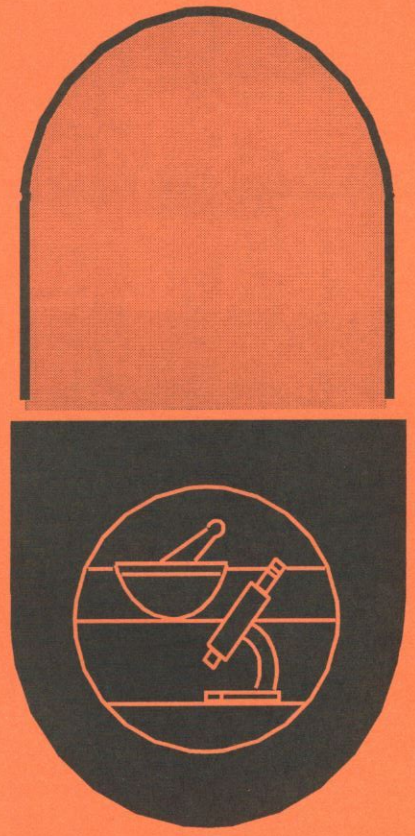
CUMULATIVE
SUPPLEMENT 2
FEB'00



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

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

20TH EDITION

Cumulative Supplement 2

FEBRUARY 2000

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with
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20TH EDITION

CUMULATIVE SUPPLEMENT 2
FEBRUARY 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 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)
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 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			
SINGLE SOURCE	2599 (25.9%)			
MULTISOURCE	7335 (73.0%)			
THERAPEUTICALLY EQUIVALENT	6986 (69.5%)			
NOT THERAPEUTICALLY EQUIVALENT	349 (3.5%)			
EXCEPTIONS[1]	111 (1.1%)			
NEW MOLECULAR ENTITIES APPROVED	0			
NUMBER OF APPLICANTS	576			

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

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
LORTAB

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

> ADD > ALOSETRON HYDROCHLORIDE

> ADD > TABLET; ORAL
> ADD > LOTRONEX

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

ALTRETAMINE

CAPSULE; ORAL
HEXALEN

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

AMIFOSTINE

INJECTABLE; INJECTION
ETHYOL

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

BUPROPION HYDROCHLORIDE

TABLET; ORAL
BUPROPION HCL

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

CALCIUM CHLORIDE

INJECTABLE; INJECTION
CALCIUM CHLORIDE 10% IN PLASTIC CONTAINER

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

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

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

CEFTIBUTEN DIHYDRATE

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

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER

+	ROCHE	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

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC

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

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

LOTION; TOPICAL
LOPROX
> DLT > + HOECHST MARION RSSL 1% N19824 001
> DLT > DEC 30, 1988

CLADRIBINE

INJECTABLE; INJECTION
> ADD > CLADRIBINE
> ADD > AP BEDFORD 1MG/ML N75405 001
> ADD > FEB 28, 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
> ADD > AB ALTANA 0.05% N75368 001
> ADD > FEB 15, 2000

CROMOLYN SODIUM

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

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

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
AP GENSIA SICOR PHARMS EQ 5MG BASE/ML N65035 001
JAN 24, 2000

DEMECLOCYCLINE HYDROCHLORIDE

> DLT > CAPSULE; ORAL
> DLT > DECLOMYCIN
> DLT > + LEDERLE 150MG N50262 001
> ADD > @ 150MG N50262 001

DESMOPRESSIN ACETATE

INJECTABLE; INJECTION

DESMOPRESSIN ACETATE

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

DESMOPRESSIN ACETATE PRESERVATIVE FREE

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

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 SODIUM

SOLUTION/DROPS; OPHTHALMIC

DICLOFENAC SODIUM

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

VOLTAREN

> DLT >	AB	+ CIBA	0.1%	N20037 001	
> DLT >				MAR 28, 1991	
> ADD >		+	0.1%	N20037 001	
> ADD >				MAR 28, 1991	

TABLET, EXTENDED RELEASE; ORAL

DICLOFENAC SODIUM

> ADD >					
> ADD >	AB	BIOVAIL	100MG	N75492 001	
> ADD >				FEB 11, 2000	

VOLTAREN-XR

> ADD >	AB	+ NOVARTIS	100MG	N20254 001	
> ADD >				MAR 08, 1996	
> DLT >		+	100MG	N20254 001	
> DLT >				MAR 08, 1996	

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILTIAZEM HCL

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

INJECTABLE; INJECTION

DILTIAZEM HCL

> ADD >	AP	ABBOTT	5MG/ML	N75004 001	
> ADD >				FEB 16, 2000	

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

> ADD >	AB	+ BERLEX LABS	0.05MG/24HR	N20375 001	
> ADD >				DEC 22, 1994	

† SEE SECTION 1.3 OF INTRODUCTION

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

> ADD >	AB	+	BERLEX LABS	0.1MG/24HR	N20375 002 DEC 22, 1994	
> ADD >						
> DLT >	BX	+		0.05MG/24HR	N20375 001 DEC 22, 1994	
> DLT >						
> DLT >	BX	+		0.1MG/24HR	N20375 002 DEC 22, 1994	
> DLT >						
> ADD >			**ESTRADIOL**			
> ADD >	AB		MYLAN TECHNOLOGIES	0.05MG/24HR	N75233 001 FEB 24, 2000	
> ADD >						
> ADD >	AB			0.1MG/24HR	N75182 001 FEB 24, 2000	
> ADD >						

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

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

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

TRIVORA-21

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

TABLET; ORAL-28

TRIVORA-28

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

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

OVCON-35

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

OVCON-50

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

TABLET; ORAL-28

OVCON-35

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

OVCON-50

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

FEXOFENADINE HYDROCHLORIDE

TABLET; ORAL

ALLEGRA

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

FLUCONAZOLE

TABLET; ORAL

DIFLUCAN

> DLT >			PFIZER	150MG	N20322 001 JUN 30, 1994
> DLT >					
> ADD >				150MG	N19949 004 JUN 30, 1994
> ADD >					

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

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

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
GENTAMICIN SULFATE

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

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION
HALOPERIDOL DECANOATE

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

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

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION
HYDRALAZINE HCL

	+ LUITPOLD	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	

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	
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	

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

> ADD >	AN STERIPAK	0.02%	N75313 001	
> ADD >			FEB 07, 2000	

ISOPROTERENOL HYDROCHLORIDE

SOLUTION; INHALATION
ISUPREL

> DLT >	+ SANOFI SYNTHELABO	0.5%	N06327 002	
> DLT >	+	1%	N06327 003	
> ADD >	@	0.5%	N06327 002	
> ADD >	@	1%	N06327 003	

KETOCONAZOLE

CREAM; TOPICAL
NIZORAL

> DLT >	+ JANSSEN	2%	N19084 001	
> DLT >			DEC 31, 1985	
> ADD >	+ MCNEIL CONS	2%	N19084 001	
> ADD >			DEC 31, 1985	

SHAMPOO; TOPICAL
NIZORAL

> DLT >	+ JANSSEN	2%	N19927 001	
> DLT >			AUG 31, 1990	
> ADD >	+ MCNEIL CONS	2%	N19927 001	
> ADD >			AUG 31, 1990	

> ADD > LEVOBETAXOLOL HYDROCHLORIDE

SUSPENSION/DROPS; OPHTHALMIC
BETAXON

> ADD >	+ ALCON	EQ 0.5% BASE	N21114 001	
> ADD >			FEB 23, 2000	

MEGESTROL ACETATE

TABLET; ORAL
MEGESTROL ACETATE

> DLT >	AB PHARMACHEMIE	40MG	N74745 001	
> DLT >			FEB 27, 1998	
> ADD >	AB TEVA	40MG	N74745 001	
> ADD >			FEB 27, 1998	

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION
MENOTROPINS

> ADD >	@ FERRING	75 IU/VIAL;75 IU/VIAL	N73598 001	
> ADD >			JAN 30, 1997	
> ADD >	@	150 IU/VIAL;150 IU/VIAL	N73599 001	
> ADD >			JAN 30, 1997	
> DLT >	REPRONEX			
> DLT >	AB FERRING	75 IU/VIAL;75 IU/VIAL	N73598 001	
> DLT >			JAN 30, 1997	
> DLT >	AB	150 IU/VIAL;150 IU/VIAL	N73599 001	
> DLT >			JAN 30, 1997	

MESTRANOL; NORETHINDRONE

TABLET; ORAL-20
NORINYL

> DLT >	@ SEARLE	0.1MG;2MG	N13625 004	
> ADD >	@ WATSON LABS	0.1MG;2MG	N13625 004	

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

> DLT >	AB SEARLE	0.05MG;1MG	N13625 002	
> ADD >	AB WATSON LABS	0.05MG;1MG	N13625 002	

METAPROTERENOL SULFATE

SYRUP; ORAL
METAPROTERENOL SULFATE

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

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL
MORPHINE SULFATE

AB	ESI LEDERLE	**15MG**	**N75407 001**	
			JAN 28, 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

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

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL
ORPHENADRINE CITRATE

> ADD >	**AB**	EON	**100MG**	**N40327 001**
> ADD >				FEB 15, 2000

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
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

> ADD > PANTOPRAZOLE SODIUM

> ADD > TABLET, DELAYED RELEASE; ORAL
> ADD > PROTONIX
> ADD > + WYETH AYERST EQ 40MG BASE N20987 001
> ADD > FEB 02, 2000

PEMOLINE

TABLET; ORAL
PEMOLINE

> ADD >	**AB**	AMIDE PHARM	**18.75MG**	**N75595 001**
> ADD >				FEB 28, 2000

PEMOLINE

TABLET; ORAL

			PEMOLINE			
> ADD >	AB		AMIDE PHARM	37.5MG	N75595 002	
> ADD					FEB 28, 2000	
> ADD >	AB			75MG	N75595 003	
> ADD					FEB 28, 2000	
> ADD >	AB		COPLEY PHARM	18.75MG	N75030 003	
> ADD >					FEB 22, 2000	

TABLET, CHEWABLE; ORAL

			CYLERT			
> ADD >	AB	+	ABBOTT	37.5MG	N17703 001	
> DLT >		+		37.5MG	N17703 001	
> ADD >			**PEMOLINE**			
> ADD >	AB		COPLEY PHARM	37.5MG	N75555 001	
> ADD >					FEB 18, 2000	

> ADD > PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL

> ADD >		SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE			
> ADD >		AGENTS			
> ADD >	+	US ARMY	50%;50%	N21084 001	
> ADD >				FEB 17, 2000	

PREDNISOLONE

SYRUP; ORAL

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

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	
AT		EQ 0.9% PHOSPHATE	N81044 001	
			OCT 24, 1991	

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	
AT	STERIS	EQ 0.23% PHOSPHATE;10%	N73630 001	
			MAY 27, 1993	

PROGESTERONE

CAPSULE; ORAL

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

SOTALOL HYDROCHLORIDE

TABLET; ORAL

> ADD >		**BETAPACE AF**		
> ADD >		BERLEX LABS	80MG	N21151 001
> ADD >				FEB 22, 2000
> ADD >			120MG	N21151 002
> ADD >				FEB 22, 2000
> ADD >	+		160MG	N21151 003
> ADD >				FEB 22, 2000

SULFACETAMIDE SODIUM

SOLUTION/DROPS; OPHTHALMIC

	SULFACETAMIDE SODIUM			
AT	ALCON UNIVERSAL	10%	N89560 001	
			OCT 18, 1988	
AT	STERIS	10%	N89560 001	
			OCT 18, 1988	

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HCL

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

TESTOSTERONE

GEL; TOPICAL

ANDROGEL

> ADD >		+ UNIMED PHARMS	1%	N21015 001	
> ADD >				FEB 28, 2000	

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

SLO-PHYLLIN

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

TRETINOIN

GEL; TOPICAL

RETIN-A

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

TRIAMCINOLONE ACETONIDE

SPRAY, METERED; NASAL

TRI-NASAL

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

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL

TRIHEXYPHENIDYL HCL

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

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

TROGLITAZONE

TABLET; ORAL

PRELAY

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

TROGLITAZONE

> DLT >		TABLET; ORAL		
> DLT >		**PRELAY**		
> DLT >	**AB**	**SANKYO**	**400MG**	**N20719 002**
				JAN 29, 1997
> DLT				
> ADD >		@	200MG	N20719 001
> ADD >				JAN 29, 1997
> ADD >		@	300MG	N20719 003
> ADD >				AUG 04, 1997
> ADD >		@	400MG	N20719 002
> ADD >				JAN 29, 1997
> DLT >		**REZULIN**		
> DLT >	**AB**	**PARKE DAVIS PHARMS**	**200MG**	**N20720 001**
				JAN 29, 1997
> DLT >	**AB**		**300MG**	**N20720 003**
				AUG 04, 1997
> DLT >	**AB**		**400MG**	**N20720 002**
				JAN 29, 1997
> ADD >		@	200MG	N20720 001
> ADD >				JAN 29, 1997
> ADD >		@	300MG	N20720 003
> ADD >				AUG 04, 1997
> ADD >		@	400MG	N20720 002
> ADD >				JAN 29, 1997

TROPICAMIDE

		SOLUTION/DROPS; OPHTHALMIC		
		TROPICAMIDE		
	AT	ALCON UNIVERSAL	**1%**	**N89172 001**
				DEC 28, 1990
	AT	**STERIS**	**1%**	**N89172 001**
				DEC 28, 1990

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL

> ADD >	ACETAMINOPHEN				
> ADD >	PERRIGO	650MG	N75077 001	> DLT >	
> ADD >			FEB 25, 2000	> DLT >	

ASPIRIN

TABLET, EXTENDED RELEASE; ORAL

> DLT >	8-HOUR BAYER				
> DLT >	+ BAYER	650MG	N16030 001	> ADD >	
> ADD >	@	650MG	N16030 001	> ADD >	
> DLT >	MEASURIN			> DLT >	
> DLT >	+ BAYER	650MG	N16030 002	> DLT >	
> ADD >	@	650MG	N16030 002		

CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

	CONTAC				
> DLT >	@ SMITHKLINE	8MG;75MG	N18099 001		
> ADD >	+	8MG;75MG	N18099 001	> ADD >	
				> ADD >	
				> DLT >	
				> DLT >	

CIMETIDINE

TABLET; ORAL

	CIMETIDINE				
> ADD >	LEINER	200MG	N74961 001		
> ADD >			JUN 19, 1998		
> DLT >	NOVOPHARM	200MG	N74961 001		
> DLT >			JUN 19, 1998		

IBUPROFEN

CAPSULE; ORAL

	IBUPROFEN				
	PHARM FORM	200MG	N74782 001		
			JUL 06, 1998	> ADD >	
	+	200MG	N74782 001	> ADD >	
			JUL 06, 1998		

TABLET; ORAL

	IBUPROFEN				
> ADD >	LEINER	200MG	N74931 001	> DLT >	
> ADD >			JUL 20, 1998	> DLT >	

IBUPROFEN

TABLET; ORAL

	IBUPROFEN				
	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		

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

	RANITIDINE				
	CHELSEA LABS	EQ 75MG BASE	N75212 001		
			JAN 14, 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		

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

CUMULATIVE SUPPLEMENT NUMBER 2 FEB '00

NO FEBRUARY 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
February 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
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
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
Halofuginone TN= Stenorol	Treatment of systemic sclerosis.	Collgard Biopharmaceuticals Ltd. Textile House, 2 Koifman St. Tel-Aviv 68012 Israel, IL DD=02/07/2000

Orphan Product Designations and Approvals List
February 2000

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

Orphan Product Designations and Approvals List
February 2000

Name Generic Name TN=Trade Name	Indication Designated	Sponsor & Address DD= Date Designated MA=Marketing Approval
Recombinant N-terminal truncated form of the human CXC 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
Technetium Tc 99m pterotetramide TN=	For the identification of ovarian carcinomas.	Endocyte, Inc. 1205 Kent Ave. Lafayette, IN 47906 DD=02/16/2000
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	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 FEBRUARY 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	5994329	JUL 17, 2018			
>ADD>			6008207	JUN 06, 2015	U-303		
>ADD>	020560 002	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303		
>ADD>			5994329	JUL 17, 2018			
>ADD>	020560 003	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303		
>ADD>			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
>ADD>	021007 001	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2013	U-257		
>ADD>			5646180	JUL 08, 2014	U-257		
>ADD>			5585397	DEC 17, 2013			
>ADD>	021007 002	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2015	U-257		
>ADD>			5646180	JUL 08, 2014	U-257		
>ADD>			5585397	DEC 17, 2013			
>ADD>	021039 001	AMPRENAVIR;AGENERASE	5723490	MAR 03, 2015	U-257		
>ADD>			5646180	JUL 08, 2014	U-257		
>ADD>	020971 001	ARTICAINE HYDROCHLORIDE;SEPTOCAINE				NC	APR 03, 2003
	021055 001	BEXAROTENE;TARGRETIN				ODE	DEC 29, 2006
>ADD>	020711 002	BUPROPION HYDROCHLORIDE;ZYBAN				D-54	SEP 10, 2002
>ADD>	020711 003	BUPROPION HYDROCHLORIDE;ZYBAN				D-54	SEP 10, 2002
>ADD>	020297 001	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
>ADD>	020297 002	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
>ADD>	020297 003	CARVEDILOL;COREG	5902821	FEB 07, 2016	U-313		
>ADD>	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		
>ADD>	020154 004	DIDANOSINE;VIDEX	5580880	JUN 06, 2015	U-310		
>ADD>	021027 001	DOXERCALCIFEROL;HECTOROL	5616566	AUG 29, 2006	U-180		
>ADD>						NDF	APR 06, 2003
	019221 001	ENALAPRIL MALEATE;VASERETIC				NCE	JUN 09, 2004
			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			

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
	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			
	021040 001	ESTRADIOL;ORTHO-PREFEST	5108995	APR 28, 2009	U-311		
			5382573	JAN 17, 2012			
>ADD>	020584 001	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
>ADD>	020584 002	ETODOLAC;LODINE XL	4966768*PED	APR 30, 2008			
>ADD>	020584 003	ETODOLAC;LODINE XL	4966768*PED	OCT 30, 2008			
	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017	U-138		
>ADD>	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5375693	AUG 03, 2012	U-138	NDF	FEB 25, 2003
>ADD>			5578610	NOV 26, 2013	U-139		
>ADD>	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5375693	AUG 03, 2012	U-138	NDF	FEB 25, 2003
>ADD>			5578610	NOV 26, 2013	U-139		
>ADD>	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5375693	AUG 03, 2012	U-138	NDF	FEB 25, 2003
>ADD>			5578610	NOV 26, 2013	U-139		
	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	6037353	MAR 14, 2017	U-138		
>ADD>	019949 004	FLUCONAZOLE;DIFLUCAN	4416682	JUN 02, 2001			
>ADD>			4404216	JAN 29, 2004			
	020235 001	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
			5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
			4894476*PED	NOV 02, 2008			
			4087544*PED	JUL 16, 2000	U-86		
			5084479*PED	JUL 02, 2010	U-125		
			4894476	MAY 02, 2008			
	020235 002	GABAPENTIN;NEURONTIN	4894476	MAY 02, 2008		PED	MAR 29, 2002
			5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
			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		
	020235 003	GABAPENTIN;NEURONTIN	4087544	JAN 16, 2000	U-86	PED	MAR 29, 2002
			5084479	JAN 02, 2010	U-125	D-43	SEP 29, 2001
			4894476	MAY 02, 2008			
			4087544*PED	JUL 16, 2000	U-86		
			5084479*PED	JUL 02, 2010			
			4894476*PED	NOV 02, 2008			
	020882 001	GABAPENTIN;NEURONTIN	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			
	020882 002	GABAPENTIN;NEURONTIN	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		

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
	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			
>ADD>	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>	020563 002	INSULIN LISPRO;HUMALOG PEN	5474978	JUN 16, 2014		NCE	JUN 14, 2001
>ADD>			5514646	MAY 07, 2013	U-111		
>ADD>	020857 001	LAMIVUDINE;COMBIVIR	5905082	MAY 18, 2016	U-248		
>ADD>	020564 001	LAMIVUDINE;EPIVIR	5047407	NOV 17, 2009			
>ADD>	020596 001	LAMIVUDINE;EPIVIR	5047407	NOV 17, 2009			
>ADD>	021088 001	LEUPROLIDE ACETATE;VIADUR	5728396	JAN 30, 2017	U-316	NP	MAR 03, 2003
>ADD>			5932547	JUN 13, 2017			
>ADD>			5985305	JAN 30, 2017			
>ADD>	021114 001	LEVOBETAXOLOL HYDROCHLORIDE;BETAXON				NP	FEB 23, 2003
>ADD>	020612 001	LIDOCAINE;LIDODERM				NP	MAR 19, 2002
	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>	020357 001	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
>ADD>						NCE	MAR 03, 2000
>ADD>	020357 002	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
>ADD>						NCE	MAR 03, 2000
>ADD>	020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
>ADD>						NCE	MAR 03, 2000
	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			

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
>ADD>	019715 001	OLSALAZINE SODIUM;DIPENTUM	4559330	JUL 31, 2004	U-58		
>ADD>	021014 001	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>	021014 002	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>	021014 003	OXCARBAZEPINE;TRILEPTAL				NCE	JAN 14, 2005
>ADD>	020987 001	PANTOPRAZOLE SODIUM;PROTONIX	4758579	JUL 19, 2005		NCE	FEB 02, 2005
>ADD>	020819 001	PARICALCITOL;ZEMPLAR	5246925	SEP 21, 2010	U-314		
			5587497	DEC 24, 2013			
	021084 001	PERFLUOROPOLYMETHYLISOPROPYL ETHER;SKIN EXPOSURE REDUCTI				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			
>ADD>	020630 001	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583*PED	AUG 15, 2009		NPP	OCT 15, 2002
>ADD>			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
>ADD>			5019583	FEB 15, 2009		PED	JAN 12, 2002
>ADD>			5466700*PED	MAR 01, 2014	U-156	NCE	JUL 12, 2001
>ADD>	020630 002	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
>ADD>			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
>ADD>			5019583*PED	AUG 15, 2009		PED	JAN 12, 2002
>ADD>			5466700*PED	MAR 01, 2014		NCE	JUL 12, 2001
>ADD>	020630 003	REMIFENTANIL HYDROCHLORIDE;ULTIVA	5019583	FEB 15, 2009		NPP	OCT 15, 2002
>ADD>			5466700	AUG 30, 2013	U-156	PED	APR 15, 2003
>ADD>			5019583*PED	AUG 15, 2009		PED	JAN 12, 2002
>ADD>			5466700*PED	MAR 01, 2014	U-156	NCE	JUL 12, 2001
	020588 001	RISPERIDONE;RISPERDAL	5453425	JUL 11, 2014			
			5616587	JUL 11, 2014			
>ADD>	020864 001	RIZATRIPTAN BENZOATE;MAXALT	5602162	FEB 11, 2014			
			5602162	FEB 11, 2014			
>ADD>	020864 002	RIZATRIPTAN BENZOATE;MAXALT	5602162	FEB 11, 2014			
			5602162	FEB 11, 2014			
>ADD>	021071 002	ROSIGLITAZONE MALEATE;AVANDIA				I-289	APR 03, 2003
>ADD>	021071 003	ROSIGLITAZONE MALEATE;AVANDIA				I-289	APR 03, 2003
>ADD>	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		
	019721 001	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019721 002	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019676 001	SOMATROPIN RECOMBINANT;NUTROPIN				M-2	DEC 01, 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
	019676 002	SOMATROPIN RECOMBINANT;NUTROPIN				M-2	DEC 01, 2002
	020522 001	SOMATROPIN RECOMBINANT;NUTROPIN AQ				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
>ADD>	021015 001	TESTOSTERONE;ANDROGEL				NDF	FEB 28, 2003
	020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
	020326 002	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
>ADD>	020552 001	VERAPAMIL HYDROCHLORIDE;COVERA-HS	5232705	AUG 31, 2010			
>ADD>			5200196	JAN 22, 2008			
>ADD>			5141752	JUN 27, 2006			
>ADD>			5082668	JAN 21, 2009			
>ADD>			5030456	NOV 07, 2008			
>ADD>			4946687	OCT 02, 2007			
>ADD>			5785994	OCT 22, 2009	U-315	-	
>ADD>	020552 002	VERAPAMIL HYDROCHLORIDE;COVERA-HS	5232705	AUG 31, 2010			
>ADD>			5200196	JAN 22, 2008			
>ADD>			5141752	JUN 27, 2006			
>ADD>			5082668	JAN 21, 2009			
>ADD>			5030456	NOV 07, 2008			
>ADD>			4946687	OCT 02, 2007			
>ADD>			5785994	OCT 22, 2009	U-315		
>ADD>	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**

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**

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**

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.S. GOVERNMENT PRINTING OFFICE: 2000 - 460-922 / 20004