ 0.2MG BASE/ML

EQ 0.5MG BASE/ML

EQ 1MG BASE/ML

N19836 001
 DEC 24, 1991

N19836 002
 DEC 24, 1991

N19836 003
 DEC 24, 1991

N19836 001
 DEC 24, 1991

N19836 002
 DEC 24, 1991

N19836 002
 DEC 24, 1991

N19836 003
 DEC 24, 1991

N19836 002
 DEC 24, 1991

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL

AP GENESIA SICOR PHARMS
AP + LUTIPOLD

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

N40373 001
 FEB 23, 2000

N40136 001
 JUN 30, 1997

N40156 001
 JUN 30, 1997

N75640 001
 JAN 28, 2000

N20504 001
 DEC 27, 1996

N20504 001
 DEC 27, 1996

N85098 001
 N85098 001

N85098 001
 N85098 001

CAPSULE; ORAL
HYDROCHLOROTHIAZIDE

AB MYLAN

MICROZIDE
AB + WATSON LABS

12.5MG
12.5MG
12.5MG

AB
AB
AB

TABLET; ORAL
HYDROCHLOROTHIAZIDE

AB GENEALI PHARM
@ IMPAX LABS

100MG
100MG
100MG

N85098 001
 N85098 001

HYDROCORTISONE

CREAM; TOPICAL
HYDROCORTISONE

ZENITH GOLDLINE
AB ZENITH GOLDLINE

1%
1%
1%

NOGENIC HC
AB ZENITH GOLDLINE

1%
1%
1%

NUTRACORT
AB ZENITH GOLDLINE

0.5%
0.5%
0.5%

HEALTHPOINT
AB

GEL; TOPICAL
NUTRACORT
@ ZENITH GOLDLINE LABS

1%
1%
1%

184698 001

HYDROCORTISONE

GEL; TOPICAL NUTRACORT @ HEALTHPOINT	1%	N84698 001	DISC; TOPICAL EPIFOAM SCHWARZ PHARMA PROCTOFOAM HC	1%:1%	#86457 001
LOTION; TOPICAL <u>HYDROCORTISONE</u> ALTANA	<u>2.5%</u>	N40351 001			#86195 001
> ADD > AT > > ADD >	NUTRACORT GEL CALIFORNIA LABS	0.5% 1% 1% 1%	N80443 002 N80443 003 N87644 001 AUG 24, 1982 N80443 003 N87644 001 AUG 24, 1982 N80443 002	CREAM; TOPICAL LOCOID @ CALIFORNIA LABS 0.1% @ YAMANOUCHI 0.1% OINTMENT; TOPICAL LOCOID @ CALIFORNIA LABS 0.1% @ YAMANOUCHI 0.1%	JUL 25, 2000 N18795 001 JUN 07, 1983 N18795 001 JAN 07, 1983 N19106 001 JUL 03, 1986 N19106 001 JUL 03, 1984
AT AT @	HEALTHPOINT <u>HYDROCORTISONE</u> ALTANA	1% <u>2.5%</u> 0.5%			
SUSPENSION/DROPS; OPHTHALMIC <u>NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE</u>			SOLUTION; TOPICAL LOCOID @ CALIFORNIA LABS 0.1% @ YAMANOUCHI 0.1%		
AT STERIS	ALCON UNIVERSAL 1% EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62874 001 MAY 11, 1988 N62874 001 MAY 11, 1988	N62874 001 MAY 11, 1988 N62874 001 MAY 11, 1988		N19819 001 SEP 15, 1988 N19819 001 SEP 15, 1988
SUSPENSION/DROPS; OTIC <u>NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE</u>			HYDROCORTISONE VALERATE		
AT STERIS	ALCON UNIVERSAL 1% EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62488 001 NOV 06, 1985 N62488 001 NOV 06, 1985	AB CLAY PARK 0.2%		N75666 001 MAY 24, 2000

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL EPIFOAM SCHWARZ PHARMA PROCTOFOAM HC	1%:1%	N86457 001
BX BX	SCHWARZ PHARMA SCHWARZ PHARMA	N86195 001

HYDROXYUREA

CAPSULE; ORAL HYDROXYUREA DURAMED	250MG
---	-------

N75020 002
JUN 26, 2000

INSULIN ASPART RECOMBINANT

INJECTABLE; INJECTION

NOVOLOG

+ NOVO NORDISK

100 UNITS/ML

N20986 001
JUN 07, 2000
> ADD >
> ADD >

INJECTABLE; INJECTION

HUMALOG MIX

50/50

N21018 001
DEC 22, 1999
> ADD >
> ADD >

INJECTABLE; INJECTION

HUMALOG MIX

75/25

N21017 001
DEC 22, 1999
> ADD >
> ADD >INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION

HUMALOG MIX

50 UNITS/ML;50 UNITS/ML

N21018 001
DEC 22, 1999
> ADD >
> ADD >

INJECTABLE; INJECTION

HUMALOG MIX

75 UNITS/ML;75 UNITS/ML

N21017 001
DEC 22, 1999
> ADD >
> ADD >INULIN

INJECTABLE; INJECTION

HUMALOG MIX

50/50

N21018 001
DEC 22, 1999
> ADD >
> ADD >TOPAMIDOL

INJECTABLE; INJECTION

TOPAMIDOL

200 COOK IMAGING

N74881 001
JUL 28, 2000
> ADD >
> ADD >TOPAMIDOL

INJECTABLE; INJECTION

TOPAMIDOL

250 COOK IMAGING

N74881 002
JUL 28, 2000
> ADD >
> ADD >TOPAMIDOL

INJECTABLE; INJECTION

TOPAMIDOL

300 COOK IMAGING

N74881 003
JUL 28, 2000
> ADD >
> ADD >LOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION

CIBEROS

QUESTCOR PHARM

N17279 001
N17279 001
250-300 uCi/ML
250-300 uCi/MLIPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM

BROMIDE STERI PAK

0.02%
AN
> ADD >ISOCARBOXAZID

TABLET; ORAL

MARPLAN

+ OXFORD PHARM

10MG
N11961 001
> ADD >
> ADD >ISOETHARINE HYDROCHLORIDE

SOLUTION; INHALATION

BROMOBOS

+ SANOFI SYNTHEDABO

1%
1/4
N12339 008
N12339 008
ISOETHARINE HCL
ROXANE
+ AN +INULIN

INJECTABLE; INJECTION

INULIN AND SODIUM CHLORIDE

100MG/ML

100MG/ML

QUESTCOR PHARM

+ QUESTCOR PHARM

N86899 001
N86899 001
N86899 001
N86899 001

ISOETHARINE MESYLATE

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

AEROSOL, METERED; INHALATION
BRONCHOMETER
* **SAROFI SYNTHESLABS** 0.34MG/INH
0.34MG/INH

ISOPROTERENOL HYDROCHLORIDE
AEROSOL, METERED; INHALATION
ISUPREL
* **SAROFI SYNTHESLABS** 0.103MG/INH
0.103MG/INH

SOLUTION; INHALATION
ISUPREL
* **SAROFI SYNTHESLABS** 0.5%
0.5%
1/2
@

ISOSORBIDE MONONITRATE

> DLT >	N12339 007	AB	TABLET, EXTENDED RELEASE; ORAL
> DLT >	N12339 007	AB	<u>ISOSORBIDE MONONITRATE</u>
> DLT >		KV PHARM	30MG
> ADD >		AB	30MG
@		AB	60MG
		AB	120MG
		AB	60MG
		N11178 001	JUN 19, 2000

ISOSORBIDE DINITRATE
TABLET, EXTENDED RELEASE; ORAL
AB * **FREETH AXERS** \$1962
@ 40MG

ISOSORBIDE DINITRATE

IMWOOD LABS 10MG

+ 40MG

ISOSORBIDE MONONITRATE
DEXCEL LTD 60MG

+

AP + ABBOTT

N20225 003
MAR 30, 1995

N20225 003
Mar 30, 1995

N75522 001
APR 17, 2000

N40147 001
JUN 25, 1997

N40147 001
JUN 25, 1997

N40347 001
APR 25, 2000

N40335 001
APR 20, 2000

KETOCONAZOLE

N06327 002	AB	CREAM; TOPICAL
N06327 003	AB	<u>KETOCONAZOLE</u>
N06327 002	TEVA	2%
N06327 003	AB	NIZORAL
	AB	+ MCNEIL CONS
	AB	*
	N12882 001	SHAMPOO; TOPICAL
	N12882 001	NIZORAL
	JUL 29, 1988	*
	N12882 001	SCHERING
	JUL 29, 1988	*
	N40009 001	+
	DEC 30, 1998	MCNEIL CONS
	N40009 001	2%
	DEC 30, 1998	

LEUCOVORIN CALCIUM

AP + ABBOTT	EQ 10MG BASE/ML	N40147 001
*	EQ 10MG BASE/ML	JUN 25, 1997
AB	BEDFORD	N40147 001
*	AP	JUN 25, 1997
AB	AP	N40347 001
	EQ 10MG BASE/ML	APR 25, 2000
	EQ 350MG BASE/VIAL	N40335 001
		APR 20, 2000

LEUCOVORIN CALCIUM PRESERVATIVE FREE

AP + ABBOTT	EQ 10MG BASE/ML	N40147 001
*	EQ 10MG BASE/ML	JUN 25, 1997
AB	BEDFORD	N40147 001
*	AP	JUN 25, 1997
AB	AP	N40347 001
	EQ 10MG BASE/ML	APR 25, 2000
	EQ 350MG BASE/VIAL	N40335 001
		APR 20, 2000

RX DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'2000 - JUL'2000

1-24

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN
 GLAXO WELLCOGNIS
 @
 DLT
 ADD
 ADD
 >
 >
 >

EQ 100MG BASE/VIAL
 EQ 100MG BASE/VIAL
 MAR 23, 1999
 N89834 001
 JAN 23, 1999
 N89834 001
 JAN 23, 1999

LEUPROLIDE ACETATE

IMPLANT; IMPLANTATION
 VIADUR
 + ALZA
 EQ 65MG BASE
 MAR 03, 2000

N08720 001
 DEC 19, 1991
 NT74278 001
 MAR 31, 2000

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN
 * ICN
 2MG
 AB
 LEVORPHANOL TARTRATE
 ROXANE
 2MG

LEVOSPIRON HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
 BETAXON
 + ALCON
 EQ 0.5% BASE
 FEB 23, 2000

N21088 001
 MAR 03, 2000
 N21132 001
 APR 18, 2000

LEVOCETILOL HYDROCHLORIDE

INJECTABLE; INJECTION
 CHIROCAINE
 DARWIN DISCOVERY
 EQ 2.5MG BASE/ML

N21114 001
 FEB 23, 2000
 N20997 001
 AUG 05, 1999
 N20997 002
 AUG 05, 1999
 N20997 003
 AUG 05, 1999
 N20997 004
 AUG 05, 1999
 N20997 002
 AUG 05, 1999
 N20997 003
 AUG 05, 1999
 N20997 003
 AUG 05, 1999

N21131 001
 APR 18, 2000
 N21130 002
 APR 18, 2000

TABLET; ORAL
 ZYVOX
 + PHARMACIA AND UPJOHN 200MG/100ML
 PHARMACIA AND UPJOHN 400MG
 ZYVOX
 PHARMACIA AND UPJOHN 600MG
 +

N21130 001
 APR 18, 2000
 N21130 002
 APR 18, 2000

LINEZOLID

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

INJECTABLE; INJECTION

ZYVOX
 + PHARMACIA AND UPJOHN 200MG/100ML
 TABLET; ORAL
 ZYVOX
 PHARMACIA AND UPJOHN 400MG
 ZYVOX
 PHARMACIA AND UPJOHN 600MG
 +

N21130 001
 APR 18, 2000
 N21130 002
 APR 18, 2000

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN
 AB + ICN
 2MG

N08720 001
 DEC 19, 1991
 AP
 + AM PHARM PARTNERS
 500MG/ML

N75151 001
 APR 25, 2000
 N19316 001
 SEP 08, 1986

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE
 * AN PHARM PARTNERS

N00067444
 SEP 08, 1986

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
 AMEN
 BP AMARIN PHARMS 1.0MG
 BP CARBICK 1.0MG

N83242 001
 N83242 001

MENOTROPINS (FSH; LH)

INJECTABLE; INJECTION
 MENOTROPINS
 @ FERRING
 @
 REPORER
 FERRING

75 IU/VIAL; 75 IU/VIAL
 150 IU/VIAL; 150 IU/VIAL
 75 IU/VIAL; 75 IU/VIAL
 150 IU/VIAL; 150 IU/VIAL

N73598 001
 N73599 001
 N73598 001
 N73599 001

JAN 30, 1997
 JAN 30, 1997
 JAN 30, 1997
 JAN 30, 1997

NORINYL 0.1MG; 2MG
 NORINYL 0.1MG; 2MG
 NORINYL 0.15MG; 3MG
 NORINYL 0.15MG; 3MG

N13625 001
 N13625 001
 N13625 002
 N13625 002

MEPERIDINE HYDROCHLORIDE

TABLET; ORAL
MEPERIDINE HCL
 MALLINCKRODT
 AA
 AA
 AA

N40352 001
 JUN 13, 2000
 N40352 002
 JUN 13, 2000
 NO8248 001
 NO8248 001

MESALAMINE

CAPSULE, EXTENDED RELEASE; ORAL
 PENTASA
 * ROBERTS LABS
 250MG
 + SHIRE LABS
 250MG
 SUSPENSION; RECTAL
 ROBERTS
 * SOLAX
 500MG
 @
 DLT >
 DLT >
 DLT >
 ADD >
 ADD >
 ADD >
 ADD >
 DLT >
 DLT >
 DLT >
 ADD >
 ADD >
 ADD >

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
 NORINYL
 * SEPARATE
 @ WATSON LABS
 TABLET; ORAL-21
 NORINYL 1+50 21-DAY
 SEPARATE
 WATSON LABS
 AB
 AB

N13625 001
 N13625 001
 N13625 002
 N13625 002

METAPROTERENOL SULFATE

SOLUTION: INHALATION

ALUPENT
AB + **HOPFINGER INSETH INC.** 5%
PROTICA
NERO
AN @

SYRUP; ORAL
AA METAPROTERENOL SULFATE 1.0MG/5ML

METHANTHeline BROMIDE

TABLET; ORAL
BANTHINE
ROBERTS LABS
SHIRE LABS
> DLT >
> ADD >

METHIMAZOLE

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

METADATE ER
AB + **MEDEVAC** 1.0MG

N17659 001
N17659 001

N73340 001
NMR 30, 1.89%
N73340 001
MAR 30, 1992

METHYLIN ER
AB MALLINCKRODT 1.0MG

AB 2.0MG

SYRUP; ORAL
AA NOVEX

N75235 001
JAN 27, 2000

METHYLTESTOSTERONE

TABLET; ORAL
ORETON Methyl SCHIZING
ED **ED** 1.0MG
ED **ED** 2.5MG
ED **ED** 1.0MG
ED **ED** 2.5MG

MIDAZOLAM HYDROCHLORIDE

INJECTABLE; INJECTION

MIDAZOLAM HCL
AP ABBOTT EQ 1MG BASE/ML

N40320 001
MAR 31, 2000

EQ 1MG BASE/ML
AP NT5409 001
MAR 20, 2000

EQ 5MG BASE/ML
AP NT5293 002
MAR 20, 2000

EQ 5MG BASE/ML
AP NT5409 001
MAR 20, 2000

EQ 1MG BASE/ML
AP NT5154 002
MAR 20, 2000

EQ 5MG BASE/ML
AP NT5154 001
MAR 20, 2000

EQ 5MG BASE/ML
AP NT5263 001
MAR 26, 2000

EQ 1MG BASE/ML
AP NT5324 001
MAR 20, 2000

EQ 5MG BASE/ML
AP NT5324 002
MAR 20, 2000

EQ 1MG BASE/ML
AP NT5247 002
MAR 23, 2000

MIDAZOLAM HYDROCHLORIDE

<u>INJECTABLE; INJECTION</u>	
<u>MIDAZOLAM HCL</u>	
<u>BEDFORD</u>	
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>EQ 1MG BASE/ML</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>EQ 1MG BASE/ML</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>EQ 1MG BASE/ML</u>
<u>AP</u>	<u>FAULDING</u>
<u>AP</u>	<u>EQ 1MG BASE/ML</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>TAYLOR</u>
<u>AP</u>	<u>EQ 5MG BASE/ML</u>
<u>AP</u>	<u>TAYLOR PHARMA</u>
<u>AP</u>	<u>VERSED</u>
<u>AP</u>	<u>+ ROCHE</u>
<u>AP</u>	<u>+ </u>
*	*
*	*
<u>MINOCYCLINE HYDROCHLORIDE</u>	
<u>CAPSULE; ORAL</u>	
<u>MINOCYCLINE HCL</u>	
<u>AB + DANBURY PHARMA</u>	<u>EQ 75MG BASE</u>
*	*

MONTELUKAST SODIUM

<u>TABLET, CHEWABLE; ORAL</u>	
<u>SINGULAIR</u>	<u>EQ 4MG BASE</u>
<u>MERCK</u>	
	<u>N20830 002</u>
	<u>MAR 03, 2000</u>
<u>MORPHINE SULFATE</u>	
<u>TABLET, EXTENDED RELEASE; ORAL</u>	
<u>MORPHINE SULFATE</u>	
<u>ESI LEDERLE</u>	<u>15MG</u>
	<u>N75407 001</u>
	<u>JAN 28, 2000</u>
<u>NABUMETONE</u>	
<u>TABLET; ORAL</u>	
<u>NABUMETONE</u>	
<u>AB</u>	<u>COOPLEY PHARM</u>
	<u>750MG</u>
<u>AB</u>	<u>TEVA</u>
	<u>500MG</u>
<u>RELAFEN</u>	
<u>SMITHKLINE BEECHAM</u>	
<u>AB</u>	<u>500MG</u>
	<u>N19583 001</u>
	<u>DEC 24, 1991</u>
	<u>N19583 002</u>
	<u>DEC 24, 1991</u>
	<u>N19583 003</u>
	<u>DEC 24, 1991</u>
	<u>N19583 002</u>
	<u>DEC 24, 1991</u>
<u>NADOLOL</u>	
<u>TABLET; ORAL</u>	
<u>CORGARD</u>	
<u>NEOTHECON</u>	
<u>AB</u>	<u>40MG</u>
	<u>N18063 001</u>
	<u>N18063 001</u>
<u>NAFCILLIN SODIUM</u>	
<u>TABLET; ORAL</u>	
<u>NAFCILLIN</u>	
<u>AB</u>	<u>40MG</u>
	<u>N63065 002</u>
	<u>JUN 10, 1999</u>
	<u>N63065 002</u>
	<u>JUN 10, 1999</u>

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION
REVEX

+ BAXTER PHARM PROD
EQ 0 .1MG BASE/ML

EQ 1MG BASE/ML

~~EQ 0 .1MG BASE/ML~~

~~EQ 1MG BASE/ML~~

N20459 001
APR 17, 1995
N20459 002
APR 17, 1995
N20459 001
APR 17, 1995
N20459 002
APR 17, 1995

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES
RANBAXY
EQ 0 .5MG BASE;
EQ 50MG BASE

N75523 001
MAR 17, 2000

AB + BAYER
30MG

NIFEDIPINE
ELAN PHARM
30MG

N75434 001
MAR 08, 2000
AB + SHIRE LABS
30MG

NALTRXONE HYDROCHLORIDE

TABLET; ORAL

NALTRXONE HCL
EON
50MG

N75061 001
FEB 18, 1998
N75061 002
FEB 18, 1998
N75061 001
FEB 18, 1998

NAPROXEN
NAPROXEN
GENEVA PHARMS TECH
375MG

AB + SHIRE LABS
375MG
NITROGLYCERIN
PARKE DAVIS
0 .3MG

N75061 001
FEB 18, 1998
N75061 002
FEB 18, 1998
N75061 001
FEB 18, 1998

N21134 001
MAY 01, 2000
N21134 002
MAY 01, 2000
N21134 003
MAY 01, 2000

+
N5795 001
NO5795 001

NIACIN
NIACIN
GENERAL PHARM
300MG

N83115 001

NIACIN

TABLET; ORAL

NIACIN
@ IMPAX LABS

NIACOR
UPSHER SMITH
AA
APR 17, 1995

N20459 001
APR 17, 1995
N20459 002
APR 17, 1995
N20459 001
APR 17, 1995
N20459 002
APR 17, 1995

500MG
500MG

N20198 001
APR 21, 1993
N83789 001
N83789 001

N20198 001
APR 21, 1993
N75128 001
MAR 10, 2000

N20198 001
APR 21, 1993
N75128 001
MAR 10, 2000

NITROFURAZONE

CREAM; TOPICAL

FURACIN
* ROBERTS LABS
+ SHIRE LABS
0 .2%

NITROGLYCERIN
* ROBERTS LABS
+ SHIRE LABS
0 .2%

NITROGLYCERIN
* ROBERTS LABS
+ SHIRE LABS
0 .2%

NORTRIPTYLINE HYDROCHLORIDE

CAPSULE; ORAL
NORTRIPTYLINE HCL

<u>AB</u>	<u>EQ 10MG BASE</u>	N75520 004 MAY 08, 2000
<u>AB</u>	<u>EQ 25MG BASE</u>	N75520 003 MAY 08, 2000
<u>AB</u>	<u>EQ 50MG BASE</u>	N75520 001 MAY 08, 2000
<u>AB</u>	<u>EQ 75MG BASE</u>	N75520 002 MAY 08, 2000

INJECTABLE; INJECTION
SANDOSTATIN LAR
NOVARTIS

+ EQ 0.2MG BASE/ML	N19667 004 JUN 12, 1991
+ EQ 0.2MG BASE/ML	N19667 005 JUN 12, 1991
+ EQ 1MG BASE/ML	N19667 004 JUN 12, 1991
+ EQ 1MG BASE/ML	N19667 005 JUN 12, 1991

EQ 1MG BASE/VIAL
SANDOSTATIN LAR
NOVARTIS

+ EQ 20MG BASE/VIAL	N21008 001 NOV 25, 1998
+ EQ 10MG BASE/VIAL	N21008 002 NOV 25, 1998
+ EQ 20MG BASE/VIAL	N21008 001 NOV 25, 1998
+ EQ 20MG BASE/VIAL	N21008 002 NOV 25, 1998

OLANZAPINE

TABLET; ORAL
ZYPREXA
LILLY

1.0MG + 1.5MG + 2.5MG	N20592 004 SEP 30, 1996 N20592 005 SEP 09, 1997 N21086 001 APR 06, 2000 N21086 002 APR 06, 2000 N21086 003 APR 06, 2000 N21086 004 APR 06, 2000
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OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL
NOVARTIS

1.50MG + 3.00MG + 6.00MG +	N40327 001 FEB 15, 2000 N40284 001 JUN 19, 1998 N40368 001 JUN 23, 2000 N40284 001 JUN 19, 1998
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OLANZAPINE

TABLET; ORAL
ZYPREXA
LILLY

1.0MG + 1.5MG + 2.5MG	N20592 001 SEP 30, 1996 N20592 004 SEP 09, 1997 N20592 001 SEP 30, 1996
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TABLET, ORALLY DISINTEGRATING; ORAL
ZYPREXA ZYDIS
LILLY

5MG	N21086 001 APR 06, 2000 N21086 002 APR 06, 2000 N21086 003 APR 06, 2000 N21086 004 APR 06, 2000
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TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE
EON

1.00MG	N40327 001 FEB 15, 2000 N40284 001 JUN 19, 1998
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TABLET; ORAL
GENEVA PHARMS TECH

1.00MG	N40368 001 JUN 23, 2000
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TABLET; ORAL
IMPAX PHARM

1.00MG	N40284 001 JUN 19, 1998
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TABLET; ORAL
INTAMED

1.00MG	
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OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

OXYCONTIN
HARPER PHARMS
10MG+
10MG> ADD >
> ADD >ROXICODONE
ROXANNE
10MG@
10MG

30MG

@
30MGPANTOPRAZOLE SODIUM
PROTONIX
+ WYETH AYERSTTABLET, DELAYED RELEASE; ORAL
EQ 40MG BASEFEB 02, 2000
N20987 001

PENTAMIDINE ISETHIONATE

PEMOLINE

TABLET; ORAL

PEMOLINE
INAMED
37.5MGAB
37.5MGN20553 001
DEC 12, 1995
N20553 001
DEC 12, 1995
N20553 005
MAR 15, 2000

160MG

AB
VINTAGE PHARMS
18.75MGN20932 001
OCT 26, 1998
N20932 002
OCT 26, 1998

10MG

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

30MG

AB
> ADD >
> ADD >PEMOLINE
AMIDE PHARM
37.5MGCOPLEY PHARM
37.5MG

PEMOLINE

TABLET; ORAL
PEMOLINE
AMIDE PHARM
18.75MGAB
37.5MGAB
75MGAB
COPLEY PHARM
37.5MGAB
37.5MGPENTOXIFYLLINE

TABLET, EXTENDED RELEASE; ORAL

PENTOXIFYLLINE
ARMOUR PHARM
400MG/VIALAB
400MG/VIALN73447 001
APR 28, 1994N73447 001
APR 28, 1994N75093 001
AUG 10, 1999N75093 001
AUG 10, 1999

<u>PERFLUOROPOLY(2-METHYLISOPROPYL) ETHER; POLY(TETRAFLUOROETHYLENE)</u>		<u>PREDNISOLONE SODIUM PHOSPHATE</u>
PASTE; TOPICAL SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS + US ARMY	50%; 50%	N21084 001 FEB 17, 2000
<u>PERINDOPRIL ERBITUME</u>		
TABLET; ORAL ACEON		N20184 001 DEC 30, 1993
@@@		N20184 002 DEC 30, 1993
@@@		N20184 003 DEC 30, 1993
@@@		N20184 003 DEC 30, 1993
SOLVAY PHARMA	2MG	N20184 001 DEC 30, 1993
	4MG	N20184 002 DEC 30, 1993
+	8MG	N20184 003 DEC 30, 1993
<u>PHENDIMETRAZINE TARTRATE</u>		
TABLET; ORAL BONTRIL PDM		N85272 001 N85272 001
AA ANARIN PHARMS CARMICK		35MG 35MG
<u>PREDNISOLONE</u>		
SYRUP; ORAL PRENDISOLONE		15MG/5ML
AA COPLEY PHARM		
<u>TABLET; ORAL PRENDISOLONE</u>		
@@@ GLOBAL PHARMA		N80780 001
@@@ IMPAX LABS		N80780 001
@@@ PHOENIX LABS NY		N80322 001
@@@		N80322 001
<u>PROCHLORPERAZINE</u>		
SUPPOSITORY; RECTAL COMPRO		AB PADDOCK
		25MG

PROGESTERONE

CAPSULE; ORAL
PROMETRUM
 SCHERING PLough

<u>100MG</u>	N19781 001 MAY 14, 1998 N19781 002 OCT 15, 1999
<u>200MG</u>	
*	
UNIMED PHARMS	
+	

PROMETHAZINE HYDROCHLORIDE

<u>INJECTABLE; INJECTION</u>	
<u>PROMETHAZINE HCL</u>	
<u>AB</u>	<u>25MG/ML</u>
<u>AP</u>	<u>50MG/ML</u>

PROPANTHELINE BROMIDE

CAPSULE; ORAL	
PRO-BANTHINE	
* ROBERTS LABS	
BP *	7.5MG 15MG
BP + SHIRE LABS	7.5MG 15MG
BP +	
> DLT >	
> DLT >	
> ADD >	
> ADD >	

PROPRAKACAINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC	
<u>PROPRACAINE HCL</u>	
<u>AT TAYLOR PHARMA</u>	<u>0.5%</u>

PROTOKYLOL HYDROCHLORIDE

CAPSULE; ORAL	
VENTAIRE	
@ AVENTIS PHARMS	
* HORCHST MARION RESSL	
BP 2MG	2MG

	N19781 001
	MAY 14, 1998
	N19781 002
	OCT 15, 1999
	N19781 003

TABLET; ORAL	
<u>QUINIDINE SULFATE</u>	
<u>RANBAXY</u>	

TABLET; ORAL	
<u>QUINIDINE SULFATE</u>	
<u>RANBAXY</u>	

RANITIDINE HYDROCHLORIDE

CAPSULE; ORAL	
<u>RANITIDINE</u>	
<u>RANBAXY</u>	
BP	EQ 150MG BASE

RESERPINE

CAPSULE; ORAL	
RESERPINE	
GLOBUL PHARM	0.1MG
BP	0.25MG

RIVASTIGMINE TARTRATE

CAPSULE; ORAL	
EXELON	EQ 1.5MG BASE
NOVARTIS	
+	

SOLUTION; OPHTHALMIC	
<u>PROPARACAIN HCL</u>	
<u>AT TAYLOR PHARMA</u>	<u>0.5%</u>
BP	EQ 4.5MG BASE
	N20823 005
+	

RIVASTIGMINE TARTRATE

SOLUTION; ORAL EXELON + NOVARTIS	EQ 2MG BASE/ML	N21025 001 APR 21, 2000	<u>AB</u> <u>BETAPACE</u> BERLEX LABS	<u>80MG</u> <u>120MG</u>	N19865 001 OCT 30, 1992 N19865 005 APR 20, 1994 N19865 002 OCT 30, 1992 N19865 003 OCT 30, 1992 N19865 004 OCT 30, 1992 N19865 005 APR 20, 1994 N19865 006 APR 20, 1994 N19865 007 OCT 30, 1992 N19865 008 OCT 30, 1992	
<u>SELENIUM HYDROCHLORIDE</u>						
LOTION/SHAMPOO; TOPICAL SELENIUM SULFIDE ZENITH COSMETICS 2.5%	N85777 001 N85777 001 @	N85777 001 N85777 001 2.5%	<u>AB</u> +	<u>160MG</u> <u>240MG</u> <u>80MG</u> <u>120MG</u> <u>160MG</u> <u>240MG</u>	N19865 001 OCT 30, 1992 N19865 002 APR 20, 1994 N19865 003 OCT 30, 1992 N19865 004 APR 20, 1994 N19865 005 OCT 30, 1992 N19865 006 APR 20, 1994 N19865 007 OCT 30, 1992 N19865 008 OCT 30, 1992	
SEVELAMER HYDROCHLORIDE						
> ADD > > ADD > > ADD > > ADD > > ADD >	TABLET; ORAL RENAGEL GELTEX	400MG 800MG	N21179 001 JUL 12, 2000 N21179 002 JUL 12, 2000 +	BETAPACE AF BERLEX LABS	80MG 120MG 160MG	N21151 001 FEB 22, 2000 N21151 002 FEB 22, 2000 N21151 003 FEB 22, 2000
<u>SODIUM FLUORIDE, F-18</u>						
INJECTABLE; INTRAVENOUS FLUORINE F-18 @ NYCOMED AMERSHAM	2mCi/ML	N17042 001	<u>AB</u> +	<u>80MG</u> <u>120MG</u> <u>160MG</u>	N75366 001 MAY 01, 2000 N75366 002 MAY 01, 2000 N75366 003 MAY 01, 2000 N75366 004 MAY 01, 2000 N75237 001 MAY 01, 2000 N75237 002 MAY 01, 2000 N75237 003 MAY 01, 2000 N75237 004 MAY 01, 2000 N75429 001 MAY 01, 2000 N75429 002 MAY 01, 2000	
<u>SOMATOTROPIN RECOMBINANT</u>						
INJECTABLE; INJECTION NORDITROPIN NOVO NORDISK	5MG/1.5ML	N21148 001 JUN 20, 2000 N21148 002 JUN 20, 2000 N21148 003 JUN 20, 2000 +	<u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u> <u>AB</u>	<u>GENPHARM</u> <u>120MG</u> <u>160MG</u> <u>240MG</u> <u>80MG</u> <u>120MG</u> <u>160MG</u> <u>240MG</u>	N75366 001 MAY 01, 2000 N75366 002 MAY 01, 2000 N75366 003 MAY 01, 2000 N75237 001 MAY 01, 2000 N75237 002 MAY 01, 2000 N75237 003 MAY 01, 2000 N75237 004 MAY 01, 2000 N75429 001 MAY 01, 2000 N75429 002 MAY 01, 2000	

TERAZOSIN HYDROCHLORIDE

<u>AB</u>	CAPSULE; ORAL TERAZOSTIN HCL MYLAN	<u>EQ 10MG BASE</u>	N75140 004 FEB 11, 2000
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TABLET; ORAL
TERAZOSTIN HCL

<u>AB</u>	TABLET; ORAL TERAZOSTIN HCL INVAMED	<u>EQ 1MG BASE</u>	N74657 001 APR 28, 2000
<u>AB</u>		<u>EQ 2MG BASE</u>	N74657 002 APR 28, 2000
<u>AB</u>		<u>EQ 5MG BASE</u>	N74657 003 APR 28, 2000
<u>AB</u>		<u>EQ 10MG BASE</u>	N74657 004 APR 28, 2000
<u>AB</u>	NOVOPHARM	<u>EQ 1MG BASE</u>	N74446 001 MAY 18, 2000
<u>AB</u>		<u>EQ 2MG BASE</u>	N74446 002 MAY 18, 2000
<u>AB</u>		<u>EQ 5MG BASE</u>	N74446 003 MAY 18, 2000
<u>AB</u>		<u>EQ 10MG BASE</u>	N74446 004 MAY 18, 2000
<u>AB</u>	ZENITH GOLDLINE	<u>EQ 1MG BASE</u>	N74530 001 APR 21, 2000
<u>AB</u>		<u>EQ 2MG BASE</u>	N74530 002 APR 21, 2000
<u>AB</u>		<u>EQ 5MG BASE</u>	N74530 003 APR 21, 2000
<u>AB</u>		<u>EQ 10MG BASE</u>	N74530 004 APR 21, 2000

TESTOSTERONE

<u>BX</u>	FILM, EXTENDED RELEASE; TRANSDERMAL ANDRODERM	<u>5MG/24HR</u>	N20489 002 MAY 02, 1997
<u>BX</u>	+ WATSON LABS	<u>2.5MG/24HR</u>	N20489 001 SEP 29, 1995
	+	<u>5MG/24HR</u>	N20489 002 MAY 02, 1997

TICLOPIDINE HYDROCHLORIDE

<u>BX</u>	FILM, EXTENDED RELEASE; TRANSDERMAL ANDRODERM	<u>5MG/24HR</u>	N20489 002 MAY 02, 1997
<u>AB</u>	TABLET; ORAL TICLOPIDINE HCL	<u>250MG</u>	N75309 001 APR 26, 2000

<u>AB</u>	<u>TABLET; ORAL TICLOPIDINE HCL</u>	<u>250MG</u>
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TRIFLUOPERAZINE HYDROCHLORIDE

TABLET; ORAL
TRIFLUOPERAZINE HCL

<u>AA</u>	DLT >		EQ 1MG BASE	
<u>AA</u>	DLT >		EQ 2MG BASE	
<u>AA</u>	DLT >		EQ 5MG BASE	
<u>AA</u>	DLT >		EQ 10MG BASE	
<u>AA</u>	DLT >			
<u>AA</u>	DLT >	@		
<u>AA</u>	ADD >			
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		
<u>AA</u>	ADD >	@		

<u>AA</u>	WEST WARD	<u>TRIHEXYPHENIDYL HCL</u>	<u>2MG</u>	
<u>AA</u>			<u>5MG</u>	

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL

<u>AA</u>	WEST PHARMACEUTICALS PRESERVE	<u>EQ 25MG BASE/5ML</u>	<u>100ML</u>	
	+			

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
NEUTREXIN

<u>AA</u>	MEDIMMUNE ONCOLOGY	<u>EQ 25MG BASE/VIAL</u>	<u>N20326 001</u>	
			<u>DEC 17, 1993</u>	

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
NEUTREXIN

<u>AA</u>	WES BIOCILIANA	<u>EQ 25MG BASE/VIAL</u>	<u>N20326 001</u>	
			<u>DEC 17, 1993</u>	

TRIPTORELIN PAMOATE

INJECTABLE; INJECTION
TRELSTAR DEPOT

<u>AA</u>	DEBIO RECHERCHE	<u>EQ 3.75MG BASE/VIAL</u>	<u>JUN 15, 2000</u>	

TROGLITTAZONE

TABLET; ORAL
PERRAY

<u>AA</u>	SANKO	<u>100MG</u>	<u>N20719 001</u>	
			<u>JAN 29, 1997</u>	

INJECTABLE; INJECTION
REZULIN

<u>AA</u>	DAVIS PHARMS	<u>200MG</u>	<u>N20720 001</u>	
			<u>JAN 29, 1997</u>	

<u>AA</u>		<u>N20326 001</u>	<u>DEC 17, 1993</u>

<u>TROPICAMIDE</u>	
<u>SOLUTION/DRIPS; OPHTHALMIC</u>	
<u>AT</u>	<u>ALCON UNIVERSAL</u>
<u>> ADD ></u>	<u>MIZA PHARMS USA</u>
<u>> ADD ></u>	<u>OPTORICS</u>
<u>> ADD ></u>	<u>VERTEPORFIN</u>
<u>> ADD ></u>	<u>URSODIOL</u>
<u>> ADD ></u>	<u>CAPSULE; ORAL</u>
<u>> ADD ></u>	<u>ACTIGALL</u>
<u>> ADD ></u>	<u>300MG</u>
<u>> ADD ></u>	<u>300MG</u>
<u>> ADD ></u>	<u>URSODIOL</u>
<u>> ADD ></u>	<u>AMIDE PHARM</u>
<u>> ADD ></u>	<u>300MG</u>
<u>> ADD ></u>	<u>300MG</u>
<u>> ADD ></u>	<u>TABLET; ORAL</u>
<u>> ADD ></u>	<u>URSO</u>
<u>> ADD ></u>	<u>250MG</u>
<u>> ADD ></u>	<u>+ AXCAN SCANDIPHARM</u>
<u>> ADD ></u>	<u>250MG</u>

VERAPAMIL HYDROCHLORIDE

<u>VERAPAMIL HYDROCHLORIDE</u>	
<u>TABLET, EXTENDED RELEASE; ORAL</u>	
<u>COVERA-HS</u>	<u>180MG</u>
<u>N89172 001</u>	<u>N20552 001</u>
<u>DEC 28, 1990</u>	<u>FEB 26, 1996</u>
<u>N87636 001</u>	<u>N20552 001</u>
<u>JUL 30, 1982</u>	<u>FEB 26, 1996</u>
<u>N87637 001</u>	<u>N20552 002</u>
<u>AUG 09, 1982</u>	<u>FEB 26, 1996</u>
<u>N87636 001</u>	<u>N20552 002</u>
<u>DEC 30, 1982</u>	<u>FEB 26, 1996</u>
<u>N87637 001</u>	<u>N20552 002</u>
<u>DEC 09, 1982</u>	<u>FEB 26, 1996</u>
<u>N89172 001</u>	<u>N20552 001</u>
<u>DEC 28, 1990</u>	<u>FEB 26, 1996</u>
<u>INJECTABLE; INJECTION</u>	
<u>VISUDYNE</u>	<u>15MG/VIAL</u>
<u>+ QLT</u>	<u>N21119 001</u>
	<u>APR 12, 2000</u>
<u>VITAMIN A</u>	
<u>CAPSULE; ORAL</u>	
<u>VITAMIN A</u>	<u>50,000 USP UNITS</u>
<u>GLOBAL PHARM</u>	<u>50,000 USP UNITS</u>
<u>@ IMPAX LABS</u>	<u>50,000 USP UNITS</u>
<u>N75517 001</u>	<u>N80952 001</u>
<u>MAR 14, 2000</u>	<u>N80952 001</u>
<u>N75592 001</u>	<u>N80952 001</u>
<u>MAY 25, 2000</u>	<u>N80952 001</u>
<u>VITAMIN A PALMITATE</u>	
<u>CAPSULE; ORAL</u>	
<u>VITAMIN A</u>	<u>EQ 50,000 UNITS BASE</u>
<u>GLOBAL PHARM</u>	<u>EQ 50,000 UNITS BASE</u>
<u>@ IMPAX LABS</u>	<u>EQ 50,000 UNITS BASE</u>
<u>@</u>	<u>EQ 50,000 UNITS BASE</u>
<u>N20675 001</u>	<u>N80953 001</u>
<u>DEC 10, 1997</u>	<u>N80955 001</u>
<u>N20675 001</u>	<u>N80953 001</u>
<u>DEC 10, 1997</u>	<u>N80955 001</u>
<u>WARFARIN SODIUM</u>	
<u>TABLET; ORAL</u>	
<u>WARFARIN SODIUM</u>	<u>3MG</u>
<u>INVAMED</u>	<u>6MG</u>
<u>> ADD ></u>	<u>JUL 26, 2000</u>
<u>> ADD ></u>	<u>N40196 009</u>
<u>> ADD ></u>	<u>JUL 26, 2000</u>
<u>> ADD ></u>	<u>N40196 008</u>
<u>> ADD ></u>	<u>N40196 009</u>
<u>> ADD ></u>	<u>JUL 26, 2000</u>
<u>VECURONIUM BROMIDE</u>	
<u>INJECTABLE; INJECTION</u>	
<u>VECURONIUM BROMIDE</u>	<u>10MG/VIAL</u>
<u>BEDFORD</u>	<u>20MG/VIAL</u>
<u>> ADD ></u>	<u>JUN 13, 2000</u>
<u>> ADD ></u>	<u>N75549 002</u>
<u>> ADD ></u>	<u>JUN 13, 2000</u>
<u>> ADD ></u>	<u>N75549 002</u>
<u>> ADD ></u>	<u>JUN 13, 2000</u>

ZOLMITRIPTAN

TABLET; ORAL	
ZOMIG	
IPR	
+	
2 . 5MG	N20768 001
5MG	NOV 25, 1997
2 . 5MG	N20768 002
5MG	NOV 25, 1997
2 . 5MG	N20768 001
5MG	NOV 25, 1997
2 . 5MG	N20768 002
5MG	NOV 25, 1997

ZONISAMIDE

CAPSULE; ORAL	
ZONEGRAN	
+	
DAINTIPPON	100MG
	N20789 001
	MAR 27, 2000

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'2000 - JUL'2000

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN
PERRIGO 650MG

N75077 001
FEB 25, 2000

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
BAYER BAYER 650MG
* BAYER 650MG
@ MERKERIN 650MG
* BAYER 650MG
@ BAYER 650MG

DIMETANE

TABLET, EXTENDED RELEASE; ORAL
DIMETANE @ WHITEHALL ROBINS 12MG
DIMERAPP * WHITEHALL ROBINS 12MG

BROMPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL
DIMETANE @ WHITEHALL ROBINS 12MG
DIMERAPP * WHITEHALL ROBINS 12MG

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

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

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL
SPONGE; TOPICAL
E-Z SCRUB
BECTON DICKINSON 4%

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

SOLUTION; TOPICAL
CHLORAPREP
+ MEDI FLEX HOSP 2%; 70%

CHLORPHENIRAMINE MALEATE; PHENYLPROPAOLAMINE HYDROCHLORIDE

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

CIMETIDINE

TABLET; ORAL
CIMETIDINE LEINER
200MG
NOVOPHARM
200MG

CLOTRIMAZOLE

CREAM; VAGINAL
TRIVAGIZOLE 3
+ TARO
2%

N10799 011
JUN 10, 1983
N10799 011
JUN 10, 1983
> ADD >
> ADD >
> ADD >
> ADD >

DOCOSANOL
CREAM; TOPICAL
ABREVA
+ AVANIR
10%

IBUPROFEN

CAPSULE; ORAL
IBUPROFEN
PHARM FORM
200MG

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

TABLET; ORAL
IBUPROFEN
LEINER
NOVOPHARM
200MG

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

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

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

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

OTC DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 7 / JAN'2000 - JUL'2000

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL LOPERAMIDE HCL LEINER	2MG N73254 001 JUL 30, 1993	TABLET; ORAL RANITIDINE LEINER	EQ 75MG BASE N75094 001 JUN 21, 1999
NOVOPHARM NC PERRIGO	2MG N73254 001 JUL 30, 1993	RANBAXY	EQ 75MG BASE N75132 001 JAN 14, 2000
NAPROXEN SODIUM	2MG N75232 001 JAN 06, 2000	PORPHARM	EQ 75MG BASE N75254 001 JAN 14, 2000

NAPROXEN SODIUM

TABLET; ORAL NAPROXEN SODIUM LEINER	EQ 200MG BASE N74635 001 JAN 13, 1997	ZENTITH GOLDLINE NOVOBID®	EQ 75MG BASE N75094 001 JUN 21, 1999
PERMETHRIN	EQ 260MG BASE N74635 001 JAN 13, 1997	TABLET; EFFERVESCENT; ORAL ZANTAC 75 * GLAXO WELLCOME	EQ 75MG BASE N20745 001 FEB 26, 1998

PERMETHRIN

LOTION; TOPICAL PERMETHRIN ALPHARMA	1% N75014 001 MAR 28, 2000	TERBINAFINE HYDROCHLORIDE	SOLUTION; TOPICAL LAMISIL AT + NOVARTIS
PIPERONYL BUTOXIDE; PYRETHRINS AEROSOL; TOPICAL RID MOUSSE + PFIZER	4%; EQ 0.33% BASE N21043 001 MAR 07, 2000		N21124 001 MAR 17, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL RANITIDINE CHELSEA LABS	EQ 75MG BASE N75212 001 JAN 14, 2000	TABLET; ORAL RANITIDINE CHEMINOR DRUGS	EQ 75MG BASE N75294 001 MAR 28, 2000
GENPHARM	EQ 75MG BASE N75497 001 JAN 14, 2000		

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

CUMULATIVE SUPPLEMENT NUMBER 7 JULY '00

NO JULY 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 July 2000

Name: Generic Name <u>TN=Trade Name</u>	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
1-(11-dodecylamino-10-hydronoxyundecyl)-3,7-dimethylxa prostate carcinoma. nethine hydrogen methanesulfonate	Treatment of hormone refractory prostate carcinoma.	Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle WA 98119 DD= 1/18/00 MA=
TN=		
3-(3,5-Dimethyl-1H-2yilmethylene)-1,3-dihydro-indol-2-one	Treatment of von Hippel-Lindau disease.	Sugen, Inc. 230 East Grand Ave. South San Francisco CA 94080 DD= 3/23/00 MA=
TN=		
Abetimus	Treatment of lupus nephritis.	La Jolla Pharmaceutical Co. 6455 Nancy Ridge Dr. San Diego CA 92121 DD= 7/28/00 MA=
TN=		
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 400 Seattle WA 98119 DD= 4/28/00 MA=
TN=Atrivex		

Orphan Products Designations and Approvals List
January through July, 2000

Name:		Sponsor & Address
Generic Name		DD=Date Designated
<u>TN=Trade Name</u>	<u>Indication Designated:</u>	<u>MA=Marketing Approval</u>
Bis(4-fluorophenyl)phenyla	Treatment of sickle cell disease.	ICAgén Inc.
cetamide		Ion Channel Advances
		PO Box 14487
		Durham NC 27709
TN=		DD= 3/2/00 MA=
 Brimonidine	 Treatment of anterior ischemic optic neuropathy.	 Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine CA 92623-9534
TN= Alphagan		DD= 2/7/00 MA=
 Carmustine	 Treatment of intracranial malignancies.	 Direct Therapeutics, Inc. 1001 Bayhill Dr., Suite 100 San Bruno CA 94066
TN=		DD= 7/3/00 MA=
 Centruroides immune F(ab)2	 Treatment of scorpion envenomations requiring medical attention.	 Silanes Laboratories S.A. de Amores #1034 Col Del Valle C.P. 03100 Mexico D.F.
TN= Alacramyn		DD= 6/12/00 MA=
 Cetuximab	 Treatment of squamous cell cancer of the head and neck in patients who express epidermal growth factor receptor.	 ImClone Systems Incorporated Branchburg Corporate Center 22 Chubb Way Somerville NJ 08876
TN=		DD= 7/3/00 MA=

Orphan Products Designations and Approvals List
January through July, 2000

Name: Generic Name <u>TN=</u> Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Cisplatin/epinephrine <u>TN=</u> 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=
Deoxyribose, phosphorothioate <u>TN=</u>	Treatment of advanced malignant melanoma (Stages II, III, IV).	Genta, Inc. 99 Hayden Ave., Suite 200 Lexington MA 02421-7966 DD= 7/31/00 MA=
DNA-lipid complex (DMRIE/DOPE) /plasmid vector (VCL-1102, Vical) expressing human interleukin-2 <u>TN=</u> 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 <u>TN=</u>	Treatment of Huntington's disease.	Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA=
Flucinolone <u>TN=</u>	Treatment uveitis involving the posterior segment of the eye.	Bausch & Lomb 8500 Hidden River Parkway Tampa FL 33637 DD= 7/31/00 MA=

Orphan Products Designations and Approvals List
January through July, 2000

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

Orphan Products Designations and Approvals List
January through July, 2000

Name:
Generic Name
TN=Trade Name

Indication Designated:

Sponsor & Address
DD=Date Designated
MA=Marketing Approval

Iodine I 131 bis(indium-diethylenetriam inepentacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')2 bispecific monoclonal antibody <u>TN=Pentacea</u>	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 <u>TN=Duodopa</u>	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215
		DD= 1/18/00 MA=
Liposomal nystatin <u>TN=Nyotran</u>	Treatment of invasive fungal infections.	Aronex Pharmaceuticals, Inc. 8707 Technology Forest Place The Woodlands TX 77381-1191
		DD= 6/13/00 MA=
Meropenem <u>TN=Merrem IV</u>	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 <u>TN=</u>	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 July, 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=

4-6

Orphan Products Designations and Approvals List

January through July, 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 July, 2000

Name: Generic Name <u>TN=Trade Name</u>	<u>Indication Designated:</u>	Sponsor & Address DD=Date Designated MA=Marketing Approval
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Technetium Tc 99m pterotetramide	For the identification of ovarian carcinomas.	Endocyte, Inc. 1205 Kent Ave. Lafayette IN 47906
----------------------------------	---	--

TN=	DD= 2/16/00	MA=
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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.
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TN=	Underhill VT 05489	DD= 5/1/00	MA=
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Thymalfasin	Treatment of hepatocellular carcinoma.	SciClone Pharmaceuticals, 901 Mariner's Blvd., Suite San Mateo CA 94404
-------------	--	--

TN= Zadaxin	DD= 3/6/00	MA=
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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=
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Vapreotide	Prevention of early postoperative complications following pancreatic resection.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland CH
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TN= Octastatin	DD= 3/6/00	MA=
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8

Orphan Products Designations and Approvals List

January through July, 2000

Name:
Generic Name
TN=Trade Name

Indication Designated:

Sponsor & Address
DD=Date Designated
MA=Marketing Approval

vapreotide

Treatment of esophageal variceal hemorrhage patients with portal hypertension.

Debiopharm S.A.
17 rue des Terreaux
CH-1000 Lausanne 9
Switzerland CH
DD= 1/10/00 MA=

TN=Octastatin

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 JULY 2000 ADDITIONS

A-1

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 EXPIRES	PATENT/PED EXCL USE CODE	EXCL CODE	EXCLUS EXPIRES
>ADD> 075077 001	ACETAMINOPHEN ; ACETAMINOPHEN	4717720	MAY 31, 2010	PC	NOV 12, 2000	
>ADD> 020338 001	ADAPALENE ; DIFFERIN	4717720	MAY 31, 2010	NCE	MAY 31, 2001	
>ADD> 020380 001	ADAPALENE ; DIFFERIN	4717720	MAY 31, 2010	U-275 NDF	MAY 26, 2003	
>ADD> 020748 001	ADAPALENE ; DIFFERIN	RE34440	MAY 31, 2010			
>ADD> 020760 001	ALATROFLOXACIN MESYLATE ; TROVAN PRESERVATIVE	6080756	JUL 05, 2016			
>ADD> 020760 002	ALATROFLOXACIN MESYLATE ; TROVAN PRESERVATIVE	6080756	JUL 05, 2016			
>ADD> 020560 001	ALENDRONATE SODIUM ; FOSAMAX	6090410	DEC 02, 2012	U-303	M-3	NOV 24, 2002
>ADD> 020560 002	ALENDRONATE SODIUM ; FOSAMAX	6008207	JUN 06, 2015	DEC 02,	U-303	NOV 24, 2002
>ADD> 020560 003	ALENDRONATE SODIUM ; FOSAMAX	6090410	JUN 06, 2015	DEC 02,	U-303	NOV 24, 2002
021107 001	ALOSETRON HYDROCHLORIDE ; LOTRONEX	6008207	JUN 06, 2015	DEC 02,	M-3	NOV 24, 2002
020221 001	AMIFOSTINE ; ETHYOL	5723490	MAR 03, 2013	U-257		
020221 002	AMIFOSTINE ; ETHYOL	5646180	JUL 08, 2014	U-257		
021007 001	AMPRENAVIR ; AGENERASE	5585397	DEC 17, 2013			
021007 002	AMPRENAVIR ; AGENERASE	5723490	MAR 03, 2015	U-257		
021039 001	AMPRENAVIR ; AGENERASE	5646180	JUL 08, 2014	U-257		
020541 001	ANASTROZOLE ; ARIMIDEX	5585397	DEC 17, 2013			
020883 001	ARGATROBAN ; ACOVIA	5723490	MAR 03, 2015	U-257		
020971 001	ARTICAINE HYDROCHLORIDE ; SEPTOCAINE	5646180	JUL 08, 2014	U-257		
021127 001	AZELASTINE HYDROCHLORIDE ; OPTIVAR	RE36617	DEC 27, 2009			
>ADD>						
020610 001	BALSALAZIDE DISODIUM ; COLAZAL	5164194	NOV 01, 2010	NCE	JUN 30, 2005	
021055 001	BEVAROTENE ; TARGETRETIN	5164194*	MAY 01, 2011	NC	APR 03, 2003	
021056 001	BEVAROTENE ; TARGETRETIN			NDF	NOV 01, 2001	
019982 001	BISOPROLOL FUMARATE ; ZEBETA			PED	MAY 22, 2003	
019982 002	BISOPROLOL FUMARATE ; ZEBETA			PED	MAY 01, 2002	
				PED	NOV 22, 2003	
				PED	NOV 22, 2003	
>ADD>				NCE	JUL 18, 2005	
020155 001	BEXAROTENE ; TARGETRETIN	4412992	JUL 08, 2001	ODE	DEC 29, 2006	
021056 001	BEXAROTENE ; TARGETRETIN			NCE	DEC 29, 2004	
019982 001	BISOPROLOL FUMARATE ; ZEBETA					
020186 001	BISOPROLOL FUMARATE ; ZIAC	4258062	MAR 24, 2000	U-63		
020186 002	BISOPROLOL FUMARATE ; ZIAC	4258062	SEP 24, 2000	U-63		
020186 003	BISOPROLOL FUMARATE ; ZIAC	4258062	MAR 24, 2000	U-63		
		4258062	SEP 24, 2000	U-63		
		4258062	MAR 24, 2000	U-63		
		4258062	SEP 24, 2000	U-63		
		4258062	MAR 24, 2000	U-63		
		4258062	SEP 24, 2000	U-63		
		4258062	MAR 24, 2000	U-63		
		4258062	SEP 24, 2000	U-63		
		4258062	MAR 24, 2000	U-63		
		4358062	SEP 24, 2000	U-63		

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 CODE		EXCLUS CODE EXPIRES	
			EXPIRES	CODE	CODE	EXPIRES
>ADD>	BLEOMYCIN SULFATE; BIENOXANE	4787536	FEB 27,	2006	ODE	FEB 20, 2003
050443 002	BUDENSONIDE; PULMICORT RESPULES	4787536	FEB 27,	2006	NDF	AUG 08, 2003
020929 001	BUDENSONIDE; PULMICORT RESPULES				NDF	AUG 08, 2003
>ADD>	BUPROPION HYDROCHLORIDE; ZYBAN				D-54	SEP 10, 2002
020711 002	BUPROPION HYDROCHLORIDE; ZYBAN				D-54	SEP 10, 2002
020711 003	BUSPIRONE HYDROCHLORIDE; BUSPAR					
018731 001	BUSPIRONE HYDROCHLORIDE; BUSPAR	4182763	MAY 22,	2000	U-13	
		5015646	MAY 14,	2008		
		4182763*PED	NOV 22,	2000	U-13	
018731 002	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646*PED	NOV 14,	2008		
		4182763	MAY 22,	2000	U-13	
		5015646	MAY 14,	2008		
		4182763*PED	NOV 22,	2000	U-13	
018731 003	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646*PED	NOV 14,	2008		
		4182763	MAY 22,	2000	U-13	
		5015646	MAY 14,	2008		
		4182763*PED	NOV 22,	2000	U-13	
018731 004	BUSPIRONE HYDROCHLORIDE; BUSPAR	5015646*PED	NOV 14,	2008		
		4182763	MAY 22,	2000	U-13	
		5015646	MAY 14,	2008		
		4182763*PED	NOV 22,	2000	U-13	
		5015646*PED	NOV 14,	2008		
020793 001	CAFFEINE CITRATE; CAFCIT	6051567	AUG 02,	2019		
018874 001	CALCITRIOL; CALCITREX	6051567	AUG 02,	2019		
018874 002	CALCITRIOL; CALCITREX	4966891	JAN 13,	2011		
>ADD>	CAPECTABINE; XELODA	4966891	JAN 13,	2011	U-272	
020896 001	CAPECTABINE; XELODA	5902821	FEB 07,	2016		
>ADD>	CAPECTABINE; XELODA	5902821	FEB 07,	2016	U-313	
020297 002	CARVEDILOL; COREG	5902821	FEB 07,	2016	U-313	
020297 001	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					
020740 002	CERIVASTATIN SODIUM; BAYCOL					
020740 003	CERIVASTATIN SODIUM; BAYCOL					
020740 004	CERIVASTATIN SODIUM; BAYCOL					
020740 005	CERIVASTATIN SODIUM; BAYCOL					
>ADD>	CERIVASTATIN SODIUM; BAYCOL					
>ADD>	CEVIMELINE HYDROCHLORIDE; EVOXAC	5006530	JAN 17,	2009		
020740 006	CEVIMELINE HYDROCHLORIDE; EVOXAC	5177080	JAN 26,	2011		
020989 002	CEVIMELINE HYDROCHLORIDE; EVOXAC	4855290	AUG 08,	2006		
		5340821	AUG 23,	2011		
		5580880	JUN 06,	2015		
					U-309	
					U-310	
					NS	
					JUN 11,	2005

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

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXPIRES
020832 001	CHLORHEXIDINE GLUCONATE; CHLORAPREP					NC	JUL 14, 2003
021142 001	CLOBETASOL PROPIONATE; OLUX FOAM					NDF	MAY 26, 2003
021143 001	CLOTRIMAZOLE; TRIVAGIZOLE ³					NP	NOV 24, 2001
021141 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	5624963	APR 29, 2014	DEC 02, 2014	JUN 10, 2014	U-323 NCE	MAY 26, 2005
		5679717	APR 29, 2014	DEC 02, 2014	U-323 NCE	U-323	
		5693675					
021176 001	COLESEVELAM HYDROCHLORIDE; WELCHOL	5607669	JUN 10, 2014	DEC 02, 2014	U-323 NCE	U-323	
		5917007	APR 29, 2014	DEC 02, 2014	U-323 NCE	U-323	
		5919832	JUN 10, 2014	DEC 02, 2014	U-323 NCE	U-323	
		5919832	JUN 10, 2014	DEC 02, 2014	U-323 NCE	U-323	
		5917007	APR 29, 2014	DEC 02, 2014	U-323 NCE	U-323	
		5607669	JUN 10, 2014	DEC 02, 2014	U-323 NCE	U-323	
020154 002	DIDANOSINE; VIDEX	5693675	JUN 10, 2014	DEC 02, 2014	U-323 NCE	U-323	
020154 003	DIDANOSINE; VIDEX	5679717	APR 29, 2014	DEC 02, 2014	U-323 NCE	U-323	
020154 004	DIDANOSINE; VIDEX	5624963	APR 29, 2014	DEC 02, 2014	U-323 NCE	U-323	
020154 005	DIDANOSINE; VIDEX					D-58	OCT 28, 2002
020154 006	DIDANOSINE; VIDEX					D-58	OCT 28, 2002
020939 001	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5616566	AUG 29, 2006	DEC 02, 2014	JUN 10, 2014	U-180 NS	OCT 28, 2002
020939 002	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5288505	JUN 26, 2011	DEC 02, 2014	JUN 25, 2013	D-58 NS	OCT 28, 2002
020939 003	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5529791	JUN 26, 2011	DEC 02, 2014	JUN 25, 2013	D-58 NS	OCT 28, 2002
020939 004	DILTIAZEM HYDROCHLORIDE; DILTIAZEM HCL	5288505	JUN 26, 2011	DEC 02, 2014	JUN 25, 2013	D-58 NS	OCT 28, 2002
>ADD>	021168 001	DIVALPROEX SODIUM; DEPAKOTE ER	4988731	JAN 29, 2008	APR 03, 2007	NP	AUG 04, 2003
>ADD>	020941 001	DOCOSANOL; ABREVA	4913906	APR 03, 2007		NCE	JUL 25, 2005
>ADD>	020941 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET	4906775	MAR 06, 2007			
>ADD>	020623 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET	4906775	MAR 06, 2007			
>ADD>	020623 002	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET	4906775	MAR 06, 2007			
>ADD>	020624 001	DOLASETRON MESYLATE MONOHYDRATE; ANZEMET	4797413	APR 28, 2008	OCT 28, 2003	U-103	
>ADD>	020869 001	DORZOLAMIDE HYDROCHLORIDE; COSOPT	4619939	APR 03, 2007			
>ADD>	021027 001	DOXERCALCIFEROL; HECTROL	5602116	APR 03, 2007			
>ADD>	021145 001	EFLORNITHINE HYDROCHLORIDE; VANIQA	5707980	FEB 11, 2000			
>ADD>	019221 001	ENALAPRIL MALEATE; VASERETIC	4472380	JAN 19, 2005			
>ADD>			4374829	FEB 22, 2000			
>ADD>			4374829*PED	AUG 22, 2000			
>ADD>			4472380*PED	MAR 18, 2002			

PRESCRIPTION AND OTC DRUG PRODUCT

PATENT AND EXCLUSIVITY DATA

* PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXPIRES
019221 003	ENALAPRIL MALEATE; VASERETIC	4472380 4374829	SEP 18, 2001 FEB 22, 2000				
018998 001	ENALAPRIL MALEATE; VASOTEC	4374829*PED 4472380*PED	FEB 22, 2000 MAR 18, 2002				
018998 002	ENALAPRIL MALEATE; VASOTEC	4374829 4374829*PED	FEB 22, 2000 AUG 22, 2000				
018998 003	ENALAPRIL MALEATE; VASOTEC	4374829 4374829*PED	FEB 22, 2000 AUG 22, 2000				
018998 005	ENALAPRIL MALEATE; VASOTEC	4374829 4374829*PED	FEB 22, 2000 AUG 22, 2000				
019309 001	ENALAPRILAT; VASOTEC	4374829 4374829*PED	FEB 22, 2000 AUG 22, 2000				
020444 001	EPPROSTENOL SODIUM; FLOLAN	4374829 4374829*PED	FEB 22, 2000 AUG 22, 2000				
020444 002	EPPROSTENOL SODIUM; FLOLAN	4374829 4374829*PED	FEB 22, 2000 AUG 22, 2000				
020907 001	ESTRADIOL; ACTIVELLE	5108995 5382573	APR 28, 2009 JAN 17, 2012	U-311			
021040 001	ESTRADIOL; ORTHO-PREFEST						
<u>>ADD></u>	ETODOLAC; ETODOLAC	4966768*PED	APR 30, 2008				
020584 001	ETODOLAC; LODINE XL	4966768	OCT 30, 2007				
020584 002	ETODOLAC; LODINE XL	4966768*PED	APR 30, 2008				
020584 003	ETODOLAC; LODINE XL	4966768*PED	OCT 30, 2007				
019304 002	FENOFIBRATE; TRICOR (MICRONIZED)	6037353 5578610	MAR 14, 2017 NOV 26, 2013	U-138			
019304 003	FENOFIBRATE; TRICOR (MICRONIZED)	5932247 5855912	FEB 28, 2015 FEB 28, 2015	U-139 NDF			
019304 004	FENOFIBRATE; TRICOR (MICRONIZED)	4254129 6037353	FEB 17, 2001 MAR 14, 2017	U-139 U-138			
020625 001	FEKOENADINE HYDROCHLORIDE; ALLEGRA	6037353 5578610	NOV 26, 2013 FEB 28, 2015	U-139 U-139 NDF			
020872 001	FEKOENADINE HYDROCHLORIDE; ALLEGRA	5932247 5855912	FEB 28, 2015 FEB 28, 2015	U-139 NDF			
020872 002	FEKOENADINE HYDROCHLORIDE; ALLEGRA	4254129 5855912	FEB 17, 2001 FEB 28, 2015	U-139 U-139 NDF			
020872 004	FEKOENADINE HYDROCHLORIDE; ALLEGRA	4254129 6037353	MAR 14, 2017 NOV 26, 2013	U-139 U-139 NDF			

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

*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020786 001	FEXOFFENADINE HYDROCHLORIDE; ALLEGRA-D	6037353 6039974 4416682 4404216	MAR 14, 2017 JUL 31, 2018 JUN 02, 2001 JAN 29, 2004	U-138			
019949 004	FLUCONAZOLE; DIFLUCAN						
020378 001	FOLLITROPIN ALFA/BETA; GONAL-F						
>ADD>	020378 002	FOLLITROPIN ALFA/BETA; GONAL-F					
>ADD>	020235 001	GABAPENTIN; NEURONTIN					
020235 002	GABAPENTIN; NEURONTIN						
020235 003	GABAPENTIN; NEURONTIN						
020882 001	GABAPENTIN; NEURONTIN						
020882 002	GABAPENTIN; NEURONTIN						

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 EXPIRES	PATENT/PED EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
021037 001	GADOPENTETATE DIMEGLUMINE; MAGNEVIST	5362475 5560903 4647447 4957939 4963344 4507305 4423050 4355032 4642346 5606040 5693762 5739116 5767285 5773001 5790198 5079233 5585059 5981589 6054430	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	
020460 002	GANCICLOVIR; CYTOVENE	5362475 5560903 4647447 4957939 4963344 4507305 4423050 4355032 4642346 5606040 5693762 5739116 5767285 5773001 5790198 5079233 5585059 5981589 6054430	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	
021174 001	GEMTuzumab Ozogamicin; MYLOTARG	5362475 5560903 4647447 4957939 4963344 4507305 4423050 4355032 4642346 5606040 5693762 5739116 5767285 5773001 5790198 5079233 5585059 5981589 6054430	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	
020622 001	GLATIRAMER ACETATE; COPAXONE	5362475 5560903 4647447 4957939 4963344 4507305 4423050 4355032 4642346 5606040 5693762 5739116 5767285 5773001 5790198 5079233 5585059 5981589 6054430	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	
>ADD> >ADD> >ADD>	021178 001 021178 002 021178 003 020125 001 020125 002 020125 003 020125 003 019778 001 019778 002 019778 003 019771 001 >ADD> >ADD>	GLYBURIDE; GLUCOVANCE GLYBURIDE; GLUCOVANCE HYDROCHLOROTHIAZIDE; ACCURETIC HYDROCHLOROTHIAZIDE; ACCURETIC HYDROCHLOROTHIAZIDE; ACCURETIC HYDROCHLOROTHIAZIDE; PRINZIDE HYDROCHLOROTHIAZIDE; PRINZIDE HYDROCHLOROTHIAZIDE; PRINZIDE IBUPROFEN; ADVIL; COLD AND SINUS 019778 001 019778 002 019778 003 019771 001 019763 003 019763 004 020986 001 021081 001 020563 001 021018 001 020563 002 020571 001 020966 001 019084 001	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	
	IFOSFAMIDE; IFEX/MESNEX KIT IFOSFAMIDE; IFEX/MESNEX KIT INSULIN ASPART RECOMBINANT; NOVOLOG INSULIN GLARGINE; LANTUS INSULIN LISPRO; HUMALOG INSULIN LISPRO; HUMALOG MIX 50/50 INSULIN LISPRO; HUMALOG PEN IRINOTECAN HYDROCHLORIDE; CAMPTOSAR ITRACONAZOLE; SPORANOX KETOCONAZOLE; NIZORAL	5362475 5560903 4647447 4957939 4963344 4507305 4423050 4355032 4642346 5606040 5693762 5739116 5767285 5773001 5790198 5079233 5585059 5981589 6054430	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	
	IFOSFAMIDE; IFEX/MESNEX KIT IFOSFAMIDE; IFEX/MESNEX KIT INSULIN ASPART RECOMBINANT; NOVOLOG INSULIN GLARGINE; LANTUS INSULIN LISPRO; HUMALOG INSULIN LISPRO; HUMALOG MIX 50/50 INSULIN LISPRO; HUMALOG PEN IRINOTECAN HYDROCHLORIDE; CAMPTOSAR ITRACONAZOLE; SPORANOX KETOCONAZOLE; NIZORAL	5362475 5560903 4647447 4957939 4963344 4507305 4423050 4355032 4642346 5606040 5693762 5739116 5767285 5773001 5790198 5079233 5585059 5981589 6054430	NOV 08, 2011 OCT 01, 2013 MAR 03, 2004 MAR 03, 2004 MAR 03, 2004 MAY 21, 2001 MAY 21, 2001 JUN 23, 2003 JUN 24, 2005 FEB 25, 2014 DEC 02, 2014 APR 14, 2015 JUN 16, 2015 JUN 30, 2015 NOV 30, 2007 JAN 07, 2009 DEC 17, 2013 MAY 24, 2014 MAY 24, 2014	ODE NCE	MAY 17, 2007 MAY 17, 2005	

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

APPL/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	EXCLUS CODE	EXCLUS EXPIRES
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
020837 001	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5932547	JUN 13, 2017			
020837 002	LEVALBUTEROL HYDROCHLORIDE; XOPENEX	5985305	JAN 30, 2017			
>ADD>		5362755	NOV 08, 2011	U-332		
>ADD>		5547994	AUG 20, 2013	U-332		
>ADD>		5760090	JAN 05, 2010	U-332		
>ADD>		5844002	JAN 05, 2010	U-332		
021114 001	LEVOTAXOLOL HYDROCHLORIDE; BETAXON	5362755	NOV 08, 2011	U-332		
>ADD>	020634 001 LEVOFLOXACIN; LEVAQUIN	5547994	AUG 20, 2013	U-332		
>ADD>	020634 002 LEVOFLOXACIN; LEVAQUIN	5760090	JAN 05, 2010	U-332		
>ADD>	020635 001 LEVOFLOXACIN; LEVAQUIN IN DEXTROSE	5844002	JAN 05, 2010	U-332		
>ADD>	020635 002 LEVOFLOXACIN; LEVAQUIN IN DEXTROSE	5888792	NOV 18, 2014	U-319	NP	FEB 23, 2003
>ADD>	020635 003 LEVOFLOXACIN; LEVAQUIN IN DEXTROSE	5688792	NOV 18, 2014	U-319	NCE	I-305
>ADD>	020612 001 LIDOCAINE; LIDODERM	5688792	NOV 18, 2014	U-319	NCE	FEB 02, 2003
021130 001 LINEZOLID; ZYVOX	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
021130 002 LINEZOLID; ZYVOX	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
021131 001 LINEZOLID; ZYVOX	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
021132 001 LINEZOLID; ZYVOX	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019558 001 LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019558 002 LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019558 003 LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019558 004 LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019558 005 LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019558 006 LISINOPRIL; PRINIVIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019777 001 LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019777 002 LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019777 003 LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019777 004 LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019777 005 LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
019777 006 LISINOPRIL; ZESTRIL	4374829	DEC 29, 2001	U-319	NCE	I-305	FEB 02, 2003
>ADD>	019658 001 LORATADINE; CLARITIN	4282233	JUN 19, 2004	U-77		
>ADD>		4659716	APR 21, 2004	U-142		
>ADD>		4863931	SEP 15, 2008			
>ADD>		4282233	DEC 19, 2002	U-77		
>ADD>		4659716*	OCT 21, 2004	U-142		
>ADD>		4659716*	OCT 21, 2004	U-77		
>ADD>		4863931	SEP 15, 2008			
>ADD>		4659716*	OCT 21, 2004	U-142		
>ADD>		4863931*	PED MAR 15, 2009			
>ADD>		4282233	DEC 19, 2002	U-77		

PRESCRIPTION AND OTC DRUG PRODUCT

PATENT AND EXCLUSIVITY DATA
* PED and PED represent Pediatric Exclusivity

APP#,/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	USE CODE	EXCLUS CODE	EXCLUS CODE
>ADD> >ADD> >ADD> >ADD> >ADD> >ADD> >ADD> >ADD> >ADD> >ADD>	LORATADINE;CLARITIN REDITABS	4659716 4282233 4371516 4863931 4659716*PED 4282233*PED 4371516*PED 4863931*PED	APR 21, JUN 19, FEB 01, SEP 15, OCT 21, DEC 19, AUG 01, MAR 15,	2004 2002 2000 2008 2004 2002 2002 2000	U-142 U-77 U-77 U-142 U-77 U-142 U-77 U-77	
020704 001						
019670 001	LORATADINE;CLARITIN-D	4659716 4282233 4659716 4863931	JUN 19, APR 21, APR 21, SEP 15,	2002 2004 2004 2008	U-77 U-142 U-142 U-77	
020470 001	LORATADINE;CLARITIN-D 24 HOUR	4282233*PED 4659716*PED 4863931*PED 4659716 4282233 5314697 4863931 4659716*PED 4282233*PED 5314697*PED 4863931*PED	OCT 21, OCT 21, MAR 15, APR 21, JUL 19, OCT 23, SEP 15, OCT 21, JAN 19, OCT 23, MAR 15,	2002 2004 2009 2004 2002 2012 2008 2004 2003 2012	U-77 U-142 U-142 U-142 U-77 U-77 U-77 U-77 U-77 U-77	
020938 001	MELOXICAM;MOBIC	4980173 5696172	JAN 29, OCT 06,	2002 2013	U-78	NCE
020049 001 019884 001 020357 001	MESALAMINE,PENTASA MESNA;MESNEX METFORMIN HYDROCHLORIDE;GLUCOPHAGE				APR 13 , 2005	
020357 002	METFORMIN HYDROCHLORIDE;GLUCOPHAGE					
020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE					
>ADD> >ADD> >ADD> >ADD>	METHYLPHENIDATE HYDROCHLORIDE;CONCERTA METHYLPHENIDATE HYDROCHLORIDE;CONCERTA MIDODRINE HYDROCHLORIDE;PROAMATINE MIDODRINE HYDROCHLORIDE;PROAMATINE MONTELUKAST SODIUM;SINGULAIR	5256664 5256664 5256664 5256664 5256664	APR 28, APR 28, APR 28, APR 28, APR 28,	2012 2012 2012 2012 2012		
020152 001 020152 002 020152 003 020152 004 020152 005 020152 006	NEFAZODONE HYDROCHLORIDE;SERZONE NEFAZODONE HYDROCHLORIDE;SERZONE NEFAZODONE HYDROCHLORIDE;SERZONE NEFAZODONE HYDROCHLORIDE;SERZONE NEFAZODONE HYDROCHLORIDE;SERZONE NEFAZODONE HYDROCHLORIDE;SERZONE	5256664 5256664 5256664 5256664 5256664 5256664	APR 28, APR 28, APR 28, APR 28, APR 28, APR 28,	2012 2012 2012 2012 2012 2012		

PRESCRIPTION AND OTC DRUG PRODUCT

PATENT AND EXCLUSIVITY DATA

* PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME / TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXCLUSIVITY EXPIRES
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 4551456	SEP 02, 2003 NOV 14, 2003	U-80	I-297 NCE	I-297 NCE	MAR 17, 2003
020592 001	OLANZAPINE; ZYPREXA	5457895 5229382	SEP 30, 2013 APR 23, 2011	U-324	I-297 U-324	I-297 U-324	MAR 17, 2003
020592 002	OLANZAPINE; ZYPREXA	5605897	FEB 25, 2014	U-325			
020592 003	OLANZAPINE; ZYPREXA	5627178	APR 23, 2011	U-326			
020592 004	OLANZAPINE; ZYPREXA	5736541	MAR 24, 2015	U-328			
020592 005	OLANZAPINE; ZYPREXA	5817655	APR 23, 2011	U-327			
020592 006	OLANZAPINE; ZYPREXA	5817656	APR 23, 2011	U-326			
021086 001	OLANZAPINE; ZYPREXA ZYDIS	5457895 5229382	SEP 30, 2013 APR 23, 2011	U-324 U-324	NCE	SEP 30, 2001	
021086 002	OLANZAPINE; ZYPREXA ZYDIS	5605897 5627178	FEB 25, 2014 APR 23, 2011	U-325 U-326			
021086 003	OLANZAPINE; ZYPREXA ZYDIS	5736541 5736541	MAR 24, 2015 MAR 24, 2015	U-326 U-328			
021086 004	OLANZAPINE; ZYPREXA ZYDIS	5817655 5229382 5605897 5627178	APR 23, 2011 APR 23, 2011 FEB 25, 2014 APR 23, 2011	U-324 U-326 U-325 U-326	NCE	SEP 30, 2001	
		5457895 5229382 5605897 5627178	APR 23, 2011 APR 23, 2011 FEB 25, 2014 APR 23, 2011	U-326 U-327 U-324 U-326	NCE	SEP 30, 2001	

PRESCRIPTION AND OTC DRUG PRODUCT

PATENT AND EXCLUSIVITY DATA

*PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL USE CODE	EXCLUS CODE	EXCLUS EXPRIES
020885 004	PAROXETINE HYDROCHLORIDE ; PAXIL	6062927	APR 23, 2019			
020936 001	PAROXETINE HYDROCHLORIDE ; PAXIL CR	6080759	MAY 19, 2015			
020936 002	PAROXETINE HYDROCHLORIDE ; PAXIL CR	6063927	APR 23, 2019			
021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER ; SKIN EXPOSURE REDUCT	6080759	MAY 19, 2015			
019898 002	PRAVASTATIN SODIUM ; PRAVACHOL	5607979	MAY 30, 2015	NCE	FEB 17, 2005	
019898 003	PRAVASTATIN SODIUM ; PRAVACHOL			I-281	JUN 09, 2003	
019898 004	PRAVASTATIN SODIUM ; PRAVACHOL			I-304	JAN 18, 2003	
019898 005	PRAVASTATIN SODIUM ; PRAVACHOL			I-287	FEB 10, 2003	
019157 001	PREDNISOLONE SODIUM PHOSPHATE ; PEDIAPRED	4448774	DEC 22, 2002			
020630 001	REMIFENTANIL HYDROCHLORIDE ; ULTIVA	5019583 * PED	AUG 15, 2009	NPP	OCT 15, 2002	
020630 002	REMIFENTANIL HYDROCHLORIDE ; ULTIVA	5466700	AUG 30, 2013	U-156	APR 15, 2003	
020630 003	REMIFENTANIL HYDROCHLORIDE ; ULTIVA	5019583	FEB 15, 2009	PED	JAN 12, 2002	
020903 001	RIBAVIRIN ; REBETOL	5466700 * PED	MAR 01, 2014	U-156	NCE JUL 12, 2001	
020835 001	RISEDRONATE SODIUM ; ACTONEL	5019583	FEB 15, 2009	NPP	OCT 15, 2002	
020588 001	RISPERIDONE ; RISPERDAL	5466700	AUG 30, 2013	U-156	PED APR 15, 2003	
020659 001	RITONAVIR ; NORVIR	5019583 * PED	AUG 15, 2009	PED	JAN 12, 2002	
		5466700 * PED	MAR 01, 2014	U-156	NCE JUL 12, 2001	
		6051252	DEC 22, 2017			
020588 001	RISPERIDONE ; RISPERDAL	5453425	JUL 11, 2014	APR 14, 2003		
020659 001	RITONAVIR ; NORVIR	5616587	JUL 11, 2014	APR 14, 2003		
		6037157	JUN 26, 2016	I-290	APR 14, 2003	
		5674882	OCT 07, 2014	I-293	APR 14, 2003	
		5886036	DEC 29, 2012			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL USE CODE	EXCLUS CODE	EXCLUS EXPIRES
020823 003	RIVASTIGMINE TARTRATE; EXELON	4948807 5602176	AUG 14, 2007 FEB 11, 2014	U-322 NCE	APR 21, 2005	
020823 004	RIVASTIGMINE TARTRATE; EXELON	4948807 5602176	AUG 14, 2007 FEB 11, 2014	U-322 NCE	APR 21, 2005	
020823 005	RIVASTIGMINE TARTRATE; EXELON	4948807 5602176	AUG 14, 2007 FEB 11, 2014	U-322 NCE	APR 21, 2005	
020823 006	RIVASTIGMINE TARTRATE; EXELON	4948807 5602176	AUG 14, 2007 FEB 11, 2014	U-322 NCE	APR 21, 2005	
021025 001	RIVASTIGMINE TARTRATE; EXELON	4948807 5602176	AUG 14, 2007 FEB 11, 2014	U-322 NCE	APR 21, 2005	
020864 001	RIZATRIPTAN BENZOATE; MAXALT	5602162	FEB 11, 2014			
020864 002	RIZATRIPTAN BENZOATE; MAXALT	5602162	FEB 11, 2014			
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	ROSSIGLITAZONE MALEATE; AVANDIA	5002953	AUG 30, 2008	U-329	I-289	APR 03, 2003
021071 003	ROSSIGLITAZONE MALEATE; AVANDIA	5741803	APR 21, 2015	U-329	I-289	APR 03, 2003
021071 004	ROSSIGLITAZONE MALEATE; AVANDIA	5741803	APR 21, 2015	U-329	I-289	APR 03, 2003
020990 001	SERTRALINE HYDROCHLORIDE; ZOLOFT	4536518 4940731	DEC 30, 2005 AUG 30, 2009	U-286		
021179 001	SEVELAMER HYDROCHLORIDE; RENAGEL	5496545 5667775	AUG 11, 2013 SEP 16, 2014	U-246	NCE	OCT 30, 2003
021179 002	SEVELAMER HYDROCHLORIDE; RENAGEL	5496545 5667775	AUG 11, 2013 SEP 16, 2014	U-246	NCE	OCT 30, 2003
>ADD2	020478 001	SEVOFLURANE; ULTANE	5990176 6074668	JAN 27, 2017 JAN 09, 2018	U-246 NCE PED	JUN 07, 2000 DEC 07, 2000
>ADD2	020280 006	SOMATOTROPIN RECOMBINANT; GENOTROPIN	6074668*PED	JUL 27, 2017		
>ADD2	020280 007	SOMATOTROPIN RECOMBINANT; GENOTROPIN		JUL 09, 2018		
>ADD2	020280 001	SOMATOTROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076 5716338	APR 16, 2013 FEB 10, 2015	I-302	JUN 20, 2003
>ADD2	020280 002	SOMATOTROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076 5716338	APR 16, 2013 FEB 10, 2015	I-302	JUN 20, 2003
>ADD2	020280 003	SOMATOTROPIN RECOMBINANT; GENOTROPIN PRESERVAT	5435076 5716338	APR 16, 2013 FEB 10, 2015	I-302	JUN 20, 2003
>ADD2	020280 004	SOMATOTROPIN RECOMBINANT; GENOTROPIN PRESERVAT			I-302	JUN 20, 2003
>ADD2					ODE	JUN 20, 2007

PREScription AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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APPL / PROD NUMBER	INGREDIENT NAME ; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES		EXCLUS USE CODE		EXCLUS CODE EXPRIES	
			PATENT EXPIRES	PED EXPIRES	CODE	CODE	EXPIRES	
>ADD> 020280 005	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	FEB 10, 2015	I-302	JUN 20, 2003	ODE	JUN 20, 2007
>ADD> 020280 008	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5716338	APR 16, 2013	APR 16, 2013	I-302	JUN 20, 2003	ODE	JUN 20, 2007
>ADD> 020280 009	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5435076	FEB 10, 2015	APR 16, 2013	I-302	JUN 20, 2007	ODE	JUN 20, 2007
>ADD> 020280 010	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5716338	APR 16, 2013	FEB 10, 2015	ODE	JUN 20, 2003	ODE	JUN 20, 2007
>ADD> 020280 011	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	APR 16, 2013	I-302	JUN 20, 2007	ODE	JUN 20, 2007
>ADD> 020280 012	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5716338	FEB 10, 2015	FEB 10, 2015	I-302	JUN 20, 2007	ODE	JUN 20, 2007
>ADD> 020280 013	SOMATROPIN RECOMBINANT ; GENOTROPIN PRESERVAT	5435076	APR 16, 2013	FEB 10, 2015	I-302	JUN 20, 2007	ODE	JUN 20, 2007
>ADD>	SOMATROPIN RECOMBINANT ; NORDITROPIN	5716338	FEB 10, 2015	APR 10, 2015	I-302	JUN 20, 2003	ODE	JUN 20, 2007
019721 001	SOMATROPIN RECOMBINANT ; NORDITROPIN	56333352	MAY 27, 2014	APR 16, 2013	I-302	JUN 20, 2003	ODE	JUN 20, 2007
019721 002	SOMATROPIN RECOMBINANT ; NUTROPIN	56333352	MAY 27, 2014	APR 16, 2013	I-302	JUN 20, 2003	ODE	JUN 20, 2007
019676 001	SOMATROPIN RECOMBINANT ; NUTROPIN	56333352	MAY 27, 2014	APR 16, 2013	I-302	JUN 20, 2003	ODE	JUN 20, 2007
020522 001	SOMATROPIN RECOMBINANT ; NUTROPIN AQ	M-2	D-55	APR 13, 2003	M-2	DEC 01, 2002	APR 13, 2003	M-2
021151 001	SOTALOL HYDROCHLORIDE ; BETAPACE AF	4680291	JUL 14, 2004	DEC 30, 2006	NDF	DEC 01, 2002	APR 13, 2003	D-55
021151 002	SOTALOL HYDROCHLORIDE ; BETAPACE AF	4755534	OCT 28, 2014	OCT 28, 2014	NCE	DEC 01, 2002	APR 13, 2003	M-2
021151 003	SOTALOL HYDROCHLORIDE ; BETAPACE AF	5681849	U-73	U-73	NP	DEC 01, 2002	APR 13, 2003	M-2
021124 001	TERBINAFINE HYDROCHLORIDE ; LAMISIL AT				NP	DEC 01, 2002	APR 13, 2003	M-2
021015 001	TESTOSTERONE ; ANDROGEL	55559269	MAY 05, 2015	MAY 05, 2015	U-318	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
>ADD> 020484 001	TINZAPARIN SODIUM ; INNOHEP	55559269	MAY 05, 2015	MAY 05, 2015	U-318	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
020771 001	TOLTERODINE TARTRATE ; DETROL				PED	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
020771 002	TOLTERODINE TARTRATE ; DETROL				PED	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
020281 001	TRAMADOL HYDROCHLORIDE ; ULTRAM				PED	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
020281 002	TRAMADOL HYDROCHLORIDE ; ULTRAM				NCE	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
074973 001	TRIMETHOPRIM HYDROCHLORIDE ; PRIMSOL	5763449	AUG 07, 2016	AUG 07, 2016	D-44	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
020326 001	TRIMETREXATE GLUCURONATE ; NEUTREXIN	5962461	AUG 07, 2016	AUG 07, 2016	D-44	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
020326 002	TRIMETREXATE GLUCURONATE ; NEUTREXIN	6017922	MAY 18, 2018	MAY 18, 2018	D-44	DEC 22, 2003	APR 13, 2003	DEC 22, 2003
		6017922	MAY 18, 2018	MAY 18, 2018				

PRESCRIPTION AND OTC DRUG PRODUCT

PATENT AND EXCLUSIVITY DATA

* PED and PED represent Pediatric Exclusivity

APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	EXCL CODE	USE CODE	EXCLUSIVITY CODE	EXPIRES
>ADD>	TRIPTORELIN PAMOATE; TRELSTAR DEPOT	5134122	JUL 20, 2010	NCE	JUN 15, 2005		
>ADD>	TROGLITAZONE; PRELAY	5225205	JUL 20, 2010				
>ADD>	TROGLITAZONE; PRELAY	5192741	MAR 09, 2010				
020719 001	TROGLITAZONE; PRELAY	6046202	SEP 15, 2013	U-317			
020719 002	TROGLITAZONE; PRELAY	6046202	SEP 15, 2013	U-317			
020719 003	TROGLITAZONE; PRELAY	6046202	SEP 15, 2013	U-317			
020720 001	TROGLITAZONE; REZULIN	6046202	SEP 15, 2013	U-317			
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	5232705	AUG 31, 2010				
		5200196	JAN 22, 2008				
		5141752	JUN 27, 2006				
		5082668	JAN 21, 2009				
		5030456	NOV 07, 2008	OCT 02, 2007			
		4946687	OCT 02, 2007				
		5785994	OCT 22, 2009	U-315			
		5232705	AUG 31, 2010				
020552 002	VERAPAMIL HYDROCHLORIDE; COVERA-HS	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	NCE	APR 12, 2005	
021119 001	VERTEPORFIN; VISUDYNE	I-294	APR 26, 2003				
021036 001	ZANAMIVIR; RELenza	NCE	MAR 27, 2005				
020789 001	ZONISAMIDE; ZONEGRAN						

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 LISINOPRIL 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	U-321
I-295	PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS	U-322
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	U-323
I-297	SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER	U-324
I-298	TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA	U-325
I-299	USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUOROURACIL AND LEUCOVORIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM	U-326
I-300	PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE	U-327
I-301	TREATMENT OF SIGNS AND SYMPTOMS OF ALLERGIC CONJUNCTIVITIS	U-328
I-302	TREATMENT OF PEDIATRIC PATIENTS WITH PRADER-WILLI SYNDROME	U-329
I-303	INCREASING HDL-CHESTEROL IN PATIENTS WITH PRIMARY HYPERCHOLESTEROLEMIA AND MIXED DYSLIPIDEMIAS	
I-304	TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IV	U-330
I-305	TREATMENT OF LEVOFLOXACIN SUSCEPTIBLE STRAINS OF PENICILLIN-RESISTANT STREPTOCOCCUS PNEUMONIAE IN PATIENTS WITH COMMUNITY ACQUIRED PNEUMONIA	U-331
I-306	INDUCTION OF SPERMATOGENESIS IN MEN WITH PRIMARY AND SECONDARY HYPOGONADOTROPIC HYPOGONADISM IN WHOM THE CAUSE OF INFERTILITY IS NOT DUE TO PRIMARY TESTICULAR FAILURE	U-332
		U-333
		U-334

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 COMPRISSES 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

PATENT AND EXCLUSIVITY TERMS

PATENT USE CODE

REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS
TREATMENT OF ALZHEIMER'S DEMENTIA
USE AS A BILE ACID SEQUESTRANT
METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE
METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE
METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER
METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE
METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH
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
TREATMENT OF NAUSEA AND VOMITING
METHOD OF TREATING HYPERLIPIDEMIA WITH NICOTINIC ACID BY DOSING ONCE PER DAY IN THE EVENING OR AT NIGHT
TREATMENT OR PREVENTION OF BRONCHOSPASM
METHOD OF TREATING OCULAR HYPERTENSION
TREATMENT OF EXCESSIVE FEMALE FACIAL HAIR