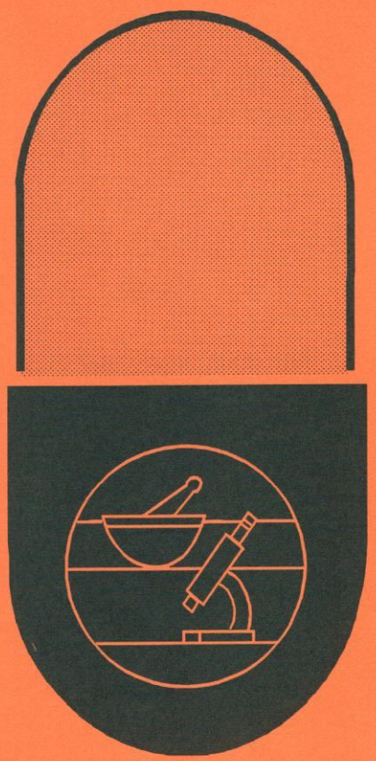
CUMULATIVE SUPPLEMENT 3
MAR'00



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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with
THERAPEUTIC EQUIVALENCE EVALUATIONS

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Cumulative Supplement 3

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CONTENTS

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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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

1.2 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When

this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section

APPLICANT NAME CHANGES

FORMER APPLICANT NAME (FORMER ABBREVIATED NAME)	NEW APPLICANT NAME (NEW ABBREVIATED NAME)
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)
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

CATEGORIES COUNTED	DEC 1999	MAR 2000	JUN 2000	SEP 2000
DRUG PRODUCTS LISTED	10045	10082		
SINGLE SOURCE	2599 (25.9%)	2596 (25.7%)		
MULTISOURCE	7335 (73.0%)	7375 (73.2%)		
THERAPEUTICALLY EQUIVALENT	6986 (69.5%)	7040 (69.8%)		
NOT THERAPEUTICALLY EQUIVALENT	349 (3.5%)	335 (3.3%)		
EXCEPTIONS[1]	111 (1.1%)	111 (1.1%)		
NEW MOLECULAR ENTITIES APPROVED	0	6		
NUMBER OF APPLICANTS	576	575		

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

ACETAMINOPHEN; BUTALBITAL

CAPSULE; ORAL
PHRENILIN FORTE

> DLT >	AB	+	CARNRICK	650MG;50MG	N88831 001	
> DLT >					JUN 19, 1985	
> ADD >	AB	+	ELAN PHARMS	650MG;50MG	N88831 001	
> ADD >					JUN 19, 1985	

TABLET; ORAL
PHRENILIN

> DLT >	AB	+	CARNRICK	325MG;50MG	N87811 001	
> DLT >					JUN 19, 1985	
> ADD >	AB	+	ELAN PHARMS	325MG;50MG	N87811 001	
> ADD >					JUN 19, 1985	

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE

> DLT >	AA	CARNRICK	120MG/5ML;12MG/5ML	N86024 001	
> ADD >	AA	ELAN PHARMS	120MG/5ML;12MG/5ML	N86024 001	

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
LORTAB

	UCB	325MG;5MG	N40099 001	
			JUN 25, 1997	
	@	325MG;5MG	N40099 001	
			JUN 25, 1997	

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE HCL AND ACETAMINOPHEN

> ADD >					
> ADD >	AB	WATSON LABS	650MG;EQ 25MG BASE	N74699 001	
> ADD >				MAR 24, 2000	
		TALACEN			
> ADD >	AB	+ SANOFI SYNTHELABO	650MG;EQ 25MG BASE	N18458 001	
> ADD >				SEP 23, 1982	
> DLT >		+	650MG;EQ 25MG BASE	N18458 001	
> DLT >				SEP 23, 1982	

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

> ADD >	AN	BAUSCH AND LOMB	EQ 0.083% BASE	N75358 001	
> ADD >				MAR 29, 2000	

ALOSETRON HYDROCHLORIDE

TABLET; ORAL
LOTRONEX

+	GLAXO WELLCOME	EQ 1MG BASE	N21107 001
			FEB 09, 2000

ALTRETAMINE

CAPSULE; ORAL
HEXALEN

+	MEDIMMUNE ONCOLOGY	50MG	N19926 001
			DEC 26, 1990
+	US BIOSCIENCE	50MG	N19926 001
			DEC 26, 1990

AMIFOSTINE

INJECTABLE; INJECTION
ETHYOL

+	MEDIMMUNE ONCOLOGY	500MG/VIAL	N20221 001
			DEC 08, 1995
+	US BIOSCIENCE	500MG/VIAL	N20221 001
			DEC 08, 1995

AMINOPHYLLINE

TABLET; ORAL
AMINOPHYLLINE

> DLT >	AB	GLOBAL PHARM	100MG	N84574 001
> DLT >	AB		200MG	N84576 001
> ADD >		@ IMPAX LABS	100MG	N84574 001
> ADD >		@	200MG	N84576 001

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

INJECTABLE; INJECTION

KABIVITE PED P + W KIT

> DLT >	+ FRESENIUS KABI	N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A, 0.001MG/VIAL;400 IU/10ML,N/A;N/A, 0.14MG/VIAL;N/A,17MG/VIAL;N/A, 5MG/VIAL;0.2MG/10ML,N/A;N/A, 1MG/VIAL;N/A,1.4MG/VIAL;N/A, 1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML, N/A;7 IU/10ML,N/A	N20176 001 DEC 29, 1993
> ADD >	VITAPED		
> ADD >	@ FRESENIUS KABI	N/A,80MG/VIAL;N/A,0.02MG/VIAL;N/A, 0.001MG/VIAL;400 IU/10ML,N/A;N/A, 0.14MG/VIAL;N/A,17MG/VIAL;N/A, 5MG/VIAL;0.2MG/10ML,N/A;N/A, 1MG/VIAL;N/A,1.4MG/VIAL;N/A, 1.2MG/VIAL;EQ 2,300 UNITS BASE/10ML, N/A;7 IU/10ML,N/A	N20176 001 DEC 29, 1993

ATROPINE SULFATE; EDROPHONIUM CHLORIDE

INJECTABLE; INJECTION

ENLON-PLUS

> ADD >	+ BAXTER PHARM PROD	0.14MG/ML;10MG/ML	N19677 001 NOV 06, 1991
> ADD >	+	0.14MG/ML;10MG/ML	N19678 001 NOV 06, 1991
> DLT >	+ OHMEDA	0.14MG/ML;10MG/ML	N19677 001 NOV 06, 1991
> DLT >	+	0.14MG/ML;10MG/ML	N19678 001 NOV 06, 1991

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

BLEOMYCIN

> ADD >	**AP**	FAULDING	**EQ 15 UNITS BASE/VIAL**	**N65031 001** MAR 10, 2000
> ADD >	**AP**		**EQ 30 UNITS BASE/VIAL**	**N65031 002** MAR 10, 2000

BUPROPION HYDROCHLORIDE

TABLET; ORAL

BUPROPION HCL

	AB	INVAMED	**75MG**	**N75584 001** FEB 07, 2000
	AB		**100MG**	**N75584 002** FEB 07, 2000

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

BUTORPHANOL TARTRATE

> ADD >	**AP**	ABBOTT	**1MG/ML**	**N75559 001** MAR 20, 2000
> ADD >	**AP**		**2MG/ML**	**N75559 002** MAR 20, 2000

CALCIUM CHLORIDE

INJECTABLE; INJECTION

CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER

	+ ABBOTT	100MG/ML	N21117 001 JAN 28, 2000

CANDICIDIN

OINTMENT; VAGINAL

VANOBID

> ADD >	@ AVENTIS PHARMS	0.6MG/GM	N61596 001
> DLT >	+ HOECHST MARION RSSL	0.6MG/GM	N61596 001

TABLET; VAGINAL

VANOBID

> ADD >	@ AVENTIS PHARMS	3MG	N61613 001
> DLT >	+ HOECHST MARION RSSL	3MG	N61613 001

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CARTEOLOL HCL

AT	ALCON	**1%**	**N75476 001** JAN 03, 2000
AT	BAUSCH AND LOMB	**1%**	**N75546 001** JAN 20, 2000

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

		OCUPRESS				
AT	+	CIBA	1%	N19972 001	> DLT >	
				MAY 23, 1990	> DLT >	
	+		1%	N19972 001	> DLT >	
				MAY 23, 1990		

CEFDINIR

CAPSULE; ORAL

		OMNICEF				
	+	ABBOTT	300MG	N50739 001		
				DEC 04, 1997		
	+	PARKE DAVIS	300MG	N50739 001		
				DEC 04, 1997		

POWDER FOR RECONSTITUTION; ORAL

		OMNICEF				
	+	ABBOTT	125MG/5ML	N50749 001		
				DEC 04, 1997		
	+	PARKE DAVIS	125MG/5ML	N50749 001		
				DEC 04, 1997		

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

> ADD >		CEFOTAXIME				
> ADD >	AP	AM PHARM PARTNERS	EQ 500MG BASE/VIAL	N64200 001		
> ADD >				MAR 24, 2000		
> ADD >	AP		EQ 1GM BASE/VIAL	N64200 002		
> ADD >				MAR 24, 2000		
> ADD >	AP		EQ 2GM BASE/VIAL	N64200 003		
> ADD >				MAR 24, 2000		
> ADD >	AP		EQ 10GM BASE/VIAL	N64201 001		
> ADD >				MAR 24, 2000		
> ADD >	+		EQ 20GM BASE/VIAL	N64201 002		
> ADD >				MAR 24, 2000		
		CLAFORAN				
> ADD >	AP	+ AVENTIS PHARMS	EQ 500MG BASE/VIAL	N50547 001		
> ADD >	AP	+	EQ 1GM BASE/VIAL	N50547 002		
> ADD >	AP	+	EQ 2GM BASE/VIAL	N50547 003		
> ADD >	AP	+	EQ 10GM BASE/VIAL	N50547 004		
> ADD >				DEC 29, 1983		
> DLT >		+ HOECHST MARION RSSL	EQ 500MG BASE/VIAL	N50547 001		
> DLT >		+	EQ 1GM BASE/VIAL	N50547 002		

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

		CLAFORAN				
	+	HOECHST MARION RSSL	EQ 2GM BASE/VIAL	N50547 003		
	+		EQ 10GM BASE/VIAL	N50547 004		
				DEC 29, 1983		

CEFTIBUTEN DIHYDRATE

CAPSULE; ORAL

		CEDAX				
	+	DJ PHARMA	EQ 400MG BASE	N50685 002		
				DEC 20, 1995		
	+	SCHERING PLOUGH	EQ 400MG BASE	N50685 002		
				DEC 20, 1995		

POWDER FOR RECONSTITUTION; ORAL

		CEDAX				
		DJ PHARMA	EQ 90MG BASE/5ML	N50686 001		
				DEC 20, 1995		
	+		EQ 180MG BASE/5ML	N50686 002		
				DEC 20, 1995		
	+	SCHERING PLOUGH	EQ 90MG BASE/5ML	N50686 001		
				DEC 20, 1995		
	+		EQ 180MG BASE/5ML	N50686 002		
				DEC 20, 1995		

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION

		ROCEPHIN				
	+	HLR	EQ 250MG BASE/VIAL	N50585 001		
				DEC 21, 1984		
	+		EQ 500MG BASE/VIAL	N50585 002		
				DEC 21, 1984		
	+		EQ 1GM BASE/VIAL	N50585 003		
				DEC 21, 1984		
	+		EQ 2GM BASE/VIAL	N50585 004		
				DEC 21, 1984		
	+		EQ 10GM BASE/VIAL	N50585 005		
				DEC 21, 1984		
	+	ROCHE	EQ 250MG BASE/VIAL	N50585 001		
				DEC 21, 1984		
	+		EQ 500MG BASE/VIAL	N50585 002		
				DEC 21, 1984		

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN

+	ROCHE	EQ 1GM BASE/VIAL	N50585 003 DEC 21, 1984				
+		EQ 2GM BASE/VIAL	N50585 004 DEC 21, 1984				
+		EQ 10GM BASE/VIAL	N50585 005 DEC 21, 1984				

ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

@	HLR	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987				
+		EQ 20MG BASE/ML	N50624 002 FEB 11, 1987				
+		EQ 40MG BASE/ML	N50624 003 FEB 11, 1987				
@	ROCHE	EQ 10MG BASE/ML	N50624 001 FEB 11, 1987				
+		EQ 20MG BASE/ML	N50624 002 FEB 11, 1987				
+		EQ 40MG BASE/ML	N50624 003 FEB 11, 1987				

CEFTRIAXONE SODIUM; LIDOCAINE

INJECTABLE; INJECTION
ROCEPHIN KIT

+	HLR	EQ 1GM BASE/VIAL,N/A;N/A, 1%	N50585 006 MAY 08, 1996				
+		EQ 500MG BASE/VIAL,N/A;N/A, 1%	N50585 007 MAY 08, 1996				
+	ROCHE	EQ 1GM BASE/VIAL,N/A;N/A, 1%	N50585 006 MAY 08, 1996				
+		EQ 500MG BASE/VIAL,N/A;N/A, 1%	N50585 007 MAY 08, 1996	> ADD > > ADD >			

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC

+	SNOWBRAND	EQ 30MG BASE	N20989 002 JAN 11, 2000				

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

				> DLT >	**AA**	GLOBAL PHARM **4MG**	**N80809 001**
				> ADD >		@ IMPAX LABS 4MG	N80809 001

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

+	HOECHST MARION RSSL	1%	N18748 001 DEC 30, 1982				

LOTION; TOPICAL
LOPROX

+	HOECHST MARION RSSL	1%	N19824 001 DEC 30, 1988				

CIMETIDINE HYDROCHLORIDE

SOLUTION; ORAL
CIMETIDINE HCL

				> ADD >	**AA**	NOVEX **EQ 300MG BASE/5ML**	**N75560 001** MAR 15, 2000

CLADRIBINE

INJECTABLE; INJECTION
CLADRIBINE

					AP	BEDFORD **1MG/ML**	**N75405 001** FEB 28, 2000

CLARITHROMYCIN

>ADD< TABLET, EXTENDED RELEASE; ORAL
>ADD< BIAXIN XL
>ADD< + ABBOTT 500MG N50775 001
>ADD< MAR 03, 2000

CLINDAMYCIN PHOSPHATE

GEL; TOPICAL
CLEOCIN T
AB + PHARMACIA AND UPJOHN EQ 1% BASE N50615 001
JAN 07, 1987
+ EQ 1% BASE N50615 001
JAN 07, 1987

CLINDAMYCIN PHOSPHATE
AB ALTANA EQ 1% BASE N64160 001
JAN 28, 2000

CLOBETASOL PROPIONATE

GEL; TOPICAL
CLOBETASOL PROPIONATE
AB ALTANA 0.05% N75368 001
FEB 15, 2000

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE
>DLT< BP GLOBAL PHARM 25MG N09458 001
>ADD< @ IMPAX LABS 25MG N09458 001

CROMOLYN SODIUM

SOLUTION; INHALATION
CROMOLYN SODIUM
AN STERIPAK 10MG/ML N75271 001
JAN 18, 2000

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN
>ADD< @ AVENTIS PHARMS 1MG/ML N80564 001

CYANOCOBALAMIN

INJECTABLE; INJECTION
CYANOCOBALAMIN
>DLT< AP HOECHST MARION RSSL 1MG/ML N80564 001

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC
CYCLOPENTOLATE HCL
AT ALCON UNIVERSAL 1% N89162 001
JAN 24, 1991
AT STERIS 1% N89162 001
JAN 24, 1991

CYCLOSPORINE

CAPSULE; ORAL
CYCLOSPORINE
AB EON 25MG N65017 002
JAN 13, 2000
AB 100MG N65017 001
JAN 13, 2000

NEORAL
AB NOVARTIS 25MG N50715 001
JUL 14, 1995
AB + 100MG N50715 002
JUL 14, 1995
BX 25MG N50715 001
JUL 14, 1995
BX + 100MG N50715 002
JUL 14, 1995

SOLUTION; ORAL
>ADD< CYCLOSPORINE
>ADD< AB ABBOTT 100MG/ML N65025 001
>ADD< MAR 03, 2000

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL
AP + BEDFORD EQ 5MG BASE/ML N50731 001
JAN 30, 1998
+ EQ 5MG BASE/ML N50731 001
JAN 30, 1998

DAUNORUBICIN HYDROCHLORIDE

INJECTABLE; INJECTION
DAUNORUBICIN HCL

AP	GENSIA SICOR PHARMS	EQ 5MG BASE/ML	N65035 001	JAN 24, 2000
> ADD >	+	EQ 50MG BASE/VIAL	N64212 002	MAY 03, 1999
> ADD >				

DEMECLOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
DECLOMYCIN

+	LEDERLE	150MG	N50262 001
@		150MG	N50262 001

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION
DESMOPRESSIN ACETATE

AP	BEDFORD	0.004MG/ML	N74575 001	FEB 18, 2000

DESMOPRESSIN ACETATE PRESERVATIVE FREE

AP	BEDFORD	0.004MG/ML	N74574 001	FEB 18, 2000

SPRAY, METERED; NASAL
STIMATE

> ADD >	+ AVENTIS BEHRING	0.15MG/SPRAY	N20355 001	MAR 07, 1994
> ADD >				
> DLT >	+ CENTEON	0.15MG/SPRAY	N20355 001	MAR 07, 1994
> DLT >				

DEXAMETHASONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND DEXAMETHASONE

AT	ALCON UNIVERSAL	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62721 001	NOV 17, 1986
AT	STERIS	0.1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62721 001	NOV 17, 1986

DEXAMETHASONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.1% PHOSPHATE	N88771 001	JAN 16, 1985

SOLUTION/DROPS; OPHTHALMIC, OTIC
DEXAMETHASONE SODIUM PHOSPHATE

AT	STERIS	EQ 0.1% PHOSPHATE	N88771 001	JAN 16, 1985

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML	N62714 001	JUL 21, 1986
AT	STERIS	EQ 0.1% PHOSPHATE; EQ 3.5MG BASE/ML	N62714 001	JUL 21, 1986

DICLOFENAC POTASSIUM

TABLET; ORAL
DICLOFENAC POTASSIUM

> ADD >	AB GENEVA PHARMS TECH	50MG	N75229 001	NOV 20, 1998
> ADD >				
> DLT >	AB INVAMED	50MG	N75229 001	NOV 20, 1998
> DLT >				

DICLOFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
DICLOFENAC SODIUM

AB	FALCON PHARMS	0.1% †	N20809 001	MAY 04, 1998
@		0.1%	N20809 001	MAY 04, 1998

VOLTAREN

AB	+ CIBA	0.1%	N20037 001	MAR 28, 1991
	+	0.1%	N20037 001	MAR 28, 1991

† SEE SECTION 1.3 OF INTRODUCTION

† SEE SECTION 1.3 OF INTRODUCTION

DICLOFENAC SODIUM

TABLET, EXTENDED RELEASE; ORAL

		DICLOFENAC SODIUM				
AB		BIOVAIL	100MG	N75492 001 FEB 11, 2000	> ADD >	
		VOLTAREN-XR				
AB	+	NOVARTIS	100MG	N20254 001 MAR 08, 1996	> DLT >	
	+		100MG	N20254 001 MAR 08 1996		

DIENESTROL

SUPPOSITORY; VAGINAL

		DV				
> ADD >	@	AVENTIS PHARMS	0.7MG	N83517 001	> ADD >	
> DLT >	+	HOECHST MARION RSSL	0.7MG	N83517 001		

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

		DILTIAZEM HCL				
AB3		BIOVAIL	120MG	N20939 001 JAN 28, 2000	> DLT >	
AB3			180MG	N20939 002 JAN 28, 2000	> DLT >	
AB3			240MG	N20939 003 JAN 28, 2000	> DLT >	
AB3			300MG	N20939 004 JAN 28, 2000	> DLT >	

INJECTABLE; INJECTION

		DILTIAZEM HCL				
AP		ABBOTT	5MG/ML	N75004 001 FEB 16, 2000	> DLT >	
					> ADD >	BX JOHNSON RW 0.05MG/24HR N21048 001 SEP 20, 1999
					> ADD >	BX 0.075MG/24HR N21048 002 SEP 20, 1999
					> ADD >	BX 0.1MG/24HR N21048 003 SEP 20, 1999

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

		DIPHENHYDRAMINE HCL				
> DLT >	AA	GLOBAL PHARM	25MG	N80807 001		
> DLT >	AA		50MG	N80807 002		
> ADD >		IMPAX LABS	25MG	N80807 001		
> ADD >	@		50MG	N80807 002		

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL

		ZONALON				
+		BIOGLAN PHAR	5%	N20126 001 APR 01, 1994	> ADD >	
+		MEDICIS	5%	N20126 001 APR 01, 1994	> DLT >	

ESTRADIOL

CREAM; VAGINAL

		ESTRACE				
+		BRISTOL MYERS SQUIBB	0.01%	N86069 001 JAN 31, 1984	> DLT >	
					> DLT >	
+		WARNER CHILCOTT	0.01%	N86069 001 JAN 31, 1984	> ADD >	

FILM, EXTENDED RELEASE; TRANSDERMAL

		CLIMARA				
AB	+	BERLEX LABS	0.05MG/24HR	N20375 001 DEC 22, 1994		
AB	+		0.1MG/24HR	N20375 002 DEC 22, 1994		
BX	+		0.05MG/24HR	N20375 001 DEC 22, 1994		
BX	+		0.1MG/24HR	N20375 002 DEC 22, 1994		
		ESTRADIOL				
BX		CYGNUS CA	0.05MG/24HR	N21048 001 SEP 20, 1999		
BX			0.075MG/24HR	N21048 002 SEP 20, 1999		
BX			0.1MG/24HR	N21048 003 SEP 20, 1999		
AB		MYLAN TECHNOLOGIES	0.05MG/24HR	N75233 001 FEB 24, 2000		
AB			0.1MG/24HR	N75182 001 FEB 24, 2000		

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION
ETHAMOLIN

+	CYPROS	50MG/ML	N19357 001 DEC 22, 1988	> ADD > > ADD >	
+	QUESTCOR PHARM	50MG/ML	N19357 001 DEC 22, 1988	> DLT > > DLT >	

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
TRIVORA-21

AB	SEARLE	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 001 DEC 18, 1997	
AB	WATSON LABS	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 001 DEC 18, 1997	

TABLET; ORAL-28
TRIVORA-28

AB	SEARLE	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 002 DEC 18, 1997	
AB	WATSON LABS	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	N74538 002 DEC 18, 1997	

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
OVCON-35

+	BRISTOL MYERS SQUIBB	0.035MG;0.4MG	N18127 001	
+	WARNER CHILCOTT	0.035MG;0.4MG	N18127 001	

OVCON-50

@	BRISTOL MYERS SQUIBB	0.05MG;1MG	N18128 001	
@	WARNER CHILCOTT	0.05MG;1MG	N18128 001	

TABLET; ORAL-28
OVCON-35

	BRISTOL MYERS SQUIBB	0.035MG;0.4MG	N17716 001	
	WARNER CHILCOTT	0.035MG;0.4MG	N17716 001	> ADD >

OVCON-50

	BRISTOL MYERS SQUIBB	0.05MG;1MG	N17576 001	> ADD >
	WARNER CHILCOTT	0.05MG;1MG	N17576 001	> ADD >

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION
CORLOPAM

+	ABBOTT	EQ 10MG BASE/ML	N19922 001 SEP 23, 1997	
+	ELAN PHARMA	EQ 10MG BASE/ML	N19922 001 SEP 23, 1997	

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL
ALLEGRA

	AVENTIS PHARMS	30MG	N20872 001 FEB 25, 2000
		60MG	N20872 002 FEB 25, 2000
+		180MG	N20872 004 FEB 25, 2000

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN

	PFIZER	150MG	N20322 001 JUN 30, 1994
		150MG	N19949 004 JUN 30, 1994

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

AP	GENSIA SICOR PHARMS	50MG/ML	N40333 001 JAN 27, 2000
AP		50MG/ML	N40334 001 FEB 25, 2000

GABAPENTIN

SOLUTION; ORAL
NEURONTIN

+	PARKE DAVIS	250MG/5ML	N21129 001 MAR 02, 2000

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST

> ADD >		+ BERLEX LABS	469.01MG/ML	N21037 001	
> ADD >				MAR 10, 2000	

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

AT	ALCON UNIVERSAL	**EQ 0.3% BASE**	**N62523 001**	
			NOV 25, 1985	
AT	STERIS	**EQ 0.3% BASE**	**N62523 001**	
			NOV 25, 1985	

GLYBURIDE

TABLET; ORAL
GLYBURIDE (MICRONIZED)

> ADD > **AB**	AVENTIS PHARMS	**6MG**	**N20055 003**	
> ADD >			MAR 08, 2000	

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

AO	APOTEX	**EQ 50MG BASE/ML**	**N75440 001**	
			FEB 28, 2000	
AO		**EQ 100MG BASE/ML**	**N75440 002**	
			FEB 28, 2000	
AO	KING PHARMS	**EQ 50MG BASE/ML**	**N75176 001**	
			FEB 09, 2000	
AO		**EQ 100MG BASE/ML**	**N75176 002**	
			FEB 09, 2000	

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN LOCK FLUSH

	@ STERIS	100 UNITS/ML	N17064 001	
	@	100 UNITS/ML	N17064 001	

HEPARIN SODIUM

AP	STERIS	**5,000 UNITS/ML**	**N17064 003**	
AP		**10,000 UNITS/ML**	**N17064 004**	

HEPARIN SODIUM

INJECTABLE; INJECTION
HEPARIN SODIUM

AP	STERIS	**20,000 UNITS/ML**	**N17064 005**	
AP		**40,000 UNITS/ML**	**N17064 006**	
	@	5,000 UNITS/ML	N17064 003	
	@	10,000 UNITS/ML	N17064 004	
	@	20,000 UNITS/ML	N17064 005	
	@	40,000 UNITS/ML	N17064 006	

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL

AP	GENSIA SICOR PHARMS	**20MG/ML**	**N40373 001**	
			FEB 23, 2000	
AP +	LUITPOLD	**20MG/ML**	**N40136 001**	
			JUN 30, 1997	
	+	20MG/ML	N40136 001	
			JUN 30, 1997	

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL
HYDROCHLOROTHIAZIDE

AB	MYLAN	**12.5MG**	**N75640 001**	
			JAN 28, 2000	

MICROZIDE

AB +	WATSON LABS	**12.5MG**	**N20504 001**	
			DEC 27, 1996	
	+	12.5MG	N20504 001	
			DEC 27, 1996	

TABLET; ORAL
HYDROCHLOROTHIAZIDE

> DLT > **AB**	GLOBAL PHARM	**100MG**	**N85098 001**	
> ADD >	@ IMPAX LABS	100MG	N85098 001	

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT	ALCON UNIVERSAL	**1%;EQ 3.5MG BASE/ML;**		
		10,000 UNITS/ML	**N62874 001**	
			MAY 11, 1988	

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SUSPENSION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62874 001	MAY 11, 1988

SUSPENSION/DROPS; OTIC
NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT	ALCON UNIVERSAL	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62488 001	NOV 06, 1985
AT	STERIS	1%;EQ 3.5MG BASE/ML; 10,000 UNITS/ML	N62488 001	NOV 06, 1985

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50

>ADD>	+	LILLY	50 UNITS/ML;50 UNITS/ML	N21018 001	
>ADD>				DEC 22, 1999	

HUMALOG MIX 75/25

>ADD>	+	LILLY	25 UNITS/ML;75 UNITS/ML	N21017 001	
>ADD>				DEC 22, 1999	

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50

>DLT>	+	LILLY	100 UNITS/ML	N21018 001	
>DLT>				DEC 22, 1999	

HUMALOG MIX 75/25

>DLT>	+	LILLY	100 UNITS/ML	N21017 001	
>DLT>				DEC 22, 1999	

INULIN

INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE

+	CYPROS	100MG/ML	N02282 001	
+	QUESTCOR PHARM	100MG/ML	N02282 001	

IOTHALAMATE SODIUM, I-125

INJECTABLE; INJECTION
GLOFIL-125

CYPROS	250-300 uCi/ML	N17279 001	
QUESTCOR PHARM	250-300 uCi/ML	N17279 001	

IPRATROPIUM BROMIDE

SOLUTION; INHALATION
IPRATROPIUM BROMIDE

AN	STERIPAK	0.02%	N75313 001	FEB 07, 2000

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION
ISUPREL

+	SANOFI SYNTHELABO	0.5%	N06327 002
+		1%	N06327 003
@		0.5%	N06327 002
@		1%	N06327 003

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
IMDUR

>ADD>	AB	+	SCHERING	120MG	N20225 003
>ADD>					MAR 30, 1995
>DLT>		+		120MG	N20225 003
>DLT>					MAR 30, 1995
>ADD>		**ISOSORBIDE MONONITRATE**			
>ADD>	AB		KREMERS URBAN	30MG	N75155 002
>ADD>					JAN 13, 2000
>ADD>	AB		KV PHARM	30MG	N75395 001
>ADD>					MAR 16, 2000
>ADD>	AB			60MG	N75395 002
>ADD>					MAR 16, 2000
>ADD>	AB			120MG	N75395 003
>ADD>					MAR 16, 2000

KETOCONAZOLE

CREAM; TOPICAL
NIZORAL
+ JANSSEN 2% N19084 001 DEC 31, 1985
+ MCNEIL CONS 2% N19084 001 DEC 31, 1985

SHAMPOO; TOPICAL
NIZORAL
+ JANSSEN 2% N19927 001 AUG 31, 1990
+ MCNEIL CONS 2% N19927 001 AUG 31, 1990

LEUPROLIDE ACETATE

> ADD > IMPLANT; IMPLANTATION
> ADD > VIADUR
> ADD > + ALZA EQ 65MG BASE N21088 001 MAR 03, 2000
> ADD >

LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETAXON
+ ALCON EQ 0.5% BASE N21114 001 FEB 23, 2000

LEVOBUPIVACAINE HYDROCHLORIDE

INJECTABLE; INJECTION
CHIROCAINE
> DLT > DARWIN DISCOVERY EQ 2.5MG BASE/ML N20997 001 AUG 05, 1999
> DLT > EQ 5MG BASE/ML N20997 002 AUG 05, 1999
> DLT > + EQ 7.5MG BASE/ML N20997 003 AUG 05, 1999
> ADD > PURDUE PHARMA EQ 2.5MG BASE/ML N20997 001 AUG 05, 1999
> ADD > EQ 5MG BASE/ML N20997 002 AUG 05, 1999
> ADD > + EQ 7.5MG BASE/ML N20997 003 AUG 05, 1999

LEVORPHANOL TARTRATE

TABLET; ORAL
LEVO-DROMORAN
> ADD > AB + ICN 2MG N08720 001 DEC 19, 1991
> ADD >
> DLT > + 2MG N08720 001 DEC 19, 1991
> DLT >
> ADD > LEVORPHANOL TARTRATE
> ADD > AB ROXANE 2MG N74278 001 MAR 31, 2000
> ADD >

LORAZEPAM

INJECTABLE; INJECTION
LORAZEPAM
> ADD > AP MOVA 2MG/ML N74793 001 MAR 16, 2000
> ADD >
> ADD > AP 4MG/ML N74793 002 MAR 16, 2000
> ADD >

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
AMEN
> DLT > BP CARNRICK 10MG N83242 001
> ADD > BP ELAN PHARMS 10MG N83242 001

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE
AB PHARMACHEMIE 40MG N74745 001 FEB 27, 1998
AB TEVA 40MG N74745 001 FEB 27, 1998

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
MENOTROPINS
@ FERRING 75 IU/VIAL;75 IU/VIAL N73598 001 JAN 30, 1997
@ 150 IU/VIAL;150 IU/VIAL N73599 001 JAN 30, 1997

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
REPRONEX

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

MEPHENTERMINE SULFATE

INJECTABLE; INJECTION
WYAMINE SULFATE

> DLT >	+	WYETH AYERST	EQ 30MG BASE/ML	N08248 001
> ADD >	@		EQ 30MG BASE/ML	N08248 001

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
NORINYL

@	SEARLE	0.1MG;2MG	N13625 004
@	WATSON LABS	0.1MG;2MG	N13625 004

TABLET; ORAL-21
NORINYL 1+50 21-DAY

AB	SEARLE	0.05MG;1MG	N13625 002
AB	WATSON LABS	0.05MG;1MG	N13625 002

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE

AA	NOVEX	10MG/5ML	N75235 001	JAN 27, 2000

METHIMAZOLE

TABLET; ORAL
METHIMAZOLE

> ADD >				
> ADD >	AB	APPLIED ANAL	5MG	N40320 001
> ADD >				MAR 31, 2000
> ADD >	AB		10MG	N40320 002
> ADD >				MAR 31, 2000
> ADD >	AB	GENPHARM	5MG	N40350 001
> ADD >				MAR 29, 2000

METHIMAZOLE

TABLET; ORAL
METHIMAZOLE

> ADD >				
> ADD >	AB	GENPHARM	10MG	N40350 002
> ADD >				MAR 29, 2000

TAPAZOLE

> ADD >	AB	LILLY	5MG	N07517 002
> ADD >	AB +		10MG	N07517 004
> DLT >			5MG	N07517 002
> DLT >	+		10MG	N07517 004

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL
MINOCYCLINE HCL

> ADD >	AB	+	DANBURY PHARMA	EQ 75MG BASE	N63065 002
> ADD >					JUN 10, 1999
> DLT >		+		EQ 75MG BASE	N63065 002
> DLT >					JUN 10, 1999

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

AB	ESI LEDERLE	15MG	N75407 001	JAN 28, 2000

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION
REVEX

> ADD >	+	BAXTER PHARM PROD	EQ 0.1MG BASE/ML	N20459 001	
> ADD >					APR 17, 1995
> ADD >	+		EQ 1MG BASE/ML	N20459 002	
> ADD >					APR 17, 1995
> DLT >	+	OHMEDA	EQ 0.1MG BASE/ML	N20459 001	
> DLT >					APR 17, 1995
> DLT >	+		EQ 1MG BASE/ML	N20459 002	
> DLT >					APR 17, 1995

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE AND NALOXONE HYDROCHLORIDES

> ADD >	AB	RANBAXY	EQ 0.5MG BASE; EQ 50MG BASE	N75523 001	MAR 17, 2000

NALTREXONE HYDROCHLORIDE

TABLET; ORAL
NALTREXONE HCL

> ADD >	AB	EON	50MG	N75434 001	MAR 08, 2000

NAPROXEN

TABLET, DELAYED RELEASE; ORAL
NAPROXEN

> ADD >	AB	GENEVA PHARMS TECH	375MG	N75061 001	FEB 18, 1998
> ADD >	AB		500MG	N75061 002	FEB 18, 1998
> DLT >	AB	INVAMED	375MG	N75061 001	FEB 18, 1998
> DLT >	AB		500MG	N75061 002	FEB 18, 1998

NIACIN

TABLET; ORAL
NIACIN

> DLT >	AA	GLOBAL PHARM	500MG	N83115 001	
> ADD >		@ IMPAX LABS	500MG	N83115 001	

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL
ADALAT CC

> ADD >	AB	+ BAYER	30MG	N20198 001	APR 21, 1993
> DLT >	BC	+	30MG	N20198 001	APR 21, 1993
> ADD >		**NIFEDIPINE**			
> ADD >	AB	ELAN PHARM	30MG	N75128 001	MAR 10, 2000

OCTREOTIDE ACETATE

INJECTABLE; INJECTION
SANDOSTATIN

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

SANDOSTATIN LAR

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

OLANZAPINE

TABLET; ORAL
ZYPREXA

LILLY	2.5MG	N20592 001	SEP 10, 1996
*	10MG	N20592 004	SEP 30, 1996
@	15MG	N20592 005	SEP 09, 1997
+	2.5MG	N20592 001	SEP 30, 1996
	10MG	N20592 004	SEP 30, 1996
+	15MG	N20592 005	SEP 09, 1997

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

	AB	EON	100MG	N40327 001	FEB 15, 2000
> ADD >	AB	GENEVA PHARMS TECH	100MG	N40284 001	JUN 19, 1998

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

> DLT >	AB	INVAMED	100MG	N40284 001 JUN 19, 1998		
> DLT						

OXCARBAZEPINE

TABLET; ORAL
TRILEPTAL

		NOVARTIS	150MG	N21014 001 JAN 14, 2000		
			300MG	N21014 002 JAN 14, 2000		
	+		600MG	N21014 003 JAN 14, 2000		

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
OXYCONTIN

> DLT >	BX	+ PURDUE PHARMA	10MG	N20553 001 DEC 12, 1995		
> DLT >						
> ADD >		+	10MG	N20553 001 DEC 12, 1995		
> ADD >						

ROXICODONE

	BX	ROXANE	10MG	N20932 001 OCT 26, 1998		
		+	30MG	N20932 002 OCT 26, 1998		
		@	10MG	N20932 001 OCT 26, 1998		
		@	30MG	N20932 002 OCT 26, 1998		

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL
PROTONIX

		+ WYETH AYERST	EQ 40MG BASE	N20987 001 FEB 02, 2000		

PEMOLINE

TABLET; ORAL
PEMOLINE

	AB	AMIDE PHARM	18.75MG	N75595 001 FEB 28, 2000		
	AB		37.5MG	N75595 002 FEB 28, 2000		
	AB		75MG	N75595 003 FEB 28, 2000		
	AB	COPLEY PHARM	18.75MG	N75030 003 FEB 22, 2000		
> ADD >	AB	GENEVA PHARMS TECH	18.75MG	N75286 001 DEC 27, 1999		
> ADD >						
> ADD >	AB		37.5MG	N75286 002 JUN 30, 1999		
> ADD >						
> ADD >	AB		75MG	N75286 003 JUN 30, 1999		
> ADD >						
> DLT >	AB	INVAMED	18.75MG	N75286 001 DEC 27, 1999		
> DLT >						
> DLT >	AB		37.5MG	N75286 002 JUN 30, 1999		
> DLT >						
> DLT >	AB		75MG	N75286 003 JUN 30, 1999		
> DLT >						

TABLET, CHEWABLE; ORAL
CYLERT

	AB	+ ABBOTT	37.5MG	N17703 001		
		+	37.5MG	N17703 001		

PEMOLINE

	AB	COPLEY PHARM	37.5MG	N75555 001 FEB 18, 2000		

PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL
SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS

		+ US ARMY	50%;50%	N21084 001 FEB 17, 2000		

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
BONTRIL PDM

> DLT >	AA	CARNRICK	35MG	N85272 001		
> ADD >	AA	ELAN PHARMS	35MG	N85272 001		

PREDNISOLONE

SYRUP; ORAL
PREDNISOLONE

AA	COPLEY PHARM	15MG/5ML	N40322 001 JAN 19, 2000		

TABLET; ORAL
PREDNISOLONE

> DLT >	BX	GLOBAL PHARM	5MG	N80780 001	
> ADD >		@ IMPAX LABS	5MG	N80780 001	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.11% PHOSPHATE	N81043 001 OCT 24, 1991		
AT		EQ 0.9% PHOSPHATE	N81044 001 OCT 24, 1991		
AT	STERIS	EQ 0.11% PHOSPHATE	N81043 001 OCT 24, 1991	> ADD >	
AT		EQ 0.9% PHOSPHATE	N81044 001 OCT 24, 1991	> DLT >	

PREDNISOLONE SODIUM PHOSPHATE; SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE

AT	ALCON UNIVERSAL	EQ 0.23% PHOSPHATE;10%	N73630 001 MAY 27, 1993	> DLT >	
AT	STERIS	EQ 0.23% PHOSPHATE;10%	N73630 001 MAY 27, 1993	> ADD >	

PROGESTERONE

CAPSULE; ORAL
PROMETRIUM

	SCHERING PLOUGH	100MG	N19781 001 MAY 14, 1998		
		200MG	N19781 002 OCT 15, 1999		
+		300MG	N19781 003 OCT 15, 1999		
	UNIMED PHARMS	100MG	N19781 001 MAY 14, 1998		

PROGESTERONE

CAPSULE; ORAL
PROMETRIUM

+	UNIMED PHARMS	200MG	N19781 002 OCT 15, 1999		
@		300MG	N19781 003 OCT 15, 1999		

PROPARACAINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC
PROPARACAINE HCL

> ADD >	AT	TAYLOR PHARMA	0.5%	N40277 001 MAR 16, 2000	
> ADD >					

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL
VENTAIRE

> ADD >	@	AVENTIS PHARMS	2MG	N83459 001	
> DLT >	+	HOECHST MARION RSSL	2MG	N83459 001	

RESERPINE

TABLET; ORAL
RESERPINE

> DLT >	BP	GLOBAL PHARM	0.1MG	N09627 001	
> DLT >	BP		0.25MG	N09627 002	
> ADD >		@ IMPAX LABS	0.1MG	N09627 001	
> ADD >		@	0.25MG	N09627 002	

SOTALOL HYDROCHLORIDE

TABLET; ORAL
BETAPACE AF

		BERLEX LABS	80MG	N21151 001 FEB 22, 2000	
			120MG	N21151 002 FEB 22, 2000	
	+		160MG	N21151 003 FEB 22, 2000	

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC
SULFACETAMIDE SODIUM

AT	ALCON UNIVERSAL	10%	N89560 001	> DLT >	
			OCT 18, 1988	> ADD >	
AT	STERIS	10%	N89560 001	> DLT >	
			OCT 18, 1988	> ADD >	

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL
TERAZOSIN HCL

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

TESTOSTERONE

GEL; TOPICAL
ANDROGEL

+	UNIMED PHARMS	1%	N21015 001
			FEB 28, 2000

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-PHYLLIN

@	AVENTIS PHARM PROD	60MG	N85206 001
			MAY 24, 1982
@		125MG	N85203 001
			MAY 24, 1982
@		250MG	N85205 001
			MAY 24, 1982
BC	RHONE POULENC RORER	125MG	N85203 001
			MAY 24, 1982
BC		250MG	N85205 001
			MAY 24, 1982
		60MG	N85206 001
			MAY 24, 1982

TOLBUTAMIDE

TABLET; ORAL
TOLBUTAMIDE

AB	CHELSEA LABS	500MG	N86109 001
AB	+	500MG	N86109 001
AB	+ EON	500MG	N12678 001
	@	500MG	N12678 001

TRETINOIN

GEL; TOPICAL
RETIN-A

AB	+ JOHNSON AND JOHNSON	0.025%	N17579 002	
BT	+	0.025%	N17579 002	
	TRETINOIN			
AB	SPEAR PHARMS	0.025%	N75529 001	
			FEB 22, 2000	

TRIAMCINOLONE ACETONIDE

SPRAY, METERED; NASAL
TRI-NASAL

+	MURO	0.05MG/SPRAY	N20120 001
			FEB 04, 2000

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHEXYPHENIDYL HCL

AA	WEST WARD	2MG	N40337 002
			FEB 16, 2000
AA		5MG	N40337 001
			FEB 16, 2000

TRIMETHOPRIM HYDROCHLORIDE

SOLUTION; ORAL
PRIMSOL

	ASCENT PEDS	EQ 25MG BASE/5ML	N74374 001
			JUN 23, 1995
+		EQ 25MG BASE/5ML	N74374 001
			JUN 23, 1995
+		EQ 50MG BASE/5ML	N74973 001
			JAN 24, 2000

TRIMETREXATE GLUCURONATE

INJECTABLE; INJECTION
NEUTREXIN
+ MEDIMMUNE ONCOLOGY — EQ 25MG BASE/VIAL — N20326 001 DEC 17, 1993 — > ADD >
+ US BIOSCIENCE — EQ 25MG BASE/VIAL — N20326 001 DEC 17, 1993 — > DLT > > ADD >

TROGLITAZONE

TABLET; ORAL
PRELAY

AB	SANKYO	200MG	N20719 001 JAN 29, 1997	
AB		300MG	N20719 003 AUG 04, 1997	> DLT >
AB		400MG	N20719 002 JAN 29, 1997	> ADD >
	@	200MG	N20719 001 JAN 29, 1997	
	@	300MG	N20719 003 AUG 04, 1997	
	@	400MG	N20719 002 JAN 29, 1997	> DLT >

REZULIN

AB	PARKE DAVIS PHARMS	200MG	N20720 001 JAN 29, 1997	> ADD >
AB		300MG	N20720 003 AUG 04, 1997	> ADD >
AB		400MG	N20720 002 JAN 29, 1997	> ADD >
	@	200MG	N20720 001 JAN 29, 1997	
	@	300MG	N20720 003 AUG 04, 1997	> ADD >
	@	400MG	N20720 002 JAN 29, 1997	> ADD >

TROPICAMIDE

SOLUTION/DROPS; OPHTHALMIC
TROPICAMIDE

AT	ALCON UNIVERSAL	1%	N89172 001 DEC 28, 1990	
AT	STERIS	1%	N89172 001 DEC 28, 1990	> DLT > > DLT >

URSODIOL

CAPSULE; ORAL
ACTIGALL

AB	+ NOVARTIS	300MG	N19594 002 DEC 31, 1987	> ADD >
	+	300MG	N19594 002 DEC 31, 1987	> DLT > > ADD >

URSODIOL

AB	AMIDE PHARM	300MG	N75517 001 MAR 14, 2000	> ADD > > ADD >

VITAMIN A

CAPSULE; ORAL
VITAMIN A

AA	GLOBAL PHARM	50,000 USP UNITS	N80952 001	> DLT >
	@ IMPAX LABS	50,000 USP UNITS	N80952 001	> ADD >

VITAMIN A PALMITATE

CAPSULE; ORAL
VITAMIN A

AA	GLOBAL PHARM	EQ 50,000 UNITS BASE	N80953 001	> DLT >
AA		EQ 50,000 UNITS BASE	N80955 001	> DLT >
	@ IMPAX LABS	EQ 50,000 UNITS BASE	N80953 001	> ADD >
	@	EQ 50,000 UNITS BASE	N80955 001	> ADD >

ZOLMITRIPTAN

TABLET; ORAL
ZOMIG

	IPR	2.5MG	N20768 001 NOV 25, 1997	> ADD >
	+	5MG	N20768 002 NOV 25, 1997	> ADD >
	ZENECA	2.5MG	N20768 001 NOV 25, 1997	> DLT > > DLT >
	+	5MG	N20768 002 NOV 25, 1997	> DLT > > DLT >

> ADD > ZONISAMIDE

> ADD > CAPSULE; ORAL
> ADD > ZONEGRAN
> ADD > + DAINIPPON 100MG N20789 001
> ADD > MAR 27, 2000

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL
ACETAMINOPHEN
PERRIGO 650MG N75077 001 FEB 25, 2000

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL
8-HOUR BAYER
+ BAYER 650MG N16030 001
@ 650MG N16030 001
MEASURIN
+ BAYER 650MG N16030 002
@ 650MG N16030 002

CHLORHEXIDINE GLUCONATE

SPONGE; TOPICAL
> ADD > E-Z SCRUB
> ADD > BECTON DICKINSON 4% N73416 001 MAR 14, 2000
> ADD >

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
CONTAC
@ SMITHKLINE 8MG;75MG N18099 001
+ 8MG;75MG N18099 001

CIMETIDINE

TABLET; ORAL
CIMETIDINE
LEINER 200MG N74961 001 JUN 19, 1998
NOVOPHARM 200MG N74961 001 JUN 19, 1998 > ADD >

IBUPROFEN

CAPSULE; ORAL
IBUPROFEN
PHARM FORM 200MG N74782 001 JUL 06, 1998
+ 200MG N74782 001 JUL 06, 1998

TABLET; ORAL
IBUPROFEN
LEINER 200MG N74931 001 JUL 20, 1998
NOVOPHARM 200MG N74931 001 JUL 20, 1998

LOPERAMIDE HYDROCHLORIDE

TABLET; ORAL
LOPERAMIDE HCL
LEINER 2MG N73254 001 JUL 30, 1993
NOVOPHARM NC 2MG N73254 001 JUL 30, 1993
PERRIGO 2MG N75232 001 JAN 06, 2000

NAPROXEN SODIUM

TABLET; ORAL
NAPROXEN SODIUM
LEINER EQ 200MG BASE N74635 001 JAN 13, 1997
NOVOPHARM NC EQ 200MG BASE N74635 001 JAN 13, 1997

PERMETHRIN

LOTION; TOPICAL
PERMETHRIN
> ADD > ALPHARMA 1% N75014 001 MAR 28, 2000
> ADD >

> ADD > PIPERONYL BUTOXIDE; PYRETHRINS

> ADD > AEROSOL; TOPICAL
> ADD > RID MOUSSE
> ADD > + SOLTEC RES 4%;EQ 0.33% BASE N21043 001
> ADD > MAR 07, 2000

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE
CHELSEA LABS EQ 75MG BASE N75212 001
JAN 14, 2000
> ADD > CHEMINOR DRUGS EQ 75MG BASE N75294 001
> ADD > MAR 28, 2000
GENPHARM EQ 75MG BASE N75497 001
JAN 14, 2000
LEINER EQ 75MG BASE N75094 001
JUN 21, 1999
RANBAXY EQ 75MG BASE N75132 001
JAN 14, 2000
EQ 75MG BASE N75254 001
JAN 14, 2000
ZENITH GOLDLINE EQ 75MG BASE N75296 001
JAN 14, 2000
RANITIDINE HCL
NOVOPHARM EQ 75MG BASE N75094 001
JUN 21, 1999

TERBINAFINE HYDROCHLORIDE

> ADD > SOLUTION; TOPICAL
> ADD > LAMISIL AT
> ADD > + NOVARTIS 1% N21124 001
> ADD > MAR 17, 2000

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

CUMULATIVE SUPPLEMENT NUMBER 3 MAR '00

NO MARCH 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 Product Designations and Approvals List
March 2000

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
1-(11-dodecylamino-10-hydroxyundecyl)-3,7-dimethylxanthine hydrogen methanesulfonate TN=	Treatment of hormone refractory prostate carcinoma.	Cell Therapeutics, Inc. 201 Elliott Avenue West Suite 400 Seattle, WA 98119 DD=01/18/2000
3-(3,5-Dimethyl-1H-2ylmethylene)-1,3-dihydro-indol-2-one TN=	Treatment of von Hippel-Lindau disease.	Sugen, Inc. 230 East Grand Ave. South San Francisco, CA 94080 DD=03/23/2000
Angiotensin 1-7 TN=	Treatment of neutropenia associated with autologous bone marrow transplantation.	Maret Pharmaceuticals 4041 MacArthur Blvd. Suite 375 Newport Beach, CA 92660 DD=02/16/2000
Bis(4-fluorophenyl)phenylacetamide TN=	Treatment of sickle cell disease.	ICAgen Inc. Ion Channel Advances PO Box 14487 Durham, NC 27709 DD=03/02/2000
Brimonidine TN= Alphagan	Treatment of anterior ischemic optic neuropathy.	Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine, CA 92623 DD=02/07/2000

Orphan Product Designations and Approvals List
March 2000

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Halofuginone TN= Stenorol	Treatment of systemic sclerosis.	Collgard Biopharmaceuticals Ltd. Textile House, 2 Koifman St. Tel-Aviv 68012 Israel, IL DD=02/07/2000
Histamine TN= Maxamine	For use as an adjunct to cytokine therapy in the treatment of malignant melanoma.	Maxim Pharmaceuticals, Inc. 8899 University Center Lane Suite 400 San Diego, CA 92122 DD=02/01/2000
Hypericin TN=	Treatment of cutaneous T-cell lymphoma.	Nexell Therapeutics, Inc. 2751 Centerville Rd., Suite 210 Wilmington, DE 19808 DD=02/07/2000
Iodine I 131 bis(indium-diethylenetriaminepentaacetic acid)tyrosyllysine/hMN-14 x m734 F(ab')2 bispecific monoclonal antibody TN= Pentacea	Treatment of small-cell lung cancer.	IBC Pharmaceuticals, L.L.C. 300 American Rd. Morris Plains, NJ 07950 DD=02/22/2000
Levodopa and carbidopa TN= Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa, KS 66215 DD=01/18/2000

Orphan Product Designations and Approvals List
March 2000

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Natural human lymphoblastoid interferon-alpha TN=	Treatment of Behcet's disease.	Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo, TX 79101 DD=01/18/2000
Phenylbutyrate TN=	Treatment of acute promyelocytic leukemia.	Elan Corporation 1300 Gould Dr. Gainesville, GA 30504 DD=01/19/2000
Recombinant N-terminal of the human CXC truncated form chemokine GR0Beta, expressed in E. coli TN=	For use alone or in combination with granulocyte colony-stimulating factor in hematopoietic stem cell mobilization for the purposes of autologous stem cell transplantation following high dose chemotherapy.	SmithKline Beecham Pharmaceuticals Mail Code UP4340 1250 S. Collegeville Rd. Collegeville, PA 19426 DD=01/27/2000
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=02/16/2000
Remacemide TN= Ecovia	Treatment of Huntington's disease.	AstraZeneca LP 725 Chesterbrook Blvd. Wayne, PA 19087 DD=03/06/2000
Soluble complement receptor type 1 TN=	Prevention of post-cardiopulmonary bypass syndrome in children undergoing cardiopulmonary bypass.	Avant Immunotherapeutics, Inc. 119 Fourth Ave. Needham, MA 02494 DD=03/06/2000

Orphan Product Designations and Approvals List
March 2000

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Synthetic human secretin TN=	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=03/07/2000
Synthetic porcine secretin TN=	For use in conjunction with diagnostic procedures for pancreatic disorders to increase pancreatic fluid secretion.	ChiRhoClin, Inc. 15500 Gallaudet Ave. Silver Spring, MD 20905 DD=03/07/2000
Technetium Tc 99m pterotetramide TN=	For the identification of ovarian carcinomas.	Endocyte, Inc. 1205 Kent Ave. Lafayette, IN 47906 DD=02/16/2000
Thymalfasin TN= Zadaxin	Treatment of hepatocellular carcinoma.	SciClone Pharmaceuticals, Inc. 901 Mariner's Blvd., Suite 205 San Mateo, CA 94404 DD=03/06/2000
Vapreotide TN= Octastatin	Treatment of gastrointestinal and pancreatic fistulas.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland, CH DD=01/10/2000
Vapreotide TN= Octastatin	Prevention of early postoperative complications following pancreatic resection.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland, CH DD=03/06/2000
Vapreotide TN= Octastatin	Treatment of esophageal variceal hemorrhage patients with portal hypertension.	Debiopharm S.A. 17 rue des Terreaux CH-1000 Lausanne 9 Switzerland, CH DD=01/10/2000

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

NO MARCH 2000 ADDITIONS

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020560 001	ALENDRONATE SODIUM;FOSAMAX	6015801	JUL 17, 2018		M-3	NOV 24, 2002
			5994329	JUL 17, 2018			
			6008207	JUN 06, 2015	U-303		
>ADD>	020560 002	ALENDRONATE SODIUM;FOSAMAX	6015801	JUL 17, 2018		M-3	NOV 24, 2002
			6008207	JUN 06, 2015	U-303		
			5994329	JUL 17, 2018			
>ADD>	020560 003	ALENDRONATE SODIUM;FOSAMAX	6015801	JUL 17, 2018		M-3	NOV 24, 2002
			6008207	JUN 06, 2015	U-303		
			5994329	JUL 17, 2018			
	021107 001	ALOSETRON HYDROCHLORIDE;LOTRONEX				NCE	FEB 09, 2005
	020221 001	AMIFOSTINE;ETHYOL				I-283	JUN 24, 2002
	020221 002	AMIFOSTINE;ETHYOL				I-283	JUN 24, 2002
	021007 001	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2013	U-257		
			5646180	JUL 08, 2014	U-257		
			5585397	DEC 17, 2013			
	021007 002	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2015	U-257		
			5646180	JUL 08, 2014	U-257		
			5585397	DEC 17, 2013			
	021039 001	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2015	U-257		
			5646180	JUL 08, 2014	U-257		
	020971 001	ARTICAINE HYDROCHLORIDE;SEPTOCAINE				NC	APR 03, 2003
	021055 001	BEXAROTENE;TARGRETIN				ODE	DEC 29, 2006
>ADD>	019982 001	BISOPROLOL FUMARATE;ZEBETA	4258062	MAR 24, 2000	U-63		
>ADD>			4258062*PED	SEP 24, 2000	U-63		
>ADD>	019982 002	BISOPROLOL FUMARATE;ZEBETA	4258062	MAR 24, 2000	U-63		
>ADD>			4258062*PED	SEP 24, 2000	U-63		
>ADD>	020186 001	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
>ADD>			4258062*PED	SEP 24, 2000	U-63		
>ADD>	020186 002	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
>ADD>			4258062*PED	SEP 24, 2000	U-63		
>ADD>	020186 003	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
>ADD>			4358062*PED	SEP 24, 2000	U-63		
	020711 002	BUPROPION HYDROCHLORIDE;ZYBAN				D-54	SEP 10, 2002
	020711 003	BUPROPION HYDROCHLORIDE;ZYBAN				D-54	SEP 10, 2002
>ADD>	020793 001	CAFFEINE CITRATE;CAFCIT				ODE	SEP 21, 2006
	020297 001	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
	020297 002	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
	020297 003	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
	020297 004	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
	020989 002	CEVIMELINE HYDROCHLORIDE;EVOXAC	4855290	AUG 08, 2006		NCE	JAN 11, 2005
			5340821	AUG 23, 2011	U-309		
			5580880	JUN 06, 2015	U-310		
	020154 004	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
	021027 001	DOXERCALCIFEROL;HECTOROL				NDF	APR 06, 2003
						NCE	JUN 09, 2004

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	019221 001	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
			4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
			4472380*PED	MAR 18, 2002			
	019221 003	ENALAPRIL MALEATE;VASERETIC	4472380	SEP 18, 2001			
			4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
			4472380*PED	MAR 18, 2002			
	018998 001	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
	018998 002	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
	018998 003	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
	018998 005	ENALAPRIL MALEATE;VASOTEC	4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
	019309 001	ENALAPRILAT;VASOTEC	4374829	FEB 22, 2000			
			4374829*PED	AUG 22, 2000			
>ADD>	020444 001	EPOPROSTENOL SODIUM;FLOLAN				ODE	APR 14, 2007
>ADD>	020444 002	EPOPROSTENOL SODIUM;FLOLAN				ODE	APR 14, 2007
	021040 001	ESTRADIOL;ORTHO-PREFEST	5108995	APR 28, 2009	U-311		
			5382573	JAN 17, 2012			
	020584 001	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
			4966768	OCT 30, 2007			
	020584 002	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
			4966768	OCT 30, 2007			
	020584 003	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
			4966768	OCT 30, 2007			
	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017	U-138		
	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5375693	AUG 03, 2012	U-138	NDF	FEB 25, 2003
			5578610	NOV 26, 2013	U-139		
	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5375693	AUG 03, 2012	U-138	NDF	FEB 25, 2003
			5578610	NOV 26, 2013	U-139		
	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5375693	AUG 03, 2012	U-138	NDF	FEB 25, 2003
			5578610	NOV 26, 2013	U-139		
	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	6037353	MAR 14, 2017	U-138		
	019949 004	FLUCONAZOLE;DIFLUCAN	4416682	JUN 02, 2001			
			4404216	JAN 29, 2004			
>ADD>	020235 001	GABAPENTIN;NEURONTIN	6054482	APR 25, 2017		PED	MAR 29, 2002
>ADD>			6054482*PED	OCT 25, 2017		D-43	SEP 29, 2001
			4087544	JAN 16, 2000	U-86		
			5084479	JAN 02, 2010	U-125		
			4894476*PED	NOV 02, 2008			
			4087544*PED	JUL 16, 2000	U-86		
			5084479*PED	JUL 02, 2010	U-125		
			4894476	MAY 02, 2008			

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020235 002	GABAPENTIN;NEURONTIN	6054482	APR 25, 2017		PED	MAR 29, 2002
>ADD>			6054482*PED	OCT 25, 2017		D-43	SEP 29, 2001
			4894476	MAY 02, 2008			
			5084479	JAN 02, 2010	U-125		
			4087544	JAN 16, 2000	U-86		
			5084479*PED	JUL 02, 2010	U-125		
			4894476*PED	NOV 02, 2008			
			4087544*PED	JUL 16, 2000	U-86		
>ADD>	020235 003	GABAPENTIN;NEURONTIN	6054482	APR 25, 2017		PED	MAR 29, 2002
>ADD>			6054482*PED	OCT 25, 2017		D-43	SEP 29, 2001
			4087544	JAN 16, 2000	U-86		
			5084479	JAN 02, 2010	U-125		
			4894476	MAY 02, 2008			
			4087544*PED	JUL 16, 2000	U-86		
			5084479*PED	JUL 02, 2010			
			4894476*PED	NOV 02, 2008			
>ADD>	020882 001	GABAPENTIN;NEURONTIN	6054482	APR 25, 2017			
>ADD>			6054482*PED	OCT 25, 2017			
			4087544	JAN 16, 2000	U-106		
			4894476	MAY 02, 2008			
			5084479	JAN 02, 2010	U-258		
			5084479*PED	JUL 02, 2010	U-258		
			4087544*PED	JUL 16, 2000	U-106		
			4894476*PED	NOV 02, 2008			
>ADD>	020882 002	GABAPENTIN;NEURONTIN	6054482	APR 25, 2017			
>ADD>			6054482*PED	OCT 25, 2017			
			4087544	JAN 16, 2000	U-106		
			4894476	MAY 02, 2008			
			5084479	JAN 02, 2010	U-258		
			4087544*PED	JUL 16, 2000	U-106		
			4894476*PED	NOV 02, 2008			
			5084479*PED	JUL 02, 2010	U-258		
	020460 002	GANCICLOVIR;CYTOVENE	4507305	MAY 21, 2001	U-64		
			4423050	MAY 21, 2001	U-64		
			4355032	JUN 23, 2003	U-64		
			4642346	JUN 24, 2005			
	020622 001	GLATIRAMER ACETATE;COPAXONE	5981589	MAY 24, 2014			
	020125 001	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
	020125 002	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
	020125 003	HYDROCHLOROTHIAZIDE;ACCURETIC				NC	DEC 28, 2002
	019778 001	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001			
	019778 002	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001			
	019778 003	HYDROCHLOROTHIAZIDE;PRINZIDE	4374829	DEC 29, 2001	U-3		
>ADD>	021018 001	INSULIN LISPRO;HUMALOG MIX 50/50				NC	DEC 22, 2002

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020563 002	INSULIN LISPRO;HUMALOG PEN	5474978	JUN 16, 2014		NCE	JUN 14, 2001
			5514646	MAY 07, 2013	U-111		
>ADD>	019084 001	KETOCONAZOLE;NIZORAL	4942162	FEB 11, 2003			
	020857 001	LAMIVUDINE;COMBIVIR	5905082	MAY 18, 2016	U-248		
	020564 001	LAMIVUDINE;EPIVIR	5047407	NOV 17, 2009			
	020596 001	LAMIVUDINE;EPIVIR	5047407	NOV 17, 2009			
	021088 001	LEUPROLIDE ACETATE;VIADUR	5728396	JAN 30, 2017	U-316	NP	MAR 03, 2003
			5932547	JUN 13, 2017			
			5985305	JAN 30, 2017			
	021114 001	LEVOBETAXOLOL HYDROCHLORIDE;BETAXON				NP	FEB 23, 2003
	020612 001	LIDOCAINE;LIDODERM				NP	MAR 19, 2002
>ADD>	021130 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
>ADD>	021130 002	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
>ADD>	021131 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
>ADD>	021132 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	019558 001	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 002	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 003	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 004	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019558 006	LISINOPRIL;PRINIVIL	4374829	DEC 29, 2001			
	019777 001	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 002	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 003	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 004	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 005	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
	019777 006	LISINOPRIL;ZESTRIL				I-288	FEB 07, 2003
>ADD>	020938 001	MELOXICAM;MOBIC				NCE	APR 13, 2005
	020357 001	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000
	020357 002	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000
	020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000
>ADD>	019815 001	MIDODRINE HYDROCHLORIDE;PROAMATINE				ODE	SEP 06, 2003
>ADD>	019815 002	MIDODRINE HYDROCHLORIDE;PROAMATINE				ODE	SEP 06, 2003
	020152 001	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 002	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 003	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 004	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 005	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
	020152 006	NEFAZODONE HYDROCHLORIDE;SERZONE	5256664	APR 28, 2012			
>ADD>	021134 001	NITROGLYCERIN;NITROGLYCERIN				NDF	MAY 01, 2003
>ADD>	021134 002	NITROGLYCERIN;NITROGLYCERIN				NDF	MAY 01, 2003
>ADD>	021134 003	NITROGLYCERIN;NITROGLYCERIN				NDF	MAY 01, 2003

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	019715 001	OLSALAZINE SODIUM;DIPENTUM	4559330	JUL 31, 2004	U-58		
	021014 001	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
	021014 002	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
	021014 003	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
	020987 001	PANTOPRAZOLE SODIUM;PROTONIX	4758579	JUL 19, 2005		NCE	FEB 02, 2005
	020819 001	PARICALCITOL;ZEMPLAR	5246925	SEP 21, 2010	U-314		
			5587497	DEC 24, 2013			
>ADD>	021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER;SKIN EXPOSURE REDUCT	5607979	MAY 30, 2015		NCE	FEB 17, 2005
	019898 002	PRAVASTATIN SODIUM;PRAVACHOL				I-287	FEB 10, 2003
						I-286	JAN 18, 2003
						D-51	JAN 18, 2003
	019898 003	PRAVASTATIN SODIUM;PRAVACHOL				I-287	FEB 10, 2003
						I-286	JAN 18, 2003
						D-51	JAN 18, 2003
	019898 004	PRAVASTATIN SODIUM;PRAVACHOL				I-287	FEB 10, 2003
						I-286	JAN 18, 2003
						D-51	JAN 18, 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
			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
			5019583	FEB 15, 2009		PED	JAN 12, 2002
			5466700*PED	MAR 01, 2014	U-156	NCE	JUL 12, 2001
	020630 002	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
			5019583*PED	AUG 15, 2009		PED	JAN 12, 2002
			5466700*PED	MAR 01, 2014		NCE	JUL 12, 2001
	020630 003	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
			5019583*PED	AUG 15, 2009		PED	JAN 12, 2002
			5466700*PED	MAR 01, 2014	U-156	NCE	JUL 12, 2001
>ADD>	020835 001	RISEDRONATE SODIUM;ACTONEL				I-292	APR 14, 2003
>ADD>						I-291	APR 14, 2003
>ADD>						I-290	APR 14, 2003
>ADD>						I-293	APR 14, 2003
	020588 001	RISPERIDONE;RISPERDAL	5453425	JUL 11, 2014			
			5616587	JUL 11, 2014			
	020864 001	RIZATRIPTAN BENZOATE;MAXALT	5602162	FEB 11, 2014			
			5602162	FEB 11, 2014			
	020864 002	RIZATRIPTAN BENZOATE;MAXALT	5602162	FEB 11, 2014			
			5602162	FEB 11, 2014			
	021071 002	ROSIGLITAZONE MALEATE;AVANDIA				I-289	APR 03, 2003
	021071 003	ROSIGLITAZONE MALEATE;AVANDIA				I-289	APR 03, 2003
	021071 004	ROSIGLITAZONE MALEATE;AVANDIA				I-289	APR 03, 2003
	020990 001	SERTRALINE HYDROCHLORIDE;ZOLOFT	4536518	DEC 30, 2005	U-286		
			4940731	AUG 30, 2009	U-312		

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	019721 001	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019721 002	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
>ADD>	019676 001	SOMATROPIN RECOMBINANT;NUTROPIN				D-55	APR 13, 2003
						M-2	DEC 01, 2002
>ADD>	019676 002	SOMATROPIN RECOMBINANT;NUTROPIN				D-55	APR 13, 2003
						M-2	DEC 01, 2002
>ADD>	020522 001	SOMATROPIN RECOMBINANT;NUTROPIN AQ				D-55	APR 13, 2003
						M-2	DEC 01, 2002
	021151 001	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
	021151 002	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
	021151 003	SOTALOL HYDROCHLORIDE;BETAPACE AF				NP	FEB 22, 2003
	021015 001	TESTOSTERONE;ANDROGEL				NDF	FEB 28, 2003
>ADD>	020771 001	TOLTERODINE TARTRATE;DETROL	5559269	MAY 05, 2015	U-318		
>ADD>	020771 002	TOLTERODINE TARTRATE;DETROL	5559269	MAY 05, 2015	U-318		
>ADD>	020281 001	TRAMADOL HYDROCHLORIDE;ULTRAM				PED	SEP 03, 2000
>ADD>						PED	FEB 21, 2002
>ADD>						NCE	MAR 03, 2000
>ADD>						D-44	AUG 21, 2001
>ADD>	020281 002	TRAMADOL HYDROCHLORIDE;ULTRAM				PED	FEB 21, 2002
>ADD>						PED	SEP 03, 2000
>ADD>						NCE	MAR 03, 2000
>ADD>						D-44	AUG 21, 2001
	020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
	020326 002	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
>ADD>	020719 001	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
>ADD>	020719 002	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
>ADD>	020719 003	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
>ADD>	020720 001	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
>ADD>	020720 002	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
>ADD>	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			
			4946687	OCT 02, 2007			
			5785994	OCT 22, 2009	U-315		
	020552 002	VERAPAMIL HYDROCHLORIDE;COVERA-HS	5232705	AUG 31, 2010			
			5200196	JAN 22, 2008			
			5141752	JUN 27, 2006			
			5082668	JAN 21, 2009			
			5030456	NOV 07, 2008			
			4946687	OCT 02, 2007			
			5785994	OCT 22, 2009	U-315		

PRESCRIPTION AND OTC DRUG PRODUCT
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021119 001	VERTEPORFIN;VISUDYNE				NCE	APR 12, 2005
	020789 001	ZONISAMIDE;ZONEGRAN				NCE	MAR 27, 2005

PATENT AND EXCLUSIVITY TERMS

DUE TO SPACE LIMITATIONS IN THE PATENT AND EXCLUSIVITY COLUMNS, ABBREVIATIONS AND REFERENCES HAVE BEEN DEVELOPED. PLEASE REFER BACK TO THE APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 20TH EDITION FOR A FULL LISTING OF PATENT AND EXCLUSIVITY TERMS (ABBREVIATIONS, NEW DOSING SCHEDULE, NEW INDICATIONS AND PATENT USE CODES). THE CUMULATIVE SUPPLEMENT WILL LIST NEW CODES ADDED SINCE THE LAST ANNUAL EDITION.

ABBREVIATIONS

NPP	**NEW PATIENT POPULATION**

REFERENCES

NEW DOSING SCHEDULE

D-51	**OPTIONAL STARTING DOSE OF 40MG/DAY**
D-52	**ALTERNATE DOSING REGIMEN OF 1250MG TWICE DAILY**
D-53	**USE IN PEDIATRIC PATIENTS FROM 1 MONTH TO 16 YEARS OF AGE**
D-54	**USE OF ZYBAN FOR MAINTENANCE THERAPY. TREATMENT UP TO 6 MONTHS WAS SHOWN EFFICACIOUS**
D-55	**ADDITION OF A HIGHER DOSE OF NUTROPIN FOR PUBERTAL PATIENTS (PUBERTAL DOSE LESS THAN OR EQUAL TO 0.7MG/KG/WEEK)**

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 MELLLITUS WHEN DIET AND EXERCISE WITH EITHER SINGLE AGENT DOES NOT ACHIEVE ADEQUATE GLYCEMIC CONTROL**
I-290	**TREATMENT OF CORTICOSTEOID-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

MISCELLANEOUS EXCLUSIVITY CODES

M-2	APPROVAL FOR ADDTION 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-309	TREATING SJOEGREN SYNDROME
U-310	TREATMENT OF XEROSTOMIA
U-311	HORMONE REPLACEMENT
U-312	PANIC DISORDER OBSESSIVE-COMPULSIVE DISORDER POSTTRAUMATIC STRESS DISORDER
U-313	TREATMENT OF CONGESTIVE HEART FAILURE
U-314	METHOD FOR TREATING HYPERPARATHYROIDISM WHICH COMPRISES SUPPRESSING PARATHYROID ACTIVITY
U-315	METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT
U-316	METHOD OF TREATING A SUBJECT SUFFERING FROM PROSTATE CANCER
U-317	METHOD OF USING TROGLITAZONE TO TREAT PATIENTS HAVING INSULIN RESISTANCE
U-318	TREATMENT OF PATIENTS WITH AN OVERACTIVE BLADDER WITH SYMPTOMS OF URINARY FREQUENCY, URGENCY, OR URGE INCONTINENCE
U-319	TREATMENT OF MICROBIAL INFECTIONS

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