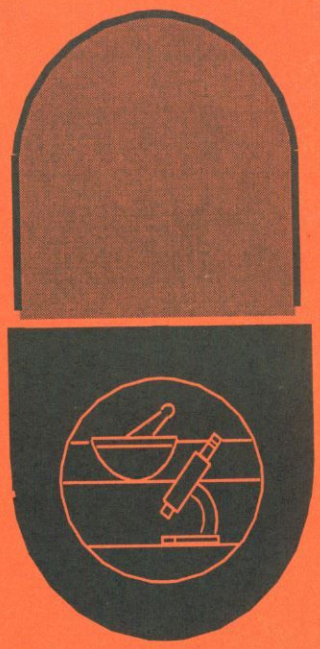
CUMULATIVE
SUPPLEMENT 3
MARCH 2003



APPROVED DRUG PRODUCTS

WITH THERAPEUTIC EQUIVALENCE EVALUATIONS

23rd EDITION

Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs

2003

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DRU

PAT

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

23RD EDITION

Cumulative Supplement 3

March 2003

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23rd EDITION

CUMULATIVE SUPPLEMENT 3
March 2003

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, 23rd 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have never been marketed, are for exportation, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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.

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 mark 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.

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.)

Products that have never been marketed, are for exportation, 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 23rd Edition List will then be added to the "Discontinued Drug Product List" appearing in the 24th Edition. The current edition Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

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. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section A, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >**A**>. 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 **>D>** (DELETE) to the left of the line. The information line with the **>D>** symbol is dropped in subsequent Cumulative Supplements for that item.

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)
SYNTEX (USA) INC LLC (SYNTEX USA INC)	ROCHE PALO ALTO LLC (ROCHE PALO)

1.3 AVAILABILITY OF THE EDITION

The 22nd 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 or toll free 866-512-1800. The cost is $108.00 annually. A GPO Orange Book Subscription form is provided at the end of each cumulative supplement.

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 monthly cumulative supplements.

The Internet version of the Orange Book annual edition is at
http://www.fda.gov/cder/orange/adp.htm.

The Internet version of the monthly supplement is at
http://www.fda.gov/cder/orange/supplement/cspreface.htm.

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 monthly cumulative supplements. Appendix A and Appendix B are updated quarterly.

The 23rd annual edition of the 2002 Orange Book Patent and Exclusivity List is at
http://www.fda.gov/cder/orange/23bookpub.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 Patent Term Extension and new Patents, Docket Number *95S-0117, is at
http://www.fda.gov/cder/orange/docket.pdf. It is updated monthly as soon as available and as otherwise needed.
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.htm

			ACETAMINOPHEN; BUTALBITAL; CAFFEINE						
			SOLUTION; ORAL						
			ACETAMINOPHEN AND BUTALBITAL AND CAFFEINE						
		+	MIKART	325MG/15ML;50MG/15ML;40MG/15ML	N40387 001	JAN 31, 2003	JAN	NEWA	
			ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE						
			CAPSULE; ORAL						
			FIORICET W/ CODEINE						
>D>	AB	+	NOVARTIS	325MG;50MG;40MG;30MG	N20232 001	JUL 30, 1992	MAR	CAHN	
>A>	AB	+	WATSON PHARMS	325MG;50MG;40MG;30MG	N20232 001	JUL 30, 1992	MAR	CAHN	
			ACETAMINOPHEN; CODEINE PHOSPHATE						
			TABLET; ORAL						
			ACETAMINOPHEN AND CODEINE PHOSPAHTE						
	AA		ANDRX PHARMS	300MG;15MG	N40443 001	JAN 22, 2003	JAN	NEWA	
	AA			300MG;30MG	N40443 002	JAN 22, 2003	JAN	NEWA	
	AA			300MG;60MG	N40443 003	JAN 22, 2003	JAN	NEWA	
			ACETAMINOPHEN AND CODEINE PHOSPHATE						
	AA		RANBAXY	300MG;60MG	N87083 001		JAN	CAHN	
			ACETAMINOPHEN W/ CODEINE PHOSPHATE #3						
	AA		RANBAXY	300MG;30MG	N85868 001		JAN	CAHN	
			CODRIX						
>A>		+	ANDRX PHARMS	500MG;30MG	N40441 001	MAR 27, 2003	MAR	NEWA	
		+		500MG;15MG	N40447 001	FEB 26, 2003	FEB	NEWA	
>A>		+		500MG;60MG	N40488 001	MAR 28, 2003	MAR	NEWA	
			ACETAMINOPHEN; HYDROCODONE BITARTRATE						
			TABLET; ORAL						
			ACETAMINOPHEN AND HYDROCODONE BITARTRATE						
	AA		ABLE	650MG;7.5MG	N40474 001	JAN 02, 2003	JAN	NEWA	
			HYDROCODONE BITARTRATE AND ACETAMINOPHEN						
	AA		MIKART	325MG;7.5MG	N40432 001	JAN 22, 2003	JAN	NEWA	
			ALFENTANIL HYDROCHLORIDE						
			INJECTABLE; INJECTION						
			ALFENTA						
>A>	AP	+	AKORN	EQ 0.5MG BASE/ML	N19353 001	DEC 29, 1986	MAR	CAHN	
>D>	AP	+	GD SEARLE LLC	EQ 0.5MG BASE/ML	N19353 001	DEC 29, 1986	MAR	CAHN	
>D>			ALPHA-TOCOPHEROL; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A						
>D>			INJECTABLE; INJECTION						
>D>			CERNEVIT-12						
>D>		+	BAXTER HLTHCARE	11.2 IU/VIAL;125MG/VIAL;60UGM/VIAL;200 IU/VIAL;5.5MG/VIAL;414UGM/VIAL;46MG /VIAL;17.25MG/VIAL;4.53MG/VIAL;4.14 MG/VIAL;3.51MG/VIAL;3,500 IU/VIAL	N20924 001	APR 06, 1999	MAR	DISC	
>A>		@		11.2 IU/VIAL;125MG/VIAL;60UGM/VIAL;200 IU/VIAL;5.5MG/VIAL;414UGM/VIAL;46MG /VIAL;17.25MG/VIAL;4.53MG/VIAL;4.14					

				MG/VIAL;3.51MG/VIAL;3,500 IU/VIAL	N20924 001	APR 06, 1999	MAR	DISC
			ALPRAZOLAM					
			TABLET, EXTENDED RELEASE; ORAL					
			XANAX XR					
			PHARMACIA AND UPJOHN	0.5MG	N21434 001	JAN 17, 2003	JAN	NEWA
				1MG	N21434 002	JAN 17, 2003	JAN	NEWA
				2MG	N21434 003	JAN 17, 2003	JAN	NEWA
		+		3MG	N21434 004	JAN 17, 2003	JAN	NEWA
			AMCINONIDE					
			OINTMENT; TOPICAL					
			AMCINONIDE					
>A>	AB		TARO PHARM INDS	0.1%	N76367 001	MAR 19, 2003	MAR	NEWA
			AMIODARONE HYDROCHLORIDE					
			INJECTABLE; INJECTION					
			CORDARONE					
>D>	AP	+	WYETH AYERST	50MG/ML	N20377 001	AUG 03, 1995	MAR	CAHN
>A>	AP	+	WYETH PHARMS INC	50MG/ML	N20377 001	AUG 03, 1995	MAR	CAHN
			TABLET; ORAL					
>D>	AB		WYETH AYERST	200MG	N18972 001	DEC 24, 1985	MAR	CAHN
>A>	AB		WYETH PHARMS INC	200MG	N18972 001	DEC 24, 1985	MAR	CAHN
			AMITRIPTYLINE HYDROCHLORIDE; PERPHENAZINE					
			TABLET; ORAL					
>D>			ETRAFON 2-10					
>D>	BP		SCHERING	10MG;2MG	N14713 007		MAR	DISC
>A>			@	10MG;2MG	N14713 007		MAR	DISC
>D>			ETRAFON 2-25					
>D>	BP		SCHERING	25MG;2MG	N14713 004		MAR	DISC
>A>			@	25MG;2MG	N14713 004		MAR	DISC
>D>			ETRAFON-FORTE					
>D>	BP		SCHERING	25MG;4MG	N14713 006		MAR	DISC
>A>			@	25MG;4MG	N14713 006		MAR	DISC
			AMOXICILLIN; CLAVULANATE POTASSIUM					
			FOR SUSPENSION; ORAL					
			AMOXICILLIN AND CLAVULANATE POTASSIUM					
>A>	AB		RANBAXY	200MG/5ML;EQ 28.5MG BASE/5ML	N65132 001	MAR 19, 2003	MAR	NEWA
>A>	AB			400MG/5ML;EQ 57MG BASE/5ML	N65132 002	MAR 19, 2003	MAR	NEWA
			AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE					
			CAPSULE, EXTENDED RELEASE; ORAL					
			ADDERALL XR 10					
			SHIRE LABS	2.5MG;2.5MG;2.5MG;2.5MG	N21303 001	OCT 11, 2001	JAN	CAHN
			ADDERALL XR 15					
			SHIRE LABS	3.75MG;3.75MG;3.75MG;3.75MG	N21303 006	MAY 22, 2002	JAN	CAHN
			ADDERALL XR 20					
			SHIRE LABS	5MG;5MG;5MG;5MG	N21303 002	OCT 11, 2001	JAN	CAHN
			ADDERALL XR 25					
			SHIRE LABS	6.25MG;6.25MG;6.25MG;6.25MG	N21303 004	MAY 22, 2002	JAN	CAHN
			ADDERALL XR 30					

AMPHETAMINE ASPARTATE; AMPHETAMINE SULFATE; DEXTROAMPHETAMINE SACCHARATE; DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

ADDERALL XR 30

	+	SHIRE LABS	7.5MG;7.5MG;7.5MG;7.5MG	N21303	003	OCT 11, 2001	JAN	CAHN

ADDERALL XR 5

		SHIRE LABS	1.25MG;1.25MG;1.25MG;1.25MG	N21303	005	MAY 22, 2002	JAN	CAHN

TABLET; ORAL

ADDERALL 12.5

>D>		SHIRE LABS	3.125MG;3.125MG;3.125MG;3.125MG	N11522	012	AUG 31, 2000	MAR	CFTG
>A>	AB		3.125MG;3.125MG;3.125MG;3.125MG	N11522	012	AUG 31, 2000	MAR	CFTG

ADDERALL 15

>D>		SHIRE LABS	3.75MG;3.75MG;3.75MG;3.75MG	N11522	013	AUG 31, 2000	MAR	CFTG
>A>	AB		3.75MG;3.75MG;3.75MG;3.75MG	N11522	013	AUG 31, 2000	MAR	CFTG

ADDERALL 7.5

>D>		SHIRE LABS	1.875MG;1.875MG;1.875MG;1.875MG	N11522	011	AUG 31, 2000	MAR	CFTG
>A>	AB		1.875MG;1.875MG;1.875MG;1.875MG	N11522	011	AUG 31, 2000	MAR	CFTG
>A>		DEXTROAMP SACCHARATE, AMP ASPARTATE, DEXTROAMP SULFATE AND AMP SULFATE						
>A>	AB	BARR	1.875MG;1.875MG;1.875MG;1.875MG	N40422	005	MAR 19, 2003	MAR	NEWA
>A>	AB		3.125MG;3.125MG;3.125MG;3.125MG	N40422	006	MAR 19, 2003	MAR	NEWA
>A>	AB		3.75MG;3.75MG;3.75MG;3.75MG	N40422	007	MAR 19, 2003	MAR	NEWA

AMPRENAVIR

CAPSULE; ORAL

AGENERASE

>D>		@ GLAXOSMITHKLINE	50MG	N21007	001	APR 15, 1999	MAR	CMFD
>A>			50MG	N21007	001	APR 15, 1999	MAR	CMFD
>D>		@	150MG	N21007	002	APR 15, 1999	MAR	CMFD
>A>		+	150MG	N21007	002	APR 15, 1999	MAR	CMFD

SOLUTION; ORAL

>D>		@ GLAXOSMITHKLINE	15MG/ML	N21039	001	APR 15, 1999	MAR	CMFD
>A>		+	15MG/ML	N21039	001	APR 15, 1999	MAR	CMFD

>A> APREPITANT

>A> CAPSULE; ORAL

>A> EMEND

>A>		MERCK	80MG	N21549	001	MAR 26, 2003	MAR	NEWA
>A>		+	125MG	N21549	002	MAR 26, 2003	MAR	NEWA

ASPIRIN; BUTALBITAL; CAFFEINE

CAPSULE; ORAL

FIORINAL

>D>	AB	+ NOVARTIS	325MG;50MG;40MG	N17534	005	APR 16, 1986	MAR	CAHN
>A>	AB	+ WATSON PHARMS	325MG;50MG;40MG	N17534	005	APR 16, 1986	MAR	CAHN

TABLET; ORAL

>D>	AB	+ NOVARTIS	325MG;50MG;40MG	N17534	003	APR 16, 1986	MAR	CAHN
>A>	AB	+ WATSON PHARMS	325MG;50MG;40MG	N17534	003	APR 16, 1986	MAR	CAHN

ASPIRIN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE
CAPSULE; ORAL
FIORINAL W/CODEINE NO 3

>D>	AB	+	NOVARTIS	325MG;50MG;40MG;30MG	N19429 003	OCT 26, 1990	MAR	CAHN
>A>	AB	+	WATSON PHARMS	325MG;50MG;40MG;30MG	N19429 003	OCT 26, 1990	MAR	CAHN

AZATHIOPRINE
TABLET; ORAL
AZASAN

			AAIPHARMA LLC	25MG	N75252 002	FEB 03, 2003	FEB	NEWA
	AB			50MG	N75252 001	JUN 07, 1999	FEB	NEWA
				75MG	N75252 003	FEB 03, 2003	FEB	NEWA
				100MG	N75252 004	FEB 03, 2003	FEB	NEWA

BECLOMETHASONE DIPROPIONATE
AEROSOL, METERED; INHALATION

>D>			BECLOVENT					
>D>	BN		GLAXOSMITHKLINE	0.042MG/INH	N18153 001		MAR	DISC
>A>			@	0.042MG/INH	N18153 001		MAR	DISC
>D>			AEROSOL, METERED; NASAL					
>D>			BECONASE					
>D>	BN	+	GLAXOSMITHKLINE	0.042MG/INH	N18584 001		MAR	DISC
>A>			@	0.042MG/INH	N18584 001		MAR	DISC
>D>			VANCENASE					
>D>	BN		SCHERING	0.042MG/INH	N18521 001		MAR	DISC
>A>			@	0.042MG/INH	N18521 001		MAR	DISC

BETAMETHASONE
TABLET; ORAL
CELESTONE

			@ SCHERING	0.6MG	N12657 003		FEB	DISC

BISOPROLOL FUMARATE
TABLET; ORAL
ZEBETA

>D>	AB		LEDERLE	5MG	N19982 002	JUL 31, 1992	MAR	CAHN
>D>	AB	+		10MG	N19982 001	JUL 31, 1992	MAR	CAHN
>A>	AB		WYETH PHARMS INC	5MG	N19982 002	JUL 31, 1992	MAR	CAHN
>A>	AB	+		10MG	N19982 001	JUL 31, 1992	MAR	CAHN

BISOPROLOL FUMARATE; HYDROCHLOROTHIAZIDE
TABLET; ORAL
ZIAC

>D>	AB		LEDERLE	2.5MG;6.25MG	N20186 003	MAR 26, 1993	MAR	CAHN
>D>	AB			5MG;6.25MG	N20186 001	MAR 26, 1993	MAR	CAHN
>D>	AB	+		10MG;6.25MG	N20186 002	MAR 26, 1993	MAR	CAHN
>A>	AB		WYETH PHARMS INC	2.5MG;6.25MG	N20186 003	MAR 26, 1993	MAR	CAHN
>A>	AB			5MG;6.25MG	N20186 001	MAR 26, 1993	MAR	CAHN
>A>	AB	+		10MG;6.25MG	N20186 002	MAR 26, 1993	MAR	CAHN

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

>D>			DIMETANE-DX						
>D>	AA	+	ROBINS AH	2MG/5ML;10MG/5ML;30MG/5ML	N19279	001	AUG 24, 1984	MAR	DISC
>A>			@	2MG/5ML;10MG/5ML;30MG/5ML	N19279	001	AUG 24, 1984	MAR	DISC
			MYPHETANE DX						
>D>	AA		MORTON GROVE	2MG/5ML;10MG/5ML;30MG/5ML	N88811	001	JUN 07, 1985	MAR	CTEC
>A>	AA	+		2MG/5ML;10MG/5ML;30MG/5ML	N88811	001	JUN 07, 1985	MAR	CTEC

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

			BUSPIRONE HCL						
	AB		EGIS	15MG	N75119	003	JAN 23, 2003	JAN	NEWA

CALCITRIOL

INJECTABLE; INJECTION

			CALCITRIOL						
	AP		AAIPHARMA	0.001MG/ML	N75766	001	FEB 20, 2003	FEB	NEWA
	AP			0.002MG/ML	N75766	002	FEB 20, 2003	FEB	NEWA
>A>	AP		GENSIA SICOR PHARMS	0.001MG/ML	N75823	001	MAR 31, 2003	MAR	NEWA
>A>	AP			0.002MG/ML	N75823	002	MAR 31, 2003	MAR	NEWA

>A> CARBINOXAMINE MALEATE

>A> TABLET; ORAL

>A>			CARBINOXAMINE MALEATE						
>A>		+	MIKART	4MG	N40442	001	MAR 19, 2003	MAR	NEWA

CEFADROXIL/CEFADROXIL HEMIHYDRATE

FOR SUSPENSION; ORAL

>A>			CEFADROXIL						
>A>	AB		RANBAXY	EQ 125MG BASE/5ML	N65115	001	MAR 26, 2003	MAR	NEWA
>A>	AB			EQ 250MG BASE/5ML	N65115	002	MAR 26, 2003	MAR	NEWA
>A>	AB			EQ 500MG BASE/5ML	N65115	003	MAR 26, 2003	MAR	NEWA
			DURICEF						
>D>			WARNER CHILCOTT	EQ 125MG BASE/5ML	N50527	002		MAR	CFTG
>A>	AB			EQ 125MG BASE/5ML	N50527	002		MAR	CFTG
>D>				EQ 250MG BASE/5ML	N50527	003		MAR	CFTG
>A>	AB			EQ 250MG BASE/5ML	N50527	003		MAR	CFTG
>D>		+		EQ 500MG BASE/5ML	N50527	001		MAR	CFTG
>A>	AB	+		EQ 500MG BASE/5ML	N50527	001		MAR	CFTG

CEFOXITIN SODIUM

INJECTABLE; INJECTION

			MEFOXIN IN PLASTIC CONTAINER						
>D>			MERCK	EQ 20MG BASE/ML	N63182	001	JAN 25, 1993	MAR	CRLD
>A>		+		EQ 20MG BASE/ML	N63182	001	JAN 25, 1993	MAR	CRLD
>D>				EQ 40MG BASE/ML	N63182	002	JAN 25, 1993	MAR	CRLD
>A>		+		EQ 40MG BASE/ML	N63182	002	JAN 25, 1993	MAR	CRLD

CEPHALOTHIN SODIUM
INJECTABLE; INJECTION
CEPHALOTHIN SODIUM

>D>	AP	BRISTOL	EQ 1GM BASE/VIAL	N62464	001	MAY 07, 1984	MAR	CRLD
>A>	+		EQ 1GM BASE/VIAL	N62464	001	MAY 07, 1984	MAR	CRLD
>D>	AP		EQ 2GM BASE/VIAL	N62464	002	MAY 07, 1984	MAR	CRLD
>A>	+		EQ 2GM BASE/VIAL	N62464	002	MAY 07, 1984	MAR	CRLD
>D>	AP		EQ 4GM BASE/VIAL	N62464	003	MAY 07, 1984	MAR	CRLD
>A>	+		EQ 4GM BASE/VIAL	N62464	003	MAY 07, 1984	MAR	CRLD
>D>		KEFLIN						
>D>	AP +	LILLY	EQ 1GM BASE/VIAL	N50482	001		MAR	DISC
>A>		@	EQ 1GM BASE/VIAL	N50482	001		MAR	DISC
>D>	AP +		EQ 2GM BASE/VIAL	N50482	002		MAR	DISC
>A>		@	EQ 2GM BASE/VIAL	N50482	002		MAR	DISC
>D>	AP +		EQ 4GM BASE/VIAL	N50482	003		MAR	DISC
>A>		@	EQ 4GM BASE/VIAL	N50482	003		MAR	DISC

CICLOPIROX
SHAMPOO; TOPICAL
LOPROX

	+	MEDICIS	1%	N21159	001	FEB 28, 2003	FEB	NEWA

CLINDAMYCIN HYDROCHLORIDE
CAPSULE; ORAL
CLINDAMYCIN HCL

>A>	AB	WATSON LABS	EQ 300MG BASE	N63083	002	MAR 18, 2003	MAR	NEWA

COPPER
INTRAUTERINE DEVICE; INTRAUTERINE
COPPER T MODEL TCU 380A

>A>	+	FEI	309MG/COPPER	N18680	001	NOV 15, 1984	MAR	CAHN
>D>	+	POPULATION COUNCIL	309MG/COPPER	N18680	001	NOV 15, 1984	MAR	CAHN

CYCLOBENZAPRINE HYDROCHLORIDE
TABLET; ORAL
FLEXERIL

>D>		@ MCNEIL CONS SPECLT	5MG	N17821	001		MAR	CMFD
>A>	AA		5MG	N17821	001		MAR	CMFD

CYCLOSPORINE
CAPSULE; ORAL
GENGRAF

	AB1	ABBOTT	25MG	N65003	001	MAY 12, 2000	FEB	CTNA
	BX		50MG	N65003	002	MAY 12, 2000	FEB	CTNA
	AB1		100MG	N65003	003	MAY 12, 2000	FEB	CTNA

EMULSION; OPHTHALMIC
RESTASIS

>A>	+	ALLERGAN	0.05%	N50790	001	DEC 23, 2002	MAR	CMS1
>D>			0.05%	N50790	001	DEC 23, 2002	MAR	CMS1

DALFOPRISTIN; QUINUPRISTIN

INJECTABLE; IV (INFUSION)

SYNERCID

	+	KING PHARMS	350MG/VIAL;150MG/VIAL	N50748 001	SEP 21, 1999	FEB	CAHN
		@	420MG/VIAL;180MG/VIAL	N50748 002	AUG 24, 2000	FEB	CAHN

DEMECLOCYCLINE HYDROCHLORIDE

TABLET; ORAL

DECLOMYCIN

>D>		@ LEDERLE	75MG	N50261 001		MAR	CAHN
>D>			150MG	N50261 002		MAR	CAHN
>D>	+		300MG	N50261 003		MAR	CAHN
>A>		@ WYETH PHARMS INC	75MG	N50261 001		MAR	CAHN
>A>			150MG	N50261 002		MAR	CAHN
>A>	+		300MG	N50261 003		MAR	CAHN

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-21

ORTHO-CEPT

>D>	AB	+	ORTHO MCNEIL PHARM	0.15MG;0.03MG	N20301 001	DEC 14, 1992	MAR	DISC
>A>			@	0.15MG;0.03MG	N20301 001	DEC 14, 1992	MAR	DISC

TABLET; ORAL-28

>D>	AB		ORTHO MCNEIL PHARM	0.15MG;0.03MG	N20301 002	DEC 14, 1992	MAR	CRLD
>A>	AB	+		0.15MG;0.03MG	N20301 002	DEC 14, 1992	MAR	CRLD

DIGOXIN

TABLET; ORAL

DIGOXIN

AB		CARACO	0.125MG	N76363 001	JAN 31, 2003	JAN	NEWA
AB			0.25MG	N76363 002	JAN 31, 2003	JAN	NEWA

DILTIAZEM HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

	+	BIOVAIL	120MG	N21392 001	FEB 06, 2003	FEB	NEWA
	+		180MG	N21392 002	FEB 06, 2003	FEB	NEWA
	+		240MG	N21392 003	FEB 06, 2003	FEB	NEWA
	+		300MG	N21392 004	FEB 06, 2003	FEB	NEWA
	+		360MG	N21392 005	FEB 06, 2003	FEB	NEWA
	+		420MG	N21392 006	FEB 06, 2003	FEB	NEWA

DOXAPRAM HYDROCHLORIDE

INJECTABLE; INJECTION

DOPRAM

AP	+	BAXTER HLTHCARE CORP	20MG/ML	N14879 001		JAN	CAHN

DOXAPRAM HCL

AP		BEDFORD	20MG/ML	N76266 001	JAN 10, 2003	JAN	NEWA

DOXYCYCLINE HYCLATE

CAPSULE, COATED PELLETS; ORAL

DORYX

		FAULDING	EQ 75MG BASE	N50582 002	AUG 13, 2001	FEB	NEWA

DOXYCYCLINE HYCLATE
INJECTABLE; INJECTION
DOXY 100

>D>	AP	AM PHARM PARTNERS	EQ 100MG BASE/VIAL	N62475 001	DEC 09, 1983	MAR	CRLD
>A>	+		EQ 100MG BASE/VIAL	N62475 001	DEC 09, 1983	MAR	CRLD

DOXY 200

>D>	AP	AM PHARM PARTNERS	EQ 200MG BASE/VIAL	N62475 002	DEC 09, 1983	MAR	CRLD
>A>	+		EQ 200MG BASE/VIAL	N62475 002	DEC 09, 1983	MAR	CRLD

VIBRAMYCIN

>D>	AP	+ PFIZER	EQ 100MG BASE/VIAL	N50442 002		MAR	DISC
>A>		@	EQ 100MG BASE/VIAL	N50442 002		MAR	DISC
>D>	AP	+	EQ 200MG BASE/VIAL	N50442 001		MAR	DISC
>A>		@	EQ 200MG BASE/VIAL	N50442 001		MAR	DISC

ELETRIPTAN HYDROBROMIDE
TABLET; ORAL
RELPAX

>D>		PFIZER	EQ 20MG BASE	N21016 001	DEC 26, 2002	MAR	CAHN
>D>	+		EQ 40MG BASE	N21016 002	DEC 26, 2002	MAR	CAHN
>A>		PFIZER IRELAND	EQ 20MG BASE	N21016 001	DEC 26, 2002	MAR	CAHN
>A>	+		EQ 40MG BASE	N21016 002	DEC 26, 2002	MAR	CAHN

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE
TABLET; ORAL
ENALAPRIL MALEATE AND HYDROCHLOROTHIAZIDE

>A>	AB	IVAX PHARMS	5MG;12.5MG	N75736 001	MAR 25, 2003	MAR	NEWA
>A>	AB		10MG;25MG	N75736 002	MAR 25, 2003	MAR	NEWA

>A> ENFUVIRTIDE
>A> INJECTABLE; SUBCUTANEOUS
>A> FUZEON

>A>	+	ROCHE	90MG/VIAL	N21481 001	MAR 13, 2003	MAR	NEWA

ENOXAPARIN SODIUM
INJECTABLE; SUBCUTANEOUS
LOVENOX

	+	AVENTIS	300MG/3ML	N20164 009	JAN 23, 2003	JAN	NEWA

EPINEPHRINE BITARTRATE; ETIDOCAINE HYDROCHLORIDE
INJECTABLE; INJECTION
DURANEST

>D>	+	DENTSPLY PHARM	0.005MG/ML;1.5%	N21384 001		MAR	DISC
>A>		@	0.005MG/ML;1.5%	N21384 001		MAR	DISC

ERGOTAMINE TARTRATE
TABLET; SUBLINGUAL
ERGOMAR

>A>	+	HARVEST PHARMS	2MG	N87693 001	FEB 24, 1983	MAR	CAHN
>D>	+	NEW RIVER	2MG	N87693 001	FEB 24, 1983	MAR	CAHN

	ESMOLOL HYDROCHLORIDE						
	INJECTABLE; INJECTION						
>A>	BREVIBLOC DOUBLE STRENGTH IN PLASTIC CONTAINER						
>A>	+ BAXTER HLTHCARE CORP	2GM/100ML	N19386 005	JAN 27, 2003	MAR	NEWA	
>A>	BREVIBLOC IN PLASTIC CONTAINER						
>A>	+ BAXTER HLTHCARE CORP	1GM/100ML	N19386 004	FEB 16, 2001	MAR	NEWA	
>A>	ESTRADIOL ACETATE						
>A>	INSERT, EXTENDED RELEASE; VAGINAL						
>A>	FEMRING						
>A>	GALEN LTD	0.05MG/24HR	N21367 001	MAR 20, 2003	MAR	NEWA	
>A>	+	0.1MG/24HR	N21367 002	MAR 20, 2003	MAR	NEWA	
	ESTROGENS, CONJUGATED						
	CREAM; TOPICAL, VAGINAL						
	PREMARIN						
>D>	+ AYERST	0.625MG/GM	N20216 001		MAR	CAHN	
>A>	+ WYETH PHARMS INC	0.625MG/GM	N20216 001		MAR	CAHN	
	INJECTABLE; INJECTION						
>D>	+ WYETH AYERST	25MG/VIAL	N10402 001		MAR	CAHN	
>A>	+ WYETH PHARMS INC	25MG/VIAL	N10402 001		MAR	CAHN	
	TABLET; ORAL						
>D>	WYETH AYERST	0.3MG	N04782 003		MAR	CAHN	
>D>	+	0.625MG	N04782 004		MAR	CAHN	
>D>		0.9MG	N04782 005	JAN 26, 1984	MAR	CAHN	
>D>	+	1.25MG	N04782 001		MAR	CAHN	
>D>		2.5MG	N04782 002		MAR	CAHN	
>A>	WYETH PHARMS INC	0.3MG	N04782 003		MAR	CAHN	
>A>	+	0.625MG	N04782 004		MAR	CAHN	
>A>		0.9MG	N04782 005	JAN 26, 1984	MAR	CAHN	
>A>	+	1.25MG	N04782 001		MAR	CAHN	
>A>		2.5MG	N04782 002		MAR	CAHN	
	ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE						
	TABLET; ORAL-28						
	PREMPHASE (PREMARIN;CYCRIN 14/14)						
>D>	@ WYETH AYERST	0.625MG,0.625MG;5MG	N20303 002	DEC 30, 1994	MAR	CAHN	
>A>	@ WYETH PHARMS INC	0.625MG,0.625MG;5MG	N20303 002	DEC 30, 1994	MAR	CAHN	
	PREMPHASE 14/14						
>D>	+ WYETH AYERST	0.625MG,0.625MG;5MG	N20527 002	NOV 17, 1995	MAR	CAHN	
>A>	+ WYETH PHARMS INC	0.625MG,0.625MG;5MG	N20527 002	NOV 17, 1995	MAR	CAHN	
	PREMPRO						
>D>	+ WYETH AYERST	0.625MG,0.625MG;2.5MG,2.5MG	N20527 001	NOV 17, 1995	MAR	CAHN	
>D>	+	0.625MG,0.625MG;5MG,5MG	N20527 003	JAN 09, 1998	MAR	CAHN	
>A>	+ WYETH PHARMS INC	0.45MG;1.5MG	N20527 004	MAR 12, 2003	MAR	NEWA	
>A>	+	0.625MG,0.625MG;2.5MG,2.5MG	N20527 001	NOV 17, 1995	MAR	CAHN	
>A>	+	0.625MG,0.625MG;5MG,5MG	N20527 003	JAN 09, 1998	MAR	CAHN	
	PREMPRO (PREMARIN;CYCRIN)						
>D>	@ WYETH AYERST	0.625MG,0.625MG;2.5MG,2.5MG	N20303 001	DEC 30, 1994	MAR	CAHN	
>A>	@ WYETH PHARMS INC	0.625MG,0.625MG;2.5MG,2.5MG	N20303 001	DEC 30, 1994	MAR	CAHN	

ESTROGENS, ESTERIFIED

TABLET; ORAL

MENEST

			MONARCH PHARMS	0.3MG	N84951 001		JAN	CRLD

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21

ALESSE

>D>	AB1	+	WYETH AYERST	0.02MG;0.1MG	N20683 001	MAR 27, 1997	MAR	CAHN
>A>	AB1	+	WYETH PHARMS INC	0.02MG;0.1MG	N20683 001	MAR 27, 1997	MAR	CAHN

NORDETTE-21

>D>	AB	+	WYETH AYERST	0.03MG;0.15MG	N18668 001	MAY 10, 1982	MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	0.03MG;0.15MG	N18668 001	MAY 10, 1982	MAR	CAHN

TRIPHASIL-21

>D>	AB	+	WYETH AYERST	0.03MG,0.04MG,0.03MG;0.05MG,0.125MG ,0.075MG	N19192 001	NOV 01, 1984	MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	0.03MG,0.04MG,0.03MG;0.05MG,0.125MG ,0.075MG	N19192 001	NOV 01, 1984	MAR	CAHN

TABLET; ORAL-28

ALESSE

>D>	AB1		WYETH AYERST	0.02MG;0.1MG	N20683 002	MAR 27, 1997	MAR	CAHN
>A>	AB1		WYETH PHARMS INC	0.02MG;0.1MG	N20683 002	MAR 27, 1997	MAR	CAHN

NORDETTE-28

>D>	AB		WYETH AYERST	0.03MG;0.15MG	N18782 001	JUL 21, 1982	MAR	CAHN
>A>	AB		WYETH PHARMS INC	0.03MG;0.15MG	N18782 001	JUL 21, 1982	MAR	CAHN

TRIPHASIL-28

>D>	AB		WYETH AYERST	0.03MG,0.04MG,0.03MG;0.05MG,0.125MG ,0.075MG	N19190 001	NOV 01, 1984	MAR	CAHN
>A>	AB		WYETH PHARMS INC	0.03MG,0.04MG,0.03MG;0.05MG,0.125MG ,0.075MG	N19190 001	NOV 01, 1984	MAR	CAHN

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

TRI-NORINYL 21-DAY

>D>			@ WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977 001	APR 13, 1984	MAR	CPOT
>A>			@	0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .5MG	N18977 001	APR 13, 1984	MAR	CPOT
			@	0.035MG,0.035MG;0.5MG,1MG	N18977 001	APR 13, 1984	FEB	DISC

TABLET; ORAL-28

ORTHO-NOVUM 7/7/7-28

	AB	+	ORTHO MCNEIL PHARM	0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .75MG	N18985 002	APR 04, 1984	FEB	CRLD

OVCON-35

		+	WARNER CHILCOTT	0.035MG;0.4MG	N17716 001		JAN	CRLD

OVCON-50

		+	WARNER CHILCOTT	0.05MG;1MG	N17576 001		JAN	CRLD

TRI-NORINYL 28-DAY

>D>		+	WATSON LABS	0.035MG,0.035MG;0.5MG,1MG	N18977 002	APR 13, 1984	MAR	CPOT
>A>		+		0.035MG,0.035MG,0.035MG;0.5MG,1MG,0 .5MG	N18977 002	APR 13, 1984	MAR	CPOT

		+		0.035MG,0.035MG;0.5MG,1MG	N18977 002	APR 13, 1984	JAN	CRLD

ETHINYL ESTRADIOL; NORGESTREL

TABLET; ORAL-21

LO/OVRAL

>D>	AB	+	WYETH AYERST	0.03MG;0.3MG	N17612 001		MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	0.03MG;0.3MG	N17612 001		MAR	CAHN

OGESTREL 0.5/50-21

	AB		WATSON LABS	0.05MG;0.5MG	N75406 001	DEC 15, 1999	FEB	CAHN

OVRAL

>D>	AB	+	WYETH AYERST	0.05MG;0.5MG	N16672 001		MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	0.05MG;0.5MG	N16672 001		MAR	CAHN

TABLET; ORAL-28

LO/OVRAL-28

>D>	AB		WYETH AYERST	0.03MG;0.3MG	N17802 001		MAR	CAHN
>A>	AB		WYETH PHARMS INC	0.03MG;0.3MG	N17802 001		MAR	CAHN

OGESTREL 0.5/50-28

	AB		WATSON LABS	0.05MG;0.5MG	N75406 002	DEC 15, 1999	FEB	CAHN

OVRAL-28

>D>	AB		WYETH AYERST	0.05MG;0.5MG	N16806 001		MAR	CAHN
>A>	AB		WYETH PHARMS INC	0.05MG;0.5MG	N16806 001		MAR	CAHN

ETHIONAMIDE

TABLET; ORAL

TRECATOR-SC

>D>		+	WYETH AYERST	250MG	N13026 002		MAR	CAHN
>A>		+	WYETH PHARMS INC	250MG	N13026 002		MAR	CAHN

ETHOTOIN

TABLET; ORAL

PEGANONE

>D>		+	ABBOTT	250MG	N10841 001		MAR	CAHN
>D>		@		500MG	N10841 003		MAR	CAHN
>A>		+	OVATION PHARMS	250MG	N10841 001		MAR	CAHN
>A>		@		500MG	N10841 003		MAR	CAHN

ETIDRONATE DISODIUM

TABLET; ORAL

ETIDRONATE DISODIUM

	AB		GENPHARM	200MG	N75800 001	JAN 24, 2003	JAN	NEWA
	AB			400MG	N75800 002	JAN 24, 2003	JAN	NEWA

ETODOLAC

CAPSULE; ORAL

LODINE

>D>	AB		WYETH AYERST	200MG	N18922 002	JAN 31, 1991	MAR	CAHN
>D>	AB	+		300MG	N18922 003	JAN 31, 1991	MAR	CAHN
>A>	AB		WYETH PHARMS INC	200MG	N18922 002	JAN 31, 1991	MAR	CAHN
>A>	AB	+		300MG	N18922 003	JAN 31, 1991	MAR	CAHN

TABLET; ORAL

>D>	AB		WYETH AYERST	400MG	N18922 004	JUL 29, 1993	MAR	CAHN
>D>	AB	+		500MG	N18922 005	JUN 28, 1996	MAR	CAHN
>A>	AB		WYETH PHARMS INC	400MG	N18922 004	JUL 29, 1993	MAR	CAHN

>A>	AB	+		500MG	N18922 005	JUN 28, 1996	MAR	CAHN
		TABLET, EXTENDED RELEASE; ORAL							
		ETODOLAC							
>A>	AB		TARO	400MG	N76174 001	MAR 13, 2003	MAR	NEWA
>A>	AB			500MG	N76174 002	MAR 13, 2003	MAR	NEWA
>A>	AB			600MG	N76174 003	MAR 13, 2003	MAR	NEWA
		LODINE XL							
>D>	AB	+	WYETH AYERST	400MG	N20584 001	OCT 25, 1996	MAR	CAHN
>D>	AB	+		500MG	N20584 003	JAN 20, 1998	MAR	CAHN
>D>	AB	+		600MG	N20584 002	OCT 25, 1996	MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	400MG	N20584 001	OCT 25, 1996	MAR	CAHN
>A>	AB	+		500MG	N20584 003	JAN 20, 1998	MAR	CAHN
>A>	AB	+		600MG	N20584 002	OCT 25, 1996	MAR	CAHN
		FELBAMATE							
		SUSPENSION; ORAL							
		FELBATOL							
>A>		+	MEDPOINTE	600MG/5ML	N20189 003	JUL 29, 1993	MAR	CAHN
>D>		+	WALLACE LABS	600MG/5ML	N20189 003	JUL 29, 1993	MAR	CAHN
		TABLET; ORAL							
>A>			MEDPOINTE	400MG	N20189 001	JUL 29, 1993	MAR	CAHN
>A>		+		600MG	N20189 002	JUL 29, 1993	MAR	CAHN
>D>			WALLACE LABS	400MG	N20189 001	JUL 29, 1993	MAR	CAHN
>D>		+		600MG	N20189 002	JUL 29, 1993	MAR	CAHN
		FENOFIBRATE							
		CAPSULE; ORAL							
		FENOFIBRATE (MICRONIZED)							
>D>	AB		TEVA	67MG	N75753 001	SEP 03, 2002	MAR	CTEC
>A>				67MG	N75753 001	SEP 03, 2002	MAR	CTEC
>D>	AB			134MG	N75753 002	APR 09, 2002	MAR	CTEC
>A>				134MG	N75753 002	APR 09, 2002	MAR	CTEC
>D>	AB			200MG	N75753 003	APR 09, 2002	MAR	CRLD
>A>		+		200MG	N75753 003	APR 09, 2002	MAR	CRLD
>D>			TRICOR (MICRONIZED)						
>D>	AB		ABBOTT	67MG	N19304 002	FEB 09, 1998	MAR	DISC
>A>			@	67MG	N19304 002	FEB 09, 1998	MAR	DISC
>D>	AB			134MG	N19304 003	JUN 30, 1999	MAR	DISC
>A>			@	134MG	N19304 003	JUN 30, 1999	MAR	DISC
>D>	AB	+		200MG	N19304 004	JUN 30, 1999	MAR	DISC
>A>			@	200MG	N19304 004	JUN 30, 1999	MAR	DISC
		FLAVOXATE HYDROCHLORIDE							
		TABLET; ORAL							
		URISPAS							
>D>		+	GLAXOSMITHKLINE	100MG	N16769 001		MAR	CAHN
>A>		+	ORTHO-MCNEIL PHARMAC	100MG	N16769 001		MAR	CAHN
		FLECAINIDE ACETATE							
		TABLET; ORAL							
		FLECAINIDE ACETATE							
>A>	AB		RANBAXY	50MG	N76421 001	MAR 28, 2003	MAR	NEWA
>A>	AB			100MG	N76421 002	MAR 28, 2003	MAR	NEWA

>A>	AB			150MG	N76421 003	MAR 28, 2003	MAR	NEWA
	AB		ROXANE	50MG	N76278 001	JAN 14, 2003	JAN	NEWA
	AB			100MG	N76278 002	JAN 14, 2003	JAN	NEWA
	AB			150MG	N76278 003	JAN 14, 2003	JAN	NEWA
		FLUDROCORTISONE ACETATE						
		TABLET; ORAL						
		FLUDROCORTISONE ACETATE						
	AB		BARR	0.1MG	N40425 001	JAN 21, 2003	JAN	NEWA
		FLUORESCEIN SODIUM						
		INJECTABLE; INJECTION						
		FUNDUSCEIN-25						
		@	NOVARTIS	25%	N17869 001		JAN	DISC
		FOLIC ACID						
		INJECTABLE; INJECTION						
		FOLVITE						
>D>	AP	+	LEDERLE	5MG/ML	N05897 008		MAR	CAHN
>A>	AP	+	WYETH PHARMS INC	5MG/ML	N05897 008		MAR	CAHN
		TABLET; ORAL						
>D>		@	LEDERLE	1MG	N05897 004		MAR	CAHN
>A>		@	WYETH PHARMS INC	1MG	N05897 004		MAR	CAHN
		GATIFLOXACIN						
>A>		SOLUTION/DROPS; OPHTHALMIC						
>A>		ZYMAR						
>A>		+	ALLERGAN	0.3%	N21493 001	MAR 28, 2003	MAR	NEWA
		GEMTUZUMAB OZOGAMICIN						
		INJECTABLE; INJECTION						
		MYLOTARG						
>D>		+	WYETH AYERST	5MG/VIAL	N21174 001	MAY 17, 2000	MAR	CAHN
>A>		+	WYETH PHARMS INC	5MG/VIAL	N21174 001	MAY 17, 2000	MAR	CAHN
		GENTAMICIN SULFATE						
		CREAM; TOPICAL						
		GARAMYCIN						
		@	SCHERING	EQ 0.1% BASE	N60462 001		FEB	DISC
		GENTAMICIN SULFATE						
	AT	+	FOUGERA	EQ 0.1% BASE	N62531 001	JUL 05, 1984	FEB	CRLD
		GLIMEPIRIDE						
		TABLET; ORAL						
		AMARYL						
		+	AVENTIS PHARMS	1MG	N20496 001	NOV 30, 1995	JAN	CRLD
				4MG	N20496 003	NOV 30, 1995	JAN	CRLD
		HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE						
		TABLET; ORAL						
		INDERIDE-40/25						
>D>	AB		WYETH AYERST	25MG;40MG	N18031 001		MAR	CAHN
>A>	AB		WYETH PHARMS INC	25MG;40MG	N18031 001		MAR	CAHN

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERIDE-80/25

>D>	AB	+	WYETH AYERST	25MG;80MG	N18031 002			MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	25MG;80MG	N18031 002			MAR	CAHN

HYDROCORTISONE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE

SOLUTION/DROPS; OTIC

NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE

AT			ALCON	1%;EQ 3.5MG BASE/ML;10,000 UNITS/ML	N62423 001	AUG 25, 1983	FEB	CMFD

SUSPENSION/DROPS; OPHTHALMIC

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

SUSPENSION/DROPS; OTIC

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

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

ATARAX

			@ PFIZER	10MG	N10392 001		FEB	DISC
			@	25MG	N10392 004		FEB	DISC
			@	50MG	N10392 006		FEB	DISC
			@	100MG	N10392 005		FEB	DISC

HYDROXYZINE HCL

AB	+		SIDMAK LABS NJ	10MG	N88617 001	JAN 10, 1986	FEB	CRLD
AB	+			25MG	N88618 001	JAN 10, 1986	FEB	CRLD
AB	+			50MG	N88619 001	JAN 10, 1986	FEB	CRLD
			@	100MG	N81054 001	SEP 25, 1995	FEB	DISC

IPRATROPIUM BROMIDE

SPRAY, METERED; NASAL

ATROVENT

>D>		+	BOEHRINGER INGELHEIM	0.021MG/SPRAY	N20393 001	OCT 20, 1995	MAR	CFTG
>A>	AB	+		0.021MG/SPRAY	N20393 001	OCT 20, 1995	MAR	CFTG
>D>		+		0.042MG/SPRAY	N20394 001	OCT 20, 1995	MAR	CFTG
>A>	AB	+		0.042MG/SPRAY	N20394 001	OCT 20, 1995	MAR	CFTG

>A> IPRATROPIUM BROMIDE

>A>	AB		BAUSCH AND LOMB	0.021MG/SPRAY	N76025 001	MAR 31, 2003	MAR	NEWA
>A>	AB			0.042MG/SPRAY	N76103 001	MAR 31, 2003	MAR	NEWA
>A>	AB		DEY	0.021MG/SPRAY	N75552 001	MAR 31, 2003	MAR	NEWA
>A>	AB			0.042MG/SPRAY	N75553 001	MAR 31, 2003	MAR	NEWA

ISOSORBIDE DINITRATE

TABLET; ORAL

ISORDIL

>D>	AB		WYETH AYERST	5MG	N12093 007	JUL 29, 1988	MAR	CAHN
>D>	AB			10MG	N12093 002	JUL 29, 1988	MAR	CAHN
>D>	AB			20MG	N12093 006	JUL 29, 1988	MAR	CAHN
>D>	AB	+		30MG	N12093 005	JUL 29, 1988	MAR	CAHN
>D>	AB			40MG	N12093 001	JUL 29, 1988	MAR	CAHN
>A>	AB		WYETH PHARMS INC	5MG	N12093 007	JUL 29, 1988	MAR	CAHN
>A>	AB			10MG	N12093 002	JUL 29, 1988	MAR	CAHN

>A>	AB		20MG	N12093 006	JUL 29, 1988	MAR	CAHN
>A>	AB	+	30MG	N12093 005	JUL 29, 1988	MAR	CAHN
>A>	AB		40MG	N12093 001	JUL 29, 1988	MAR	CAHN
		TABLET; SUBLINGUAL					
>D>	AB	WYETH AYERST	2.5MG	N12940 004	JUL 29, 1988	MAR	CAHN
>D>	AB		5MG	N12940 003	JUL 29, 1988	MAR	CAHN
>D>		+	10MG	N12940 005	JUL 29, 1988	MAR	CAHN
>A>	AB	WYETH PHARMS INC	2.5MG	N12940 004	JUL 29, 1988	MAR	CAHN
>A>	AB		5MG	N12940 003	JUL 29, 1988	MAR	CAHN
>A>		+	10MG	N12940 005	JUL 29, 1988	MAR	CAHN
		KETOPROFEN					
		CAPSULE, EXTENDED RELEASE; ORAL					
		ORUVAIL					
>D>	AB	WYETH AYERST	100MG	N19816 003	FEB 08, 1995	MAR	CAHN
>D>	AB		150MG	N19816 002	FEB 08, 1995	MAR	CAHN
>D>	AB	+	200MG	N19816 001	SEP 24, 1993	MAR	CAHN
>A>	AB	WYETH PHARMS INC	100MG	N19816 003	FEB 08, 1995	MAR	CAHN
>A>	AB		150MG	N19816 002	FEB 08, 1995	MAR	CAHN
>A>	AB	+	200MG	N19816 001	SEP 24, 1993	MAR	CAHN
		LACTULOSE					
		SOLUTION; ORAL					
		LACTULOSE					
>D>	AA	LACHMAN CONSULT	10GM/15ML	N74138 001	SEP 30, 1992	MAR	CAHN
>A>	AA	VISTAPHARM	10GM/15ML	N74138 001	SEP 30, 1992	MAR	CAHN
		LEFLUNOMIDE					
		TABLET; ORAL					
		ARAVA					
>D>		AVENTIS PHARMS	20MG	N20905 002	SEP 10, 1998	MAR	CRLD
>A>		+	20MG	N20905 002	SEP 10, 1998	MAR	CRLD
>D>		+	100MG	N20905 003	SEP 10, 1998	MAR	DISC
>A>		@	100MG	N20905 003	SEP 10, 1998	MAR	DISC
		LEUPROLIDE ACETATE					
		INJECTABLE; SUBCUTANEOUS					
		ELIGARD					
		+ ATRIX	30MG/VIAL	N21488 001	FEB 13, 2003	FEB	NEWA
		LEVOBETAXOLOL HYDROCHLORIDE					
		SUSPENSION/DROPS; OPHTHALMIC					
		BETAXON					
>D>		+ ALCON	EQ 0.5% BASE	N21114 001	FEB 23, 2000	MAR	CAHN
>A>		+ MEDPOINTE	EQ 0.5% BASE	N21114 001	FEB 23, 2000	MAR	CAHN
		LEVONORGESTREL					
		IMPLANT; IMPLANTATION					
		LEVONORGESTREL					
>D>	BX	+ WYETH AYERST	75MG/IMPLANT	N20627 001	AUG 15, 1996	MAR	CAHN
>A>	BX	+ WYETH PHARMS INC	75MG/IMPLANT	N20627 001	AUG 15, 1996	MAR	CAHN
		NORPLANT SYSTEM IN PLASTIC CONTAINER					
>D>		+ WYETH AYERST	36MG/IMPLANT	N20088 001	DEC 10, 1990	MAR	CAHN

>A>		+ WYETH PHARMS INC	36MG/IMPLANT	N20088 001	DEC 10, 1990	MAR	CAHN

LEVORPHANOL TARTRATE
TABLET; ORAL

		LEVO-DROMORAN					
		@ ICN	2MG	N08720 001	DEC 19, 1991	FEB	DISC
		LEVORPHANOL TARTRATE					
		+ ROXANE	2MG	N74278 001	MAR 31, 2000	FEB	CRLD

LIDOCAINE HYDROCHLORIDE
JELLY; TOPICAL

		LIDOCAINE HCL					
AT		AKORN	2%	N40433 001	FEB 12, 2003	FEB	NEWA

LISINOPRIL
TABLET; ORAL

		LISINOPRIL					
AB		RANBAXY	30MG	N75944 006	FEB 11, 2003	FEB	NEWA

LITHIUM CARBONATE
CAPSULE; ORAL

		LITHIUM CARBONATE					
AB		ROXANE	150MG	N17812 002	JAN 28, 1987	FEB	CTEC
AB		WEST WARD	150MG	N76243 002	FEB 24, 2003	FEB	NEWA

LORAZEPAM
INJECTABLE; INJECTION

		ATIVAN					
AP	+	BAXTER HLTHCARE CORP	2MG/ML	N18140 001		FEB	CAHN
AP	+		4MG/ML	N18140 002		FEB	CAHN

MEPHENTERMINE SULFATE
INJECTABLE; INJECTION

		WYAMINE SULFATE					
		@ BAXTER HLTHCARE CORP	EQ 15MG BASE/ML	N08248 002		FEB	CAHN
		@	EQ 30MG BASE/ML	N08248 001		FEB	CAHN

METFORMIN HYDROCHLORIDE
TABLET; ORAL

		METFORMIN HCL					
AB		PUREPAC PHARM	1GM	N76033 003	JAN 24, 2002	FEB	CMS1

METHADONE HYDROCHLORIDE
INJECTABLE; INJECTION

		DOLOPHINE HCL					
		+ ROXANE	10MG/ML	N21624 001		FEB	CMS1

METHOCARBAMOL
TABLET; ORAL

		METHOCARBAMOL					
>A>	AA	ABLE	500MG	N40413 001	MAR 17, 2003	MAR	NEWA
>A>	AA		750MG	N40413 002	MAR 17, 2003	MAR	NEWA
>A>	AA	LANNETT	500MG	N84756 002	MAR 31, 2003	MAR	NEWA

	AA		VINTAGE PHARMS	500MG	N40489 001	JAN 29, 2003	JAN	NEWA
	AA			750MG	N40489 002	JAN 29, 2003	JAN	NEWA
		METHOTREXATE SODIUM						
		INJECTABLE; INJECTION						
		METHOTREXATE LPF						
>D>	AP	+	LEDERLE	EQ 25MG BASE/ML	N11719 007	MAR 31, 1982	MAR	CAHN
>A>	AP	+	WYETH PHARMS INC	EQ 25MG BASE/ML	N11719 007	MAR 31, 1982	MAR	CAHN
		METHOTREXATE SODIUM						
>D>		@	LEDERLE	EQ 2.5MG BASE/ML	N11719 004		MAR	CAHN
>D>		+		EQ 20MG BASE/VIAL	N11719 001		MAR	CAHN
>D>	AP	+		EQ 25MG BASE/ML	N11719 005		MAR	CAHN
>D>		@		EQ 50MG BASE/VIAL	N11719 003		MAR	CAHN
>D>		@		EQ 100MG BASE/VIAL	N11719 006		MAR	CAHN
>A>		@	WYETH PHARMS INC	EQ 2.5MG BASE/ML	N11719 004		MAR	CAHN
>A>		+		EQ 20MG BASE/VIAL	N11719 001		MAR	CAHN
>A>	AP	+		EQ 25MG BASE/ML	N11719 005		MAR	CAHN
>A>		@		EQ 50MG BASE/VIAL	N11719 003		MAR	CAHN
>A>		@		EQ 100MG BASE/VIAL	N11719 006		MAR	CAHN
		METHOTREXATE SODIUM PRESERVATIVE FREE						
>D>	AP	+	LEDERLE	EQ 1GM BASE/VIAL	N11719 009	APR 07, 1988	MAR	CAHN
>A>	AP	+	WYETH PHARMS INC	EQ 1GM BASE/VIAL	N11719 009	APR 07, 1988	MAR	CAHN
		METHSCOPOLAMINE BROMIDE						
		TABLET; ORAL						
		PAMINE FORTE						
>A>		+	BRADLEY PHARMS	5MG	N08848 002	MAR 25, 2003	MAR	NEWA
		MINOCYCLINE HYDROCHLORIDE						
		CAPSULE; ORAL						
		MINOCIN						
>D>	AB		LEDERLE	EQ 50MG BASE	N50649 001	MAY 31, 1990	MAR	CAHN
>D>	AB			EQ 75MG BASE	N50649 003	FEB 12, 2001	MAR	CAHN
>D>	AB	+		EQ 100MG BASE	N50649 002	MAY 31, 1990	MAR	CAHN
>A>	AB		WYETH PHARMS INC	EQ 50MG BASE	N50649 001	MAY 31, 1990	MAR	CAHN
>A>	AB			EQ 75MG BASE	N50649 003	FEB 12, 2001	MAR	CAHN
>A>	AB	+		EQ 100MG BASE	N50649 002	MAY 31, 1990	MAR	CAHN
		INJECTABLE; INJECTION						
>D>		+	LEDERLE	EQ 100MG BASE/VIAL	N50444 001		MAR	CAHN
>A>		+	WYETH PHARMS INC	EQ 100MG BASE/VIAL	N50444 001		MAR	CAHN
		MIRTAZAPINE						
		TABLET; ORAL						
		MIRTAZAPINE						
	AB		TEVA	15MG	N76119 001	JAN 24, 2003	JAN	NEWA
	AB			30MG	N76119 002	JAN 24, 2003	JAN	NEWA
		REMERON						
	AB	+	ORGANON	15MG	N20415 001	JUN 14, 1996	JAN	CFTG
	AB			30MG	N20415 002	JUN 14, 1996	JAN	CFTG

MUPIROCIN
OINTMENT; TOPICAL
MUPIROCIN

BX	CLAY PARK LABS	2%	N50788 001	DEC 04, 2002	JAN	CRLD

MYCOPHENOLATE MOFETIL
CAPSULE; ORAL
CELLCEPT

+	ROCHE PALO	250MG	N50722 001	MAY 03, 1995	FEB	CAHN

SUSPENSION; ORAL

+	ROCHE PALO	200MG/ML	N50759 001	OCT 01, 1998	FEB	CAHN

TABLET; ORAL

+	ROCHE PALO	500MG	N50723 001	JUN 19, 1997	FEB	CAHN

MYCOPHENOLATE MOFETIL HYDROCHLORIDE
INJECTABLE; INJECTION

+	ROCHE PALO	500MG/VIAL	N50758 001	AUG 12, 1998	FEB	CAHN

NABUMETONE
TABLET; ORAL
NABUMETONE

AB	IVAX PHARMS	500MG	N76009 001	JAN 24, 2003	JAN	NEWA
AB		750MG	N76009 002	JAN 24, 2003	JAN	NEWA

NAPROXEN SODIUM
TABLET, EXTENDED RELEASE; ORAL
NAPRELAN

>D>		+	ELAN PHARM	EQ 500MG BASE	N20353 002	JAN 05, 1996	MAR	CFTG
>A>	AB	+		EQ 500MG BASE	N20353 002	JAN 05, 1996	MAR	CFTG
>A>			NAPROXEN SODIUM					
>A>	AB		ANDRX PHARMS	EQ 500MG BASE	N75416 001	AUG 27, 2002	MAR	NEWA

NITROFURAZONE
OINTMENT; TOPICAL
>D> FURACIN

>D>	+	SHIRE PHARM	0.2%	N05795 001		MAR	DISC
>A>		@	0.2%	N05795 001		MAR	DISC

NIZATIDINE
CAPSULE; ORAL
NIZATIDINE

AB	TORPHARM	150MG	N76383 001	JAN 23, 2003	JAN	NEWA
AB		300MG	N76383 002	JAN 23, 2003	JAN	NEWA

NOREPINEPHRINE BITARTRATE
INJECTABLE; INJECTION
LEVOPHED

>D>		+	ABBOTT	EQ 1MG BASE/ML	N07513 001		MAR	CFTG
>A>	AP	+		EQ 1MG BASE/ML	N07513 001		MAR	CFTG
>A>			NOREPINEPHRINE BITARTRATE					
>A>	AP		GENSIA SICOR PHARMS	EQ 1MG BASE/ML	N40455 001	MAR 03, 2003	MAR	NEWA

NORETHINDRONE ACETATE
TABLET; ORAL
AYGESTIN

>D>	AB	+	WYETH AYERST	5MG	N18405 001	APR 21, 1982	MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	5MG	N18405 001	APR 21, 1982	MAR	CAHN

NORGESTREL
TABLET; ORAL
OVRETTE

>D>		+	WYETH AYERST	0.075MG	N17031 001		MAR	CAHN
>A>		+	WYETH PHARMS INC	0.075MG	N17031 001		MAR	CAHN

OMEPRAZOLE
CAPSULE, DELAYED REL PELLETS; ORAL
OMEPRAZOLE

	AB		LEK SVCS	10MG	N75757 001	JAN 28, 2003	JAN	NEWA
	AB			20MG	N75757 002	JAN 28, 2003	JAN	NEWA

ORPHENADRINE CITRATE
INJECTABLE; INJECTION
ORPHENADRINE CITRATE

>A>	AP		BEDFORD LABS	30MG/ML	N40463 001	MAR 04, 2003	MAR	NEWA

OXYBUTYNIN
FILM, EXTENDED RELEASE; TRANSDERMAL
OXYTROL

		+	WATSON LABS (UTAH)	3.9MG/24HR	N21351 002	FEB 26, 2003	FEB	NEWA

PANTOPRAZOLE SODIUM
INJECTABLE; IV (INFUSION)
PROTONIX IV

>D>		+	WYETH AYERST	EQ 40MG BASE/VIAL	N20988 001	MAR 22, 2001	MAR	CAHN
>A>		+	WYETH PHARMS INC	EQ 40MG BASE/VIAL	N20988 001	MAR 22, 2001	MAR	CAHN

TABLET, DELAYED RELEASE; ORAL
PROTONIX

>D>		+	WYETH AYERST	EQ 20MG BASE	N20987 002	JUN 12, 2001	MAR	CAHN
>D>		+		EQ 40MG BASE	N20987 001	FEB 02, 2000	MAR	CAHN
>A>		+	WYETH PHARMS INC	EQ 20MG BASE	N20987 002	JUN 12, 2001	MAR	CAHN
>A>		+		EQ 40MG BASE	N20987 001	FEB 02, 2000	MAR	CAHN

>A> PEGVISOMANT
>A> INJECTABLE; SUBCUTANEOUS
>A> SOMAVERT

>A>		+	PHARMACIA AND UPJOHN	10MG/VIAL	N21106 001	MAR 25, 2003	MAR	NEWA
>A>		+		15MG/VIAL	N21106 002	MAR 25, 2003	MAR	NEWA
>A>		+		20MG/VIAL	N21106 003	MAR 25, 2003	MAR	NEWA

PERPHENAZINE
TABLET; ORAL
PERPHENAZINE

	AB	+	IVAX PHARMS	16MG	N89457 001	SEP 10, 1987	FEB	CRLD

		PERPHENAZINE						
		TABLET; ORAL						
		TRILAFON						
		@ SCHERING	2MG	N10775 001			FEB	DISC
		@	4MG	N10775 002			FEB	DISC
		@	8MG	N10775 003			FEB	DISC
		@	16MG	N10775 004			FEB	DISC
		PHENTERMINE HYDROCHLORIDE						
		CAPSULE; ORAL						
		PHENTERMINE HCL						
>A>	AA	ABLE	15MG	N40497 001	MAR 13, 2003		MAR	NEWA
	AA	AMIDE PHARM	15MG	N40460 001	JAN 14, 2003		JAN	NEWA
	AA		30MG	N40448 001	JAN 22, 2003		JAN	NEWA
		PHENYTOIN						
		SUSPENSION; ORAL						
		PHENYTOIN						
>D>	AB	UDL	125MG/5ML	N40342 001	JAN 31, 2001		MAR	CAHN
>A>	AB	VISTAPHARM	125MG/5ML	N40342 001	JAN 31, 2001		MAR	CAHN
		PHENYTOIN SODIUM						
		INJECTABLE; INJECTION						
>D>		DILANTIN						
>D>	AP +	PARKE DAVIS	50MG/ML	N10151 001			MAR	DISC
>A>		@	50MG/ML	N10151 001			MAR	DISC
		PHENYTOIN						
>D>	AP	ELKINS SINN	50MG/ML	N84307 001			MAR	CRLD
>A>	+		50MG/ML	N84307 001			MAR	CRLD
>D>		PHENYTOIN SODIUM						
>D>	AP	ABBOTT	50MG/ML	N89521 001	MAR 17, 1987		MAR	DISC
>A>		@	50MG/ML	N89521 001	MAR 17, 1987		MAR	DISC
>D>	AP		50MG/ML	N89744 001	DEC 18, 1987		MAR	DISC
>A>		@	50MG/ML	N89744 001	DEC 18, 1987		MAR	DISC
		PHENYTOIN SODIUM, EXTENDED						
		CAPSULE; ORAL						
		DILANTIN						
		PARKE DAVIS	30MG	N84349 001			FEB	CRLD
		PIPERACILLIN SODIUM						
		INJECTABLE; INJECTION						
		PIPRACIL						
>D>	+	LEDERLE	EQ 2GM BASE/VIAL	N50545 002			MAR	CAHN
>D>			EQ 2GM BASE/VIAL	N62750 001	OCT 13, 1987		MAR	CAHN
>D>	+		EQ 3GM BASE/VIAL	N50545 003			MAR	CAHN
>D>			EQ 3GM BASE/VIAL	N62750 002	OCT 13, 1987		MAR	CAHN
>D>	+		EQ 4GM BASE/VIAL	N50545 004			MAR	CAHN
>D>			EQ 4GM BASE/VIAL	N62750 003	OCT 13, 1987		MAR	CAHN
>D>	@		EQ 40GM BASE/VIAL	N50545 006	SEP 30, 1985		MAR	CAHN
>A>	+	WYETH PHARMS INC	EQ 2GM BASE/VIAL	N50545 002			MAR	CAHN

>A>			EQ 2GM BASE/VIAL	N62750 001	OCT 13, 1987	MAR	CAHN
>A>	+		EQ 3GM BASE/VIAL	N50545 003		MAR	CAHN
>A>			EQ 3GM BASE/VIAL	N62750 002	OCT 13, 1987	MAR	CAHN
>A>	+		EQ 4GM BASE/VIAL	N50545 004		MAR	CAHN
>A>			EQ 4GM BASE/VIAL	N62750 003	OCT 13, 1987	MAR	CAHN
>A>		@	EQ 40GM BASE/VIAL	N50545 006	SEP 30, 1985	MAR	CAHN
	PIPERACILLIN SODIUM; TAZOBACTAM SODIUM						
	INJECTABLE; INJECTION						
	ZOSYN						
>D>	+	WYETH AYERST	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	N50684 001	OCT 22, 1993	MAR	CAHN
>D>	+		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	N50684 002	OCT 22, 1993	MAR	CAHN
>D>	+		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	N50684 003	OCT 22, 1993	MAR	CAHN
>D>	+		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	N50684 004	OCT 22, 1993	MAR	CAHN
>A>	+	WYETH PHARMS INC	EQ 2GM BASE/VIAL;EQ 250MG BASE/VIAL	N50684 001	OCT 22, 1993	MAR	CAHN
>A>	+		EQ 3GM BASE/VIAL;EQ 375MG BASE/VIAL	N50684 002	OCT 22, 1993	MAR	CAHN
>A>	+		EQ 4GM BASE/VIAL;EQ 500MG BASE/VIAL	N50684 003	OCT 22, 1993	MAR	CAHN
>A>	+		EQ 36GM BASE/VIAL;EQ 4.5GM BASE/VIAL	N50684 004	OCT 22, 1993	MAR	CAHN
	ZOSYN IN PLASTIC CONTAINER						
>D>	+	LEDERLE	EQ 4GM BASE/100ML;EQ 500MG BASE/100ML	N50750 003	FEB 24, 1998	MAR	CAHN
>D>	+		EQ 40MG BASE/ML;EQ 5MG BASE/ML	N50750 001	FEB 24, 1998	MAR	CAHN
>D>	+		EQ 60MG BASE/ML;EQ 7.5MG BASE/ML	N50750 002	FEB 24, 1998	MAR	CAHN
>A>	+	WYETH PHARMS INC	EQ 40MG BASE/ML;EQ 5MG BASE/ML	N50750 001	FEB 24, 1998	MAR	CAHN
>A>	+		EQ 60MG BASE/ML;EQ 7.5MG BASE/ML	N50750 002	FEB 24, 1998	MAR	CAHN
>A>	+		EQ 4GM BASE/100ML;EQ 500MG BASE/100ML	N50750 003	FEB 24, 1998	MAR	CAHN
	PRALIDOXIME CHLORIDE						
	INJECTABLE; INJECTION						
	PRALIDOXIME CHLORIDE						
>A>		@ BAXTER HLTHCARE CORP	300MG/ML	N18799 001	DEC 13, 1982	MAR	CAHN
>D>		@ WYETH AYERST	300MG/ML	N18799 001	DEC 13, 1982	MAR	CAHN
	PREDNISOLONE						
	SYRUP; ORAL						
	PREDNISOLONE						
	AA	HI TECH PHARMA	15MG/5ML	N40401 001	FEB 27, 2003	FEB	NEWA
>A>	AA	PHARM ASSOC	15MG/5ML	N40399 001	MAR 05, 2003	MAR	NEWA
	PREDNISOLONE SODIUM PHOSPHATE						
	SOLUTION; ORAL						
	PREDNISOLONE SODIUM PHOSPHATE						
>A>	AA	HI TECH PHARMA	EQ 5MG BASE/5ML	N75183 001	MAR 26, 2003	MAR	NEWA
	PREDNISONE						
	TABLET; ORAL						
	PREDNISONE						
	AB	VINTAGE PHARMS	20MG	N40392 001	FEB 12, 2003	FEB	NEWA

PROMETHAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

PROMETHAZINE HCL

>A>	AP		PHARMAFORCE	25MG/ML	N40515 001	MAR 19, 2003	MAR	NEWA

SUPPOSITORY; RECTAL

PHENERGAN

>D>			WYETH AYERST	12.5MG	N10926 002		MAR	CAHN
>D>	AB	+		25MG	N10926 001		MAR	CAHN
>D>	AB	+		50MG	N11689 001		MAR	CAHN
	AB	+		50MG	N11689 001		FEB	CTEC
>A>	AB		WYETH PHARMS INC	12.5MG	N10926 002		MAR	CAHN
>A>	AB	+		25MG	N10926 001		MAR	CAHN
>A>	AB	+		50MG	N11689 001		MAR	CAHN

PROMETHAZINE HCL

>A>								
	AB		ABLE	50MG	N40449 001	FEB 27, 2003	FEB	NEWA
>A>	AB		G AND W LABS	12.5MG	N40428 002	MAR 31, 2003	MAR	NEWA

TABLET; ORAL

PHENERGAN

>D>			WYETH AYERST	12.5MG	N07935 002		MAR	CAHN
>D>	BP			25MG	N07935 003		MAR	CAHN
>D>	BP	+		50MG	N07935 004		MAR	CAHN
>A>			WYETH PHARMS INC	12.5MG	N07935 002		MAR	CAHN
>A>	BP			25MG	N07935 003		MAR	CAHN
>A>	BP	+		50MG	N07935 004		MAR	CAHN

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

INDERAL LA

>D>			WYETH AYERST	60MG	N18553 004	MAR 18, 1987	MAR	CAHN
>D>				80MG	N18553 002	APR 19, 1983	MAR	CTEC
>D>				120MG	N18553 003	APR 19, 1983	MAR	CTEC
>D>		+		160MG	N18553 001	APR 19, 1983	MAR	CAHN
>A>			WYETH PHARMS INC	60MG	N18553 004	MAR 18, 1987	MAR	CAHN
>A>	BX			80MG	N18553 002	APR 19, 1983	MAR	CTEC
>A>	BX			120MG	N18553 003	APR 19, 1983	MAR	CTEC
>A>		+		160MG	N18553 001	APR 19, 1983	MAR	CAHN

INNOPRAN XL

>A>								
>A>	BX		RELIANT PHARMS	80MG	N21438 001	MAR 12, 2003	MAR	NEWA
>A>	BX			120MG	N21438 002	MAR 12, 2003	MAR	NEWA

INJECTABLE; INJECTION

PROPRANOLOL HCL

	AP		SABEX 2002	1MG/ML	N76400 001	FEB 26, 2003	FEB	NEWA

TABLET; ORAL

INDERAL

>D>	AB	+	WYETH AYERST	10MG	N16418 001		MAR	CAHN
>D>	AB			20MG	N16418 003		MAR	CAHN
>D>	AB			40MG	N16418 002		MAR	CAHN
>D>	AB			60MG	N16418 009	OCT 18, 1982	MAR	CAHN
>D>	AB	+		80MG	N16418 004		MAR	CAHN
>D>		@		90MG	N16418 010	OCT 18, 1982	MAR	CAHN
>A>	AB	+	WYETH PHARMS INC	10MG	N16418 001		MAR	CAHN
>A>	AB			20MG	N16418 003		MAR	CAHN

>A>	AB		40MG	N16418 002			MAR	CAHN
>A>	AB		60MG	N16418 009	OCT 18, 1982		MAR	CAHN
>A>	AB	+	80MG	N16418 004			MAR	CAHN
>A>		@	90MG	N16418 010	OCT 18, 1982		MAR	CAHN

PYRIDOSTIGMINE BROMIDE
TABLET; ORAL
PYRIDOSTIGMINE BROMIDE

		@ US ARMY	30MG	N20414 001	FEB 05, 2003		FEB	NEWA

QUETIAPINE FUMARATE
TABLET; ORAL
SEROQUEL

>D>		ASTRAZENECA	EQ 25MG BASE	N20639 001	SEP 26, 1997		MAR	CRLD
>A>		+	EQ 25MG BASE	N20639 001	SEP 26, 1997		MAR	CRLD

QUINIDINE GLUCONATE
TABLET, EXTENDED RELEASE; ORAL

>D>		QUINAGLUTE						
>D>	BX	+ BERLEX LABS	324MG	N16647 001			MAR	DISC
>A>		@	324MG	N16647 001			MAR	DISC
		QUINIDINE GLUCONATE						
>D>	BX	WATSON LABS	324MG	N87810 001	SEP 29, 1982		MAR	CRLD
>A>		+	324MG	N87810 001	SEP 29, 1982		MAR	CRLD

QUINIDINE SULFATE
TABLET, EXTENDED RELEASE; ORAL
QUINIDEX

>D>	AB	+ ROBINS AH	300MG	N12796 002			MAR	CAHN
>A>	AB	+ WYETH PHARMS INC	300MG	N12796 002			MAR	CAHN

RILUZOLE
TABLET; ORAL
RILUTEK

	AB	+ AVENTIS	50MG	N20599 001	DEC 12, 1995		JAN	CFTG
		RILUZOLE						
	AB	IMPAX LABS	50MG	N76173 001	JAN 29, 2003		JAN	NEWA

RIMANTADINE HYDROCHLORIDE
TABLET; ORAL
RIMANTADINE HCL

	AB	AMIDE PHARM	100MG	N76375 001	JAN 14, 2003		JAN	NEWA

SIROLIMUS
SOLUTION; ORAL
RAPAMUNE

>D>		+ WYETH AYERST	1MG/ML	N21083 001	SEP 15, 1999		MAR	CAHN
>A>		+ WYETH PHARMS INC	1MG/ML	N21083 001	SEP 15, 1999		MAR	CAHN
		TABLET; ORAL						
>D>		+ WYETH AYERST	1MG	N21110 001	AUG 25, 2000		MAR	CRLD
>A>		WYETH PHARMS INC	1MG	N21110 001	AUG 25, 2000		MAR	CRLD
>A>		+	2MG	N21110 002	AUG 22, 2002		MAR	NEWA

SODIUM IODIDE, I-131
CAPSULE; ORAL
SODIUM IODIDE I 131

	+	DRAXIMAGE	1-250mCi	N21305	002	JAN 24, 2003	JAN	NEWA
	+		1-500mCi	N21305	003	JAN 24, 2003	JAN	NEWA

SOLUTION; ORAL
SODIUM IODIDE I 131, KIT

	+	DRAXIMAGE	1-250mCi/0.25ML	N21305	002	JAN 24, 2003	FEB	CDFR
	+		1-500mCi/0.5ML	N21305	003	JAN 24, 2003	FEB	CDFR

SOMATROPIN RECOMBINANT
INJECTABLE; INJECTION
BIO-TROPIN

>D>		+ BIO TECH GEN	4.8MG/VIAL	N19774	001	MAY 25, 1995	MAR	DISC
>A>		@	4.8MG/VIAL	N19774	001	MAY 25, 1995	MAR	DISC

TEV-TROPIN

	BX +	BIO TECH GEN	5MG/ML	N19774	002	JAN 04, 2002	FEB	CTNA

SOTALOL HYDROCHLORIDE
TABLET; ORAL
BETAPACE AF

>A>		BERLEX LABS	100MG	N21151	005	MAR 14, 2003	MAR	NEWA

STRONTIUM CHLORIDE, SR-89
INJECTABLE; INJECTION
METASTRON

	AP +	AMERSHAM HLTH	1mCi/ML	N20134	001	JUN 18, 1993	JAN	CFTG

STRONTIUM CHLORIDE SR-89

	AP	BIO NUCLEONICS	1mCi/ML	N75941	001	JAN 06, 2003	JAN	NEWA

TAMOXIFEN CITRATE
TABLET; ORAL
NOLVADEX

	AB	ASTRAZENECA	EQ 10MG BASE	N17970	001		FEB	CTEC
	AB +		EQ 20MG BASE	N17970	002	MAR 21, 1994	FEB	CTEC

TAMOXIFEN CITRATE

>A>	AB	AEGIS PHARMS	EQ 10MG BASE	N76398	001	MAR 31, 2003	MAR	NEWA
>A>	AB		EQ 20MG BASE	N76398	002	MAR 31, 2003	MAR	NEWA
	AB	ANDRX PHARMS	EQ 10MG BASE	N76179	001	FEB 20, 2003	FEB	NEWA
	AB		EQ 20MG BASE	N76179	002	FEB 20, 2003	FEB	NEWA
	AB	BARR	EQ 10MG BASE	N70929	001	FEB 20, 2003	FEB	NEWA
	AB		EQ 20MG BASE	N70929	002	FEB 20, 2003	FEB	NEWA
	AB	IVAX PHARMS	EQ 10MG BASE	N75740	001	FEB 20, 2003	FEB	NEWA
	AB		EQ 20MG BASE	N75740	002	FEB 20, 2003	FEB	NEWA
	AB	MYLAN	EQ 10MG BASE	N74732	002	FEB 20, 2003	FEB	NEWA
	AB		EQ 20MG BASE	N74732	001	FEB 20, 2003	FEB	NEWA
	AB	PHARMACHEMIE	EQ 20MG BASE	N74858	001	FEB 20, 2003	FEB	NEWA
	AB	ROXANE	EQ 10MG BASE	N76027	001	FEB 20, 2003	FEB	NEWA
	AB		EQ 20MG BASE	N76027	002	FEB 20, 2003	FEB	NEWA
>A>	AB	TEVA	EQ 10MG BASE	N74539	001	MAR 31, 2003	MAR	NEWA
	AB		EQ 10MG BASE	N75797	001	FEB 20, 2003	FEB	NEWA

TECHNETIUM TC-99M MEDRONATE KIT
INJECTABLE; INJECTION
TECHNESCAN MDP KIT

>D>	AP		DRAXIMAGE	N/A	N18035 001		MAR	CRLD
>A>	AP	+		N/A	N18035 001		MAR	CRLD

THALIDOMIDE
CAPSULE; ORAL
THALOMID

			CELGENE	100MG	N20785 002	JAN 17, 2003	JAN	NEWA
		+		200MG	N20785 003	JAN 17, 2003	JAN	NEWA

THIOTHIXENE
CAPSULE; ORAL
NAVANE

	AB		PFIZER	1MG	N16584 001		FEB	CAHN
	AB			2MG	N16584 002		FEB	CAHN
	AB	+		5MG	N16584 003		FEB	CAHN
	AB			10MG	N16584 004		FEB	CAHN
				20MG	N16584 005		FEB	CAHN

THIOTHIXENE HYDROCHLORIDE
CONCENTRATE; ORAL

	AA	+	PFIZER	EQ 5MG BASE/ML	N16758 001		FEB	CAHN

INJECTABLE; INJECTION

		@	PFIZER	EQ 2MG BASE/ML	N16904 001		FEB	CAHN
		+		EQ 10MG BASE/VIAL	N16904 002		FEB	CAHN

TIZANIDINE HYDROCHLORIDE
TABLET; ORAL
TIZANIDINE HCL

>A>	AB		MYLAN	EQ 2MG BASE	N76354 001	MAR 28, 2003	MAR	NEWA
>A>	AB			EQ 4MG BASE	N76354 002	MAR 28, 2003	MAR	NEWA

TRAMADOL HYDROCHLORIDE
TABLET; ORAL
TRAMADOL HCL

>D>	AB		ABLE	50MG	N75963 001	JUL 03, 2002	MAR	CAHN
>A>	AB		IVAX PHARMS	50MG	N75963 001	JUL 03, 2002	MAR	CAHN

UREA, C-13
FOR SOLUTION; ORAL
PYLORI-CHEK BREATH TEST

>D>			@ ALIMENTERICS	100MG/VIAL	N20900 001	FEB 04, 1999	MAR	CAHN
>A>			@ DEVICES	100MG/VIAL	N20900 001	FEB 04, 1999	MAR	CAHN

VENLAFAXINE HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE; ORAL
EFFEXOR XR

>D>			WYETH AYERST	EQ 37.5MG BASE	N20699 001	OCT 20, 1997	MAR	CAHN
>D>		+		EQ 75MG BASE	N20699 002	OCT 20, 1997	MAR	CRLD
>D>		@		EQ 100MG BASE	N20699 003	OCT 20, 1997	MAR	CAHN

>D>		EQ 150MG BASE	N20699 004	OCT 20, 1997	MAR	CRLD
>A>	WYETH PHARMS INC	EQ 37.5MG BASE	N20699 001	OCT 20, 1997	MAR	CAHN
>A>		EQ 75MG BASE	N20699 002	OCT 20, 1997	MAR	CRLD
>A>	@	EQ 100MG BASE	N20699 003	OCT 20, 1997	MAR	CAHN
>A>	+	EQ 150MG BASE	N20699 004	OCT 20, 1997	MAR	CRLD
	TABLET; ORAL					
	EFFEXOR					
>D>	@ WYETH AYERST	EQ 12.5MG BASE	N20151 001	DEC 28, 1993	MAR	CAHN
>D>	+	EQ 25MG BASE	N20151 002	DEC 28, 1993	MAR	CRLD
>D>		EQ 37.5MG BASE	N20151 006	DEC 28, 1993	MAR	CAHN
>D>		EQ 50MG BASE	N20151 003	DEC 28, 1993	MAR	CAHN
>D>		EQ 75MG BASE	N20151 004	DEC 28, 1993	MAR	CAHN
>D>	+	EQ 100MG BASE	N20151 005	DEC 28, 1993	MAR	CAHN
>A>	@ WYETH PHARMS INC	EQ 12.5MG BASE	N20151 001	DEC 28, 1993	MAR	CAHN
>A>		EQ 25MG BASE	N20151 002	DEC 28, 1993	MAR	CRLD
>A>		EQ 37.5MG BASE	N20151 006	DEC 28, 1993	MAR	CAHN
>A>		EQ 50MG BASE	N20151 003	DEC 28, 1993	MAR	CAHN
>A>		EQ 75MG BASE	N20151 004	DEC 28, 1993	MAR	CAHN
>A>	+	EQ 100MG BASE	N20151 005	DEC 28, 1993	MAR	CAHN
	VINORELBINE TARTRATE					
	INJECTABLE; INJECTION					
	NAVELBINE					
AP	+ GLAXOSMITHKLINE	EQ 10MG BASE/ML	N20388 001	DEC 23, 1994	FEB	CFTG
	VINORELBINE TARTRATE					
AP	GENSIA SICOR PHARMS	EQ 10MG BASE/ML	N76028 001	FEB 03, 2003	FEB	NEWA
	ZOLEDRONIC ACID					
	INJECTABLE; IV (INFUSION)					
	ZOMETA					
>A>	+ NOVARTIS	EQ 4MG BASE/5ML	N21223 002	MAR 07, 2003	MAR	NEWA

ALUMINUM HYDROXIDE; MAGNESIUM TRISILICATE
TABLET, CHEWABLE; ORAL
FOAMICON

>D>	GENEVA PHARMS TECH	80MG;20MG	N72687 001	JUN 28, 1989	MAR	CAHN
>A>	NOVARTIS	80MG;20MG	N72687 001	JUN 28, 1989	MAR	CAHN

>D> CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE HYDROCHLORIDE
>D> CAPSULE, EXTENDED RELEASE; ORAL
>D> PSEUDOEPHEDRINE HCL AND CHLORPHENIRAMINE MALEATE

>D>	+ CENT PHARMS	8MG;120MG	N19428 001	AUG 02, 1988	MAR	DISC
>A>	@	8MG;120MG	N19428 001	AUG 02, 1988	MAR	DISC

CIMETIDINE
TABLET; ORAL
CIMETIDINE

>D>	LEK PHARM	100MG	N75122 001	JUN 19, 1998	MAR	CAHN
>D>		200MG	N75122 002	JUN 19, 1998	MAR	CAHN
>A>	@ LEK PHARMS	100MG	N75122 001	JUN 19, 1998	MAR	CAHN
>A>		200MG	N75122 002	JUN 19, 1998	MAR	CAHN

GUAIFENESIN
TABLET, EXTENDED RELEASE; ORAL
MUCINEX

	ADAMS LABS	600MG	N21282 001	JUL 12, 2002	JAN	CRLD
+		1.2GM	N21282 002	DEC 18, 2002	JAN	NEWA

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE
TABLET; ORAL
IMODIUM ADVANCED

+	MCNEIL CONS SPECLT	2MG;125MG	N21140 001	NOV 30, 2000	JAN	CRLD

LORATADINE
SYRUP; ORAL
CLARITIN

>A>	SCHERING	1MG/ML	N20641 002	NOV 27, 2002	MAR	NEWA

TABLET; ORAL

>A>	SCHERING	10MG	N19658 002	NOV 27, 2002	MAR	NEWA
	LORATADINE						
	GENEVA PHARMS	10MG	N75209 001	JAN 21, 2003	JAN	NEWA

TABLET, ORALLY DISINTEGRATING; ORAL
CLARITIN REDITABS

>A>	SCHERING	10MG	N20704 002	NOV 27, 2002	MAR	NEWA
	LORATADINE						
	WYETH CONS	10MG	N75822 001	FEB 10, 2003	FEB	NEWA

LORATADINE; PSEUDOEPHEDRINE SULFATE
TABLET, EXTENDED RELEASE; ORAL
CLARITIN-D

>A>	SCHERING	5MG;120MG	N19670 002	NOV 27, 2002	MAR	NEWA

CLARITIN-D 24 HOUR

>A>	SCHERING	10MG;240MG	N20470 002	NOV 27, 2002	MAR	NEWA

LORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

LORATADINE AND PSEUDOEPHEDRINE HCL

	ANDRX PHARMS	10MG;240MG	N75706	001	FEB 21, 2003	FEB	NEWA

LORATADINE AND PSEUDOEPHEDRINE SULFATE

	IMPAX LABS	5MG;120MG	N76050	001	JAN 30, 2003	JAN	NEWA

MINOXIDIL

SOLUTION; TOPICAL

MINOXIDIL EXTRA STRENGTH (FOR MEN)

	MORTON GROVE	5%	N75438	001	FEB 27, 2003	FEB	NEWA

PERMETHRIN

LOTION; TOPICAL

NIX

>A> +	INSIGHT PHARMS	1%	N19918	001	MAY 02, 1990	MAR	CAHN
>D> +	WARNER LAMBERT	1%	N19918	001	MAY 02, 1990	MAR	CAHN

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

CUMULATIVE SUPPLEMENT NUMBER 3 MARCH '03

NO MARCH 2003 APPROVALS

This data is provided to the Office of Generic Drugs from the Office of Orphan Products Development and it is not edited prior to publication.

Orphan Products Designations and Approvals List
March 2003

Generic Name/ Trade Name (if present):	Date Designated = DD Date Approved= MA	Indication Designated:	Sponsor and Address
(+/-)-7-[3-(4-acetyl-3-methoxy-2-propylphenoxy)propoxy]-3,4-dihydro-8-propyl-2H-1-benzopyran-2-carboxylic acid	DD: 3/31/2003 MA:	Prevention of serious adverse events associated with vascular leak syndrome caused by Interleukin-2 therapy	BioMedicines, Inc. 2000 Powell Street Suite 1640 Emeryville CA 94608
2',3',5'-tri-o-acetyluridine	DD: 1/13/2003 MA:	Treatment of mitochondrial disease	Repligen Corporation 41 Seyon Street Building 1, Suite 100 Waltham MA 02453
a-(3-aminophthalimido) *Actimid*	DD: 1/15/2003 MA: MA:	Treatment of multiple myeloma	Celgene Corporation 7 Powder Horn Drive Warren NJ 07059
a-Galactosidase A *Plant-Produced Human a-Glactosidase*	DD: 1/21/2003 MA:	Treatment of Fabry's disease	Large Scale Biology Corporation 3333 Vacaville Parkway Suite 1000 Vacaville CA 95688
alendronate *Fosamax*	DD: 3/31/2003 MA:	Treatment of osteogenesis imperfecta in pediatric patients 4 years of age and older	Merck & Co., Inc. 126 East Lincoln Ave. Rahway NJ 07065-0900
alteplase *Activase*	DD: 1/27/2003 MA:	Treatment of intraventricular hemmorage associated with intracerebral hemmorrhage	Daniel F. Hanley, MD Johns Hopkins University 600 N. Wolfe St., Jefferson 1-109 Baltimore MD 21287
AMG 531	DD: 3/27/2003 MA:	Treatment of immune thrombocytopenic purpura.	Amgen, Inc. One Amgen Center Drive Thousand Oaks CA 91320-1799
anti-CD23 IgG1, kappa monoclonal antibody	DD: 2/12/2003 MA:	Treatment of chronic lymphocytic leukemia	IDEC Pharmaceuticals, Inc. 3030 Callan Road San Diego CA 92121
bifidobacterium longum infantis 35624	DD: 1/16/2003 MA:	Treatment of pediatric Crohn's disease	Alimentary Health Limited Guardwell, Kinsale County Cork, Ireland

Orphan Products Designations and Approvals List
March 2003

dextran 1	DD: 3/21/2003 MA:	Treatment of cystic fibrosis	BCY LifeSciences Inc. 160 Eglinton Ave. East Suite 600 Toronto, Ontario M4P 3B5
Human Anti-tumor Necrosis factor alpha monoclonal antibody Parkway	DD: 1/16/2003 MA:	Treatment of uveitis of the posterior segment of non-infectious etiology, and uveitis of the anterior segment of non-infectious etiology and refractory to conventional therapy	Centocor, Inc. 200 Great Valley Malvern PA 19355-1307
INGN 201 Inc. *ADVEXIN*	DD: 1/27/2003 MA: MA:	Treatment of head and neck cancer	Introgen Therapeutics, 2250 Holcombe Blvd Houston TX 77030
Mafosfamide (formerly	DD: 1/21/2003 MA:	Treatment of neoplastic meningitis	Baxter Oncology GmbH ASTA Medica Oncology) Daimlerstrasse 40 60314 franfurt/Main Germany
MaxAdFVIII Corporation	DD: 3/3/2003 MA:	Treatment of Hemophilia A	GenStar Theraeutics 10865 Altman Row Suite 200 San Diego CA 92121- 1113
motexafin gadolinium *Xcytrin* 4521	DD: 1/27/2003 MA: MA:	For use in conjunction with whole brain radiation for the treatment of brain metastases arising from solid tumors	Pharmacyclics, Inc. 999 East Arques Avenue Sunnyvale CA 94085-
polyinosinic-polycytidilic acid NW *Poly-ICLC*	DD: 3/3/2003 MA: MA:	Treatment of flavivirus infections including those due to West Nile, Japanese encephalitis, dengue, St. Louis encephalitis, yellow fever, Murray valley, and Banzai viruses	Ribopharm, Inc. 3203 Cleveland Ave., Washington DC 20008- 3450

Orphan Products Designations and Approvals List
March 2003

recombinant adeno-associated virus alpha 1-antitrypsin vector *rAAV-AAT* Technologies Corp.	DD: 1/27/2003 MA: MA:	Treatment of alpha1-antitrypsin deficiency	Applied Genetic 12085 Research Drive Suite 110 Alachua FL 32615
recombinant inhibitor of human plasma kallikrein	DD: 2/4/2003 MA:	Treatment of angioedema	Dyax Corp 300 Technology Square Cambridge MA 02139
repertaxin	DD: 1/27/2003 MA:	Prevention of delayed graft function in solid organ transplant	Dompe s.p.a. Via Campo di Pile 67100 - L'Aquila Italy
Sodium pyruvate	DD: 3/31/2003 MA:	Treatment of cystic fibrosis	Cellular Sciences, Inc. 84 Park Avenue P. O. Box 968 Flemington NJ 08822
Tezacitabine	DD: 1/27/2003 MA:	Treatment of adenocarcinoma of the esophagus and stomach	Chiron Corporation 4560 Horton Street Emeryville CA 94608 -2916

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

NO MARCH 2003 ADDITIONS

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	020213 001	ACETYLCHOLINE CHLORIDE;MIOCHOL-E	6261546	APR 29, 2019	U-506		
>ADD>	020899 001	ALBUMIN HUMAN;OPTISON	5573751	APR 25, 2012			
>ADD>			5529766	JUN 25, 2013	U-505		
>ADD>			5558094	FEB 28, 2012	U-505		
	021434 001	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	021434 002	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	021434 003	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	021434 004	ALPRAZOLAM;XANAX XR				NDF	JAN 17, 2006
	020221 002	AMIFOSTINE;ETHYOL	5424471	JUL 31, 2012			
	020965 001	AMINOLEVULINIC ACID HYDROCHLORIDE;LEVULAN	5954703	OCT 31, 2017	U-289		
	021303 001	AMPHETAMINE ASPARTATE;ADDERALL XR 10	6322819	OCT 21, 2018			
	021303 006	AMPHETAMINE ASPARTATE;ADDERALL XR 15	6322819	OCT 21, 2018			
	021303 002	AMPHETAMINE ASPARTATE;ADDERALL XR 20	6322819	OCT 21, 2018			
	021303 004	AMPHETAMINE ASPARTATE;ADDERALL XR 25	6322819	OCT 21, 2018			
	021303 003	AMPHETAMINE ASPARTATE;ADDERALL XR 30	6322819	OCT 21, 2018			
	021303 005	AMPHETAMINE ASPARTATE;ADDERALL XR 5	6322819	OCT 21, 2018			
>ADD>	040422 005	AMPHETAMINE ASPARTATE;DEXTROAMP SACCHARATE				PC	SEP 15, 2003
>ADD>	040422 006	AMPHETAMINE ASPARTATE;DEXTROAMP SACCHARATE				PC	SEP 15, 2003
>ADD>	040422 007	AMPHETAMINE ASPARTATE;DEXTROAMP SACCHARATE				PC	SEP 15, 2003
>ADD>	021549 001	APREPITANT;EMEND				NCE	MAR 26, 2008
>ADD>	021549 002	APREPITANT;EMEND				NCE	MAR 26, 2008
	021436 001	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 002	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 003	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 004	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 005	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021436 006	ARIPIPRAZOLE;ABILIFY	4734416	MAR 29, 2005			
			5006528	OCT 20, 2009			
	021411 001	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494	NCE	NOV 26, 2007
			5658590*PED	JUL 11, 2015	U-494	PED	MAY 26, 2008
	021411 002	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494	NCE	NOV 26, 2007
			5658590*PED	JUL 11, 2015	U-494	PED	MAY 26, 2008
	021411 003	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494	NCE	NOV 26, 2007
			5658590*PED	JUL 11, 2015	U-494	PED	MAY 26, 2008
	021411 004	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494	NCE	NOV 26, 2007
			5658590*PED	JUL 11, 2015	U-494	PED	MAY 26, 2008
	021411 005	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494	NCE	NOV 26, 2007
			5658590*PED	JUL 11, 2015	U-494	PED	MAY 26, 2008
	021411 006	ATOMOXETINE HYDROCHLORIDE;STRATTERA	5658590	JAN 11, 2015	U-494	NCE	NOV 26, 2007
			5658590*PED	JUL 11, 2015	U-494	PED	MAY 26, 2008

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	075766 001	CALCITRIOL;CALCITRIOL				PC	SEP 17, 2003
>ADD>	075766 002	CALCITRIOL;CALCITRIOL				PC	SEP 17, 2003
>ADD>	075836 001	CALCITRIOL;CALCITRIOL				PC	SEP 17, 2003
>ADD>	075836 002	CALCITRIOL;CALCITRIOL				PC	SEP 17, 2003
	020637 001	CARMUSTINE;GLIADEL	4789724	AUG 01, 2006		I-382	FEB 25, 2006
			4757128	AUG 01, 2006			
	021150 001	CETIRIZINE HYDROCHLORIDE;ZYRTEC-D 12 HOUR	4525358	JUN 25, 2007	U-295		
			4525358*PED	DEC 25, 2007	U-295		
			6469009	JUL 13, 2019	U-295		
			6469009*PED	JAN 13, 2020	U-295		
			6489329	APR 08, 2016			
			6489329*PED	OCT 08, 2016			
	021473 001	CIPROFLOXACIN;CIPRO XR				NDF	DEC 13, 2005
	020839 001	CLOPIDOGREL BISULFATE;PLAVIX	6504030	JUN 10, 2019			
	019758 001	CLOZAPINE;CLOZARIL				I-380	DEC 18, 2005
	019758 002	*CLOZAPINE;CLOZARIL*				I-380	DEC 18, 2005
>ADD>	021141 001	COLESEVELAM HYDROCHLORIDE;WELCHOL	6066678	JUN 10, 2014	U-323		
>ADD>	017821 001	CYCLOBENZAPRINE HYDROCHLORIDE;FLEXERIL				D-78	FEB 03, 2006
	021165 001	DESLORATADINE;CLARINEX	4659716	APR 21, 2004	U-427	NCE	DEC 21, 2006
			4863931	SEP 15, 2008		PED	JUN 21, 2007
			4804666	FEB 14, 2006	U-428		
			5595997	DEC 30, 2014	U-429		
			6100274	JUL 07, 2019			
			4659716*PED	OCT 21, 2004	U-427		
			4804666*PED	AUG 14, 2006	U-428		
			4863931*PED	MAR 15, 2009			
			5595997*PED	JUN 30, 2015	U-429		
			6100274*PED	JAN 07, 2020			
	021312 001	DESLORATADINE;CLARINEX				NCE	DEC 21, 2006
						PED	JUN 21, 2007
	020401 006	DILTIAZEM HYDROCHLORIDE;TIAZAC	5529791	JUN 25, 2013			
	021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6511678	DEC 18, 2018			
	021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6511678	DEC 18, 2018			
	021360 001	EFAVIRENZ;SUSTIVA	5663169	SEP 02, 2014			
>ADD>	021481 001	ENFUVIRTIDE;FUZEON	5464933	JUN 07, 2013		NCE	MAR 13, 2008
>ADD>			6133418	JUN 07, 2013			
>ADD>			6475491	JUN 07, 2015	U-248		
>ADD>	021437 001	EPLERENONE;INSPRA	6534093	DEC 08, 2019	U-3		
>ADD>	021437 002	EPLERENONE;INSPRA	6534093	DEC 08, 2019	U-3		
>ADD>	021437 003	EPLERENONE;INSPRA	6534093	DEC 08, 2019	U-3		
>ADD>	019386 004	ESMOLOL HYDROCHLORIDE;BREVIBLOC	6528540	JAN 12, 2021			
>ADD>	019386 006	ESMOLOL HYDROCHLORIDE;BREVIBLOC	6528540	JAN 12, 2021			
>ADD>	019386 005	ESMOLOL HYDROCHLORIDE;BREVIBLOC DOUBLE STR	6528540	JAN 12, 2021			
>ADD>	021367 001	ESTRADIOL ACETATE;FEMRING				NP	MAR 20, 2006

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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
						NP	MAR 20, 2006
>ADD>	021367 002	ESTRADIOL ACETATE;FEMRING					
>ADD>	020747 001	FENTANYL CITRATE;ACTIQ	4863737	SEP 05, 2006			
>ADD>			5785989	SEP 05, 2006			
>ADD>	020747 002	FENTANYL CITRATE;ACTIQ	4863737	SEP 05, 2006			
>ADD>			5785989	SEP 05, 2006			
>ADD>	020747 003	FENTANYL CITRATE;ACTIQ	4863737	SEP 05, 2006			
>ADD>			5785989	SEP 05, 2006			
>ADD>	020747 004	FENTANYL CITRATE;ACTIQ	4863737	SEP 05, 2006			
>ADD>			5785989	SEP 05, 2006			
>ADD>	020747 005	FENTANYL CITRATE;ACTIQ	4863737	SEP 05, 2006			
>ADD>			5785989	SEP 05, 2006			
>ADD>	020747 006	FENTANYL CITRATE;ACTIQ	4863737	SEP 05, 2006			
>ADD>			5785989	SEP 05, 2006			
	019813 001	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	019813 002	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	019813 003	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	019813 004	FENTANYL;DURAGESIC	4588580	JUL 23, 2004	U-43		
			4588580*PED	JAN 23, 2005	U-43		
	020625 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-192		
			5855912	FEB 28, 2015			
			5738872	FEB 28, 2015			
			5932247	FEB 28, 2015			
			6037353	MAR 14, 2017	U-138		
			6113942	FEB 28, 2015			
			6187791	MAY 11, 2012	U-138		
			6399632	MAY 11, 2012	U-468		
			5578610*PED	MAY 26, 2014	U-192		
			5738872*PED	AUG 28, 2015			
			5855912*PED	AUG 28, 2015			
			5932247*PED	AUG 28, 2015			
			6037353*PED	SEP 14, 2017	U-138		
			6113942*PED	AUG 28, 2015			
			6187791*PED	NOV 11, 2012	U-138		
			6399632*PED	NOV 11, 2012	U-468		
	020872 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
			5932247	FEB 28, 2015		PED	AUG 25, 2003
			5855912	FEB 28, 2015			
			6037353	MAR 14, 2017	U-138		
			6113942	FEB 28, 2015			
			6187791	MAY 11, 2012	U-138		
			6399632	MAY 11, 2012	U-468		
			5578610*PED	MAY 26, 2014	U-139		
			5855912*PED	AUG 28, 2015			
			5932247*PED	AUG 28, 2015			
			6037353*PED	SEP 14, 2017	U-138		
			6113942*PED	AUG 28, 2015			
			6187791*PED	NOV 11, 2012	U-138		
			6399632*PED	NOV 11, 2012	U-468		

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
	020872 002	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
			5932247	FEB 28, 2015		PED	AUG 25, 2003
			5855912	FEB 28, 2015			
			6037353	MAR 14, 2017	U-138		
			6113942	FEB 28, 2015			
			6187791	MAY 11, 2012	U-138		
			6399632	MAY 11, 2012	U-468		
			5578610*PED	MAY 26, 2014	U-139		
			5855912*PED	AUG 28, 2015			
			5932247*PED	AUG 28, 2015			
			6037353*PED	SEP 14, 2017	U-138		
			6113942*PED	AUG 28, 2015			
			6187791*PED	NOV 11, 2012	U-138		
			6399632*PED	NOV 11, 2012	U-468		
	020872 004	FEXOFENADINE HYDROCHLORIDE;ALLEGRA	5578610	NOV 26, 2013	U-139	NDF	FEB 25, 2003
			5932247	FEB 28, 2015		PED	AUG 25, 2003
			5855912	FEB 28, 2015			
			6037353	MAR 14, 2017	U-138		
			6113942	FEB 28, 2015			
			6187791	MAY 11, 2012	U-138		
			6399632	MAY 11, 2012	U-468		
			5578610*PED	MAY 26, 2014	U-139		
			5855912*PED	AUG 28, 2015			
			5932247*PED	AUG 28, 2015			
			6037353*PED	SEP 14, 2017	U-138		
			6113942*PED	AUG 28, 2015			
			6187791*PED	NOV 11, 2012	U-138		
			6399632*PED	NOV 11, 2012	U-468		
	020786 001	FEXOFENADINE HYDROCHLORIDE;ALLEGRA-D	5578610	NOV 26, 2013			
			5855912	FEB 28, 2015			
			6037353	MAR 14, 2017	U-138		
			6039974	JUL 31, 2018			
			6113942	FEB 28, 2015			
			6187791	MAY 11, 2012	U-138		
			6399632	MAY 11, 2012	U-468		
			5578610*PED	MAY 26, 2014			
			5855912*PED	AUG 28, 2015			
			6037353*PED	SEP 14, 2017	U-138		
			6039974*PED	JAN 31, 2019			
			6113942*PED	AUG 28, 2015			
			6187791*PED	NOV 11, 2012	U-138		
			6399632*PED	NOV 11, 2012	U-468		
>ADD>	020038 001	FLUDARABINE PHOSPHATE;FLUDARA	4357324	FEB 24, 2003			
>ADD>			4357324*PED	AUG 24, 2003			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020101 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
						PED	JUL 03, 2006
	020974 001	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
						PED	JUL 03, 2006
	020974 002	FLUOXETINE HYDROCHLORIDE;PROZAC				NPP	JAN 03, 2006
						PED	JUL 03, 2006
>ADD>	021077 001	FLUTICASONE PROPIONATE;ADVAIR DISKUS 100/50	4335121*PED	MAY 14, 2004		NC	AUG 24, 2003
			4335121	NOV 14, 2003		PED	FEB 24, 2004
			5270305	SEP 07, 2010	U-387		
			4992474	FEB 12, 2008	U-211		
			4992474*PED	AUG 12, 2008	U-211		
			5225445*PED	AUG 12, 2008	U-211		
			5290815*PED	SEP 01, 2011	U-396		
			5270305*PED	MAR 07, 2011	U-387		
			5126375*PED	AUG 12, 2008			
			5225445	FEB 12, 2008	U-211		
			5126375	FEB 12, 2008			
			5290815	MAR 01, 2011	U-386		
	021077 002	FLUTICASONE PROPIONATE;ADVAIR DISKUS 250/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
			5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
			4992474	FEB 12, 2008	U-211		
			5225445	FEB 12, 2008	U-211		
			5126375	FEB 12, 2008			
			5290815	MAR 01, 2011	U-386		
			4335121*PED	MAY 14, 2004			
			4992474*PED	AUG 12, 2008	U-211		
			5126375*PED	AUG 12, 2008			
			5225445*PED	AUG 12, 2008	U-211		
			5270305*PED	MAR 07, 2011	U-387		
			5290815*PED	SEP 01, 2011	U-386		
	021077 003	FLUTICASONE PROPIONATE;ADVAIR DISKUS 500/50	4335121	NOV 14, 2003		NC	AUG 24, 2003
			5270305	SEP 07, 2010	U-387	PED	FEB 24, 2004
			4992474	FEB 12, 2008	U-211		
			5225445	FEB 12, 2008	U-211		
			5126375	FEB 12, 2008			
			5290815	MAR 01, 2011	U-386		
			4335121*PED	MAY 14, 2004			
			4992474*PED	AUG 12, 2008	U-211		
			5126375*PED	AUG 12, 2008			
			5225445*PED	AUG 12, 2008	U-211		
			5270305*PED	MAR 07, 2011	U-387		
			5290815*PED	SEP 01, 2011	U-386		
	019957 001	FLUTICASONE PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
			4335121*PED	MAY 14, 2004			

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	019958 001	FLUTICASONE PROPIONATE;CUTIVATE	4335121	NOV 14, 2003			
			4335121*PED	MAY 14, 2004			
	020121 001	FLUTICASONE PROPIONATE;FLONASE	4335121	NOV 14, 2003		D-76	MAY 23, 2005
			4335121*PED	MAY 14, 2004		PED	NOV 23, 2005
	020548 001	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
			4335121*PED	MAY 14, 2004			
	020548 002	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
			4335121*PED	MAY 14, 2004			
	020548 003	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003			
			4335121*PED	MAY 14, 2004			
	020549 001	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
			4335121*PED	MAY 14, 2004	U-409		
	020549 002	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
			4335121*PED	MAY 14, 2004	U-409		
	020549 003	FLUTICASONE PROPIONATE;FLOVENT	4335121	NOV 14, 2003	U-409		
			4335121*PED	MAY 14, 2004	U-409		
	020833 001	FLUTICASONE PROPIONATE;FLOVENT DISKUS 50	4335121	NOV 14, 2003	U-409		
			4335121*PED	MAY 14, 2004	U-409		
	020833 002	FLUTICASONE PROPIONATE;FLOVENT DISKUS 100	4335121	NOV 14, 2003	U-409		
			4335121*PED	MAY 14, 2004	U-409		
	020833 003	FLUTICASONE PROPIONATE;FLOVENT DISKUS 250	4335121	NOV 14, 2003	U-409		
			4335121*PED	MAY 14, 2004	U-409		
	020261 001	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011	U-109		
			5354772	OCT 11, 2011	U-413		
	020261 002	FLUVASTATIN SODIUM;LESCOL	5354772	OCT 11, 2011	U-109		
			5354772	OCT 11, 2011	U-413		
	021192 001	FLUVASTATIN SODIUM;LESCOL XL	5354772	OCT 11, 2011	U-413		
			5354772	OCT 11, 2011	U-109		
>ADD>	020831 001	FORMOTEROL FUMARATE;FORADIL	6488027	MAR 08, 2019		I-342	SEP 25, 2004
	019915 002	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
			5006344	JUL 10, 2009			
			5006344*PED	JAN 10, 2010			
			4337201*PED	JUN 04, 2003			
	019915 003	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
			5006344	JUL 10, 2009			
			5006344*PED	JAN 10, 2010			
			4337201*PED	JUN 04, 2003			
	019915 004	FOSINOPRIL SODIUM;MONOPRIL	4337201	DEC 04, 2002			
			5006344	JUL 10, 2009			
			5006344*PED	JAN 10, 2010			
			4337201*PED	JUN 04, 2003			
	020286 001	FOSINOPRIL SODIUM;MONOPRIL-HCT	4337201	DEC 04, 2002			
			5006344	JUL 10, 2009			
			5006344*PED	JAN 10, 2010			
			4337201*PED	JUN 04, 2003			

PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA
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	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020286 002	FOSINOPRIL SODIUM;MONOPRIL-HCT	4337201	DEC 04, 2002			
			5006344	JUL 10, 2009			
			5006344*PED	JAN 10, 2010			
			4337201*PED	JUN 04, 2003			
>ADD>	021158 001	GEMIFLOXACIN MESYLATE;FACTIVE	6262071	SEP 21, 2019			
>ADD>			6331550	SEP 21, 2019			
>ADD>			6340689	SEP 14, 2019			
>ADD>			6455540	SEP 21, 2019			
>ADD>	020329 001	GLIPIZIDE;GLUCOTROL XL	5091190	SEP 05, 2009	U-111		
>ADD>			5545413	JUL 21, 2008	U-111		
>ADD>	020329 002	GLIPIZIDE;GLUCOTROL XL	5091190	SEP 05, 2009	U-111		
>ADD>			5545413	JUL 21, 2008	U-111		
>ADD>	020329 003	GLIPIZIDE;GLUCOTROL XL	4612008	SEP 16, 2003			
>ADD>			5024843	SEP 05, 2009			
>ADD>			5082668	SEP 16, 2003			
>ADD>			5091190	SEP 05, 2009	U-111		
>ADD>			5545413	JUL 21, 2008	U-111		
>ADD>			5591454	JAN 07, 2014	U-111		
>ADD>	021282 002	GUAIFENESIN;MUCINEX	6372252	APR 28, 2020	U-489		
	021321 001	ICODEXTRIN;EXTRANEAL	6248726	JUN 19, 2018	U-495		
			4761237	AUG 02, 2005	U-495		
			4886789	DEC 12, 2006	U-495		
			6077836	JUN 20, 2017	U-495		
	021425 001	IOPROMIDE;ULTRAVIST (PHARMACY	4364921	MAR 06, 2005	U-498		
	021425 002	IOPROMIDE;ULTRAVIST (PHARMACY	4364921	MAR 06, 2005	U-498		
	020857 001	LAMIVUDINE;COMBIVIR	5047407*PED	MAY 17, 2010			
			5047407	NOV 17, 2009			
	021003 001	LAMIVUDINE;EPIVIR-HBV	5047407	NOV 17, 2009			
			5047407*PED	MAY 17, 2010			
	021004 001	LAMIVUDINE;EPIVIR-HBV	5047407	NOV 17, 2009			
			5047407*PED	MAY 17, 2010			
>ADD>	021488 001	LEUPROLIDE ACETATE;ELIGARD				NP	FEB 13, 2006
>ADD>	020612 001	LIDOCAINE;LIDODERM	5589180	MAR 17, 2009	U-485		
>ADD>			5411738	MAY 02, 2012			
>ADD>			5827529	OCT 27, 2015	U-486		
>ADD>			5709869	MAR 17, 2009	U-485		
>ADD>			5601838	MAY 02, 2012	U-488		
	021130 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021130 002	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021131 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021132 001	LINEZOLID;ZYVOX				NPP	DEC 19, 2005
	021226 001	LOPINAVIR;KALETRA	6521651	NOV 01, 2017			
>ADD>	075209 001	LORATADINE;LORATADINE				PC	JUL 21, 2003
>ADD>	076050 001	LORATADINE;LORATADINE AND PSEUD				PC	JUL 30, 2003

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
	020386 001	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
	020386 002	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
	020386 003	LOSARTAN POTASSIUM;COZAAR	5210079	MAY 11, 2010	U-496	I-383	SEP 17, 2005
	021410 001	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
	021410 002	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
	021410 003	METFORMIN HYDROCHLORIDE;AVANDAMET				NCE	MAY 25, 2004
	076119 001	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 16, 2003
	076119 002	MIRTAZAPINE;MIRTAZAPINE				PC	JUN 16, 2003
>ADD>	021277 001	MOXIFLOXACIN HYDROCHLORIDE;AVELOX IN SODIUM CHL	4990517	JUN 30, 2009	U-298		
>ADD>			5607942	MAR 04, 2014	U-298		
>ADD>			5849752	DEC 05, 2016	U-298		
>ADD>	021330 001	NICOTINE POLACRILEX;COMMIT	5110605	AUG 21, 2010			
>ADD>	021330 002	NICOTINE POLACRILEX;COMMIT	5110605	AUG 21, 2010			
>ADD>	020845 002	NITRIC OXIDE;INOMAX	5873359	JAN 23, 2013	U-297		
>ADD>	020845 003	NITRIC OXIDE;INOMAX	5873359	JAN 23, 2013	U-297		
	019921 001	OFLOXACIN;OCUFLOX	4382892	SEP 02, 2003		ODE	MAY 22, 2003
			4551456	NOV 14, 2003	U-80	PED	NOV 22, 2003
			4382892*PED	MAR 02, 2004			
			4551456*PED	MAY 14, 2004	U-80		
>ADD>	021286 002	OLMESARTAN MEDOXOMIL;BENEVAS	5616599	APR 01, 2014	U-500		
>ADD>	021286 001	OLMESARTAN MEDOXOMIL;BENICAR	5616599	APR 01, 2014	U-500		
>ADD>	021286 003	OLMESARTAN MEDOXOMIL;BENICAR	5616599	APR 01, 2014	U-500		
>ADD>	020007 003	ONDANSETRON HYDROCHLORIDE;ZOFRAN PRESERVATIVE	4695578	JAN 25, 2005			
>ADD>			4753789	JUN 24, 2006	U-44		
	020776 001	OXAPROZIN POTASSIUM;DAYPRO ALTA	6030643	MAY 16, 2017	U-497		
>ADD>	021106 001	PEGVISOMANT;SOMAVERT	6057292	SEP 21, 2015	U-507	NCE	MAR 25, 2008
>ADD>			5849535	SEP 21, 2015			
>ADD>			5958879	SEP 27, 2011	U-507		
>ADD>			5350836	SEP 27, 2011	U-507		
>ADD>			5681809	SEP 27, 2011	U-507		
>ADD>	021106 002	PEGVISOMANT;SOMAVERT	6057292	SEP 21, 2015	U-507	NCE	MAR 25, 2008
>ADD>			5849535	SEP 21, 2015			
>ADD>			5958879	SEP 27, 2011	U-507		
>ADD>			5350836	SEP 27, 2011	U-507		
>ADD>			5681809	SEP 27, 2011	U-507		
>ADD>	021106 003	PEGVISOMANT;SOMAVERT	6057292	SEP 21, 2015	U-507	NCE	MAR 25, 2008
>ADD>			5849535	SEP 21, 2015			
>ADD>			5958879	SEP 27, 2011	U-507		
>ADD>			5350836	SEP 27, 2011	U-507		
>ADD>			5681809	SEP 27, 2011	U-507		
>ADD>	020629 001	PENCICLOVIR SODIUM;DENAVIR	6469015	OCT 22, 2019	U-501		
>ADD>	076061 001	PERGOLIDE MESYLATE;PERGOLIDE MESYLATE				PC	MAY 31, 2003
>ADD>	076061 002	PERGOLIDE MESYLATE;PERGOLIDE MESYLATE				PC	MAY 31, 2003
>ADD>	076061 003	PERGOLIDE MESYLATE;PERGOLIDE MESYLATE				PC	MAY 31, 2003

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021438 001	PROPRANOLOL HYDROCHLORIDE;INNOPRAN XL	6500454	DEC 31, 2022		NP	MAR 12, 2006
>ADD>	021438 002	PROPRANOLOL HYDROCHLORIDE;INNOPRAN XL	6500454	DEC 31, 2022		NP	MAR 12, 2006
>ADD>	020903 001	RIBAVIRIN;REBETOL	6524570	NOV 01, 2016	U-499		
>ADD>			6524570*PED	MAY 01, 2017	U-499		
>ADD>	021071 002	ROSIGLITAZONE MALEATE;AVANDIA				I-384	FEB 27, 2006
>ADD>	021071 003	ROSIGLITAZONE MALEATE;AVANDIA				I-384	FEB 27, 2006
>ADD>	021071 004	ROSIGLITAZONE MALEATE;AVANDIA				I-384	FEB 27, 2006
>ADD>	019414 001	RUBIDIUM CHLORIDE RB-82;CARDIOGEN-82	4562829	MAY 01, 2004	U-503		
>ADD>	019839 001	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-261	FEB 07, 2006
>ADD>	019839 002	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-261	FEB 07, 2006
>ADD>	019839 003	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-261	FEB 07, 2006
>ADD>	019839 004	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-261	FEB 07, 2006
>ADD>	019839 005	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-261	FEB 07, 2006
>ADD>	020990 001	SERTRALINE HYDROCHLORIDE;ZOLOFT				I-261	FEB 07, 2006
	020926 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
	021179 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
	021179 002	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 13, 2013			
	020280 007	SOMATROPIN RECOMBINANT;GENOTROPIN				ODE	OCT 31, 2004
	020280 001	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 002	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 003	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 005	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 008	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 009	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 010	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 011	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 012	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
	020280 013	SOMATROPIN RECOMBINANT;GENOTROPIN PRESERVAT				ODE	OCT 31, 2004
>ADD>	020749 001	TERBINAFINE HYDROCHLORIDE;LAMISIL	6121314	MAY 18, 2012	U-502		
>ADD>	021124 001	TERBINAFINE HYDROCHLORIDE;LAMISIL AT	6121314	MAY 18, 2012	U-504		
>ADD>	020489 001	TESTOSTERONE;ANDRODERM	4863970	NOV 14, 2006			
>ADD>			4983395	NOV 12, 2007			
>ADD>			5152997	DEC 11, 2010	U-490		
>ADD>			5164190	DEC 11, 2010			
>ADD>			4849224	NOV 12, 2007			
>ADD>			4855294	SEP 06, 2008			
>ADD>	020489 002	TESTOSTERONE;ANDRODERM	4849224	NOV 12, 2007			
>ADD>			4855294	SEP 06, 2008			
>ADD>			4863970	NOV 14, 2006			
>ADD>			4983395	NOV 12, 2007			
>ADD>			5152997	DEC 11, 2010	U-490		
>ADD>			5164190	DEC 11, 2010			
	021454 001	TESTOSTERONE;TESTIM				NP	OCT 31, 2005
>ADD>	021257 001	TRAVOPROST;TRAVATAN				M-23	FEB 13, 2006

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

	APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	USE CODE	EXCLUS CODE	EXCLUS EXPIRES
>ADD>	021108 001	TRETINOIN;RENOVA	6531141	MAR 07, 2020			
	020550 001	VALACYCLOVIR HYDROCHLORIDE;VALTREX				I-381	SEP 09, 2005
	020550 002	VALACYCLOVIR HYDROCHLORIDE;VALTREX				I-381	SEP 09, 2005
>ADD>	020699 001	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-261	FEB 11, 2006
>ADD>	020699 002	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-261	FEB 11, 2006
>ADD>	020699 003	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-261	FEB 11, 2006
>ADD>	020699 004	VENLAFAXINE HYDROCHLORIDE;EFFEXOR XR				I-261	FEB 11, 2006
>ADD>	020552 001	VERAPAMIL HYDROCHLORIDE;COVERA-HS	4612008	SEP 16, 2003			
>ADD>			6146662	AUG 14, 2007	U-366		
>ADD>	020552 002	VERAPAMIL HYDROCHLORIDE;COVERA-HS	4612008	SEP 16, 2003			
>ADD>			6146662	AUG 14, 2007	U-366		

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, 23RD 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.

EXCLUSIVITY DOSING SCHEDULE

D-78	USE OF FLEXERIL 5MG FOR THE RELIEF OF MUSCLE SPASM ASSOCIATED WITH ACUTE, PAINFUL, MUSCULOSKELETAL CONDITIONS

EXCLUSIVITY INDICATION

I-380	TO TREAT PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER AT RISK FOR EMERGENT SUICIDAL BEHAVIOR
I-381	TREATMENT OF COLD SORES (HERPES LABIALIS) IN ADULT AND ADOLESCENT PATIENTS 12 YEARS OF AGE AND OLDER
I-382	FOR NEWLY-DIAGNOSED HIGH GRADE MALIGNANT GLIOMA PATIENTS AS AN ADJUNCT TO SURGERY AND RADIATION
I-383	TREATMENT OF TYPE 2 DIABETIC NEPHROPATHY

EXCLUSIVITY MISCELLANEOUS

M-23	INFORMATION REGARDING ELIMINATION ADDED TO CLINICAL PHARMACOLOGY, STUDY RESULTS IN PATIENTS WITH HEPATIC AND RENAL IMPAIRMENT

PATENT USE

U-494	TREATMENT OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER
U-495	PERITONEAL DIALYSIS SOLUTION
U-496	METHOD FOR TREATING CHRONIC RENAL FAILURE
U-497	RELIEF OF THE SIGNS AND SYMPTOMS OF OSTEOARTHRITIS AND RHEUMATOID ARTHRITIS
U-498	INTRA-ARTERIAL AND INTRAVENOUS USES OF ULTRAVIST
U-499	METHOD OF USING REBETOL CAPSULES IN COMBINATION WITH A CONJUGATE COMPRISING POLYETHYLENE GLYCOL(PEG) AND AN ALPHA INTERFERON, INCLUDING, FOR EXAMPLE, PEG-INTRON POWDER FOR INJECTION
U-500	USE AS AN ANTIHYPERTENSIVE AGENT
U-501	TREATMENT OF RECURRENT HERPES LABIALIS (COLD SORES) IN ADULTS
U-502	PITYRIASIS VERSICOLOR
U-503	GENERATOR MUST BE USED WITH INFUSION SYSTEM SPECIFICALLY LABELED FOR USE WITH GENERATOR
U-504	TINEA PEDIS, TINEA CRURIS, TINEA CORPORIS
U-505	ULTRASOUND CONTRAST AGENT
U-506	PHARM PRODUCT CONTAINER 1ST CHAMBER IS DISPOSED AQUEOUS DILUENT SOL 2ND CHAMBER PHARM ACTIVE AGENT COMPRISING ACETYLCHOLINE,BUFFER IN 1ST CHAM IS SUFFICIENT TO BUFFER PH OF MIXED SOL RESULTING MIXTURE OF AQUEOUS DILUENT SOL & PHARM ACTIVE..
U-507	ACROMEGALY IN PATIENTS W/INADEQUATE RESPONSE TO SURGERY AND/OR RADIATION THERAPY AND/OR MEDICAL THERAPIES, OR FOR WHOM THESE THERAPIES ARE NOT APPROPRIATE

United States Government INFORMATION
PUBLICATIONS ★ PERIODICALS ★ ELECTRONIC PRODUCTS

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