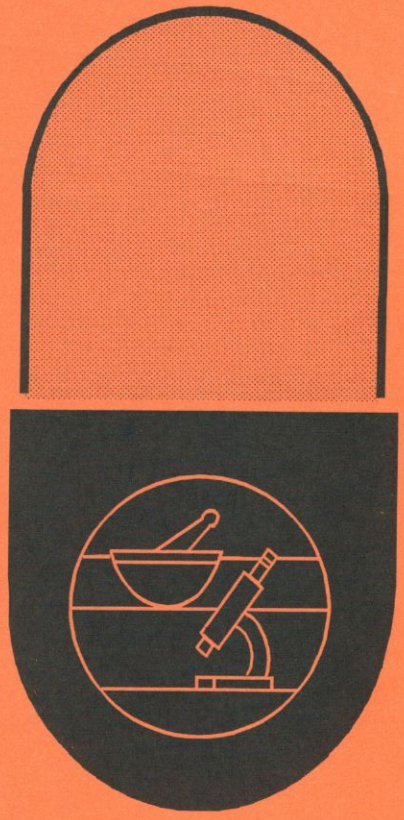
CUMULATIVE SUPPLEMENT 4

~~MAR~~ 2000

APR



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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Cumulative Supplement 4

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CONTENTS

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20TH EDITION

CUMULATIVE SUPPLEMENT 4
APRIL 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and products that have never been marketed, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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)
GALDERMA LABS INC (GALDERMA)	GALDERMA LABORATORIES LP (GALDERMA LABS LP)
GLOBAL PHARMACEUTICAL CORP (GLOBAL PHARM)	IMPAX LABORATORIES INC (IMPAX LABS)
HOECHST MARION ROUSSEL INC (HOECHST MARION RSSL)	AVENTIS PHARMACEUTICALS INC (AVENTIS PHARMS)
RHONE POULENC RORER PHARMACEUTICALS INC (RHONE POULENCE RORER)	AVENTIS PHARMACEUTICALS PRODUCTS INC (AVENTIS PHARM PROD)
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

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

TABLET; ORAL
PHRENILIN

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

ACETAMINOPHEN; CODEINE PHOSPHATE

SUSPENSION; ORAL
ACETAMINOPHEN AND CODEINE PHOSPHATE

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

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL
HYDROCODONE BITARTRATE AND ACETAMINOPHEN

> ADD >	AA		UCB	325MG;10MG	N40248 002 APR 28, 2000
> ADD >					
> ADD >		+		325MG;7.5MG	N40248 001 APR 28, 2000
> ADD >					
			LORTAB		
			UCB	325MG;5MG	N40099 001 JUN 25, 1997
			@	325MG;5MG	N40099 001 JUN 25, 1997
			NORCO		
> ADD >	AA	+	WATSON LABS	325MG;10MG	N40148 001 FEB 14, 1997
> ADD >					
> DLT >		*		325MG;10MG	N40148 001 FEB 14, 1997
> DLT >					

ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL
PENTAZOCINE HCL AND ACETAMINOPHEN

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

ALBUTEROL SULFATE

SOLUTION; INHALATION
ALBUTEROL SULFATE

AN		BAUSCH AND LOMB	EQ 0.083% BASE	N75358 001 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

AMANTADINE HYDROCHLORIDE

CAPSULE; ORAL
AMANTADINE HCL

> ADD >	AB	GENEVA PHARMS TECH	100MG	N71293 001 FEB 18, 1987
> ADD >				
> DLT >	AB	INVAMED	100MG	N71293 001 FEB 18, 1987
> DLT >				

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
AB GLOBAL PHARM **100MG** **N84574 001**
AB **200MG** **N84576 001**
@ IMPAX LABS 100MG N84574 001
@ 200MG N84576 001

ARDEPARIN SODIUM

INJECTABLE; INJECTION
NORMIFLO
> ADD > + PHARMACIA AND UPJOHN 5,000 UNITS/0.5ML N20227 002 MAY 23, 1997
> ADD > + 10,000 UNITS/0.5ML N20227 001 MAY 23, 1997
> DLT > + WYETH AYERST 5,000 UNITS/0.5ML N20227 002 MAY 23, 1997
> DLT > + 10,000 UNITS/0.5ML N20227 001 MAY 23, 1997

> ADD > ARTICAINE HYDROCHLORIDE; EPINEPHRINE

> ADD > INJECTABLE; INJECTION
> ADD > SEPTOCAINE
> ADD > + DEPROCO 4%;EQ 0.01MG BASE/ML N20971 001 APR 03, 2000

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

INJECTABLE; INJECTION
KABIVITE PED F + W KIT
+ 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

VITAPED
@ 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
+ BAXTER PHARM PROD 0.14MG/ML;10MG/ML N19677 001 NOV 06, 1991
+ 0.14MG/ML;10MG/ML N19678 001 NOV 06, 1991
+ OHMEDA 0.14MG/ML;10MG/ML N19677 001 NOV 06, 1991
+ 0.14MG/ML;10MG/ML N19678 001 NOV 06, 1991

BENZTROPINE MESYLATE

TABLET; ORAL
BENZTROPINE MESYLATE
> ADD > **AA** GENEVA PHARMS TECH **0.5MG** **N72264 001** FEB 27, 1989
> ADD > **AA** **1MG** **N72265 001** FEB 27, 1989
> ADD > **AA** **2MG** **N72266 001** FEB 27, 1989

BENZTROPINE MESYLATE

TABLET; ORAL

		BENZTROPINE MESYLATE			
> DLT >	AA	INVAMED	0.5MG	N72264 001	
> DLT >				FEB 27, 1989	
> DLT >	AA		1MG	N72265 001	
> DLT >				FEB 27, 1989	
> DLT >	AA		2MG	N72266 001	
> DLT >				FEB 27, 1989	

BETHANECHOL CHLORIDE

INJECTABLE; INJECTION

		URECHOLINE			
> DLT >	+	MERCK	5MG/ML	N06536 001	
> ADD >		@	5MG/ML	N06536 001	

TABLET; ORAL

> DLT >		**BETHANECHOL CHLORIDE**			
> DLT >	AA	SIDMAK LABS NJ	5MG	N89095 001	
> DLT >				DEC 19, 1985	
> DLT >	AA		10MG	N88440 001	
> DLT >				MAY 29, 1984	
> DLT >	AA		25MG	N88441 001	
> DLT >				MAY 29, 1984	
> DLT >	AA		50MG	N89096 001	
> DLT >				DEC 19, 1985	
> DLT >		**URECHOLINE**			
> DLT >	AA +	MERCK	5MG	N06536 003	
> DLT >	AA +		10MG	N06536 002	
> DLT >	AA +		25MG	N06536 004	
> DLT >	AA +		50MG	N06536 005	
> ADD >		@	5MG	N06536 003	
> ADD >		@	10MG	N06536 002	
> ADD >		@	25MG	N06536 004	
> ADD >		@	50MG	N06536 005	
> ADD >	AA +	SIDMAK LABS NJ	5MG	N89095 001	
> ADD >				DEC 19, 1985	
> ADD >	AA +		10MG	N88440 001	
> ADD >				MAY 29, 1984	
> ADD >	AA +		25MG	N88441 001	
> ADD >				MAY 29, 1984	
> ADD >	AA +		50MG	N89096 001	
> ADD >				DEC 19, 1985	

BLEOMYCIN SULFATE

INJECTABLE; INJECTION

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

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION

	BRETYLIUM TOSYLATE			
> DLT > AP	ASTRAZENECA	50MG/ML	N71151 001	
> DLT >			AUG 10, 1987	
> ADD >	@	50MG/ML	N71151 001	
> ADD >			AUG 10, 1987	

BUPROPION HYDROCHLORIDE

TABLET; ORAL

	BUPROPION HCL			
AB	INVAMED	75MG	N75584 001	
			FEB 07, 2000	
AB		100MG	N75584 002	
			FEB 07, 2000	
> ADD > AB	MYLAN	75MG	N75491 001	
> ADD >			APR 17, 2000	
> ADD > AB		100MG	N75491 002	
> ADD >			APR 17, 2000	

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

	BUTORPHANOL TARTRATE			
AP	ABBOTT	1MG/ML	N75559 001	
			MAR 20, 2000	
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	

CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE

SOLUTION; PERFUSION, CARDIAC

> ADD >		**CARDIOPLEGIC IN PLASTIC CONTAINER**			
> ADD >	**AT**	BAXTER HLTHCARE	**17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML**		**N75323 001** APR 21, 2000
> ADD >		**PLEGISOL IN PLASTIC CONTAINER**			
> ADD >	**AT** +	ABBOTT	**17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML**		**N18608 001** FEB 26, 1982
> DLT >	+		17.6MG/100ML;325.3MG/100ML; 119.3MG/100ML;643MG/100ML		N18608 001 FEB 26, 1982

CANDICIDIN

OINTMENT; VAGINAL

VANOBID			
@	AVENTIS PHARMS	0.6MG/GM	N61596 001
+	HOECHST MARION RSSL	0.6MG/GM	N61596 001

TABLET; VAGINAL

VANOBID			
@	AVENTIS PHARMS	3MG	N61613 001
+	HOECHST MARION RSSL	3MG	N61613 001

CARBIDOPA; LEVODOPA

TABLET, EXTENDED RELEASE; ORAL

	CARBIDOPA AND LEVODOPA			
> ADD > **AB**	MYLAN	**25MG;100MG**		**N75091 002** APR 21, 2000
	SINEMET CR			
> ADD > **AB**	DUPONT PHARMS	**25MG;100MG**		**N19856 002** DEC 24, 1992
> DLT >		25MG;100MG		N19856 002 DEC 24, 1992

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

	CARTEOLOL HCL			
AT	ALCON	**1%**		**N75476 001** JAN 03, 2000

CARTEOLOL HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

	CARTEOLOL HCL			
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

CEFOTAXIME SODIUM

INJECTABLE; INJECTION

	CEFOTAXIME			
AP	AM PHARM PARTNERS	**EQ 500MG BASE/VIAL**		**N64200 001** MAR 24, 2000
AP		**EQ 1GM BASE/VIAL**		**N64200 002** MAR 24, 2000
AP		**EQ 2GM BASE/VIAL**		**N64200 003** MAR 24, 2000
AP		**EQ 10GM BASE/VIAL**		**N64201 001** MAR 24, 2000
+		EQ 20GM BASE/VIAL		N64201 002 MAR 24, 2000
	CLAFORAN			
AP +	AVENTIS PHARMS	**EQ 500MG BASE/VIAL**		**N50547 001**
AP +		**EQ 1GM BASE/VIAL**		**N50547 002**
AP +		**EQ 2GM BASE/VIAL**		**N50547 003**

CEFOTAXIME SODIUM

INJECTABLE; INJECTION
CLAFORAN

AP	+	AVENTIS PHARMS	EQ 10GM BASE/VIAL	N50547 004 DEC 29, 1983
	+	HOECHST MARION RSSL	EQ 500MG BASE/VIAL	N50547 001
	+		EQ 1GM BASE/VIAL	N50547 002
	+		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

CEFTRIAXONE SODIUM

INJECTABLE; INJECTION
ROCEPHIN

+	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
+		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

CEPHALEXIN

POWDER FOR RECONSTITUTION; ORAL
KEFLEX

> DLT >	AB	+	LILLY	EQ 125MG BASE/5ML	N50406 001
> DLT >	AB	+		EQ 250MG BASE/5ML	N50406 002
> DLT >	AB			EQ 250MG BASE/5ML	N62117 003
> ADD >	AB	+		EQ 250MG BASE/5ML	N62117 003
> ADD >		@		EQ 125MG BASE/5ML	N50406 001
> ADD >		@		EQ 250MG BASE/5ML	N50406 002

CEVIMELINE HYDROCHLORIDE

CAPSULE; ORAL
EVOXAC

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

CHENODIOL

TABLET; ORAL
CHENIX

> DLT >		@ AXCAN	250MG	N18513 002 JUL 28, 1983
> DLT >				
> ADD >		@ AXCAN SCANDIPHARM	250MG	N18513 002 JUL 28, 1983
> ADD >				

CHLORPHENIRAMINE MALEATE

TABLET; ORAL
CHLORPHENIRAMINE MALEATE

AA	GLOBAL PHARM	4MG	N80809 001
	@ 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

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

CITALOPRAM HYDROBROMIDE

TABLET; ORAL
CELEXA

> DLT >		FOREST LABS	EQ 40MG BASE	N20822 003 JUL 17, 1998
> DLT >				
> DLT >	+		EQ 60MG BASE	N20822 004 JUL 17, 1998
> DLT >				
> ADD >	+		EQ 40MG BASE	N20822 003 JUL 17, 1998
> ADD >				
> ADD >	@		EQ 60MG BASE	N20822 004 JUL 17, 1998
> ADD >				

CLADRIBINE

INJECTABLE; INJECTION
CLADRIBINE

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

CLARITHROMYCIN

TABLET; ORAL
BIAXIN

> DLT >		ABBOTT	250MG	N50662 001 OCT 31, 1991
> DLT >				

CLARITHROMYCIN

TABLET; ORAL
BIAXIN
> ADD > + ABBOTT 250MG N50662 001
> ADD > OCT 31, 1991

TABLET, EXTENDED RELEASE; ORAL
BIAXIN XL
+ ABBOTT 500MG N50775 001
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

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL
CLORAZEPATE DIPOTASSIUM
> ADD > **AB** TARO **3.75MG** **N75731 003**
> ADD > APR 27, 2000
> ADD > **AB** **7.5MG** **N75731 002**
> ADD > APR 27, 2000
> ADD > **AB** **15MG** **N75731 001**
> ADD > APR 27, 2000

CORTISONE ACETATE

TABLET; ORAL
CORTISONE ACETATE
BP GLOBAL PHARM 25MG N09458 001
@ IMPAX LABS 25MG N09458 001

CROMOLYN SODIUM

> DLT > CONCENTRATE; ORAL
> DLT > GASTROCROM
> DLT > + MEDEVA 100MG/5ML N20479 001
> DLT > FEB 29, 1996

SOLUTION; INHALATION
CROMOLYN SODIUM
AN STERIPAK **10MG/ML** **N75271 001**
JAN 18, 2000
> ADD > **AN** WARRICK PHARMS **10MG/ML** **N75437 001**
> ADD > APR 21, 2000

> ADD > SOLUTION, CONCENTRATE; ORAL
> ADD > GASTROCROM
> ADD > + MEDEVA 100MG/5ML N20479 001
> ADD > FEB 29, 1996

CYANOCOBALAMIN

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

		CYCLOSPORINE		
AB		ABBOTT	**100MG/ML**	**N65025 001** 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
AP		GENSIA SICOR PHARMS	**EQ 5MG BASE/ML**	**N65035 001** JAN 24, 2000
	+		EQ 50MG BASE/VIAL	N64212 002 MAY 03, 1999

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		
	+	AVENTIS BEHRING	0.15MG/SPRAY	N20355 001 MAR 07, 1994
	*	CENTEON	0.15MG/SPRAY	N20355 001 MAR 07, 1994

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

DEXAMETHASONE SODIUM PHOSPHATE; NEOMYCIN SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN SULFATE-DEXAMETHASONE SODIUM PHOSPHATE

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

DICLOFENAC POTASSIUM

TABLET; ORAL
DICLOFENAC POTASSIUM

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

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	

TABLET, EXTENDED RELEASE; ORAL
DICLOFENAC SODIUM

AB	BIOVAIL	100MG	N75492 001 FEB 11, 2000	

VOLTAREN-XR

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

DIENESTROL

SUPPOSITORY; VAGINAL
DV

	@ AVENTIS PHARMS	0.7MG	N83517 001	> ADD >

DIENESTROL

SUPPOSITORY; VAGINAL
DV

	+ HOECHST MARION RSSL	0.7MG	N83517 001	

DIFLORASONE DIACETATE

CREAM; TOPICAL
DIFLORASONE DIACETATE

AB	TARO	0.05%	N75508 001 APR 24, 2000	> ADD >

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL
DILTIAZEM HCL

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

INJECTABLE; INJECTION
DILTIAZEM HCL

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

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
TIAMATE

	+ HOECHST MARION RSSL	EQ 120MG HCL	N20506 001 OCT 04, 1996	> DLT >
	+	EQ 180MG HCL	N20506 002 OCT 04, 1996	> DLT >
	+	EQ 240MG HCL	N20506 003 OCT 04, 1996	> DLT >
	+ MERCK	EQ 120MG HCL	N20506 001 OCT 04, 1996	> ADD >
	+	EQ 180MG HCL	N20506 002 OCT 04, 1996	> ADD >

† SEE SECTION 1.3 OF INTRODUCTION

DILTIAZEM MALATE

TABLET, EXTENDED RELEASE; ORAL
TIAMATE

> ADD >	+	MERCK	EQ 240MG HCL	N20506 003	
> ADD >				OCT 04, 1996	

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL
DIPHENHYDRAMINE HCL

AA	GLOBAL PHARM	**25MG**	**N80807 001**	
AA		**50MG**	**N80807 002**	
	IMPAX LABS	25MG	N80807 001	
	@	50MG	N80807 002	

DOXEPIN HYDROCHLORIDE

CREAM; TOPICAL
ZONALON

+	BIOGLAN PHAR	5%	N20126 001	
			APR 01, 1994	
+	MEDICIS	5%	N20126 001	
			APR 01, 1994	

> ADD > DOXERCALCIFEROL

> ADD > INJECTABLE; INJECTION
> ADD > HECTOROL

> ADD >	+	BONE CARE	2 UGM/ML	N21027 001
> ADD >				APR 06, 2000

DOXYCYCLINE

CAPSULE; ORAL
> ADD > **DOXYCYCLINE**

> ADD > **AB**		HALSEY	**EQ 50MG BASE**	**N65041 001**
> ADD >				APR 28, 2000
> ADD > **AB**			**EQ 100MG BASE**	**N65041 002**
> ADD >				APR 28, 2000

MONODOX

> ADD > **AB**		OCLASSEN	**EQ 50MG BASE**	**N50641 002**
> ADD >				FEB 10, 1992
> ADD > **AB**	+		**EQ 100MG BASE**	**N50641 001**
> ADD >				DEC 29, 1989

DOXYCYCLINE

CAPSULE; ORAL
MONODOX

> DLT >		OCLASSEN	EQ 50MG BASE	N50641 002
> DLT >				FEB 10, 1992
> DLT >	+		EQ 100MG BASE	N50641 001
> DLT >				DEC 29, 1989

ENFLURANE

LIQUID; INHALATION
ETHRANE

> ADD > **AN**	+	BAXTER PHARM PROD	99.9%	N17087 001	
> DLT > **AN**	+	OHMEDA	99.9%	N17087 001	

ERYTHROMYCIN ETHYLSUCCINATE

GRANULE; ORAL
PEDIAMYCIN

> DLT > **AB**		ROSS LABS	EQ 200MG BASE/5ML	N62305 001
> ADD >		@	EQ 200MG BASE/5ML	N62305 001

SUSPENSION/DROPS; ORAL
PEDIAMYCIN

> DLT >	+	ROSS LABS	EQ 100MG BASE/2.5ML	N62305 002
> ADD >	@		EQ 100MG BASE/2.5ML	N62305 002

TABLET, CHEWABLE; ORAL
PEDIAMYCIN

> DLT > **AB**		ROSS LABS	**EQ 200MG BASE**	**N62306 001**
> ADD >	@		EQ 200MG BASE	N62306 001

ESTRADIOL

CREAM; VAGINAL
ESTRACE

+	BRISTOL MYERS SQUIBB	0.01%		N86069 001
				JAN 31, 1984
+	WARNER CHILCOTT	0.01%		N86069 001
				JAN 31, 1984

FILM, EXTENDED RELEASE; TRANSDERMAL
CLIMARA

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

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

	AB	+	BERLEX LABS	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

> DLT >	BX		CYGNUS CA	0.05MG/24HR	N21048 001 SEP 20, 1999
> DLT >	BX			0.075MG/24HR	N21048 002 SEP 20, 1999
> DLT >	BX			0.1MG/24HR	N21048 003 SEP 20, 1999
> ADD >		@	JOHNSON RW	0.05MG/24HR	N21048 001 SEP 20, 1999
> ADD >		@		0.075MG/24HR	N21048 002 SEP 20, 1999
> ADD >		@		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

TABLET; ORAL

ESTRADIOL

> ADD >	AB		APPLIED ANAL	0.5MG	N40138 001 JAN 30, 1998
> ADD >	AB			1MG	N40138 002 JAN 30, 1998
> ADD >	AB			2MG	N40138 003 JAN 30, 1998
> DLT >	AB		ENDEAVOR	0.5MG	N40138 001 JAN 30, 1998
> DLT >	AB			1MG	N40138 002 JAN 30, 1998
> DLT >	AB			2MG	N40138 003 JAN 30, 1998

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

		+	CYPROS	50MG/ML	N19357 001 DEC 22, 1988

ETHANOLAMINE OLEATE

INJECTABLE; INJECTION

ETHAMOLIN

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

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

TRIVORA-21

AB		SEARLE	0.03MG,0.04MG,0.03MG;0.05MG,0.075MG, 0.125MG	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
OVCON-50			
	BRISTOL MYERS SQUIBB	0.05MG;1MG	N17576 001
	WARNER CHILCOTT	0.05MG;1MG	N17576 001

ETODOLAC

TABLET; ORAL
ETODOLAC

> ADD >	AB	TARO PHARM INDS	500MG	N75074 002	
> ADD >				APR 25, 2000	

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	

FENTANYL CITRATE

INJECTABLE; INJECTION
SUBLIMAZE PRESERVATIVE FREE

> ADD >	AP	+	AKORN MFG	EQ 0.05MG BASE/ML	N16619 001
> DLT >	AP	+	JANSSEN	EQ 0.05MG BASE/ML	N16619 001

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	

FLOXURIDINE

INJECTABLE; INJECTION
FLOXURIDINE

> ADD >					
> ADD >	AP		BEDFORD	500MG/VIAL	N75387 001
> ADD >					APR 16, 2000
		FUDR			
> ADD >	AP	+	ROCHE	500MG/VIAL	N16929 001
> DLT >		+		500MG/VIAL	N16929 001

FLUCONAZOLE

TABLET; ORAL
DIFLUCAN

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

FLUMAZENIL

INJECTABLE; INJECTION
ROMAZICON

> ADD >	+	HLR	0.1MG/ML	N20073 001
> ADD >				DEC 20, 1991
> DLT >	+	ROCHE	0.1MG/ML	N20073 001
> DLT >				DEC 20, 1991

FLUOROURACIL

INJECTABLE; INJECTION
FLUOROURACIL

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

FURAZOLIDONE

SUSPENSION; ORAL
FUROXONE

> DLT >	+	ROBERTS LABS	50MG/15ML	N11323 002
> ADD >	+	SHIRE LABS	50MG/15ML	N11323 002

TABLET; ORAL
FUROXONE

> DLT >	+	ROBERTS LABS	100MG	N11270 002
> ADD >	+	SHIRE LABS	100MG	N11270 002

GABAPENTIN

SOLUTION; ORAL
NEURONTIN

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

GADOPENTETATE DIMEGLUMINE

INJECTABLE; INJECTION
MAGNEVIST
+ BERLEX LABS 469.01MG/ML N21037 001 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)
AB AVENTIS PHARMS 6MG N20055 003 MAR 08, 2000

GRAMICIDIN; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OPHTHALMIC
NEOMYCIN AND POLYMYXIN B SULFATES AND GRAMICIDIN
> DLT > AT IPHARM 0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML N62818 001 OCT 11, 1988
> ADD > @ 0.025MG/ML;EQ 1.75MG BASE/ML; 10,000 UNITS/ML N62818 001 OCT 11, 1988

GRISEOFULVIN, ULTRAMICROCRYSTALLINE

TABLET; ORAL
GRIS-PEG
> DLT > AB ALLERGAN HERBERT 125MG N50475 001
> DLT > AB 250MG N50475 002
> ADD > AB PEDINOL 125MG N50475 001
> ADD > AB 250MG N50475 002

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
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

HISTRELIN ACETATE

INJECTABLE; INJECTION
SUPPRELIN
> DLT > + ROBERTS LABS EQ 0.2MG BASE/ML N19836 001 DEC 24, 1991
> DLT > + EQ 0.5MG BASE/ML N19836 002 DEC 24, 1991
> DLT > + EQ 1MG BASE/ML N19836 003 DEC 24, 1991
> ADD > + SHIRE LABS EQ 0.2MG BASE/ML N19836 001 DEC 24, 1991
> ADD > + EQ 0.5MG BASE/ML N19836 002 DEC 24, 1991
> ADD > + EQ 1MG BASE/ML N19836 003 DEC 24, 1991

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

AB	GLOBAL PHARM	100MG	N85098 001		
	@ 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		
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		

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL
EPIFOAM

> ADD >	BX	SCHWARZ PHARMA	1%;1%		N86457 001

PROCTOFOAM HC

> ADD >	BX	SCHWARZ PHARMA	1%;1%		N86195 001

DISC; TOPICAL
EPIFOAM

> DLT >	BX	SCHWARZ PHARMA	1%;1%		N86457 001

PROCTOFOAM HC

> DLT >	BX	SCHWARZ PHARMA	1%;1%		N86195 001

INSULIN GLARGINE

INJECTABLE; INJECTION
LANTUS

> ADD >	+	AVENTIS PHARMS	100 UNITS/ML		N21081 001 APR 20, 2000

INSULIN LISPRO; INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50

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

HUMALOG MIX 75/25

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

INSULIN LISPRO PROTAMINE

INJECTABLE; INJECTION
HUMALOG MIX 50/50

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

HUMALOG MIX 75/25

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

INULIN

INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE

	+	CYPROS	100MG/ML		N02282 001

INULIN

INJECTABLE; INJECTION
INULIN AND SODIUM CHLORIDE
+ 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

AEROSOL, METERED; INHALATION
ISUPREL
> DLT > + SANOFI SYNTHELABO 0.103MG/INH N11178 001
> ADD > @ 0.103MG/INH N11178 001

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
AB + SCHERING **120MG** **N20225 003** MAR 30, 1995
+ 120MG N20225 003 MAR 30, 1995

ISOSORBIDE MONONITRATE
> ADD > AB DEXCEL LTD **60MG** **N75522 001** APR 17, 2000
> ADD >

ISOSORBIDE MONONITRATE

TABLET, EXTENDED RELEASE; ORAL
ISOSORBIDE MONONITRATE
AB KREMERS URBAN **30MG** **N75155 002** JAN 13, 2000
AB KV PHARM **30MG** **N75395 001** MAR 16, 2000
AB **60MG** **N75395 002** MAR 16, 2000
AB **120MG** **N75395 003** MAR 16, 2000

KETOCONAZOLE

CREAM; TOPICAL
> ADD > **KETOCONAZOLE**
> ADD > AB TEVA **2%** **N75581 001** APR 25, 2000
> ADD >

NIZORAL
> ADD > AB + MCNEIL CONS **2%** **N19084 001** DEC 31, 1985
> ADD > + 2% N19084 001 DEC 31, 1985
> DLT >
> DLT >

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

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM PRESERVATIVE FREE
> ADD > AP + ABBOTT **EQ 10MG BASE/ML** **N40147 001** JUN 25, 1997
> ADD >
> DLT > + EQ 10MG BASE/ML N40147 001 JUN 25, 1997
> DLT >
> ADD > AP BEDFORD **EQ 10MG BASE/ML** **N40347 001** APR 25, 2000
> ADD >
> ADD > AP **EQ 350MG BASE/VIAL** **N40335 001** APR 20, 2000
> ADD >

LEUPROLIDE ACETATE

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

LEVOBETAXOLOL HYDROCHLORIDE

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

LEVOBUPIVACAINE HYDROCHLORIDE

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

LEVORPHANOL TARTRATE

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

> ADD > LINEZOLID

> ADD > GRANULE, FOR RECONSTITUTION; ORAL
> ADD > ZYVOX
> ADD > + PHARMACIA AND UPJOHN 100MG/5ML — N21132 001 APR 18, 2000
> ADD >

> ADD > INJECTABLE; INJECTION
> ADD > ZYVOX
> ADD > + PHARMACIA AND UPJOHN 200MG/100ML — N21131 001 APR 18, 2000
> ADD >

> ADD > TABLET; ORAL
> ADD > ZYVOX
> ADD > PHARMACIA AND UPJOHN 400MG — N21130 001 APR 18, 2000
> ADD >
> ADD > + 600MG — N21130 002 APR 18, 2000
> ADD >

LORAZEPAM

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

MAGNESIUM SULFATE

INJECTABLE; INJECTION
MAGNESIUM SULFATE
> ADD > **AP** ABBOTT — **500MG/ML** — **N75151 001** APR 25, 2000
> ADD >
> ADD > **AP** + AM PHARM PARTNERS — **500MG/ML** — **N19316 001** SEP 08, 1986
> ADD >
> DLT > + 500MG/ML — N19316 001 SEP 08, 1986
> DLT >

MEDROXYPROGESTERONE ACETATE

TABLET; ORAL
AMEN
BP CARNRICK — 10MG — N83242 001
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

> ADD > MELOXICAM

> ADD > TABLET; ORAL

> ADD > MOBIC

> ADD > + BOEHRINGER INGELHEIM 7.5MG N20938 001 APR 13, 2000

> ADD >

MENOTROPINS (FSH;LH)

INJECTABLE; INJECTION

	MENOTROPINS			
	@ FERRING	75 IU/VIAL;75 IU/VIAL	N73598 001	JAN 30, 1997
	@	150 IU/VIAL;150 IU/VIAL	N73599 001	JAN 30, 1997
	REPRONEX			
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			
	+ WYETH AYERST	EQ 30MG BASE/ML	N08248 001	
	@	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**	

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

	NORINYL 1+50 21-DAY			
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			
AB	APPLIED ANAL	**5MG**	**N40320 001**	MAR 31, 2000
AB		**10MG**	**N40320 002**	MAR 31, 2000
AB	GENPHARM	**5MG**	**N40350 001**	MAR 29, 2000
AB		**10MG**	**N40350 002**	MAR 29, 2000
	TAPAZOLE			
AB	LILLY	**5MG**	**N07517 002**	
AB	+	**10MG**	**N07517 004**	
	+	5MG	N07517 002	
	+	10MG	N07517 004	

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

	MINOCYCLINE HCL			
AB	+ DANBURY PHARMA	**EQ 75MG BASE**	**N63065 002**	JUN 10, 1999
	+	EQ 75MG BASE	N63065 002	JUN 10, 1999

MONTELUKAST SODIUM

TABLET, CHEWABLE; ORAL

> ADD > SINGULAIR

> ADD > MERCK EQ 4MG BASE N20830 002 MAR 03, 2000

MORPHINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

AB		ESI LEDERLE	15MG	N75407 001 JAN 28, 2000

NADOLOL

TABLET; ORAL

CORGARD

> DLT >	AB		APOTHECON	40MG	N18063 001
> ADD >	AB	+		40MG	N18063 001

NALMEFENE HYDROCHLORIDE

INJECTABLE; INJECTION

REVEX

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

NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE

TABLET; ORAL

PENTAZOCINE AND NALOXONE HYDROCHLORIDES

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

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HCL

AB	EON	50MG	N75434 001 MAR 08, 2000

NAPROXEN

TABLET, DELAYED RELEASE; ORAL

NAPROXEN

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

NIACIN

TABLET; ORAL

NIACIN

AA	GLOBAL PHARM	500MG	N83115 001
	@ IMPAX LABS	500MG	N83115 001

NIFEDIPINE

TABLET, EXTENDED RELEASE; ORAL

ADALAT CC

AB	+	BAYER	30MG	N20198 001 APR 21, 1993
BC	+		30MG	N20198 001 APR 21, 1993

NIFEDIPINE

AB	ELAN PHARM	30MG	N75128 001 MAR 10, 2000

NITROFURAZONE

OINTMENT; TOPICAL

FURACIN

> DLT >	AT	+	ROBERTS LABS	0.2%	N05795 001
> ADD >	AT	+	SHIRE LABS	0.2%	N05795 001

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

SANDOSTATIN

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

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

SANDOSTATIN				
NOVARTIS	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 30, 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		

> ADD > TABLET, ORALLY DISINTEGRATING; ORAL

> ADD >	ZYPREXA ZYDIS			
> ADD >	LILLY	5MG	N21086 001 APR 06, 2000	
> ADD >		10MG	N21086 002 APR 06, 2000	
> ADD >		15MG	N21086 003 APR 06, 2000	
> ADD >	+	20MG	N21086 004 APR 06, 2000	

ORPHENADRINE CITRATE

TABLET, EXTENDED RELEASE; ORAL

	ORPHENADRINE CITRATE			
AB	EON	100MG		N40327 001 FEB 15, 2000
AB	GENEVA PHARMS TECH	100MG		N40284 001 JUN 19, 1998
AB	INVAMED	100MG		N40284 001 JUN 19, 1998

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			
BX	+ PURDUE PHARMA	10MG		N20553 001 DEC 12, 1995
	+	10MG		N20553 001 DEC 12, 1995
	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	> DLT >	
				FEB 28, 2000	> DLT >	
AB			37.5MG	N75595 002	> DLT >	
				FEB 28, 2000	> DLT >	
AB			75MG	N75595 003	> DLT >	
				FEB 28, 2000	> DLT >	
AB		COPLEY PHARM	18.75MG	N75030 003	> ADD >	
				FEB 22, 2000	> ADD >	
AB		GENEVA PHARMS TECH	18.75MG	N75286 001	> ADD >	
				DEC 27, 1999	> ADD >	
AB			37.5MG	N75286 002	> ADD >	
				JUN 30, 1999	> ADD >	
AB			75MG	N75286 003		
				JUN 30, 1999		
AB		INVAMED	18.75MG	N75286 001		
				DEC 27, 1999		
AB			37.5MG	N75286 002		
				JUN 30, 1999		
AB			75MG	N75286 003		
				JUN 30, 1999		
> ADD > AB		VINTAGE PHARMS	18.75MG	N75328 001		
> ADD >				APR 19, 2000		
> ADD > AB			37.5MG	N75328 002		
> ADD >				APR 19, 2000		
> ADD > AB			75MG	N75328 003		
> ADD >				APR 19, 2000		

TABLET, CHEWABLE; ORAL
CYLERT

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

PEMOLINE

AB		COPLEY PHARM	37.5MG	N75555 001	> DLT >	
				FEB 18, 2000	> ADD >	

PERFLUOROPOLYMETHYLISOPROPYL ETHER; POLYTETRAFLUOROETHYLENE

PASTE; TOPICAL
SKIN EXPOSURE REDUCTION PASTE AGAINST CHEMICAL WARFARE AGENTS

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

PERINDOPRIL ERBUMINE

TABLET; ORAL
ACEON

	@	SOLVAY	2MG	N20184 001		
				DEC 30, 1993		
	@		4MG	N20184 002		
				DEC 30, 1993		
	@		8MG	N20184 003		
				DEC 30, 1993		
		SOLVAY PHARMA	2MG	N20184 001		
				DEC 30, 1993		
			4MG	N20184 002		
				DEC 30, 1993		
	+		8MG	N20184 003		
				DEC 30, 1993		

PHENDIMETRAZINE TARTRATE

TABLET; ORAL
BONTRIL PDM

AA	CARNRICK	35MG	N85272 001	
AA	ELAN PHARMS	35MG	N85272 001	

PREDNISOLONE

SYRUP; ORAL
PREDNISOLONE

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

TABLET; ORAL
PREDNISOLONE

BX	GLOBAL PHARM	5MG	N80780 001	
@	IMPAX LABS	5MG	N80780 001	
BX	PHOENIX LABS NY	5MG	N80322 001	
@		5MG	N80322 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	

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION/DROPS; OPHTHALMIC
PREDNISOLONE SODIUM PHOSPHATE

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

PREDNISONE

TABLET; ORAL
PREDNISONE

> DLT >	BX	PHOENIX LABS NY	5MG	N80321 001	
> DLT >	BX		20MG	N83807 001	
> ADD >		@	5MG	N80321 001	
> ADD >		@	20MG	N83807 001	

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

PROPARACAINE HYDROCHLORIDE

SOLUTION; OPHTHALMIC
PROPARACAINE HCL

AT	TAYLOR PHARMA	0.5%	N40277 001	MAR 16, 2000

PROTOKYLOL HYDROCHLORIDE

TABLET; ORAL
VENTAIRE

	@ AVENTIS PHARMS	2MG	N83459 001
	+ HOECHST MARION RSSL	2MG	N83459 001

QUINIDINE SULFATE

TABLET; ORAL
QUINIDINE SULFATE

> DLT >	AB	PHARMAVITE	200MG	N84627 001
> ADD >		@	200MG	N84627 001

RANITIDINE HYDROCHLORIDE

TABLET; ORAL
RANITIDINE

> ADD >	AB	RANBAXY	EQ 150MG BASE	N75439 001 APR 19, 2000
> ADD >	AB		EQ 300MG BASE	N75439 002 APR 19, 2000

RESERPINE

TABLET; ORAL
RESERPINE

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

> ADD > RIVASTIGMINE TARTRATE

CAPSULE; ORAL
EXELON

> ADD >		NOVARTIS	EQ 1.5MG BASE	N20823 003 APR 21, 2000

> ADD > RIVASTIGMINE TARTRATE

> ADD > CAPSULE; ORAL
> ADD > EXELON
> ADD > NOVARTIS EQ 3MG BASE N20823 004
> ADD > APR 21, 2000
> ADD > EQ 4.5MG BASE N20823 005
> ADD > APR 21, 2000
> ADD > + EQ 6MG BASE N20823 006
> ADD > APR 21, 2000

> ADD > SOLUTION; ORAL
> ADD > EXELON
> ADD > + NOVARTIS EQ 2MG BASE/ML N21025 001
> ADD > APR 21, 2000

SODIUM FLUORIDE, F-18

INJECTABLE; INTRAVENOUS
FLUORINE F-18
> ADD > @ NYCOMED AMERSHAM 2mCi/ML N17042 001

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**
OCT 18, 1988
AT STERIS **10%** **N89560 001**
OCT 18, 1988

TELMISARTAN

TABLET; ORAL
MICARDIS
> ADD > + BOEHRINGER INGELHEIM 20MG N20850 003
> ADD > APR 04, 2000

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

TABLET; ORAL
TERAZOSIN HCL
> ADD > **AB** INVAMED **EQ 1MG BASE** **N74657 001**
> ADD > APR 28, 2000
> ADD > **AB** **EQ 2MG BASE** **N74657 002**
> ADD > APR 28, 2000
> ADD > **AB** **EQ 5MG BASE** **N74657 003**
> ADD > APR 28, 2000
> ADD > **AB** **EQ 10MG BASE** **N74657 004**
> ADD > APR 28, 2000
> ADD > **AB** ZENITH GOLDLINE **EQ 1MG BASE** **N74530 001**
> ADD > APR 21, 2000
> ADD > **AB** **EQ 2MG BASE** **N74530 002**
> ADD > APR 21, 2000
> ADD > **AB** **EQ 5MG BASE** **N74530 003**
> ADD > APR 21, 2000
> ADD > **AB** **EQ 10MG BASE** **N74530 004**
> ADD > APR 21, 2000

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM
> DLT > **BX** + THERATECH 5MG/24HR N20489 002
> DLT > MAY 02, 1997
> DLT > + 2.5MG/24HR N20489 001
> DLT > SEP 29, 1995

TESTOSTERONE

FILM, EXTENDED RELEASE; TRANSDERMAL
ANDRODERM

> ADD	BX	+ WATSON LABS	5MG/24HR	N20489 002	
> ADD >				MAY 02, 1997	
> ADD >		+	2.5MG/24HR	N20489 001	
> ADD >				SEP 29, 1995	

GEL; TOPICAL
ANDROGEL

		+ UNIMED PHARMS	1%	N21015 001
				FEB 28, 2000

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL
SLO-PHYLLIN

		@ AVENTIS PHARM PROD	60MG	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

TICLOPIDINE HYDROCHLORIDE

TABLET; ORAL
TICLOPIDINE HCL

> ADD >	**AB**	DANBURY PHARMA	**250MG**	**N75309 001**
> ADD >				APR 26, 2000

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

OINTMENT; TOPICAL
ARISTOCORT A

> DLT >	**AT**	+ FUJISAWA HLTHCARE	**0.5%**	**N80745 003**	
> ADD >	**AT**		**0.5%**	N80745 003	

FLUTEX

> DLT >	**AT**	ZENITH GOLDLINE	**0.025%**	**N87375 001**	
> DLT >				NOV 01, 1988	
> ADD >	**AT**	+	**0.025%**	**N87375 001**	
> ADD >				NOV 01, 1988	
> DLT >	**AT**		**0.1%**	**N87377 001**	
> DLT >				NOV 01, 1988	
> ADD >	**AT**	+	**0.1%**	**N87377 001**	
> ADD >				NOV 01, 1988	
> DLT >	**AT**		**0.5%**	**N87376 001**	
> DLT >				NOV 01, 1988	
> ADD >	**AT**	+	**0.5%**	**N87376 001**	
> ADD >				NOV 01, 1988	

KENALOG

> DLT >	**AT**	+ APOTHECON	**0.025%**	**N11600 003**
> ADD >	**AT**		**0.025%**	**N11600 003**
> DLT >	**AT**	+	**0.1%**	**N11600 001**
> ADD >	**AT**		**0.1%**	**N11600 001**

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

TRIHEXYPHENIDYL HYDROCHLORIDE

TABLET; ORAL
TRIHEXYPHENIDYL HCL

AA	WEST WARD	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
+	US BIOSCIENCE	EQ 25MG BASE/VIAL	N20326 001	DEC 17, 1993

TROGLITAZONE

TABLET; ORAL
PRELAY

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

REZULIN

AB	PARKE DAVIS PHARMS	200MG	N20720 001	JAN 29, 1997

TROGLITAZONE

TABLET; ORAL
REZULIN

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

URSODIOL

CAPSULE; ORAL
ACTIGALL

AB	+ NOVARTIS	300MG	N19594 002	DEC 31, 1987
	+ [illegible]	300MG	N19594 002	DEC 31, 1987

URSODIOL

AB	AMIDE PHARM	300MG	N75517 001	MAR 14, 2000

TABLET; ORAL
URSO

+	AXCAN	250MG	N20675 001	DEC 10, 1997
+	AXCAN SCANDIPHARM	250MG	N20675 001	DEC 10, 1997

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

		COVERA-HS			
> DLT >	BC	SEARLE	180MG	N20552 001	
> DLT >				FEB 26, 1996	
> ADD >	BC +		180MG	N20552 001	
> ADD >				FEB 26, 1996	
> DLT >	BC		240MG	N20552 002	
> DLT >				FEB 26, 1996	
> ADD >	BC +		240MG	N20552 002	
> ADD >				FEB 26, 1996	

> ADD > VERTEPORFIN

INJECTABLE; INJECTION

> ADD >		VISUDYNE		
> ADD >		+ QLT	15MG/VIAL	N21119 001
> ADD >				APR 12, 2000

VITAMIN A

CAPSULE; ORAL

	VITAMIN A		
AA	GLOBAL PHARM	50,000 USP UNITS	N80952 001
	@ IMPAX LABS	50,000 USP UNITS	N80952 001

VITAMIN A PALMITATE

CAPSULE; ORAL

	VITAMIN A		
AA	GLOBAL PHARM	EQ 50,000 UNITS BASE	N80953 001
AA		EQ 50,000 UNITS BASE	N80955 001
	@ IMPAX LABS	EQ 50,000 UNITS BASE	N80953 001
	@	EQ 50,000 UNITS BASE	N80955 001

ZOLMITRIPTAN

TABLET; ORAL

	ZOMIG		
	IPR	2.5MG	N20768 001
			NOV 25, 1997
	+	5MG	N20768 002
			NOV 25, 1997

ZOLMITRIPTAN

TABLET; ORAL

	ZOMIG		
	ZENECA	2.5MG	N20768 001
			NOV 25, 1997
	+	5MG	N20768 002
			NOV 25, 1997

ZONISAMIDE

CAPSULE; ORAL

	ZONEGRAN		
	+ DAINIPPON	100MG	N20789 001
			MAR 27, 2000

ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL

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

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

E-Z SCRUB		
BECTON DICKINSON	4%	N73416 001 MAR 14, 2000

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

CLOTRIMAZOLE

CREAM; VAGINAL

TRIVAGIZOLE 3		
+ TARO	2%	N21143 001 APR 12, 2000

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
ALPHARMA 1% N75014 001
MAR 28, 2000

PIPERONYL BUTOXIDE; PYRETHRINS

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

RANITIDINE HYDROCHLORIDE

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

> DLT > TABLET, EFFERVESCENT; ORAL
> DLT > ZANTAC 75
> DLT > + GLAXO WELLCOME EQ 75MG BASE N20745 001
> DLT > FEB 26, 1998
> ADD > @ WARNER LAMBERT EQ 75MG BASE N20745 001
> ADD > FEB 26, 1998

TERBINAFINE HYDROCHLORIDE

SOLUTION; TOPICAL
LAMISIL AT
+ NOVARTIS 1% N21124 001
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 4 APR '00

NO APRIL 2000 APPROVALS

This data is provided to the Division of Data Management and Services from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Products Designations and Approvals List
April 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= 1/18/00 MA=
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= 3/23/00 MA=
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= 2/16/00 MA=
Arsenic trioxide TN=Atrivex	Treatment of multiple myeloma.	Cell Therapeutics, Inc. 201 Elliott Ave. West, Suite Seattle WA 98119 DD= 4/28/00 MA=
Bis(4-fluorophenyl)phenylacetamide	Treatment of sickle cell disease.	ICAgen Inc. Ion Channel Advances PO Box 14487 Durham NC 27709

Orphan Products Designations and Approvals List
April 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Brimonidine TN=Alphagan	Treatment of anterior ischemic optic neuropathy.	Allergan, Inc. 2525 Dupont Dr. P.O. Box 19534 Irvine CA 92623-9534 DD= 2/7/00 MA=
Cisplatin/epinephrine TN=IntraDose	Treatment of squamous cell carcinoma of the head and neck.	Matrix Pharmaceutical, Inc. 34700 Campus Drive Fremont CA 94555-3612 DD= 4/3/00 MA=
DNA-lipid complex (DMRIE/DOPE)/plasmid vector (VCL-1102, Vical) expressing human interleukin-2 TN=Leuvectin	Treatment of renal cell carcinoma.	Vical Incorporated 9373 Towne Center Dr. Suite 100 San Diego CA 92121-3088 DD= 4/28/00 MA=
Ethyl eicosapentaenoate TN=	Treatment of Huntington's disease.	Laxdale Ltd. Kings Park House, Laurelhill Polmaise Road, Stirling FK7 United Kingdom UK DD= 4/6/00 MA=
Halofuginone TN=Stenorol	Treatment of systemic sclerosis.	Collgard Biopharmaceuticals Textile House, 2 Koifman St. Tel-Aviv 68012 Israel IL DD= 2/7/00 MA=

Orphan Products Designations and Approvals List
April 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= 2/1/00 MA=
Hypericin TN=	Treatment of cutaneous T-cell lymphoma.	Nexell Therapeutics, Inc. 2751 Centerville Rd., Suite Wilmington DE 19808 DD= 2/7/00 MA=
IL-4 Pseudomonas Toxin Fusion Protein (IL-4(38-37)-PE38KDEL) TN=	Treatment of astrocytic glioma.	Neurocrine Biosciences, Inc. 10555 Science Center Dr. San Diego CA 92121 DD= 4/6/00 MA=
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= 2/22/00 MA=
Levodopa and carbidopa TN= Duodopa	Treatment of late stage Parkinson's disease.	Nouvel Pharma, Inc. 11322 Acuff La. Lenexa KS 66215 DD= 1/18/00 MA=

Orphan Products Designations and Approvals List
April 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
Meropenem TN=Merrem IV	Management of acute pulmonary exacerbations, in cystic fibrosis patients, due to respiratory tract infection with susceptible organisms.	Zeneca Pharmaceuticals 1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437 DD= 4/27/00 MA=
Natural human lymphoblastoid interferon-alpha TN=	Treatment of Behcet's disease.	Amarillo Biosciences, Inc. 800 West Ninth Avenue Amarillo TX 79101-3206 DD= 1/18/00 MA=
Phenylbutyrate TN=	Treatment of acute promyelocytic leukemia.	Elan Corporation 1300 Gould Dr. Gainesville GA 30504 DD= 1/19/00 MA=
Recombinant human antithrombin III TN=	Treatment of antithrombin III dependent heparin resistance requiring anticoagulation.	AT III LLC c/o Genzyme Corporation 15 Pleasant St. Connector, Framingham MA 01701 DD= 4/6/00 MA=
Recombinant human insulin-like growth factor-I TN= PV802	Treatment of short-bowel syndrome as a result of resection of the small bowel or as a result of congenital dysfunction of the intestines.	GroPep Pty Ltd. Gate 11, Victoria Dr. Adelaide SA 5000 Australia AU DD= 2/16/00 MA=

Orphan Products Designations and Approvals List
April 2000

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

Orphan Products Designations and Approvals List

April 2000

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

Orphan Products Designations and Approvals List
April 2000

Name: Generic Name TN=Trade Name	Indication Designated:	Sponsor & Address DD=Date Designated MA=Marketing Approval
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= 1/10/00 MA=

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

NO APRIL 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
	020560 001	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303	M-3	NOV 24, 2002
	020560 002	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303	M-3	NOV 24, 2002
	020560 003	ALENDRONATE SODIUM;FOSAMAX	6008207	JUN 06, 2015	U-303	M-3	NOV 24, 2002
	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
>ADD>	021127 001	AZELASTINE HYDROCHLORIDE;AZELASTINE HCL				NCE	NOV 01, 2001
>ADD>						NDF	MAY 22, 2003
	021055 001	BEXAROTENE;TARGRETIN				ODE	DEC 29, 2006
	019982 001	BISOPROLOL FUMARATE;ZEBETA	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	019982 002	BISOPROLOL FUMARATE;ZEBETA	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	020186 001	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	020186 002	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
			4258062*PED	SEP 24, 2000	U-63		
	020186 003	BISOPROLOL FUMARATE;ZIAC	4258062	MAR 24, 2000	U-63		
			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>	018731 001	BUSPIRONE HYDROCHLORIDE;BUSPAR	4182763	MAY 22, 2000	U-13		
>ADD>			5015646	MAY 14, 2008			
>ADD>			4182763*PED	NOV 22, 2000	U-13		
>ADD>			5015646*PED	NOV 14, 2008			
>ADD>	018731 002	BUSPIRONE HYDROCHLORIDE;BUSPAR	4182763	MAY 22, 2000	U-13		
>ADD>			5015646	MAY 14, 2008			
>ADD>			4182763*PED	NOV 22, 2000	U-13		
>ADD>			5015646*PED	NOV 14, 2008			
>ADD>	018731 003	BUSPIRONE HYDROCHLORIDE;BUSPAR	5015646	MAY 14, 2008			
>ADD>			4182763	MAY 22, 2000	U-13		
>ADD>			4182763*PED	NOV 22, 2000	U-13		
>ADD>			5015646*PED	NOV 14, 2008			
>ADD>	018731 004	BUSPIRONE HYDROCHLORIDE;BUSPAR	4182763	MAY 22, 2000	U-13		
>ADD>			5015646	MAY 14, 2008			
>ADD>			4182763*PED	NOV 22, 2000			
>ADD>			5015646*PED	NOV 14, 2008	U-13		

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
	020793 001	CAFFEINE CITRATE;CAFCIT				ODE	SEP 21, 2006
>ADD>	018874 001	CALCITRIOL;CALCIJEX	6051567	AUG 02, 2019			
>ADD>	018874 002	CALCITRIOL;CALCIJEX	6051567	AUG 02, 2019			
	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		
>ADD>	021143 001	CLOTRIMAZOLE;TRIVAGIZOLE 3				NP	NOV 24, 2001
>ADD>	021141 001	COLESEVELAM HYDROCHLORIDE;WELCHOL	5624963	APR 29, 2014	U-323	NCE	MAY 26, 2005
>ADD>			5679717	APR 29, 2014	U-323		
>ADD>			5693675	DEC 02, 2014			
>ADD>			5607669	JUN 10, 2014	U-323		
>ADD>			5917007	APR 29, 2014	U-323		
>ADD>			5919832	JUN 10, 2014			
>ADD>	021176 001	COLESEVELAM HYDROCHLORIDE;WELCHOL	5919832	JUN 10, 2014		NCE	MAY 26, 2005
>ADD>			5917007	APR 29, 2014	U-323		
>ADD>			5607669	JUN 10, 2014	U-323		
>ADD>			5693675	DEC 02, 2014			
>ADD>			5679717	APR 29, 2014	U-323		
>ADD>			5624963	APR 29, 2014	U-323		
	020154 004	DIDANOSINE;VIDEX	5616566	AUG 29, 2006	U-180		
>ADD>	021027 001	DOXERCALCIFEROL;HECTOROL	5602116	APR 03, 2115	U-321	NDF	APR 06, 2003
>ADD>			5707980	FEB 11, 2117	U-321	NCE	JUN 09, 2004
	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			

PRESCRIPTION AND OTC DRUG PRODUCT
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020444 001	EPOPROSTENOL SODIUM;FLOLAN				ODE	APR 14, 2007
>ADD>						I-296	APR 14, 2003
	020444 002	EPOPROSTENOL SODIUM;FLOLAN				ODE	APR 14, 2007
>ADD>						I-296	APR 14, 2003
>ADD>	020907 001	ESTRADIOL;ACTIVELLE				I-295	APR 11, 2003
	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			
>ADD>	019304 002	FENOFIBRATE;TRICOR (MICRONIZED)				I-298	APR 24, 2003
>ADD>	019304 003	FENOFIBRATE;TRICOR (MICRONIZED)				I-298	APR 24, 2003
>ADD>	019304 004	FENOFIBRATE;TRICOR (MICRONIZED)				I-298	APR 24, 2003
	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	6037353	MAR 14, 2017	U-138		
>ADD>	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5932247	FEB 28, 2015		NDF	FEB 25, 2003
>ADD>			5855912	FEB 28, 2015			
>ADD>			4254129	FEB 17, 2001	U-139		
>ADD>			6037353	MAR 14, 2017	U-138		
			5578610	NOV 26, 2013	U-139		
>ADD>	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5932247	FEB 28, 2015		NDF	FEB 25, 2003
>ADD>			5855912	FEB 28, 2015			
>ADD>			4254129	FEB 17, 2001	U-139		
>ADD>			6037353	MAR 14, 2017	U-138		
			5578610	NOV 26, 2013	U-139		
>ADD>	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5932247	FEB 28, 2015		NDF	FEB 25, 2003
>ADD>			5855912	FEB 28, 2015			
>ADD>			4254129	FEB 17, 2001	U-139		
>ADD>			6037353	MAR 14, 2017	U-138		
			5578610	NOV 26, 2013	U-139		
>ADD>	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	6039974	JUL 31, 2018			
			6037353	MAR 14, 2017	U-138		
	019949 004	FLUCONAZOLE;DIFLUCAN	4416682	JUN 02, 2001			
			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			
			6054482	APR 25, 2017			
			6054482*PED	OCT 25, 2017			

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	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		
			6054482	APR 25, 2017			
			6054482*PED	OCT 25, 2017			
	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			
			6054482	APR 25, 2017			
			6054482*PED	OCT 25, 2017			
	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			
			6054482	APR 25, 2017			
			6054482*PED	OCT 25, 2017			
	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		
			6054482	APR 25, 2017			
			6054482*PED	OCT 25, 2017			
>ADD>	021037 001	GADOPENTETATE DIMEGLUMINE;MAGNEVIST	5362475	NOV 08, 2011			
>ADD>			5560903	OCT 01, 2013			
>ADD>			4647447	MAR 03, 2004			
>ADD>			4957939	MAR 03, 2004			
>ADD>			4963344	MAR 03, 2004			
	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>	021174 001	GEMTUZUMAB ZOGAMICIN;MYLOTARG	5606040	FEB 25, 2014		ODE	MAY 17, 2007
>ADD>			5693762	DEC 02, 2014		NCE	MAY 17, 2005
>ADD>			5739116	APR 14, 2015			
>ADD>			5767285	JUN 16, 2015			
>ADD>			5773001	JUN 30, 2015	U-320		
>ADD>			4970198	NOV 30, 2007			
>ADD>			5079233	JAN 07, 2009			
>ADD>			5585089	DEC 17, 2013			

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020622 001	GLATIRAMER ACETATE;COPAXONE	6054430	MAY 24, 2014			
			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>	021081 001	INSULIN GLARGINE;LANTUS				PED	OCT 20, 2005
>ADD>						NCE	APR 20, 2005
>ADD>	020563 001	INSULIN LISPRO;HUMALOG				D-56	APR 04, 2003
	021018 001	INSULIN LISPRO;HUMALOG MIX 50/50				NC	DEC 22, 2002
>ADD>	020563 002	INSULIN LISPRO;HUMALOG PEN	5474978	JUN 16, 2014		D-56	APR 04, 2003
			5514646	MAY 07, 2013	U-111	NCE	JUN 14, 2001
>ADD>	020571 001	IRINOTECAN HYDROCHLORIDE;CAMPTOSAR				I-299	APR 20, 2003
	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
	021130 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	021130 002	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	021131 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	021132 001	LINEZOLID;ZYVOX	5688792	NOV 18, 2014	U-319	NCE	APR 18, 2005
	019558 001	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
	020938 001	MELOXICAM;MOBIC				NCE	APR 13, 2005
>ADD>	020049 001	MESALAMINE;PENTASA	4980173	JAN 29, 2002	U-78		
	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

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020357 005	METFORMIN HYDROCHLORIDE;GLUCOPHAGE				PED	SEP 03, 2000
						NCE	MAR 03, 2000
	019815 001	MIDODRINE HYDROCHLORIDE;PROAMATINE				ODE	SEP 06, 2003
	019815 002	MIDODRINE HYDROCHLORIDE;PROAMATINE				ODE	SEP 06, 2003
>ADD>	020830 002	MONTELUKAST SODIUM;SINGULAIR	5565473	NOV 30, 2010	U-228	I-300	MAR 03, 2003
>ADD>						NS	MAR 03, 2003
>ADD>						NCE	FEB 20, 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			
	021134 001	NITROGLYCERIN;NITROSTAT				NDF	MAY 01, 2003
	021134 002	NITROGLYCERIN;NITROSTAT				NDF	MAY 01, 2003
	021134 003	NITROGLYCERIN;NITR0STAT				NDF	MAY 01, 2003
>ADD>	020592 001	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
>ADD>	020592 002	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
>ADD>	020592 003	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
>ADD>	020592 004	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
>ADD>	020592 005	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
>ADD>	020592 006	OLANZAPINE;ZYPREXA				I-297	MAR 17, 2003
>ADD>	021086 001	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
>ADD>			5229382	APR 23, 2011	U-324		
>ADD>			5605897	FEB 25, 2014	U-325		
>ADD>			5627178	APR 23, 2011	U-326		
>ADD>			5736541	MAR 24, 2015	U-328		
>ADD>			5817655	APR 23, 2011	U-327		
>ADD>			5817656	APR 23, 2011	U-326		
>ADD>	021086 002	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
>ADD>			5229382	APR 23, 2011	U-324		
>ADD>			5605897	FEB 25, 2014	U-325		
>ADD>			5627178	APR 23, 2011	U-326		
>ADD>			5736541	MAR 24, 2015	U-328		
>ADD>			5817655	APR 23, 2011	U-327		
>ADD>			5817656	APR 23, 2011	U-326		
>ADD>	021086 003	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
>ADD>			5736541	MAR 24, 2015	U-328		
>ADD>			5817655	APR 23, 2011	U-327		
>ADD>			5817656	APR 23, 2011	U-326		
>ADD>			5229382	APR 23, 2011	U-324		
>ADD>			5605897	FEB 25, 2014	U-325		
>ADD>			5627178	APR 23, 2011	U-326		
>ADD>	021086 004	OLANZAPINE;ZYPREXA ZYDIS	5457895	SEP 30, 2013		NCE	SEP 30, 2001
>ADD>			5229382	APR 23, 2011	U-324		
>ADD>			5605897	FEB 25, 2014	U-325		
>ADD>			5627178	APR 23, 2011	U-326		
>ADD>			5736541	MAR 24, 2015	U-328		
>ADD>			5817655	APR 23, 2011	U-327		
>ADD>			5817656	APR 23, 2011	U-326		

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	019715 001	OLSALAZINE SODIUM;DIPENTUM	4559330	JUL 31, 2004	U-58		
>ADD>	020781 001	ONDANSETRON;ZOFRAN ODT	5955488	NOV 14, 2015			
>ADD>	020781 002	ONDANSETRON;ZOFRAN ODT	5955488	NOV 14, 2015			
>ADD>	020766 001	ORLISTAT;XENICAL	6004996	JAN 06, 2018			
	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			
	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>	020903 001	RIBAVIRIN;REBETOL	6051252	DEC 22, 2017			
	020835 001	RISEDRONATE SODIUM;ACTONEL				I-292	APR 14, 2003
						I-291	APR 14, 2003
						I-290	APR 14, 2003
						I-293	APR 14, 2003
	020588 001	RISPERIDONE;RISPERDAL	5453425	JUL 11, 2014			
			5616587	JUL 11, 2014			
>ADD>	020659 001	RITONAVIR;NORVIR	6037157	JUN 26, 2016			
>ADD>			5674882	OCT 07, 2014			
>ADD>			5886036	DEC 29, 2012			
>ADD>	020823 003	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
>ADD>			5602176	FEB 11, 2014	U-322		

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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020823 004	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
>ADD>			5602176	FEB 11, 2014	U-322		
>ADD>	020823 005	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
>ADD>			5602176	FEB 11, 2014	U-322		
>ADD>	020823 006	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
>ADD>			5602176	FEB 11, 2014	U-322		
>ADD>	021025 001	RIVASTIGMINE TARTRATE;EXELON	4948807	AUG 14, 2007	U-322	NCE	APR 21, 2005
>ADD>			5602176	FEB 11, 2014	U-322		
	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		
	019721 001	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019721 002	SOMATROPIN RECOMBINANT;NORDITROPIN	5633352	MAY 27, 2014			
	019676 001	SOMATROPIN RECOMBINANT;NUTROPIN				D-55	APR 13, 2003
						M-2	DEC 01, 2002
	019676 002	SOMATROPIN RECOMBINANT;NUTROPIN				D-55	APR 13, 2003
						M-2	DEC 01, 2002
	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
>ADD>	021124 001	TERBINAFINE HYDROCHLORIDE;LAMISIL AT	4680291	JUL 14, 2004	U-73		
>ADD>			4755534	DEC 30, 2006	U-73		
>ADD>			5681849	OCT 28, 2014			
	021015 001	TESTOSTERONE;ANDROGEL				NDF	FEB 28, 2003
	020771 001	TOLTERODINE TARTRATE;DETROL	5559269	MAY 05, 2015	U-318		
	020771 002	TOLTERODINE TARTRATE;DETROL	5559269	MAY 05, 2015	U-318		
	020281 001	TRAMADOL HYDROCHLORIDE;ULTRAM				PED	SEP 03, 2000
						PED	FEB 21, 2002
						NCE	MAR 03, 2000
						D-44	AUG 21, 2001
	020281 002	TRAMADOL HYDROCHLORIDE;ULTRAM				PED	FEB 21, 2002
						PED	SEP 03, 2000
						NCE	MAR 03, 2000
						D-44	AUG 21, 2001
	020326 001	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			
	020326 002	TRIMETREXATE GLUCURONATE;NEUTREXIN	6017922	MAY 18, 2018			

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020719 001	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
	020719 002	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
	020719 003	TROGLITAZONE;PRELAY	6046202	SEP 15, 2013	U-317		
	020720 001	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
	020720 002	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
	020720 003	TROGLITAZONE;REZULIN	6046202	SEP 15, 2013	U-317		
	020552 001	VERAPAMIL HYDROCHLORIDE;COVERA-HS	5232705	AUG 31, 2010			
			5200196	JAN 22, 2008			
			5141752	JUN 27, 2006			
			5082668	JAN 21, 2009			
			5030456	NOV 07, 2008			
			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		
	021119 001	VERTEPORFIN;VISUDYNE				NCE	APR 12, 2005
>ADD>	021036 001	ZANAMIVIR;RELENZA				I-294	APR 26, 2003
	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)**
D-56	**ADDITION OF POSTPRANDIAL DOSING**

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**
I-294	**TREATMENT OF UNCOMPLICATED ACUTE ILLNESS DUE TO INFLUENZA A AND B IN PEDIATRIC PATIENTS 7 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS**
I-295	**PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS FOR WOMEN WITH AN INTACT UTERUS**
I-296	**LONG-TERM INTRAVENOUS TREATMENT OF PULMONARY HYPERTENSION ASSOCIATED WITH THE SCLERODERMA SPECTRUM OF DISEASE IN NYHA CLASS III AND CLASS IV PATIENTS WHO DO NOT RESPOND TO CONVENTIONAL THERAPY**
I-297	**SHORT-TERM TREATMENT OF ACUTE MANIC EPISODES ASSOCIATED WITH BIPOLAR I DISORDER**

PATENT AND EXCLUSIVITY TERMS

NEW INDICATION

I-298	TREATMENT OF PATIENTS WITH FREDERICKSON TYPE IIA AND IIB HYPERLIPOPROTEINEMIA
I-299	USE OF CAMPTOSAR AS A COMPONENT OF FIRST-LINE THERAPY IN COMBINATION WITH 5-FLUROURACIL AND LEUCOVARIN FOR PATIENTS WITH METASTATIC CARCINOMA OF THE COLON OR RECTUM
I-300	PROPHYLAXIS FOR ASTHMA IN CHILDREN 2-5 YEARS OF AGE

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
U-320	INHIBITING OR ELIMINATING ACUTE MYELOID LEUKEMIA
U-321	REDUCTION OF ELEVATED IPTH LEVELS IN THE MGT OF SECONDARY HYPERPARATHYROIDISM IN PATIENTS UNDERGONG CHRONIC RENAL DIALYSIS
U-322	TREATMENT OF ALZHEIMER'S DEMENTIA
U-323	USE AS A BILE ACID SEQUESTRANT
U-324	METHOD OF TREATING AN ANIMAL, INCLUDING A HUMAN, SUFFERING FROM OR SUSCEPTIBLE TO PSYCHOSIS OR ACUTE MANIA EMPLOYING OLANZAPINE
U-325	METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS, INCLUDING "BIPOLAR DISORDER NOS" EMPLOYING OLANZAPINE
U-326	METHOD OF TREATING SCHIZOPHRENIA AND BIPOLAR DISORDER
U-327	METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED PSYCHOTIC CONDITIONS EMPLOYING OLANZAPINE
U-328	METHOD OF TREATING A PATIENT SUFFERING FROM ANY OF A NUMBER OF LISTED CONDITIONS INCLUDING "A PSYCHOTIC CONDITION" EMPLOYING AN OLANZAPINE POLYMORPH